High-intensity laser therapy for hamstring muscle tightness: rationale and study design for a single-blinded randomized controlled trial

Terapia a laser de alta intensidade para rigidez muscular dos isquiotibiais: fundamentação e desenho do estudo para estudo controlado randomizado simples-cego

ABSTRACT | BACKGROUND: Prolonged sitting and a sedentary lifestyle may result in hamstring shortness. A decline in regular physical activity could lead to a decrease in the flexibility of the muscle in a younger adult. Increasing hamstring muscle flexibility could decrease the possibility of injuries and prevent low back pain. The application of high-intensity laser therapy (HILT) has proved to be innumerable benefits for many conditions. However, to date, no published research is available on the effectiveness of this therapy in improving hamstring muscle length in healthy young adults. This article describes the study protocol for investigating the benefits of HILT in treating hamstring muscle tightness among young adults. METHODS: 136 healthy young individuals will be recruited, by purposive sampling method, to participate in a randomized, single-blinded, sham-controlled study. Recruited participants will be randomly divided into two groups, the active HILT group, and the sham HILT group. The treatment duration will be 8-10 minutes per session, on both lower limbs, for alternate days a week, for two weeks. The active knee extension test and sit-toe and touch test are the outcome measures that will be recorded at baseline, end of the 2-week post-intervention period. The p-value ≤0.05 will be considered statistically significant. DISCUSSION: The study findings will provide the data to determine whether HILT would be a future non-pharmacological non-invasive intervention to reduce hamstring muscle tightness among young adults. TRIAL REGISTRY: Clinical Trials Registry NCT05077761.


RESUMO | CONTEXTO: Sentar-se por muito tempo e um estilo de vida sedentário podem resultar em encurtamento dos isquiotibiais. Um declínio na atividade física regular pode levar a uma diminuição da flexibilidade do músculo em um adulto mais jovem. Aumentar a flexibilidade dos músculos isquiotibiais pode diminuir as possibilidades de lesões e prevenir a dor lombar. A aplicação da terapia a laser de alta intensidade (TLAI) tem demonstrado inúmeros benefícios para diversas condições. No entanto, até o momento, não há pesquisas publicadas sobre a eficácia dessa terapia para melhorar o comprimento dos músculos isquiotibiais em adultos jovens saudáveis. Este artigo descreve o protocolo de estudo para investigar os benefícios do TLAI no tratamento da rigidez muscular dos isquiotibiais em adultos jovens. MÉTODOS: 136 indivíduos jovens saudáveis serão recrutados, pelo método de amostragem intencional, para participar de um estudo randomizado, simples-cego e controlado por simulação. Os participantes recrutados serão divididos aleatoriamente em dois grupos, o grupo TLAI ativo e o grupo TLAI placebo. A duração do tratamento será de 8 a 10 minutos por sessão em ambos os membros inferiores, em dias alternados, durante duas semanas. O teste de extensão ativa do joelho e o teste de sentar e tocar são as medidas de resultado que serão registradas na linha de base, no final do período pós-intervenção de 2 semanas. O valor de p ≤0,05 será considerado estatisticamente significativo. DISCUSSÃO: Os resultados do estudo fornecerão os dados para determinar se aTLAI seria uma futura intervenção não farmacológica não invasiva para reduzir a tensão muscular dos isquiotibiais em adultos jovens. REGISTRO DE ENSAIO: Registro de Ensaios Clínicos NCT05077761.


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Introduction

Hamstring tightness is characterized as a loss of range of motion associated with a feeling of limitation in the posterior thigh. The inability to extend the knee over 160 degrees with the hip in 90 degrees of flexion is referred to as hamstring tightness. Due to the sedentary lifestyle of individuals, resulting in less physical activity, less energy expenditure, and decreased basal metabolic rate. Maintaining physical activity is one of the techniques to prevent muscle loss.

Researchers reported that hamstring muscle tightness can be corrected with various therapeutic approaches and conservative treatments. Literature shows that stretching is not effective in reducing the occurrence of injury and increasing hamstring muscle length. Cold and hot packs have been shown to affect the contractile properties of muscles. In a study, it has been reported that during isometric contraction of the gastrocnemius muscle, the connection between estimated muscle force and elongation of each structure (tendon–aponeurosis complex, tendon) remained unchanged in both hot and cold immersions. Clinical trials have shown the benefits of low-level laser therapy modality in the treatment of muscle injuries.

Light has a modulatory effect on the body, which causes local and/or systemic biological reactions in the organism. The anti-inflammatory benefits of phototherapy, such as its potential to lower reactive oxygen species release, boost antioxidant capacity, and improve mitochondrial function, may explain these hopeful results in muscle functions. Many studies reported the positive effect of laser therapy on muscle performance, muscle damage, muscle strength, muscle fatigue, muscular hypertrophy, and muscle gain in symptomatic and asymptomatic individuals. High-intensity laser therapy (HILT) produces very short bursts and duty cycles and produces greater radiation in target tissue with very mild histological risks and provides effect to the deep tissues and structures. HILT is effective over low-level laser therapy because of the high-power pulsed emission and the photochemical effect that also improves muscle performance by micro-massaging the soft tissue structure.

However, no research reported the therapeutic effect of HILT to improve hamstring muscle length. There is no research conducted on HILT to determine the proper parameters necessary to increase flexibility. There is a definite need to establish a HILT protocol to determine whether this intervention will have a significant effect on hamstring muscle tightness. This study aims to evaluate the effects of HILT on hamstring muscle length (HML) in young adults, as well as to verify the effect of 2-week of such therapy in improving hamstring flexibility in individuals with hamstring tightness.

Hypothesis

There will be no significant difference in HML after HILT intervention when compared to active HILT in the experimental, and the control group is a null hypothesis. While in the alternative hypothesis, there will be significant changes in HML after the application of HILT on hamstring muscle length (HML) in young adults, as well as to verify the effect of 2-week of such therapy in improving hamstring flexibility in individuals with hamstring tightness.

Methods

Study design

This protocol study design will be a pretest-posttest controlled group design. The study design’s blueprint to be adopted is explained with a flow diagram for individual randomized controlled trials of non-pharmacologic treatments, displayed in Figure 1.
Figure 1. Study Flow Chart

Enrollment
Assessed for eligibility (n = X)
- Excluded (n = x)
  - Not meeting inclusion criteria (n = x)
  - Refused to participate (n = x)
  - Other reason (n = x)

Randomized (n = 136)

Allocation: Patients
Allocated to intervention (n = 68)
- Received allocated intervention (n = x)
- Did not receive allocated intervention (give reasons) (n = x)

Allocation: Care Providers
Care providers (n = x), teams (n = x), centers (n = x) performing the intervention
Number of patients treated by each care provider, team, and center (median = ... [IQR, min, max])

Follow-up Patients
Lost to follow-up (give reason) (n = x)
Discontinued intervention (give reasons) (n = x)

Analysis Patients
Analysed (n = x)
Excluded from analysis (give reasons) (n = x)

Source: the authors (2023).
Study setting

The study will be performed at a tertiary care teaching institution.

Study participants

Participants recruitment

This study aims to recruit young adults between the age group of 18-30 years. A survey of flexibility-related issues of hamstring muscles will be done among college students. Participants will be invited to participate in the study through e-mail/message and will be asked for voluntary participation. Participants will be recruited according to the purposive sampling method in this study. The investigator will recruit participants who will provide written informed consent to voluntary participation in the study according to inclusion and exclusion criteria. Inclusion criteria will be as follows: asymptomatic young adults, both male and female, age 18-30 years, tightness of hamstring muscles (unilateral/bilateral). Exclusion criteria will be as follows: any leg length discrepancy, skin allergy, presence of flat back/increased lordosis, any deviation from normal posture, gym-going individuals, any athletes, any other musculoskeletal disorder, any disc pathology, nerve root irritation, surgical history or trauma, malignancy, pregnancy, sensory dysfunctions, cardiac pacemaker.

The study protocol was approved by the institutional research and ethics committee at Maharishi Markandeshwar Institute of Medical Sciences and Research, Maharishi Markandeshwar (Deemed to be University) (MMDU/IEC/2151 on 13/10/2021). The study will be done strictly in accordance with the guidelines of the Helsinki Declaration, revised in 2013. The study will also follow the ethical guidelines issued by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), titled International Ethical Guidelines for Health-related Research Involving Humans, 2016. After obtaining ethical approval from the institutional ethics committee, a unique Universal Trial Number (UTN), U1111-1269-9595, was obtained for the study. The study protocol was uploaded to open access clinical trial registry platform, Clinical Trials Registry NCT05077761, registered on October 1st, 2021, and approved by WHO’s International Clinical Trials Registry Platform (ICTRP) and International Committee of Medical Journal Editors (ICMJE). The data will be collected from the tertiary care teaching institution.

A brief Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule is provided in Figure 2.
### Figure 2. Detailed study description

<table>
<thead>
<tr>
<th>TIMEPOINT**</th>
<th>0 week</th>
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<td>Sit and toe touch test</td>
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<td></td>
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<td></td>
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</tbody>
</table>

Source: the authors (2023).
Randomization and allocation concealment

136 participants will be selected based on the inclusion criteria for the single-blind, two-group pretest-posttest randomized controlled design. Demographic data will be recorded for all the participants. The participants with hamstring muscle length will be allocated into two groups, the active HILT group and the sham HILT group, by block randomization technique. According to it, there will be four blocks, with the matrix design of $4 \times 34$, where 34 is rows. Each row could have four blocks, with one chit (SNOSE - sequentially numbered, opaque sealed, envelopes) in each block containing either the name of active HILT or sham HILT. A total of four chits (2 chits for each group) will be assigned to each row, and then a patient with hamstring muscle length will be allotted to one of the two groups based on the randomly chosen chit (SNOSE). Once the entire first row is allotted, the next row block will be opened for enrolment. The advantage of this randomization method is that the number of patients assigned to each group over time would have been approximately equal. By this, the unequal allocation of sample size will be avoided. The concealed allocation of a patient with hamstring muscle length to the treatment groups will be explained by using SNOSE. After randomization, participants will be allocated into their groups accordingly. Participants in the HILT group will be provided with active HILT. The control group will receive sham HILT, and pre-post changes in the outcome measures will be documented.

Blinding

Participants in the study will be blinded. There will be no blinding for the therapist and outcome assessor.

Interventions

All the interventions will be provided by an experienced and qualified physiotherapist. Participants in the active HILT group will receive HILT intervention on the hamstring muscle. The dosage and parameters will be calculated. (Table 1).

| Source: the authors (2023). |

<table>
<thead>
<tr>
<th>Wavelength</th>
<th>980 nm</th>
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<tr>
<td>Power</td>
<td>10 Watt</td>
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<tr>
<td>Emission mode</td>
<td>Continuous emission</td>
</tr>
<tr>
<td>Energy (Joules)</td>
<td>3000-4000 Joules</td>
</tr>
<tr>
<td>Irradiation time</td>
<td>4-5 minutes on each extremity</td>
</tr>
</tbody>
</table>

The laser will be used in a contact manner, with the beam spread over the belly of the hamstring muscle in the scanning method. The irradiation treatment spots (active or placebo) will be set at the midpoint of the total measurement obtained between ischial tuberosity to the Antero/posteromedial aspect of the tibia and head of fibula bilaterally with 2cm between each point to standardise the laser application. The irradiation area will be on the hamstring muscle belly, 1/3rd part of the total muscle length. The laser will be applied in the transverse area at an equal area of the muscle belly with an equal distance from the midpoint to the lateral side. The total muscle length will be measured with the measuring tape and marked separately. All protective measures during HILT will be taken during application. Participants and therapists will use eye-protective glasses during the treatment procedure. The participants will be in a prone lying position with a pillow placed below the legs. Each session will be of 8-10 minutes in the bilateral lower limb for alternate days a week for up to two weeks. The primary outcomes of this study are the active knee extension test and sit toe and touch test to measure the tightness of the hamstring muscle.
Outcome assessment

Outcomes will be assessed at baseline and at the end of the 2-week post-intervention period.

1. Active knee extension (AKE) test

2. Sit-toe and touch (STT) test

Primary outcome measure

1. Active knee extension (AKE) test

The AKE test is an active test that involves movement of the knee joint, and it is generally regarded as safe because the patient controls the movement’s endpoint. Participants will be placed in a supine position without a pillow beneath their heads, with the left lower extremity at a 0 degree of hip flexion, which will be maintained by a velcro strap secured to the table. The right ischial tuberosity will be placed against the metallic bar, and the participant's right thigh will be bent to 90 degrees. To maintain the position, the right mid-thigh will be fastened to the box. After that, the subjects would be asked to slowly extend their right knee until they felt the initial stretch feeling while keeping their foot in plantar flexion. The participants would be told to keep their right thigh's posterior part in contact with the box. The position will be temporarily sustained in able to use of a goniometer to measure the AKE angle. A goniometer's stationary arm will be positioned along the femur, with the greater trochanter of the femur providing a reference point. The lateral femoral condyle at the knee joint will be used to define the axis of movement, and the moving arm will be positioned in line with the lateral malleolus. The technique of knee extension would be repeated three times, with the average measurement serving as the basis for study inclusion.

In other investigations, the measurement of this angle and related procedures were utilised as a screening exam for active knee extension. The AKE testing should offer practitioners and researchers a reliable way of evaluating hamstring muscle tightness, and these measurements will allow researchers and practitioners to document muscle tightness and change after a specific course of treatment. Intratester correlation coefficients for test and retest measurements were ICC 0.99 for the left lower extremity and ICC 0.99 for the right lower extremity.

Secondary outcome measure

2. Sit-toe and touch (STT) test

The STT test requires the individuals to sit on the floor with legs extended over in front of them, and footwear should be taken off. The feet's soles are placed flat on the box. Both knees should be locked and placed flat on the floor, with the tester holding them down if necessary. The individual stretches forward as far as possible along the measuring line, palms facing downwards and hands on top of each other or side by side. Make sure both hands are at the same level, with neither stretching forward further than the other stretches. Distance will be measured from the mid-finger of the hand to the greater toe of the foot with inextensible tape.

The person extends out and holds that position for at least one-two seconds while the distance is measured. Confirm that there were not any jerky motions. The Sit toe and touch test is a valid test of back and leg flexibility, insofar as its validity is measured by the Standing Bobbing test. This is indicated by the validity coefficient (r) of 0.90.

Sample size calculation

The sample size was calculated using the free-access software G*Power, ver. 3.1.9.7 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; http://www.gpower.hhu.de/). The AKE test is considered a primary outcome in the current study. Power was set as 90%, with an alpha level of 5% and an estimated effect size of 0.62, considering 30% dropouts, resulting in a sample size of 68 subjects per group, resulting total sample size of 136 in both groups.
**Statistical method**

If the data follow the normal distribution, descriptive statistics will be expressed in mean ± standard deviation. A paired t-test will be adopted to determine the experimental and control groups' differences for pre-post intervention changes. In contrast, the independent t-test will be used to compare the changes in mean values of the outcome measures between the experimental and control groups. If the data does not follow a normal distribution, the descriptive statistics will be reported in the median with a 95% confidence interval (CI) and range. Wilcoxon signed-rank test will be adopted to find out the differences between the experimental group and control group for pre-post intervention changes. Mann Whitney U test will be used to compare the changes in mean values of the AKE and STT test variables between the experimental group and control group at baseline and the end of 2 weeks of intervention. All the data will be analyzed using statistical software, statistical package for social science (SPSS), and IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). The p-value ≤0.05 will be considered to be statistically significant.

**Perspective**

To our knowledge, there is no randomized controlled study to assess the effectiveness of HILT on hamstring muscle length among young adults. HILT is known to boost metabolism and accelerate blood circulation through systemic vasodilatation, resulting in the reabsorption of stored tissue material and the rapid elimination of exudates. In this study, hamstring muscle length changes will be observed and recorded by measuring the changes in length with the help of an active knee extension test. However, available studies are only done on low-level laser therapy but, to date, there is a lack of evidence on HILT. This study will help to establish an effective treatment protocol for the normal adult population.

Risks are any potentially harmful circumstances brought on by unforeseen contact with or exposure to tissues or materials to laser energy. These can be either direct beam hazards (those caused by the actual beam interaction), such as tissue burns, eye damage, endotracheal tube fires, drape fires, and gas explosions, or non-beam hazards (those caused by laser-generated airborne contaminants, such as surgical plumes), electrical damage, toxic dyes, and system malfunctions. The degree of possibility for exposure to, or injury resulting from, exposure to specific hazards is frequently used to describe risk. Each individual working with the laser equipment and each member of the laser team may be exposed to varying levels of risk. Depending on the delivery device, power settings, target tissues, as well as the levels of education, training, and experience of both operators and users, the level of risk may also change with the therapeutic uses of a system.

The strength of the study is that it will be a randomized controlled study. The dosage of HILT will be calculated and established for the hamstring muscle tightness. Calculation of sample size was done before the study. The findings of the study could have a significant impact on improving the sedentary lifestyle of young adults by improving hamstring flexibility by using HILT intervention.

The weakness of the study is that other various factors, including hormonal changes, occurring within the subjects will not be taken into consideration. The study included only participant blinded; other blinding could not be done, which might lead to the risk of bias.

In this study, participants will be benefited from HILT as it improves an individual’s daily activities and prevent the probability of muscle injury by improving the length of the hamstring muscle. The probability of low back pain and muscle injury will be decreased, and it result in improved living status and active lifestyle. This protocol details the trial to investigate the efficacy of the HILT in improving hamstring flexibility among normal individuals.

**Authors’ contributions**

Samuel Aj, Goyal M, and Srivastav AK participated in the study conception and design, data acquisition, analysis and data interpretation, drafting of the manuscript, and critical revision.

**Conflicts of interest**

No financial, legal or political conflicts involving third parties (government, companies and private foundations, etc.) were declared for any aspect of the submitted work (including, but not limited to grants and funding, participation in an advisory board, study design, preparation manuscript, statistical analysis, etc.).
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