Traditional Acupuncture and Laser Acupuncture in Chronic Nonspecific Neck Pain: Study Protocol for a Randomized Controlled Trial

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Abstract

Background: Nonspecific neck pain is a multifactorial and very common condition in adult individuals. No reports were found in the literature comparing the effectiveness of Traditional Acupuncture (TA) and Laser Acupuncture (LA) in cases of chronic nonspecific neck pain. Therefore, the aim of the present study is to investigate the effectiveness of TA and LA therapies in individuals with chronic nonspecific neck pain.

Methods/design: This study will be a controlled and randomized clinical trial. A total of 60 individuals will be randomized into two groups (30 each). The TA group will receive the acupuncture treatment using needles, while the LA group will receive the laser acupuncture treatment. The acupuncture points (*Tianzhu*, *Fengchi*, *Jianjing*, and *Jianzhongshu*) will be stimulated bilaterally with needles or laser. The primary outcome will be pain intensity, determined using the numerical rating scale. The secondary outcomes will be pressure pain threshold, temporal summation of pain, conditioned pain modulation, use of analgesic drugs after treatment, and the global perceived effect scale. The assessments will be performed immediately before and after treatment. At the follow-up, 1 months after the end of the treatments, evaluation will be made of the pain intensity and the global perceived effect. Statistical analysis of the data obtained will consider a significance level of $p < 0.05$.

Discussion: This study will provide evidence concerning the effects of LA treatment, in comparison to TA, leading to benefits for individuals suffering from chronic nonspecific neck pain.

Trial registration: RBR-7vbw5gd (Brazilian Registry of Clinical Trials - ReBEC)

Introduction

Background and rationale {6a}

Neck pain is a very common condition that causes considerable disability and economic losses (1,2). Between the years 1990 and 2017, high indices of neck pain were reported in 195 countries, therefore it can be considered a serious global public health problem, ranked fourth among the causes of disability, with an annual prevalence rate higher than 30% (2,3). Neck pain is more common in women and usually increases with age, reaching peaks in the age groups 45-49 and 50-54 years for men and women, respectively, with a decrease for older persons (2). Several risk factors are associated with neck pain, including obesity and a sedentary lifestyle. Risk factors usually result in restrictions and disabilities that can have major impacts on the physical, social, and psychological well-being of the individual (2,4,5). Neck pain can be classified according to its etiology. This kind of pain is considered specific when there are anatomical changes resulting from dysfunctions in neck structures, such as the deterioration of nerve roots, capsule damage, nerve root compression, or fractures (3). Nonspecific neck pain is multifactorial in nature and is not associated with a specific disease or anatomical modification (6,7). Neck pain is classified according to the duration of symptoms, being acute (up to one month), subacute (one to three months), and chronic (at least three months) (8–10). Chronic neck pain is defined as any continuous pain

in the cervical spine region between the base of the head and the upper shoulder, lasting at least 12 weeks and usually accompanied by reduced cervical movement (11).

Various strategies can be used for the treatment of neck pain, including traditional acupuncture (TA), which originated over 3,000 years ago and constitutes part of Traditional Chinese Medicine (12–15). The technique, performed with needles, produces good results and is effective in reducing pain and disability (16–23). TA provides clinical benefits in individuals with neck pain, being a viable option for use by health services (24). Furthermore, TA is considered a safe treatment, with serious side effects being rare, compared to conventional techniques used for the treatment of pain (25,26).

There are now alternative acupuncture techniques available that do not use needles, such as laser acupuncture (LA), which combines use of the traditional Chinese acupuncture points with stimulation by laser light energy (15,27,28). The lasers most indicated for LA are red or infrared, due to their deeper penetration into human tissue, with power outputs ranging from 5 to 500 mW (28–30). Laser acupuncture acts to enhance enzymatic defense systems, increasing plasma levels of superoxide dismutase (SOD), glutathione reductase (GRd), reduced glutathione (GSH), and catalase. LA assists in maintaining the integrity of the redox cycle and can promote reductions of malondialdehyde (MDA, a plasma marker of oxidative stress), the inflammation markers C-reactive protein (CRP) and interleukin-6 (IL-6), and glutathione peroxidase (GPx). Such alternative acupuncture technique can reduce oxidative stress damage, inflammation, joint edema, and pain in patients with rheumatoid arthritis (31).

An obvious difference between acupuncture using needles and LA is that the laser enables stimulation of acupuncture points without damaging the skin tissue (30). The laser induces a photochemical reaction in the cells, in a process known as photobiomodulation, at acupuncture points selected using the same rules as traditional Chinese acupuncture (32,33). Using an optical power of around 40 mW, the effect of LA is similar to that obtained with metal needles (28), being an attractive option for the treatment of chronic pain (34).

Acupuncture using needles is a widely accepted technique that provides good results and can be effective in reducing chronic neck pain (16,17,19,20,35–45). Meanwhile, the clinical use of LA is increasing, since this technique offers the advantages of being totally painless, non-invasive, and safe (30,33,43), which is appropriate for people who have phobia of needles. There are few reports in the scientific literature using AL for cervical pain condition (39,46,47). However, until the present moment, no studies were found that compared traditional acupuncture with LA in patients with chronic nonspecific neck pain. There is a need for thorough research concerning LA, with robust methodologies, large sample sizes, and standardized and reproducible parameters, in order to increase understanding of this therapy and establish possible future clinical applications (30,48,49).

Objectives {7}

The aim of this study is to compare the effects of Traditional Acupuncture and Laser Acupuncture therapies in individuals with chronic nonspecific neck pain.

Trial design {8}

This study will be a randomized clinical trial (RCT) conducted according to the established standards for reporting clinical trials: CONSORT (Consolidated Standards of Reporting Trials) and STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture). The protocol was developed following the recommendations of SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials). The RCT will have a blinded evaluator and the acupuncture styles adopted will be Traditional Acupuncture and Laser Acupuncture.

Methods

Participants, interventions and outcomes

Study setting {9}

The study will be undertaken at the Physiotherapy Department of the Federal University of São Carlos (UFSCar), in the city of São Carlos, São Paulo State, Brazil.

Eligibility criteria {10}

After screening using an online form, the potential participants will be registered and checks will be performed considering the inclusion and exclusion criteria.

Inclusion criteria

- Individuals with complaints of nonspecific neck pain, reported during the screening;
- Neck pain for at least 3 months;
- Numerical rating scale (NRS) score ≥ 3 for pain intensity;
- Age between 18 and 60 years;
- Men and women;
- Completed primary education;

Exclusion criteria

- Fracture or history of spinal injury;
- Spondylolisthesis;
- Stenosis of the spinal canal;
- Ankylosing spondylitis;
- Signs of radiculopathy;
- Cancer;
- Acute infections;

- Hemorrhagic disease;
- Rheumatological disease;
- Systemic inflammatory disease;
- Rheumatoid arthritis;
- Alteration in skin sensitivity;
- Hearing difficulty (without correction);
- Difficulty in answering questionnaires;
- Pregnancy, puerperium, and breastfeeding;
- Individuals who have started or been submitted to any type of intervention or treatment in the three months prior to the date of screening.
- Individuals who do not accept to remain in the ventral decubitus position, upper limbs along the body and cervical in neutral position, during the time of interventions.
- Individuals who do not having ingested any sedative, anti-inflammatory and analgesic medications (narcotics and non-narcotics), and alcoholic substance in the last 48 hours before the intervention.

Who will take informed consent? {26a}

Data collection will only start after the participants have signed an informed consent form, which will be explained by the evaluator.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable for this study.

Interventions

Explanation for the choice of comparators {6b}

No studies were found in the literature that effectively compared Traditional Acupuncture with Laser Acupuncture for treatment of chronic nonspecific neck pain. Therefore, the proposed research will focus on evaluating and comparing changes in pain symptoms and neck functional capacity, after application of TA and LA in cases of chronic nonspecific neck pain.

Intervention description {11a}

The interventions will follow a standardized therapy protocol. Four acupuncture points (*Tianzhu*, *Fengchi*, *Jianjing*, and *Jianzhongshu*) will be stimulated bilaterally with needles or laser. The participant will be positioned in a ventral decubitus position, upper limbs along the body and cervical in neutral position, asked to rest for 5 minutes, prior to the intervention. At the locations where the needles or laser will be applied, the skin will be hygienized with gauze and 70% alcohol solution. A dermatograph pencil (COLOURED®) will be used to draw circles with diameters of 2 cm around the application points. The

same researcher, an acupuncturist with specialization in the field and 9 years of clinical experience, will perform all the interventions. The individuals will be asked not to use any other treatment for neck pain during the study period. All the data collected about the participants will be confidential.

Traditional Acupuncture (TA)

For the TA group, the interventions will be performed using disposable Goldlife[®] needles (0.25 mm diameter, 40 mm length; Brazilian product registration number MS80553910002) supplied in packages containing 10 surgical steel needles and a needle guide tube. Using the guide tube, the needles will be appropriately positioned in the centers of the areas demarcated on the skin and manually inserted into the muscle to a depth of 20 mm. The acupuncture points (*Tianzhu*, *Fengchi*, *Jianjing*, and *Jianzhongshu*) will be stimulated bilaterally. The manual needle stimulation technique known as sparrow pecking will be used (35,50,51). After the stimuli, the needles will be left in position for 20 minutes (43,47,52), followed by removal using a stainless-steel collecting cup and disposal in an appropriate container for sharps (Descarpack[®]), in each session new needles will be used.

Laser Acupuncture (LA)

For the LA group, the interventions will be performed using an Antares[®] laser (IBRAMED, Amparo, São Paulo, Brazil). The laser probe will be appropriately positioned at the locations demarcated on the skin, the acupuncture points: *Tianzhu*; *Fengchi*; *Jianjing*; *Jianzhongshu*. The dose (Table 1) being based on previous work using LA for neck pain (47), following the criteria suggested by Baxter (49).

Criteria for discontinuing or modifying allocated interventions {11b}

There will be no changes in the allocations and no migration of individuals between groups will be allowed. If individuals discontinue treatment, recent data will be computed for the analyses according to the intention-to-treat principle, and the motive for the desistence will be recorded.

Strategies to improve adherence to interventions {11c}

To minimize data loss, all the participants in the trial will receive a card with the date and time of session. The therapist responsible for the session will send a WhatsApp message from a cellphone account used only for this research, confirming the session, one day in advance. For the evaluations and reevaluations, the blinded evaluator will contact the participants by WhatsApp, confirming the initial and final evaluations, as well as the follow-up 1 months after the end of the intervention, which will be performed by telephone. In cases of abandonment or impossibility of continuing the study, the data will be analyzed according to an intention-to-treat protocol.

Relevant concomitant care permitted or prohibited during the trial {11d}

Concomitant treatments such as continuous use medications for hypertension and diabetes will be permitted during the trial. The participants will not be permitted to start any new type of intervention or

activity during the trial period.

Provisions for post-trial care {30}

A follow-up will be performed by telephone, 1 month after the end of the intervention.

Outcomes {12}

The primary outcome will be the pain intensity before-after data. It will be evaluated using the numerical rating scale (NRS). Secondary outcomes will be as follows: pressure pain threshold (PPT); temporal summation of pain (TS); conditioned pain modulation (CPM); use of analgesic drugs after treatments; and Global Perceived Effect Scale (GPE). These outcomes will be evaluated before and after the treatments. Evaluation using the NRS and the global perceived effect scale will be performed at the end of the 1-month follow-up period.

Numeric rating scale (NRS)

The NRS employs a simple and easy to use scale, where the individual is asked to indicate the intensity of the current pain, using a scale ranging from 0 (“no pain”) to 10 (“worst pain imaginable”) (53). The participants will be instructed to rate the pain experienced at rest and during movements (flexion, extension, lateral inclination to the left and right, and rotation to the left and right). All before-after data will be individually recorded and compared for their respective positions.

Pressure pain threshold (PPT)

Measurements will be made using a pressure algometer (Somedic®, Hörby, Sweden), with the tip of the instrument (1 cm²) positioned on cervical zygapophysial joints C5/6 (54), between C7 and the acromion, bilaterally at the midpoint of the upper trapezius muscle (55), and on the middle third of the right tibialis anterior muscle. All these points will be previously marked with a dermatograph pencil. The algometer probe will be positioned perpendicular to the skin and pressure will be applied at a rate of 40 kPa/s. Three consecutive PPT measurements will be made, with an interval of 30 s between them, and the average value will be recorded. The participants will be instructed to close their eyes and to press the algometer sensor when the pressure sensation becomes painful, with the corresponding value being recorded. A test will be performed to familiarize the individuals with the algometer, explaining the procedure, and a demonstration will be made using the thenar region of the hand. During the actual measurements, the individuals will not be allowed to see the algometer. The intra-examiner reliability of the PPT measurements will be evaluated using measurements at the same points for 10 healthy and asymptomatic individuals, performed by a single examiner at intervals of 48 hours. The reliability will then be estimated by calculating intraclass correlation coefficients (ICC) (54–57).

Temporal summation of pain (TS)

Measurements will be made using the pressure algometer (Somedic®, Hörby, Sweden), applying a total of 10 stimuli, at a rate of 40 kPa/s, using the average value from the previous algometry test performed on the most painful upper trapezius muscle (or the dominant side if there is no evident difference). Each stimulus will be maintained for 1 s, using a timer to ensure the correct intervals (1 s). The individuals will be asked about their pain at the 1st, 5th, and 10th seconds of stimulus, using the NRS. In order to avoid any interference, the test will begin 5 minutes after the PPT (57,58).

Conditioned pain modulation (CPM)

Cold nociceptive stimulus will be employed. Individuals will receive instructions before the test. Conditioned stimulus will be provided by the hand on the side ipsilateral to the region of the greatest neck pain, which will be immersed for 1 minute in a water bath kept at 22 °C, in order to standardize the hand temperature. After that, the same hand will be submerged (up to the wrist) for 1 minute in ice water (kept at 4 °C). After 30 seconds, the individual will be asked to report (using the NRS) the intensity of the pain in the hand, caused by the ice water. After immersion for 1 minute, the patient will be asked to remove the hand from the ice water. The PPT will be performed (between C7 and the acromion, at the mid-point of the upper trapezius muscle), using the side contralateral to the immersed hand. The PPT evaluation will be performed before and immediately after the cold stimulus. The mean PPT value before the stimulus will be subtracted from the mean value after the stimulus, with a lower value indicating that the endogenous system is less efficient in inhibiting pain (57,59,60).

Use of analgesic drugs

It will be important to record the use of analgesic drugs, in order to determine whether their use decreased after treatment. The participants will be asked to report, all the medications used. This information will be collected and recorded. In tables, the analgesic medications will be converted into opioids, considering the equianalgesic dose of morphine (61), and non-opioids, considering the equianalgesic dose of acetaminophen (paracetamol) (62).

Global perceived effect scale (GPE)

The global perceived effect scale is used to assess the perception of the individual regarding any improvement, comparing the initial symptoms with the current condition. This scale, which has been translated into Portuguese and validated, provides good reliability when applied to musculoskeletal disorders. It uses 11 points, ranging from -5 (much worse), through 0 (no change), to 5 (completely recovered). After treatment, the participants will be asked: "Compared to when this problem first started, how would you describe the condition of your neck today?" A higher score indicates an improved condition (63,64).

Participant timeline {13}

Sample size {14}

The calculation of the sample size considered a difference of 1.5 points between groups, which would be a clinically relevant value for the outcome of neck pain intensity, as measured using the numeric rating scale (NRS) (65), with an estimated standard deviation of 1.6 points (37). Statistical power of 90% and a possible sample loss of 20% were considered. Consequently, a total of 60 individuals will be needed, with 30 in each group. This calculation was performed using Minitab v.17 software (State College, PA, USA).

Recruitment {15}

Recruitment of participants in the research will be achieved by means of announcements using local media, internet, radio, and posters distributed throughout the city of São Carlos.

Assignment of interventions: allocation

Sequence generation {16a}

The individuals included in the study will be randomized using block exchange methods available at the website <http://randomization.com>, with allocation to the TA group (n = 30) or the LA group (n = 30).

Concealment mechanism {16b}

Concealment of the allocation will be achieved using sequential numbering, in sealed opaque envelopes, which will only be opened before the first session, by the researcher responsible for application of the treatments.

Implementation {16c}

Randomization will be performed by a researcher responsible only for the randomization, with no other role in this study.

Assignment of interventions: Blinding

Who will be blinded {17a}

The evaluator will be blinded to the randomization and intervention processes, be responsible only for recruitment and evaluations, and receive no information regarding the allocation of the individuals to the groups. The participants and the researcher responsible for the treatment will not be blinded, due to the nature of the interventions.

Procedure for unblinding if needed {17b}

The evaluator will not be allowed to unblock the blinding. However, the acupuncturist researcher responsible for applying the treatments will not be blinded.

Data collection and management

Plans for assessment and collection of outcomes {18a}

The interventions will follow an application protocol. The evaluator will be trained in application of the questionnaires and tests, while intra-examiner reliability will be estimated by calculation of ICC.

Plans to promote participant retention and complete follow-up {18b}

The participants will be provided with guidance when they sign the informed consent form and commit to attending on the scheduled treatment dates. They will receive a card with the dates of the treatment sessions, a contact telephone number, and a WhatsApp contact number used only for this research. This procedure will ensure that participants receive the necessary attention and will assist in fully accompanying them during the research. If individuals abandon the trial, the reasons will be recorded, the most recent data will be compiled, and analysis will be performed using the intention-to-treat principle.

Data management {19}

All the data will be collected weekly, saved as PDF files, and stored on the UFSCar institutional Google Drive. The person responsible for data management will be the principal investigator, namely the acupuncturist researcher who applies the treatments.

Confidentiality {27}

The data will be stored on the institutional Google Drive of Federal University of São Carlos (UFSCar). Only researchers from the UFSCar, who participate in this research, will have authorization to access these stored documents. The metadata will be stored for the long term in the UFSCar research data repository.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable to this research.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The statistical inferences for the primary and secondary outcomes will be made by an assessor blinded to the randomization and assessment processes. The intention-to-treat principle will be adopted in the analyses. The normality of the data will be evaluated using the Kolmogorov-Smirnov test. Specific analyses will be used, depending on the distribution (normality and homogeneity) of the data. Parametric and nonparametric analyses will be used for normally and non-normally distributed data, respectively. These analyses will be performed using SPSS v.17 statistical software (SPSS, Inc., IL, USA), considering a statistical power of 90% for all the tests, with a significance level of $p < 0.05$.

Interim analyses {21b}

No provisional analyses will be performed. In cases of discontinuity, the intention-to-treat principle will be adopted.

Methods for additional analyses (e.g. subgroup analyses) {20b}

No subgroups will be analyzed.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

In the case of discontinuity, missing data will be handled by adopting the intention-to-treat principle, in order to make statistical inferences.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Not applicable to this research.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

Not applicable to this research.

Composition of the data monitoring committee, its role and reporting structure {21a}

Data monitoring committees are usually established for large studies. The present study is not multi-center and will be performed at UFSCar. The researcher will be responsible for organizing and monitoring the data obtained in this research.

Adverse event reporting and harms {22}

In the case of any harm or complication related to the treatments, this will be reported to the UFSCar Ethics Committee for Human Research. The same applies to possible ethical issues that may arise during the research. The guideline recommendations will be strictly followed.

Frequency and plans for auditing trial conduct {23}

Not applicable to this research.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

This study it was registered with RBR-7vbw5gd (Brazilian Registry of Clinical Trials - ReBEC) and there will be no substantial alterations to the protocol, such as changes in the eligibility criteria and analyses. If

there is any modification, it will be reported in writing, in a document sent to the trial registration office.

Dissemination plans {31a}

After publication of the results in a scientific journal, all data will be available over the long term and kept in the UFSCar research data repository.

Discussion

The purpose of this study is to compare the TA and LA techniques, assessing which is most effective in reducing chronic nonspecific neck pain. Since the 1970s, the World Health Organization (WHO) has encouraged the use of TA (66), considered to be a low-cost therapy (24) that can provide clinical benefits relevant to neck pain (19, 36). In contrast, there have been few studies of the use of LA for conditions involving neck pain (47). LA is an efficient analgesic and anti-inflammatory therapy that is totally painless, non-invasive, safe, and without adverse effects or complications. This technique may be used in locations where the insertion of needles is complicated or risky (30, 33, 43), being a useful option for individuals with needle phobia. Until the present moment, there are no studies in the literature that have effectively compared TA and LA in cases of chronic nonspecific neck pain.

This research will be based on evaluating and comparing changes in pain symptoms and the functional capacity of the neck, after application of the treatments. The results obtained for the two groups will be quantified and compared. Based on the findings, it will be possible to establish the therapeutic potential of each treatment, considering the outcomes of pain and cervical disability, making possible to identify whether there is a difference between the techniques in the treatment of chronic nonspecific neck pain.

Trial status

The protocol registration was approved on 6th June 2021. The initial recruitment date will be 10th August 2021 and the approximate date of completion of the recruitment of participants will be up to the second half of 2022.

Abbreviations

Global Perceived Effect Scale (GPE)

Conditioned Pain Modulation (CPM)

Temporal summation of pain (TS)

Pressure Pain Threshold (PPT)

Numerical Rating Scale (NRS)

Traditional Acupuncture (TA)

Laser Acupuncture (LA)

Federal University of São Carlos (UFSCar)

Brazilian Registry of Clinical Trials (ReBEC)

Declarations

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Authors' contributions {31b}

Peron, R.: Conceptualization, Methodology, Writing original draft.

Rampazo, É. P.: Methodology, Review.

Liebano, R. E.: Conceptualization, Methodology, Review, Supervision.

All authors have given final approval of the version to be published.

Funding {4}

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Availability of data and materials {29}

Not applicable.

Ethics approval and consent to participate {24}

The authors declare that they have obtained the approval of the Research Ethics Committee of the Federal University of São Carlos (UFSCar), under protocol number CAAE 39912520.1.0000.5504. In order to participate in this research, the volunteers must sign free and informed consent forms.

Consent for publication {32}

Not applicable.

Competing interests {28}

There are no conflicts of interest.

Authors' information (optional)

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Tables

Table 1
– Laser acupuncture parameters

Parameters	Infrared laser
<i>Center wavelength [nm]</i>	<i>808</i>
<i>Operating mode</i>	<i>Continuous wave</i>
<i>Output Power [mW]</i>	<i>80</i>
<i>Power density [W/cm²]</i>	<i>1.14</i>
<i>Beam profile</i>	<i>unique</i>
<i>Irradiance at target [W/cm²]</i>	<i>1.14</i>
<i>Energy density [J/cm²]</i>	<i>137.1</i>
<i>Total time per point [s]</i>	<i>120</i>
<i>Radiant energy per point [J]</i>	<i>9.6</i>
<i>Number of points irradiated</i>	<i>8</i>
<i>Area irradiated [cm²]</i>	<i>0.07</i>
<i>Total radiant energy [J]</i>	<i>76.8</i>
<i>Angle of application</i>	<i>90°</i>
<i>Application technique</i>	<i>Contact</i>

Figures

1.Tianzhu; 2.Fengchi; 3.Jianjing; 4. Jianzhongshu

Figure 1

Acupuncture points that will be used in therapies.

Figure 2

Flow diagram of the randomized clinical trial. NRS Numeric rating scale PPT Pressure pain threshold TS Temporal summation of pain CPM Conditioned pain modulation GPE Global perceived effect scale