



Protocol

Acupuncture and Dry Needling in the Reduction of Peripheral Acute Fatigue Induced in the Biceps Braquii: Protocol for a Single-blinded Randomized Controlled Clinical Trial



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ARTICLE INFO

Article history:

Received 1 February 2019

Received in revised form

30 July 2020

Accepted 24 August 2020

Available online 1 September 2020

Keywords:

acupuncture

dry needling

electromyography

muscle fatigue

thermography

ABSTRACT

The present study aims to propose a protocol to verify the efficacy and acute effects of traditional Chinese acupuncture, dry needling, and the rest in peripheral acute fatigue (PAF) induced by intermittent isometric contractions of the nondominant biceps brachii (BB) of nonphysically active men in a randomized, single-blind clinical trial assessed with surface electromyography, contraction time in seconds, infrared thermal imaging, and visual analog scale applied to the PAF. These instruments will evaluate the median frequency, endurance time, temperature (°C), and perceived fatigue in BB of the volunteers. The measurements will be collected in four moments (Test 0, 01, 02, and 03) divided between the beginning and the end of two sets of exercises (Exercises 01 and 02) of intermittent isometric contractions.

Trial identifier: NCT03448120 in www.clinicaltrials.gov.

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1. Introduction

Peripheral acute fatigue (PAF) is caused by factors that reduce the contractile capacity of the muscle, making it incapable of generating force [1,2]. There are several methods for your treatment from synthetic products like amphetamine, ephedrine, caffeine, and some natural products [3], supplementation [4], rest [5], massage [6,7], cryotherapy [8], electrotherapy and other procedures [4]. More and more therapies such as traditional Chinese acupuncture (TCA) and dry needling (DN) have been studied the effects of recovery and reduction of PAF [2,9].

The main evaluation of PAF is with surface electromyography (EMG) that analyzes the median frequency (MF) emitted by the active muscle, while also quantifies the contraction time [3].

With the increase of muscular activity, there is an inevitable increase in cutaneous temperature due to circulatory changes, thus, it becomes possible to evaluate PAF by measuring body temperature with infrared thermographic imaging (ITI) [10]. Concomitantly, there is a greater energy expenditure and rupture of muscle fibers, which alters the perception of effort and pain, therefore, the visual analog scale (VAS) is sensitive to evaluate the perception of PAF, bringing the psychological aspects related to PAF and its modulation [11].

Some studies use the DN to treat lesions in sports practice access the influence of DN on blood flow, oxygenation, and myofascial control [12–15]. Although recent studies attested the DN efficacy on flexibility [16] and quadriceps muscle fatigue [17], there is still no defined protocol for inducing and recovery of PAF using DN, nor one that compares the DN with the already known effects of TCA [2,18]. Nevertheless, understanding the relationship between different needling therapies on a standardized protocol for induction and recovery of PAF may lead to better and, effective usage of these interventions.

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Therefore, this study aims to delimit the protocol of a single-blinded randomized controlled clinical trial to evaluate the efficacy and acute effects of TCA, DN, and the rest (as a control) in PAF induced by intermittent isometric contractions of the nondominant biceps brachii (BB) of nonphysically active young men.

2. Methods

This is a protocol for a single-blinded randomized controlled clinical trial, published in Clinical Trials (www.clinicaltrials.gov) under registration number NCT03448120. It has three arms in which volunteers will be randomly allocated. The study will be carried out at the *Laboratório de Cinesioterapia e Recursos Terapêuticos Manuais*, located in the Physiotherapy Department of the Universidade Federal de Pernambuco, in Recife, PE.

2.1. Eligibility criteria

The eligibility criteria included male volunteers aged 18–40 years having body mass index (BMI) between 18.5 and 29.9 and nonphysically active in accordance with the international physical activity questionnaires (IPAQ) short version.

The volunteers excluded from the study are as follows: (i) who use food supplementation; (ii) who have lesions on the upper limb; (iii) who have metabolic problems; (iv) who use hormone therapy; (v) who have ingested caffeine within two hours before the study; (vi) who have the presence of myofascial trigger points (MTPs) in the areas of needle insertion; (vii) who have BMI less than 18.5 or more than 29.9; (viii) “active” or “very active” in accordance with the IPAQ short version.

Initially, a Socio-Anthropometric Profile Form will be used to obtain information from volunteers to evaluate volunteer eligibility, presenting their weight, height, and BMI, the group they will belong and the blood pressure.

2.2. Assessments

a. Electromyographic activity and time (endurance) assessment

In accordance with the surface EMG for the non-invasive assessment of muscles (SENIAM) guidelines [19], for the acquisition of the EMG signal during the exercises, we will be using the Electromyograph Miotool SDS 500, from MIOTEC®, with 4.5×3.8 cm disposable Ag/AgCl surface electrodes, arranged in parallel to the BB muscle fibers.

The BB will be prepared with abrasion, and, when necessary, the trichotomy. Afterward, the surface electrodes positioned between the middle third and the distal third of the BB muscle of the nondominant limb of the subject will be applied with a distance of 2 centimeters between the poles of detection. The reference electrode will be placed over the lateral epicondyle of the tested limb.

The electromyographic signal will be captured using the Miotool software, version 2.0.15 of MIOTEC®. We will analyze the EMG parameters of the MF for the PAF study. In addition, a maximum voluntary isometric contraction (MVIC) test will be performed with an SDS 1000S rigid load cell of the Miotec® coupled to the Miotool Electromyograph with feedback to the analysis computer.

b. ITI assessment

The ITI camera will be calibrated before data acquisition: The camera is turned on and its lens is directed to the region of interest (RI); one should expect an average of 10 minutes for the uncooled camera to adjust to the ambient conditions (temperature and

relative air humidity) and electronic devices in the same environment, that is, acclimatization [20].

The ITI data collection room should have a minimum of 6 to 9 m², with black walls so that the ambient temperature is maintained between 18 and 25 °C, as well as the relative air humidity, which should vary between 40 and 70% [20]. The parameters of ambient temperature and relative humidity must be constantly monitored with an indoor thermo-hygrometer, model TA298.

The camera will be attached to an adapted tripod, with the lens facing perpendicularly to the side view of the subject's RI at a distance of one meter. The ITI will be recorded by a noncooled thermographic camera (FLIR® Model E40bx), with an emissivity of 0.98, used to monitor the temperature of the human body surface [20].

c. Perceived subject assessment of PAF

A 10 cm scale with a “no fatigue” field (0) at one end and “maximum fatigue” (10) on the opposite side will be used.

2.3. Delimitation and analysis of primary and secondary outcome variables

a. Surface EMG (MF)

For the data analysis, the first and last contractions will be excluded to normalize the sample and the specter of each remaining contraction selected for analysis of EMG variables (MF).

The MF evaluation will be carried out with a window of 500 milliseconds in the center of each of the first three and last three contractions of the intermittent isometric exercises (Exercises 01 and 02). From these, the mean of the initial and final contractions will be calculated, resulting, respectively, in the initial MF and final MF of each exercise.

b. Contraction time (endurance)

The time of intermittent isometric contractions will be delimited by the number of valid contractions during each exercise. A valid contraction equals 10 seconds of muscle activity for each isometric contraction. Rest intervals during exercise will not be measured.

c. ITI assessment

This variable will be the mean temperature of the RI adapted from the Glamorgan protocol [21], in an ellipsoid shape appropriate to the area of the BB medial view, in which its vertices will be aligned with the volunteer's axillary line and the cubital fossa. The ITI will be captured in four moments (Test 0, 01, 02, and 03). These images will be processed with the FLIR® Tools software.

d. VAS assessment

The PAF perception of each volunteer will be acquired by an evaluator who presents the VAS with 10 cm in four moments (Test 0, 01, 02, and 03) in which will be marked his PAF perception in the active muscle during the exercises.

3. Procedure

3.1. Randomization, allocation, and blinding

The volunteers that meet the eligibility criteria will be divided into three groups: the TCA group, the DN group, the control group (CG); in which volunteers are going to be randomly allocated

through the website www.randomization.com, following the CONSORT flowchart and guidelines.

Five independent researchers will perform the data acquisition and interventions as follows: (1) one researcher is responsible for the recruitment, application of questionnaires, anthropometric data assessment, randomization, acquisition, and VAS assessment; (2) another researcher is responsible for the acquisition and processing of EMG and time data; (3) a researcher will acquire and process the ITIs and the application of the DN; (4) a previously trained and experienced researcher will perform the TCA; (5) a researcher will exclusively analyze the statistical data. Researcher 5 and volunteers will be blinded to all interventions. To apply TCA and DN, disposable Dong Bang® filiform needles of 0.25 × 40 mm will be used.

3.2. TCA description

The TCA will be made in the following acupoints in this order: large intestine (LI1; *Hegu*), triple heat (TH5; *Waiguan*), LI10 (*Shousanli*), LI11 (*Quchi*), LI14 (*Binao*) e gallbladder (GB21; *Jianjing*). Usichenko et al. [22] presents these acupoints as the ones that show greater variation in temperature in the upper limb in accordance with ITI. The needle direction will be at 90° with the cutaneous surface. Its depth varies with the topographic location of each acupoint.

To localize the six acupoints, the *tsun* measure will be used, which corresponds to the volunteer's interphalangeal or thumb measurements. This measure is unique for each individual, therefore, for each new volunteer, this measure should be taken with a manual caliper of the brand Mototem.

3.3. DN description

Six needles will be inserted into the volunteer's bicipital region: one needle in the center of the muscle belly, another two centimeters below, and another two centimeters above that which was first applied. Two needles in the tendons, one applied proximally (long head of the biceps) and one distally (tendon of insertion) and finally, one in the bicipital retinaculum. A fast-in and fast-out technique will be used as stimulation as described by Hong [23] and similarly used by Ershad et al. [17] and Ansari et al. [16] for immediate effects.

There are no DN protocols for conditions other than myofascial pain; therefore, the positioning of the needles is justified in the objective that this protocol is not for the treatment of MTP, but for the attempt to create a new protocol for the relief of PAF symptoms. Therefore, its topographical location is based on the anatomy of BB and the needle insertion in nonacupoints.

3.4. Volunteer positioning

To properly position the volunteer's limb, a simple manual goniometer of the Carci® brand will be used. The volunteers, without a shirt, will lie down in a supine position, on a stretcher with articulated arms, shoulder abduction and rotation, elbow flexion, and hand supination at 90°.

3.5. PAF induction

The MVIC test will be performed after the volunteer is positioned. Three to five maximum isometric contractions of five seconds with a minute interval between them shall be made. The highest value among these three contractions will be chosen, and then the exercise load (80% of the MVIC) and exercise failure point (EFP; 50% of the MVIC associated with the homogeneous fall of the

muscle force periodogram) will be defined [24,25]. After the MVIC test, the subject will rest in the same position for 10 minutes for acclimatization [20] before starts the steps for acquisition.

Two series of intermittent contractions will be performed to capture the EMG in two different moments (Exercise 01 and 02). For each contraction, the individual will be instructed to perform it up to 80% of the MVIC controlled by visual feedback (10 seconds of sustention and 5 seconds of relaxation). The subject will cease contractions upon reaching EFP.

a. Steps for acquisition:

- I. Test 0 (Baseline): VAS and ITI assessment;
- II. Exercise 01: The exercise will begin with 80% of the MVIC and 50% for EFP;
- III. Test 01: VAS (after 5 minutes acclimatization) and ITI assessment;
- IV. Intervention: TCA, DN or rest;
- V. Test 02: VAS and ITI assessment;
- VI. Exercise 02: Again, the exercise will begin with 80% of the MVIC and 50% for EFP;
- VII. Test 03: VAS (after 5 minutes acclimatization) and ITI assessment.

3.6. Statistical analysis

The data will be analyzed by SPSS®, version 25.0. The distribution of the data will be verified by the Kolmogorov-Smirnov test with Lillefords correction. This analysis will determine whether the data should be treated with parametric tests (repeated measures ANOVA (The one-way analysis of variance. A statistical test.)) or nonparametric tests (Kruskal–Wallis), thereby performing inductive statistics. The homogeneity of the sample will be verified by the Levene test. In addition, we will estimate the effect sizes of the treatments with Cohen's d. For descriptive statistics, data should be presented by arithmetic mean and standard deviation for sample characterization. The level of significance of the tests will be stated in $p \leq 0.05$, and when necessary, Bonferroni correction should be used together with the t-test for paired samples, for intragroup analysis.

Initially, a descriptive analysis will be performed to characterize a sample. For this, measures of central and standard tendency (mean and standard deviation) can be used for continuous variables and frequency measures for strategic variables.

4. Ethical approval

This study was approved under registration n. 2.419.094., of the Research Ethics Committee in human beings as foreseen in Resolution 466/12 of the National Health Council and the Declaration of Helsinki.

5. Anticipated results

We emphasize that this is a new protocol to reduce PAF symptoms generated by an intermittent isometric exercise, mainly for the DN technique, which is based in the TCA and the nonacupoints needling, thus, we can hypothesize that the same results for each procedure can be expected, given the similar physiological responses found in each technique. In addition, the CG should expect the same importance regarding the PAF treatment with rest because it is a major procedure to muscle recovery and PAF reduction.

6. Anticipated discussion

In accordance with other studies of muscle electrical activities [24,26], contraction time [27,28], temperature variations [29], and fatigue perception [15,30,31], our protocol indicates that it can generate peripheral muscle fatigue. Regarding the fatigue recovery, the needling techniques such as TCA [30,31] and DN [32] can generate this effect. Although, we cannot yet affirm if any of these therapies are better than each other, or more effective when compared with a control, to provide higher muscle fatigue recovery.

Thus, the future results of this study might reveal that the application of the TCA and the DN can show significant results, and that they may not differ from the CG. Therefore, the TCA and DN techniques should provide the same capacity to reduce the PAF induced in the BB in nonphysically active men.

Funding

This research was funded by Fundação de Amparo à Ciência e Tecnologia do Estado de Pernambuco (FACEPE) APQ No. 0337-13. With thanks to Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES).

Declaration of Competing Interest

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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