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Effects of Sliding Cupping Therapy on Pain Intensity, Fatigue Perception and Muscle Performance After a 10 Km Run: Protocol for a Sham-Controlled Randomized Clinical Trial

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SUMMARY

Background. Running induces adaptive responses, such as muscle fatigue that alter muscle strength and power. Button cupping therapy has been applied in clinical practice, under the theories that its application influences the microcirculation and the nervous system, however, there is a scarcity of studies that investigate its effects in athletes. In this context, this protocol aims to evaluate the effects of sliding cupping therapy on pain, perception of fatigue and muscle performance after a 10 km run, with the hypothesis that cupping will produce expected changes when it occurs to the other group.

Methods. This is a sham-controlled, randomized, double-blind clinical trial, in which 64 volunteers will be randomly allocated into two groups of 32 participants: intervention group (sliding suction cup with gentle suction on the quadriceps) and sham group (sliding suction cup without compression on the quadriceps). The participants will be evaluated before the race, after the race, immediately, 24 h and 48 h after the intervention, through isokinetic dynamometry, vertical jump test, algometry, and scales of perception of pain and fatigue and perception of recovery. Statistical significance will be set at 5% and a 95% confidence interval (95%CI).

Conclusions. This sham-controlled, randomized and blinded clinical trial protocol may serve as a basis for further research, contributing with a scientific direction for the application of sliding cupping therapy after physical activity.

Study registration. Brazilian Clinical Trials Registry (identifier RBR-10fg77vk).

KEY WORDS

Athletes; fatigue; physical functional performance; recovery of physiological function; running; sliding cupping.

INTRODUCTION

In addition to the various benefits that regular running practice provides (1), we observed the presence of adaptive responses, such as muscle fatigue, which is related to the adaptation mechanism of the neuromuscular system in response to prolonged or intense exercise (2), which it alters the homeostasis of the local musculature and the neural inputs for the motoneurons (3), reducing the strength and speed of muscle contraction, consequently, reducing the power (4), in addition to decreasing the proprioceptive feedback (5).

When the training dosage is not performed properly, the fatigue caused by running can impair performance (6), influence the risk of musculoskeletal injuries in amateur runners (7) and cause acute pain that, when not treated, can worsen or become chronic (8). To help with recovery, some therapeutic resources can be used, such as cryo-immersion (9), massage (10) and cupping therapy (11).

Cupping therapy is widespread as an auxiliary resource in muscle recovery, pain relief and treatment of various alterations (11). Cupping therapy was classified as dry, when a vacuum was used, or wet, when bleeding occurred (12). Currently these classifications have been updated, adding the sliding cup (12). The application of the suction cup mobilizes cutaneous, subcutaneous and muscular tissue, depending on the suction exerted (13), being slid for 5 to 10 minutes. Local vasodilation is observed with the presence of edema that can progress to erythema that disappears in a few days (14).

Although widespread in clinical practice, cupping therapy lacks studies with methodological rigor to substantiate its effectiveness, especially in relation to recovery after physical exertion (11). A study carried out a review addressing some theories about the effects of cupping therapy on microcirculation, but there are few clinical trials that actually prove its effectiveness in recovery (15).

Because of this, the present study aims to describe a clinical study protocol to evaluate the effect of sliding cupping therapy on pain, perception of fatigue and muscle performance in runners after a 10 km run. The hypothesis is that its application will provide better recovery of the evaluated outcomes compared to sham.

METHODS

Study design

This is a protocol for conducting a randomized, double-blind, sham-controlled clinical trial. The study was registered on the Brazilian Clinical Trials Registry (ReBEC) platform, identifier: RBR-10fg77vk and was approved by the Ethics Committee of the Federal University of Rio Grande do Norte (Number: 5.411.218 – Date of approval: May 16, 2022). The study follows the principles described in the Declaration of Helsinki and the privacy of participants is respected in accordance with Resolution 466/12 of the National Health Council. Research reports will be in accordance with the recommendation of the TIDieR (Template for Intervention Description and Replication) (16) and the SPIRIT (Standard Protocol Items: Recommendations for International Trials) checklist (17). The flowchart is shown in **figure 1**.

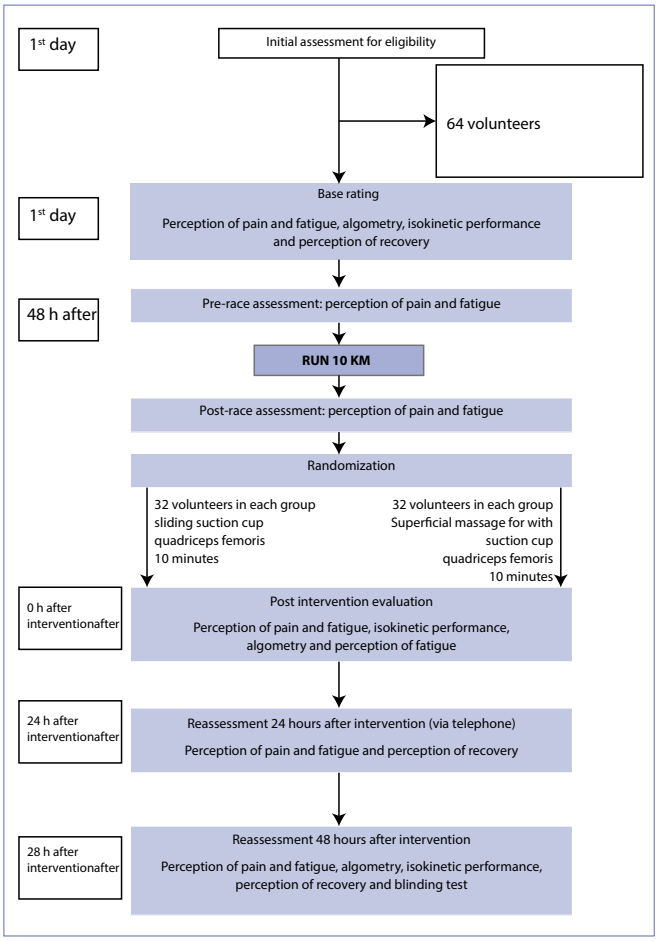

Figure 1. Study flow diagram.

Participants

Participants will be recruited through disclosure on social media and through direct contact with running advisors in the metropolitan region of Natal/RN. The first contact will take place via telephone to schedule the screening, which will

be carried out by a single evaluator. If eligible, participants will be informed about the objectives and procedures of the study and must sign the Informed Consent Form (TCLE).

Inclusion criteria

- Showing disorders in the quadriceps femoris, such as, for example, hematoma and cramps, during the study procedures.
- Failing to complete the 10 km run.
- Failure to correctly perform assessment procedures.
- Make use of anti-inflammatory drugs, corticoids, analgesics or muscle relaxants during the collection period.
- Carry out another type of intervention for muscle recovery during the development of the research.

Research team

This study will involve six researchers. Researcher A: screening and assessments; B: randomization of participants and intervention; C: scheduling of volunteers; D: monitoring of races; E: data tabulation; F: statistical analysis.

Randomization

The randomization table will be generated by researcher B, on the website www.randomization.com. The participants selected in the screening, carried out by researcher A, will be randomly allocated through an individual, opaque and sealed envelope, into two groups: intervention group that will receive the sliding cup, and sham group that will receive cup without negative pressure.

Blinding

All evaluations will be carried out by researcher A, who will not be involved with the interventions and will remain blind to the identification of groups.

Each participant will remain identified by numbers. Participants will be informed about the objective of the study to evaluate the effect of two different cupping techniques: the classic and the sham cupping. During the application of the technique, participants will be positioned in dorsal decubitus with a physical barrier above the hip to prevent visualization of the lower limb. The intervention times will be different so that there is no contact between the groups and possible exchanges of information. The data collected during the evaluations will not be revealed to other researchers.

At the end of the last assessment, each participant will be asked which intervention they believe they have received, in order to verify the effectiveness of the blinding strategy. After the last evaluation, researcher E will tabulate the data that will be delivered to researcher F, responsible for the statistical analysis and who did not participate in the previous stages of the research.

Procedures and interventions

Participants will be informed about the procedures adopted in the research, which will take place at the Neuromuscular Performance Analysis Laboratory (LAPERN), of the Department of Physiotherapy at UFRN. The baseline assessment will take place 48 hours before the race. After the race, there will be a new evaluation. Then, participants will be randomized and receive the intervention and reassessment. 24 h after the intervention, researcher A will contact the participant via telephone to carry out the subjective evaluation, and 48 h after the intervention, the final reassessment will be carried out.

Intervention group

There is no established protocol in the literature, however, one study suggests that, for sliding, humectant should be used, and negative pressure should be gentle, equivalent to suction performed with a pistol (13).

In the protocol adopted in this study, an acrylic cup with a diameter of 4.5 centimeters and sunflower oil will be used. The application will take place in the entire length of the quadriceps femoris, in the longitudinal direction, respecting the path of the muscle bundles, starting 5 cm below the anterior superior iliac spine up to 5 cm above the base of the patella, for 10 minutes and, at the end, the excess of the oil with wet wipes.

Sham group

The same cupping patterns of the intervention group will be used, but the cupping will be perforated superiorly, so that the vacuum escapes slowly, guaranteeing the blinding of the participants.

Sunflower oil will be applied and the suction cup on the quadriceps. A suction will be carried out producing a vacuum that will be gradually eliminated. The slide will be smooth, simulating the execution of the technique for 10 minutes. After the simulation, excess oil will be removed with wet wipes.

Assessments

After screening (T0), the volunteers will undergo the evaluation (T1), as well as after the race (T2), after the intervention (T4), remotely 24 hours after the intervention (T5) and 48 hours after the intervention (T6).

Primary outcome

Perception of pain and fatigue

The subjective perception of pain and fatigue will be evaluated from the numeric analogue scale that has a graduation from 0 to 10, where 0 would be no pain and fatigue

and 10 would be an extreme level of pain and fatigue. This scale has adequate reliability and applicability for subjective pain measurement and is responsive to changes in fatigue (18). The volunteer will be asked to perform a squat and soon after report the feeling of pain and fatigue based on the scale.

Secondary outcomes

Isokinetic performance of the quadriceps femoris

The evaluation of the isokinetic performance of the quadriceps femoris will be performed using an isokinetic dynamometer (Biodex Joint Multi-System 4, Biodex Biomedical System Inc, New York, USA). The participant will be positioned sitting on the dynamometer chair with the thigh, chest and pelvic region fixed by belts. The axis of rotation of the dynamometer will be aligned with the lateral epicondyle of the femur and the lever arm will be adjusted in the distal portion of the leg, fixed 5 cm above the medial malleolus of the ankle. The gravity correction factor will be calculated using the dynamometer with the lower limb relaxed at 30° of knee flexion (19). Five concentric knee contractions will be performed at an angular velocity of 60°/s and 30 contractions at 240°/s. The movements will start in 90° of flexion until the complete extension of the knee. Participants will be familiarized with the equipment before each evaluation through 3 contractions at each speed, with 1 minute of rest between series. During the test, the participant will be encouraged to perform with maximum strength and at their highest contraction speed. In addition to verbal commands, the participant will receive visual feedback via the computer monitor (19). Peak torque normalized by weight, power, total work and dynamometric fatigue index will be evaluated.

Power

The power will be calculated using the jump mat linked to the Jump System software (Cefise, São Paulo, BR) which calculates the flight time in milliseconds after the loss of contact with the ground and estimates the vertical displacement in centimeters (20), based on the equation $h = t^2 \times g \times 8\text{-}1$, where "h" refers to the height of the jump, "t" to the flight time measured in seconds and "g" to the acceleration of gravity, with a value of 9.81 m/s^2 (21). The individuals will be instructed to perform three jumps with their hands resting on their waists, with an interval of 30 seconds between tests. The highest projection will be considered for future analysis (22). The jumps must follow an execution pattern so that there is no discrepant alteration in the results obtained (20), thus, the individual must position himself for the test with the knees in extension and trunk erect and will perform a knee flexion at an angle of approximately 120°, followed by knee extension in order to propel the body upwards, in a vertical movement (23). During the flight and landing phase, the trunk must remain stable and the knees extended, with upper limb movements not being allowed (23).

Pain

Pain will be measured using a pressure algometer model Wagner Pain Teste – Model FPX Digital Algometer. Pressure will be applied on the skin with a perpendicular incidence, in the center of the rectus femoris muscle belly, with a constant speed of 1 kg/s, until the volunteer reports the onset of pain. Three measurements will be performed with an interval of 20 seconds between pressures and the highest value will be considered for analysis (24).

Perception of recovery

The total quality of recovery (TQR) scale was created based on the subjective perception of exertion scale and has validity, according to previous studies, to assess the athlete's recovery after activity. The scale evaluates the individual's perception of this variable through a score. The final score ranges from 6 to 20 points, where 20 points indicates a complete recovery of the individual and the lower the score, the less recovered he is (25).

Blinding test

A questionnaire with 5 questions will be applied, at the end of the procedures, to assess the volunteer's perception in relation to the group in which he was allocated and his belief about the proposed treatment (26). The questions are: 1) What treatment do you think you received? With the answer options for suction cup real, false or don't know; 2) Did you feel any sensation during the application of the suction cup? With yes or no answer; 3) What sensations did you experience? With the following alternatives: pressing, inflating, painful, squeezing, relaxing, cooling, burning, pulling or hot tingling sensations; 4) Where was the sensation located? With the responses being the cupping area, a large area around the cupping application, or the entire anterior thigh area; 5) How much sensation did you feel? Being answered through the visual analogue scale, in which 0 represents nothing and 10 represents a very strong sensation.

Involvement of participants and the public

Participants will not be involved in designing this study, establishing the research question, or developing recruitment procedures. At the end of the study, the results can be reported to the participants in the form of a lecture, presenting the effects found in the studied variables.

Researcher training

For the evaluation and treatment, a series of training steps will be implemented before the start of the study, aimed at registering the actions taken. In these training stages, treatment techniques and measures will be used to reach a consensus among the researchers involved.

Sample calculation

The sample size was calculated based on the numeric pain scale of a previous study (18). A statistical power of 80% was used to detect a minimum difference between means of 1 point, with an estimated SD of 1.7 points and equivalence limit of 2.4, 5% significance level, and possible sample loss of up to 10%. For that, 32 individuals per group will be needed. The calculation was performed using the G-power software.

Statistical analysis

Statistical analysis will be performed by researcher E, who will be blind. Data will be analyzed using the software SPSS 22.0. The Kolmogorov-Smirnov test will be applied to verify the data distribution and the Levene test will be used to analyze the homogeneity of variance. If the data are normally distributed, the mean differences (difference between the two groups) for all variables will be estimated using the ANOVA mixed model, which incorporates the two intervention groups, time and group × time interaction. When a significant F-value is found, the Bonferroni *post-hoc* test will be applied to identify the differences. If the data are not normally distributed, the Friedman test is used.

An intention-to-treat analysis will be applied to ensure randomization effects, so that prognostic factors are evenly distributed in both groups. A significance level of 5% and 95%CI will be adopted for all statistical analyses.

DISCUSSION

Cupping has become part of recovery protocols for athletes, both amateur and professional (13). Recently, a study by Hou *et al.* and Liao *et al.* investigated the effects of fixed cupping therapy on biceps brachii fatigue after exercise (27, 28). However, until now, no well-defined protocols have been reported on the use of cupping therapy in the sliding modality for pain outcomes, perception of fatigue and muscle performance after physical activity.

This protocol presents all the procedures to favor a study of high methodological quality. Procedures and outcome measures were well defined, there is adequate randomization, previously calculated sample size and adequate blinding. Despite this, the heterogeneity of the sample can be a limiting factor.

CONCLUSIONS

Even so, this sham-controlled, randomized and blinded clinical trial protocol may serve as a basis for further research, contributing with a scientific direction for the application of sliding cupping therapy after physical activity as a way to improve pain, fatigue and muscle performance, contributing for better muscle recovery.

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DATA AVAILABILITY

N/A.

CONTRIBUTIONS

MMXF: writing – original draft, assistance in the study protocol development. YTP: writing – original draft, final approval. ELDAF, JOA, EBC: assistance in the study protocol development. IFO, LON: conceptualization. CAAL: conceptualization, final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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