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Dry cupping in the treatment of individuals with non-specific chronic low back pain: a protocol for a placebo-controlled, randomised, double-blind study

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ABSTRACT

Background Low back pain is a very prevalent condition in the population and cupping therapy has been presented as a frequently used non-pharmacological treatment in this population. However, there is a lack of well-designed studies that evaluate the effects of this technique. This protocol describes a placebo-controlled, randomised, double-blind study that aims to evaluate the effect of dry cupping therapy on pain, physical function, trunk range of motion, quality of life and psychological symptoms in individuals with non-specific chronic low back pain.

Methods and analysis Ninety individuals with chronic non-specific low back pain, aged from 18 to 59 years, will be randomised into two groups: intervention group, which will be submitted to dry cupping therapy application with two suctions; and placebo group which will undergo placebo dry cupping therapy. Both applications will occur bilaterally in parallel to the vertebrae from L1 to L5. The application will be performed once a week for 8 weeks. The volunteers will be evaluated before the treatment (T0), immediately after the first intervention (T1), after 4 weeks of intervention (T4) and after 8 weeks of intervention (T8). The primary outcome will be pain intensity, and secondary outcomes will be physical function, lumbar range of motion, patient expectation, overall perception of effect, quality of life and psychological factors.

Ethics and dissemination This protocol has been approved by the Ethics Committee of FACISA/UFRN (number: 3639814). The results of the study will be disseminated to participants through social networks and will be submitted to a peer-reviewed journal and scientific meetings.

Trial registration number NCT03909672.

Strengths and limitations of this study

- This is the first study to use a group of cupping therapy placebo in chronic low back pain.
- There is no standardised interventional protocol for use of cupping therapy in individuals with chronic back pain.
- This study will show effect of short-term, medium-term and long-term application of Cupping therapy in individuals with chronic low back pain.
- This study will have evaluator and blind participants, and will be further analysed with the intention to treat.

BACKGROUND

Low back pain is the leading cause of years-lived with disability in the population,[1] affecting all age groups, and more prevalent in adults.[1] It can be classified as acute when it lasts less than 6 weeks, subacute when it lasts between 6 weeks and 12 weeks, and chronic when it persists for more than 12 weeks,[2] with non-specific causes.[3] The diagnosis of non-specific low back pain is done by physical examination and history of pain, not necessarily by imaging.[3–5] Risk factors for chronic low back pain may be related occupational and leisure activities[6] and/or the individual's lifestyle,[7] in which psychosocial factors may have an important influence.[8–10] The symptom of pain may also be associated with physical impairments (eg, decreased trunk range of motion, ROM),[11 12] activity and participation limitation,[13] and work absenteeism, causing negative economic and social impacts.[14 15]

With regard to the treatment of non-specific chronic low back pain, recommendations from a recent guideline suggest that pharmacological approaches are used with low dosage and for a short period of time due to its potential side effects.[16] Non-pharmacological treatments, which includes pain education, exercise, and manual therapy are the most recommended approaches according to the most recent clinical practice

guidelines.[17] Nevertheless, Traditional Chinese Medicine (TCM) are commonly used in these patients and, according to a recent systematic review,[18] it may have positive effects on decreasing pain in individuals with chronic low back pain. TCM includes a wide range of mental and body practices, which aim at homeostasis and energetic and organic completeness, bringing well-being to the individual,[19] such as acupuncture and Tai Chi, in addition to cupping therapy.[18 20 21]

Cupping therapy has already been used in various health conditions such as fibromyalgia,[22] rheumatoid arthritis,[23] neck and shoulder pain,[24–26] carpal tunnel syndrome,[27] facial paralysis[28 29] and in low back pain.[30 31] It involves the application of glass, bamboo, ceramic or acrylic cups, which can be manually, automatic and self-removal, thus causing negative pressure in the subcutaneous tissues.[30 32] There are various application forms (dry cupping, wet cupping, massage cupping and flash cupping), different suction strengths (light cupping, medium cupping, strong cupping and pulsating cupping) and the application time is usually 5–10 min.[33 34] These applications may result in local stretching, releasing the muscle and decreasing local stiffness, and the onset of ecchymosis usually disappears in up to 10 days as a result, requiring an interval between the sessions for tissue re-establishment.[35] It is believed that fresh blood supply may increase at the site by suctioning the affected area, accelerating the elimination of metabolites and favouring recovery.[30]

Dry cupping is widely used in clinical practice with the goal of reducing pain in individuals with low back pain. A pilot study[35] used the dry cupping therapy as a treatment for 8 weeks and showed satisfactory results for the outcome of pain and improving ROM and function related to chronic low back pain. However, the study had a small number of participants, poor methodological quality (eg, inappropriate randomisation, no evaluator blinding and no placebo group), indicating the need for high-quality studies in this area. Another recent randomised clinical trial[36] combined dry cupping therapy with low-intensity laser, observing a reduction of two points on the analogue visual pain scale in individuals with non-specific chronic low back pain.

Cupping therapy is commonly used globally with promising results on low back pain;[37] however, its efficacy is controversial due to a lack of high-quality studies evaluating such effects. Although there is no theoretical support for its alleged effects,[38] the absence of studies with placebo-controlled groups makes the evidence on the efficacy of cupping therapy on improving chronic low back pain insufficient, according to a recent systematic review with meta-analysis.[37] In addition, there is no well delineated and standardised treatment protocol to be followed, according to a systematic review.[39] Thus, it is necessary to carry out more clinical trials with good methodological quality which contribute to clarify the effects of this technique on the clinical outcomes of patients with non-specific chronic low back pain.

Therefore, the aim of this study is to evaluate the effects of dry cupping therapy application on pain intensity, physical function, trunk ROM, quality of life and psychological symptoms in individuals with non-specific chronic low back pain compared with a placebo group. The hypothesis is that individuals with non-specific chronic low back pain treated with dry cupping therapy will show improvement in pain, trunk ROM, quality of life, physical function and psychological factors compared with subjects treated with placebo dry cupping therapy.

METHODS

Design

A double-blind, placebo-controlled randomised clinical trial. All personal data will be confidential. Participants will be randomised to receive dry cupping therapy and placebo dry cupping therapy application, with each group containing 45 participants (figure 1). The study follows the TIDieR (Template for Intervention Description and Replication) checklist[40] and the 2013 Standard Protocol Items: Recommendations for International Trials statement[41] (figure 2).

Participants

Ninety male and female individuals aged 18–59 years old, with a pain score ranging from 3 to 8 points and non-specific low back pain for more than 3 months will be recruited. The volunteers will be recruited from the waiting list of patients of the Physiotherapy School Clinic, and the project will also be announced by the local radio. After this, the first telephone contact will be made to clarify any questions from the participants, and the first screening for inclusion will be performed. When eligible for inclusion after being informed about the objectives of the study and procedures, the participants will be requested to sign the informed consent form.

Personal information (name, address and telephone number), anthropometric data (age, height, body mass and body mass index), demographic partner (profession, race, income and education) and pathological and clinical history will be collected. The personal data of the participants will be numerically coded and stored in a database, which can only be accessed by the researcher responsible for the randomisation and blinding process.

Inclusion criteria

- Individuals, male and female, 18–59 years of age, non-obese (BMI <30 kg/m^2), presenting non-specific low back pain for more than 3 months.[42]
- Report pain intensity between 3 and 8 according to the pain numerical rating scale.[43]

Exclusion criteria

- Travel plans in the next 2 months.

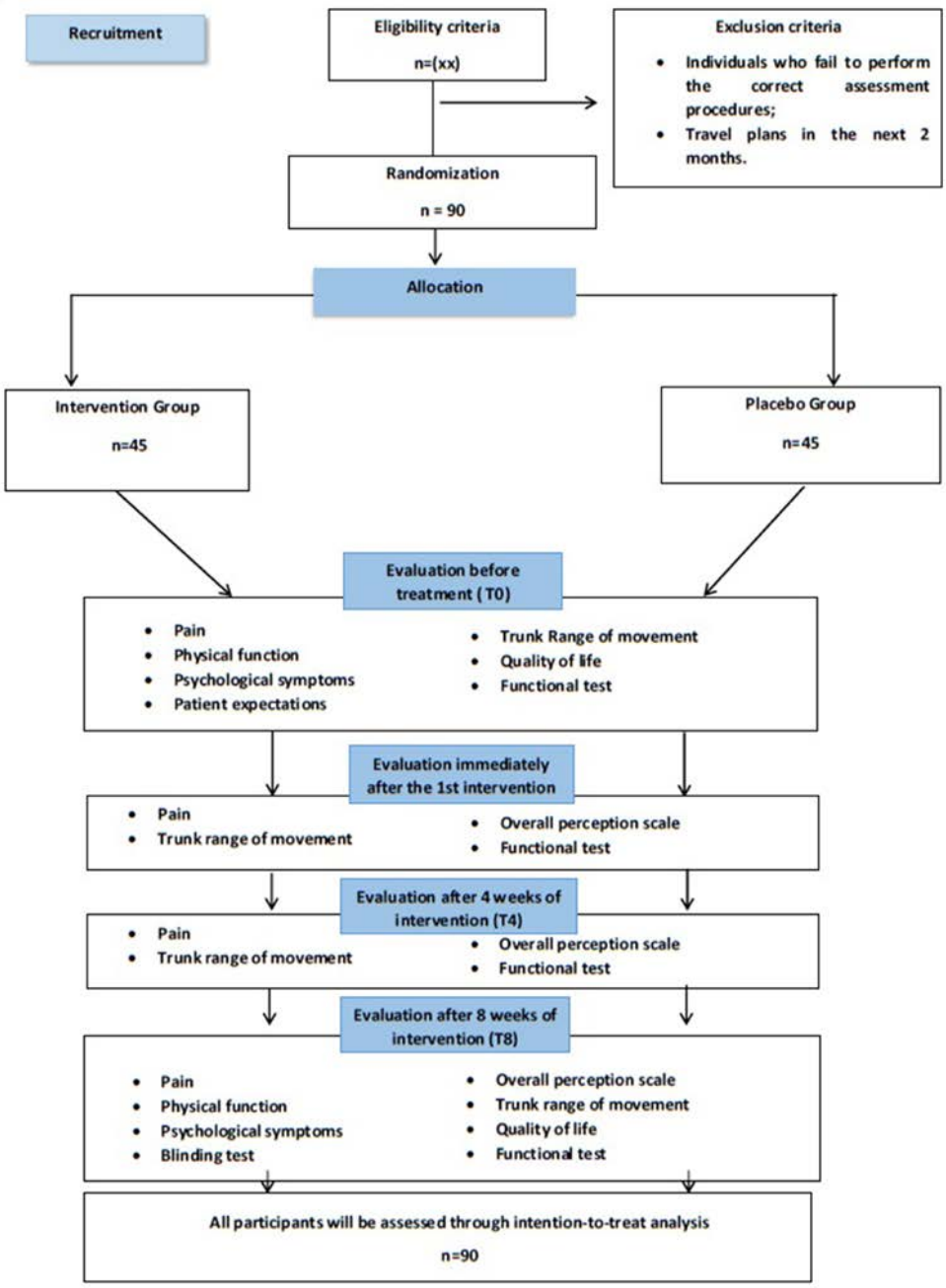

Figure 1 Study fluxogram.

- Individuals who have been treated with cupping in the past.
- Currently performing physical therapy.[44]
- Neurological, vestibular, visual or auditory deficits.
- Contraindication for cupping therapy.[30]
- Signs of serious pathology of the spine (eg, fractures, inflammatory diseases, infection or tumours).
- Irradiated lumbar[45] or sacroiliac pain.
- Other rheumatic diseases such as fibromyalgia[46] or ankylosing spondylitis.[47]

Research team

This study will involve four researchers; one researcher responsible for evaluations; one researcher responsible for interventions; one researcher responsible for randomising participants and one researcher who will perform the statistical analysis.

Randomisation and blinding

Participants who are eligible in the screening phase and who agree to sign the consent form will be randomly assigned to the dry cupping therapy group or the placebo application of dry cupping therapy. The random sequence numbering will be performed through the website www.randomization.com. The allocation will be concealed using consecutively numbered sealed and opaque envelopes. For this, an independent researcher

	STUDY PERIOD				
	Screening	Baseline	Post-allocation		
TIMEPOINT	$-t_1$	0	After the first intervention T1	Week 4 T4	Week 8 T8
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Dry cupping therapy			←	—	→
Placebo dry cupping therapy			←	—	→
ASSESSMENTS:					
Pain		X	X	X	X
Physical function		X			X
Trunk ROM		X	X	X	X
Functional test		X	X	X	X
Quality of life		X			X
Psychological factors		X			
GPE			X	X	X
Patient's expectation		X			
Blinding and suction sensation test					X
Medication consumption					X

Figure 2 Schedule of the study protocol according to the Standard Protocol Items: Recommendations for Interventional Trials checklist. GPE, Global Perception Scale; Trunk ROM, trunk range of movement.

who will not participate in other study procedures will carry out the randomisation process in order to avoid bias.

The researcher responsible for evaluations (assessor) will be blinded to all intervention groups. Participants will be informed that two different cupping techniques will be tested: classic versus placebo. Both groups will be questioned about which treatment technique they believe they received at the end of the treatment.[48 49]

The participants will respond to the questionnaires and perform the functional tests in their clothes for all evaluations, because bruising may occur from the dry cupping therapy application. Further, the intervention schedule will be different so that they do not have contact between groups, and the data collected during the evaluations of the participants will not be revealed to the researchers responsible for the interventions.

Finally, the researcher responsible for statistical analysis will be blinded. Once the intervention is completed, this researcher will receive a data table with all necessary data without identification of subjects and groups.

Interventions

All participants will be in the prone position for the application of the technique and will be informed about the initial suction sensation, about the possible appearance of bruising at the application site and possible adverse effects that will be registered, and that they can be referred to a specialised professional if the participant needs. If necessary, trichotomy of the application region will be individually performed as hair might interfere with the application. The interventions will take place in an air-conditioned room at the physiotherapy school clinic of the *FACISA/UFRN*.

A manual suction pump and 4 Dong Yang acrylic cups will be necessary for each group to apply the cupping technique. Both groups will receive dry cupping therapy applications for 10 min once a week for 8 weeks. The cups will be fixed by means of adhesive tapes so that they do not fall. The groups will be divided into intervention group with dry cupping therapy (IG) and placebo dry cupping therapy (PG).

Dry cupping therapy group (IG)

There is no well-defined protocol regarding the suction amount and application time for low back pain in the literature. However, one study suggests that the suction force for musculoskeletal pain is equivalent to 300 millibar, two suctions.[50] There is also no consensus for application time, but it is suggested to be between 5 and 10 min.[34] Studies aim to use a time of 10 min and suction with elevation of the subcutaneous tissue by 1.6 cm to not cause discomfort during the application.[35 51] A force with two suctions is used for 10 min in clinical practice. Therefore, we will use this application parameter in our intervention group. The treatment protocol is detailed in box 1.

Box 1 Treatment protocol performed by dry cupping therapy group and placebo

Drydry cupping therapy group (IG)—dry cupping therapy application with two suctions

Participants in the intervention group will receive the dry cupping therapy application with two acrylic size 1 cups (4.5 cm internal diameter) with a distance of 3 cm each cup, bilaterally parallel to the L1–L5 vertebrae (figure 3). This group will consist of the dry cupping therapy application with two suctions for 10 min, once a week, for 8 weeks.[34]

Placebo group (PG)—application of placebo dry cupping therapy

The placebo group will receive the placebo dry cupping therapy application with two acrylic type 1 cups (4.5 cm internal diameter) with a distance of 3 cm between each cup, bilaterally parallel to the L1–L5 vertebrae (figure 4). This group will consist of placebo dry cupping therapy application for 10 min, 1 time per week, for 8 weeks. However, the cups will be prepared with small holes<2 mm in diameter to release the negative pressure in seconds. Double-sided tapes will be used so that the glass does not fall off and lose contact with the skin.[48]

Figure 3 Application of dry cupping therapy with two suctions.

Placebo group (PG)

The placebo group will undergo the same procedures as the intervention group, with two suctions for 10 min. We will follow the recommendations of the literature, where the cups are prepared with small holes to release the suction in seconds.[48] The treatment protocol is detailed in box 1.

Evaluations

The volunteers will be evaluated before the treatment (T0), immediately after the first intervention (T1), after 4 weeks of intervention (T4) and after 8 weeks of intervention (T8).

Primary outcome measures

Pain

- Pain intensity will be measured by the Numeric Pain Rating Scale (NPRS),[52] in which patients are asked to choose a number between 0 (no pain at all) and 10 (worst pain possible). The NPRS score will be collected with the individual at rest, during the evaluation of the trunk range of movement and during performance of the timed up and go test.

Secondary outcome measures

Physical function

- The Oswestry Disability Index questionnaire will be used to assess the participants' physical function.[53 54] This instrument contains 10 items which assess the impact of low back pain on various functional activities. Values range from 0 to 5, with the highest value indicating greater disability. The end result is the sum of all items. The Portuguese version will be used.

Functional test

- Timed up and go (TUG): this is a functional test which quantifies the mobility of an individual in seconds through the time in which they perform the task, that is, in how many seconds can they lift themselves from a chair, walk 3 m, turn, return to the chair and sit down again. The test has already been used in individuals to assess function in individuals with low back pain,[55] and has the following scores: less than 20 s for performance, corresponding to low risk of falls, 20–29 s, average risk of falls and 30 s or more equates to a high risk of falling. The individual will perform the test three times and the average between the three trials will be recorded.[56]

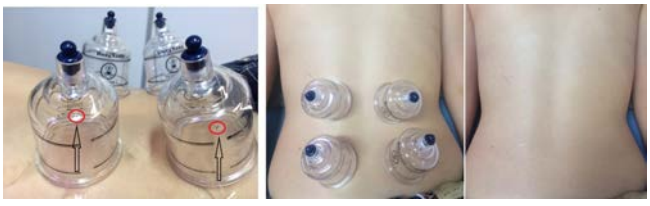

Figure 4 Application of placebo dry cupping therapy.

Trunk range of motion

- The ROM will be evaluated through the finger-to-floor test. This test presents high reliability and can be used for clinical practice and scientific studies.[57] The finger-to-floor test is performed with the subject standing erect and with their feet together. The participant will be instructed to lean forward as far as possible, keeping their knees, arms and fingers fully extended. The vertical distance between the tip of the middle finger and the floor is measured with a tape measure, and the pain will be measured during this active movement.

Perception of the overall effect

- Global Perceived Effect (GPE) Scale is a direct scale about the patient's self-perception when the intervention is performed. The Portuguese version will be used. The GPE evaluates using 11 points, starting from a negative 5 (much worse than when starting the treatment), a neutral rating of 0 and 5 is positive (much improvement from starting the treatment).[58 59]

Quality of life

- The quality of life will be evaluated by the Portuguese version of the Short-Form 36 (SF-36) questionnaire.[60 61] The instrument is composed of 36 questions and evaluates eight different domains which influence quality of life, considering the individual's perception regarding aspects of their health in the last 4 weeks. Each item has a group of responses distributed on a graded Likert scale, with the following dimensions: physical function, physical aspect, pain, general health, vitality, social function, emotional aspect and mental health. Their total score ranges from 0 to 100, where the higher the value, the better quality of life indicated.

Psychological symptoms

- Anxiety and depression will be evaluated through the Hospital Anxiety and Depression Scale,[62 63] a questionnaire which has also been validated and translated into Portuguese. This scale has 14 items, 7 for anxiety subscale and 7 for depression. For each item, there is a score of 0–3, with a total of 21 points for the scale. The cut-off value for each scale is ≥9. Absence of anxiety value is 0–8, with anxiety ≥9; anxiety/mild depression: 8–10; moderate anxiety/depression: 11–14; severe anxiety/depression: 15–21.

Blindness test and suction sensation

- The blinding and suction sensation evaluation will be evaluated through questions about the patient's belief in the proposed treatment. This questionnaire contains five questions related to which group the participant was allocated, actual dry cupping therapy intervention or placebo, which are: (1) *Which treatment do you think you received?* with the following three choices: real cupping treatment, sham cupping treatment or don't know. (2) *Did you have any sensations during dry cupping?* with a yes or no response. (3) *What sensations did you experience?* with the following options: pressing, inflating, painful, squeezing, relaxing, refreshing, burning, pulling or hot tingling sensations. (4) *Where was the feeling of cupping located?* with the answers being the cupping area, a broad area around the cupping jar or the whole lower back area. (5) *How much sensation did you feel?* using a 100 mm visual analogue scale (0 mm: not at all; 100 mm: very strong).[48]

Patient's expectation

- A Likert scale will be used for the patient's expectation regarding the treatment: the patient will be questioned about their expectation of the intervention with the following question: 'With the dry cupping therapy application, do you think you will': with the possible answers being: (1) get worse; (2) get a little worse; (3) not improve or get worse; (4) improve a little and (5) improve a lot.[64]

Medication consumption

Patients will be given a daily control list of medication use to mark the amount of their use for low back pain during the study period.

Table 1 lists the primary and secondary outcomes along with the time of evaluations during the study.

Patient and public involvement

Patients were not involved in the design of this trial, establishing the research question or developing recruitment procedures. At the end of the study, the results will be reported to the participants in the form of a lecture, showing the effects found in the studied variables. If the superiority of one technique is found on the other, it will be offered and guaranteed to the participant.

Researcher training

A series of training steps will be implemented before the beginning of the study for the evaluation and treatment, aimed at registering the actions performed in the study. Techniques and treatment measures will be used in these training stages to reach a consensus among the researchers involved.

Sample size calculation

Based on study values using similar methods,[65] a total sample of 90 participants (45 in IG and 45 in PG) will be sufficient to detect a clinically important difference between the two-point groups on the NPRS scale. A statistical power of 90% and an alpha of 5% and a loss rate of 10% were considered for the sample calculation. Gpower 3 software was used for the calculation.

Statistical analysis

The analysis will be descriptive for all the outcomes included in the study, expressing quantitative results with their mean±SD and qualitative outcomes with their absolute values, percentages and 95% CI.

Table 1 Evaluation time of primary and secondary outcomes

Outcomes	Before treatment, T0	Immediately after the first intervention, T1	4 weeks of intervention, T4	8 weeks of intervention, T8
Primary				
NPRS	✓	✓	✓	✓
Secondary				
ODI	✓			✓
Trunk ROM	✓	✓	✓	✓
GPE		✓	✓	✓
SF-36	✓	✓	✓	✓
TUG	✓			✓
HADS	✓			✓
PE	✓			
BSST				✓
MC				✓

BSST, blindness and suction sensation test; GPE, Global Perception Scale; HADS, Hospital Anxiety and Depression Scale; MC, medication consumption; NPRS, Numerical Pain Rating Scale; ODI, Oswestry Disability Index; PE, patient's expectations; SF-36, short-form 36;Trunk ROM, trunk range of movement; TUG, timed up and go test.

The Kolmogorov-Smirnov test will initially be performed to evaluate the normality of the data. Intergroup comparisons will be evaluated using ANOVA or Kruskal-Wallis analysis of variance, depending on the normality of the data. The SPSS (Statistical Package Social Science) V.21.0 software program will be used to analyse the data. A significance level of 5% ($p<0.05$) and CI of 95% (95% CI) will be implemented for all statistical analyses. All participants will be assessed through intention-to-treat analysis.

DISCUSSION

The purpose of this study is to evaluate the effectiveness of the dry cupping therapy on relieving pain and other symptoms which cause a negative impact on the quality of life in these individuals with non-specific chronic low back pain. To do, the study involves two arms with an intervention and a placebo, and interventions being one time per week for 8 weeks.

Psychological factors[66] may influence the inability of individuals with chronic low back pain. Based on this, this is the first study to evaluate the dry cupping therapy effect on the mental health of individuals with non-specific chronic low back pain. Previous expectation of the intervention may influence treatment outcome as well as patient satisfaction after treatment.[67] With this, we will evaluate the perception of the overall effect in order to know the patient's satisfaction with the proposed technique.

According to a recent review, existing studies using the dry cupping therapy technique to treat low back pain present methodological flaws (without adequate randomisation, did not present placebo, without blindness of the evaluators and participants), failing to evaluate its effectiveness on symptoms.[37] Our study may present high methodological quality because it presents adequate randomisation and allocation procedures, blinding of the assessor and researcher responsible for the statistical analyses and, finally it plans to use an intention-to-treat approach.

Blinding of the evaluator and of the participants is strongly discussed by the fact that the bruising is present at the end of the application and its permanence for up to 10 days.[68 69] To do this, we will try to blind participants by informing them that they will be tested on two different techniques of classic (traditional) dry cupping therapy versus placebo, and they will be asked questions at the end of the treatment on which treatment technique they believe they were submitted to. We will also follow the recommendations used in other studies that used placebo dry cupping therapy.[22 48] In addition, participants will respond to the questionnaires and perform the functional tests in their clothing for all evaluations; thus, the evaluator will not know which group the participant was allocated and the intervention times will be different so they do not have contact between groups.

Some limitations are expected in this study. First, we will not have control of participants' medication intake, but medication use will be monitored by a diary delivered to participants. Second, the pain threshold in women may present a difference when related to their menstrual cycle. To try to reduce this bias, both groups will be composed of women with an active menstrual cycle.

There is still no agreement on applying dry cupping therapy in individuals with non-specific chronic low back pain, and there is not enough evidence available to demonstrate such an effect of this technique in this population; therefore, this protocol will serve as a basis for new studies to be performed in order to analyse the effect of dry cupping therapy on non-specific chronic low back pain.

Dissemination

Respect for individuals will be insured and their autonomy will be maintained. Participants will be informed of the study objectives, its risks and benefits. Participants will be free to abandon the study at any time without the obligation of giving any explanation. Participants must sign the informed consent before the study begins. There will be prior contact with individuals through social networks, when all information about the study and the objectives will be presented, as well as the Resolution No. 466/2012 of the Brazilian National Health Council of 2012, which provides guidelines and standards for research involving human subjects. In addition, the study results will be circulated to peer-reviewed journals, lectures and scientific meetings.

Trial status

Volunteers were not yet being recruited at the time of manuscript submission.

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Contributors CAdAL and MCdS led the study design, and designed and planned the statistical analysis. HJdAS, BTS and RSS have made substantial contributions to the design of the study. HJdAS, BTS, RSS, CAdAL and MCdS reviewed the manuscript critically and gave final approval for publication.

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Disclaimer SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents. This study was performed with the authors' own resources and without external sources.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study was approved by the Ethics Committee of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi (FACISA/UFRN) with registration code (3639814). The ethical principles agreed in the Declaration of Helsinki will be respected for all study procedures. Respect for individuals will be insured and their autonomy will be maintained. Participants will be informed of the study objectives, its risks and benefits. Participants will be free to abandon the study at any time without the obligation of giving any explanation. Participants must sign the informed consent before the study begins.

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REFERENCES

1 Vos T, Abajobir AA, Abate KH, *et al*. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the global burden of disease study 2016. *Lancet* 2017;390:1211–59.
2 Manchikanti L, Singh V, Falco FJE, *et al*. Epidemiology of low back pain in adults. *Neuromodulation* 2014;17(Suppl 2):3–10.
3 Maher C, Underwood M, Buchbinder R. Non-Specific low back pain. *Lancet* 2017;389:736–47.
4 Carvalho FA, Maher CG, Franco MR, *et al*. Fear of movement is not associated with objective and subjective physical activity levels in chronic nonspecific low back pain. *Arch Phys Med Rehabil* 2017;98:96–104.
5 Chou R, Qaseem A, Snow V, *et al*. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of physicians and the American pain Society. *Ann Intern Med* 2007;147:478–91.
6 Waters T, Genaidy A, Barriera Viruet H, *et al*. The impact of operating heavy equipment vehicles on lower back disorders. *Ergonomics* 2008;51:602–36.
7 Shiri R, Karppinen J, Leino-Arjas P, *et al*. The association between smoking and low back pain: a meta-analysis. *Am J Med* 2010;123:87.e7–35.
8 George SZ, Fritz JM, Childs JD. Investigation of elevated fear-avoidance beliefs for patients with low back pain: a secondary analysis involving patients enrolled in physical therapy clinical trials. *J Orthop Sports Phys Ther* 2008;38:50–8.
9 Wessels T, van Tulder M, Sigl T, *et al*. What predicts outcome in non-operative treatments of chronic low back pain? A systematic review. *Eur Spine J* 2006;15:1633–44.
10 Pinheiro MB, Ferreira ML, Refshauge K, *et al*. Symptoms of depression and risk of new episodes of low back pain: a systematic review and meta-analysis. *Arthritis Care Res (Hoboken)* 2015;67:1591–603.
11 Alschuler KN, Neblett R, Wiggert E, *et al*. Flexion-relaxation and clinical features associated with chronic low back pain. *Clin J Pain* 2009;25:760–6.
12 Demoulin C, Crielaard J-M, Vanderthommen M. Spinal muscle evaluation in healthy individuals and low-back-pain patients: a literature review. *Joint Bone Spine* 2007;74:9–13.
13 Young AE, Wasiak R, Gross DP. Recurrence of work-related low back pain and disability: association between self-report and workers' compensation data. *Spine* 2013;38:2279–86.
14 Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J* 2008;8:8–20.
15 Maetzel A, Li L. The economic burden of low back pain: a review of studies published between 1996 and 2001. *Best Pract Res Clin Rheumatol* 2002;16:23–30.
16 Qaseem A, Wilt TJ, McLean RM, *et al*. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of physicians. *Ann Intern Med* 2017;166:514–30.
17 Powers CM, Bolgla LA, Callaghan MJ, *et al*. Patellofemoral pain: proximal, distal, and local factors, 2nd international research retreat. *J Orthop Sports Phys Ther* 2012;42:A1–54.
18 Yuan Q-ling, Guo T-mao, Liu L, *et al*. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis. *PLoS One* 2015;10:e0117146.
19 de Lacey S, Smith C. Traditional Chinese medicine. In: *How to improve your ART success rates: an evidence-based review of adjuncts to IVF (Cambridge medicine (Paperback))*, 2011: 208–12.
20 Manheimer E, Wieland S, Kimbrough E, *et al*. Evidence from the Cochrane collaboration for traditional Chinese medicine therapies. *J Altern Complement Med* 2009;15:1001–14.
21 Vickers AJ, Cronin AM, Maschino AC, *et al*. Acupuncture for chronic pain: individual patient data meta-analysis. *Arch Intern Med* 2012;172:1444–53.
22 Lauche R, Spitzer J, Schwahn B, *et al*. Efficacy of cupping therapy in patients with the fibromyalgia syndrome-a randomised placebo controlled trial. *Sci Rep* 2016;6:37316.
23 Ahmed SM, Madbouly NH, Maklad SS, *et al*. Immunomodulatory effects of blood letting cupping therapy in patients with rheumatoid arthritis. *Egypt J Immunol* 2005;12:39–51.
24 Lauche R, Cramer H, Hohmann C, *et al*. The effect of traditional cupping on pain and mechanical thresholds in patients with chronic nonspecific neck pain: a randomised controlled pilot study. *Evid Based Complement Alternat Med* 2012;2012:429718:1–10.
25 Lauche R, Materdey S, Cramer H, *et al*. Effectiveness of home-based cupping massage compared to progressive muscle relaxation in patients with chronic neck pain--a randomized controlled trial. *PLoS One* 2013;8:e65378.
26 Saha FJ, Schumann S, Cramer H, *et al*. The Effects of Cupping Massage in Patients with Chronic Neck Pain - A Randomised Controlled Trial. *Complement Med Res* 2017;24:26–32.
27 Michalsen A, Bock S, Lüdtke R, *et al*. Effects of traditional cupping therapy in patients with carpal tunnel syndrome: a randomized controlled trial. *J Pain* 2009;10:601–8.
28 Cao H, Liu J. P04.46. Cupping therapy for facial paralysis: a systematic review of randomized controlled trials. *BMC Complement Altern Med* 2012;12:P316.
29 Zhang C-Y, Wang Y-X. [Comparison of therapeutic effects between plum-blossom needle tapping plus cupping and laser irradiation in the treatment of acute facial palsy patients with concomitant peri-auricular pain]. *Zhen Ci Yan Jiu* 2011;36:433–6.
30 Aboushanab TS, AlSanad S. Cupping therapy: an overview from a modern medicine perspective. *J Acupunct Meridian Stud* 2018;11:83–7.
31 Teut M, Ullmann A, Ortiz M, *et al*. Pulsatile dry cupping in chronic low back pain - a randomized three-armed controlled clinical trial. *BMC Complement Altern Med* 2018;18:115.
32 Chirali IZ. *Traditional Chinese medicine cupping therapy: third edition*. 3 edn. London: Churchill Livingstone Elsever, 2015.
33 Mehta P, Dhapte V. Cupping therapy: a prudent remedy for a plethora of medical ailments. *J Tradit Complement Med* 2015;5:127–34.
34 Tham LM, Lee HP, Lu C. Cupping: from a biomechanical perspective. *J Biomech* 2006;39:2183–93.
35 Markowski A, Sanford S, Pikowski J, *et al*. A pilot study analyzing the effects of Chinese cupping as an adjunct treatment for patients with subacute low back pain on relieving pain, improving range of motion, and improving function. *J Altern Complement Med* 2014;20:113–7.
36 Lin M-L, Wu J-H, Lin C-W, *et al*. Clinical effects of laser acupuncture plus Chinese cupping on the pain and plasma cortisol levels in patients with chronic nonspecific lower back pain: a randomized controlled trial. *Evid Based Complement Alternat Med* 2017;2017:3140403:1–7.
37 Wang Y-T, Qi Y, Tang F-Y, *et al*. The effect of cupping therapy for low back pain: a meta-analysis based on existing randomized controlled trials. *J Back Musculoskelet Rehabil* 2017;30:1187–95.
38 Qureshi NA, Ali GI, Abushanab TS, *et al*. History of cupping (Hijama): a narrative review of literature. *J Integr Med* 2017;15:172–81.
39 Moura CdeC, Chaves Érika de Cássia Lopes, Cardoso ACLR, *et al*. Cupping therapy and chronic back pain: systematic review and meta-analysis. *Rev Lat Am Enfermagem* 2018;26:e3094.
40 Yamato T, Maher C, Saragiotto B, *et al*. The TIDieR checklist will benefit the physiotherapy profession. *Physiother Theory Pract* 2017;33:267–8.
41 Chan A-W, Tetzlaff JM, Altman DG, *et al*. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
42 Airaksinen O, Brox JI, Cedraschi C, *et al*. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J* 2006;15(Suppl 2):s192–300.
43 Kovacs FM, Abraira V, Royuela A, *et al*. Minimal clinically important change for pain intensity and disability in patients with nonspecific low back pain. *Spine* 2007;32:2915–20.
44 Magalhães MO, Muzi LH, Comachio J, *et al*. The short-term effects of graded activity versus physiotherapy in patients with chronic low back pain: a randomized controlled trial. *Man Ther* 2015;20:603–9.
45 Benzon HT, Asher YG, Hartrick CT. Back pain and neuraxial anesthesia. *Anesth Analg* 2016;122:2047–58.
46 Wolfe F, Clauw DJ, Fitzcharles M-A, *et al*. The American College of rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care Res* 2010;62:600–10.
47 Raine C, Keat A. Axial spondyloarthritis. *Medicine* 2018;46:231–6.
48 Lee MS, Kim J-I, Kong JC, *et al*. Developing and validating a sham cupping device. *Acupunct Med* 2010;28:200–4.

49 Bang H, Flaherty SP, Kolahi J, *et al*. Blinding assessment in clinical trials: a review of statistical methods and a proposal of blinding assessment protocol. *Clin Res Regul Aff* 2010;27:42–51.
50 Al-Bedah A, Aboushanab TS, Alqaed M, *et al*. Classification of cupping therapy: a tool for modernization and standardization. *J Complement Altern Med Res* 2017;1:1–10.
51 Cupping therapy. *J. Acupunct. Tuina. Sci.* 2003;1.
52 Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs* 2005;14:798–804.
53 Fairbank JC, Pynsent PB. The Oswestry disability index. *Spine* 2000;25:2940–53.
54 Vigatto R, Alexandre NMC, Correa Filho HR. Development of a Brazilian Portuguese version of the Oswestry disability index: cross-cultural adaptation, reliability, and validity. *Spine* 2007;32:481–6.
55 Hirano K, Imagama S, Hasegawa Y, *et al*. Impact of low back pain, knee pain, and timed up-and-go test on quality of life in community-living people. *J Orthop Sci* 2014;19:164–71.
56 Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc* 1991;39:142–8.
57 Perret C, Poiraudeau S, Fermanian J, *et al*. Validity, reliability, and responsiveness of the fingertip-to-floor test. *Arch Phys Med Rehabil* 2001;82:1566–70.
58 Freitas P, Pires D, Nunes C, *et al*. Cross-Cultural adaptation and psychometric properties of the European Portuguese version of the global perceived effect scale in patients with chronic low back pain. *Disabil Rehabil* 2019:1–7.
59 Costa LOP, Maher CG, Latimer J, *et al*. Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: which one is the best? *Spine* 2008;33:2459–63.
60 Ware JE, Sherbourne CD. The mos 36-item short-form health survey (SF-36). I. conceptual framework and item selection. *Med Care* 1992;30:473–83.
61 Ciconelli R, Ferraz M, Santos W, *et al*. Tradução para a língua portuguesa E validação do questionário genérico de avaliação de qualidade de vida SF-36 (Brasil SF-36). *Revista Brasileira de Reumatologia* 1999.
62 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
63 Botega NJ, Bio MR, Zomignani MA, *et al*. [Mood disorders among inpatients in ambulatory and validation of the anxiety and depression scale HAD]. *Rev Saude Publica* 1995;29:355–63.
64 Beasley MJ, Ferguson-Jones EA, Macfarlane GJ. Treatment expectations but not preference affect outcome in a trial of CBT and exercise for pain. *Can J Pain* 2017;1:161–70.
65 Akbarzadeh M, Ghaemmaghami M, Yazdanpanahi Z, *et al*. The effect dry cupping therapy at Acupoint BL23 on the intensity of postpartum low back pain in primiparous women based on two types of questionnaires, 2012; a randomized clinical trial. *Int J Community Based Nurs Midwifery* 2014;2:112–20.
66 Hartvigsen J, Hancock MJ, Kongsted A, *et al*. What low back pain is and why we need to pay attention. *Lancet* 2018;391:2356–67.
67 Hush JM, Cameron K, Mackey M. Patient satisfaction with musculoskeletal physical therapy care: a systematic review. *Phys Ther* 2011;91:25–36.
68 Lauche R, Cramer H, Choi K-E, *et al*. The influence of a series of five dry cupping treatments on pain and mechanical thresholds in patients with chronic non-specific neck pain--a randomised controlled pilot study. *BMC Complement Altern Med* 2011;11:63.
69 Yoo SS, Tausk F. Cupping: East meets West. *Int J Dermatol* 2004;43:664–5.