Journal of Physiotherapy 67 (2021) 132–139

Journal of PHYSIOTHERAPY

journal homepage: www.elsevier.com/locate/jphys

Research

Dry cupping therapy is not superior to sham cupping to improve clinical outcomes in people with non-specific chronic low back pain: a randomised trial

Hugo Jário Almeida Silva [a], Germanna Medeiros Barbosa [b], Rodrigo Scattone Silva [a], Bruno T Saragiotto [c], Jaine Maria Pontes Oliveira [b], Yago Tavares Pinheiro [a], Caio Alano Almeida Lins [a], Marcelo Cardoso de Souza [a]

[a] *Postgraduate Program in Rehabilitation Sciences, Faculty of Health Sciences of Trairi, Federal University of Rio Grande do Norte (UFRN), Santa Cruz, Rio Grande do Norte, Brazil;* [b] *Faculty of Health Sciences of Trairi, Federal University of Rio Grande do Norte (UFRN), Santa Cruz, Rio Grande do Norte, Brazil;* [c] *Masters and Doctoral Programs in Physical Therapy, Universidade Cidade de São Paulo (UNICID), São Paulo, Brazil*

KEY WORDS

Chronic pain
Placebo
Traditional Chinese Medicine
Physical therapy

ABSTRACT

Question: What are the effects of dry cupping on pain intensity, physical function, functional mobility, trunk range of motion, perceived overall effect, quality of life, psychological symptoms and medication use in individuals with chronic non-specific low back pain? **Design**: Randomised controlled trial with concealed allocation, intention-to-treat analysis and blinding of participants and assessors. **Participants**: Ninety participants with chronic non-specific low back pain. **Interventions**: The experimental group (n = 45) received dry cupping therapy, with cups bilaterally positioned parallel to the L1 to L5 vertebrae. The control group (n = 45) received sham cupping therapy. The interventions were applied once a week for 8 weeks. **Outcome measures**: Participants were assessed before and after the first treatment session, and after 4 and 8 weeks of intervention. The primary outcome was pain intensity, measured with the numerical pain scale at rest, during fast walking and during trunk flexion. Secondary outcomes were physical function, functional mobility, trunk range of motion, perceived overall effect, quality of life, psychological symptoms and medication use. **Results**: On a 0-to-10 scale, the between-group difference in pain severity at rest was negligible: MD 0.0 (95% CI −0.9 to 1.0) immediately after the first treatment, 0.4 (95% CI −0.5 to 1.5) at 4 weeks and 0.6 (95% CI −0.4 to 1.6) at 8 weeks. Similar negligible effects were observed on pain severity during fast walking or trunk flexion. Negligible effects were also found on physical function, functional mobility and perceived overall effect, where mean estimates and their confidence intervals all excluded worthwhile effects. No worthwhile benefits could be confirmed for any of the remaining secondary outcomes. **Conclusion**: Dry cupping therapy was not superior to sham cupping for improving pain, physical function, mobility, quality of life, psychological symptoms or medication use in people with non-specific chronic low back pain. **Protocol registration number**: NCT03909672. **[Almeida Silva HJ, Barbosa GM, Scattone Silva R, Saragiotto BT, Oliveira JMP, Pinheiro YT, Lins CAA, de Souza MC (2021) Dry cupping therapy is not superior to sham cupping to improve clinical outcomes in people with non-specific chronic low back pain: a randomised trial. *Journal of Physiotherapy* 67:132–139]**

Introduction

Non-specific chronic low back pain is a common problem in adults[1] and can result in disability,[2,3] physical and psychological impairment,[2,4,5] limitations in daily activities and participation restriction.[6] In addition, it has important economic[7] and social impacts on individuals with low back pain and on societies.[8] Clinical practice guidelines recommend non-pharmacological interventions as the first-line management for low back pain, including exercises, psychological therapies and, in some cases, multidisciplinary biopsychosocial rehabilitation.[9] The use of pharmacological therapies is often restricted to patients who have not improved after non-pharmacological management.[10] Although alternative therapies are not recommended by the guidelines, they are commonly used with great influence from the media.[11–13]

Cupping is an ancient Chinese alternative therapy, which became famous worldwide after the 2016 Olympic Games held in Brazil.[14] Google Trends reported a 2,100% spike in searches for cupping therapy in 2016, and cupping therapy became a trending topic that year.[15] Even with a lack of scientific support, the popularity of the technique amongst physiotherapists and patients has grown since then, especially due to its low-cost and non-invasive nature.[16] This treatment involves specific techniques, with different forms of application such as massage cupping, flash cupping, wet cupping and dry cupping. Dry

https://doi.org/10.1016/j.jphys.2021.02.013

cupping is the most common method of cupping therapy,[17] where glass or acrylic cups are applied to the uninjured skin, providing negative pressure and suction of the target area.[17] This application generates ecchymosis that usually disappears in up to 10 days.[18] The ideal application time and suction force are still unknown; however, between 5 and 10 minutes with a negative pressure of 300 millibars (two suctions in the manual suction pump) has been recommended for the treatment of low back pain.[18–21] Several hypotheses have been proposed to explain the effects of cupping therapy on pain, such as the Pain-Gate Theory, diffuse noxious inhibitory controls and reflex zone theory.[22] However, the mechanisms of action of this treatment are still unknown and, at present, it is not possible to rule out the possibility that the method has only a placebo therapeutic effect.[22,23]

Currently, there is a lack of studies that investigate the effects of cupping therapy in individuals with chronic low back pain.[24] A recent systematic review with meta-analysis[25] showed important methodological limitations in the included studies, such as lack of blinding of the evaluator and of the participants, absence of an intention-to-treat analysis, inadequate randomisation, high heterogeneity and absence of a sham group. Recently, it was observed that cupping therapy improves pain and disability in comparison with sham cupping in patients with non-specific chronic low back pain.[26] It should be mentioned, however, that this study only verified the effects of a single session of cupping therapy and presented important methodological limitations such as unconcealed allocation and lack of blinding.

The aim of this study was to estimate the effects of dry cupping in people with chronic non-specific low back pain. It was hypothesised that dry cupping would reduce pain and improve other relevant subjective and objective outcomes when compared with a sham intervention.

Therefore, the research question for this randomised trial was:

What are the effects of dry cupping on pain intensity, physical function, functional mobility, trunk range of motion, perceived overall effect, quality of life, psychological symptoms and medication use in individuals with chronic non-specific low back pain?

Method

Design

This study was a prospectively registered, two-arm, randomised sham-controlled trial with blinded participants, blinded outcome assessment and intention-to-treat analysis. The methods of this trial have previously been published in detail in the study protocol.[27] Participants were screened for eligibility by a physiotherapist. A blinded assessor conducted the assessments of all participants' outcome measures before the intervention, immediately after the first session and after 4 and 8 weeks of treatment.

Participants were randomly allocated to an experimental group or a control group. The experimental group received dry cupping therapy and the control group received a sham intervention. Random allocations were determined by a computer-generated random numbers program. Allocation was concealed by using sequentially numbered, sealed and opaque envelopes. Each participant's random allocation was only revealed to the physiotherapist who provided the treatments immediately before the first intervention. The participants were not aware of which treatment they were receiving (blind participants); however, they were informed that they would receive one of the two interventions. Due to the nature of the interventions, it was not possible to blind the therapist who treated the patients.

Participants, therapists and centres

Participants were recruited by means of local radio and waiting lists of the University School Clinic. People were eligible for inclusion if: they had low back pain of $\geq$ 3 months of duration,[28] the pain intensity was 3 to 8 on a numerical pain rating scale,[29] they were aged between 18 and 59 years, and had a body mass index < 35 kg/m^2. The exclusion criteria were the following: individuals who had ever been treated with cupping; presence of any contraindication for cupping therapy;[17] individuals who were undergoing physical therapy treatment at that time;[30] presence of neurological, vestibular, visual or auditory deficits that could interfere with the assessments; signs of serious pathology of the spine, including fractures, inflammatory diseases, infection or tumours; radiating lumbar[31] or sacroiliac pain; rheumatic diseases such as fibromyalgia[32] or ankylosing spondylitis[33]; travel plans in the next 2 months; and participants who for any reason were unable to complete the assessment procedures properly.

One physiotherapist who was not involved in the assessments treated the participants (non-blinded therapist). The physiotherapist who was responsible for the interventions was a certified cupping therapist with experience in this particular modality of treatment. The trial was conducted in a physiotherapy school clinic of the University.

Intervention

The treatments consisted of eight dry cupping therapy or sham therapy sessions performed for 10 minutes once a week for 8 weeks. During each session, the participants were positioned in prone lying on a comfortable plinth. They were informed that they would feel a suction sensation and that they could experience local bruising in the locations where the cupping treatment was applied. Trichotomy was not necessary, since no participant presented with local hair that could interfere with the skin suction. To avoid contact and exchange of treatment experiences between participants, the treatments were delivered individually, and participants in different groups were treated on different days.

For the experimental group, a manual suction pump and four acrylic cups[a] size one (internal diameter = 4.5 cm) were used for the interventions. The cups were applied to the lower back, parallel to L1 to L5 vertebrae, with a 3-cm distance between them, bilaterally. The dry cupping application consisted of a negative pressure of 300 millibars (two suctions in the manual suction pump) sustained for 10 minutes once a week for 8 weeks.[27]

In the control group, the exact same procedures were used except that the cups were prepared with small holes < 2 mm in diameter to release the negative pressure in approximately 3 seconds. Double-sided adhesive tape was applied to the border of the cups in order to keep them in contact with the participants' skin.[27,34]

Outcome measures

A detailed description of the outcomes measures was presented in the previously published study protocol.[27] The description of the outcomes and the smallest worthwhile effect thresholds considered in this study are presented in Table 1. In addition to these main outcome measures, the participants' expectations of the treatment were also measured at baseline with a 5-point Likert scale. In this assessment, the participants marked 1 if they believed that they would 'get worse' with the treatment and 5 if they thought they would 'improve a lot' with the treatment.[35] Medication consumption was registered by means of a diary. At the end of the interventions, the participants were questioned about the suction sensation that they felt during the treatments with regards to location and intensity of sensation (0 = no sensation, 100 = very strong sensation).[34] Finally, in the post-intervention assessment, the participants were asked about which treatment they thought they had received, so that the effectiveness of the blinding strategy could be verified.[21]

Data analysis

The study was designed to detect a between-group difference of 2 points, with a standard deviation of 2.7 in pain intensity measured by the numerical pain rating scale based on the findings of a study that used similar methods.[52] A statistical power of 90%, an alpha of 5% and a loss rate of 10% were considered for the sample calculation, which

Table 1
Detailed description of the outcomes of the study.

Outcome	Test/tool	Description of the test	Scoring	Evaluation time[a]	Worthwhile effect
Pain intensity	Numerical pain rating scale	The scale was placed in front of the patient, who was asked to rate their pain intensity[36] at rest, during the evaluation of the trunk ROM and during performance of the Timed Up and Go test. This self-reported pain score is a valid and reliable measure among people with chronic LBP.[37]	0 (no pain) to 10 (maximum pain intensity)	Pre Post Week 4 Week 8	2.4 points reduction in pain[38]
Physical function	Oswestry Disability Index	This self-report questionnaire is translated and validated into Portuguese,[39] and assesses the impact of LBP on various functional activities. It contains 10 sections: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling.	0 (no disability) to 100 (maximum disability)	Pre Week 8	10 to 17 points decrease in the score[38,40]
Functional mobility	Timed Up and Go test	This test assesses: balance moving from sitting to standing, stability in walking, and gait course changes without using compensatory strategies. The participants were asked to stand up from a chair, walk 3 m, turn around, return and sit back in the chair. It is a valid and reliable measure among people with chronic LBP.[41,42]	Total time to complete the test	Pre Post Week 4 Week 8	3.4 s reduction in total time to complete the test[43]
Trunk range of motion	Finger-to-floor	With the participants standing erect, they were asked to lean forward as far as possible, keeping the knees, arms and fingers fully extended. The vertical distance between the tip of the middle finger and the floor was measured with a tape measure. This measure presents excellent reliability values in individuals with chronic LBP.[44]	Closer to the ground indicates greater posterior chain flexibility	Pre Post Week 4 Week 8	4.5 cm improvement in finger-to-floor distance[45]
Perceived overall effect	Global perception scale	Participants were asked: compared to the beginning of the treatment, how would you describe your lower back today? This scale has good psychometric properties.[46]	Likert scale: −5 (extremely worse), 0 (without modification) and +5 (completely recovered)	Post Week 4 Week 8	2.5 points improvement in the scale[47]
Quality of life	Short-Form 36	This self-report questionnaire is translated and validated into Portuguese,[48] and assesses the quality of life. It contains 36 questions in eight domains on health aspects in the past 4 weeks.	0 (worst) to 100 (best)	Pre Week 8	3.6 to 4.6 points improvement in the score[49]
Psychological symptoms	Hospital Anxiety and Depression Scale	This self-report questionnaire assesses anxiety and depression. It is translated and validated into Portuguese.[50] It has 14 items: 7 for depression and 7 for anxiety.	0 (no symptom) to 21 (most severe symptoms)	Pre Week 8	1.5 points decrease in the score[51]

Shaded row = primary outcome, ROM = range of motion, LBP = lower back pain.
[a] The terms 'Pre' and 'Post' signify immediately before and after the first intervention.

resulted in a total sample of 90 participants (45 per group). Commercial software[b] was used for the calculation.

All statistical analyses were performed by a researcher who was not involved in the recruitment, assessment or intervention aspects of the study. The Kolmogorov-Smirnov test was applied to evaluate data distribution. The statistical analysis was conducted on an intention-to-treat basis. For the missing data, results obtained in the last available assessment of each participant were repeated. Analysis of variance with a linear mixed model was used to compare the effects of dry cupping therapy between the experimental and control groups. The mean difference (MD) and 95% confidence interval (CI) were also calculated for each between-group comparison. The statistical analyses were processed using a commercial statistical software[c] and a level of significance of $p < 0.05$ was adopted for all tests.

Results

Flow of participants, therapists and centres through the study

Figure 1 shows the flow of participants through the trial. From the 120 participants who were screened, 90 matched the eligibility criteria and were randomised; 86 completed all intervention procedures. The demographic characteristics of the participants of both groups were similar and are presented in Table 2. The baseline values of the primary and secondary outcome measures were also similar and are presented in the first two columns of data in Table 3.

Compliance with the study protocol

All registered outcome measures are reported in this manuscript. There was minimal loss to follow-up, as presented in Figure 1.

Effect of the intervention

Primary and secondary outcomes

The data about pain intensity are presented in Table 3. The individual participant data are presented in Table 4 on the eAddenda. The mean between-group differences for the primary outcome of pain intensity immediately after the first intervention, after 4 weeks of intervention and after 8 weeks of intervention were, respectively: 0.0 (95% CI −0.9 to 1.0), 0.4 (95% CI −0.5 to 1.5) and 0.6 (95% CI −0.4 to 1.6) at rest; 0.4 (95% CI −0.5 to 1.4), 0.6 (95% CI −0.3 to 1.6) and 0.7 (95% CI −0.3 to 1.8) during the performance of the Timed Up and Go test; and 0.8 (95% CI −0.2 to 1.8), 0.7 (95% CI −0.4 to 1.8) and 0.7 (95% CI −0.2 to 1.8) during the evaluation of trunk range of motion. All of these differences and the confidence intervals were smaller than the minimal clinically important difference for pain intensity in low back pain patients (2.4 points).[38]

The results of physical function, functional mobility, trunk range of motion and perceived overall effect are presented in Table 3. The individual participant data are presented in Table 4 on the eAddenda. For these secondary outcome measures, no important between-group differences were detected. The between-group differences were all small positive or small negative effects, which were too small to be

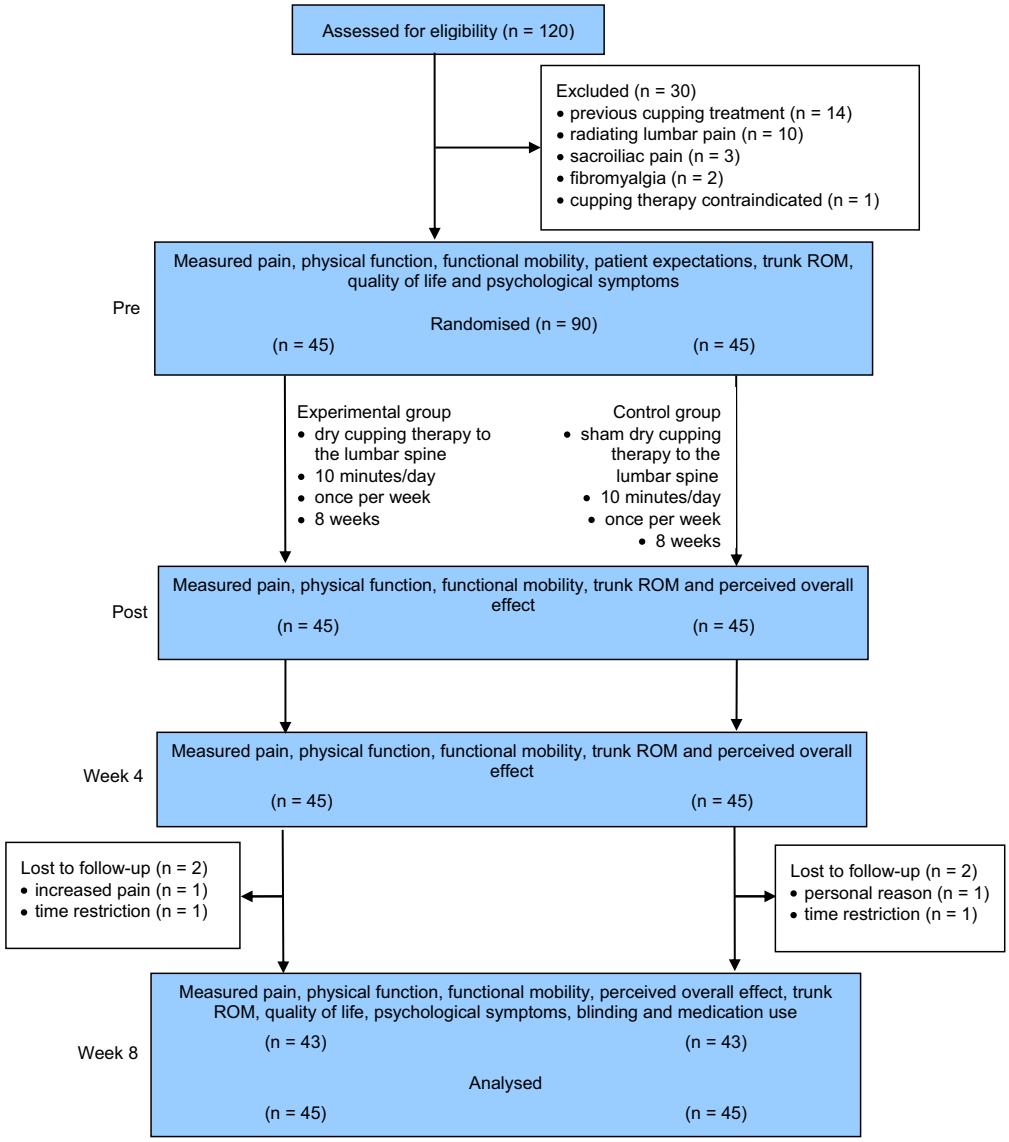

Figure 1. Flow of participants through the trial. ROM = range of motion.

Table 2
Baseline characteristics of the participants.

Characteristics	Exp (n = 45)	Con (n = 45)
Age (*yr*), mean (SD)	30 (11.0)	32 (13.0)
Gender, n (%)		
female	29 (64)	38 (84)
male	16 (36)	7 (16)
Pain duration (*mth*), mean (SD)	44 (32)	58 (51)
Body mass index (kg/m^2), mean (SD)	22.8 (4.4)	21.9 (4.2)
Expectation with treatment (*1 to 5*), mean (SD)	4.6 (0.4)	4.6 (0.5)
Profession, n (%)		
manual labour	13 (29)	17 (38)
other	32 (71)	28 (62)
Education, n (%)		
incomplete primary school	0 (0)	4 (9)
complete primary school	0 (0)	4 (9)
incomplete secondary school	8 (18)	7 (16)
complete secondary school	18 (40)	16 (36)
incomplete tertiary degree	14 (31)	8 (18)
complete tertiary degree	5 (11)	6 (13)
Away from work, n (%)	1 (2)	2 (4)
Receiving sick leave, n (%)	0 (0)	0 (0)
Physically active, n (%) [a]	13 (29)	18 (40)
Use of medication for pain (%) [b]	8 (8)	9 (20)

Con = control group, Exp = experimental group.
[a] Physical activity undertaken at least twice a week.
[b] Analgesic or anti-inflammatory medication for low back pain at least once in the previous week.

clinically worthwhile. The confidence intervals around these estimates of the treatment effect generally excluded worthwhile effects as well.

Results of quality of life and psychological symptoms are presented in Table 5. The individual participant data are presented in Table 4 on the eAddenda. For these secondary outcome measures, no significant between-group differences were detected, and the between-group differences were generally small negative or small positive effects, which were mostly too small to be clinically worthwhile. The confidence intervals were less precise than those of the previous secondary outcomes.

Medication use

The four participants (9%) who used analgesics and/or anti-inflammatory medication used between one and eight times during the intervention period. In the control group, three participants (7%) used these medications once.

Success of blinding and suction sensation

In order to verify whether the blinding strategies were successful, participants were asked to indicate which therapy they believed that they had received at the end of the intervention. In the experimental group, 22 participants (49%) believed that they had received the real therapy and 23 participants (51%) believed that they had received the

Table 3
Mean (SD) of groups, mean (SD) within-group differences and mean (95% CI) between-group differences.

Outcomes	Groups								Within-group differences						Between-group differences			
	Pre		Post		Week 4		Week 8		Post minus Pre		Week 4 minus Pre		Week 8 minus Pre		Post minus Pre	Week 4 minus Pre	Week 8 minus Pre
	Exp (n = 45)	Con (n = 45)	Exp (n = 45)	Con (n = 45)	Exp (n = 45)	Con (n = 45)	Exp (n = 45)	Con (n = 45)	Exp	Con	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con	Exp minus Con
Pain at rest *(0 to 10)*	5.1 (1.5)	5.3 (1.6)	3.6 (2.4)	3.5 (2.4)	3.2 (2.8)	2.7 (2.0)	3.3 (2.9)	2.7 (1.9)	−1.5 (0.3)	−1.8 (0.3)	−1.9 (0.3)	−2.6 (0.3)	−1.8 (0.3)	−2.6 (0.3)	0.0 (−0.9 to 1.0)	0.4 (−0.5 to 1.5)	0.6 (−0.4 to 1.6)
Pain on TUG test *(0 to 10)*	4.7 (2.3)	3.7 (2.6)	2.8 (2.5)	2.3 (2.2)	3.0 (2.7)	2.3 (2.1)	2.8 (3)	2.1 (2.1)	−1.8 (0.3)	−1.3 (0.3)	−1.6 (0.4)	−1.3 (0.4)	−1.8 (0.5)	−1.5 (0.5)	0.4 (−0.5 to 1.4)	0.6 (−0.3 to 1.6)	0.7 (−0.3 to 1.8)
Pain on Trunk ROM test *(0 to 10)*	5.3 (2.0)	4.8 (1.9)	3.8 (2.6)	3.0 (2.2)	3.4 (3.2)	2.6 (2.2)	3.3 (2.8)	2.5 (2.1)	−1.4 (0.3)	−1.7 (0.3)	−1.9 (0.4)	−1.7 (0.3)	−2.0 (0.4)	−2.3 (0.4)	0.8 (−0.2 to 1.8)	0.7 (−0.4 to 1.8)	0.7 (−0.2 to 1.8)
ODI *(0 to 100)*	24 (11)	26 (12)	N/A	N/A	N/A	N/A	19 (12)	19 (12)	N/A	N/A	N/A	N/A	−5 (1)	−8 (1)	N/A	N/A	1 (−4 to 5)
TUG test *(s)* [a]	10.4 (1.7)	10.8 (1.9)	9.8 (1.6)	10.4 (2.0)	9.7 (1.4)	10.1 (1.7)	9.3 (1.4)	9.8 (1.6)	−0.5 (0.1)	−0.4 (0.1)	−0.6 (0.1)	−0.6 (0.1)	−1.0 (0.1)	−1.0 (0.1)	−0.5 (−1.2 to 0.2)	−0.3 (−1 to 0.2)	−0.4 (−1 to 0.1)
Trunk ROM *(cm)* [a]	18.2 (10.5)	13.8 (9.1)	15.3 (10.1)	12.7 (9.1)	13.9 (10.3)	10.7 (9.4)	14.1 (11.1)	11.6 (10.5)	−2.8 (0.6)	−1.1 (0.6)	−4.3 (1.0)	−3.1 (1.0)	−4.1 (1.2)	−2.1 (1.2)	2.6 (−1.3 to 6.7)	3.1 (−0.9 to 7.3)	2.4 (−2.1 to 6.9)
Global Perceived Effect *(−5 to +5)*	N/A	N/A	1.7 (1.6)	1.1 (1.9)	2.1 (2.0)	2.3 (1.7)	2.0 (2.1)	2.6 (1.9)	N/A	N/A	N/A	N/A	N/A	N/A	0.5 (−0.1 to 1.3)	−0.2 (−1.3 to 0.5)	−0.6 (−1.4 to 0.2)

Shaded cells = primary outcomes. Small anomalies in subtraction are due to the effects of rounding.
Con = control group, Exp = experimental group, N/A = not applicable, ODI = Oswestry Disability Index, ROM = range of motion, TUG = Timed Up and Go.
[a] Lower scores reflect better performance.

sham treatment. In the control group, 27 participants (60%) believed that they had received the real therapy and 18 participants (40%) believed that they had received the sham therapy. These results indicate that the blinding of the participants in both groups was successful.

Regarding the suction sensations experienced, 43 participants (96%) in the experimental group reported that they had felt a suction sensation during the interventions. Thirty-four of them (76%) reported that they felt the suction sensation in the location where the treatment was applied (cupping area). The average intensity of the suction sensation reported by this group was 60 (SD 21). In the control group, 41 participants (91%) reported that they had felt a suction sensation during the interventions. Thirty-four (76%) reported that they felt the suction sensation in the location where the treatment was applied (cupping area). The average of the suction sensation reported by this group was 49 (SD 20). These results are presented in detail in Table 6, with individual participant data presented in Table 4 on the eAddenda.

Adverse events

In the experimental group, three adverse events were observed. One participant reported an increase in back pain after the beginning of treatment with dry cupping and two participants reported that they developed flu-like symptoms. For the participant who had an increase in pain intensity with the cupping treatment, the sessions of treatment with dry cupping were ceased and the participant was evaluated by a general practitioner and then treated by a physiotherapist during the duration of the research. No adverse events were observed in the control group.

Discussion

It is believed that this is the first high-quality randomised controlled trial comparing dry cupping therapy with sham cupping in people with non-specific chronic low back pain, assessing outcomes of pain intensity, physical function, functional mobility, trunk range of motion, perceived overall effect, quality of life, psychological symptoms and medication use. It found that both groups showed similar reductions in pain intensity after the first intervention, and after 4 and 8 weeks of treatment, with no important differences between groups at any point in time. No clinically worthwhile effects of cupping could be confirmed among any of the secondary outcomes. The results of this trial call into question the clinical use of dry cupping as a non-pharmacological therapy for people with non-specific chronic low back pain.

A recent systematic review[25] suggested that cupping therapy is effective at decreasing pain and disability in people with non-specific chronic low back pain. However, the high heterogeneity and risk of bias in the included trials – such as lack of randomisation, lack of blinding, unconcealed allocation, small sample sizes, and small intervention periods (< 3 weeks) – are important limitations that need to be considered. Thus, the results of that systematic review should be viewed with caution. In addition, all studies included in the review[25] used either medication or 'usual care' as a control group. The lack of studies using sham therapy as a comparative intervention limits the ability of this previous systematic review to determine the actual effectiveness of dry cupping therapy.

It is believed that only one recent study has compared the effectiveness of dry cupping therapy in comparison with sham cupping (same sham procedure used in the present trial: cups with small holes < 2 mm in diameter) for patients with non-specific low back pain.[26] Contrasting with our results, that previous study found a significant improvement in pain and disability in people with non-specific chronic low back pain after a single session of dry cupping therapy.[26] However, this study had strong methodological limitations: the participants were not randomised, the assessors were not blinded, the participants' blinding was not evaluated, an intention-to-treat analysis was not conducted and the authors did not present sample size calculations.[26] These biases may have contributed to an overestimation of the effects of the intervention.

Table 5
Mean (SD) of groups regarding quality of life and psychological symptoms and mean (95% CI) within and between-group differences.

Outcomes	Groups				Within-group differences		Between-group differences
	Pre		Week 8		Week 8 minus Pre		Week 8
	Exp (n = 45)	Con (n = 45)	Exp (n = 45)	Con (n = 45)	Exp	Con	Exp minus Con
SF-36 *(0 to 100)*							
functional capacity	54 (23)	53 (18)	62 (23)	61 (20)	8 (3)	8 (3)	1 (−8 to 11)
physical limitation	32 (31)	32 (34)	56 (38)	54 (40)	24 (6)	22 (6)	2 (−14 to 19)
pain	41 (15)	44 (17)	56 (23)	57 (19)	14 (3)	13 (3)	−1 (−10 to 8)
general health status	52 (18)	58 (18)	60 (19)	57 (18)	8 (2)	−1 (2)	2 (−5 to 10)
vitality	43 (19)	42 (19)	49 (20)	48 (21)	6 (3)	6 (3)	2 (−7 to 10)
social aspects	65 (23)	64 (24)	71 (24)	71 (22)	6 (4)	7 (4)	0 (−10 to 10)
emotional aspects	38 (40)	38 (41)	54 (38)	47 (42)	17 (6)	10 (6)	7 (−9 to 24)
mental health	61 (20)	55 (19)	67 (18)	59 (22)	7 (3)	4 (3)	10 (1 to 18)
HADS *(0 to 21)*							
anxiety	9.0 (3.7)	10.0 (4.1)	8.0 (3.6)	9.0 (4.4)	−1.0 (0.4)	−1.0 (0.4)	1.0 (−2.4 to 0.8)
depression	5.0 (3.3)	6.0 (3.3)	5.0 (3.4)	5.0 (3.1)	−1.0 (0.4)	−1.0 (0.4)	−0.2 (−1.5 to 1.1)

Con = control group, Exp = experimental group, HADS = Hospital Anxiety and Depression Scale, SF-36 = Short-Form 36.
Small anomalies in subtraction are due to the effects of rounding.

Regarding the secondary outcomes in the present trial, the mean between-group differences and their confidence intervals clearly excluded the possibility of clinically worthwhile effects on physical function, functional mobility and perceived overall effect. The estimates for the remaining secondary outcomes were also generally below the smallest worthwhile effect thresholds that were nominated, and the confidence intervals all spanned no effect. Therefore, no clinically worthwhile effects of cupping could be confirmed among any of the secondary outcomes. Previous studies using cupping for the treatment of low back pain have used a large variety of outcome measures to assess function and quality of life, which made them difficult to compare with our results.[53,54] The recent systematic review discussed above concluded that cupping therapy was effective at improving physical function in patients with low back pain.[25] However, this conclusion was based on the findings of four clinical trials with high risk of bias and there was no overview of the certainty of evidence in this review.[25] It is believed that no other study has evaluated the effects of dry cupping therapy on psychological symptoms of patients with low back pain.

Table 6
Sensations experienced during the interventions, location of sensation and intensity of sensation.

Sensation characteristics	Exp (n = 45)	Con (n = 45)
Suction sensation, n (%)	43 (96)	41 (91)
Pressure, n (%)	18 (40)	12 (27)
Inflation, n (%)	4 (9)	7 (16)
Pain, n (%)	13 (29)	0 (0)
Squeeze, n (%)	21 (47)	11 (24)
Relaxation, n (%)	15 (33)	33 (73)
Refreshing, n (%)	3 (7)	9 (20)
Burning, n (%)	10 (22)	1 (2)
Pulling, n (%)	34 (76)	14 (31)
Tingling, n (%)	10 (22)	1 (2)
Location of sensation, n (%)		
precise area of application	34 (76)	34 (76)
broad area of application	6 (13)	6 (13)
whole lower back	5 (11)	5 (11)
Intensity of sensation *(0 to 100)*, mean (SD)	60 (21)	49 (20)

Con = control group, Exp = experimental group.

The findings of the present study also question the main mechanisms by which dry cupping therapy is purported to decrease pain. Theoretical perspectives have suggested that the negative pressure has a major role in explaining how dry cupping therapy causes analgesia.[22] It has been suggested that dry cupping causes: mechanoreceptor stimulation, which produces nerve impulses that 'close the gates of pain' (Pain-Gate Theory); tissue damage to the skin and blood vessels – due to the negative pressure – and the pain caused by this damage would compete with the patient's pain (Diffuse Noxious Inhibitory Control); or improvement in the local blood flow and blood supply to the skin and internal organs, causing an activation of biological processes on the treated area (ie, the disturbed reflex zone, Reflex Zone Theory).[22] However, it is unlikely that any clinical improvements observed after cupping are due to negative pressure, since the participants in the sham cupping group in our trial had similar improvements in all outcomes. It is likely that any clinical improvements observed after cupping are a consequence of the placebo effect,[55] positive expectations with regards to the treatment,[56] natural recovery and regression to the mean,[57] therapeutic alliance[58] and the environmental context.[59]

Previous researchers have reported difficulties in blinding participants who were treated with dry cupping, particularly because participants with previous experience with dry cupping therapy were included.[54,60] In the present study, none of the participants had previous experience with dry cupping therapy, and participants in the different groups were treated on different days. These precautions were taken in order to minimise the interaction between participants in different groups, especially about the presence/absence of bruising. In addition, similar sensations were reported by participants in both groups and the blinding questionnaire results revealed that participants in both groups were unable to accurately guess which group they were in.

This study had limitations that need to be acknowledged. Due to the nature of the intervention, it was not possible to blind the therapist who administered the intervention to the participants in both groups. The study did not control for the menstrual cycle stage of the female participants in the assessments. This could be important, considering that it has been suggested that the pain threshold of women varies according to the menstrual cycle.[61] However, this potential bias was minimised by the equivalent presence of women with

active menstrual cycles in both groups due to the randomisation. The fact that the thresholds for the smallest worthwhile effects used in this study were not prospectively defined may also be considered a limitation. However, the thresholds were based on published literature. Finally, the conclusions of this study were limited to the application of dry cupping therapy in isolation, which might not reflect the treatment typically provided by therapists in their clinical practice. Future studies should look into the effects of dry cupping as a complement to other interventions that are recommended by clinical guidelines, such as exercise therapy.[9,10]

In conclusion, dry cupping therapy was similar to sham therapy in terms of reducing pain or improving physical function, functional mobility, trunk range of motion, perceived overall effect, quality of life, psychological symptoms or medication use in people with non-specific chronic low back pain. Until stronger evidence of effectiveness is available, clinicians should rethink the application of dry cupping for reducing pain and improving function in patients with non-specific low back pain. They should also inform their patients about the uncertainty of benefit with this therapeutic modality and encourage them to consider interventions with established efficacy.

What was already known on this topic: People with non-specific chronic low back pain tend to experience poor physical performance and psychological dysfunction. Dry cupping therapy is commonly used to treat non-specific chronic low back pain. Recent systematic reviews about dry cupping therapy for people with non-specific chronic low back pain have concluded that the existing literature has high risk of bias and that high-quality studies are needed.

What this study adds: Dry cupping therapy applied for 10 minutes once a week for 2 months was not superior to a sham therapy for people with non-specific chronic low back pain in terms of pain, physical function, perceived overall effect, quality of life, psychological symptoms and medication use.

Footnotes: [a] Dong yang produtos de acupuntura ltda, São Caetano do Sul, Brazil. [b] G*Power software V.3.1, University of Trier, Trier, Germany. [c] SPSS 24.0 software, SPSS Inc, Chicago, USA.

eAddenda: Table 4 can be found online at https://doi.org/10.1016/j.jphys.2021.02.013.

Ethics approval: This study was approved by the Ethics Committee for Research of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi (UFRN/FACISA). All participants gave written informed consent before data collection began.

Competing interests: Nil.

Source(s) of support: This study was partially funded by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Master's degree scholarship, Financial code 001. Dr Bruno T Saragiotto is supported by the Sao Paulo Research Foundation (FAPESP).

Acknowledgements: The authors would like to acknowledge the participants who dedicated their time to the development of this study. The authors also acknowledge the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) for their financial support to this research.

Provenance: Not invited. Peer reviewed.

Correspondence: Marcelo Cardoso de Souza, Postgraduate Program in Rehabilitation Sciences of Federal University of Rio Grande do Norte, Faculty of Health Sciences of Trairi, Santa Cruz, RN, Brazil. Email: marcelocardoso@facisa.ufrn.br

References

1. Manchikanti L, Singh V, Falco FJE, Benyamin RM, Hirsch JA. Epidemiology of low back pain in Adults. *Neuromodulation*. 2014;17:3–10.
2. Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, et al. What low back pain is and why we need to pay attention. *Lancet*. 2018;391:2356–2367.
3. Vos T, Abajobir AA, Abbafati C, Abbafati C, Abbas KM, Abd-Allah F, 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;390:1211–1259.
4. Pinheiro MB, Ferreira ML, Refshauge K, Ordoñana JR, Machado GC, Prado LR, et al. Symptoms of depression and risk of new episodes of low back pain: a systematic review and meta-analysis. *Arthritis Care Res*. 2015;67:1591–1603.
5. Alschuler KN, Neblett R, Wiggert E, Haig AJ, Geisser ME. Flexion-relaxation and clinical features associated with chronic low back pain. *Clin J Pain*. 2009;25:760–766.
6. 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;38:2279–2286.
7. Krismer M, van Tulder M. Low back pain (non-specific). *Best Pract Res Clin Rheumatol*. 2007;21:77–91.
8. Hoy D, Toole MJ, Morgan D, Morgan C. Low back pain in rural Tibet. *Lancet*. 2003;361:225–226.
9. Almeida M, Saragiotto B, Richards B, Maher CG. Primary care management of non-specific low back pain: key messages from recent clinical guidelines. *Med J Aust*. 2018;208:272–275.
10. Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2017;166:514–530.
11. Lowe DT. Cupping therapy: an analysis of the effects of suction on skin and the possible influence on human health. *Complement Ther Clin Pract*. 2017;29:162–168.
12. Rozenfeld E, Kalichman L. New is the well-forgotten old: the use of dry cupping in musculoskeletal medicine. *J Bodyw Mov Ther*. 2016;20:173–178.
13. Kim N, Shin BC, Shin JS, Lee J, Lee YJ, Kim MR, et al. Characteristics and status of Korean medicine use in whiplash-associated disorder patients. *BMC Complement Altern Med*. 2018;18:1–10.
14. Qureshi NA, Ali GI, Abushanab TS, El-Olemy AT, Alqaed MS, El-Subai IS, et al. History of cupping (Hijama): a narrative review of literature. *J Integr Med*. 2017;15:172–181.
15. Lyons K. Interest in cupping therapy spikes after Michael Phelps gold win; 2016. https://www.theguardian.com/sport/2016/aug/08/cupping-therapy-interest-spikes-michael-phelps-rio-olympics. Accessed 19 January, 2021.
16. Trofa DP, Obana KK, Herndon CL, Noticewala MS, Parisien RL, Popkin CA, et al. The evidence for common nonsurgical modalities in sports medicine, part 2: cupping and blood flow restriction. *J Am Acad Orthop Surg Glob Res Rev*. 2020;4:1.
17. Aboushanab TS, AlSanad S. Cupping therapy: an overview from a modern medicine perspective. *J Acupunct Meridian Stud*. 2018;11:83–87.
18. Markowski A, Sanford S, Pikowski J, Fauvell D, Cimino D, Caplan S. 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*. 2013;20:113–117.
19. Moura C, Chaves É de CL, Cardoso ACLR, Nogueira DA, Corrêa HP, Chianca TCM. Cupping therapy and chronic back pain: systematic review and meta-analysis. *Rev Lat Am Enfermagem*. 2018;26:e3094.
20. Tham LM, Lee HP, Lu C. Cupping: From a biomechanical perspective. *J Biomech*. 2006;39:2183–2193.
21. Al-Bedah A, Aboushanab TS, Alqaed M, Qureshi NA, Suhaibani I, Ibrahim G, et al. Classification of cupping therapy: a tool for modernization and standardization. *J Complement Altern Med Res*. 2017;1:1–10.
22. Al-Bedah AMN, Elsubai IS, Qureshi NA, Aboushanab TS, Ali GI, El-Olemy AT, et al. The medical perspective of cupping therapy: effects and mechanisms of action. *J Tradit Complement Med*. 2019;9:90–97.
23. Ahmadi A, Schwebel DC, Rezaei M. The efficacy of wet-cupping in the treatment of tension and migraine headache. *Am J Chin Med*. 2008;36:37–44.
24. Cramer H, Klose P, Teut M, Rotter G, Ortiz M, Anheyer D, et al. Cupping for patients with chronic pain: a systematic review and meta-analysis. *J Pain*. 2020;0:1–14.
25. Wang YT, Qi Y, Tang FY, Li FM, Li QH, Xu CP, 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;30:1187–1195.
26. Volpato MP, Breda ICA, de Carvalho RC, de Castro Moura C, Ferreira LL, Silva ML, et al. Single cupping thearpy session improves pain, sleep, and disability in patients with nonspecific chronic low back pain. *J Acupunct Meridian Stud*. 2020;13:48–52.
27. Silva HJDA, Saragiotto BT, Silva RS, Lins CADA, De Souza MC. Dry cupping in the treatment of individuals with non-specific chronic low back pain: a protocol for a placebo-controlled, randomised, double-blind study. *BMJ Open*. 2019;9:e0302416.
28. Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. Chapter 4: European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J*. 2006;15:S192–S300.
29. Kovacs FM, Abraira V, Royuela A, Corcoll J, Alegre L, Tomás M, et al. Minimal clinically important change for pain intensity and disability in patients with nonspecific low back pain. *Spine*. 2007;32:2915–2920.
30. Magalhães MO, Muzi LH, Comachio J, Burke TN, França FJ, Ramos LA, 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;20:603–609.
31. Benzon HT, Asher YG, Hartrick CT. Back pain and neuraxial anesthesia. *Anesth Analg*. 2016;122:2047–2058.
32. Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Katz RS, Mease P, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care Res*. 2010;62:600–610.
33. Raine C, Keat A. Axial spondyloarthritis. *Medicine*. 2018;46:231–236.
34. Lee MS, Kim JL, Kong JC, Lee DH, Shin BC. Developing and validating a sham cupping device. *Acupunct Med*. 2010;28:200–204.
35. 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;1:161–170.
36. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs*. 2005;14:798–804.
37. Shafshak TS, Elnemr R. The visual analogue scale versus numerical rating scale in measuring pain severity and predicting disability in low back pain. *J Clin Rheumatol*. 2020;1.

38. Maughan EF, Lewis JS. Outcome measures in chronic low back pain. *Eur Spine J*. 2010;19:1484–1494.
39. Fairbank JCT, Pynsent PB. The Oswestry Disability Index. *Spine*. 2000;25:2940–2953.
40. Ostelo RWJG, de Vet HCW. Clinically important outcomes in low back pain. *Best Pract Res Clin Rheumatol*. 2005;19:593–607.
41. Hirano K, Imagama S, Hasegawa Y, Ito Z, Muramoto A, Ishiguro N. 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;19:164–171.
42. Richardson S. The Timed "Up & Go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc*. 1991;39:142–148.
43. Gautschi OP, Stienen MN, Corniola MV, Joswig H, Schaller K, Hildebrandt G, et al. Assessment of the minimum clinically important difference in the timed up and go test after surgery for lumbar degenerative disc disease. *Neurosurgery*. 2017;80:380–385.
44. Perret C, Poiraudeau S, Fermanian J, Lefèvre Colau MM, Mayoux Benhamou MA, Revel M. Validity, reliability, and responsiveness of the fingertip-to-floor test. *Arch Phys Med Rehabil*. 2001;82:1566–1570.
45. Kitagawa R, Kato S, Demura S, Kurokawa Y, Shinmura K, Yokogawa N, et al. Efficacy of abdominal trunk muscles-strengthening exercise using an innovative device in treating chronic low back pain: a controlled clinical trial. *Sci Rep*. 2020;10:21883.
46. Freitas P, Pires D, Nunes C, Cruz EB. 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.
47. Bobos P, Ziebart C, Furtado R, Lu Z, MacDermid JC. Psychometric properties of the global rating of change scales in patients with low back pain, upper and lower extremity disorders. A systematic review with meta-analysis. *J Orthop*. 2020;21:40–48.
48. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care*. 1992;30:473–483.
49. Yao M, Yao M, Xu BP, Zhu S, Tian ZR, Li DH, et al. A comparison between the low back pain scales for patients with lumbar disc herniation: Validity, reliability, and responsiveness. *Health Qual Life Outcomes*. 2020;18.
50. Botega NJ, Bio MR, Zomignani MA, Garcia C, Pereira WA. Mood disorders among inpatients in ambulatory and validation of the anxiety and depression scale HAD. *Rev Saude Publica*. 1995;29:355–363.
51. Strøm J, Nielsen CV, Jørgensen LB, Andersen NT, Laursen M. A web-based platform to accommodate symptoms of anxiety and depression by featuring social interaction and animated information in patients undergoing lumbar spine fusion: a randomized clinical trial. *Spine J*. 2019;19:827–839.
52. Akbarzadeh M, Ghaemmaghami M, Yazdanpanahi Z, Zare N, Azizi A, Mohagheghzadeh A. 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;2:112–120.
53. Huang CY, Choong MY, Li TS. Effectiveness of cupping therapy for low back pain: a systematic review. *Acupunct Med*. 2013;31:336–337.
54. Teut M, Ullmann A, Ortiz M, Rotter G, Binting S, Cree 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.
55. Vase L, Vollert J, Finnerup NB, Miao X, Atkinson G, Marshall S, et al. Predictors of the placebo analgesia response in randomized controlled trials of chronic pain: a meta-analysis of the individual data from nine industrially sponsored trials. *Pain*. 2015;156:1795–1802.
56. Bishop MD, Bialosky JE, Cleland JA. Patient expectations of benefit from common interventions for low back pain and effects on outcome: secondary analysis of a clinical trial of manual therapy interventions. *J Man Manip Ther*. 2011;19:20–25.
57. Menezes Costa LDC, Maher CG, Hancock MJ, McAuley JH, Herbert RD, Costa LOP. The prognosis of acute and persistent low-back pain: a meta-analysis. *CMAJ*. 2012;184:E613–E624.
58. Ferreira PH, Ferreira ML, Maher CG, Refshauge KM, Latimer J, Adams RD. The therapeutic alliance between clinicians and patients predicts outcome in chronic low back pain. *Phys Ther*. 2013;93:470–478.
59. Rossettini G, Carlino E, Testa M. Clinical relevance of contextual factors as triggers of placebo and nocebo effects in musculoskeletal pain. *BMC Musculoskelet Disord*. 2018;19:1.
60. Lauche R, Spitzer J, Schwahn B, Ostermann T, Bernardy K, Cramer H, et al. Efficacy of cupping therapy in patients with the fibromyalgia syndrome-a randomised placebo controlled trial. *Sci Rep*. 2016;6:37316.
61. Fillingim RB, King CD, Ribeiro-Dasilva MC, Rahim-Williams B, Riley JL. Sex, gender, and pain: a review of recent clinical and experimental findings. *J Pain*. 2009;10:447–485.