An RCT with Controlled Cupping Therapy for Persistent Non-Specific Low Back Pain to Assess Pain and Functional Disability

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ABSTRACT

Context: Musculoskeletal disorders, such as low back pain, are treated with cupping therapy.
Study goals: To evaluate the impact of dry cupping on pain and functional impairment resulting from persistent, nonspecific low back pain.
Methods: This was a randomized controlled trial in which participants were divided into two groups: one for sham cupping therapy (n = 18) and the other for cupping therapy (n = 19). The goal of the cupping therapy sessions was to stimulate the acupoints (HT3 and ST36) and GV4, BL23, BL24, BL25, BL30, BL40, and BL58) associated with low back pain. The sessions lasted 10 minutes each. Every participant underwent assessments using the Oswestry Disability Index (ODI) and a visual analogue scale (VAS) at baseline, post-treatment, and follow-up (a four-week finalization period). Cohenœs d was used to calculate the effect size and analysis of covariance (ANCOVA) was used to compare the groups.
Results: At post-treatment (mean difference: –2.36; standard error [SE]: 0.58; p < 0.001; "large" effect size: –0.94) and follow-up (mean difference: –1.71; SE: 0.81; p < 0.042; "large" effect size: –0.83), the cupping therapy group showed a lower mean VAS in comparison to the sham. In the follow-up, there was no difference between the groups (mean difference: 4.16; SE: 2.97; p: 0.17; "medium" effect size: –0.70), but the cupping therapy group had a lower mean ODI than the sham post-treatment (mean difference: –4.68; SE: 1.85; p: 0.017; "large" effect size: –0.87).
Conclusion: dry cupping was superior to the sham in terms of reducing pain and functional disability in patients with chronic nonspecific low back pain.

Keywords: Cupping, Sham treatment, people with disabilities, low back pain
DOI Number: 10.48047/nq.2022.20.3.NQ22987 **NeuroQuantology 2022;20(3):1249-1260**

INTRODUCTION

People's functionality and quality of life are greatly impacted by low back pain, which is categorized as nonspecific when the cause of the pain cannot be identified and persistent when symptoms persist for longer than three months.

Therapeutic exercises and manual therapy are generally recommended for the physiotherapeutic treatment of nonspecific low back pain, which is the most common cause of low back pain. One option for treating low back pain is complementary therapy, such as cupping therapy, which has shown promise in recent years in terms of reducing pain and enhancing function.

The two primary methods of application, dry cupping and wet cupping, involve applying suction to the skin at a particular acupuncture point (acupoint) or area. The reason for the

distinction between the two forms of cupping therapy is that wet cupping requires making a tiny skin incision and drawing blood from it. When it comes to reducing low back pain, both kinds work similarly.

But compared to wet cupping, dry cupping is a non-invasive intervention that is thought to be safer, simpler to perform, and have fewer side effects. Variations in the suction method may arise during treatment with dry cupping. A method of creating suction known as "fire cupping" involves using fire to create a vacuum and an additional material called moxa. Nevertheless, there are certain drawbacks to this procedure because it is deemed risky because it could result in burns and lesions on the recipients' skin. On the other hand, suction can also be obtained manually with a hand pump, which is regarded in the literature as a simple and safe way to create suction in the cup.

As a result, dry cupping therapy may be employed to treat low back pain. Nevertheless, there are currently few studies on this technique's efficacy, and in many of them, the method and intervention are still only partially described.

Moreover, there is disagreement in the literature about the number of sessions (ranging from one to eight) and treatment duration (studies vary between 8 and 20 minutes) required for dry cupping to provide pain relief and enhanced functionality.

The most often used acupoints for cupping therapy to relieve low back pain are BL23, BL24, and BL25. These points can be used singly or in combination. Although not included in low back pain surveys, additional acupoints (GV4, BL30, BL40, and BL58) of the bladder and the governing vessel meridian are related to low back pain and strengthening the lower back region, and they should be included in treatment for a more comprehensive approach to low back pain.

The research also indicates that behaviors related to the genesis and chronification of low back pain, as well as the factors that determine disability, should be linked to interventions aimed at managing emotional and psychosocial problems. The HT3 and ST36 points are therefore associated with the heart and stomach meridians in the treatment of low back pain because they influence the amelioration of painful symptoms as well as acting on depression, anxiety, and insomnia. They also stabilize the mind and emotions. There were no studies found that used points associated with these psychosocial factors, which the literature suggests are predictive factors of disability associated with low back pain.

Thus, it is possible to speculate that applying cupping therapy in conjunction with stimulating the acupoints listed above (BL23, BL24, and BL25), along with additional points linked to the aspect of low back pain (GV4, BL30, BL40, and BL58) and points pertaining to the emotional state (HT3, ST36), may have a more significant impact on reducing pain and enhancing functionality.

Considering the foregoing, the current study's goal is to evaluate how cupping therapy affects pain and functional disability in people who have chronic, non-specific low back pain. Furthermore, the study aims to evaluate the effects of cupping therapy on both physical and psychosocial factors, as well as the frequency of low back pain episodes per week.

MATERIALS AND METHODS

1. Type of study:
   A randomized controlled clinical trial was conducted here. The Universidade Federal de Pernambuco's Ethics and Research Committee approved the study, which was carried out in accordance with CONSORT and registered on the Brazilian Registry of Clinical Trials (RBR-3s7g4t) (Protocol number: 3.492.806). The informed consent form was signed by each participant
2. Participants:
   Adults between the ages of 18 and 59 who had nonspecific low back pain (lasting longer than three months) were

included in the study. The following conditions resulted in their exclusion: taking anticoagulants; pregnant; women in the puerperium period; anemia; red flags of low back pain; systemic diseases; fibromyalgia; lumbar herniated disk; symptomatic irradiated pain; altered skin integrity; or a history of cupping therapy treatment.

3. Randomization:
   distribution and occlusion With allocation confidentiality, participants were randomized using the www.randomization.com program into two groups (sham and cupping therapy) in blocks of ten. To compare the effectiveness of cupping therapy and the sham group, the study's statisticians, participants, and evaluators were all blinded.
   A researcher not involved in the study coded each patient's assignment to one of the study groups using computer systems, ensuring blinding to the random distribution process. The treatments the patients would receive were given to them in opaque, sealed envelopes. Throughout the study, participants were kept in the dark about which group they had been assigned to. In order to maintain blinding, the groups were separated into two distinct locations and participants were not allowed to communicate with one another about the intervention. Moreover, participants were not informed about the technique beforehand.
4. Intervention:
   Five sessions, held twice a week, totaling twenty minutes of treatment were given to the participants in both groups. During these sessions, the suction cups were applied for ten minutes each to the anterior and posterior regions of the body. For ten minutes, the cups were left on the acupoints. For each session, seventeen medium-diameter (3.5 cm) reusable acrylic cups (Dong Yang) were used for each individual. If the therapist saw any signs of dehydration before the session started, coconut oil was applied to the area to hydrate the skin.
   Each patient was given a unique measurement, called tsun (cun), which was used to find the points. The distance or fraction fixed between two established references—bone or morphological—that are used to locate the points is known as the tsun, or cun. Given that it offers appropriate measurements for every individual, it is the most suitable measurement. The only extra treatments the patients underwent during data collection were sham or cupping therapy, but they also continued to take their regular medications as directed by their doctors.
   With more than three years of experience in the field of traditional Chinese medicine and over six years of experience treating low back pain, the professionals who identified the points and carried out the interventions were highly qualified.

   1) The group for cupping therapy
      Using the dry cupping method, the cups were first applied using two "moderate" hand pump suctions that produced a negative pressure of about 300 millibar. In accordance with each participant's unique experience, the pressure was somewhat reduced for those who expressed a great deal of discomfort. Every cup was arranged so that the acupoint was in the middle. There was no other tool or material used to create the vacuum; only a hand pump.

The cupping therapy group's intervention protocol was created based on a prior study that recommended BL23 (Shenshu), BL24 (Qihaishu), and BL25 (Dachangshu) as specific acupuncture points for the treatment of low back pain. This protocol also included points relating to low back pain, GV4 (Mingmen), BL30 (Baihuanshu), BL40 (Weizhong), and BL58 (Feiyang), as well as points related to emotional factors, HT3 (Shaohai) and ST36 (Zusanli).

In order to apply the cups, the participants were first put in the supine position. For about ten minutes, four cups were applied bilaterally to the points HT3 (Shaohai) and ST36 (Zusanli).

After that, the subjects were placed in the prone position, and 13 cups were positioned bilaterally on the points GV4 (Mingmen), BL23 (Shenshu), BL24 (Qihaishu), BL25 (Dachangshu), BL30 (Baihuanshu), B40 (Weizhong), and BL58 (Feiyang). For an additional ten minutes, the cups were left in place.

2) The phony organization

The cups were placed using the same acupoints and protocol as the group receiving cupping therapy. Nevertheless, a tiny hole in the wall of these cups—made with a heated 1.9mm crochet hook—made it impossible to maintain the suction that had been applied.

A transparent double-sided adhesive tape was used along the cup's edge to ensure that it would stay affixed to the skin in each area. Concerning ethical concerns, all participants were treated with actual cupping therapy after the study was over, as documented with the ethics committee, in order to provide the sham group with an efficient low back pain treatment. Patients who showed no improvement after receiving cupping therapy were given the option of conventional physiotherapy.

5. Adverse effects and follow-up control:
Following the application of cupping therapy, a change in skin pigmentation is anticipated at specific locations, along with a minor elevation in pain sensitivity (VAS < 4) in the area where the cup was placed. If participants developed blisters or skin eruptions where the applications were applied, therapy would end.
6. Outcomes:
The main results were pain level and functional impairment. The visual analogue scale was used to measure pain (VAS). The Oswestry Disability Index (ODI) questionnaire was utilized to quantify functional disability. The Start Back Screening Tool (SBST) questionnaire was used to gather information on the physical and psychosocial characteristics of individuals with low back pain, and a weekly pain diary was used to track the number of days the participant reported experiencing pain. Three points in time were evaluated for the variables VAS, ODI, and SBST: the baseline assessment, the post-treatment assessment after five sessions, and the follow-up assessment four weeks after the treatment. At baseline, one week into treatment (two sessions), two weeks into treatment (four sessions), and post-treatment (after five sessions), the variable number of days per week of pain was measured.
7. Sample size calculation:

Taking into account the main findings of this investigation, the researchers' pilot study (n = 30; 15 per group) served as the basis for calculating the sample. The cupping therapy group (mean: 2.25; standard deviation: 1.71) and the sham group (mean: 4.59; standard deviation: 2.18), along with the effect size of 1.179, were taken into account for the VAS. The suction cup group (mean: 11.44; standard deviation: 6.68) and sham group (mean: 18.12; standard deviation: 8.93) and effect size (0.847) are the values for the ODI. Based on the ODI outcome that yielded the largest estimated sample size, a minimum sample size of 17 participants per group was determined by taking into account 5% alpha and 80% power. A sample of 19 people per group was used, accounting for potential losses (n = 38).

8. Statistical analysis:

With SPSS 20.0, the statistical analysis was carried out. The normality of the data was examined using the Shapiro-Wilk test. The sample's characteristics and the baseline outcome variables' values were displayed as mean and standard deviations in addition to absolute and percentage values. Using the t-tests for independent samples for continuous data and, when appropriate, the Pearson's χ 2 tests, χ 2 with continuity correction, or Fisher's χ 2 tests for categorical data, the comparability of variables between groups at baseline was guaranteed.

Univariate analyses of covariance (ANCOVA), which modeled each post-treatment and follow-up result according to the treatment group—suction cup or sham—and their respective baseline values (linear covariate), were carried out for the variables VAS, ODI, and STBS. The mean and standard error were used to represent the estimated data from the ANCOVA follow-up and post-treatment results. Furthermore, the 95% confidence interval, the p-value, the standard error, and the mean of the group differences were provided.

Using the estimated mean and standard error of each group for the variables VAS, ODI, and SBST, the effect size of the cupping therapy compared to the sham was computed and interpreted using Cohen's criterion (small ≤ 0.2 to 0.49; medium: 0.5 to 0.79; large ≥ 0.8). Repeated measures ANOVA and the Bonfferoni post-hoc test were used to examine four assessment periods for the outcome number of days per week of pain in each group: baseline, after the first week of treatment, after the second week of treatment, and post-treatment. The t test for independent samples was used to compare the groups at each point.

The mean difference in the scores of each scale at baseline, post-treatment, and follow-up was obtained in order to assess whether the minimal important difference (MID) for the variable (VAS and ODI) was reached in each group. In each treatment group (sham and cupping therapy), the MID was examined in relation to the VAS, where a MID was worth two points on the scale, and the ODI, where a MID was worth ten points on the questionnaire. The Bonferroni posthoc test and repeated measures ANOVA were employed in this analysis. It was also possible to determine the precise number and percentage of people who attained the MID at each assessment point.

Since there was no notable participant loss during the trial, the intention to treat primary or secondary outcomes was not examined.

RESULTS

1. Participants:
   Thirty-eight participants were randomized for the study.

2. Primary outcomes:
   When compared to the sham group, the VAS for the cupping therapy group was lower at posttreatment (mean difference: 2.36; standard error: 0.58; 95% CI: –3.55 to –1.17; p: < 0.001; "large" effect size: –0.94) and follow-up (mean difference: –1.71; standard error: 0.81; 95% CI: –3.37 to –0.06; p: < 0.042; "large" effect size: 0.83).
   In comparison to the sham group, the cupping therapy group's ODI post-treatment score was lower (mean difference: –4.68; standard error: 1.85; 95% CI: –8.45 to –0.90; p: <0.017; "large" effect size: –0.87). When the groups were compared again, there were no differences (mean difference: –4.16; standard error: 2.97; 95% CI: –10.20 to 1.87; p: < 0.001; "medium" effect size: –0.70).

3. The ODI and VAS Minimal Important Difference (MID):
   Between the post-treatment and baseline periods (mean difference –2.47, standard error: 0.50, p: <0.001), as well as between the follow-up and baseline periods (mean difference –2.78, standard error: 0.55, p: <0.001), the cupping therapy group showed a decrease in the pain score (VAS). The follow-up and post-treatment periods did not differ from one another (mean difference 0.31, standard error: 0.36, p: 1,000). Between the assessment moments, there was no discernible decrease in pain intensity in the sham group.
   According to the percentage analysis per individual who reached a MID, 26.31% of the participants in the follow-up and posttreatment periods (against 27.77% in the sham group), 63.15% of the participants in the cupping therapy group reached a MID for the VAS between the follow-up and baseline periods (against 50% in the sham group), and 68.42% of the participants in the post-treatment and baseline periods (against 22% in the sham group).
   Regarding the ODI, the functional disability of the cupping therapy group was found to have improved both between the follow-up and baseline periods (mean difference –8.63 standard error: 1.97, p: < 0.001) and between the posttreatment period and baseline (mean difference –6.52, standard error: 1.45, p: < 0.001). Between the follow-up and post-treatment periods, there was no discernible difference (mean difference –2.10, standard error: 1.00, p: 0.154). Between the assessment periods, there was no discernible decline in the ODI score in the sham group.
   The cupping therapy group's participants achieved a MID for the ODI between the post-treatment and baseline periods (36.85% vs. 16.66% in the sham group), between the follow-up and baseline periods (36.85% vs. 38.85% in the sham group), and between the follow-up and posttreatment periods (5.2 % vs. 22.22% in the sham group), according to the percentage analysis per individual who achieved a MID.

4. Secondary outcomes:
   Comparing the cupping therapy group to the sham group, the SBST scores showed a lower rate in both the post-treatment (mean difference: –1.46; SE: 0.53; 95% CI: –2.54 to –0.38; p: < 0.01, ‘large’ effect size: –0.89) and follow-up (mean difference: –1.04; SE: 0.49; 95%

CI: - 2.04 to –0.04; p < 0.04; 'large' effect size: –0.83) periods.

Both groups showed a decrease in the number of days they reported having pain in the weekly pain diary over the course of the study (repeated measures ANOVA, p < 0.01). This decrease in the number of days of reported pain in the cupping therapy group happened between the baseline and the first week (post hoc: 0.001), the second week (post hoc: <0.0001), and the post-treatment period (post hoc: < 0.0001). The difference was seen in the sham group between baseline and post-treatment (post hoc: 0.02) and second week (post hoc: < 0.0001). When the groups were compared, it was found that the cupping therapy group had a larger reduction in days after the first week (p < 0.01) and in the post-treatment period (p < 0.02).

5. Adverse consequences:
   Not a single participant exhibited any moderate or severe symptoms that would have required them to withdraw from the study. The majority of the participants (n = 19) experienced a slight change in skin pigmentation, which was the only adverse event noted and vanished after four days.

DISCUSSION

One low back pain treatment option that works well for a variety of low back pain types is dry cupping therapy. The Eastern viewpoint holds that energy function can be regulated and symptoms can be alleviated by applying stimulation to acupoints.

The main theories and hypotheses regarding the physiological effects of pain reduction from the perspective of Western medicine are the theory of the reflection zone, which states that pain relief is accomplished by inhibiting receptors conducting pain stimuli, the theory of gate control of pain, and the control of diffuse harmful inhibitors. The precise acupoints to treat nonspecific low back pain are BL23, BL24, and BL25. But it's crucial to take into account all of the possible causes of this pain condition, including psychosocial variables that have a significant impact on when pain first manifests.

Considering acupoints correlated with emotional factors (HT3 and ST36) associated with local (GV4, BL23, BL24, BL25, and BL30) and distal points (BL40 and BL58) related to low back pain, the current study is, to the best of our knowledge, a pioneer in addressing dry cupping therapy.

The current study found that, in comparison to the sham group, the cupping therapy group showed a significant improvement in pain intensity, with a mean difference of –2.36 (0.58) points on the VAS scale following treatment and –1.71 (0.81) points at follow-up. A study by Volpato et al. that compared a cupping therapy group with a sham also found improvement in pain intensity, with a difference of 3.78 points at the post-treatment period and 3.23 points after a week of follow-up, measured using the Brief Pain Inventory (BPI). The study used acupoints BL23, BL24, and BL25.

The present study's and Volpato et al.'s findings show that cupping therapy improves low back pain both immediately and over time. Similar to Volpato et al.'s study, the current study showed a sizable effect size in posttreatment. Regarding follow-up, it is noteworthy that Volpato et al. only conducted a follow-up assessment one week following a single cupping session. This limited the ability to determine whether the effects of a single session are sufficient to last longer than a week. But after four weeks of follow-up, the current study found that five sessions had a significant impact on pain relief.

Research has also been done on cupping therapy and medication combined treatments. According to Teut et al., three groups—the minimum pressure group (–70 mbar), the cupping therapy group (–150 to –350 mbar), and the control group—were given analgesics in conjunction with pulsatile dry cupping. Throughout the study period, participants in all

three groups took paracetamol. It was observed that after eight sessions, the minimum pressure and cupping therapy groups showed a significant improvement in pain intensity ($p < 0.001$) in comparison to the control group. Only the cupping therapy group, however, showed a statistically significant difference from the control group after a 12-week follow-up.

Based on prior research, the moderate level of negative pressure applied to the cupping therapy group was found to have a longer-lasting effect on pain intensity than either the medication-only group or the group using the least amount of pressure. This finding illustrates the effectiveness of negative dry cupping pressure in reducing low back pain and supports the findings of the current study, which used a pressure of about 300 hPa to achieve a large effect size on pain relief both during and after treatment without the need for medication.

Furthermore, it should be mentioned that, in contrast to Teut et al.'s study, the current study employed a hand pump to create the negative pressure of the suction cup on the skin. This pressure was graded based on each patient's sensitivity threshold and was maintained through the end of the session. Nonetheless, pain relief outcomes were comparable in the two trials, suggesting that the effects of pulsating or continuous pressure on pain intensity might be comparable.

As seen in the study by Akbarzadeh et al., whose sample consisted of women in the puerperium period, cupping therapy has also shown effects on low back pain in various populations. Using the McGill Pain Questionnaire, this study found that the experimental group (dry cupping over the BL23 point) experienced less low back pain than the control group (no treatment).

But one thing to keep in mind when using dry cupping is the placebo effect of applying the suction cup to the skin, which, unlike in this study, was not controlled in the research by Teut et al. or Akbarzadeh et al. Consequently, the lack of control over the placebo effect may have led to an overestimation of the findings of Teut et al. and Akbarzadeh et al.

As indicated by the weekly pain diary, the current study not only reduced pain but also the number of days participants reported having low back pain during the study's weeks. It was noted that in the group receiving cupping therapy, the difference was noticeable from the first to the second week and even after treatment. After the second week and throughout the post-treatment phase, there was a difference in the sham group; however, when the groups were compared, the cupping therapy group showed a larger and more significant difference. These results could not be compared with those of other comparable studies because no studies that had made this assessment could be located in the literature.

It is anticipated that people will progressively regain their functionality as their low back pain improves.

With a difference of –4.68 (1.85) on the ODI scale, the cupping therapy group in this study showed less post-treatment disability than the sham group, with an effect size deemed to be large. The cupping therapy and sham group showed no differences in the ODI during the follow-up. This finding implies that cupping therapy may result in a quicker improvement in low back pain and functionality, which is maintained after treatment has ended, given that the majority of cases of nonspecific low back pain are self-limiting. Respecting the duration of the nonspecific pain, the group that did not receive treatment should see improvements in pain and functionality over a longer time frame.

Prior studies have also demonstrated benefits of the dry cupping method for low back pain-related functional disability. In Teut et al.'s study, only the cupping therapy group demonstrated a statistically significant improvement in the function of the disability questionnaires (Funktionsfragebogen Hannover Rücken) in comparison to the control group during the post-treatment phase. After a 12-week follow-up, however, the improvement in

the cupping therapy group was not sustained. Though it was only one week after follow-up, the Volpato et al. treatment plan also improved the functional disability outcome as measured by the Roland-Morris disability questionnaire.

This improvement may have occurred both immediately upon achieving a MID with the VAS and later, one month after follow-up, as a result of the treatment in this study incorporating more acupuncture points and other regions associated with low back pain, along with the inclusion of points related to psychosocial factors.

By using this method and taking into account the points that are related to emotional factors, it can be seen that, in comparison to the sham group, the cupping therapy group's participants showed a higher degree of clinical improvement regarding the prognosis of low back pain based on SBST scores during the posttreatment and follow-up periods. These findings set up the biopsychosocial component, which is mediated by fear and self-efficacy, in the relationship between pain and functional disability.

Therefore, even though cupping therapy is thought to be safe and simple to use, it is also known that this method may have some negative effects. This is true even though cupping therapy is a resource that may be used to treat low back pain and improve functional disability, as observed in the present study. Anemia and panniculitis are the most prevalent and are more common with wet cupping therapy. Furthermore, the significance of the professional's qualifications was underscored in order to prevent significant complications. The current study took all the required steps to reduce any negative effects. The only thing that happened was that most of the participants experienced a slight change in skin pigmentation, which went away after four days as was predicted.

- Limitations:

  There are certain limitations to this study that should be considered when interpreting the results. The study results had limited significance for older individuals with low back pain because the majority of participants were young females. For the study to include a greater variety of patients with non-specific low back pain, a larger sample size is required. Another constraining factor is the absence of the pain diary results from the follow-up period, which may have led to a forgetfulness bias because the participants' assessments of the outcome were retrospective in nature.

CONCLUSIONS

Compared to a sham group, cupping therapy treatment was more successful in reducing pain and functional disability in patients with persistent nonspecific low back pain. It also improved the prognosis for patients with persistent nonspecific low back pain and the number of days of low back pain reported during the course of treatment.

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