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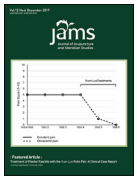

Research Paper

Wet Cupping—Traditional Hijamah Technique versus Asian Cupping Technique in Chronic Low Back Pain Patients: A Pilot Randomized Clinical Trial†

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cupping;
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Abstract
To evaluate the feasibility of comparing the effect of the traditional Hijamah and the Asian wet cupping techniques in the management of patients with chronic low back pain (CLBP), a randomized clinical trial comparing traditional and Asian wet cupping techniques for CLBP was conducted in two secondary care hospitals in Saudi Arabia. Seventy eligible participants with CLBP were randomized to receive one session of wet cupping using either Asian technique (34 patients) or traditional Hijamah technique (36 patients). Cupping was performed at four sites of the bilateral bladder meridian (BL23, BL24, and BL25). The numeric rating scale, Present Pain Intensity, and Oswestry Disability Questionnaire scores were measured immediately after intervention, at seven days, and 14 days

Abbreviations: CAM, Complementary and Alternative Medicine; CLBP, Chronic Low Back Pain; D0, Day 0; DOBC, Day 0 Before Cupping; D14, Day 14; D7, Day 7; DALY, Disability-Adjusted Life Year; MCID, Minimal Clinical Improvement Difference; NRS, Numeric Rating Scale; ODQ, Oswestry Disability Questionnaire; PPI, Present Pain Intensity; SD, Standard Deviation.

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after intervention. In both groups, there was a significant decrease in the numeric rating scale, Present Pain Intensity, and Oswestry Disability Questionnaire scores, immediately after intervention, at seven days, and 14 days after intervention. However, there was no significant difference between the two groups across all the outcome measures up to 14 days after intervention. The study did not show a superiority of one technique compared with the other. Longer follow-up periods and more than one cupping session may be needed to evaluate the difference, if any, between both the techniques.
Trial Registration: NCT02012205.

1. Introduction

1.1. Background

Chronic low back pain (CLBP) is a common complaint in primary care [1,2], occupational health departments, and musculoskeletal health-care services [3]. It ranks directly second to common cold [4,5], with relatively similar prevalence across communities around the world [6].

Twelve-week duration is usually used as a cutoff point for chronic nonspecific low back pain. The prevalence of CLBP is estimated to be about 23%, with 11—12% of the population being disabled by low back pain [11].

In Saudi Arabia, musculoskeletal and mental disorders are becoming a major challenge for the health-care system. Low back pain was the 4th leading causes of disability-adjusted life years in males (5.77%) and in females (5.06%) [12].

Low back pain is expected to increase as people age, and the low back pain will increase as a result of the degeneration of intervertebral discs that occurs with the human aging process [4].

In addition to other supportive measures and behavioral modification, CLBP is mainly treated with analgesia [1,16]. Accordingly, individuals with a long history of this condition will consider an alternative option that may ease the pain for them and decrease the long-term use of painkillers [16,17] including complementary and alternative medicine practices [18].

1.1.1. Wet cupping (AlHijamah) therapy

Wet cupping (AlHijamah) has been used as an alternative therapy in the management of patients with low back pain [21-24]. It is widely used in the Middle East region and other parts of Asia and Europe [21,25].

The evidence so far suggests that wet cupping (AlHijamah) is effective especially for patients with musculoskeletal system disorders and migraine headache [25-28]. However, high-quality trials are needed to generate more robust evidence [25].

Wet cupping (AlHijamah) technique used in the Middle East is different from the technique used in Asia. Published studies showed that both techniques were apparently effective for patients with low back pain compared with the inactive control group [22-24], but they were not compared in a clinical study before.

The Middle East technique uses a three-step technique (the order of steps being cupping, puncturing, and cupping) in general, for which a sharp surgical blade is used for scarification, and the nomenclature of the cupping sites is also different [24,29]. The Asian technique uses a two-step technique. Cupping is applied only after puncturing (puncturing followed by cupping), for which auto-lancet needles are used rather than surgical blades. In certain countries or protocols they are guided by the acupuncture points as the sites of cupping [23]. The main difference is that in the Middle East, cupping is applied before and after scarification of the skin [24,30]. Both techniques are currently used in the cupping training programs in Saudi Arabia. However, traditional healers in Muslim countries favor the local technique as it was used during the times of the Prophet of Islam.

The mechanism behind wet cupping (AlHijamah) therapy is still not completely understood. Congested blood is sucked out of the skin, thereby increasing blood and lymphatic circulation and relieving painful muscle tension spasms, and this will result in producing the desired effect [31]. Wet cupping may lead to the production of endogenous nitric oxide (which is considered to be a vasodilator, antineoplastic, and antimicrobial agent) or to the removal of oxidants, which would decrease oxidative stress [22]. In addition, laceration of the skin can trigger diffuse noxious inhibitory control, acting eventually as a nociceptive stimulus [23].

2. Materials and methods

2.1. Overall design

This study was a pilot randomized clinical trial to evaluate the feasibility of comparing the effect of the traditional Hijamah (three-step) and the Asian wet cupping (two-step) techniques in the management of patients with CLBP.

Participants, the coordinator, the outcome assessor, and the statistical analyst were blinded. CLBP was defined as "pain localized below the lower posterior costal margin and above the inferior horizontal gluteal folds." This pain should last at least 12 weeks, with no specific underlying cause [2,3,32].

2.2. Participants

Study participants were recruited between February and May 2016 from King Fahad Hospital in Jeddah city and King Fahd Hospital in Al Madinah city in the western region of Saudi Arabia. Of the 90 participants invited and who agreed to participate in the study, 70 were eligible for the study in both

centers (in Al Madinah and Jeddah) after screening for the eligibility criteria and signing the informed consent. All participants were examined and evaluated by consultant orthopedics.

Inclusion criteria were as follows: males and females, age ≥18 years up to 60 years, CLBP (at least for a duration of ≥three months), and the participants should not have had wet cupping therapy in the previous three months. The exclusion criteria were as follows: patients who have low back pain due to specific and known etiological causes such as fracture, infection, cancer, ankylosing spondylitis, or cauda equina syndrome; patients who have AIDS, hepatitis, tuberculosis, and syphilis; patients receiving any anticoagulant or antiplatelet medications; patients who have anemia, thrombocytopenia, coagulopathy, or hemorrhagic diseases such as hemophilia; patients who had undergone a surgery; patients who had bleeding injury or who had blood donation in the previous three months; patients who have uncontrolled hypertension, ischemic heart disease, previous transient ischemic attack, or stroke; patients who have diabetes and known renal and/or hepatic diseases; patients who are pregnant or have plans to conceive; and patients with any other severe disease or disabling medical condition.

All participants gave their written, informed consent before the study. The study was approved by the Central Institutional Review Board of the Saudi Ministry of Health in King Fahd Medical City, Riyadh (15 — 260E).

The participants were prohibited from using any medications that can improve low back pain for two weeks before and during the study. However, they were permitted to take up to three tablets (500 mg each) of acetaminophen per day as a rescue treatment for pain.

2.3. Intervention

The participants were randomized to receive one session of wet cupping using either Asian technique or traditional Hijamah technique. Forty—cubic centimeter disposable plastic cups with a manual pump were used for both groups. The cupping session was given using the clean wet cupping technique. The cupping sites are shown in Fig. 1.

2.3.1. Asian technique

This intervention included the following steps: (1) marking cupping points by selecting two (total four) most painful points of the bilateral bladder meridian BL23, BL24, and BL25, (2) puncturing (using auto-lancet needles) in 2-mm depth, (3) attaching the cups, (4) exhausting inner air of the cups using a manual pump with maximum negative pressure, (5) retaining the cup for 5 minutes, and (6) opening the exhaust valve and removing the cup.

2.3.2. Traditional Hijamah technique

This intervention included the following steps: (1) marking cupping points by selecting two bilateral points (total four) were selected depending on the most painful points in the low back area and irrespective of acupoints, (2) attaching the cups, (3) exhausting inner air of the cups using a manual pump with maximum negative pressure, (4) retaining the cup for 5 minutes, (5) opening the exhausting valve and removing the cup, (6) scarification using a sharp surgical blade (six scarifications along the marked site to 3-mm length and 0.5-mm depth), (7) attaching the cups again, (8) exhausting inner air of the cups using a manual pump with maximum negative pressure, (9) retaining the cup for 5 minutes, and (10) opening the exhaust valve and removing the cup.

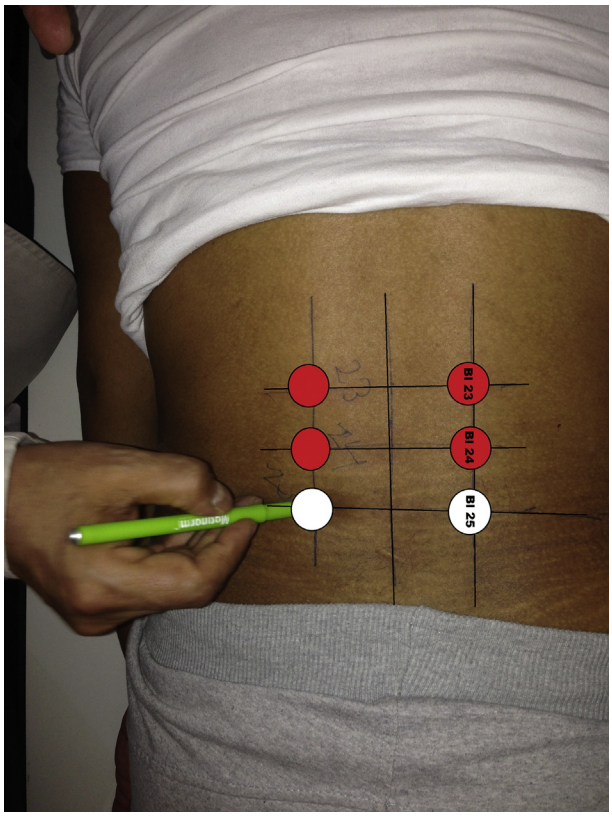

Figure 1 Cupping sites used in the trial.

2.4. Outcome measures

Pain and functional status were measured using the validated Arabic version of the numeric rating scale (NRS) [33], the Present Pain Intensity (PPI) scale [34], and the Oswestry Disability Questionnaire (ODQ) [35].

The primary outcome measure was a difference in the change in the NRS [33] for pain from baseline to the end of the first week (primary end point). The secondary outcome measures were as follows: PPI [34] and ODQ [35]. All outcome measures were measured before the intervention, immediately after intervention (within 15 minutes), at 7 days, and 14 days after intervention. Patient satisfaction was measured using the Integrative Medicine Patient Satisfaction Scale [36] at Day 7 after intervention (while the participants are still blinded to the type of intervention technique) and Day 14 after informing them about their allocation group.

2.5. Interpretation of the outcome measures

The NRS was used to assess pain in general in the past week on a scale ranging from 0 to 100, in which 0 represented "no pain" and 100 represented "extreme pain"

Fifteen points were considered the minimal clinical improvement difference (MCID) for the NRS score.

The PPI scale, which is an index of the standard McGill Pain Questionnaire, was used to assess pain at the time of the visit. The PPI scale had six answer options, scored from 0 to 5, where 0 reflects "no pain" and 5 reflects "excruciating pain." Thirty percent of improvement was considered the MCID for the PPI score percentage.

The ODQ scoring consists of 10 questions addressing common daily activities. Each question has six answer options, scored from 0 to 5, where 0 reflects "no restriction in daily activities" and 5 reflects "the most restrictions in daily activities." Ten percent of improvement was considered the MCID for the ODQ score percentage [37].

Adverse events were ascertained during each visit by patient reporting and physician examination. An adverse event was defined as any untoward medical occurrence associated with the use of the intervention, whether or not intervention-related events are considered [38]. The severity of the adverse event was classified by practitioners as Grade 1 (mild) to 4 (life-threatening), as per the criteria of World Health Organization (WHO Toxicity Grading Scale for Determining The Severity of Adverse Events) [39].

2.5.1. Sample size

The purpose of the present pilot study was not to give a formal assessment of efficacy or to prove superiority of one intervention but mainly to test trial procedures and processes [40]. It can give estimates of parameters for the main trial sample size calculation. We decided to include 30 participants in each group as a convenient sample. Allowing for 30% dropout, 45 patients were recruited in each group.

2.5.2. Randomization and concealment

Random numbers were generated using a block randomization method, with randomly selected block sizes, available at https://www.sealedenvelope.com. Sealed opaque envelopes were used for allocation concealment. Randomization and concealment were conducted by a research assistant. Before allocation, the patient's expectation was measured using a 5-point Likert scale.

2.5.3. Blinding

The participants, coordinator, outcome assessor, and statistical analyst were blinded.

2.6. Statistical analysis

As the distribution did not approximate a normal distribution, nonparametric tests were used to compare between and within the two groups. The Mann—Whitney U test was used to compare the outcome measures between the two groups, whereas the Wilcoxon signed-rank test was used to compare the outcome measures within the groups. A P-value less than 0.05 was considered statistically significant differences. The Chi-square test or Fisher's exact test was used for categorical data. Statistical analysis was based on the intention-to-treat concept. Analysis of covariance (ANCOVA) was also attempted, taking into consideration the sample size.

3. Results

3.1. Participant flow

Ninety participants were assessed for eligibility, and 20 were excluded. The randomization process resulted in 36 patients in the Asian technique group and 34 patients in the traditional technique group. One participant in each group was lost to follow-up after Day 7, ending up with 35 patients in the Asian group and 33 patients in the traditional group. The analysis was performed as an intention-to-treat analysis. Figure 2 shows the Consolidated Standards of Reporting Trials flow diagram.

3.2. Recruitment

The study participants were recruited between February and May 2016 from King Fahad Hospital in Jeddah city and King Fahd Hospital in Al Madinah city in the western region of Saudi Arabia.

3.3. Baseline data

There was no statistically significant difference between the two groups regarding the sociodemographic characteristics, except for the employment status (Table 1); in addition, there was no statistically significant difference in the baseline readings of the outcome measures before the intervention (Table 2).

3.3.1. Effect of intervention on outcome measures within each group (before and after intervention)

There was a significant decrease in NRS, PPI, and ODQ scores immediately after intervention in both groups compared with those before intervention. This effect was maintained at 7 and 14 days after intervention in both groups ($p = <0.001$). (Table 3).

3.3.2. Comparing the two groups after intervention

There were no statistically significant differences in the outcomes between the Asian and the traditional techniques of wet cupping therapy immediately after intervention, at Day 7, or at Day 14 after the intervention (Tables 3 and 4). The ANCOVA results, with baseline data also as a covariate, did not show any significant difference between the two groups. The group mean difference of the NRS score at Day 7 after intervention between the Asian and the traditional (the primary outcome time point) techniques was −3.881 (confidence interval: 12.19, 4.43).

3.4. Safety

No adverse events were reported in both groups.

4. Discussion

The present study was the first study that aimed to evaluate the feasibility of comparing two different techniques of wet cupping and to evaluate which of the technique is more effective for low back pain. The current

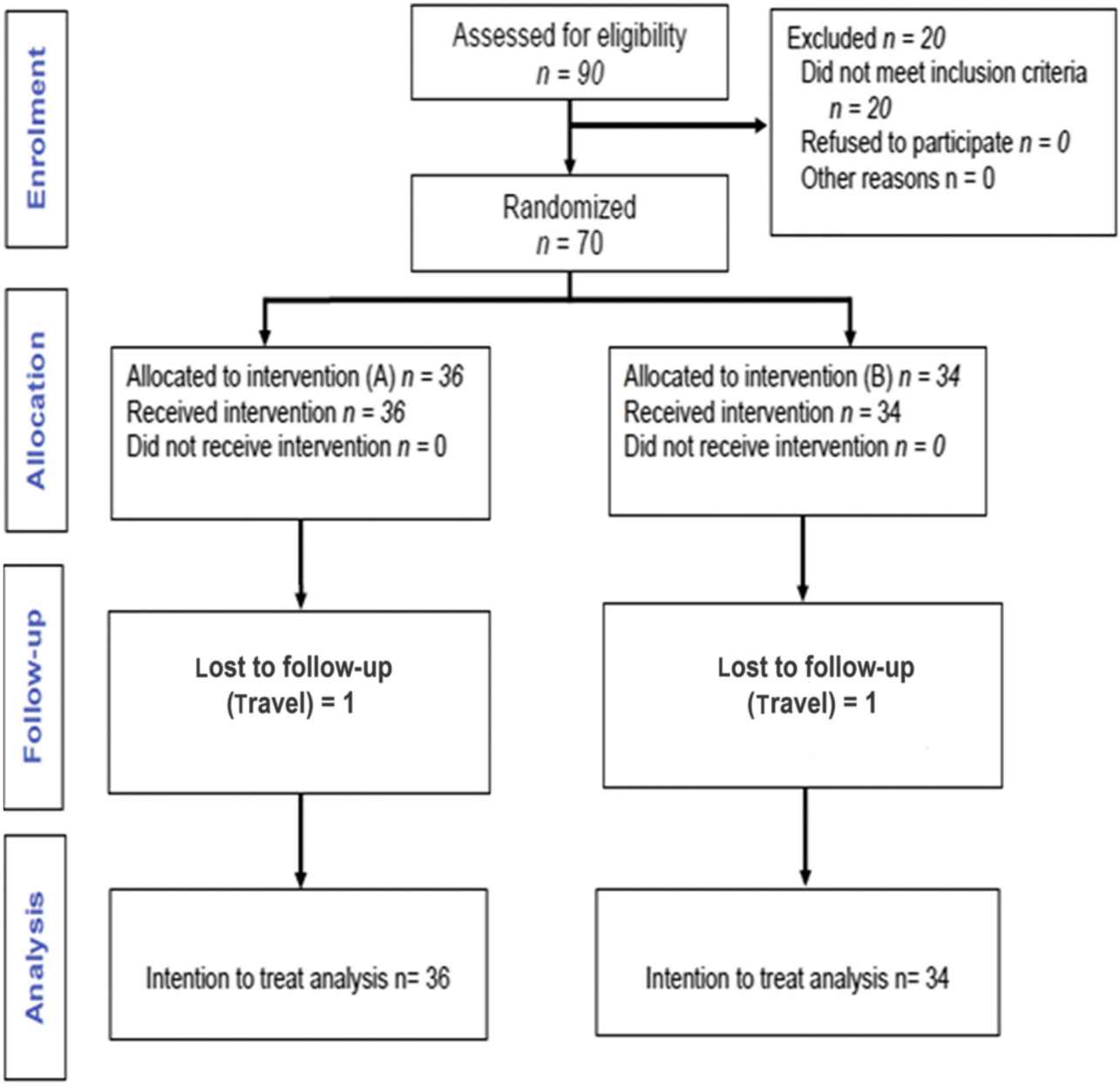

Figure 2 CONSORT flow diagram. CONSORT = Consolidated Standards of Reporting Trials.

randomized comparative clinical trial may help in conducting larger clinical trials and the standardization process for wet cupping therapy especially in Saudi Arabia where traditional wet cupping procedures are mainly used.

In the present study, the two wet cupping (AlHijamah and Asian) therapy technique groups have shown a significant decrease in the NRS, PPI, and ODQ scores immediately after intervention, at Day 7, and at Day 14 after intervention within each group. This effect was also shown in other published studies [22-24]. However, there were no significant differences across all the outcome measures including adverse events between the two groups up to 14 days after the intervention, including patient satisfaction. This means that, until proven otherwise, both techniques can be used for low back pain.

The main reason for such a good recruitment rate and the low dropout might be related to the belief of the general population in the favorable effects of wet cupping (AlHijamah) technique. We planned to recruit 90 participants and ended up with 60 patients, thirty participants in each group allowing for 30% dropout. However, we decided to stop recruitment after we reached 70 participants because of the low dropout rate, the achievement of the target sample in each group, the study time limit, and the pilot nature of the study design.

The community beliefs and strong religious drive of the advantage of this traditional practice are considered to be

Table 1 Sociodemographic data in the two groups.

Characteristics	Asian (n = 36)	Traditional (n = 34)	P-value
Age (y) (mean, SD)	38.08, 8.24	40.62, 8.90	0.22*
Sex M/F (no.)	21/15	18/16	0.65§
Saudi/non-Saudi (no.)	25/11	23/11	0.87§
Married/unmarried (no.)	27/9	31/3	0.07§
Education level			
Uneducated/only read and write (no.)	1	1	0.78§
Primary/intermediate/ high school (no.)	14	16	
University and higher (no.)	21	17	
Employment: working/not working (no.)	30/6	21/13	0.04§
Smoking			
Current smoker (no.)	9	3	0.19§
Former smoker (no.)	4	4	
Never a smoker (no.)	23	27	
LBP history			
Age at the onset of LBP (y) (mean, SD)	35.38, 7.94	36.99, 8.72	0.42*
Duration of LBP (y) (mean, SD)	2.71, 1.77	3.74, 3.52	0.65†
Treatments used for LBP			
Medications used for LBP (no.)	6	7	0.69§
Physiotherapy LBP (no.)	13	14	
Other Tx used for LBP (no.)	11	9	
Medications and physiotherapy (no.)	2	0	
No Tx used for LBP (no.)	4	4	
Need sick leave (yes/no) (no.) (%)	8/28	4/30	0.25§

*1 missing value.
LBP = low back pain; SD = standard deviation; Tx = treatments.
* Independent-samples t test.
† Mann–Whitney U test.
§ Pearson Chi-Square.

Table 2 Baseline outcome values in the double cupping and single cupping groups.

Measures	Asian group (n = 36) (Mean, SD)	Traditional group (n = 34) (Mean, SD)	P-value
Expectations	4.31, 0.71	4.44, 0.75	0.40*
D0, NRS, before	58.19, 23.24	65, 16.56	0.18*
D0, PPI, before	2.75, 1.16	2.79, 1.04	0.82*
D0, ODQ components			
(1) Pain intensity	2.47, 0.94	2.71, 0.87	0.15*
(2) Personal care	1.44, 0.84	1.35, 0.92	0.77*
(3) Lifting	2.36, 1.13	2.62, 1.48	0.48*
(4) Walking	1.53, 0.91	1.50, 1.02	0.58*
(5) Sitting	2.39, 1.08	2.21, 1.15	0.57*
(6) Standing	2.69, 1.06	2.82, 1.11	0.57*
(7) Sleeping	1.50, 1.21	1.68, 1.12	0.47*
(8) Sex life	0.85, 0.72	1.21, 1.11	0.28*
(9) Social life	1.64, 1.13	1.80, 1.04	0.51*
(10) Traveling	1.75, 0.87	1.59, 0.86	0.56*
D0, ODQ score (%)	37.76, 12.90	39.30, 15.10	0.39*

D0 = Day 0; NRS = numeric rating scale; ODQ = Oswestry Disability Questionnaire; PPI = Present Pain Intensity; SD = standard deviation.
* By using the Mann–Whitney U test.

one of the major concerns regarding these types of modalities when trying to investigate them in Saudi Arabian society [24]. The authors avoided the use of "traditional" or "Asian" as the group's labels to not affect the patient's expectations. The traditional wet cupping technique, which uses the blade for scarification, is linked to the local wet cupping practices in the Middle East and other Muslim countries. However, it was interesting to note that when the group allocation was disclosed before the Day 14 visit and the participants knew the technique used for them, no significant differences were still found across all measures including patient satisfaction. The same outcome measures were used in previously published clinical trials to facilitate the comparison with other published studies [22,33-35].

The mean value of the expectations and satisfaction of patients in the Asian technique group regarding the interventions was almost the same as the mean value of the expectations and satisfaction of patients in the traditional group. Patients' expectations from a specific intervention may intervene with the targeted health outcomes. The process of blinding the patients to the assigned interventions is considered to be a crucial factor to avoid any possibility of introducing bias.

In these types of studies that investigate any manual healing practices, blinding continues to be a challenge;

Table 3 Comparing outcome measures after intervention between the groups.

Outcome measures	Asian (n = 36) Mean, SD	Traditional (n = 34) Mean, SD	P-value
D0, NRS, before	58.19, 23.24	65, 16.56	0.18*
D0, NRS, after	10.56, 17.23	12.06, 17.02	0.77*
D7, NRS	13.47, 16.16	17.35, 18.64	0.34*
D14, NRS	12.36, 18.38	15.88, 17.43	0.13*
D0, PPI, before	2.75, 1.16	2.79, 1.04	0.82*
D0, PPI, after	0.33, 0.54	0.44, 0.56	0.37*
D7, PPI	0.81, 0.75	0.88, 0.81	0.74*
D14, PPI	0.58, 0.81	0.82, 0.80	0.13*
D0, ODQ score (%)	37.76, 12.90	39.30, 15.10	0.39*
D7, ODQ score (%)	16.79, 10.93	19.85, 11.94	0.26*
D14, ODQ score (%)	16.57, 12.72	17.91, 13.12	0.48*
D7, satisfaction	4.25, 0.91	4.44, 0.66	0.47*
D14, satisfaction	4.25, 0.94	4.26, 0.62	0.62*

D0 = Day 0; D7 = Day 7; D14 = Day 14; NRS = numeric rating scale; ODQ = Oswestry Disability Questionnaire score; PPI = Present Pain Intensity; SD = standard deviation.
* By using the Mann–Whitney U test.

Table 4 Comparing proportion with minimal clinical improvement difference (MCID) outcome measures after intervention between the groups.

Outcome measures	Asian (n = 36)	Traditional (n = 34)	P-value
D0BC-D7, NRS, MCID (≥15) (no.) (%)	32/36 (89%)	32/34 (94%)	0.67*
D0BC-D7, PPI, MCID (≥30%) (no.) (%)	31/36 (86%)	31/34 (91%)	0.71*
D0BC-D7, ODQ score (%), MCID (≥10%) (no.) (%)	27/36 (75%)	26/34 (77%)	0.89†

Mann—Whitney U test.
D0BC-D7 = the difference between baseline D0 before cupping and D7; MCID = minimal clinical improvement difference; NRS = Numeric Rating Scale; ODQ = Oswestry Disability Questionnaire score; PPI = Present Pain Intensity; SD = standard deviation.
* By using Fisher's exact test.
† By using Pearson Chi-Square.

the authors arrange to blind the participants for the type of wet cupping technique used as the majority do not know the differences. We used the prone position during the wet cupping process, so participants cannot see the instruments or follow the actual steps. In the informed consent, we avoided the use of terms such as "Islamic," "traditional," or "Prophetic" to minimize the association of the present study with the participant's past knowledge and experience. At Day 14 after intervention, outcomes were measured after informing the participants about their assigned group. Still, no difference was found in the outcome measures and satisfaction, and this may reflect the success of blinding. However, the sham device may be the most appropriate method in participant's blindness. Assessors' blinding and concealments were also important in this aspect.

Although we used only one cupping session, the effect of wet cupping in both groups followed the same pattern observed in previous studies [22,23] as sustained effects in all outcome measures were observed in both techniques 14 days after intervention. Further studies including longer follow-up periods may be needed.

The traditional method practiced in Saudi Arabia and the Middle East (cupping, puncturing, followed by cupping) is claimed by local traditional practitioners in Saudi Arabia to give a longer opportunity for the filtration process to achieve better results and better excretory outcomes. In addition, the presence of the suctioning step as the first step may help in protecting the dermal capillaries from being damaged by this intervention. In addition, the superficial scarification/puncturing after initial cupping is considered to give a chance for the suction pressure to help in excretion of the local intercellular fluids and assist in the capillary filtration process. Traditional practitioners believe that when they do not start with the suctioning first, this approach will lead to increase in the possibility of pain compared with the anesthetic effect that resulted from suctioning first [41]. However, this is only a theoretical explanation and cannot be used to favor one technique over the other.

Wet cupping, which includes draining the blood from dermal microcirculation, can lead to draining excess fluids and toxins, loosening adhesions, and lifting connective tissue. This will bring blood flow to stagnant skin and muscles, treating muscle pain and spasms and stimulating the peripheral nervous system [42]. This may explain the effect of cupping in reducing pain and improving functionality.

The findings of this research support the recommendation of considering complementary and alternative medicine practices and specifically wet cupping (AlHijamah) to be integrated into the current health-care systems to enhance any improvements regarding these chronic conditions [25]. Regulating and developing a clinical guideline for complementary therapies is an essential step in this direction.

The sharp decrease in pain or in also reporting no pain after intervention in the present study may be influenced by both specific and nonspecific effects. The use of self-reported outcome measures may be also a contributing factor. Developing more objective outcomes may be necessary in the future, rather than depending on individual feedback from patients.

4.1. Limitations

Although the study protocol was feasible to conduct, a longer follow-up period with multiple sessions should be considered in future study protocols to compare the two cupping techniques. The present study compared both the specific and nonspecific effects of the two techniques. However, no placebo-controlled trial was conducted to ascertain the specific effect of wet cupping on low back pain. The study did not include an inactive control group as the third group, but at the same time, the aim was to compare the two cupping techniques and not to evaluate the effectiveness of cupping on CLBP, which was evaluated in other published trials [22,23].

5. Conclusion

The present study showed the feasibility of recruitment, randomization, intervention implementation, and retentions of the participants. However, blinded assessment procedures and the use of novel outcomes measures are needed. The result of the study supports that of previously published studies [22,23] that wet cupping is effective in reducing pain and improving disability in patients with CLBP. Solid evidence cannot be generated without neutralizing the nonspecific effects of wet cupping especially when we use self-reported outcome measures. Both Asian and traditional Hijamah techniques are apparently equally effective. The study did not show a superiority of one technique compared with the other including safety issues. A larger sample, longer follow-up, multiple cupping sessions, and the inclusion of an inactive control group may be needed to evaluate the differences, if any, between both techniques.

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Availability of data and material

The data set generated and analyzed during the study are available from the corresponding author on reasonable request.

Disclosure statement

The authors declare that there are no conflicts of interest.

Author contributions

S.M.A.-E., A.G.M., A.M.A., and M.K.M.K. conceived the study concept and the trial conduction. R.A.A. supervised the clinical selection of cases and clinical care.

Consent for publication

Not applicable.

Ethics approval and consent to participate

This study was approved by the central Ministry of Health Institutional Review Board (IRB) Committee based in King Fahad Medical City, Riyadh (approval number: (15 — 260E)). The monitoring site visit was conducted by the IRB. The participants signed the informed consent before participation in the study.

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