



## Research Article

# The Effectiveness of AeroFlow Cupping in Patients with Non-Specific Low Back Pain. A Clinical Trial.

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## Abstract

The present clinical trial aimed to compare the clinical results of using an exercise program with those of an exercise program and the AeroFlow cupping in patients with non-specific low back pain. Patients were allocated to two groups by sequential allocation. Pain, functionality, strength, mobility and drop out were measured. An exercise programme and the AeroFlow cupping reduced the pain and improved function and strength in patients with non-specific low back pain at the end of the treatment and at the follow-ups. Future well-designed randomised controlled clinical trials are needed to establish the effectiveness AeroFlow in the management of non-specific low back pain.

**Keywords:** Low back pain; AeroFlow; Cupping

## Introduction

Non-Non-specific low Back Pain (NSLBP) is a common condition in the population. A variety of treatments have been proposed for the management of this condition. These treatments are either medical or physiotherapeutic. The medical ones are either conservative or surgical. Conservative medicine includes either drugs or injections. Physiotherapy includes either physical agents or electrotherapy, such as therapeutic ultrasound, shock waves, phototherapy, analgesic currents, or manual therapy, such as various soft tissue techniques, joint mobilization techniques, and exercise. There is evidence from several randomized clinical trials that an exercise program may be more effective than other interventions [1]. Still, there is no difference in outcomes between

different types of exercise, which advocates the use of a supervised or in-clinic exercise program [1]. Supplementing the exercise protocol with one more intervention may shorten the treatment period. Cupping therapy is usually recommended as a supplement to an exercise program for the management of NSLBP [2]. Cupping is a physical treatment typically used by acupuncturists and other complementary medicine therapists, which uses glass or plastic cups placed on the skin over a painful area or acupuncture point to create negative pressure through suction [3]. The rationale for the use of cupping is not yet fully understood; it is described as a detoxification process by which waste matter and toxins are removed, and as a harmonization process for the imbalance of Qi, a traditional Chinese medicine term for 'vital energy' [4]. Cupping therapy with the AERO FLOW CUPPING device, a new therapeutic approach, can be used by clinicians in the management

of NSLBP. However, no studies found to assess the effectiveness of AERO FLOW CUPPING in the management of NSLBP. Therefore, the present trial aimed to assess the effectiveness of AERO FLOW CUPPING in the management of NSLBP.

## Methods

A controlled, monocentre trial was conducted in a clinical setting over 22 months to assess the effectiveness of a home exercise program and a supervised exercise program. A parallel group design was used because crossover designs are limited in situations where the intervention cures patients and do not have the opportunity to receive the other treatments after crossover [5]. Three investigators were involved in the study: 1. a physiotherapist (PhD student) who administered the treatments (AS); 2. the primary investigator (DS) who had over 20 years of experience in musculoskeletal physiotherapy and who evaluated the patients to confirm the diagnosis; and 3. a PhD physiotherapy student (GK), who performed all baseline and follow-up assessments, and gained informed consent. GK who was blind to the patients' therapy group conducted all assessments. Each patient to ascertain baseline demographic and clinical characteristics, including sex, age of the patient, name, duration of symptoms, affected arm and dominant arm, occupation, and previous treatment interviewed by GK.

Patients over 18 years old who were experiencing LBP were examined and evaluated in a private outpatient physiotherapy clinic located in Athens, Greece, between September 2023 and July 2024. All patients lived in Greece, were native speakers of Greek, and were either self-referred or referred by their physician or physiotherapist. The selection criteria for the study were [2]:

1. Presenting localized and non-specific lower back pain for more than 3 months;
2. Have not used cupping therapy before;
3. Report pain between 3 and 8 by NRS;
4. Individuals who are not under physiotherapeutic treatment during the intervention;
5. Individuals without neurological, vestibular, visual, or auditory deficits that make evaluations impossible

Patients were excluded from the study if they had one or more of the following conditions [2]:

1. Individuals with cutaneous lesions in the region where they will be applied to cupping therapy,
2. Individuals with uncontrolled diabetes and hypertension;
3. Irradiated and sacral lumbar pain;
4. Individuals with contraindications to windsurf therapy

were: cancer, renal failure, hepatic and cardiac insufficiency, pacemaker, and pregnancy;

5. Individuals with severe spinal pathology (including fractures, inflammatory diseases, and tumors;
6. Travel planning in the next 2 months.

All patients received a written explanation of the trial before entry into the study and then gave signed consent to participate. This trial was approved by the Bioethics Committee of West Attica University (27/06/2023- 61410), and access to patients was authorized by the manager of the clinic (AS).

The patients were allocated to two groups by sequential allocation. For example, the first patient with NSLBP was assigned to the exercise program group, the second patient with NSLBP to the exercise program plus AEROFLOW cupping group, and so on. All patients were instructed to use their bodies during the course of the study but to avoid activities that irritated the joints such as jumping, hopping, and running. They were also told to refrain from taking anti-inflammatory drugs throughout the course of the study. Patient compliance with this request was monitored using a treatment diary.

Communication and interaction (verbal and non-verbal) between the therapist and patient were kept to a minimum, and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided. For example, patients did not indicate the potentially beneficial effects of the treatments or any feedback on their performance in the preapplication and post-application measurements [6]. The exercise program was the same for both groups. It consisted of a program of lumbopelvic stabilization exercises and strengthening of the core: awareness of breathing, front and side plate abdominal, glute bridge/hip elevations, lift of the extended leg, pelvic tilt, hamstring stretch, strengthening lower abdominals, cat-camel posture, trunk rotations with flexed knees, rolling in sitting and lumbar extension with hip extension in prone.

The exercise program was given 3 times per week for 4 weeks in the clinic. 3 sets of 12 repetitions in each exercise. 30-60 seconds rest among sets. The program was composed of different exercises with their progressions, divided by complexity levels:

- 1<sup>st</sup> level: Awareness of breathing, pelvic tilt, hamstring stretch, rolling in sitting, trunk rotations with flexed knees.
- 2<sup>nd</sup> level: half plank, half lateral plank, cat-camel posture, two legs glute bridge/hip elevations
- 3<sup>rd</sup> level: Complete plank + lateral plank, one leg glute bridge, lumbar extension with hip extension in prone.

To jump from the first to the second level, the movement was understood and properly executed by the patient under the physiotherapist's supervision in two different sessions (the first session was teaching-learning, and the second one was performed by the patient). The exercises did not increase the pain levels. 2nd to 3rd level: The movement was properly executed by the patient, it did not increase the pain levels and it was able to complete the goal repetitions without effort (perceived effort around 3/10).

The AEROFlow protocol comprised 8 cupping sessions over 4 weeks. The treatment was performed with the AEROFlow device (INDIBA®) using 2 fixed plastic cups located in the low back area (80x60mm) (ACC0829) and two fixed plastic cups on the hamstrings (75x60mm) (ACC0905). Each session consisted of 12 minutes of treatment. Firstly, 4 minutes of a 2-second pulsatile 80mbar negative pressure was applied. Then, 8 minutes of a 2-second 250m bar negative pulsatile pressure.

Treatments were aleatorily assigned using the RedCap platform before the aleatory procedure.

➤ The pain, functionality, strength, mobility, and dropout rate were measured in the present study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 4), 1 month (week 8), 2 months (week 12), and at 3 months (week 16) after the end of treatment.

➤ The principal variable was the Change from the Numeric Rating Scale (NRS) of Pain (2,7). It was used to analyze the quality of life in people with low back pain. This instrument contains 10 items that assess the impact of low back pain on several functional activities. Values range from 0 to 5, with the highest value indicating greater disability. The result is the sum of all items.

➤ The second variable was (2,7).

➤ Pressure pain threshold (PPT). It was measured in each session just before the treatment. Using the finger, the physiotherapist applied pressure over the lower back and the pain scale was measured.

➤ Range of motion of the lower back (ROM). It was evaluated through the finger-to-floor test. This test presents high reliability and can be used for clinical practice and scientific studies.

➤ The health-related quality of life was measured with the SF-36 questionnaire.

➤ Global Perceived Effect Scale (GPE). Is a direct scale of the patient's self-perception when the intervention is performed? The GPE evaluates using 11 points, starting from a negative 5 (much worse than when starting the treatment), a neutral rating of 0, and 5 positives (much improvement from starting the

treatment). The Portuguese version was used. The GPE evaluates using 11 points, starting from a negative 5 (much worse than when starting the treatment), a neutral rating of 0, and 5 positives (much improvement from starting the treatment).

➤ Disability index. It was measured via the Quebec back pain disability scale. The 20-item Quebec Back Pain Disability Scale for Back Pain was created to measure the degree of functional disability in people who have low back pain. The scale is a dependable and valid measurement used to evaluate each patient's improvement during treatment or rehabilitation programs.

Adverse events were measured across the whole study period.

A dropout rate was also used as an indicator of treatment outcome. Reasons for patient dropout were categorized as follows: (1) withdrawal without reason, (2) not returning for follow-up, and (3) request for an alternative treatment.

Descriptive statistics were used to summarize the baseline characteristics of the study population. Continuous variables were expressed as means and standard deviations (SD) or medians and interquartile ranges (IQR), depending on the normality of the distribution. The distribution of all dependent variables was assessed using the Shapiro-Wilk normality test. Baseline differences between the treatment and control groups were evaluated using the independent samples t-test for normally distributed continuous variables and the Mann-Whitney U test for non-normally distributed continuous variables.

A linear mixed-effects model (LMM) was used to examine the effects of treatment over time on the seven outcome variables. The model included fixed effects for time (Baseline, End of Treatment, 1-month, 2-Month, and 3-month Follow-up), treatment group (AeroFlow + Exercise vs. Exercise Only), and their interaction (Time × Treatment). To account for within-subject variability, random intercepts for participants were included. The model was fitted using the restricted maximum likelihood (REML) approach, and statistical significance was assessed at a two-sided  $\alpha = 0.05$  level.

The lme4 package in R (version 4.4.2; R Foundation for Statistical Computing, Vienna, Austria) was used to fit the linear mixed-effects model. Post-hoc comparisons between the treatment and control groups were performed using the means package, with Tukey's Honest Significant Difference (HSD) adjustment for multiple comparisons. Results were reported as estimated marginal means with 95% confidence intervals (CIs).

## Results

### Baseline Characteristics

The baseline characteristics of the study population are summarized

in Table 1. A total of 100 participants were included in the study, with 50 participants in the treatment group (Aeroflow + Exercise) and 50 in the control group (Exercise Only). The median Numeric Rating Scale (NRS) score for pain was 8.0 (IQR: 1.0) in both groups, indicating no significant difference at baseline ( $p = 0.48$ ). Similarly, the median pressure measurements were 8.80 (IQR: 1.0) in the treatment group and 8.0 (IQR: 1.0) in the control group, with no significant difference ( $p = 0.78$ ). The range of motion was also comparable between the two groups, with a median of 25.0 (IQR: 2.0) in both groups ( $p = 0.86$ ). The mean SF-36 score was 45.6 (SD: 2.7) in the treatment group and 46.7 (SD: 2.6) in the control group, showing no significant difference ( $p = 0.73$ ). Other baseline measures, including the time up and go test, disability index, and global perceived effect scale, were also similar between the two groups (all  $p > 0.05$ ). These results indicate that the two groups were comparable at baseline.

Variable	Treatment Aeroflow + Exercise (n=50)	Exercise only (n=50)	p-value
NRS, median (IQR)	8.0 (1.0)	8.0 (1.0)	0.48*
Pressure, median (IQR)	8.80 (1.0)	8.0 (1.0)	0.78*
Range of motion, median (IQR)	25.0 (2.0)	25.0 (2.0)	0.86*
SF-36, mean (SD)	45.6 (2.7)	46.7 (2.6)	0.73+
Time up and go test, mean (SD)	17.7 (2.5)	16.7 (2.5)	0.06+
Disability index, median (IQR)	84.00 (5.0)	83.5 (4.0)	0.26*
Global perceived effect scale, median (IQR)	-3.0 (1.0)	-3.0 (1.0)	0.79*
+ Independent sample t-test; * Mann-Whitney U test			

**Table 1:** Baseline measurements of the treatment and control groups (n=100)<sup>§</sup>.

## Treatment Outcomes

A linear mixed-effects model (LMM) was used to analyze the effects of the treatment over time, adjusting for within-subject variability. The estimated marginal means and corresponding 95% confidence intervals (CIs) for each outcome variable at different time points are presented in Table 2 and Figure 1.

Outcome variable	Mean (SD) for each group		p-value <sup>+</sup>	Estimated Mean Difference Between Groups <sup>†</sup> (95% CI)	p-value
	Aeroflow +Exercise	Exercise only			
NRS					
End of treatment	2.9 (0.91)	4.2(0.83)	<0.01	-1.24 (-1.75, -0.73)	<0.01
1 month follow up	2.8 (0.81)	3.9 (0.81)	<0.01	-1.10 (-1.61, -0.59)	<0.01
2 months follow up	2.6 (0.78)	3.8 (0.74)	<0.01	-1.18 (-1.70, -0.67)	<0.01
3 months follow up	2.4 (0.83)	3.6 (0.83)	<0.01	-1.22 (-1.73, -0.71)	<0.01
Pressure					
End of treatment	2.6 (0.76)	4.2 (0.92)	<0.01	-1.68 (-2.19, -1.17)	<0.01
1 month follow up	2.4 (0.67)	4.0 (0.85)	<0.01	-1.64 (-2.15, -1.13)	<0.01
2 months follow up	2.2 (0.76)	3.8 (0.81)	<0.01	-1.64 (-2.15, -1.13)	<0.01
3 months follow up	2.1 (0.83)	3.6 (0.73)	<0.01	-1.54 (-2.05, -1.03)	<0.01
Range of motion					
End of treatment	14.6 (2.76)	17.6 (2.06)	<0.01	-3.04 (-4.39, 1.69)	<0.01
1 month follow up	14.6 (2.23)	17.3 (1.86)	<0.01	-2.70 (-4.05, -1.35)	<0.01
2 months follow up	14.4 (2.18)	17.0 (1.68)	<0.01	-2.60 (-3.95, -1.25)	<0.01

3 months follow up	14.3 (2.08)	17.0 (1.71)	<0.01	-2.72 (-4.07, -1.37)	<0.01
SF-36					
End of treatment	85.8 (3.44)	77.7 (3.89)	<0.01	8.06 (5.87, 10.25)	<0.01
1 month follow up	85.9 (3.29)	78.0 (3.79)	<0.01	7.90 (5.71, 10.09)	<0.01
2 months follow up	86.0 (3.19)	78.1 (3.94)	<0.01	7.88 (5.68, 10.07)	<0.01
3 months follow up	86.2 (3.25)	78.3 (3.69)	<0.01	7.90 (5.70, 10.09)	<0.01
Time up and go test					
End of treatment	9.6 (1.89)	11.1 (2.01)	<0.01	-1.50 (-2.73, -0.27)	<0.01
1 month follow up	9.4 (1.70)	10.9 (1.87)	<0.01	-1.44 (-2.67, -0.21)	<0.01
2 months follow up	9.2 (1.51)	10.6 (1.74)	<0.01	-1.38 (-2.61, -0.15)	0.02
3 months follow up	9.1 (1.45)	10.5 (1.68)	<0.01	-1.48 (-2.71, -0.25)	<0.01
Disability index					
End of treatment	36.0 (6.43)	42.8 (4.96)	<0.01	-6.88 (-10.08, -3.68)	<0.01
1 month follow up	33.0 (6.31)	42.2 (4.47)	<0.01	-9.12 (-12.32, -5.92)	<0.01
2 months follow up	32.4 (5.84)	41.1 (4.30)	<0.01	-8.74 (-11.94, -5.53)	<0.01
3 months follow up	31.5 (5.21)	40.4 (4.47)	<0.01	-8.90 (-12.10, -5.70)	<0.01
Global perceived effect scale					
End of treatment	2.8 (0.72)	2.6 (0.64)	0.3	0.14 (-0.37, 0.65)	0.99
1 month follow up	2.9 (0.63)	2.7 (0.60)	0.26	0.14 (-0.37, 0.65)	0.99
2 months follow up	2.9 (0.63)	2.9 (0.70)	0.65	0.06 (-0.45, 0.57)	1
3 months follow up	3.0 (0.64)	2.9 (0.74)	0.66	0.06 (-0.45, 0.57)	1
<sup>+</sup> Independent samples t-test <sup>†</sup> 95% Confidence Interval (CI) computed based on the estimated marginal means (EMMs) and their standard errors from the linear mixed effect model <sup>*</sup> Tukey-Adjusted p-values for multiple comparison					

**Table 2:** Results of analysis comparing outcomes between treatment and control groups§.

**Pain (NRS):** At the end of treatment, the NRS scores were significantly lower in the Aeroflow + Exercise group compared to the Exercise Only group (mean difference = -1.24, 95% CI: -1.75 to -0.73,  $p < 0.01$ ). This difference remained statistically significant at 1-month (-1.10, 95% CI: -1.61 to -0.59,  $p < 0.01$ ), 2-month (-1.18, 95% CI: -1.70 to -0.67,  $p < 0.01$ ), and 3-month follow-up (-1.22, 95% CI: -1.73 to -0.71,  $p < 0.01$ ), suggesting sustained pain reduction in the treatment group.

**Pressure:** The Aeroflow + Exercise group also demonstrated a significant reduction in pressure measurements compared to the Exercise Only group at all time points ( $p < 0.01$ ). The mean differences ranged from -1.68 (95% CI: -2.19 to -1.17) at the end of treatment to -1.54 (95% CI: -2.05 to -1.03) at 3-month follow-up.

**Range of Motion:** The Aeroflow + Exercise group showed a significant improvement in the range of motion compared to the Exercise Only group. At the end of treatment, the mean range of motion was 14.6 (SD: 2.76) in the Aeroflow + Exercise versus 17.6 (SD: 2.06) in the Exercise Only group, with a mean difference of -3.04 (95% CI: -4.39, -1.69;  $p < 0.01$ ). This improvement was maintained at all follow-up time points (all  $p < 0.01$ ).

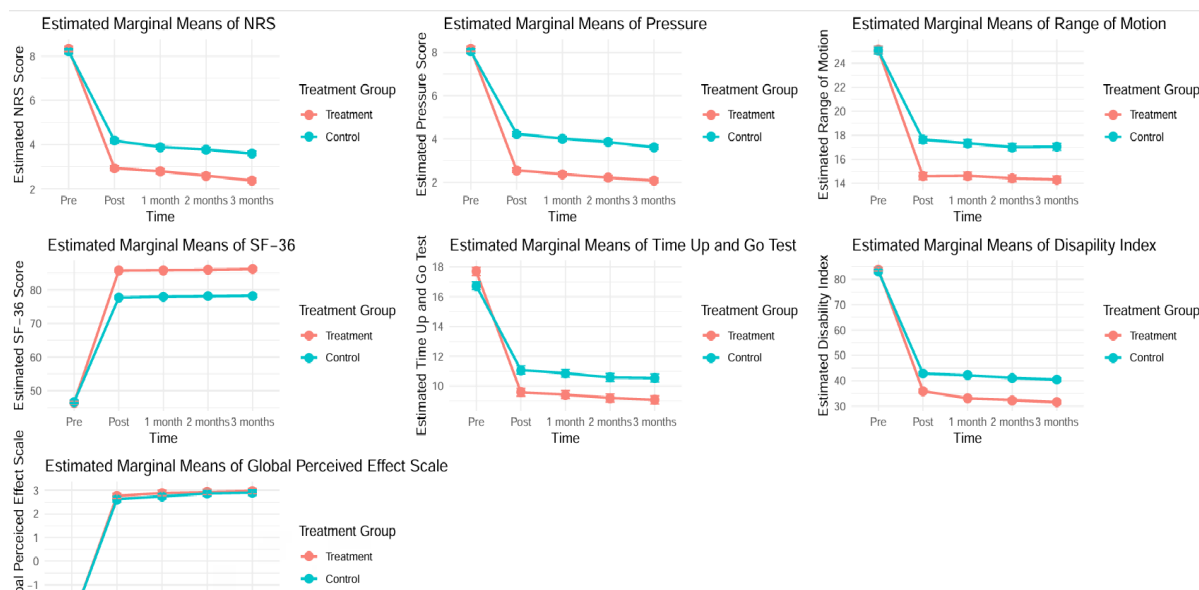
**SF-36:** The Aeroflow + Exercise group reported significantly higher SF-36 scores, indicating better quality of life, compared to the Exercise-only group. At the end of treatment, the mean SF-36 score was 85.8 (SD: 3.44) in the Aeroflow + Exercise group versus 77.7 (SD: 3.89) in the Exercise Only group, with a mean difference of 8.06 (95%CI: 5.87, 10.25;  $p < 0.01$ ). This difference remained significant at all follow-up time points (all  $p < 0.01$ ).



**Time Up and Go Test:** The Aeroflow + Exercise group performed significantly better on the time up and go test compared to the Exercise Only group. At the end of treatment, the mean time was 9.6 seconds (SD: 1.89) in the Aeroflow + Exercise group versus 11.1 seconds (SD: 2.01) in the Exercise Only group, with a mean difference of -1.50 (95% CI: -2.73, -0.27;  $p < 0.01$ ). This improvement was consistent at all follow-up time points (all  $p < 0.01$ , except for the 2-month follow-up where  $p = 0.02$ ).

**Disability Index:** The disability index was significantly lower in the Aeroflow + Exercise group across all time points ( $p < 0.01$ ). The mean difference at the end of treatment was -6.88 (95% CI: -10.08 to -3.68), increasing to -8.90 (95% CI: -12.10 to -5.70) at 3-month follow-up.

**Global Perceived Effect Scale:** There were no significant differences between the two groups on the global perceived effect scale at any time point (all  $p > 0.05$ ).



**Figure 1: Outcome Measures Results.**

## Discussion

The results obtained from this controlled clinical trial are novel. To date, no data have been comparing the effectiveness of an exercise program with Aeroflow cupping and an exercise program alone for the management of symptoms in patients with NSLBP.

The Aeroflow cupping with Exercise group demonstrated significantly improved pain, pressure, range of motion, quality of life, physical function, and disability index compared to the control group (Exercise Only) at all time points. The global perceived effect scale did not show any significant differences between the two groups. These results suggest that the addition of Aeroflow to the exercise regimen provides significant benefits over exercise alone in the management of the studied condition.

Two types of exercise programs exist: exercise programs carried out in a clinical setting and home exercise programs. A home exercise program is commonly advocated for subjects with NSLBP because

it can be carried out at any time during the day without requiring supervision by a clinician [1]. Our clinical experience, however, has shown that patients fail to comply with the regimen of home exercise programs [8]. This problem can be solved by exercise programs performed in a clinical setting under the supervision of a physiotherapist. For this report, “supervised exercise program” will refer to such programs. Therefore, such a supervised exercise program was used in the present trial.

Although a supervised exercise program is an effective treatment approach for NSLBP, a supplement to the exercise program should be found to reduce the treatment period. One such modality is the cupping.

Cupping therapy is an ancient technique used by such civilizations as the Chinese, Egyptians, Greeks, and Arabians [9]. Different cultures have been using traditionally different materials for the cups, like glass, bamboo, or cups made from the horns of different animals [3]. Dry cupping is a technique in which cups are applied

to the skin to create a vacuum for suction without drawing blood, whereas in wet cupping, blood is drawn with scarification before applying the cups for blood-letting [3]. Traditionally, this vacuum has been generated in different ways, such as by lighting a cotton inside the cups or by extreme heating them before application [3].

Cupping therapy is a promising, potentially effective, and safe therapy method for the treatment of NSLBP in adults [9]. However, the notable heterogeneity among studies raises concerns about the certainty of these findings [2,7]. Moreover, there is the need to establish standardized application protocols for this intervention, for example, cupping technique, sessions, minutes of treatments, suction strength, pumping, and day intervals between applications [2,7]. In addition, the effect on pain reduction has not yet been fully elucidated [2,7], but different mechanisms of action, based on several assumptions [10], are attributed to cupping therapy, such as the metabolic, neuronal hypotheses [11] and Traditional Chinese Medicine [12]. The actual therapeutic effects of cupping could be confirmed by using objective pain assessments [2,7]. Studies with at least six- to twelve-month follow-ups are needed to investigate the long-term efficacy of cupping in managing LBP [2,7].

Cupping therapy with the AERO FLOW CUPPING device, a new therapeutic approach, can be used by clinicians in the management of NSLBP. AERO Flow is a non-invasive device that uses negative pressure through a vacuum system using different cups that adapt to different areas of the body. It consists of 5 outlets, one of which works in dynamic mode with glass cups, while the other 4 outlets work in static mode with plastic cups. There are different cup sizes, with the choice depending on the size of the application area. With the AERO Flow this vacuum is generated through an electric suction pump.

The mechanism of action of negative pressure through vacuum using cups is not clear, according to current scientific literature [2,3,7,9]. Hypothesis on the mechanism of action is:

- ☐ Local vascular activation, generating an improvement of tropism.
- ☐ Local drainage, producing toxin elimination.
- ☐ Superficial and/or deep fascial release (depending on the technique applied).

Cupping is a vacuum technique, also known as suction or negative pressure, which the World Health Organization Standard Terminologies on Traditional Medicine in the Western Pacific Region (2007) defines as a therapeutic method involving the application of suction by placing a vacuumized, usually by fire, cup or jar onto the affected or any part of the body surface. The latter is the traditional way of application, more mother ways create the sub atmospheric pressure by suction, that is using a pump, that can

be either mechanical pump by hand or electrically controlled. The difference among these three different types of application is the sub atmospheric pressure control which cannot precisely be done by other means than by electric control. The possibility to control the pressure inside the sucking cups allows for a more efficient and safer treatment. AERO is based on the classic cupping method to be applied utilizing an electrical vacuum pressure control system, so the vacuumed massage produced by each cup is under a controlled pressure differently from the classical procedure where strict control of the suction power is not possible (it creates an air deficit in a glass cup with an open flame or hand pumping) so that the efficacy and safety of its application are enhanced.

Since pain relief and improvements in function and strength were noted in the present study in the long term, it is proposed that AeroFlow cupping may potentially have promoted an important effect in the management of soft tissues. However, to understand the potential changes to the tissues in response to AeroFlow cupping treatment, future studies should consider employing outcome assessments that are capable of monitoring the changes in deeper tissues.

The present trial was the first trial to examine the effectiveness of AeroFlow cupping on NSLBP. Previous studies assessed the effectiveness of cupping in the management of NSLBP [2,7]. A future study to compare AeroFlow cupping with classical cupping in the management of NSLBP is needed.

A course of AeroFlow cupping treatment was applied in the present study based on manufacturers' claims. It is a dose-response modality and the optimal treatment dose has obviously not yet been discovered. Future studies are needed to standardize AeroFlow cupping parameters in the management of NSLBP.

However, this trial does have some shortcomings. First, no treatment group or no sham (placebo) was included in the present study. The no-treatment/sham (placebo) group is important when the absolute effectiveness of a treatment is assessed. However, the absolute effectiveness of method-based interventions is difficult to find out because a trustworthy and good no treatment/sham (placebo) control for many physiotherapy methods appears to be impossible or difficult to devise, due in part to difficulties in defining the active element of these methods. Absolute effectiveness also does not provide clinicians with information as to which is the most appropriate method for the treatment of a condition, in this case, NSLBP. Second, other activities and treatments patients might be getting when not in the clinic were not monitored. Subjects' diaries suggested that subjects were compliant with the trial orders, although subjects may have given incorrect answers to please the researchers. For example, it was possible that subjects followed the treatment but received painkiller drugs at the same time, and the improvement of symptoms may be due to those

drugs. Therefore, ways should be discovered to measure how other treatments such as painkiller drugs contribute to the improvement of symptoms. Finally, the blinding of subjects and clinicians would be problematic in that trial, if not impossible, because subjects know if they are receiving the exercise program treatment and clinicians need to be aware of the treatment to administer it correctly. More research is required to determine the possible mechanism of action of this modality, and the cost-effectiveness of such a technique, because reduced cost is an important factor for the recommendation of any given technique.

## Conclusion

This trial showed that the Aero flow cupping and an exercise program had reduced pain and improved function and strength in patients with NSLBP at the end of the treatment and the follow-ups. However, further well-designed randomized controlled clinical trials are required to determine the effectiveness and the mechanism of action of Aeroflow cupping in NSLBP. In addition, a cost-effectiveness analysis should be incorporated into the analysis of the effectiveness of Aeroflow cupping in a future study, because reduced costs are important issues for the recommendation of a technique.

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