Innovations

Effectiveness of Cupping Therapy Over Stretching on Hamstring Flexibility - A Study Protocol for RCT

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Abstract:

Background: *Traditional forms of therapy include cupping with wet and dry cupping as the two distinct forms of it. In wet cupping, tiny incisions or skin scarring are made with a lancet or knife and then strong suction is applied for five to seven minutes whereas in dry cupping, cups are placed on the skin and negative pressure is applied using a human pump, an automatic pump, or a fire technique. Various studies have demonstrated the effectiveness of cupping in treating a variety of illnesses. Cupping therapy has reported to improve the skin's blood flow alongwith changes in the skin's biomechanical characteristics, elevates the pain threshold, improves anaerobic metabolism locally, reduces inflammation, and other changes. Many methods are used to improve the flexibility of the hamstring muscles. To enhance or develop hamstring flexibility, various techniques are employed, including stretching, proprioceptive neuromuscular facilitation stretching, muscle energy technique, dry cupping etc. Very few studies have shown the efficacy of dry cupping in improving hamstring flexibility, thus this study needed to be carried out*

Keywords: *Cupping therapy, Dry cupping, wet cupping, hamstring, flexibility, stretching*

Methodology: Participants from different constituent colleges of Sumandeep Vidyapeeth and Dhiraj Hospital will be screened as per the routine musculoskeletal assessment. Participants willing to participate and meet the inclusion criteria will be included by asking them to fill informed consent form. Participants will be randomly allocated to either to the Interventional group (Dry cupping) or the control group (Passive stretching) with the use of simple randomization. The subjects will be treated as per the treatment protocol devised.

Outcome Measures:

Primary Outcome: Active Knee Extension Test (AKET)
Secondary Outcome: Lower Extremity Functional Scale (LEFS)
Statistical Analysis

Descriptive statistics using the latest version of SPSS software will be done by taking help of a Biostatistician.

Conclusion:

This study protocol presents a RCT which will show the efficacy of dry cupping to improve hamstring flexibility in subjects having hamstring tightness, the results of which will provide important information.

Clinical Trial Registration:

The study is registered with Clinical Trials Registry- India (CTRI), with the registration number for the trial being CTRI/2023/12/060621.

Traditional forms of therapy include cupping. This therapy has to be revitalized in the present because of its lengthy history. In the Far East, Eastern Europe, and the Middle East, both dry and wet cupping are commonly utilized [1].Wet and dry cupping are the two distinct forms of therapeutic therapies. In wet cupping, tiny incisions or skin scarring are caused with a lancet or knife, strong suction is applied for five to seven minutes, and cups are placed over the area. In dry cupping, cups are placed on the skin and negative pressure is applied using a human pump, an automatic pump, or a fire technique. To extract blood from the wounds, this procedure gets repeated [2].

Numerous studies have demonstrated the effectiveness of cupping in treating a variety of illnesses, including headaches, abscess evacuation, narcolepsy, musculoskeletal disorders of the back and extremities, pharyngitis, herpes zoster, stroke rehabilitation, hypertension, and lung disorders [1, 3]. The therapy should not be used in individuals with cancer, blood thinners or bleeding disorders, elderly patients, pregnant or menstruating women, broken or damaged bones, over critical nerve and artery locations, or deep vein thrombosis [2].

Reports state that cupping therapy improves the skin's blood flow, changes the skin's biomechanical characteristics, elevates the pain threshold, improves anaerobic metabolism locally, reduces inflammation, and modulates cellular immune function. The main mechanisms of action proposed were the

enhancement of immunity, the increase of peripheral blood circulation, and the suction effects of sub-atmospheric pressure [2].

The hamstring group is made up of four muscles. These are the thigh's posterior compartment muscles. This muscle group allows a person to run, walk, and jump since it serves as the hip extensor and the knee flexor [3]. Sedentary lifestyles, poor posture, age, and immobility are the main causes of tight hamstring muscles [4]. Most jobs need long stretches of sitting, and learning environments may also restrict the range of motion of soft tissues, especially the muscles in two joints [5].

Reduced muscle deformation leads to a restricted range of motion at the affected joint, which is the main cause of muscular tightness. Numerous factors, such as a genetic predisposition, muscle injury, and adaptive shortening brought on by a chronic illness, can result in hamstring tightness [5]. Tightness in the hamstring muscle complex (HMC) has been linked to a number of issues, including plantar fasciitis, lumbar spine curvature loss, sacroiliac joint disorders, and muscle strains. Incorrect body alignment and an uneven force distribution between the muscles and joints are the main causes of these issues [6].

Many methods are used to improve the flexibility of the hamstring muscles. To enhance or develop hamstring flexibility, various techniques are employed, including stretching, proprioceptive neuromuscular facilitation stretching, muscle energy technique, myofascial techniques, active release techniques, and Mulligan's fixed leg lift technique. Certain muscle groups have also been treated with cupping treatment to increase their flexibility [7].

There are numerous researches that have looked at how wet cupping therapy affects pain, range of motion, and muscle activity, but there are very few articles which show the effect of dry cupping therapy on hamstring flexibility. Therefore, the goal of this study is to determine how dry cupping therapy affects the flexibility of the hamstring muscles.

Objectives of the study are to:

- To measure hamstring muscle length using active knee extension test before and after dry cupping therapy.
- To measure hamstring muscle length using active knee extension test before and after manual passive stretching.
- To evaluate subject's ability to perform everyday tasks using lower extremity functional scale (LEFS).

Ethical Approval:

All the procedures that will be involved in this trial had been taken approval from the Sumandeep Vidyapeeth Institutional Ethics Committee. The approval received from the Sumandeep Vidyapeeth Institutional Ethics Committee had the outward number, SVIEC/ON/Phys/BNMPT22/Oct/23/25 dated on 31/10/2023.

Clinical Trial Registration:

Registration with Clinical Trials Registry- India (CTRI) has been done with CTRI/2023/12/060621 as being the registration number for this study trial.

Sample size calculation:

For calculating the sample size the below formula had been used:

$n=4Pq/L^2$

n= sample size = 40

P= expected proportion = 82%

L= allowable error = 15%

Q= prevalence of negative character = 100-P = 18

$N= 4(82)(18) /(12.3)^2$

Thus the final sample size is 40 and per group sample sizes are 20.

Inclusion Criteria

- Individuals of age group 18-30 years with hamstring tightness
- Both male and female
- Subjects willing to participate
- Subjects able to read, write and understand English

Exclusion Criteria

- Any previous hamstring injuries
- Any recent hip, knee, ankle and spine surgery
- Any Neuromuscular or musculoskeletal conditions which restricts participation of subject in the study
- Any history of vascular conditions like peripheral arterial disease and venous disease
- Subjects with history of bleeding disorders and skin disorders

Method:

Participants from different constituent college of Sumandeep Vidyapeeth and also Dhiraj hospital, Sumandeep Vidyapeeth will be approached and explained about the study. All participants will be screened as per the routine musculoskeletal

assessment. Participants who meet the inclusion criteria and who are willing to participate in the study will be requested to fill the informed consent form. Participant information sheet which describes in detail about patient participation during the study will be given to the participants. Participants will be randomly allocated to either to the Interventional group or the control group with the use of simple randomization like the lottery method. On completion of the assessment the subjects in Intervention Group will receive Dry cupping where as the control group will receive passive stretching manoeuvre. Subjects in both the groups (Interventional group and control group) will receive 2 days treatment (on 1st day and 4th day) in a week. Details of the treatment are given in table 1. All the outcome measures will be taken as per Table 1.

Randomization:

This study is a single blinded randomized controlled trial, where the subjects will not be able to know in which group they are going to get allotted. The allocator and the assessor are not blinded during the study as they are aware about the study groups i.e. the Intervention group and the control group in which the subjects are going to be distributed and are also aware regarding the intervention the subjects are going to undergo.

In this study, subjects will be divided randomly using simple randomization technique i.e. the lottery method in which half chits will be marked with number 1 representing Interventional group and half chits will be marked with number 2 representing the Control group on it which will be picked by the allocator for group allotment of patients. Total number of chits in this trial represents the total sample size of the subjects with Hamstring tightness.

Fig 1: Flowchart summarising the overall trial design

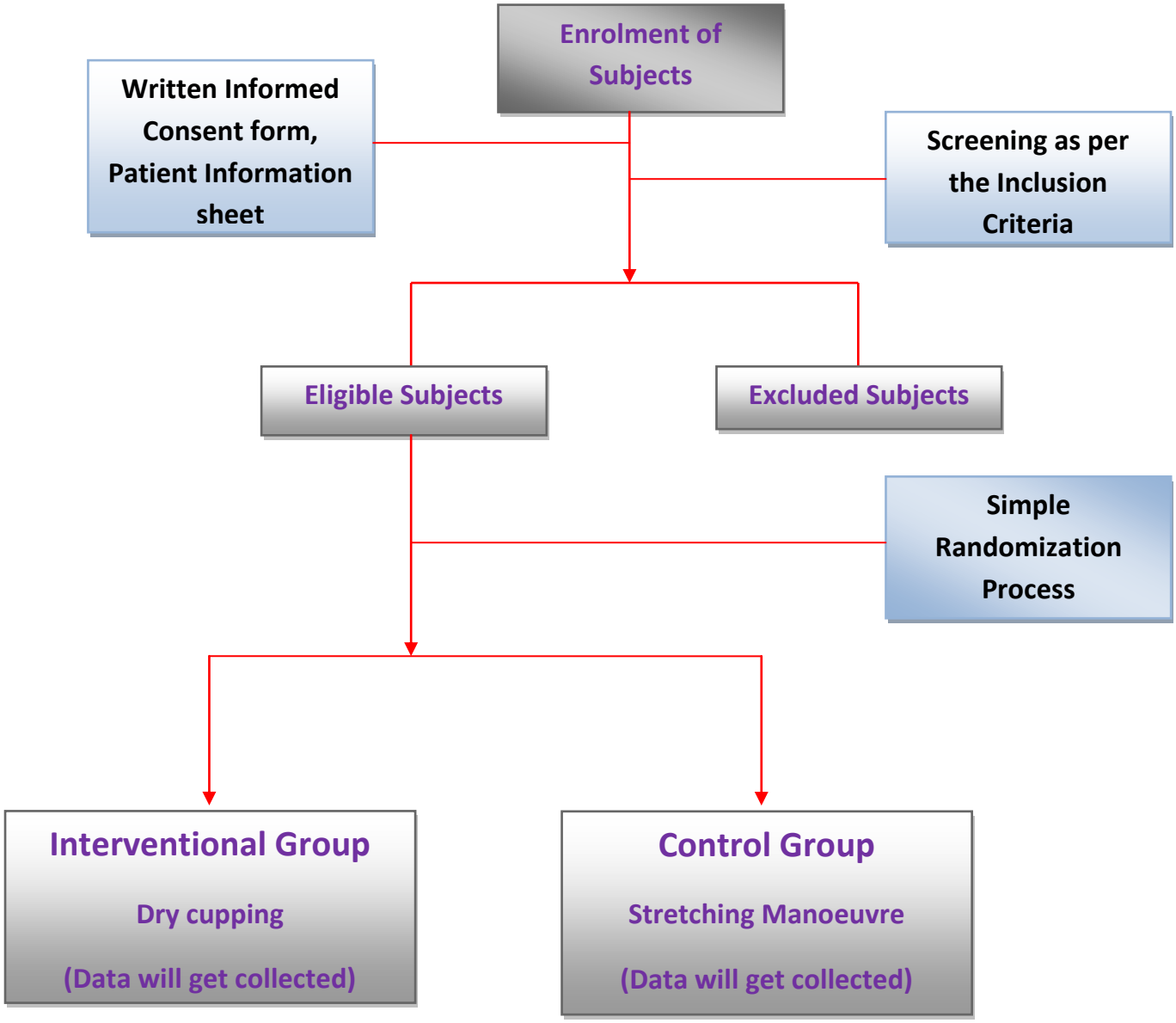

Table 1: The schedule of enrolment, interventions and assessments in accordance with the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT)

	Time Point	Study Period							
		Enrolment & Allocation	Day 1 Pre Rx	Day 1 Rx	Day 1 Post Rx	Day 4 Pre Rx	Day 4 Rx	Day 4 Post Rx	Day 7 Post Rx
Enrolment	Eligibility Screen	×							
	Informed Consent	×							
	Patient Information Sheet	×							
Intervention	Application of Dry Cupping			×			×		
	Application of Stretching Manoeuvre			×			×		
Assessments	Baseline	×							
	Active Knee Extension test		×		×			×	×
	Lower Extremity Functional Scale (LEFS)		×						×

(where, Rx represents Treatment)

Group-1 (Interventional Group):

Cupping Therapy application:

- The therapy can be applied using human pump, an automatic pump or fire technique [2]. The centrally focused negative pressure causes distraction of the skin and underlying tissue inside the cup as well as compression of the skin when the cup is applied. Three cups will be placed along the hamstrings with the participant in prone position. Three cups will be applied: one at the insertion of the biceps femoris (posterior lateral aspect of the knee), one in between the two in the middle of the muscle belly, and one near the ischial tuberosity below the gluteal fold. To make the skin more comfortable, lubrication gel will be administered to the back of the thigh. For a total of 10 minutes, the cups will be placed. The cup's negative pressure force will be changed as necessary to ensure comfort during the entire procedure [8].

- **Group -2 (Control Group):**
  Passive Stretching application
  - During the stretch, subjects will remain in a supine position with flat backs. The leg will be passively elevated till there is "slight discomfort" in the hamstring, held for 30 seconds, then slowly brought back; this process will be carried out five times. This procedure will be repeated twice a week, once a day with 30 sec hold and 10 sec interval between stretches [9].

Similar to the Intervention group, treatment were given for the Control group on day 1 and day 4. Measurement of the AKET as an outcome measures was done before treatment, immediately after the treatment on day 1, and at the end of 1 week to examine the time course of the treatment effects. Here the Lower extremity functional score as a secondary outcome measure which is taken pre intervention on day 1 and during assessment on day 7.

Outcome measures

Primary Outcome:

Active Knee Extension Test (AKET)

The patient will be examined while lying supine on the exam table during the active knee extension test. Patient will be told to maintain vertical position of thigh. Using a universal goniometer, the 90-degree angle will be confirmed. In order to maintain the vertical posture of the thigh, a plastic stick will be placed on the anterior surface of the thigh. In case it is necessary, the rater's hand will stabilize the contralateral limb while it is extended. The participant's knee will be asked to be extended as far as it can go, and the maximum knee extension angle will be measured with the use of a universal goniometer [10].

Secondary Outcome:

Lower Extremity Functional Scale (LEFS)

LEFS is a questionnaire, which consists of 20 questions related to a person's ability to perform everyday tasks. It can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. The maximum score is 80. The test-retest reliability is 0.94. It will be taken before the 1st session and after the last session [11].

Data Management:

A master chart file will be generated in Microsoft excel sheet, the data collected from the assessment of the outcome measures along with the baseline assessment of the subjects will be entered on daily basis for the number of subjects included for that particular day. Once the data collection will be completed, the fully filled

master chart created in Microsoft excel sheet will be sent to the Biostatistician for the statistical analysis process.

Table 2: shows the treatment received by the subjects in the Interventional group and the Control group

Group	Treatment on Day 1	Sets/ Repetition (Reps) /Time	Treatment on Day 4	Sets/ Repetition (Reps) /Time
Interventional Group (Cupping Therapy application)	3 Cups applied along the length of Hamstring muscle	Post application 10 mins	3 Cups applied along the length of Hamstring muscle	Post application 10 mins
Control Group (Passive Stretching application)	Hamstring muscle stretching	1 set of 5 repetition with 30 seconds hold with 10 seconds rest interval	Hamstring muscle stretching	1 set of 5 repetition with 30 seconds hold with 10 seconds rest interval

Statistical Analysis

Descriptive statistics using the latest version of IBM SPSS for windows statistical software will be done by taking help of a Biostatistician. Statistical analysis using a paired and unpaired t test will be used to see the difference in the means of the same group and in between two groups respectively. The quantitative analysis of the primary and the secondary outcomes will also be done. For all statistical analyses, probability levels of $p < 0.05$ will be considered as statistically significant.

Discussion

The number of studies of research evaluating dry cupping is still under development. One of the studies done by Khan T et al. has shown that there is improvement in the passive length of the hamstring muscle. As the hamstring muscle is remaining relaxed and not working the effect may be transferred to the ligaments and other popliteal structures [9].

One of the systematic review showed that Patients with non-specific low back discomfort and chronic neck pain have experienced relief with dry cupping. However, the low-moderate quality of the data precluded drawing firm conclusions on the safety and efficacy of dry cupping for musculoskeletal discomfort and range of motion [8]. We strongly believe that this study will contribute with vital information required related to dry cupping. If the results of the study demonstrate significant favourable results for range of motion, the study will add to the pool of evidence the effectiveness of dry cupping therapy on the hamstring muscle flexibility.

Conclusion:

This study protocol presents a RCT which will show the efficacy of dry cupping to improve hamstring flexibility in subjects having hamstring tightness. The results of this RCT will be helpful by contributing further evidence to see the effects of dry cupping in improving the flexibility of the muscles.

Conflicts of Interest

The authors hereby state that we have no potential conflicts of interest to declare.

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