



# A RANDOMIZED CLINICAL TRIAL ON THE EFFECTIVENESS OF MODIFIED BUERGER- ALLEN EXERCISES IN REDUCING LOWER EXTREMITY OEDEMA DURING LATE PREGNANCY

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## I. INTRODUCTION

One of the most significant phases of a woman's life is pregnancy. While most women see this as a wonderful time, there are physiological and psychological changes that seem to make it a difficult time as well [1]. It may be the cause of several alterations in the body system, some of which may take several weeks to reverse [2]. The lower body organs are impacted by some of these alterations [3]. Oedema, which affects 80% of pregnant women, is not thought to be a sign of preeclampsia or pregnancy-induced hypertension [4].

According to Varney, significant fluid builds up in tissues without proteinuria or hypertension is known as gestational oedema [4, 5]. In late pregnancy, 35–80% of normal pregnancies result in lower limb oedema [6]. According to a 2015 study done in India, 67% of pregnant women had this type of swelling, compared to 49% in the legs, 33% in the sacral area, and 14% [7] in both places. An investigation carried out in Turkey found that 80% of people had physiological leg edoema [6]. This prevalence ranged from 26 to 62.2% in another Iranian study [8, 9].

The most serious consequence of physiologic oedema during pregnancy may not be the condition itself, but rather the pain that goes along with it. Other symptoms of edoema include severe paresthesia, cramping at night, numbness (weakness), paleness, discomfort, and a change in the form of the limb [10]. Disorders related to sleep can have their roots in physiological oedema of the feet. Six hours or less of sleep per night has been linked to longer labour times and a higher rate of instrumental deliveries [11]. It would appear necessary to evaluate and treat such an issue. Both the venous blood circulation system and the extravascular space's interstitial fluids are stimulated by buerger-Allen activities. Combining the two mechanisms i.e 1. fluid flow within the extravascular space and 2. fluid migration from the extravascular space to the venous system will enable this. There are no health effects from it [12].

Furthermore, the majority of third-trimester pregnant women find it difficult to sleep on their backs for extended periods of time. It may cause the great vein below to become compressed, impede blood return to the heart, and restrict blood flow to the developing foetus [13]. Sleeping on one's back during the third trimester of pregnancy has been linked to an increased risk of both IUGR and stillbirth, according to studies [14, 15]. The goal of the modified Buerger-Allen exercises we present in this study is to transfer the pressure of the foetus from the collapsed inferior vena cava to the left aorta, which is resistant to compression, by tilting the pregnant woman's body to the left (the left lateral tilt (LLT) position replaced the supine position). Additionally, this may quicken blood flow [13].

The current study sought to ascertain the impact of modified Berger-Allen exercises on the physiological peripheral oedema of pregnancy in the lower limbs due to the paucity of research on the treatment of oedema associated with pregnancy and the contraindications of lying pregnant women in the supine position during these exercises.

## II. METHODS AND METHODOLOGY

### 2.1 Study Design

This randomized clinical trial was conducted on 90 pregnant women who went to the prenatal care at primary health center at Thirumalayampalayam, Coimbatore. The study was performed from January 2023 to March 2024, after obtaining the informed consent from the patient.

## 2.2 Selection Criteria

The criteria for entering the research include: first pregnancy and singleton, age between 18 and 35, normal pregnancy between 30 and 40 weeks, presence of bilateral oedema in the feet and legs of two plus or more, BMI in the normal range, normal state of amniotic fluid, not having the history of infertility, no symptom of systemic diseases such as heart and lung disorders, diabetes, thrombophlebitis, and high blood pressure, no skin disease such as severe eczema and absolute rest, no mental problems, no preeclampsia and eclampsia, no drug use except for the supplements during pregnancy, not having the history of drug addiction, no pain except to the area of the soles of the feet and ankles that spread from other organs. Evaluated in terms of compliance with the inclusion criteria, the samples of the research were randomly selected from the primary health centers. They were divided equally into three groups, Experimental A, Experimental B and Control group consists of 30 patients.

## 2.3 Data Collection

Data collection tools include demographic characteristics and obstetric history forms that was completed by the participants, pain ruler, inflexible tape measure, and volumeter of the lower limb Intervention.

The participant of the study included 90 primiparous pregnant women who met the inclusion criteria and were referred by primary health center. Then, demographic characteristics and obstetric history forms were completed. Considering the privacy of the research samples, the researcher helped them sit on the examination bed.

In order to check the amount of oedema, the examiner's thumb was pressed firmly and gently for 2 seconds on the area around the sole of the foot, behind the inner ankle or on the leg. Then, the depth of the indentation was estimated in centimeters. The size of the circumference around the ankle, around the heel, and between the fingers and metatarsal phalangeal joint (MPJ) metatarsal bones was measured using an inflexible tape measure.

Then, the volume of each leg was evaluated by a volumeter. Measuring the amount of water, the patient was asked to slowly dip her foot into the volumeter until the horizontal rod which is placed at the end of the volumeter is between the second and third toes.

The severity of the pain reported by the participants was evaluated using the VAS scale.

## 2.4 Procedure

Subjects were selected by convenient sampling method. 90 subjects who fulfilled inclusion and exclusion criteria were selected and by random sampling method 30 were allotted in Experimental Group A and 30 in Experimental Group B and 30 subjects in control group.

Subjects were clearly explained about the study and written informed consent was obtained from the subjects or from their caregivers. Proper instructions such as purpose, safety measures, comfort, precautions and psychological support were given to the subjects.

After completing the informed consent, all the participants were screened for the study. While performing the assessment, the subject's willingness to continue the procedure with or without rest was given preference.

All 3 groups were involved for Pre test assessment. Experimental Group A consist of 30 subjects has performed modified Buerger–Allen exercises at home for 20 days for once in a day for 30 minutes, Experimental Group B consist of 30 subjects performed modified Buerger–Allen exercises at home for 10 days for 30 minutes. All subjects of Experiment and control groups received routine pregnancy care including massage and walking. The measurements were done once again on the end of 10 day and 20 days respectively. The total duration of the study is about 14 months.

A training session on modified Buerger–Allen exercises along with the presentation of slides and a training booklet was performed in the Experimental groups. Following the intervention, the researcher contacted the research units daily in the Experimental groups to ensure that the exercises were carried out (by phone or social networks).

### Modified Buerger- Allen Exercises

The exercises performed by the pregnant woman were as follows: First, the sample was lain down on the left hand with an angle of 30° toward the supine (LLT), and at the same time, the lower limb was raised up to an angle of 45°–90° and was kept until the skin turns white (appears dead white). Then, sitting on a chair, she lowered her legs below the surface of the rest of the body until redness appears (note that there is no pressure on the back of the knees) and the toes are bent and stretched. Finally, straightening her legs, she lay on the bed on her left side for a few minutes.

The duration of each position depends on the patient's tolerance and the amount of skin colour change. Typically, exercises were prescribed in such a way that the legs were raised for 2–3 min and lowered for 4–6 min. Then, the participant was straightened on the bed for 10 min.

The sample in the control group also completed the questionnaire of demographic and midwifery information. The measurements were done by the researcher in the same way as the test group. After that, they were asked to return on the end of 10 days and 20 days respectively to re-measure the above-mentioned indicators.

Modified Buerger- Allen exercises steps



Figure 1: Lower Limb was raised up to an angle of 45°- 90°



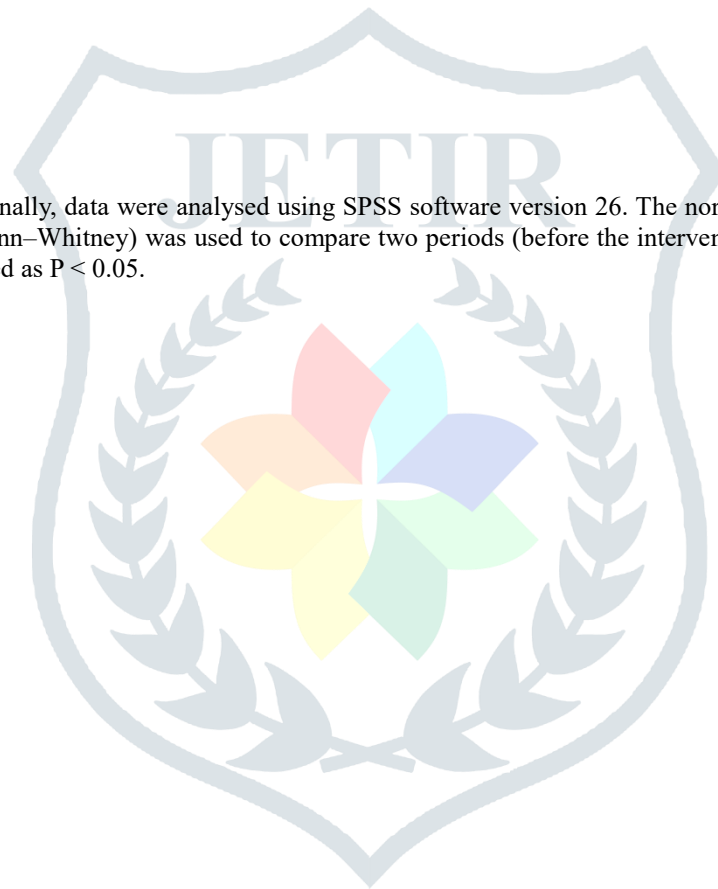
Figure 2: Legs lowered below the surface of the rest of the body



**Figure 3: Legs straighten and lay on left side for a few minutes**

#### **DATA ANALYSIS**

Statistical Analysis Finally, data were analysed using SPSS software version 26. The normality of the data was checked, and the independent t test (Mann–Whitney) was used to compare two periods (before the intervention and after the intervention). Significant level was considered as  $P < 0.05$ .



Variables	Experimental Group A (20 days)				Experimental Group B (10 days)				Control Group			
	Pre	Post	SD	P value	Pre	Post	SD	P value	Pre	Post	SD	P value
<b>Right Foot</b>												
<i>Ankle</i>	23.54	21.20	2.10	3.11	23.28	22.99	2.92	2.75	24.82	24.23	2.71	2.5
<i>Instep</i>	26.75	24.72	1.70	3.25	25.92	25.11	2.42	2.05	26.11	25.90	2.66	2.5
<i>MPJ</i>	21.19	20.21	1.27	3.82	22.16	21.97	2.10	2.12	21.71	21.30	1.50	1.3
<i>Volume</i>	264.33	260.22	27.9	45.5	274.54	273.85	32.5	37.3	275.5	274.2	24.3	23.8
<i>Pain</i>	9.0	4.2	3.1	3.1	9.1	7.8	3.7	2.95	9.1	8.4	3.5	3.3
<b>Left Foot</b>												
<i>Ankle</i>	23.44	21.22	2.11	3.25	23.21	22.99	2.32	2.55	24.82	24.23	2.70	2.40
<i>Instep</i>	26.65	24.70	1.73	3.33	25.92	25.61	2.02	2.00	26.11	25.90	2.60	2.60
<i>MPJ</i>	21.29	20.11	1.25	3.81	22.76	21.17	2.15	2.10	21.71	21.30	1.50	1.30
<i>Volume</i>	264.30	260.02	27.5	45.2	275.44	273.05	32.8	37.8	275.5	274.2	24.3	22.8
<i>Pain</i>												

**Table 1:** The mean and standard deviation was measured in the legs in centimetres and the volume of the legs in millimetres, separately for the 20-days, 10-days test groups and the control group, before, and after the interventions.

### III.RESULTS

The study sample comprised 30 patients on each group, based on the Wilcoxon and Mann–Whitney U test (independent t test), in experimental group A (20 days’ intervention), the pre and post test values of mean difference, Standard deviation and P value for right and left sided were calculated at ankle, Instep, MPJ, volume of legs and pain were calculated and represented in the table. The calculated P values for right side is 3.11, 3.25, 3.82, 45.5 and 9.1 and for left side is the value is 3.25, 3.33, 3.81, 45.2 and 3.01 respectively.

In experimental group B (10 days’ intervention), the pre and post test values of mean difference, SD and P value for right and left sided were calculated at ankle, Instep, MPJ, volume of legs and pain were calculated and represented in the table. The

calculated P values for right side is 2.75, 2.05, 2.12, 37.3 and 2.75 and for left side is the value is 2.55, 2.00, 2.10, 37.8 and 2.75 respectively.

In control group, the pre and post test values of mean difference, SD and P value for right and left sided were calculated at ankle, Instep, MPJ, volume of legs and pain were calculated and represented in the table. The calculated P values for right side is 2.50, 2.50, 1.30, 23.8 and 3.30 and for left side is the value is 2.40, 2.60, 1.30, 22.8 and 1.32 respectively.

When compare with all three groups, the calculated paired 't' test value is more than table value ( $p < 0.05$ ) at 5% level of significance, there was a significant difference in all averages of right ankle circumference, left ankle circumference, right heel circumference, left heel circumference, right foot circumference, right foot circumference, right foot volume, left foot volume, and pain in all three groups. But in 20 days' intervention group, there is significant differences were observed between the 10 days' intervention group B and control group in any of the above parameters. Thus this study shows the major improvement in Intervention Group A when compare with other two groups.

#### IV.DISCUSSION

The goal of the current study was to examine the potential impact of a novel adaptation of Buerger-Allen exercises on lower limb oedema in late pregnancy [2]. According to the study's findings, pregnant women's lower limb pain and swelling can be decreased by doing the modified Buerger-Allen exercise for 20 days. The average volume of the right leg compared to before the study did not significantly differ from the average circumference of the legs following the intervention in the 10-day test group, according the study's findings.

All averages of right ankle circumference, left ankle circumference, right heel circumference, left heel circumference, right foot circumference, right foot volume, left foot volume, and pain score were significantly different in the 20-day intervention group compared to the pre-intervention group.

Coban and Sirin investigated how massage could lessen lower limb physiological oedema in expectant mothers. The average of all leg circumferences, with the exception of the left ankle, was found to be considerably lower in the test group following 10 days of daily massage than in the control group. It attests to the benefit of massage in lowering pregnancy-related physiological oedema [16]. On the other hand, the study's findings indicate that the average leg circumference on the left side decreased, which is likely because of the adjusted LLT posture.

It was found that effleurage massage was superior to water immersion in reducing the symptoms of oedema in women's lower limbs in a study conducted by Ahmed et al. with the aim of comparing effleurage massage and water immersion exercise in reducing physiological leg swelling among primiparous women for 10 days. This decrease was noted in the degree of oedema and all foot circumferences. The findings might be explained by the fact that aphrodisiac massage stimulates lymphatic system activity, blood flow, and fluid movement. It is also capable of transferring extra fluid within the arteries without interfering with intravascular fluid [17].

According to the findings of Rahimikian et al.'s study, foot massage can help lessen pregnancy's physiological oedema. Additionally, the findings demonstrated that, following 10 days of 20-minute daily massages, there is a significant statistical difference ( $P < 0.001$ ) between the average amount of the measured circumference in the legs (around the ankle, heel, and joint between the fingers and metatarsals) between the two test groups and the control group [18]. Despite the similarities in the duration of the intervention, one possible explanation for the discrepancy between this trial and the current investigation could be the distinct processes of massage in relation to modified Buerger-Allen exercises.

When Hartmann and Huch examined how pregnant women with leg oedema responded to a water immersion session, they found that both the average leg size and the volume of the right foot decreased, which is consistent with the findings of the current investigation. The use of the same instrument to estimate the level of oedema and measure the volume of the legs appears to be the cause of this correlation [19].

The improvement of the lower limbs blood supply throughout the ten days of practicing modified Buerger-Allen exercises can be related to the notable and satisfactory difference in the improvement of the average foot circumferences, foot volume, and pain.

As a result, it can be concluded that ten days of modified Buerger-Allen exercises improves peripheral blood flow to the lower limbs. This is consistent with findings from Hassan et al. [20], who found a significant difference in the average ankle-brachial index (ABI) score following a fifteen-day workout regimen. Nonetheless, following a five-day intervention, the ABI score did not show any discernible variation [20]. The improvement in peripheral blood circulation, blood perfusion, and lower limb lateral blood circulation could be the cause of the ensuing shift. Like other fitness programs, extending the duration could also aid in achieving the intended outcomes.

The investigations on diabetic patients were similar, taking into account the unique situations faced by expectant mothers. In this context, a systematic study conducted by Chyong-Fang Chang et al. (2015) with the goal of examining the efficacy of Buerger-Allen exercise on enhancing peripheral blood circulation revealed that there may be some evidence supporting the safety, affordability, and positive effects of Buerger exercises for diabetic patients when performed at home [12, 21]. This review has demonstrated that by enhancing local blood circulation, Buerger-Allen exercises can be advantageous for patients with peripheral artery disease, postoperative orthopedic patients, and gynecological issues.

According to research by Hafid et al. [22] and Kumari et al. [23], the Buerger-Allen exercise can help diabetes patients' peripheral blood circulation in their lower limbs. This finding is consistent with the current study's findings, which also revealed a decrease in oedema.

According to this study, compared to before the intervention, the modified Buerger-Allen exercise was able to somewhat reduce oedema in the 20-day intervention group and in the 10-day intervention group. It might result from the postures taken to enhance peripheral blood flow and blood circulation. This results in the lower limb oedema being reduced. To maximize the exercise's ability to reduce oedema, modified Buerger-Allen training should be used for a longer duration.

The results of this study suggested that modified Buerger-Allen exercises may have a higher impact as an intervention to lessen pregnancy-related physiological oedema or to stop leg oedema from developing. Therefore, physiotherapists can practice

modified Buerger-Allen exercises as a practical, low-risk, and low-cost method in women's homes or at prenatal care centers. Thus physiotherapist in prenatal care centers or homes can administer modified Buerger-Allen exercises with proper positions as a helpful technique for healthy pregnant women without obstetric difficulties.

Additionally, given the frequency of pregnancy-related physiological issues during courtship and the detrimental effects these issues have on quality of life, it is advised that physicians and health personnel learn about and employ these exercises.

## V.CONCLUSION

Therefore, it is recommended that more research be done on how the modified Berger-Allen exercise affects pregnant women's lower limb oedema. If the low-cost, low-complication comprehensive treatment is successful in lessening the intensity of symptoms associated with such physiological issues during pregnancy, we stand to gain. The results of this study generally suggest that the modified Buerger-Allen exercise can help pregnant women with lower limb oedema by lessening the severity of their symptoms.

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