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Research Protocol

Physiotherapy Section

Effect of Blood Flow Restriction Training on Lipid Profile and Cardiopulmonary Endurance among Overweight and Obese Individuals: A Research Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Overweight and obesity have become a major public health concern as they contribute to the development of co-morbid conditions like Cardiovascular Diseases (CVD), type 2 diabetes, and respiratory problems, causing a significant impairment in lipid metabolism, known as dyslipidaemia. Resistance and Aerobic Exercise (AE) are effective in reducing dyslipidaemia and improving cardiopulmonary endurance, but require moderate to high intensity to gain these physiological benefits.

Need of the study: Blood Flow Restriction Training (BFRT) emerged as a novel exercise modality that uses a compression device in the proximal part of the limb to restrict blood flow. To our knowledge, existing evidence for the BFRT effect on lipid profile and cardiopulmonary endurance is limited and available studies are also confined to specific demographic cohorts, i.e., young obese males, overweight females, or other special populations. Therefore, the authors will evaluate the effectiveness of BFRT along with AE on these outcomes in both males and females.

Aim: To evaluate the effectiveness of AE along with BFRT on lipid profile and cardiopulmonary endurance among overweight and obese individuals.

Materials and Methods: An assessor blinded randomised controlled trial will take place at Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, Haryana, India, from May 2026 to March 2027. Sixty participants aged 18-35 with a Body Mass Index (BMI) ≥25 kg/m^2 will be divided into experimental and control groups. Both groups will engage in treadmill walking for eight weeks (3 days/week, 45 minutes/session), while the experimental group will use a Blood Flow Restriction (BFR) cuff on their thighs. Lipid profiles and cardiopulmonary endurance will be measured at baseline and after eight weeks through a digital lipid analyser and a 2 km walk test, respectively. Statistical analysis will utilise a paired t-test or Wilcoxon signed-rank test for within-group comparisons, and an independent t-test or Mann-Whitney U test for between-group comparisons, with $p<0.05$ considered significant.

Keywords: Cardiovascular diseases, Compression device, Dyslipidaemia, Lipid metabolism, Walk test

INTRODUCTION

Overweight and obesity have emerged as global health challenges in the 21st century, with high rates in both developing and developed countries [1,2]. At least 2.8 million people die each year due to overweight or obesity [3]. The percentage of adults 18 years of age and older living with obesity has more than doubled from 7% in 1990 to 16% in 2022 [4], and there is a projection that by 2030 their prevalence will cross 57.8% [5]. Overweight is defined as abnormal or excessive fat accumulation that presents a health risk, and BMI ≥25 kg/m^2 is considered overweight [6]. An increase in BMI/body weight is a modifiable risk factor for many health conditions. Obesity is strongly linked to more than fifty medical conditions like CVDs, Type 2 Diabetes Mellitus (T2DM), joint and respiratory problems [7]. Weight gain during adulthood is also associated with a significantly increased risk of major chronic diseases [8]. One of the major concerns in overweight is the development of dyslipidaemia. Dyslipidaemia is characterised by an increase in Triglycerides (TG), Free Fatty Acids (FFA) and Low-Density Lipoprotein Cholesterol (LDL-C), and a decrease in High-Density Lipoprotein Cholesterol (HDL-C) and it is greatly associated with overweight individuals [7]. Dyslipidaemia contributes to atherosclerosis and sclerotic plaque formation and then increases the risk of CVDs. So obesity is considered the main modifiable risk factor for non communicable diseases [9]. Another impact of obesity is a reduction in cardiopulmonary endurance. Cardiopulmonary fitness/endurance is the ability of the heart, lungs, and muscles to supply oxygen during exercise, and it is usually expressed as maximal oxygen consumption (VO_{2max}) [10]. Low cardiopulmonary endurance is associated with a high risk of CVD and all-cause mortality [11]. Cardiopulmonary fitness is inversely related to BMI; it means that as BMI increases, cardiopulmonary fitness decreases [12]. Physically less active and sedentary overweight youth exhibit lower cardiopulmonary fitness than their normal weight peers [13]. Few mechanisms explain the reduction in cardiopulmonary fitness. These are due to decreased muscle mass, elevated adipose tissue, deteriorated cardiovascular function, reduced metabolic efficiency such as mitochondrial dysfunction and decreased oxidative phosphorylation. These factors limit oxygen delivery and utilisation, therefore lowering endurance among overweight individuals [14].

Currently, there are many weight management strategies, among them are bariatric surgery, pharmacotherapy, and lifestyle modifications. Exercise is an effective non pharmacological intervention for management and prevention of overweight or obesity as it increases energy expenditure and controls body weight [9]. Conventional resistance exercises, AEs, High Intensity Interval Training (HIIT) positively influence lipid profiles, decreasing TG, low density lipoprotein while increasing high-density lipoprotein, enhancing cardiopulmonary endurance/fitness and reducing body fat, but require moderate to high intensity exercise to gain their physiological benefits [15,16]. However, performing moderate to high intensity exercise may not be tolerated by individuals who are overweight due to excessive mechanical stress on weight-bearing joints and other musculoskeletal structures [16].

BFRT/KAATSU training was developed by Dr. Yoshiaki Sato in Japan and has emerged as a novel exercise modality that uses a compression device, such as a cuff or tourniquet, combined with general exercise. A compressive cuff is applied to the proximal thigh, which reduces arterial blood flow and restricts venous return. The main mechanism underlying BFRT may be an increase in metabolic stress, including hormone secretion, regulation, and inhibition of protein synthesis [17].

Primary objectives:

- To determine the effectiveness of BFR-AE on lipid profile and cardiopulmonary endurance.
- To determine the effectiveness of AE alone on lipid profile and cardiopulmonary endurance.

Secondary objective: To compare the effects and to find out which intervention is superior: BFR-AE or AE alone in improving lipid profile and cardiopulmonary endurance.

Null hypothesis: There may be no significant differences in lipid profile and cardiopulmonary endurance in BFR-AE and AE among overweight individuals.

Alternate hypothesis: There may be significant differences in lipid profile and cardiopulmonary endurance in BFR-AE and aerobic AE among overweight individuals.

REVIEW OF LITERATURE

The South Asian region, including India, has one of the fastest-growing obesity rates in the world. The prevalence of obesity across India is 40.3%, and it is estimated that there are 135 million obese individuals in India [18]. Being overweight puts an individual at risk of co-morbidities such as heart diseases, type 2 diabetes, cancer and diminished quality of life. It is also strongly associated with metabolic syndrome, which is characterised by central obesity, hypertension, and dyslipidaemia [19]. In addition to dyslipidaemia, it has been observed that obese individuals have a reduction in cardiopulmonary endurance [14].

Physical activity, such as AE, has been recommended for improving lipid and lipoprotein levels in adults. A systematic review and meta-analysis by Zhang Z et al., (2025), including 20 RCTs (420 subjects), reported that BFR training significantly improved VO_{2max} (ES=0.465, $p<0.001$) and aerobic capacity (ES=0.315, $p<0.05$) compared to conventional training. These effects were attributed to localised hypoxia stimulating mitochondrial biogenesis and enhancing cardiovascular efficiency [20].

Su Y et al., (2024) conducted a 12-week RCT among obese college students (n=26) and found that low-intensity resistance training combined with BFR improved body composition, muscle mass, strength, endurance, and glucolipid metabolism [21]. Similarly, Razi O et al., (2022) reported that treadmill walking with BFR improved TGs ($p\leq0.05$) but did not affect HDL or LDL in overweight middle-aged men [22].

In a pilot study, Chen Y et al., (2021) showed that obese college students (n=37) performing cycling with BFR had significant improvements in body composition, BMI, and lipid/glucose profiles, while controls showed limited changes [17]. A systematic review by Zheng X et al., included 24 studies with 607 participants. Aerobic capacity was assessed through VO_{2max} or VO_{2peak}, while anaerobic capacity was measured using Peak Power Output (PPO) or Mean Power Output (MPO). Muscle strength was evaluated via peak force or torque in knee extension, or knee flexion/one-Repetition Maximum (1RM) if needed. The effect size (ES) of Blood Flow Restricted Interval Training (BFRIT) showed a significant small impact on aerobic capacity {Standardised Mean Difference (SMD)=0.33, $p<0.001$} and a moderate impact on muscle strength (SMD=0.61, $p<0.001$). However, the ES of BFRIT on PPO was not significant (SMD=-0.07, p=0.74), and MPO had a small non significant effect (SMD=0.23, p=0.25). Subgroup analysis indicated that training intensity, duration, status, cuff pressure modes, types, and application phases influenced the results [23]. There are very limited studies on the overweight population who have used BFR-AE and have seen its effect on lipid profile and cardiopulmonary endurance. The present study aims to evaluate the effect of AE along with Blood Flow Restriction (BFR-AE) training on lipid profile and cardiopulmonary endurance among overweight individuals.

MATERIALS AND METHODS

An assessor blinded randomised controlled trial will be conducted at Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, Haryana, India, from May 2026 to March 2027. Overweight adults will be included and demographic and anthropometric variables (e.g., age, gender, height, weight, BMI) will be recorded. A bilingual informed consent will be obtained from the participants before inclusion. This study has obtained ethical clearance from the Institutional Ethical Committee (IEC) of the Maharishi Markandeswar Institute of Medical Science and Research, Mullana (Ref.No.: IEC-PT-26/86). The trial has been registered prospectively with the Clinical Trial Registry of India (CTRI) with registration number CTRI/2026/05/109906 and follows the Declaration of Helsinki.

Sample size calculation: The total cholesterol values in the experimental group were 4.99±0.20 before intervention and 4.59±0.27 after intervention. In the control group, the values were 5.01±0.17 before intervention and 4.96±0.16 after intervention [17].

$$SD_{pooled}=\sqrt{\frac{SD_1^2+SD_2^2}{2}}=0.22$$

$$\text{Cohen's effect size (d)} = \frac{M_1-M_2}{SD_{pooled}}=1.67$$

The sample size formula used was:

$n=(Z_{\alpha/2}+Z_{\beta})^2\times2\times\sigma^2/d^2$

where,

$Z_{\alpha/2}$: critical value of the Normal distribution at $\alpha/2$ (for a confidence level of 95%, α is 0.05 and the critical value is 1.96),

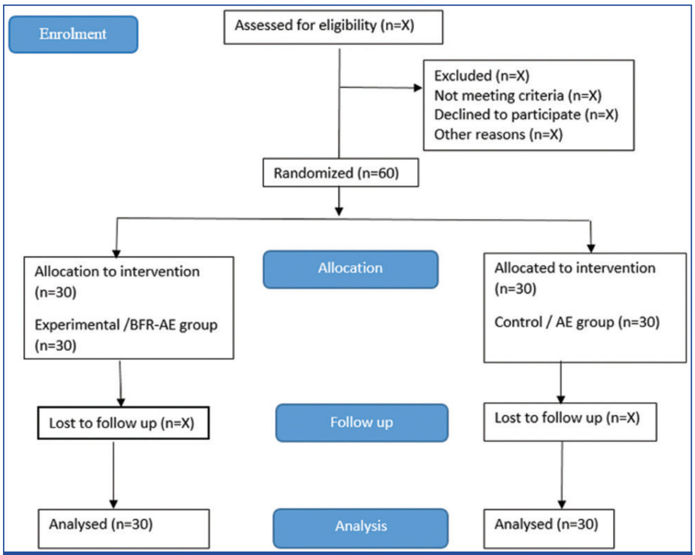
Z_{β}: critical value of the Normal distribution at β (for a power of 80%, β is 0.2, and the critical value is 0.84),

σ^2: population variance

The calculated effect size was 1.67, and the sample size with this effect size was very small. Therefore, following Cohen's conventions for standardised mean differences, we adopted d=0.8 (large effect) for sample size estimation, with 80% power and 5% level of significance.

Therefore, 26 participants are estimated for each group. After considering a possible dropout rate of 15%, the actual sample size is 60.

Inclusion and Exclusion criteria: In this present study, aged between 18-35 years and having BMI ≥25 kg/m² [6] will be included and participants having any known cardiopulmonary disease that may hamper functional capacity of participant, participation in other structured exercise/training programme in past three months, any known CVDs {such as Peripheral vascular disease, Deep Vein Thrombosis (DVT) history, active clotting disorders}, pregnancy, any contraindication to limb occlusion (such as sickle cell disease, severe varicose veins, severe neuropathy) will be excluded. All the participants will be instructed to continue and maintain their usual lifestyle habits and diets till the end of their intervention period, and these factors will be recorded.The Consolidated Standards of Reporting Trials (CONSORT) flowchart is given in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow of the study.

All the participants will be screened to select them for the eligibility criteria, and the eligible candidates will be enrolled either into the experimental or the control group via randomisation, which is performed using a computer-generated random sequence. This study will be assessor-blinded. The outcome assessor will be unaware of the experimental and control group participants, and participants will also be instructed not to disclose their allocated group.

Study Procedure

Participants in the control group will receive only AE [Table/Fig-2] [24,25]. On the other hand, participants in the intervention group will perform AE with the application of BFR.BFR will be provided using an 11.5 cm wide pneumatic cuff. BFR cuff will be applied around the bilateral proximal part of the thigh at 60% Limb Occlusion Pressure (LOP) [25]. LOP will be determined by handheld doppler. The doppler probe will be placed at the posterior tibialis artery. The BFR cuff will be inflated until the posterior tibialis arterial pulse is no longer felt. After the determination of LOP, 60% LOP will be determined. For intermittent occlusion, cuff pressure will be maintained for 15 minutes of treadmill walking and during the rest period of one minute, the cuff will be deflated. Again, after one minute of rest period, the cuff will be reinflated. LOP will be assessed by a physiotherapist who is trained in the application of BFRT. To reduce the variability in measurement of LOP, the same assessor will assess and determine the LOP throughout the study.

Aerobic exercises	Duration
Warm up phase	
• Ankle-toe pump	5 min
• Heel-toe raise	
• ROM exercises	
• Slow walking	2 min
Training phase	45 min
• Frequency	3 sessions/week
• Time	3 sets; 15 min/set (1 min rest between set)
• Intensity	45% of heart rate reserve
• Exercise mode	Treadmill walking
Cool down phase	5 minute
• Slow walking	

[Table/Fig-2]: Aerobic Exercises (AE) protocol for control group.

Both groups will undergo training three times a week for a duration of eight weeks. For participant safety, a familiarisation session will be conducted two days before the first intervention session under the trained physiotherapist on BFRT and will explain the BFRT procedure, cuff application, safety, precautions and reporting to the intervention provider if an adverse event occurs. For safety monitoring, prior to enrollment, contraindications to the BFRT will be screened. During intervention, if any adverse event occurs like excessive pain, numbness then BFR cuff will immediately be deflated and appropriate medical evaluation will be arranged.

Outcome Measures

All outcome measures will be assessed at baseline and after an intervention of eight weeks.

1. **Lipid profile:** Lipid profile will be measured using the using a digital lipid analyser (SD Lipido Care, SD Biosensor, Inc.). SD Biosensor has good reliability {Intraclass Correlation Coefficient (ICC): 0.75-0.9} for HDL and excellent reliability (ICC >0.9) for TG. The sensitivity, specificity, and accuracy of SD LipidoCare is 92.9 (95% CI: 80.7-97.7), 90.5 (95% CI: 0.78-0.96), and 91.4 (95% CI: 80.7-0.97), respectively [26]. Furthermore, analytical performance data submitted for regulatory evaluation demonstrated high agreement between SD LipidoCare and laboratory comparator methods for total cholesterol, triglycerides, and HDL cholesterol [27].
2. **Cardiopulmonary endurance:** It will be assessed using the 2 km walking test, developed by the UKK Institute. It is a valid test for assessing cardiopulmonary endurance in overweight adult individuals. This test will be conducted by a trained physiotherapist. Participants will be informed about the test and will be asked to inform the physiotherapist immediately if chest pain, severe shortness of breath, or dizziness occurs. If these symptoms occur, the test will be terminated immediately and will be documented. Just before the test, participants will undergo five minutes warm-up exercise consisting of slow walking and mobility exercises. The participants will then be instructed to walk as fast as they can (not to run) for a two-kilometre distance on a 500-metre stretch of flat surface. Time taken (in minutes) for covering a total distance of 2 km and Heart rate immediately at the end of the walk (beats·min^{-1}) will be recorded and documented. For calculating VO_{2max} (mL·kg^{-1}·min^{-1}), separate equation will be used for man and women [28]:

   For men: VO_{2max} (mL/min/kg)=184.9-(4.65×walk time)-(0.22×HR)-(0.26×age)-(1.05×BMI)

   Women: VO_{2max} (mL/min/kg)=116.2-(2.98×walk time)-(0.11×HR)-(0.14×age)-(0.39×BMI)

STATISTICAL ANALYSIS

Data will be analysed using the statistical software Statistical Package for the Social Sciences (SPSS) 26(Armonk, New York: IBM Corporation). The normality of data will be assessed by the Kolmogorov-Smirnov test as the sample size is more than 50. If the data will be normally distributed, then the parametric test, the paired t-test for comparison within the group, and the independent t-test will be used for between-group analysis. If the data are not normally distributed, then the non parametric test, the Wilcoxon signed rank test, will be used for comparison within the group, and the Mann-Whitney U test will be used between the groups. The level of significance will be set as p<0.05.

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