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Research Protocol

Physiotherapy Section

Effect of Continuous Training versus Interval Training on Functional Parameters of Stage-1 Hypertensive Patients: A Randomised Clinical Study

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ABSTRACT

Introduction: Hypertension is one of the major risk factors for heart attack and stroke, often referred to as the "silent killer." Non pharmacological therapy can be used to manage hypertension in addition to pharmacological therapy. Exercise such as continuous and interval training are types of physical exercises. Findings indicate that Moderate-Intensity Continuous Training (MICT) and High-Intensity Interval Training (HIIT), lower average blood pressure in Stage-1 hypertensive patients.

Need of the study: To evaluate the effectiveness of interval training and continuous training on patients with Stage-1 hypertension and to prevent the progression to the next stage of hypertension.

Aim: To compare the effects of continuous training versus interval training on blood pressure, heart rate, and Rate of Perceived Exertion (RPE) in Stage-1 hypertension.

Materials and Methods: This randomised clinical study will be conducted at the Cardiovascular and Thoracic Surgery Unit, Acharya Vinobha Bhave Rural Hospital, Sawangi, Wardha, Maharashtra, India, for a duration of six months. In this study, 130 patients diagnosed with Stage-1 hypertension will be divided into two groups. The first 65 will be randomly assigned to Group A as the interval training group, while the remaining 65 will be assigned to Group B as the continuous training group. Each patient's demographic information, including name, age, gender, height, and weight, will be recorded. Before the intervention, patients' blood pressure and heart rate will be measured, taking an average of three readings. Training will then commence, and patients will be reassessed to determine the effectiveness. Statistical analysis will be performed using paired and unpaired t-tests.

Keywords: Aerobic exercise, Blood pressure, Heart rate, Physiotherapy

INTRODUCTION

Hypertension is described by the World Health Organisation (WHO) as having a Systolic Blood Pressure (SBP) of 140 mmHg or higher and/or a Diastolic Blood Pressure (DBP) of 90 mmHg or higher [1]. Physiological factors such as salt consumption genetic predisposition, age, gender, weight, smoking etc., can effect blood pressure [2]. It can get impacted by the interconnection of multiple genetic, environmental, and demographic factors that affect haemodynamic, changes such as cardiac flow rate and Total Peripheral Resistance (TPR) [2].

TPR is primarily evaluated at the arteriole level and is influenced by hormonal factors. Normal arterial tone is determined by the consistency of humoral vasoconstriction effects (such as angiotensin II and catecholamines) and vasodilators (including kinins, prostaglandins, and nitric oxide) [2]. Elevated autonomic nervous system action stimulates peripheral vasculature, the heart, and the kidneys, raising blood pressure and facilitating the occurrence and perpetuation of hypertension. This leads to increased vascular resistance, cardiac output, and fluid retention [3]. Increased sympathetic nervous system activity is seen due to the changes in different pathways such as, peripheral, central baroreflex, chemoreflex in the hypertension [4-6].

Recent research in India, conducted by Kothavale et al., suggest that, only 48% and 43% of urban and rural patients aged (15-49 years) with hypertension are aware of their disease [7]. The prevalence of hypertension in eastern rural India is notably higher (20-59%) compared to northern and western non rural India, with Assam having the highest prevalence due to excessive alcohol, salt, and Khaini intake among Assam tea plantation workers. Other southern rural parts of India, including the Andaman and Nicobar Islands, also show excessive frequency [7].

The new classification of blood pressure was given under the hypertension guidelines from 2019 by American College of Cardiology (ACC)/American Heart Association (AHA) are as follows: stage-1 hypertension (130-139 SBP or 80-89 mmHg DBP), stage-2 hypertension (140 SBP or 90 mmHg DBP), normal (120 SBP and 80 mmHg DBP), and elevated (120-129 mmHg SBP and <80 mmHg DBP) [8].

Aerobic activity has been recommended for both the reduction and prevention of high blood pressure in hypertensive individuals [9]. There are numerous protocols and programmes available to help people to get started with physical activities like active sports, (such as basketball or tennis), cycling, climbing stairs, dancing, jogging, swimming, and walking [9]. Interval training involves alternating between work and rest times while exercising. This programme alternates between a high-intensity work bout and a low-intensity rest interval to vary the intensity of the training session [10].

Studies have evaluated the effectiveness of interval training and continuous training on hypertension [9,11-13]. Both the techniques have shown encouraging results in terms of the control of blood pressure done in studies conducted by Pescatello LS et al., Sikiru L and Okoye G and, Lamina S, on Stage-2 and Stage-3 hypertension and results were obtained whereas present study will be specifically done on Stage-1 to prevent further complications and progression in young adults [11-13]. The objective of the current study will be compare the effect of continuous training versus interval training on blood pressure, heart rate and RPE of Stage-1 hypertensive

patients. Though the available litterature on the aerobic exercises is limited, the objective of the current study will be compare the effectiveness of continuous training versus interval training on individuals with Stage-1 hypertension.

REVIEW OF LITERATURE

The blood pressure reducing effect of exercise is intensity dependent [1]. The exercise training induced safe lowering in resting SBP and DBP which will be comparable between MICT and HIIT. A meta-analysis and systemic review of randomised controlled trials discovered that there is significant reductions in 24-hour (5.4 and 3.0 mmHg for SBP and DBP, respectively), daytime (4.5 and 3.2 mmHg) which is resulted by exercise training interventions and night-time SBP (4.7 and 3.1 mmHg) among hypertensive individuals [14].

Another randomised trial by Clark T et al., on HIIT for reducing blood pressure vs. MICT in males with overweight or obesity elucidated found the overweight to obese cohort's blood pressure decreased (by 3-5 mmHg) as a result of HIIT. The central (aortic) BP improved after exercise training. Exercise training lowers blood pressure more effectively in people with higher baseline blood pressure, with HIIT showing a larger link than MICT [15]. A systematic review and meta-analysis by de Souza Mesquita FO et al., found that HIIT effectively improved VO_2 peak, BP, and resting HR when compared with controls [16].

Morgan RE and Anderson GT developed continuous training at the University of Leeds in England in 1953. Continuous training, doesn't appear to raise resting blood pressure and may benefit borderline hypertensives by lowering resting blood pressure [10].

A meta-analysis conducted by Cornelissen VA and Smart NA on the effects of endurance exercise, dynamic resistance, training isometric resistance training, and combined endurance and resistance training on resting blood pressure in adults found that continuous aerobic exercise training lowers resting systolic and diastolic blood pressure by an average of 2.1 and 1.7 mmHg for prehypertensives and 8.3 and 5.2 mmHg for hypertensives [17]. Higher reductions in resting blood pressure were concluded for interventions lasting less than 24 weeks, which involved exercise training sessions lasting 30 to 45 minutes and requiring less than 210 minutes of exercise per week. This meta-analysis discovered comparable reductions in resting diastolic and systolic blood pressure for moderate and high-intensity aerobic exercise training interventions [17].

Way KL et al., in a systematic review on the effect of HIIT versus MICT on arterial stiffness and 24-hour blood pressure response, stated that compared to MICT, HIIT causes a greater decrease in night-time DBP. In addition, HIIT was found to significantly lower daytime blood pressure compared to MICT [18].

MATERIALS AND METHODS

This randomised clinical study will be conducted in the Cardio vascular and Thoracic Surgery Unit, Acharya Vinobha Bhave Rural Hospital, Sawangi, Wardha, Maharashtra, after approval from the Institutional Ethical Committee (IEC) of Datta Meghe Institute of Medical Sciences, Deemed to be University (IEC no. DMIMS (DU)/IEC/2022/901). The study duration will be December 2022 to June 2023.

Inclusion criteria: Patients aged between 20 to 55 years, irrespective of gender. Patients with SBP between 130 mmHg to 139 mmHg and DBP between 80 mmHg to 89 mmHg will be included in the study.

Exclusion criteria: Patients with known neurological and musculoskeletal diseases/disorders, those who have developed haemodynamic difficulties (e.g., preoperative myocardial infarction, postoperative renal failure, lung congestion, arrhythmia requiring a pacemaker, or patients on an intra-aortic balloon pump). Patients with a previous history of heart failure and an ejection fraction less than 55% will be excluded from the study.

Sample size: The sample size calculation was done using the Daniel formula.

Daniel formula for sample size:

$$n=\frac{Z\alpha/2_{:}\,P.(1-P)}{d^2}$$

Where, $Z_{\alpha/2}$ is the level of significance at 5%, i.e., 95% confidence interval=1.96

P=Prevalence of Stage-1 hypertension=20%=0.20 [7]

d=Desired margin of error=1%=0.01

$$n=\frac{1.96^2\times0.20\times(1-0.20)}{(0.01)^2}$$

=125.44

=130 patients are needed in the study.

Data collection: Patients who meet the inclusion criteria will be explained about the study objectives, details, and approaches, and written patient consent forms will be signed by them. Randomisation will be done by the primary researcher. The parameters assessed will be SBP, DBP, heart rate, and RPE, which will be assessed by the modified Borg scale (Borg CR10 scale). The Borg RPE scale was created by Swedish researcher Gunnar Borg as a measure for assessing an individual's effort and exertion, breathlessness, and weariness during physical labour [19]. It offers a measurement of how hard the body is working based on bodily feelings such as elevated heart rate, increased respiration or breathing rate, increased perspiration, and muscular weariness. The Borg CR10 is a generic intensity scale with an anchor at 10, denoting an intense intensity of activity [20]. Participants The subjects will be asked to select the number that best describes their feelings of breathlessness, on average, over the last 24 hours [Table/Fig-1].

Score	Level of exertion
0	No exertion at all
0.5	Very, very slight (just noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	Very severe
7	Very, very severe (almost maximal)
8	Maximal

[Table/Fig-1]: Borg scale (CR10).

Scoring and interpretation: During the exercise, participants will be asked to assess their exertion on a scale that incorporates all physical stress and fatigue-related symptoms and feelings. They would be instructed to consider their overall feelings after exerting themselves and to ignore any one aspect, such as leg discomfort or shortness of breath. This value indicates the level of activity that allows participants to adjust their movements.

Procedure

Each patient will be required to complete six weeks of rehabilitation after enrolment in the study. There will be five sessions per week for six weeks. The analysis will be performed at the starting point, at the

end of the last recovery session, and at the 6-week follow-up after completing the sessions.

In this study, two groups will be included: Group A as the interval training group and Group B as the continuous training group. A total of 130 patients with stage-1 hypertension will be randomised into two groups, with 65 subjects in each group.

Group A: Interval Training

- Interval training will be given as an intervention on the treadmill in Group A and will be evaluated using the Frequency, Intensity, Time, and Type (FITT) principle [21].
- This training will last 30 minutes after a 5-minute warm-up period, with one minute of high intensity (70%) and two minutes of moderate intensity (40-60%), followed by 7 repetitions and a 5-minute cool-down period [Table/Fig-2] [21].

Time in (min)	Components	Intensity
5	Warm up	
2	MIIT	40% -59% HRR
1	HIIT	60%-89% HRR
2	MIIT	40% -59% HRR
1	HIIT	60%-89% HRR
2	MIIT	40% -59% HRR
1	HIIT	60%-89% HRR
2	MIIT	40% -59% HRR
1	HIIT	60%-89% HRR
2	MIIT	40%-59% HRR
1	HIIT	60%-89% HRR
2	MIIT	40%-59% HRR
1	HIIT	60%-89% HRR
2	MIIT	40%-59% HRR
5	Cool down	

[Table/Fig-2]: Showing the progression of intensities as per the training components. Phases of interval training as per ACSM guidelines.
MIIT: Moderate intensity interval training; HIIT: High intensity interval training; HRR: Heart rate reserve

- The Maximum Heart Rate (MHR) will be calculated using the 220-Age formula. The Karvonen formula will be used to calculate the Target Heart Rate (THR) [22]. Each individual's heart rate will be monitored using a heart rate monitor machine (Polar H10 Heart Rate Sensor) during all exercise and workout sessions.

Group B: Continuous Training

- Continuous training will be administered as a treadmill intervention and will be evaluated using the FITT principle. After a 5-minute warm-up period, this training will last 35 minutes.
- Moderate continuous training exercise at 60% of Heart Rate Reserve (HRR) will be performed for 20 minutes, followed by a 10-minute cool-down period. Patients will be trained for five days each week for six weeks as part of this continuous training.

OUTCOME MEASURES

Primary outcome measures:

- Systolic Blood Pressure (SBP)
- Diastolic Blood Pressure (DBP)
- Heart rate

Secondary outcomes:

- Rating of Perceived Exertion (RPE)

ETHICAL APPROVAL AND DISSEMINATION

The patients participating in the study and DMIMSU, which will finance it, will have access to the study's results. Data will be stored in the DMIMSU storage device following the study's conclusion and the publication of its findings.

Patient Consent

The participant's written consent permission (in their native language) will be obtained by the principal investigators on a printed form with their signatures and verification of confidentiality.

Confidentiality

The study protocol will be explained to the patients, and the main researcher will gather subjective information. The consent form will be signed by the principal investigator, the patient, and a witness, in addition to the confidentiality statement. The patient will be provided complete guarantee of their privacy if their agreement is needed to disclose certain information for the study.

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