NON-MECHANIZED EXERCISE TRAINING TO IMPROVE PAIN FREE WALKING DISTANCE IN PATIENTS WITH PERIPHERAL ARTERY OCCLUSION

Dissertation submitted in

the Partial fulfillment

for the degree of

MASTER OF PHYSIOTHERAPY

(CARDIO RESPIRATORY)

The Tamil Nadu Dr. M.G.R. Medical University

Chennai

May 2018

PSG COLLEGE OF PHYSIOTHERAPY

Coimbatore

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Coimbatore

CERTIFICATE

This is to certify that the research work entitled **"NON MECHANIZED EXERCISE TRAINING TO IMPROVE PAIN FREE WALKING DISTANCE IN PATIENTS WITH PERIPHERAL ARTERY OCCLUSION"** was carried out by **Reg. No. 271630241,** of P.S.G. College of Physiotherapy, towards the partial fulfillment for the degree of **MASTER OF PHYSIOTHERAPY (Physiotherapy in Cardio Respiratory)** affiliated to The TamilNadu Dr. M.G.R. Medical University, Chennai.

Internal Examiner **External Examiner**

Date of Evaluation:

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ABBREVIATIONS

PAD	-	Peripheral Artery Disease.
IC	-	Intermittent Claudication
ABI	-	Ankle Brachial Index
6MWT	-	Six Minute Walk Test
WIQ	-	Walking Impairment Questionnaire

CONTENTS

LIST OF ANNEXURES

CHAPTER-I

INTRODUCTION

Peripheral artery disease (PAD) is also called as Peripheral artery occlusive disease (PAOD) is the most commonly defined as gradual obstruction of arteries leading to impaired blood flow[(1)].

The risk of developing PAD can be predicted by the patient's age and well-defined atherosclerotic risk factors, including cigarette smoking, dyslipidemia, diabetes mellitus, and arterial hypertension[(2)].

It is common in diabetic and in chain smokers. The prevalence of PAD in diabetic patients was found to be 3.2% in a study from south India and as high as 15.9% in a western population[(3)].It can be increase with ageing, in general population it accounts for 12% to 14% affecting up to 25% of subjects over 75 years[(2)].

Intermittent Claudication (IC), which is defined as a reproducible lower extremity muscular pain induced by exercise and relieved by rest[(2)].Superficial femoral and popliteal arteries are most commonly affected by atherosclerotic plaques. As plaques grow they reduce blood flow through, to the tissues distal to the obstruction, ischemia to the muscles are accompanied by sensation of the local muscle pain which is increased during periods of increased oxygen consumption (Vo_2) such as during exercise[(2)].

FONTAINE'S CLASSIFICATION [(8)] :

STAGE	CLINICAL SYMPTOMS
Stage 1	Asymptomatic
Stage 2 a	Pain with walking more than 200 meters
Stage 2 b	Pain with walking less than 200 meters
Stage 3	Rest pain
Stage 4	Necrosis or gangrene of the lower limb

Non-mechanized exercise training is a form of exercise programme without the use of any mechanical equipments like Treadmill, bicycle ergometry which helps to improve blood flow in the peripheral arteries of lower extremities.

1.1 NEED FOR THE STUDY

PAD is a condition leading to increased morbidity and mortality rate in males with smoking history who present with decreased walking ability and functional status. This study mainly focuses on justifying the effects of non-mechanized exercise training in improving peripheral blood circulation and pain free walking distance in patients with peripheral artery occlusive disease.

Due to increased prevalence of PAD, evaluating and implementing different types of rehabilitation through equipments are available. So, the primary goal of this study is to train with activity as exercise in home based set up without the use of machines that promote a better health related quality of life in patients by

- Decreasing claudication pain.
- Improving pain free walking distance.

1.2 OBJECTIVE

To find out the effects of non-mechanized exercise training in improving pain free walking distance in patients with peripheral artery occlusion.

1.3 HYPOTHESIS

Null hypothesis:

There is no significant difference in pain free walking distance in patients with peripheral artery occlusion after a non-mechanized exercise training programme.

Alternative hypothesis:

There is significant difference in pain free walking distance in patients with peripheral artery occlusion after a non-mechanized exercise training programme.

1.4 OPERATIONAL DEFINITIONS

Peripheral Arterial Disease (PAD)

Peripheral arterial disease is characterized by the development of obstructive atherosclerotic plaques in the arteries of peripheral limbs [(1)].

Intermittent Claudication (IC)

The term "claudication" comes from Latin, where *claudiactio* means "limping". Intermittent claudication is the pain in the lower limbs during walking, which forces the person to stop walking[(7)].

Non-mechanized exercise training

Non-mechanized exercise training is a form of exercise programme without using any mechanical equipments helping to improve blood flow in the peripheral arteries of the lower extremities.

Pain Free Walking Distance

The distance that a person with Peripheral arterial disease can walk before the claudication pain begins.

1.5 PROJECTED OUTCOME

Based on the literature review, it is expected that the result of the study will be clinically significant and there is be a significant difference in pain free walking distance.

CHAPTER-II

REVIEW OF LITERATURE

- **Maria Szymczak, Marian Majchrzycki, et al (2014)** conducted the most common form of rehabilitation of patients with PAD is unassisted treadmill training in a home environment or assisted treadmill training. Alternative options include strength exercises of the lower limbs, osteopathic techniques, stationary bike exercises or the combination of the mentioned methods. The alternative methods of rehabilitation have a positive effect on PAD patients; however, their efficacy has been studied only recently. Currently, treadmill training is the most effective, evidence-based, form of rehabilitation of patients with IC.

- **Fokkenrood Bendermacher BLW, et al (2013)** total of 14 studies involving a total of 1002 participant with PAD were included in this review. Follow-up ranged from six weeks to 12 months. In general, supervised exercise regimens consisted of three exercise sessions per week. All trials used a treadmill walking test as one of the outcome measures. The overall quality of the included trials was moderate to good, although some trials were small with respect to the number of participants, ranging from 20 to 304. Supervised exercise therapy (SET) showed statistically significant improvement in maximal treadmill walking distance compared with non-supervised exercise therapy regimens, with an overall effect size of 0.69 (95% confidence interval (CI) 0.51 to 0.86) and 0.48 (95% CI 0.32 to 0.64) at three and six months, respectively.This translates to an increase in walking distance of approximately 180 meters that favoured the supervised group. SET was still beneficial for maximal and pain-free walking distances at 12 months, but it did not have a significant effect on quality of life parameters concluded SET has statistically significant benefit on treadmill walking distance (maximal and pain-free) compared with non-supervised regimens. However, the clinical relevance of this has not been demonstrated definitively; additional studies are required that focus on quality of life or other disease-specific functional outcomes, such as walking behaviour, patient satisfaction, costs, and long-term follow-up. Professionals in the vascular field should make SET available for all patients with IC.

- **Atul Jain, MD, Kiang Liu, et al (2012)** 1048 men and women with and without PAD were identified from Chicago-area medical centers. Participants completed the WIQ at baseline and were followed for a median of 4.5 years. Cox proportional hazards models were used to relate baseline WIQ scores with mortality, adjusting for age, sex, race, the ankle brachial index (ABI), co-morbidities, and other covariates. Results- 461 participants (44.0%) died during follow-up, including 158 deaths from cardiovascular disease. PAD participants in the lowest baseline quartile of the WIQ stair-climbing scores had higher all-cause mortality (HR = 1.70 [95% Confidence Interval (CI) 1.08-2.66, p=0.02] and higher CVD mortality (HR = 3.11 [95% CI 1.30 – 7.47, p=0.01]) compared to those with the highest baseline WIQ stair climbing score. Among PAD participants there were no significant associations of lower baseline WIQ distance or speed scores with rates of all-cause mortality (p for trend = 0.20 and 0.07, respectively) or CVD mortality (p for trend = 0.51 and p for trend = 0.33, respectively). Among non-PAD participants there were no significant associations of lower baseline WIQ stair climbing, distance, or speed score with rates of all-cause mortality (p for trend = 0.94, 0.69, and 0.26, respectively) or CVD mortality (p for trend = 0.28, 0.68, and 0.78 respectively). finally, author Concluded Among participants with PAD, lower WIQ stair climbing scores are associated with higher all-cause and CVD mortality, independently of the ABI and other covariates.

- **Naomi M. Hamburg, MD et al (2011)** Reviewed 22 studies with > 1200 participants conducted by the coherence group in 2008 compared supervised programs with usual care in treatment of claudication. The American heart association/American association of cardio vascular and pulmonary rehabilitation core components of cardiac rehabilitation secondary prevention programs outline the comprehensive nature of such programs with goal of reducing physical disability and cardiovascular risk while restoring optimal physical, psychological, and social functioning. such programs integrate exercise into the overall treatment plan that includes lipid management, blood pressure control, smoking cessation, nutrition education, and weight reduction, diabetes mellitus treatment and psycho social intervention with the use of this multifaceted approach, cardiac rehabilitation/secondary prevention programs have been associated up to a 56% improvement in survival among patients after myocardial infarction and a 28% reduction

in the risk of recurrent myocardial infarction. Such benefits are seen despite age gender and ethnic back ground. Furthermore benefits of such programs appear to be dose related in patients who attend 36 sessions have a 14%,22% and 47% lower risk of mortality than those who attend 24 sessions,12 sessions and 1 session respectively. However, no study has yet been conducted to evaluate the effect of exercise rehabilitation in PAD patients on mortality.

- **Andrew W. Gardner, et al., 2011)** randomized 119 patients and concluded that 29 patients completed home-based exercise, 33 completed supervised exercise and 30 completed usual care control as secondary prevention. Both exercise programs consisted of intermittent walking to near maximal claudication pain for 12 weeks. Patients wore a step activity monitor during each exercise session. Primary outcome measures included claudication onset time (COT) and peak walking time (PWT) obtained from a treadmill exercise test, and secondary outcome measures included daily ambulatory cadences measured during a 7-day monitoring period. Home-based exercise appears more efficacious in increasing daily ambulatory activity in the community setting than supervised exercise.

- **J.C. Tsai et al., (2002)** conducted prospective randomized control trial on 64 patients. Thirty two of 64 patients with fontaine stage 2 peripheral arterial occlusive disease (PAOD) were randomized to exercise training and 32 to usual care control. Results shows that the compliance of exercise programme was 83% of possible sessions. Exercise training increased treadmill walking time to onset of cladication pain by 88% ($P < 0.001$), time to maximal pain by 70%($P < 0.001$), and six minute walk distance by 21% %($P < 0.001$).

- **Mary MeGrace, Mc Dermott et al., (1999)** conducted cross sectional study in RCT 147 Participants were analyses patients with atypical exertional leg symptoms IC pain at rest respectively had poorer scores for walking distance, walking speed and stair climbing. Among PAD patients only pain at rest was associated independently with WIQ scores and SF 36 domains with ABI was independent predictor of WIQ distance scores. Results showed Both PAD related leg symptoms ABI Predict patient received walking ability in PAD.

- **Judith G. Regensteiner, et al., (1994)** conducted RCT 29 men with disabling IC were randomized to 12 weeks of either supervised treadmill training 3hr/wk at a work intensity sufficient to produce claudication, strength training (3hr/wk of resistive training of 6 muscle groups of each legs or to non-exercising control group. After 12 weeks of treadmill training PAR (Physical Activity Recall) scores increased by 48 metabolic equivalent hr/wk, medical outcome measures (MOS) Physical Functioning Score by 24 Percentage points and the number of bouts of walking activity measured by vitalog by 4.5 bouts/hr (all $p< 0.05$).A Supervised treadmill training program improved functional status during daily activities with 24 weeks more effective than 12 weeks. In addition, treadmill training alone was more effective in improving functional status in patients with IC than strength training or combinations of the training modalities.

CHAPTER-III

MATERIALS AND METHODOLOGY

3.1 MATERIALS

A. Tools used for measuring 6 MWT

- Pulse oximeter
- Sphygmomanometer
- Stop watch
- Cones

B. Tools used for measuring ABI

- Sphygmomanometer with appropriately sized cuff(s) for both arm and ankle.
- Handheld Doppler device with vascular probe.
- Conductivity gel compatible with Doppler device.

3.2 STUDY DESIGN

A QUASI EXPERIMENTAL STUDY DESIGN: (Pre-test and post-test design with treatment comparison)

Quasi Experimental Study Design is adopted for the study. With the help of this study design, the pre-test and post-test values are assessed for Group-A & Group-B.

In my study, the pre-test measurement of ABI, 6MWT and WIQ scores were measured before starting medications and the routine management (conventional management) for Group-A or medications along with the non-mechanized exercise training that is structured for Group-B**.** The post-test ABI, 6MWT pain free walking distance and WIQ scores were measured after the 12 weeks of home-based exercise.

3.3 STUDY SETTING

Department of Cardio thoracic and Vascular Surgery, P.S.G Hospitals, Coimbatore.

3.4 STUDY DURATION

Duration of 8 months was adopted for this study.

3.5 HUMAN PARTICIPATION PROTECTION

The study was reviewed and approved by institutional human ethics committee of PSG IMSR.

3.6 SAMPLING

A total of 20 patients were selected by Simple Random Sampling.

Group-A: 10 patients received medications along with routine management (conventional management)

Group-B: 10 patients received medications along with the non-mechanized exercise training Programme that is structured.

3.7 TREATMENT DURATION

Group-A: Medications along with routine management (conventional management) continued for 12 weeks.

Group-B: Medications along with the non-mechanized exercise training for 1 session per day, thrice weekly for 12 weeks.

3.8 CRITERIA FOR SAMPLE SELECTION

3.8.1 Inclusion Criteria

- Age above 40 to 65 years.
- Subjects with fontaine stage 2(Intermittent Claudication pain) & fontaine stage 3 (nocturnal pain).
- Unilateral Peripheral artery occlusion.

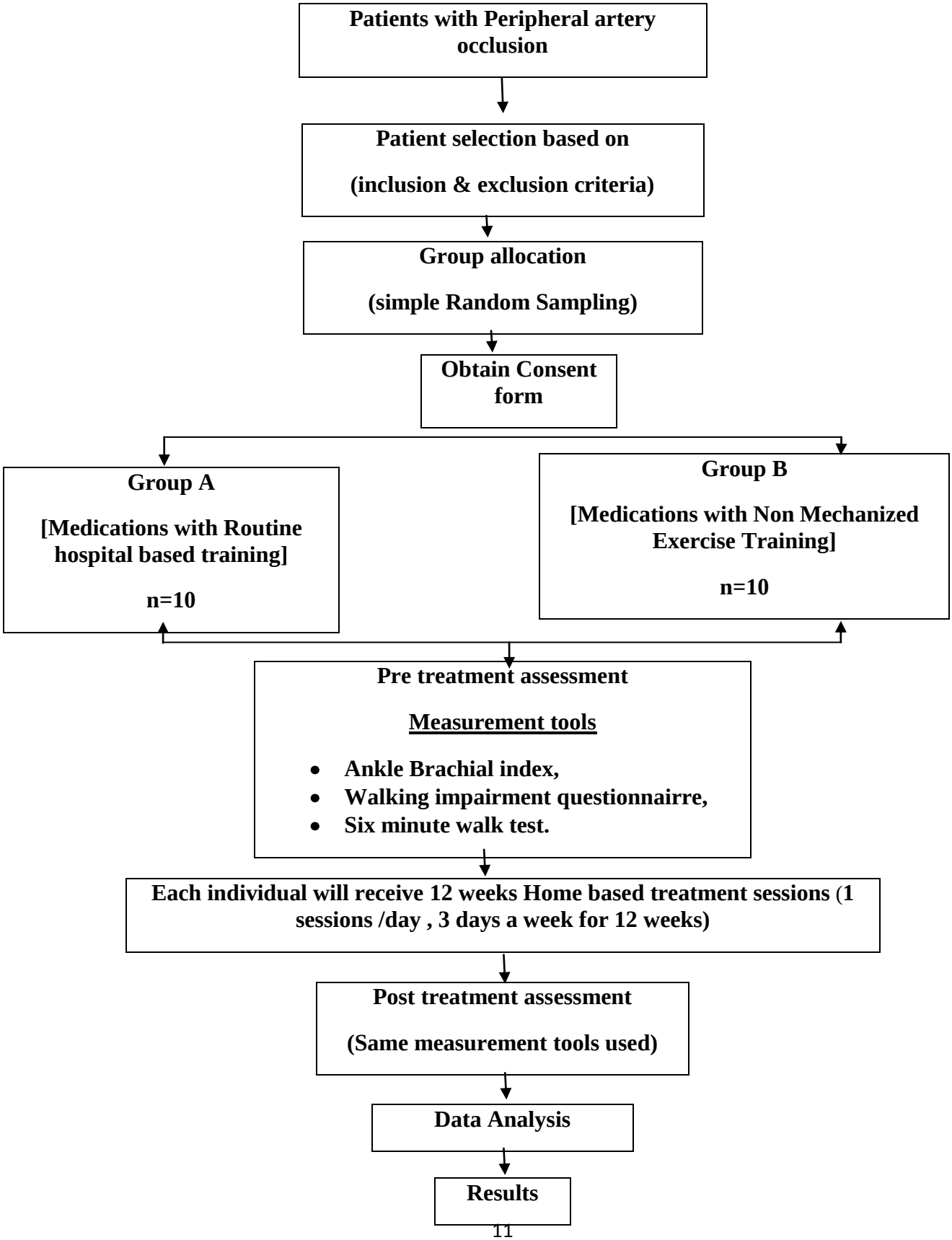
3.8.2 Exclusion Criteria

- History of exertional angina.
- Exercise tolerance limited by leg pain due to non-vascular origin (e.g. arthritis, orthopedic pain).
- Myocardial infarction with in the preceding 3 months.
- Surgery related to PAOD during the preceding 3 months.
- Lower extremity ulcers.

3.9 TECHNIQUE OF DATA COLLECTION

- In Group-A ABI, 6MWT distance and WIQ scores were measured before starting, the review was done on the 6^{th} week to follow up or any changes(improvement) clarification in the exercise programme and end of the 12^{th} week.
- In Group-B ABI, 6MWT distance and WIQ scores were measured before starting, the review was done on the 6^{th} week to follow up or any changes(improvement) clarification in the exercise programme and 6th week and end of the 12th week.
- Peripheral Artery occlusion classification was done using fontaine classification stage 2 & stage 3.
- Walking speed, and distance were measured using WIQ.

METHODOLOGY FLOW CHART



CHAPTER-IV

STATISTICAL ANALYSIS AND INTERPRETATION

A total of 20 patients were selected by Simple Random sampling method. 10 participants were randomly selected and assigned to Group-A and Group-B.

Group-A: 10 patients received medications along with routine management (conventional management)

Group-B: 10 patients received medications along with the non-mechanized exercise training that is structured.

The pre-test and post-test values were taken for interpretation of Degree of walking difficulty, Pain free walking distance and classification of artery occlusion with the WIQ, 6MWT pain free walking distance and ABI respectively. The mean, standard deviation and Paired 't' test is used to find out whether there is any significant difference between pre-test and post-test values within the groups.

Independent 't' test, mean difference values for ABI, 6MWT and WIQ of Group-A and Group-B were used to find out whether there is any significant difference between the two groups.

Paired 't' test

$$SD = \sqrt{\frac{\sum (d - \overline{d})^2}{n-1}}$$

$$t = \frac{\overline{d}\sqrt{n}}{SD}$$

$\overline{d}$ = Calculated Mean Difference of pretest & posttest values

SD = Standard Deviation

n = Number of samples

d = Difference b/w pretest & post test values

Independent 't' test:

$$t = \frac{|\overline{x}_1 - \overline{x}_2|}{SD\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

Where,

$$SD = \sqrt{\frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{n_1 + n_2 - 2}}$$

$\overline{X_1}$ = Mean difference in Group A

$\overline{X_2}$ = Mean difference in Group B

SD = Combined standard deviation of Group A and Group B

n_1 = Number of patients in Group A

n_2 = Number of patients in Group B

SD_1 = Standard Deviation of Group A

SD_2 = Standard Deviation of Group B

TABLE-1

PAIRED 't' TEST VALUES OF ANKLE BRACHIAL INDEX–GROUP A& GROUP B

(n=20)

Groups	Mean	Mean Difference	Standard Deviation	't' Value	'p' Value
Group A					
Pre-test	0.624	0.217	0.079	8.714	p<0.05
Post-test	0.841				
Group B					
Pre-test	0.633	0.308	0.096	10.145	p<0.05
Post-test	0.941				

Based on Table-1, the mean difference of Group-A is found to be 0.217, Standard deviation is 0.079, the 't' value using the paired 't' test is 8.714 which is greater than the table value of 2.262 at $p<0.05$. In Group-B the mean difference is 0.308, Standard deviation is 0.096, the 't' value using the paired 't' test is 10.145 which is greater than the table value of 2.262 at $p<0.05$. This shows there is a significant in ABI values in both groups. The result shows that pre-test and post-test mean difference of ABI values of Group-B is statistically significant than Group-A.

TABLE-2

PAIRED 't' TEST VALUES OF 6MWT (PAIN FREE WALKING DISTANCE) GROUP A & GROUP B

(n=20)

Groups	Mean	Mean Difference	Standard Deviation	't' Value	'p' Value
Group A					
Pre-test	130.50	60	41.633	4.557	$p<0.05$
Post-test	190.50				
Group B					
Pre-test	145.00	120.50	55.899	6.817	$p<0.05$
Post-test	265.50				

Based on Table-2, the mean difference of Group-A is found to be 60, Standard deviation is 41.633, the 't' value using the paired 't' test is 4.557 which is greater than the table value of 2.262 at $p>0.05$. In Group-B the mean difference is 120.50, Standard deviation is 55.899, the 't' value using the paired 't' test is 6.817 which is greater than the table value of 2.262 at $p<0.05$. This shows there is a significant improvement in Group-A & Group-B 6MWT Pain free walking distance. This result shows that pre-test and post-test mean difference of 6MWT Pain free walking distance of Group-B is statistically significant than Group-A.

TABLE-3

PAIRED 't' TEST VALUES OF WIQ SCORES- GROUP A & GROUP B

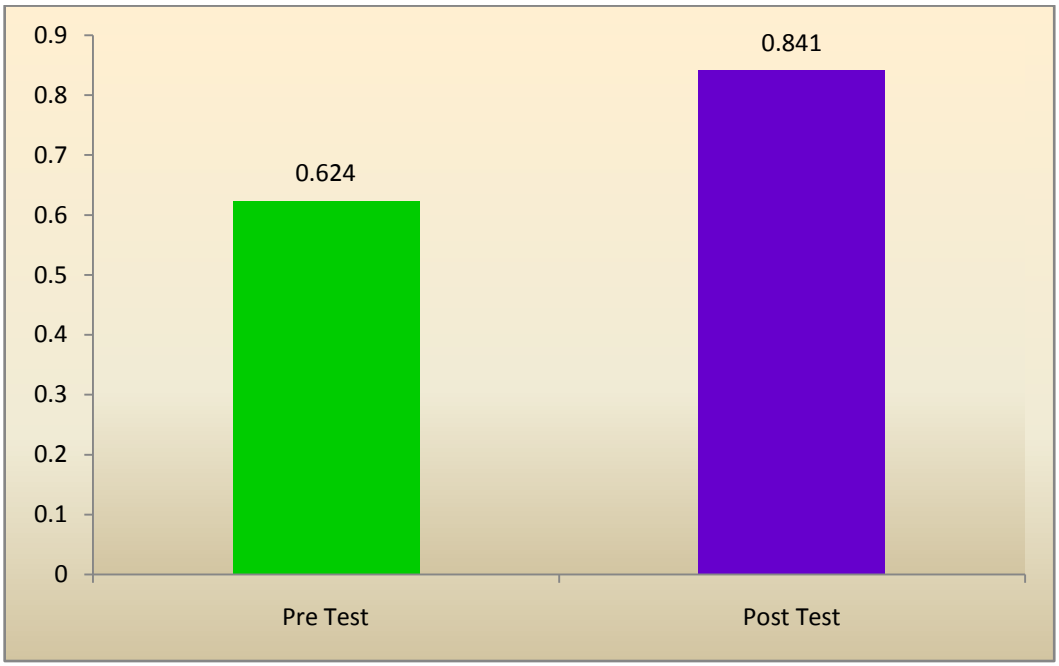
(n=20)

Groups	Mean	Mean Difference	Standard Deviation	't' Value	'p' Value
Group A					
Pre-test	24.30	6.2	3.583	7.235	$p<0.05$
Post-test	32.50				
Group B					
Pre-test	23.60	22.8	8.093	8.908	$p<0.05$
Post-test	46.40				

Based on Table 3, the mean difference of Group-A is found to be 6.2, Standard deviation is 3.583, the 't' value using the paired 't' test is 7.235 which is greater than the table value of 2.262 at $p<0.05$. In Group-B the mean difference is 22.8, Standard deviation is 8.093, the 't' value using the paired 't' test is 8.908 which is greater than the table value of 2.262 at $p<0.05$. This shows there is a significant improvement in WIQ scores in both groups. The result shows that pre-test and post-test mean difference of WIQ scores Group-B is statistically significant than Group-A.

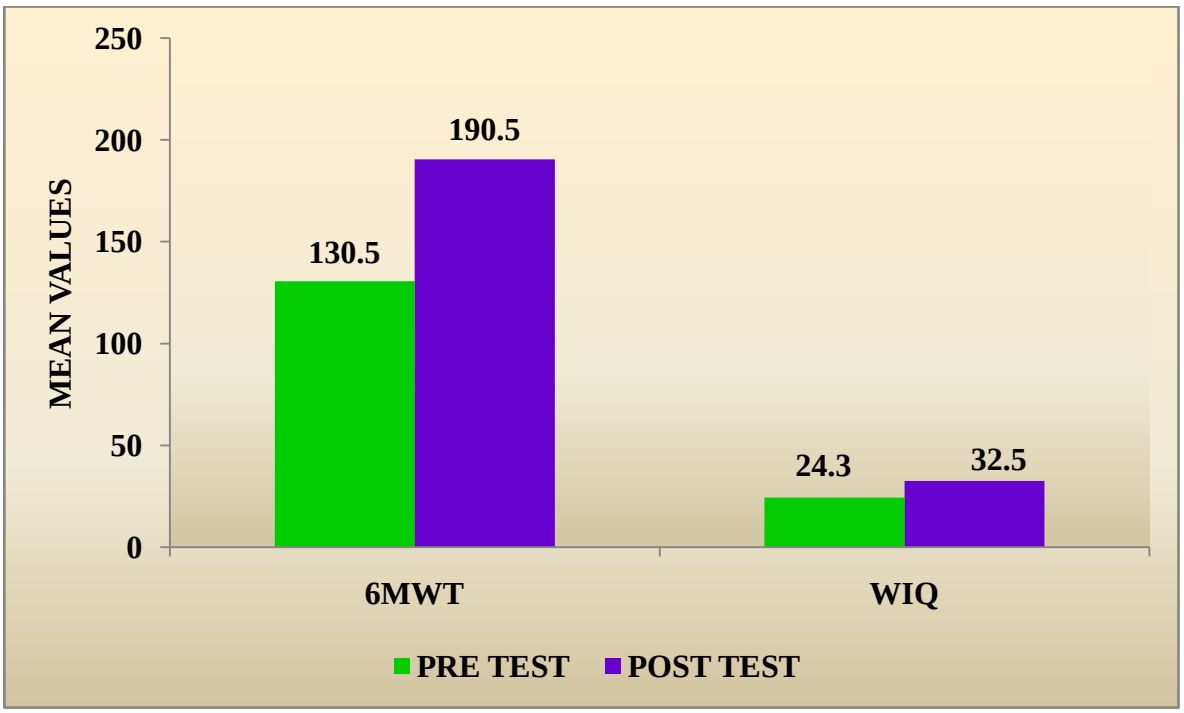
GRAPH-1

PRE TEST AND POST TEST MEAN VALUES FOR ABI OF GROUP A



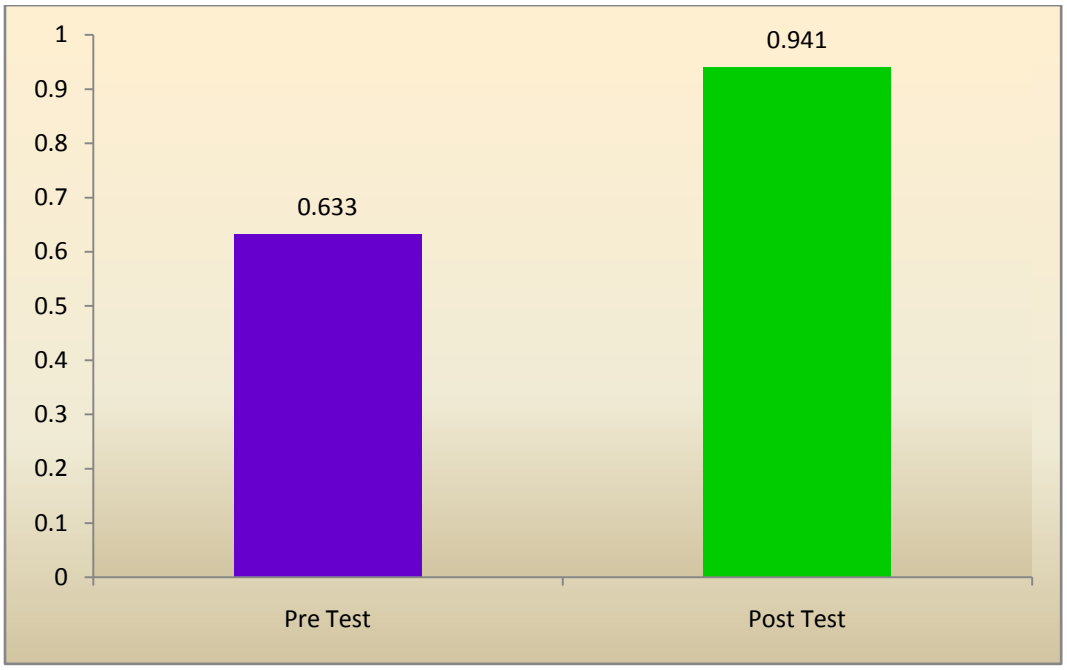
GRAPH-2

PRE TEST AND POST TEST MEAN VALUES FOR 6MWT (PAIN FREE WALKING DISTANCE)& WIQ OF GROUP A



GRAPH-3

PRE TEST AND POST TEST MEAN VALUES FOR ABI OF GROUP B



GRAPH-4

PRE TEST AND POST TEST MEAN VALUES FOR 6MWT (PAIN FREE WALKING DISTANCE) & WIQ OF GROUP B

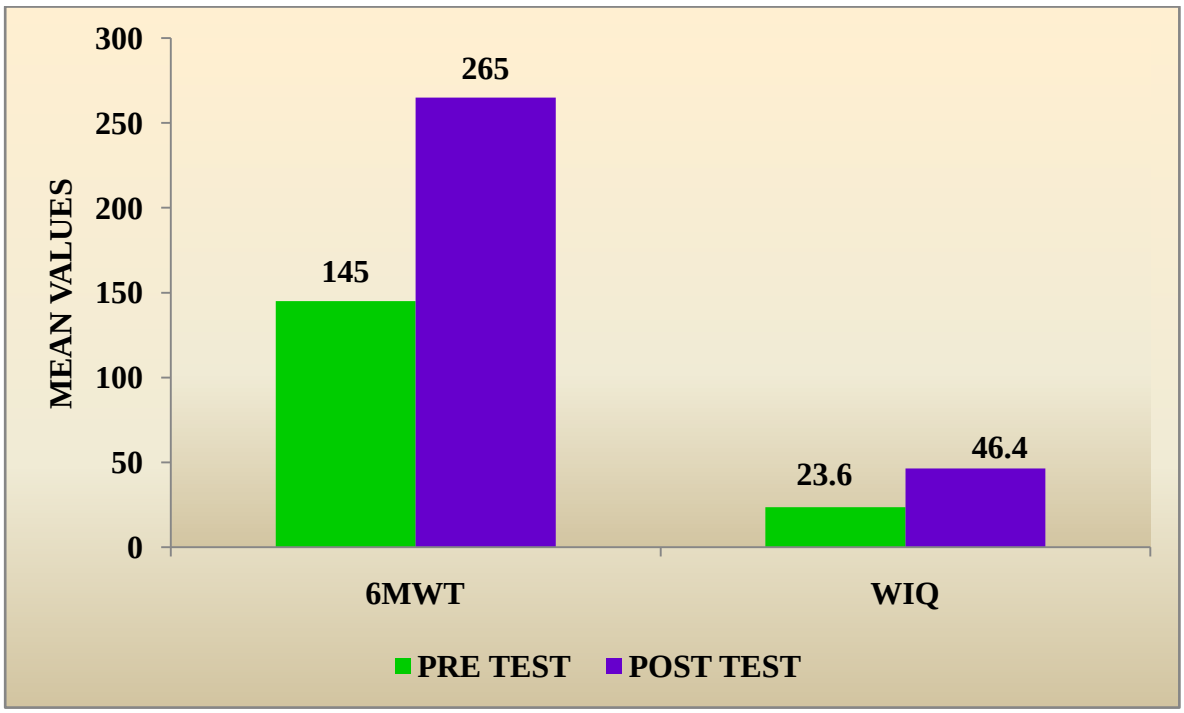


TABLE-4

INDEPENDENT ‘t’ TEST VALUES OF GROUP A & GROUP B

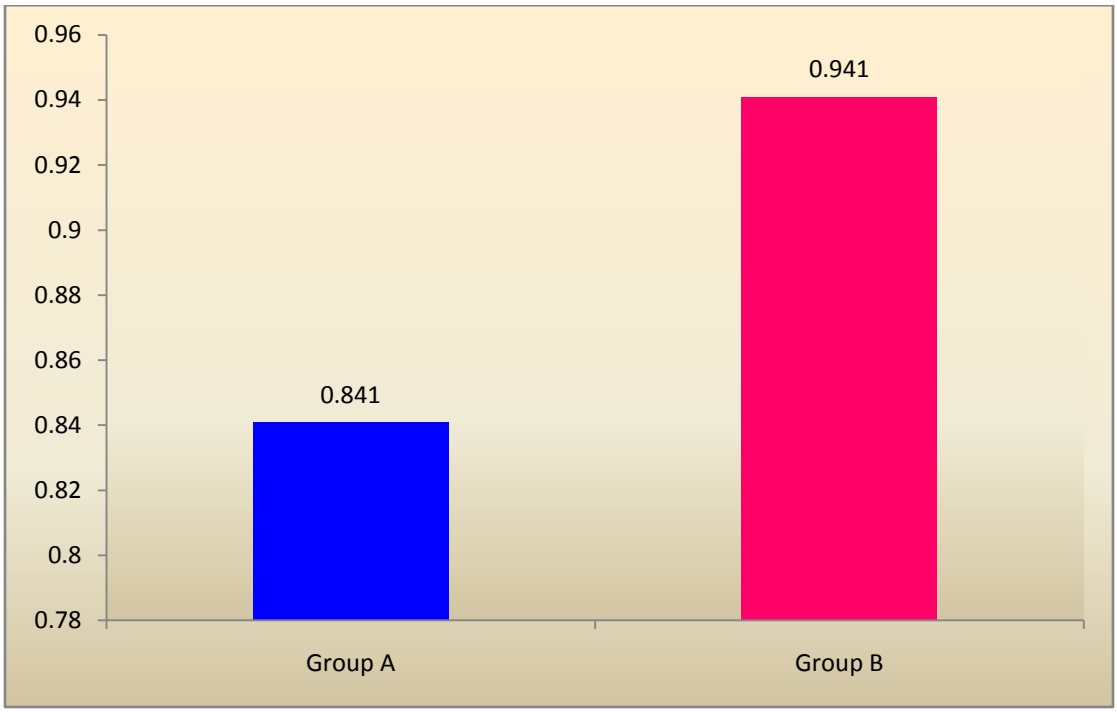
Outcome Measures		Mean	Mean Difference	Standard Deviation	‘t’ value	‘p’ value
ABI	A	0.841	1.00	0.027	7.368	p<0.05
	B	0.941				
6MWT	A	190.50	75.00	51.50	2.097	p>0.05
	B	265.50				
WIQ	A	32.50	13.90	5.378	5.284	p<0.05
	B	46.40				

The independent ‘t’ test is performed between the Group-A and Group-B to analyze the significance of routine management(conventional management) and non-mechanized exercise training on improving pain free walking distance in PAD patients.

For ABI, between the groups the calculated ‘t’ value is 7.368 which is greater than the table value of 2.101 at $p<0.05$. For 6 MWT pain free walking distance, between the groups the calculated ‘t’ value is 2.097 which is less than the table value of 2.101 at $p<0.05$. For WIQ, between the groups the calculated ‘t’ value is 5.284 which is greater than the table value of 2.101 at $p<0.05$. Therefore, the statistical analysis showed that there is a significant improvement in ABI& WIQ and statistically there is no significant improvement in 6 MWT pain free walking distance.

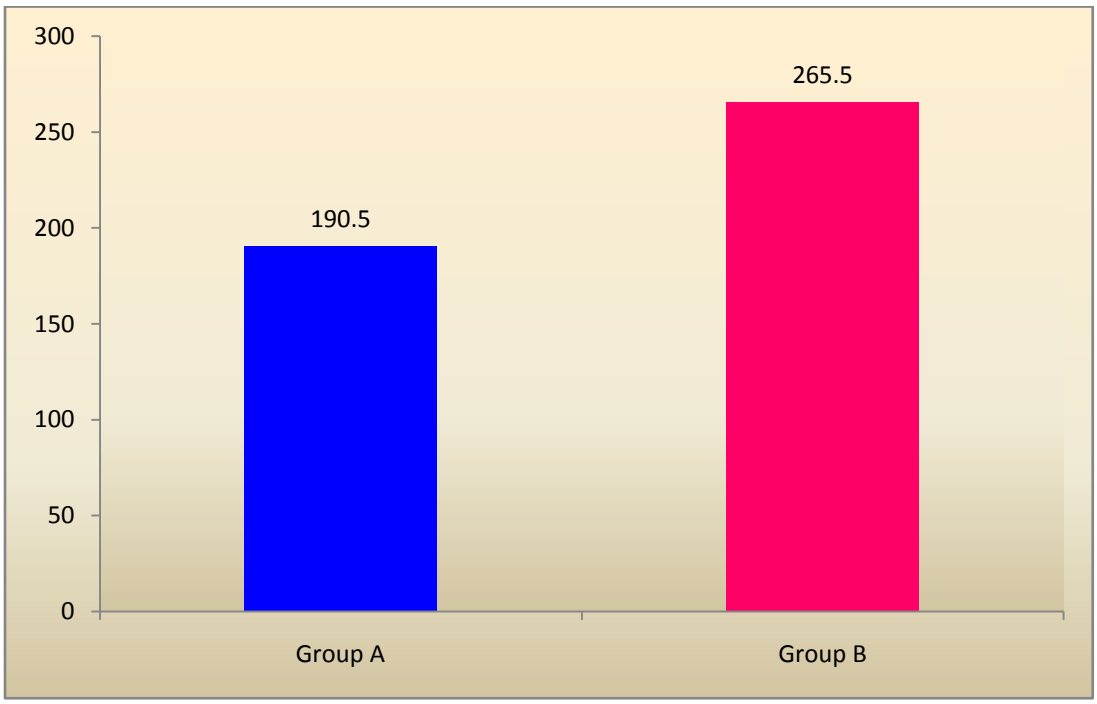
GRAPH-5

POST MEAN VALUES FOR ANKLE BRACHIAL INDEX OF GROUP A & GROUP B



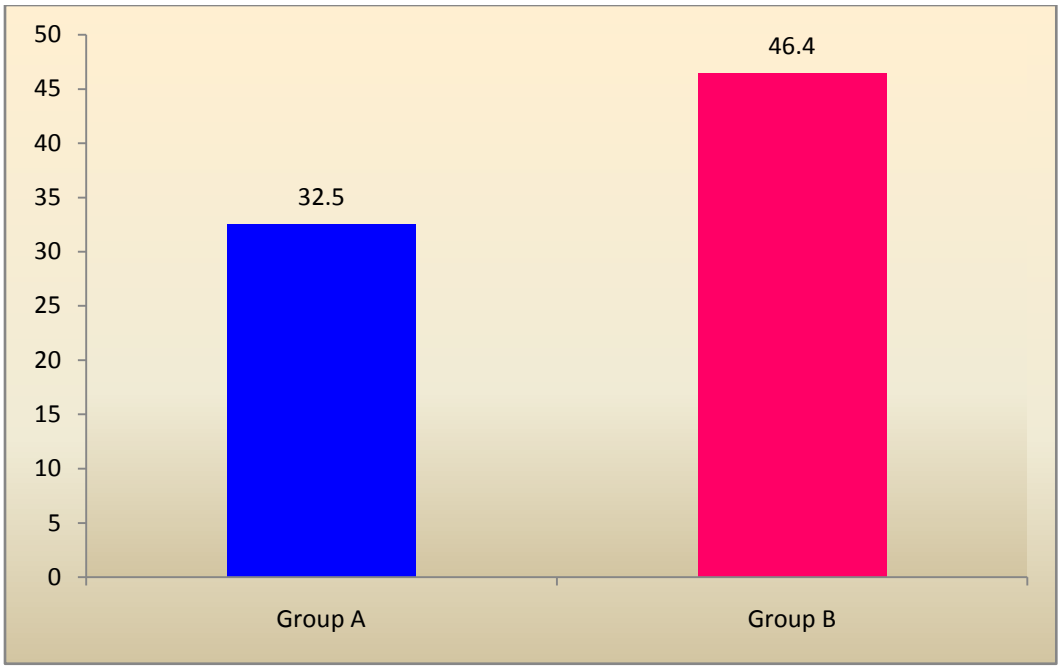
GRAPH-6

POST MEAN VALUES FOR 6 MWT (PAIN FREE WALKING DISTANCE) OF GROUP A & GROUP B



GRAPH-7

POST MEAN VALUES FOR WIQ OF GROUP A & GROUP B



CHAPTER-V

RESULTS AND DISCUSSION

Patients with IC have an impact on their walking ability that may limit their function to meet the personal or social demands of daily living.In our study the aim is to improve the pain free walking distance in patients with PAD.

Andrew C Bulmer et. al, (2004) Since 1960's numerous studies have identified training induced performance effects in patients with PAD and have progressed from using traditional walking training.

A total of 20 participants in age group of 40 to 65 years of PAD was taken for this study. The participants were randomly assigned into two groups. Measurements were taken at base line using Ankle Brachial Index, Walking Impairment Questionnaire for degree of difficulty in walking, Six Minute walk test for calculating the pain free walking distance and total distance.

Casillas Jm et al., (2011) 6MWT is an equally important diagnostic tool evaluating the capacity of peripheral arteries in the lower extremities rehabilitation in patients with peripheral artery disease.

In WIQ, it measures walking distance, speed, and stair climbing.Group-A received medications along with routine management (conventional management) Group-B received medications along with non-mechanized exercise training programme which is structured.

J.c.tsai et.al suggested that two different mechanisms appear to explain the exercise mediated in walking function. improvements in walking economy and calf perfusion are two mechanism that act synergistically to relieve claudication by decreasing the metabolic demands of walking and increasing oxygen delivery.

Paired t test values for ankle brachial index, the mean difference of Group-A is found to be 0.217, Standard deviation is 0.079, the 't' value using the paired 't' test is 8.714 which is greater than the table value of 2.262 at $p<0.05$. In Group-B the mean difference is 0.308, Standard deviation is 0.096, the 't' value using the paired 't' test is 10.145 which is greater

than the table value of 2.262 at $p<0.05$. This shows there is significant in Ankle brachial index values in both groups. The result shows that pre-test and post-test mean difference of Ankle brachial index values of Group-B is statistically significant than Group-A. In 6 MWT Pain free walking distance the mean difference of Group-A is found to be 60, Standard deviation is 41.633, the 't' value using the paired 't' test is 4.557 which is greater than the table value of 2.262 at $p>0.05$. In Group-B the mean difference is 120.50, Standard deviation is 55.89, the 't' value using the paired 't' test is 6.817 which is greater than the table value of 2.262 at $p<0.05$. This shows there is significant improvement in 6MWT pain free walking distance in Group-A &Group-B. This result shows that pre-test and post-test mean difference of 6MWT pain free walking distance of Group-B is statistically significant than Group-A. In WIQ the mean difference of Group-A is found to be 6.2, Standard deviation is 3.583, the 't' value using the paired 't' test is 7.235 which is greater than the table value of 2.262 at $p<0.05$. In Group-B the mean difference is 22.8, Standard deviation is 8.093, the 't' value using the paired 't' test is 8.908 which is greater than the table value of 2.262 at $p<0.05$. This shows there is significant improvement in WIQ scores in both groups. The result shows that pretest and posttest mean difference of WIQ scores Group-B is statistically significant than Group-A.

The independent 't' test is performed between Group-A and Group-B to analyze the significance of routine management (conventional management) and non-mechanized exercise training on improving pain free walking distance in PAD patients. For ABI, between the groups the calculated 't' value is 7.368 which is greater than the table value of 2.101 at $p<0.05$. For 6 MWT pain free walking distance, between the groups the calculated 't' value is 2.097 which is less than the table value of 2.101 at $p<0.05$. For WIQ, between the groups the calculated 't' value is 5.284 which is greater than the table value of 2.101 at $p<0.05$. Therefore the statistical analysis showed that there is a significant improvement in ABI, WIQ and there is no significant improvement in 6 MWT pain free walking distance.

Judith G. Regensteiner et.al (2002) states that walking ability can be reduced due to patients did not change their medication use or smoking status during the course of the study.

Some patients are mostly depressed due to prolonged duration of the intolerable claudication pain it forces the person to stop walking.

Exercise training health related quality of life as assessed by medical outcome SF-36. We are not assessed psychological aspect of the patient. It may interfere with walking. For 6 MWT pain free walking distance there is significant improvement in total distance. participants did not understand the claudication pain or could not tell the therapist during walking.Due to lack of communication, we can assess the individual difference because some participants did not have smoking history, dyslipidemia and hypertension.

Mc.dermott.et.al (1999)stated that previous studies of patients with IC have shown inconsistent results regarding the ability of ABI.

From my study there is a difficulty with the participants those who are illiterate were not clearly understood the clear pathology of the disease and exercise effects.

Schefifler et.al suggested that supervised exercise training in treadmill increase pain free walking distance which improves walking ability over the 4^{th} week. In future the study can be done with 4 weeks of duration to see the immediate effects of non mechanized exercise training under supervision.

In my study majority of patients were 45-55 years and male : female ratios were approximately 9:1 . one explanation for this discrepancy in male : female ratios may be higher prevalence rates for PAD in men with symptomatic claudication more likely to obtain medical attention than woman.

There is statistically significant improvement in ABI and WIQ when comparing two groups and there is no significant changes in 6MWT pain free walking distance in patients with peripheral artery occlusion following Non-mechanized exercise training than conventional training.

5.1 LIMITATIONS

- Very Small sample size based on low outpatients census during the period of the study.
- There is a difficulty with the participants those who are illiterate were not clearly understood the clear pathology of the disease and exercise effects.
- Many participants were prone to peripheral artery surgery for immediate pain relief because some patient may had poor pain tolerance.
- Male: female ratio is 9: 1. Variations may be interfering with the effect of the study, may be higher prevalence rate for PAD in men when compare to female.
- Patients with risk factors like diabetic, dyslipidemia and hypertension are also included in this study.

5.2 RECOMMENDATIONS

- Large sample size can be taken for the effectiveness of the study.
- The study can be done with bilateral PAD patients to assess the degree of difficulty
- The study could be segregated with either superficial femoral or popliteal artery occlusion to assess the percentage of the artery occlusion.
- We advise the exercise protocols for the PAD related risk factors for the preventive measures.
- In future we can correlate the different age groups of the patients with PAD.
- In future we can see the individual difference for the study.
- In this study we are not included the intermediate test values for statistical analysis. We can include the intermediate test for the statistical analysis.

CHAPTER-VI

SUMMARY AND CONCLUSION

This study is conducted to analyses the effects of Non-mechanized exercise training to improve pain free walking distance in patients with peripheral artery occlusion in home-based patients. Thus, the statistical analysis of data concluded that

"There is statistically significant improvement in ABI and WIQ when comparing two groups and there is no significant changes in 6MWT pain free walking distance in patients with peripheral artery occlusion following Non-mechanized exercise training than conventional training."

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ANNEXURE I

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee
Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Ms M Suganya
I Year MPT
Guide/s: Mr R Mahesh / Mr M Mahendiran
PSG College of Physiotherapy
Coimbatore

Ref: Project No.17/219

Date: September 8, 2017

Dear Ms Suganya,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 11.07.2017 to conduct the research study entitled *"Non mechanized exercise training to improve pain free walking distance in patients with peripheral artery occlusion"* during the IHEC meeting held on 21.07.2017.

The following documents were reviewed and approved:

1. Project submission form
2. Study protocol (Version 2 dated 25.08.2017)
3. Informed consent forms (Version 2 dated 25.08.2017)
4. Data collection tool (Version 2 dated 07.09.2017)
5. Permission letter from concerned Head of the Department
6. Current CVs of Principal investigator, Co-investigator
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 21.07.2017 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Mr R Nandakumar (Chairperson, IHEC)	BA., BL	Legal Expert	Male	No	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Dr S Shanthakumari	MD	Pathology	Female	Yes	Yes
4	Dr Sudha Ramalingam	MD	Epidemiologist Alt. member-Secretary	Female	Yes	Yes
5	Dr D Vijaya	M Sc., Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
   a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
   c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
   d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
   e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
   f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,

SECRETARY
PSG IMS&R
COIMBATORE-641004.
INSTITUTIONAL HUMAN ETHICS COMMITTEE

Dr Sudha Ramalingam
Alternate Member - Secretary
Institutional Human Ethics Committee

ANNEXURE II

Assessment Form

DEMOGRAPHIC DATA

Name : OP No :

Age : Address :

Gender : Date :

Phone /Mobile No :

Referred by :

PATIENT HISTORY

Peripheral artery occlusion : Unilateral/bilateral :

Fontine stage classification :

Chief complaints:

History of present illness:

1. Cough
2. Sputum
3. Dyspnea
4. Hemoptysis

Past medical history:

Surgical history:

Personal History:

1. Smoking
   - Duration :
   - Pack years :
2. Alcoholic
   - Duration :
3. Tobacco Chewing

Family History:

Drug history:

Risk factors:

Occupational History:

History of Living Environment:

Previous Functional Status:

Pain History

Side :
Site :
Onset :
Duration :
Type :
Aggravating factors :
Relieving factors :
Intensity :

Vital signs

Temperature :
Heart rate :
Blood pressure :
Respiratory rate :
Sao_2 :

OBJECTIVE EXAMINATION

ON OBSERVATION

Built :
Attitude of limbs :
Gait :
Pressure sore :
Tropical changes :
Clubbing :
Cyanosis :
Chest wall deformity :
Breathing pattern :

Posture :
Muscle wasting :
Edema :
External appliances :

ON PALPATION

Palpation of pulses :
Tone :
Edema :

Tenderness :
Warmth :

ON EXAMINATION

1. HIGHER MENTAL FUNCTION

Level of consciousness

Orientation

- Person :
- Place :
- Time :
- Immediate :

Memory

- Recent :
- Remote :

Attention :
Communication :
Emotional status :

2. RANGE OF MOTION FOR LOWER LIMBS

	RIGHT	LEFT
Hip: Flexion Extension Abduction Adduction External rotation Internal rotation		
Knee: Flexion Extension		
Ankle: Dorsi flexion Plantar flexion Inversion Eversion		

3.MUSCLE POWER FOR LOWER LIMBS

	RIGHT	LEFT
Hip: Flexors Extensors Abductors Adductors External rotators Internal rotators		
Knee: Flexors Extensors		
Ankle: Dorsi flexors Plantar flexors Invertors Evertors		

4. INTEGUMENTARY

1.Skin Color

2. Skin Texture

5.CARDIO PULMONARY

1. Cough
2. Sputum
3. Clubbing
4. Cyanosis
5. Edema

SENSORY INTEGRITY

Superficial :

Deep :

GAIT

ASSISTIVE DEVICES

FUNCTIONAL STATUS

Bed mobility :

Transfer :

ADL :

AUSCULTATION

Breath sounds :

Added sounds :

Vocal sounds :

Heart sounds :

INVESTIGATIONS AND FINDINGS

MEDICAL DIAGNOSIS

PHYSICAL THERAPY DIAGNOSIS

Direct impairments

Indirect impairments

Functional limitations

PHYSIOTHERAPY MANAGEMENT

Aims:

Means:

Signature of the Principal Investigator

FOLLOW UP FORM

Patient name: O.P.NO:

Age: Contact No:

Sex: Date of 1st assessment:

Occupation: Date of follow up:

Address:

Diagnosis:

Grading:

Vitals: BP: mmHg HR: bpm RR: bpm Temperature: deg C

OUTCOME MEASUREMENTS:

S.NO	OUTCOME MEASURES	SCORES		
		Pre Test	**6 th Week**	**Post Test (12th Week)**
1.	Ankle Brachial Index			
2.	6 Minute Walk Test			
3.	Walking Impairment Questionnaire			

Signature of the Primary Investigator

ANNEXURE – III

PSG Institute of Medical Science and Research, Coimbatore
Institutional Human Ethics Committee

INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS

I SUGANYA.M, am carrying out a study on the topic: **"Non-mechanized Exercise Training to improve pain free walking distance in patients with Peripheral Artery Occlusion",** as part of my research project being carried out under the aegis of the Departments of cardio thoracic and vascular surgery.

My research guide is: Prof. Mahesh, MPT (Cardio Respiratory)

The justification for this study is:
Peripheral artery occlusion leads to pain in the calf muscle and walking disability. So non-mechanized exercise training can improve peripheral blood circulation, pain free walking distance and activities of daily living in patients with peripheral artery occlusion.

The objectives of this study:
To find out the effect of non-mechanized exercise training to improve pain free walking distance in patients with peripheral artery occlusion.
Sample size: 20

Study volunteers / participants are peripheral artery occlusion patients, age group above 40 to 65 years
Location: Department of Cardio Thoracic and vascular surgery, PSG IMS&R Hospitals.
We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Initial interview: 20-30 minutes.
Final interview: 30 minutes.

Health Education: YES.

Clinical examination (specify details purpose)**: YES**
Blood sample collection: Specify quantity of blood being drawn: _____ml. **NOT APPLICABLE**

No. of times it will be collected: _____. **NOT APPLICABLE**

Whether blood sample collection is part of routine procedure or for research (study) purpose:

1. Routine procedure 2. Research purpose **NOT APPLICABLE**

Specify **purpose**, discomfort likely to be felt and side effects, if any: _____**NOT APPLICABLE** _____

Whether blood sample collected will be stored after study period: Yes / No, it will be destroyed **NOT APPLICABLE**

Whether blood sample collected will be sold: Yes / No **NOT APPLICABLE**

Whether blood sample collected will be shared with persons from another institution: Yes / No **NOT APPLICABLE**

Medication given, if any, duration, side effects, purpose, benefits: **NOT APPLICABLE**

Whether medication given is part of routine procedure: Yes / No (If not, state reasons for giving this medication) **NOT APPLICABLE**

Whether alternatives are available for medication given: Yes / No (If not, state reasons for giving this medication) **NOT APPLICABLE**

If **photograph t**aken, purpose: **yes,** without revealing the identity of yours we want to publish it in the project book, conferences and journals.

Data collected will be stored for a period of **5** years. We **will not use** the data as part of another study.

Benefits from this study: Performing non-mechanized exercises can reduce the pain in the calf muscle which improves the peripheral blood circulation and thereby it improves the walking distance.

Risks involved by participating in this study: There are no possible risks or discomforts will be experienced during this study. Patients should take the medications properly at time. If the patient feels any discomfort during exercise they can take rest for 10 to 15 minutes and continue the exercise.

How the **results** will be used:
Peer-reviewed scientific journals,
Conference presentation
Internal report
The data collected during the study will be used without revealing your identity. Your identity will be confidential even if the results of the study are published.
If you are uncomfortable in answering any of our questions during the course of the interview, **you have the right to withdraw from the interview / study at anytime.** You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered nor would it attract any penalty. You will continue to have access to the regular services offered to a patient. You will **NOT**

be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings - including adverse events, if any, – whether directly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation.

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date: Witness:

Contact number of PI: 8220838169

பூ சா கோ மருத்துவக் கல்லூரி மற்றும் ஆராய்ச்சி நிறுவனம், கோவை

மனித நெறிமுறைக் குழு

ஒப்புதல் படிவம்

தேதி:

மு. சுகன்யா, ஆகிய நான் பூ சா கோ மருத்துவக் கல்லூரியின் / மருத்துவமனையின் இயன்முறை மருத்துவத் துறையின் கீழ், **"இயந்திர உதவியின்றி, இரத்த நாள அடைப்பு நோய் உள்ளவர்களுக்கு ஐசோடோனிக் பயிற்சியினால் வலியின்றி நடக்கும் தூரத்தை அதிகப் படுத்துதல்"** என்ற தலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வு வழிகாட்டி: திரு. ரா. மகேஷ், முதல்வர், பூ சா கோ இயன்முறை மருத்துவக் கல்லூரி

ஆய்வு மேற்கொள்வதற்கான அடிப்படை:

இரத்த நாள அடைப்பு நோய் ஏற்படுவதால் கெண்டைக் கால் தசையில் வலி மற்றும் நடக்க இயலாமை ஏற்படுகிறது. இதனால் அன்றாட வாழ்வில் நடைமுறை சார்ந்த செயல்கள் குறைகிறது. இந்த ஆய்வில் இயந்திர உதவியின்றி, தசைகளை பலப்படுத்தும் பயிற்சி மற்றும் நடைப்பயிற்சிகளின் மூலம் கெண்டைக் கால் வலியினை குறைத்து, வலியின்றி நடக்கும் தூரத்தை அதிகரிக்க முயற்சிக்கப்படுகிறது

ஆய்வின் நோக்கம்:

1. கெண்டைக்கால் வலியைக் குறைத்தல்.
2. நடைப்பயிற்சியினால், வெளிப்புறத் தசைக்களுக்கு செல்லும் இரத்த ஓட்டத்தை அதிகரித்தல்.
3. அன்றாட செயல்பாடுகளை அதிகரித்தல்

ஆய்வில் பங்கு பெறும் நபர்களின் எண்ணிக்கை: 20

ஆய்வில் பங்கு பெறுவோர் மற்றும் வயது: 40 - 65 வயதுள்ள இரத்தக்குழாய் அடைப்பு நோய் உள்ளவர்கள்.

ஆய்வு மேற்கொள்ளும் இடம்: இருதய அறுவைச் சிகிச்சை மற்றும் இரத்த நாளத் துறை, பூ சா கோ மருத்துவமனை, கோயம்புத்தூர்.

இந்த ஆய்வில் எங்களுடன் ஒத்துழைக்குமாறு கேட்டுக்கொள்கிறோம். நாங்கள் சில தகவல்களை இந்த ஆய்விற்காக சேகரிக்க உள்ளோம்.

ஆய்வு செய்யப்படும் முறை:

இந்த ஆய்வின் மொத்த கால அளவு 8 மாதங்கள். இந்த ஆய்வில் இரத்த குழாய் அடைப்பினால் நடைத்திறன் குறைவாக உள்ள 20 நபர்களில் 10 நபர்களைக் கொண்ட இரு குழுக்களாகப் பிரித்துக் கொள்ளப்படும்.

முதல் வருகையின் போது ஒவ்வொருவரின் இரத்தக்குழாய் அடைப்பினால், வலுக் குறைந்த நடக்க இயலாமைக்கான கேள்வித்தாளை (Walking Impairment Questionnaire) என்ற படிவத்தின் உதவியுடன் அளந்து கொள்ளப்படும் பின்னர் (Amkle Brachial Index) கணுக்கால் புய குறியீடு முறையின் மூலம் நாடியழுத்த மானியினால் (Sphygmomanometer) அளந்து கொள்ளப்படும்.

பிறகு 6 நிமிட நடை ஆய்வு (6 minutes walk test) மூலம் எவ்வளவு தூரம் வலியின்றி நடக்கும் தூரத்தை அளந்து கொள்ள வேண்டும். 12 வாரங்கள் அவர்களுக்கு, தயார் நிலைக்கான பயிற்சிகள் (warm up Exercise) தசைகளை வலுப்படுத்தும் பயிற்சிகள் (Muscle Strengthening Exercise) தளர்வு நிலைப் பயிற்சிகள் (Cool Down Exercise) நடைப்பயிற்சிகள் (Walking Exercise) ஆகியுவைகளை உள்ளடக்கிய துண்டுப் பிரசுரம் (Phamplet) அளிக்கப்படும்.

பின்னர் 12 வாரங்களுக்கு பிறகு, வலுக்குறைந்த நடக்க இயலாமைக்கான கேள்விப்படிவம் (walking Impairment Questionnaire) கணுக்கால் புய குறியீடு (Ankle Brachial Index) 6 நிமிட நடை ஆய்வு (6 minutes walk test) ஆகியவைகள் அளவிடப்படும்.

முதன்மை நேர்காணல்: 20-30 நிமிடங்கள்

முடிவு நேர்காணல்: 30 நிமிடங்கள்

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் **5 வருடங்கள்** பாதுகாக்கப்படும். இந்த தகவல்கள் வேறு ஆய்விற்குப் **பயன்படுத்தப் பட மாட்டாது.**

சுகாதாரக் கல்வி: அமர்வுகள்: **1** முறை, **12** வாரங்கள், வீட்டிலிருந்தே பயிற்சிகளை கடைப்பிடிக்க வேண்டும்.

மருத்துவ பரிசோதனைகள்: உண்டு

இரத்த மாதிரி சேகரிப்பு: இல்லை

இரத்த மாதிரி எடுப்பது வழக்கமான சிகிச்சைக்காகவோ அல்லது இந்த ஆய்விற்காகவோ:

பொருந்தாது

இதனால் ஏற்படக் கூடிய அசௌகரியங்கள் / பக்க விளைவுகள்: பொருந்தாது

இரத்த மாதிரிகள் ஆய்விற்குப் பின் பாதுகாத்து வைக்கப்படுமா? ஆம் / இல்லை, அழிக்கப்படும்: **பொருந்தாது**

சேகரிக்கப்பட்ட இரத்தம் விற்கப்படுமா? ஆம் / இல்லை **பொருந்தாது**

சேகரிக்கப்பட்ட இரத்தம் வேறு நிறுவனத்துடன் பகிர்ந்து கொள்ளப்படுமா? ஆம் / இல்லை: **பொருந்தாது**

மருந்துகள் ஏதேனும் கொடுக்கப்படவிருந்தால் அவை பற்றிய விவரம் (கொடுக்கப்படும் காரணம், காலம், பக்க விளைவுகள், பயன்கள்): **பொருந்தாது**

மருந்துகள் கொடுக்கப்படுவது வழக்கமான சிகிச்சை முறையா?: ஆம் / இல்லை (இல்லை என்றால் கொடுக்கப்படும் காரணம்) **பொருந்தாது**

கொடுக்கப்படும் மருந்துகளுக்கு மாற்று உள்ளதா?: ஆம் / இல்லை (ஆம் என்றால் இந்த குறிப்பிட்ட மருந்து கொடுக்கப்படும் காரணம்) **பொருந்தாது**

ஆய்வில் பங்குபெறுவதால் ஏற்படும் பலன்கள்:

1. கெண்டைக்கால் வலி குறையும்.
2. வலுக் குறைவினால் நடக்க இயலாமையை நடைப்பயிற்சி செய்வதால் இரத்த ஓட்டம் அதிகரித்து, நடக்கும் தூரம் அதிகமாகும்.

ஆய்வில் பங்கேற்பதால் ஏற்படும் அசௌகரியங்கள் / பக்க விளைவுகள்: இந்த ஆய்வினால் தங்களுக்கு எந்த விதமான அபாயங்களும் அசௌகரியங்களும் ஏற்படாது. சரியான நேரத்தில் மருந்துகளை உட்கொள்ள வேண்டும். பயிற்சியின் போது ஏதெனும் அசௌகரியங்கள் ஏற்பட்டால் பயிற்சியை 10-20 நிமிடங்கள் நிறுத்திவிட்டு சிறிது நேர ஓய்விற்கு பின் தொடரலாம்.

ஆய்வின் முடிவுகள் எந்த முறையில் பயன்படுத்தப்படும்?

அகநிலை அறிக்கை, கலந்தாய்வுகளில் சமர்ப்பிப்பு, உணர்வு ஆற்றல், பத்திரிக்கைகள் ஆய்வில் சார்ந்த ஆராய்ச்சி பத்திரிக்கைகள்.

இந்த ஆய்வின் கேள்விகளுக்கு பதிலளிப்பதோ, இரத்த மாதிரிகள் அல்லது திசு மாதிரிகள் எடுப்பதிலோ உங்களுக்கு ஏதேனும் அசௌகரியங்கள் இருந்தால், எந்த நேரத்தில் வேண்டுமானாலும்

ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சை முறையில் எந்த வித பாதிப்பும் இருக்காது என்று உங்களுக்கு உறுதியளிக்கிறோம். மருத்துவ மனையில் நோயாளிகளுக்கு அளிக்கப்படும் சேவைகளை நீங்கள் தொடர்ந்து பெறலாம். இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்ளுவதால் வேறு எந்த விதமான கூடுதலான பலனும் உங்களுக்குக் கிடைக்காது. நீங்கள் அளிக்கும் தகவல்கள் இரகசியமாக வைக்கப்படும். ஆய்வில் பங்கேற்பவர்கள் பற்றியோ அவர்கள் குடும்பத்தைப் பற்றியோ எந்தத் தகவலும் எக்காரணம் கொண்டும் வெளியிடப்படாது என்று உறுதியளிக்கிறோம். நீங்கள் அளிக்கும் தகவல்கள் / இரத்த மாதிரிகள் / திசு மாதிரிகள் அங்கீகரிக்கப்பட்ட ஆய்விற்கு மட்டுமே பயன்படுத்தப்படும். இந்த ஆய்வு நடைபெறும் காலத்தில் குறிப்பிடத்தகுந்த புதிய கண்டுபிடிப்புகள் அல்லது பக்க விளைவுகள் ஏதும் ஏற்பட்டால் உங்களுக்குத் தெரிவிக்கப்படும். இதனால் ஆய்வில் தொடர்ந்து பங்கு பெறுவது பற்றிய உங்கள் நிலைப்பாட்டை நீங்கள் தெரிவிக்க ஏதுவாகும்.

ஆய்வுக்குட்படுபவரின் ஒப்புதல்: இந்த ஆய்வைப் பற்றிய மேற்கூறிய தகவல்களை நான் படித்து அறிந்து கொண்டேன் / ஆய்வாளர் படிக்கக் கேட்டுத் தெரிந்து கொண்டேன். ஆய்வினைப் பற்றி நன்றாகப் புரிந்து கொண்டு இந்த ஆய்வில் பங்கு பெற ஒப்புக்கொள்கிறேன். இந்த ஆய்வில் பங்கேற்பதற்கான எனது ஒப்புதலை கீழே கையொப்பமிட்டு, கை ரேகை பதித்து நான் தெரிவித்துக் கொள்கிறேன்.

பங்கேற்பாளரின் பெயர், முகவரி:

பங்கேற்பாளரின் கையொப்பம் / கை ரேகை / சட்டப்பூர்வ பிரதிநிதியின் கையொப்பம்:

தேதி :

ஆய்வாளரின் கையொப்பம்:
தேதி :

ஆய்வாளரின் தொலைபேசி எண்: 8220838169
மனித நெறிமுறைக் குழு அலுவலகத்தின் தொலைபேசி எண்: 0422-4345818

ANNEXURE – IV

OUTCOME MEASURES

CARDIAC STUDY CENTER, INC., P.S.

Tacoma (253) 572-7320
Puyallup (253) 841-4347
Lakewood (253) 588-7778
Gig Harbor (253) 851-0404
Covington (253) 630-3300

Walking Impairment Questionnaire (WIQ)

Patient Name_____ Date of Birth_____

Walking Impairment: These questions ask about the reasons why you are having difficulty walking. We would like to know how much difficulty you had walking during the past week. By difficulty, we mean how hard it was or how much physical effort it took to walk because of each of these problems.

Peripheral Arterial Disease (PAD) Specific Questions

		Degree of Difficulty				
		None	Slight	Some	Much	Very
Pain, aching or cramps in your calves or buttocks?	Right Leg	4	3	2	1	0
	Left Leg	4	3	2	1	0
	Both Legs	4	3	2	1	0

Differential Diagnosis

	Degree of Difficulty				
	None	Slight	Some	Much	Very
1. Pain, stiffness or aching in your joints (ankles, knees or hips)?	4	3	2	1	0
2. Weakness in one or both of your legs?	4	3	2	1	0
3. Pain or discomfort in your chest?	4	3	2	1	0
4. Shortness of breath?	4	3	2	1	0
5. Heart palpitations?	4	3	2	1	0
6. Other problems (please list)	4	3	2	1	0

Walking Distance: Report the degree of physical difficulty that best describes how hard it was for you to walk on level ground without stopping to rest for each of the following distances during the last week.

Distance

	Degree of Difficulty				
	None	Slight	Some	Much	Very
1. Walking indoors such as around your home?	4	3	2	1	0
2. Walking 50 feet?	4	3	2	1	0
3. Walking 150 feet (1/2 block)?	4	3	2	1	0
4. Walking 300 feet (1 block)?	4	3	2	1	0
5. Walking 600 feet (2 blocks)?	4	3	2	1	0
6. Walking 900 feet (3 blocks)?	4	3	2	1	0
7. Walking 1500 feet (5 blocks)?	4	3	2	1	0

Walking Speed: Report the degree of difficulty that best describes how hard it was for you to walk one city block on level ground at each of these speeds without stopping to rest during the last week.

Speed

	Degree of Difficulty				
	None	Slight	Some	Much	Very
1. Walking one block slowly?	4	3	2	1	0
2. Walking one block at an average speed?	4	3	2	1	0
3. Walking one block quickly?	4	3	2	1	0
4. Walking or jogging one block?	4	3	2	1	0

Stair Climbing: For each of these questions, report the degree of physical difficulty that best describes how hard it was for you to climb stairs without stopping to rest during the past week.

Stairs

	Degree of Difficulty				
	None	Slight	Some	Much	Very
1. Climbing one flight of stairs?	4	3	2	1	0
2. Climbing two flights of stairs?	4	3	2	1	0
3. Climbing three flights of stairs?	4	3	2	1	0

3/22/07 kk - New Pt

WALKING IMPAIRMENT QUESTIONNAIRE

The WIQ measures walking distance, walking speed and stair climbing in the community. For walking distance, the participant ranks his or her degree of difficulty walking specific distances on a 0 to 4 Likert scale, where 0 represents inability to walk the distance and 4 represents no difficulty. Distances range from walking indoors around the home to walking five blocks (1,500 feet). For walking speed, the participant ranks the degree of difficulty walking slowly, at average speed, quickly, or running or jogging one block .In the stair climbing component, patients rank their ability to walk up and down one, two or three flights of stairs respectively.

SCORING THE WALKING IMPAIRMENT QUESTIONNAIRE

In the stair climbing component, each distance expressed as "feet" is multiplied by the Likert score selected for that distance. Products are summed and divided by the maximum possible score to obtain the percentage score. similar percentage scores are obtained for the walking speed and stair climbing WIQ components. For the walking speed component, each speed is given a "weight," ranging from 1 mile per hour to 5 miles per hour, which is multiplied by the Likert scale response. In the stair climbing component each stair climbing category is weighted according to the number of stairs in each category.

ANKLE-BRACHIAL INDEX

A Diagnostic Tool for Peripheral Arterial Disease

Step-by-step instructions on how to perform and interpret the ABI

ABI:

The ankle-brachial index (ABI) is a simple, noninvasive tool used to screen for peripheral arterial disease (PAD), a vascular condition affecting more than 8 million adult Americans and associated with significant morbidity and mortality. Despite its prevalence and cardiovascular risk implications, only 25% of PAD patients are undergoing treatment. As only about 10% of patients with PAD present with classic claudication-40% of patients are asymptomatic clinicians need to have a high level of suspicion for this disease in their adult patient population. According to AHA/ACC guidelines, an ABI should be conducted on patients presenting with risk factors for PAD so that therapeutic interventions known to diminish their increased risk of myocardial infarction (MI), stroke, and death may be offered.

Risk Factors for PAD

- Age >70 years
- Age >50 years if atherosclerosis risk
    - ✓ Smoking
    - ✓ Diabetes
    - ✓ Hypertension
    - ✓ Dyslipidemia
    - ✓ Hyperhomocysteinemia

Tools Needed for Measuring ABI

- Sphygmomanometer with appropriately sized cuff(s) for both arm and ankle
- Handheld Doppler device with vascular probe
- Conductivity gel compatible with the Doppler device

How to perform the ABI

Measurement of the ABI can be easily performed in a clinician's office using a blood pressure (BP) cuff and handheld Doppler device with a vascular probe. Systolic BP is determined in both arms and both ankles. An ABI measurement can usually be performed in less than 10 minutes.

Step 1: Measure the brachial systolic pressure in both arms:

- Allow patient to rest for 5-10 minutes in the supine position.
- Place the BP cuff on patient's upper arm with the lower edge approximately 1 inch above the antecubital fossa.
- Palpate for the brachial pulse and apply conductivity gel over the brachial artery. Place the tip of the probe into the gel at a 45-60-degree angle until clear arterial pulse sounds are heard.
- Inflate the cuff to the point that pulse sounds disappear, then go 20 mm Hg above that point. Slowly deflate at a rate of 2 mm Hg per sec and record the point where arterial pulse sounds resume. This is the brachial systolic pressure.
- Repeat this procedure in the other arm.
- The higher of the two brachial systolic pressure readings will be used to calculate the ABI. There should be a difference of a less than 10mm Hg. Between each brachial BP.

Step 2: Measure the posterior tibial and dorsalis pedis systolic pressures in both legs:

- Place the BP cuff on the patient's leg approximately 2 inches above the ankle's medial malleolus.
- Locate the posterior tibial (PT) pulse, apply gel, and position the Doppler probe. Measure the systolic pressure following the same procedure described for the brachial artery.
- On the same leg, locate the dorsalis pedis (DP) pulse and measure systolic pressure.
- Repeat measurement of both the PT and DP systolic pressures on the other leg.
- Select the higher of the two ankle readings for each leg (PT or DP). These numbers will serve as the ankle systolic pressures in the ABI calculation.
- If either the PT or DP ankle pulse is absent, use the measurable reading to calculate the ABI.

Step 3: To calculate the ABI, divide each ankle systolic pressure by the brachial systolic pressure.

- Divide the higher of the two systolic pressures for each leg by the higher of the two arm pressures to get the right and left ABI.
- For example, consider the results at the right. The ABI for this patient is calculated by using 130 (the higher of the two brachial pressures) as the denominator and 95 and 130 as the numerators for the right and left legs, respectively. The ABI for the right leg is 0.73 and for the left leg is 1.0.

ABI RESULTS

SYSTOLIC PRESSURE	RIGHT	LEFT
Brachial	130	129
Posterior Tibial	95	120
Dorsalis Pedis	90	130
ABI= Ankle systolic/brachial systolic		
	95/130	130/130
ABI	0.73	1.0

ABI Key

Normal: 1.0 - 1.1

Borderline: 0.91 - 0.99

Abnormal: <0.9 or >1.3

How to interpret the ABI

An abnormal ABI may be an independent predictor of mortality, as it reflects the burden of atherosclerosis. Most will agree that a normal ABI is >0.9. An ABI <0.9 suggests significant narrowing of one or more blood vessels in the leg. The majority of patients with claudication have ABIs ranging from 0.3 to 0.9. Rest pain or severe occlusive disease typically occurs with an ABI <0.5. ABIs <0.2 are associated with ischemic or gangrenous extremities. Conditions such as diabetes mellitus or end stage-renal disease can give falsely elevated ABIs (1.3-1.5). The ABI test approaches 95% accuracy in detecting PAD. However, a normal ABI value does not absolutely rule out the possibility of PAD. Some patients with normal or near-normal ABI results may have symptoms suggesting PAD. If the resting ABI is normal, an exercise ABI should be conducted.

Six-minute walk test

Each patient was administered 6 min walk test pain free walking distance measurements were taken thrice within 12 weeks. Two cones were placed 30 meters apart in a marked corridor. Patients were instructed to walk as many laps around the cones as possible and to inform the therapist when the claudication occurred. patients were permitted to stop walking during the test if their claudication becomes intolerable, but the time continued to run during the period. Patients who stopped walking because of claudication pain were encouraged to continue walking as soon as possible. The therapist recorded the total distance walked and calculate the pain free walking distance.

SIX MINUTE WALK TEST ASSESSMENT SHEET

Patient Name: Date :

Age/ Sex : OP No :

Diagnosis :

Total distance walked :

Pain free walking distance :

Claudication Pain begins :

Therapist Signature:

ANNEXURE – V

TREATMENT PROTOCOL

GROUP A- MEDICATIONS ALONG WITH ROUTINE MANAGEMENT (CONVENTIONAL MANAGEMENT):

1. Medications along with deep breathing Exercise.
2. Active Range of motion exercise to lower limbs.
3. General Walking
4. Do's and Don's advised.

Group B:

Exercise Instructions:

1. Record your heart rate while exercising

2. Gradually increase the intensity and duration of exercise

3.Exercise which includes (warm up, isotonic exercises, walking program, cool down)

4. Exercise should be stop when if you feel discomfort or any these problems (breathing difficulty, chest pain, palpitation ,leg pain ,excessive sweating, giddiness)

Precaution[13]:

1.Avoid restrictive clothing which may interfere with the circulation. eg. tight belts.

2.Stop Smoking and alcoholic or reduce as much as possible.

3. Avoid prolonged standing.

4. Avoid exposure to excessive heat or cold or take care with the application of heat. eg. hot water bottles.

5. A gradual return to normal function and increasing the amount of physical activity.

Exercise prescription:

Endurance training:

Frequency : 1 hour per day, 3days per week for 12 weeks
Intensity : Based on the karvonen formula
Duration : walking as per chart.
Type : Aerobic Exercise (Ground walking).

Resistance training:

Frequency : 1 hour per day, 3days per week for 12 weeks
Intensity : Based on the RM (Repetition maximum).
Duration : 30 to 60 minutes.
Type : Isotonic Exercise.

Example training heart rate zone

For example, 25 year old male who has resting heart rate of 65, want to know his resting heart rate for the intensity level 60% to 70%.

His Minimum Heart Rate:

220-25(age) =195

195-65(Resting Heart Rate)=130

130*0.60(Minimum Intensity)+65(Resting Heart Rate)=143 Beats/Minute

His Maximum Heart Rate:

220-25(age)=195

195-65(Resting Heart Rate)=130

130*0.70(Minimum Intensity)+65(Resting Heart Rate)=156 Beats/Minute

His training heart rate zone will therefore be 143-156 beats per minute.

Repetition Maximum Calculation For Lower Body

= (4-6Rm * 1.097 03) + 14.2546

According to Epley formula=1 RM=w (1+r/30) r>1

Training Programs[1]:

Frequency of training:

A training frequency increases to 3 days per week for 12 weeks.

Duration of training:

Training session duration has varied from 10 to 60 minutes.

Work to rest ratios :

Patients with PAD engage in intermittent training where patients walk encounter ,stop to rest and once claudication pain subsides, resume walking.

Resistance Training[1]:

Exercise training began with 5 minutes of warm up and 5 minutes of cool down. Subjects to train for 60 minutes, three times a week for 12 weeks. subjects performed concentric contractions of five different muscle groups in legs at a resistance that caused fatigue after six contractions muscles including the gastrocnemius, tibialis anterior, quadriceps femoris, hamstrings and gluteus maximus were trained in this manner. The resistance to the muscle contraction was applied by attaching weight cuffs using sand to appropriate location on the leg. A six repetition maximum was assessed every 2 weeks and training intensity was altered accordingly by increasing the resistance.

Isotonic exercise :

Type Of Exercise: Isotonic Exercises.

Equipment : ½ Kg Sand Bags For 2weeks.

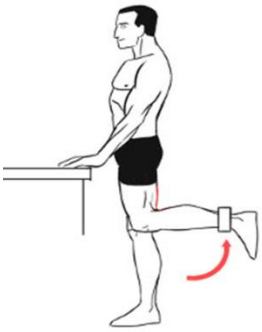
Progression: It depends on the Repetition Maximum 12 weeks after target 6 to 8 Repetitions.

1.Target Muscle:Gluteus Maximus

Action : Hip Extension

2.Target Muscle :Hamstring

Action : Knee Flexion

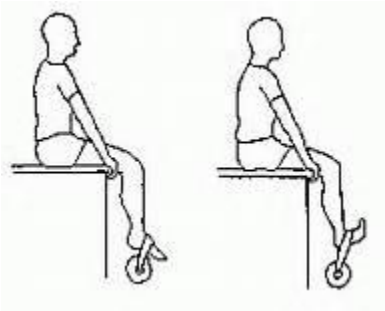


.**3.Target Muscle** : Quadriceps

Action : Extension of the knee joint.

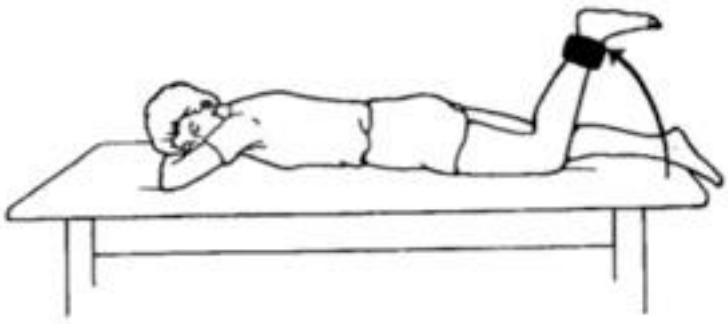
4. Target Muscle : Tibialis anterior

Action :Dorsi flexion and inversion of the ankle.



5.Target Muscle : Gastronemius

Action : Flexion of the knee joint& Plantar flexion at the ankle joint.



. **Walking program[8] :**

The walking time started with 20 minutes in the first two weeks of the program. After two weeks, It increased by 5 minutes biweekly. In the last two weeks of the study, the walking time was 40-45 minutes.

Weeks	Warm up	Walking	Cool Down
week 1	5 minutes	20 minutes	5 minutes
week 2	5 minutes	20 minutes	5 minutes
week 3	5 minutes	25 minutes	5 minutes
week 4	5 minutes	25 minutes	5 minutes
week 5	5 minutes	30 minutes	5 minutes
week 6	5 minutes	30 minutes	5 minutes
week 7	5 minutes	35 minutes	5 minutes
week 8	5 minutes	35 minutes	5 minutes
week 9	5 minutes	40 minutes	5 minutes
week 10	5 minutes	40 minutes	5 minutes
week 11	5 minutes	45 minutes	5 minutes
week 12	5 minutes	45 minutes	5 minutes

ANNEXURE – VI

PRE TEST AND POST TEST VALUES FOR ABI IN GROUP-A - (n=10)

S.NO	ABI PRE TEST	ABI POST TEST
1.	0.54	0.83
2.	0.50	0.86
3.	0.61	0.81
4.	0.66	0.80
5.	0.69	0.84
6.	0.58	0.88
7.	0.60	0.80
8.	0.59	0.83
9.	0.70	0.87
10.	0.77	0.89

PRE TEST AND POST TEST VALUES FOR ABI IN GROUP-B - (n=10)

S.NO	ABI PRE TEST	ABI POST TEST
1.	0.55	0.94
2.	0.50	0.99
3.	0.62	0.91
4.	0.67	0.93
5.	0.70	0.90
6.	0.59	0.95
7.	0.61	0.96
8.	0.60	0.92
9.	0.71	0.97
10.	0.78	0.94

PRE TEST AND POST TEST VALUES FOR 6MWT PAIN FREE WALKING DISTANCE IN GROUP-A

(n=10)

S.NO	6MWT PRE TEST	6MWT POST TEST
1.	70	120
2.	120	165
3.	125	195
4.	240	255
5.	130	210
6.	95	90
7.	100	210
8.	105	240
9.	150	210
10.	170	210

*6MWT Distance calculated in Percentage

PRE TEST AND POST TEST VALUES FOR 6MWT PIN FREE WALKING DISTANCE IN GROUP-B

(n=10)

S.NO	6MWT PRE TEST	6MWT POST TEST
1.	240	390
2.	155	335
3.	100	210
4.	45	125
5.	210	390
6.	220	285
7.	125	270
8.	105	240
9.	160	315
10.	90	95

*6MWT Distance calculated in Percentage

PRE TEST AND POST TEST VALUES FOR WIQ IN GROUP-A (n=10)

S.NO	WIQ SCORE PRE TEST	WIQ SCORE POST TEST
1.	26	32
2.	25	31
3.	30	41
4.	21	26
5.	19	21
6.	15	28
7.	32	40
8.	25	33
9.	25	35
10.	25	38

PRE TEST AND POST TEST VALUES FOR WIQ IN GROUP-B -(n=10)

S. NO	WIQ SCORE PRE TEST	WIQ SCORE POST TEST
1.	22	46
2.	13	39
3.	15	45
4.	29	53
5.	21	52
6.	27	44
7.	31	50
8.	23	43
9.	21	53
10.	34	39

ABSTRACT

NON-MECHANIZED EXERCISE TRAINING TO IMPROVE PAIN FREE WALKING DISTANCE IN PATIENTS WITH PERIPHERAL ARTERY OCCLUSION

BACKGROUND Peripheral arterial disease (PAD) is most commonly defined as gradual obstruction of arteries leading to impaired blood flow. The prevalence of PAD increase with aging, in general population it accounts for 12% to 14 % affecting up to 25% of subjects over 75 years. Intermittent claudication is the pain in lower limbs during walking, which forces the person to stop walking. Superficial femoral and popliteal arteries are most commonly affected by atherosclerosis. It is associated with increased mortality, major limitations in mobility, physical conditioning and decreased quality of life. Non-mechanized exercise training is a form of exercise programme without using any mechanical equipments helping to improve blood flow in the peripheral arteries of the lower extremities.

Objective: To find out the effects of non-mechanized exercise training in improving pain free walking distance in patients with peripheral artery occlusion.

Design: Pre- test-Post- test Quasi experimental study design.

Setting: Department of Cardio thoracic and Vascular Surgery, P.S.G hospitals, Coimbatore.

Participants:

Group-A: 10 patients received medications along with routine management (conventional management)

Group-B: 10 patients received medications along with the non-mechanized exercise training that is structured.

Intervention:

Group-A: medications with active exercise 10 repetitions per day, 3 days for week for continued for 12 weeks.

Group-B: medications with non-mechanized exercise training for 10 repetitions per day, 3 days for week for continued for 12 weeks.

Outcome Measures: Ankle Brachial Index.(ABI).
Six Minute Walk Test (6MWT).
Walking Impairment Questionnaire (WIQ).

Results: All participants in Group-A and Group-B showed significant improvement in ABI scores with a mean difference of 0.207 and 0.308 respectively. The calculated 't' value using the paired 't' test for Group A 8.714 which was greater than the table value of 2.262 at $p<0.05$ and B were 10.145 ($p<0.05$) respectively. In 6MWT distance Group-A and Group-B showed significant improvement with a mean difference of 60 and 120.50 respectively. The calculated 't' value using the paired 't' test for Group-A and B were 4.557 and 6.817 ($p<0.05$) respectively. In WIQ scores Group-A and Group-B showed significant improvement with a mean difference of 6.2 and 22.8 respectively. The calculated 't' value using the paired 't' test for group A and B were 7.235 and 8.908 ($p<0.05$) respectively. When comparing between the groups using independent 't' test, the ABI scores showed mean difference of 1.00 and 't' value of 7.368 ($p<0.05$) ,6MWT distance showed mean difference of 75.00 and 't' value of 2.097 ($p>0.05$) and WIQ scores showed mean difference of 13.90 and 't' value of 5.284 ($p<0.05$).

Conclusion: There was statistically significant improvement in ABI and WIQ. when comparing two groups there was no significant changes in 6MWT pain free walking distance in patients with peripheral artery occlusion following Non-mechanized exercise training than conventional training.

Keywords: Ankle Brachial Index, Walking Impairment Questionnaire, Peripheral Artery Disease, Six Minute Walk Test