Cover Page

Official Title of the study: Effect of Aerobic Interval Training Versus Resistance Interval Training on Ejection Fraction in Post Stable Myocardial Infarction Patients

ClinicalTrials.gov Identifier: NCT03708484

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DESIGN: Randomized Control Trail

DATA COLLECTION PROCEDURE:

After screening of more than 50 MI patients 26 stable post MI patients both males and females on the basis of inclusion and exclusion criteria were enrolled. After enrollment final step for inclusion in study was 6 minute walk test. All patients performed treadmill 6 minute walk test. Patients that successfully completed initial 3 min of walk test were included in the study. Informed consent was signed by all patients as an agreement to participate in research. Total patients at end of study was 26 with drop outs of 4 .After enrollment in study 1st day was pre assessment day.1st step was selection in either control or experimental group. Lottery method was used for random allocation of patients. Self structured questionnaire was filled that included demographics, patient past medical, surgical, drug history, comorbidites, risk stratification. Basic baseline evaluation was done that included ECG, urea, creatinine, lipid profile. Pre echocardiography of all patients was done Pre MAC New QLMI was filled by examiner herself. After completion of all pre assessment exercise session of the patient was started from next session. Total weeks of treatment session were 6. Exercise was performed 3 times a week on alternating days. Total days of exercise were 18. Before treatment session proper warm up for 15 minutes was done Pre vitals including heart rate, BP, Respiratory rate, SpO2 was recorded. Karvonens formula was used to calculate 60-80% of target heart rate in all patients .The goal of exercise was to reach target heart rate. Emergency trolley consisting of major life saving drugs was available that included (Angisid, Injection Atropine, Adrenaline, Heparin, Lignocaine, Streptokinase, Nitroglycin, Normal Saline, Glucose) plus examiner was qualified in ACLS. Patient speed was increased gradually from first to six weeks depending on each patient target heart rate. Likewise weight in quadriceps resistive exercise and hand grippers were increased gradually with number of repetitions remaining same. Rating of perceived exertion and fatigue scale was used to mark patient dyspnea and fatigue level. Patients in control group were given standard aerobic interval treatment while patient in experimental group was given aerobic plus resistance interval treatment. During session continuous vital monitoring was done using saturation probe and cardiac monitor. After completion of session post vitals HR, BP, RR, Spo2 RPE and fatigue Cool down exercises were performed to stabilize patient. After completion of total 6 weeks of intervention patients post tests were done that included Echocardiography, lipid profile post and Mac New QLMI.

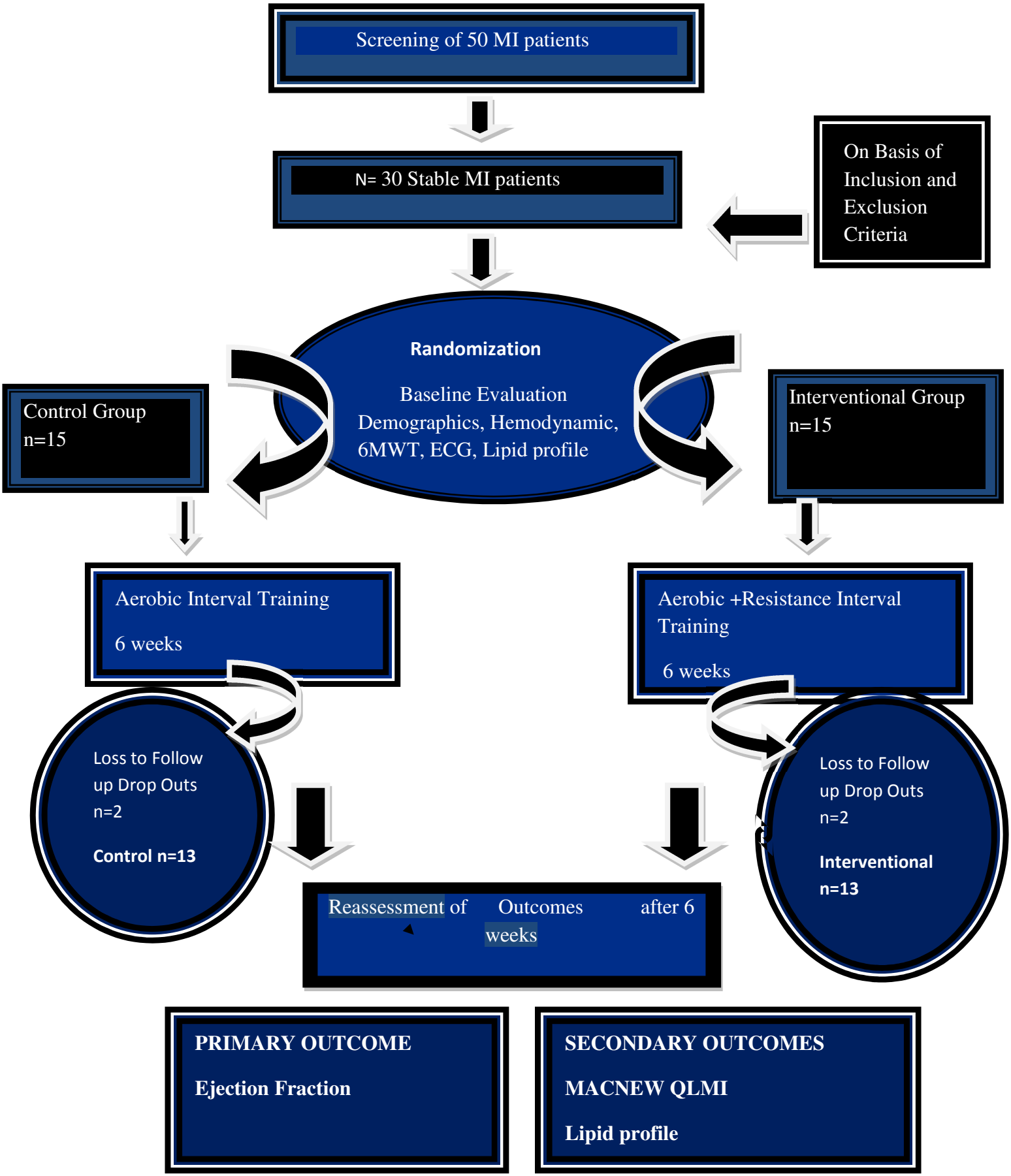

Figure 2: Flow chart showing Data collection procedure

TREATMENT PROTOCOL:

Patients in both group received standard treatment that is Aerobic Interval training whereas patients in interventional group was given Resistance Interval Training as well.

Before initiation of treatment protocol vitals (HR, BP, RR and SPO2) will be recorded. Treatment of both groups will start with 3-5 minutes of warm up that includes breathing exercises and stretching of major large muscles. Exercise will be performed at 60-80 % of intensity calculated by karvonen formula. Throughout training monitoring will be done.

CONTROL GROUP:

Patients in control group will perform 6 minutes of cycling followed by 3 minutes of pause and again 6 minutes of cycling followed by 3 minutes of pause and finally 6 minutes of treadmill followed by 3 minutes of rest.

INTEREVNTIONAL GROUP:

Patients in Interventional group in first set will perform 3 minute of cycling ,1 set of hand grippers 1.5 to 2.5 lbs (10 to 12 reps) and 1 set of biceps resistive exercises 1 Kg to 3 kg (10 to 12 reps) followed by 3minute of pause. In second set patient will perform 3 minutes of stationary cycling , 1 set of quadriceps resistive exercises 1 to 3 Kg (10 to 12 reps) again followed by 3 minutes of pause and in third set patient will perform 3 minutes of treadmill walk at 1.5 to 4 speed, and 1 set of standing ankle pumps (10 to 12 reps).

Patients in both groups will perform cool down exercises that include again breathing exercises, stretching and active exercises. Post exercise vitals will be recorded in both groups.

Figure 3**:** Patient performing treadmill as a part of treatment protocol

DATA ANALYSIS PROCEDURE:

All the patients were assessed at the baseline before the intervention and at the completion of the study. Data was analyzed by using IBM SPSS 21 (Statistical Package for Social Sciences) and expressed in the form of tables and graphs.

CURVES OF NORMALITY

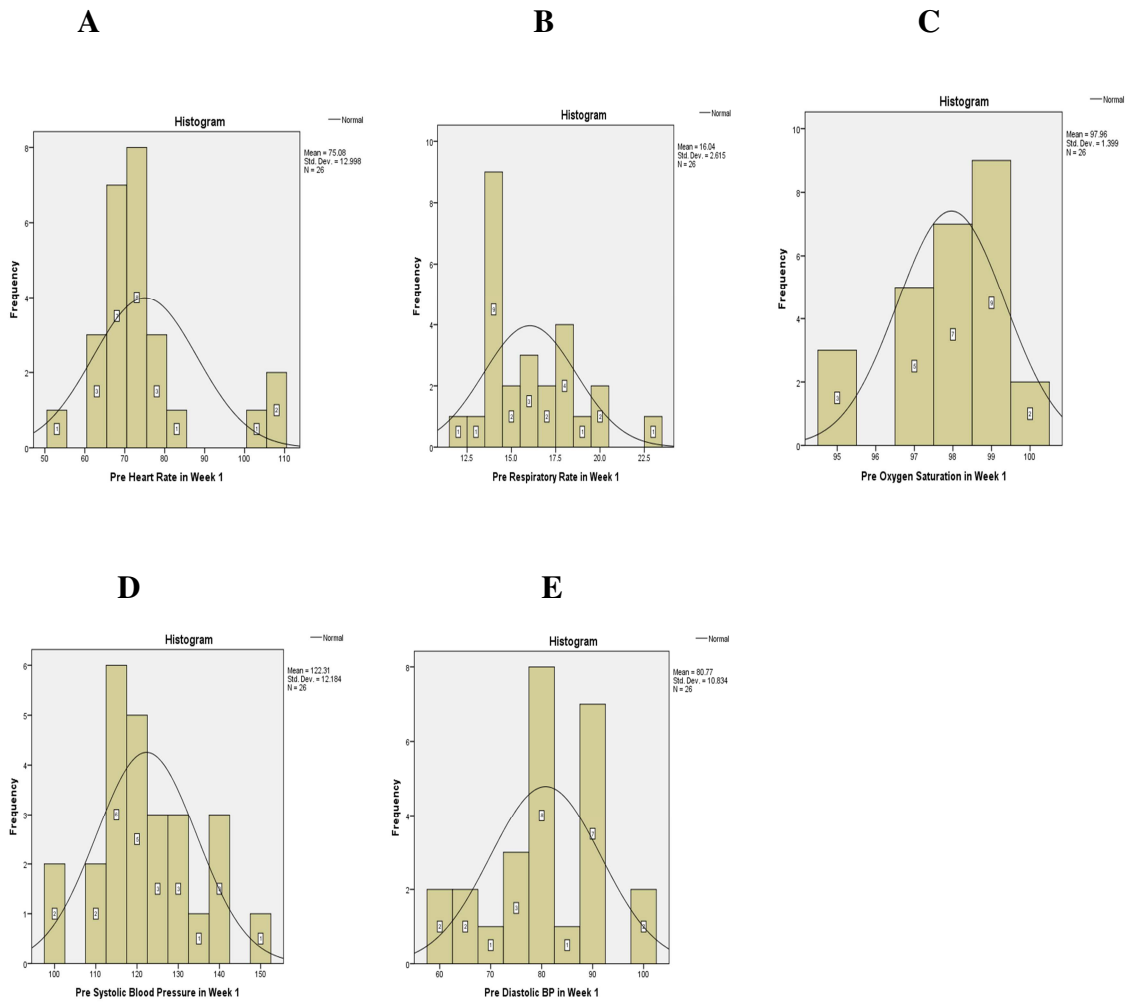

Figure 4: Normality test (histograms) for Baseline Vitals, A: Heart rate, B: Respiratory rate, C: Saturation, D: Systolic BP, E: Diastolic BP

We applied normality test on Baseline vitals. Histogram showed abnormally skewed curves for Heart rate, respiratory rate and oxygen saturation (p=0.000, 0.030, 0.004) respectively and normally skewed curves for systolic and diastolic BP (p=0.396 and 0.108) respectively. Test of choice is non-parametric, Mann-Whitney U test for the comparison between groups (sample size < 30 in each group.

A

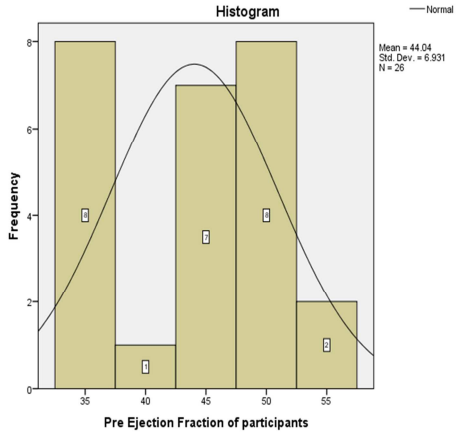

Figure 5: Normality test (histograms), A: Ejection Fraction

We applied normality test on baseline ejection fraction. Histogram showed abnormally skewed curve for ejection fraction (p=0.001). Test of choice is non-parametric, Mann-Whitney U test for the comparison between groups (sample size < 30 in each group.)

A **B**

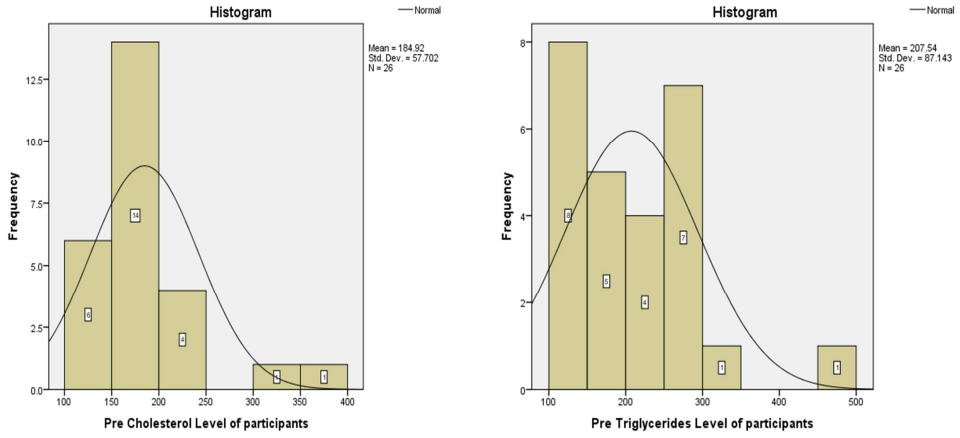

Figure 6: Normality test (histograms), A: Cholesterol, B: Triglycerides

We applied normality test on baseline cholesterol and triglycerides. Histogram showed abnormally skewed curves for cholesterol and triglycerides (p=0.000, 0.026 respectively). Test of choice is non-parametric, Mann-Whitney U test for the comparison between groups (sample size < 30 in each group

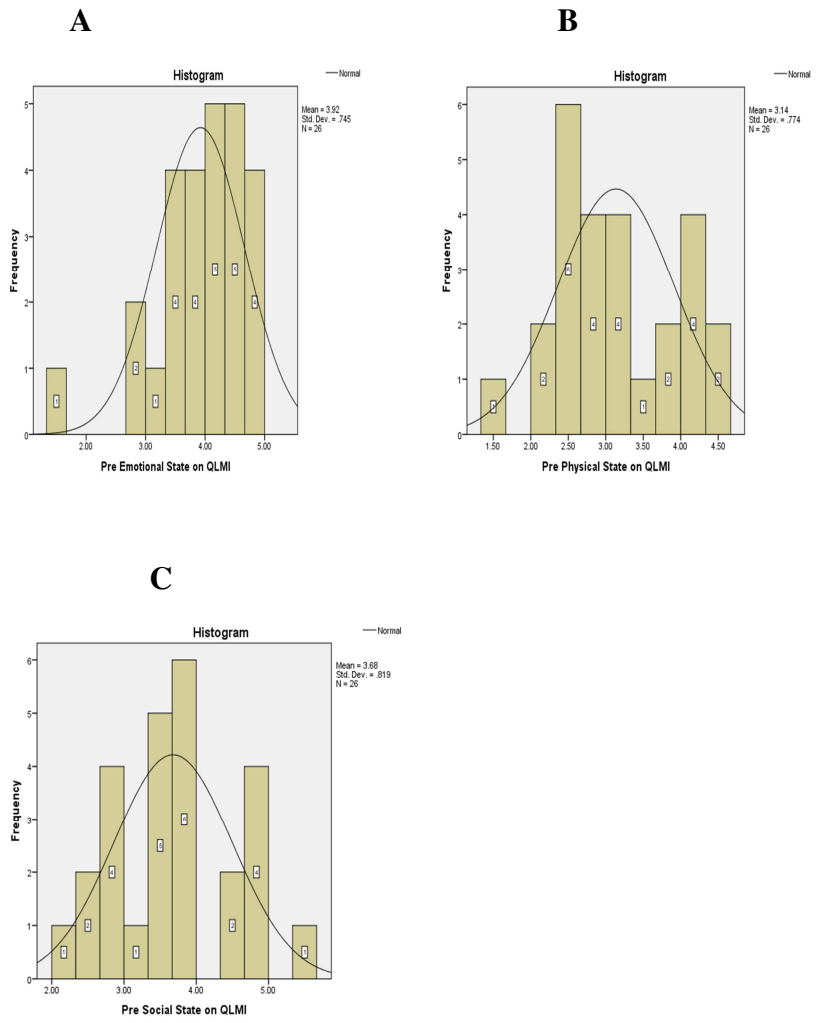

Figure 7: Normality test (histograms) for Baseline Quality of life, A: Emotional state, B: Physical state, C: Social state

We applied normality test on baseline quality of life including its three domains of emotional, physical and social state. Histogram showed abnormally skewed curve for emotional (p=0.025) and normally skewed curves for physical and social state (p=0.129 and 0.577 respectively). Test of choice is non-parametric, Mann-Whitney U test for the comparison between groups (sample size < 30 in each group.)