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Research Protocol

Physiotherapy Section

Impact of Structured Patient Education and Outpatient Cardiac Rehabilitation Program on the Disability Profile of Conservatively Treated Medically Stable Postmyocardial Infarction Individuals: A Protocol

VAROON CHANDRAMOHAN JAISWAL[1], LATA PARMAR[2], SNEHAL GHODEY[3]

ABSTRACT

Introduction: Cardiac rehabilitation and patient education are the two parallel components in the management of coronary heart disease. Although, it is recommended strongly to join an outpatient cardiac rehabilitation program, the enrollment rates are always low. The role of structured patient education in increasing the enrollment in an outpatient cardiac rehabilitation program and its impact on the disability profile of conservatively treated medically stable postmyocardial infarction individuals, after joining and completing the rehabilitation program has not been studied.

Aim: To study the impact of structured patient education and outpatient cardiac rehabilitation program on the disability profile of conservatively treated medically stable postmyocardial infarction individuals.

Materials and Methods: The study is a mixed method design and will be conducted in two steps. Step 1: It is a qualitative study in which a structured patient education program will be developed based on the framework given by the working Group of Exercise Rehabilitation and Sports (GERS). Step 2: Implementation of the developed program and an outpatient cardiac rehabilitation program in an open-label non randomised clinical trial.

Conclusion: The findings of this study will evaluate the need for the development of structured patient education programs for coronary artery disease patients, which may increase the enrollment rates in outpatient cardiac rehabilitation programs and thereby, reducing their disability.

Keywords: Coronary artery disease, Enrollment rates, Group of exercise rehabilitation and sports

INTRODUCTION

Cardiac rehabilitation and patient education are the two parallel components in the management of coronary heart disease. Myocardial infarction is a continuum of coronary artery disease and a leading cause of death and disability in developing countries like India. According to the global burden disease study 2020, death and disability have shown an alarming rise [1-3].

Components of cardiac rehabilitation designed to optimise cardiovascular risk reduction, promote healthy behaviours, and becoming compliant to the program reduce cardiovascular disability. Despite established benefits and consensus, it has been documented globally that the patient enrollment rates are always low for outpatient supervised cardiac rehabilitation programs [4,5]. Supervised outpatient cardiac rehabilitation is recommended (Class 1) by the American Heart Association and American College of Cardiology for conservatively managed medically stable postmyocardial infarction individuals and can be instrumental in reducing their disability [6].

Cardiac rehabilitation facility remains underutilised due to various barriers [7]. Structured patient education regarding the benefits of the cardiac rehab program may likely help the patients to overcome their barriers and encourage them to join the rehab program to reduce their levels of disability and become functionally more independent. As part of cardiovascular disease care, patient education has proved to improve physical activity, enhance healthy dietary habits, smoking cessation, improves patient knowledge about the disease, and brings a positive behaviour change. It is been also proven that patient education reduces fatal and non fatal myocardial infarction and improves health related quality of life [8,9]. A growing body of evidence suggests that the implementation of a structured patient education program as part of the care of coronary artery disease patients may increase their enrollment in an outpatient cardiac rehab program after their discharge from the hospital [10-12].

Patient education as a component of the care of coronary patients cannot be limited to simple information. Working GERS and therapeutic education commission of French society has proposed a reference framework and a structured method to facilitate the development of structured patient education program for coronary artery disease patients. According to their recommendations, interviews of the patients with coronary artery disease will be conducted and transcribed. Objectives of the education program will be derived from the extracts of the transcripts. These objectives will serve as the basis for structuring a patient education program [11]. The developed program will cover the following domains, knowledge of coronary artery disease, management of the disease, awareness of cardiac rehabilitation, effects of exercises, and benefits of joining an outpatient cardiac rehabilitation program. The evolved "patient education program" will be used to educate the study participants, which may increase their enrollment in the outpatient cardiac rehab program and thereby reducing their disability. This study aims to study the impact of structured education and outpatient cardiac rehabilitation on the disability profile of conservatively treated medically stable postmyocardial infarction individuals referred to the cardiac rehab program.

MATERIALS AND METHODS

The study has been approved by Maharashtra Academy of Engineering and Education Research Physiotherapy College Ethics

Committee No. EC/NEW/INST/2019/377/16 and Sumandeep Vidyapeeth Institutional Ethics Committee No: SVIEC/ON/PHYS/PhD/20028. The study is registered in the clinical trial registry of India with the registration number CTRI/2021/01/030851.

The study is a mixed method design and shall be complete in two steps. Step 1 is a qualitative design to develop a structured patient education program based on the needs of the patients as per the framework given by GERS. Step 2 involves implementing the structured patient education program and enrolling the patients in an outpatient cardiac rehabilitation program by an open label non randomised clinical trial.

Sample size calculation: The estimated sample size for the study is 78 minimum per group. The sample size is calculated by using the effect sizes from the previously published study [13] and with the help of the following formula:

$$n\ (Per\ Group) = 2[\frac{\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)\sigma}{\Delta}]^2$$

Where n=Sample size (per group).

$Z_{\alpha/2}$=(1.96) for 95% confidence (i.e.α=0.05)=1.96 [5% type I error probability]

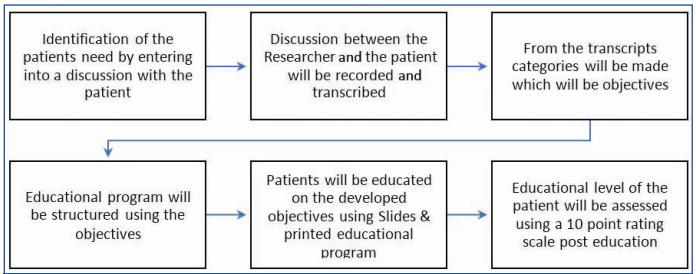
Z_{β}=Cut-off value for Power (1-β)=0.8416 [80.0% Power]

Δ=Mean difference to be detected (minimum difference)=12.0 units of WHODAS Score.

Inclusion and Exclusion criteria: Conservatively managed, stable, postmyocardial infarction patients, on regular medical management, with no signs of uncompensated heart failure will be included in the study. Patients showing signs of uncompensated heart failure and unstable haemodynamics will be excluded.

Procedure

For step 1 of the study, patients shall be recruited from the Outpatient Cardiology Department, who are attending their first follow-up after the discharge from the hospital. After screening for the inclusion criteria, consent will be obtained to participate in the study. Focused interviews will be conducted on one-to-one basis to explore knowledge and willingness to join supervised outpatient cardiac rehabilitation program. The entire discussion will be recorded and it will be transcribed by a person not involved in the study. Interview extracts will be formed from the transcripts and coding of each extract will be done. From these codes, themes will be developed. These themes will serve as an objective to develop the structured education program. The framework is detailed in [Table/Fig-1].



[Table/Fig-1]: Reference framework and method to develop structured patient education program [11].

Step 2 starts with the implementation of the structured patient education program and Outpatient Cardiac Rehabilitation. A structured patient education program will be delivered through face-to-face or group sessions using Audio Visual (AV) aids, show cards, and a printed pamphlet with the information of disease and benefits of joining outpatient cardiac rehabilitation after 4 to 6 weeks of the discharge as recommended by the physician.

Patients reporting for cardiac rehab will be grouped based on the open label non randomised clinical trial. The ones who agree to come for the 12 weeks program 3-4 times a week will be the experimental group and others will be given the detailed home program and shall be the control group.

The experimental and control group shall undergo risk stratification as per American Heart Association Guidelines [14] and a six-minute walk test as per American Thoracic Society Guidelines [15]. The experimental group will receive a supervised outpatient cardiac rehab program as per the guidelines of the American Heart Association [Table/Fig-2] [16]. Control group baseline parameters will be recorded on their same visit and regular reminders for exercises will be given to them telephonically and also exercise diary will be issued to them to guide their exercise program.

Endurance training	Resistance training
Frequency: ≥5 d/wk **Intensity:** 55%-90% maximum predicted HR or 40%-80% Vo2max or HR reserve or RPE: 12-16 **Modality:** Walking, treadmill, cycling, etc. **Duration:** 30-60 min	**Frequency:** 2-3 d/wk **Intensity:** 50%-80% of 1-RM or RPE 12-16 1-3 sets of 8-15 repetitions per exercise **Lower extremity:** leg extensions, leg curls, leg press. **Upper extremity:** bench press, lateral pull-downs, biceps curl, triceps extension **Duration:** 30-45 min

[Table/Fig-2]: Standard AHA guidelines for supervised outpatient exercises prescription in cardiac rehab program [16].
d/wk: Day per week; HR: Heart rate; Vo2max: Maximal oxygen consumption; RPE: Rating of perceived exertion; RM: Repetition maximum

Baseline parameters World Health Organisation Disability Assessment Schedule 2.0 (WHODAS 2.0) [17] will be recorded. Individuals will be assessed periodically after 4 weeks, 8 weeks, and 12 weeks on the WHODAS 2.0. Data of experimental group and control group will be analysed and compared. Cardiac Rehab Program and Progress (Experimental Group): Outpatient supervised cardiac rehab program will consist of:

a. Aerobic exercise prescription
b. Strength training (to start after three weeks of joining the rehab program as per the guidelines by The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)) [18]
c. Flexibility (as part of a warm-up and cool down)
d. Physician consultation for the review of medication
e. Dietician consultation for the review of cardiac diet.

Home exercise program (Control group): Control group will receive an exercise diary to monitor their exercise program. The intensity of the exercise will be prescribed based on the Borg Rating of Perceived Exertion (RPE) scale [19]. An exercise program will be discontinued, if the participant shows signs and symptoms detailed in [Table/Fig-3] and will be considered dropouts.

Signs and symptoms
Moderately severe or increasing angina
Marked Dyspnoea
Dizziness, lightheadedness or ataxia
Cyanosis or pallor
Excessive fatigue
Leg cramps or claudication
Other abnormal responses
Failure of the systolic pressure to rise as exercise continues
A hypertensive Blood Pressure (BP) response, including a systolic pressure of greater than 200 mmHg and/or a diastolic pressure greater than 110 mmHg
A progressive fall in systolic pressure of 10-15 mmHg
A significant change in cardiac rhythm detected either by palpation or by Electrocardiogram (ECG) monitoring (e.g., arrhythmias, ST-T wave changes).

[Table/Fig-3]: Criteria for discontinuation of exercise program [16].

Two outcome measures will be used in the study, first to record the enrollment rates and it will be measured by calculating the percentage of patients joined after receiving the structured patient education. Disability will be measured using WHODAS 2.0 scale.

1. To record the enrollment rates: Percentages of patients joined after receiving the structured patient education=
$$\frac{\text{Total number of patient joined}}{\text{Total number of patients received the intervention}} \times 100$$
2. WHODAS 2.0: It is generic tool which measures health and disability at population level or in clinical practice. Functioning is measured across six domains of life namely, cognition, mobility, self-care, getting along, life activities and participation. It is a valid tool to measure disability in patients with postmyocardial infarction patients [17].

Enrollment rates will be reported as a percentage of total patients who received the structured patient education to a number of patients who joined the outpatient rehabilitation program. WHODAS 2.0 score will be recorded in the excel sheet calculator of WHODAS 2.0 and the mean score will be compared within the group and between the groups.

Participants will be recruited from the cardiology wards for step 1 for the focused discussion and step 2 from the follow-up cardiology outpatients. In step 1 demographic data of all the patients will be recorded. Interviews of the patients will be recorded with the help of a voice recorder and the identity of the patients will be kept confidential. Interviews will be transcribed by the person who is not involved in the study and thematic analysis will be made from the transcripts. The total number of participants educated with structured patient education will be recorded. Under step 2, demographic data of all the patients will be recorded. Joining rates will be calculated based on participants joining the outpatient cardiac rehab after the discharge. Baseline WHODAS 2.0 will be assessed to measure the disability of the participants. WHODAS 2.0 will be measured after the completion of the 4 weeks, 8 weeks and 12 weeks during and after the outpatient cardiac rehabilitation program or home exercise program.

Baseline and post outpatient cardiac rehab or home exercise program WHOAD 2.0 measures will be assessed by the trained physiotherapist blinded to the intervention [Table/Fig-4]. Data Collection will be monitored by the Ph.D. supervisor and the Principal Investigator will be reported to the research advisory committee every six months and the same will be updated in the Central Trial Registry of India. Any serious adverse events will be reported to the Institutional Ethics Committee within seven days. The trial will be audited every six months research advisory committee of the University. The complete research plan is detailed in [Table/Fig-4].

STATISTICAL ANALYSIS

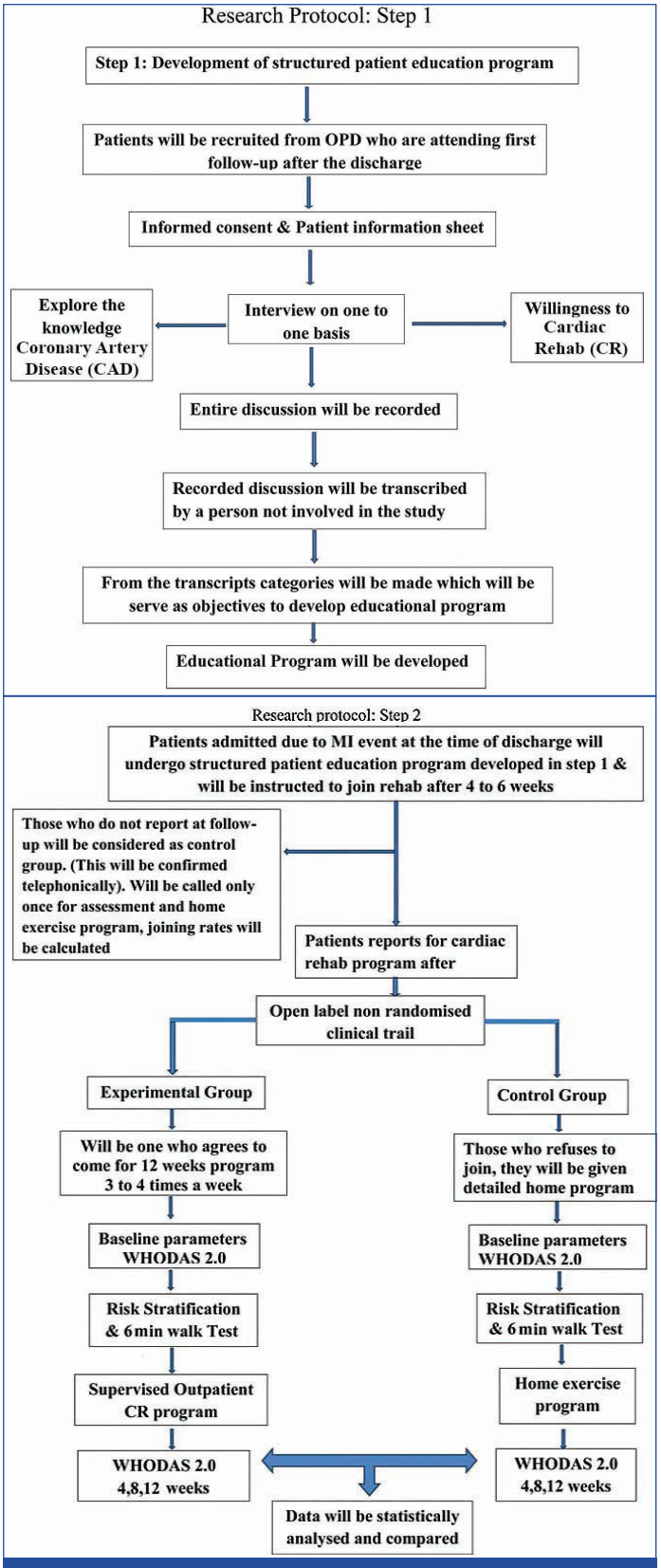
The data on categorical variables will be presented as n (% of cases) and the values on continuous variables will be presented as Mean±Standard Deviation (SD) across two study groups. An Independent sample t-test will be used to test the statistical significance of the difference of average of continuous variables across two groups. Intragroup comparisons will be tested using paired t-tests. The underlying assumption of normality will be tested before subjecting the study variables to the t-test. In the absence of normality, the appropriate non parametric tests will be used.

The p-values less than 0.05 will be considered as statistically significant. All the hypothesis will be formulated using two-tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data will be statistically analysed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation) for MS Windows.

DISCUSSION

There is strong evidence suggesting that disability due to myocardial infarction increasing the burden on the healthcare system globally [20]. Cardiac rehabilitation has proved to improve the functional status of postmyocardial infarction patients [21,22]. Despite all proven benefits, enrollment at cardiac rehabilitation programs has always been reported low [23,24].

Patient education is a process by which professionals and others impart knowledge to the patients that will bring a positive change in their behaviour and also improve their health [8]. Current



[Table/Fig-4]: Detailed research plan.

research has shown a positive impact of patient education on the utilisation of cardiac rehab programs. Strategies like LC-REHAB, motivational telephone intervention, educational mail out reminders were successful in increasing the attendance, adherence, and completion of cardiac rehab programs [25-27]. There is a need to develop a structured patient education program based on the needs of the patients. A structured patient education program that is to be developed in this study will be tested to measure, if it can increase the attendance or joining rates in the outpatient cardiac rehabilitation program. Later, the disability of the patients who participated in the program will be measured after 12 weeks of joining by WHODAS 2.0 scale. The study highlights the need to

develop structured patient education programs which may improve enrollment in cardiac rehabilitation programs.

CONCLUSION(S)

The findings of this study will evaluate the need for the development of structured patient education programs for coronary artery disease patients, which may increase the enrollment rates in outpatient cardiac rehabilitation programs and thereby, reducing their disability.

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PARTICULARS OF CONTRIBUTORS:
1. Ph.D. Scholar, Department of Cardiovascular and Respiratory Physiotherapy, Sumandeep College of Physiotherapy, Sumandeep Vidyapeeth, Vadodara, Gujarat, India.
2. Professor and Principal, Department of Physiotherapy, Sumandeep College of Physiotherapy, Sumandeep Vidyapeeth, Vadodara, Gujarat, India.
3. Professor and Principal, Department of Physiotherapy, Maharashtra Academy of Engineering and Education Research Physiotherapy College, Pune, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Varoon Chandramohan Jaiswal,
Maharashtra Academy of Engineering and Education Research Physiotherapy College, Talegaon, Dabhade, Pune, Maharashtra, India.
E-mail: drvaroon@gmail.com

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