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Protocol For A Prospective Study of The Effect of Nurse Led Cardiac Rehabilitation In Heart Failure Patients At A Short Term Follow-Up.

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Abstract

Introduction

Patients with heart failure (HF) due to decreased left ventricular systolic function demonstrate large end-diastolic volumes and have little contractile reserve. Heart failure has significant mortality, morbidity, readmissions and high health costs. There is need to emphasize the importance of preventing heart failure by treating the risk factors or even preventing the risk factors like hypertension, smoking, diabetes etc. to intervene at an early stage. A nurse-led cardiac rehabilitation can provide secondary care to HF patients and provide patients and their families with adequate knowledge, skills for symptom management and support as well as life style modification. The nurse-led cardiac rehabilitation can lead to significant reduction of hospital readmission, improved control of the patients' blood pressure, treatment compliance and Quality of life. Home-based physical training programmes are feasible even in severe chronic heart failure and have a beneficial effect on exercise tolerance, peak oxygen consumption, and symptoms.

The study protocol is aimed to investigate the effect of Nurse led Rehabilitation programme on the Quality of life, serum BNP and echocardiography parameters of systolic and diastolic left ventricular function in patients with heart failure. The echo-cardiographic parameters include Left ventricular end diastolic diameter, Left ventricular end systolic diameter, Left ventricular end diastolic volume, Left ventricular end systolic volume, Left ventricular ejection fraction percentage, Left ventricular diastolic function, Presence of pulmonary artery hypertension.

Methods

The ethics committee and administrative approval is obtained. After obtaining the written consent from the patients with heart failure, a sample of 100 subjects will be enrolled by convenient sampling with random allocation of subjects to the experimental and control groups. The investigator would assess Echocardiographic parameters, Serum BNP values, Six Minute Walk Test distance and Quality of life at the time of discharge in the IPD and at 3 months follow up in the cardiac OPD. Quality of life will be assessed by MacNew Heart Related Quality of Care questionnaire. Nurse-led Cardiac Rehabilitation involving physical assessment, HF symptom monitoring, medication compliance and life style modification would be given to the experimental group and control group will receive the routine care.

Results: Data will be analyzed by independent t-test, paired t-test using SPSS.

Conclusion

The protocol underlines the critical role of nurses in delivering holistic care, educating patients, and bridging gaps in cardiac rehabilitation services. The nurse-led cardiac rehabilitation is expected to improve outcomes, reduce hospital readmission and support the integration of nurse-led cardiac rehabilitation into routine care of patients with heart failure.

Keywords: Heart failure, Nurse led cardiac rehabilitation, Quality of life, brain natriuretic peptide (BNP)

Introduction

Heart Disease is one of the most common illnesses seen in elderly and middle-aged. Patients with heart failure due to decreased left ventricular systolic function demonstrate large end-diastolic volumes and have little contractile reserve **[1]**. The burden of Heart failure (HF) is rising globally. The developed nations have identified this as a major health problem and have adopted measures to contain it using the strategies of risk stratification, prevention, education and treatment.

There is a dearth of data regarding incidence or prevalence of HF not only from India, but the whole of the developing world outside the

United States and Europe **[2]**. The present estimates are extrapolated from the data from the West. The lifetime risk of HF increases with age. The number of people above 60 years of age is projected to increase (21.6%) to 376 million in 2051 in India **[3]**.

The prevalence of HF in India is estimated to range from 1.3 to 4.6 million, with an annual incidence of 0.5-1.8 million. Heart failure has significant mortality, morbidity, readmissions and high health costs **[4]**.

There is need to emphasize the importance of preventing heart failure by treating the risk factors or even preventing the risk factors like hypertension, smoking, diabetes etc., i.e., to intervene at an early stage. The concept of prevention should prevail at the population level as well as the health care provider level. HF poses a huge burden to the health expenditure, accounting for about 2% of the total health care budget in developed countries **[5]**. In our country, 90 % of patients with congestive heart disease meet their medical expenses on their own. Therefore, the financial impact of HF at the population level will be huge.

A nurse-led cardiac rehabilitation can provide secondary care to HF patients and provide the patients and their families with adequate knowledge, skills for symptom management and support as well as life style modification **[6]**. It can lead to significant reduction of hospital readmission, improved control of the patients' blood pressure, treatment compliance and Quality of life.

Establishment of dedicated HF programs with clinics and rehabilitation programs will help to provide focused care on such patients. This would also ensure in adherence to the available guidelines and improve clinical outcomes including readmissions.

Patients with symptomatic HF often show physical inactivity. This further causes its progression. Regular, initially supervised, resistance or endurance physical training improves autonomic control by enhancing vagal tone and reducing sympathetic activation, improves muscle strength, vasodilator capacity, and endothelial dysfunction, and decreases oxidative stress **[7]**. Several systematic reviews and meta-analyses of small studies have shown that physical conditioning by exercise training reduces mortality and hospitalization when compared with usual care alone and improves exercise tolerance and health-related quality of life **[8, 9]**. All patients with heart failure are recommended to do regular, moderate daily activity. Literature does not recommend that exercise training should be limited to any particular HF patient subgroups like etiology, New York Heart Association (NYHA) class, Left Ventricular Ejection Fraction, or medication. Exercise training programmes appear to have similar effects whether provided in a hospital or at home **[7]**.

HF reduces the ability to perform aerobic exercise. Impaired cardiac output leads to inadequate blood flow to active skeletal muscle **[7]**. One of the common problems in patients with heart failure is exercise intolerance, which may be due to mass loss of muscle power leading to reduced performance in individuals' daily affairs and ultimately loss of ejection fraction and Quality of life **[10]**. Significant improvement in patient-rated symptom scores were observed after training exercises. There were no adverse events seen during the training phase. In patients with severe chronic heart failure, physical training programmes improved exercise tolerance, peak oxygen consumption, and symptoms. Rest is no more the treatment of specific groups of patients with chronic heart failure **[7]**.

There is a significantly compromised Quality of life affecting physical and social functioning as well as increased psychological distress in patients with congestive heart failure. Patients also often experience anxiety and depression. Community CHF disease management programmes are needed in these patients11. Exercise training is recommended alongside pharmacological and non-pharmacological therapies in patients with asymptomatic (NYHA Class II) chronic heart failure **[12]**.

Exercise Training induces a delay in the increase in blood lactate, the rates of creatinine phosphate consumption and glycolysis are frequently high and blood free-fatty acids increase gradually during exercise. Exercise may cause increase in left ventricular end-diastolic volume in these patients. Also, it could improve total peripheral vascular resistance and peripheral perfusion. Asymptomatic individuals with chronic heart failure benefit with aerobic training in terms of reversal of left ventricular remodeling **[7]**. Studies have shown that patients with stable conditions that have regular and moderate exercise have better Quality of life and less mortality rates compared to the patients who do not exercise **[13]**. Because of low cost, accessibility, and easy use, exercise training is an intervention that could be recommended for most patients with heart failure **[14]**. Compared with usual care, exercise training reduces heart failure-related hospitalizations and results in clinical betterments in Quality of life among heart failure patients **[7]**. Quality of life improves with exercise by reducing signs and symptoms of disease progression15. These changes in lifestyle of cardiac patients require follow-up, care, education, and interventions such as physical activity under the supervision of health care teams especially nurses **[16]**.

Physical conditioning by exercise training improves exercise tolerance, health-related Quality of life and HF hospitalization rates in patients with HF. A single large RCT showed a modest and non-significant reduction in the primary composite outcome of all-cause mortality or all-cause hospitalization. There was no reduction in mortality and no safety concerns were raised. The most recent Cochrane review of exercise training included 33 trials with 4740 patients with HF (predominantly Heart failure with reduced ejection fraction). There was a trend towards a reduction in mortality with exercise in trials with 1 year of follow-up. Compared with the control group, exercise training reduced the rate of overall and HF-specific hospitalization and improved Quality of life.

European Cardiology Society recommends regular aerobic exercise in patients with HF to improve functional capacity and symptoms.

The risk of HF hospitalization reduces by regular aerobic exercise in stable patients with Heart failure with reduced ejection fraction (HF*r*EF).

Grace et al. (2011) reported that on average only 34% of those eligible are referred to Cardiac Rehabilitation **[17]**. Under-utilization of Cardiac Rehabilitation is another gap between evidence and clinical practice in patients with heart disease. Because of low cost, accessibility, and easy use, exercise training is an intervention that could be recommended for most patients with heart failure. There is a need to evaluate the effectiveness of a cardiac rehabilitation that is led by a nurse.

There are huge gaps in our knowledge base about many fundamental aspects of HF care. Some key examples include an effective management strategy for patients with Heart Failure Preserved Ejection Fraction (HF*p*EF) beyond blood pressure control; a convincing method to use biomarkers in the optimization of medical therapy; the recognition and treatment of cardiorenal syndrome; and the critical need for improving patient adherence to therapeutic regimens. Pre-discharge NT-proBNP is also more strongly associated with outcomes than admission levels. In 182 consecutive patients admitted with HF, the risk of death or readmission was higher for those who did not have a significant reduction in NT-proBNP, defined as a decrease >30%, compared with those who did (HR, 2.03; 95% CI, 1.14–3.64) **[18]**.

Guidelines for Brain Natriuretic peptide (BNP) testing in HF

The Canadian Cardiovascular Society Consensus Conference update 2007 **[19]** made recommendations on the use of Brain natriuretic BNP or N Terminal pro BNP (NT-proBNP) testing in the diagnosis and treatment of heart failure.

The National Academy of Clinical Biochemistry and International Federation for Clinical Chemistry for Standardization of Markers of Cardiac Damage Laboratory Medicine Practice Guidelines (2007) made recommendations addressing the analytical aspects of B-type natriuretic peptide (BNP) and N-terminal proBNP (NT-proBNP) for clinical use in heart failure **[19]**. The guidelines stated that BNP and NT-proBNP assays must be carried out in patients with Heart Failure. At admission, BNP and NT-proBNP, have been shown to predict in-hospital and post-discharge mortality, independently from and often better than other prognostic variables.

Aim of the study: The study is aimed to investigate the effect of Nurse led Rehabilitation programme on the Quality of life and echocardiography parameters of systolic and diastolic left ventricular function in patients with heart failure. The objectives were i) to compare the Quality of life (QOL) Scores of patients with heart failure at the time of discharge with the QOL scores and at three month follow up in OPD, ii) to compare the echocardiographic parameters of patients with heart failure (left ventricular end diastolic diameter, left ventricular end systolic diameter, left ventricular end diastolic volume, left ventricular end systolic volume, left ventricular ejection fraction percentage, left ventricular diastolic function, presence of pulmonary artery hypertension) at the time of discharge and at three months follow up in OPD, iii) To compare the serum BNP value of patients with heart failure at the time of discharge with serum BNP values at three month follow up in OPD.

Hypotheses

H1: The mean Left Ventricular ejection fraction at three month follow up period in the patients is significantly different than their mean Left Ventricular ejection fraction at the time of discharge as measured by echocardiography at 0.05 level of significance.

H2: The mean Left Ventricular ejection fraction of the experimental group is significantly different than the mean Left Ventricular ejection fraction of the control group at three month follow up period as measured by echocardiography at 0.05 level of significance.

H3: The mean Left ventricular End diastolic diameter at three month follow up period in the patients is significantly different than their mean Left ventricular End diastolic diameter at the time of discharge as measured by echocardiography at 0.05 level of significance.

H4: The mean Left ventricular End diastolic diameter of the experimental group is significantly different than the mean Left ventricular End diastolic diameter of the control group at three month follow up period as measured by echocardiography at 0.05 level of significance.

H5: The mean serum BNP value of the experimental group is significantly different than the mean serum BNP value of the control group at three month follow up period at 0.05 level of significance.

H6: The mean serum BNP value at the time of discharge is significantly different than the mean serum BNP value at three month follow up period in the experimental group at 0.05 level of significance.

H7: The mean QOL score at three month follow up period in the patients of the experimental group is significantly different than their mean QOL score at the time of discharge, as measured by the MacNew Heart Disease Health-Related Quality of Life questionnaire at 0.05 level of significance.

H8: The mean QOL score of the patients in the experimental is significantly different than the mean QOL score of patients in the control group at three month follow up period as measured by the MacNew Heart Disease Health-Related Quality of Life questionnaire at 0.05 level of significance.

Delimitations: The study is delimited to the patients who are aged 18 years or above, who are known cases of diagnosis of heart failure and in NYHA Class II and III post treatment, who are in sinus rhythm, have the ability to perform the exercise program after medication therapy, and willing to participate in the study.

Operational Definitions

Heart Failure, in the study, refers to the diagnosis established by a cardiologist on the basis of clinical assessment, echocardiography and

BNP values. Heart Failure is a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood. The cardinal manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance and fluid retention, which may lead to pulmonary and/or splanchnic congestion and/or peripheral edema **[20]** (American Heart Association).

Heart Failure with reduced ejection fraction (HFrEF) is defined as the clinical diagnosis of HF and EF ≤40%.

Heart Failure with preserved ejection fraction (HFpEF) includes patients who do not have entirely normal EF but also do not have a major reduction in systolic function.

Heart Failure is a Clinical syndrome characterized by abnormal cardiac systolic and/or diastolic function and resulting symptoms of low cardiac output of venous congestion or congestion due to abnormal myocardial function **[21]**.

NYHA Functional Classification of Heart Failure

Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath). No pulmonary congestion or peripheral hypotension. Patient is considered asymptomatic. Usually no limitations of activities of daily living (ADLs)

Class II: Slight limitation of physical activity; Comfortable at rest; Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).

Class III: Marked limitation of physical activity; Comfortable at rest; Less than ordinary activity causes fatigue, palpitation, or dyspnea.

Class IV: Unable to carry on any physical activity without discomfort; Symptoms of heart failure at rest; If any physical activity is undertaken, discomfort increases

Definition by European Society of Cardiology:

Heart Failure is a clinical syndrome characterized by typical symptoms (e.g. breathlessness, ankle swelling and fatigue) that may be accompanied by signs (e.g. elevated jugular venous pressure, pulmonary crackles and peripheral edema) caused by a structural and/or functional cardiac abnormality, resulting in a reduced cardiac output and/ or elevated intra-cardiac pressures at rest or during stress. The current definition of HF restricts itself to stages at which clinical symptoms are apparent. Before clinical symptoms become apparent, patients can present with asymptomatic structural or functional cardiac abnormalities [systolic or diastolic left ventricular (LV) dysfunction], which are precursors of HF. Acute Heart Failure refers to the rapid onset or worsening of symptoms and/or signs of HF. It is a life-threatening medical condition requiring urgent evaluation and treatment, typically leading to urgent hospital admission **[22]**.

BNP Testing

BNP is the biomarker used for diagnosis of heart failure and have a high-sensitivity for the detection of HF. A low result (i.e., <100 for BNP or <300 for NT-proBNP) for either test is associated with a high negative predictive value for the clinical syndrome of HF, while elevated values (i.e., > 400 for BNP or > 450–1800, depending on age, for NT-proBNP) have a high positive predictive value for the diagnosis of HF. BNP concentrations < 300–400 pg/mL at discharge are predictive of a better outcome than higher values **[23]**.

Patients include those who are above 18 years of age and either in NYHA class II or class III of heart failure and are getting discharged from cardiac wards/Unit of Max Super Specialty Hospital, Saket, at the time of data collection.

Quality of life refers to score obtained by self-administration of MacNew Heart Disease Quality of life instrument (a standardized tool), by the patient.

Physical performance: Ability of the patient to perform six minute walk test without signs of dyspnea and fatigue. Six Minute Walk Test (6 MWT) is a sub-maximal exercise test that entails the measurement of distance walked over a span of 6 minutes. The 6-minute walk distance provides a measure for integrated global response of multiple cardiopulmonary and musculoskeletal systems involved in exercise **[24]**.

Nurse Led Cardiac rehabilitation refers to the Nurse supervised cardiac rehabilitation program to help heart patients recover and improve their overall physical, mental and social function and includes: i) a structured assessment to figure out the patient's needs and limitations, ii) a prescribed physical exercises program specific to the patient's needs and limits, iii) counseling and patient education regarding patient's current condition, and iv) telephonic reminders regarding diet modification, use of prescribed medication and weight monitoring, fluid restriction and other related health activities.

Physical exercises are a part of Nurse led rehabilitation, tailored according to the patient's ability and depend upon the patient's symptoms. These are designed as below:

For NYHA Class II

1. Walking

a. 5 minute walk, 3 times a day before meals in the first week
b. Increased to 10 minutes walk, 3 times a day in the II week
c. Increased to 15 minute walk, 3 times a day in the III week

2. Arm Exercises (any time in sitting or standing position) including

a. Extension and flexion at the elbow
b. Adduction and abduction
c. Shoulder raising
d. Circumduction

3. Breathing exercises (to be done before meals in sitting position and two times a day)

The exercise schedule is done till the patient has stable symptoms and is immediately stopped on worsening of the symptoms. The duration of the exercise then would be decreased, accordingly.

For NYHA Class III

1. **Walking (to be done before meals)**

a. 5 minute walk, 3 times a day in the first week of discharge follow-up

b. Increased to 10 minutes walk, 3 times a day in the II week

2. **Arm Exercises (any time in sitting or standing position) including:**

a. Extension and flexion at the elbow

b. Adduction and abduction

c. Shoulder raising

d. Circumduction

e. Breathing exercises (To be done before meals two times a day)

Warning: The exercise schedule is done till the patient has stable symptoms and is immediately stopped on worsening of the symptoms. The duration of the exercise then would be decreased, accordingly in the subsequent exercise schedule.

Methodology

The experimental study is proposed to be conducted in Cardiology wards of a single centre i.e. Max Heart and Vascular Institute, Saket, New Delhi. The target population comprises of the patients who are known cases of Heart Failure, either in NYHA class II or class III and are attending follow–up OPD of Max Heart and Vascular Institute, Saket, at the time of the study.

Sample size estimation: The primary objective of the study is to find out the improvement in echocardiographic parameters and Quality of life after Nurse led cardiac rehabilitation. However, we could not locate a previous study where these parameters have been measured before and after a nurse led cardiac intervention. Therefore, we are not able to compute sample size on the basis of previous data. However, considering the availability of cases in the hospital (study setting) during the period of study, we propose to include 100 cases that look significantly large to find out the statistical significance of the difference in averages before and after the intervention. For example, if the difference in the MacNew score before and after is only 3 points on average and standard deviation is 8, the sample size comes to 75 for power 80% with the following formula:

$$\frac{\sigma^2 (z_{\alpha/2} + z_{\beta})^2}{\delta^2}$$

where,

σ^2 = variance of the difference

$z_{\alpha/2}$= 1.96 corresponding to 5% level of significance

z_{β} = 0.84 corresponding to 80% power.

Thus the sample size of 100 looks appropriate for this study with 50 patients in experimental and control group each.

Convenient sampling with random allocation of subjects to experimental and control group would be done. The log of all patients having heart failure and admitted in cardiology wards will be maintained. Patients getting discharged from the hospital will be approached. The sampling criteria would be verified. If the sampling criteria are met, the patients will be selected as study participant, provided, they are willing to participate. The patients will be randomly allocated to experimental and control group. Every day the patient's admission register will be maintained. The patient's entry will be made according to their day and time of admission. Every alternate patient will be assigned to the control group. A total of 50 patients in experimental group and 50 in control group would be enrolled. The sampling would continue till the sample size is achieved.

The inclusion criteria for sampling comprise of patients aged 18 years or more, in heart failure of NYHA Class II or III post treatment, having sinus rhythm, able to perform the exercise program after the medication therapy and willing to participate in the study. Whereas, the patients in NYHA class IV heart failure despite treatment, cases of a heart transplant, pacemaker implantation, undergoing coronary bypass surgery during the research and data collection time, having neurological disease that may interfere in movement, orthopaedic conditions such as rheumatoid arthritis, fracture, osteoarthritis, peripheral vascular or severe pulmonary disease and having traveling plans during the data collection time will be excluded from the study.

The investigator would assess the dependent variables that are i) Echocardiographic parameters, ii) Serum BNP values, iii) Six Minute Walk Test distance and iv) Quality of life scores

The intervention is Nurse-led Cardiac Rehabilitation that includes physical assessment, HF symptom monitoring, medication compliance and life style modification. All the patients getting discharge from the cardiac wards/inpatient areas will be attended by the investigator. At the time of discharge, patients' physical examination, physical status, including blood pressure, pulse and weight will be monitored. Individualized care plan will be formulated after assessing a patient's risk factors, severity of symptoms, treatment compliance and educational needs. Patients will receive regular follow-up, for early detection of deterioration and treatment readjustment as needed.

The patients in the experimental group would undergo Nurse Led Cardiac Rehabilitation Program.

These patients will be provided with face to face educational discussions on self-care, medications, lifestyle modification and tailored exercises schedule on the day of discharge.

As a part of the discharge advice in the study protocol, the emphasis is given to all patients in the experimental group and their relatives to immediately report to the cardiac OPD/hospital in case of complaints of dyspnea, dizziness, syncope, chest pain, fatigue, hypotension (BP < 100/70 mm Hg). Any weight gain of more than 1 to 2 Kg in one week or increasing pedal edema, uncontrolled blood sugar levels, uncontrolled hypertension (BP > 150/90 mm Hg) would require

urgent cardiologist consultation. The patients will be followed through telephonic reminders by the investigator, regarding: i) Compliance of daily Medications, ii) Diet modification, iii) Fluid restriction, iii) Daily weight monitoring, iv) Prescribed Exercise sessions as advised at the time of discharge at least 3 per week for a period of 3 months' time. The exercise session is patient specific and will require modification as per the symptoms of the patient.

The Patients in the experimental group will do the exercises according to their physical ability. The patient is instructed to immediately stop the exercises in case s/he feels tired physically or develops severe dyspnea, fatigue, dizziness or any other problems that could jeopardize health.

Patient counselling will be done telephonically. The call logs will be maintained by the investigator as well as the patient. Patients will be asked to maintain a log of cardiac rehabilitative activities that are carried out by him/her. Heart rate and blood pressure will be checked by the patient before and after each exercise session. The reminder to the attend follow up clinic at OPD is also given.

The patients in control group will get the routine discharge advice and follow up advice as per the hospital protocol.

Procedure of data collection

The patients in the experimental and control group will be assessed twice for their NYHA classification, echocardiographic parameters, Serum BNP value, Six minute walk distance and Quality of life:

i. At the time of discharge.

ii. At 3 months follow up in the cardiac OPD.

Once the informed consent is obtained, the investigator will assess the base line parameters. She will give the counseling for the cardiac rehabilitation to the patients in experimental group, at the time of discharge. She will explain the importance of the cardiac rehabilitation program and the patient's role. The patient will maintain a patient log book daily wherein he keeps a record of daily weight monitoring, exercise schedule, diet and fluid intake etc. The investigator will give a telephonic call, two times a week. During the telephonic conversation investigator reminds the patient about his/her prescribed medication, diet, fluid restriction and notes its compliance. The complaints of patients, exercise schedule maintained, any complain that might have raised, are recorded. The investigator evaluates any excessive weight gain, changes in BP, Blood sugar, worsening of symptoms and functional capacity concurrently following the telephonic call session. Any need of follow up in cardiac OPD is evaluated and conveyed, specific modification in the diet/fluid restriction/exercise schedule is recommended. This is in addition to his/her routine follow up as advised by the treating cardiologist. The emphasis is given to the patients and their relatives to immediately report to the cardiac OPD/hospital in case of: complaints of dyspnea, dizziness, syncope, chest pain, fatigue, hypotension (BP < 100/70 mm Hg), any weight gain of more than 1- 2 Kg in one week or increasing pedal edema, uncontrolled blood sugar levels. Uncontrolled hypertension (BP > 150/90 mm Hg) would require urgent cardiologist consultation. Any need of patient's hospitalization (whether due to cardiac cause or any other) is recorded.

Data collection instruments: Six tools proposed for collection of data are as follows:

1. Questionnaire to collect demographic profile including NYHA class and medication prescription
2. Proforma for Physical Assessment for assessment of pulse, BP, evaluation for status of dyspnea, fatigue, dizziness, fainting or chest pain, cardiovascular and respiratory examination, "six minute walk test"
3. Call log by Nurse
4. Patient Diary log
5. Information sheet (Record Analysis)
6. MacNew Heart Disease Health-Related Quality of Life questionnaire to assess the Quality of life. The MacNew is a self-administered heart disease-specific health-related quality of life (HRQL) instrument. The MacNew heart disease questionnaire addresses three major Heart disease- specific health related quality of life (HRQL) domains, the Emotional, Physical, and Social domains which can be combined to give a Global HRQL score. The scores range from a minimum of 27 to a maximum of 189 score. The higher the score the better the QOL.

Plan for Data Analysis

1. Paired t-Test on baseline Mean Ejection fraction (%) in Experimental group at the time of discharge and its Mean Ejection fraction (%) at 3 month follow up.
2. Paired t-Test on baseline Mean QOL score in Experimental group and its Mean QOL score at 3 month follow up time.
3. Independent t-test on Mean Ejection fraction (%) in the Experimental group and Mean Ejection fraction (%) in control group at three month follow up.
4. Independent t-Test on QOL score in Experimental group and Mean QOL score in control at 3 month follow up time.
5. Independent t-test in mean BNP value in experimental group and mean BNP value in control group at 3 months follow up.
6. Paired t-Test on baseline Mean Serum BNP Value in Experimental group at the time of discharge and its Mean Serum BNP value at 3 month follow up.
7. Independent t-test in mean' six minute walk distance' in experimental group and in control group at 3 months follow up.

Ethical Consideration

This protocol has been approved by the Institutional Ethical Committee (IEC) of Max Hospital vide letter dated, 25th April, 2020, REF NO.: TS/MSSH/DDF/SKT - 2/IEC/CARDIO/20-19.

Patient information sheet would be discussed and informed written consent will be obtained from the participants after explaining the purpose, risks and benefits of the study. For the subjects who cannot read and write in English, informed written consent will be taken in Hindi.

Any data, forms, reports, and other records that leave the site will be identified only by a participant identification number (participant /patient id) to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entries and networking programs will be done using patients' identification number only. Information will not be released, without written permission of the participant, except as necessary for monitoring by IEC and any regulatory authority.

Outcome

Primary Outcome

The study would help to compare the findings at the time of discharge and at 3 months follow-up and determine any improvement in

- Functional class (NYHA)
- Quality of life
- Echocardiographic parameters
- Serum BNP value

Secondary Outcome

Effectiveness of Nurse led cardiac rehabilitation program in decreasing the incidence of hospital readmission.

Strengths

Random allocation of subjects to intervention and control arm using a random number generator. The outcome is measured in terms of echocardiography and serum BNP in addition to NYHA class, symptoms and Quality of life. The Nurse led intervention includes the telephonic follow-up by the investigator.

Conclusion

The study protocol outlines a structured investigation to evaluate the effectiveness of a nurse-led cardiac rehabilitation program in improving outcomes for heart failure patients. The nurse-led cardiac rehabilitation is feasible to implement in clinical settings and can be seamlessly integrated into standard care for heart failure patients. The program is expected to demonstrate significant improvement in clinical outcomes echocardiographic parameters, functional capacity in terms of NYHA class and serum BNP. Enhanced Quality of life and psychological well-being are anticipated as direct benefits of nurse-led intervention. The study may highlight a reduction in hospital readmissions and emergency visits due to better self-management and adherence to treatment protocols facilitated by the program. The protocol could underline the critical role of nurses in delivering holistic care, educating patients, and bridging gaps in rehabilitation services. By improving outcomes and reducing healthcare resource utilization, the nurse-led cardiac rehabilitation might prove cost-effective for both healthcare systems and patients. The study is expected to support the integration of nurse-led rehabilitation programs into routine heart failure care, promoting a multidisciplinary approach to managing chronic conditions. Further research may be suggested to validate these findings in diverse patient populations and settings.

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Competing interests: None

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