

Feasibility of Cardiac Rehabilitation in Patients with Heart Failure at the Moi

Teaching and Referral Hospital

by

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Duke Global Health Institute
Duke University

Date: _____

Approved:

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Gerald S. Bloomfield, Co-Chair

Joseph Egger

Thesis submitted in partial fulfillment of
the requirements for the degree of
Master of Science in the Duke Global Health Institute
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ABSTRACT

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Abstract

Background: Cardiovascular diseases form a large part of a growing pandemic of non-communicable diseases afflicting Sub-Saharan Africa(1–3) Heart failure is one of the most debilitating of these diseases. The global 5-year life expectancy of patients afflicted by heart failure is less than 50%(4–6). Cardiac rehabilitation (CR) has been demonstrated to improve functional status, quality of life, and reduce depression in patients with heart failure(7,8). Even though CR is a simple and comparatively low-cost intervention, adherence rates of CR remains poor and are estimated at 20% in the US(9–11). In Western Kenya, CR is non-existent. We sought to establish the feasibility of two different models of cardiac rehabilitation for heart failure in Western Kenya and to identify potential barriers to participation.

Methods: This was a feasibility study using mixed methods to describe characteristics and changes in a cohort of patients with heart failure. Study participants were prospectively recruited and allocated by convenience into an institution based cardiac rehabilitation (IBCR) arm, a home based cardiac rehabilitation (HBCR) arm and an observational arm (OA). At completion of 3 month follow up period, participants were invited to take part in focus group discussions exploring perspectives on heart failure and cardiac rehabilitation. The primary measure of feasibility was the ability of study

participants to attain a mean adherence rate of at least 25%, of prescribed rehabilitation sessions.

Results: This study found that cardiac rehabilitation is a feasible intervention for patients with heart failure in Western Kenya with an adherence rate of 46% for institutional based cardiac rehabilitation and an adherence rate of 28% for home based cardiac rehabilitation. All study arms demonstrated significant change in depression screening and quality of life scores. Participants in focus group discussions identified competing interests, distance to the facility and forgetfulness as barriers to cardiac rehabilitation.

Conclusions: Cardiac rehabilitation is a feasible treatment intervention for heart failure in Western Kenya. However, the barriers to delivery of care are similar to barriers in other health systems around the world(12). There is need for further research to evaluate the efficacy of cardiac rehabilitation and development of innovative ways to improve treatment adherence.

Dedication

This work is dedicated to the all the people affected by heart failure, the study participants involved in this study and to my family, fiancée and friends who have toiled and supported me through this journey.

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Abbreviations

6MWT D – Six-minute walk time distance

AMPATH - Academic Model Providing Access to Healthcare

CR – Cardiac rehabilitation

HBCR – Home based cardiac rehabilitation

IBCR – Institution based cardiac rehabilitation

MTRH – Moi teaching and referral hospital

NYHA – New York heart association

PHQ9 – Patient health questionnaire nine

SF36 – Short form thirty-six questionnaire

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1. Introduction

1.1 Heart failure disease burden and cardiac rehabilitation

Cardiovascular disease is a major contributor to disease burden globally (4–6,13). Low and middle income countries account for over 80% of cardiovascular mortality (1,2). In Africa, cardiovascular disease is now the second most common cause of death after infectious disease, accounting for 11 percent of total deaths(1,14,15). Heart failure, which is a terminal complication of these cardiovascular diseases, is often a worrisome and debilitating diagnosis with far reaching implications to patients, their families and society in general(16). The estimated 5 year mortality of heart failure is greater than 50% in developed countries and is estimated to be higher in resource limited settings (4,5,17,18). In addition, it is associated with extensive debility, attendant depression and deterioration in quality of life as the disease progresses(19)

Cardiac rehabilitation is defined as a multidisciplinary approach providing physical, psychological and social support to patients recovering from cardiac illnesses(9). It typically involves engaging patients in a monitored exercise prescription conducted in a tertiary health institution over a period of 12 weeks with incorporation of lifestyle modification, counseling and health education (20). It has been demonstrated to be effective in improving overall functional status, reducing morbidity, mortality and

improving quality of life (21) and has been incorporated into standard of care practices in several parts of the world (9,19,22)

1.2 Effects of cardiac rehabilitation

Cardiac rehabilitation has been demonstrated to have a significant health benefits in different populations around the world(7,23). Cardiac rehabilitation leads to reductions in morbidity, mortality and overall improvement in quality of life(21,24). In addition to a mortality risk reduction of approximately 20% metanalysis of systematic review studies and RCTs have shown overall improvements in heart failure symptoms as well as comorbidities such as depression (25–27). The economic value of cardiac rehabilitation has also been shown through reduction in hospital lengths of stay and treatment costs (28–30). Unfortunately, none of the benefits associated with Cardiac rehabilitation accrue to patients with heart failure in the region because the service is not available (12).

1.3 Models and Components of cardiac rehabilitation

There are two main models for delivery of cardiac rehabilitation: Institutional based cardiac rehabilitation (IBCR) and home based cardiac rehabilitation (HBCR), also known as community based cardiac rehabilitation(31). Through randomized control trials and systematic reviews, HBCR has been shown to have similar efficacy and comparable low risk profile when compared to IBCR (32,33).

IBCR adherence has been reported to be low and associated with barriers such as inaccessibility of rehabilitation centers (34,35). HBCR is thought to mitigate some factors associated with poor adherence such as lack of transportation (31). However, HBCR programs face shortcomings such as lower exercise performance in the absence of supervision(36). Furthermore, though demonstrated to be safe, HBCR is less likely to be the preferred option in high risk patients in whom closer monitoring may be necessary(37,38). Appreciably, some of these shortcomings have been mitigated by the advent of wearable devices and use of mobile monitoring to reach a wider population and offer greater monitoring capacity (39,40).

1.4 Barriers to cardiac rehabilitation

Despite the known benefits, utilization of cardiac rehabilitation has been limited. It is not prescribed often enough and when it is prescribed, enrollment rates have been reported to be as low as 14% and dropout rates are as high as 30%. Where patients sign up and attend cardiac rehabilitation, completion rates have been as low as 8%(24,36,41). Commonly cited barriers to utilization are poor motivation, inaccessibility of rehabilitation centers and the cost of the intervention (24).

Despite being a simple and comparatively low-cost intervention, there has been little development of CR in in sub-Saharan Africa except in high income regions. In Western Kenya, where there is significant heart failure disease burden(42), CR is non-existent(12). This is presumably as a result of lack of capacity and inaccessibility of health institutions and the means to make it accessible to those populations that are most at need (38,43).

1.5 Problem Statement

Cardiac rehabilitation(CR) has been shown to offer clinical benefit and improve outcomes in patients with heart failure including a 22% reduction in mortality (23,25,44). As such, the development of CR in resource limited settings like Western Kenya, is urgently needed. However, given the region's unique socioeconomic and environmental factors, feasibility of CR and the optimal approach to implementation in Western Kenya is unknown.

This study sought to assess whether cardiac rehabilitation in western Kenya is feasible as measured by participant protocol adherence to two common cardiac rehabilitation models: institution based cardiac rehabilitation (IBCR) and home based cardiac rehabilitation (HBCR). We hypothesized that subjects recruited to cardiac rehabilitation protocols would adhere to a mean proportion of at least 25% of prescribed rehabilitation sessions in keeping with an anticipated protocol completion rates of 25 % as reported in other studies (36,45,46).

2. Methods

2.1 Study design

This was an observational mixed methods study design involving quantitative and qualitative assessments of study participants enrolled into two different models of cardiac rehabilitation represented by two study arms, namely, institution based cardiac rehabilitation (IBCR), and home based cardiac rehabilitation (HBCR). After tracking a baseline adverse event rate in the study population, the study protocol was modified (see appendix 6.3) to incorporate an observational arm (OA) amongst whom there was no intervention.

2.2 Study Setting

The study was conducted at the Moi Teaching and Referral Hospital (MTRH) in Uasin Gishu County, Kenya. The facility and its affiliated clinics cover a catchment area that extends across several counties in western Kenya, serving an estimated population of 25 million people. The hospital has a dedicated outpatient cardiology clinic which cares for an average of 320 patients per month, the majority of whom have symptomatic heart failure (42). Cardiologists from this clinic are the main specialty care providers in the region. They also referred participants from their clinics at two affiliated private institutions, the Eldoret Hospital and Transcare clinic.

2.3 Sample size determination

We planned to enroll a total of 100 subjects based on a reasonable estimate of expected subject recruitment over the time frame of the study as well as anticipated facility capacity. Twenty-five participants were enrolled into the IBCR arm and seventy-five participants into the HBCR arm in consideration of the potentially larger population and a wider geographical spread of HBCR. Clinically significant events not related to the intervention, including 2 deaths summarized in appendix 6.3, were observed during the study. After review by the study data safety and monitoring board (DSMB) the HBCR arm intervention prescriptions were stopped after recruitment of 31 participants. The remaining 44 participants who had no intervention prescribed, formed an observational arm as illustrated in Figure 1 below.

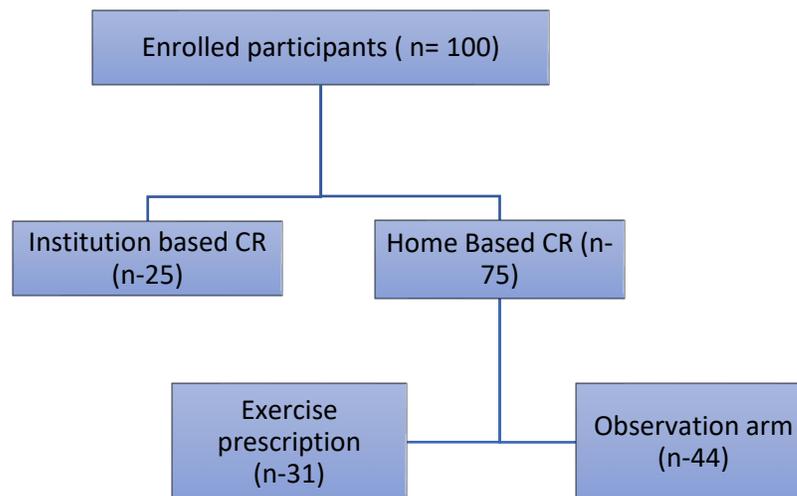


Figure 1: Outline of study participant allocation

2.4 Study Population

Male or female patients with heart failure as defined by symptomatic shortness of breath with exertion and documented record of the diagnosis of heart failure in the patient's medical records, were identified from screening of patient records and clinic attendance registers. Study participants were then voluntarily recruited using a convenience sampling approach.

2.4.1 Inclusion Criteria

The following inclusion criteria were used to identify potential study participants.

1. NYHA Class II or III heart failure
2. Have had an echocardiographic study in the past 5 years
3. Owns a mobile telephone
4. Can participate in exercise
5. Can read/ primary care giver can read in English or Kiswahili
6. Can travel to hospital three times a week

2.4.2 Exclusion Criteria

The following exclusion criteria were used to identify potential study participants.

1. Recent acute illness requiring hospitalization or initiation of new cardiac medication in the preceding 4 weeks,
2. Limitation of activity because of factors other than fatigue or exertional dyspnea, such as arthritis, claudication in the legs, angina, advanced comorbidities.
3. Known arrhythmia
4. Heart failure due to congenital heart disease
5. Pregnant patients as may be confirmed by patient report or urine pregnancy tests
6. Heart failure due to obstructive cardiomyopathy including mitral stenosis and aortic stenosis
7. Use of pacemakers

2.3 Procedures

All study procedures were approved by the ethical review boards at Duke University and Moi University

2.3.1 Initial evaluation, safety screening and enrollment

After giving informed consent, screening logs were used to collect general demographic data and basic medical history. Participant anthropometric measurements

were recorded and screening for coronary artery disease was conducted using the Masters two step test(47). This test served as an additional safety assessment of participant's physical ability to participate in cardiac rehabilitation.

Upon successful completion of the safety screen, participants were enrolled into the study by electing to enter one of two study arms. Entry into either arm was on a rolling basis based on study participant preference. Each study arm would fill up its allotted slots on a "first come first serve" basis.

2.3.2 Establishment of baseline exercise capacity and step rate

Enrolled participants were oriented to the exercise equipment and taught how to rate their perceived exertion using the Borg rate of perceived exertion scale (48). Their aerobic threshold target heart rate was calculated using the Karvonen formula(49,50) Participants were asked to walk on a treadmill starting at a level gradient and speed of 1km/h. The speed was gradually increased by 0.05km/h at three-minute intervals until attainment of their aerobic threshold (AT). AT was measured as the earlier of attainment of target heart rate or attainment of moderate perceived rate of exertion as reflected on the Borg scale. Upon attainment of aerobic threshold, the participants step rate would be computed as the number of steps covered in one minute at the participants AT speed level.

2.3.3 Exercise prescription

For each participant, an exercise prescription was then generated. The prescription comprised characterization of the exercise type, duration and intensity, tailored to match the participants baseline exercise capacity and their interventional arm.

2.3.3.1 Institutional based rehabilitation (IBCR)

IBCR sessions comprised 36 individually tailored rehabilitation sessions of aerobic activity. The exercise intensity was incremental and focused achievement of the earlier of AT as measured using the Borg scale or target heart rate using Karvonen's formula while exercising on a treadmill or cycle ergometer. During the first 4 weeks target heart rate was set to 50-60% of max HR. During week 5-8 target heart rate was increased to 60-70% of their max HR and during week 8-12, 70- 80% of their max HR. Duration of aerobic exercise was also increased by 5- 10 minutes with each session with a goal of attaining 60 minutes of aerobic exercise by the end of 36 sessions.

2.3.3.2 Home based CR (HBCR)

HBCR comprised 12 individualized weekly step targets. Participants were instructed to set aside a daily, convenient time when they would exercise by brisk walking. Participants were taught how to assess moderate exertion based on interval measurements of their heart rates and sensation of moderate exertion as trained during

establishment of their baseline step rate. The first weekly step goal was imputed from their step rate at AT multiplied by 140 representing a 20 min target duration of exercise walking for 7 days. Subsequent increments were based on a 10% increment on the preceding week's step goal. Walking distance was measured with the aid of a pedometer issued to participants who were also instructed to log daily readings from the pedometer. Some subjects (see appendix 6.3) received thrice weekly calls to match contact frequency with participants in the IBCR arm. Participants were evaluated in clinic every 4 weeks for functional capacity and to download data from their pedometers and track their individual logs.

2.3.3.3 Observational arm (OA)

Midway through the study protocol, a subset of HBCR participants (see appendix 6.3) were enrolled into the observational (usual care arm) to characterize the underlying risk profile for heart disease amongst the study population. Participants were informed about the known benefits of exercise, but no weekly exercise targets were prescribed. Participants were given pedometers that track their activity levels and asked to come for a follow up every 4th week for three months in a comparable fashion to participants in the active rehabilitation. During these visits monitoring data from their pedometers was downloaded into a database and functional assessments were conducted.

2.3.4 Participant questionnaires

Enrolled participants were guided through two standardized questionnaires: the PHQ9 depression screening questionnaire (51,52) and the SF36 quality of life questionnaire (53–55). These were administered at the start of the rehabilitation protocol and at the end of the 3 month follow up period.

2.3.5 Focus group discussions

Upon completion of the cardiac rehabilitation protocol, participants were invited to participate in focus group. Three groups comprising 4-6 study participants were invited as follows:

- Group 1 – Participants in the institution based cardiac rehabilitation (IBCR) arm who adhered to the study protocol,
- Group 2 – Participants in the home based cardiac rehabilitation (HBCR) arm who adhered to the study protocol, and
- Group 3 – Participants from both IBCR and HBCR arms who did not who adhere to the study protocol

Discussions were led by a moderator using a guide as shown in the appendixes, and audio recordings of the discussion were stored on the study computer. The

discussions explored study participant perspectives and understanding of heart failure, their cardiac rehabilitation experience, barriers to participation in cardiac rehabilitation and potential areas for improvement.

2.4 Measures

2.4.1. Primary outcome measure

Whereas feasibility is a very broad construct, feasibility of cardiac rehabilitation in this study was measured based on ability of participants to adhere to at least 25% of scheduled activities on their cardiac rehabilitation protocol. For participants in the IBCR arm, adherence was measured as a proportion of subjects recruited who participated in at least 9 of 36 prescribed rehabilitation sessions and attained pre-defined exercise targets. In the HBCR arm, this was measured as a proportion of subjects who completed at least 3 of their 12 weekly exercise prescriptions of HBCR. Completion of the exercise prescriptions was self-reported via phone and validated at monthly visits based on data downloaded from pedometer devices.

2.4.2 Secondary outcome measures

The study also sought to assess other outcome measures including potential benefits of cardiac rehabilitation, that would offer greater insight into feasibility of the intervention. Functional capacity assessment was conducted at enrollment using a six-minute walk time distance test(56). This measure was repeated monthly for all study participants. Depression screening was conducted using a PHQ9 screening questionnaire (52) and repeated at the end of the rehabilitation session. Quality of living

was also measured using a SF 36 questionnaire (54,55) at the start and at the end of the rehabilitation protocol.

2.5 Analysis

Study data were collected and managed using REDCap electronic data capture tools hosted at Duke University(57). Summary statistics and analysis of quantitative data was conducted using STATA software V.14. Numeric data were expressed as number (percent), means (standard deviation [SD]) or median (interquartile range [IQR]). For comparisons, we used paired t-tests for continuous variables.

Qualitative data from focus group discussions were manually transcribed and translated into English. Data was entered into a web-based analysis platform, Dedoose V 8.3. Using a deductive constant comparison approach as described by Onuwegbuzie et al (58,59), each focus group discussion transcript was reviewed and codes assigned to excerpts. The codes were then grouped into categories and summarized as themes.

3. Results

3.1 Participant enrollment

A total of 640 participants were screened over a period of 9 months. Of these, 516 were excluded due to ineligibility. After secondary safety screening using a master's 2 step test, 24 participants were excluded based on symptoms such as angina, physical discomfort or ECG changes. Eventually, 100 study participants were enrolled into three arms as illustrated in figure 2 below.

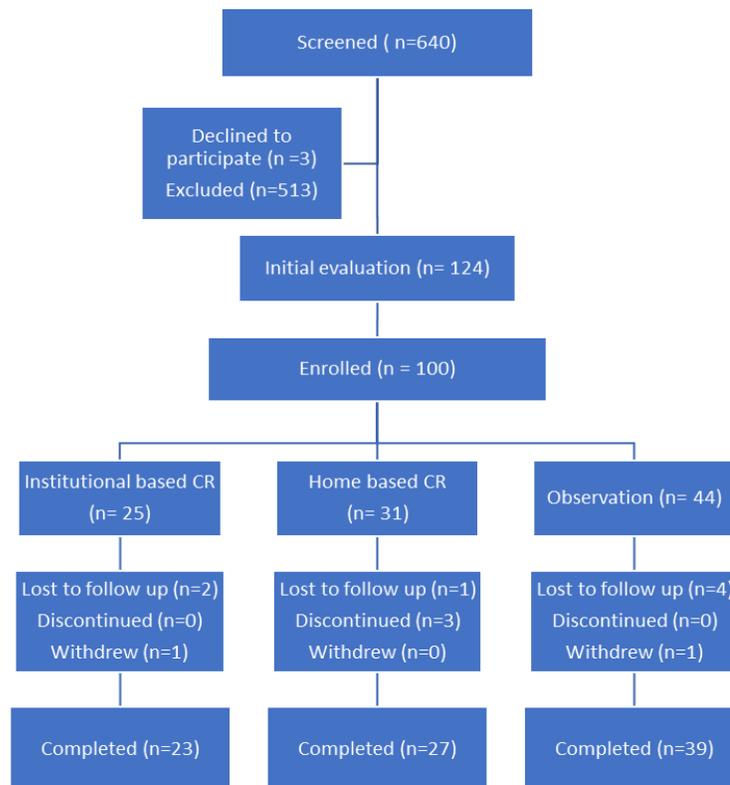


Figure 2: Summary of participant enrollment

3.2 Description of the research population

The main reasons for exclusion included stenotic valvular lesions, co-affliction with arrhythmias such as atrial fibrillation and degenerative joint diseases. Of the participants who declined to participate most cited inability to travel regularly to the rehabilitation center. Demographic characteristics of participants are summarized in Table 1 below.

Table 1: Summary of study participants by enrollment arm

| Variable | IBCR (n=25) | | HBCR (n=31) | | OA (n=44) | |
|---------------------------------------|----------------|------|----------------|------|--------------|------|
| Sex, male n (%) | 8 | (32) | 3 | (10) | 17 | (39) |
| Age in years: mean, (SD) | 56 | (17) | 44 | (16) | 54 | (16) |
| Weight in Kgs: pre-rehab mean, (SD) | 73 | (22) | 71 | (17) | 64 | (14) |
| Height in meters: mean, (SD) | 162 | (7) | 163 | (7) | 164 | (9) |
| BMI mean, (SD) | 28 | (8) | 27 | (7) | 24 | (6) |
| Waist circumference in cm: mean, (SD) | 96 | (24) | 91 | (16) | 89 | (14) |
| Hip circumference in cm: mean, (SD) | 106 | (17) | 106 | (13) | 97 | (13) |
| Resting heart rate bpm: mean, (SD) | 71 | (9) | 71 | (15) | 77 | (13) |
| Systolic BP in mmHg: mean, (SD) | 138 | (17) | 132 | (21) | 132 | (20) |
| Diastolic BP in mmHg: mean, (SD) | 84 | (12) | 79 | (11) | 82 | (12) |
| Ejection fraction % (SD) | 50 | (15) | 49 | (14) | 45 | (15) |

IBCR- institution based cardiac rehabilitation, HBCR – home based cardiac rehabilitation, OA – observational arm

3.3 Rehabilitation protocol adherence

Participants in both the HBCR and the IBCR arm were mostly adherent to their respective rehabilitation protocols as shown by Figure 3.

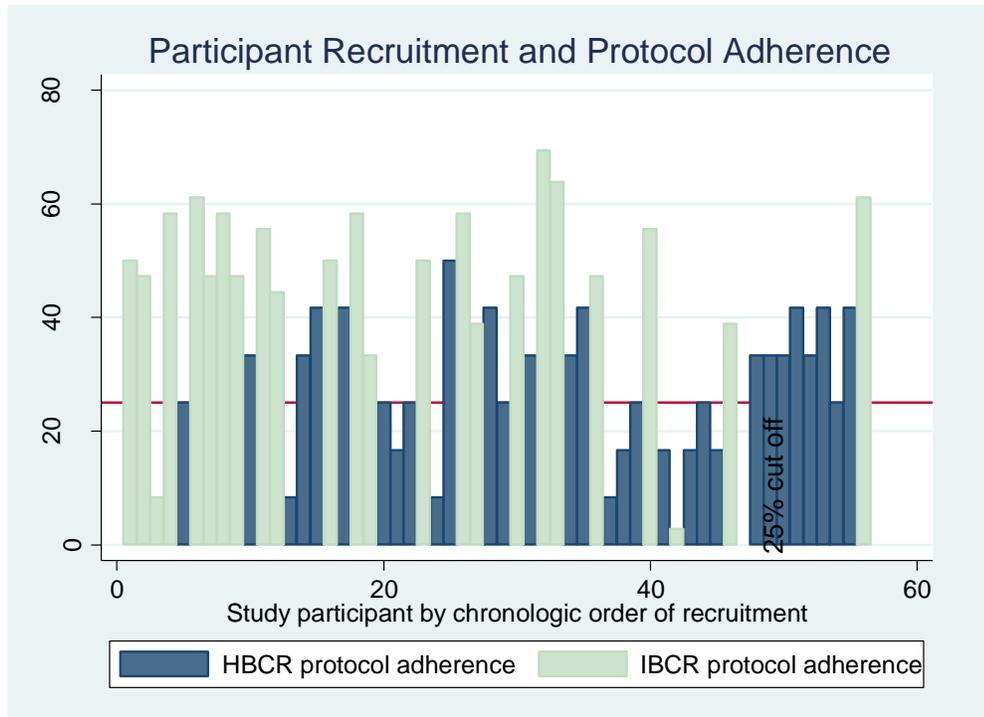


Figure 3: Protocol adherence by participant

Enrolled participants were able to attain a mean adherence attendance rate of more than 25 percent in both arms. The mean protocol adherence rate in the IBCR arm was 46.11%. The HBCR arm participants achieved a mean protocol adherence rate of 28.76% as shown in Figure 4 below

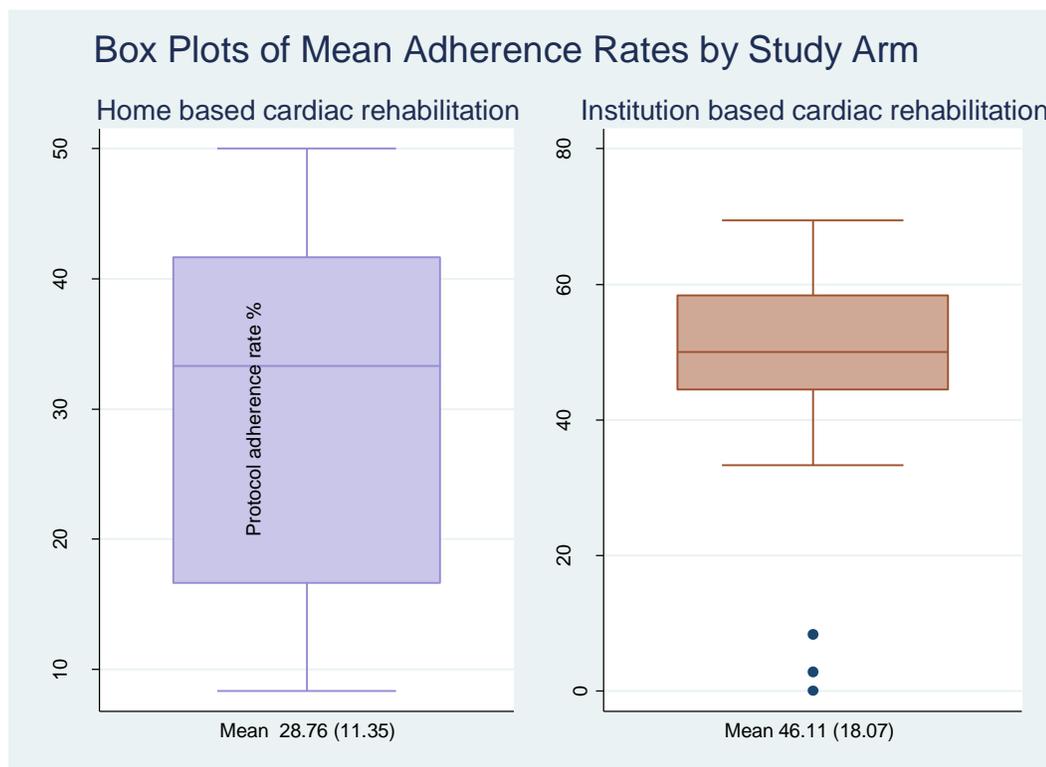


Figure 4: Mean percentage of protocol adherence by rehabilitation arm

Participants in the IBCR arm had the highest rate of attendance across all monthly follow up visits. Amongst all study arms, month two of the HBCR arm had the highest study dropout rate as outlined in table 2 below.

Table 2: Participant attendance for each monthly visit by study arm

| Initial enrolment (100%) | IBCR | HBCR | OA |
|---------------------------------|-------------|-------------|-----------|
| Visit 1 attendance % | 88.00 | 87.10 | 81.82 |
| Visit 2 attendance % | 88.00 | 64.52 | 65.91 |
| Visit 3 attendance % | 88.00 | 67.74 | 70.45 |

3.4 Description of functional capacity changes

Participant functional capacity increased in all categories. Most improvement was seen in the HBCR arm over the course of three months. Some improvements made in functional capacity in the IBCR arm were lost between month 2 and 3 as shown in table 3 below.

Table 3: Change in 6MWT - distance per rehab arm over time

| Variable | IBCR (n=25) | | HBCR (n=31) | | OA (n=44) | |
|---|-------------|-------|-------------|-------|-----------|-------|
| | Mean | SD | Mean | SD | Mean | SD |
| 6MWT (meters) initial | 277.90 | 78.32 | 291.94 | 59.12 | 259.36 | 68.18 |
| 6 MWT (meters) month 1 | 313.95 | 56.64 | 315.02 | 56.98 | 302.69 | 58.37 |
| 6 MWT (meters) month 2 | 322.93 | 66.46 | 330.95 | 55.90 | 303.91 | 59.11 |
| 6 MWT (meters) month 3 | 315.65 | 74.30 | 339.19 | 51.57 | 304.41 | 80.50 |
| Change in 6 MWT distance pre and post CR (meters) | 31.25 | 64.98 | 40.15 | 54.68 | 38.24 | 71.42 |
| P (Paired t-test) | 0.027 | | <0.001 | | 0.0025 | |

The change in functional capacity was also seen in subjective assessments as reported by study participants with 8% of OA participants feeling worse by the end of the follow up study period as shown in table 4 below

Table 4: Change in NYHA Class over three months

| Change in NYHA class | Difference | IBCR (n =25) | | HBCR (n=31) | | OA (n=44) | |
|-------------------------|------------|--------------|-------|-------------|-------|-----------|-------|
| | | Freq. | % | Freq. | % | Freq | % |
| Got worse | -1 | 0 | 0 | 0 | 0 | 3 | 8.11 |
| No change | 0 | 7 | 29.17 | 16 | 59.26 | 14 | 37.84 |
| Improved by one class | 1 | 15 | 62.5 | 10 | 37.04 | 20 | 54.05 |
| Improved by two classes | 2 | 2 | 8.33 | 1 | 3.7 | 0 | 0 |

3.5 Description of changes in depression screening

Several participants screened positive for different levels of depression at enrollment.

The screening depression scores improved in all groups after rehabilitation as summarized in table 5 below.

Table 5: Proportion per study arm, of participants depression severity grade, pre and post cardiac rehabilitation based on PHQ9 scores

| Depression severity | IBCR (n = 25) | | HBCR (n =31) | | OA (n=44) | |
|---------------------------|---------------|---------|--------------|---------|-----------|---------|
| | Pre CR | Post CR | Pre CR | Post CR | Pre CR | Post CR |
| Absent (score 0-4) % | 40 | 66.67 | 19.35 | 62.96 | 29.55 | 54.05 |
| Mild (score 5-9) % | 40 | 29.17 | 64.52 | 33.33 | 52.27 | 32.43 |
| Moderate (score 10- 14) % | 20 | 4.17 | 12.9 | 3.7 | 13.64 | 10.81 |
| Severe (score 15-19) % | | | 3.23 | | 4.55 | 2.7 |

The average change in depression screening scores was statistically significant in all arms as shown in table 6 below

Table 6: Average change in depression screening score

| Variable | IBCR | | HBCR | | OA | |
|----------------------|-------|------|--------|------|-------|------|
| | Mean | SD. | Mean | SD | Mean | SD |
| PHQ9 score baseline | 7.96 | 5.29 | 9.23 | 5.17 | 8.43 | 5.55 |
| PHQ9 score follow up | 4.75 | 4.41 | 4.19 | 2.99 | 6.14 | 6.1 |
| Change in PHQ9 score | 3.21 | 4.69 | 4.26 | 4.41 | 2.24 | 4.57 |
| P (Paired t-test) | 0.003 | | <0.001 | | 0.005 | |

3.6 Description of Changes in quality of living

Participants demonstrated an improvement in quality of living based on their physical component summary, as well as their mental component summary scores. However, the physical component summary score changes were statistically insignificant as measured using the student t- test.

Table 7: Change in SF36 Component summary scores

| Variable | IBCR | | | HB CR | | | OA | | |
|----------|------|-------|--------|-------|-------|--------|------|-------|--------|
| | Mean | SD. | p | Mean | SD. | p | Mean | SD. | p |
| PCS* | 2.65 | 14.82 | 0.39 | 0.89 | 10.10 | 0.66 | 2.90 | 12.63 | 0.16 |
| MCS* | 8.81 | 10.12 | <0.001 | 8.74 | 11.58 | <0.001 | 8.92 | 10.48 | <0.001 |

PCS – Physical component summary; MCS mental component summary;

3.7 Description of adverse events

Participants and their primary care givers reported health concerns that would arise or limit exercise participation. Participants in the IBCR identified 25 health concerns, participants in the HBCR identified 22 health concerns and participants in the observational arm reported 9 health concerns. Significant events including two deaths were reviewed by the DSMB as summarized in appendix 6.3. Fatigue was the most frequently reported health concern in all three arms as summarized in figure 5 below.

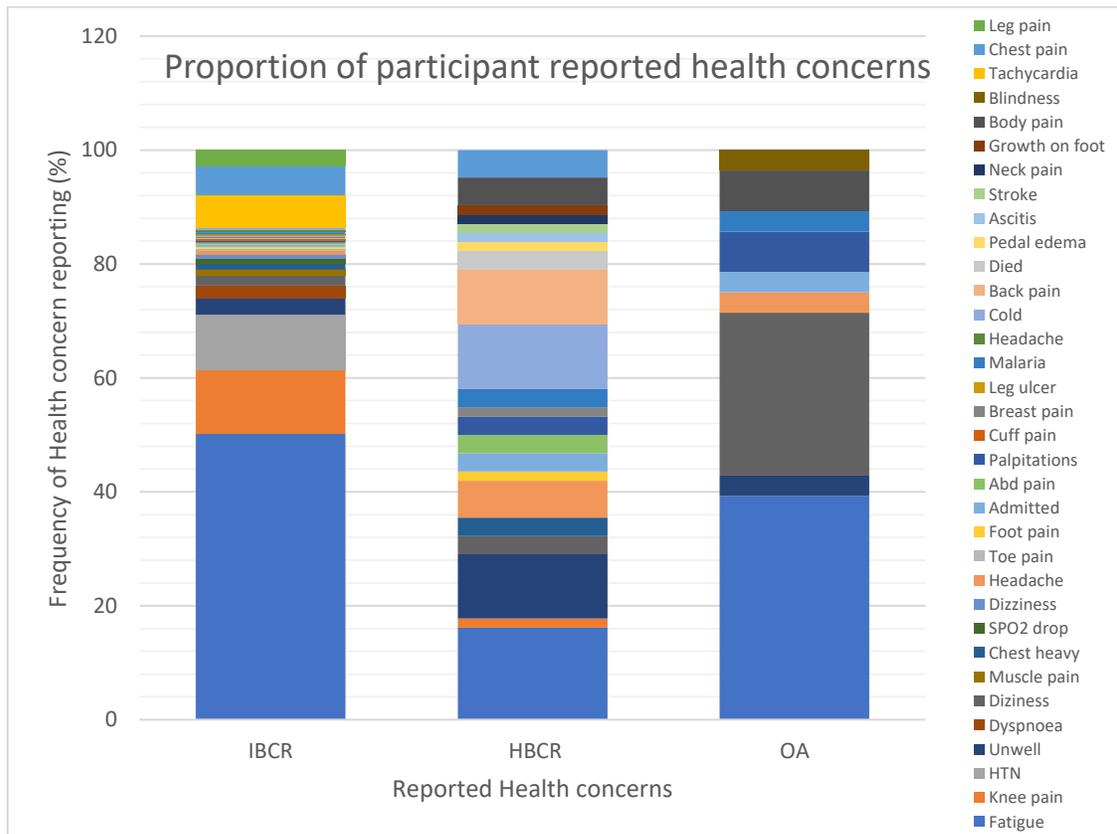


Figure 5: Self-reported exercise limiting factors by study arm

3.8 Description of focus group discussions (FGD)

Three focus group discussions were conducted as summarized in table 8. Participants in the third focus group discussion were from a combined pool of home and institution based cardiac rehabilitation participants.

Table 8: Demographic characteristics of focus group discussion participants

| Characteristics | FGD 1. Completed IBCR protocol | FGD 2. Completed HBCR protocol | FGD 3. Completed neither protocol |
|---------------------|--------------------------------|--------------------------------|-----------------------------------|
| No. of participants | 6 | 6 | 4 |
| Gender m/f | 2/4 | 1/5 | 1/3 |
| Age mean (SD) | 60 (19.8) | 45 (14.61) | 35 (15.94) |

From the transcribed and translated focus group discussions, eighty-five codes were identified and applied across one hundred and forty-seven excerpts. The codes were applied three hundred and three times and reviewed and summarized into fifteen themes. An excerpt of the summarized themes is listed in Table 9.

Table 9: Themes codes and excerpts from focus group discussions

| Theme | Code | Sample excerpt |
|-----------------------------------|-----------------------|--|
| Challenges in seeking health care | Chronicity of disease | <i>It was 2013 when I started becoming ill and before I became bed-ridden. I would feel I get tired a lot when I walk, and generally I was weak. Then I became bed-ridden. I went to so many hospitals but there was no change</i> |
| | Associated diagnosis | <i>I started getting tired for quite some time and I would be told I have Typhoid, Malaria and Brucella. Sometimes they would say it's very rare to find typhoid in an aged person. Until my legs started swelling and I started feeling tired while walking even the shortest distance.</i> |
| | Treatment sources | <i>.... I decided not to come to MTRH because they are treating me and prescribing very expensive medication.... tomorrow I wake up again am told to stop using medication that I haven't even opened and another one is prescribed., and they prescribed twice. The third one, I decided to go back to a private hospital. Maybe they will look at my body or order an x-ray of the chest</i> |

| | | |
|------------------------------------|---------------------------------------|--|
| | Movement from one facility to another | <p>... I was treated in a private hospital in Kapsabet and given medication to reduce it but when it reduced, I felt a lot of pain. I joined form one, form two, form three I was not sick. On joining form four I started becoming ill. I had chest pain all the time and I would feel choked and my chest was heavy. If I sleep without using a pillow to raise me to an almost sitting position. I was taken to Tenwek hospital where I was treated for around three years. Tenwek didn't know where the problem was. When I was in second year, I became very sick and was admitted here in MTRH</p> |
| | Perceived causes of heart failure | <p>As for me, when I was told I have heart disease, I was shocked but what came to mind was how I can reduce the fats in my body. Because I had heard that when the heart and arteries are covered by fat, cannot move properly. And you can easily get heart attack and die. So that's what I was worried about and I decided to follow the doctor's instructions.</p> |
| Physical symptoms of heart disease | Feeling fatigued | <p>I would still get tired when walking, due to high blood pressure. Even walking a short distance I'd feel very tired and I res</p> |
| | Feeling bad/sickly/difficult | <p>Breathing was a problem, walking, I couldn't carry anything heavy and my heart kept beating fast all the time but at the moment, I'd say I feel bad, like when my heart beats fast, my mum would tell me, "you're very young, what is the stress for?"</p> |
| | Inability to walk | <p>I also couldn't walk. I was unable to work, I felt weak. My feet were swollen, and I could not even walk a kilometer, I kept resting on the way. That was the main problem</p> |
| | Limitations in daily activities | <p>.... I couldn't wash my clothes, I had to hire someone to wash clothes. I could cook because it's just me and my husband. I have a small business where I sell food, but I could not cook. I would get severe headache that was worsened by smoke.</p> |
| | Lower extremity swelling | <p>... I couldn't even move my legs because they were swollen</p> |
| | Orthopnea | <p>...I had chest pain all the time and I would feel choked and my chest was heavy. If I sleep without using a pillow to raise me to an almost sitting position.</p> |

| | | |
|---|---------------------------|---|
| | Palpitations | <i>... because when I was feeling unwell; palpitations, the heart beating fast, I could not lie flat.</i> |
| | Shortness of breath | <i>.... on reaching home it became worse and I would experience difficulty in breathing</i> |
| | weight changes | <i>Before I began exercising, my body was heavy, and I couldn't even walk for one kilometer. I would be forced to board a motorcycle</i> |
| Psycho-social changes associated with heart disease | Acceptance | <i>When I came to MTRH, I was tested and told I have heart disease and that's when I believed it. I said to myself since I've been diagnosed let me just pray to God.</i> |
| | Anxiety/Worry | <i>...I was worried. At home I would even preach to the neighbors but now I was very scared</i> |
| | Association with death | <i>I've heard that with heart disease, one can easily collapse and die.</i> |
| | Association with religion | <i>I was also given medicine and I hoped I would be healed, so I put God first. Isn't God there?</i> |
| | Fear of missing work | <i>..... I couldn't miss work, so I'd go and sit on a stool</i> |
| | Feeling limited | <i>I was told I won't be able to get another child</i> |
| | Helplessness | <i>I lost hope until I decided to discontinue school</i> |
| | Positive/hopeful | <i>Then I came to see the young and the aged. That's when I said so people can live long with the disease? So, I got courage</i> |
| | Shock/disbelief | <i>Personally, I never expected it because it shocked me. I am young, I was fresh out of high school and had just finished a year after finishing form four and then you're told you have heart disease. I was like how do I live after this?</i> |
| | Sick role | <i>At least people can stop stressing me because they know how it will affect me. I don't engage much when I see that something will cause my pressure to rise, I leave it there.</i> |

| | | |
|---|---------------------------------------|--|
| | Social isolation | <i>You know earlier, someone would say you have heart disease and people would say they should not do any work. Just stay, you have heart disease. Do not laugh, run or cry a lot or overdo anything. Until you ask yourself, where will you get another world like this</i> |
| | Stress | <i>I said to myself if I have heart disease, I have to reduce stress. And you know if you're healthy you can do your work just by using your brain.</i> |
| Advocacy | Personal experience of benefit | <i>..... we reach out and see if we can bring others because we have been helped and that's what we have just testified, so if we can help others out there, I think it will be good</i> |
| | Referral - from patients/participants | <i>..... so, I told her to come and see this program.</i> |
| Barriers to cardiac rehabilitation - home | Competing interests-time | <i>... in the process of dealing with things going from one point to another, before you know it, it's 12.00pm and you're still busy you've forgotten. But if it has an alarm on your body it just rings and you download. You can even remember when you put it somewhere, but if you've gone somewhere maybe to a ceremony.... three months is long.</i> |
| | Faulty pedometers | <i>.... I went through this when it becomes faulty. When I bring it to the doctor to be reset, by the time I get to town it will have jumped again</i> |
| | Fears of adverse events | <i>.... I was not so sure I would be able to exercise</i> |
| | Forgetfulness to wear pedometer | <i>.... maybe you've gone up to somewhere then you remember you've forgotten it in the house, it becomes a problem because you feel that no one will be able to count the steps you've made without the pedometer</i> |
| | Forgetfulness to exercise | <i>.... What made you not to come? You just forget.</i> |
| | Perceived high expectations | <i>So, when am at home and I haven't met the target, in my thoughts, you know it stresses you up. When I will be called on Wednesday to give out target, what stress is this!</i> |

| | | |
|--|--|---|
| Barriers to cardiac rehabilitation - institution | Competing interests and life events - work, school | <i>I just missed once, and I called her.... Why did you miss? We had lost a loved one.</i> |
| | Distance from hospital | <i>.... Though I come from far, Siaya all the way.... Yes, I school in Siaya.</i> |
| | Forgetfulness to come to hospital | <i>Most of the time I used to tell her I'll arrive around 2.00 pm. Then when it gets to 2.00pm you find that maybe I have forgotten</i> |
| | Limited equipment - only one treadmill | <i>... if they could add another treadmill so that two people can exercise at the same time. The stationary bikes should also be made four so that at any given time we have six people exercising and one at the weight lifter to make seven. For now, since we have one treadmill, you all have to wait until someone gets tired, so it consumes a lot of time.</i> |
| | Poor health | <i>... I was admitted in memorial; my chest was heavy, and I was unwell</i> |
| Cost of cardiac rehabilitation | Fears about high cost | <i>If they start charging, I won't lie to am telling the truth, I don't want to say something and then later, I say it would have been like this. To tell you the truth, if we were to pay, people would have surrendered a long time ago. We would not even have a discussion here today. (laughter)</i> |
| | limited ability to pay for cardiac rehabilitation | <i>If we were to cater for our own transport every day for three months I don't think we'd be able to. I don't know if someone else can but as for me, I'd skip for two days as I look for money.</i> |
| | Willingness to pay for cardiac rehabilitation | <i>As for me, three thousand per month.</i> |
| CR model preferred | Prefer home based rehabilitation | <i>..... I told her to let me do it at home because I saw I might not be able to come three times a week</i> |

| | | |
|--|---|--|
| | Prefer institution-based rehabilitation | <i>..... As for me, it's difficult because you need to be guided by a doctor</i> |
| Health system challenges | Health awareness and education | <i>.... I became ill in 2013 and I did not follow up but recently I discovered it's the same problem." Then now I asked, "How does this problem come about? Because I have never been ill". He told me they had looked into my problem and they also didn't know what caused it but I think it's age. I told him there are people older than me, but they don't have this problem.</i> |
| | Insurance | <i>.....that became a problem and sometimes I would go without it. Here, I wouldn't get the medication and I went and got NHIF (national health insurance fund policy) but it wasn't of help because I couldn't use it to buy medication.</i> |
| Perceived physical effects of cardiac rehabilitation | blood pressure control | <i>My pressure is even normal now, at 72</i> |
| | Improved ability to carry out chores/Daily activities | <i>I couldn't plough, I had to use money to get my small shamba ploughed. But nowadays I can plough. I couldn't draw water from the well but now I can. So, I see I have really improved... As for me, I couldn't walk but now I can walk with my friends. They would tell me to take a motorbike and go ahead but now I can walk with them up to where we are going.... I can also walk. I can split firewood using an axe... I couldn't walk nor plough. But now I can tie the cows and plough with my children. Even when I had the machine, it was like exercise because I would plough with the cows. I tie the cows and tell my son let's go. I take the hoe and I go round the entire farm.</i> |
| | Improved self-care | <i>I couldn't even walk, I'd just stay at home. I couldn't even walk from my house up to there, I couldn't even bathe I needed help to bathe. But now, I can bathe myself, I can draw water from the well, I can walk from the stage up to here, yeah</i> |

| | | |
|--|----------------------------------|---|
| | Less sickly | <i>... before I began exercising, my body was heavy, and I couldn't even walk for one kilometer. I would be forced to board a motorcycle</i> |
| | Medication adherence | <i>... Am taking my medication as directed and now I have no difficulty doing my work. I walk and do my businesses well.</i> |
| | Pleasurable | <i>... I enjoyed the exercises to the point that I felt I was missing out before</i> |
| | Reduced leg swelling | <i>... I couldn't even move my legs because they were swollen but now it's coming back to normal.</i> |
| | Weight loss | <i>I was fat, now am shedding weight. I was about 100kgs but now it has gone back to eighty something.</i> |
| Perceived psychosocial effects of cardiac rehabilitation | Alleviation of social isolation | <i>As for me, I couldn't walk but now I can walk with my friends. They would tell me to take a motorbike and go ahead but now I can walk with them up to where we are going</i> |
| | I am peaceful/less anxious | <i>... I stopped quarreling with the children and grandchildren.</i> |
| | I feel better/stronger/energetic | <i>... today I can say am stronger. I can do my work and even though I wouldn't say am healed</i> |
| | I feel happier | <i>I take things how they are to be happy.</i> |
| | I feel less fearful | <i>It has taken away the fear of saying if someone has heart disease, they are isolated</i> |
| | I feel less stressed | <i>Now I feel better. I reduced stress and felt better.</i> |

| | | |
|------------------------|--------------------------------------|--|
| Positive feedback | Availability | <i>Another thing, you know long time ago, when you go to other hospitals you find a coat hanged on the chair. You wait for that coat and maybe the doctor is very far away. You start thinking too much and become sicker</i> |
| | Reassurance | <i>doctors in the rehabilitation unit are very jovial and because of that happiness, you can even get healed. You know when you're sick and someone hurls out hurting words to a sick person, you are adding more sickness</i> |
| Suggested improvements | Increase available equipment | <i>Let me add one thing. Exercise is very good but the problem we have, if they could add another treadmill so that two people can exercise at the same time. The stationary bikes should also be made four so that at any given time we have six people exercising and one at the weight lifter to make seven. For now, since we have one treadmill, you all have to wait until someone gets tired, so it consumes a lot of time. That's my request</i> |
| | Provide access post rehab monitoring | <i>Doctor, you've said we should never stop exercising. Now my question is, after we complete this program, can we still be monitored? How?</i> |
| | Ways to improve exercise tracking | <i>They should have put something like a ring, something like an alarm, so that for example when it gets to 6.00 am, it wakes you up. It tells you have this thing in the body. Then when it gets to 11.00 pm, it alerts you, tells you it's approaching one hour to, there's something you should have done.</i> |
| Understanding of CR | How it works | <i>As for me, I think all of them are the same. They are good because everything you do until you sweat, that's when you know its effective and it will remove dirt from the body. So I think all of them are good.</i> |
| | Indications and prescription | <i>As for me, it's difficult because you need to be guided by a doctor</i> |

4. Discussion

This study found that cardiac rehabilitation is a feasible treatment intervention for patients with heart failure in Western Kenya. The study was designed to explore patient's perspectives on cardiac rehabilitation and evaluate participant adherence to two models of cardiac rehabilitation using a "can it work" approach as described by Bowen' et al (60).

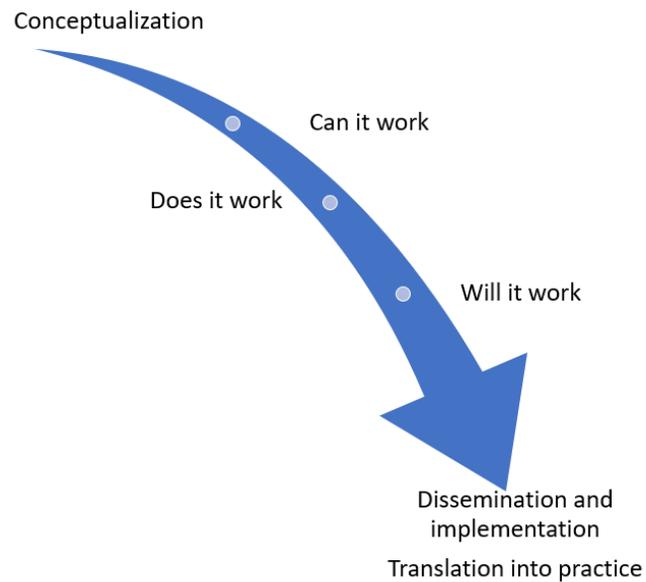


Figure 6: Stages in testing the "fit" of an intervention in real world settings

The study focused on using mixed methods to describe adherence, acceptability, implementation and limited efficacy testing.

4.1 Adherence

Study participants in both rehabilitation models were able to participate in exercise training activities. Participants in the IBCR arm attained a mean adherence rate of 46% while those in the HBCR arm attained a mean protocol adherence rate of 28%. Both interventional study arms attained greater than the target 25% mean adherence rates as hypothesized based on adherence rates in developed countries estimated at 20-30% (10).

Appreciably, there is wide variation in how adherence rates are reported globally as reflected in a recent review on use of cardiac rehabilitation in low and middle income countries which identified regions with rates as high as 90.3% in Mexico and 31% in Bulgaria (36,61). This variation is driven by wide disparities in exercise protocols and models around the world, not including different home and institution based strategies (9,62). Even where institutions adhere to the same protocols, there are multiple variations in metrics tracking adherence (36,63).

Variations in adherence reporting are not unique to participants in IBCR. HBCR participants acknowledged forgetting to track or record their exercise activities. In other instances, their pedometers would malfunction. Consequently, the mean adherence in the HBCR arm was likely under reported. This was highlighted in the focus group discussion theme on barriers to home based cardiac rehabilitation with codes on forgetfulness, or malfunction of the pedometer devices as noted by one of the

participants who said, *“As for me, one of the challenges I went through is when it becomes faulty. When I bring it to the doctor to be reset, by the time I get to town it will have jumped again.”*

In addition, IBCR arm participants were more likely to benefit from social interactions and help groups formed amongst themselves. Participants in the IBCR arm would check on each other as noted in the theme on perceived psychosocial benefits of cardiac rehabilitation. One of the participants said, *“When I joined this program, I’d see my colleagues who looked very sick, even while seated, you could tell they are very sick. When they begin exercising, they are supported for a while. They go on with the exercise and within one week they are up and a very active. I’ve seen so many of them there. In the end I saw this is medicine.”* These interactions demonstrate a sense of collegiality amongst the participants which is known to encourage participant adherence (64).

Adherence in all study arms was also noted to decline overtime with fewer participants completing the study protocol than enrolled in each arm as demonstrated by failure to present to monthly follow up visits as summarized in table 2. A greater proportion of participants in the HBCR arm than in the IBCR arm did not complete their rehabilitation sessions (33% vs 12%) respectively. The highest rate of loss to follow up was seen between month 1 and 2 of follow up in all study arms.

Attendance amongst participants in the IBCR arm was also more consistent over time compared to the HBCR arm and the observational arm. This was potentially an effect of IBCR participants being highly motivated as evidenced by their lower dropout rate. It is also plausible that less frequent contact, prompting and minimal social bonding in the HBCR arm led to higher dropout rates.

Amongst participants in the HBCR arm some of the study participants dropped out of the study because of health issues limiting them from participating in exercise training, such as stroke or death. Some voluntarily withdrew from the study citing reasons such as moving to a different city or town (n = 1), while others (n=7) were lost to follow up with no explanation. Notably, of the two participants who died during the follow up period, one died from sepsis and one died from progression of heart failure. None of the deaths were attributable to the intervention.

Participants who drop out or are not adherent to cardiac rehabilitation have been described in findings from other centers and systematic reviews of adherence (36,65). The participants in these studies were likely to live further away, be younger in age, have fewer comorbidities or be from marginalized communities or lower socioeconomic strata. Though this study was not primarily designed to characterize these associations, participants who dropped out or were lost to follow up shared some of these characteristics including age and distance from the rehabilitation center.

4.2 Acceptability

The burden of heart failure as a rapidly emerging disease in the region has been previously described (42) and is projected to grow exponentially (1). Through focus group discussions, this study found that participants are aware of functional and social limitations arising from heart failure. Themes on physical effects of heart disease and psychosocial effects of heart disease were identified in the discussions wherein participants highlighted inability to perform activities that are important to them and willingness to participate in rehabilitation in the hope of reducing some of these limitations. One participant remarked, “... someone would say you have heart disease and people would say they should not do any work. Just stay, you have heart disease. Do not laugh, run or cry a lot or overdo anything. Until you ask yourself, where will you get another world like this?”

In all three focus group discussions, acceptance of the intervention was driven by participant expectation of an improvement in their health as identified by themes on perceived physical and psychosocial benefits of cardiac rehabilitation as noted in the excerpt, “...I couldn't even walk, I'd just stay at home. I couldn't even walk from my house up to there, I couldn't even bathe I needed help to bathe. But now, I can bathe myself, I can draw water from the well, I can walk from the stage up to here.”.”; “As for me, I couldn't walk but now I can

walk with my friends. They would tell me to take a motorbike and go ahead but now I can walk with them up to where we are going”

The focus group discussion participants also expressed that some of them were hesitant at the start and doubted their ability to participate in exercise as noted in the theme on barriers to cardiac rehabilitation and would only accept to exercise under guidance from their doctor. The participants remarked that over the course of the rehabilitation sessions, they were more accepting and had a positive attitude towards the intervention as highlighted by comments such as, “...*So actually, the person who came up with the idea that people can exercise has been of great help. It has taken away the fear of saying if someone has heart disease*

Acceptance was also driven by participants seeing health improvements in their peers and development of social networks within the research pool as well as amongst fellow patients seen in the cardiology clinic from where they were recruited into the study. This was identified in the theme on “Advocacy” where focus group discussion participants noted that they referred other patients to come and join the study and were planning to recommend more to join in as highlighted in the excerpt “...*we reach out and see if we can bring others because we have been helped and that’s what we have just testified, so if we can help others out there, I think it will be good”*

Notably, not all participants who were approached to participate in cardiac rehabilitation were interested in participating. Some participants who were approached to participate in the study declined, citing reasons such as distance and inconvenience. Some focus group discussion participants also noted that they missed rehabilitation and exercise sessions because they were busy at work or other engagements competing for time such as taking care of their infants or going to school as noted in the theme on barriers to home based cardiac rehabilitation.

Acceptance of cardiac rehabilitation was also different between the intervention modalities. When enrollment was open to either study arm, several participants expressed hesitance to join the HBCR arm directly citing they wished to be supervised as they started exercises and were afraid that they would feel unwell. This was corroborated by the focus group discussion theme on barriers to home based cardiac rehabilitation as highlighted in Table 9. This finding may also explain in part, the faster rate of recruitment into the IBCR arm as depicted in Figure 1.

4.3 Implementation

Development of a cardiac rehabilitation program requires pooling together resources to deliver multifaceted rehabilitation as outlined by the International Council of Cardiovascular Prevention and Rehabilitation (66). Using exercise training as the core deliverable in the rehabilitation process, this study successfully simulated implementation of two models of cardiac rehabilitation to ascertain key resources necessary for establishment and delivery of two models of cardiac rehabilitation services.

Lack of infrastructure has been reported in other studies as a barrier to establishment of cardiac rehabilitation programs especially where space and equipment is expensive (12,61,66). In this study, both institution based, and home based cardiac rehabilitation models utilized shared infrastructure resources at initiation of either protocol. Approximately 50sq meters of space was used for delivery of cardiac rehabilitation services, to store equipment, and to provide a workspace for conducting initial evaluations as well as ongoing inpatient cardiac rehabilitation. The space was sufficient to accommodate 4 patients with heart failure per given rehabilitation session. Of note, majority of study participants (75%) were in the home-based CR and observational arms. Therefore 75% of participants utilized the infrastructure only at enrollment and during monthly follow up sessions.

Most equipment including a treadmill and cycle ergometers were procured locally. The equipment required minimal maintenance for a period of one year except for one cycle ergometer which needed repair at the end of the study. Pedometers, pulse oximeters and blood pressure machines which are also available locally, were procured abroad at discounted prices. However, as highlighted in the focus group discussions, several pedometers were faulty and reliability of remote monitoring devices remains a key factor in success of home based cardiac rehabilitation models.(67)

Lack of technical expertise has been cited as a barrier to development of CR programs in a review of global availability of cardiac rehabilitation(12,61,68). Though cardiac rehabilitation was not a service available in Western Kenya, this feasibility study was able to rely on combined technical expertise from the local medical school as well as training programs for allied health professionals offered by local institutions. However, this may present a barrier to establishment in community centers where trained expertise may not be readily available.

4.4 Limited efficacy assessment

Cardiac rehabilitation has been shown to have multiple health benefits in patients with cardiovascular diseases and is a central part of cardiovascular disease secondary prevention strategies with benefits in morbidity and mortality (23,69). More specifically, amongst patients with heart failure, cardiac rehabilitation has been demonstrated to improve functional capacity, improve depression and improve quality of life(39). In this feasibility study, we performed limited efficacy assessments of participants pre and post cardiac rehabilitation and found that the implementation of cardiac rehabilitation led to improvements in several performance metrics.

4.4.1 Functional capacity and exercise tolerance

One of the anticipated effects of cardiac rehabilitation is improvement in functional capacity(70–72). Improvements in functional capacity were measured on two scales: change in New York Heart Association (NYHA) class and change in six-minute walk time distance. Both measures showed improvement with more participants in the IBCR arm demonstrating a change in NYHA functional class from baseline (62.5 %) compared to participants in the HBCR arm (37 %). Only 20% of participants in the observational arm (OA) noted improvement and 8% reported worsening in their functional class. Assessments based on NYHA are subjective and it is plausible that the absence of negative changes in the interventional arms is an indirect effect arising from

frequent contact with the study participants. Further studies are necessary to characterize how significant these changes are.

Participants in all three arms demonstrated a statistical improvement in 6MWT distance assessments. The changes, though small and underpowered for intergroup comparisons, were in keeping with overall improvements seen in studies measuring 6mwt distance. A clinically significant increases in 6 minute walk time distance of 55m has been reported to be associated with moderate improvement in clinical symptoms (56,73,74). A larger study to measure effect size would be important to further characterize changes in this population.

4.4.2 Depression Screening

Seventy one percent of participants screened positive for mild, moderate or severe depression at enrollment. This is higher than estimates from a meta-analysis where estimated prevalence of co-affliction is approximately 21.5% of patients with heart failure(26). However studies in Nigeria have reported prevalence rates as high as 39 to 66%(75). Interpretation of these results however is guarded given that the cohort of participants sampled were all symptomatically unwell as required in the study inclusion criteria. In addition, some studies have described an increase in self-reported depressive symptoms after previous screening amongst participants with cardiac rehabilitation (76). Nevertheless, participants in all study arms demonstrated statistically significant

improvements in mean depression screening scores when compared to their initial scores as shown in table 5. This is consistent with findings on outcomes of patients undergoing cardiac rehabilitation reported in other studies on effects of cardiac rehabilitation(8,26,77).

4.4.3 Quality of living

Assessment of quality of living in patients refers to the multidimensional impact of a clinical condition and its treatment on the daily lives of patients(16). Amongst patients with heart failure there is a significant impairment attributable to negative symptoms of shortness of breath, fatigue and attendant depressive symptoms (8). It is thought that increased muscle strength that results from muscle training in rehabilitation improves participant adherence to perform activities for longer with less fatigue (78). As a result, they have more independence to perform tasks they wish to perform on their own and are less dependent on others alongside improvement in depressive symptoms as highlighted above. These changes collectively lead to an improved sense of self-worth and satisfaction with life (16).

The baseline multidimensional quality of life scores for the participants in this study were below the median reference range of 50 in all dimensions measured against locally validated norms and published reference population cohorts (54,79,80). The participants in this feasibility study demonstrated improvements across all eight

dimensions scored using the SF 36 questionnaire. Improvements in both physical component summary scores and mental component summary scores were statistically significant in all study arms. This is in keeping with expected findings from previous studies which demonstrated improved mental and physical component summary scores upon initiation of cardiac rehabilitation(7,8,81). The study however is underpowered to measure differences in changes between the different study arms.

4.4.4 Adverse events associated with cardiac rehabilitation

There were no adverse events directly associated with either interventional study arm. However, over the course of the follow up period, several participants had adverse events related to their underlying disease. Of the 100 participants enrolled there were 2 deaths reported during the follow up period of 3 months as summarized in appendix 6.3. All the significant events were initially observed in the home based cardiac rehabilitation. Though the study sample size is too small to evaluate cause and effect mechanisms, no further events reported after the study protocol was modified to contact all participants three times a week. It is plausible that in this environment, limited access to healthcare would necessitate implementation of a higher safety standard including closer contact with patients taking part in cardiac rehabilitation and consideration of initial run in phase to ensure optimization of therapies before full deployment of home based cardiac rehabilitation.

4.5 Implications for policy and practice

Given the known benefits of cardiac rehabilitation, and findings of feasibility of two delivery models, there is adequate justification for development of cardiac rehabilitation services in limited resource settings like Western Kenya. Though the exact effect size in his population is unknown findings from this study suggest that there is likely to be a positive gain in functional capacity, depression symptoms and quality of life, to patients with heart failure. The findings of this study provide a foundation of knowledge for design and implementation of cardiac rehabilitation models in Western Kenya. The findings also provide a justification for advocacy towards promoting awareness on heart failure and cardiovascular diseases.

4.6 Implications for further research

It is widely accepted that the ideal approach to cardiac rehabilitation is patient centered with outcomes tailored to the patient's goals (9,36,61). Future research should focus on characterizing the effect size and extent of benefits attributable to cardiac rehabilitation in this environment as well as defining optimal mechanisms for delivery of cardiac rehabilitation services. Further research into the role played by external factors that shape healthcare delivery such as geographical access, patient disease

profile, scarcity of time, costs of service delivery motivation and socialization will be useful in determining the impact of these factors on disease and intervention outcomes.

4.7 Study limitations

Being an observational cohort study design, the study participants were not randomized and as such results are susceptible to confounding from selection biases. By participants self-selecting into study arms, some may be more motivated if they enrolled into their desired study arm while others who missed out on their desired study arm may be less motivated. In addition, external factors such as different transport costs amongst participants wherein some participants who had lower travel costs, may have been more motivated to attend rehabilitation sessions as opposed to participants who had higher travel costs.

Compared to a “real world setting,” the study’s inclusion and exclusion criteria were very stringent with recruitment of 20% of screened participants. This may limit the generalizability of the result findings when expanded to more centers. Furthermore, monitoring supervision, motivation and contact with participants may be difficult to replicate.

5. Conclusion

This study found that cardiac rehabilitation is a feasible treatment intervention for patients with heart failure in Western Kenya based on attainment of greater than 25% mean adherence to individualized exercise prescriptions in two models of cardiac rehabilitation. In addition, most participants were able to report some improvement in their functional capacity, decrease in depression screening scores or improved quality of life indices. The study has also identified costs of cardiac rehabilitation, time away from work and travel to the hospital as potential barriers to uptake of cardiac rehabilitation. The adherence rates and identified barriers to participation are similar to findings reported in other centers around the world.

Whereas feasibility of cardiac rehabilitation was measured primarily on protocol adherence by participants, successful implementation of a CR program is contingent on integration of several factors including access to technical expertise, availability of rehabilitation equipment, administrative resources as well as favorable reimbursement frameworks. There is need for further research into the efficacy of cardiac rehabilitation and development of innovative ways that improve treatment adherence

6. Appendices

6.1 Sample data collection forms

Confidential Cardiac Rehabilitation for Heart Failure
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Screening

Study ID _____
(this number is permanent)

Screening - Data from file

Date subject screened _____
(YYYY-MM-DD)

MRN/AMRS number _____

Primary cardiology clinic site
 MTRH
 Eldoret hospital
 Fountain
 Transcare
 St.Lukes

First Name _____

Last Name _____

Gender
 Female
 Male

Date of birth _____
(yyyy-mm-dd)

Has patient had an echo study in the past 5 years
 Yes
 No

Most recent ECHO date _____

EF (%) _____

Valvular lesion
(mark all that apply)
 MR
 MS
 TR
 TS
 AR
 AS
 PR
 PS
 none

Right Ventricle
 Normal
 Abnormal

Diastolic Heart failure grade
 None
 I
 II
 III
 IV

Does the participant have a known arrhythmia
 Yes
 No

Does the participant have a known congenital heart disease
 Yes
 No

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Enrollment

Enrollment

Date subject recruited

(YYYY-MM-DD)

Name of researcher conducting enrollment

- TN
- SK
- CW
- NO

P. O Box

Town

Postal Code

mobile phone number

(Participant's phone number)

Name of alternate contact

(person who lives with subject)

Alternate contact relationship

alternate phone number

(person who lives with subject)

Closest health facility (eg health center/hospital)

Patient characteristics

Cause of Heart Failure

- RHD
 - HTN
 - Ischemic heart disease (CAD)
 - Pregnancy
 - Pulmonary/lung Disease
 - HIV
 - Pericarditis
 - Unknown
- (tick all that apply)

Current Treatment regimen
(mark all that apply)

- diuretic
- beta-blocker
- ACE/ARB
- aldosterone antagonist

Anthropometrics

Height (cm) _____

Weight (kilograms) _____

BMI _____

Waist circumference(cm) _____

Hip Circumference (cm) _____

Vitals

Initial resting HR _____

Pulse Oximetry at rest _____

Resting Blood pressure (systolic) _____

Resting Blood pressure (diastolic) _____

Respiratory rate at rest _____
((number of breaths in 30sec x2))

Master¹ step test

Weight in pounds (lb) _____

Age (years) _____

Number of ascents _____
(According to gender, based off Masters reference table)

Metronome rate _____
(ascent rate x 0.667 x 5)

ECG Rhythm at rest (Before masters step test) Normal sinus rhythm
 Abnormal rhythm

ECG Rhythm (after step test) Normal sinus rhythm
 Abnormal rhythm

Does the participant's Masters two step test have significant ST changes Yes
 No

Functional Assessment

Enrollment

Date of 6 MWT enrollment

(YYYY-MM-DD)

Functional class

- I - no symptoms
- II - shortness of breath walking up a hill
- III - shortness of breath walking on a flat surface
- IV - shortness of breath at rest

Stride length (how many steps over 10 meters?)

How many seconds to walk 10 meters?

6MWT distance (m)

Follow up functional assessment 1

Follow up date 1

(YYYY-MM-DD)

Functional class

- I - no symptoms
- II - shortness of breath walking up a hill
- III - shortness of breath walking on a flat surface
- IV - shortness of breath at rest

Stride length (how many steps over 10 meters?)

How many seconds to walk 10 meters?

6MWT distance (m)

Follow up Functional Assessment 2

Follow up date 2

(YYYY-MM-DD)

Functional class

- I - no symptoms
- II - shortness of breath walking up a hill
- III - shortness of breath walking on a flat surface
- IV - shortness of breath at rest

Stride length (how many steps over 10 meters?)

How many seconds to walk 10 meters?

6MWT distance (m)

Exercise Prescription

Exercise Prescription

| | |
|---------------------------------|-----------------------------------|
| Max Heart rate | _____ |
| | (220 minus age) |
| Heart rate reserve | _____ |
| | (Max heart rate minus resting HR) |
| Target heart rate Week 1-4 min | _____ |
| | (40% of HRR) |
| Target heart rate Week 1-4 max | _____ |
| | (60% of HRR) |
| Target heart rate Week 8-12 max | _____ |
| | (80% of HRR) |

RPE assessment

| | |
|---|-----------------------|
| HR at moderate RPE (borg scale 12-13) | _____ |
| | (from pulse oximeter) |
| Step rate at moderate RPE (borg scale 12-13) | _____ |
| | (steps per minute) |
| Treadmill speed at mod RPE (borg scale 12-13) | _____ |
| | (km/h) |
| Exercise duration before fatigue | _____ |

Treadmill to Bike Conversion

| | |
|--|-------|
| Work load at Moderate RPE (Borg 10-12) | _____ |
| Bike target speed | _____ |
| Bike difficulty setting | _____ |

Institution Ex

Session 1

Rehab Date _____
(YYYY-MM-DD)

Exercise modality
 treadmill
 bike

Target max heart rate _____

Target min heart rate _____

Starting heart rate _____

Starting blood pressure/systolic _____

Starting Blood pressure/diastolic _____

HR at Mod RPE _____

Exercise duration target _____

Exercise duration achieved _____

Exercise speed at mod RPE (borg scale 12-13) _____
(km/h)

Exercise limiting factors
 None
 Shortness of breath
 Chest pain
 Falls
 Fatigue
 Other

Session 2

Rehab Date _____
(YYYY-MM-DD)

Exercise modality
 treadmill
 bike

Target max heart rate _____

Target min heart rate _____

Starting heart rate _____

Starting blood pressure/systolic _____

Starting Blood pressure/diastolic _____

HR at Mod RPE _____

Home Ex

Start Date _____

Week 1

Wk 1 Step count target _____
({ (step rate*20min) + 5000 } x 7 days)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 1)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 2)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 3)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 4)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 5)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 6)

Wk 1 Step count achieved- (participant report via phone) _____
(Day 7)

Wk 1 Step count achieved- (participant report via phone) _____
(Total)

Wk 1 Step Count achieved -device _____
(obtained from device)

Exercise limiting factors (SoB, CP, falls, none, other)
 none
 shortness of breath
 Chest pain
 falls
 other

Number of days forgot to wear pedometer _____

Number of days forgot to record steps in book _____

Week 2

Step count target _____
(Previous week step count achieved + 10 %)

Step count achieved- (participant report via phone) _____
(Day 1)

Step count achieved- (participant report via phone) _____
(Day 2)

6.2 Focus Group Discussion Questions

Objectives – FGD

- o To identify barriers to exercise and motivating factors to
- o To characterize perceptions on understanding of exercise
- o To elicit ways to improve the service provision and support rehabilitation goals

FGD Date: ___/___/___Day/Month/Year. Start Time: _____

Participant Id: _____

1. Age (in years)?
2. Sex: M or F?
3. Marital status: Single, Married, Divorced, Separated, Widowed, Co-habiting
4. Highest educational level: None, Primary, Secondary, Certificate, Diploma, University

Introduction: Explain study procedures and details to participant, including audio recording, confidentiality, and rights to refuse participation. Obtain informed consent.

Opening questions

- What was your life/health like before you were diagnosed with hearth failure?
- What did the heart failure diagnosis mean to you?

- What has your life/health been like since you were diagnosed with hearth failure?
- Generally what impact has heart failure had on you?

Exercise related Questions

A. Those who completed (whether hospital or home based)

1. What has your experience with the exercise program been?
2. What was most helpful bit of the program? What would you recommend to others?
3. What was not helpful? What would you not include in future programs?
4. What motivated you to keep going?
5. What would you do differently?
6. If you were to be asked to pay for the exercise sessions how much would be an affordable fee?
7. What are some of the activities that you engage in now which you couldn't do in the past?

B. Those who did not complete

1. Tell me your experience with the exercise program.
2. What was most helpful?
3. What would you recommend to others?
4. What was not helpful?

5. What would you not include in future programs?
6. What stopped you from continuing?
7. What would you do differently?

6.3 Summary of Adverse events and Protocol Re-design

Case Review of adverse events

Case 1: Participant who died following an acute illness. Noted to have had what seemed to be infectious prodromal symptoms. The event was deemed not attributable to the exercise intervention

Case 2: Participant suffered an acute left sided ischemic stroke while at rest at home. The event was deemed not attributable to the exercise intervention. Withdrawn from study by the investigators given her inability to safely participate in protocol as she recovers from the stroke.

Case 3: Participant suffered a heart failure exacerbation and died. The presentation was thought to reflect progression of underlying heart disease in the context of the participants multiple comorbidities. The event was deemed not attributable to the study intervention

Discussion

The research population comprised participants who are very sick and adverse events were not unexpected. Whereas these adverse events are not attributable to the study intervention, the events were thought to represent an unknown rate of adverse heart failure outcomes.

The adverse events were seen preferentially in participants in HBCR arm and none in the IBCR arm. Potential factors contributing to this included:

- Increased frequency of contact with health personnel in the IBCR arm
- Supervised exercise in the IBCR arm
- Access to shared experiences and group health awareness amongst participants in the IBCR arm

In light of the summative signal of adverse events in the HBCR arm, and the unknown rate of adverse events in the general hear failure population, it was thought to be prudent to find out more about the natural history of the population and establish a baseline adverse event/outcome.

Therefore, the DSMB recommended that:

1. That the research team should increase frequency of contact with already enrolled home based participants to match contact frequency with institutional based rehabilitation participants (three times a week).
2. That the research team seek IRB approval to modify the study design to continue participant recruitment into an observational (usual care) cohort without a home-based cardiac rehabilitation prescription to establish background adverse event rates.

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