

IRAS ID: 290193

Reference Number: 17

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Version Number: 2

**To Examine the Effectiveness of Physical Activity, Quality of  
Life and Hospital Anxiety and Depression Outcomes in  
Cardiovascular Patients Using Either Traditional, Web-based  
or a Combined Cardiac rehabilitation Programme.**

**NCT 05326529**

**12<sup>th</sup> April 2022**

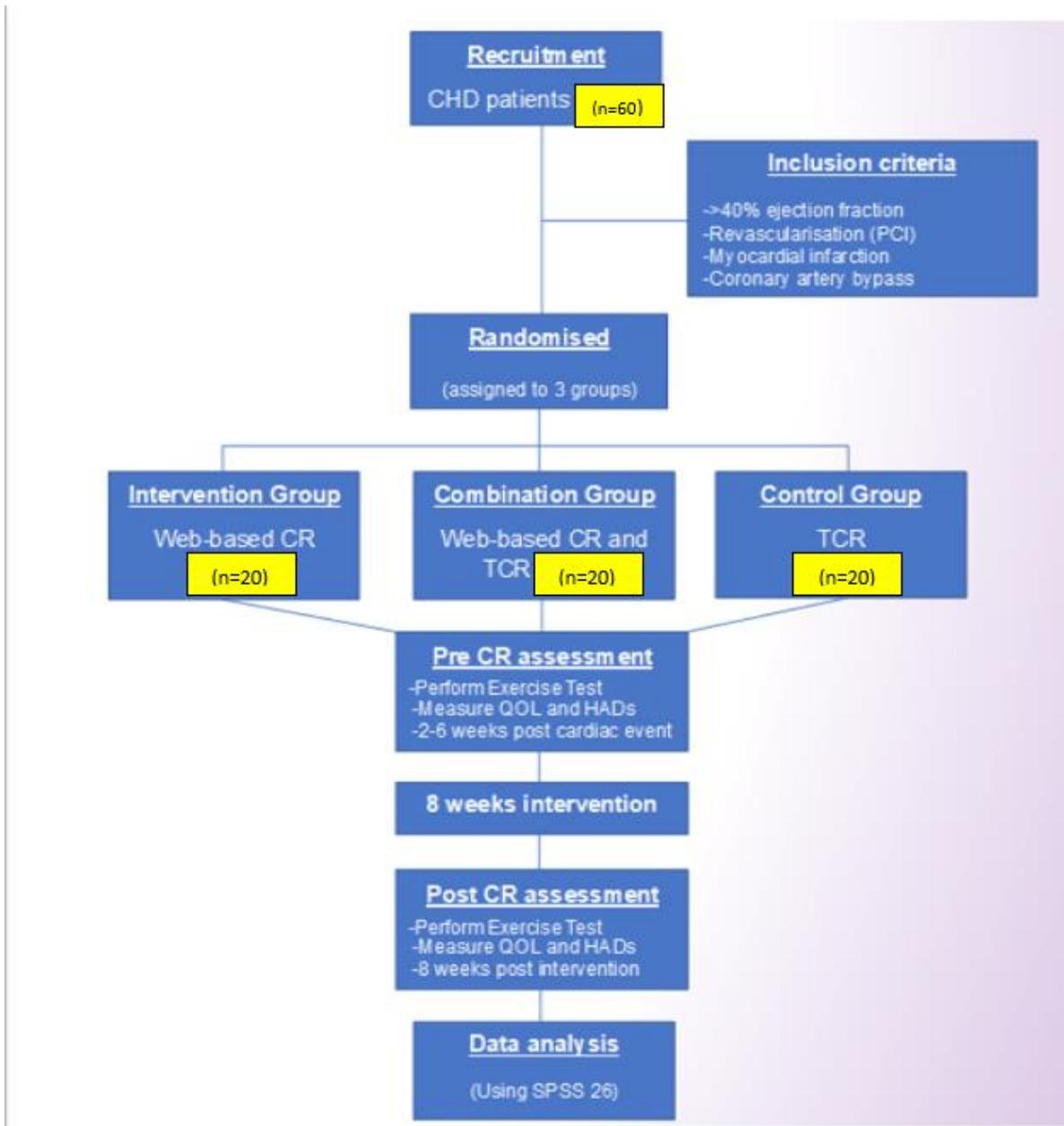
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### Research Study Protocol Flow Chart



**Figure 1.** Participant and study design flow chart

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## **Research Study Protocol Description**

### **Aim and Objectives**

This Study aims to examine the effectiveness of Physical Activity, Quality of Life and Hospital Anxiety and Depression outcomes in Cardiovascular patients using an web-based Cardiac Rehabilitation application compared with a conventional Cardiac Rehabilitation programme or a combination of both.

### **Recruitment**

Low-moderate risk Coronary Heart Disease Patients (n=60) will be recruited from Burton Hospitals NHS Foundation Trust, Cardiac Rehabilitation service. Patients will be invited in accordance with the following inclusion and exclusion criteria;

#### **Inclusion Criteria-**

- Low-moderate risk patients (low-mod Ejection Fraction (>40% EF), including clinically stable Myocardial Infarction, Percutaneous Coronary Intervention, Coronary Artery Bypass Graft diagnoses.
- Age group 50-70 years old, male and female populations
- Acute in-hospital patients in phase 3 of Cardiac Rehabilitation
- Low-moderate Anxiety and depression scores (<11)
- Level 4 (180metres, 4.2 cardiac METs) - level 5 (250metres, 4.9 cardiac METs) on the Incremental Shuttle Walking Test (ISWT).
- Internet and device access.

#### **Exclusion Criteria-**

- <40% Ejection Fraction
- High risk Heart Failure patients (no HFPEF)
- Co-morbidities preventing exercise or PA
- No internet access
- Unstable angina
- Language barrier (English only, due to app)
- Clinically depressed anxiety or depression scores (>11)
- Incremental Shuttle Walk Test <Level 4 (180metres, 4.2 cardiac METs)

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### **Randomisation-**

We will have 60 blank envelopes all containing a slip stating which study group the participant will be assigned to, i.e., each study group will have 20 slips placed in a blank envelope.

Following the phase 2 nurse telephone contact, the nurses will randomly select one of the envelopes to assign each individual patient to either the web-based Cardiac Rehabilitation (intervention group), web-based Cardiac Rehabilitation combined with Traditional Cardiac Rehabilitation (combination group) or Traditional Cardiac Rehabilitation (control group).

The nurses will then add the patient details onto the study group list and store it in a confidential place.

### **Pre Cardiac Rehabilitation Assessment**

Patients will be invited to an initial assessment at Queens Hospital Burton between 2-6 weeks post cardiac event which will take approximately 60 minutes. Patients will be introduced to their allocated study group and a consent form will be completed. The Incremental Shuttle Walk Test will be performed with the use of a heart rate monitor and the Quality of Life and Hospital Anxiety and Depression questionnaires will be completed by the patient to gain necessary baseline measures. All medical checks as usual care will be completed. Patients will be given the opportunity to confidentially ask any questions or concerns with the Cardiac Rehabilitation Nurse and Exercise Instructor.

If the patient is selected for the web-based programme the initial assessment will take approximately 75 minutes to allocate time for the web-based application introduction and the patient will be logged onto the programme.

### **Eight Weeks Intervention**

#### **Intervention Group**

Patients will follow the Web-based Cardiac Rehabilitation, using MyHeart application, introduced during a pre-Cardiac Rehabilitation assessment. This consists of an 8-week individualised self-managed platform, allowing contact with the Cardiac

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Rehabilitation health professionals via app messages only (no direct contact for web-based Cardiac Rehabilitation). The application will involve;

- 8 weeks of unlimited access to the online walking or exercise programmes
- A minimum frequency of once per week online exercise session
- A self-perceived effort scale will be used to ensure you are working to the appropriate exercise intensity
- Flexible access to the online education component

### Combination Group

Patients will be offered the Web-based Cardiac Rehabilitation combined with Traditional Cardiac Rehabilitation, consisting of;

- 8 hospital-based exercise sessions lasting 60minutes in duration
- A self-perceived effort scale will be used to ensure you are working to the appropriate exercise intensity
- One education day delivered, lasting 5 hours in duration via Microsoft Teams, consisting of workshops including nutrition, heart health, medications, physical activity, stress and relaxation
- Patients would also have access to the online education

### Control Group

Patients will be assigned to the Traditional Cardiac Rehabilitation involving 8 hospital-based exercise sessions and one education day over 8-weeks, supervised by Cardiac Rehabilitation health care professionals. This will involve;

- 8 supervised sessions over an 8 week duration
- Each exercise session will last 60minutes in duration
- The exercise involves a 15 minute group-based warm-up, 15-20 minute individualised circuit programme followed by a 10minute cool-down
- A self-perceived effort scale will be used to ensure you are working to the appropriate exercise intensity
- Virtual education sessions are delivered via teams including various topics and speakers over a 5 hour period of duration (heart health, stress, relaxation, medications, exercise, nutrition)

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All patients in each group will have access to our clinical support and advice team during our usual clinical hours, Monday-Friday 9-5pm. If the patient was to feel unwell outside of these usual hours, we will advise them to contact NHS 111 for further support and advice.

### **Post Cardiac Rehabilitation Assessment**

Following the 8-weeks intervention, the patient will be invited to a final assessment at Queens Hospital Burton which will take approximately 60 minutes. The Incremental Shuttle Walk Test will be performed with the use of a heart rate monitor and the Quality of Life and Hospital Anxiety and Depressions questionnaires will be completed by the patient to gain necessary post measures. All medical checks as usual care will be completed. Patients will be given the opportunity to ask any final questions or discuss concerns with the Cardiac Rehabilitation Nurse and Exercise Instructor.

Please note, we will be monitoring the following pre and post-measures and intend to repeat the following measures only twice throughout the study; Quality of Life, Anxiety and Depression Scores, Heart Rate and energy levels. These measures will be completed during the initial and final assessments. All data will be analysed confidentially to review the benefits of the different Cardiac Rehabilitation groups in association with the University of Chester.

### **Data Analysis**

All data will be analysed on SPSS 26 over a two week period. For Quality of Life and Hospital Anxiety and Depression outcomes, Kruskal Wallis ANOVA and Wilcoxon tests will be conducted. For Physical Activity outcomes, mixed ANOVA and multiple t-tests will be performed to assess between and within group differences.

### **Sponsor Details**

This study is sponsored by the University of Chester, sponsor contact details are Marie-Ann O'Neil, 01244 511481, [m.oneil@chester.ac.uk](mailto:m.oneil@chester.ac.uk).