PREhabilitation in patients awaiting Acute inpatient Cardiac SurgEry (PreP-ACe): A pilot study

Abstract

Introduction

The concept of prehabilitation is well established in cancer and orthopaedic populations. However, amongst the cardiac surgery population, this concept is relatively new. Over the last 10 years, only a handful of studies were published. All the studies focused on elective cardiac surgery population. Over the last 5 years, three further registered studies have focused on the elective cardiac surgery population. This pilot study will focus on the acute inpatient cardiac surgery population. We aim to assess the feasibility and impact of multimodal prehabilitation on inpatients waiting for cardiac surgery.

Methods and analysis

In advance of the study, we will be conducting a separate audit with the local trusts permission. The purpose of the audit is to understand the population that present to our department for cardiac surgery. This will hopefully help us identify the number of patients that could benefit from the intervention, the demographics, how they present, diagnosis and the potential impact of waiting times on these patients. This audit is performed based on pre-collected data from patients who had cardiac surgery in 2022. All patients who had cardiac surgery in our department will be entered onto an audit database as routine. Information from this database is extracted for national audit purposes when required. We will be extracting the required information from this database to answer the questions outlined above. All the information will be anonymous. As this information is routinely collected by the cardiac audit department, we will be seeking local institutional approval for this.

Trials involving patients should be co-designed with them to improve the engagement and success of the program. We will be doing a survey on inpatients waiting for cardiac surgery in Castle Hill Hospital to gauge their interest. These patients will not be enrolled into the main pilot study but we will seek their opinion on the intervention and trial design based on their experience waiting for cardiac surgery. Patients will be approached in person, informed about the purpose of the survey, consented and they will be asked set questions regarding their opinion on the concept of inpatient prehabilitation, the patient information sheet, psychoeducation leaflet, and the intensity of the program. We will enquire about their interest in participating if they had the opportunity. The data collected will be anonymous.

This single centre, prospective, pilot feasibility trial will recruit 20 inpatients awaiting cardiac surgery. Measurements will be take at the start of the trial, 7 days after intervention, and 14 days after the intervention or before the day of surgery. The primary outcome measure will be feasibility and practicality of the programme in acute inpatient population. We will be looking into participant eligibility, acceptability, recruitment rates, completion rates and barriers to implementing a prehabilitation programme. Secondary outcomes include safety (incidence of adverse events directly related to the study), improvement in 6 minutes walk test (6MWT), hand grip strength, quality of life, anxiety scores and spirometry. At the end of the trial, we will be seeking the feedback of the participants to help us improve the design further.

Ethics and dissemination

Trial Registration number

Introduction

According to the National Adult Cardiac Surgery Audit (NACSA) over 30,000 heart surgeries are performed every year in the UK.[1] With the increased life expectancy in the UK, the number of heart surgeries is unlikely to reduce. Advancing age is often associated with frailty; a physiological state of diminished response to stressors due to decreased reserve secondary to multiple comorbidities and homeostatic dysregulation.[2] Accordingly, it is unsurprising that frail patients have poorer outcomes following an illness and incur a higher healthcare cost. There is evidence that frailty is a reversible condition with an improvement of diet, and exercise.[3] A randomised control trial found a combination of resistance training and nutritional supplement led to not only an increase in muscle bulk and strength but also improved mobility.[3] The possibility of reversing or slowing down this medical condition has led to a lot of interest in the subject.

The concept of prehabilitation whilst not new, has evolved over the years. It has been used to describe preoptimization of medical conditions[4] to interventions aimed at improving nutritional (N), Exercise capacity (E), and worry reduction (W) to reduce the effect of health deconditioning.[5] This concept has been adopted by the Society of Enhanced Recovery after Surgery (ERAS). Regardless of the definition, prehabilitation is any intervention that prepares a patient, before an actual stress or physiological insult with the aim of improving their ability to recover. Evidence of the benefits of prehabilitation is well established in cancer and orthopaedic patients. However, evidence amongst cardiac surgery population is lacking. Prehabilitation is slow to develop in this group partly due to the concerns of adverse events amongst those with pre-existing heart condition.

During the COVID-19 pandemic, waiting times for coronary artery bypass graft (CABG) increased by 94%.[1] According to NACSA, it takes an average of 11 days from angiography to surgery for an urgent inpatient coronary artery bypass graft (CABG).[1] Median waiting time ranged form 7 to 24 days.[1] This is in contrast to the national guidelines stating that these operations should be carried out within 7 days.[1] Only 34% of acute patients receive their surgery within 7 days in 2019/2020 compared to 37% in 2017/2018.[1] The delay could be due to a multitude of reasons such as waiting for anti-platelet therapy to wear off, optimisation of medical conditions, lack of beds in tertiary hospitals, or awaiting further investigations. Traditionally, inpatients are told to minimise activity and maintain bed rest. This advice is mainly due to fear that physical activity may worsen the condition or precipitate complications. In some cases, this has led to a phenomenon now know as 'pyjama paralysis' where patents become psychologically bed-bound from not being encouraged to mobilise or retaining independence whilst being in hospital. As a result of prolonged inactivity, patients become deconditioned, leading to extended hospital stays for non-medical reason.

Prehabilitation- *Nutrition*

Prehabilitation often focus on exercise or physical conditioning. Over the years, there is increased realisation of the important role of nutrition in healing, recovery and reduction of complication from surgery. In 1985, an analysis of > 150,00 patients found 3.7% to be malnourished and after 3 weeks of hospitalisation, they had significant worsening of nutritional status.[6] Fifteen years later, McWhirter identified malnourishment in 40% of the population and this is associated with poor recovery.[7] Traditionally, malnourishment is associated with a low BMI; the usual picture being either an anorexic or older and frailer patient. A study in 2016, reported that 42% of patients awaiting cardiac surgery patients were 60 and above, 51.4% were classed as overweight and 39% had hypolabuminaemia.[8] Poor diet of snacking, fast food, and fizzy drinks was associated with male smokers with elevated BMI levels.[9] The easy availability of affordable fast food have contributed to the rise in high BMI in this population. Patients with post- operative complication were more likely to have raised BMI and low albumin.[8] Illness, surgery, deconditioning and frailty are associated with loss of weight and muscle bulk due to the increased nutritional demand.

Good preoperative nutritional practices have been shown to reduce post-operative hospital stay, mortality rates, complications and improved the cardiac rehabilitation outcomes.[10] Nutrition in combination with exercise increased muscle strength by almost 50% compared to exercise alone.[3] Nutritional support has been shown to not only reduce 30 days mortality by over 50%, but also improve quality of life compared to standard hospital food.[11] Given these findings, we would assume nutrition to be at the forefront of managing acutely ill patients. Unfortunately, this is often not the case. A meta- analysis by Cermak et al concluded that protein supplementation increased both muscle mass and strength during resistance exercise irrespective of age.[12] Therefore, prehabilitation trials should consider the feasibility of increasing protein intake; the building blocks of muscle, to help reverse the sarcopenia processes of ageing, frailty and deconditioning.

Prehabilitation- *Exercise*

The discipline of physiology teaches us that coronary blood flow is determined by coronary perfusion pressure, perfusion time and vessel wall diameter. In patients without heart conditions, blood flow is auto regulated according to the individual's requirement at a certain point in time. However, in disease states, auto regulation is affected. For instance, in patients with ischaemic heart disease, the coronary arteries are narrowed. A shortening of perfusion time (diastole), as would happen when the heart rate increases, will lead to reduction and possibly obliteration of coronary blood flow. This will in turn lead to chest pain (angina) or even precipitate myocardial ischaemia (MI). Despite this, exercise interventions have been shown to be safe and beneficial in elective patients awaiting CABG.[13, 14] Despite the concept of prehabilitation being around for many years, there is no standard approach to what constitutes effective prehabilitation. There is unclear evidence as to the type of exercise that confers the highest benefit. Various combinations of aerobic,[14, 15, 16] flexibility,[14] strength/ resistance training,[15] inspiratory muscle training.[15] Regardless of exercise type, none of the studies reported any increase in adverse events due to exercise in elective patients. To date, there are no published trials looking at the feasibility, safety or benefits of exercise on inpatients awaiting cardiac surgery. There is concerns that physical exertion may induce symptoms or lead to adverse events in inpatient cardiac surgery population. However, there is evidence that 45 minutes per day of resistance training improved muscle strength, size, and mobility without causing adverse event in frail, elderly population.[3] According to World Health Organisation, global life expectancy increased by > 6 years but healthy life expectancy increased only 5 years between 2000-2019. In addition, COVID-19 has negatively impacted on population health. The impact of COVID-19 has been attributed to deconditioning, muscle atrophy and decreased exercise capacity.[17] A Delphi study conducted by the WHO reported that the most common post-COVID symptoms included tiredness, breathlessness, and worsening daily function.[18] Frailty is associated with muscle wasting, loss of endurance, decreased balance and mobility, slowed performance, relative inactivity. All these symptoms, are associated with patients requiring cardiac surgery.

Post-operative pneumonia is one of the commonest complication after cardiac surgery. The incidence varies from 2-35% depending on the population and type of surgery; with aortic dissection having the highest rate of chest infection.[19, 20, 21, 22] A systematic review by Wang et al identified age, smoking history, chronic lung disease, and raised body mass index (BMI) to be amongst the risk factors for pneumonia after cardiac surgery.[22] Patients that suffer from pneumonia are over 4 times more likely to die post-CABG, and experience longer hospital stays[19] which translates to increased cost of care. Inspiratory muscle training (IMT) has been shown to improve post operative function[23, 24, 25] and reduce pulmonary complications.[24, 25] Hulzebo et al noted that IMT reduced post-operative pulmonary complications by almost 50%, pneumonia by 25% and in-patient stay by 1 day in high-risk CABG patients.[25] Interestingly, IMT and incentive spirometry (IS) not only reduced pulmonary complications but also increased the 6-minute walk test (6-MWT),[23, 24] and reduced the reduction in 6-MWT performance in the first week post-

surgery.[24] The improvements in pulmonary function tests, 6-MWT, quality of life and psychosocial parameters have been noted with IMT in just 5 days from surgery.[23] However, the same study did not mention how these improvements related to post-operative complication and inpatient stay. We have chosen cardiorespiratory performance, strength/ resistance, flexibility/ balance and inspiratory muscle training for the study as we believe they are most appropriate for our population.

Prehabilitation- *Worry*

It is not surprising that a new illness diagnosis and news of impending surgery will lead to a degree of stress, and worry for patients and their family. This could be a precursor to anxiety and depression. Prevalence of depression, anxiety and stress in the CABG population is 20%, 23%, and 21% before the surgery.[26] Depression, anxiety and stress is attributed to the surgery itself as the risk of being depressed decreased by 33% after CABG.[27] The impact of cardiac surgery on mental health, is not solely due to the wait for the surgery or limited to the pre-operative phase. Anxiety, depression, and stress only decrease by 33% after CABG and 20% of those who had CABG suffer from new onset of depression months after the operation.[27] The INTERHEART study found psychosocial factors (depression, stress, critical life condition) increased the risk of myocardial infarction by nearly 3.5 times in females and 2.5 times in males.[28] Psychosocial factors accounted for 43.5% of myocardial infarction in younger patients compared to 25.2% in older patient.[28]

Whilst the focus has always been skewed towards the physical health, there is mounting evidence of interlink between the metal and physical health. Individuals with low resilience have more circulating norepinephrine and cortisol which is likely to explain the higher prevalence of hypertension in this population.[29] Strong emotions such as anger and negative emotions can precipitate MI[30] Preoperative anxiety is associated with increased risk of mortality by over 80%.[26] A meta analysis by Raven et al concluded that preoperative depression is associated with decreased cardiac symptom relief, quicker return of symptom, frequent hospitalisation, and increased mortality in the post operative period.[27] Post operative depression is associated with poor wound healing and increased likelihood of wound infection.[27] Mental health problems are often multifactorial and whilst difficult to pin-point a single cause, the negative impact on health is significant. Despite this, psychological support is often not offered to cardiac surgery population.

Methods and analysis

Setting

This trial will be conducted in Castle Hill Hospital CHH) which is part of Hull University Teaching Hospital NHS Trust, a tertiary hospital in United Kingdom. Assessments will be conducted on the cardiac surgery and cardiology ward. Ahead of the pilot study, we will be conducting an audit looking into patients who had cardiac surgery in 2022. This information will be obtained from an existing audit database in the department. All patients who had cardiac surgery in our hospital

have information relating to their admission collected as a routine. This is done for audit, clinical assurance and service evaluation purposes. We will be requesting the relevant information for our analysis. All patient information will be anonymous. The purpose of this audit is to try and build a picture of the population that present for cardiac surgery. We will be interested to know the demographic, comorbidities and how the present to the service. This audit should help us identify the number of patients that could potentially benefit from our intervention and the potential impact of preoperative waiting time on patient outcome such as post-operative complications and post-operative stay.

Patient and public involvement (PPI) is very important in ensuring the success of a study or program. Whilst our preliminary survey has indicated an interest in prehabilitation, we will be doing further interviews to refine the design of this study and of any future studies. Inpatients waiting for cardiac surgery will be approached and given information about the project. They will then be invited to participate in the survey which is done via 1:1 interview. Once they consent, we will then be providing them with details of what the prehabilitation would entail, the patient information sheet and psychoeducation leaflet. Patients will be consulted on the frequency, duration and intensity of the program. The survey will hopefully identify any potential barriers to success as well as solutions to improve engagement. Participants for the PPI will not be recruited into the pilot study.

Potential participants for the pilot study will be identified from the cardiology team on the ward and acute admission board in the hospital. The cardiology team will give an indication that the patient is likely for surgery and any language barrier. For the purposes of this pilot, only patients that present directly to CHH and able to communicate in English will be considered. Initial screening for the patient will be done by the research team upon speaking to the cardiology team. Eligible participants will be approached by a member of the research team, provided verbal information and following that given the patient information leaflet. They will then be allowed some time to go through the information. The researcher will then return to ask if they would like to participate and consent them if they agree. Once consented, participants will be asked to perform the baseline test. Interventions will begin soon after this. Interventions will be delivered as a mix of information leaflet, face to face session and online video. Surgery and post-operative hospitalisation will take place in the same hospital.

Objective

Primary objective

The primary objective is to determine the feasibility of a prehabilitation program in acute in patient population. We will be looking at the eligibility rates, enrolment/ recruitment rates, practicality of a prehabilitation program in terms of logistical challenges to developing and implementing the program (deliverability), uptake rates, acceptability and completion rates of an inpatient prehabilitation program.

Secondary objective

Secondary objectives are to identify any changes in 6-MWT, hand grip strength, quality of life, spirometry and mental health before and after the program. We will be collecting information on adverse events, length of stay, complication(s) and readmission during this study. This will give us signals for safety concerns and potential efficacy of the program.

Eligibility criteria

Inclusion criteria

All patients over the age of 18 scheduled for acute cardiac surgery will be given consideration to participate in this clinical trial.

Exclusion criteria

Patients who are unable or unwilling to participate in any of the elements of prehabilitation will be excluded. These include those that have cognitive disability (including unconsciousness), cardiac or clinical instability, functional or anatomical impairment which impairs ability to participate, language barrier or patient refusal. Any language barrier will be identified by the primary clinical team and communicated to the research team. These patients will be excluded as we do not have the translating facility for the purposes of this study. Patients that have impending surgery within 72 hours of arrival to hospital will be excluded. Patients who are awaiting surgery in district hospitals or outside of Castle Hill Hospital will be excluded. A non-exhaustive list of exclusion criteria is included below.

Cardiac/ clinical instability such as:

- Recurrent unstable angina/ crescendo angina
- Untreated decompensated heart failure
- Malignant arrhythmias awaiting treatment
- Resting tachycardia (HR>100 bpm)
- Left ventricular outflow obstruction such as Aortic Stenosis with pre-syncopal or syncopal symptoms
- Unresolved acute pericarditis or myocarditis
- Second or third degree heart block without pacemaker
- Aortic Dissection
- Myxoma

Functional/ anatomical impairment such as:

- Severe musculoskeletal conditions that would prohibit exercise
- Amputees
- Registered blind

Patient recruitment and screening

Patients will be identified on admission via the acute admission board and during multi-disciplinary team (MDT) meeting. All acute patients waiting for cardiac surgery in CHH will be eligible to participate in the survey. As such, they will be approached, given information and invited to do so by a member of the research team.

With regards to the pilot study, acute patients over 18 years old are first of all screened according to their route of admission (directly to CHH or via a DGH). Those that present directly to CHH and able to communicate in English will then be further screened with the above exclusion criteria. Whilst an interpreter can be organised for routine hospital care, this cannot be accommodated for the purposes of this pilot study. The language barrier may impede the participant from full participation. However, if this intervention was being implemented as routine practice or part of a bigger trial, the patient information leaflet, consent, questionnaires can be translated into the required language. In addition, a translator could be hired when the patient is undergoing the intervention. All eligible patients will be invited to participate in the project. They will be approached and provided information regarding the study. This will be explained in written and oral forms to each participant. Written consent is mandatory prior to any study related measures, intervention or questionnaire. Patients will also be asked if they would be happy to be contacted after the study to obtain feedback on the program as this guide future development.

Baseline data collection

The primary outcome will look into the acceptability of a multimodal acute inpatient prehabilitation program for patients and clinical staff. The study aims to identify barriers (if any) to organising, implementing and completing an inpatient prehabilitation program.

Secondary objectives are as follows:

1. Recording any physical changes to patient before prehabilitation, 7 days and 14 days after the intervention. If the surgery happens any other time before day 7 or 14, The measurements are repeated the day before the surgery. Measurements include
    - 6 minute walk test
    - Spirometry
    - Hand grip strength with dynamometer

2. Assessing quality of life and mental health before the prehabilitation, after prehabilitation but before surgery
    - EuroQoL (EQ-5D-5L)
    - Cardiac anxiety questionnaire (CAQ)

3. Identify any safety concerns related to prehabilitation program for this population, if any exist. This will be identified by patient reported diary and notes entry from the staff.

Patients will be given a diary to document the duration of time they spent exercising, mood and any cardiac symptoms.
Information on post-operative complications and length of in hospital stay will also be collected.

Intervention

Nutrition

Obesity (OR 1.12) and diabetes (OR 2.37) are some of the risk factors associated with coronary artery disease.[28] Whilst malnourishment is a well recognised health issue, with well recognised treatments which have shown to improve patient outcome, the problem in cardiac surgery is often one of over-nourishment. We consulted with dieticians in hospital and abroad; despite the prevalence of over-nourished of patients, there are no scoring systems to guide the management of these patients. Moreover, due to the acute patient population for this study, active weight loss 1-2 weeks before surgery is discouraged. Due to the short time frame between diagnosis and surgery, there was no nutritional supplement or weight loss advice that could be offered.

We considered the possibility of hospital admission as an opportunity to educate patients on nutrition. However, our preliminary PPI revealed that patients did not view their diet or nutrition as an issue. We discussed this with a dietician regarding the provision of dietary advice via written information and classes. Due to the small numbers in the study, this would likely be one-to-one to a non-receptive audience. The hospital dietician is unable to support such intensive input at this moment in time.

In the future, the possibility of nutritional and dietary advice in hospital should be explored. However, this needs to be done in a tactful manner to an audience that may not realise they have a problem.

Exercise

Participants will undergo a combination of aerobic, resistance/ strength as well as balance and flexibility exercise. The exercise will be individualised according to the participant's ability

Aerobic exercise

Aerobic exercises will be performed on a cycle ergometer (Watt bike). Due to the nature of the acute admission and the lack of evidence in this area, all aerobic exercises will be supervised. Patients will be supervised by a trained exercise physiologist and attached to an ECG/ heart rate monitor throughout the exercise. We will be aiming for a low to moderate intensity exercise based on the Borg Rating of Perceived Exertion (RPE 11). The patients will be exercised using the intermittent protocol of alternating 1 minute moderate and 1 minute low intensity aerobic exercise. This duration can be gradually increased during subsequent sessions depending on the patient's ability. Aerobic exercise will be conducted 2- 3 times per week depending on patient's ability.

Patients that are unable to use the exercise bikes will be asked to walk or use the arm crank as an alternative exercise. Both these activities will be tailored to the individual ability.

Regardless of the type of aerobic exercise, the aim would be to achieve a target heart rate for each patient (40%-50% heart rate reserve). During the exercise, their heart rate will be recorded every minute alongside the corresponding exercise wattage. RPE will be recorded at the end of each session.

Resistance/ strength exercise

Patients will be given the option of an in hospital application (Physiotech) or pictorial and written information on how to perform resistance exercise by their bedside. The physiotech application is currently in use by the hospital physiotherapy team for other surgeries such as orthopaedic. However, this application has not been used in cardiac surgery. The physiotherapy team will be tailoring the exercise for the patients and setting the appropriate recommended targets. The application will require basic data on age, weight and height. The exercises will be using single-use resistance bands. Participants are encouraged to perform the exercise as often as possible with the aim of achieving at least 2 session per week.

Patients who are unable to perform the aerobic exercise (eg due to physical limitation or symptoms) will be asked to perform resistance exercise only. The frequency of exercise will be individualised according to patient's ability and fitness level.

Inspiratory muscle training

Patients at high risk of respiratory complications are given spiroball after the surgery for inspiratory muscle training. As part of the prehabilitation, patients will be given spiroball before the surgery and taught how to use it. The importance of inspiratory muscle training will be explained. Patient can access spiroball training on the physiotech application. The target will be for patients to do 3 sets (consisting of 6 breath each), 5 times a day. Preoperative training should also aid better post operative compliance.

Worry

All study participants will be given a booklet containing psychoeducation information. The booklet aims to explain the emotions they may feel whilst being in hospital, symptoms of anxiety, suggest how to manage anxiety, behavioural strategies that may help and signposting if they require further support. In addition to this, the participants will be given access to audio on guided meditation and relaxation. Both the booklet and audio are designed with input from in-house clinical psychologist.

Patients will be asked to score themselves on CAQ and EQ-5D-5L on day 0 and on day 7 or day before surgery. During the second assessment of CAQ and EQ-5D-5L, patients will be asked if they have read or used either the psychoeducation booklet or audio. Hospital staff will be alerted of participants that score highly and considered high risk. In addition, they will be referred to the clinical psychologist or in-hospital psychiatry liaison team.

Additional information collection

All participants will be given a diary. They will be requested to record number of times they performed unsupervised exercise, and for how long. They are also asked to document their food intake. The diary is also used as a mood monitor. Participants are encouraged to write down how they felt, if they used the recommended technique and any benefit they may experience.

Participants will be interviewed for a feedback on the prehabilitation program. The questions will centre around their opinion of the intervention in terms of acceptability, enjoyment, usefulness, accessibility and achievability. We will be gauging their reception to the exercise, psychoeducation booklet as well as mindfulness audio.

Patient and public involvement

New interventions and ideas are more likely to be successful when all stakeholders are involved in the planning as much as possible. Prior to designing our program, we interviewed inpatients awaiting cardiac surgery and those who had acute cardiac surgery to gauge their interest in prehabilitation. All the patients agreed with the concept of prehabilitation. Patients were keen to at least try and exercise whilst waiting for surgery. Patients were reporting that they have been told to avoid physical activity whilst awaiting surgery. We had mixed reaction the proposed psychological intervention. Patients did not want any guidance on nutrition. They felt they knew what they needed and did not want nutritional information of their food displayed. Given this and the restrictions we have with time and budget, this element of prehabilitation is removed. All the patients interviewed admitted to a level of anxiety. This was mostly related to the waiting time for surgery, not receiving adequate information regarding the treatment plan and cancellations of surgery. Despite this, there was mixed reaction to our suggestion of providing psychoeducational information.

Based on the positive response from our sample group, we have designed our pilot inpatient prehabilitation program. Patient involvement will be an ongoing part in our project. We will be asking patients who will not be part of the intervention their opinion of the proposed program (investigations, assessments and interventions), the information provided to participants, potential barriers and how to overcome this. We will be consulting them on the materials and patient information sheet that will be provided to the participants. This will help guide us in further refining and improving the design of this study as well as future studies.

Safety

Safety of exercise has not been assessed in this group of patients. To ensure safety of participants, the interventions will be done within the cardiology and cardiac surgery department area in Castle Hill. This enables the participant to have access to round the clock medical and surgical care. The exercise will be stopped if the patient develops symptoms such as angina (chest pain, or pain radiating down the left arm), arrhythmias or any syncopal symptoms. If the symptoms do not improve with rest, they will receive appropriate medical treatment. The exercise will then be stepped down in a gradual fashion with the minimum expectation of resistance exercise only. Participants who cannot perform at least resistance only exercise will be withdrawn from the study and the surgeons will be informed.

We anticipate that the most intense intervention in this study will be the aerobic exercise. As such, it will only be performed under 1:1 direct supervision. Participants who are able to perform the aerobic exercise will only exercise until they achieve their target heart rate. If the target heart rate is exceeded, the intensity of the exercise will be reduced. If however, they are unable to achieve their target heart rate, we will reduce the intensity of the exercise to a level that is acceptable for them. At any stage of the intervention, if the patient develop symptoms as described above, the intervention will be stopped, they will be assessed and treated by the medical team in the same hospital.

We anticipate some patients with cardiac conditions may experience symptoms of postural hypotension which may impact their ability to perform the test. If this occurs, it will be documented by the assessor and patients are told to rest before trying the test again. If they are unable to perform the test at all, they will be withdrawn from the study. We will record adverse and serious adverse events.

In the event that the patient develop evidence of worsening cardiac condition either related or unrelated to the intervention, they will be assessed by the medical team and treated appropriately either with alteration of medication or possibly have the surgery expedited. The decision for treatment options lie with the medical team directly involved in the patient's care. The researchers will not influence the decision regarding the patient's treatment.

We will be sending out questionnaires pertaining to the patient's mental health. Patient's that score highly or show any features of mental health problem that could impact their safety will either be asked to self refer for help or be contacted by a clinical psychologist. The intervention offered will depend on the severity of condition.

Outcome measures

The primary outcome is the feasibility and acceptability of the multimodal program. Feedback will be obtained from the patient regarding the acceptability, achievability and general interest in the program.

Feasibility will be assessed by determining the number of eligible patients, participants recruited, participated and retained at the end of the intervention, the proportion of intervention sessions delivered and fidelity of delivery. Moreover, participant recruitment, retention and adherence to the intervention will be measured, as well as any adverse events.

To determine the acceptability of the intervention and to explore barriers and enablers to the implementation of the intervention, interviews will be conducted amongst participants, and staff involved in referral and intervention delivery.

Secondary objectives:

- To identify a signal of efficacy for positive changes in physical health exercise, mental wellbeing, and quality of life (using tools described);
- To identify differences in length of hospital stay, complications and readmission rates to hospital following surgery compared to usual care (based on previously collected data);
- Indications of safety concerns with prehabilitation in acute inpatient population. This is based on reported adverse events

The 6 minute walk test, hand grip, quality of life measure, spirometry and cardiac anxiety score will be measured at three points, before the intervention, day 7 and day 14 or before the surgery. If the surgery happens before day 7, there will only be two measurements. Information on any cardiac symptoms and their association with the exercise will be documented.

The end of the trial is defined as the day of surgery for the last participant. Participants may choose to withdraw at any point of the trial. If they are changes in circumstances which would impact their ability to complete the trial, they will be withdrawn by the clinician.

Statistical method

Data will be analysed at the end of the study. We will be analysing the data for the eligibility rate, recruitment rates, number of patient that participated and completed the intervention. We will be looking at the number supervised of sessions that were successfully delivered before the surgery as well as the number of unsupervised sessions that the participants achieved. Qualitative analysis will be used to determine the acceptability of the intervention and barriers to implementation.

Data of length of stay, complication rates and readmission rates will be collected and analysed. These can be compared to national data. Improvement in 6MWT, hand grip, EQ-5D-5L and CAQ will indicate potential efficacy of intervention.

Ethics

Ethical approval has been obtained from Hull York Medical School ethics committee. We have received REC approval via IRAS.

Data management

All staff handling patient data will need to comply with hospital data protection policy. The research team will need to have evidence of up-to-date Information Governance training. Data will be used according to the General Data Protection Regulation (GDPR) regulation. Only authorised research members will be given access to the required data. Electronic information on the study will be stored on approved devices provided by the institution. Written data obtained from the study will be kept in a locked cabinet in the department. All information collected will be anonymised. Individuals will not be identified through any reports or publications that result from the trial.

Discussion

Prehabilitation is one of the recommendations of Enhance Recovery After Surgery (ERAS). Although ERAS is well practiced in other surgical population (the society has been around since 2001), ERAS-C is relatively new (established 2017). Despite this, the implementation of prehabilitation in the UK has been slow. A recent survey found that only 13% of cardiac centres in the UK offered prehabilitation program to their patients compared to 66% for other surgical specialties.[31] Only one centre offered multimodal prehabilitation as recommended by ERAS (nutrition, exercise, and psychological).[31] The reluctance in adopting prehabilitation is likely to be multifactorial from financial, logistics, hesitance from clinician due to fear of precipitating an acute event, perceived limited waiting time and inconclusive evidence of improving outcome.

Inpatients waiting for cardiac surgery are well monitored. Being admitted to hospital forces a person to accept that they have a problem that need sorting out. This should make them a receptive audience to our intervention. If exercise is proven possible in this population, this will open the opportunity for larger studies to ascertain its benefit and safety. Once safety is known in this population, this may then encourage a wider acceptance of prehabilitation for all population.

Whilst we are unable to incorporate nutrition into our study, we still firmly believe there is a role for nutrition in prehabilitation. However, in the acute setting, this will be limited in the form of advice and information. The education will need to be continued post operatively to consolidate the knowledge for patients.

Deterioration in mental health is associated with increased mortality after cardiac surgery.[26] Despite this, mental health has remained a taboo topic up until recently. The younger population maybe more comfortable talking about emotions and seeking help. However, the cardiac surgery population are generally older and it is not clear if they will take up the psychological intervention offered.

Cardiac surgery is a tertiary service which means that patients could live hundreds of miles from the closest centre. Larger studies need to demonstrate the benefits of prehabilitation (if any) for the patients and hospitals. Once the benefits and safety of prehabilitation is established, there is a need to have prehabilitation centres that are easily accessible to patients to reduce care inequality. The centralisation of service also leads to increased strain on the tertiary services. As a result, the waiting times for both elective and urgent cardiac surgery have increased over the years.[1] This waiting time is unlikely to resolve soon enough. Whilst waiting, patients should be working on improving their general health and well being. Surgery should not be viewed as an end point but an opportunity to improve their general wellbeing.

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