**Evaluating a Physical Activity Intervention at the Coorparoo CCU**

**Project Title**

Evaluating effects of a physical activity intervention implemented at a residential mental health rehabilitation unit

**Background:**

The gap between physical health morbidity in mental health patients compared to the general population is well established. (1). Mortality rates of patients with schizophrenia are 2-3 times the general population (2)

Cardiovascular disease (CVD) has been shown to contribute a substantial number of years of life lost in these patients (3)

The pathophysiology of increased cardiovascular risk in patients with schizophrenia is complex and multifactorial. Genetic, cardiometabolic side effects of psychiatric medications, and health inequalities (4) have been identified, in addition to high rates of diabetes, and dyslipidemia. The contribution of modifiable lifestyle factors such as– poor diet, smoking, substance misuse and sedentary behavior has been increasingly recognized. Hence promoting physical activity is a high priority that may improve and maintain cardiorespiratory health. (5)

Health benefits of exercise are now well known in the general population – both improving cardiovascular fitness, in addition to improvements in cognition, reduction in anxiety and depression, improvements in self-efficacy (6)

In a recent meta-analysis, physical activity was shown to be as broadly effective as pharmacological interventions in reducing cardiovascular disease mortality. (7)

Physical activity programs have been shown to have clear positive affects on physical and mental health in patients with schizophrenia and serious mental illness (8, 9) and these programs are well accepted by people with serious mental illness (4,5). In a prior review of evidence, they can even be considered one of the most valued components of treatment by patients (11).

Despite this, individuals with established mental illness and schizophrenia are less likely to engage in physical activity than the general population (12, 14).

Implementation

The body of evidence supporting the effectiveness of physical activity programs continues to grow rapidly (15). It is clear that promoting physical activity can improve cardiorespiratory fitness. It is therefore a vital strategy in the prevention of CVD and in improving overall health in mental health patients. (4) There is an increasing call to translate this research into clinical practice, and to invest in physical activity programs given the established benefits.(4, 5)

Residents of the Coorparoo Continuing Care Unit (CCU) frequently come to residential rehabilitation to address personal recovery across a broad range of psychosocial domains, with a large proportion of residents listing health and fitness goals as high priority during their stay at the CCU.

Physical activity programs are a vital component of a biopsychosocial approach to recovery-orientated mental health treatment. (16) and should be seen as essential rather than an adjunct to standard practice. Whilst the physical health of patients with mental illness has not been previously prioritized, there is an increasing recognition of physical activity being a significant domain in the holistic recovery for patients within mental health services. (17)

There are now examples of exercise programs being delivered within psychiatric treatment facilities (Keep the Body in Mind, in Early psychosis in Bondi, Mental Health Intensive Care Unit, Randwick.) Following these successful examples; 3 dedicated exercise physiology positions were recently established in mental health services in Sydney – this is an example of translation of research findings into policy (5). However there are currently few exercise programs embedded in standard practice in Australian mental health services. Research in this area to date has tended to focus more on early intervention patient groups than chronic patient groups (HeAL Healthy Active live, and ‘Headspace’).

For this reason, the present pilot study aims to implement a physical activity program within usual care of mental health services, in a residential environment that can address some of the typical barriers to engagement in physical activity seen in patients with Severe and Persistent Mental Illness (SPMI) such as chronic schizophrenia.

Consistent with a recent meta-analysis and proposed recommendations in implementing cardiorespiratory rehabilitation programs in patients with schizophrenia, this pilot study will address the four main recommendations from that review (4): (a) assessment of risk level (b) assessment of cardiorespiratory fitness status (c) an achievable intensity level and (d) the implementation of strategies to improve motivation and adherence

Risk level and Assessment of cardiorespiratory status

It can be challenging for mental health staff in a standard Multidisciplinary team to know how to assess, plan and deliver exercise safely for patients who have been previously sedentary and without recent experience of engaging in a regular exercise program. (5). Exercise physiologists have expertise in screening risk, exercise prescription and programming, and are better placed to ensure the program delivered is evidence based (5)

In the present study Exercise Physiology (EP) students in their fourth (senior) year of an undergraduate degree in Exercise physiology will be engaged in a training rotation at the CCU, and will be supervised by both the psychiatric consultant who has an exercise background, and by their own Exercise physiology lecturers from their university (Queensland University of Technology).

EP students will administer the Adult pre-Exercise screening tool and assess Cardiorespiratory status in accordance with Vancampfort’s first 2 recommendations(4).

 Exercise physiology students will be given basic education on severe and persistent mental illness, such as schizophrenia and Bipolar disorder, common medications prescribed and their side effects, and the typical barriers to engagement in physical activity in this population. This will allow EP students a more informed approach when working with the CCU residents and facilitate greater sensitivity to the challenges faced by these patients. This is a unique opportunity for collaboration between a mental health facility and university to embed an evidence- based physical activity intervention in standard practice.

Achievable intensity level

The physical activity program will be titrated to the capacity of the individual participating and closely monitored for any emerging physical or health risks. Exercise physiology students will develop a safe program and monitor progress during all sessions of “GO HEART” provided at the CCU during the 10 weeks. A doctor will be on site at the CCU at all times when GO HEART is run.

Whilst the International Organisation of Physical Therapists in Mental Health (IOPTMH) recommend aiming for a minimum of 150 mins per week of moderate intensity, or 75 minutes per week of vigorous physical activity (18), in this program residents are unlikely to have much previous recent exercise experience.

Accordingly, this program will start in the low –moderate intensity range and Increments in intensity and duration of exercise will be titrated depending on progress, enjoyment and tolerability. This is to ensure safe participation, maximize regular engagement in the program and offer enjoyable activity such that the participant may be able to perceive

success in the achievement of realistic fitness goals (5).

It is not expected that participants will achieve the 150 minutes per week optimal recommendation from the outset of the study. This will act as a guide for the study, but it is anticipated that physical activity duration will need to be increased slowly. Previous research in the general population has shown that even exercise for less than 150 minutes per week can improve life expectancy significantly. (15)

 Previous attempts at the Coorparoo CCU to engage residents in physical activity using personal trainers (rather than Exercise physiologists or physiotherapists) resulted in high drop out rates as the residents were given high intensity exercises that were not perceived as achievable or enjoyable.

Strategies to address Motivation

Challenges to engagement in physical activity programs for patients with severe and persistent mental illness(SPMI) include avolition and other negative symptoms of schizophrenia, medication side effects, (4) established morbid obesity, and little experience in regular physical activity,

 In addition, financial constraints and availability of fitness facilities are often cited as challenges to involvement in structured sport or exercise by patients living in the community. (18)

Frontal/executive difficulties in planning and initiating new activities impacts on patients planning and implementing their own physical activity program without help (27)

Residents living at a CCU frequently present for rehabilitation at a time in their recovery journey when they are most likely able to address broader concerns than just symptoms of their mental illness. A staffed Residential rehabilitation unit has many advantages as a setting to implement a physical activity intervention to address some of these barriers to engaging in physical activity programs (cost, availability of equipment, CCU staff available as health coaches, to assist with goal setting and help with planning of scheduled activities).

This present study will include a number of the evidence- based motivational strategies that were recently differentiated as a result of meta-analysis of cardiorespiratory fitness promotion in patients with schizophrenia (4). This includes facilitating: empathy, validation and encouragement of participants, individualized exercise plan based on participants’ preference that addresses potential barriers to engagement, adaptation of the physical activity to the participant’s health status and fitness, cognitive behavioural strategies such as realistic goal setting, self monitoring and contracting, enjoyable social interactions with peers, a focus on perceived cardiorespiratory gains following individual sessions rather than on longer term goals such as weight loss.

Given the large number of barriers to engagement noted, the program must be realistic, acceptable, and enjoyable. Group activity programs at the Coorparoo CCU have usually been well attended, social factors influencing attendance and enjoyment. Social connectedness during physical activity has been identified as one of the 3 psychological constructs patients with schizophrenia can use to address barriers to engagement (4).

Consequently in this pilot study the physical activity intervention will be carried out in a circuit style within a group setting.

Exercise physiology students will be given basic education on severe and persistent mental illness, such as schizophrenia and Bipolar disorder, common medications prescribed and their side effects, and the typical barriers to engagement in physical activity in this population. This will allow EP students a more informed approach when working with the CCU residents and facilitate greater sensitivity to the challenges faced by these patients.

In this study there is an important opportunity for collaboration between a mental health facility and university to embed an evidence- based physical activity intervention in standard practice.

The priority will be to maximize enjoyment and adherence without overwhelming the participant, minimize any risks and offer something that the individual participant may integrate into their weekly activities once the study has finished.

Based on the foregoing considerations, the present project will be a pilot study addressing acceptability and evaluation of outcomes of a physical activity program implemented at a residential rehabilitation unit (Group Occupational Health Exercise And Rehabilitation Treatment, “GO HEART”)

**Hypothesis:**

The hypothesis evaluated in this study is that engagement in a physical activity program available in standard mental health rehabilitation will improve cardiovascular fitness and a range of other health outcomes such as mood, psychiatric symptoms and quality of life.

Blood tests measuring lipids, blood sugars and abdominal circumference will be measured pre and post the intervention, however it is not anticipated that there will be significant changes across the 10 week study period.

**Aims:**

The aim of the pilot study is to implement a physical activity program in a residential setting and assess outcomes of this physical activity program across a range of measures for individual residents

The primary outcome will be to assess cardiovascular fitness.

Secondary outcomes include social functioning, quality of life, positive and negative symptoms of schizophrenia and metabolic profile.

**Methods**

**Design:**

The project will be a prospective cohort pilot study using a planned assessment battery pre and post the 10 week physical activity program intervention to better understand the impact of the physical activity program on a range of fitness, health and functioning outcomes.

The program length will be for a total duration of 10 weeks, after the initial assessments have been performed. It will occur three times per week at the CCU (Monday, Wednesday, Friday) supervised by the Recreation officer and Exercise physiology students from a University undergraduate exercise physiology degree program.

The Exercise physiology students will be supervised by their own University lecturers and by the consultant psychiatrist. The physical and mental health of the participants will be overseen by the Psychiatric Registrar and the Consultant Psychiatrist.

 The circuit program will be an individualized supervised exercise prescription based on best-practice recommendations. There will be a range of exercises and equipment that will be offered including a seated exercise bike, punching pads and gloves, therabands, seated and standing exercises on a mat involving lower and upper limbs.

There will be short breaks between exercises, as in a circuit.

Intensity level will be aimed for low-moderate intensity in the beginning. It will potentially increase several weeks into the program, after orientation and familiarity to the circuit program occurs and some early successes in fitness have been perceived by participants.

Participants will be provided with a log book at the beginning of the program to monitor their own progress and given information on the health benefits of exercise.

Prior to starting the circuit, participants will meet with the consultant psychiatrist and Exercise physiology students in a joint meeting to set realistic goals and develop an individual action plan based on their current preferences. This will take into account potential barriers to attendance.

The consultant psychiatrist will employ evidence -based cognitive behavior therapy strategies, such as self monitoring, goal setting, cuing and contracting during weekly sessions with participants outside of the GO HEART program.

 Participants will be encouraged to avoid between- peer comparisons and instead to directed to focus on individual gains, hence allowing optimal enjoyment from the social setting of the circuit.

Music will be played during the circuit to enhance pleasure and social connectedness.

The program will be modified according to individual concerns elicited (intensity, equipment type). For example participants who are uncomfortable utilising a seated fitness bike, but are willing to engage in alternative exercises, will be offered an individualised program involving only resistance training therabands and lower intensity exercises on a mat, however still carried out in the group setting to capture benefits of social connectedness whilst exercising.

Participants will be required to wear safe, appropriate foot wear and comfortable exercise clothing.

There will be a warm up and cool down before and after the circuit.

**Participants:**

Staff at the CCU will approach residents and provided with information about the program. They will be offered involvement in the physical activity program and its evaluation. Participation will be via voluntary informed consent. Participants will have their capacity to consent evaluated by a Consultant Psychiatrist with expertise and training in assessing capacity to consent.

The CCU occupancy has capacity for 20 residents who are admitted for psychosocial rehabilitation, who present with severe and persistent mental illness. (SPMI).

Residents of the Coorparoo CCU may only be admitted and reside at the facility provided their risk of suicide or aggression remains low. This is routinely assessed prior to admission and throughout the resident’s stay at the CCU, by a Consultant psychiatrist with expertise and training in the assessment of risk.

**Inclusion criteria** –Any Resident at the Coorparoo CCU who is admitted for residential rehabilitation will be potentially eligible. Residents are typically admitted with (SPMI) illness, that predominantly includes chronic Schizophrenia, schizoaffective disorder, and less often biploar disorder,and chronic depression.

Residents of the CCU are aged 18-65.

Participants who are interested in participating will undergo the Adult pre-Exercise Screening tool (19) administered by the Exercise Physiology students.

Anyone deemed low or negligible risk will be eligible for inclusion.

**Exclusion Criteria** – anyone deemed medically unfit to exercise as determined by the psychiatric registrar performing the medical examination will be excluded.

The Adult Pre -Exercise screening tool (APSS) (19) will be administered by the Exercise physiology students, who by their fourth year of study have experience in administering this well established tool.

Those screened to have greater than low risk associated with exercise will be referred for a thorough medical examination by the CCU registrar. Only those deemed fit to exercise up to a moderate intensity will be included in the program.

The APSS is accepted as the industry standard pre-exercise screening system by Exercise and Sports Science Australia (ESSA). It is an evidence- based system for managing and identifying health risk for exercise (ESSA) (19).

 Any resident whose mental state is considered to be too unstable to be included in the program as deemed by the consultant psychiatrist will be excluded.

An unstable mental state precluding engagement in programs at the CCU would usually result in admission to the acute mental health inpatient unit and further intensive mental health treatment.

24 hour multidisciplinary staff at the CCU are available and trained to assess the mental state of residents when the consultant psychiatrist is not present.

Any resident who is pregnant will be excluded.

Any resident who is admitted to the CCU but has a planned stay of less than the 10 week program or a discharge date before the end of the program will be excluded.

We will aim to recruit 10 residents to engage in the 10 week program. Participation will end after the individual has completed the baseline assessments, the 10 week GO HEART program and post measures.

**Setting:**

The evaluation will occur at the Coorparoo CCU residential rehabilitation unit.

Individual assessments will occur in the confidential interview rooms of the CCU.

The exercise program will occur in the dedicated fitness courtyard of the residential unit where other group programs have been previously run.

**Measures:**

The following assessments will occur at baseline and immediately following the 10 week GO HEART program.

1. The Simple Physical Activity Questionnaire (SIMPAQ) is a simple 5-item clinical tool designed to assess physical activity amoung populations at high risk of sedentary behavior. A multinational validation study of SIMPAQ is being completed in 2016. (20)

The SIMPAQ will be administered by the Exercise Physiology students.

1. 6 minute walk test (6MWT). This test is commonly utilized as a proxy measure of fitness to test exercise capacity in elderly or chronic disease populations (given a large proportion of this cohort will have been chronically sedentary with little exercise background at the time of the study, this submaximal test is appropriate.). VO2max is then estimated based on the relationship between Heart rate and work rate. (28)

Direct tests of V02max are the gold standard in measuring cardiorespiratory fitness. In this study there are concerns that a maximal approach to gaining a baseline fitness measure would actually produce negative attitudes in this cohort of participants and interfere with adherence before the program has even started. 6MWT is low cost, and can be easily performed.

The 6MWT will be administered by Exercise Physiology students in the fitness courtyard of the CCU.

1. Scale for the Assessment of Negative Symptoms (SANS). The SANS is a clinician rated measure based on clinical interview. The Interview guide for Assessment of Negative symptoms (IG-SANS) will be used as a guide to the clinical interview on which the SANS is scored. (29)

The SANS will be administered by the Consultant Psychiatrist, who is trained in it’s use.

1. Brief Psychiatric Rating Scale. The BPRS is a widely used instrument for assessing the positive, negative and affective symptoms of individuals with psychotic disorders. Fidelity of data will be enhanced through the use of a semi-structured interview guide and the use of an anchored scoring version of the (BPRS-A) (21,22)

The BPRS-A will be administered by the Consultant Psychiatrist who has experience in it’s use.

5. The Assessment of Quality of Life (AQoL)-8D is a reliable and valid instrument which is particularly suitable when psychosocial elements of health are of importance. (23).

7. Standardised metabolic measurements – fasting lipids and Blood sugar level, Body Mass Index (BMI), abdominal circumference.

Metabolic measurements will be collected by the psychiatric registrar, these measurements arising from best practice guidelines for patients suffering SPMI.

8. Each participant will be encouraged to record their attendance and number of minutes engaged in physical activity and perceived intensity following each session of the GO HEART program in their individual diary. This will be facilitated by the Recreation officer.

9. A brief attitude to exercise scale will be administered by EP students- Behavioural Exercise Regulations Questionaniare, BREQ-2. This questionnaire has been validated in a 2013 study in patients with Schizophrenia, and examines attitudes toward motivation to exercise. (24)

This questionnaire will be administered by the Recreation Officer.

**Statistical Analysis:**

Pre test scores will be compared with post test scores using a student t test.

**Potential benefit:**

Participants will benefit from the chance to improve their physical fitness, and hence reduce longer term cardiovascular risks. Benefits may also be seen in social functioning, reduction in mental health symptoms, improved mood and perceived quality of life, and perceived enjoyment in structured physical activity.

**Ethical Issues:**

Health Risks

Whilst there may be possible health risks associated with exercise in this sedentary population who are predominantly obese, the risks of participating in low to moderate intensity exercise would be minor. The average age of admissions to the CCU is 30 years, and few if any have actual cardiovascular disease during their current CCU admission, although they are obviously at long term risk of developing unless CVD risk factors are modified.

All potential participants will complete the Adult pre-exercise questionnaire, and any person screened as greater than low risk to exercise or who harbors concerns about engaging in exercise will be referred for thorough medical examination by the psychiatric registrar at the CCU.

The medical examination will consist of routine physical observations (postural Blood pressure, heart rate, temperature, respiratory rate), in addition to full examination of cardiovascular, gastrointestinal, respiratory and neurological examination, musculoskeletal system including gait. Referral for necessary investigations may be required, in order to allow medical clearance of the patient or exclusion from the program (ie ECG, blood tests).

Patients who have actual pre-existing cardiovascular disease or who present with emerging cardiovascular risks as a result of physical

 However for participants deemed medically fit enough to be included in the study, any risks anticipated from engaging in low to moderate intensity activity would be minor, such as post exercise fatigue or muscle soreness; moderate intensity activity being considered relatively safe (11). In fact, there is overwhelming evidence of significant morbidity and mortality in these patients if they remain sedentary, so any small risks associated low- moderate intensity exercise must be balanced against the serious and possibly deadly consequences of no activity at all.

Whilst almost all residents at the Coorparoo CCU will be on psychiatric medication, there are no known serious complications to the combination of physical exercise and psychotropic medication (25). Some patients experience sedation and fatigue from their medications, which may contribute to motivation and engagement issues, but should not preclude inclusion due to safety concerns (and in fact exercise will likely mitigate against some of these medication side effects). Muscle soreness and fatigue post exercise may occur but it is anticipated that this would be minor and participants would be warned of this. However musculoskeletal injury will be minimized by gradually increasing intensity, having a warm-up and cool-down pre and post the circuit program and ensuring proper footwear (26).

Ongoing monitoring of physical health of participants will occur by the Exercise physiology students. In addition to this, the Consultant Psychiatrist and Psychiatric Registrar will oversee the general physical and mental health of participants. The Go HEART program will be suspended in any participant deemed to be at risk of physical or mental health deterioration, injury or anticipated harm and further physical care of the patient will be attended to immediately by the psychiatric registrar, consultant psychiatrist and other allied health staff present 24 hours per day at the CCU. Further medical care from local G.P or other physicians will be sought as necessary.

There may be very minor or negligible risks associated with collection of blood for the purposes of fasting lipids, and fasting blood sugar levels. However standardized collection techniques will be employed from local pathology collection centers however these risk are anticipated to be very transient and very low.

Consent

Capacity to provide Informed consent to the study will be assessed by the Consultant Psychiatrist who has expertise in doing so. Any resident of the CCU who doesn’t consent to the study will still have access to the Adult pre-exercise questionnaire, and the medical examination if screened necessary.

 Residents who decline participation in the study will still be allowed use of the CCU fitness equipment supervised by the recreation officer, at alternative times to when the GO HEART program would be run.(ie they will still be encouraged to address fitness goals they may have at the CCU even if they do not consent to and participate in the study), however they will not undergo the formal battery of assessments beyond the Adult pre-exercise screening questionnaire or undertake the GO HEART program developed by the Exercise Physiology Students.

 Any resident may decline participation or withdraw consent at any time. Residents will be reassured that participation is entirely voluntary and their refusal will not jeopardise their continuing rehabilitation and psychiatric treatment in any way. They will be routinely offered alternative programs already in existence at the CCU, such as Zumba and walking groups.

This will aim to address any ethical concerns regarding coercion and the fact that the Principal Investigator is also the treating inpatient consultant psychiatrist who will continue to have a primary doctor-patient relationship with each resident at the CCU irrespective of consent to research at the CCU.

The Coorparoo CCU is involved in several other ongoing research projects and residents are used to being offered involvement in various studies; they are made aware that all participation is voluntary and their ongoing residence at the CCU is not affected by their refusal to participate or withdrawal of consent (if already consented) to any research. New residents are orientated to this approach and philosophy when admitted to the CCU.

Confidentiality

Confidentiality of participants will be maintained at all times. Data will be de-identified. Data will be stored for 7 years in a locked filing cabinet in a locked room in a Queensland Health facility. Electronic files will be stored in a password protected computer in a Queensland Health facility.

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