An Analysis of the Partial Feasibility of a Novel Cardiac Exercise Rehabilitation Programme for Patients Suffering from Cardiovascular Disease

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Abstract

Introduction: Substantial research has shown that the inclusion of exercise in cardiac rehabilitation has a favourable effect on many outcome variables, and that exercise should be considered a vital and central component for cardiovascular disease (CVD) rehabilitation. South Africans are facing a growing epidemic of CVD, which has major implications for health-care services and has placed increasing strain on the already grabbling South African health-care system. Cost-effective primary and secondary prevention and management strategies are needed to slow down the growing CVD epidemic and relieve strain on health-care systems. The need exists for more evidence to demonstrate that cardiac exercise rehabilitation programmes (CRPs) can significantly reduce readmissions, mortality, comorbidities, and improve quality of life. **Aims**: The aims of this study were to determine the partial feasibility of a novel CRP in a South African public hospital setting by evaluating the following: 1) The recruitment potential and sample population characteristics of those considered eligible to partake in the exercise component of a novel CRP; and 2) The test-retest reliability of the tools utilized for the safe monitoring of the exercise intensity during the prospective CRP. **Methods:** The recruitment potential and sample population characteristics of the target population were determined via retrospective analysis of a hospital admission patient database spreading over three months. The database was searched for demographic data including age, sex, height, weight, waist circumference and BMI, the admission diagnosis, patient co-morbidities and medications. The test-retest reliability of the monitoring tools was conducted on apparently healthy participants who underwent a series of monitoring measures before and after a 6-min motion test on two separate occasions. The test-retest reliability of each monitoring tool was determined using intraclass correlation coefficients (ICCs), effect size calculation and Bland-Altman plots. **Results**: One hundred and nine patients (52.2%) were considered ineligible for a CRP, whereas 100 individuals (47.8%) were considered eligible. Significant differences were identified between the eligible and ineligible populations were for four comorbidities and two medications. Twenty-two outcome measures were assessed for reliability, five of which were classified as having “poor” reliability, nine as “moderate”, three as “good” and five as “excellent’ according to ICCs. Eighteen measures revealed excellent test-retest reliability, and

the remaining 8 measures (Baseline Systolic Blood Pressure; Baseline Diastolic Blood Pressure; Baseline Oxygen Saturation; Immediately Post-Exercise Oxygen Saturation; Immediately Post-Exercise RPE; 5-Minutes Post-Exercise Systolic Blood Pressure; 5-Minutes Post-Exercise Oxygen Saturation; and 5-Minutes Post-Exercise RPE) had showed small effect sizes between 0.2-0.5, which was considered acceptable. **Conclusion:** The results from the analysis of the recruitment potential from a public hospital setting reveal that approximately 33 patients (100 patients/3 months) will be eligible per CRP intake, and the recruitment potential of eligible patients currently exceeds the prospective resource and staff capacity of the CRP. Further investigation is required to address and resolve the shortcoming in resources to offer the CRP to all eligible participants. The results from the test-retest reliability of the monitoring tools used within the CRP revealed that most of the equipment and measures achieved sound reliability, except for the blood pressure monitors, pulse oximeters and RPE scale. Alternative devices for monitoring blood pressure, oxygen saturation and RPE are recommended.

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Chapter 1

Literature Review

Introduction

Cardiovascular disease (CVD) has been defined by the World Health Organisation (WHO) as a group of disorders that affect the heart and vasculature (Francula-Zaninovic et al., 2018; WHO, 2017). The global burden of CVD is high, with 422.7 million CVD cases globally in 2015 (Supervia et al., 2019). The increase in CVD cases can be attributed to the continued increase in risk factors such as smoking, hypertension, and dyslipidaemia (Deaton et al., 2011). For individuals who fortunately do not succumb to CVD, there is still a burden of disease affecting their quality of life, their ability to return to their activities of daily living, recreational activity as well as occupational activities. In older adults, CVD is the second greatest cause of disability and is also a significant factor leading to a decline in self-reported health (Yazdanyar et al., 2009). CVD is also considered to contribute significantly to both a decline in function and dementia, through a decrease in independence and a lower capacity to perform activities of daily living (Newman et al., 2001; Newman et al., 2003; Yazdanyar et al., 2009).

Cardiac rehabilitation is an established form of care designed to alleviate the burden of CVD (Supervia et al., 2019). Previously, it has been defined as the coordination of a number of different interventions, which are required to ensure the best social, psychological and physical conditions to allow patients with chronic or post-acute CVD to preserve or resume optimal functioning through improved health behaviours and slowed or reversed disease progression (Taylor et al., 2004). Physical activity delivered in the form of a cardiac exercise rehabilitation programme (CRP) has been shown to improve patients' cardiorespiratory fitness, cardiac recovery index and psychological well-being (Dugmore et al., 1999). A meta-analysis of 34 randomised control trials by Lawler and colleagues (2011) showed that exercise-based cardiac rehabilitation lead to statistically significant reductions in cardiac mortality, all-cause mortality and rate of reinfarction (Lawler et al., 2011). Therefore, exercise should be considered as a vital intervention and should remain a central component to the

rehabilitation and prevention of CVD (Anderson et al., 2016; Kachur et al., 2017).

CRPs have shown strong evidence as a successful and vital component in the recovery and improvement of CVD. However, gaps still remain in service delivery and implementation worldwide. In 2014, it was estimated that CRPs are unavailable in more than 60% of countries across the globe, and where CRPs do exist, there is insufficient capacity to meet a growing demand (Turk-Adawi et al., 2019). A massive discrepancy in the availability of CRPs exists between high-income countries (HICs), such as those in European region, and low-income and middle-income countries (LMICs), such as those in Africa. The availability of CRPs in LMICs is low relative to the growing burden of CVD that they face (Ragupathi et al., 2017).

South Africans are facing a rise in non-communicable diseases and a growing problem of CVD as a result of physical inactivity and an associated shift in lifestyle and culture. The high levels of morbidity and mortality associated with CVD have major implications for health-care services and place increasing strain on the already struggling South African health care system (Mayosi et al., 2009; Mbewu A, 2008). Cost-effective primary and secondary prevention and management measures are needed to slow down the growing CVD epidemic and relieve strain on health-care systems (Mbewu A, 2008).

The purpose of this literature review is to evaluate the available evidence surrounding cardiovascular disease and cardiac rehabilitation in LMICs, particularly South Africa, and provide evidence of the need for further investigation into cost-effective management strategies and their feasibility for CVD within developing countries.

An Introduction to Cardiovascular Disease

Cardiovascular disease (CVD) has been defined by the World Health Organisation (WHO) as a group of disorders that affect the heart and vasculature (Francula-Zaninovic et al., 2018; WHO, 2017). The group includes hypertensive heart disease, coronary heart disease, stroke, peripheral vascular disease, heart failure, rheumatic heart disease, congenital heart disease and cardiomyopathies (WHO, 2017). CVD is a set of heterogenous diseases which evolve throughout an individual's lifespan and are typically asymptomatic for a long time, with only

advanced disease leading to symptoms or even death (Francula-Zaninovic & Nola, 2018).

CVD has a complex and multifactorial aetiology and develops as a consequence of complex interactions between an individual's genetic makeup and their environment (Sing et al., 2003). Risk factors for CVD typically fall into a modifiable or non-modifiable category. Modifiable risk factors are those factors which can be changes or improved, such as modifiable lifestyle risk factors and certain physiological characteristics, whereas non-modifiable risks are those personal characteristics which cannot be changed (Kumar, 2018). In adults, the effects of risk factors are cumulative. Therefore, the greater number of risk factors present, the greater the risk of developing CVD (Kumar, 2018). Modifiable risk factors include smoking and tobacco use, hypertension, hyperlipidaemia, diabetes, overweight and obesity, physical inactivity, alcohol abuse and an unhealthy diet (Francula-Zaninovic et al., 2018; Mayosi et al., 2009; WHO, 2017.). Non-modifiable risk factors include age, gender, ethnicity, familial history and genetics (Francula-Zaninovic et al, 2018; Kumar, 2018; Mayosi et al., 2009). A study by Emdin and colleagues (2016) showed that mental health disorders, such as anxiety, increase the risk of CVD development (Emdin et al., 2016). They demonstrated that anxiety was associated with a 41% higher risk of cardiovascular mortality, a 41% higher risk of coronary heart disease, a 71% higher risk of stroke, and a 35% higher risk of heart failure (Emdin et al., 2016). Depression has also been linked to greater risk of CVD development, with a meta-analysis showing that depression was associated with a 81% higher risk of coronary artery disease (Nicholson et al, 2006).

The INTERHEART study, a case-control study of acute myocardial infarction in 52 countries, aimed to determine the relation of risk factors, such as smoking and hypertension, to myocardial infarction. It was found that abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, consumption of fruits and vegetables, alcohol use, and regular physical activity were all significantly related to acute myocardial infarction ($p < 0.0001$)(Yusuf et al., 2004). The adjusted odds ratios for the above-mentioned risk factors were as follows: 2.95 for current smoking; 2.27 for current and former smoking; 3.08 for diabetes; 2.48 for hypertension; 1.36 for abdominal obesity; 2.24 for abdominal obesity; 2.51 for psychosocial factors; 0.70 for fruit and vegetable intake, 0.72 for exercise and 0.79 for alcohol intake (Yusuf et al., 2004). These risk factors account for over 90% of the risk of

myocardial infarction worldwide in both sexes, at all ages and in all regions (Yusuf et al., 2004).

The Burden of Cardiovascular Disease

The global burden of CVD is high, with 422.7 million CVD cases globally in 2015 (Supervia et al., 2019). According to researchers, CVD was responsible for one-third of deaths worldwide in 2011 (Deaton et al., 2011) and it is predicted that CVD mortality will continue to increase to 23.4 million by 2030, a staggering 37% increase from the 2004 rates (Deaton et al., 2011). The increase in CVD cases can be attributed to the continued increase in risk factors such as smoking, hypertension, and dyslipidaemia (Deaton et al., 2011).

For individuals who fortunately do not succumb to CVD, there is still risk of readmission and a burden of disease affecting their quality of life, their ability to return to their activities of daily living, recreational activities as well as occupational activities. Yazdanyar and colleagues (2009) stated that CVD is the second leading cause of disability amongst older adults, second to arthritis, and is an important cause of the decline in self-reported health (Yazdanyar et al., 2009). CVD is also considered to contribute significantly to dementia, functional decline and frailty, through a loss of independence, the ability to perform activities of daily living and increased age-related decline (Newman et al., 2001; Newman et al., 2003; Yazdanyar et al., 2009). In a review by Ades and colleagues (2013) on the effects of exercise training for individuals with chronic heart failure, lower depression scores as well as improved quality of life (QoL) were observed with exercise training (Ades et al., 2013). Risk of readmission has also shown to be reduced with exercise training when compared to usual care (Anderson et al., 2016). Anderson and colleagues (2016) also reported higher levels of health-related QoL following exercise-based CRP compared to control (Anderson et al., 2016). Kachur and colleagues (2017) reported similar results of improved outcomes in CVD patients after exercise training, including reduced recurrent CVD events and improved health-related QoL (Kachur et al., 2017).

CVD also places a large financial burden on healthcare systems and the national economy (Gaziano, 2005). CVD has a number of direct and indirect costs including cost of hospitalisation and treatment, medication costs, professional fees, costs arising from

disability and loss of productivity. In South Africa, it has been estimated that 2-3% of the country's gross national income and 25% of healthcare expenditure was devoted to direct treatment of CVD (Gaziano, 2005). In 2009, CVD was the most expensive disease category in the United States, with costs exceeding $475 billion (Yazdanyar et al., 2009). The financial burden of CVD is particularly evident in low- to middle-income developing countries, particularly due to the scarcity of financial resources and CVD management strategies (Deaton et al., 2011). African countries typically face a double burden of communicable diseases, such as HIV and Tuberculosis, along with CVD (Mbewu A, 2008). The high levels of morbidity and the financial burden of CVD place a particular strain on the African healthcare systems which are already struggling to cope with infectious disease (Mbewu A, 2008).

The economic impact comes both in the forms of direct costs to the healthcare system, and as indirect costs due to decreased productivity and work loss (Gaziano, 2007). A 2004 report, *A Race Against Time*, reported that between 5 countries (Brazil, India, China, South Africa and Mexico) at least 21 million future productive life years are lost due to CVD each year (Gaziano, 2007). This has a large impact on a countries economic viability (Gaziano, 2007).

Cardiac Rehabilitation

Cardiac rehabilitation is an established and integral model of care designed to mitigate the burden of CVD (Abreu et al., 2019; Ades et al., 2013; Anderson et al., 2016; Supervia et al., 2019). It has been previously defined as the coordinated sum of interventions required to ensure the best physical, psychological and social conditions so that patients with chronic or post-acute cardiovascular disease may preserve or resume optimal functioning through improved health behaviours and slowed or reversed disease progression (Taylor et al., 2004).

Cardiac rehabilitation services are typically multicomponent and are delivered through an interdisciplinary, multifaceted approach (Balady et al., 2007; Hamm et al., 2011). The core components differ between regions and countries, but the following components are typically included: assessment of risk factors, nutritional guidance, weight management, blood pressure management, cholesterol management, diabetes management, smoking cessation, psychosocial management, physical activity guidance and exercise training (Hamm et al.,

2011). Programmes that consist of exercise training alone are not considered cardiac rehabilitation (Balady et al., 2007). The aim of these multicomponent programmes is to stabilise, slow or even reverse disease progression, optimise functioning, reduce risk factors, foster healthy behaviours, improve quality of life and reduce disability (Balady et al., 2007; Cartledge et al., 2019; Turk-Adawi et al., 2014) .

Role of Exercise and Physical Activity

The multiple health benefits of physical activity and exercise are well-established, and physical activity is now regarded as a cornerstone to maintaining cardiovascular health (Ades et al., 2013; Anderson et al., 2016; Arnett et al., 2019; Kachur et al., 2017; Schuler et al., 2013). Physical activity has been associated with a marked decrease in cardiovascular mortality, reduction in all-cause mortality, reduced risk of reinfarction and improvements in several primary cardiac risk factors (Abreu et al., 2019; Lawler et al., 2011; Lear et al., 2017; Nocon et al., 2008; Taylor et al., 2004). The American Heart Association, European Society of Cardiology and American College of Cardiology have given exercise therapy a Class I recommendation for the management of CVD (Anderson et al., 2016). A consistent and strong inverse dose-response relationship between physical activity and CVD associated events or death has been shown (Arnett et al., 2019; Lear et al., 2017; Schuler et al., 2013). Consequently, it is recommended by the American Heart Association that all adults should engage in at least 150 minutes of accumulated moderate-intensity exercise per week (Arnett et al., 2019).

Substantial research has shown that the inclusion of exercise in cardiac rehabilitation has a favourable effect on functional capacity, hospital readmissions and mortality in coronary artery disease patients (Anderson et al., 2016; Kabboul et al., 2018; Valkeinen, Aaltonen, & Kujala, 2010; Xia et al., 2018). However, a 2018 meta-analyses by Powell and colleagues (2018) found no concrete evidence that shows exercise-based cardiac rehabilitation programmes reduce mortality rates (Powell et al., 2018). Although there is evidence showing that the inclusion of exercise in cardiac rehabilitation programmes does not reduce all-cause mortality, majority of the evidence show there are reductions in mortality rates, but more importantly, a reduction in hospital readmissions and improved quality of life.

In the most recent systematic review of exercise-based cardiac rehabilitation intervention effects on quality of life (QoL), the same research team found favourable outcomes of exercise-based programmes on QoL (McGregor, Powell, Kimani, & Underwood, 2020). Kachur and colleagues (2017) stated that exercise training after myocardial infarction and heart failure is associated with favourable ventricular remodelling, decreased CVD and all-cause mortality rates and reduced hospital readmission (Kachur et al., 2017). A meta-analysis of 34 randomised control trials by Lawler and colleagues (2011) showed that exercise-based cardiac rehabilitation lead to statistically significant reductions in cardiac mortality, all-cause mortality and rate of reinfarction (Lawler et al., 2011). Exercise should be considered as a vital intervention and should remain a central component to the rehabilitation and prevention of CVD (Abell et al., 2017; Anderson et al., 2016; Cartledge et al., 2019; Kachur et al., 2017; Taylor et al., 2004; Xia et al., 2018)

Global Presence of Cardiac Rehabilitation Programmes

CRPs have shown strong evidence as a successful and vital component in the recovery and improvement of CVD. However, gaps still remain in service delivery and implementation worldwide. In 2014, it was estimated that CRPs are not available in over 60% of countries worldwide and where CRPs do exist, there is insufficient capacity to meet a growing demand (Turk-Adawi et al., 2019). Turk-Adawi and colleagues (2019) reported the availability of CRPs to be as follows: 80.7% of countries in the European region, 70% of countries in the Americas, 54.5% of countries in South East Asia, 54.5% of countries in Eastern Mediterranean Region, 42.7% of countries in the Western Pacific and 17% of countries in the African region (Turk-Adawi et al., 2019). A massive discrepancy in the availability of CRPs exists between high-income countries (HICs), such as those in European region, and low-income and middle-income countries (LMICs), such as those in Africa. In addition to discrepancy in availability, density, delivery, core components offered and funding of CRPs also differs greatly between HICs and LMICs (Pesah et al., 2019; Supervia et al., 2019; Turk-Adawi et al., 2019).

Across Europe, there are approximately 1500 CRPs existing in 90% of European countries (Abreu et al., 2019). CRP density has been reported to be one programme per < 500 000 inhabitants in HICs (Turk-Adawi et al. , 2014). Core components of CRPs including depression

screening, nutrition counselling, stress management, tobacco cessation interventions and return to work counselling were provided significantly more often than in LMICs (Pesah et al., 2019). CRPs in HICs were also more likely to provide patients with an alternative model of CR delivery to supervised clinical care and also more likely to be publicly funded (Abreu et al., 2019; Pesah et al., 2019). Yusuf and colleagues (2014) stated that cardiovascular mortality has declined significantly in HICs with only 3.99 events per 1000 person-years in HICs, compared to 5.38 and 6.43 events per 100 person-years in middle- and low-income countries respectively. This is most likely due to better control of risk factors and improved management in HICs (Yusuf et al., 2014).

Approximately 80% of CVD-related deaths occur in LMICs (Turk-Adawi et al., 2014). Unfortunately, cardiac rehabilitation is only available in 23% of the LMICs where majority of the deaths are occurring (Turk-Adawi et al., 2014). Much of the available evidence shows that CRPs reduce mortality by up to 25% over an average of five years when compared to usual care (Turk-Adawi et al., 2014). The existing cardiac rehabilitation programmes in LMICs are believed to have insufficient capacity to meet the growing burden of CVD in these countries (Pesah et al., 2019). Across all LMICs, it is believed that 14 766 930 more cardiac rehabilitation spots are required to treat all ischemic heart disease cases annually with more required to treat other indications (Pesah et al., 2019). As mentioned above, CRPs in LMICs offer fewer components, such as return to work counselling and tobacco cessation interventions, than those in HICs (Pesah et al., 2019). In middle-income countries, such as South Africa, it is believed that the density of CRPs was one programme to 1-6 million inhabitants (Turk-Adawi et al., 2014).

The availability of CRPs in LMICs is low relative to the growing burden of CVD that they face (Ragupathi et al., 2017). In addition to this, there are several barriers which prevent attendance to available CRPs. In LMICs, two major barriers include a lack of resources and poor affordability (Ragupathi et al., 2017). Majority of LMICs in Africa rely on out-of-pocket payment systems which limits CRP utilization (Ragupathi et al., 2017).

A South African Context

South Africans are facing a rise in non-communicable diseases and a growing problem of CVD as a result of physical inactivity and an associated shift in lifestyle and culture. The South African population as a whole is considered to be insufficiently active, with only 49% of women and 43% of men meeting physical activity guidelines to achieve health benefits (Joubert et al., 2007). In 2000, approximately 3.3% of all deaths in South Africa were a result of physical inactivity, majority of these deaths were specifically related to ischemic heart disease (Joubert et al., 2007). Ischemic heart disease was attributable to 58.9% of the disability-adjusted life year (DALY; the number of years lost due to poor health, disability, or premature death) burden in men and 40.6% in women. This was followed closely by ischemic stroke which accounted for 20.5% in men and 27.6% in women (Joubert et al., 2007). Previous research from the Heart of Soweto Study, based in an urban informal settlement in Soweto, South Africa, has shown that due to the adoption of a more westernized culture, the urban black population are at increasing risk for CVD (Tibazarwa et al., 2009). Tibazarwa and colleagues (2009) found that 78% of their participants had more than one major risk factor for the development of CVD (Tibazarwa et al., 2009). They also noted that 70% of the participants were overweight, with 48% being considered obese (Tibazarwa et al., 2009).

The high levels of morbidity and mortality associated with CVD have major implications for health-care services and place increasing strain on the already struggling South African health care system (Mayosi et al., 2009; Mbewu A, 2008). In 2019, South Africa had an estimated population of approximately 58.8 million (Statistics South Africa, 2019), majority of whom rely on public clinics and hospitals to access necessary health care. It is believed that the private sector serves only 16% of the South African population, while the public sector serves 84% (Naidoo, 2012). Discrepancies between health services in the public and private sectors lead to the problem of inadequate health care for those in the public health care system. The public health care system is characterised by numerous problems, including long waiting times, poor-quality health care delivery, poorly maintained infrastructure, inadequate human resources, lack of material resources, equipment and supplies (Maphumulo et al., 2019). Overall, this has resulted in prolonged patient stays within the hospital, further complications, incorrect diagnoses and in some cases, death (Maphumulo et al., 2019).

Cost-effective primary and secondary prevention and management measures are needed to

slow down the growing CVD epidemic and relieve strain on health-care systems (Mbewu A, 2008). Currently, South Africa has 23 CRPs (Supervia et al., 2019). Of the 23 programmes available, all are within the private health care sector and are funded by the patient in full or partially supported by their private health insurance policy, making them unsustainable and unavailable for those in the public health care system. Of the 23 programmes, 2 major barriers were reported, which were lack of patient referral and lack of financial resources (Turk-Adawi et al., 2019). The yearly incidence of ischemic heart disease (IHD) in South Africa is 108 455 persons per year, however the national CRP capacity is 2070 persons (Turk-Adawi et al., 2019). Clearly, a massive discrepancy exists between the South Africa annual IHD incidence rate and the capacity of our available programmes.

To our knowledge, there are no known CRPs within the South African public health care sector. Government should develop plans and policies to ensure that similar resources and standards of care that are available to the private system is also available to those in the public system. The need exists for more evidence to demonstrate that CRPs can significantly reduce readmissions, mortality, comorbidities, and improve quality of life throughout the country. This research will potentially lead to further investigations that may elicit changes within legislation and recommendations for use of these programmes within the in public healthcare sector. These developments may possibly pave the way in finding solutions to provide the necessary resources and capacity required for programme implementation.

Conclusion and Problem Statement

Feasibility studies are used to determine whether or not a study can be done (Orsmond et al., 2015). They encompass any study which can help investigators prepare for full-scale research leading to intervention (Bowen et al., 2009) and allow researchers to determine if an intervention is appropriate for further testing, and if findings are relevant and sustainable (Bowen et al., 2009). Feasibility studies are typically implemented prior to a pilot or randomised control trial to assess the research and intervention process (Orsmond et al., 2015). According to Orsmond and colleagues (2015), a feasibility study has five main objectives: 1) evaluation of the recruitment capability and resulting sample characteristics; 2) evaluation and refinement of data collection procedures and outcome measures; 3)

evaluation of acceptability and sustainability of intervention and study procedures; 4) evaluation of resources and ability to manage and implement the study and intervention; and 5) preliminary evaluation of participant responses to intervention (Orsmond et al., 2015). This study is recognized as a partial feasibility study, for it will specifically investigate the first two objectives of the five main objectives described above.

The following factors from the literature described above warrant the investigation of the partial feasibility of a CRP for cardiac event patients in South Africa: 1) The lack of evidence of successfully CRPs in LMIC compared to high-income countries. This can be attributed to the lack of equipment, locations, human resources, and expertise in LMICs compared to HICs. 2) Not all CRPs can unequivocally prove that the inclusion of exercise in cardiac rehabilitation will reduce mortality, other co-morbidities, and quality of life in patients suffering from a cardiac condition or event. 3) There is great value in conducting a feasibility study prior to full-scale research. Many researchers have identified that intervention effectiveness research can be accelerated if a feasibility study is completed prior. Feasibility studies are critical in the successful implementation of randomised controlled trials (Tickle-Degnen, 2013).

Currently, it is difficult to foresee how CRP's can be successfully implemented within the South African public health care sector, particularly due to the shortage of appropriate staff. A possible solution to this problem is to engage with biokineticists, as they are ideally suited to fulfil the role of implementing and managing an evidence-based, supervised exercise training programme. Biokineticists are healthcare providers that focus on the final-phase rehabilitation and return to everyday functioning for a wide range of individuals and conditions. Biokineticists evaluate individuals of all ages and prescribe exercise for the treatment of orthopaedic conditions, sport injuries, chronic diseases, and neurological conditions, as well as exercise testing and rehabilitation for athletes, and promotion of health and wellness for the general population. Biokineticists are ideally suited to address the problem of cardiovascular disease management through evidence-based, individualised exercise prescription to minimise risk of injury or death, careful patient monitoring, patient education and wellness promotion.

The prospective research can be divided into three parts: 1) An investigation into the partial

feasibility of a novel CRP by determining the recruitment capacity and research methods reliability. 2) Evaluation of the remaining 3 objectives of a feasibility study by conducting a modified Delphi study and a pilot study of the CRP intervention. 3) Implementation of a randomised control trial to determine the efficacy of the of the full-scale CRP intervention on the health outcomes, hospital readmissions and overall quality of life in a cohort of cardiac rehabilitation patients.

This study consists of two subsequent chapters, focussing on the first part of the prospective research described above. The purpose of this study was to describe and determine the partial feasibility of a novel cardiac rehabilitation programme in a South African public hospital setting to provide optimal and sustainable health care to patients with cardiac conditions. This was achieved by evaluating the recruitment potential and sample population characteristics of the target population, as done in Chapter 2, and by determining the test-retest reliability of data collection procedures at rest and after exercise, as done in Chapter 3.

Chapter 2

The recruitment potential and sample population characteristics of the target population eligible to take part in an Outpatient Cardiac Exercise Rehabilitation Programme (CRP).

Introduction

Cardiac rehabilitation is an established model of care designed to mitigate the burden of CVD (Supervia et al., 2019). Substantial research has shown that the inclusion of exercise in cardiac rehabilitation has a favourable effect on functional capacity, hospital readmissions and mortality in coronary artery disease patients (Anderson et al., 2016; Kabboul et al., 2018; Valkeinen et al., 2010; Xia et al., 2018). Cardiac exercise rehabilitation programmes (CRPs) have shown strong evidence as a successful and vital component in the recovery and improvement of CVD. Despite recommendations and supporting evidence, gaps in CRP service delivery and implementation still exist worldwide.

In 2014, it was estimated that CRPs are not available in over 60% of countries worldwide and where CRPs do exist, there is insufficient capacity to meet a growing demand (Turk-Adawi et al., 2019). A massive discrepancy in the availability of CRPs exists between high-income countries (HICs) and low-income and middle-income countries (LMICs). In middle-income countries, such as South Africa, it is believed that the density of CRPs was one programme to 1-6 million inhabitants (Turk-Adawi et al., 2014). In addition to an insufficient capacity, there are several barriers which prevent attendance to available CRPs, including a lack of resources and poor affordability (Ragupathi et al., 2017). Majority of LMICs in Africa rely on out-of-pocket payment systems which limits CRP utilization (Ragupathi et al., 2017).

South Africans are facing a growing problem of CVD because of physical inactivity and an associated shift in lifestyle and culture. The high levels of morbidity and mortality associated with CVD have major implications for health-care services and place increasing strain on the already struggling South African health care system (Mayosi et al., 2009; Mbewu A, 2008). Cost-effective primary and secondary prevention and management measures are needed to

slow down the growing CVD epidemic and relieve strain on health-care systems (Mbewu A, 2008). Currently, South Africa has 23 CRPs (Supervia et al., 2019). Of the 23 programmes available, all are within the private health care sector and are funded by the patient in full or partially supported by their private health insurance policy, making them unsustainable and unavailable for those in the public health care system. To our knowledge, there are no known CRPs (of any scale and/or setting)_within the South African public health care sector which can be found in scientific literature. The need exists for more evidence to demonstrate that CRPs can significantly reduce readmissions, mortality, comorbidities, and improve quality of life throughout the country. This research will potentially lead to further investigations that may elicit changes within legislation and recommendations for use of these programmes within the in public healthcare sector. These developments may possibly pave the way in finding solutions to provide the necessary resources and capacity required for programme implementation. Currently, it is difficult to foresee how a CRP can be successfully implemented within the South African public health care sector. For this reason, an investigation into the feasibility of implementing a CRP within South African public health care is necessary.

Feasibility studies encompass any study which can help investigators prepare for full-scale research leading to intervention (Bowen et al., 2009) and allow researchers to determine if an intervention is appropriate for further testing, and if findings are relevant and sustainable (Bowen et al., 2009). One component of a feasibility study is evaluating the recruitment capacity and resulting population characteristics (Orsmond et al., 2015). The purpose of this is to address recruitment rates, eligibility criteria, and the relevance of the proposed intervention to the intended study population (Orsmond et al., 2015). Several studies have evaluated the recruitment potential for CRPs for different reasons. One such study evaluated the number of individuals with heart failure with reduced ejection fraction eligible to participate in a second phase CRP at the University of Vermont Medical Centre (Rengo et al., 2018). These individuals were either hospitalised inpatients at the medical centre, or stable outpatients referred from the cardiology or heart failure units (Rengo et al., 2018). In their case, significant barriers to recruitment and enrolment were experienced (Rengo et al., 2018). Out of 83 potential participants, only 17% (14 individuals) were considered eligible to enrol in a CRP (Rengo et al., 2018). This information was used to address barriers to recruitment and

enrolment to improve upon the procedures used for their CRP (Rengo et al., 2018). Another study evaluated the recruitment and attrition rates of individuals from Harefield Hospital, United Kingdom, with transcatheter aortic valve implant to demonstrate the feasibility of performing a multicentre cardiac rehabilitation trial (Rogers et al., 2018). In their case, the team from Harefield Hospital determined that they could expect to enrol 72 patients into a CRP over the period of two years, which was deemed acceptable (Rogers et al., 2018). In the case of the prospective intervention, assessing recruitment capacity and the characteristics of the resulting sample population is important in determining whether the implementation of a CRP in the South African public health sector is practical. It will also allow us to determine a suitable structure for the CRP and the number of resources and staff needed to make a CRP possible. Recruitment potential numbers are also required to determine the financial implications of the management and implementation of a CRP. To our knowledge, a study evaluating the feasibility of a novel CRP in the South African public health care sector has not yet been performed.

The aim of this study is to evaluate the recruitment potential and sample population characteristics of the target population in a public health care setting that will be eligible to take part in the CRP. Our hypothesis is that a large number of individuals will be eligible, due to the over-population of public hospitals and the high prevalence of CVD within South Africa.

Study Design

This portion of the study was a retrospective database feasibility study design. Once ethical approval was received, we were granted permission to utilise the Victoria Hospital VIMRI Database (HREC/REF: R043/2020) by one of the principle investigators, Dr Nasief van der Schyff. No recruitment was required for this study as all patients registered on the VIMRI database were automatically included and screened according to the inclusion/exclusion criteria as possible recruitment cases for the CRP intervention. The available sample population characteristics of patients that qualified to be part of the CRP intervention was retrieved from the VIMRI research database. No additional data collection was conducted, therefore patients involved in this data processing and analysis did not need to complete any

additional consent forms apart from the consent given to be logged onto the VIMRI database. The full research data base was searched for: 1) Demographic data including age, sex, height, weight, waist circumference and BMI; 2) Admission and discharge dates and time spent in hospital; 3) Admission diagnosis; 4) Co-morbidities; 5) Precipitants; 6) Complications; 7) Medications and 8) Any other health marker or measure that may indicate the current health status of the patient. The research design and methods were approved by the University of Cape Town's Human Research Ethics Committee (HREC REF: 612/2021, Appendix A).

Study Participants

The sample consisted of data from all patients registered and logged onto the VIMRI RedCap database system with CVD-related issue admitted to Victoria hospital from September 2020 to end of November 2020. Individuals who passed away from during their stay at Victoria Hospital were excluded from the study. Thereafter, the remaining population was screened according to the ACSM's contraindications for inpatient and outpatient rehabilitation (Table 1; (American College of Sports Medicine, 2016). Any patients with complications such as cardiogenic shock, gastrointestinal (GIT) bleeding, stroke or renal failure were also considered not eligible for the CRP intervention. Patients with one or more of the contraindications were excluded.

***Table 1**. Criteria used to determine eligibility for the prospective CRP (American College of Sports Medicine, 2016).*

Indications (Eligible to Partake)	Contraindications (Ineligible to Partake)
• **Medically stable post-myocardial infarction** • **Stable angina** • **Coronary artery bypass surgery** • **Percutaneous transluminal coronary angioplasty** • **Stable heart failure** • **Heart transplantation** • **Valvular heart disease** • **Peripheral artery disease** • **Any risk for coronary artery disease (Diabetes, dyslipidaemia, hypertension, obesity etc.)** • **Other patients who may benefit from structured exercise.**	• Unstable angina • Uncontrolled hypertension • Orthostatic hypotension • Significant aortic stenosis • Uncontrolled arrhythmias • Uncontrolled sinus tachycardia • Uncompensated heart failure • Complete heart blocks • Myocarditis or pericarditis • Recent embolism • Acute thrombophlebitis • Aortic dissection • Acute systemic illness or fever • Uncontrolled diabetes • Severe orthopaedic or metabolic conditions • Severe psychological disorders

CRP: Cardiac Exercise Rehabilitation Programme

Detailed Experimental Procedures

Data, including patient information was extracted from the VIMRI Registry database for any individual admitted to Victoria Hospital for a CVD-related issue from September to November 2020. The VIMRI database was searched by the same researcher to find all the information possible stipulated in the inclusion and exclusion criteria. Further, the following information from each patient was collected: 1) Demographic data including age, sex, height, weight, waist circumference and BMI; 2) Diagnosis; 3) Co-morbidities and 4) Medications.

Data Analysis

Data was analysed using IBM SPSS Statistical Software (Version 27, 2020, IBM Corporation, New York, USA). Data cleaning and data processing consisted of checking each spreadsheet for accuracy. From the data spreadsheet, the sample population was analysed in terms of gender, age, medical history, type of cardiac condition/event admitted, and any other

relevant and available information. Based on the relative data, the individuals were screened according to the ACSM's indications and contraindications for inpatient and outpatient cardiac rehabilitation. The latter criteria determined how many were eligible to participate in an exercise intervention (American College of Sports Medicine, 2016). Descriptive statistics were reported as mean ± standard deviation (SD), unless otherwise stated, and frequencies were calculated to depict the proportion of participants characterized by disease, co-morbidities, medications etc. Independent samples T-test and chi-square analysis were conducted to determine if any differences in the characteristics, distributions of co-morbidities and medications exist between the eligible and ineligible groups. The level of statistical significance level was set at $P < 0.05$. All data is expressed as mean $\pm$ SD.

Results

A total of 225 individuals were admitted to Victoria Hospital from 1 September to 1 December 2020. Of the 225, 16 individuals (7.1%) passed away due to their condition and were therefore excluded from further analysis. The remaining 209 patients were then screened according to the inclusion and exclusion criteria specified above. Of the 209 individuals, 109 (52.2%) were considered ineligible for the CRP, whereas 100 individuals (47.8%) were considered eligible to participate in the CRP safely.

The mean ± SD age of the participants was 59 ± 14.5 years (Range: 22 – 90), and majority of the individuals admitted were men (113 individuals, 54.1%). Ten individuals were under the age of 35 years (4.8%), 92 individuals were between the ages of 35 and 60 years (44%), 106 individuals were above the age of 60 years (50.7%) and one individual's age category was missing. Within the total population of 209 patients screened, 193 individuals were admitted for a cardiovascular event (92.3%), 15 for chest pain syndrome (7.2%) and one was admitted for other reasons (0.5%). The most common diagnosis upon discharge within the total population was Acute Decompensated Heart Failure (40.7%), followed by Non-ST-Elevation Myocardial Infarction (NSTEMI; 22%) and ST-Elevation Myocardial Infarction (STEMI; 18.7%).

For the eligible population, 86% of participants were admitted for a cardiovascular event, 13%

for chest pain syndrome and 1% for other reasons. The most common diagnosis for the eligible population was NSTEMI, (35%), followed by ST-Elevation Myocardial Infarction (STEMI; 30%) and Other (23%). In some cases, participants had more than one diagnosis. Table 2 shows the distribution of diagnoses in both the total and eligible populations.

Table 2. *The distribution of diagnoses in the total and eligible populations.*

	Total Population (N = 209)		Eligible Population (N = 100)	
Diagnosis	**n**	**Proportion (%)**	**n**	**Proportion (%)**
STEMI	39	18.7	30	30
ADHF	85	40.7	0	0
AF	12	5.7	3	3
VT	2	1	1	1
NSTEMI	46	22	35	35
Heart Block	1	0.5	0	0
Atrial Flutter	1	0.5	0	0
Pericardial Effusion	4	1.9	3	3
Unstable Angina	4	1.9	0	0
Cor Pulmonale	10	4.8	0	0
Other SVT	0	0	0	0
Other Diagnosis	31	14.8	23	23

STEMI: ST-Elevation Myocardial Infarction, ADHF: Acute Decompensated Heart Failure, AF: Atrial Fibrillation, VT: Ventricular Tachycardia, NSTEMI: Non-ST-Elevation Myocardial Infarction, SVT: Supraventricular Tachycardia

Table 3 shows the physical characteristics of the eligible and ineligible populations and the results of the chi-square (or Fisher Exact's test) test of two proportions. The reasons for ineligibility varied, but the most common reason was uncompensated heart failure in the form of ADHF (40.7%). No statistically significant differences were identified between the eligible and ineligible populations for the physical characteristics. The ineligible group was similar in age and stature compared to the eligible group. Although, not statistically significantly higher, the ineligible group was 4% heavier in weight, had a 6% higher BMI and an 8% greater waist circumference compared to the eligible group. For the eligible population, the mean age was 59 years (Range: 33-90), and the majority were men (61%). The mean weight of this group was 75.7kg, mean BMI was 27.78 kg/m^2 and mean waist circumference was 97.49cm.

Table 3. *Physical characteristics and Independent Samples T-Test's significant differences between eligible and ineligible populations.*

	Eligible Population (N = 100)		Ineligible Population (N = 109)		
Variable	**Mean**	**SD**	**Mean**	**SD**	**Significance (p-value)**
Age (y)	58.75	13.21	59.83	15.59	0.59
Height (cm)	166	10	1.64	0.1	0.41
Weight (kg)	75.71	18.65	78.69	27.84	0.47
BMI (kg/m^2)	27.78	6.12	29.39	8.39	0.22
Waist (cm)	97.49	16.86	105.29	24.69	0.06

BMI: Body Mass Index

Sixty-five individuals in the eligible population had less than three comorbidities (65%), whereas 35 individuals (35%) had greater than three. In the ineligible population, 62 individuals had less than three comorbidities (56.9%) whereas 47 individuals had greater than three comorbidities (43.1%).The most common comorbidities in the eligible population were hypertension (71% of participants), followed by smoking (63%) and dyslipidaemia (44%). The most common comorbidity in the ineligible population was hypertension, with 74.3% participants having hypertension, followed by smoking (45.9%) and diabetes (41.3%). Significant differences were identified between the eligible and ineligible populations with almost double the incidence of dyslipidaemia ($p = 0.002$) in the eligible group and a higher incidence of smoking history ($p = 0.013$) compared to the ineligible group. The ineligible group had a higher proportion of history of chronic kidney disease ($p = 0.011$) and history of congestive cardiac failure ($p = 0.011$) compared to eligible participants. Table 3 shows the distribution of comorbidities for the eligible and ineligible populations.

Table 4. *Distributions of risk factors or comorbidities and Chi-Square (Fisher's Exact's) significance within the eligible and ineligible populations.*

	Eligible Population (N = 100)		Ineligible Population (N = 109)		
Risk Factor or Comorbidity	**n**	**Proportion (%)**	**n**	**Proportion (%)**	**Significance (p-value)**
Less than 4 Comorbidities	65	65	62	56.9	0.230
4 Or Greater Comorbidities	35	35	47	43.1	0.230
Hypertension	71	71	81	74.3	0.591
Diabetes	39	39	45	41.3	0.737
COPD	10	10	23	21.1	0.28
Asthma	2	2	4	3.7	0.470
Dyslipidaemia	44	44	26	23.8	0.002
Smoking History	63	63	50	45.9	0.013
Drugs	10	10	9	8.3	0.661
Alcohol	10	10	11	10.1	0.982
VHD History	2	2	4	3.7	0.685
CKD History	6	6	19	17.4	0.011
IHD History	34	34	30	27.5	0.310
CCF History	6	6	25	22.9	0.001
Cancer	1	1	0	0	0.478
Other	7	7	16	14.7	0.076

COPD: Chronic Obstructive Pulmonary Disorder, VHD: Ventricular Heart Disease, CKD: Chronic Kidney Disease, IHD: Ischemic Heart Disease, CCF: Congestive Cardiac Failure

In the ineligible population, 32.1% of participants were on no medications, 36.7% were on between one and four medications and 31.1% were on greater than four medications. The most common medication was Furosemide, a strong diuretic used to treat fluid build-up associated with heart failure (37.6%), followed by Statins, a lipid-lowering medication (33.9%), and Beta-Blockers, which are typically used to manage arrhythmias and hypertension (29.4%). The average number of medications for the both the eligible and ineligible populations was 2.75, 34% of eligible participants were on no medications, 35% were on between one and four medications and 31% were on greater than four medications. The most common medication was Statins, with 37% of eligible participants making use of statins, followed by Aspirin, a medication used to prevent blood clot formation (35%) and ACE Inhibitors, which are used for the treatment of both hypertension and heart failure (34%). Significant differences were found between the eligible and ineligible populations for the use of spironolactone ($p = 0.008$) and furosemide ($p = 0.002$), which are both used to manage fluid accumulation due to heart failure. There was also quite a big difference between

populations for the use of ACE Inhibitors, with a greater number of participants using ACE inhibitors in the eligible group, but this was not found to be significant (p = 0.076). There was no significant difference for the number of medications used. Table 4 shows the distribution of the medications used in the eligible and ineligible populations and the associated p-values.

Table 5. *The distribution of medication use in the eligible and ineligible populations.*

	Eligible Population (N = 100)		Ineligible Population (N = 109)		
Medication	**n**	**Proportion (%)**	**n**	**Proportion (%)**	**Significance (p-value)**
Less than 4 Medications	57	57	67	61.5	0.511
4 and Greater Medications	43	43	42	38.5	0.511
ACE Inhibitor	34	34	25	22.9	0.076
Calcium Channel Blocker	26	26	27	24.8	0.838
Spironolactone	1	1	10	9.2	0.008
Clopidogrel	6	6	8	7.3	0.699
Sulphonylurea	7	7	6	5.5	0.655
ARB	5	5	6	5.5	0.870
Furosemide	18	18	41	37.6	0.002
Asprin	35	35	30	27.5	0.243
Statin	37	37	37	33.9	0.645
Insulin	11	11	13	11.9	0.834
Beta Blocker	29	29	32	29.4	0.955
Hydrochlorothiazide	18	18	13	11.9	0.217
Warfarin	2	2	5	4.6	0.448
Metformin	15	15	22	20.2	0.327
PPI	9	9	6	5.5	0.328
Other	22	22	19	17.4	0.406

ACE: Angiotensin Converting Enzyme, ARB: Angiotensin II Receptor Blocker

Discussion

The aim of this study was to determine the partial feasibility of a novel CRP by evaluating the recruitment potential and sample population characteristics of the target population in a public health care setting.

A screening database was created by the hospital personnel at the local public hospital, Victoria Hospital in Wynberg, of every patient admitted for a cardiac event or severe chest pain over the period of three months (12 weeks). A total of 225 patients were admitted

between 1 September 2020 and 1 December 2020. Sixteen patients passed away due to their condition and were therefore excluded from further data analysis. The remaining 209 individuals were screened according to the inclusion and exclusion criteria, of which 109 individuals (52.2%) were found to be ineligible, and 100 individuals (47.8%) were considered eligible. Our hypothesis was that a high volume of people will be considered eligible, as admissions to a public hospital are typically high, South African public hospitals are generally overburdened and the burden of CVD in South Africa is substantial. We were unsure what to expect in terms of the distribution of ineligible patients according to our criteria from the ACSM's contraindications for inpatient and outpatient rehabilitation (American College of Sports Medicine, 2016). Our hypothesis was correct, as 100 individuals (47.8%) within the span of three months (1 September 2020 – 1 December 2020) were considered eligible to participate in the prospective CRP safely. Although there are high volumes of eligible patients coming through Victoria Hospital, there were also a high volume of ineligible patients. One hundred and nine individuals (52.2%) were considered ineligible for the CRP, and the split of eligible and ineligible patients was almost equal. It is clear that individuals admitted to Victoria Hospital for a cardiac-related event suffer from severe illness as 52.2% had symptoms too severe to partake in a CRP. Anecdotally, we can assume that the reason for this is that due to the overburdening of public hospitals, only those with severe CVD are admitted. This can be presumed based on the severity of illness seen in the ineligible population, with many ineligible participants having severe diagnoses such as heart failure, and additional comorbidities such as chronic kidney disease and congestive cardiac failure. It may be that patients with not life-threatening symptoms are sent home, due to a lack of bed space, for treatment or observation. Additionally, due the COVID-19 pandemic and National Lockdown regulations, only individuals with severe or critical disease were admitted to South African public hospitals (Reddy et al., 2021).

Within the original protocol of the prospective CRP (Appendix B) we would have had the capacity to manage two groups of six CRP participants every month, where each group would have two supervised exercise sessions per week, and that the total number of participants would not exceed 12 patients per month. The staff required was estimated at three students or intern biokineticists for patient monitoring, one instructing intern biokineticist and one supervising biokineticist per intake group. Based on the recruitment potential from Victoria

Hospital above, it has been revealed that we can expect approximately 33 patients to be eligible every month (100 participants/3 months). This is nearly triple the expected intake of 12 patients per month, and currently exceeds the prospective resource and staff capacity of the CRP. However, it is expected that not everyone will attend or complete the CRP. Attendance rates for cardiac rehabilitation programmes have been reported to vary across the globe, but most are considered sub-optimal (Ragupathi et al., 2017). In Johannesburg, a completion rate of 50% was reported at a single CRP centre between 1986 and 1990 (Ragupathi et al., 2017). It was not clear if this centre was within the private or public health care sector. In a study by Martin and colleagues (2012), it was found that the completion rate of a cardiac rehabilitation programme was 49.3% (Martin et al., 2012). Predictors of poor attendance included female sex, older age and inability to drive, whereas higher income was a prediction for cardiac rehabilitation attendance (Martin et al., 2012). With this in mind, we can estimate that of the 33 individuals eligible each month, approximately 50% will attend and complete the programme. Should this be the case, it may be that only 17 individuals will enrol in the programme, which currently will be sustainable and achievable for the prospective resource and staff capacity planned for the CRP. However, for the CRP to be adequately prepared for eligible patient intake, we suggest solving the resource and staff capacity shortage, to allow an 80% attendance rate, which is approximately 27 patients per intake.

Eligibility was defined according to criteria from the ACSM's contraindications for inpatient and outpatient rehabilitation (American College of Sports Medicine, 2016). This criteria was chosen due to its relevance to the population, to ensure participant safety, as well as allow for the programme to be of significant enough intensity to elicit CVD improvements. The use of this criteria is one of the reasons that biokineticists are suitable in working with the prospective patient. When comparing the eligible and ineligible populations, the eligible population had significantly more cases of dyslipidemia ($p = 0.002$) and smoking ($p = 0.013$) than the ineligible population. However, the ineligible population had significantly more severe comorbidities, such as chronic kidney disease ($p = 0.011$) and history of congestive cardiac failure ($p = 0.011$). This was expected, as the ineligible patients are considered to have a higher degree of severe illness than the eligible population. Additionally, the use of spironolactone and furosemide was greater in the ineligible population ($p = 0.008$ and 0.002).

This was to be expected, as most of the ineligible patients were those with heart failure. Both furosemide and spironolactone are strong diuretics used to prevent fluid congestion or build-up as a result of heart failure, as well as treat hypertension. Although the use of these medications may improve exercise tolerance in individuals with heart failure, there are risks of dehydration and electrolyte imbalance (Medline Plus, 2017; Medline Plus, 2018) which is further exacerbated by exercise. For this reason, patients with heart failure utilising this medication should be carefully supervised. The ineligible group was 4% heavier in weight, had a 6% higher average BMI and an 8% greater waist circumference when compared to the eligible group. Although this was not statistically significantly higher, it is clinically meaningful and shows that the ineligible group were generally at higher risk. Exercise training has shown to be beneficial for patients with heart failure in reducing cardiovascular mortality, reducing hospitalisation rates and improving exercise capacity and quality of life (Ades et al., 2013; Davies et al., 2010; Rengo et al., 2018). However, these patients often have unique and prominent comorbidity profiles compared to patients with other CVDs, and have more severe limitations (Forman et al., 2015; Rengo et al., 2018). Only patients with stable heart failure (determined by a primary medical physician) should take part in a supervised exercise programme (Selig et al., 2010), and the highest level of caution should be taken due to the higher risk for an adverse event in these patients. Therefore, we are in agreement with Selig and colleagues (2010) and believe that these patients are not suitable for biokinetics supervision only, and that a specialist doctor should be present during exercise for patients with heart failure. It is recommended that there be access to the necessary equipment and medical personnel to manage any acute event which may occur, such as cardiac arrect or ischemia (Selig et al., 2010). For this reason, we recommend and emphasize that although ineligible participants will also benefit from a CRP, this will require a greater level of supervision, such as presence of a cardiologist or specialist physician, during exercise sessions. Programmes catering to this higher risk population do exist both abroad and in South Africa, but are exclusively in the private health care sector and at a high financial cost (Supervia et al., 2019).

We could not find any evidence or published literature of a CRP or formal cardiac rehabilitation intervention that has been implemented on cardiac patients within the public health care sector of South Africa. This is the first partial feasibility study of its kind to analyse

the possibility of a cardiac rehabilitation intervention for cardiac patients within public health care. Within the South African private health care system, there are 23 CRP's reported to be available throughout the country (Supervia et al., 2019). These programmes are funded in full by the patient or are partially supported by the patient's private health insurance policy. As a result, these programmes are unsustainable and unavailable for those in the public health care system who cannot afford it. Due to this inaccessibility, as well as severe staff shortages and financial constraints, cardiac exercise rehabilitation is not currently a standard of care in South Africa, and currently most formal programmes exist within academic universities and private hospitals (Saner et al., 2003). Therefore, it is of utmost importance that feasible interventions are tested, adapted and implemented, to overcome these barriers and reduce the high burden of CDV in South Africa

South Africa is without a public health care professional who is adequately equipped to develop and implement a physical activity programmes, such as CRPs (Evans, 2017). Currently, it is difficult to forsee how a CRP can be successfully implemented within the South African public health care sector, particularly due to the shortage of appropriate staff. Biokineticists are ideally suited to address the problem of cardiovascular disease management through evidence-based, individualised, and supervised exercise prescription; and are currently implementing CRPs in private health care. A managed and supervised CRP by a biokineticist will minimise patient risk of injury or death, careful patient monitoring, patient education and wellness promotion. Based on these skills and the current burden of CVD within South Africa, it is evident that there is an overwhelming need for the skills and expertise of biokineticists within the public health care sector to cater for the vast majority of South Africans (Evans, 2017).

This study has several limitations. The VIMRI database, Victoria Hospital's database consisting of medical information for all individuals admitted to the hospital for a cardiac event, is missing several key health markers such as blood pressure, oxygen saturation, blood glucose levels, cholesterol levels and mental illness. As a result, we were limited in the information we could utilise to describe the total population, the eligible and ineligible groups. The data found on the VIMRI database was collected over the period of the COVID-19 pandemic. It is possible that the number of patients admitted to Victoria Hospital for events or illness other

than COVID-19 may have been reduced, and consequently this may have influenced the true recruitment potential. There is also a lack of evidence in the literature for the eligibility criteria used for cardiac rehabilitation under the supervision of a biokineticist. It is possible that recruitment potential could have been better evaluated if additional information, such as medication dosage, functional capacity, resting ejection fraction, and level of ST depression, were known. This information, alongside symptoms and the above-mentioned health markers, could then be utilised to stratify the patient as low to high risk, which would better inform the healthcare professionals on the level of supervision required for exercise and if the patient is suitable for a CRP under the supervision of a biokineticist only.

Conclusion

One hundred individuals (47.8%) were found to be eligible for the CRP, whereas 109 individuals (52.2%) were considered ineligible. Based on the recruitment potential above, it has been revealed that we can expect 33 patients to be eligible every month (100 participants/3 months), which is nearly triple the expected intake of 12 patients per month. This exceeds the resource and staff capacity of the prospective CRP. Should the attendance rate of the CRP be 80%, additional resources, staff and time is required to double for the successful implementation of the CRP. We recommend that the investigators on the prospective CRP adapt and increase the number of resources and trained staff before implementation. Future studies should look at the feasibility of a CRP in different provinces across South Africa, as well as analyse and test the other components of a feasibility study.

Chapter 3

An evaluation of the test-retest reliability of the monitoring tools utilized during a Supervised Exercise Rehabilitation Programme (CRP).

Introduction

Cardiac monitoring during cardiac exercise rehabilitation serves to optimise exercise prescription by ensuring the desired intensity is reached, and enhance safety by monitoring for any undesired signs or symptoms (Contractor, 2011). It is recommended that exercise intensity be closely monitored through perceived exertion using the Borg's Scale or through heart rate monitoring (Bunker, 2002; Price et al., 2016). The monitoring of blood pressure, and signs and symptoms including excessive dyspnea, fatigue, chest pain and light-headedness is also encouraged for medical safety (Price et al., 2016). Therefore, understanding the accuracy and reproducibility of the monitoring tools is essential. Precise patient monitoring allows the medical professional to make any necessary changes to exercise intensity, should there be unwanted changes in measures such as RPE, blood pressure or heart rate. Monitoring also provides the patient with a sense of security and safety and allows the professional to accurately track progress and changes in health metrics and evaluate the effectiveness and results of an intervention (Lassere, 2006). For this reason, it is essential that the tools used to monitor these patients regularly are evaluated for accuracy and reliability.

Although there are many different outcomes which can be measured, blood pressure, oxygen saturation and rate of perceived exertion are some of the most important measures within cardiac rehabilitation. Manual blood pressure instruments require the judgement of the healthcare practitioner to determine the systolic and diastolic pressures, whereas automated machines, also called oscillometer devices, produce a value that is measured electronically (Skirton et al.,2011). There are definite concerns regarding the accuracy of these automated machines. In a review by Skirton and colleagues (2011), the authors concluded that automated devices are generally less accurate than manual devices (Skirton et al.,2011).

These differences are of particular concern when BP measurement is required for assessment and management of hypertension (Skirton et al.,2011). Pulse oximeters are an easy-to-use and non-invasive tool that provides information about the oxygenation status of a patient's blood (DeMeulenaere, 2007). They are believed to improve patient safety, by alerting the healthcare practitioner to potential hypoxia (DeMeulenaere, 2007). Although pulse oximeters are considered reliable, there are many confounding factors which can negatively impact on the ability to get an accurate and reliable reading, such as low cardiac output, oedema, vasoconstriction, vasoactive drugs, hypothermia, motion artifact due to excessive movement,, skin pigmentation and nail polish (DeMeulenaere, 2007; Jubran, 2004).The Borg RPE Scale is widely used in clinical settings to subjectively quantify an individual's perception of the physical demands of an activity (Lamb, Eston, & Corns, 1999; Ritchie, 2012). It is often the exercise prescription method of choice for cardiac patients and individuals on medications affecting heart rate (Lamb et al., 1999; Ritchie, 2012). Both the Borg (6-20 AU) and Modified Borg (0-10 AU) scales have shown reliability and validity in healthy, clinical and athletic adult populations (Ritchie, 2012). However, these ratings are influenced by psychological factors, mood states, environmental conditions, exercise modes and age (Ritchie, 2012).

There is great value in conducting a feasibility study prior to full-scale research (Bowen et al.,2009), one component being the evaluation of validity and reproducibility of the data collection procedures. The purpose of this is to determine if the data is relatively complete and useable, and if the measures are appropriate for the specific population and intervention (Orsmond & Cohn, 2015). It is of great importance to ensure that the tools chosen for measurement are valid, and reliably replicate the result more than once in the same situation and population as well as over different time points (Hobbs, 2016). Tools which provide this level of consistency are regarded as having high test-retest reliability (Hobbs, 2016). Without a high level of test-retest reliability, administrators cannot assume that the data obtained from measurement is accurate, and it could well be that environmental, psychological, or methodological factors have affected the data (Hobbs, 2016). In the case of low reliability, it is difficult to ascertain if changes within the data are due to the intervention itself, or due to other confounding factors (Hobbs, 2016). Consequently, low reliability can negatively affect the conclusions drawn from research. In the case of the prospective CRP, high reliability is essential so that changes in health markers such as blood pressure, heart rate, oxygen

saturation and rate of perceived exertion can be carefully and accurately monitored to ensure participant safety and monitor any physiological changes that may occur in response to the programme itself. As there are many different brands of monitoring tools, knowing the reproducibility of one brand does not necessarily prove the reproducibility of another or of the tool in general. Therefore, it is essential that the tools to be utilised are tested for test-retest reproducibility prior to an intervention. The aims of the study to determine the test-retest reliability of data collection procedures at rest, immediately after, and five minutes post-exercise that will be used within the Cardiac Rehabilitation Programme.

Study Design

This study focussed on the test-retest reliability of protocol testing measures and exercise intensity monitoring measures that will be utilized during the prospective CRP intervention. Thirty-three apparently healthy members of the public, staff and students at the Sports Science Institute of South Africa, Newlands, Cape Town, who volunteered to take part in the testing were asked to visit the testing site on two separate occasions two to three days apart. During visit one, participants signed an informed consent form (Appendix C) which explained the test procedures which they underwent, and the possible risks involved in their participation. This was followed by baseline measures of resting rate of perceived exertion (RPE), heart rate (HR), blood pressure (BP) and oxygen saturation (SPO_2). Following the baseline measures, anthropometric measures including height, weight, waist circumference and hand grip strength were recorded. The participant was then asked to walk/run at maximum voluntary effort (MVE) for six minutes around an indoor track. The maximum distance (in meters) that the participant can cover was be recorded as the outcome variable for functional capacity and aerobic fitness. Immediately after exercise cessation and again five minutes after exercise cessation, RPE, HR, BP and SPO_2 measurements were be repeated. All participants repeated the test protocol 48-72 hours after visit one. All testing took place on an indoor track on the first floor of the Sport Science Institute of South Africa (SSISA), Boundary Road, Newlands, Cape Town.

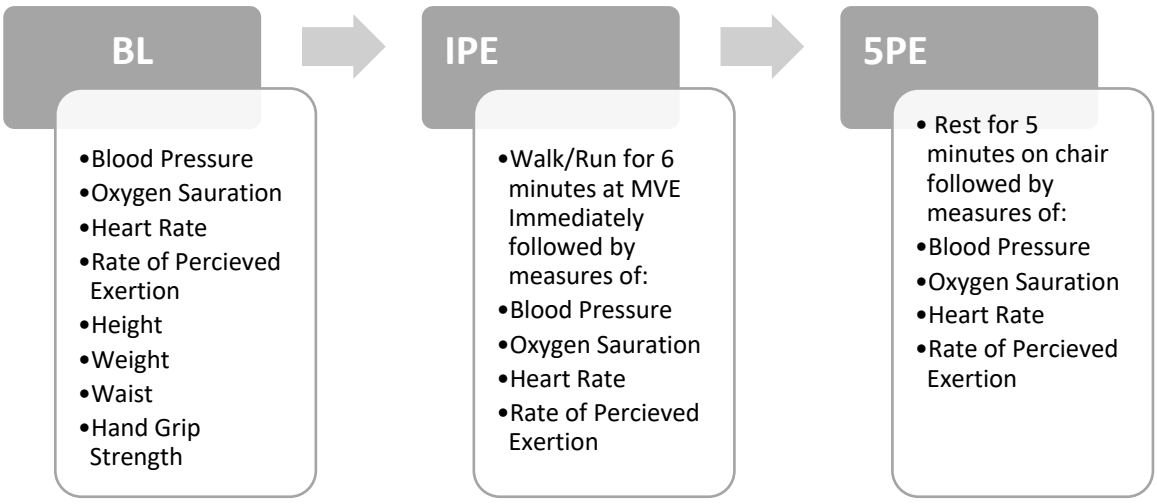

Figure 1. *Schematic illustration of the test-retest reliability protocol. BL: Baseline testing, IPE: Immediately post exercise, 5PE: 5 minutes post exercise.*

Study Participants

Thirty-three apparently healthy volunteers, male or female between the ages 20 – 65 years of age who either came to gym, work or study at SSISA were recruited to participate in the study. Poster advertisements (Appendix D) were placed on the SSISA website and on several advertisement boards in the building and were sent via email to the individuals working or studying in the building.

Participants were included if they were apparently healthy, with no known disease or illness at the time of testing, between the ages 20 – 65 years, and, at the time of testing, passed the COVID-19 regulation screening to enter the building.

Participants were excluded if they were injured or ill, had any pre-existing conditions that limited them from participating in physical activity, suffered from a chronic condition/illness that affected their normal physiological changes in HR, BP and SPo_2, were on any medications that affect HR, BP, SPO_2 or physical activity performance, suffered from any severe mental or cognitive disorder, and/or were pregnant or lactating at the time of testing.

Detailed Experimental Procedures

Height:

Height was assessed using a stadiometer (ShorrBoard™, Weight and Measure LLC, Maryland USA) which was mounted to a wall and placed on a flat and level surface. Participants were required to remove their shoes and socks prior, and stand with their feet together, heels, buttocks and upper back touching the stadiometer and head in the Frankfort plane as described by Norton (Norton, 2019). Height was taken from the highest point of the skull upon a deep inspiratory manoeuvre.

Weight:

Weight was assessed using an electronic scale (Body Analyzer Digital Scale VP42349-0000, Guangdong Transtek Medical Electronics C, China) which was calibrated prior to use. The participant was required to stand in the centre of the scale with weight evenly distributed across both feet, as described by Norton (Norton, 2019).

Waist:

Waist circumference was measured using an anthropometric tape measure (CESCORF, Brazil) at the narrowest point between the lowest costal rib and iliac crest as described by Norton (Norton, 2019). The participant stood in a relaxed, standing position with the arms crossed at the chest. The measurement was taken after expiration.

Hand-Grip Strength:

Muscular strength was assessed by measuring grip strength on the dominant hand using a hydraulic hand dynamometer (Exacta ™, North Coast Medical and Rehabilitation Products©, Morgan Hill, CA, USA). The measurement was repeated three times and the best of all the attempts was recorded as the final measurement. Grip strength has shown to be strongly correlated with total muscle strength in young adults and is considered useful in a clinical setting as a rapid indicator of total muscle strength (Wind et al., 2010).

Rate of Perceived Exertion (RPE):

RPE was verbally communicated to the participant using the Modified Borg Scale (Appendix

E) The researcher held up a clipboard with the Modified Borg scale and asked the participant just before the termination of the exercise bout: “How tired do you feel right now?”. The participant was able to see the verbal description of the score that he/she feels most appropriate for the perceived exertion at the time of the question. Although previous reliability studies have shown good reliability of the Borg RPE scale, the reliability of the RPE scale decreases as exercise intensity increases (Lamb et al., 1999; Skinner et al., 1973).

Heart Rate (HR):

HR (beats per minute) was recorded from two devices, during blood pressure measurements using the automated blood pressure monitor (OMRON©, Model M6, Hoofdorp, Netherlands), which automatically records heart rate at the same time as blood pressure. The pulse oximeter (ChoiceMMed©, Beijing, China) also calculated the heart rate and was recorded with the oxygen saturation measurement.

Blood Pressure (BP):

BP was taken from the left upper arm using an automated BP monitor (OMRON©, Model M6, Hoofdorp, Netherlands) with the participant in a relaxed, seated position with the feet flat on the floor and the arm relaxed on a table. BP was taken after sitting for at least five minutes prior to the commencement of any exercise or fitness test. After exercise, no resting time was allowed before the BP measurement is taken. Automated BP monitors have previously shown good long-term reproducibility (Sergiou et al., 2009).

Oxygen Saturation (SPO_2) using Pulse Oximetry:

SPO_2 was measured using a fingertip pulse oximeter (ChoiceMMed©, Beijing, China). Oximeter readings were taken on a warm finger, with the patient in an upright, seated position. The instrument was left to stabilise for a minute before confirming the reading. Fingertip pulse oximeters are relatively simple and quick to use and generally accurate and reliable (Jensen et al., 1998).

Six Minute Walk/Run Test (6MWT):

Cardiorespiratory fitness (CRF) was assessed using the 6-Minute Walk/Run Test (6MWT). The 6MWT has been used previously to evaluate populations considered to have reduced CRF. Participants were required to walk or run on a track for six minutes on their own, after which the distance, in meters, walked/run was measured (6 minute walk/run distance [6MWD]). A meta-analysis has found strong-evidence that the 6MWT is responsive to clinical change following outpatient cardiac rehabilitation (Bellet et al., 2012). The 6MWT has been found to be reliable and repeatable (Mak et al., 2021). In this investigation, we did not assess the test-retest reliability of the 6MWT itself, but rather used it as a tool to fatigue the participants and assess the reliability of our other measurement tools after exercise. In the prospective CRP intervention, the 6MWT will be utilised to evaluate cardiorespiratory fitness of the participants.

Data Analyses

The *a priori* sample size calculation (Arifin, 2022) of N = 18 was required to produce adequate statistical power (0.80) for a minimum acceptable test-retest reliability (ICC) of 0.65 with expected test-retest reliability (ICC) of 0.90 (Walter et al., 1998). We managed to recruit a larger sample size (N = 33) than N = 18. The test-retest reliability of each of the outcome measures of resting and post- exercise BP, HR, SPO_2, and RPE (Visit 1 vs Visit 2) and height, weight, waist circumference and grip strength (Visit 1 vs Visit 2) were visually inspected using Bland-Altman plots reporting the mean differences and limits of agreement (Bland et al., 1986). Test-retest reliability was further determined using intraclass correlation coefficient (ICC) estimates and their 95% confident intervals based on a mean rating (k=2), absolute-agreement, 2-way mixed-effects model. The ICC value were classified as follows: Poor (<0.50), Moderate (between 0.5 and 0.75), Good (between 0.75-0.90) and Excellent (>0.90) (Koo et al., 2016). Cohen's *d* effect sizes were calculated to evaluate the magnitude of the change between the visits. Effect sizes between 0.2 – 0.5 are considered as small, between 0.5 – 0.8 as medium and >0.8 as large (Cohen, 2013). In attempt to identify a practically meaningless effect size, the researchers are preselecting a lower than small effect size (d<0.2) as acceptable for near identical repeated measures representing excellent test-retest reliability. Effect sizes (with 95% CI) of the mean differences (Visit 1 and Visit 2) of the physical health and fitness outcome variables were illustrated using forest plots (Hyde et al., 2008). Data was

analysed using IBM SPSS Statistical Software (IBM Corporation, New York, USA) and the level of statistical significance level will be set at $P < 0.05$.

Results

Table 1 shows the intraclass correlation coefficients for each outcome variable. Of the 22 total outcome measures, five outcomes were classed as "poor", nine were classed as "moderate", three as "good" and five as "excellent' based on the criteria given above.

Table 6. *Table to show intraclass correlation coefficients for the different variables.*

		Confidence Interval			
Variable	**Intraclass Correlation**	**Lower CI**	**Upper CI**	**F**	**p-value**
BL SBP	0.53	0.22	0.74	3.73	< 0.001
BL DBP	0.56	0.25	0.76	4.05	< 0.001
BL HR (BP Cuff)	0.71	0.49	0.85	5.81	< 0.001
BL SPO_2	0.10	-0.21	0.41	1.25	0.266
BL HR (Oximeter)	0.72	0.50	0.85	6.01	< 0.001
BL RPE	0.81	0.65	0.90	9.7	< 0.001
Weight	1.00	1.00	1.00	1001.2	< 0.001
Waist	0.99	0.98	1.00	240.43	< 0.001
Grip Strength	0.95	0.91	0.98	41.42	< 0.001
IPE SBP	0.53	0.23	0.74	3.21	0.001
IPE DBP	0.38	0.04	0.65	2.21	0.015
IPE HR (BP Cuff)	0.78	0.60	0.89	8.03	< 0.001
IPE SPO_2	0.48	0.18	0.70	2.92	0.002
IPE HR (Oximeter)	0.79	0.61	0.89	8.78	< 0.001
IPE RPE	0.71	0.42	0.86	7.4	< 0.001
5PE SBP	0.47	0.17	0.70	2.92	0.002
5PE DBP	0.71	0.48	0.85	5.65	< 0.001
5PE HR (BP Cuff)	0.72	0.50	0.85	6.12	< 0.001
5PE SPO_2	0.41	0.08	0.66	2.39	0.009
5PE HR (Oximeter)	0.92	0.85	0.96	25.43	< 0.001
5PE RPE	0.69	0.45	0.84	6.15	< 0.001

BL: Baseline, IPE: Immediately Post-Exercise, 5PE: 5-Minutes Post-Exercise, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, SPO_2: Oxygen Saturation, HR: Heart Rate, RPE: Rate of Perceived Exertion

Figures 2 and 3 show the effect sizes with the 95% confidence intervals for each of the groups of outcome measures, BL, IPE, 5PE and Anthropometry respectively. Eighteen outcome measures had lower than small effect size ($d<0.2$), indicating near identical repeated

measures representing excellent test-retest reliability. The remaining eight outcome measures had effect sizes between 0.2-0.5, which is considered small.

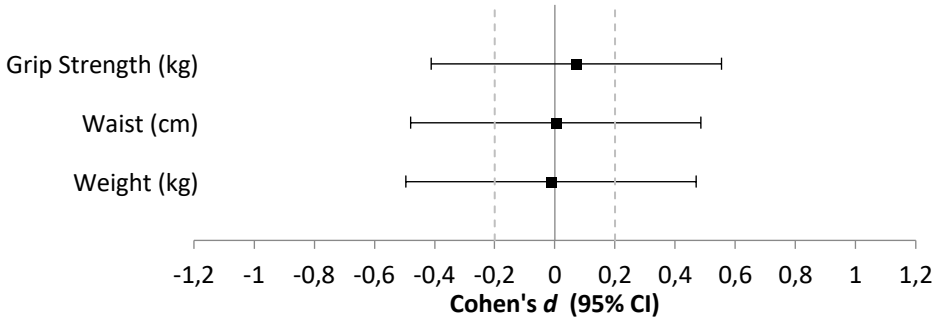

Figure 2. *Forest Plot showing effect sizes (squares) and 95% confidence intervals (error bars) for the anthropometric measures between visits 1 and 2. The dotted lines represent a lower than small effect size.*

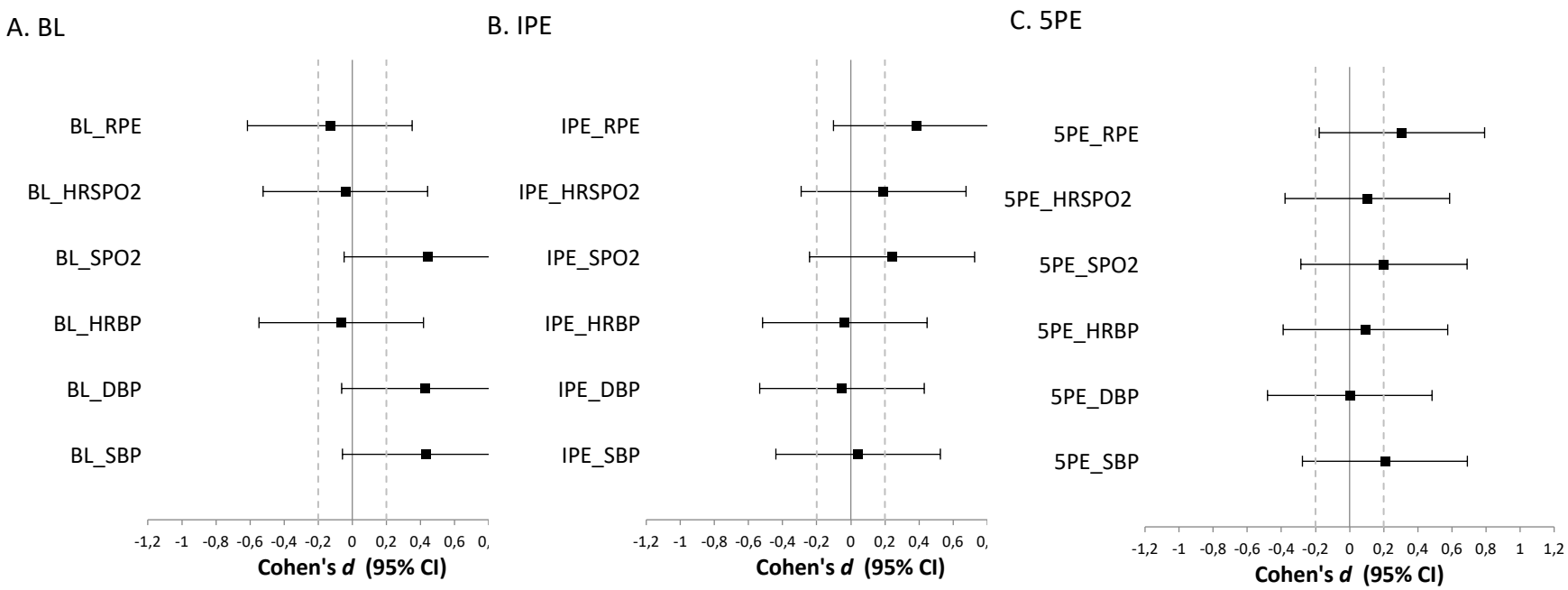

Figure 3*. Forest Plot showing effect size (squares) and 95% confidence intervals (error bars) for the BL (A), IPE (B) and 5PE (C) outcome measures between visits 1 and 2. The dotted lines represent a lower than small effect size. BL: Baseline, IPE: Immediately Post-Exercise, 5PE: 5-Minutes Post-Exercise, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, SPO_2: Oxygen Saturation, HR: Heart Rate, RPE: Rate of Perceived Exertion*

Bland-Altman Plots for each of the outcome measures at the different time points (BL, IPE, 5PE) as well as Bland-Altman plots for the anthropometric measures are illustrated in Figures 4 to 6. The Bland-Altman plots illustrate the differences between the visit 1 and 2 (v1 – v2, y-axis) against the mean of the two measurements (v1 and v2, x-axis). The upper and lower limits of agreement (LOA) are indicated by the dotted lines on the graphs. These dotted lines represent the upper and lower 1.96 x SD (± 2SD) of the mean within-pair differences. The scattered dots represent the individual differences between the 2 visits. Negative differences reveal a higher score during test two compared to test one, and positive differences vice versa. The solid horizontal line indicates the mean difference between visits for the outcome variable.

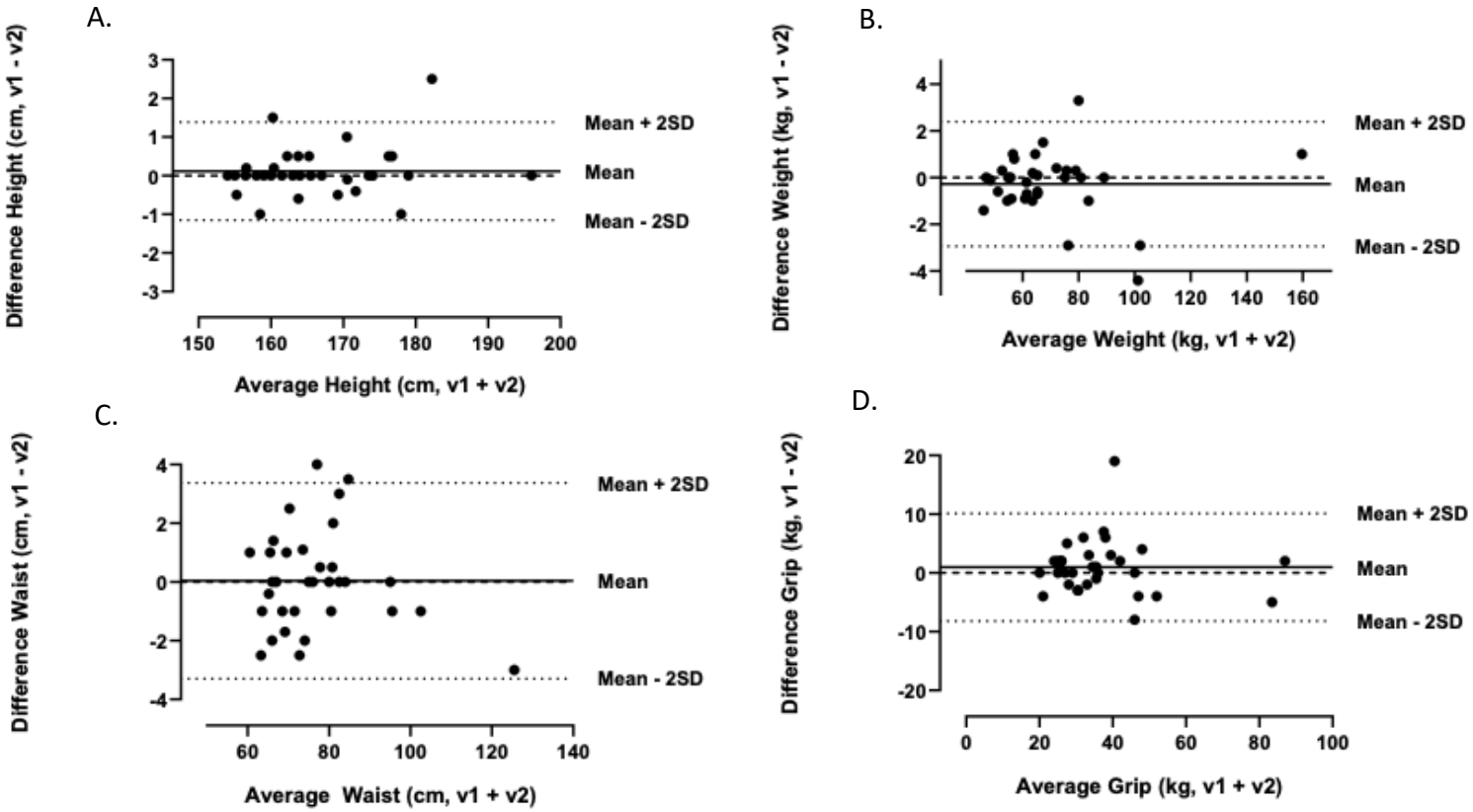

Figure 4. *Bland-Altman plots illustrating the differences in outcome measures (A. Height, B. Weight, C. Waist Circumference, D. Grip Strength) between visits 1 and 2. Solid line = mean difference, dotted line = 0 (y-axis), fine dotted lines ± 95% limits of agreement (LOA).*

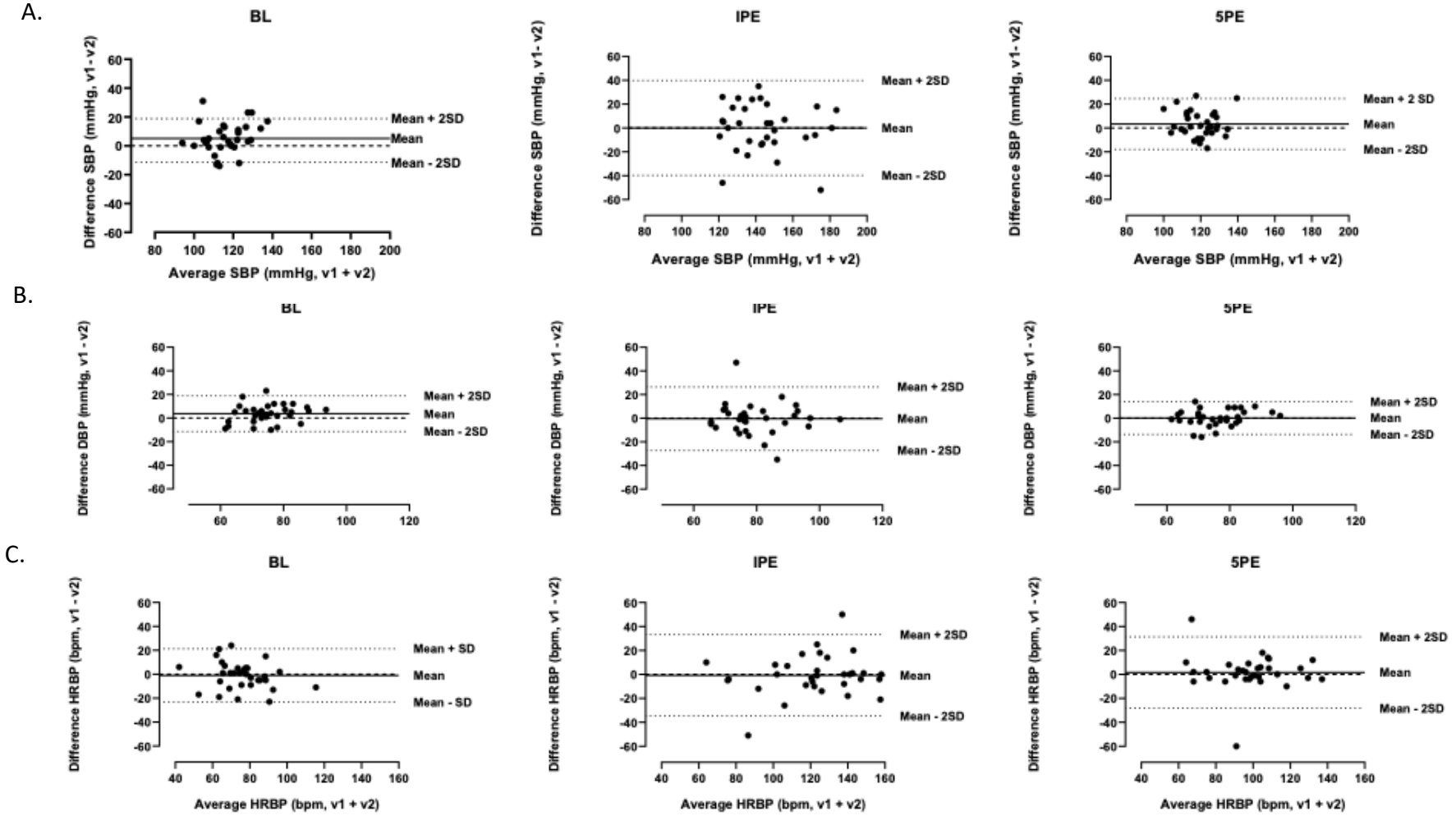

Figure 5. *Bland-Altman plots illustrating the differences in outcome measures (A. Systolic BP, B. Diastolic BP, C. Heart Rate [BP]) between visits 1 and 2. Solid line = mean difference, dotted line = 0 (y-axis), fine dotted lines ± 95% limits of agreement (LOA).*

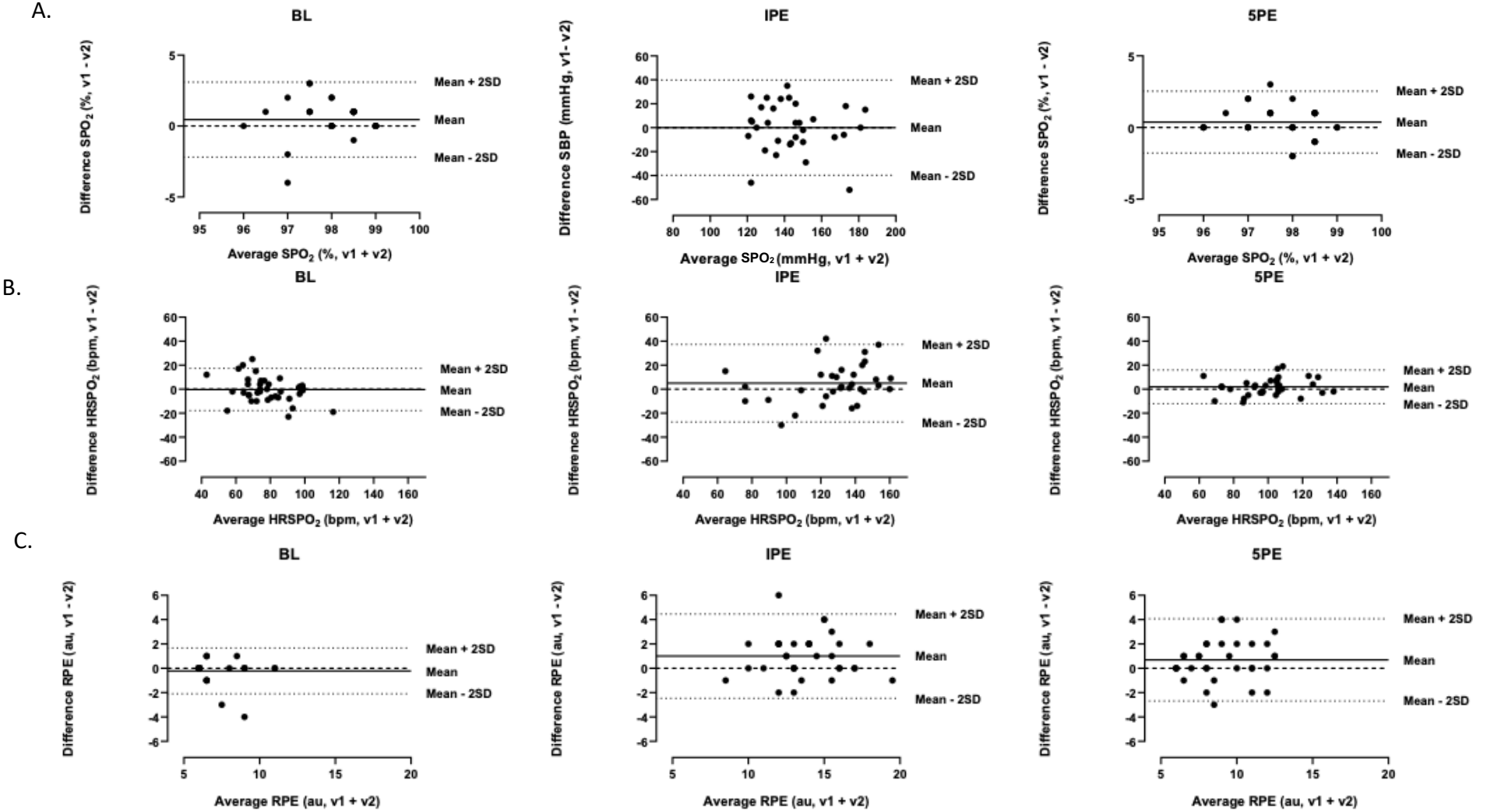

Figure 6. *Bland-Altman plots illustrating the difference in outcome measures (A. SPO2, B. Heart rate [SPO2], C. RPE) between visits 1 and 2. Solid line = mean difference, dotted line = 0 (y-axis), fine dotted lines ± 95% limits of agreement (LOA).*

Discussion

The aim of this study was to determine the test-retest reliability of data collection procedures that will be used in a prospective CRP at rest, immediately after, and five minutes post-exercise.

An in-depth analysis of reliability and reproducibility was performed, using three different methods: Intraclass correlation coefficients, Bland-Altman plots, and effect sizes. Looking collectively at the three different measures, all data collection procedures were acceptable, except for blood pressure, oxygen saturation and rate of perceived exertion.

For the systolic blood pressure (SBP) readings, the intraclass correlation coefficients (ICC) ranged from 0.47 to 0.53, which is considered poor to moderate reliability. The effect sizes for SBP ranged from 0.04 to 0.43. For diastolic blood pressure (DBP), ICC ranged from 0.38 to 0.71, which is also considered poor to moderate reliability. Effect sizes for DBP ranged from -0.05 to 0.43, with only the immediately post-exercise readings and the 5-minutes post-exercise diastolic blood pressure reading considered to have a small effect size. In our study, blood pressure was measured using an automated, or oscillometric device, and was not found to be reproducible across the two testing sessions. This is in agreement with previous research, where automated devices used by patients with hypertension were not considered reliable (Skirton et al., 2011; Wong et al., 2005) Blood pressure is an extremely volatile and sensitive measure that has shown great variability in both normal and hypertensive individuals (Floras et al., 1988). A range of internal and external factors including the position of the cuff or location of measurement, the oscillometric technique or algorithm used by the brand, body position or posture during measurement, inappropriate cuff size, the white coat effect and diurnal variation have the potential to affect the blood pressure measurement, and are therefore potential reasons for the lack of reproducibility of the automated cuffs (Ogedegbe et al., 2010). Although we did control for human error by ensuring that the test administrator was the same for all three measurements and was trained correctly on how to take blood pressure accurately, this does not exclude human error as a potential cause of the lack of reproducibility. In contrast to our findings, Altunkan and colleagues (2008) found that the OMROM M6 Model passed the criteria used for international validation and could be

reliably used in elderly patients (Altunkan et al., 2008), and Skirton and colleagues (2011) reported that there is greater within-subject reliability with oscillometric devices, due to the absence of digit preference, observer bias and white coat effect (Skirton et al., 2011). Possible reasons for their findings include device validation prior to use, clinician training, tailoring of cuff size to the individuals arm size, and taking a greater number of sequential measurements (Altunkan et al., 2008).

Our pulse oximetry measurements were performed on apparently healthy members of the public, with care taken to place the sensors correctly. However, SpO_2 was not found to be reproducible. The intraclass correlation coefficients were 0.10, 0.48 and 0.41 for the baseline, immediately post- and 5-minutes post-exercise respectively, which is considered to be poor. The effect sizes were 0.44, 0.24 and 0.20 for the three respective conditions. Effect sizes which are equal to or greater than 0.2 is recognised as a meaningful difference between measure one and measure two. Our findings are in contrast to De Meulenaere, who previously stated that oxygen saturation measured by a pulse oximeter has a 95% confidence rate of $\pm$ 4%, and therefore pulse oximetry can be considered a reliable method of determining oxygen saturation (DeMeulenaere, 2007). Khattak and colleagues (2021) found moderate test-retest reliability (ICC = 0.557) of a fingertip pulse oximeter when used on apparently healthy adults between the ages of 18 and 75 years (Khattak et al., 2021). This is in contrast to our findings of poor reliability. Plausible reasons for Khattak and colleague's contrasting findings are the use of a larger sample (N = 126), and the repetition of the pulse oximetry measurement three times (Khattak et al., 2021). There are a number of factors which can affect pulse oximetry measures, including conditions of severe or rapid desaturation, hypotension, hypothermia, dyshemagloinemia and a state of low perfusion (Jensen et al., 1998). Decreased perfusion due to hypotension or hypothermia, low cardiac output, vasoconstriction, vasoactive drugs, shivering or tremors, oedema or venous congestion, high-intensity or fluorescent lights, skin pigmentation and nail polish can have an impact on pulse oximetry readings (DeMeulenaere, 2007; Jubran, 2004). The population used in this study was apparently healthy, and so it is unlikely that factors such as hypotension, low cardiac output, venous congestion or medication affected the reproducibility of our results. However, it is possible that exercise in the form of the 6MWT resulted in a reduction of blood flow to the periphery, causing a state of low perfusion and consequently affecting the pulse

oximetry measurements (Kelly et al., 2021; Mengelkoch et al., 1994).

RPE was determined using the modified Borg scale. The intraclass correlation coefficients for RPE were 0.81, 0.71 and 0.69 for baseline, immediately post- and 5-minutes post-exercise respectively. Baseline RPE was consequently classified as good, whereas the two post-exercise measures were class as moderate. The effect sizes were -0.13, 0.39 and 0.31 respectively. Again, baseline RPE was found to have a less than small effect size, whereas the post-exercise measures had small effect sizes that exceeded the cut-off value of 0.2. Lamb and colleagues (1999) have previously reported that test-retest reliability of the Borg 6-20 Scale for estimating exercise effort during graded exercise as questionable, for RPE Pearson's correlations decline in magnitude as exercise intensity increases (Lamb et al., 1999). Monitoring exercise intensity is essential for the safety and efficacy of exercise prescription (Ritchie, 2012). Unreliability of the Borg scale undermines the efficacy of perceptually-based exercise, which is of great concern in a cardiac rehabilitation setting (Lamb et al., 1999). In this study, RPE was not found to be reproducible after exercise. Although test administrators were trained in explaining and utilising the RPE scale, it is possible that the participants did not understand the RPE scale thoroughly after receiving instruction, resulting in a subsequently incorrect RPE recording.

A similar phenomenon was explained by Lamb and colleagues (1999), where individuals are assumed to have an understanding of the RPE scale after being introduced to it once with a set of standardised instructions (Lamb et al., 1999). It is possible that with repeated instruction and assistance given to participants regarding the RPE scale, understanding will be improved, resulting in a more correct RPE and better repeatability. There are many other factors which may influence RPE, including psychological factors, such as stress and mood states (Ritchie, 2012). Exercise mode has also been shown to affect RPE (Ritchie, 2012). It is possible that the 6MWT, where participants were required to run around an indoor track, was difficult for the participants who were not recreational runners, which subsequently affected RPE. In contrast to our findings, a study by Grant and colleagues (1999) has reported that the modified Borg scale can reproducibly measure symptoms of breathlessness and fatigue during steady state exercise, and that the scale is sensitive to changes caused by medication (Grant et al., 1999). Reasons for their different findings could be that the

participants, who were male recreational exercisers, returned for four repeated testing sessions at the same time of day (Grant et al., 1999). Previous research has identified that a morning-evening difference exists in RPE (Mhenni et al., 2017). By ensuring participants return at the same time of day, it is possible that repeatability of the RPE scale improves and minimises the effect of a morning-evening difference.

Heart rate measurements from both the automated blood pressure cuff and pulse oximeter were considered to have good test-retest reproducibility, with ICC values ranging from 0.71 to 0.91 and effect sizes ranging from -0.06 to 0.19. This is consistent with the findings of Stanforth and colleagues (2000), where heart rate measured from an automated blood pressure cuff had good reproducibility with an ICC of 0.73 (Stanforth et al., 2000). Grip strength also had good reproducibility, with an ICC value of 0.95 and an effect size of 0.07. This is in agreement with Janda and colleagues (1987) who have previously reported that hand dynamometers provide a reproducible objective assessment of grip strength (Janda et al., 1987). It is, however, important to note that grip strength is a composite measure, and can be influenced by dysfunction in any of the muscles, tendons and joints of the wrist (Helliwell et al., 1987). Accurate measurement also requires that the participant give maximal effort on each occasion of measurement (Helliwell et al., 1987). Anthropometric measures of height, weight and waist circumference also had good reproducibility with ICC values ranging between 0.99 and 1.00 and effects sizes between -0.01 and 0.01. These findings are in agreement with Wilmore and colleagues (1997), who demonstrated that body composition measurements including mass and stature had a high level of reproducibility (Wilmore et al., 1997).

This study has several limitations. Due to COVID-19 regulations, and the risks of testing high-risk CVD patients in a hospital setting, the test-retest reliability of the measurement tools was performed on an apparently healthy population. This population is not reflective of the population that will be recruited for the prospective CRP. It is possible that the reproducibility of the measurement tools may change in a population affected by CVD. The measurement tools, including the blood pressure cuffs, pulse oximeters and scale, were not calibrated before use. This is because the only option for calibration is factory-based calibration which is completed during manufacturing. Participants were also given the option of returning for

subsequent testing either two or three days after their first testing session and testing was not kept to a specific time. It is likely that due to morning-evening fluctuations in physiological measures such as heart rate, blood pressure and RPE, that this could have impacted on results (Giles, 2006; Mhenni et al., 2017; Vandewalle et al., 2007).

Conclusion

Based on the three measures of reliability above, most of the monitoring tools to be utilised for the prospective CRP are acceptable in terms of test-retest reliability. However, the methods used to measure BP, SpO_2 and RPE are questionable. We recommend that different devices are utilised for these variables, and that test administrators and staff are taught how to minimise confounding factors, such as the white coat effect with blood pressure measurement, and perform the measurement techniques accurately through correct placement of the blood pressure cuff, pulse oximeter and explanation of the RPE scale. We would encourage the inclusion of familiarisation sessions, particularly for the Borg RPE Scale, and the use of quality-controlled standardised instructions for each measure to minimise error. Future studies should look at the test-retest reliability of questionnaires used, such as the physical activity readiness questionnaire, (PAR-Q), patient health question (PHQ-2) and general anxiety disorder (GAD-2) within the target population that will participate in the perspective CRP.

Final Summary

The purpose of this study was to describe and determine the partial feasibility of a novel cardiac rehabilitation programme in a South African public hospital setting to provide optimal and sustainable health care to patients with cardiac conditions. This was achieved by evaluating the recruitment potential and sample population characteristics of the target population, and by determining the test-retest reliability of data collection procedures at rest and after exercise.

With regards to the recruitment potential for the prospective CRP, our hypothesis was that a high volume of people will be considered eligible to take part in a CRP. Admissions to a public hospital are typically high in South Africa and are generally overburdened . The burden of CVD in South Africa is substantial. Our hypothesis was correct, as 100 individuals (47.8%) within the span of three months (1 September 2020 – 1 December 2020) were considered eligible to participate in the prospective CRP safely. Based on this recruitment potential, we can expect 33 patients to be eligible every month (100 participants/3 months), which is nearly triple the expected intake. This recruitment potential unfortunately exceeds the prospective resource and staff capacity, and is much greater than what can currently be accommodated. We recommend that the investigators of the prospective CRP adapt and increase the number of resources and trained staff before implementation.

For the evaluation of the test-retest reliability of the prospective data collection procedures, an in-depth analysis of reliability and reproducibility was performed using three different methods (Intraclass correlation coefficients, Bland-Altman plots, and effect sizes). Looking collectively at the three different methods of assessing reproducibility, most of the monitoring tools to be utilised for the prospective CRP are acceptable in terms of test-retest reliability. However, the methods used to measure BP, SpO_2 and RPE are considered questionable. We recommend that different devices are utilised for these variables, and that test administrators are taught how to minimise confounding factors. We encourage the inclusion of familiarisation sessions, particularly for the Borg RPE Scale, and the use of quality-controlled standardised instructions for each measure to minimise error.

Based on the findings of this partial feasibility study, we recommend that additional research, such as a pilot or Delphi study, is conducted prior to the implementation of the prospective CRP. We also recommend that the additional components of a feasibility study are explored, such as the acceptability and sustainability of intervention and study procedures, the available resources and ability to manage and implement the intervention, and a preliminary evaluation of participant responses to intervention (Orsmond et al., 2015).

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HREC REF: 612/2021 Ethics Approval (Appendix A)

UNIVERSITY OF CAPE TOWN
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30 September 2021

HREC REF: 612/2021

Dr J Kroff
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Dear Dr Kroff

PROJECT TITLE: AN INVESTIGATION INTO THE FEASIBILITY OF A NOVEL CARDIAC EXERCISE REHABILITATION PROGRAMME FOR PATIENTS SUFFERING FROM CARDIOVASCULAR DISEASE-MPIL CANDIDATE-TAYLA ROSS-SUB-STUDY LINKED TO R043/2020

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020: 06 July 2020 & 01 July 2021.

Approval is granted for one year until the 30 September 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

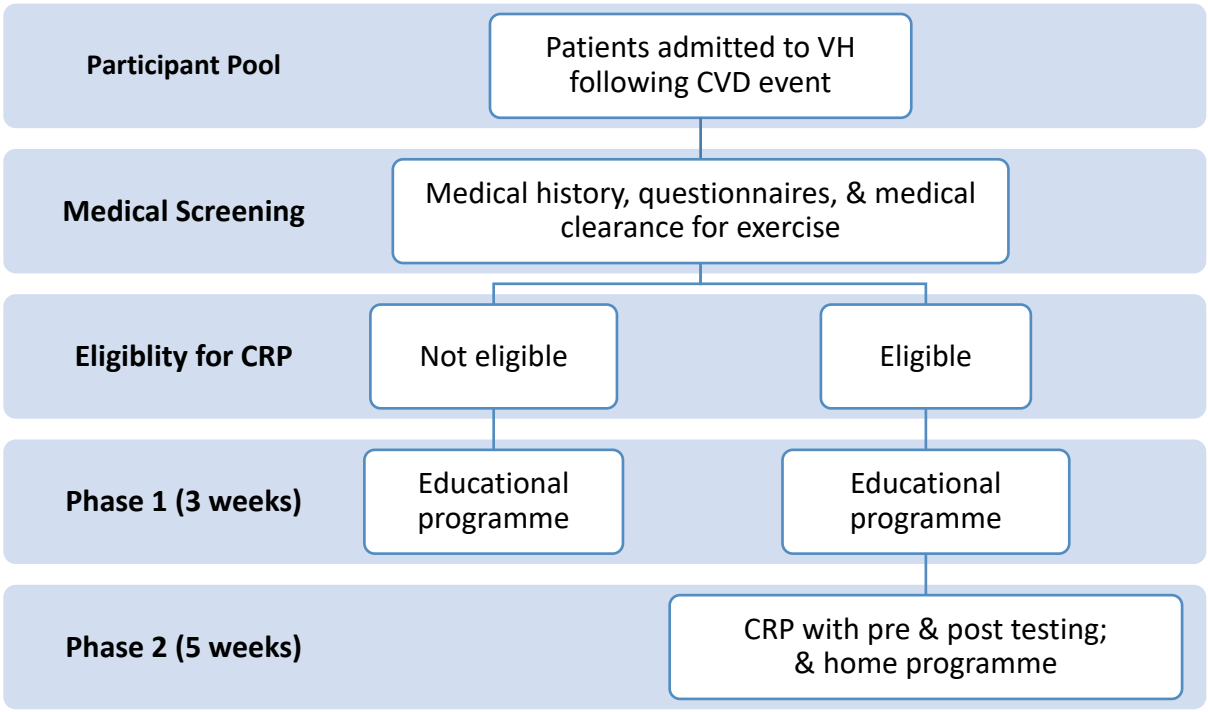
The HREC acknowledge that the student: Miss Tayla Ross will also be involved in this study.

Please quote the HREC REF 612/2021 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Proposed Structure of the Prospective CRP (Appendix B)



Weeks	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
Cycle 1																				
Cycle 2																				
Cycle 3																				
Cycle 4																				

	Educational-only portion of CRP
	Pre & post testing for Exercise CRP
	Exercise portion of CRP

Informed Consent (Appendix C)

THE TEST-RETEST RELIABLITY OF HEALTH AND FITNESS MEASURES IN APPARENTLY HEALTHY AND ACTIVE INDIVIDUALS

INFORMED CONSENT

ALL participants to read and sign

WHAT IS THE STUDY ABOUT?

I have been fully informed about the University of Cape Town's study entitled "**The test-retest reliability of health and fitness measures in apparently healthy and active individuals"** to be conducted by researchers from the UCT Division of Physiological Sciences. The aim of the study is determine how reliable the equipment measures my resting and exercise measurements of blood pressure, heart rate, perceived tiredness, oxygen carrying capacity of my blood and submaximal endurance effort.

WHAT WILL BE REQUIRED OF ME?

I understand that I will be asked to visit the UCT laboratories on **two** separate occasions for testing. Each visit will last approximately **45 minutes**, and the two visits will each be separated by **2-3 days**. I agree to avoid alcohol and vigorous exercise 24 hours prior to both visits.

Visit 1 (45 minutes)

I understand that the following baseline measurements / tests **will** be conducted on me during visit 1 of study, as described below:

Questionnaire: The researcher will ask me questions about my medical history, medications, physical activity readiness, current medical symptoms, health, stress and mental status.

Hand grip strength: I will be asked to create as much force by squeezing my hand around a hand grip device to make a fist while standing upright. The device will measure the force that I can exert against the device. I will be asked to perform three efforts with sufficient rest period between efforts with my dominant hand. The best of the three measures will serve as

my outcome of muscular strength. The hand grip test will be done during visit 1 and visit 2 prior to the exercise test.

6 min walk/run test: I will be asked to walk or run around an indoor track using a painted blue line on the floor as a guide. The purpose of the test is for me to try and complete as many rounds as possible around the track covering the greatest possible distance that I can achieve in 6 minutes. The researcher will measure my distance covered around the track which will be the outcome of my submaximal fitness test.

The following four different measurements will be repeated **three times**: before the 6min walk/run test, immediately after the 6 min walk/run test, and 5 min after the 6min walk/run test:

Blood pressure: My blood pressure will be measured on my left upper arm with an automated blood pressure meter. Once the cuff is placed neatly over my upper arm by the researcher, the researcher will press the start button and the blood pressure cuff will inflate air into the cuff, at a certain point, the cuff will start to deflate until all air are out of the cuff while measuring my blood pressure. I understand that during this time I need to sit back and relax as much as possible with my arm and hand in relaxed position on the table top.

Oxygen Saturation: I will be asked to clip a small fingertip device onto my middle finger of my right hand. This device will have a digital display that will take a few seconds to stabilize and then show my oxygen saturation and at the same time, my heart rate on the display. My oxygen saturation is the ability of blood to carry/transport oxygen from my lungs to the working parts of my body.

Heart Rate: It was explained to me that my heart rate will be taken at the same time of the blood pressure measurement by the automated blood pressure monitor. As a second measure my heart rate will also be measured automatically by the fingertip device during the oxygen saturation measurement.

Rate of Perceived exertion (RPE): I will be asked to indicate on a scale from 0 to 10 how tired I feel at any given time during rest and during exercise. The scale will also have descriptive words next to the scale number, and I will verbally express how tired I feel based on my perception at that point in time.

Visit 2 (45 minutes)

Visit 2 will be a replica of all procedures and measurements during visit 1.

WHAT ARE THE RISKS AND DISCOMFORTS TO ME?

In answering the questionnaire it my inflict emotional discomfort I will be asked to reveal personal information about my mental status, general health status, medications, medical history and overall feeling of depression, anxiety and stress levels.

I may experience slight discomfort with the hand grip strength test due to muscular exertion and gripping with my hand onto the hand grip device, this will be minimized by ensuring the tests are performed as carefully but efficiently as possible.

I may experience some discomfort in the blood pressure measurement using the automated blood pressure monitor. The inflation of air into the cuff around the upper arm will cause compression against my arm.

I understand that there a slight risk of physical injury by possibly falling or hurting one or more of my muscle groups during the activity. This is minimized by the researchers ensuring the area wherein the test will be conducted are cleared and clean. I was also informed that I may experience sweating, breathlessness, breathing and muscle fatigue or slight body pain during the 6 minute walk or runt test and will be well informed that they can stop the test at any time.

WHAT ARE THE ADDITIONAL RISKS, RULES AND REGULATIONS DURING COVID-19 PANDEMIC?

I understand that there is a higher risk involved to me in possibly being exposed to the Covid-19 virus based on my choice to volunteer to take part in the study requiring the interaction between me and the researchers within a location used for exercise by members of the public. I understand that I will have to complete the Covid-19 Screening test to be allowed into the building for testing. I understand that the researcher will also ask me a few questions regarding Covid-19 screening via telephone when I book my appointment for visit 1. The researcher explained that social distancing during all assessments will executed as far as possible, except for during the placement of the blood pressure cuff around the arm. I understand that is compulsory to wear a mask during the assessments. I was informed that I can take off my mask during the last few minutes of the 6 min walk/run test if I feel the need to do so. I was informed that there will be hand sanitiser and surface cleaner at the testing stations to make use of at any time. The researchers have informed me that equipment and surfaces will be thoroughly sterilised between participants.

WHAT ARE THE BENEFITS TO ME?

I understand that there are no direct benefits to me for participating in this study. However, I may receive, where applicable, feedback pertaining to my health and fitness status.

WHAT IS SOMETHING GOES WRONG?

The University of Cape Town (UCT) undertakes that in the event of me suffering any significant deterioration in health or well-being, or from any unexpected sensitivity or toxicity, that is caused by my participation in the study, it will provide immediate medical care. UCT has appropriate insurance cover to provide prompt payment of compensation for any trial-related injury according to the guidelines outlined by the Association of the British Pharmaceutical Industry, ABPI 1991. Broadly-speaking, the ABPI guidelines recommend that the insured company (UCT), without legal commitment, should compensate me without me having to prove that UCT is at fault. An injury is considered trial-related if, and to the extent that, it is caused by study activities. I must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, my injury came about because I chose not to follow the instructions that I was given while I was taking part

in the study. My right in law to claim compensation for injury where I prove negligence is not affected. Copies of these guidelines are available on request.

WHAT WILL BE DONE WITH MY INFORMATION?

I understand that all the information collected during the study will be treated confidentially, will only be used for scientific research purposes and that my name and personal particulars will not be released under any circumstances.

CONSENT

I have read the detailed description of the study procedures above and have had the opportunity to ask questions. The researchers have answered any questions that I have relating to the study. I have been informed that I will be free to withdraw from the study at any time if I so wish without explanation. Similarly, I understand that the researchers may also withdraw me from the study at any time without explanation. I will be free to ask any questions about the procedures and results of the study.

I agree to participate in the study.

Participant's name: _____

Signature: _____

Date: _____

Investigator's name: _____

Signature: _____

Date: _____

Witness's name: _____

Signature: _____

Date: _____

Recruitment Poster (Appendix D)

Division of Physiological Sciences
Department Of Human Biology, Faculty of Health Sciences
University of Cape Town, South Africa

PARTICIPANTS WANTED FOR UCT RESEARCH

Cardiac Rehabilitation Feasibility Study

The aim of this study is to determine the test-retest reliability of a screening questionnaire and exercise intensity monitoring measures that will be utilized during a prospective cardiac rehabilitation intervention.

Testing includes:

- **Two** visits to the Sports Science Institute, each lasting approximately 1 hour.
- **Visit 1**: Screening questionnaire, resting blood pressure, rate of perceived exertion, heart rate and oxygen saturation measurements and a maximum voluntary effort cardiovascular fitness test followed by repeat of the before-mentioned measures.
- **Visits 2:** Exact repeat of Visit 1.

Those interested in participating should:

- ✓ Be between the ages of 20 and 65 years.
- ✓ No COVID-19 signs or symptoms.
- ✓ Participate in regular exercise at least 2 days per week.
- ✓ Have no known medical condition and should not require any chronic medication.
- ✓ Are not pregnant or lactating.

Benefits of participating in the study include:

- Individualised report on your health and fitness outcomes which would otherwise have a financial cost.

If you are interested in taking part in the study and would like additional information, please contact: ***Jacolene Kroff***

Jacolene.Kroff@uct.ac.za
021 650 4568

SSISA SPORTS SCIENCE INSTITUTE OF SOUTH AFRICA

Modified Borg Scale (Appendix E)

Rating	Descriptor
0	Rest
1	Very, Very Easy
2	Easy
3	Moderate
4	Somewhat Hard
5	Hard
6	.
7	Very Hard
8	.
9	.
10	Maximal

Turnitin Report (Appendix F)

rsstay001:Turnitin_2.docx

ORIGINALITY REPORT

12%	8%	8%	6%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.iacom.org.uk Internet Source	<1%
2	www.ncbi.nlm.nih.gov Internet Source	<1%
3	Submitted to University of Wolverhampton Student Paper	<1%
4	open.bu.edu Internet Source	<1%
5	"The Palgrave Handbook of Ageing and Physical Activity Promotion", Springer Nature, 2018 Publication	<1%
6	Submitted to Colorado Technical University Student Paper	<1%
7	"ASPC Manual of Preventive Cardiology", Springer Science and Business Media LLC, 2021 Publication	<1%
8	Submitted to University of Salford Student Paper	<1%