The University of Hull

Quantification of exercise training dose in phase III cardiac rehabilitation: A UK perspective

by

Alaa Khushhal MSc

A thesis submitted in partial fulfilment of the requirements of the University of the Hull for the degree of Doctor of Philosophy

This research programme was carried out in collaboration with the Department of Sport, Health & Exercise Science

August 2019

Acknowledgments

First of all big especial thanks to Professor Lee Ingle for his support and encouragement during my PhD study as a principal supervisor, from the beginning until the end of my PhD degree. His knowledge and experience was helpful during my PhD journey. I would also like to thank Dr Grant Abt and Professor Sean Carroll for all their advices, supervision, support and help during my PhD study. The success of completing this PhD thesis is something you can be proud of.

Thanks to Dr Simon Nichols for his support during the design of my PhD studies and for his help to obtain the ethical approval for the main study and to run the main study in my PhD. In addition, special thanks to the cardiac rehabilitation team in Hull for their help and support for collecting the data for my main study in my PhD. Also, many thanks to Will Evans, Damien Gleadall-Siddall, Richard Page, and Alasdair O'Doherty for their help and support for collecting the data for my first study and many thanks to Laura Correia and Sean Pymer for their help and support during data collection for my second study. I am grateful to all of the participants in these projects, without their willingness to participate; none of this would have been possible.

I am so grateful for my family including, my parents, wife, sons and daughter for their support throughout this journey to get my PhD degree.

List of publications

Khushhal, A., Nichols, S., Evans, W., Gleadall-Siddall, D. O., Page, R., O'Doherty, A. F.,Carroll, S., Ingle, L & Abt, G. (2017). Validity and reliability of the Apple Watch for measuring heart rate during exercise. *Sports medicine international open*, *1*(06), E206-E211.

Khushhal, A., Nichols, S., Carroll, S., Abt, G., & Ingle, L. (2019). Insufficient exercise intensity for clinical benefit? Monitoring and quantification of a community-based Phase III cardiac rehabilitation programme: A United Kingdom perspective. *PloS one*, *14*(6), e0217654.

Posters and presentation

I have presented two academic posters from my PhD data; firstly, at the BASEM/FSEM Annual Congress in 2016, and, the following year, at the Postgraduate Student Conference at the University of Hull:

1- Khushhal, A., Nichols, S., Evans, W., Gleadall-Siddall, D. O., Page, R., O' Doherty, AF, Carroll, S, Ingle, L, & Abt, G. BASEM/FSEM Annual Congress 2016, Validity of the Apple watch for measuring step count during exercise, poster presentation.

2- Khushhal, A., Nichols, S., Evans, W., Gleadall-Siddall, D. O., Page, R., O'Doherty, A. F., Carroll, S, Ingle, L, & Abt, G. PhD conference, University of Hull 2017, Validity of the Apple watch for measuring heart rate during exercise, poster presentation.

General Abstract

The Apple watch was a new technology first introduced in 2015. At that time, its validity and reliability for measuring stepping frequency and heart rate monitoring during exercise was unknown. Current evidence indicates that the effectiveness of cardiac rehabilitation (CR) programmes for improving patient outcomes may be questionable in the United Kingdom (UK). We postulated that the exercise dose that patients receive during Phase III CR may not be a high enough stimulus to invoke a positive physiological adaptation. Therefore, this thesis aims to examine the validity and reliability of the Apple watch for measuring heart rate and step frequency. We then planned, based on our initial findings, to apply this technology to patients undertaking Phase III CR in order to monitor and quantify exercise dose and training progression to determine the fidelity of the intervention.

The aim of the first study was to examine the validity and variability of the Apple watch for measuring step count. On two occasions, 21 males completed treadmill exercise while wearing two Apple watches (left and right wrists) and an ActivPAL (criterion). Exercise involved 5 min bouts of walking, jogging, and running at speeds of 4 $km \cdot h^{-1}$, 7 $km \cdot h^{-1}$, and 10 $km \cdot h^{-1}$, followed by 11 min of rest between each bout. There was a small under-estimation in step count during walking but large and very large over-estimations during jogging and running. There were poor to very poor correlations during walking, jogging and running. The inter-device variability showed good to nearly perfect intraclass correlations and small to moderate standardised typical errors. Intra-device variability was large to very large for all exercise intensities. The Apple watch has adequate validity for measuring step count during walking, but very poor validity during jogging and running. On this basis, we concluded that quantifying stepping frequency during Phase III CR using the Apple watch should not be pursued.

The aim of the second study was to examine the validity and reliability of the Apple watch heart rate sensor during and in recovery from exercise. Twenty-one males completed treadmill exercise while wearing two Apple watches (left and right wrists) and a Polar S810i monitor (criterion). Exercise involved 5 min bouts of walking, jogging, and running at speeds of 4 $km \cdot h^{-1}$, 7 $km \cdot h^{-1}$, and 10 $km \cdot h^{-1}$, followed by 11 min of rest between bouts. At all exercise intensities the mean bias was trivial. There were very good correlations with the criterion during walking (L: r = 0.97; R: r = 0.97), and good (L: r = 0.93; R: r = 0.92) but poor/good (L: r = 0.81; R: r = 0.86) correlations during jogging and running. Standardised typical error of the estimate was small, moderate, and moderate to large. There were good correlations following walking, but poor correlations following jogging and running. The percentage of heart rates recorded reduced with increasing intensity but increased over time. Intra-device standardised typical errors decreased with intensity. Inter-device standardised typical errors were small to moderate with very good to nearly perfect intraclass correlations. The Apple watch heart rate sensor has very good validity during walking but validity decreases with increasing intensity. On this basis, we chose to introduce the Apple watch to a Phase III CR programme for monitoring individual exercise dose via heart rate.

The aim of the third study was to investigate the fidelity of a structured Phase III cardiac rehabilitation (CR) programme in the United Kingdom (UK), by monitoring and quantifying exercise training intensity. We compared the mean % heart rate reserve (%HRR) achieved during the cardiovascular training component (%HRR-CV) of a circuit-based programme, with the %HRR during the active recovery phases (%HRR-AR) in a randomly selected cohort of patients attending standard CR. We then compared the mean %HRR-CV achieved with the minimal exercise intensity threshold during supervised exercise (40% HRR) recommended by national governing bodies. The programme comprised 16 sessions over 8 weeks, where patients undertook an interval, circuit training approach within national guidelines for exercise prescription (40-70% heart rate reserve [HRR]). All patients wore an Apple watch (Series 0

or 2, Watch OS2.0.1, Apple Inc., California, USA). Thirty cardiac patients (83% male; mean age [SD] 67 [10] years; BMI 28.3 [4.6] $kg \cdot m^{-2}$) were recruited. We captured 332 individual training sessions. The mean %HRR-CV and %HRR-AR were 37 (10) %, and 31 (13) %, respectively. There was weak evidence to support the alternative hypothesis of a difference between the %HRR-CV and 40% HRR. There was very strong evidence to accept the alternative hypothesis that the mean %HRR-AR was lower than the mean %HRR-CV (median standardised effect size 1.1 (95%CI: 0.563 to 1.669) with a moderate to large effect. Mean exercise training intensity was below the lower limit of the minimal training intensity guidelines for a Phase III CR programme. These findings may be in part responsible for previous reports highlighting the significant variability in effectiveness of UK CR services and poor CRF improvements observed from several prior investigations.

The aim of the final study was to characterise the weekly progression of exercise training dose/load over an 8-week Phase III cardiac rehabilitation (CR) programme based in the United Kingdom (UK). Patients with a history of cardiovascular (CV) disease were recruited to an 8-week CR programme (16 sessions in total). During each training session, patients wore an Apple Watch (Series 0 or 2, Watch OS2.0.1, Apple Inc., California, USA) and we quantified the weekly progression of exercise training dose/load for % heart rate reserve (%HRR) during the CV training component (%HRR-CV), CV training duration, estimated changes in cardiorespiratory fitness (change in estimated METS), session rating of perceived exertion (sRPE), sRPE training load (sRPE-TL), and training impulse (TRIMP). Thirty cardiac patients [83% male; age (SD) 67.0 (10.0) years; body mass index (SD) 28.3 (4.6) $kg \cdot m^{-2}$] were recruited to the Phase III CR programme. Overall our analysis is based on 332 individual training sessions. Bayesian repeated-measures ANOVA resulted in a BF_{10} of 1.1 to 3.1, indicating weak to moderate evidence for the alternative hypothesis of an effect of time on %HRR-CV, sRPE, and change in estimated METs. Conversely, Bayesian repeated-measures ANOVA resulted in a BF_{10} of between 103,977 to 1,018,000, indicating extremely strong evidence for the alternative hypothesis of an effect of time on CV training duration, TRIMP, and sRPE-TL. The training principle of progressive overload is being applied consistently in CR. However, the increases observed in exercise training dose were mostly the result of increases in the duration of CV training rather than increases in exercise training intensity (%HRR-CV and sRPE). Therefore, allied health professionals must ensure that weekly increases in exercise intensity are consistently applied in order to optimise exercise training prescription and improve patient outcomes.

We can conclude from the studies within this PhD thesis that allied health professionals involved in CR should undertake more advanced training in exercise training, programming and prescription to ensure that principles of training including progressive overload are understood and implemented correctly. Allied health professionals should also have a greater understanding of the benefits of exercise and physical activity, and this knowledge should be passed on to patients in the hope that they adopt a more active lifestyle beyond Phase III CR. The increased use of digital/wearable technology should be actively encouraged which will help support allied health professionals monitor, track, and up-titrate exercise dose over the course of a CR programme. Predictive heart rate training zones should be re-calculated regularly, as resting heart should be re-checked before the start of each training session. We also recommend using more cohort-specific predictive equations such as the Brawner equation which accounts for use of beta-blockers. We recommend to allied health professionals the Apple watch for monitoring heart rate throughout each training session, our studies show that at lower intensities of exercise the Apple watch is a valid and reliable tool. One downside to using the Apple watch is their excessive cost in relation to other activity trackers. Cost needs to weighed against the accuracy of the data provided.

List of Abbreviations

AACVPR	American Association of Cardiovascular and Pulmonary Rehabilitation
ACPICR	Association of Chartered Physiotherapists in Cardiac Rehabilitation
ACS	Acute Coronary Syndrome
ACSM	American College of Sports Medicine
AR	Active recovery
AEE	Activity Energy Expenditure
AF	Atrial Fibrillation
BACPR	British Association for Cardiovascular Prevention and Rehabilitation
BMI	Body Mass Index
CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CHD	Coronary Heart Disease
CHF	Chronic Heart Failure
COPD	Chronic Obstructive Pulmonary Disease
CPET	Cardiopulmonary Exercise Test
CR	Cardiac Rehabilitation
CR10	Category Ratio 10
CRF	Cardiorespiratory Fitness
CV	Cardiovascular
CVD	Cardiovascular Disease
CHD	Chronic Heart Disease
ECG	Electrocardiogram
EE	Energy Expenditure
ES	Effect Size
Fig	Figure
GPS	Global Positioning System
GPAQ	Global Physical Activity Questionnaire
HR	Heart Rate
HRR	Heart Rate Reserve

HRV	Heart Rate Variability
HF	Heart Failure
HRM	Heart Rate Monitor
ISWT	Incremental Shuttle Walk Test
ICC	Intraclass Correlation
IPAQ	International Physical Activity Questionnaire
MCID	Minimal Clinically Importance Difference
METs	Metabolic Equivalents
MI	Myocardial Infarction
MVPA	Moderate-to-Vigorous Physical Activity
ΔHR	Mean Heart Rate
NACR	National Audit for Cardiac Rehabilitation
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PA	Physical Activity
PCI	Percutaneous Coronary Intervention
PPG	Photoplethysmography
pNN50	Proportion of NN50 Divided by Total Number of NNs
RAMIT	Rehabilitation after myocardial infarction trail
R-R interval	Beat-to-beat interval
RCT	Randomised Controlled Trial
RHR	Resting Heart Rate
RPE	Rating of Perceived Exertion
RMSSD	Heartbeat Interval Difference
VMU	Vector Magnitude Units
VT	Ventilatory Thresholds
%HRR	Percent Heart Rate Reserve
%VO_2 peak	Percent peak oxygen uptake
SD	Standard Deviation
SDNN	Standard Deviation of NN Intervals
session RPE	Session Rating of Perceived Exertion
STEMI	ST Elevation Myocardial Infarction
SMS	Short Message Service
TEE	Total Energy Expenditure

TRIMP	Training Impulse
UK	United Kingdom
US	United States
W	Watt
WHO	World Health Organisation

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Chapter 1: Introduction

1.1 Background

According to the Association of Chartered Physiotherapists in Cardiac Rehabilitation (CR) (ACPICR, 2015), approximately 180,000 people die each year because of cardiovascular disease (CVD) in the UK. In 2014, CVD was the second-highest cause of death in the UK (Townsend, Bhatnagar, Wilkins, Wickramasinghe & Rayner, 2014), with approximately 2.5 million people living with cardiac disease, and >7 million people living with CVD (BACPR, 2012). Coronary artery disease (CAD) led to 46,000 deaths in the UK in 2010 (ACPICR, 2015), while chronic heart disease (CHD) leads to approximately 70,000 annual deaths (BACPR, 2012). In 2015, there were 80,000 people diagnosed with heart failure (HF); while 900,000 women, and 1.2 million men had a diagnosis of angina pectoris (ACPICR, 2015). In addition, approximately 110,000 men and 65,000 women are diagnosed with acute myocardial infarction (MI) each year in the United Kingdom (UK) (Dalal, Doherty & Taylor, 2015).

The cornerstone of secondary prevention strategies for patients suffering from these cardiovascular-related conditions is comprehensive cardiac rehabilitation (CR), including optimal medical therapy and lifestyle interventions which have been endorsed within United Kingdom (BACPR, 2012; ACPICR, 2015), and in conjunction with European (Piepoli et al., 2014) and American (Balady et al., 2007) guidelines. CR is defined by the British Association for Cardiac Prevention and Rehabilitation (BACPR) as: ''The coordinated sum of activities required to influence favourably the underlying cause of CVD, as well as to provide the best possible physical, mental and social conditions, so that the individuals may, by their own efforts, preserve or resume

optimal functioning in their community and through improved health behaviour, slow or reverse progression of disease ''(ACPICR, 2015. p 9).

Comprehensive CR has many facets, including exercise programming, psychological counselling, and dietary support. At the core of CR is structured exercise training (ACPICR, 2015). CR has been shown to increase cardiorespiratory fitness and quality of life, decrease the total mortality rate by between 11-26% (ACPIR, 2015), reduce cardiac mortality by 26-36% (ACPIR, 2015), and reduce hospital readmissions (Dalal et al., 2015; Perk et al., 2012).

Ideally, a structured exercise programme within a Phase III community-based CR programme, following hospital discharge, should be 20-60 minutes of moderate exercise intensity, three to five times per week. Typically, programmes consist of circuit training following an interval approach which include a cardiovascular (CV) conditioning component, and an active recovery (AR) exercise. Initially, patients would perform interval training using a 1:1 ratio between CV training and AR. The ultimate aim is to increase the duration of CV activity at the expense of AR so the patient is eventually undertaking continuous CV exercise within an intensity range of 40-70% heart rate reserve (HRR) (BACPR, 2012; ACPICR, 2015 & NICE, 2013). The range 40-70% of HRR is recommended as this intensity should cause a training stimulus in order to invoke positive physiological adaptations (AACVPR, 2006). The ACPICR (2015) also recommends that exercise intensity should be monitored through both %HRR, and through ratings of perceived exertion (RPE), in the range between 11-14 on the RPE 6-20 scale, or between 2-4 on the category ratio (CR)10 scale. The exercise training guidelines for cardiac patients in the UK are conservative compared to international equivalents, with the American College of Sports Medicine (ACSM)

recommending training intensities between 40-85% HRR for cardiac patients (AACVPR, 2006).

There is currently concern regarding the effectiveness of UK CR programmes in relation to patient outcomes compared to other countries including the US or in Western Europe. Previous studies have shown that exercise volume in UK CR is one-third that of other countries (Sandercock, Cardoso, Almodhy & Pepera, 2013), with an increased mean metabolic equivalents (METs) of 0.52 METs compared to international studies indicating a mean improvement of 1.5 METs. In another UK study, West, Jones and Henderson also found there was no difference in the health-related quality of life and survival risk in cardiac patients undertaking CR for two years, compared to usual care (West, Jones & Henderson, 2011).

Exercise intensity can be prescribed or estimated based on a number of methods, such as the RPE scale, %HRR, and also % peak oxygen uptake (%VO_2 peak) (American College of Sports Medicine, 2013; Perk et al., 2012). Estimated heart rate training zones can be calculated from a number of formulas with differing degrees of precision in the UK. Perhaps the most well-known method is the Karvonen formula: "220 – age (years)", which is used to calculate exercise intensity in cardiac patients ≤45 years of age (American College of Sports Medicine, 2013, p. 168). Whereas, in patients >45 years, UK convention is to use: 206 - (0.7 x age) (Tanaka et al., 2001; Dalal, Doherty & Taylor, 2015).

Exercise load/dose is defined as the integration of the intensity, frequency and duration of exercise (American College of Sports Medicine, 2013), and can be classified as internal or external load. HR or RPE measure internal load, whilst external load can be measured with an accelerometer, global positioning system (GPS) tracking, or by

distance covered (Akubat, Barrett & Abt, 2014). Banister's training impulse (TRIMP) is one method for measuring internal exercise load, and the hypothesis is that each training session creates a fatigue and fitness impulse (Akubat, Barrett & Abt, 2014). Banister's equation for measuring exercise load is as follows: time (mins) x mean heart rate x *y*. Where *y* is the weighting factor (Banister, 1991). Session RPE can be calculated by multiplying the duration of a training session by its intensity to gain arbitrary units (Akubat, 2012).

There is a strong association between session RPE and HR, (r = 0.89) (Gabbett & Domrow, 2007). Previous studies ''including Akubat et al (2012)'' have shown that Banister's TRIMP is related to session RPE and, by using these two methods, we can state that we can quantify exercise load both subjectively and objectively.

There are now a number of new devices, including smart watches on the market for measuring heart rate and steps number but, as we do not know how accurate and reliable they are, it is important to test the validity and reliability of any device before using it. Existing devices which have been shown to measure HR accurately include the Polar heart rate monitoring, however, this may cause discomfort for the user as a chest strap must be worn (Lee & Gorelick, 2011). In our thesis, we aim to rigorously test new technology in the form of the Apple watch, which was initially introduced in 2015 using photoplethysmography (PPG) technology. PPG is a non-invasive measure that uses a light source and a detector to identify a change in blood flow (Kurylyak, Lamonaca & Grimaldi, 2012). A tri-accelerometer embedded within the Apple watch is used to measure frequency of steps.

Other smartwatches, including the Samsung Galaxy S5, are able to measure heart rate, but it is difficult to use during exercise sessions because it measures the heart rate only when the user places his/her finger on the camera lens (Tom's guide, 2018).

The apple watch is an expensive device compared to the polar chest strap but it is more comfortable to use in the practise than wearing the chest polar strap , it also has an internet connection to allow monitoring the heart rate regularly during the exercise class. Furthermore, the polar heart is not recordable, while this is an advantage of using the Apple watch and the apple watch can be used outside the class such as using it at home, as we advised the cardiac patients to do exercise at home (BACPR, 2012 ; ACPICR, 2015 & NICE, 2013). Moreover, version 4 and 5 in the apple watch has an ECG wave , so the apple watch is more safer than the polar to use in the practise.

There are only two studies (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016; Wang et al., 2017) that have measured heart rate during exercise in healthy subjects using smartwatches. Wallen et al (2016) reported that the Apple watch was the most accurate smartwatch for measuring heart rate when compared to Fitbit Charge HR, Samsung Gear S, and the Mio Alpha during lower intensity exercise. The authors measured heart rate manually during one hour of exercise, however, the method in which they extracted data was unclear (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016). Wallen et al (2016) showed that the Apple watch demonstrated poor validity in measuring frequency of stepping during low exercise intensity (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016). Wang and colleagues (2017) compared the Apple watch against ECG in 50 healthy individuals. The participants performed exercise on a treadmill at 3.2 km/h, 4.8 km/h, 6.4 km/h, 8 km/h and 9.6 km/h respectively for 3 min, and the participants were wearing two of the four

smartwatches (Basis Peak, Fitbit charge HR, Apple watch and Mio Alpha). They found that the correlation was (r=0.91) between the Apple watch and the ECG and they reported the accuracy of the Apple watch decreased with increasing exercise intensity (Wang et al ., 2017). Falter et al (2019) recently measured the HR from the Apple watch in 40 cardiac patients, and reported that the Apple watch was acceptable for recording HR during rest and exercise (Falter, Budts, Goetschalckx, Cornelissen & Buys, 2019).

Therefore, this thesis will initially examine the validity and reliability of the Apple watch for measuring frequency of steps and heart rate during rest, exercise and recovery. Secondly, based on our initial findings we will introduce the Apple watch to a community-based Phase III cardiac rehabilitation in order to monitor and quantify the dose of exercise that patients receive over the course of a standard 8-week programme. We will pay particular attention to the exercise intensity patients are required to train at, and whether this intensity falls within national guidelines for exercise prescription, and secondly, whether a principle component of exercise training, specifically, *progressive overload*, is routinely incorporated into the programme on a group and individual level.

1.2 Aims

The aims of the thesis are as follows:

1- To examine the validity and inter-and intra-device reliability of the Apple watch for measuring frequency of steps during walking, jogging, and running.
2- To examine the validity and inter-and intra-device reliability of the Apple watch for measuring heart rate during walking, jogging, and running, and in recovery.

3- The investigate to fidelity of a structured Phase III CR programme in the UK, by monitoring and quantifying exercise training intensity.
4- To investigate the weekly progression in duration and intensity of cardiovascular training over an 8-week Phase III CR programme based in the UK.

1.3 Structure of the thesis

The thesis consists of seven chapters; the first chapter is an introductory section focused on providing a brief background and rationale for why the research needs to be conducted, and the aims of the thesis will be presented. The second chapter "review of literature" presents a review of the current evidence and highlights why this thesis is important and timely. The third chapter is the first experimental study which is focused on determining the validity and inter-and intra-device reliability of the Apple watch for measuring frequency of steps during walking, jogging, and running. The fourth chapter will examine the validity and inter-and intra-device reliability of the Apple watch for measuring heart rate during walking, jogging, and running, and in recovery. Chapter 5 will focus on the the fidelity of a structured Phase III cardiac CR programme in the UK, by monitoring and quantifying exercise training intensity. Chapter 6 will examine the weekly progression characteristics in duration and intensity of cardiovascular training over the 8-week Phase III programme with a view to determining if the "progressive overload" principle is consistently applied to a patient's training programme. Chapter 7 is the "general discussion" which will summarise findings from all the experimental studies and provide pragmatic implications for UK-based cardiac rehabilitation programmes. Study limitations will

be addressed, and overall conclusions and recommendations for future research will also be discussed.

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Chapter 2: Review of literature

2.1 Introduction

This chapter provides a critical review of current literature in relation to the effectiveness of UK-based CR. A specific focus will be monitoring and quantification of exercise dose. The chapter initially focuses on terminology and definitions that are relevant to the thesis. It discusses subjective and objective methods for assessing and quantifying physical activity, and exercise programming and prescription in cardiac patients. It also critically compares different types of accelerometers, pedometers and heart rate monitors which are currently available for physiological monitoring. This chapter then presents the available evidence regarding training load and the use of accelerometers before, during and following CR in different countries, and the different methods used to measure training load including the Apple watch. It also critically evaluates studies that have been conducted to assess CR in the UK. Towards the end of the chapter, it provides a summary of the limitations of previous works and the rationale for the studies within this thesis.

2.2 Physical activity and exercise definitions

There are four important definitions for the reader to bear in mind within this thesis. The definition of physical activity (PA) is "any bodily movement produced by skeletal muscles that results in energy expenditure beyond resting expenditure" (Thompson et al., 2003, p.3109). Exercise is defined as "a subset of physical activity that is planned, structured, repetitive, and purposeful in the sense that improvement or maintenance of physical fitness is the objective" (Thompson et al., 2003, p.3109). Exercise load/dose is defined as the integration of the intensity, frequency and duration of exercise (American College of Sports Medicine, 2013). Exercise intensity is defined

as how hard the body works during exercise or physical activity (American College of Sports Medicine, 2013).

2.3 Measuring and quantifying PA and exercise training

Up to 70% of the UK population do not do enough physical activity to achieve their health goals and protect their hearts (NICE, 2013). There are two main approaches to assess and quantify PA and exercise. The first is subjective measurement, which uses self-reporting such as diaries, recall or questionnaires. The second is objective measurement, which involves accelerometers, pedometers, heart rate monitoring, direct observation, doubly labelled water and direct and indirect calorimetry (Anastasopoulou et al., 2014; Warren et al., 2010). When quantifying or measuring PA, we have to consider three main aspects - duration, intensity and the frequency of activity - in order to calculate energy expenditure (EE) (Warren et al., 2010). The EE is measured by calories "burned" (Steele et al., 2003). EE, frequency of steps and heart rate are used to assess and quantify PA and exercise (Anastasopoulou et al., 2014; Steele et al., 2003). Moreover, there is a linear association between EE and HR monitoring (Li, Deurenberg & Hautvast, 1993) during moderate to vigorous PA (Vanhees et al., 2005).

2.3.1 Measuring and quantifying PA and exercise via subjective measures

The self-report method, which includes diaries, recall and questionnaires, is a subjective measure of PA with a number of limitations and some advantages. Although the self-report method is financially the cheapest way to collect PA data in

large numbers within a short period of time, it has five main limitations (Warren et al., 2010). The first limitation is that self-reporting cannot measure all three main aspects of PA: frequency, intensity and duration. For example, there are a number of questionnaires for measuring PA such as the International Physical Activity Questionnaire (IPAQ) and the Global Physical Activity Questionnaire (GPAQ) but none of the available questionnaires can measure and assess all three dimensions of PA (Warren et al., 2010). The second limitation is that self-reporting, particularly recall and questionnaires, is based on the memory of the respondents and their cognitive abilities to remember the three elements of PA. This memory differs from person to person based on age, as different ages have different responses to the self-report method (Warren et al., 2010). For example, questionnaires which are valid for young people are unsuitable for older individuals (Washburn, 2000), and cognitive ability differs in young people compared to adults, and declines with age (Warren et al., 2010). The third disadvantage with questionnaires is that they depend on ethnic groups and are influenced by different cultures. For instance, if a questionnaire is valid to measure PA in the American population, it does not mean that it is valid globally, it needs to be tested in different populations/cultures. The fourth disadvantage is that measuring PA by questionnaire can cause bias as respondents overestimate PA to meet social desirability (Warren et al., 2010). The last and most important disadvantage is that the self-report method, particularly questionnaires, is subjective, with low to moderate accuracy, and moderate to good reliability (Warren et al., 2010). In brief, the majority of previous studies found that self-report methods, particularly recall and questionnaires, did not measure PA accurately, and to measure the exact amount of PA with a high level of accuracy, objective measurements are

recommended (Anastasopoulou et al., 2014; Sallis & Saelens, 2000 & Warren et al., 2010).

2.3.2 Measuring PA and exercise via objective measures

There are many objective methods for measuring PA, and choosing the most appropriate method depends on several factors such as cost, ease of use, portability and acceptability to patients.

2.3.2.1 Measuring PA and exercise via objective measures but inappropriate for cardiac patients

Direct observation, doubly labelled water, and indirect or direct calorimetry are some of the objective methods to quantify or assess PA and exercise. Direct observation involves the motor activities being observed by an expert observer, but it consumes a lot of time and effort, although it is most suitable to use with children, as other techniques (such as questionnaires, accelerometers or pedometers) are less practicable (Vanhees et al., 2005). The doubly labelled water technique measures EE using two stable isotopes (H_2 and O) as water (H2O) but it takes from 5 to 14 days to analyse (Vanhees et al., 2005), it does not analyse information by time (Anastasopoulou et al., 2014) and it is very expensive to analyse (Vanhees et al., 2005). Indirect calorimetry is another objective technique for measuring PA; it does so by measuring oxygen consumption and carbon dioxide (Warren et al., 2010). Direct calorimetry measures heat production to quantify PA (Vanhees et al., 2005). All of the above-mentioned methods have high accuracy in measuring PA, as they subtract the resting EE from

the total EE but they are very costly (Anastasopoulou et al., 2014). Moreover, in practice with cardiac patients, all the above objective methods are unsuitable to use as they constrain the patient from doing exercise during CR.

2.3.2.2 Measuring PA and exercise via objective measures (accelerometers) that may be appropriate for cardiac patients

The suitable objective method in practice to quantify PA or exercise are motion sensor devices, including accelerometers or pedometers. These devices are used to measure and quantify free daily living activity, including exercise and PA. Motion sensors are valuable tools because even a small improvement in PA can produce an increase in fitness. Pedometers are used to monitor daily activity in the form of frequency of steps. The Yamax pedometer has been shown to be more valid than Pacer and Accusplit pedometers at slow-to-moderate walking speeds, but not as walking speeds increase beyond moderate intensity (Steele et al., 2003). A study of 52 healthy participants who wore a Yamax pedometer and a CSA accelerometer for 7 days found that the CSA accelerometer was more accurate than the Yamax pedometer. This may be because the CSA accelerometer is more sensitive (Tudor-Locke, Ainsworth, Thompson, & Matthews, 2002). Moreover, an accelerometer is a motion sensor device, which can quantify daily physical activity including exercise as a continuous variable, even at low levels of PA or exercise (Steele et al., 2003). Accelerometers are also used to give feedback about ambulatory activity and measure the exercise adherence of participants. Accelerometers measure frequency of steps and EE (Steele et al., 2003). Therefore, one of the most appropriate objective methods to quantify PA and exercise in CR is by accelerometer, as it is cheap and easy to use with cardiac patients and is portable during exercise sessions. An accelerometer can also provide

precise information for measuring the activity of daily living during unsupervised exercise sessions (Steele et al., 2003). Accelerometers and digital pedometers have been shown to assist in increasing exercise adherence by allowing self-monitoring (Steele et al., 2003). Regarding the reported validity of accelerometers, a cross-sectional study with 63 chronic obstructive pulmonary disease (COPD) patients showed that there was a strong relationship between accelerometer measurement and walking ability measured using the 6-minute walk test (Belza et al., 2001).

2.3.2.2.1 Uni-axial vs tri-axial accelerometers for quantifying PA and exercise

A study that compared uniaxial and tri-axial accelerometers found that a tri-axial accelerometer was more sensitive in detecting light activity, such as slow walking (Patterson et al., 1993) than a uniaxial device, as the uniaxial device measures movement in the vertical axis only, and cannot quantify movement with a static trunk, such as rowing or cycling. Moreover, there are two units on an accelerometer for measuring activity (activity count, or vector magnitude units [VMU]).

A systematic review was conducted of a number of studies that tested uni-accelerometer, tri-accelerometer and multi-sensors accelerometers in healthy individuals and patients with chronic disease in order to estimate EE and total energy expenditure (TEE) (Van Remoortel et al., 2012). On measuring TEE, the review concluded that the uni-accelerometer underestimated TEE compared to the tri-accelerometer, while it appeared less accurate compared with multi-sensors devices. In term of measuring EE, the review showed that the uni-accelerometer was slightly less valid for measuring EE compared with the tri-accelerometer and multi-sensors devices, but difference were not significant (Van Remoortel et al., 2012).

2.3.2.2.2 ActivPAL accelerometer

A study of 42 students tested the validity of an activPAL accelerometer during 5 minutes on the treadmill at different slow walking speeds of 0.45, 0.67, 0.90 and 1.33 metres per second, respectively. The authors found the activPAL to be a valid tool for measuring steps at slow walking speeds of 0.67, 0.90 and 1.33m.s (Kanoun, 2009). Another study tested the validity of an activPAL on 62 women walking on a treadmill at various speeds from 3.2 to 7 km/h; 18 of the 62 women also wore an actigraph. The results revealed that both the activPAL and the actigraph were accurate in measuring the step frequency at moderate walking speed, but the activPAL was more accurate than the actigraph at slow walking speeds, which gave the activPAL a distinct advantage for use in measuring low intensity physical activity or during sedentary living (Harrington, Welk, & Donnelly, 2011). Kozey-Keadle and colleagues (2011) also assessed the validity of the activPAL and actigraph during sedentary living in 20 healthy individuals aged between 46 to 57 years old. Participants wore an activPAL and actigraph (AG100) for two 6- hour periods compared to direct observation, and the results revealed that the activPAL was more valid and sensitive than the actigragh for detecting sitting times due to its in-built inclinometer. The correlation between the activPAL and direct observation was more than double that between the actigragh and direct observation (Kozey-Keadle, Libertine, Lyden, Staudenmayer, & Freedson, 2011). A crossover randomized controlled trial (RCT) tested the validity of an actiheart and CTX3 in estimating sedentary time and breaks in free living-conditions, using an activPAL as the reference. The results revealed that there was a low agreement between the actiheart

and GTX3 with the activPal in estimating sedentary time and breaks in free living-conditions (Júdice, Santos, Hamilton, Sardinha, & Silva, 2015).

2. 4 Combining two accelerometers to measure PA and exercise

A study testing 17 individuals performing different activities, including sitting, walking, standing, running, cycling and climbing stairs whilst wearing a tri-accelerometer on the thigh reported high levels of validity. The addition of a second hip-based tri-accelerometer enhanced the validity of the device further for measuring incidental PA during sitting, standing, and lying (Skotte, Korshøj, Kristiansen, Hanisch & Holtermann, 2014). Another study examined the frequency of steps using wrist and waist-attached accelerometers, and found that the waist-mounted device reported a higher frequency of steps than the wrist-worn device, in a laboratory environment, however, in free-living conditions, the wrist accelerometer counted a higher step frequency than the waist-worn accelerometer (2500 -8700 steps per day). The researchers concluded that measuring frequency of steps from accelerometers worn on the waist and wrist were not comparable (Tudor-Locke, Barreira, & Schuna, 2015).

Rosenberger et al (2013) evaluated the effect of wearing tri-axial accelerometers on the hip and wrist to estimate activity energy expenditure (AEE) during 20 different activities in 37 healthy individuals. Estimated AEE recorded by the accelerometer worn on the hip was more accurate than the wrist device. However, using a wearable accelerometer on the hip could not detect some arm movements (Steele et al., 2003).

2.5 Using accelerometers, pedometers and telemonitoring after CR

A randomised controlled trial (RCT) with 110 Australian patients attending a 6-week Phase II CR programme revealed that monitoring PA with a pedometer showed increased PA after a 6-week intervention, and this observation remained at 6 months follow-up. The 6-week intervention "included self-monitored physical activity using a pedometer and step calendar and 2 behavioural counselling and goal-setting sessions. Self-reported physical activity and psychosocial status were collected at baseline, 6 weeks, and 6 months" (Butler, Furber, Phongsavan, Mark, & Bauman, 2009, p. 1). The results also showed there was an increase in cardiorespiratory fitness after 6 months in the intervention group when compared to controls (Butler, Furber, Phongsavan, Mark & Bauman, 2009).

A pilot study was conducted to compare the use of pedometers and accelerometers in nine patients with coronary artery disease and found that there was a positive relationship between step frequency and calories "burned" measured by accelerometer and ventilatory gas analysis, but not by pedometer (Frederix et al., 2011). However, this was a pilot study and a larger, adequately powered study is needed to confirm this finding. A study with 80 Belgian patients with coronary artery disease using tri-axial accelerometers for telemonitoring during and after Phase II CR, employed an intervention group who wore accelerometers for 18 weeks, including 6 weeks of CR, and 12 weeks follow up. Patients received weekly feedback about their PA target goal, which was to achieve between 6500-8500 steps per day as this was " the recommended daily step count for the secondary prevention of cardiovascular disease" (Frederix et al., 2013, p. 3). The control group wore modified accelerometers, which did not allow the patient to monitor their PA levels. The PA was measured in the control group for 7 days from the beginning of CR, at week 6,

and in the last week of study. The study found an increase in VO2 peak, and a reduction in hospital readmission rate in the intervention group compared to controls (Frederix et al., 2013). However, the study did not aim to investigate the effect of a telemonitoring programme on PA levels during the CR intervention.

A RCT investigated the effectiveness of web-based CR in 94 UK-based patients with angina for improving PA after 6 weeks CR and then at 6-months follow up. Web-based CR was more effective for angina patients for increasing PA but the researchers advocated a larger, appropriately powered study in order to confirm the finding (Devi, Powell, & Singh, 2014). The authors did not quantify the exercise volume achieved during CR, and they did not monitor HR during or after the CR intervention.

Another trial measured the effect of mobile and internet-based CR on improving PA behaviour using international physical activity questionnaires at baseline, at discharge, and at 1 month and 3 months after discharge from a CR programme. They initially recruited 64 patients (although only seven patients in the intervention group and 12 controls completed the study), which limited the ability to draw firm conclusions (Antypas & Wangberg, 2014). A RCT in the Netherlands showed that telemonitoring, including accelerometer measurement for home-based CR, has similar effects to centre-based CR for outcomes including quality of life and exercise capacity during a 12-week programme (Kraal, Peek, Van den Akker-Van Marle & Kemps, 2014).

2.6 Using accelerometers during CR and the effect on exercise adherence

A US study including 25 males with CAD attending Phase III CR, measured PA for 7 days using uniaxial accelerometers. Habitual PA was higher on days when CR occurred than on other days, and those who did home-based exercise were more active

than those who did not. Monitoring PA could help encourage patients to reach their PA goals (Jones, Schneider, Kaminsky, Riggin & Taylor, 2007). However, the sample size was small and the researchers did not measure PA during the whole of phase III CR. A Japanese RCT assessed the PA of 126 patients undertaking a CR programme. The intervention group (n=63) monitored their PA but the controls (n=63) did not. Both groups had PA measured by a uni-axial accelerometer at baseline for 1 week, and 1 week before phase II. The PA in the intervention group was higher than the controls, suggested that monitoring PA influences PA behaviour (Izawa et al., 2012). The study did not quantify the amount of exercise during the CR intervention.

In 40 Japanese patients with chronic heart failure (New York Heart Association class 2 and 3) attending Phase III CR for one session per week for 5 months, were encouraged to walk for at least 20 minutes per day at RPE level 13. A uniaxial accelerometer monitored PA for 7 days at the start and end of the study. Cardiorespiratory fitness was measured before and after the 5 months of CR. There was a correlation between increased VO2 peak and the mean number of daily steps, but not to the time in moderate-to-vigorous PA (MVPA) during CR. Limitations of the study included only patients with CHF were recruited and the small sample size (Sato, Origuchi, Yamamoto, Takanaga, & Mohri, 2012) so we are unable to generalise these findings to larger, more heterogenous groups of patients with CVD.

In a French randomised controlled trial including 29 patients with stable CAD who had completed a CR intervention, PA was measured during 8 weeks of Phase II CR using a telephone support system and accelerometry. Controls used uni-axial accelerometry only. The intervention group produced nearly double the average EE of the controls during the eight weeks, indicating that telephone support system that

includes an accelerometer is effective in increasing adherence to PA (Guiraud et al., 2012). The authors would need to test the intervention on a larger, appropriately powered intervention.

2.7 Mobile phone service with accelerometer in CR

An Australian RCT compared 6 weeks of CR in a community centre with home-based CR using a mobile phone programme, including an accelerometer to measure the adherence to PA. The 6-week period included weekly sessions with a mentor who developed the first exercise session. Patients were asked to perform a daily home-based exercise session and the mentor monitored and assessed the patients' progress in PA and behavioural change. Patients also received a daily short message service (SMS) containing motivational material. The exercise target was to achieve moderate intensity PA for at least 30 minutes on most days of the week (Barr et al., 2007). After the 6-week intervention, patients were followed for 6 months without monitoring. The primary outcome was adherence to PA assessed by the 6-minute walk test, a pedometer was worn measuring walking activity over 7 days, and the Active Australia Survey was conducted at baseline, week 6, and after 6 months; the secondary outcomes were quality of life, risk factors, mobility and morbidity, medication compliance and psychological function (Walters et al., 2010). At this time, the study is still recruiting and study results will be published in due course. The protocol did not quantify the amount of exercise conducted during the CR programme.

2.8 Measuring exercise load

Exercise load can be classified by internal and external load. Measuring internal load can be carried out using HR or perceived exertion rate (session RPE), while external load can be measured with an accelerometer, GPS or by distance completed (Akubat, Barrett, & Abt, 2014). There are a number of methods for measuring training load, such as Banister's (1991), Edwards'(1993) and Lucia et al (2003) session RPE, and individual Training IMPulse (TRIMP).

2.8.1 Edwards TRIMP

Edwards (1993) suggested five training zones, as shown in Table 1 below. To calculate the training load, the coefficient is multiplied by the time spent in the zone (Akubat, 2012).

Table 1. Edwards' zones (1993)

Heart Rate Zones	**Coefficient**
50-60%	**1**
60-70%	**2**
70-80%	**3**
80-90%	**4**
90-100%	**5**

The limitation of this method is that the coefficient has no physiological base and the zone limits are not related to any physiological or metabolic threshold (Akubat, 2012). Moreover, the weightings used are not valid against any physiological response (Akubat, 2012).

2.8.2 Lucia's TRIMP

Lucia and colleagues based their measurements on ventilatory thresholds (VT1, VT2) and utilise three zones: the first zone is low (> VT1), the second zone is moderate (VT1-VT2), and the third zone is high (> VT2). The time spent in each zone is multiplied by the zone number. The limitation of this method is that there is no underpinning validation of this approach (Akubat, 2012).

2.8.3 Individualised TRIMP

Individualised TRIMP was developed by Manzi et al. (2009) and measures HR at the individual level during a training session. The calculation in this method is based on heart rate and blood lactate response to gradual exercise and does not give an arbitrary number. However, this method has some practical difficulties, such as relatively high associated costs, and the need for blood analysis (Akubat, 2012).

2.8.4 Banister's TRIMP

Banister's (1991) TRIMP is a method of measuring internal exercise load and it was Banister's hypothesis that each training session creates a fatigue impulse and a fitness impulse (Akubat, Barrett, & Abt, 2014). Banister measured exercise intensity using

the mean HR or HR reserve during a whole session and then multiplied it by the duration, as explained in the following equation:

time (mins) x ΔHR x y

Where Y is the weighting factor (Akubat, 2012).

2.8.5 Session RPE

Session RPE is a subjective method of measuring exercise load. To calculate session RPE, the duration of the training session is multiplied by the intensity of the session (Akubat, 2012). The intensity ranges from 0-10, and there is a relationship between session RPE and HR, with a very good correlation (r = 0.89) (Gabbett & Domrow, 2007). Previous studies have shown that Banister's TRIMP is related to session RPE (Akubat, 2012) and, by using these two methods, we can state that we can quantify exercise both subjectively and objectively in our thesis.

2.8.6 Using session RPE and TRIMP with cardiac patients

A study compared session RPE against TRIMP in 20 male patients with stable chronic heart failure. All patients taking beta-blockers, were randomised to either aerobic continuous or interval training for 12 weeks. The internal load was quantified during the exercise training sessions. For each session, TRIMP was measured and session RPE calculated using the Foster scale (0 to 10). Patients used the treadmill twice per week for the first three weeks, then three times per week for the second three weeks, and four times per week for the third three weeks, finally, five times per week for final three weeks. Patients in the aerobic continuous exercise group walked on the treadmill for the 30-45 min at 45-60% HRR, whilst the patients undertaking interval

training completed 4 minutes walking at 75-80% HRR between 2-4 occasions with active recovery for 3 minutes at 45-50% HRR. Each session RPE was recorded 30 minutes after finishing each exercise session. 16 patients completed the study and 4 patients withdrew. Session RPE was reported as a useful method for prescribing exercise in cardiac patients (Lellamo et al., 2014).

2.9 Combining heart rate monitoring and an accelerometry for monitoring PA

Combing HR monitoring with an accelerometer gives more accurate data for estimating EE, as the advantages of both devices can be combined to provide more valid and reliable data for measuring PA in adults and children (Warren et al., 2010; Vanhees et al., 2005).

2.10 Heart rate monitoring to quantify the amount of PA and exercise

Another objective measure to quantify PA and exercise intensity is heart rate (HR) monitoring. HR monitoring has been validated in many studies against doubly labelled water and indirect calorimetry methods to estimate EE (Livingstone, et al, 1990; Livingstone, et al. 1992; Spurr et al., 1988). Moreover, there is a linear association between EE and HR monitoring (Li, Deurenberg & Hautvast, 1993) during MVPA (Vanhees et al., 2005). However, there are many factors that can affect this relationship, such as sex, age, and baseline fitness level (Dugas, Van Der Merwe, Odendaal, Noakes, & Lambert, 2005).

2.11 The gold standard method of heart rate monitoring

The gold standard method for measuring heart rate is via 12-lead electrocardiography (ECG), however, in practice it is diffcult to measure outside of the laboratory, and is impractical during CR. Polar HR monitoring has been succesfully validated against ECG for measuring HR during exercise (Lee & Gorelick, 2011; Vanderlei et al .,2008 & Weippert et al ., 2010).

2.12 Polar HR monitoring

The measurement of HR during acute exercise is one of the most common and pragmatic methods for estimating exercise intensity and prescribing exercise-training thresholds (Anastasopoulou et al., 2014; Warren et al., 2010). Similarly, heart rate recovery following acute maximal or sub-maximal exercise is a well-accepted method for characterising cardiorespiratory fitness and predicting mortality risk (Cole et al., 1999 ; Shetler et al ., 2001). Although the 12-lead electrocardiogram (ECG) may be the 'gold standard' for measuring HR, the ECG monitoring equipment may be impractical or unrealistic for use outside of laboratory settings. Surrogate measures including HR monitors that connect wirelessly to an in-situ chest strap have been successfully validated against 12-lead ECG devices for measuring HR and heart rate variability at rest and during exercise (Lee & Gorelick, 2011; Vanderlei et al .,2008 & Weippert et al ., 2010). Weippert and colleagues (2010) examined a 5-lead ambulatory ECG system against a Polar S810i and Suunto t6 during 10 minutes of supine rest, 10 minutes of light walking, followed by 5 minutes of moderate-to-high isometric upper and lower limb exercise with 5 minutes rest between each exercise. They found that the R-R intervals between the devices was similar, with excellent

ICC (> 0.99) (Weippert et al., 2010). In another study, 25 healthy individuals performed 3 minutes of standing, followed by walking at 3.2 km-h^{-1} , brisk walking at 5.6 km-h^{-1}, jogging at 7.2 km-h^{-1}, and running at 9.6 km-h^{-1}. The study tested heart rate measured by 12-lead ECG versus Polar HR monitoring and found excellent associations between the devices for all exercise intensities and at rest (r= 0.95-0.98) (Lee& Gorelick, 2011).

2.13 Photoplethysmoygraphy (PPG)

Photoplethsmoygraphy (PPG) is a non-invasive optical technique taking measurements at the skin surface to detect beat-to-beat changes in heart rate by measuring changes in blood volume in microvascular tissue and converting these changes into blood flow (Allen, 2007; Priyadarsini & Priyameenakshi, 2015). The PPG technology uses a light source and a sensor or detector to detect changes in blood volume. The light is required to illuminate the tissue and the detector is used to measure the change in light intensity with the change in blood volume (Allen , 2007). Pulsated blood can be detected by the PPG signal if there is no change in blood flow (Priyadarsini & Priyameenakshi, 2015).

2.14 Features of the Apple watch device

The Apple watch includes PPG technology to measure heart rate, and includes a tri-axial accelerometer for measuring frequency of stepping. There are currently four series of watches with little technological differences between them.

2.15 Apple watch studies

There are few validation studies that have examined the Apple watch for measuring HR. Wallen and colleagues (2016) compared the Apple watch against three other smart watches (Fit Bit, Mio Alpha and Samsung Gear S) during a 1-hour protocol of low exercise intensity, seated and supine rest, walking and running on a treadmill and cycling on an ergometer, in 22 healthy males and females (Wallen et al., 2016). The authors reported a mean (SD) difference of -1.3 (4.4) beats.min^{-1}, and limits of agreement of -9.9 to 7.3 beats.min^{-1} between the Apple watch and an ECG. The Apple watch was the most accurate smartwatch compared with the others, as the mean difference between the Apple watch and the ECG was -1.3 to 4.4 beats.min^{-1}; it was -24 to 7.4 beats.min^{-1} between the Fitbit Charge and the ECG; -27.3 to 13.1 beats.min^{-1} between the Samsung Gear S and the ECG; and 4.4 to -0.44 beats.min^{-1} between the Mio Alpha and the ECG. However, HR was recorded manually and the process by which HR data were extracted was not clearly explained.

A second study by Wang and collagues (2017) examined the validity of the Apple watch compared to an ECG and Polar heart rate monitor (in conjunction with a chest strap) in 50 apparently healthy males and females. Participants exercised on a motorised treadmill at 3.2 km.h^{-1}, 4.8 km.h^{-1}, 6.4 km.h^{-1}, 8 km.h^{-1}, and 9.6 km.h^{-1}, for 3 min per stage whilst wearing two of the four wrist-worn devices (Fitbit Charge HR, Apple watch, Mio Alpha, and Basis Peak). There was a correlation of r =0.91 (95%CI: 0.88 to 0.93) between the Apple watch and the ECG (Wang et al., 2017). The limits of agreement ranged from -27 to +29 beats.min^{-1} compared to the ECG. However, HR was only taken once manually at the end of each 3-min stage, which is a serious

limitation and raises the questions how well each data point represents the true mean HR. There was also no indication regarding which wrist the Apple watch was worn.

A recent study measured the HR from an Apple watch against an ambulatory ECG patch (ePatch) for approximately one week in 226 participants who had a relatively common cardiac arrhythmia, atrial fibrillation (AF). The Apple watch detected AF accurately in most instances (FDA, 2018).

Falter et al (2019) assessed HR responses in 40 cardiac patients (32 male and 8 female), including ischaemic patients (28/40), and valve replacements (9/40). Patients were prescribed beta-blockers, however, none had any form of diagnosed arrhythmias. All patients wore an Apple watch on the left wrist, which was validated against 12-lead ECG and indirect calorimetry at rest, moderate intensity, and high intensity exercise during a cardiopulmonary exercise test (CPET). Heart rate was measured for 30 seconds, and ECG measurements were taken constantly from rest until the end of the CPET. Step frequency recorded by the Apple watch was compared to indirect calorimetry. The study reported that the Apple watch could measure HR accurately in cardiac patients during exercise but its step frequency was overestimated. The correlation between the Apple watch and the ECG was moderate (0.729) during rest, good (0.828) during moderate exercise, and excellent (0.958) during high intensity exercise (Falter et al., 2019). A good feature of this study was that heart rate was measured with no arm movement; any effect of arm motion was avoided. However, patients with common arrhythmias including AF were excluded therefore we cannot generalise the findings of this study to a broader group of cardiac patients.

Thomson and colleagues (2019) examined the validity of the Fitbit Charge 2 and the Apple watch against ECG during treadmill exercise (Bruce protocol in 30 young, apparently healthy individuals (18-30 years), for very light (<20% HRR), light (20–40% HRR), moderate (40–60% HRR), vigorous (60–85% HRR), and very vigorous (>85% HRR) exercise intensities. The Apple watch had lower relative error rates than the Fitbit Charge 2 during all exercise intensities. The infrared light and one extra photodetector available in the Apple watch may allow more accurate measurement of heart rate with less error than the Fitbit Charge 2. The researchers also found that both the Apple watch and Fitbit have acceptable validity at very light to light intensities (ICC=0.98), however, the validity decreased as the exercise intensity increased. The Apple watch and Fitbit Charge 2 both underestimated the HR during all exercise intensities except the very light intensity but the average difference was not more than 6 beats per minute (Thomson et al ., 2019). The study was conducted in young people only, and it is unclear how the Fitbit Charge 2 would have dealt with patients with cardiac arrhythmias including AF.

The Apple watch can measure heart rate variability (HRV) accurately during rest and under stress. Twenty healthy individuals wore an Apple watch on the left wrist and a Polar H7 on the chest (Hernando et al., 2018). The study showed that the Apple watch could measure HRV parameters (SDNN, RMSSD, pNN50 and HRM) accurately during rest and stress periods. The RR intervals showed excellent validity and reliability compared to the Polar H7 and these results agree with previous studies (Wallen et al., 2016; Wang et al., 2017; Khushhal et al., 2017 & Abt , Bary & Benson, 2017).

A recent study by Abt and colleagues (2017) showed that the Apple watch has good to very good performance in measuring maximum heart rate (Abt , Bary & Benson , 2017). The study measured the heart rate on the treadmill at 3 km/h increasing by 0.5 km/h every 30 seconds. Each participants wore an Apple watch on both hands and Polar T31. The Apple watch was found to have very good to good validity in measuring the maximum heart rate, compared to the Polar T31.

Sixty-two healthy participants (36 female and 26 male) aged between 18 to 38 years wore a Garmin Forerunner 225, Fitbit Charge HR and Apple watch, which were compared with a Polar T31 chest strap to test the validity of these devices for measuring heart rate and step number. All participants completed 10 minutes baseline assessment time then four separate stages on the treadmill; three minutes each at 2.5 mph, 3.5 mph, and 5.5 mph with 1 minute break between each stage, followed by cooling down for 10 minutes. The heart rate was assessed every 3 minutes in each stage. The EE was assessed during all stages. The Apple watch had the strongest correlation (r=.59-.99) with the Polar T31 for measuring heart rate and had lower errors in reading heart rate. The error in the accuracy of heart rate was lower for the Apple watch during all stages, compared to the other smartwatches (Garmin Forerunner 225 and Fitbit Charge HR). The Apple watch was similar to Polar heart rate monitoring at start, baseline and during vigorous exercise, but gave a lower heart rate reading during light and moderate exercise and in recovery from exercise. However, 47% of the participants had non-white skin, which may affect the accuracy of heart rate results especially for the Apple watch (Dooley, Golaszewski & Bartholomew, 2017).

2.16 Measuring exercise intensity in CR

Exercise intensity in CR can be prescribed or estimated based on many methods such as the Borg scale rating of perceived exertion, talk test, feeling scale, OMNI scale, % heart rate reserve, target heart rate , % Vo_2peak, % Vo_2reserve. Heart rate reserve, target heart rate, % Vo_2peak, % Vo_2reserve are objective measures for measuring exercise intensity during exercise sessions, while the talk test, feeling scale, OMNI scale, and perceived exertion scale are subjective measurements. The talk test, feeling scale and OMNI scale are rarely used in practice, while the commonly Borg scale rating of perceived exertion, target heart rate exercise, %HRR %, Vo_2peak, and % Vo_2reserve can be used to detect exercise intensity in practice during CR (American College of Sports Medicine, 2013; Perk et al.,2012). Predicting maximum HR/target HR via the formula"220-age" can be used to estimate exercise intensity but it can be overestimated or underestimated using this method (American College of Sports Medicine, 2013, p.168). Another method to estimate exercise intensity is the metabolic equivalent (METs) but it could lead to misclassification as it does not consider indivdual factors such as age, sex, fitness level and body weight. Therefore, using %HRR or %Vo_2 reserve may be the most preferable method to measure exercise intensity. In UK CR, %HRR is commonly used to estimate intensity of exercise in conjunction with ratings of perceived exertion.

2.16.1 Borg and Foster RPE scale

The Rating of Perceived Exertion (RPE) is a subjective means of measuring exercise intensity or PA. There are two main scales. The first is Borg's Ratings of Perceived Exertion scale, which rates from 6 (no exertion at all) to 20 (maximum exertion) and

is commonly used in patients with cardiac disease. The second scale is the Foster RPE, which rates from 0 (nothing at all) to 10 (extremely strong). Both the Borg and Foster scales have shown validity and reliability when used with healthy individuals and clinical patients (Ritchie, 2012).

2.17 Health-related quality of life questionnaire

Measuring health-related quality of life is essentail in CR to measure individual changes as a consequence of participating in the CR programme (National Heart Foundation of Australia., 2010). There are general and specific health-related quality of life questionnaires. The specific questionnaires are typically used for a specific disease group such as ischaemic heart disease or chronic heart failure. General questionnaires are commonly used in broader patient groups (National Heart Foundation of Australia., 2010). Examples of specific questionnaires include the Kansas City Cardiomyopathy Questionnaire (KCCQ) (Green, Bresnahan & Spertus, 2000), and the Minnesota Living with Heart Failure Questionnaire (Rector, Kubo & Cohn, 1987), both of which are used in patients with chronic heart failure (National Heart Foundation of Australia, 2010) and the HeartQoL questionnaire (De Smedt et al ., 2016) and MacNew questionnaire (Valenti, Heller & Knapp, 1996) which are usually used in patients with ischaemic heart disease (National Heart Foundation of Australia, 2010).

General health- related quality of life questionnaires used in cardiac patients include the SF-36 questionnaire and the Duke health profile for assesment of quality of life (National Heart Foundation of Australia, 2010). In the UK, the SF-36 is the most commonly used in patients with cardiac disease; however, it is a long questionnaire

containing 36 items which can be off-putting to some patients. A shorter, 12-item version (SF-12) has been developed which has retained similar levels of validity and reliabilty as the longer version in patients with coronary heart disease (Müller-Nordhorn & Willich, 2004). The SF- 12 questionnaire takes about five minutes to complete (Ware Kosinski & Keller, 1998), and is easier for patients to manage (Müller-Nordhorn & Willich, 2004).

The SF-12 health-related quality of life questionnaire has two aspects. The first one is a physical aspect or physical component summary (PCS), and the second one is an emotional dimension or mental component summary (MCS) (Shepherd & While, 2012). The minimum clinincally significant difference in the SF- 12 PCS is 8.8 points and in the SF- 12 MCS it is 9.3 points (Parker et al ., 2012) but another study showed that minimum clinincally important difference in the SF- 12 PCS is 8.1 points and in the SF-12 MCS, 4.7 points (Parker et al ., 2013). There are two versions of the SF-12 questionnaire. The difference in the scores may be minor due to the difference in scoring system between version 1 and 2 (Orthotoolkit, 2017). The SF- 12 questionnaire is often used in the US population, however, there is little difference between scores between the UK and US populations (Ware Kosinski & Keller, 1998). The average score for the SF-12 questionnaire is 50 points for both PCS and MCS and the standard deviation is 10 points (Orthotoolkit , 2017).

2.18 Fitness tests (Maximum and sub maximum tests)

A maximal intensity cardiopulmonary exercise test (CPET) is the “gold standard” test to measure directly individual levels of cardiorespiratory fitness. Maximal protocols include the Bruce or modified Bruce treadmill tests. The difference between them is

that the modified protocol has a lower starting intensity for patients with lower levels of baseline fitness (Noonan & Dean, 2000). In clinical practice in the UK, it is very rare to conduct a maximal test due to safety concerns (Noonan & Dean, 2000), therefore submaximal alternative tests are regularly used in practice. These tests include the 6-minute walk test, incremental shuttle walk test, step tests e.g. Chester, and submaximal cycle ergometer tests (American College of Sports Medicine , 2013). Submaximal tests use predictive equations to estimate cardiorespiratory fitness in patients. The 6-minute walk test is a self-paced test to measure the furthest distance covered in 6 minutes; it is often used in patients with cardiac and pulmonary disease who may be at an increased risk (Noonan & Dean, 2000; ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002). A significant association between the 6-min walk test and directly measured Vo_2peak ($r = 0.78$) has been previously reported in patients with respiratory disease (ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002).

The incremental shuttle walk test (ISWT) measures distance walked during a 10 meter course, starting at low speed which gradually increases every minute for 12 levels. There is a strong association between the distance walked and Vo_2peak in patients with coronary heart disease (Fowler , Singh & Revill, 2005). The minimum clinically important different (MCID) in the 6-min walk test and the ISWT was 86 meters in patients with COPD (Wise & Brown, 2015). However, the MCID for the ISWT after patients engaged in CR was 70 meters (Houchen-Wolloff, Boyce, & Singh, 2015).

There are many different cycle ergometer protocols including the YMCA and the modified YMCA protocol. The original YMCA test consisted of three-minute stages

where the participants started at 25 Watts, the HR in the final 15 seconds of the stage was used to determine the workload for the next stage. The modified YMCA protocol used 4-minute stages in order to more likely achieve a steady state heart rate (Akalan, Robergs & Kravitz, 2008). In the community-based Phase III CR programme based in Hull, a submaximal cycle ergometer protocol is used to determine patient outcomes. Patients cycle for approximately 10 minutes with an initial workload of 25 Watts (with two-minute increments). Heart rate and RPE is recorded every minute. Higher-risk patients perform the 6-min walk test.

2.19 Exercise adherence during CR programmes

There is a strong relationship between high adherence to CR programmes and longer-term survival, as attending all 36 sessions of CR was associated with lower risk of MI and death at 4 years, compared to attending fewer than 36 sessions (Hammill, Curtis, Schulman & Whellan, 2010) Participation in UK CR programmes is low with 20-50% of eligible cardiac patients choosing to engage in CR programmes (Dalal, Doherty &Taylor, 2015). In reality, there are many reasons why adherence is low, for example, difficulty getting to the venue, dislike of group-based exercise, lack of time to attend classes, lack of support from general practitioner, etc (Dalal, Doherty & Taylor, 2015).

2.20 Cardiorespiratory fitness changes and CR

A metabolic equivalent (MET) is a unit used to measure the cost of an activity and is defined as "…the resting metabolic rate, that is, the amount of oxygen consumed at

rest, sitting quietly in a chair, approximately 3.5 ml O_2/kg/min (1.2 kcal/min for a 70-kg person)" (Jette, Sidney, & Blümchen, 1990, p. 1). A 1-MET increase in cardiorespiratory fitness (CRF) could result in a 13% risk reduction in all-cause mortality and 15% in cardiovascular disease events (Lee, Artero, Sui & Blair, 2010), while a 1% increase in VO_2peak is associated with a 2% reduction in mortality risk (Vanhees, Fagard, Thijs & Amery, 1995). A recent meta-analysis tested the change in CRF during a CR programme, the mean improvement in CRF from 31 international studies was 1. 55 METs. Based on this result, the reduction in cardiac mortality should be between 16-54%, and an improved CRF led to a decrease in mortality and morbidity risk, and increased quality of life (Sandercock, Hurtado & Cardoso, 2013).

2.21 Secondary prevention strategies

The cornerstone of secondary prevention strategies is comprehensive CR, including dietary advice, educational support, and psychological counselling (BACPR, 2012 ; Nice, 2013), American (Balady et al., 2007) and European (Piepoli et al ., 2014). However, UK CR programme often lack these core components (Brodie, Bethell & Breen , 2006) and is mainly focused on the exercise component.

2.22 Exercise and CR

Structured exercise is a main component of CR. CR has been shown to improve the CRF and quality of life in cardiac patients, contributing to decreased mortality risk and reduced hospital re-admission rates (Perk et al., 2012). Exercise classes within the community normally focus on circuit type exercises following an interval

approach. UK CR guidelines suggest that exercise intensity should be between 40–70 % HRR (BACPR, 2012; ACPICR, 2015; Nice, 2013). Previous research has quantified exercise volume before and after CR (Sandercock, Cardoso, Almodhy & Pepera, 2013), but not during an active CR programme in the UK.

2.23 CR in the UK

A multicentre RCT of comprehensive CR in patients following myocardial infarction (MI) (RAMIT trial) compared two groups of patients: the first group comprised patients who were referred to CR after MI; the control group contained patients following MI who were treated with the usual approach of care. Study outcomes were mortality at 2 years and after 7-9 years, health-related quality of life, and general well-being at 1 year. The study revealed that CR had no valuable effect on reducing cardiac mortality, morbidity, and health-related quality of life, however, the study did not measure CRF (West, Jones & Henderson, 2012). A separate retrospective cohort study examined the change in CRF and quantified exercise volume before and after CR in 950 patients in four different centres in the UK. The average improvement in the four centres was an increase in CRF of 0.52 METs, which is only one third of what was expected from the meta-analysis of international studies (mean increase = 1.55 METs) (Sandercock et al., 2013). This small improvement reflects the low exercise volume provided by UK CR programmes when compared to international studies (Sandercock et al., 2013). Sandercock and colleagues suggested that more trials and systematic reviews are required to confirm these data. They also suggested increasing funds for CR to raise the frequency and duration of exercise sessions and to focus on making behavioural changes including increasing patient motivation and

adherence to exercise training (Sandercock et al., 2013). The sample size for this study was large, which is effective for testing changes in CRF, but there was no control group and the cohort design did not allow the authors to quantify how much improvement in CRF occurred per CR session. Another limitation was that the assessment tests for CRF differed between centres. The retrospective design is also a limiting factor as issues such as level of patient motivation between and within the four centres could not be influenced. Ingle and Carroll (2013) strongly agreed that the low volume of prescribed exercise in the UK could cause the low CRF reported, adding that submaximal testing was a weakness in UK practice which was contributing to the issue.

A meta-analysis conducted by Almodhy and colleagues (2016) aimed to determine the changes in CRF elicited by UK CR programmes. The authors found 11 studies which matched their criteria relating to 1,578 patients using the ISWT as the mode of exercise. The mean improvement in ISWT was 84 meters following CR. Based on this finding, they estimated that the MET change was between 0.4-0.8 METs. The researchers reported the effect size (ES) for the change in CRF was 0.48 (Almodhy, Ingle & Sandercock, 2016), which was similar to their previous systematic review (ES:0.49) (Sandercock et al., 2013). Both of these effect sizes were less than half of what has been reported from international studies (ES: 0.98) (Almodhy, Ingle & Sandercock, 2016). A recent UK-based systematic review which included 22 studies with 4,834 patients reported that CR has zero effect on all-cause mortality, and a small effect on cardiovasular mortality and hospital re-admission rates (Powell et al ., 2018). However, this review did not measure the effectivness of CR for other outcomes measurements including CRF and quality of life.

2.24 Rationale for the studies within the thesis

To date, there have been no studies which have directly evaluated the effectiveness of Phase III CR in the UK by measuring exercise intensity and training progression using telemonitoring methods. However, data is not available to show whether the Apple watch is an appropriate device for measuring frequency of stepping and heart rate responses during exercise. Therefore, our initial studies were to determine the validity and reliability of the Apple watch. Dependent on the findings of our initial studies, we aim to apply the Apple watch to a Phase III CR programme in order to quantify exercise intensity and training progression.

2.25.0 Aims and Hypotheses:

2.25.1 Aim and hypothesis for study one

Aim: to test the validity and reliability of the Apple watch for measuring frequency of stepping during rest, walking, jogging, and running in apparently healthy adults.

Research hypothesis (H_1): The Apple watch is a valid and reliable device for quantifying stepping frequency during rest, walking, jogging, and running in apparently healthy adults.

Null hypothesis (H_0): The Apple watch is not a valid and reliable device for quantifying stepping frequency during rest, walking, jogging, and running in apparently healthy adults.

2.25.2 Aim and hypothesis for study two

Aim: to test the validity and reliability of the Apple watch for measuring heart rate during rest, walking, jogging, running, and recovery in apparently healthy adults.

Research hypothesis (H_1): The Apple watch is a valid and reliable device for quantifying heart rate during rest, walking, jogging, running, and in recovery in apparently healthy adults.

Null hypothesis (H_0): The Apple watch is not a valid and reliable device for quantifying heart rate during rest, walking, jogging, running, and in recovery in apparently healthy adults.

2.25.3 Aim and hypothesis for study three

Aim: To investigate the fidelity of a structured Phase III community-based CR programme in the UK, by monitoring and quantifying exercise training intensity over an eight-week intervention period.

Research hypothesis (H_1): The mean exercise intensity achieved during an 8-week Phase III CR programme is below the minimal national guidelines for exercise prescription of 40% HRR in patients with CHD.

Null hypothesis (H_0): The mean exercise intensity achieved during an 8-week Phase III CR programme is not below the minimal national guidelines for exercise prescription of 40% HRR in patients with CHD.

2.25.4 Aim and hypothesis for study four

We divided the aims and hypotheses into two sections for this study:

Aim 1: To investigate the weekly progression in duration of cardiovascular training over an 8-week Phase III CR programme based in the UK.

Research hypothesis (H_1): The weekly progression in duration of cardiovascular training increased over an eight-week intervention period.

Null hypothesis (H_0): The weekly progression in duration of cardiovascular training remained unchanged over an eight-week intervention period.

Aim 2: To investigate the weekly progression in intensity of cardiovascular training over an 8-week Phase III CR programme based in the UK.

Research hypothesis (H_2): The weekly progression in intensity of cardiovascular training increased over an eight-week intervention period.

Null hypothesis (H_0): The weekly progression in intensity of cardiovascular training remained unchanged over an eight-week intervention period.

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Chapter 3: Validity and variability of the Apple watch for quantifying stepping frequency during submaximal exercise

3.1 Abstract

The aim of this study was to examine the validity and variability of the Apple watch for quantifying stepping frequency. On two occasions, 21 males completed treadmill exercise while wearing two Apple watches (left and right wrists) and an ActivPAL (criterion). Exercise involved 5 min bouts of walking, jogging, and running at speeds of 4 $km \cdot h^{-1}$, 7 $km \cdot h^{-1}$, and 10 $km \cdot h^{-1}$, followed by 11 min of rest between each bout. There was a small under-estimation in step count during walking but large and very large over-estimations during jogging and running. There were poor to very poor correlations during walking, jogging and running. The inter-device variability showed

good to nearly perfect intraclass correlations and small to moderate standardised typical errors. Intra-device variability was large to very large for all exercise intensities. The Apple watch has adequate validity for measuring stepping frequency during walking, but very poor validity during jogging and running.

Key words: steps number, accelerometer, smartwatch

3.2 Introduction

Previous studies investigating methods of quantifying physical activity have reported that subjective methods, particularly recall, diaries and questionnaires, do not measure physical activity accurately (Bussmann, Ebner-Priemer and Fahrenberg, 2009; Warren et al., 2010), or are either not practical to use or too costly. As a consequence, objective measurements are recommended (Anastasopoulou et al., 2014; Sallis & Saelens, 2000 & Warren et al., 2010), with the accelerometer being considered as the "gold standard" for measuring daily physical activity, including exercise (Anastasopoulou et al., 2014). For example, the validity of the ActivPAL accelerometer has been examined in a number of studies, and was found to be highly accurate for measuring daily physical activity compared to other accelerometers (Harrington, Welk and Donnelly, 2011;

Kanoun , 2009 & Kozey-Keadle, Libertine, Lyden, Staudenmayer & Freedson , 2011). Harrington, Welk, and Donnelly (2011) examined the validity of the ActivPAL in 62 women when walking on a treadmill at various speeds from 3.2 $km \cdot h^{-1}$ to 7 $km \cdot h^{-1}$. Results showed that the ActivPAL step count was not statistically different from direct observation at moderate walking speeds of 4.8 $km \cdot h^{-1}$ to 7 $km \cdot h^{-1}$. Ryan, Grant, Tigbe and Granat (2006) reported that the absolute percent error for the ActivPAL was < 1% for step count, regardless of the walking speed.

Although accelerometer-based devices such as the ActivPAL are valid and reliable for measuring physical activity under free-living conditions, they are more suited to the research environment and are cumbersome to wear. A practical alternative is a consumer device such as the Apple watch, which is a wrist-worn 'smartwatch' that uses an embedded accelerometer to measure stepping frequency. While the Apple watch is reported to be the world's highest selling smartwatch (Canalys, 2016), there are very few studies that have examined its validity for measuring stepping frequency under controlled conditions. It is important to examine the validity and variability of modern wearable devices because stepping frequency is promoted as a useful indicator of the level of physical activity for an individual (Strath et al.,2013; Warren et al., 2010) and has also been reported to be related to health and well-being (Van Remoortel et al., 2012). To our knowledge, there has been only one recent study that has examined the validity of the Apple watch for measuring total stepping frequency compared with direct observation (Wallen, Gomersall, Keating, Wisloff and Coombes, 2016). These authors reported a strong correlation (r = 0.70) between the Apple watch total stepping frequency and direct observation total stepping frequency. However, the study only reported total stepping frequency following a range of activities including treadmill exercise (Bruce protocol) and cycling, with the individual treadmill speeds,

grades and step counts not reported. Moreover, the standard Bruce treadmill protocol uses grades starting at 10%, which may not reflect the type of exercise performed under free-living conditions. The study also didn't examine the intra- or inter-device variability (reliability) in stepping frequency for the Apple watch. The current study therefore investigated the validity and variability of the Apple watch for measuring stepping frequency during dedicated treadmill exercise across a range of exercise intensities.

3.3 Methods

3.3.1 Study population

The study was approved by the departmental human ethics committee with written informed consent obtained from all participants prior to commencement of the study. All participants were apparently healthy, not taking any form of medication, and aged >18 years. Participants with a diagnosis of cardio-metabolic disease were excluded. Twenty-nine healthy male participants were recruited for the study. Eight did not complete the study; one participant withdrew due to an unrelated injury and seven were excluded as they were not fit enough to complete all three exercise intensities (walking, jogging and running). Twenty-one healthy male participants (mean (SD) age 31.4 (7.2) y; BMI 26.1 (2.9) $kg{\cdot}m^{-2}$) completed the study. Twenty participants were right-hand dominant. Step count data from one participant was lost (right Apple watch) during running in trial 1 due to a data recording error.

3.3.2 Experimental design

Participants visited the exercise testing laboratory on three separate occasions. The first visit was used to screen participants for eligibility and to familiarise them with the exercise protocol. The second visit was the first testing session, and included walking, jogging, and running on a treadmill (GE T 2100 treadmill) at 1% incline for 5 min at 4 $km \cdot h^{-1}$, 7 $km \cdot h^{-1}$, and 10 $km \cdot h^{-1}$, respectively. These speeds were selected based on pre-study pilot testing and were mean values representing walking, jogging, and running speeds. Each bout of exercise was followed by approximately 11 min of rest. The final visit replicated the testing protocol conducted in the second visit. The mean (SD) days between the second and third sessions was 7 (4). All testing visits were scheduled at the same time of the day. All participants were advised not to eat a large meal or consume caffeine for at least three hours before testing, and to avoid moderate to vigorous physical activity in the 24 hours before testing.

3.3.3 Instrumentation and data acquisition

During each trial participants wore an ActivPAL (ActivPAL 3 MTM) and two Apple watch Sport devices (one on the left wrist and one on the right wrist) (Series 0, watchOS 2.0.1, Apple Inc., California, USA). Both Apple watches connected wirelessly via Bluetooth to two iPhone 5S smartphones (Apple Inc., California, USA). After exercise, the step data were transferred from the ActivPAL (ActivPAL 3 MTM) to the ActivPAL software. The Apple watch 'Workout' app was used to measure step count. On cessation of each trial the step data were synced automatically to the 'Health' database on its paired iPhone. To retrieve the raw step data from the Health database a bespoke iPhone app was written. The bespoke app was written in Xcode 7.2.1 using

the language Swift 2.1 and using the methods provided by the HealthKit framework (Apple Inc., California, USA).

3.3.4 Statistical analysis

Data were log transformed prior to analysis to avoid bias resulting from non-uniformity of error. All data were analysed using custom-designed Microsoft Excel spreadsheets (Hopkins, 2015). Mean and standard deviation (SD) are used to report descriptive data. We used the standardised typical error of the estimate, standardised mean bias and Pearson correlation to measure validity. Standardised typical error and intraclass correlation were used to assess inter- and- intra-device variability. Precision in our estimates of validity and variability are reported as 90% confidence intervals. The following definitions were used to interpret the strength of the Pearson product moment coefficients used to measure the validity of the step count data, and the intraclass correlation coefficients used to measure the inter- and intra-device variability: very poor (r = 0.45 to 0.69), poor (r = 0.70 to 0.84), good (r = 0.85 to 0.94), very good (r = 0.95 to 0.994) and excellent (r = ≥0.995) (Hopkins, 2016). Standardised typical error was doubled before being interpreted using the following scale: trivial, <0.2; small, 0.2 to 0.59; moderate, 0.6 to 1.19; large, 1.2 to 1.99; very large, 2.0 to 3.99; extremely large, ≥4.0 (Hopkins, 2015). The following definitions were used to interpret the validity of the step count data using the standardised typical error of the estimate; trivial, <0.1; small, 0.1 to 0.29; moderate 0.3 to 0.59; large ≥0.6 (Hopkins, 2015).

3.4 Results

3.4.1 Validity of the Apple watch for measuring stepping frequency during walking, jogging and running

There were small under-estimations of the mean step count during walking but large to very large over-estimations during jogging and running (Table 1). There was a very poor correlation between the left Apple watch and the criterion and a poor correlation between the right Apple watch and the criterion during walking. There were very poor correlations between the left and right Apple watches and the criterion during jogging and running (Table 1). Standardised typical error of the estimate was large during all exercise intensities.

Table 2. Validity of the Apple watch for measuring stepping frequency compared to the ActivPAL during walking, jogging and running.

Exercise Mode	Left Wrist	Right Wrist
Walking		
Mean (SD) of criterion (ActivPAL)	539 (29)	539 (29)
Mean (SD) of practical (Apple watch)	524 (38)	525 (33)
Standardised mean bias (90%CI)	-0.56 (-1.01 to -0.12)	-0.52 (-0.78 to -0.26)
Standardised typical error of the estimate (90%CI)	0.85 (0.68 to 1.17)	0.61 (0.49 to 0.84)
Pearson correlation (90%CI)	0.56 (0.23 to 0.77)	0.80 (0.62 to 0.90)
Jogging		
Mean (SD) of criterion (ActivPAL)	696 (53)	695 (53)
Mean (SD) of practical (Apple watch)	771 (47)	772 (45)
Standardised mean bias (90%CI)	1.34 (0.86 to 1.83)	1.37 (0.88 to 1.85)
Standardised typical error of the estimate (90%CI)	1.03 (0.81 to 1.40)	1.02 (0.81 to 1.40)
Pearson correlation (90%CI)	-0.04 (-0.40 to 0.34)	-0.09 (-0.44 to 0.29)
Running		
Mean (SD) of criterion (ActivPAL)	628 (64)	628 (64)
Mean (SD) of practical (Apple watch)	820 (48)	819 (48)
Standardised mean bias (90%CI)	2.66 (2.14 to 3.18)	2.56 (2.12 to 3.17)
Standardised typical error of the estimate (90%CI)	0.89 (0.71 to 1.22)	0.88 (0.69 to 1.20)
Pearson correlation (90%CI)	-0.49 (-0.73 to -0.15)	-0.52 (-0.75 to -0.19)

CI=Confidence Interval; SD= Standard deviation.

3.4.2 Variability of the Apple watch when measuring stepping frequency during walking, jogging and running

The inter-device variability between the left and right Apple watches during exercise decreased with increasing exercise intensity as the typical error was moderate, small and small during walking, jogging and running, respectively during trial 2. The ICC

was good during walking and very good during jogging and running (Table 3). The intra-device variability between trial 1 and 2 was good for the left Apple watch but it increased with increasing exercise intensity. However, for the right Apple watch it was very poor and poor during jogging and running, respectively with large to very large standardised typical error at all exercise intensities (Table 3).

Table 3. Intra-device and inter-device variability in stepping frequency as measured by the Apple watch during walking, jogging, and running.

Intra-device

Mode	N	Time	Wrist	ICC (90%CI)	STE (90%CI)
Walk	21	T1 vs T2	Left	0.91 (0.81 to 0.96)	0.68 (0.54 to 0.94)
Walk	21	T1 vs T2	Right	0.68 (0.42 to 0.84)	1.44 (1.14 to 1.96)
Jog	21	T1 vs T2	Left	0.89 (0.78 to 0.95)	0.74 (0.60 to 1.02)
Jog	21	T1 vs T2	Right	0.74 (0.51 to 0.87)	1.26 (1.00 to 1.72)
Run	21	T1 vs T2	Left	0.84 (0.69 to 0.92)	0.92 (0.72 to 1.26)
Run	20	T1 vs T2	Right	0.84 (0.68 to 0.92)	0.92 (0.74 to 1.26)

Inter-device

Wrist	N	Time	Mode	ICC	STE
Left vs Right	21	T2	Walk	0.89 (0.77 to 0.95)	0.74 (0.58 to 1.00)
Left vs Right	21	T2	Jog	0.99 (0.98 to 0.99)	0.22 (0.18 to 0.30)
Left vs Right	21	T2	Run	0.99 (0.98 to 1.00)	0.20 (0.16 to 0.28)

T1: Trial 1; T2: Trial 2; ICC: Intraclass correlation; CI: Confidence interval; STE: Standardised typical error

3.5 Discussion

The major findings of our study are that (1) the Apple watch has a small under-estimation in stepping frequency compared to the ActivPAL during walking but large and very large over-estimations of stepping frequency compared to the ActivPAL during jogging and running, (2) based on the validity correlations, the Apple watch has very poor validity for measuring stepping frequency during jogging and running,

(3) the inter-device variability between the left and right Apple watches decreased with increasing exercise intensity with good to nearly perfect ICCs and moderate to small-standardised typical errors, and (4) the intra-device variability decreased with exercise intensity in the right Apple watch but increased with exercise intensity in the left Apple watch.

The small under-estimation in stepping frequency compared with the criterion (ActivPAL) during walking at 4 $km \cdot h^{-1}$ is in agreement with Wallen et al. (2016). However, the Apple watch showed large and very large over-estimations in stepping frequency compared to the criterion during jogging and running together with very poor correlations. The possible reasons for the Apple watch under-estimating stepping frequency during walking yet over-estimating during jogging and running are largely unknown, but is most likely related to movement artefact. Arm movement increases at moderate and high intensities thereby increasing the magnitude of 'noise' (relative to signal) leading to algorithm classification errors.

The present study is the first to examine the inter- and intra-device variability for measuring stepping frequency during walking, jogging and running. The data shows that the variability between watches (inter-device) is lower than within watches (intra-device), suggesting that stepping frequency is less variable within a given exercise session than between sessions. Our results also show that the left Apple watch has better intra-device variability than the right Apple watch and this may be related to the dominant hand, as 20 of our 21 participants were right-hand dominant and would therefore typically wear a watch on their left wrist.

The decrease in the steps number observed between jogging and running speeds could be as a result of the step length on the flight phase during running is longer than the step length on the flight phase during jogging.

The strength of the present study is that we measured stepping frequency for each exercise intensity separately. Given that we separated the periods of exercise by including approximately 11 minutes of rest between each treadmill stage (walking, jogging and running) we could therefore quantify the number of steps for each exercise intensity separately. However, our criterion measure of stepping frequency was taken from an ActivPAL device rather than direct observation. While the ActivPAL has been reported to have excellent step count validity compared to direct observation (< 1%; Ryan et al., 2006), there will inevitably be some error introduced compared to direct observation. We also examined the validity of the Apple watch during constant-speed treadmill exercise, and while this increases the internal validity, the external validity is decreased. Free-living conditions inevitably mean that on occasions the user will be doing other tasks while moving. However, it is impossible to examine the validity of a wearable device under all conditions, and therefore there must be a balance between internal and external validity.

The future research could consider to produce a corrective algorithm for the Apple watch to measure the steps number accurately, particularly at the higher exercise intensity.

3.6 Conclusion

The Apple watch has adequate validity for measuring stepping frequency during walking, with a small under-estimation compared to the ActivPAL. However, there were large and very large over-estimations in stepping frequency during jogging and running. The Apple watch is therefore useful for measuring daily stepping frequency during walking but we would advise against using the Apple watch for quantifying stepping frequency during jogging and running activities. The Apple watch has good to very good inter-device variability, suggesting that the watch could be worn on either wrist during the same training session. However, intra-device variability was very poor to good showing that stepping frequency measured between training sessions can vary quite substantially.

3.7 Acknowledgements: We would like to thank Wagar Khalil for his help with data collection and all of the participants in our study for their time and commitment.

3.8 Study conclusions in relation to thesis aims and objectives

On the basis of these findings, we conclude that we cannot use stepping frequency quantified by the Apple watch as an outcome measure for our main study. The aim is to quantify the exercise dose of cardiac patients undertaking Phase III community-based CR. Our findings confirm that we cannot rely on the stepping frequency data provided by the Apple watch as exercise intensity increases. The next aim of the thesis is to determine the validity and reliability of the Apple watch for measuring heart rate responses during walking, jogging, and running activities.

3.9 References

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Chapter 4: Validity and reliability of the Apple watch for measuring heart rate during exercise

4.1 Abstract

We examined the validity and reliability of the Apple watch heart rate sensor during and in recovery from exercise. Twenty-one males completed treadmill exercise while wearing two Apple watches (left and right wrists) and a Polar S810i monitor (criterion). Exercise involved 5 min bouts of walking, jogging, and running at speeds of 4 $km \cdot h^{-1}$, 7 $km \cdot h^{-1}$, and 10 $km \cdot h^{-1}$, followed by 11 min of rest between bouts. At all exercise intensities the mean bias was trivial. There were very good correlations with the criterion during walking (L: r = 0.97; R: r = 0.97), but good (L: r = 0.93; R: r = 0.92) and poor/good (L: r = 0.81; R: r = 0.86) correlations during jogging and running. Standardised typical error of the estimate was small, moderate, and moderate to large. There were good correlations following walking, but poor correlations following jogging and running. The percentage of heart rates recorded reduced with increasing intensity but increased over time. Intra-device standardised typical errors decreased

with intensity. Inter-device standardised typical errors were small to moderate with very good to nearly perfect intraclass correlations. The Apple watch heart rate sensor has very good validity during walking but validity decreases with increasing intensity.

Keywords: smartwatch, wearables, technology.

4.2 Introduction

The measurement of heart rate (HR) during acute exercise is one of the most common and pragmatic methods for estimating exercise intensity and prescribing exercise training thresholds (Anastasopoulou et al., 2014 ; Warren et al ., 2010), although some studies suggest that the linear relationship between HR and oxygen consumption is sometimes altered (Crisafulli et al ., 2006). Similarly, heart rate recovery following acute maximal or sub-maximal exercise is a common method for characterising cardiorespiratory fitness and predicting mortality risk (Cole, Blackstone, Pashkow, Snader & Lauer, 1999 ; Shetler et al., 2001). Some studies though have reported that cardiac drift over time will result in a fixed HR recovery overestimating the time required to recover fully between exercise bouts (Tocco et al., 2015). Although the 12-lead electrocardiogram (ECG) may be the 'gold standard' for measuring HR, the ECG monitoring equipment may be impractical or unrealistic for use outside of laboratory settings. Surrogate measures including HR monitors that connect wirelessly to an in-situ chest strap have been successfully validated against 12-lead ECG devices for

measuring HR and heart rate variability at rest and during exercise (Lee & Gorelick, 2011; Vanderlei, Silva, Pastre, Azevedo & Godoy, 2008 & Weippert et al ., 2010)

Recent advances in technology have led to the integration of photoplethysmography (PPG) into wrist-worn devices for the purpose of estimating HR. The PPG technique is a simple non-invasive optical method that detects beat-to-beat pulsatile changes in blood flow (Allen, 2007 ; Priyadarsini & Priyameenakshi, 2015) . The Apple watch, commercially released in 2015, is one such device that uses PPG to measure HR. Although the Apple watch has become the world's highest selling smartwatch with almost 12 millions sales in 2016 (Canalys, 2016), there are very few studies that have examined its validity or reliability for measuring HR. Wallen et al. (2016) recently examined the validity of the Apple watch in 22 healthy males and females during a 1-hour protocol of low exercise intensity, supine and seated rest, walking, and running on a treadmill and cycling on an ergometer. These authors reported a mean (SD) difference of -1.3 (4.4) beats·min^{-1} and limits of agreement of -9.9 to 7.3 beats·min^{-1} between the Apple watch and an ECG (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016). However, HR was recorded manually and the process of how HR data were extracted is not clearly explained. Wang et al. (2017) examined the validity of the Apple watch HR compared to an ECG and a Polar chest strap in 50 males and females. Participants exercised on a motorised treadmill at 3.2 km·h^{-1}, 4.8 km·h^{-1}, 6.4 km·h^{-1}, 8 km·h^{-1}, and 9.6 km·h^{-1}, for 3 min at each stage while wearing two of four wrist-worn devices (Fitbit Charge HR, Apple watch, Mio Alpha, and Basis Peak). There was a correlation of r = 0.91 (95%CI: 0.88 to 0.93) between the Apple watch and the ECG. The limits of agreement ranged from -27 to +29 beats·min^{-1} compared to the ECG (Wang et al., 2017). However, HR was only taken once manually at the end of each 3-min stage, which is a serious limitation and questions how well each

data point represents the mean HR. There was also no indication on which wrist the Apple watch was worn.

To our knowledge, no study has investigated the validity of the Apple watch HR sensor during controlled walking, jogging and running, during recovery from controlled exercise, or the intra- and inter-device reliability. It is important to examine the validity and reliability of modern wearable devices because it is well established that a dose-response relationship exists between exercise intensity and health outcomes, which places emphasis on the accurate monitoring of exercise intensity. Therefore, the aim of the study was to investigate the validity, and intra- and inter-device reliability of the Apple watch HR sensor during walking, jogging, and running activities and during recovery from each of these activities.

4.3 Materials and Methods

4.3.1 Study population

Our study was approved by the institutional ethics committee and meets the ethical standards of the journal (Harriss & Atkinson, 2015). Twenty-nine healthy male participants were recruited and provided written informed consent. However, eight did not complete the study; one participant withdrew due to an unrelated injury, and given the heterogeneity in participant fitness, seven others were excluded because they were unable to complete all three bouts of exercise (walking, jogging, and running). Participant cardiorespiratory fitness was not assessed because the relative physiological response was not a primary measure of interest. Twenty-one healthy male participants (mean [SD]; age 31.4 [7.2] y; BMI 26.1 [2.9] $kg \cdot m^{-2}$) completed the

study, and of these, 20 were right-hand dominant. Eleven participants were British (white skin) and 10 were Asian (brown skin), with no participant having black skin. All participants were recreationally active and involved in a wide range of activities including walking, running, resistance training and soccer. Ten participants described their fitness status as highly fit, nine as moderately fit, and one as unfit. We lost heart rate data from one participant from the right Apple watch during running only in trial 1 due to a data recording error. The inclusion criteria were that participants be free from known disease, not taking any form of medication, and aged >18 years. Participants with a diagnosis of cardio-metabolic disease were excluded.

4.3.2 Experimental design

Participants visited the exercise testing laboratory on three separate occasions. The first visit was used to screen participants for eligibility and to familiarise them with the exercise protocol. The second visit was the first testing session and included walking, jogging, and running on a treadmill (GE T2100 treadmill) at 1% inclination for 5 min at 4 $km \cdot h^{-1}$, 7 $km \cdot h^{-1}$, and 10 $km \cdot h^{-1}$, respectively. These speeds were selected based on pre-study pilot testing and were mean values representing walking, jogging, and running speeds. Each bout of exercise was followed by approximately 11 min of rest. Based on data from pilot testing, 11 min was sufficient time to allow data from the Apple watches to be transferred to the paired iPhone, together with allowing the HR to return to baseline in order to avoid any carry-over effects between intensity stages. The final visit replicated the testing protocol conducted in the second visit, with the laboratory conditions maintained between trials. The mean (SD) days between the second and third sessions was 7 (4). All testing visits were scheduled at the same time

of the day. All participants were advised not to eat a large meal or consume caffeine for at least three hours before testing, and to avoid moderate to vigorous physical activity in the 24 hours before testing.

4.3.3 Instrumentation and data acquisition

During each trial participants wore a Polar HR monitor chest strap (T13, Polar Electro, OY, Finland) with the corresponding watch (Polar S810i, Polar Electro, OY, Finland), placed over the handrail of the treadmill and two Apple watch Sport devices (Series 0, watchOS 2.0.1, Apple Inc., California, USA) – one on the left wrist and another on the right wrist. Both Apple watches are connected wirelessly via Bluetooth to two iPhone 5S smartphones (Apple Inc., California, USA). The sampling time for the Polar S810i HR monitor was set at 5 s intervals. Following exercise the HR data were transferred from the Polar S810i HR monitor to the Polar Pro Trainer 5 software. To measure HR on each Apple watch, we used the 'Workout' app. The 'Workout' app nominally records HR at 5-s intervals. On cessation of each trial the HR data were synced automatically to the 'Health' database on its paired iPhone. To retrieve the raw HR and sampling time data from the 'Health' database, a bespoke iPhone app was written. The bespoke app was written in Xcode 7.2.1 using the language Swift 2.1 and using the methods provided by the HealthKit framework (Apple Inc., California, USA).

4.3.4 Data analysis

Data were log transformed prior to analysis to avoid bias resulting from non-uniformity of error. All data were analysed using custom-designed Microsoft Excel

spreadsheets (Hopkins, 2015). The mean and standard deviation (SD) for each exercise and recovery period were used to report descriptive data. We report the standardised typical error of the estimate, standardised mean bias, and Pearson product moment correlation coefficients to assess validity, together with the 95% limits of agreement to aid comparisons with other studies. Standardised typical error and intraclass correlation were used to measure inter- and intra-device reliability. Uncertainties in these estimates are reported as 90% confidence intervals. The following definitions were used to interpret the strength of the Pearson correlation coefficients used to assess the validity of the HR data and the intraclass correlation coefficients used to assess the inter- and intra-device reliability of the HR data: very poor (r = 0.45 to 0.69), poor (r = 0.70 to 0.84), good (r = 0.85 to 0.94), very good (r = 0.95 to 0.994) and excellent (r ≥ 0.995) (Hopkins, 2016). The following definitions were used to interpret the validity of the HR data using the standardised typical error of the estimate: trivial, <0.1; small, 0.1 to 0.29; moderate 0.3 to 0.59; large ≥0.6 (Hopkins, 2015). Standardised typical error was doubled prior to interpretation using the following scale: trivial, <0.2; small, 0.2 to 0.59; moderate, 0.6 to 1.19; large, 1.2 to 1.99; very large, 2.0 to 3.99; extremely large, ≥4.0 (Hopkins, 2015).

4.4 Results

4.4.1 Validity of Apple watch HR during walking, jogging and running

The standardised mean bias showed there was no obvious under- or overestimation of the mean HR at any of the exercise intensities (Table 4). There were very good correlations between the left and right Apple watches and the criterion during walking, and good correlations during jogging. For running, there was a poor correlation for the

left Watch, but a good correlation for the right Watch. Standardised typical error of the estimate increased as the exercise intensity increased, being small, moderate, and moderate/large, for walking, jogging, and running, respectively (Table 4). The 95% limits of agreement are displayed in Table 4. Although the Apple watch nominally measures HR every 5 s, we were able to test this by examining the exact time that each HR was recorded. The mean (SD) percent of all possible HRs recorded by the Apple watch reduced with increasing exercise intensity but increased over time (Figure 1).

Table 4. Validity of measuring HR with the Apple watch during and in recovery from walking, jogging, and running.

Exercise Mode	**Left Wrist**	**Right Wrist**
Walking		
Mean (SD) of criterion (Polar) (beats·min^{-1})	95 (14)	95 (14)
Mean (SD) of practical (Apple watch) (beats·min^{-1})	94 (13)	95 (14)
Standardised mean bias (90%CI)	-0.03 (-0.11 to 0.06)	0.01 (-0.09 to 0.11)
Standardised typical error of the estimate (90%CI)	0.23 (0.18 to 0.32)	0.26 (0.21 to 0.36)
Correlation coefficient (90%CI) vs criterion (Polar)	0.97 (0.94 to 0.99)	0.97 (0.93 to 0.98)
Mean bias (95% limits of agreement) (beats·min^{-1})	0 (-6 to 6)	0 (-8 to 8)
In recovery from walking		
Mean (SD) of criterion (Polar) (beats·min^{-1})	83 (14)	83 (14)
Mean (SD) of practical (Apple watch) (beats·min^{-1})	88 (14)	89 (13)
Standardised mean bias (90%CI)	0.32 (0.15 to 0.49)	0.37 (0.22 to 0.52)
Standardised typical error of the estimate (90%CI)	0.46 (0.36 to 0.63)	0.41 (0.32 to 0.56)
Correlation coefficient (90%CI) vs criterion (Polar)	0.89 (0.78 to 0.95)	0.92 (0.83 to 0.96)
Mean bias (95% limits of agreement) (beats·min^{-1})	5 (-8 to 18)	5 (-7 to 17)
Jogging		
Mean (SD) of criterion (Polar) (beats·min^{-1})	133 (15)	133 (15)
Mean (SD) of practical (Apple watch) (beats·min^{-1})	132 (16)	133 (16)
Standardised mean bias (90%CI)	-0.03 (-0.18 to 0.11)	0.01 (-0.15 to 0.16)

Standardised typical error of the estimate (90%CI)	0.37 (0.29 to 0.50)	0.40 (0.32 to 0.55)
Correlation coefficient (90%CI) vs criterion (Polar)	0.93 (0.86 to 0.97)	0.92 (0.84 to 0.96)
Mean bias (95% limits of agreement) (beats·min^{-1})	1 (-19 to 21)	1 (-19 to 21)
In recovery from jogging		
Mean (SD) of criterion (Polar) (beats·min^{-1})	118 (19)	118 (19)
Mean (SD) of practical (Apple watch) (beats·min^{-1})	131 (19)	130 (21)
Standardised mean bias (90%CI)	0.59 (0.32 to 0.86)	0.53 (0.30 to 0.77)
Standardised typical error of the estimate (90%CI)	0.72 (0.57 to 0.98)	0.61 (0.49 to 0.84)
Correlation coefficient (90%CI) vs criterion (Polar)	0.71 (0.47 to 0.86)	0.80 (0.61 to 0.90)
Mean bias (95% limits of agreement) (beats·min^{-1})	12 (-18 to 42)	11 (-16 to 38)
Running		
Mean (SD) of criterion (Polar) (beats·min^{-1})	155 (17)	155 (17)
Mean (SD) of practical (Apple watch) (beats·min^{-1})	157 (18)	157 (18)
Standardised mean bias (90%CI)	0.11 (-0.12 to 0.35)	0.11 (-0.09 to 0.31)
Standardised typical error of the estimate (90%CI)	0.61 (0.48 to 0.83)	0.53 (0.42 to 0.72)
Correlation coefficient (90%CI) vs criterion (Polar)	0.81 (0.62 to 0.91)	0.86 (0.72 to 0.93)
Mean bias (95% limits of agreement) (beats·min^{-1})	2 (-21 to 25)	2 (-18 to 22)
In recovery from running		
Mean (SD) of criterion (Polar) (beats·min^{-1})	144 (22)	144 (22)
Mean (SD) of practical (Apple watch) (beats·min^{-1})	156 (19)	155 (20)
Standardised mean bias (90%CI)	0.50 (0.25 to 0.75)	0.44 (0.19 to 0.69)
Standardised typical error of the estimate (90%CI)	0.67 (0.54 to 0.92)	0.67 (0.53 to 0.92)
Correlation coefficient (90%CI) vs criterion (Polar)	0.76 (0.54 to 0.88)	0.75 (0.53 to 0.88)
Mean bias (95% limits of agreement) (beats·min^{-1})	12 (-18 to 42)	10 (-20 to 40)

CI: Confidence interval

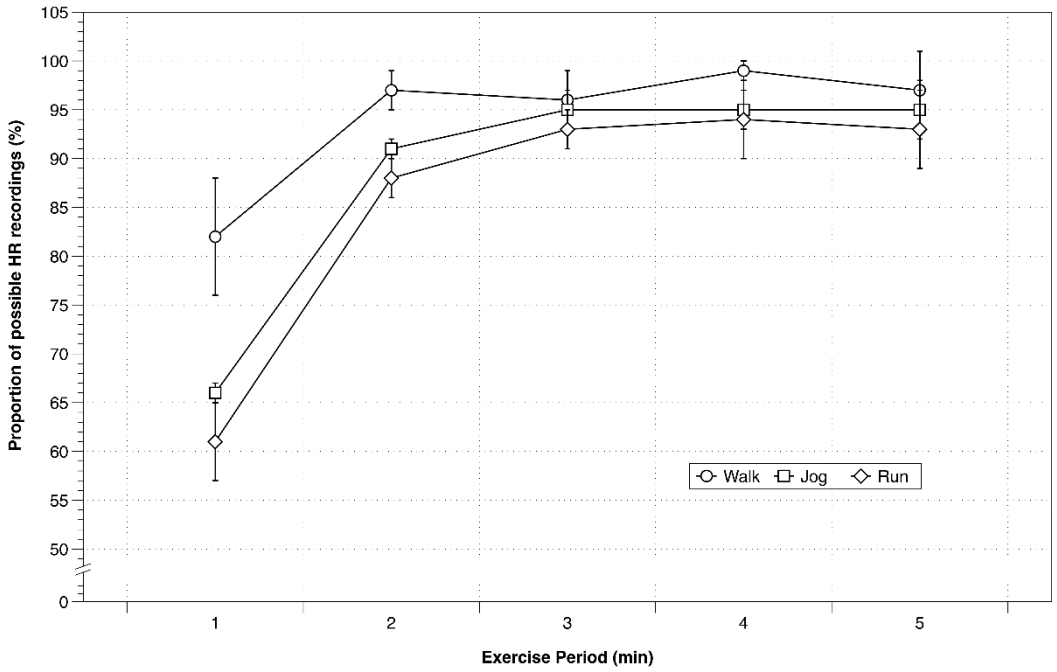

Fig 1 The mean (SD) of all possible heart rate recordings actually measured by the Apple watch during each minute of the 5-min exercise period for walking, jogging and running.

4.4.2 Validity of Apple watch HR in recovery from walking, jogging and running

The standardised mean bias showed there were small over-estimations of the mean HR after walking, jogging and running, and standardised typical error of the estimate increased as the exercise intensity increased (Table 4). There were good correlations between the left and right Apple watches and the criterion after walking. There were poor correlations following jogging and running (Table 4).

4.4.3 Reliability of the Apple watch HR during walking, jogging and running

The intra-device reliability (Trial 1 vs Trial 2) increased with exercise intensity such that the ICCs increased and the standardised typical errors decreased (Table 2). The

inter-device reliability between the left and right Apple watches during Trial 2 showed very good to nearly perfect ICCs and small to moderate standardised typical errors.

Table 5. Intra-device and inter-device reliability of HR as measured by the Apple watch during and in recovery from walking, jogging, and running.

Intra-device					
Mode	**N**	**Time**	**Wrist**	**ICC (90%CI)**	**STE (90%CI)**
Walk	21	T1 vs T2	Left	0.84 (0.68 to 0.92)	0.92 (0.74 to 1.62)
Walk	21	T1 vs T2	Right	0.74 (0.51 to 0.87)	1.24 (0.98 to 1.70)
Jog	21	T1 vs T2	Left	0.82 (0.64 to 0.91)	1.00 (0.80 to 1.38)
Jog	21	T1 vs T2	Right	0.95 (0.88 to 0.97)	0.26 (0.20 to 0.35)
Run	21	T1 vs T2	Left	0.91 (0.82 to 0.96)	0.64 (0.52 to 0.88)
Run	20	T1 vs T2	Right	0.92 (0.84 to 0.97)	0.60 (0.48 to 0.84)
Walk – Rec	21	T1 vs T2	Left	0.86 (0.73 to 0.93)	0.84 (0.66 to 1.16)
Walk – Rec	21	T1 vs T2	Right	0.86 (0.72 to 0.93)	0.84 (0.68 to 1.16)
Jog – Rec	21	T1 vs T2	Left	0.86 (0.72 to 0.93)	0.84 (0.68 to 1.16)
Jog – Rec	21	T1 vs T2	Right	0.91 (0.82 to 0.96)	0.66 (0.52 to 0.90)
Run – Rec	20	T1 vs T2	Left	0.96 (0.91 to 0.98)	0.44 (0.36 to 0.62)
Run – Rec	20	T1 vs T2	Right	0.90 (0.79 to 0.95)	1.40 (0.46 to 0.98)
Inter-device					
Wrist	**N**	**Time**	**Mode**	**ICC (90%CI)**	**STE (90%CI)**
L vs R	21	T2	Walk	0.97 (0.94 to 0.99)	0.36 (0.30 to 0.50)
L vs R	21	T2	Jog	0.91 (0.82 to 0.96)	0.66 (0.52 to 0.90)
L vs R	21	T2	Run	0.99 (0.97 to 0.99)	0.26 (0.20 to 0.34)
L vs R – Rec	21	T2	Walk	0.98 (0.95 to 0.99)	0.32 (0.26 to 0.44)
L vs R – Rec	21	T2	Jog	0.96 (0.91 to 0.98)	0.44 (0.34 to 0.60)
L vs R – Rec	21	T2	Run	0.99 (0.98 to 1.00)	0.20 (0.16 to 0.26)

T1: Trial 1; T2: Trial 2; ICC: Intraclass correlation; CI: Confidence interval; STE: Standardised typical error; Rec: Recovery.

4.4.4 Reliability of the Apple watch HR in recovery from walking, jogging and running

The intra-device reliability (Trial 1 vs Trial 2) in recovery from exercise increased with exercise intensity such that the ICCs increased and the standardised typical errors decreased (Table 5). The inter-device reliability between the left and right Watches during Trial 2 showed nearly perfect ICCs and small to moderate standardised typical errors.

4.5 Discussion

This is the first study to examine the validity and intra- and inter-device reliability of the Apple watch for measuring HR during and in recovery from controlled walking, jogging, and running. We observed that the Apple watch has very good validity for measuring HR during walking and good validity in recovery from walking. However, the validity of the Apple watch for measuring HR during exercise decreases with increasing intensity and the proportion of HR values recorded by the watch decreases with increasing exercise intensity. The intra-device reliability is good during walking and in recovery from walking and improved with the higher exercise intensity associated with jogging and running. The inter-device reliability is very good with low standardised typical errors and good to very good ICCs.

Our findings are largely in agreement with Wallen et al. (2016) who reported HR from the Apple watch during rest, cycling and walking at three speeds: 2.7, 4.0 and 5.5 $km{\cdot}h^{-1}$ (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016). They reported a trivial under-estimation of the mean HR from the Apple watch compared to an ECG

(1 beat·min^{-1}) with the 95%LoA being -10 to 7 beats·min^{-1}. The Apple watch was the most accurate among the four devices at low exercise intensity. Our results revealed a trivial mean bias during walking at 4 km·h^{-1}, with the mean bias and 95%LoA being 0 (-6 to 6) and 0 (-8 to 8) for the left and right Apple watches, respectively. The difference between our results and Wallen and colleagues (2016) may be because they measured the mean HR across different exercise modes but we measured HR during treadmill exercise only (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016).

Wang and colleagues (2017) examined the accuracy of wrist-worn watches in 50 participants during walking, jogging, and running on a treadmill for three minutes at 3.2, 4.8, 6.4, 8 and 9.6 km·h^{-1}, respectively (Wang et al ., 2017). However, only 25 of the 50 participants wore an Apple watch. These authors reported that the accuracy of the four devices, including the Apple watch, decreased with increasing exercise intensity and our findings are in agreement with this. Although they reported a correlation of r = 0.91 (95%CI: 0.88 to 0.93) between the Apple watch and an ECG, the limits of agreement ranged from -27 to +29 beats·min^{-1}. Moreover, 7 of their 50 participants were African American, yet a previous study reported that the correlation between Apple watch HR and an ECG was different between those with darker and lighter skin (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016), which may have affected their results. However, our study did not include any participants with dark skin colour (Wallen, Gomersall, Keating, Wisløff & Coombes, 2016). Wang and colleagues (2017) also recorded the HR manually at the end of each 3-min stage, which questions how well each data point represents the mean HR (Wang et al .,2017).

We have extended the findings of Wallen et al. (2016) and Wang et al. (2017) by measuring HR continuously (but nominally) every 5 s (rather than every 3 min, or

manually) thereby substantially increasing the validity of the measured mean and standard deviation. The development of our bespoke in-house software allowed us to continuously record HR from the wrist watches and facilitated the collection of more frequent measurements which is previously unreported in the published literature. Although the Apple watch nominally measures HR every 5 s, our data shows that the proportion of HR values actually measured by the Apple watch decreases with increasing exercise intensity (Figure 1), which is most likely contributing to the decreased validity of the Apple watch for measuring HR at higher exercise intensities during running. This finding might suggest that the more rapid arm movement at higher exercise intensities is increasing the movement artefact, thereby affecting the ability of the Apple watch to measure HR. Although logic would suggest that blood flow to the wrist would be increased at higher exercise intensities, the increased movement artefact might disproportionately counteract this, leading to a degraded frequency in the HR measurement. Although we do not have direct access to the algorithms used to calculate HR from the PPG data, we can speculate that the missing HR values from the Apple watch could result from the software purposefully not reporting HR values determined to be physiologically implausible.

It is also clear from Figure 1 that during the first minute of exercise (particularly at higher exercise intensities), the Apple watch is not recording between approximately 20% and 40% of HRs. Although we cannot say for certain, we suspect this is also related to a combination of blood-flow and motion artefact issues previously mentioned. Given that the PPG sensor estimates HR by measuring changes in blood flow, the limited blood flow to the wrist at the initiation of exercise (Johnson, 1998) might lower the confidence of the predictive algorithms to accurately measure HR. As suggested before when related to the effect of exercise intensity on the proportion of

HRs recorded, the Apple watch software may discard all measured HRs until the algorithm is confident that it is recording a physiologically plausible value. Given these issues and based on our data, we would urge caution when analysing Apple watch HR data of less than three minutes in duration.

Our study is also the first to examine the reliability of HR measured by the Apple watch. Although we did not measure gait parameters during trials, there is clearly variation in the arm movement of participants within and between trials leading to variation in the amount of movement artefact. However, our data shows that the reliability between watches (inter-device) is higher than within watches (intra-device), suggesting that HR is more reliable within a given exercise session than between sessions. Future studies could examine the independent and combined contribution of both blood flow and movement to the variation in HR measured by the Apple watch.

In summary, the Apple watch has very good validity during walking and good validity in recovery from walking. However, the validity of measuring HR decreases with increasing exercise intensity. Caution should be employed when interpreting HR data obtained with the Apple watch during jogging and running. The proportion of HR values actually measured by the Apple watch decreases with increasing exercise intensity, and particularly during the first minute of measurement. The intra-device reliability is good during walking and in recovery from walking and improved with increasing exercise intensity. The inter-device reliability is very good.

4.6 Acknowledgments

We would like to thank Wagar Khalil for his help with the data collection and all the participants in our study for their time and commitment.

4.7 Study conclusions in relation to thesis aims and objectives

On the basis of these findings, we conclude that we can incorporate the Apple watch for measuring heart rate as an outcome measure into our main study. Our findings confirm that we can rely on heart rate data provided by the Apple watch especially at low to moderate exercise intensities, which is likely to be mirrored by the community-based Phase III CR programme (national guidelines advocate working patients between 40-70% HRR). We have now found a reliable and valid method for quantifying exercise dose, our next aim of the thesis is to quantify the exercise dose achieved from a physiotherapist-led, 8-week community-based Phase III CR programme.

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Chapter 5: Monitoring and quantification of a community-based Phase III cardiac rehabilitation programme: A United Kingdom perspective

5.1 Abstract

Background

In recent years, criticism of the percentage range approach for individualised exercise prescription has intensified and we were concerned that sub-optimal exercise dose (especially intensity) may be in part responsible for the variability in the effectiveness of cardiac rehabilitation (CR) programmes in the United Kingdom (UK). The aim was to investigate the fidelity of a structured Phase III CR programme, by monitoring and quantifying exercise training intensity.

Design

Observational study.

Methods

The programme comprised 16 sessions over 8 weeks, where patients undertook an interval, circuit training approach within national guidelines for exercise prescription (40-70% heart rate reserve [HRR]). All patients wore an Apple watch (Series 0 or 2, Watch OS2.0.1, Apple Inc., California, USA). We compared the mean % heart rate reserve (%HRR) achieved during the cardiovascular training component (%HRR-CV) of a circuit-based programme, with the %HRR during the active recovery phases (%HRR-AR) in a randomly selected cohort of patients attending standard CR. We then compared the mean %HRR-CV achieved with the minimal exercise intensity threshold during supervised exercise (40% HRR) recommended by national governing bodies.

Results

Thirty cardiac patients (83% male; mean age [SD] 67 [10] years; BMI 28.3 [4.6] kg·m^{-2}) were recruited. We captured 332 individual training sessions. The mean %HRR-CV and %HRR-AR were 37 (10) %, and 31 (13) %, respectively. There was weak evidence to support the alternative hypothesis of a difference between the %HRR-CV and 40% HRR. There was very strong evidence to accept the alternative hypothesis that the mean %HRR-AR was lower than the mean %HRR-CV, median standardised effect size 1.1 (95%CI: 0.563 to 1.669), with a moderate to large effect.

Conclusion

Mean exercise training intensity was below the lower limit of the minimal training intensity guidelines for a Phase III CR programme. These findings may be in part responsible for previous reports highlighting the significant variability in effectiveness of UK CR services and poor CRF improvements observed from several prior investigations.

Key words: exercise intensity, monitor, cardiac rehabilitation

5.2 Introduction

Cardiovascular disease accounted for 15 million deaths worldwide in 2015 (World Health Organization, 2017). The cornerstone of secondary prevention strategies is comprehensive CR, including optimal medical therapy and lifestyle interventions which have been endorsed within UK (NICE, 2013 ; BACPR, 2012), European (Piepoli et al .,2014) and North American (Balady et al., 2007) guidelines. The literature on supervised, structured exercise training as a key component of comprehensive CR has been less than convincing. The largest RCT of structured CR within the UK showed no benefits to all-cause mortality. In 2013, Sandercock *et al* quantified exercise training volumes and changes in cardiorespiratory fitness (CRF) in 950 cardiac patients undertaking Phase III CR across 4 centers in the UK (Sandercock, Cardoso, Almodhy & Pepera, 2013). Patients completed 6 to 16 (median 8) supervised exercise sessions. CRF improvements showed an overall mean increase of only 0.52 METs; a third the mean estimate (1.55 METs) reported from the investigators earlier systematic review of the international CR literature (Sandercock, Hurtado, & Cardoso, 2013). In 2016, Almodhy et al. (2016) conducted a meta-analysis of UK CR studies in order to determine if programmes could promote meaningful changes in CRF (Almodhy, Ingle & Sandercock, 2016). It was concluded that UK studies provided approximately one-third of the exercise "dose", and produced gains in CRF less than half the magnitude reported in the wider international studies (Almodhy, Ingle & Sandercock, 2016). There are also challenges regarding the reporting of CR studies; Mitchell and colleagues (Mitchell et al ., 2018), published a comprehensive systematic review and meta-analysis reporting a lack of consensus in the consistency of reporting of exercise interventions in CR studies. This highlights ongoing issues regarding lack of standardisation indicating the need for further high quality, robust CR trials.

The FITT principle describes the four components of exercise prescription: Frequency, Intensity, Time (duration), and Type of exercise which combine to create the exercise "dose". Of these, exercise intensity is arguably the most critical component for improving CRF, and is the least standardised in clinical practice (Casillas et al., 2017). In the UK, CR programmes follow traditional approaches by prescribing exercise intensity based on a percentage range of heart rate reserve (%HRR; heart rate reserve being the differences between the maximal and resting heart rate, often with an adjustment if a patient is prescribed a medication which impacts chronotropic response, e.g. beta blockers). This method is recommended by a number of national associations including the American College of Sports Medicine (American College of Sports Medicine, 2017), and in the UK, the Association of Chartered Physiotherapists in Cardiovascular Rehabilitation (ACPICR) (ACPICR, 2015), and the British Association of Cardiovascular Prevention and Rehabilitation (BACPR) (BACPR, 2012).

Typically, structured Phase III CR is delivered in a community setting with the aim of achieving 20–60 min of moderate intensity continuous or interval-based exercise, 3–5 times per week, alongside resistance-based training (ACPICR, 2015). In addition, most comprehensive CR programmes would include an educational component, dietary advice, and psychological support (Weatherwax, Harris, Kilding & Dalleck, 2019). Most often in the UK, patients undertaking a Phase III programme would initially participate in group-based circuit training, following an interval training approach. Typically, patients would alternate between cardiovascular (CV) training interspersed with a period of active recovery (AR). The initial work: rest ratio would be dependent upon initial risk stratification and knowledge of existing individual baseline fitness levels. The goal would be to increase the dose of exercise by increasing

the CV component and removing AR stations based on individual progress, with the ultimate aim that the patient is able to undertake continuous moderate intensity exercise. Importantly, for improvements in CRF, the CV component prescribed should be at an exercise intensity sufficiently high enough to induce physiological adaptation. Training intensity is based on an initial prescribed training zone utilising heart rate (HR) responses and/or ratings of perceived exertion (RPE). UK guidelines recommend an exercise intensity between 40-70% heart rate reserve (HRR) (BACPR, 2012 ; ACPICR, 2015). For AR stations, exercise HR and RPE levels should drop below prescribed exercise intensity levels to allow patients a brief period of respite (ACPICR, 2015).

In recent years, criticism of the percentage range approach for individualised exercise prescription has intensified (Weatherwax, Harris, Kilding & Dalleck , 2019 ; Wolpern, Burgos, Janot & Dalleck , 2015) and we were concerned that sub-optimal exercise dose (especially intensity) may be, in part responsible for the variability in the effectiveness of UK CR programmes, which has been previously reported (Doherty, Salman, Furze, Dalal & Harrison, 2017). To our knowledge, no previous study has investigated the fidelity of a structured Phase III CR programme by monitoring and quantifying the exercise intensity achieved during an overall 8-week programme. We aimed to compare the mean percentage heart rate reserve (%HRR) achieved during the cardiovascular training component (%HRR-CV) of the programme, with the %HRR during the AR phases (%HRR-AR). Moreover, we compared the mean %HRR-CV achieved with the minimal exercise intensity threshold (40% HRR) recommended by national governing bodies (BACPR, 2012; American College of Sports Medicine, 2017).

5.3 Materials and Methods

The study was approved by the North West National Health Service (NHS) Research Ethics Committee and institutional ethics committee prior to commencement of the study. All patients provided written informed consent before participating in the trial. The following patients were eligible to participate in the study: patients following myocardial infarction (MI), whose event had presented in the preceding 3-6 weeks, percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) within the past 6 weeks, stable angina, valvular or aortic root repair, patients with devices such as pacemaker or implantable cardioverter defibrillator, and stable heart failure. We excluded patients who had orthopaedic or neurological limitations, unstable angina, New York Heart Association class IV heart failure, uncontrolled hypertension and diabetes, symptomatic hypotension, uncontrolled tachy-arrhythmias, and febrile illness. Patients were referred from their hospital doctor or general practitioner to a Phase III CR programme based in the North Eastern region of England in 2017 and 2018.

The standard, community-based Phase III CR programme included two sessions per week for eight weeks (16 sessions in total). Each training session consisted of a 45 minute structured exercise based activities (12 training hours over eight weeks). Each training session consisted of a 15-minute warm up at the beginning of each session followed by a circuit training programme consisting of 9 exercise stations (5 CV; 4 AR). The CV stations included: treadmill, static bike, step ups, sit-to-stand, and rowing. The AR stations included biceps curls, wall press, lateral arm raises, and leg curl exercises. The session concluded with a 10-minute cool down period. All patients

were advised not to consume caffeine at least three hours before the training sessions. In the UK, maximum heart rate is routinely estimated as there is little provision to conduct a maximal cardiopulmonary exercise test prior to routine CR. The following formula for calculating heart rate reserve (HRR) was used which is consistently advocated by national governing bodies (BACPR, 2012; American College of Sports Medicine, 2017).

Maximal heart rate was estimated using the following equation; HRmax = 206 – (age x 0.7) (Inbar, 1994 ; Londeree & Moeschberger, 1982)**.** Resting heart rate was then deducted in order to calculate the HRR. A further deduction of 20-30 beats per min was made in patients who were prescribed beta-blockers, the decision to deduct 20 or 30 beats is often based on a patient's initial risk stratification (American College of Sports Medicine, 2017). Heart rate training zones were calculated between 40-70% HRR in accordance with national guidelines (BACPR, 2012; American College of Sports Medicine, 2017). In UK practice, patients often wear a heart rate monitor exercise classes which staff monitor periodically during CV exercise stations.

In our investigation, each patient wore an Apple watch (Series 0 or 2, Watch OS2.0.1, Apple Inc., California, USA) during each training session over the 8-week intervention. The Apple watch uses photoplethysmysmography (PPT) to measure heart rate. PPT is a non-invasive technique which uses a sensor to measure changes in blood flow (Allen, 2007). We have recently shown that the Apple watch heart rate sensor has very good validity during walking activities, and good validity during jogging activities. However, the validity of the device decreases as exercise intensities increase towards maximal levels (Khushhal et al., 2017). During each training session, patients wore the watch on his left wrist with the exception of one patient who wore it

on their right wrist due to an existing tattoo on their left side. Each Apple watch was connected via Bluetooth to an iPhone 5s or iPhone 6 (Apple Inc., California, USA). We used the 'Workout' app to measure heart rate nominally at five second intervals. A bespoke iPhone app was written by one of the co-authors (GA) to app was written using the Swift 2.1 language in XCode 7.2.1, utilising the methods supplied by the HealthKit framework (Apple Inc., California, USA).

5.4 Statistical Analysis

Mean and standard deviation (SD) are reported for normally distributed data. The mean %HRR for CV training and AR stations are reported separately. Data analysis was conducted in JASP (JASP Team, 2018) using Bayesian statistical methods. Below we describe the statistical analysis for two comparisons: (1) comparing the mean %HRR during CV exercise time (%HRR-CV) against the lower bound of the recommended training intensity zone (40% HRR), and (2) comparing the mean %HRR-CV against the mean %HRR for AR stations (%HRR-AR). Patients were excluded from our analysis if they failed to complete less than 12 of 16 training sessions (<75% adherence rate).

5.4.1 Comparing %HRR-CV and 40% HRR

We compared %HRR-CV and 40% HRR both in the form of a hypothesis test using Bayes factors and as a parameter estimation for the posterior distribution of the standardised effect size. Our null hypothesis test compared the observed data against a null hypothesis of no difference between the mean %HRR-CV and 40% HRR-CV,

which is the lower bound of the recommended training intensity zone (BACPR, 2012; American College of Sports Medicine, 2017). For this analysis we conducted a Bayesian one-sample t-test, using a two-sided alternative hypothesis because it is unknown if the mean %HRR-CV is above or below this lower bound. Given our uncertainty of the effect, we assigned a broad weakly informative prior using a zero-centred Cauchy distribution with scale $r = 1/\sqrt{2}$.

5.4.2 Comparing %HRR-CV and %HRR-AR

The same process was used to compare the mean %HRR-CV and mean %HRR-AR. We wanted to examine if the AR sections of the training sessions were in fact of lower intensity (and by what magnitude) compared to the CV section. For this analysis, we used a Bayesian paired-samples t-test with the same prior distributions. However, given that we were expecting the AR stations to be of lower intensity than CV sections, we used a one-sided alternative hypothesis.

To describe the strength of evidence against the null hypothesis (or for the alternative hypothesis) we used the classification scheme of Jeffreys (Jeffreys, 1939). A Bayes factor between one and three was considered as weak evidence; three and 10, moderate evidence, and above 10 is considered strong evidence. To describe the magnitude of the observed standardised effect size, we use the classification scheme of Cohen (Cohen, 1988), with 0.2, 0.5 and 0.8 representing small, moderate, and large effects, respectively. Uncertainty in the parameter estimation is quantified using 95% credible intervals.

5.5 Results

Thirty cardiac patients [83% male; age (SD) 67.0 (10.0) years; body mass index (SD) 28.3 (4.6) $kg \cdot m^{-2}$] were recruited to the Phase III CR programme. Of these, 87% were prescribed beta-blockers; 53% statins; 40% ACE-inhibitors; and 68% aspirin**.** These medications remained unchanged throughout the training intervention. Patients were randomly selected from a mixed cardiovascular disease aetiology: 11 patients had received a coronary artery bypass graft, 7 percutaneous coronary intervention, and 2 patients had undergone a mitral valve replacement. Amongst the non-surgical patients, 4 patients were post-myocardial infarction, 3 patients had diagnosed coronary heart disease, and 3 were diagnosed with chronic heart failure. Of the 30 patients who initially enrolled, 4 exhibited paroxysmal atrial fibrillation.

Twenty patients (67% of the population) completed all 16 sessions (twice a week for eight weeks) of the Phase III CR programme; the remaining 10 patients dropped out at various stages of the programme due to a deterioration in their health, or were unable to attend due to personal reasons. Our analysis is based on 21 patients who had a programme adherence ≥75% (completed a minimum of 12 of 16 sessions). In total, we monitored 370 individual exercise training sessions, although data from 5 exercise sessions on selected patients were lost due to technical problems. Overall our analysis is based on 332 individual training sessions.

As displayed in Table 6, the mean (SD) %HRR-CV was 37 (10) %, with a 95% credible interval of 33 to 42%. The Bayesian one-sample t-test (Fig 2) resulted in a $Bayes_{10}$ factor of 0.474, indicating weak evidence for the alternative hypothesis that the observed data is different from 40% HRR.

Table 6. Mean HR (beats per min) and %HRR for an 8-week Phase III circuit-based CR programme

	Mean HR during CVE	Mean HR during AR	Mean %HRR during CVE	Mean %HRR during AR
Mean	90.6	87.0	37.1	31.5
Median	88.0	84.0	37.0	34.0
SD	12.3	13.2	10.1	12.6
Minimum	74.0	67.0	17.0	10.0
Maximum	117.0	113.0	62.0	53.0

HR=heart rate (bpm); CVE=cardiovascular exercise; AR=active recovery; %HRR=% heart rate reserve; SD=standard deviation

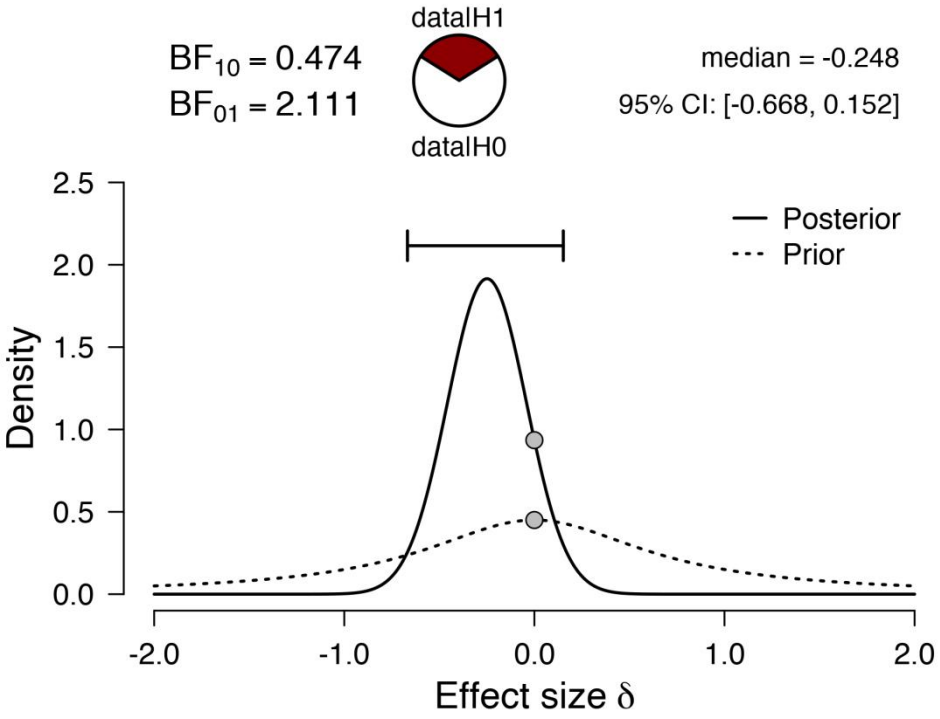

Fig 2. Prior and posterior effect size distributions, together with the effect size point estimate and associated 95% credible interval arising from a one-sample Bayesian t-test using a test value of 40. The value of 40 represents the lower bound of the recommended training intensity zone. The resulting $Bayes_{10}$ factor provides weak evidence for the alternative hypothesis. BF = Bayes factor.

The mean (SD) %HRR-AR was 31 (13) %, which is approximately 6% lower than the mean %HRR-CV (Table 6). When comparing the mean %HRR-CV against the mean %HRR-AR (Fig 3), the $Bayes_{10}$ factor of 2076 indicates very strong evidence in favour

of the alternative hypothesis. The median standardised effect size of 1.1 (95%CI: 0.563 to 1.669) suggests a moderate to large effect. Fig 4 shows the overall mean and individual mean distributions of CV and AR components of an 8-week Phase III CR interval training programme. We noted that 67% of our patients had a mean HRR-CV% below 40% HRR, which is the lowest end of the exercise prescription guidelines advocated by national governing bodies.

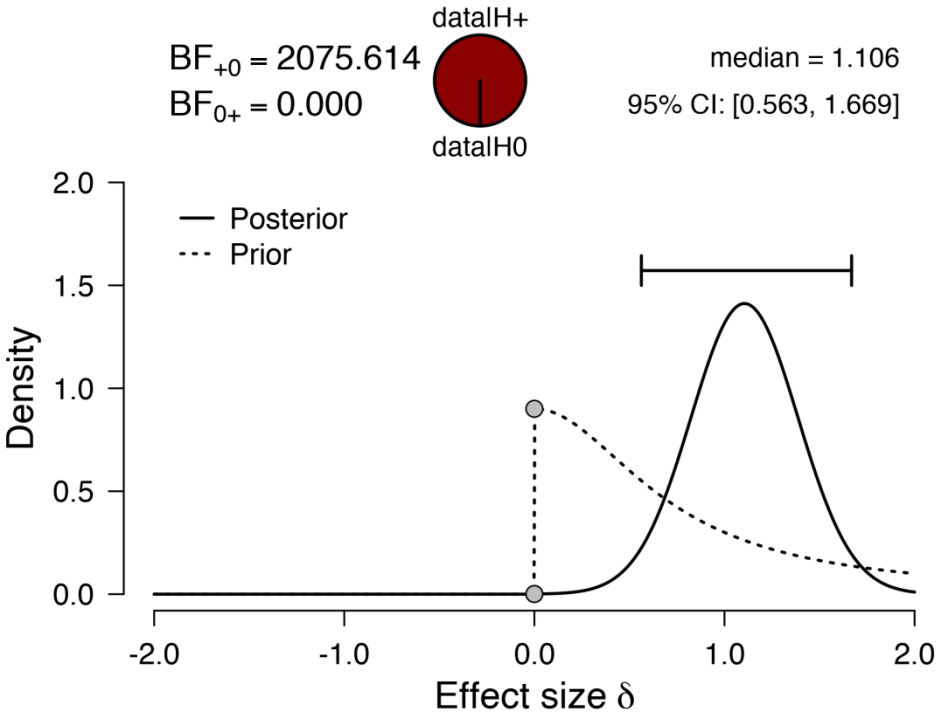

Fig 3. Prior and posterior effect size distributions, together with the effect size point estimate and associated 95% credible interval arising from a paired-sample Bayesian t-test examining the mean difference between %HRR-CV and %HRR-AR. The $Bayes_{10}$ factor provides strong evidence for the alternative hypothesis that %HRR-AR is lower than %HRR-CV. The effect size of 1.1 suggests a large difference between the two means. BF = Bayes factor.

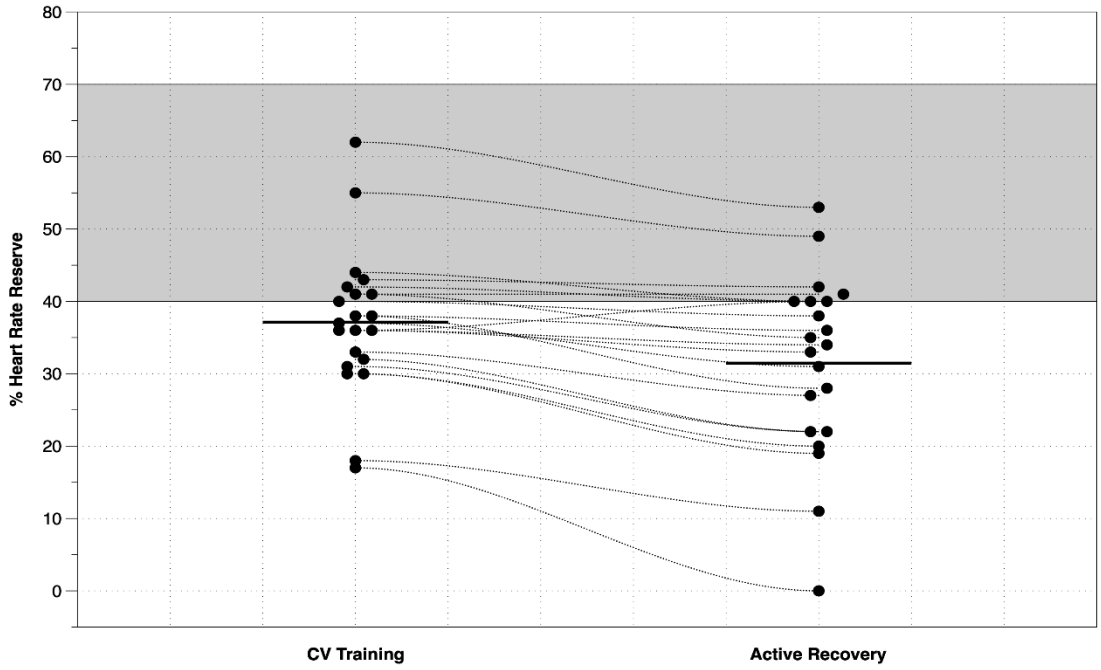

Fig 4. The means (horizontal bar) and individual mean distributions of CV and AR components of an 8-week Phase III CR interval training programme. The grey zone represents the recommended training intensity following national guidelines (BACPR, 2012; ACPICR, 2015).

5.6 Discussion

To the best of our knowledge, our study is the first UK-based study to monitor and quantify exercise training intensity during a structured, community-based Phase III CR programme. Recent reports have highlighted that CR programmes in the UK may be less effective than international programmes (Sandercock, Hurtado & Cardoso, 2013 ; Mitchell et al ., 2018) and may not attain a sufficient exercise intensity to promote physiological adaptations and corresponding improvements in CRF. Our findings provide further support for these assertions. The mean exercise intensity during the CV training component of the Phase III programme was only 37 (10) % HRR (mean HR achieved <91 [12] bpm) which is below, (but not statistically), the minimum national guidelines for training intensity (BACPR, 2012; American College of Sports Medicine, 2017). Fig 4 highlights the large variability in mean training

intensity received by patients on an individual basis, with 67% of our patients training at an intensity below the lowest threshold advocated by national governing bodies (BACPR, 2012; American College of Sports Medicine, 2017).

UK-based guidelines advocate a percentage range-based method for prescribing exercise intensity (BACPR, 2012 ; American College of Sports Medicine, 2017). However, there are a number of limitations of this method; firstly, it fails to account for individual metabolic responses e.g. ventilatory and blood lactate responses to interval exercise (Scharhag-Rosenberger, Walitzek, Kindermann & Meyer, 2012), which is problematic given that exercise prescription is required to be personalised for patients with cardiac disease (American College of Sports Medicine, 2017). Examples of this lack of personalisation have been demonstrated in previous studies (Weltman et al ., 1989 ; Weltman et al., 1990 & Meyer, Gabriel & Kindermann ,1999), which have shown considerable individual variation in blood lactate response to exercise when intensity is anchored to a relative percentage range. A heterogenous metabolic response to exercise training has been offered as a possible mechanism for the variability in effectiveness of exercise training programmes, thus resulting in positive responders and non-responders (Mann, Lamberts & Lambert , 2014). Wolpern et al (2015) conducted a randomised controlled trial to compare the effectiveness of a threshold-based model (ventilatory threshold) versus a relative percent model (%HRR) for improving cardiorespiratory fitness in 36 males and females (Wolpern, Burgos, Janot, & Dalleck , 2015). They found that the threshold-based model elicited significantly (P<0.05) greater improvements in VO_2max compared to a %HRR model following 12 weeks of training. However, an interesting finding from this study was that the threshold-based model attenuated the individual variation in VO_2max training responses when compared to the %HRR group. The authors reported considerable

heterogeneity in terms of responders (41.7%), and non-responders (58.3 %) for eliciting changes in VO_2max following training, which is consistent with other studies (Scharhag-Rosenberger, Walitzek, Kindermann & Meyer, 2012 ; Scharhag-Rosenberger et al ., 2010). Wolpern et al (2014) showed that in the threshold-based training group, 100% of participants demonstrated a positive improvement in VO_2max following training. A mean improvement of 1.1 METs (full range: +0.65 to +1.63 METs) was reported among these young or middle aged previously sedentary groups. In contrast, only 41.7 % of participants experienced a significant improvement in VO_2max in the %HRR group (Mann, Lamberts & Lambert, 2014).

In the UK, there are >300 registered CR programmes (Phase III and IV), which undoubtedly leads to issues in relation to consistency of service quality and delivery. In recent years, there have been some positive signs reported in relation to improved consistency of service provision. In 2015, the BACPR and National Association of Cardiac Rehabilitation (NACR) developed the National Certification programme for CR (NCP_CR) services, which sets out to improve delivery of CR, showcase good services, and seek to ensure the effectiveness of routine provision of CR programmes through achievement of a minimum level of service delivery across the UK (NACR, 2017 ; Furze, Doherty & Grant-Pearce, 2016).

Doherty and colleagues (2017) recently conducted an audit to investigate how many UK CR programmes met minimal standards for delivery of the NCP_CR. The analysis used UK NACR data extracted and validated for the period 2013–2014 set against six NCP_CR measures recognised as important for the delivery of high-quality CR programmes (Doherty, Salman, Furze, Dalal & Harrison, 2017). Data from 170 CR programmes revealed significant variability in terms of quality of service delivery;

30.6% were assessed as high performing, 45.9% as mid-level performing, 18.2% were classified as low performing, and 5.3% failed to meet any of the minimum criteria. These findings indicate that substantial variation, below the recommended minimum standards, exists throughout the UK. The six measures deemed important for high quality provision relate to the service being offered to all priority groups; ≥69% of patients with recorded assessments before starting a formal CR programme; ≥49% of patients with recorded assessment after completing a CR programme; median waiting time from referral to start of CR within 40 days (post-MI); median waiting time from referral to start of CR within 54 days (post-CABG); Median duration of CR programmes being 54 days for conventional delivery, or 42 days where the Heart Manual was used (Doherty, 2017). Currently, there are no criteria which relate to service effectiveness which, if incorporated, may assist with improving service outcomes at a national level.

A limitation of current UK practice is that maximum heart rate is estimated, and not directly measured. Subsequently, adjustment for beta-blockade is added, and then a resting heart rate (RHR) value is included in the calculation. Each of these steps incur error of estimation, reducing the accuracy of the training heart rate range which is prescribed to the patient (Tabet et al., 2008). Alternative and more valid equations for estimating heart rate maximum have been derived from specific cardiac cohorts which, crucially, have been adjusted for beta-blockade (Brawner, Ehrman, Schairer, Cao & Keteyian., 2004). It may be a recommendation for UK CR services to use a Brawner equation for estimating heart rate maximum. The timing of the RHR assessment is also important: cardiovascular physiology appears to follow a daily biorhythm; heart rate, blood pressure, and cardiac contractility all peak in the wake hours and reach a nadir during sleep (Tsimakouridze, Alibhai & Martino, 2015). The suppressive effect

of propranolol, for example, on the rise in HR during exercise is significantly greater if the drug is taken in the morning versus at night (Fujimura et al., 1990). Therefore, to ensure minimal variability in the daily RHR, CR staff should be mindful that offering classes at regular times of the day will help minimise biorhythm disturbance. Secondly, checking patients timing and compliance of their beta-blocker medication will also assist with this goal. It is also possible that over time, cardiorespiratory fitness may improve, potentially lowering the RHR. Furthermore, medication changes may also be responsible for an altered RHR. Therefore, CR staff should ensure that RHR is checked and recorded prior to the start of each training session in order to ensure a more precise estimation of the individualised HR training zone. Finally, the implementation of these processes are fundamental to effective practice, hence the requirement for ongoing professional development and education to ensure that CR service quality and standards are improved.

A limitation of our study is that our detailed evaluation of training intensity from a Phase III community-based CR programme is based on findings from a single NHS centre and may not be representative of exercise training intensities or prescription methods undertaken in other centres. We have already acknowledged the high levels of inconsistent and variable quality of CR service provision in the UK. It is highly probable that many of the >300 UK CR programmes would be far more effective with patient outcomes being significantly greater than in the CR service we observed. Conversely, however, it is also possible that some other CR programmes may be inferior in terms of patient outcomes, therefore, the key is trying to improve the consistency of CR service provision and quality across the UK.

Our study did not directly measure peak HR, rather it was estimated using a predictive equation, including the adjustment for beta-blockade. Therefore, we cannot say how accurately our training zone calculations were (compared to directly measured findings), however, we have systematically followed the process for estimating HR training zones as recommended by the BACPR and ACPICR in the UK. Consequently, we are confident that our study is pragmatic, and provides real-world application.

We utilised two models of Apple watch in our study. It is possible that this technical issue may have introduced some degree of systematic error to our findings as we are not aware of the differences in technical specification between the models.

In conclusion, within a heterogeneous cohort of patients with cardiovascular disease attending routine Phase III CR, mean exercise training intensity was below the minimal exercise training intensity threshold (40% HRR) recommended within national guidelines in the UK. The generalisability of these findings requires further investigation. However, they may be in part responsible for previous reports highlighting the significant variability in effectiveness of UK CR services, and the poor improvements in CRF documented in patients undertaking CR in the UK compared to international standards.

5.7Acknowledgments

The authors would like to thank each patient for their time and commitment to the study, and we would also like to thank the cardiac rehabilitation team for their immense support throughout. A particular thank you to Laura Correia and Sean Pymer for all their help with data collection. We are

also grateful to the Royal Embassy of Saudi Arabia Cultural Bureau in the UK and the Ministry of Higher Education and Umm AL-qura University in Saudi Arabia.

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Chapter 6: Characterisation of the Principle of Progressive Overload in a United Kingdom-based Community Cardiac Rehabilitation Programme

6.1 Abstract

Background: The aim of the study was to characterise the weekly progression of exercise training dose/load over an 8-week Phase III CR programme based in the UK.

Method: Patients with a history of cardiovascular (CV) disease were recruited to an 8-week CR programme (16 sessions in total). During each training session, patients wore an Apple Watch (Series 0 or 2, Watch OS2.0.1, Apple Inc., California, USA) and we quantified the weekly progression of exercise training dose/load for % heart rate reserve (%HRR) during the CV training component (%HRR-CV), CV training duration, estimated changes in cardiorespiratory fitness (change in estimated METS), session rating of perceived exertion (sRPE), sRPE training load (sRPE-TL), and training impulse (TRIMP).

Results: Thirty cardiac patients [83% male; age (SD) 67.0 (10.0) years; body mass index (SD) 28.3 (4.6) $kg \cdot m^{-2}$] were recruited to the Phase III CR programme. Overall, our analysis is based on 332 individual training sessions. Bayesian repeated-measures ANOVA resulted in a BF_{10} of 1.1 to 3.1, indicating weak to moderate evidence for the alternative hypothesis of an effect of time on %HRR-CV, sRPE, and change in estimated METs. Conversely, Bayesian repeated-measures ANOVA resulted in a BF_{10} of between 103,977 to 1,018,000, indicating extremely strong evidence for the alternative hypothesis of an effect of time on CV training duration, TRIMP, and sRPE-TL.

Conclusion: The current study suggests that the training principle of progressive overload is being applied consistently in CR. However, the increases observed in exercise training dose were mostly the result of increases in the duration of CV training rather than increases in exercise training intensity (%HRR-CV and sRPE). Therefore, allied health professionals must ensure that weekly increases in exercise intensity are consistently applied in order to optimise exercise training prescription and improve patient outcomes.

Keywords: Training intensity, cardiac rehabilitation, TRIMP, session RPE, heart rate reserve; progressive overload.

6.2 Introduction

In 2016, an updated Cochrane review (Anderson et al., 2015), synthesising 63 international studies, concluded that compared to no exercise control, exercise-based CR reduced the risk of cardiovascular mortality but not total mortality. However, in recent years, studies emanating from the United Kingdom (UK) have questioned the effectiveness of CR for improving all-cause and cardiovascular mortality. Initially, the Rehabilitation after myocardial infarction trail (RAMIT) trial (West, Jones, & Henderson, 2012), a multi-center RCT based in representative hospitals in England and Wales, compared 1,813 patients referred to comprehensive CR or discharged to 'usual care' (without referral to CR). The primary outcome measure was all-cause mortality at 2 years. The study found that CR following myocardial infarction (MI) had no important effect on mortality, cardiac or psychological morbidity, risk factors, health-related quality of life, or activity levels. The authors concluded that "the value of cardiac rehabilitation as practised in the UK is open to question". More recently, Powell and colleagues (2018) conducted a systematic review and meta-analysis to determine the effectiveness of exercise-based CR in terms of all-cause mortality, cardiovascular mortality, and hospital admissions . They included 22 studies including 4,834 patients (mean age 59.5 years, 78.4% male). Their analysis indicated "conclusively" that the current approach to exercise-based CR has no effect on all-cause mortality or cardiovascular mortality, when compared to no-exercise control. Earlier support for these findings was reported by Sandercock et al (2013) who conducted a UK-based multi-centre study to quantify changes in cardiorespiratory fitness (CRF) changes before and after CR. The authors concluded that low exercise training volumes and small increases in cardiorespiratory fitness (CRF) (0.52

metabolic equivalents) may partially explain the reported inefficacy of UK CR to improve patient mortality and morbidity.

In UK CR programmes, exercise intensity is prescribed from a fixed percentage range (% heart rate reserve (%HRR)). We aimed to determine the accuracy of this approach by comparing it with an objective, threshold-based approach incorporating the accurate determination of ventilatory anaerobic threshold (VAT) (Pymer et al., 2019). In 112 referred patients, there was a significant but relatively weak correlation ($r = 0.32$; $P = 0.001$) between measured and predicted %HRR, and values were significantly different from each other ($P=0.005$). Within this cohort, we found that 55% of patients had their VAT identified outside of the 40-70% predicted HRR exercise training zone. In the majority of participants (45%), the VAT occurred at an exercise intensity <40% HRR. These findings indicated that a fixed percentage range approach may be inaccurate in a large proportion of patients undertaking CR. Recently, we also reported that mean exercise training intensity was below the lower limit of the minimal training intensity guidelines for an 8-week Phase III CR programme (Khushhal, Nichols, Carroll, Abt & Ingle, 2019). These findings may be in part responsible for previous reports highlighting the significant variability in effectiveness of UK CR services and poor CRF improvements observed from several prior investigations. This study (Khushhal, Nichols, Carroll, Abt & Ingle, 2019) appeared to indicate that basic principles of exercise training may have not been followed. The acronym 'SPORT' can be used to describe the five main principles of training including specificity, progression, overload, recovery, tedium. We combined two of these principles into 'progressive overload' and wanted to test the hypothesis that allied health professionals were not consistently applying the principle of progressive overload to cardiac patients undertaking community-based Phase III CR programme.

We believe this may be one of the reasons for the variability in outcomes reported in UK CR programmes. Therefore, the aim of the study was to characterise the weekly progression of exercise dose over an 8-week Phase III CR programme.

6.3 Methods

6.3.1 Inclusion and Exclusion Criteria

The study was approved by the North West National Health Service (NHS) Research Ethics Committee and institutional ethics committee prior to commencement of the study. All patients provided written informed consent before participating in the trial. The following patients were eligible to participate in the study: patients following myocardial infarction (MI), whose event had presented in the preceding 3-6 weeks, percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) within the past 6 weeks, stable angina, valvular or aortic root repair, patients with devices such as pacemaker or implantable cardioverter defibrillator, and stable heart failure. We excluded patients who had orthopaedic or neurological limitations, unstable angina, New York Heart Association class IV heart failure, uncontrolled hypertension and diabetes, symptomatic hypotension, uncontrolled tachy-arrhythmias, and febrile illness. Patients were referred from their hospital doctor or general practitioner to a Phase III CR programme based in the North Eastern region of England in 2017 and 2018.

6.3.2 Cardiac Rehabilitation Programme

The 8-week Phase III CR programme contained 16 sessions in total (twice per week). Each exercise training session was conducted over a 45 minute period (~12 hours of

exercise training in total over 8 weeks). Each exercise training session included 10-15 minutes of warm-up followed by a circuit programme based on an interval approach to training; nine exercise stations of which five were cardiovascular (CV) based and four were active recovery (AR) exercises. The CV stations were designed to be conducted within the patients pre-determined heart rate training zone (40-70% heart rate reserve; HRR). These exercises included step ups, static cycling, sit to stand, treadmill walking and rowing. The AR stations were: leg curls, bicep curls, lateral arm raises, and wall presses. The training session ended with a 10-minute cool-down. The patients were advised not to drink caffeine for at least 3 hours before the exercise sessions. The exercise prescription for each patient was based on national guidelines (BACPR, 2012 ; ACPICR, 2015). Individual heart rate training zones were calculated between 40-70% HRR, in accordance with national guidelines (BACPR, 2012 ; ACPICR, 2015), using the following equation:

Maximum HR= 206 – (age x 0.7) (Inbar et al., 1994 ; Londeree & Moeschberger, 1982).

In order to calculate the HRR, we deducted the resting HR from the maximum heart rate. An additional deduction of 30 beats per min was carried out for patients prescribed beta-blockers (BACPR, 2012 ; ACPICR, 2015). To determine the effectiveness of the CR programme, a symptom-limited submaximal exercise test was conducted on a cycle ergometer at baseline and following the 8-week CR programme. Change in estimated metabolic equivalents (METS) was recorded.

6.3.3 Observational Study Protocol

During each exercise session over the 8-week programme, each patient wore an Apple Watch (Series 0 or 2, Watch OS2.0.1, Apple Inc., California, USA). Patients wore the

Apple Watch during each exercise session on their left wrist, with the exception of one patient, who wore it on the right wrist due to an existing tattoo on the left. Each Apple Watch was connected via Bluetooth to an iPhone 5s or iPhone 6 (Apple Inc., California, USA). We used the 'Workout' app to measure heart rate every 5 seconds. A bespoke iPhone app was written by one of the co-authors (GA) to extract the raw HR and sampling time data from the 'Health' database on the paired iPhone. The bespoke app was written using the Swift 2.1 language in Xcode 7.2.1, utilising the methods supplied by the HealthKit framework (Apple Inc., California, USA). The Apple Watch uses photoplethysmography (PPT) to measure HR. PPT is a non-invasive measure and uses a sensor to note changes in blood flow to measure heart rate (Allen, 2007). We recently revealed that the Apple Watch heart rate sensor has good validity during jogging and running, and very good validity during walking activities. It is clear, however, that the validity of the Apple Watch for measuring heart rate reduces as exercise intensities increases and particularly during exercise with rapid arm movements (Khushhal et al ., 2017).

6.3.4 Measurements of Exercise Dose/Load to Determine Weekly Progression

In order to calculate weekly changes in individual exercise training dose/load, we measured the following variables:

1) Exercise intensity: based on weekly changes in 40-70% HRR during CV training (%HRR-CV).
2) Exercise duration: based on weekly changes in the duration of CV training (minutes and percentage change)

3) Banister's training impulse (TRIMP) is a method of measuring internal load by combining exercise intensity based on changes in mean heart rate with exercise duration (Banister, 1991).

4) Banister's TRIMP was calculated for each patient's weekly training sessions using the following formula:

Exercise duration (mins) * mean heart rate * y; where y is a weighting factor.

5) We measured session rating of perceived exertion (sRPE), where each patient rated his/her exercise intensity subjectively at the end of every training session recalling their RPE for the entire session (Foster scale 0 to 10), where 0 is rest and 10 is maximal (Foster et al ., 2001).
6) In addition, we also calculated the weekly changes in session RPE training load (sRPE-TL) which is the product of session rating of perceived exertion (sRPE) multiplied by training session duration.
7) From the symptom-limited, submaximal cycle ergometer test we measured change in estimated METs (baseline to 8-weeks later).

In terms of progressive overload, previous work has shown that the minimum increase in weekly training load should be ≥10% to gain significant adaptations and subsequent improvements in physical performance (Foster, Daines, Hector, Snyder & Welsh, 1996).

6.3.5 Statistical Analysis

Data analysis was conducted in JASP 0.10.2 (JASP Team , 2019) using Bayesian statistical methods. Data residuals for each model described below were visually examined using Q-Q plots and found to be approximately normal.

Below we describe the statistical analysis for the following comparisons:

(1) Comparing mean %HRR-CV across each of the eight weeks of training.

(2) Comparing mean CV training duration across each of the eight weeks of training.

(3) Comparing mean TRIMP across each of the eight weeks of training.

(4) Comparing mean sRPE across each of the eight weeks of training.

(5) Comparing mean sRPE-TL across each of the eight weeks of training.

(6) Comparing pre and post estimated changes in CRF (estimated METs).

We examined the changes in mean %HRR-CV, mean sRPE, mean CV training duration, mean TRIMP, and mean sRPE-TL across each of the eight weeks of training both in the form of a hypothesis test using Bayes factors and as a parameter estimation for the posterior distribution of the standardised difference. Our null hypothesis test compared the observed data against a null hypothesis of no difference in each of these five variables across the eight weeks. For each analysis we conducted a Bayesian repeated-measures ANOVA, which is equivalent to a Bayesian linear mixed-effects model where the individual intercepts were allowed to vary for participants, using a two-sided alternative hypothesis because it is unknown if there was progressive overload in these measures across the training programme. Where Bayes Factor $(BF)_{10}$ suggested strong evidence for the alternative hypothesis (H_1), post-hoc pairwise comparisons of the standardised differences (median Cohen's *d*) are reported along

with the associated 95% credible interval for each paired difference. Given our uncertainty in the effects, we assigned a flat prior with scale r = 0.5 for fixed effects and 1 for random effects. Subject was considered as a random effect. To examine the change (if any) in cardiorespiratory fitness (estimated METs) we used a two-sided Bayesian paired-sample t-test with a broad weakly informative prior using a zero-centred Cauchy distribution with scale r = $1/\sqrt{2}$. To describe the strength of evidence for H_1 we used the classification scheme of Jeffreys (Jeffreys,1939), where a BF_{10} between one and three is indicative of weak evidence, between three and 10 indicative of moderate evidence, and above 10 indicative of strong evidence. However, we have not used these as absolute thresholds, but rather on a continuum with higher values indicative of increasingly stronger support for H_1. To describe the magnitude of the standardised effect size we use the classification scheme of Cohen (Cohen, 1988), with 0.2, 0.5 and 0.8 representing small, moderate, and large effects, respectively.

6.4 Results

Thirty cardiac patients [83% male; age (SD) 67.0 (10.0) years; body mass index (SD) 28.3 (4.6) $kg \cdot m^{-2}$] were recruited to the Phase III CR programme. Of these, 87% were prescribed beta-blockers; 53% statins; 40% ACE-inhibitors; and 68% aspirin**.** These medications remained unchanged throughout the training intervention. Patients were randomly selected from a mixed cardiovascular disease aetiology: 11 patients had received a coronary artery bypass graft, 7 percutaneous coronary intervention, and 2 patients had undergone a mitral valve replacement. Amongst the non-surgical patients, 4 patients were post-myocardial infarction, 3 patients had diagnosed coronary heart disease, and 3 were diagnosed with chronic heart failure. Of the 30 patients who initially enrolled, 4 exhibited paroxysmal atrial fibrillation.

Twenty patients (67% of the population) completed all 16 sessions (twice a week for eight weeks) of the Phase III CR programme; the remaining 10 patients dropped out at various stages of the programme due to a deterioration in their health, or were unable to attend due to personal reasons. Our analysis is based on 21 patients who had a programme adherence ≥75% (completed a minimum of 12 of 16 sessions). In total, we monitored 370 individual exercise training sessions, although data from 5 exercise sessions on selected patients were lost due to technical problems. Overall our analysis is based on 332 individual training sessions.

Changes in %HRR-CV

The mean (SD) % heart rate reserve during cardiovascular training for each of the eight training weeks is displayed in Table 7. The Bayesian repeated-measures ANOVA resulted in a BF_{10} of 3.1, indicating weak to moderate evidence for the alternative hypothesis of an effect of time on %HRR. Percentage weekly changes are displayed in Figure 5.

Table 7. Mean (SD) training intensity and training load collected over eight weeks of a cardiac rehabilitation programme.

Measure	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HRR-CV (%)	36 (15)	34 (13)	35 (13)	36 (12)	38 (12)	40 (11)	39 (12)	42 (12)
SRPE (AU)	2.6 (0.5)	2.9 (0.6)	3.0 (0.6)	3.0 (0.5)	2.9 (0.6)	3.0 (0.7)	3.0 (0.8)	3.3 (0.6)
CV time (min)	17 (6)	21 (8)	24 (9)	26 (9)	28 (8)	30 (7)	30 (8)	32 (8)
TRIMP (AU)	24 (17)	20 (13)	23 (17)	26 (18)	26 (20)	29 (18)	31 (20)	35 (23)
SRPE-TL (AU)	129 (44)	147 (40)	163 (53)	170 (43)	172(57)	184(58)	186 (68)	205 (52)

%HRR-CV = weekly mean percentage heart rate reserve during cardiovascular training; SRPE = session rating of perceived exertion (CR10); CV time = weekly mean time spent doing cardiovascular training during any given training session; TRIMP = training impulse; SRPE-TL = session rating of perceived exertion training load (SRPE x training session duration); AU = arbitrary units.

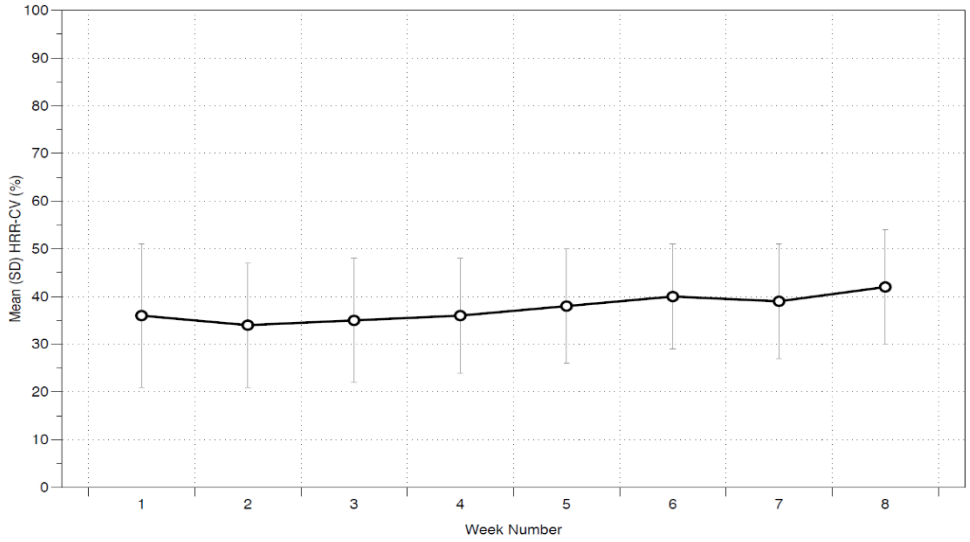

Fig 5. Weekly changes in exercise intensity based on %HRR-CV in cardiac patients undergoing 8-weeks of CR

Changes in CV Training Duration

The mean (SD) CV training duration for each of the eight training weeks is displayed in Table 1. The Bayesian repeated-measures ANOVA resulted in a BF_{10} of 2.438e+26, indicating extremely strong evidence for the alternative hypothesis of an effect of time on CV training duration (Figure 6).

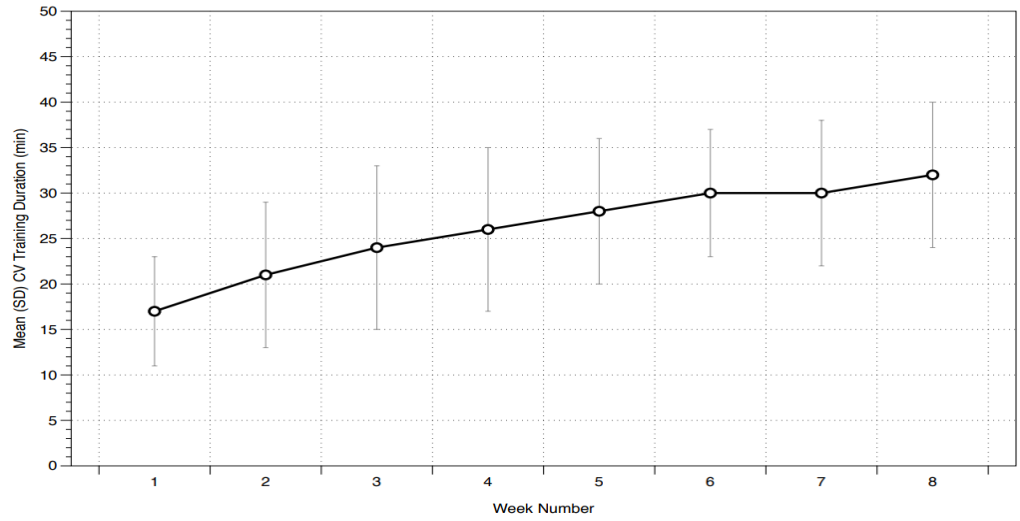

Fig 6. Weekly changes in exercise duration (minutes) in cardiac patients undergoing 8-weeks of CR

Changes in Session RPE (sRPE)

The mean (SD) sRPE for each of the eight training weeks is displayed in Table 1. The Bayesian repeated-measures ANOVA resulted in a BF_{10} of 1.1, indicating weak evidence for the alternative hypothesis of an effect of time on sRPE.

Changes in Training Impulse (TRIMP)

The mean (SD) TRIMP for each of the eight training weeks is displayed in Table 1. The Bayesian repeated-measures ANOVA resulted in a BF_{10} of 103977, indicating extremely strong evidence for the alternative hypothesis of an effect of time on TRIMP. Post-hoc pairwise comparisons of the standardised differences (95% CI) between weeks are displayed in Figure 7.

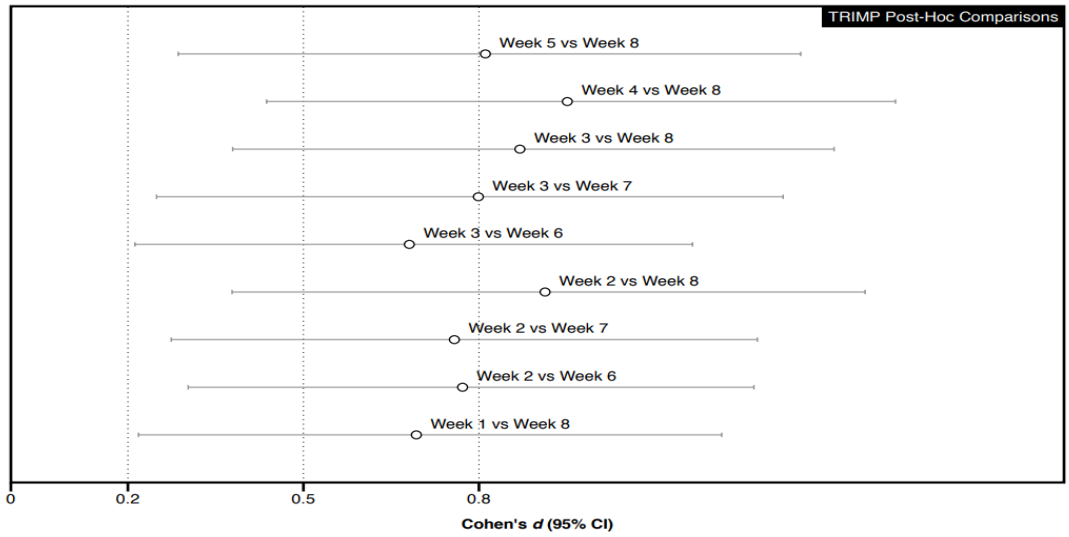

Fig 7. Post-hoc pairwise comparisons of the standardised differences (95% CI) for TRIMP

Changes in Session RPE—Training Load (sRPE-TL)

The mean (SD) sRPE-TL for each of the eight training weeks is displayed in Table 1. The Bayesian repeated-measures ANOVA resulted in a BF_{10} of 1018000, indicating extremely strong evidence for the alternative hypothesis of an effect of time on sRPE-TL. Post-hoc pairwise comparisons of the standardised differences (95% CI) between weeks are displayed in Figure 8.

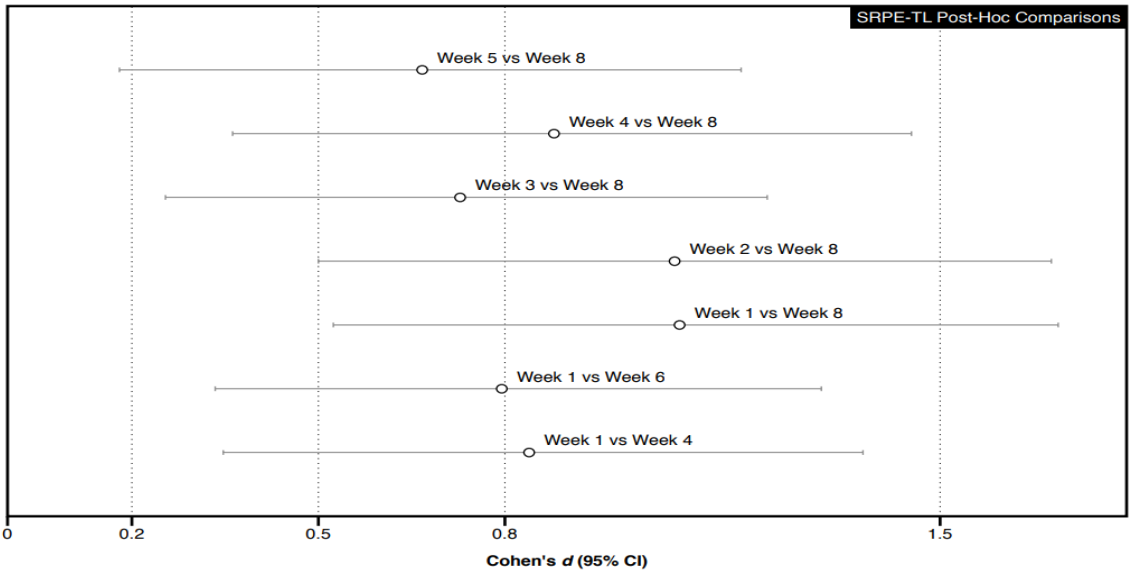

Fig 8. Post-hoc pairwise comparisons of the standardised differences (95% CI) for sRPE-TL

Estimated Changes in Cardiorespiratory Fitness (Estimated METs)

The mean (SD) estimated METs derived from pre and post cardiorespiratory fitness tests were 4.3 (1.9) and 5.2 (2.2), respectively. The Bayesian paired samples t-test resulted in a BF_{10} of 1.2, indicating weak evidence for the alternative hypothesis of an effect of time on estimated METs.

6.5 Discussion

This study is the first to characterise the weekly progression of exercise training dose/load over an 8-week Phase III cardiac rehabilitation (CR) programme based in

the United Kingdom (UK). We found that the training principle of progressive overload was consistently applied to weekly increases in the duration of CV activity (and its surrogate measures) performed by cardiac patients undergoing community-based CR in the UK. However, allied health professionals must ensure that weekly increases in exercise intensity are consistently applied in order to optimise exercise training prescription and improve patient outcomes.

Although the duration of weekly CV training increased over the 8-week intervention, alongside sRPE-TL and TRIMP which also increased over the intervention (as CV training duration is a factor within their determination), CV training intensity was not titrated consistently over this period. Our study shows that there was weak to moderate evidence for the alternative hypothesis of an effect of time for %HRR-CV over the 8-week intervention, indicating that training intensity was not individually titrated in accordance with established principles of exercise training (Figure 5). Previous work (Foster, Daines, Hector, Snyder & Welsh, 1996) highlighted that a minimum increase in weekly training load should be ≥10% in order to gain subsequent improvements in physical performance, we only observed an increase in CV training duration.

It is possible that the lack of increases in CV training intensity may be the consequence of a lack of staff training and education. We are hopeful that future interventions such as a higher level qualification in the UK – the BACPR Certified Exercise Specialist, will focus on important training principles such as progressive overload and its implementation, leading to improved service quality and outcomes in the future. Clearly, wearable technology will continue to play an increasingly important role in supporting allied health professionals when monitoring and up-titrating individualised exercise dose/load during CR.

We did not measure external load (e.g. power output from the symptom-limited cycle ergometer test), so no change in internal intensity (%HRR) does not mean that patients were unable to increase their external load (e.g. power output) for the same internal intensity over time. We have previously argued that part of the problem associated with the perceived lack of effectiveness of some UK CR programmes may be due to the widespread use of submaximal exercise testing e.g. 6-min walk test, incremental shuttle walk test, or the Chester step test (Ingle & Carroll, 2013) to determine programme effectiveness and to prescribe individual training thresholds. In the current CR programme we evaluated a submaximal cycle ergometer test with the outcome measures used including changes in estimated METs. We recently showed that changes in estimated VO_{2peak} derived from the ACSM leg cycling equation is not an accurate surrogate for directly determined changes in VO_{2peak}. We showed poor agreement between estimates of VO_{2peak} and directly determined VO_{2peak}. Applying estimates of VO_{2peak} to determine CRF change may over-estimate the efficacy of CR and lead to a different interpretation of study findings (Nichols et al., 2018a). There are very few centres in the UK which have adopted maximal cardiopulmonary exercise testing as routine for evaluating clinical populations and prescribing individualised exercise training loads. We eagerly await the outcomes of the CARE CR trial which uses criterion methods to evaluate the effectiveness of a UK CR programme (Nichols et al., 2018b).

We found that there was no change in CRF (estimated METs) determined from the symptom-limited cycle ergometer test. We can conclude therefore that either (1) TRIMP and sRPE are not valid measures of training load for cardiac patients undertaking CR, or (2) the absolute increases in training load were not large enough to induce training adaptations. Whilst we are unaware of previous studies who have

validated such measures (TRIMP and sRPE) in patients with coronary heart disease undertaking CR, Volterrani & Iellamo (2016) have undertaken some initial validation work on TRIMP in patients with chronic heart failure (Volterrani & Iellamo, 2016). The same research group have also argued that sRPE is a useful tool for long-term exercise prescription in cardiac patients (Iellamo et al ., 2014). They estimated that to reach an effective weekly training load (e.g. around 400 AU), an effective exercise intervention should comprise 4 training sessions per week, with a session duration of 40–50 min at RPE 3–5 (Borg CR-10 scale). Compared to current practice, this estimated training load is significantly greater to what is currently available to cardiac patients undertaking CR in the UK.

A limitation of our study is that our detailed evaluation of training intensity from a Phase III community-based CR programme is based on findings from a single NHS centre and may not be representative of exercise training intensities or prescription methods undertaken in other centres. A previous report has highlighted the high levels of inconsistent and variable quality of CR service provision in the UK (Doherty, Salman, Furze, Dalal, & Harrison, 2017).

We utilised two models of Apple Watch in our study. It is possible that this technical issue may have introduced some degree of systematic error to our findings as we are not aware of the differences in technical specification between the models.

In conclusion, the training principle of progressive overload was consistently applied to weekly increases in the duration of CV activity (and its surrogate measures) performed by cardiac patients undergoing community-based CR in the UK. However, allied health professionals must ensure that weekly increases in exercise intensity are consistently applied in order to optimise exercise training prescription and improve

patient outcomes. These findings may be in part responsible for previous reports highlighting the lack of effectiveness of UK CR programmes.

6.6 Acknowledgements

The authors would like to thank all the participants for their time and commitment to the study and we would also like to thank the cardiac rehabilitation team for their immense support throughout. A particular thank you to Laura Correia and Sean Pymer, for all their help with data collection. We are also grateful to the Royal Embassy of Saudi Arabia Cultural Bureau in the UK and the Ministry of Higher Education at Umm Al-Qura University in Saudi Arabia.

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Chapter 7: General Discussion

7.1 Discussion

This thesis is the first to investigate the validity and inter- and intra-device reliability of the Apple watch to measure heart rate (using a bespoke 5-second averaging

algorithm), and stepping frequency during walking, jogging and running activity on a treadmill. Moreover, it is the first study to quantify the exercise dose achieved in an 8-week community-based Phase III CR programme.

Chapter 3 showed that the Apple watch has very poor to poor validity in measuring stepping frequency during walking, jogging and running activities, which leads to a large to very large over-estimation of stepping frequency compared with the ActivPal during jogging and running, and has a small under-estimation during walking. The Apple watch has good to almost perfect inter-device variability in measuring stepping frequency during walking, jogging and running, and large to very large intra-device variability in measuring stepping frequency during walking, jogging and running. The Apple watch worn on the right hand showed better intra-device variability than when worn on the left hand, which is likely to relate to hand dominance. As a consequence of these findings we did not pursue stepping frequency as an outcome measure in our community-based Phase III CR trial.

Chapter 4 showed that the Apple watch has very good validity during walking, good validity during jogging, and good/poor validity during running. It was clear that the validity of the Apple watch decreases with an increase in exercise intensity. However, we concluded that because of the moderate intensity levels likely to be achieved in a community-based Phase III CR programme, the heart rate sensor within the Apple watch could be incorporated into our main study and we could be reassured about its effectiveness for valid and reliable data output.

Falter and colleagues (2019) examined the validity of the Apple watch in 40 cardiac patients during a CPET compared to 12-lead ECG. The patients cycled at 20 W and then increased 20 W per minute. Heart rate was recorded from the Apple watch at 30

second intervals at the start, mid-point and peak exercise intensity. The findings showed that the association increased as exercise intensity increased: there was a moderate correlation (r=0.72) during rest, good correlation (r=0.82) during low exercise intensity, and excellent correlation (r=0.95) during high exercise intensity. The mean absolute percentage error was low during high exercise intensity and high during rest. This result supports the use of the Apple watch with cardiac patients. A positive aspect of these results was that each patient's arm was stable during the whole exercise procedure, which reduced the effect of arm movement artefact. However, these results apply to non-weight bearing cycling activity where it is easier to control movement artefact. This level of control would not be achievable on different modes of exercise including a treadmill. Cardiac patients are typically medically managed with pharmacotherapy which has a blunting response to heart rate (e.g. beta-blockade) during incremental exercise. Patients may also have irregular rhythm disturbances, most commonly through atrial fibrillation and it is unclear how the Apple watch is able to deal with these irregular patterns. The study by Falter and colleagues (2019) was reassuring in that it showed that the Apple watch was able to interpret these subtle changes during exercise.

The novelty of our results is that this is the first study to measure heart rate every 5 seconds using our bespoke algorithm. Until now, no study has measured heart rate every 5 seconds and other studies do not provide sufficient description of how they measure and record HR from the Apple watch. Our data extend the findings from Wallen and colleagues (2016) and Wang and colleagues (2017) allowing us to measure heart rate continually every 5 seconds. It is likely that the reduction in validity of the Apple watch as exercise intensity increases, may be due to increased movement artefact arising from a running gait.

Our data are the first to show that, during the first minute of exercise, especially during high-intensity activity, the Apple watch only obtained between 60-80% of the available heart rate epochs (based on 5-second averaging), which could be due to the change in blood flow and increased movement artefact. In the second minute, the Apple watch obtained between 85-95% of heart rate epochs, which increased to 90-95% in the third minute, and 95-100% of heart rate epochs in the fourth and fifth minute. From our data analysis, we would conclude that caution should be taken when analysing heart rate data from the Apple watch during the first 3 minutes of exercise.

Our study is also the first to assess inter- and intra-device reliability of the Apple watch for measuring heart rate during recovery from exercise. Our results showed that the Apple watch has good validity in measuring heart rate recovery after walking but poor validity in recovery from jogging and running. The Apple watch appears to overestimate these values which may be due to a sudden reduction in blood flow and changes in arm movement artefact especially during the first minute of recovery from exercise. Dooley et al. (2017) reported that the Apple watch underestimated heart rate in recovery from different exercise intensities, however, they did not measure heart rate continuously as we did, rather they took a snap-shot of heart rates after 3.5 and 7 minutes of recovery. Therefore, it is difficult to know how accurate this approach was for accurately recording heart rate during recovery from exercise. Our observations showed there was distinct variability of movement artefact caused by arm movements between participants during exercise transitions (between walking, jogging and running).

Chapter 5 presents data from the first study to investigate the fidelity of an 8-week, physiotherapist-led Phase III CR programme in the UK. We initially recruited 30

patients but due to drop-out our final analysis is based on 21 patients who completed >75% of the 8-week intervention. In total, this equates to an analysis of >330 individual training sessions. Our overall conclusion was that the mean %HRR-CV was 37(10)%, and the mean %HRR-AR was 31(13)%.

The novelty of our study is that we are the first to measure heart rate continually every 5 seconds during each training session, which allowed us to analyse the data in more detail, and obtain heart rate data for each station of the circuit programme we observed. In total this was eight or nine exercises in the programme of which 4 were AR and 4-5 were CV activities. However, other studies (Wallen et al., 2016; Wang et al., 2017) measured heart rate every minute or every 3 minutes, which raises the question of the validity of their findings if they are taking recordings at specific points from the programme (Thomson et al., 2019; Wallen et al., 2016 &Wang et al., 2017).

If we look at individual exercise stations within the CR programme, perhaps not surprisingly the treadmill produced the highest %HRR averaged over the 8-week programme, though this was only 38% HRR which is below the lowest threshold advocated by the national and international guidelines. In descending order for CV exercises, the rower produced mean %HRR of 37%, and step ups and cycling realised 36% HRR, and half stars produced 33% HRR. For active recovery exercises, leg curls averaged 30% of HRR, lateral arm raises 29% HRR, and biceps curls produced a mean value of 27% HRR. The results of the analysis for each exercise individually in the eight-circuit also support the suggestion that all the cardiovascular exercises were higher in terms of exercise intensity than the active recovery exercises, as all the active recovery exercises were between 27-30%, and all CV exercises were between 33-38%

HRR. However, all CV exercises were well below the minimal guidelines for exercise intensity in patients with cardiovascular disease.

Our results revealed that perhaps not surprisingly there is strong evidence for %HRR-CV being higher than %HRR-AR (mean difference ~7% %HRR) averaged over an 8-week Phase III programme. However, the biggest concern from our study was that we have shown for the first time that the majority of patients (67%) worked below the minimal UK exercise prescription guidelines of 40% HRR (mean %HRR=27%). The remaining 33% of patients trained within guidelines, but only at the lower end (mean HRR 45%). It is clear from our results that there is some individual variability in terms of mean exercise dose achieved by each cardiac patient (see Chapter 5 Figure 3), however, the trend is generally very disconcerting. The main aim of Phase III CR is to increase continuous CV time to 20-60 minutes and to increase peak oxygen uptake which is strongly associated with improved survival risk. Whilst we have not measured changes in CRF directly using gold standard measures it is unlikely that any improvements were achieved as it was doubtful that a sufficient stimulus was achieved to invoke a positive physiological adaptation.

In the UK, exercise prescription guidelines promote the use of a fixed percentage range, specifically 40-70% HRR (ACPICR, 2015). Recent studies have shown that this method does not cater for individual variations in the metabolic response to exercise. Threshold-based methods, for example, using the ventilatory anaerobic threshold (VAT) for prescribing individualised exercise prescription are now advocated (Scharhag-Rosenberger, Walitzek, Kindermann & Meyer, 2012). Wolpern et al. (2015) examined the effect of %HRR against VAT in 36 healthy individuals to enhance CRF. The researchers conducted exercises for 30 minutes for 12 weeks (5 days a week)

based on a %HRR group vs a VAT group. They found that the VAT group showed greater improvement in CRF than the %HRR group after 12 months of exercise training. Nevertheless, they found there were differences in the VAT group in terms of VO_2 max compared to the %HRR group. In the %HRR group there were more non-responders to the training intervention, whereas all participants in the VAT group improved CRF indicating that they achieved a high enough stimulus to ensure adaptation. This was not the case in the percentage range group. These results suggest that using the VAT as a basis for prescribing exercise is more effective than %HRR for improving CRF (Wolpern et al., 2015).

Recently, Pymer and colleagues (2019) aimed to determine the accuracy of the %HRR approach by comparing it with an objective, threshold-based approach using VAT. A maximal CPET was conducted on a cycle ergometer or a treadmill before and following usual-care circuit training from two separate CR programmes from a single region in the UK. The heart rate corresponding to VAT was compared with current heart rate-based exercise prescription guidelines. They included 112 referred patients (61 years (59-63); body mass index 29 $kg \cdot m^{-2}$ (29-30); 88% male). There was a significant but relatively weak correlation ($r = 0.32$; $P = 0.001$) between measured and predicted %HRR, and values were significantly different from each other ($P = 0.005$). Within this cohort, they found that 55% of patients had their VAT identified outside of the 40-70% predicted HRR exercise training zone. In the majority of participants (45%), the VAT occurred at an exercise intensity <40% HRR. Moreover, 57% of patients with low levels of CRF achieved VAT at <40% HRR, whereas 30% of patients with higher CRF achieved their VAT at >70% HRR. VAT was significantly higher on the treadmill than the cycle ergometer ($P < 0.001$). The authors concluded that current guidelines for prescribing exercise intensity based on a fixed percentage range may be

an inaccurate approach in a large proportion of patients undertaking CR in the UK. These findings are in concordance with the outcomes of our study.

There are three main limitations in UK CR for measuring heart rate when prescribing exercise intensity. The first is that the maximum heart rate is not measured directly, it is estimated. UK CR teams do not have the equipment of expertise to run maximal CPET pre- and post- CR to determine effectiveness of the programme. The current methods include the Karvonen or Inbar method for estimating HRR using age, resting heart rate and whether or not the patient is prescribed beta-blockers. All of these factors may increase the inaccuracy of the exercise prescription (Tabet et al., 2008). If estimated methods are to be continued in UK practice then using more patient specific predictive equations is on solution. For example, the following equation: (HR max = 164 – 0.7 x age), has already been adjusted for beta blockers. This equation has shown more validity in predicting the maximum heart rate with cardiac patients who are prescribed beta blockers (Brawner, Ehrman, Schairer, Cao & Keteyian, 2004). Resting heart rate should be measured before each exercise session with a view to enabling individualisation (Tsimakouridze, Alibhai & Martino, 2015). Cardiac staff should also ask patients when they take their beta blockers, as this could affect heart rate measurements. For example, plasma propranolol concentration changes significantly from morning to night (Fujimura et al., 1990). Staff should then provide exercise sessions at the same time of day to ensure coherence and reduce biorhythm disturbance.

Taking all the above factors into consideration could lead to benefits in obtaining more precise resting heart rate measurements.

Current practice in the UK is for most CR programmes to be led by HCPC registered staff including nurses and physiotherapists. Most of these allied health professionals

receive little or no training in the area of exercise prescription at an undergraduate level. Most staff will receive short courses (1-5 days) run by organisations including the BACPR or ACPICR, however, these may not provide the appropriate level of training and education to allow staff to run effective CR programmes. Often staff may be conservative in their exercise prescription for patients undertaking CR, and this is borne out by the findings of our study. It is clear that there is a need for staff to receive more training and development, in particular encouraging patients to exercise at a higher exercise intensity and using a systematic approach to exercise progression incorporating regular increases in exercise duration and intensity.

With the advent of digital technology, studies need to be conducted which compare new technologies with usual care methods. If trials showed that CR outcomes can be improved by incorporating digital technology into practice, then investment in technology should be provided to services to enhance efficacy. With future investment would come staff training and education in order to improve service delivery and outcomes.

Doherty and colleagues (2017) conducted an audit to establish how many UK CR services met the minimum standards for providing the NCP-CR. The researchers examined data from 170 CR centres (approximately 50% of UK CR services) and found that 5.3% did not meet any criteria, 18.2% were low performing, 45.9% were middle performing, and 30.6% high performing (Doherty et al., 2017). However, all the criteria were about classifying the service; none were concerned with measuring programme effectiveness. These findings demonstrate that there are variations in the quality of CR services in the UK. It could be argued that if programme effectiveness was an outcome measure for NCP-CR, then services would be under greater scrutiny

to provide more effective programmes which would lead to enhanced patient outcomes.

Chapter 6 aimed to characterise the weekly progression of exercise training dose/load over an 8-week Phase III cardiac rehabilitation (CR) programme based in the United Kingdom (UK). We found that the training principle of progressive overload is being applied consistently in CR. However, the increases observed in exercise training dose were mostly the result of increases in the duration of CV training rather than increases in exercise training intensity (%HRR-CV and sRPE). Therefore, allied health professionals must ensure that weekly increases in exercise intensity are consistently applied in order to optimise exercise training prescription and improve patient outcomes.

In this chapter we also reported the outcomes of the symptom-limited, submaximal cycle ergometer test which was completed before and after the training intervention. In theory, any improvement in estimated METs should have been the result of participation in the 8-week CR intervention. There was only a small improvement in estimated MET of 0.9 units which we calculated from the available data of 16 patients. There was significant performance variability too within this cohort. Six patients achieved a significant improvement (>1.55 METs), but the other 10 patients was less than this value. Indeed, 5 patients did not achieve any change from baseline, and indeed, 3 patients had a lower estimated fitness following the 8-week intervention indicating significantly variability in test outcomes.

We also assessed psychological status before and following the 8-week intervention which we did not report in Chapter 6. We assessed status using the SF-12 questionnaire in 20 patients, and the mean difference following the intervention was 3.9 units, which

did not meet the minimal clinically important difference (MCID) threshold of 8.8 units reported by Parker et al., 2012. Moreover, the SF-12 data were below the mean values previously reported (50 units) (Orthotoolkit, 2017), as scores ranged from a mean value of 44.90 at baseline and 48.88 after the programme. Individual variability in the findings showed that 4 of 20 patients reported improvements above the MCID, but 16/20 did not. Our findings highlight the high variability in outcomes for patients undertaking CR in the UK.

It is clear from this study that there is a need for staff to receive more training and development, in particular encouraging patients to exercise at a higher exercise intensity and using a systematic approach to exercise progression incorporating regular increases in CV intensity.

The evidence provided by our studies are consistent with the suggestion that UK CR programmes have little impact on key patient outcomes including enhanced CRF, we can conclude that, at least in the CR programme we evaluated, there was insufficient exercise intensity and training progression to lead to positive changes in patient outcomes including CRF and quality of life. Therefore, significant amendments are required to lead to positive improvements in service delivery. Patients need to spend more time undertaking CV exercises which are titrated regularly towards the upper end of the prescribed training zones. In conjunction, AR time should be reduced so patients are spending more time doing CV activities. Programme progression should be systematically titrated based on individual patient progress. Ultimately, this means that allied health professionals responsible for running CR programme should be guided with more regular training and education in order to empower them to provide more effective service delivery. Patients also should be made aware of what they

should be doing and why they should be doing it. Adherence to the 8-week Phase III community-based CR programme was relatively poor, with one third of our patients recruited not completing the 8-week programme. These high levels of attrition at the local level reflect an equally depressing picture at the national level, with patients often unclear on why they have been referred to a CR programme, and what the major aims and objectives of it are. Patients need to be educated and empowered from the inception of the referral by knowledgeable and passionate allied health professionals in order to maximise retention. Furthermore, a pathway needs to exist beyond the 8-week Phase III programme which allows patients the opportunity to continue with some form of physical activity once they complete the programme. Currently, in the Hull region, no Phase IV (long-term maintenance) provision is offered, therefore, many patients do not continue with structured exercise once the Phase III programme has been completed. I believe a significant goal of Phase III CR should be to empower patients to continue with a lifelong love of physical activity beyond just the 8-week programme. The programme should be about providing patients with the knowledge, skills, and confidence to want to embed physical activity into their activities of daily living, well beyond the end of the 8-week programme. Whilst this appears to happen in a minority of cases, strategies to develop this interest and passion is required in a broader group of patients.

I observed each of the 370 exercise sessions which were conducted as part of the PhD journey. We lost five sessions due to technical record errors, and we excluded nine patients who did not complete 75% of the Phase III CR programme. Therefore, our results are based on 328 individual exercise sessions. This equates to an observation period of 344 hours during the whole study, however, 311 hours were included in the final analysis. During my observation, I noted that most patients described the CV

exercises as harder than the AR stations. It is noteworthy that there was only a mean difference of about 7% between CV and AR stations, so most patients were able to self-monitor their activity levels in a sensitive way.

I also observed that the clinical staff running the CR programme believed that patients were working at an appropriate exercise intensity because they did not monitor it regularly in each session for each patient. Each session had a ratio of patients to staff of anywhere between 2:1 to 4:1 so there were enough staff to monitor training intensity, if this was deemed a priority. This could be one of the main reasons why the CR patients were working below the recommended exercise intensity guidelines. Staff up-titrated exercise intensity at some points within the 8-week programme but this was sporadic and did not cater for individual levels of progression.

Staff were not regularly reviewing heart rates achieved by each patient from each station during the previous training session. This practice would at least give an indication of whether patients were working hard enough and whether to ask patients to increase intensity. Staff was also not being creative enough when asking patients to work harder, for example, intensity could be increased by asking patients to walk with dumb-bells in their hands whilst maintaining a similar cadence. Monitoring patient outcomes with digital technology is one solution to this issue, and I would recommend this if funding is available.

7.2 Summary of the studies within the thesis

- The Apple watch has very good validity for measuring heart rate during low exercise intensity but this validity decreases as exercise intensity increases.

- The Apple watch has good validity to measure heart rate from recovery of walking but poor validity from recovery of jogging and running.
- The novelty of our results is that we are the first to measure heart rate every 5 seconds using the Apple watch.
- Our study is the first to measure the inter- and intra-device reliability of the Apple watch for measuring heart rate and stepping frequency.
- The maximum acceptable speed to measure heart rate using an Apple watch on the treadmill is 7 km/h and caution should be taken when measuring HR on a treadmill at speeds above 7 km/h.
- The Apple watch has poor to very poor validity for measuring stepping frequency during walking, jogging and running.
- UK CR may be sub-optimal in terms of producing the necessary exercise "dose" to invoke positive physiological adaptation based on exercise intensity and programme progression characteristics.
- The analysis of each exercise separately in the eight-circuit exercise session supports the suggestion that CV exercises were at a higher intensity than AR activities (mean difference circa 7%).
- The analysis of individual mean heart rates showed there are individual differences in the mean exercise intensity: two-thirds of our patients worked below 40% of HRR; the other one-third were working in the recommended heart rate zone but at a low exercise intensity.
- Weekly progress for the UK CR programme showed there was no difference in exercise intensity and the %HRR between week 1 and week 8, although the TRIMP, session RPE and duration increased during weekly progress, which means

that there was an increase in the internal exercise load and duration but not in exercise intensity.

- Our findings support the notion that CR teams require further education, support and guidance in order to improve service delivery outcomes around effectiveness.

7.3 Recommendations for current practice

We recommend that allied health professionals involved in CR should undertake more advanced training in exercise training, programming and prescription to ensure that principles of training including progressive overload are understood and followed.

Allied health professionals should also have a greater understanding of the benefits of exercise and physical activity, and this knowledge should be passed on to patients in the hope that they adopt a more active lifestyle beyond Phase III CR.

The use of digital technology should be actively encouraged which will help support allied health professionals monitor, track, and up-titrate exercise dose over the course of the Phase III programme.

Predictive heart rate training zones should be re-calculated regularly, as resting heart should be re-checked before the start of each training session. We also recommend using more cohort-specific predictive equations such as the Brawner equation which accounts for use of beta-blockers.

We recommend to allied health professionals the Apple watch for monitoring heart rate throughout each training session, our studies show that at lower intensities of exercise the Apple watch is a valid and reliable tool. One downside to using the Apple

watch is their excessive cost in relation to other activity trackers. Cost needs to be weighed against the accuracy of the data provided.

7.4 Limitations and strengths

A limitation of the first study is that we measured the stepping frequency at fixed speeds irrespective of age, sex, height, weight, baseline fitness of each participant. Therefore, the fixed speed will have been perceived differently by each participant. Some will have found it more challenging than others, which may have affected their gait cycle. Our criterion measure in the first study was ActivPAL, which has been shown to be less valid than direct observation.

A limitation of the CR study is that we conducted our analysis on one UK centre, therefore, it is important not to generalise our findings to all centres. There are around 350 CR centres, and current findings indicate that there is mixed practice and significant variability in terms of service effectiveness around the UK. Methods are required to ensure that service effectiveness is standardised over the next few years and we hope that our findings may assist with this task.

The novelty of our studies is that we are the first to record heart rate every 5 seconds using our app, which allowed us to monitor heart rate continually and more accurately than other published studies.

7.5 Future research

Further studies could consider the combined effect of blood flow and movement artefact in order to assess the variation in HR measurements using the Apple watch.

Future research could also assess the validity of measuring heart rate during a treadmill session with one arm fixed on the handrail, in order to reduce the effect of arm movement artefact and to establish if there is a difference in accuracy when arm movement is removed.

We recommend conducting the same study in Saudi Arabia to measure exercise intensity and identify if there is any difference in intensity in the Saudi cardiac rehabilitation programme. Previous researches (Sandercock, Cardoso, Almodhy & Pepera, 2013) have shown that there are differences in some of the outcomes of CR in the US and Europe compared with the UK, but no study has tested the dose of exercise achieved in CR programmes in Saudi Arabia.

We recommend developing a digital technology platform that can be used by CR staff in the UK to help monitor exercise dose during the CR sessions. This technology could then be compared against usual care.

7.6 Conclusion

This thesis has been divided into four main data chapters. The first chapter showed that the Apple watch has adequate validity for measuring stepping frequency during walking, but very poor validity during jogging and running. The second study showed that the heart rate sensor on the Apple watch has very good validity during walking but validity decreases with increasing intensity. The Apple watch has better inter-device reliability than intra-device reliability for measuring heart rate.

The third data chapter showed that the mean %HRR-CV and %HRR-AR were 37 (10) %, and 31 (13) %, respectively. There was weak evidence to support the alternative hypothesis of a difference between the %HRR-CV and 40% HRR. There

was very strong evidence to accept the alternative hypothesis that the mean %HRR-AR was lower than the mean %HRR-CV (median standardised effect size 1.1 (95%CI: 0.563 to 1.669) with a moderate to large effect. Mean exercise training intensity was below the lower limit of the minimal training intensity guidelines for a Phase III CR programme. These findings may be in part responsible for previous reports highlighting the significant variability in effectiveness of UK CR services and poor CRF improvements observed from several prior investigations.

Our final data chapter showed that the training principle of progressive overload is being applied consistently in CR. However, the increases observed in exercise training dose were mostly the result of increases in the duration of CV training rather than increases in exercise training intensity (%HRR-CV and sRPE). Therefore, allied health professionals must ensure that weekly increases in exercise intensity are consistently applied in order to optimise exercise training prescription and improve patient outcomes.

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Appendices

Department of Sport, Health & Exercise Science

UNIVERSITY OF Hull
Faculty of Science

Appendix 8.1 Ethical approval for the first study

Ethics Independent Reviewer's Report

This form should be completed by a member of the Department of Sport, Health and Exercise Science Ethics Committee who has been assigned to review a particular ethics application by the chair of the committee. The front section of the Independent's Reviewer's Report should be printed, signed and dated, and attached to the back of the reviewed ethics application. The reviewed ethics application should be given to the Ethics Committee chair once all reviews have been completed. The checklist provided at this end of this form is to help the reviewer complete the review and guide the content of his or her written report, which

should be typed into the relevant boxes that are given before the checklist. Any checkbox highlighted red that has been checked requires attention.

Please note that the checklist is for guidance only and reviewers should be aware of other ethical considerations relevant to the ethics application being reviewed.

An electronic copy of the completed report should be stored on the reviewer's computer.

Independent reviewer's name	Dr Andrew Garrett
Application number	1415219 Validity and reliability of an AmpStrip and an Apple watch in measuring steps, calories burned and heart rate
Principal investigator's name	Lee Ingle and Sean Carroll
Student investigator's name (if applicable)	Alaa Abdulhafiz Khushhal

Reviewer's recommended outcome		
Approve ☐	Revise ☐	Reject ☐
	Refer ☐	

Reviewers comments	
Section	**Comment**
	This application is suitable for ethics approval.

Click here to enter text.	Click here to enter text.
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Dr Andrew Garrett 13/04/15

Andrew.T.Garrett

Name of independent reviewer **Date** **Signature**

Please note that this section of the form should NOT be printed out and attached to the ethics application.

Independent Reviewer's Checklist				
Section	**Question**	**Yes**	**No**	**N/A**
1,2,3,4,5	Have all details been provided in full?	☐	☐	☐
6	If there are collaborators, has the name, affiliation, email address, and telephone number for each collaborator been provided?	☐	☐	☐
7	Is the location of the project a safe place to undertake the project for both the participants and investigators?	☐	☐	☐
7	If equipment or facilities are been used other than in SHES, has a letter of support from an appropriately authorised person been included?	☐	☐	☐
8	Have realistic dates been provided?	☐	☐	☐
9	If the project has been funded, could there be any conflicts of interest between the investigators and the funding they have received?	☐	☐	☐
10	Has the purpose and benefit of the project being clearly identified?	☐	☐	☐
11.1	Is the sample size adequate?	☐	☐	☐
11.2	If not an undergraduate project, has the sample size been sufficiently rationalised (this will typically be the results of a power analysis)?	☐	☐	☐
11.3	Does the research involve people with any of the following: aged less than 18 years, suffering from acute or chronic health conditions, communication or learning difficulties, in police custody or with Her Majesty's Prison Service, engaged in illegal activities?	☐	☐	☐
11.3	Are the inclusion/exclusion criteria sufficiently detailed that it is clear who will be recruited into the project?			
11.4	Are the screening procedures appropriate for ensuring only those people that satisfy the inclusion and exclusion criteria are included in the project?	☐	☐	☐
11.5	Are recruitment strategies such that they might unduly influence someone to participate in the project that would not otherwise do so?	☐	☐	☐
11.6	Are the incentives to participate such that they might unduly influence someone to participate in the project that would not otherwise do so?	☐	☐	☐
12	Is the experimental design and methodology sufficiently comprehensive that someone could conduct the study by reading the information provided?	☐	☐	☐
12	Is deception involved?	☐	☐	☐
13	If substances are to be administered is the following information provided for each substance? The specific substance to be administered, the dosage, the timing of administration, and who will administer the substance.	☐	☐	☐

13	Are there any concerns regarding the health and safety of any substances to be administered?	■	☐
14	Are participants or investigators exposed to unacceptable risks, discomforts, or burdens?	■	☐
12,13,14	Have all relevant risk assessments been included?	☐	■
15	Are the investigators sufficiently competent to undertake each of the procedures involved in the project, or are otherwise being adequately supervised by a competent person?	☐	■
15	If an undergraduate student is testing in one of the laboratories is there a statement that a SHES member of staff will be present at all times?	☐	■
16	Is the participant debriefing sheet adequate?	☐	■
17.1	Will the confidentiality and anonymity of participants be preserved?	☐	■
17.2	If the principal investigator is not responsible, has the name, affiliation, email address, and telephone number of the person responsible been provided?	☐	■
17.3	Has anyone got named access to the data that is unnecessary?	■	☐
17.4	Have issues of data storage been adequately considered, particularly relating to security of the stored data?	☐	■
Informed consent	Is the informed consent written so that a lay person could clearly understand what is expected of them in relation to potential risks, discomforts, time commitments, and other burdens?	☐	■
Other forms	Have all other relevant documents been submitted and completed properly?	☐	■

Appendix 8.2 Invitation email for the first study

Hi Everyone,

We are conducting a research to investigate the validity and reliability of an Apple watch to measure heart rate, steps and calories burned in healthy volunteers.
The results of the study will be helpful to us to assess the suitability of Apple watch to use them in the future.
If you are aged above 18, not taking any medicines and are not pregnant do not have any health problems, we would like your help.
For more information about the study see the Participant Information Sheet attached.
If you are interested in taking part in this study, please contact me or email me at the University of Hull, Sport, Health and Exercise Science Department on mobile number 07423243117 or at my email address: A.A.Khushhal@2013.hull.ac.uk

Kind Regards,
Alaa Khushhal

Appendix 8.3 Consent form for the participant in the first study.

Informed Consent Declaration

Project title	Validity and reliability of an AmpStrip and an Apple watch in measuring steps, calories burned and heart rate
Principal investigator	Name: Dr. Lee Ingle Email address: L.ingle@hull.ac.uk Contact telephone number: 01482 463141
Student investigator (if applicable)	Name: Alaa Khushhal Email address: A.A.Khushhal@2103.hull.ac.uk Contact telephone number: 07423243117

Please Initial

I have read and understood the Participants Information Sheet (EC2) for the above research. I have been given time to ask questions about the study and all my questions about the study have been answered in full.

I understand that the study has been risk assessed and the project approved by the Department of Sport, Health and Exercise Science Research Ethics Committee at the University of Hull.

I understand that my taking part is entirely voluntary and I can withdraw at any stage and at any time without the need to give a reason. I have read and understood this Consent Form.

I have agreed to take part in this study

☐

☐

☐

☐

.....	.....	.....
Name of participant	Date	Signature
.....	.....	.....
Person taking consent	Date	Signature

Appendix 8.4 Faculty ethical approval for the second study

Professor Lee Ingle
Department of Sport, Health and Exercise Science

Date: 23 October 2015
Ref: FoSE/FEC/29.10.2015/Item7f

Dear Lee,

ETHICAL APPROVAL OF RESEARCH

Following consideration of an application submitted by you for:

> "The effect of using smartphone and wearable technology for the monitoring and quantification of exercise training dose in patients undertaking cardiac rehabilitation."

I am pleased to confirm that your study was approved by Chair's Action (via the Executive Academic Manager) on behalf of the Faculty of Science and Engineering Ethics Committee on 23 October 2015.

This approval will be reported at the next Faculty Ethics Committee meeting on 29 October 2015.

Yours sincerely

N. Cooper

Nichola Cooper
Quality and Administration Manager and
Secretary to the Faculty Ethics Committee

Cc: Prof Sean Carroll
Mr Alaa Khushhal
Mr Andrew Dowsland

Appendix 8.5 NHS Ethical approval for the second study

Professor Lee Ingle
Deputy Head of the Department of Sport, Health & Exercise Science
University of Hull
Department of Sport, Health and Exercise Science
Cottingham Road, Hull
HU6 7RX

Email: hra.approval@nhs.net

1 August 2016

Dear Professor Ingle

Letter of HRA Approval

Study title:	**The effect of using smartphone and wearable technology for monitoring and quantification of exercise training volume in patients undertaking cardiac rehabilitation**
IRAS project ID:	**177669**
Protocol number:	**V4**
REC reference:	**16/NW/0419**
Sponsor	**University of Hull**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff

in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net.
Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **177669**. Please quote this on

all correspondence. Yours sincerely

Natalie Wilson

Email: hra.approval@nhs.net

Copy to: *Mr Alaa Khushhal, University of Hull, PhD Student*
Dr Andrew Taylor, University of Hull, Sponsor contact
Ms Sue Penter, CITY HEALTHCARE PARTNERSHIP CIC, Lead R&D contact

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
GP/consultant information sheets or letters [Letter to the GP]	V2	31 March 2016

Other [Case Report Form of this study]	V1	11 May 2016
Other [Participant Information Sheet and Consent Form]	V6	27 July 2016
REC Application Form [REC_Form_11052016]		11 May 2016
Research protocol or project proposal [Research protocol]	V4	31 March 2016
Validated questionnaire [SF-12 QUEATIONNAIRE]	V1	11 May 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Alaa Khushhal (Email: A.A.Khushhal@2013.hull.ac.uk)

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Minor amendments have been made to the PIS and Consent form post REC to ensure that they conform to HRA Standards.
3.1	Protocol assessment	Yes	No comments

4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial, single site study where the sponsor is also the participating non-NHS site. The University of Hull is a venue where a Phase III Cardiac Rehabilitation service is run and provided by City Healthcare Partnerships CIC. A verbal agreement for the study to run at the venue has been obtained from the Head of Department for the service.Confirmation has been obtained from
Section	**HRA Assessment Criteria**	**Compliant with Standards**	**Comments**
			Sue Penter, Lead R&D contact at City Healthcare Partnerships CIC that this is the case.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study.
4.3	Financial arrangements assessed	Yes	Sponsor is not providing funds to the participating NHS organisation.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	

5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	
6.3	Devices – MHRA notice of no objection received	Not Applicable	
6.4	Other regulatory approvals and authorisations received	Not Applicable	

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
This is a non-commercial, single site study. There is only one site-type involved in the research. Participants will be identified by their care team whose details will be passed onto the research team if they are interested in taking part in the research. Participants will take part in a normal Cardiac Rehabilitation programme, however, some participants will be asked to wear an Apple watch Sport, as well as an HR monitor and Accelerometer. Participants will also be asked to complete a questionnaire before commencing the programme and once completed. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

The HRA has determined that participating NHS organisations in England that **are not expected to formally confirm their capacity and capability to host this research,** due to the nature of the study and verbal agreement between sponsor and site (confirmed by the Lead R&D contact).

- The HRA has informed the relevant research management offices that you intend to undertake the research by copy of this letter. However, you should
- still support and liaise with the organisation as necessary.
- Following issue of the Letter of HRA Approval the sponsor may commence the study at these organisations when it is ready to do so.
- The document "Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected" provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations. Further study specific details are provided the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this Appendix.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

Sponsor has indicated that a Principal Investigator or Local Collaborator is not required at participating NHS organisations, however, HRA do acknowledge that the relationship between Sponsor and the participating NHS site is positive and collaborative (confirmed by Lead R&D contact).

Sponsor has not identified any additional training needs.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

A standard DBS check, occupational health clearance and Letter of Access will be required for the research team members from the University of Hull if not already in place.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 8.6 Consent form for the patients in the second study

Hull and East Yorkshire Hospitals NHS Trust

University of Hull

INFORMED CONSENT

IRAS ID: 177669

The effect of using smartphone and wearable technology for the monitoring and quantification of exercise training volume in patients undertaking cardiac rehabilitation

Name of the researchers: Mr Alaa Khushhal, Prof Lee Ingle, Prof Sean Carroll, Dr. Grant Abt and Dr. Simon Nichols

Please initial box

1. I confirm that I have read and understand the Patient Information Sheet 27 / 07/ 2016 (version 6) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that my medical notes relating to my taking part in the study may be looked at by responsible individuals from the cardiac rehabiltation team. I give permission for these individuals to have access to my records. ☐
4. I give permission for the research team to inform my General Practitioner about my participation in the study. ☐
5. I understand that the relevant sections of my medical notes and data collected from the study may be looked at by the regulatory authorities or by persons from Hull University whether it is relevant to my taking part in this study. I give permission for these individuals to have access to this information ☐
6. I agree to take part in the above study. ☐

_____ _____

Name of subject (BLOCK CAPITALS) Date Signature

_____ _____

Name of person taken consent Date Signature

1 copy for the participant; 1 for the researcher; 1 to be kept with the hospital notes

Appendix 8.7 The SF-12 questionnaire

SF-12® Health Survey Scoring Demonstration

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
○	○	○	○	○

---

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○	○	○
b Climbing <u>several</u> flights of stairs	○	○	○

---

3. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	Yes	No
a <u>Accomplished less</u> than you would like	○	○
b Were limited in the <u>kind</u> of work or other activities	○	○

---

4. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	Yes	No
a <u>Accomplished less</u> than you would like	○	○

b Did work or other activities less carefully than usual ○ ○

---

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
○	○	○	○	○

---

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

   How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	○	○	○	○	○	○
b Did you have a lot of energy?	○	○	○	○	○	○
c Have you felt downhearted and blue?	○	○	○	○	○	○

---

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

Thank you for completing these questions!

Appendix 8.8 Foster scale

Modified Category Ratio (RPE) Scale
Foster *et al*. (2001)

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