
# Adherence, Efficacy and Patient Perspective of a Multi-Disease, Community-Based Exercise Programme

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PhD

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**Adherence, Efficacy and Patient Perspective of a Multi-Disease, Community-Based Exercise Programme**

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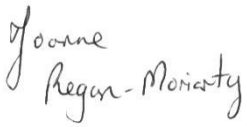
**Declaration**

I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award of Doctor of Philosophy, is entirely my own work, and that I have exercised reasonable care to ensure that the work is original, and does not to the best of my knowledge breach any law of copyright, and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

**Signed**:  **ID No.:** 17213846 **Date**: 06/01/2023

Joanne Regan-Moriarty (PhD Candidate)

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and fitness indices in people with neurological conditions. RCSI Sports Medicine Conference, Dublin 2018

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- **Regan, J,** McCallion, M, Youell. A, Collery, A and Moyna, N. Community-Based Phase IV Cardiac Rehabilitation: Participant Experiences and Perceived Benefits. RCSI Sports Medicine Conference, Dublin 2017

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**Abbreviations**

| | |
|---|---|
| 6MWT | 6-minute walk test |
| 6MWTD | 6-minute walk test distance |
| ADL | Activities of daily living |
| AIC | Akaike Information Criterion |
| ANOVA | Analysis of variance |
| ATS | American Thoracic Society |
| ATU | Atlantic Technological University |
| BACPR | British Association for Cardiovascular Prevention and Rehabilitation |
| BCT | Behavioural change technique |
| BIC | Bayesian Information Criterion |
| BL | Baseline |
| BMI | Body mass index |
| BP | Blood Pressure |
| CABG | Coronary artery bypass graft |
| CAD | Coronary artery disease |
| CAD-CG | Coronary artery disease control group |
| CBCR | Community-based cardiac rehabilitation |
| CBEP | Community-based exercise programme |
| CBSP | Community-based support programmes |
| CD | Chronic disease |
| CDM | Chronic disease management |
| COPD | Chronic obstructive pulmonary disease |
| CR | Cardiac rehabilitation |
| CrD | Crohn's disease |
| CRF | Cardiorespiratory fitness |
| CS (H) | Compound symmetry (Heterogenous) |
| CV | Cardiovascular |
| CVD | Cardiovascular disease |
| DBP | Diastolic blood pressure |
| DCU | Dublin City University |
| EU | European Union |
| GLM | Generalized linear model |

| | |
|---|---|
| GP | General Practitioner |
| GripD | Handgrip of dominant hand |
| GripND | Handgrip of non-dominant hand |
| HCP | Health Care Professional |
| HDL-C | High-density lipoprotein cholesterol |
| HGS | Handgrip strength |
| HRPF | Health-related physical fitness |
| HRQoL | Health-related quality of life |
| HR / RHR | Heart rate / Resting HR |
| HSE | Health Service Executive |
| ITT | Intention to treat |
| KMO | Kaiser-Meyer-Olkin |
| LDL-C | Low-density lipoprotein cholesterol |
| MCEP | Multi-disease, community-based exercise programmes |
| MCID | Minimal clinically important difference |
| MCS | Mental component score |
| MI | Myocardial infarction |
| MMA | Mixed model analysis |
| MS | Multiple sclerosis |
| MSK | Musculoskeletal |
| MVPA | Moderate to vigorous physical activity |
| NERF | National exercise referral framework |
| OCD | Other chronic disease |
| PA | Physical activity |
| PAET | Physical activity-Exercise training |
| PCA | Principal component analysis |
| PCI | Percutaneous coronary intervention |
| PCS | Physical component score |
| PD | Parkinson’s disease |
| PI | Post intervention |
| PP | Per protocol |
| PPI | Protein pump inhibitors |
| PR | Pulmonary rehabilitation |

| | |
|---|---|
| RCT | Randomised controlled trial |
| RM | Repetition maximum |
| RPE | Rating of perceived exertion |
| S&R | Sit and reach test |
| SBP | Systolic blood pressure |
| STS | Sit to stand test |
| SUH | Sligo University Hospital |
| T1DM | Type 1 diabetes mellitus |
| T2DM | Type 2 diabetes mellitus |
| TG | Triglycerides |
| TNF-α | Tumour necrosis factor α |
| VIF | Variation inflation factor |
| WEMWBS | Warwick Edinburgh Mental Well-Being Scale |
| WHR | Waist-to-hip ratio |

## Abstract

**Joanne Regan-Moriarty**

**Adherence, Efficacy and Patient Perspective of a Multi-Disease, Community-Based Exercise Programme**

**Background**. The growing burden of chronic disease (CD) in Ireland represents the greatest challenge to Irish Health Services. The role of physical activity/exercise training (PAET) is well established as an adjunct therapy in the management of CD. An integrated multi-disease, community-based exercise programme (MCEP) has the potential to offer a resource-efficient strategy to provide exercise in the community for either those with CD following completion of medically supervised hospital-based programmes or for individuals who do not require medical supervision. The purpose of this PhD was to assess the adherence to, efficacy of and patient perspective of a MCEP. A total of 118 patients with coronary artery disease (CAD) who had completed hospital-based cardiac rehabilitation, along with individuals with other CD (OCD), were referred by health care professionals to a newly established MCEP. CAD patients who could not attend the MCEP were assigned to a control group (CAD-CG) that received usual care advice.

**Study 1** evaluated baseline characteristics of individuals with CAD (96, 73%M) to those with OCD (98, 47%M) and a CAD-CG (22, 77%M) and compared rates and predictors of adherence to the MCEP. Outcome measures were socioeconomic and health-based demographics, health indices, functional capacity, and health-related quality of life (HRQoL). There was a significant difference in age, gender, number of comorbidities, and certain medications/conditions between the groups. Individuals with CAD had significantly better functional capacity and HRQoL scores than individuals with OCD. Females and individuals with lower mental wellbeing were less likely to attend and more likely to drop out.

**Study 2** evaluated the efficacy of participation in a MCEP for 10-weeks on selected health indices, functional capacity, and HRQoL. Lower body muscle strength increased ($p < 0.005$) in both CAD and OCD compared to CAD-CG. Within group improvements were found in aerobic fitness ($p < 0.005$) and waist circumference ($p < 0.05$) in both CAD and OCD, while upper body strength ($p = 0.003$) and perceived physical ($p = 0.013$) and mental health ($p = 0.003$) improved in OCD only.

**Study 3** explored CAD patient experiences of participation in a MCEP and dimensions influencing their physical activity engagement. Twenty-four individuals (63% M) who completed the initial 10 weeks of the MCEP attended a focus group, analysed using inductive thematic analysis. Main themes identified included 'moving from fear to confidence', 'drivers of engagement', 'challenges to maintaining exercise adherence' and 'life beyond their illness'.

**Conclusion** An integrated MCEP was found to be a safe, effective, and acceptable setting for improving or maintaining actual and perceived physical, and mental, wellbeing in individuals with CD. Females and individuals with lower mental wellbeing should be supported to encourage adherence.

# Chapter I

## Introduction

Chronic diseases (CD) such as cardiovascular disease (CVD), diabetes, musculoskeletal and neurological illnesses (e.g., multiple sclerosis (MS)) are long-term conditions that last for longer than six months in duration, are non-communicable and can impact functional capacity (D.O.H.C. 2008). Currently one third of the Irish population >18 years of age is living with ≥1 CD. (H.S.E. 2020b). This number increases to almost 50% in men and women >50yr (H.S.E. 2021b) with one study self-reporting >90% (Hernández *et al.* 2019). Many CDs are related to lifestyle choices, in particular, low levels of physical activity (PA) (Booth *et al.* 2012). Most CDs are associated with decreased functional capacity and health-related quality of life (HRQoL) (Marengoni *et al.* 2011; Maresova *et al.* 2019). CD results in decreased lifespan, with a greater impact on those living with multimorbidity (≥2CD) (DuGoff *et al.* 2014). Among European Union (EU) countries, approximately 70-80% of the annual health care budget is spent on the management of CD (Cronin *et al.* 2017).

A number of key government reports published over the past decade, including Healthy Ireland Framework (2013), National Physical Activity Plan for Ireland (2016), Living Well with a Chronic Condition (2017), Sláintecare Action Plan (2019) and Health Service Executives National Service Plan (2020b), have indicated the need to optimise treatment strategies for people living with CD. The most recent National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020-2025 (H.S.E.

2020a) places greater emphasis on facilitating individuals to manage their CD in the community. A primary aim of the framework is to move away from disease-specific to a more holistic, multidisciplinary approach to the management of CD. Interventions to support self-management of CD, including education, goal-setting, and participation in activities such as exercise, smoking cessation, resilience building, are prioritized in the proposed framework.

The role of exercise as an adjunct therapy in the management of CD is well documented (Booth *et al.* 2012; Pedersen and Saltin 2015). Indeed, exercise is the primary component of established medically managed, hospital-based cardiac and pulmonary rehabilitation programmes. Smaller, community-based support programmes (CBSP) for other CDs, such as arthritis, MS, type 2 diabetes mellitus (T2DM) and stroke, are delivered by relevant national and local associations (McKeon 2021) and, often include an exercise component. These CBSP are normally delivered in Health Service Executive (HSE) outreach therapy centres or in local community centres and are generally supervised by Health Care Professionals (HCP) or, less often, by a physical trainer specialised in exercise for CD. The exercise component of CBSPs, irrespective of the CD, have comparable designs (Desveaux *et al.* 2014) with the majority of programmes focused on aerobic and resistance training (Desveaux *et al.* 2014; Pedersen and Saltin 2015).

Cardiac rehabilitation (CR) is the most established hospital-based rehabilitation programme in Ireland and involves four phases (Irish Heart Foundation 2018). Phase I and II refers to the time immediately after the cardiac event and occurs in hospital and at home, respectively. The focus in Phase I and II CR is on medical management and

beneficial lifestyle changes prior to commencing structured, supervised hospital-based CR (Phase III). Although highly effective (Dalal *et al.* 2015; Dibben *et al.* 2021), many patients fail to independently maintain their healthy lifestyle changes, including regular exercise, following completion of Phase III CR (Bellg 2003).

Phase IV of CR is focused on maintaining the healthy lifestyle adopted during the first three stages (Irish Heart Foundation 2018). Phase IV is usually less structured than phases I-III and involves reduced healthcare support. It can take place at home, with the patient exercising independently, or in a community setting, i.e., community-based CR (CBCR). Participation in a CBCR programme has been shown to improve or maintain various indices of health, functional capacity and HRQoL (Lawlor *et al.* 2018; Sánchez-Delgado *et al.* 2020; Chowdhury *et al.* 2021). Uptake to long-term CBCR programmes in Ireland is hindered by the inadequate availability of services (Lavin *et al.* 2005; I.A.C.R. 2020).

To address the gap in service provision, a collaboration between Sligo University Hospital (SUH) and Atlantic Technological University (ATU), formally Institute of Technology, Sligo, resulted in the establishment of a CBCR programme in the northwest of Ireland in 2016. Given the commonality in programme design and delivery of CBCR with exercise programmes for other CD cohorts (Pedersen and Saltin 2015), the programme was quickly extended to include other CD (OCD). An integrated multi-disease, community-based exercise programme (MCEP) may also be viewed as a resource-efficient strategy for providing exercise in the community to those with CD who no longer require

medical supervision. The programme was delivered twice a week at ATU Sligo by clinical exercise scientists.

Unsurprisingly, coronary artery disease (CAD) accounted for approximately 50% of referrals to the MCEP, with all patients having completed a 10-week, hospital-based, phase III CR programme. In contrast, the vast majority of patients with OCD were not referred from a hospital-based, medically supervised exercise programme and may therefore present with a lower functional capacity and other health-related indices than CR patients. To facilitate design of a safe and effective programme it is important to understand the demographics, functional capacity and medical status of the disparate patient cohort who may be referred to a MCEP. To date, no published study has compared the demographics and baseline fitness levels of individuals with CAD or OCD referred to a MCEP through various referral pathways and differing preparticipation exercise experience.

The potential health benefits associated with attending MCEP are highly dependent on adherence (Murphy *et al.* 2012). Attendance, completion and dropout rates are the most common measures of adherence (Hawley-Hague *et al.* 2016). Adherence rates to MCEP are generally suboptimal (Pavey *et al.* 2012). Individuals with high attendance to MCEP during their first 4 weeks, have an increased likelihood of longer-term adherence (O'Leary 2019). Factors including individual and demographic characteristics, mental health, programme design and medical diagnosis can predict adherence in disease-specific exercise programmes (Tiedemann *et al.* 2012; Cassidy *et al.*

2014; Ruano-Ravina *et al.* 2016). To date, relatively few studies have evaluated adherence rates and predictors of adherence during the early stages of a MCEP (Pavey *et al.* 2012).

Measurement of functional capacity such as cardiorespiratory fitness (CRF), muscle strength and endurance, flexibility, and balance along with body composition and HRQoL scores are commonly used metrics to determine efficacy of MCEP. Several validated field-based tests are available to routinely assess large numbers. Statistically, beneficial effects have been reported from participation in MCEP (McNamara *et al.* 2016; Rowley *et al.* 2018; Wade *et al.* 2020). However, not all of the improvements were clinically meaningful (Wade *et al.* 2020). Despite the different disease aetiology and participant symptoms, the effectiveness of MCEP is often based on the combined data of all those attending, irrespective of their condition. Considering the high proportion of cardiac patients attending the MCEP delivered at ATU Sligo, it would be important to inform clinicians of the efficacy of the programme to ensure the MCEP continues to maintain or improve benefits shown in CBCR. It would also be pertinent to compare their response to those with OCD to ensure the MCEP can accommodate a variety of CD.

In recent years, there has been a greater emphasis on engaging the patient perspective regarding their experience and satisfaction with health interventions. Increased patient engagement has been shown to improve both the effectiveness and quality of health services delivered (Bombard *et al.* 2018). Perceived benefits, facilitators, and barriers to patients participating in a MCEP are not well understood. Most studies that have explored the patient perspective were based on disease-specific exercise programmes, primarily CBCR, and involved patients who were attending for a minimum

of 12 months (Thow *et al.* 2008; Martin and Woods 2012; Dunn *et al.* 2014; Hardcastle *et al.* 2015). There is limited research reporting facilitators and barriers of patients with a specific CD attending a MCEP. Understanding the patients' perspective of their experience of participation in a MCEP may assist in optimising the rates of enrolment and adherence to a MCEP.

The purpose of this PhD was to assess the adherence to, efficacy of and patient perspective of a MCEP.

**Aims**

1. Characterise the baseline health and demographic characteristics of patients with CAD and OCD referred to a MCEP
2. Determine adherence rate and predictors of adherence among CAD patients and those with OCD referred to a MCEP
3. Evaluate the short-term efficacy of a MCEP on selected health indices, functional capacity, and HRQoL in individuals with CAD and OCD
4. Explore the patients' perspective of their experience of initiation and early participation in a MCEP

# Chapter II

# Literature Review

## 2.1 Chronic Disease

Chronic disease is defined as a disease slow in its progress, long in its continuance and, is the result of genetic, physiological, environmental and behavioural factors (World Health Organisation 2021). The four major CD in Ireland (H.S.E. 2020a; D.O.H. 2021a) and globally (World Health Organisation 2021) are CVD, cancer, chronic respiratory disease and T2DM. Other less common CD include neurological disease (e.g., MS and Parkinson's disease (PD)) and musculoskeletal (MSK) disorders (e.g., osteoarthritis and rheumatoid arthritis) (Booth *et al.* 2012; Pedersen and Saltin 2015). According to the European Heart Network, there are approximately 268,000 people in Ireland living with CVD (Wilkins *et al.* 2017). In 2016, 110,000 people were officially diagnosed as living with chronic obstructive pulmonary disease (COPD) in Ireland (H.S.E. 2021a). Estimations for the prevalence of T2DM in Ireland is 234,398 (Diabetes-Ireland 2022), and 870,000 for the prevalence of a neurological condition (H.S.E. 2021c). In 2021, CD accounted for 76% of all deaths in Ireland (H.S.E. 2021b) and 71% globally (World Health Organisation 2021).

Approximately 32% of individuals > 18 years of age have ≥ 1 CD (H.S.E. 2020b). Among individuals > 50 years of age, 49% have one CD with 18% having been diagnosed with multiple CD (multimorbidity). (2021b). The number of individuals >50 years of age living with ≥ 1 CD is estimated to increase by 40% by 2030 (H.S.E. 2020b). Mortality rates for many CDs have declined in recent years (Marshall *et al.* 2016; D.O.H. 2021a) due in part to improved living conditions, a reduction in some health risk behaviours and

improvements in the uptake of medical interventions (Kabir *et al.* 2013; Marshall *et al.* 2016; Ferrucci and Kohanski 2022) leading to an increase in the survival rates (Abd-Allah *et al.* 2017; Dibben *et al.* 2021).

Across the EU, approximately 70 - 80% of annual health care budgets are spent on the management of CD (Cronin *et al.* 2017). Currently, CD accounts for 40% of hospital admissions, 75% of bed days, 55% of hospital expenditure and 80% of General Practitioner (GP) consultations in Ireland (H.S.E. 2021b). The predicted surge in CD levels, along with the number of individuals living with CD, represents the greatest challenge to the Irish Health Service (H.S.E. 2021b). Identifying novel and effective strategies to support self-management and improve the health and wellbeing of individuals is critical to the success of tackling the burden of CD (H.S.E. 2020a; Ferrucci and Kohanski 2022).

**2.2 Exercise and Chronic Disease**

Physical activity (PA) is defined as any bodily movement produced by the contraction of skeletal muscles resulting in energy expenditure above resting state (Booth *et al.* 2012). In contrast, exercise is planned, structured, and repetitive body movements undertaken to improve and/or maintain physical fitness or health (Chodzko-Zajko *et al.* 2009). Physical activity/exercise training (PAET) is an important therapeutic intervention in the treatment of many CD (Pedersen and Saltin 2015) and is strongly recommended as an important component in the HSE's model of care for integrated prevention and management of CD (H.S.E. 2020a).

## 2.3 Policies

Several major reports published in Ireland over the last decade (Figure 2.1) contain key sections focused on optimising treatment strategies for people living with CD, many with specific reference to the role of PAET. The vision of the Healthy Ireland report 2013-2025 (2013) is '*to build a healthy Ireland where everyone can enjoy physical, mental health and wellbeing to their full potential*'. A primary goal outlined in the report is to increase the proportion of the population who are healthy at all stages of life. PA, along with diet, smoking and alcohol were identified as the primary lifestyle risk factors that need to be addressed in order to meet this goal. There is an irrefutable and large body of evidence from cross-sectional studies, prospective longitudinal studies and randomised controlled trials (RCT) linking PAET to improved functional capacity and HRQoL in healthy individuals and those living with ≥ 1 CD (Booth *et al.* 2012; Pedersen and Saltin 2015). A 20% increase in the proportion of the population, including those living with CD, undertaking regular PA was identified as a key performance indicator in the Healthy Ireland Outcomes Framework (D.O.H. 2013).

The National Physical Activity Plan for Ireland (2016) is focused on increasing PA across the entire population. The plan emphasises that PAET should be part of the management and rehabilitation of CD. One of its actions outlined is to '*develop locally led plans and more long-term sustainable PA programmes*'. The Royal College of Physicians Ireland (RCPI) supported this recommendation and referred to exercise as an '*underutilised wonder drug*' (R.C.P.I. 2016). One of the key RCPI recommendations was

the provision of professionally supervised structured exercise programmes for the management of certain CD.

The Living Well with a Chronic Condition Framework (2017) outlined an implementation plan for self-management support of CVD, COPD, asthma and T2DM. It recommended standardising and increasing structured exercise-based programmes for targeted disease-specific populations such as CVD and COPD. The Framework document also acknowledged the evidence base for generic CD self-management programmes and their ability to improve health behaviours such as PAET. It also highlighted that many patients experience multimorbidity (coexistence of ≥ 2 CD in the same individual) and, that single disease-specific interventions may not be the most effective way to enable successful self-management among this population (H.S.E. 2020a). The Houses of the Oireachtas published Sláintecare, a ten-year programme aimed at transforming the Irish health and social care services (2017). A major objective of Sláintecare is to provide the '*right care, in the right place, at the right time'* (D.O.H. 2021b). One of the key deliverables of the Sláintecare Implementation Plan (2021b) is the establishment of chronic disease management (CDM) hubs and, a GP structured CDM programme with the aim of reducing the national burden of CD.

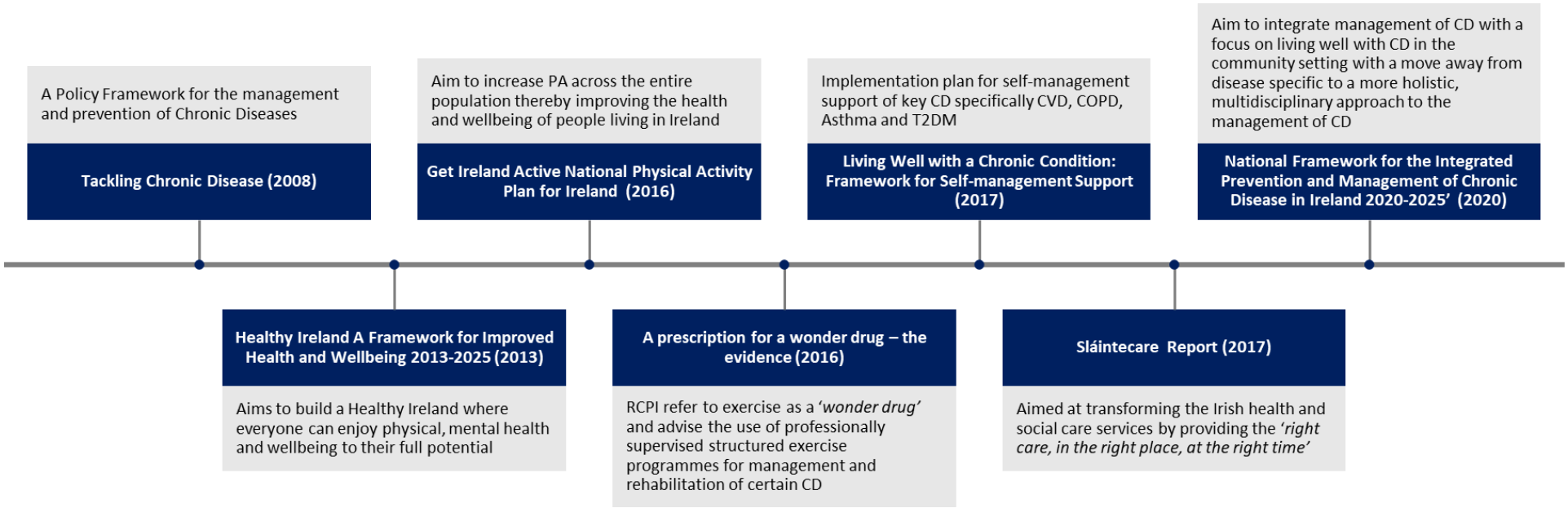



Figure 2.1 Timeline of key reports supporting integrated care for self-management of CD

## 2.4 Self-Management Support Programmes

Traditional hospital-based lifestyle intervention programmes have focused primarily on short-term, fixed-duration CR and pulmonary rehabilitation (PR) programmes and, to a lesser extent, on T2DM. Some short-term, structured community-based self-management programmes are also delivered by disease-specific societies including Arthritis Ireland, MS Ireland, and Diabetes Ireland. Weekly or monthly group support sessions that incorporate exercise/education into their meetings may also be available for CD such as stroke, MS and COPD (McKeon 2021). Exercise is included as a component in most of the self-management programmes. Hospital-based lifestyle intervention programmes typically involve a combination of supervised exercise, education sessions, relaxation techniques, managing medication, self-care and skills training to manage the specific clinical condition (McKeon 2021). Exercise is included as a component in most of the short-term, structured community-based self-management programmes. There are, however, relatively few follow-on maintenance programmes for patients following completion of a hospital-based lifestyle intervention programme.

The National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020-2025' (H.S.E. 2020a) is a 5-year framework for the integrated management of CD with a focus on living well with CD. A primary aim of the framework is to move away from disease-specific to a more holistic, multidisciplinary approach to the management of CD in the community setting, where possible. The new model of care (H.S.E. 2020a) envisages relocating the current hospital-based CR and PR programmes to CDM hubs (H.S.E. 2020a). However, step-down programmes will also be

required for those exiting medically supervised CR and PR programmes, along with provision of exercise opportunities for low-risk CD patients who will not require medical supervision in a CDM hub. Providing exercise opportunities in a community-based setting for low-to moderate-risk patients has been found to improve many health and wellbeing outcomes in patients across a wide range of CD (Rowley *et al.* 2018). Augmenting the capacity of HCP to refer low-risk patients diagnosed with CD and/or patients who have completed CR or PR to appropriate community-based, structured PAET programmes will greatly enhance service delivery.

### 2.5 Assessing PAET

Commonly used metrics to assess efficacy of a PAET programme include both morbidity and mortality rates along with use of the health services. Health-related physical fitness (HRPF) is defined as fitness aimed at promoting health and reducing the risk of CD (U.S. Department of Health and Human Services 2018). The primary components of HRPF are CRF, muscle fitness, body composition and flexibility. HRPF components along with psychological measurements such as HRQoL scores are also commonly used metrics to determine efficacy of exercise interventions. Indeed, improving HRPF is central to how PAET impacts health (U.S. Department of Health and Human Services 2018).

#### Cardiorespiratory Fitness

Cardiorespiratory fitness reflects the function of the interdependent and interacting physiological systems to deliver and utilise oxygen under increasing physical

demands. Low levels of CRF are associated with a high risk of CD and all-cause mortality (Liguori *et al.* 2021). As a physiological adaptation to exercise training, increased levels of CRF are associated with positive adaptations in the structure and function of the majority of organ systems (Xiao 2020), resulting in improved functional capacity. A one metabolic equivalent task (MET) increase in functional capacity is associated with approximately a 12% increase in survival rates in both healthy individuals and those with CVD (Myers *et al.* 2002).

The highest volume of oxygen consumed during graded exercise to volitional exhaustion ($\dot{V}O_2max$) is the gold standard measure of CRF (McArdle *et al.* 2015). Measurement of $\dot{V}O_2max$ involves collecting expired gases at regular intervals during incremental exercise, typically on a treadmill or cycle ergometer. The collection of expiratory gases during exercise is time consuming and requires expensive equipment along with trained personnel. The 6-min walk test (6MWT) is a commonly used field-based test to assess exercise capacity in CD populations (Sandberg *et al.* 2020; Macchiavelli *et al.* 2021; Allado *et al.* 2022). The test involves covering as much distance as possible in 6 min while walking between two cones placed 30 m apart on a flat indoor course (American Thoracic Society 2002). There is a high test-retest reliability of the distance covered in the 6MWT (6MWTD) across a large range of CD populations (Segura-Ortí and Martínez-Olmos 2011; Sandberg *et al.* 2020; Macchiavelli *et al.* 2021).

The minimal clinically important difference (MCID), defined as the smallest threshold change in an outcome that is perceived as beneficial to a patient (Guralnik *et al.* 2020), varies depending on the CD population. MCID estimations for the 6MWT range

from 33.5 to 66.3 m in CD populations, including intermittent claudication, haemodialysis, stroke, cardiopulmonary and Alzheimer disease (Rasekaba *et al.* 2009; Ries *et al.* 2009; Segura-Ortí and Martínez-Olmos 2011; Sandberg *et al.* 2020; Macchiavelli *et al.* 2021), with an average MCID of 50 m.

**Muscle Fitness**

Muscle strength is defined as a muscles ability to exert a maximal force, whereas muscle endurance refers to a muscles ability to continue to perform successive exertions or repetitions against a submaximal workload (Liguori *et al.* 2021). Optimal muscle fitness is associated with numerous health benefits including improvements and/or maintenance of lean muscle mass, glucose tolerance, bone mineral density, blood pressure (BP), blood lipid profile, and an individual's ability to perform activities of daily living (ADL) (Garber *et al.* 2011; Liguori *et al.* 2021). Higher levels of muscle strength and endurance are also associated with fewer CVD events and a lower risk of all-cause mortality (Garber *et al.* 2011).

Handgrip strength (HGS) is considered a reliable measure to assess overall muscle strength and muscle mass, and a reduction in grip strength is associated with age-related muscle loss (Sousa-Santos and Amaral 2017). HGS is also a significant predictor and biomarker of health, morbidity, disability, and mortality, not only in the elderly, but also in middle-aged and young people (Sayer and Kirkwood 2015). Calibrated, digital dynamometers are commonly used to assess grip strength. The test involves exerting maximal gripping effort for 3 - 5 sec (Liguori *et al.* 2021). The 'sit to stand' (STS) test involves completing a predetermined number of full stands or the highest number of full

stands in a given time period from a sitting position (Segura-Ortí and Martínez-Olmos 2011) and, is a commonly used field-based test to assess lower body muscle strength and endurance. Both HGS and STS performance are reliable measures of muscle fitness across a range of CD cohorts (Segura-Ortí and Martínez-Olmos 2011; Puthoff and Saskowski 2013; Karagiannis *et al.* 2020). The MCID for the 10-rep STS has been estimated to be 8.4 sec (Segura-Ortí and Martínez-Olmos 2011) while the estimated MCID for HGS has ranged from 1.64 to 5.2 kg among a number of CD populations (Segura-Ortí and Martínez-Olmos 2011; Puthoff and Saskowski 2013; Karagiannis *et al.* 2020).

**Body Composition**

Body composition refers to the relative amount of muscle, fat, bone and other vital tissues in the body (U.S. Department of Health and Human Services 2018). Excess body fat, particularly when located in the abdomen region is associated with higher risk of CD, including hypertension, T2DM, stroke, CVD, and dyslipidaemia (Garber *et al.* 2011; Liguori *et al.* 2021). Body mass index (BMI) and circumference measurements (Liguori *et al.* 2021) are techniques commonly used to measure body composition in clinical populations.

The relation between body mass and stature is commonly expressed in the form of BMI (body mass (kg)/height$^2$ (m$^2$). Although BMI fails to distinguish body fat, muscle, and bone, it is well accepted as a predictor of excess body fat with the exception of those with large amounts of muscle mass (Liguori *et al.* 2021). A 5% reduction in body weight has been identified as a MICD required to improve risk factors or incidence of CD among individuals at risk for obesity (Williamson *et al.* 2015). Furthermore, each kg of weight loss is associated with a 16% reduction in the risk for T2DM (Hamman *et al.* 2006).

Repeated measurements of waist circumference by a trained assessor using a standard measurement protocol can significantly reduce measurement error (Verweij *et al.* 2013; Liguori *et al.* 2021). An estimated MICD of 3.0 to 6.6 cm for waist circumference has been reported by Verweij *et al.* (2013).

**Flexibility**

Flexibility refers to the ability to move a joint thorough its complete range of motion (ROM) (Liguori *et al.* 2021). Advancing age is associated with a decrease in flexibility (Garber *et al.* 2011). Although improvements in flexibility are not directly linked to reductions in all-cause and cardiovascular (CV) mortality, there is evidence that yoga may lower the risk of heart disease by reducing stress arousal (Raghuram *et al.* 2014). Improvements in flexibility are also associated with enhanced postural stability and balance (Garber *et al.* 2011). Flexibility training, however, is a neglected health-related components of physical fitness across all populations (Gummelt 2015).

The ROM at most joints can be objectively measured using a goniometer. Accurate measurement, however, requires adherence to strict guidelines and an in-depth knowledge of bone, muscle, and joint anatomy. The sit and reach (S&R) test measures lower back and hamstring flexibility (Liguori *et al.* 2021) and had been found to be reliable in middle to older age groups (Lemmink *et al.* 2001).

**Health-Related Quality of Life**

Health-related quality of life refers to '*an individual's or a group's perceived physical and mental health*' (CDC 2021) and can be measured using generic and disease

specific questionnaires (Megari 2013). Impaired perceived wellbeing has been linked to a number of CDs (Conversano 2019), and improving wellbeing is an important outcome of interventions designed to assist individuals manage their CD. Several validated generic questionnaires have been developed to assess HRQoL and allow comparisons across different CDs and interventions (Megari 2013). The SF-12v2 Health Survey is a 12-Item Short-Form Health Survey that derives an index of both perceived physical functioning and mental and emotional wellbeing (Linde *et al.* 2009). The SF-12v2 Health Survey results in a physical component score (PCS) and a mental component score (MCS). The Warwick Edinburgh Mental Well-Being Scale (WEMWBS) assesses an individual's state of wellbeing (thoughts and feelings) (Stewart-Brown and Janmohamed 2008). Both the SF-12v2 Health Survey and WEMWBS are valid and reliable measures of subjective wellbeing (Tennant *et al.* 2007; Lindert *et al.* 2015; Huo *et al.* 2018). The MCID estimated for the SF-12 PCS and MCS ranges from 1.8 to 3.29 and 1.13 to 3.77, respectively (Díaz-Arribas *et al.* 2017; Fu *et al.* 2021). The MCID for the WEMWBS ranges from 3 to 8 points among CD populations (Maheswaran *et al.* 2012).

**2.6 Coronary Artery Disease**

According to the European Heart Network (Wilkins *et al.* 2017), there are more than 85 million people living in Europe with CVD. CAD is the most common form of CVD with over 36 million (42%) Europeans (Wilkins *et al.* 2017; World Health Organistation 2017), including approximately 67,000 Irish people diagnosed with the disease (Wilkins *et al.* 2017). CAD is also a common comorbidity in many other CD (Pedersen and Saltin 2015).

Atherosclerosis, the primary cause of CAD, is a progressive inflammatory process initiated in response to repeated injury to the vascular endothelium. It results in pathological remodelling due to the formation of fibro-fatty plaque in the subendothelial layer of medium to large size coronary arteries (Bergheanu *et al.* 2017). Major manifestations of CAD include stable and unstable angina, myocardial infarction (MI), and sudden death. The medical management of CAD usually involves a combination of lifestyle interventions and pharmacotherapy to manage risk factor burden. Some individuals may also undergo revascularisation, primarily percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) (BACPR 2016).

Hypertension, blood cholesterol levels including low-density lipoproteins (LDL-C) and high-density lipoproteins (HDL-C), smoking, unhealthy diet, obesity, diabetes, and physical inactivity are the primary modifiable risk factors of CAD. Reducing CV risk factors remains an important objective (Riebe *et al.* 2015) in those living with CAD.

**2.7 Cardiac Rehabilitation**

Cardiac rehabilitation is a multidisciplinary and multifaceted treatment designed to promote and facilitate lifestyle changes, improve exercise capacity, optimise medical treatment and risk factor control and, address social and psychological issues following a coronary event or surgical procedure such as PCI or valve replacement (Balady *et al.* 2007). CR consists of four phases. Phase I takes place in a hospital setting (acute phase) immediately following a cardiac event or surgery. Patients receive information on the factors that may have precipitated a cardiac event, the impact of the cardiac event on the heart and circulatory system, the risk factors for heart disease with special reference to

those relevant to the individual and the various medications prescribed. Phase II refers to the period of time following discharge from hospital at the end of phase I to the beginning of phase III. Patients are encouraged to address the lifestyle issues in order to improve overall cardiovascular health. Phase III involves a fixed period of hospital-based, medically supervised exercise classes (Balady *et al.* 2007) along with a comprehensive educational and behaviour change element that targets the reduction of CVD risk factor burden. Phase IV refers to the life-long maintenance of a healthy lifestyle (Fletcher and McBurney 2016; Irish Heart Foundation 2018) and involves reduced healthcare support. It is undertaken at home or in a community-based setting - CBCR. CBCR generally consists of exercise sessions conducted once or twice a week complemented with educational talks. The exercise classes involve a structured warm-up, followed by a combination of aerobic and resistance exercises finishing with a cool down (BACPR 2016).

**2.8 PAET and Phase IV CR**

Participation in CBCR following completion of Phase III CR has been shown to improve or maintain functional capacity, PA levels, BP, optimal cholesterol levels and HRQoL in the first 6-12months (Sánchez-Delgado *et al.* 2020; Chowdhury *et al.* 2021) with evidence of functional benefits up to 3 years (Pryzbek *et al.* 2019). Studies evaluating the benefits of early transition to phase IV CR have involved both home-based (Pinto *et al.* 2011; Noites *et al.* 2017) and community (Seki *et al.* 2008; Christle *et al.* 2018) programmes that varied from 8 weeks (Noites *et al.* 2017) to 6 months in duration (Seki *et al.* 2008; Pinto *et al.* 2011; Christle *et al.* 2018; Zhang *et al.* 2018). The home-based programmes were closely monitored by a team of HCPs based in the community.

Historically, CRF has been the primary health-related component of fitness targeted in phase IV CR. Some studies have reported a significant increase in CRF (Noites *et al.* 2017; Zhang *et al.* 2018) in response to participation in CBCR, while others found no change (Izawa *et al.* 2006; Seki *et al.* 2008; Pinto *et al.* 2011; Christle *et al.* 2018).

Using a RCT study design, Noites *et al*., (2017) assigned 32 individuals (61 yr., 81% male) one year following their index MI either to an 8-week home-based exercise programme three times per week or to a control group. Both groups received health education sessions. All participants had previously completed an 8-week Phase III CR programme at least 9 months prior to the study. The home-based exercise sessions were 70 to 85 min in duration and consisted of strength, endurance, and balance exercises. Participants exercised at an intensity corresponding to 60% HRmax during the first 4 weeks and, 70% thereafter. Exercise intensity was monitored using heart rate (HR) telemetry and rating of perceived exertion (RPE). The exercise programme was monitored by weekly remote supervision, using text messages, telephone calls or e-mail messages, and by fortnightly face-to-face meetings. On average, participants completed 65% of the exercise sessions. Participation in the home-based exercise programme resulted in a 10% improvement in $\dot{V}O_2$peak, body composition, BP, heart rate reserve, heart rate at peak exercise and heart rate recovery.

Phase II CR and III CR in China corresponds to phase III CR and IV CR in Ireland. Zhang *et al., (*2018) randomised 130 ST segment elevated MI (STEMI) patients (70 yr.) following PCI to either CBCR (65, 91% male) or a usual care control group (65, 83% male). Participants in both groups commenced a structured phase II CR two weeks following

hospital discharge for the index MI. Participants in the phase III CBCR exercised at home or at a designated community facility. GPs prescribed individualised exercise programmes that consisted primarily of walking or other forms of aerobic exercise at an intensity corresponding to 60 - 75% HRmax. The exercise sessions were 30 - 45 min in duration and, were undertaken 3 - 5 times per week. Both groups were assessed on discharge from the hospital following the index MI, at 3 months having completed phase II and prior to commencing phase III and, again at 6 months.

There was no significant difference in 6MWTD between the CBCR and control group at discharge. Although both experimental groups significantly improved walking distance at 6 months, the increase was 50% greater in the CBCR group than the control group. Improvements in left ventricular ejection fraction and CVD risk profile were also significantly greater in CBCR compared to the control group.

Using a RCT design Seki *et al*., (2008) examined the effects of a 6-month comprehensive CR programme, involving a combination of supervised outpatient exercise sessions (1d/week) and home-based (2d/week) exercise training, on physical status and risk factors in 70-year-old Japanese men with CAD. The control group received usual outpatient care and advice. The exercise group were prescribed 20 - 60 min of aerobic and body resistance type exercises, preceded by a warm-up, and concluding with a cool-down. There was a significant improvement in BMI, waist circumference, strength, flexibility, and total cholesterol in the exercise group. Aerobic fitness was maintained in the CR group but was significantly reduced in the control group.

Christle *et al.,* (2018) examined the effect of a once-weekly CBCR maintenance programme or an individualised CR (ICR) programme, with a 2:1 participant to therapist ratio among 70-year-old CAD patients (62% male). The CBCR programme was delivered in a local university gymnasium with 15 - 20 patients per instructor. Sessions were 60 min in duration and included calisthenics, coordination, and flexibility exercises along with education sessions regarding diet, stress, coping skills and lifestyle change. Participants undertaking the CBCR programme were encouraged to exercise at an intensity corresponding to 60 - 70% $\dot{V}O_2$peak. The ICR group completed a 60-min combination of aerobic and resistance exercises. Aerobic exercise involved 30 min of cycling at an intensity corresponding to 60 - 70% $\dot{V}O_2$peak. Resistance exercises focused on upper and lower body muscle strength. Participants initially completed 2 sets of 12 - 15 reps at 30 - 50% of 1 repetition maximum (RM), and the workload was increased to 8 - 15 reps at 50 - 60% 1RM midway through the programme.

Maximal exercise capacity remained unchanged in both groups after 6 months indicating that, once-weekly exercise sessions were effective at maintaining but not increasing $\dot{V}O_2$peak. Submaximal exercise performance, measured as the exercise time to the ventilatory threshold increased significantly in the ICR group. Importantly, studies that focus on improving $\dot{V}O_2$peak may sometimes fail to identify submaximal improvements that are more reflective of ADL. There was a significant decrease in systolic blood pressure (SBP) in both groups whereas diastolic blood pressure (DBP), resting HR (RHR) and upper and lower muscle strength were also improved in the ICR group.

Izawa *et al.,* (2006) randomly assigned post MI patients who had completed a supervised CR programme to an unsupervised 6-month exercise intervention involving either 1 h of walking, twice a week at an RPE of 11 - 13 or a combination of walking and body weight resistance exercises. Both PA levels and $\dot{V}O_2$peak were maintained but did not increase in either group. There was a significant improvement in muscle strength in the combined walking and resistance training group.

The efficacy of a 6-month home-based intervention to support exercise maintenance following hospital-based (phase II) CR was assessed in CAD patients (64 yr., 79.2% male) randomised to an exercise counselling group or a contact control group (Pinto *et al.* 2011). Both groups received phone calls weekly for the first two months, biweekly for next two months and once a month during the final two months. The exercise counselling group received activity counselling to promote adherence to prescribed exercise along with information tip sheets regarding exercise and cardiovascular health. Exercise logs and pedometers were used to monitor compliance and to provide feedback. As stated, participants in the control group received calls at the same time intervals, with a focus on enquiring about their general health. They also received the information tip sheets regarding cardiovascular health. Although the exercise counselling group self-reported significantly higher exercise participation at 6 months, there was no significant difference in $\dot{V}O_2$peak or any of the lipid measurements between the groups.

Ter Hoeve *et al.,* (2019) randomly assigned 740 patients following their participation in a 3-month medically supervised phase III hospital-based CR to face-to-face

group lifestyle counselling (58 yr., 81% male), individual telephone lifestyle counselling (57 yr., 82% male) or a control group who received no aftercare follow-up (58 yr., 80% male). Participants in the two intervention groups were advised to undertake 30 min of aerobic exercise, 5-times per week at moderate intensity. In addition, the face-to-face group received a 2 h group-based session, led by a multidisciplinary team, at 1, 3 and 9 months. The group-based sessions included a 1 h exercise session and a 1 h of healthy lifestyle counselling focusing on optimal diet and PA. The telephone intervention group received 5 - 6 calls, spaced 5 - 6 weeks apart. During the call, they were encouraged to self-monitor BP, weight, and cholesterol and to develop a personal action plan for optimal diet and PA. There was significant improvement in 6MWTD in the face-to-face group at 9 months, but this improvement was no longer evident at 15 months. There was no improvement in 6MWTD in the telephone group or the control group at 9 or 15 months, implying face-to-face contact could be an important element to maintain or improve CRF.

Reid *et al.,* (2021) examined the effect of providing facilitated exercise sessions on moderate to vigorous PA (MVPA) in men and women following completion of a standard phase III CR programme. One of the facilitated sessions was delivered in person, five involved small group counselling teleconference sessions and, three were individual phone calls. A control group received usual care advice that included an updated home-based exercise programme, information regarding suitable local exercise opportunities and exercise maintenance strategies.

There was no significant effect on weekly MVPA in either men or women at 52 weeks. There was, however, a 26% increase in the number of exercise bouts ≥10 min and

a 13% increase in exercise capacity in women who adhered to ≥66% of the facilitated sessions, compared to the control group. Among women, BP was significantly higher in the control group than the treatment group at 52 weeks. Regardless of attendance, participation in the facilitated sessions had no significant effect on the measured health indices or functional capacity in men. However, the male participants were already quite active at the start of the intervention. Among women who attended ≥ 66% of the exercise facilitated counselling sessions, both exercise capacity and long-term exercise maintenance improved significantly. The positive effects of exercise maintenance measured as MVPA was most evident during the first 6 months when participants had the highest level of contact with the exercise facilitator.

Madssen *et al.*, (2014) randomly assigned 49 CAD patients who had completed a 12-week hospital-based CR either to a 12-month, home-based high intensity interval training (HIIT) CBCR programme (24, 66yr., 75% male) or to a usual care control group (25, 59 yr., 72% male). The intervention group received a written HIIT exercise programme with the goal of undertaking three sessions per week. They were also invited to attend monthly supervised HIIT sessions with an experienced physiotherapist or exercise physiologist. The HIIT sessions consisted of an 8 - 10 min warm-up, followed by 4 x 4 min intervals at an intensity corresponding to 85 - 95% HRmax with 3 min active recovery at 70% HRmax. Participation in the 12-month home-based HIIT programme was effective in maintaining exercise capacity, HRQoL, blood biomarkers or PA levels.

A retrospective analysis of 251 patients undertaken by Ong et al., (2016) compared the effects of participation in a 12-month supervised CBCR (94, 60 yr., 81% male) to a

usual care control group (157, 61yr, 83% male). Participants in both groups completed a hospital-based CR programme. Exercise sessions were undertaken 3 days per week and consisted of a warm-up, 60 min of aerobic exercise and a cool-down. Over the 12-month period, exercise capacity in the CBCR, measured by the 6MWT, increased by 7% (37 m). Exercise capacity was not assessed in the control group. There was a significant reduction in LDL-C, triglycerides (TG), total cholesterol, blood glucose and BP in CBCR group. In contrast LDL-C, TG, total cholesterol, blood glucose and BP increased significantly in the control group.

Using a single-arm cohort study design, Kwan *et al.,* (2016) evaluated the effect of a 12-month supervised CBCR involving 136 CAD patients. Resistance exercises were included in addition to aerobic training. Participating in the physiotherapist delivered CBCR resulted in significant improvements in 6MWTD along with reductions in percentage body fat, and circulating levels of total cholesterol, LDL-C, and TG.

Attending supervised CBCR two days per week was found to be effective in maintaining exercise capacity over a 19-month period in CAD patients (79% male) with an average age of 70 yr. (Mandic *et al.* 2013). Among 160 long-term attenders (64 yr., 100% male) of a supervised CBCR programme, CRF was found to significantly increase over the first 3 years with evidence of a decline during years 4 and 5 (Pryzbek *et al.* 2019). One of the longest running studies followed attendance at a cardiac maintenance programme (CMP) for an average of 6.3 years (Christle *et al.* 2021). The format of programme has been previously described (Christle *et al.* 2018) with attendance set at once a week. Among 207 (60±9yr, 84% male) participants who attended the programme for an average

of 6.3 years, there was a 5.7% decrease in $\dot{V}O_2$peak (26.1 to 24.6 $mL \cdot kg^{-1} \cdot min^{-1}$), whereas both BMI and waist circumference increased. Even among active adult men and women, there is an approximately 1% decline in $\dot{V}O_2$max after the age of 30 years (McArdle *et al.* 2014). Interestingly, there was no difference in exercise performance or CV risk profile among a sub-sample of men attending the CMP and a group matched for age and time period since baseline measures. No information was provided regarding the PA levels of the non-CMP cohort. Long-term studies indicate that individuals attending supervised CBCR can maintain and even improve their CRF during the first 12 months and in some cases up to 3 years. Although CRF inevitably decreases with advancing age, the rate of decline is influenced by PAET.

A reduction in muscle fitness and associated deficit in functional ability and HRQoL (Puthoff and Saskowski 2013) is frequently experienced following a cardiac event (Sokran *et al.* 2015). Surprisingly, the maintenance and development of muscle strength and endurance is not always included as part of CBCR and therefore, is not assessed as frequently as CRF. Using isokinetic dynamometry, Seki *et al.,* (2008) found significant improvements in lower body strength following six months of CBCR. A 6-month unsupervised home-based exercise training programme that combined walking and resistance exercise resulted in significantly greater improvement in lower body muscle strength than walking only (Izawa *et al*., (2006). Improvements of 41% and 30% in upper and lower body strength respectively, were reported among individuals with CAD who completed an individualised gym-based resistance training programme (Christle *et al.* 2018). In contrast, no improvement in upper or lower body strength was found among

CAD participants attending a group-based calisthenics session, one day per week for six months.

Maintaining improvements in muscle fitness beyond the first 6 months of CBCR is challenging. Lower body strength assessed using the 30 sec STS chair test increased by 13% whereas HGS declined by 9% following participation in an 18-month supervised CBCR programme (Mandic *et al.,* 2013). Similarly, Pryzbek *et al.,* (2019) reported a decline in upper body strength of <1% per year and an increase in lower body strength each year during a 4-year supervised CBCR programme.

Body composition, particularly an increase in abdominal body fat, is associated with the onset and progression of CVD (Benjamin *et al.* 2019). Among CAD patients participating in a combined supervised and home-based CBCR programme, Seki *et al.,* (2008) found significant reductions in BMI and waist circumference but no change in body fat percentage or lean muscle mass. Noites *et al.,* (2017) found a significant reduction in body weight and percentage body fat and no change in waist circumference following participation in an 8-week home-based CBCR programme. In contrast, Christle *et al*., (2018) found no changes in body weight, BMI, fat-free mass or waist circumference following participation in either an individualised or group-based CBCR programme. Interestingly, studies that reported a positive effect of community-based exercise programmes (CBEP) on body composition included nutritional talks or support material as part of the programme.

Results from long-term studies examining the impact of CBEP on body composition are mixed. Body weight, BMI, percentage body fat and waist circumference were found

to significantly increase among participants attending a CBCR programme for 18 months (Mandic *et al.* 2013). Similarly, Madssen *et al.,* (2014) found a significant increase in body weight, BMI, and waist circumference over a 12-month period among CAD participants attending a monthly supervised HIIT session in combination with a home-based exercise programme. Despite the inclusion of diet and nutritional counselling, Christle *et al.,* (2021) reported an increase in body weight and BMI over an average of 6 years among men and women attending a cardiac maintenance programme.

Reid *et al.*(2021) found favourable changes in BMI but no impact on waist circumference among women following their participation in a 12-month home-based CBCR programme with tele-support. In contrast, waist circumference increased significantly among the male participants. It is possible that body composition changes during long-term CBCR may not be reflected in the measurements of BMI or body mass. For example, Kwan *et al.,* (2016) found a significant decrease in percentage body fat, an increase in waist circumference and no change in BMI or body mass following 12 months of a supervised CBCR programme.

Improvements in flexibility require regular stretching exercises that target the major muscle-tendon units of the main joints (Garber *et al.* 2011). Although some CBCR programmes include stretching exercises during class time(Izawa *et al.* 2006; Seki *et al.* 2008; Mandic *et al.* 2013; Christle *et al.* 2021), very few assessed flexibility (Seki *et al.* 2008). Seki *et al.,* (2008) included a 15-min cool-down involving stretching and calisthenics and reported significant improvements in anterior flexion of the trunk following 6 months of combined home and supervised CBCR.

There is evidence that HRQoL is better among individuals who attend phase III CR compared to those who do not attend (Dalal *et al.* 2015; Dibben *et al.* 2021). Using the 12-Item Short-Form Health Survey (SF-12v2), Zhang *et al.,* (2017) found significant improvements in HRQoL following participation in a home-based CR programme comprising 6 months of exercise counselling monitored by a community health service. Among women with CAD, HRQoL scores improved significantly following participation in a 12-week home-based exercise programme that involved walking 30 - 40 min, 3 days per week (Johnson *et al*., (2009).

A virtual reality (VR) based exercise intervention following hospital-based CR was found to significantly improve selective attention and conflict resolution among CAD patients compared to usual care advice (Viera *et al.,* (Vieira *et al.* 2018). There was no improvement in HRQoL, depression, anxiety, or stress scores, indicating that the use of VR technology does not benefit perceived mental health. Exercise studies that have shown consistent improvements in HRQoL in the first 6 months of Phase IV CR had either more face-to-face contact or included exercise counselling in their intervention. It is likely, therefore, that some form of regular contact is required in order to achieve better perceived HRQoL among CBCR participants.

Some long-term CBCR interventions lasting up to 12 months were ineffective at improving HRQoL scores compared to scores recorded following completion of a hospital-based CR or at entry to CBCR. (Madssen *et al.* 2014; Reid *et al.* 2021). In contrast, Johnson *et al.,* (2009) reported improvement an HRQoL scores following 12 months of CBCR compared to HRQoL scores recorded prior to entering a hospital-based CR programme.

## 2.9 Beneficial Effects of PAET on the pathophysiology of CAD

The beneficial effect of PAET in patients with CAD is likely to be multifactorial. It is well established that PAET can significantly influence the structure and function of the heart, blood lipids, endothelial function, fibrinolysis, autonomic nervous system, platelet aggregation, circulating levels of cytokines, BP, inflammation, antioxidants and insulin sensitivity (Booth *et al.* 2012; Pedersen and Saltin 2015; Ong *et al.* 2016; Guo *et al.* 2017). A reduction of 10 mmHg in SBP or 5mmHg in DBP has been associated with an almost 30% lower risk of CV mortality (Lewington *et al.* 2002). A reduction of 1.0 mM in LDL-C decreases major CV events by 23% (Heart Protection Study Collaborative Group 2011).

Despite the well-established physical and mental health benefits, there is a lack of short and long-term CBCR programmes available in Ireland (Lavin *et al.* 2005; I.A.C.R. 2020). Croí, located in the West of Ireland, offers individuals recovering from CVD a range of secondary prevention, short-term, exercise classes delivered in-house or online (Croi 2022). Limited research has been published based on these programmes. Preliminary research has shown that a 16-week, community based, nurse-led prevention programme (Croí MyAction) demonstrated improved CV risk factors by achieving healthier lifestyles and optimal medical management in individuals at high risk of developing CVD (Gibson *et al.* 2014). This programme was based on a 12-week, community-based, nurse-led programme (MyAction Westminster) ran in the UK which included weekly educational workshops and supervised exercise sessions (Connolly *et al.* 2017). The UK programme reported that an integrated CVD prevention programme reduced CV risk in patients with established CVD and in those at high risk of developing CVD. Similar to the Irish

programme significant improvements were found in lifestyle behaviours, such as smoking, diet, PA levels; fitness levels, and HRQoL scores. There were also significant increases in proportions achieving their blood pressure and LDL-C targets. The majority of supervised CBCR programmes inside and outside of Ireland are delivered by HCPs, including physiotherapists (Kwan *et al.* 2016; Ong *et al.* 2016), GPs (Kwan *et al.* 2016; Ong *et al.* 2016; Zhang *et al.* 2018) or a multidisciplinary team such as cardiologists, physiotherapists, CR nurses, exercise physiologists and other allied health professionals (Seki *et al.* 2008; Dunn *et al.* 2014; Christle *et al.* 2021; Croi 2022) which is unlikely to be sustainable in long-term programmes.

Many CD share common lifestyle risk factors (Pedersen and Saltin 2015), display similar pathogenesis (Furman *et al.* 2019), and result in comparable disease burden (Chou *et al.* 2021) and diminished HRQoL (Booth *et al.* 2012), as outlined in table 2.1. These common elements are subject to mutual adaptation and improvement with PAET (Pedersen and Saltin 2015).

Table 2.1 Pathophysiology, risk factors, burden, PAET recommendations, benefits, and possible mechanisms of a range of CD

| CD | Pathophysiology | Risk Factors | Burden of CD | PAET Rec. | Benefit of PAET | Mechanism |
|---|---|---|---|---|---|---|
| CAD | Atherosclerosis, narrowing of blood vessels due to the formation of plaque under the endothelium in the coronary arteries | **Non-Modifiable**<br>Age/Gender M≥45y, F≥55y<br>Family history<br>Ethnicity<br>**Modifiable**<br>HTN<br>Blood cholesterol<br>Smoking<br>Physical inactivity<br>Unhealthy diet<br>Obesity<br>Diabetes | ↓Muscle strength<br>↓CV fitness<br>↓Functional capacity<br>↓HRQoL<br>↑Fear of PA | Aerobic training<br>Resistance training | ↓ CV mortality<br>↓All-cause mortality<br>↓ Hospital admissions<br>? Risk of MI<br>↑HRQoL<br>↓CV Risk factors<br>↑CV Fitness<br>? Body composition<br>↑lower body strength<br>? upper body strength<br>? Flexibility | ↑Fibrinolysis<br>↓Platelet aggregation<br>Improved BP reg.<br>Optimised lipid profile<br>Improved endothelium function<br>↑HR variability and autonomic tone |
| Stroke | Atherosclerosis, narrowing of blood vessels due to the formation of plaque under the endothelium in the in the brain<br><br>Infarction due to cardiac embolism, intracerebral haemorrhage, or subarachnoid haemorrhage after ruptured aneurysm | **Non-Modifiable**<br>Age/Gender M≥45y, F≥55y<br>Family history<br>Ethnicity<br>**Modifiable**<br>HTN<br>Blood cholesterol<br>Smoking<br>Physical inactivity<br>Unhealthy diet<br>Obesity<br>Diabetes | Depending on location<br><br>Can be unilateral paresis of upper and lower limbs<br>Aphasia<br>Cognitively<br>Emotionally<br>Depression<br>Low physical function | Aerobic training involving walking<br>Resistance training | ? All-cause mortality<br>? CV mortality<br>↓Hospitalisation<br><br>? HRQoL<br>↑Walking speed<br>↑Walking distance<br>↑Balance<br>↑CV fitness<br>↑lower body strength<br>↑upper body strength | Improves aerobic capacity (Reduced oxidative capacity in paretic muscles)<br><br>Reduces energy exertion (energy exp is higher compared to normal due to inefficient pattens of movement and spasticity) |
| COPD | Irreversible decrease in lung function<br><br>Chronic airflow obstruction<br><br>Have chronic inflammation possibly from link to higher TNF-α levels in the blood/muscle | **Non-Modifiable**<br>Age<br>Genetic<br>**Modifiable**<br>Smoking (active/passive)<br>Exposure to noxious gases<br>Poor nutrition<br>Pneumonia/childhood respiratory infection | ↓Muscle strength<br>↓ ADL<br>↓HRQoL<br>↓Functional capacity | Endurance and strength training | ↓ Mortality<br>↓Hospitalisation<br>↑HRQoL<br>↑Functional capacity<br>↑Walking distance<br>x lung function | Improves CRF via the muscles and the heart not the lung function<br><br>Possibly impact on TNF levels |

| | | | | | | |
|---|---|---|---|---|---|---|
| MS | Autoimmune inflammatory demyelinating disease of the CNS and a major cause of chronic neurological disability<br><br>Characterised by nerve demyelination due to T cells attacking CNS | **Non-modifiable**<br>Gender (F↑)<br>Age 20-40<br><br>**Factors associated with worse prognosis**<br>Older age of onset<br>Progressive disease course<br>Multiple symptoms<br>Short intervals between attacks | Depends on presentation<br>↓Strength<br>↓Coordination<br>↓Sensation<br>↓Balance<br>↓ ADL<br>Fatigue<br>Pain<br>Incontinence<br>Cognitive deficits<br>Psychosocial issues<br>Behavioural issues | Aerobic and resistance training | ↑Walking<br>↑Muscle strength<br>↑CV fitness<br>↑HRQoL | Aim of training is to recover muscle strength, coordination and fitness that are lost due to paresis which leads to restricted muscle functions and poor physical fitness (Break the vicious cycle) |
| PD | Progressive and disabling degenerative disorder<br><br>Characterised by reduced dopamine synthesis | Age >60y<br>Family history/ Genetics<br>>20y occupational exposure to manganese, copper, insecticides<br>Smoking | Bradykinesia<br>Tremor<br>Rigidity<br>Postural instability<br>↓Muscle strength<br>↓ Functional ability<br>Speech<br>Incontinence<br>Constipation | Aerobic training (TM/Bike)<br>Balance<br>Resistance training | ↑ Walking speed but not distance<br>↑HRQoL<br>↑ Physical functioning<br>↑ Strength<br>↑Balance<br>Improved strength and physical fitness | Aim of training is to recover muscle strength, coordination and fitness that are lost due to paresis which leads to restricted muscle functions and poor physical fitness (Break the vicious cycle) |
| MSK | **Rheumatoid arthritis (RA)**<br>Chronic systematic inflammatory disease where your immune system attacks the lining of your joints<br>Can be associated with higher rates of T2DM and CVD<br>Associated with ↑TNF-α in blood<br><br>**Osteoarthritis (OA)**<br>Disease of the joints, joint loses cartilage, bone grows to try and repair damage – but grows back abnormally and results in misshapen joint | **RA/ OA**<br>Gender (F↑)<br>Age<br>Genetics<br>Smoking<br>Obesity | **RA & OA**<br>Swollen joints<br>Stiff joints<br>Pain<br>Fatigue<br>↓PAL<br>↓Muscle strength<br>↓CV fitness<br>↑CV mortality | Aerobic training*<br>Resistance training<br><br>*Note that if joint destruction evident aerobic activity should be non-weight bearing | **RA** & **OA**<br>↓Pain<br>↑CV fitness<br>↑Muscle strength<br>↑Self-reported functional capacity<br>? HRQoL | **RA**<br>Improve endothelial function, BP, lipid profile<br>↑Muscle mass<br>↑ Anti-inflammatory effect<br>↓TNF-α<br>(Trying to break vicious SCI cycle)<br>**OA**<br>↓ IL-10<br>↑ Glycosaminoglycan |

| | | | | | | |
|---|---|---|---|---|---|---|
| IBD and Stoma | IBD are chronic inflammatory diseases of the gastrointestinal tract- two most common types - ulcerative colitis (UC) and Crohn's disease (CrD)<br><br>Inflammatory bowel disease top reason for stoma formation surgery<br><br>TNF α is a major pathological marker for IBD | Stoma complications are associated with<br>Poor diet<br>Physical inactivity<br>Smoking | ↓PA<br>↓HRQoL<br>↑Fatigue<br>↓Physical ability<br>↑Fear of PA | Aerobic and resistance training | ↑ HRQoL<br>↑CV Fitness<br>↑Muscle strength<br>↑BMD | ↑Fitness and muscle strength relives fatigue and strengthen physical ability<br><br>Anti-inflammatory effects of PA – release of cytokines (IL-6) which reduces the levels of TNF-α |
| T2DM | Characterised by hyperglycaemia<br>Defective insulin secretion &<br>Insulin resistance cells<br><br>Interferes with glucose, fat, and protein metabolism<br><br>T2DM associated with accelerated atherosclerosis development and HTN | **Non modifiable**<br>Ethnicity<br>Family history/ Genetic disposition<br>**Modifiable**<br>Obesity<br>Unhealthy diet<br>Physical inactivity | Damage to the heart, vasculature, eye, kidneys, nerves | Aerobic training<br>Resistance training | ↑ Glycaemic control<br>↓HbA1c<br>Improved vascular function<br>↓ visceral adipose tissue<br>↓Diabetes related complications<br>↓Diabetes related mortality<br>↑CV fitness<br>↑ Strength<br>? Body weight<br>? HRQoL<br>x All-cause mortality | ↑ Insulin sensitivity in trained muscle<br>↑ GLUT4<br>↓release and ↑ clearance of FFA<br>↑ Muscle capillary network and blood flow<br>↑ Diastolic filling LV<br>↑ Endothelial vasodilator function<br>↑ Anti-inflammatory effect |
| CD = chronic disease, PAET = physical activity/exercise training, CAD = coronary artery disease, HRQoL = health-related quality of life, CV = cardiovascular, SCI = systemic chronic inflammation, HTN = hypertension, COPD = chronic obstructive pulmonary disease, MS = multiple sclerosis, PD = Parkinson's disease, MSK = musculoskeletal, IBD = inflammatory bowel disease, T2DM = type 2 diabetes mellites | | | | | | |

## 2.10 Community-Based Exercise Programmes for OCD

In addition to CAD, PAET has been recommended for OCD to help manage their condition. Benefits of home and community-based exercise programmes delivered to specific CD such as respiratory disease, T2DM, stroke, MS, PD have been reported (Rietberg *et al.* 2005; Goodwin *et al.* 2008; Brozic *et al.* 2017; Varas *et al.* 2018; Saunders *et al.* 2020). Most of these interventions were 8 - 20 weeks in duration, were led by HCPs and very few reported follow-up benefits once the intervention had ceased.

## 2.11 PAET and Stroke

### Pathophysiology

A stroke occurs in response to a sudden interruption of blood supply to specific regions of the brain due to rupture or obstruction of a blood vessel (Booth *et al.* 2012). Depending on the location of the rupture or obstruction, the individual may be left with unilateral paresis or experience aphasia. Atherosclerosis and hypertension are two of the major causes of blood vessel damage in the brain (Lee *et al.* 2003; Mader *et al.* 2014). Depression, inefficient patterns of movement, spasticity, decreased oxidative capacity in the paretic muscle and low physical function are a common occurrence following a stroke (Pedersen and Saltin 2015).

### Mechanism of PAET

A meta-analysis, which included 23 epidemiological studies, found that individuals who were moderately or highly active had a 20% and 27% lower risk of stroke and

mortality, respectively, compared to low-active individuals (Lee *et al.* 2003). While mortality rates in stroke survivors are not influenced by PAET interventions, there is evidence of a reduction in hospital admissions (Saunders *et al.* 2020), decreased spasticity, and an increase in muscular strength and CRF (Xiao 2020). Potential mechanisms for the beneficial effect of PAET in stroke patients include improvements in lipid metabolism and endothelial function, reductions in BP, fibrinogen levels, platelet aggregation and blood viscosity along with increased fibrinolysis (Lewington *et al.* 2002; Lee *et al.* 2003; Reimers *et al.* 2009).

**Benefits of CBEP**

Community-based exercise programmes that focus on PAET in stroke patients, in particular walking, and mixed training, result in improvements in aerobic fitness, balance, walking speed, and mobility (Pang *et al.* 2005; van de Port *et al.* 2012; Gordon *et al.* 2013; Moore *et al.* 2015). Evidence is less convincing regarding improvements in HRQoL (Globas *et al.* 2012; Gordon *et al.* 2013; Saunders *et al.* 2020). A 16-week group-based exercise programme, delivered by a physiotherapist and PA instructor to 20 stroke survivors (68 yr., 90% male), resulted in significant improvements in $\dot{V}O_2$peak, 6MWTD, balance, gait speed and cerebral blood flow (Moore *et al.* 2015). There was no improvement in the control group prescribed a home-based stretching programme.

Three months of treadmill or overground walking was found to significantly improve CRF in stroke patients, compared to usual care physiotherapy outpatient services (Globas *et al.* 2012; Gordon *et al.* 2013). Treadmill walking was also found to significantly improve gait speed and balance but not leg strength in stroke patients (Globas *et al.* 2012).

An improvement in the physical domain (PCS) of the SF-36 HRQoL has been reported following overground walking (Gordon *et al.* 2013). In contrast, stroke patients who undertook treadmill training had a significant improvement in the mental domain (MCS) of the SF12 HRQoL with no change in PCS (Globas *et al.* 2012).

## 2.12 PAET and COPD

### Pathophysiology

Chronic obstructive pulmonary disease is a heterogeneous, systemic condition characterised by persistent airflow limitation that is not fully reversible (McCarthy *et al.* 2015). It is the third leading cause of global deaths (World Health Organization 2022). Systemic inflammation in COPD patients is related to an increased risk of comorbidities, reduced pulmonary function, impaired functional capacity (Pedersen and Saltin 2015) and increased mortality and exacerbations. Airflow limitation associated with COPD alters the ventilatory mechanics and increases the work of breathing making PA more difficult (Xiao 2020).

COPD is strongly linked to a reduction in physical capacity. Furthermore, a deterioration in breathing and an increase in anxiety can lead to social isolation (Pedersen and Saltin 2015). COPD places a high financial burden on healthcare systems due to both direct costs (e.g., healthcare resources, medication prescriptions) and indirect costs (e.g. absence from paid work, consequences of disability) (Guarascio *et al.* 2013). Exposure to smoking and noxious gases are the primary modifiable risk factors that result in the irreversible decrease in lung function associated with COPD (Pedersen and Saltin 2015).

**Mechanism of PAET**

Outpatient PR typically involves an 8 to 12-week programme consisting of exercise, education, and support to help cope with breathlessness and, to insure optimal levels of functioning (Fischer *et al.* 2009; McKeon 2021). Among COPD patients, PAET increases CRF by improving both cardiovascular and skeletal muscle function without altering lung function (Pedersen and Saltin 2015). Early initiation of PR among individuals with COPD is associated with lower mortality rates compared to those who start later or not at all (Lindenauer *et al.* 2020).

**Benefits of CBEP**

Among individuals with COPD, participation in supervised maintenance exercise programmes improves HRQoL and exercise capacity at 6 and 12 months (Malaguti *et al.* 2021). Using a RCT design, Amin *et al.,* (2014) found a 30% improvement in exercise capacity and reduced breathlessness in patients with moderate COPD following their participation in a 12-week supervised gym-based programme. There was a 14% decrease in exercise capacity in a usual care group. Although HRQoL did not improve significantly in either group, the exercise group had a mean improvement of 4.6, which exceeds the MCID (4) for the St George's Respiratory QoL questionnaire. In a more recent study, Varas *et al*., (2018) randomly assigned patients with COPD who had completed a structured, medically supervised PR programme to either an 8-week monitored, home-based walking programme (70 yr., 86% male) or to usual care advice (65 yr., 68% male). Participation in the walking programme resulted in a >90% improvement in exercise capacity, along with significant improvements in daily step count and HRQoL. In contrast, there was a 10%

decrease in exercise capacity in the usual care group. Importantly, these improvements were maintained at a 12-month follow-up. Similarly, a 12-month, gym-based maintenance programme with minimal supervision following completion of a structured hospital-based PR resulted in a significant improvement in exercise capacity, muscle strength and HRQoL (Beauchamp *et al.* 2013).

## 2.13 PAET and T2DM

### Pathophysiology

T2DM is a metabolic disorder characterised by chronic hyperglycaemia that interferes with glucose, fat, and protein metabolism (Pedersen and Saltin 2015). Defective insulin secretion by pancreatic β cells and the development of insulin resistance (Galicia-Garcia *et al.* 2020) are the primary causes of T2DM. Complications that have traditionally been associated with T2DM include macrovascular conditions, such as CAD, stroke and peripheral arterial disease, as well as microvascular conditions, including diabetic kidney disease, retinopathy, and peripheral neuropathy (Pedersen and Saltin 2015). Heart failure is also a common initial manifestation of CVD in patients with T2DM (Shah *et al.* 2015). Emerging complications of T2DM include infections, cancer, liver disorders, functional disability, cognitive disability and affective disorders (Tomic *et al.* 2022).

### Mechanism of PAET

The mechanisms of PAET in the management of T2DM are multifactorial. Acute bouts of PAET increases insulin sensitively and insulin independent glucose uptake by

skeletal muscle for up to 72 h (Colberg *et al.* 2010). Other benefits associated with PAET include improved endothelial function, reduced visceral adipose tissue, increased muscle capillary network and blood flow, and anti-inflammatory effects (Maiorana *et al.* 2001; Thomas *et al.* 2006; Pedersen and Saltin 2015; Brozic *et al.* 2017).

**Benefits of CBEP**

Participation in a four day a week, 12-month supervised CBEP involving a combination of aerobic and resistance exercises significantly improved glycaemic control, $\dot{V}O_2$max, muscle strength and endurance, (Loimaala *et al.* 2003) among individuals (54 yr.) with T2DM. Similarly, Gallé *et al.,* (2019) reported significant improvements in functional capacity, body composition and glycaemic control among men and women with T2DM in response to a 9-month CBEP that consisted of aerobic and resistance exercises. In addition to improvements in functional capacity, glycaemic control and body composition, participation in a CBEP also improved blood lipid profile, BP and reduced 10-year risk of CVD among patients with T2DM (Mendes *et al.* 2016; Mendes *et al.* 2017). Surprisingly, there is limited evidence regarding the effect of participation in a CBEP on HRQoL among individuals with T2DM. Green *et al.,* (2011) found that individuals with T2DM, who had reported exercising on a regular basis, had better physical and MCSs compared to those who did not undertake regular exercise. However, their HRQoL scores were still significantly lower than non-diabetics who exercised regularly.

## 2.14 PAET and Musculoskeletal Disorders

### Pathophysiology

Osteoarthritis (OA) and rheumatoid arthritis (RA) are two common diseases of the MSK system. OA is a disease of the joints characterised by degeneration of the cartilage and its underlying bone within the joint (Booth *et al.* 2012). RA is a chronic systematic inflammatory disease (Pedersen and Saltin 2015) where the immune system attacks the lining of joints (Hurkmans *et al.* 2009). Compared to males, females are more susceptible to both OA and RA. Age, genetics and obesity are common risk factors for OA and RA (CDC 2020a; CDC 2020b). Circulating levels of inflammatory factors, tumour necrosis factor-α (TNF-$\alpha$), and interleukin-1 are increased in individuals with one, or both forms of arthritis (Pedersen and Saltin 2015; Xiao 2020). Due to the resulting swollen joints, stiffness, pain, and fatigue experienced, patients with OA and RA tend to be less active and have lower CRF, muscle strength and HRQoL (Pedersen and Saltin 2015).

### Mechanism of PAET

Although high-impact exercise is contraindicated for individuals with OA, there is accumulating evidence to support moderate to vigorous PAET for individuals with OA or RA (Booth *et al.* 2012). Systematic reviews have consistently reported a beneficial effect of PAET in reducing pain, increasing physical function and either maintaining or improving HRQoL (Hurkmans *et al.* 2009; Fransen *et al.* 2014; Geneen *et al.* 2017). An increase in muscle-derived interleukin-6 during exercise has also been linked to inhibition of TNF-$\alpha$

production (Pedersen *et al.* 2001). This could be very beneficial for individuals living with OA and RA, where chronic inflammation is a primary characteristic of the disease.

**Benefits of CBEP**

A meta-analysis of 49 RCT that included 3,909 individuals with RA, OA and spondyloarthritis found no adverse effects when PAET was undertaken in accordance with the American College of Sports Medicine (ACSM) recommendations (Rausch Osthoff *et al.* 2018). Adhering to the ACSM exercise guidelines resulted in improvements in CRF and muscle strength. Improvement in muscle strength, aerobic capacity and HRQoL were reported among community-living individuals (70 yr.) with OA who completed either a 6-week hydrotherapy strengthening programme, or a gym-based resistance training programme compared to a control group. A home-based cross-over trial compared 30 individuals with RA completing a conventional exercise programme or a virtual reality exercise programme. Both groups had a significant improvement in both CRF and muscle strength during the first 12 weeks, with maintenance of HRPF evident at 24 weeks.

**2.15 PAET and Neurological**

**Pathophysiology**

MS is an autoimmune inflammatory demyelinating disease of the central nervous system (Amatya *et al.* 2019). PD is a progressive and disabling degenerative disorder (Mehrholz *et al.* 2015) characterised by decreased levels of the neurotransmitter dopamine (Xiao 2020). Symptoms specific to PD include bradykinesia, tremor, and rigidity. Inflammation is a common mechanism associated with both MS and PD.

Individuals with neurological conditions, such as PD and MS, have reduced CRF, muscle strength, coordination, balance, and functional ability, along with increased levels of fatigue (Xiao 2020).

**Mechanism of PAET**

Medical management is the primary treatment option for individuals diagnosed with neurological diseases (Xiao 2020). Structured exercise therapy improves physical functioning (gait speed, mobility, muscle strength and aerobic capacity) and HRQoL in individuals with MS (Rietberg *et al.* 2005; Amatya *et al.* 2019) and PD (Goodwin *et al.* 2008; Tomlinson *et al.* 2013). There is evidence that dance may be a particularly good PAET intervention for patients with PD (Tang *et al.* 2019). The exact pathophysiological mechanism underpinning the beneficial effects of exercise in neurological diseases is an area of active research (Tang *et al.* 2019; Xiao 2020). An important aspect of PAET among individuals with neurological diseases is to recover the lost muscle strength, coordination, and fitness due to restricted muscle function (Pedersen and Saltin 2015).

**Benefits of CBEP**

Elsworth *et al.,*(2011) randomised 98 patients (56 yr.) with a range of neurological conditions to a 3-month CBEP in a local gym or to a control group. Although there were no between-group differences, participation in the gym-based programme resulted in significant improvements in walking distance, gait speed, muscle strength and perceived physical fitness. Salbach *et al*., (2014) conducted a single arm repeated measures trial involving a 12-week pilot CBEP that focused on transitioning individuals with neurological

conditions to exercise in a community group setting. The CBEP was administered by exercise professionals supported by physical therapists. Balance significantly improved whereas CRF, mobility and HRQoL increased, though not significantly.

### 2.16 PAET and Bowel Disease/Stoma

#### Pathophysiology

Inflammatory bowel disease (IBD) refers to chronic inflammatory diseases of the intestinal tract. The two most common types of IBD are ulcerative colitis (UC) and Crohn's disease (CrD) (Holik *et al.* 2019). Whereas inflammation associated with CrD can occur anywhere along the gastrointestinal tract, it is confined to the large intestine or colon in UC (Eckert *et al.* 2019). It is common for IBD patients to experience exacerbations and remission of symptoms. The cause of IBD is considered multifactorial with the interaction of genetics, environmental factors and abnormal immune response to gut microbes associated with higher levels of IBD (Baumgart and Carding 2007; Holik *et al.* 2019). Levels of TNFα is a major pathological marker in both CrD and UC (Eckert *et al.* 2019). Pharmacotherapy is the first line of treatment for IBD. A stoma is an artificial opening on the surface of the abdomen used to divert faeces or urine out of the body (Beeken *et al.* 2019). Stoma formation surgery may be required if the disease fails to respond to medications or there is an exacerbation of symptoms (Holik *et al.* 2019).

#### Mechanism of PAET

Regular PAET in IBD has been reported to improve physical function and has been associated with remission of symptoms (Holik *et al.* 2019). However, nearly a third of

patients with a stoma had not engaged in any PA the previous week while approximately 75% were not meeting the PA guidelines (Beeken *et al.* 2019). Stoma surgery may be a deterrent to participation in PAET (Hubbard *et al.* 2016; Beeken *et al.* 2019). The putative mechanisms underpinning the beneficial effect of PAET in individuals with IBD are not well understood. Despite the anti-inflammatory effect of PAET that is associated with other CD (Pedersen and Saltin 2015), very few studies have investigated changes in inflammatory markers (Eckert *et al.* 2019) in IBD. Only four of the studies examining the effect of structured PA interventions as a complementary therapy for individuals with IBD analysed inflammatory biomarkers, with one study reporting a reduction in the circulating levels of c-reactive protein (Eckert *et al.* 2019). Despite TNFα being a prominent pathological marker in IBD, it was only assessed in one study, with no significant change reported.

**Benefits of CBEP**

Muscle strength and HRQoL were found to be significantly improved in individuals with CrD following 6 months of resistance training (Jones *et al.* 2020). A 12-week supervised walking programme (3 d/week) resulted in significant improvements in CRF and HRQoL among individuals with CrD (38 yr., 17% male) (Loudon *et al.* 1999). Similarly, CRF, percentage body fat and lean muscle mass increased significantly among 13 (33 yr., 69% male) individuals with IBD (UC and CrD) following their participation in an 8-week gym-based aerobic and resistance training programme (Cronin *et al.* 2019). Importantly, none of the participants in these studies experienced exacerbation of disease severity in response to exercise.

There appears to be a lack of data investigating the impact of CBEP following stoma formation surgery. Almost two-thirds of individuals have reported reduced levels of PA following stoma surgery (Beeken *et al.* 2019). Fear that the pouch may loosen/leak, or the presence of an unpleasant odour, are major barriers to PA in this patient cohort.

### 2.17 Multi-Disease, Community-Based Exercise Programmes

One of the key aims of the 'National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020-2025'(H.S.E. 2020a) is to move away from disease specific programmes. Due to the high commonality in programme design and delivery of CBEP for various CD cohorts, a MCEP could be a more resource-efficient strategy for providing exercise in the community for those with CD. MCEP would be undertaken in a community facility, providing common exercises designed to cater for several CDs (Desveaux *et al.* 2014). Ideally, they would be delivered by clinical exercise instructors qualified to prescribe exercise to people with CD.

The capacity to facilitate a wide range of CD while maximising resource utilisation is a major attraction of MCEP. Preliminary evidence suggests that MCEP could provide superior outcomes to standard care with respect to improving functional capacity and HRQoL (Desveaux *et al.* 2014). MCEP's could be used as an alternative to CBCR, provide follow-on maintenance programmes for those who attended PR and provide a sustained, structured community-based exercise opportunity for those with other CD (Desveaux *et al.* 2014).

## 2.18 PAET and MCEP

The feasibility of an eight-week group-based MCEP catering for 22 individuals with chronic respiratory or cardiac disease reported an 8% improvement in 6MWTD (McNamara *et al.* 2016). The MCEP was located in a local gym, supervised by physiotherapists, and focused on CRF. The patients were highly satisfied with exercising in a community setting. However, they raised concerns about continuing to exercise without supervision. Using a RCT (Sørensen *et al.* 2008), 52 individuals with medically controlled lifestyle CD were assigned to either a group-based exercise programme (43% male) or usual care advice (37% male). Both groups attended motivational counselling following randomisation. The exercise programme was delivered in a clinic under the supervision of physiotherapists and included multiple CD such as CVD, metabolic syndrome and T2DM. CRF and perceived physical fitness, as assessed through the SF-12 PCS, improved immediately following 4 months of participation in the exercise programme. CRF and perceived physical fitness remained 7% and 8% above baseline, respectively at the 6-month follow-up. The feasibility of HCPs running long-term MCEP is, however, not resource efficient.

Exercise referral schemes (ERS) are programmes designed to facilitate exercise prescription among individuals with ≥ 1CD. Primary care professionals, usually a GP, refer individuals with a CD to a qualified exercise professional. ERS are very common in the UK, Spain, and Denmark and, are similar in concept to the MCEP. A recent meta-analysis of the UK national referral database, that included 23,731 participants, reported significant improvements in BMI, SBP and HRQoL; improvements that were not, however, clinically

meaningful (Wade *et al.* 2020). Longer duration exercise referral programmes produce better health outcomes and higher adherence to PAET (Rowley *et al.* 2018). Another meta-analysis of eight RCT comparing ERS to usual care advice or alternative PAET found weak evidence that participation in the programme increased PA levels and reduced depression. Moreover, there was no consistent evidence for improvements in CRF, body composition and serum lipid levels (Pavey *et al.* 2011). These reviews of ERS highlights the importance of critically assessing 'real world' programmes to understand their effectiveness as opposed to clinical trials designed to assess outcomes of a relatively short-term intervention. Many of the ERS studies included in the meta-analysis only included patients with CVD risk factors (e.g., impaired glucose tolerance, obesity, or hypertension) and excluded individuals with a history of CD (Murphy *et al.* 2012; Webb *et al.* 2016).

**2.19 Adherence and Predictors to PAET**

The potential physiological and psychological benefits associated with attending any type of exercise programme are highly dependent on adherence (Murphy *et al.* 2012). Attendance, completion and dropout rates are the most common measures of adherence to exercise programmes (Hawley-Hague *et al.* 2016). Attendance is defined as the number of sessions attended, expressed as a whole number or as a percentage of the total number of sessions available. Completion is defined as completing an exercise programme and is often determined by attendance at post-testing. Dropouts refer to those individuals who failed to complete a programme. These are informative measures of adherence to fixed-term programmes but are more difficult to apply to long-term programmes where

completion of a post-test may not necessarily convey adherence. Attending (or not attending) at set time points may also be a useful measure.

**Adherence and predictors to CBCR**

Despite its importance, attendance is rarely reported in CBCR. The CBCR intervention evaluated by Zhang *et al.,* (2017) reported a 65% attendance rate over the course of a 6-month, fixed-duration exercise programme. In contrast, Mandic *et al.,* (2013) reported a 39% attendance rate in the previous 12 months among participants participating in a long-term CBCR programme. Adherence can also be defined based on a predetermined proportion of sessions attended, e.g., 65% (Noites *et al.* 2017; Vieira *et al.* 2018).

Completion rates in CBCR up to 6 months in duration have used attendance at a post-testing to assess adherence. Completion rates varied from 73 – 92% (Table 2.2). The number of participants in these studies was small and attendance, in many, was only required 1 day a week. Completion rates in maintenance CBCR is more difficult to assess due to the long-term nature of these programmes and the fact that many use a combination of centre and home-based approach for programme delivery. Continued attendance at a particular time point may be indicative of adherence to a CBCR. Squires *et al.,* (2008) monitored 503 individuals participating in a long-term disease management programme after completing a hospital-based CR programme. Only 6% of participants continued to exercise in a supervised phase IV CBCR programme for > 6 months(Squires *et al.* 2008). However, individuals were exercising 134 and 139 more min per week at one and three years respectively, after completing the hospital-based CR programme.

Medically supervised, phase IV CBCR programmes are well established in Germany (Dohnke *et al.* 2010), with exercise sessions 60 to 90 min in duration (Christle *et al.* 2018). Approximately one-third of patients continue to attend at 6 months and this number is reduced by a further 21% at 12 months (Dohnke *et al.* 2010). Dropout rates were examined in a long-term CBCR programme in which CAD patients were followed for over 3 years (Carmody *et al.* 1980). The largest dropout in attendance occurred within the first 3 months.

Bellg (2003) reported that 25 - 40% of CR patients were still exercising 6 months following completion of a hospital-based CR programme. Despite the fact that some individuals continue to exercise independently, the levels of PAET are still sub-optimal with a large proportion of individuals failing to meet the PA guidelines for health benefits (Squires *et al.* 2008). A greater effort is required to encourage PAET among individuals with CVD following completion of a hospital-based CR programme. Participants in both hospital-based and long-term maintenance CBCR are more likely to be male, retired between 60 and 70 years of age and, have a partner (Mandic *et al.* 2013; Mandic *et al.* 2015; Ruano-Ravina *et al.* 2016).

**Adherence and predictors to CBEP for OCD**

Attendance at CBEP for OCD has been found to vary between 70% and 94%. Attendance at a 12-month CBEP following completion of an inpatient PR programme was reported to be 70% (Beauchamp *et al.,* (2013). Among stroke patients, attendance to CBEP over a 19-week period was 81% (Pang *et al.* 2005). Attendance among individuals with T2DM participating in a 9-month CBEP was 80% (Mendes *et al.* 2016). Similar

attendance rates have been reported among OCD as outlined in table 2.2. In contrast, a supervised group walking programme for individuals with Crohn's disease reported only 37% attendance at supervised sessions. However, individuals were also allowed to exercise independently. As the majority of the CBEP for OCD have been fixed duration, the reported completion rates have been based on attendance at post-testing. Overall completion rates range from 64 to 100% with COPD having the lowest completion rate and stroke the highest (Amin *et al.* 2014; Moore *et al.* 2015).

Table 2.2 Attendance, completion, and dropout rates for exercise interventions for a range of CD

| Author, yr. country | Condition | Programme / Length | Attendance | Completion / Dropout |
|---|---|---|---|---|
| Seki *et al.,* 2008 Japan | CAD | CBCR / 24 weeks | Not stated | 90%/10%<br>20 went to 18 |
| Noites *et al.,* 2017, Portugal | MI | HBCR / 8 weeks | Only included > 65% attendance | 89% / 11%<br>18 went to 16 |
| Zhang *et al.,* 2017, China | CAD | CBCR / 24 weeks | 65.3% | 92% / 8%<br>62 went to 57 – 8% |
| Christle *et al.,* 2018 Germany | CAD and HTN | CBCR / 24 weeks | Not reported | 86% / 14% & 91% / 9%<br>Group programme 35 went to 30<br>Individual programme 35 went to 32 |
| Vieira *et al.,* 2018 Portugal | CAD | HBCR / 6 months | Only included >65% adherence | 73% / 27%<br>15 went to 11 |
| Mandic *et al.,* 2013 New Zealand | CAD | CBCR / 12months | 38.5% | 74% / 26%<br>46 went to 34 |
| | | | | |
| Moore *et al*., 2015 UK | Stroke | CBEP / 19 weeks | >90% | 100%<br>40 - No dropout |
| Pang *et al.,* 2005, Canada | Stroke | CBEP / 19 weeks | 81% | 94% / 6%<br>32 went to 30 |
| Amin *et al.,* 2014 US | COPD | CBEP / 12 weeks | 94% | 64% / 36%<br>14 went to 9 |
| Beauchamp *et al.,* 2013, Canada | COPD | CBEP / 12 months | 70% | 79% / 21%<br>29 to 23 (21%) |
| Galle *et al.,* 2019 Italy | T2DM | CBEP / 9 months | Not reported | 75% / 25%<br>92 went to 69 |
| Mendes *et al.,* 2016, Portugal | T2DM | CBEP / 9 months | 80%% | 72% / 28%<br>60 went to 43 |
| Loudon *et al.,* 1999, Canada | CrD | CBEP / 12 weeks | 37% | 75% / 25%<br>16 went to 12 |
| | | | | |
| McNamara *et al.,* 2016, Australia | Respiratory and CVD | MCEP / 8 weeks | 94% | 69% / 31%<br>32 went to 22 |

| | | | | |
|---|---|---|---|---|
| Murphy *et al.,* 2012 Wales | High BP / BMI >28, T2DM / CAD / /Mental health | ERS / 16 weeks | Not reported | 44% / 56%<br>1080 went to 473 |
| Sorensen *et al.,* 2008, Denmark | CVD, metabolic syndrome, T2DM | Clinic EP / 4 months | 75% | 68% / 32%<br>28 went to 19 |
| Webb *et al.,* 2016, UK | Sedentary / Prediabetes / Obesity / high BP | CBEP / 8 weeks<br>ERS / 8 weeks | CBEP – only included >70% attendance | 49% / 51%<br>CBEP – 65 went to 32<br>79% / 21%<br>ERS – 14 went to 11 |

Predictors to CBEP in OCD has been reported in a limited number of studies. A 12-month community-based stroke programme reported 60% attendance (Tiedemann *et al.,* 2012), while participation rates among 743 long-term patients with MS were reported to be 54% (Ploughman *et al.* 2015). Among both cohorts, physical health was a better predictor of attendance/participation than age, gender, and marital status (Tiedemann *et al.* 2012; Ploughman *et al.* 2015). Other predictors of PA levels among individuals with MS included less fatigue, fewer years since diagnosis and fewer comorbidities (Ploughman *et al.* 2015). Better HRQoL, balance and 6MWTD predicted daily step count in stroke survivors (Tiedemann *et al.* 2012). Non-smoker/ex-smokers, those with a partner and better psychological wellbeing were strong predictors of adherence to hospital-based PR (Fischer *et al.* 2009; Cassidy *et al.* 2014).

**Adherence to MCEP/ERS**

To date, relatively few studies have evaluated adherence and predictors of adherence to MCEP, as outlined in table 2.2. Attendance rates at an 8-week CBEP for patients with respiratory and cardiac disease was reported to be 94% (McNamara *et al.* 2016). A 4-month group-based exercise programme for a range of medically controlled lifestyle diseases reported a 75% attendance rate (Sørensen *et al.* 2008). Completion of each programme was 69% and 68%, respectively. Both exercise programmes were delivered by physiotherapists and may therefore not be truly reflective of a MCEP.

The majority of research examining the effects of exercise programmes for people with different CD have involved ERS. Participation in an ERS involves either an individual

gym programme and/or a group-based programme, with most programmes 10 - 16 weeks in duration. Completion rates range from 44% to 79% (Murphy *et al.* 2012; Webb *et al.* 2016). A systematic literature review of 10 adherence studies found the ERS completion rates ranged from 12-93% with a pooled average of 48% (Pavey *et al.* 2012), indicating that completion rates of ERS may be lower than disease-specific programmes. Adherence rates of 57% have been reported for ERS up to 6 months in duration (James *et al.* 2009). Similarly, Tobi *et al.,* (2012) reported 58% adherence at 13 weeks and 45% adherence at 20-26 weeks.

Dropout rates were examined in 1,725 Dutch seniors taking part in various organised exercise programmes (Stiggelbout *et al.* 2005). Dropout among seniors with CD attending aerobic and fitness classes was highest in the initial 8 - 16 weeks. However, 31% of individuals who dropped out of an exercise programme switched to an alternative programme. High attendance during the first 4 weeks of a MCEP has been found to be predictive of long-term attendance indicating that reducing dropout rates in the early stages could foster increased adherence (O'Leary 2019).

Women were found to be more likely to begin, but less likely to adhere (Pavey *et al.* 2012) to an ERS, whereas older people were more likely to begin and adhere to an ERS (James *et al.* 2009; Pavey *et al.* 2012). Individuals with pulmonary disease were found to be less likely than those with CAD to adhere to an ERS programme in the UK (James *et al.* 2009). In contrast, Tobi *et al.,* (2012) found that among 701 individuals with CD who were participating in an ERS programme, those with CVD or orthopaedic conditions had lower odds of adhering than those with metabolic conditions.

## 2.20 Patient Perspective

Although engaging the patient's perspective has become an important aspect in the design, delivery, and evaluation of health interventions (Bombard *et al.* 2018), to date, relatively few studies have explored the factors that motivate patients with CD to engage in a MCEP. Some studies have focused on the motivators for adherence to maintenance CBCR programmes (Thow *et al.* 2008; Martin and Woods 2012; Dunn *et al.* 2014; Hardcastle *et al.* 2015). Among CR patients attending a phase IV CR programme for > 5 years, the key drivers of exercise engagement were ill health avoidance and the desire for good health, along with social support and enjoyment with other participants (Thow *et al.* 2008). Patients could identify the benefits of being active in terms of their ADL.

Similarly, individuals with CAD attending phase IV CBCR for ≥12 months identified social support of other participants, family, friends, exercise staff and health professionals along with the perceived health benefits from taking part as the primary factors influencing uptake and adherence (Martin and Woods 2012). A referral pathway and support were identified as being important for successful transition to a CBCR. Variety in relation to exercise prescription and regular assessments to reinforce the benefits of maintaining exercise had a positive effect on both short term and long-term adherence (Martin and Woods 2012).

Avoidance of ill health, social support and the provision of routine were identified as important factors influencing exercise adherence among participants who were attending a phase IV CBCR circuit training class in a local leisure centre for ≥ 2 years (Hardcastle *et al.* 2015). Being physically active was also associated with the ability to

travel and spend time with family, as well as overcoming some of the deleterious effects of aging, thereby helping to remain independent, not become a burden on their family, and reducing isolation. The group nature of the programme appeared to foster adherence.

Dunn *et al*., (2014) examined factors affecting long-term attendance to CBCR in New Zealand and the UK. Key internal drivers to maintaining exercise were enjoyment, the desire/motivation to change and the ability to do so. The strongest positive influences in both New Zealand and the UK were the social support from the professionals, family, friends, and those they exercised alongside along with the education received through the programme. A safe, non-intimidating and welcoming environment was also identified as being an important factor in promoting adherence to CBCR. Key barriers to participation were health conditions, time constraints (family/work), weather and available exercise options.

Perceived physical and psychological benefits are also important facilitators of long-term adherence to CBCR. High attenders, classified as attending a CBCR programme >12 months, identified perceived psychological (sense of accomplishment and improved mood), social (companionship), physiological (improvements in components of HRPF) and functional benefits (ability to perform ADL) as important determinants (Horwood *et al*., (2015). Key barriers included other health problems, weather, travel, and family responsibilities.

The previous studies involved participants who were attending CBCR for 12 months (Martin and Woods 2012; Dunn *et al.* 2014; Horwood *et al.* 2015) to >24 months

(Thow *et al.* 2008; Hardcastle *et al.* 2015) and were in true "maintenance" stage of change in terms of their exercise behaviour. There is value in understanding the motivations particularly in the early transition to CBCR when the dropout rate is highest (Carmody *et al.* 1980; Yohannes *et al.* 2007).

Maintenance programmes are less common for other CD compared to CVD. Individuals with chronic MSK conditions who attended a focus group on completion of a 12-week group Pilates exercise programme identified perceived physical and psychological benefits that improved their day-to-day-living as important determinants for attendance (Gaskell and Williams 2019). However, all participants agreed that the primary motivator was the fact that the structured, supervised exercise classes became part of their weekly schedule. They admitted that they would be unlikely to set dedicated time aside to exercise independently. Flexible class schedule was also important to facilitate work and family commitments.

An exploratory study was conducted into the factors that would motivate long-term stroke survivors to exercise regularly (Poltawski *et al.* 2015). Ongoing support through structured exercise opportunities was reported as a key driver to maintain exercise. While most favoured group exercise due to the social support it provided, there was evidence that some preferred one-to-one exercise guidance, highlighting the fact that group exercise may not be for everyone. There were mixed opinions regarding the composition of group exercise classes. Some expressed a preference for exercise in a stroke-specific group, while others preferred to be integrated in mainstream facilities.

However, all participants preferred exercise sessions to be located away from the health care setting to de-medicalise exercise.

Similar beliefs regarding exercise maintenance were expressed by a group of 15 individuals living with chronic pain, who reported a preference for a group-based CBEP (Dnes *et al.* 2021). They expressed the importance that these CBEP needed to be accessible, delivered by an instructor who is knowledgeable about chronic pain and tailored to their ability. There was a preference to exercise alongside individuals of similar capabilities.

McNamara *et al.,* (2016) examined the feasibility of an 8-week MCEP that provided supervised, structured exercise to individuals with chronic respiratory or cardiac disease. The exercise sessions were conducted during the day alongside other gym members with groups of up to 10 exercising at one time. Patients were highly satisfied with the exercise environment and found the venue convenient and accessible. They expressed how the community setting promoted a sense of 'normality' within the rehabilitation experience and allowed them to view exercise as a normal behaviour as opposed to a treatment for their condition. However, the programme was supervised by two physiotherapists and participants did express concern at continuing the exercise without supervision. Also, motivation to continue exercising independently and the cost of gym membership were seen as potential barriers to exercise maintenance.

A mixed methods study was used to explore patient perception of participating in a maintenance CBEP following completion of a hospital-based CR programme (Clark *et al.* 2011). A total of 81 (65 yr., 67% male) patients responded to the survey with 27 attending

one of four focus groups. The survey indicated that 95% of respondents agreed that continuing to exercise following completion of a hospital-based CR programme was important or very important. Although nearly 90% of respondents were motivated to progress to a CBEP, only 57% were participating at the time of the survey, with 35% no longer attending and 8% never having attended any class following CR. Many participants expressed strong beliefs that a CBEP had the potential for long term/continual service provision to support the habituation of exercise and maintenance of associated health benefits. Aspects that came across as important were the need for a suitably qualified instructor to prescribe exercise for their condition, the involvement of HCP in the transition into the community setting and, the sense of camaraderie when exercising. Suggestions to improve the transition included better links between the CBEP and the hospital staff/CR programme.

A recent Irish study focused on identifying barriers, facilitators and needs of patients with CD (CAD, PD, cancer and cognitive) in transitioning from hospital-based rehabilitation programmes to MCEP (Sheill *et al.* 2022). The opinions of 11 patients who had just finished a hospital-based exercise programme and 10 fitness instructors from community-based gyms were collected. Both patients and instructors welcomed the model of transitioning from structured rehabilitation programmes to exercise facilities in the community. Despite participation in a supervised hospital exercise programme designed to educate and increase their ability to exercise independently, most still felt they needed access to structured and supportive exercise opportunities in the community. Key barriers that emerged were a feeling of intimidation in the gym

environment, limitations to exercise due to the nature of the CD, instructors' knowledge of exercise prescription for CD, and lack of supervision while exercising. A number of facilitators were identified or suggested to improve the transition and adherence to MCEP such as improving the referral and induction process, strengthening the link between the hospital and exercise provider and the provision of training for instructors in exercise prescription for CD, and exercise programmes specifically for individuals with CD.

Although MCEP's are now recommended as part of the management and treatment of individuals with CD, it is important that they are effective in maintaining or improving the physical and mental health of participants with varying levels of functional capacity. Poor uptake of exercise referral schemes (Pavey *et al.* 2012) and dropout incidence among CR participants or seniors attending aerobic and fitness classes is highest within the initial 12 weeks (Carmody *et al.* 1980; Stiggelbout *et al.* 2005). Understanding the patient perspective of their experience attending a MCEP may assist in optimising the rates of enrolment, adherence, and benefits of a MCEP.

# Chapter III

## Study I

## Health and Fitness Characteristics among Individuals Referred to a Multi-Disease, Community-Based Exercise Programme, and their Impact on Adherence

### 3.1 Introduction

Life expectancy in the developed world has increased by an average of 13% over the past half-century (World Bank 2022) due in part to a reduction in some health risk behaviours such as smoking and, improvements in the uptake of medical interventions (Kabir *et al.* 2013; Marshall *et al.* 2016). Ireland is above the EU-28 average in life expectancy with an estimated age of 80.8 and 84.7 years for men and women, respectively (D.O.H. 2021a). As a result of the increased life expectancy, many older individuals in the industrialised world are now living with increased levels of age-associated CD (Abd-Allah *et al.* 2017; Dibben *et al.* 2021) such as CVD, cancer, chronic respiratory diseases, T2DM and arthritis (Booth *et al.* 2012). In Ireland, the number of individuals >50 years of age living with ≥ 1 CD is estimated to increase by 40% by 2030 (H.S.E. 2020b). Currently, CD accounts for 40% of hospital admissions, 75% of bed days, 55% of hospital expenditure, 80% of GP consultations and 76% of deaths each year (H.S.E. 2021b).

Effective strategies to support self-management have been identified by the Irish HSE as critical to tackling the increasing burden of CD (H.S.E. 2020a) and is in line with the 26$^{th}$ annual UN climate change conference (COP26) where they believe healthier populations create healthier sustainable worlds. One of the key sustainable development

goals of COP26 is to support good health and promote wellbeing across the ages with management of non-communicable diseases at the forefront (Mavrodaris *et al.* 2022). Sláintecare is a ten-year cross-government programme with the primary goal of transforming Irish health and social care services (House of the Oireachtas 2017). One of the key deliverables of the Sláintecare Implementation Plan (2021b) is the establishment of CDM hubs and, a GP-structured CDM programme with the aim of reducing the national burden of CD.

PAET has been shown to play a key role in the treatment of many CD (Pedersen and Saltin 2015) and, is strongly recommended as an important component in the model of care for integrated prevention and management of CD (H.S.E. 2020a). Currently, short-term, fixed-duration medically supervised, hospital-based exercise rehabilitation programmes are available for patients with CVD and pulmonary disease. Patients are advised to continue exercising following completion of their hospital-based programme. However, with the exception of a few government-funded agencies, voluntary bodies and support groups, access to follow-on maintenance exercise programmes for CVD and pulmonary disease patients are scarce. Likewise, structured exercise opportunities for other CD populations are also limited. Advice from HCPs regarding modality, intensity, and duration of PAET along with information leaflets and directions to websites may, however, sometimes be provided to these patients (McKeon 2021).

The new model of care for integrated prevention and management of CD (H.S.E. 2020a) envisages relocating the current hospital-based CR and PR programmes to the CDM hubs (H.S.E. 2020a). It is likely, however, that low-risk CD patients will not require

medical supervision in a CDM hub and, that step-down programmes will also be required for those exiting medically supervised CR and PR programmes. Providing exercise opportunities in a community-based setting for low- to moderate-risk patients has been found to improve many health and well-being outcomes across a number of CD (Rowley *et al.* 2018). Augmenting the capacity to refer low-risk patients diagnosed with CD and/or patients who have completed CR or PR to appropriate community-based, structured programmes has the potential to greatly enhance service delivery to individuals with CD.

The majority of exercise programmes for people with CD target common components of health-related fitness using primarily aerobic and resistance training (Pedersen and Saltin 2015), supporting the potential to develop a MCEP (Desveaux *et al.* 2014). Third-level institutions are geographically dispersed, provide excellent facilities and, have qualified staff who deliver courses in exercise science, physiotherapy, and athletic training. These institutions could offer MCEPs for individuals with CD who do not require medical supervision and, as a follow-on maintenance phase to structured hospital-based CR and PR.

Typical CR in Ireland involves in-hospital education (phase I), early outpatient/convalescence focusing on reducing relevant risk factors (phase II), and a gradual increase in outpatient supervised PA (phase III) with continuation of risk-factor modifications (Irish Heart Foundation 2018). The goal of the final phase (phase IV) is for long-term maintenance of the healthy lifestyle adopted during the previous weeks/months including the transitioning to exercising independently and/or participating in a CBCR programme. At present, CR is the most established hospital-based

CD programme in terms of infrastructure and service delivery (Mampuya 2012) with the largest intake and attendance.

Participation in CR phase III reduces premature mortality and CVD events and improves functional capacity, psychosocial outcomes and HRQoL across a range of cardiovascular conditions (Dalal *et al.* 2015; Dibben *et al.* 2021). It is likely that patients who have completed phase III CR will have a higher baseline functional capacity and better overall health than other CD patients who may not have access to a structured exercise programme prior to beginning a MCEP. When undertaking an exercise intervention, such as a MCEP, reporting the baseline characteristics (Reach in the RE-AIM framework) is valuable in describing detail regarding who actually gets referred by their HCP and the representativeness of individuals who are willing to participate in a MCEP (Gaglio *et al.* 2013). As participants are entering the MCEP with different preparticipation exercise experience understanding the demographics, functional capacity, and medical status of the disparate patient cohort referred to a MCEP is important from a safety perspective and, to facilitate programme design in order to maximise efficacy.

The potential health benefits associated with any PAET programme are highly dependent on adherence (Murphy *et al.* 2012). Despite large variability, adherence, measured as completion of a hospital-based disease specific programme such as CR and PR, is quite good, with average adherence rates reported to be >67% (Fischer *et al.* 2009; Cassidy *et al.* 2014; Ruano-Ravina *et al.* 2016). The GP exercise referral scheme (ERS) in the UK. involves referring men and women living with a CD to a 10 - 12 week PAET programme supervised by a qualified exercise professional (Tobi *et al.* 2012) and, is a

similar concept to MCEP. Adherence to an ERS, defined as completing a minimum number of exercise sessions or completion of a post-training consultation, ranges from 12 - 93%, with a lower average adherence rate (48%) compared to the disease-specific programmes (Pavey *et al.* 2012).

Attendance during the first 4 weeks has been found to predict long term adherence at an MCEP (O'Leary 2019). Dropout incidence among seniors attending exercise classes for specific CD is highest during the initial 8-16 weeks (Carmody *et al.* 1980; Stiggelbout *et al.* 2005). Data are more limited regarding adherence to long-term maintenance of lifestyle behaviours following completion of hospital-based CR programmes. One report indicated that only 25 - 40% of participants were still exercising 6-months following discharge hospital-based CR programmes (Bellg 2003). Furthermore, PA levels were reported to drop by 43% at 12 months following completion of an ERS (Martín-Borràs *et al.* 2018).

Common baseline characteristics have been associated with higher adherence rates in disease-specific exercise programmes (Fischer *et al.* 2009; Mandic *et al.* 2013; Cassidy *et al.* 2014; Mandic *et al.* 2015; Ruano-Ravina *et al.* 2016). In contrast, there is greater variability in the predictors of adherence to MCEPs (Pavey *et al.* 2012). In order to develop effective strategies to increase efficacy of MCEPs, it is important to identify and understand individual and demographic factors associated with adherence and risk of dropout.

A joint venture between ATU Sligo and SUH, resulted in the establishment of a MCEP in the north-west of Ireland. Approximately 50% of referred patients had a primary

diagnosis of CAD and had completed a phase III hospital-based CR programme. The remaining patients were referred by HCPs and included other CD (OCD) such as stroke, MS, MSK, bowel disease and T2DM. Some OCD patients may have been provided with an appropriate care management plan that may have included exercise advice. The purpose of this study was to describe and compare baseline characteristics of participants with CAD and OCD referred to a MCEP and to assess their impact on adherence.

## 3.2 Aims and Hypotheses

### 3.2.1 Aims

- To describe and compare socioeconomic and health-based demographic characteristics, health indices, functional capacity and HRQoL in individuals with CAD and OCD referred to a MCEP
- To describe and compare the socioeconomic and health-based demographic characteristics, health indices, functional capacity and HRQoL in the various OCD
- To describe and compare the adherence rates (initiation, attendance, early dropout) in participants with CAD and OCD referred to a MCEP
- To investigate the predictors of adherence to a MCEP and to compare differences between CAD and OCD

### 3.2.2 Null Hypotheses

- There will be no difference in the socioeconomic and health-based demographic characteristics, health indices, functional capacity and HRQoL between individuals with CAD and OCD who are referred to a MCEP

- There will be no difference in the socioeconomic and health-based demographic characteristics, health indices, functional capacity and HRQoL between the individual OCD's referred to a MCEP

- There will be no difference in adherence rates between individuals with CAD and OCD referred to a MCEP

- There will be no difference in predictors of short-term exercise adherence to a MCEP between individuals with CAD and OCD.

## 3.3 Methodology

### 3.3.1 PhD Overview

A non-randomised study design was used to examine the adherence (Study I, Chapter III) and efficacy (Study II, Chapter IV) of a MCEP in men and women with CAD and OCD. Participants in the intervention group attended the supervised MCEP twice a week in ATU Sligo and undertook a series of tests at baseline and, after completing 10 weeks of the MCEP. A control group, comprised of CAD participants (CAD-CG), were also tested at baseline and 10 weeks. Patient perspective of attending the MCEP was explored in individuals with CAD (Study III, Chapter V).

### 3.3.2 Research Setting

The research studies in this PhD thesis were undertaken at ATU Sligo, in the north-west of Ireland. The MCEP was designed by an interdisciplinary team of professionals from the Department of Health and Nutritional Sciences, ATU Sligo, the School of Health and Human Performance, Dublin City University (DCU), along with clinical exercise professionals and physiotherapists from SUH. The exercise programme adhered to the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) guidelines. HCPs from SUH provided medical oversight of the programme. The MCEP was coordinated by exercise scientists and delivered by certified BACPR clinical exercise instructors. The exercise instructor - participant ratio was 1:15. The number attending each class ranged from 20-35 participants.

### 3.3.3 Study One Design

A cross-sectional design was used to compare baseline socioeconomic and health-based demographic characteristics, health indices, functional capacity and HRQoL between participants in the CAD intervention group (CAD, n=96), CAD control group (CAD-CG, n=22) and OCD intervention group (OCD, n=98), as outlined in table 3.1. The same outcome variables were also compared between the different conditions in the OCD group at baseline. A prospective analysis was used to compare the rates and predictors of adherence in CAD and OCD patients who attended the MCEP (Figure 3.1).

Table 3.1 Outcome measures at baseline

| Socioeconomic Demographics | Health-Based Demographics | Health Indices | Functional Capacity | Health-Related Quality of Life |
|---|---|---|---|---|
| Marital status | Age | SBP | 6MWT | WEMWBS |
| Distance to MCEP | Gender | DBP | Sit to Stand | SF-12 (MCS/PCS) |
| Education level | Primary CD | Heart rate | Handgrip (D/ND) | |
| Principle status | Main diagnosis | Height | Sit and reach | |
| Occupation | Comorbidities | Weight | | |
| | Medications | BMI | | |
| | | Waist | | |
| | | Hip | | |
| | | WHR | | |

MCEP = multi-disease, community-based exercise programme, CD = chronic disease, SBP = systolic blood pressure, DBP = diastolic blood pressure, BMI = body mass index, WHR = waist-to-hip ratio, 6MWT = 6-minute walk test, D = dominant, ND = non-dominant, WEMWBS = Warwick Edinburgh mental well-being scale, ST-12 = 12-item short form survey, MCS = mental component score, PCS = physical component score

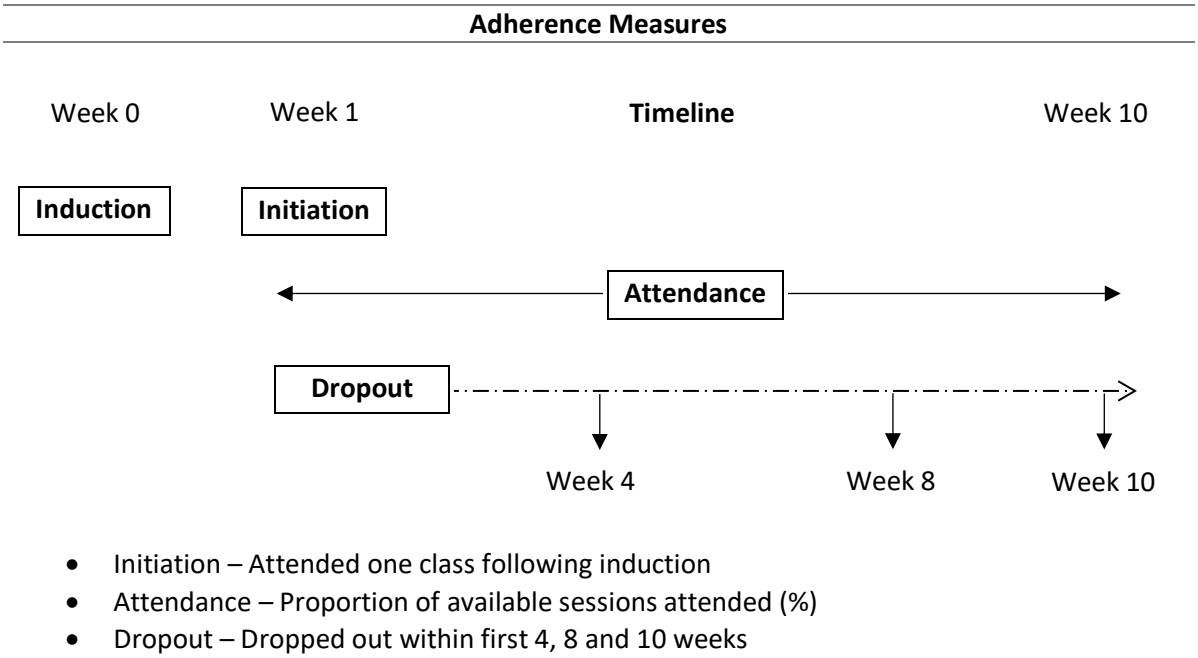



Figure 3.1 Overview of adherence measures and timeline

### 3.3.4 Study Participants

Patients with CAD were referred by a cardiologist following completion of a hospital-based phase III CR. The OCD patients were referred by a physiotherapist/nurse working with stroke support groups, MS therapy centres, physiotherapy services or by a GP. The most prevalent medical conditions in the OCD group were stroke, neurological (MS/PD), MSK (OA/RA), IBD (CrD/UC), and T2DM. A control group consisted of individuals with CAD who had also completed phase III CR but were unable attend the MCEP. The primary reasons cited for not being able to attend were distance to the exercise facility and lack of time.

The inclusion criteria for both CAD and OCD were:

- ≥30 years of age

- Presence of an established CD
- Classified as category B in the National Exercise Referral Framework (NERF) guidelines (does not require the presence of a physician or other appropriately trained healthcare professional to undertake a supervised exercise programme) (Appendix A)
- Referred by a HCP
- Able to safely participate in the MCEP

In addition, CAD participants were required to meet the following inclusion criteria:

- Have completed phase III CR
- Low risk (BACPR 2016)
- Six-months post-event and/or surgery

The exclusion criteria were:

- Presence of any absolute contraindication to exercise (Liguori *et al.* 2021)
- Classified as category A under the NERF guidelines.

### 3.3.5 Recruitment

Following referral to the MCEP, participants were invited to an induction session where the purpose, design and experimental procedures of the research study were explained. They were provided with a plain language participant information leaflet (Appendix B) and given the opportunity to ask questions. Participants were required to provide written informed consent (Appendix B) prior to participation. CAD-CG were provided with a plain language information leaflet specific to their cohort and were also

asked for informed consent (Appendix C). Ethical approval was obtained from SUH Research Ethics Committee (No. 579). Recruitment took place three times a year between May 2016 and May 2019 and, involved 15-25 individuals per induction session.

### 3.3.6 Induction

The induction session took place during the first visit to ATU Sligo. During induction, participants completed baseline outcome measures (described in detail in section 3.3.8/3.3.9), were provided with information on the purpose and content of the exercise programme and taken through logistics, such as suitable attire, car parking and class times.

### 3.3.7 MCEP Intervention

With the exception of a 4-week Christmas and summer break, the MCEP was delivered throughout the entire year at an exercise facility located on the ATU Sligo campus. Participants signed up for a 10-week block with the option to continue. They were encouraged to attend two sessions each week. For the most part, participants attended the same scheduled exercise sessions each week in order to develop social bonds, encourage habit formation and maintain the exercise instructor to participant ratio. The MCEP was a user-pay model where participants paid per class or on a monthly basis.

Prior to each exercise class, participants had their BP and HR measured and recorded. A SBP < 180 and > 90 mmHg and a DBP < 100 and > 60 mmHg was required to participate in an exercise class (BACPR 2016). Each participant was required to sign in and

confirm that they had taken all their prescribed medications and, were not experiencing any signs or symptoms such as chest pain, swelling in the legs, unusual breathlessness and/or taking their GTN spray.

Each exercise class was approximately 60 min in duration and commenced with a 15 min warm-up (BACPR 2016). This was followed by a combination of aerobic and resistance exercises in a circuit format with frequent water breaks incorporated. Aerobic exercise activities included stationary cycling, elliptical cross-training, rowing, treadmill walking, running and dance. Table 3.2 summaries a variety of class structures depending on location and type of exercise included that day. Classes catered for all abilities and participants were encouraged to work at a 'moderate' intensity, 11-14 on the 6–20-point Borg RPE scale. In accordance with the BACPR recommendations, each session concluded with a 10-min cool-down period (BACPR 2016).

Table 3.2 Examples of typical exercise class structures delivered during the MCEP

| | **Main Hall Option 1** | **Main Hall Option 2** | **Gym** |
|---|---|---|---|
| Warm-up | 15min aerobic and mobilising exercises which built up gradually in intensity with preparatory stretches (~10sec hold) | | |
| Main Phase | **Aerobic**: 10-15*min continuous dance phase (instructor led)<br>**Resistance**: 10-15min circuit-based exercises using free weight or body resistance exercises (60:20-30sec work-rest ratio) | **Aerobic**: 5-8min continuous stationary bike<br>**Resistance**: 5-8min instructor led kettle bell or resistance band exercises (60:20-30sec work-rest ratio)<br>**Combination**: 10-15min mixed circuit of free weight/body resistance and aerobic stations (60:20-30sec work-rest ratio) | **Aerobic**: 5-8min*2 continuous on two pieces of aerobic gym equipment (treadmill, stationary bike, rower, or cross trainer)<br>**Resistance**: 10-15min instructor led kettle bell or resistance band exercises (60:20-30sec work-rest ratio) |
| Cool-down | 10min low intensity aerobics, mobility and stretching (~20sec hold) | | |

Note: min = minutes, sec = seconds, *range indicates the progression

Immediately following each class, refreshments were served as part of the social aspect of the programme. During each 10-week block, two educational talks were delivered by a healthcare or exercise professional. The topics covered included 'healthy lifestyle' delivered by a cardiac nurse, 'importance of medications' delivered by a pharmacist, 'healthy eating delivered by a nutritionist' and 'increasing PA levels' delivered by an exercise professional.

### 3.3.8 Outcome Measures

Indices of health, functional capacity and HRQoL were assessed at induction. The baseline assessments were conducted as part of an induction session to the programme

for CAD and OCD. Participants in CAD-CG were invited to the ATU-Sligo campus to complete the baseline assessments. The health indices measured were resting BP, RHR, height, weight, BMI, waist and hip circumferences, and waist-to-hip ratio (WHR). CRF, flexibility, and upper and lower body strength were measured to assess functional capacity. HRQoL was determined using two validated questionnaires.

#### 3.3.8.1 Demographics

During the induction sessions participants completed an induction questionnaire (Appendix D) to obtain information regarding age, gender, residential location, marital status, highest level of education obtained, current employment status and current (past) occupation.

#### 3.3.8.2 Medical History

Participant's primary CD, other comorbidities and relevant medications were recorded from the referral form (Appendix E), completed by the HCP prior to participants commencing the programme. Participants also had the opportunity to disclose any other CD on the induction questionnaire.

### 3.3.9 Health Indices, Functional Capacity and HRQoL Measurements

Detailed standard operating procedures for all health indices and functional capacity measurements are outlined in Appendix F.

### 3.3.9.1 Health Indices

**Resting Blood Pressure and Heart Rate**

Resting BP and HR were measured using an automated sphygmomanometer (ri-champion ®N, Riester, Germany) following a 10 min rest period. Participants sat in an upright position with their feet flat on the floor and their back placed against the chair. An appropriately sized cuff was placed on bare skin, approx. 2.0 cm above the crease of their elbow. BP was measured with the arm positioned slightly above the level of the heart.

**Anthropometrics**

Footwear and heavy clothing/keys/mobile phone were removed prior to measurements. Height was measured to the nearest 0.1 cm using a stadiometer (The Leicester Height Measure, Child Growth Foundation, UK). Weight was measured to the nearest 0.1 kg using an electronic scale (Seca Digital Weight Scales, Model 875, Seca Gmbh & Co., Germany). BMI was calculated using the formula: weight (kg)/height$^2$ (m$^2$).

Waist and hip circumference measurements were taken to the nearest 0.1 cm by a trained researcher using a measuring tape (SECA 201, Seca Gmbh & Co., Germany). Participants removed any bulky clothing and were instructed to stand with their feet together with their arms by their side. The measurements were taken at the end of a normal expiration. The waist circumference was measured at the midpoint between the last palpable rib and the top of the iliac crest. The hip circumference was measured as the widest portion around the buttocks. Both waist and hip circumference measurements

were taken twice. If the difference exceeded 1.0 cm, the measurement was repeated. The average value was used for analysis. WHR was calculated by dividing waist circumference (cm) by hip circumference (cm).

#### 3.3.9.2 Functional Capacity

**Cardiorespiratory Fitness**

Cardiorespiratory fitness was estimated using the 6MWT in accordance with American Thoracic Society (ATS) (2002) guidelines. No warm-up was permitted, and one experienced tester was assigned to each participant. Participants were instructed to cover as much ground as possible in 6 min while walking as fast as possible between two cones placed 20 m apart on a flat, straight, indoor course. Standard verbal encouragement was provided every min and, a 15-sec warning was given prior to the end point. On completion of the test, participants were instructed to stop. The total distance covered was calculated to the nearest metre by adding any extra distance covered in the last lap to the total number of completed laps.

**Isometric Handgrip Strength**

Isometric HGS of both hands was measured to the nearest 0.1 kg using a handgrip dynamometer (TKK 5001 Grip-A, Takei Scientific Ins., Japan). The test was performed in a standing position with the testing arm held tight against the trunk and the forearm at a 90° angle. The handheld dynamometer was adjusted to ensure the participant could rest the middle of four fingers on the handle. With their elbow bent at an angle of 90°, participants squeezed the handheld dynamometer as hard as possible for approximately

3.0 sec. This was repeated three times on both hands. The highest score (kg) was recorded for the dominant (GripD) and non-dominant (GripND) hand. (Roberts *et al.* 2011; Segura-Ortí and Martínez-Olmos 2011; Steiber 2016).

**Sit-to-Stand Test**

Lower body muscle strength was assessed by measuring the time taken to stand up and sit down ten times from a seat height of 47.0 cm (Segura-Ortí and Martínez-Olmos 2011). Participants sat on the chair with their feet shoulder width apart, arms crossed, and hands placed on opposite shoulder and, their lower back touching the back of the chair. Participants were instructed to stand up and sit down 10 times as fast as possible, starting and finishing at the sitting position. They were instructed to stand tall and ensure that their lower back touched the back of the chair each time they sat down. The time taken to complete the 10 repetitions was recorded using a stopwatch to the nearest 0.1 sec. Each participant completed the test twice with a 2-min break between each test. The best score was recorded.

**Flexibility**

The sit and reach (S&R) test (Eveque, UK) was used to measure flexibility with the S&R box toe line at 15 cm (Riebe *et al.* 2018). With their shoes removed, participants sat on the floor with, their legs straight, feet placed flat against the S&R box and their arms fully extended. They were instructed to place one hand on top of the other and to reach forward in a slow controlled movement and hold the stretch for a minimum of 2 sec. The distance reached on the box was recorded to the nearest cm. In the event that box could

not be reached, a ruler was used to record a minus score. Participants completed three attempts, with a 20 - 30 sec interval between each trial. The best attempt was recorded.

**3.3.9.3 Health-Related Quality of Life**

The 12-item Short Form (SF-12v2) Health Survey (QualityMetric, Lincoln, RI, USA) is a multidimensional health assessment tool that measures functional health and wellbeing from the patient's perspective (Ware *et al.* 2010). It consists of 12 items grouped into seven questions (Appendix G), with predefined answers that can be combined into eight domains of health: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health (Linde *et al.* 2009). Each health domain score contributes to a physical component score (PCS) and a mental component score (MCS). Both PCS and MCS are composite measures of physical and mental health, each with four separate domains (Ware *et al.* 2010). Scores range from 0 (poor health) to 100 (perfect health). Participants responded to a series of questions by selecting a box that best described their answer. Responses were dependent on the question asked such as *"In general would you say your health is"* with responses ranging from "Excellent" to "Poor" and, *"How much of the time in the past 4 weeks did you have a lot of energy"* with responses there ranging from "All of the time" to "*None of the time*".

The Warwick Edinburgh Mental Well-Being Scale (WEMWBS) (Appendix H) is comprised of a number of statements that assess an individual's state of wellbeing (thoughts and feelings) during the previous two weeks. The questionnaire assesses subjective experience of happiness and life satisfaction, psychological functioning,

relationships with others and self-realisation (Stewart-Brown and Janmohamed 2008). Participants indicated their response on a 5-level Likert scale ranging from "None of the time" to "All of the time" to statements such as *"I've been feeling useful"* or *"I've been feeling close to other people"*.

Both questionnaires were paper-based and self-administered. All questionnaires were checked, and if incomplete, participants were encouraged to respond to any unanswered questions.

### 3.3.10 Adherence Rates

Adherence to the programme was determined by calculating initiation, attendance, and dropout rates. Initiation was defined as attending at least one exercise class following induction to the programme. Attendance was operationally defined as the number of actual sessions attended divided by the expected number and was expressed as a percentage (%). Early dropout included participants who attended at least one exercise class but stopped attending during the first 4, 8 and 10 weeks.

### 3.3.11 Data Analysis

All data analysis was conducted using IBM SPSS statistics software (ver. 26). Data cleaning was conducted by checking each variable for outliers, using boxplots. Outliers identified were initially checked against the original data in the files collected as a possible source of error. Then any outstanding outliers were discussed to determine if this reflected a natural value/change in the target population. Data was checked for normal distribution using the Shapiro-Wilks test of normality with $p > 0.05$ indicating normally

distributed data. Homogeneity of Variance was assessed by Levene's Test for Equality of Variances.

**Analysis of Baseline Data**

Two statistical approaches were conducted to compare baseline demographics, health indices, functional capacity and HRQoL between individuals with CAD and OCD referred to a MCEP.

**Approach One**: If data was normally distributed and variances were equal, then a one-way analysis of variance (ANOVA) was conducted to compare baseline data on all continuous variables between CAD, OCD and CAD-CG (see table 3.3 and table 3.5). If data was normally distributed but the variances were unequal, then a one-way Welch ANOVA was conducted. If data was not normally distributed, the skewness was checked. If the data was deemed to be fairly symmetrical (-0.5 to 0.5) or moderately skewed (-0.5 to -1.0 or 0.5 to 1.0), an ANOVA was still appropriate as ANOVAs can handle moderate violations of normality (Laerd-Statistics 2017). If significance was found between the three groups, a Bonferroni or Games-Howell post hoc analysis test was carried out depending on whether the variances were equal or unequal. If data was highly skewed (>-1.0 or >1.0), a Kruskal Wallis H test was conducted as it decreases the risk of Type I error (incorrectly rejecting a null hypothesis – false positive).

Chi-square analysis was used to explore the difference in the proportion of participant demographic variables that were categorical between CAD, OCD and CAD-CG groups (see table 3.3 and table 3.4). A post hoc test using a generalized linear model

(GLM) with a logit link function was used to identify specific group differences for dichotomous dependent variables (e.g., gender). A multinomial logistic regression with a logit link function was used to examine the difference between multiple dependent variables (e.g., education) using the Bonferroni correction for α. Fishers exact test was used where cell count was violated (n<5). All data was expressed as mean ± standard deviation (SD) or frequencies, with percentages calculated where appropriate.

A comparison of baseline data between the OCD groups was also conducted (see table 3.6). Preliminary analysis showed significant ($p \leq 0.05$) deviations from normal distribution and data was highly skewed, which was not surprising as numbers in the groups were below 30. Therefore, a Kruskal-Wallis H test was conducted to determine if there was a difference in any of the continuous baseline measures on entry into the exercise programme between the groups that comprised the OCD, i.e., stroke, neurological, musculoskeletal, inflammatory bowel disease and T2DM. The Kruskal Wallis H test is less likely to result in a type 1 error. All data was expressed as median.

**Approach Two:** Preliminary analysis identified a high degree of correlation (univariate collinearity) between the health indices, functional capacities, and HRQoL measures using a Pearson's correlation coefficient matrix. Variation inflation factor (VIF) was then examined on all continuous baseline outcome variables. Due to a high degree of multicollinearity in at least three of the baseline outcomes (primarily body composition scores), a principal component analysis (PCA) was conducted to reduce the risk of committing a type 1 error.

The PCA was performed on the 16 baseline measurements outlined under health indices, functional capacity, and HRQoL (see table 3.1). The suitability of PCA was assessed prior to analysis. Inspection of the correlation matrix was examined and only variables that had at least one correlation coefficient greater than 0.3 were retained [RHR and S&R were removed]. The Kaiser-Meyer-Olkin (KMO) measure for individual variables was retained only if ≥ 0.5 [WHR was removed]. The PCA was therefore repeated on the remaining 13 baseline measurements with the overall KMO measure 0.694. Bartletts test of sphericity was statistically significant ($p < 0.005$), indicating that the data was likely factorizable. To ensure factors derived from the PCA were orthogonal, varimax rotation was used. When deciding how many factors to retain, the following guidelines were applied (Laerd-Statistics 2015): minimum eigenvalue was set as 1, the percentage of variance explained was 8% or higher and simple structure was obtained in the rotated component matrix (see table 3.7).

A one-way ANOVA was repeated on the new components to compare baseline data between CAD, OCD and CAD-CG. A Kruskal Wallis H test was conducted with factors that were not normally distributed and highly skewed.

**Analysis of Adherence Rates and Predictors of Adherence**

Analysis of adherence rates and predictors of adherence was performed between the two intervention groups only (CAD and OCD).

Chi-square tests were used to compare the difference in proportions between intervention groups and gender with regards to initiation (see table 3.8). A Fisher's Exact

test was reported where the sample size was insufficient (cell count <5). Independent t-tests were used to compare differences in demographics, baseline health indices, functional capacities and HRQoL scores between initiators, participants who commenced the MCEP, and non-initiators, those that did not attend a single session (see table 3.10 and table 3.11). Outliers defined as residuals > ±3SD from the mean were assessed by inspection of a boxplot. Normality and homogeneity of variances was assessed using the Shapiro-Wilk's test and Levene's test, respectively. A Welch t-test was reported where homogeneity of variance was violated ($p < 0.05$). If data was highly skewed (> -1.0 or > 1.0), a Mann Whitney U test was conducted in order to decrease the risk of committing a type 1 error.

A two-way ANOVA was performed to examine the effects of intervention group and gender on attendance rates (see table 3.8). Residual analysis was performed to test the assumptions of the two-way ANOVA. Outliers defined as residuals > ±3SD from the mean were assessed by inspection of a boxplot. Normality was assessed using the Shapiro-Wilk's normality test. Skewness for each cell of the design, along with homogeneity of variances, was assessed using the Levene's test ($p = 0.390$). There were no extreme outliers. Residuals were not normally distributed ($p > 0.05$). However, since none of the residuals were highly skewed, a two-way ANOVA was deemed to be sufficiently robust to handle moderate violations of normality.

Adjusted means and standard error were reported if there was a significant interaction between intervention group and gender. This was followed with an analysis of the simple main effects. Statistical significance was probed using a manual Bonferroni

test with the adjusted alpha values set at $p < 0.025$ for gender and $p < 0.0167$ for intervention group. This was then followed by an analysis of the main effects for intervention group and gender with estimated marginal means and standard error reported. If any main effects were identified, then a pairwise comparison was performed with Bonferroni p-values adjusted automatically. In the event that no significant two-way interactions were found, then main effects were probed as outlined above.

Independent t-tests and chi square analysis were used to compare differences in demographics, baseline health indices, functional capacities and HRQoL scores between those who dropped out and those who were still attending at 4 weeks (see table 3.12 and table 3.13), 8 weeks (see table 3.14 and table 3.15), or any time during the 10 weeks (see table 3.16 and table 3.17). Outliers defined as residuals > ±3SD from the mean were assessed by inspection of a boxplot. Normality was assessed using Shapiro-Wilk's normality test. Skewness for each cell of the design and homogeneity of variances was assessed by Levene's test. A Welch t-test was reported where homogeneity of variance was violated ($p < 0.05$). If data was highly skewed (> -1.0 or > 1.0), a Mann Whitney U test was conducted to decrease the risk of a type 1 error.

A GLM with an identity link function for multivariate analysis was used to predict percentage attendance (see table 3.18 and table 3.19). A binomial logistic regression with a logit link function was used for multivariate analysis on the dichotomous outcome of dropout (see table 3.21, table 3.22 and table 3.23). Variables included in the initial model were based on published findings and, knowledge of association of the original data set. The following categorical variables were included as fixed factors: intervention group,

gender, marital status, education, and employment status. To control for heterogeneity within the population, age, number of comorbidities and distance to the MCEP, baseline PCA for mental health, functional capacity and muscle strength were included as covariates in the initial model.

Since the PCA analysis resulted in an approximate 25% decrease in the sample size used in the initial GLM analysis, the original data was re-examined. This involved generating a Pearson correlation coefficient matrix for each group; HRQoL (WEMWBS, MCS and PCS), functional capacity (6MWT and STS) and HGS (GripD and GripND). A correlation coefficient between any two variables ≥ 0.6 resulted in exclusion of one of the variables from the analysis. Since WEBWBS and MCS, 6MWT and STS and GripD and Grip ND were highly correlated, WEBWBS, STS and Grip ND were excluded. The remaining variables (MCS, PCS, 6MWT and GripD) were checked for multicollinearity using VIF. As no evidence of multicollinearity was detected, these four variables along with age, number of comorbidities and distance to the MCEP were added as covariates to the GLM along with the fixed factors of intervention group, gender, marital status, education, and employment status.

The main effects for all categorical and continuous variables and the interaction effects for intervention group against all fixed and continuous variables were included in the model. Significant ($p < 0.05$) main effects and interactions remained in the model. The Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) was used as a metric to identify the best-fit model for both GLM and binomial logistic regression. The correlations of parameter estimates were checked if the intercept was not significant

and any variable that was deemed to be highly correlated to the intercept was removed. The residuals in the model were checked for homoscedasticity to ensure that the model was representative across the entire spectrum of data. Bonferroni post hoc analysis comparing estimated marginal means was undertaken to investigate pairwise comparison between categorical variables with more than 2 groups where a significant interaction effect was present (see table 3.20).

## 3.4 Results

### 3.4.1 Participant Characteristics

A total of 216 participants were recruited. Participants were classified by primary CD into CAD (n=96), CAD-CG (n=22) and OCD (n=98). The average age of participants referred into the MCEP was 62 – 66 yrs. and were similar with respect to marital status, employment status and distance to the MCEP. Participants were more likely to be married or living with a partner, retired, and living within 17 – 24 km from the MCEP. The most common cardiac intervention in CAD was a PCI, with lipid lowering drugs, aspirin and betablockers the top three cardiac medications prescribed. On average participants had >2 comorbidities with hypertension, depression/anxiety, and rheumatic conditions the most common. Table 3.3 and 3.4 summarises the socioeconomic and health-based demographics for each group.

There was a significant main effect for age, gender, level of education, and employment status across the three groups. Participants in OCD were significantly ($p = 0.002$) younger than CAD. There were more men than women in CAD ($p < 0.005$, 73% M) and CAD-CG ($p = 0.014$, 77% M) than OCD (47% M). There was no significant difference in the level of education or employment status between the three groups. There was no significant main effect or interactions for distance to MCEP and marital status. There was a significant main effect for number of CD between the three groups. Participants in CAD had a greater number of CD ($p = 0.003$) than OCD.

There was a significant main effect between groups for the following comorbidities: hypertension, rheumatic conditions, and T2DM. The incidence of

hypertension was greater in CAD ($p = 0.013$) and CAD-CG ($p = 0.013$) than OCD. There was a higher prevalence of a rheumatic condition in CAD ($p = 0.007$) than OCD. T2DM occurred more frequently in CAD ($p = 0.017$) than OCD. The was a significant group main effect for use of protein pump inhibitors (PPI) but not for any other medication. A higher number of participants in CAD ($p < 0.005$) and CAD-CG ($p = 0.014$) were prescribed PPI than OCD. There was no significant difference between CAD and CAD-CG for cardiac history, CAD category and cardiac medication. See appendix I for all post hoc analyses of baseline variables.

Table 3.3 Participant demographics

| Variable | CAD | CAD-CG | OCD^ | Main effects |
|---|---|---|---|---|
| Sample size (n) | 96 | 22 | 98 | |
| Age (yr.) | 66.35±7.15 | 62.77±8.03 | 61.51±11.83 | F (2, 60.02) = 6.69, **p = 0.002**, partial $\eta^2$ = 0.06 |
| Gender, M:F (%M) | 70:26 (73%) | 17:5 (77%) | 46:52 (47%) | $\chi^2$(2, n=216) = 16.38, **p < 0.005** |
| Distance to MCEP (km) | 16.94±14.55 | 23.95±16.68 | 18.16±16.15 | F (2, 213) = 1.83, p = 0.163, partial $\eta^2$ = 0.02 |
| **Marital status** | | | | $\chi^2$(4, n=216) = 8.28, p = 0.082 |
| Married/living with partner | 71 (74.0%) | 18 (81.8%) | 63 (64.3%) | |
| Separated/divorced/widowed | 17 (17.7%) | 0 (0%) | 23 (23.5%) | |
| Single | 8 (8.3%) | 4 (18.2%) | 12 (12.2%) | |
| **Education** | | | | $\chi^2$(6, n=216) = 18.61, p = 0.005 |
| Some primary school | 20 (20.8%) | 1 (4.5%) | 9 (9.2%) | |
| Junior cert or equivalent | 26 (27.1%) | 8 (36.4%) | 17 (17.3%) | |
| Leaving cert or diploma | 29 (30.2%) | 12 (54.5%) | 44 (44.9%) | |
| Degree or postgraduate | 21 (21.9%) | 1 (4.5%) | 28 (28.6%) | |
| **Employment status** | | | | $\chi^2$(4, n=216) = 9.71, p = 0.046 |
| Employed or homemaker | 20 (20.8%) | 9 (40.9%) | 24 (24.5%) | |
| Unemployed or unable to work * | 18 (18.8%) | 4 (18.2%) | 31 (31.6%) | |
| Retired | 58 (60.4%) | 9 (40.9%) | 43 (43.9%) | |

Values are expressed as absolute values (percentage) or mean±SD
^OCD include stroke (26), neurological (24), musculoskeletal (28), bowel disease (12) diabetes (5) other (3)
*due to illness
M = male, F = female, MCEP = multi-disease, community-based exercise programme

Table 3.4 Medical history

| | CAD (n=96) | CAD-CG (n=22) | OCD (n=98) | Main effects |
|---|---|---|---|---|
| No. of CD | 2.56±1.34 (2) | 2.23±0.75 (2) | 2.03±1.13 (2) | $\chi^2(2) = 8.81$, **p=0.012** |
| **Cardiac history**[a] | | | | |
| Myocardial infarction | 59 (61.5%) | 11 (50%) | 0 (0%) | $\chi^2(1, n=118) = 0.97$, p = 0.324 |
| Percutaneous coronary intervention with stent | 70 (72.9%) | 18 (81.8%) | 3 (3.1%) | $\chi^2(1, n=118) = 0.75$, p = 0.387 |
| Coronary artery bypass graft (CABG) | 20 (20.8%) | 3 (13.6%) | 0 (0%) | $\chi^2(1, n=118) = 0.59$, p = 0.561 |
| Percutaneous coronary intervention without stent^ | 1 (1%) | 0 (0%) | 0(0%) | |
| Valve replacement | 12 (12.5%) | 1 (4.5%) | 1 (1%) | $\chi^2(1, n=118) = 1.16$, p = 0.457 |
| **CAD category (n)**[a, b] | (95) | (22) | (98) | $\chi^2(3, n=117) = 4.22$, p = 0.238 |
| Myocardial infarction + revascularisation | 55 (57.9%) | 11 (50%) | 0 (0%) | |
| No MI + revascularisation | 25 (26.3%) | 10 (45.5%) | 2 (2%) | |
| MI + No revascularisation^ | 5 (5.3%) | 0 (0%) | 0 (0%) | |
| Other | 10 (10.5%) | 1 (4.5%) | 1 (1%) | |
| **Cardiac medication (n)**[a] | (93) | (22) | (79) | |
| Betablockers | 59 (64.1%) | 16 (72.7%) | 6 (7.6%) | $\chi^2(1, n=114) = 0.58$, p = 0.445 |
| Angiotensin converting enzyme inhibitors (ACE inhibitors) | 32 (34.8%) | 11 (50%) | 7 (8.9%) | $\chi^2(1, n=114) = 1.75$, p = 0.186 |
| Calcium channel blockers | 17 (18.5%) | 6 (27.3%) | 9 (11.4%) | $\chi^2(1, n=114) = 0.85$, p = 0.356 |
| Lipid lowering drugs | 86 (92.5%) | 20 (90.9%) | 13 (16.5%) | $\chi^2(1, n=115) = 0.06$, p = 0.806 |
| Aspirin | 83 (89.2%) | 21 (95.5%) | 15 (19%) | $\chi^2(1, n=115) = 0.79$, p = 0.373 |
| Dual antiplatelet | 53 (57.6%) | 16 (72.7%) | 0 (0%) | $\chi^2(1, n=114) = 1.70$, p = 0.192 |
| Anticoagulants | 9 (9.8%) | 1 (4.5%) | 3 (3.8%) | $\chi^2(1, n=114) = 0.61$, p = 0.684 |
| **Other medication (n)** | (89) | (22) | (79) | |
| Protein pump inhibitors | 43 (48.3%) | 10 (45.5%) | 15 (19%) | $\chi^2(2, n=190) = 16.68$, **p < 0.005** |
| Antidepressants | 9 (10.1%) | 1 (4.5%) | 14 (17.7%) | $\chi^2(2, n=190) = 3.67$, p = 0.160 |
| Respiratory^ | 8 (9%) | 0 (0%) | 3 (3.8%) | |

| | | | | |
|---|---|---|---|---|
| Other (could be 1 other or more) | 56 (62.2%) | 11 (50%) | 57 (72.2%) | $\chi^2(2, n=191) = 4.25, p = 0.119$ |
| **Comorbidities** | | | | |
| T1DM^ | 1 (1%) | 0 (0%) | 0 (0%) | |
| T2DM | 17 (17.7%) | 2 (9.1%) | 6 (6.1%) | $\chi^2(2, n=216) = 6.51, p = 0.039$ |
| Cancer | 14 (14.6%) | 3 (13.6%) | 11 (11.2%) | $\chi^2(2, n=216) = 0.50, p = 0.781$ |
| Depression/anxiety | 19 (19.8%) | 4 (18.2%) | 22 (22.4%) | $\chi^2(2, n=216) = 0.31, p = 0.856$ |
| Rheumatic | 23 (24%) | 2 (9.1%) | 9 (9.2%) | $\chi^2(2, n=216) = 8.80$, **p = 0.012** |
| Respiratory | 15 (15.6%) | 1 (4.5%) | 10 (10.2%) | $\chi^2(2, n=216) = 2.64, p = 0.267$ |
| Osteoporosis/osteopenia^ | 2 (2.1%) | 0 (0%) | 5.1 (5%) | |
| Neurological | 10 (10.4%) | 1 (4.5%) | 7 (7.1%) | $\chi^2(2, n=216) = 1.14, p = 0.565$ |
| Digestive | 15 (15.6%) | 4 (18.2%) | 8 (8.2%) | $\chi^2(2, n=216) = 3.19, p = 0.203$ |
| Hypertension | 34 (35.4%) | 10 (45.5%) | 19 (19.4%) | $\chi^2(2, n=216) = 9.18$, **p = 0.010** |

Values are expressed as absolute values (percentage) or presented as mean and standard deviation (median),
CD = chronic disease, T1DM = type 1 diabetes mellitus, T2DM = type 2 diabetes mellitus
^ = with numbers so low no statistical comparison was carried out
[a] = Comparison was between CAD and CAD-CG only, [b] violates cell count

### 3.4.2 Health and Fitness Indices at Baseline

Similar values for SBP, DBP, weight, BMI, circumference measurements and flexibility were obtained across all three groups. Notably BMI measured 29.2±4.9 with 85% of all participants either overweight or obese with the average waist circumference >105 cm in males and >96 cm in females. The average distance reached on the sit and reach was 7.7±11.4cm with overall group measurements for SBP and DBP 140.7±18.5 mmHg and 80.0±9.2 mmHg, respectively. Table 3.5 summarises the health and fitness indices at baseline for the three experimental groups.

There was a significant group main effect for RHR, WHR, GripD, GripND, 6MWTD, STS, WEMWBS, PCS and MCS. Post hoc analysis (Appendix I) indicated CAD and CAD-CG had a significantly lower RHR and time to complete the STS compared to OCD (figure 3.2 and 3.3). Both CAD groups had a significantly higher HGS (dominant and non-dominant) and 6MWTD compared to OCD (figure 3.4 and 3.5). The OCD had significantly poorer self-reported health in WEMWBS, PCS and MCS compared to CAD and CAD-CG (figure 3.6 and 3.7), while the CAD had a significantly higher WHR compared to OCD (figure 3.8).

The health and fitness indices at baseline for each condition in the OCD are outlined in table 3.6. There was a significant group main effect between for distance to MCEP, number of CD and WHR. The post hoc analysis revealed that stroke participants lived closer ($p = 0.032$) than T2DM participants. Individuals living with bowel disease had a greater number of CD than those in the neurological ($p < 0.001$) and MSK ($p = 0.013$) group. The WHR was lower ($p = 0.002$) in patients with bowel disease than stroke patients.

Table 3.5 Health and fitness indices at baseline for each experimental group

| | n | CAD (n=96) | n | CAD-CG (n=22) | n | OCD (n=98) | Main Effect |
|---|---|---|---|---|---|---|---|
| SBP (mmHg) | 93 | 141.45±17.59 | 21 | 144.38±17.19 | 88 | 138.98±19.76 | $F (2, 199) = 0.871$, $p = 0.420$, partial $\eta^2 = 0.01$ |
| DBP (mmHg) | 93 | 78.68±9.69 | 21 | 82.43±8.40 | 88 | 80.83±8.70 | $F (2, 199) = 2.077$, $p = 0.128$, partial $\eta^2 = 0.02$ |
| RHR (bpm) | 96 | 64.99±9.94 | 22 | 67.14±7.19 | 98 | 73.84±13.08 | $F (2, 71.78) = 14.207$, **$p < 0.005$,** partial $\eta^2 = 0.13$ |
| Weight (kg) | 96 | 84.52±14.52 | 22 | 86.25±13.94 | 98 | 82.49±17.52 | $F (2, 213) = 0.693$, $p = 0.501$, partial $\eta^2 = 0.01$ |
| BMI (kg/m$^2$) | 96 | 29.13±4.44 | 22 | 29.35±3.99 | 98 | 29.19±5.47 | $F (2, 213) = 0.017$, $p = 0.983$, partial $\eta^2 = 0.00$ |
| Waist (cm) | 95 | 102.28±12.40 | 22 | 100.09±11.47 | 98 | 100.82±14.39 | $F (2, 212) = 0.409$, $p = 0.665$, partial $\eta^2 = 0.00$ |
| Hip (cm) | 82 | 105.25±7.38 (105.5) | 22 | 104.06±6.43 (103.5) | 93 | 108.42±11.64 (107.0) | $\chi^2 (2) = 4.304$, $p = 0.116$ |
| WHR | 82 | 0.97±0.09 | 22 | 0.96±0.08 | 93 | 0.94±0.09 | $F (2, 194) = 3.237$, **$p = 0.041$,** partial $\eta^2 = 0.03$ |
| GripD (kg) | 96 | 31.25±8.63 | 22 | 34.50±8.35 | 96 | 26.63±9.86 | $F (2, 211) = 9.713$, **$p < 0.005$,** partial $\eta^2 = 0.08$ |
| GripND (kg) | 96 | 30.48±8.48 | 22 | 34.59±7.56 | 97 | 25.34±10.30 | $F (2, 212) = 12.579$, **$p < 0.005$,** partial $\eta^2 = 0.11$ |
| 6MWTD (m) | 96 | 499.19±72.78 | 22 | 520.96±91.51 | 97 | 440.66±101.45 | $F (2, 57.60) = 12.570$**, $p < 0.005$,** partial $\eta^2 = 0.12$ |
| S&R (cm) | 92 | 8.82±11.55 | 21 | 4.95±13.80 | 90 | 7.14±10.72 | $F (2, 200) = 1.156$, $p = 0.317$, partial $\eta^2 = 0.01$ |
| STS (sec) | 96 | 26.52±6.22 (25.94) | 22 | 26.28±6.10 (25.70) | 94 | 28.46±7.24 (30.86) | $\chi^2 (2) = 20.50$, **$p < 0.005$** |
| WEMWBS | 85 | 56.71±8.98 | 18 | 56.89±9.21 | 91 | 50.47±10.60 | $F (2, 191) = 9.888$, **$p < 0.005$,** partial $\eta^2 = 0.09$ |
| SF-12v2 PCS | 92 | 46.84±8.32 | 22 | 46.84±7.87 | 97 | 40.90±10.01 | $F (2, 208) = 11.174$, **$p < 0.005$,** partial $\eta^2 = 0.10$ |
| SF-12v2 MCS | 92 | 53.22±8.75 | 22 | 54.24±7.75 | 97 | 48.32±10.06 | $F (2, 208) = 8.012$, **$p < 0.005$,** partial $\eta^2 = 0.07$ |

Values are presented as mean ± standard deviation (median)

SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

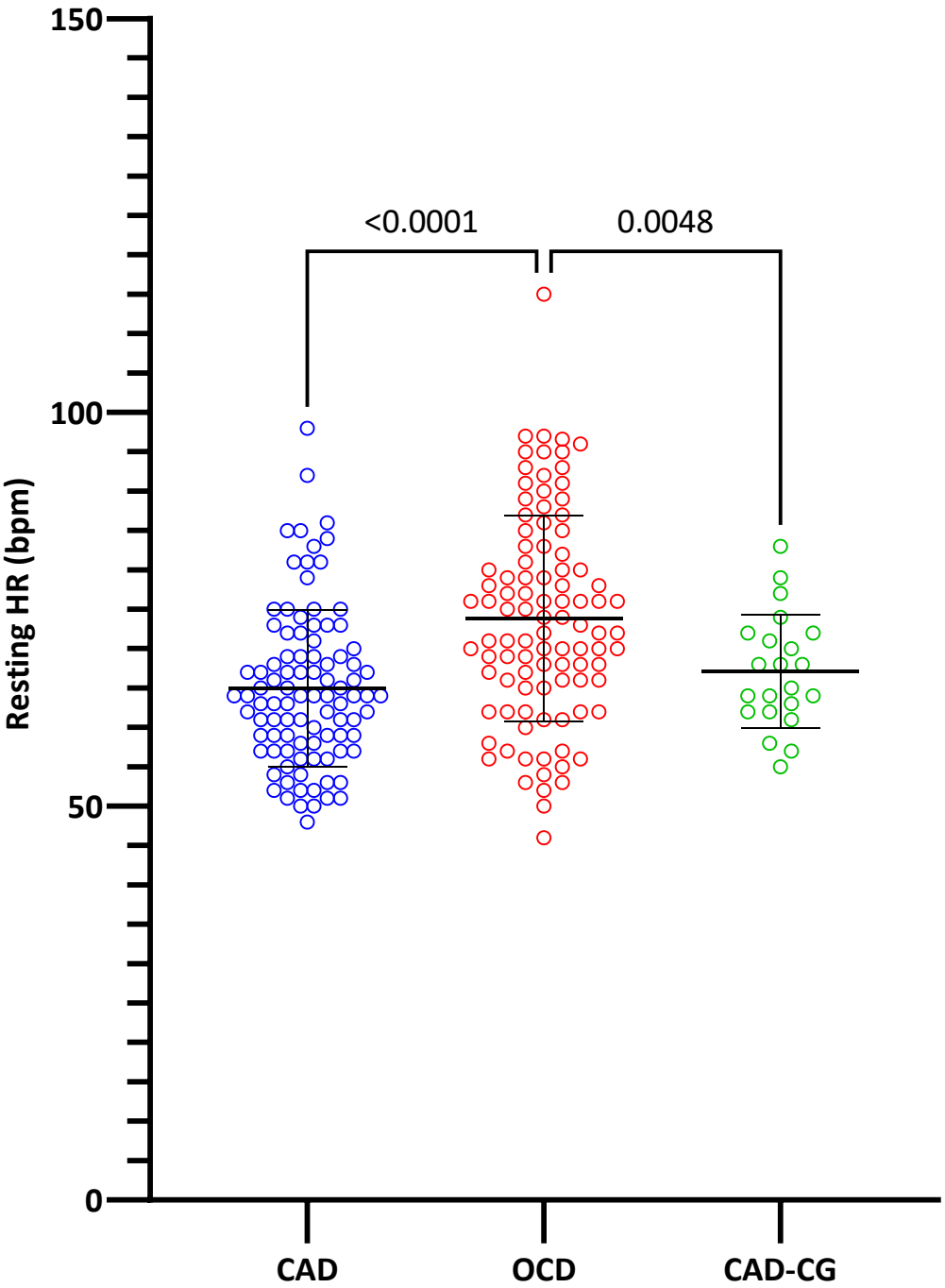



Figure 3.2 Baseline RHR for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

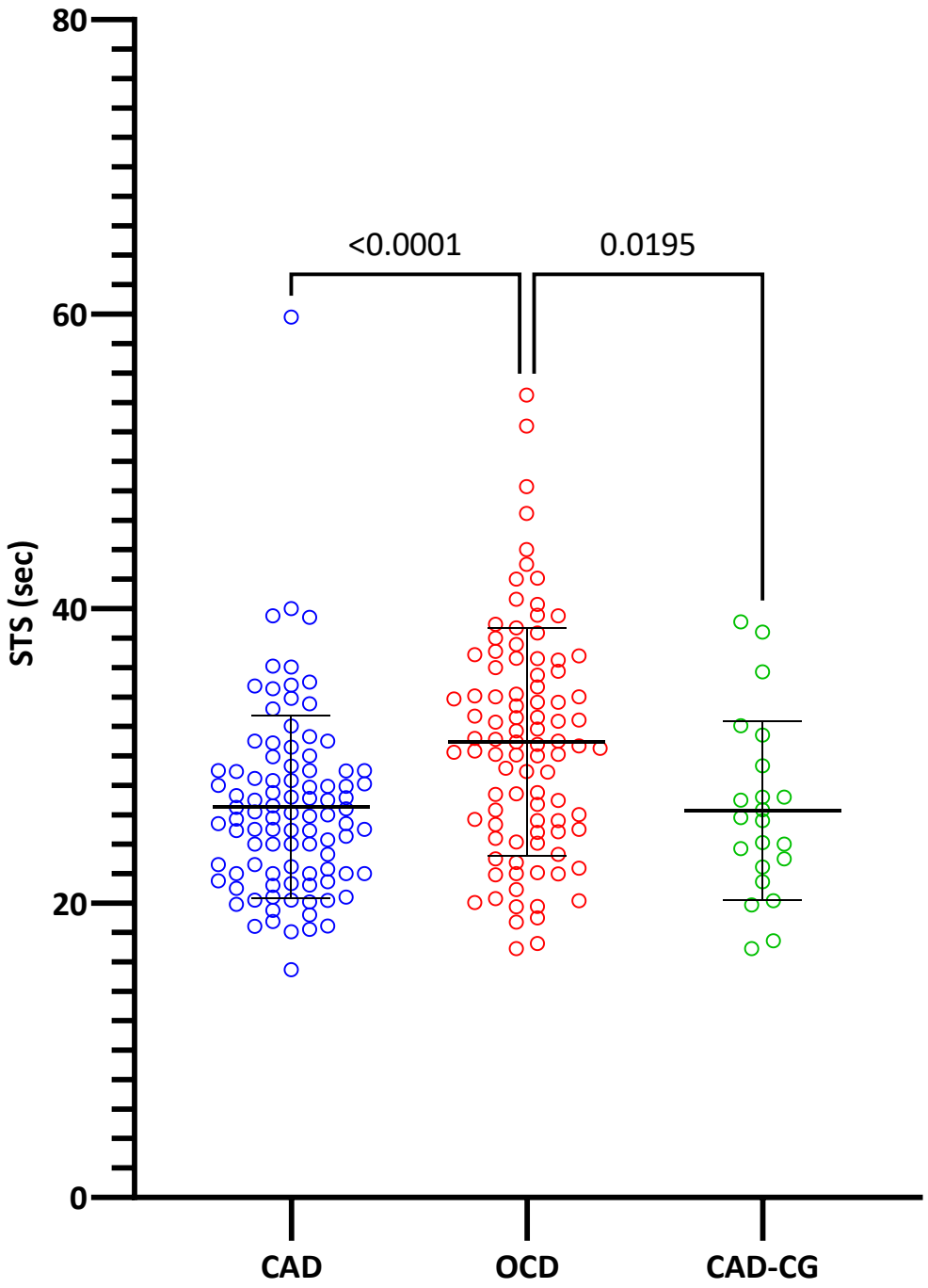



Figure 3.3 Baseline STS score for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

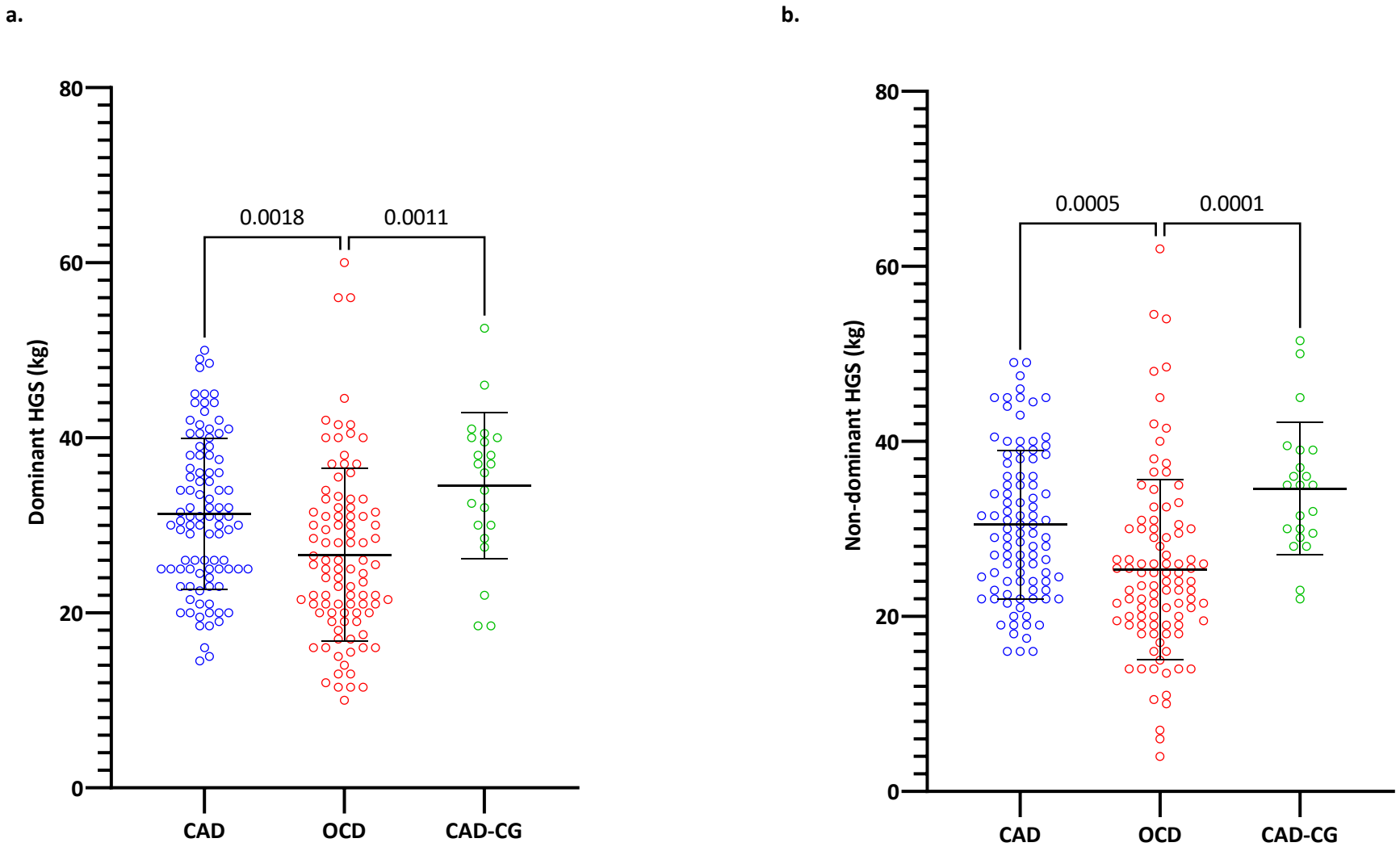



Figure 3.4 Baseline a. dominant and b. non-dominant HGS for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

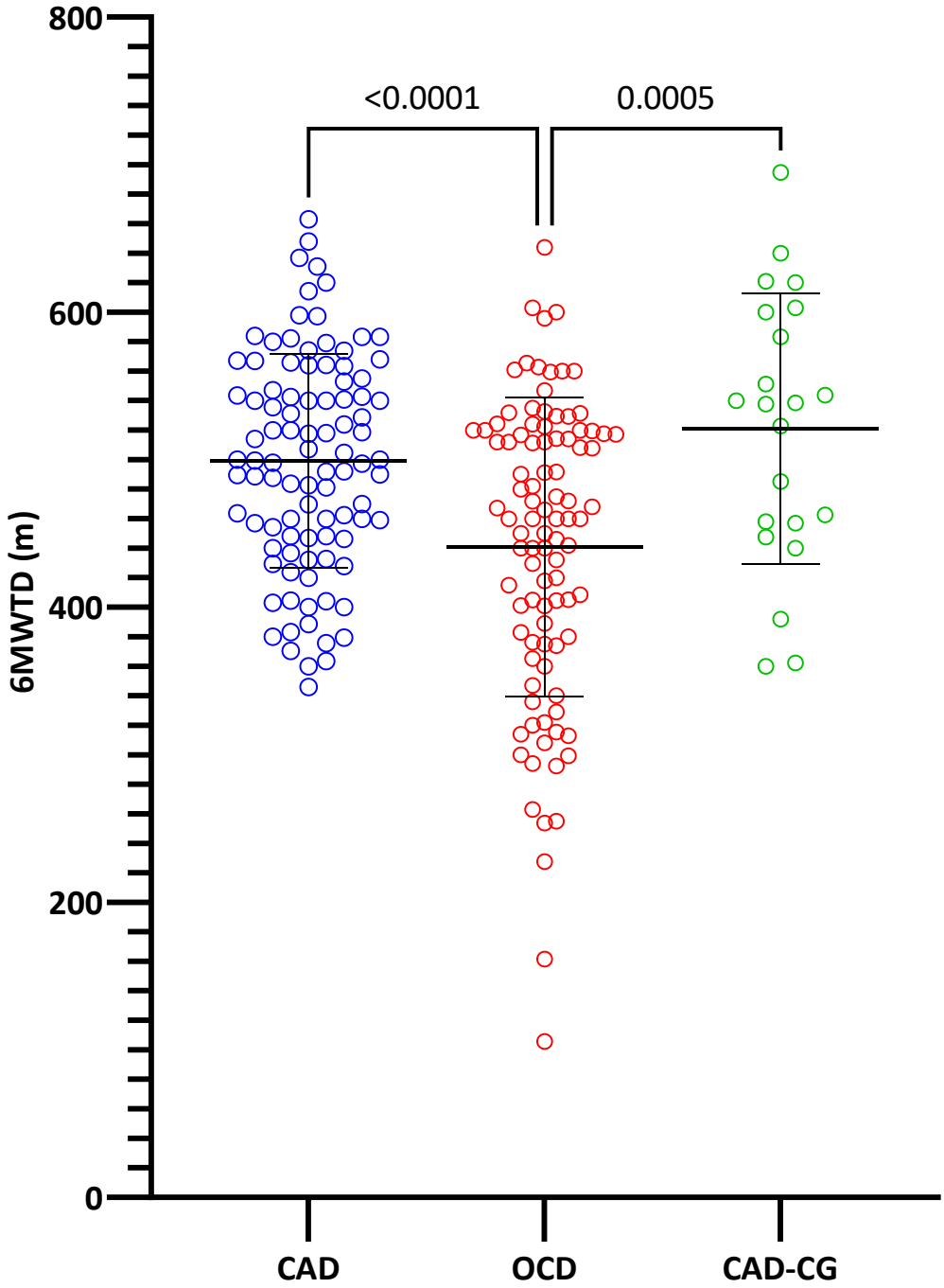



Figure 3.5 Baseline 6MWTD for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

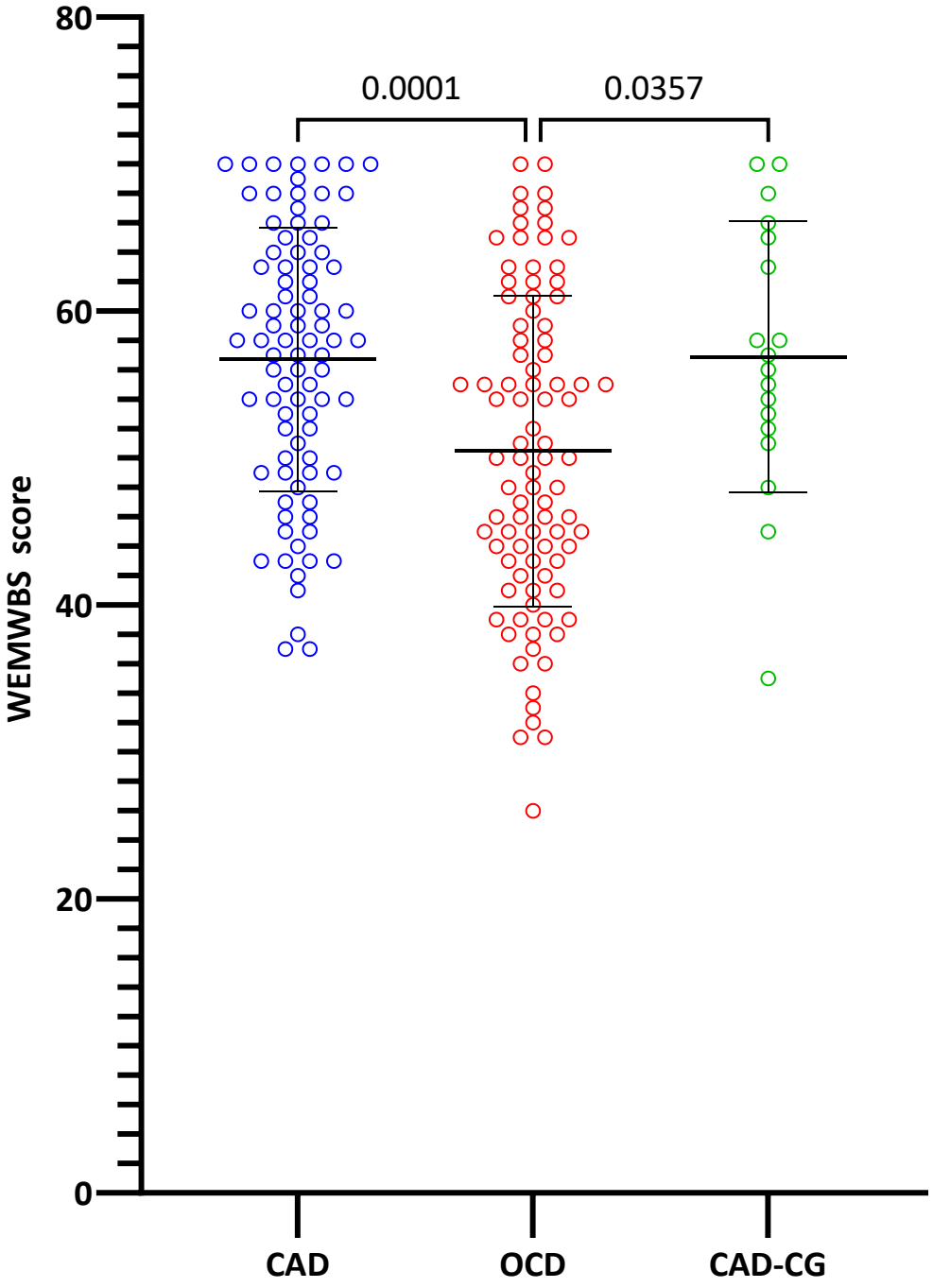



Figure 3.6 Baseline WEMWBS for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

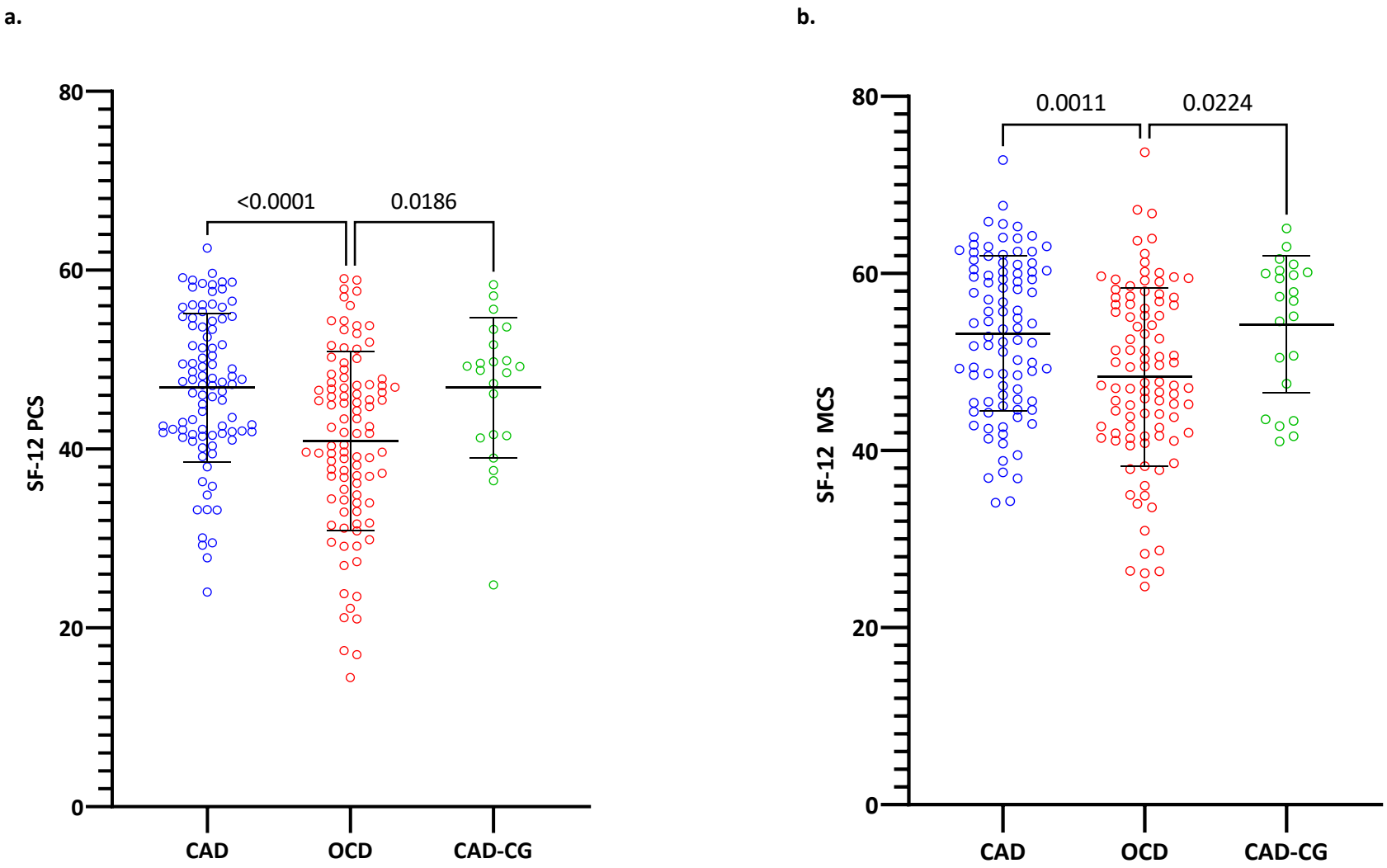



Figure 3.7 Baseline a. SF-12 PCS and b. SF-12 MCS for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

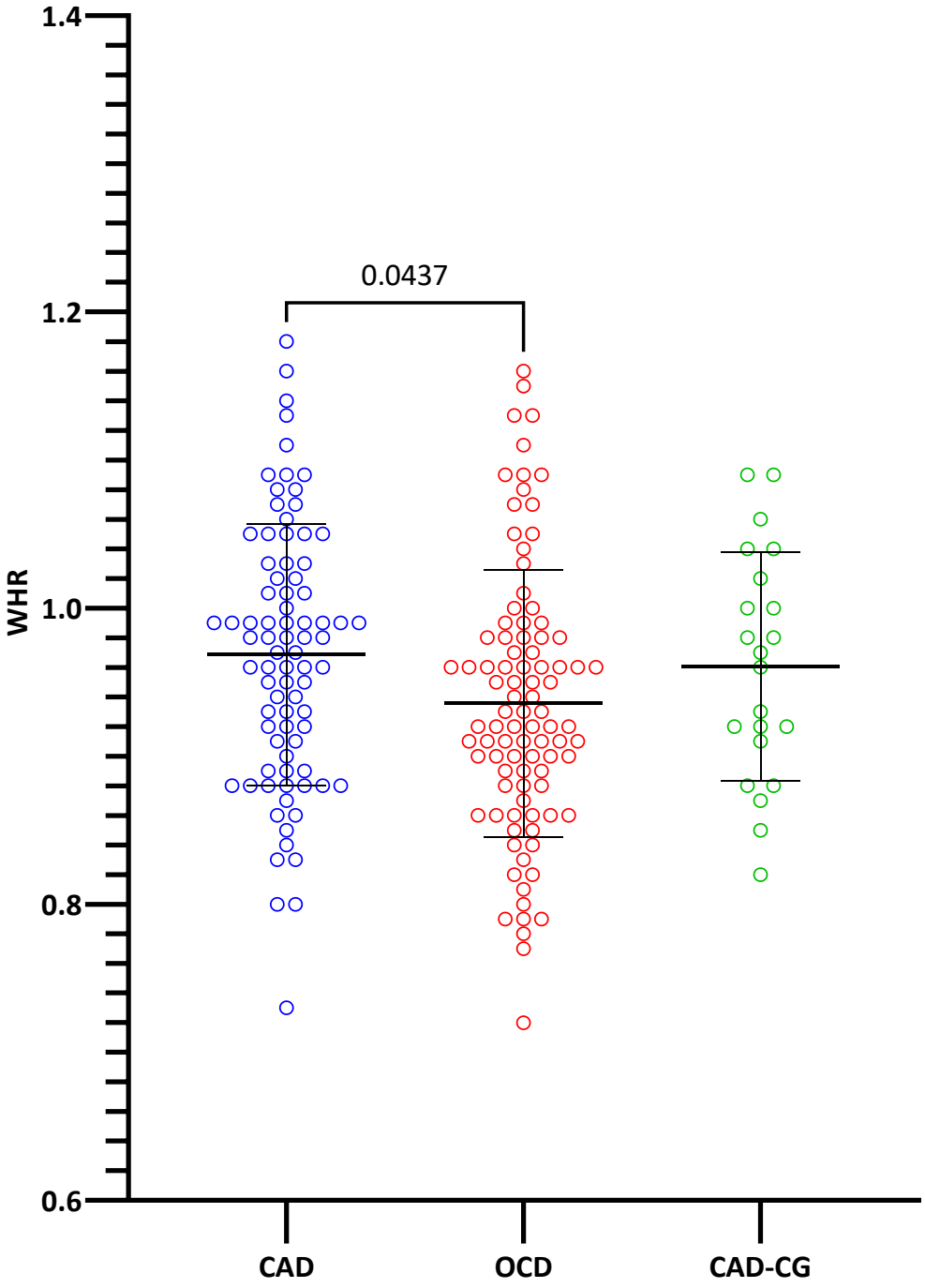



Figure 3.8 Baseline WHR for CAD, OCD and CAD-CG. Scatter dot plots represent individual scores

Table 3.6 Participant demographics, health, and fitness indices at baseline for each CD within the OCD group

| OCD^ | n | Stroke | n | Neuro | n | MSK | n | IBD | n | T2DM | Main Effects |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age (yr) | 26 | 67.0 | 24 | 55.5 | 28 | 66.0 | 12 | 64.5 | 5 | 62.0 | $\chi^2$ (4) = 7.72, p = 0.102 |
| Distance to MCEP | 26 | 9.5 | 24 | 19.5 | 28 | 10.0 | 12 | 9.0 | 5 | 36.0 | $\chi^2$ (4) = 12.18, **p = 0.016** |
| No. of CD* | 26 | 2.0 (52.15) | 24 | 1.0 (33.60) | 28 | 2.0 (44.23) | 12 | 3.0 (73.21) | 5 | 2.0 (56.10) | $\chi^2$ (4) = 20.18, **p < 0.005** |
| SBP (mmHg) | 24 | 140.5 | 23 | 133.0 | 23 | 142.0 | 11 | 134.0 | 4 | 145.0 | $\chi^2$ (4) = 4.59, p = 0.332 |
| DBP (mmHg) | 24 | 81.5 | 23 | 78.0 | 23 | 80.0 | 11 | 78.0 | 4 | 83.5 | $\chi^2$ (4) = 2.79, p = 0.593 |
| RHR (bpm) | 26 | 77.5 | 24 | 73.5 | 28 | 74.5 | 12 | 67.0 | 5 | 72.0 | $\chi^2$ (4) = 3.08, p = 0.545 |
| Weight (kg) | 26 | 81.2 | 24 | 76.8 | 28 | 83.9 | 12 | 69.6 | 5 | 95.4 | $\chi^2$ (4) = 7.33, p = 0.119 |
| BMI (kg/m$^2$) | 26 | 27.2 | 24 | 28.1 | 28 | 30.8 | 12 | 25.5 | 5 | 30.8 | $\chi^2$ (4) = 9.31, p = 0.054 |
| Waist (cm) | 26 | 99.0 | 24 | 98.5 | 28 | 104.5 | 12 | 86.0 | 5 | 109.5 | $\chi^2$ (4) = 8.29, p = 0.082 |
| Hip (cm) | 25 | 103.5 | 20 | 105.9 | 28 | 109.7 | 12 | 104.0 | 5 | 109.0 | $\chi^2$ (4) = 4.21, p = 0.379 |
| WHR | 25 | 0.96 | 20 | 0.92 | 28 | 0.92 | 12 | 0.83 | 5 | 0.92 | $\chi^2$ (4) = 14.34, **p = 0.006** |
| GripD (kg) | 24 | 28.3 | 24 | 30.5 | 28 | 21.8 | 12 | 23.5 | 5 | 29.5 | $\chi^2$ (4) = 5.87, p = 0.209 |
| GripND (kg) | 26 | 26.0 | 24 | 25.0 | 28 | 22.3 | 12 | 18.0 | 5 | 26.0 | $\chi^2$ (4) = 5.04, p = 0.284 |
| 6MWTD (m) | 26 | 469.6 | 24 | 422.6 | 28 | 448.1 | 11 | 529.5 | 5 | 472.1 | $\chi^2$ (4) = 5.89, p = 0.208 |
| S&R (cm) | 23 | 3.0 | 23 | 8.0 | 25 | 7.0 | 11 | 11.0 | 5 | 4.0 | $\chi^2$ (4) = 5.77, p = 0.217 |
| STS (sec) | 25 | 32.3 | 24 | 31.8 | 27 | 30.1 | 11 | 30.7 | 5 | 24.4 | $\chi^2$ (4) = 1.81, p = 0.770 |
| WEMWBS | 25 | 55.0 | 24 | 48.5 | 24 | 45.0 | 10 | 52.5 | 5 | 41.0 | $\chi^2$ (4) = 5.66, p = 0.226 |
| SF-12v2 PCS | 25 | 43.4 | 24 | 45.4 | 28 | 38.0 | 12 | 44.0 | 5 | 48.4 | $\chi^2$ (4) = 8.21, p = 0.084 |
| SF-12v2 MCS | 25 | 50.4 | 24 | 46.8 | 28 | 47.2 | 12 | 47.2 | 5 | 42.7 | $\chi^2$ (4) = 4.40, p = 0.355 |

Values are presented as median (and rank* if data was not similarly distributed), ^ 3 participants were not included due their diverse conditions but were included in the OCD total

Neuro = neurological, CD = chronic disease, MSK = musculoskeletal, IBD = inflammatory bowel disease, T2DM = type 2 diabetes mellitus, MCEP = multi-disease, community-based exercise programme**,** SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

### 3.4.3 Principal Component Analysis of Health and Fitness Measures

The PCA performed on the health and fitness measures revealed five distinct components. A five-component rotated solution met the interpretability criterion and exhibited simple structure. Therefore, all five components were retained. The interpretation of the data was consistent with key attributes of the tests conducted with strong loadings of body composition items on component 1, upper muscle strength items on component 2, functional capacity items on component 3, mental wellbeing items on component 4 and BP on component 5. The five distinct components had eigenvalues >1 and explained 29.0%, 20.5%, 13.2%, 10.4% and 8.8% of the total variance for component 1 through 5, respectively. Component loadings of the rotated solution are presented in table 3.7. The table also outlines the factor characteristics with item loading on which interpretation of components was based.

There was a significant main effect for muscle strength [$\chi^2$ (2) = 15.88, p<0.005], functional capacity [$\chi^2$ (2) = 17.20, p<0.005] and mental wellbeing [F (2, 157) = 6.92, p=0.001] across the three experimental groups. Based on the post hoc analysis, muscle strength values were greater in CAD (p = 0.018) and CAD-CG (p= 0.001) than OCD. Functional capacity was also greater in CAD (p = 0.001) and CAD-CG (p= 0.007) than OCD. Mental well-being was greater in CAD than OCD (p = 0.001).

Table 3.7 Factors derived from principal component analysis of health-related measures

| | Component 1 Body composition | Component 2 Muscle strength | Component 3 Functional capacity | Component 4 Mental wellbeing | Component 5 Blood pressure |
|---|---|---|---|---|---|
| BMI | 0.955 | | | | |
| Weight | 0.903 | | | | |
| Waist | 0.900 | | | | |
| Hip | 0.873 | | | | |
| GripD | | 0.957 | | | |
| GripND | | 0.940 | | | |
| STS | | | -0.849 | | |
| 6MWTD | | | 0.819 | | |
| SF-12v2 PCS | | | 0.641 | | |
| WEMWBS | | | | 0.891 | |
| SF-12v2 MCS | | | | 0.887 | |
| SBP | | | | | 0.857 |
| DBP | | | | | 0.845 |

Extraction Method: Principal component analysis
Rotation Method: Varimax with Kaiser Normalization (rotation converged in 5 iterations) Values < 0.30 are not displayed

BMI = body mass index, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, STS = sit to stand, 6MWTD = 6-minute walk test distance, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score, SBP = systolic blood pressure, DBP = diastolic blood pressure

### 3.4.4 Adherence Rates

Initiation, attendance, and dropout rates for the entire sample, by gender and by intervention group, are presented in table 3.8. The overall initiation rate was 94.8%. A total of 10 participants did not attend one class. Reasons for non-initiation are outlined in table 3.9. There were no statistically significant differences in gender, ($\chi^2$ (1) = 1.718, p = 0.205) or intervention group ($\chi^2$ (1) = 1.601, p = 0.331) for initiation. Non-initiators had a significantly lower handgrip score for their non-dominant hand and a lower perceived physical wellbeing as assessed by SF-12 PCS (Table 3.10 and 3.11). Non-initiators also had lower CRF and lower body muscle strength. Although close, the difference did not reach significance.

The average percentage of classes attended by the combined CAD and OCD groups was 60.7%. The interaction effect between intervention group and gender on attendance was not statistically significant [F (1, 180) = 0.295, p = 0.587, partial $\eta^2$ = 0.002]. An analysis of the main effect found that intervention group had a significant impact on attendance. CAD attended 9% (95%CI, 1.18-17.56) more classes than OCD. Although males attended 8% (95%CI, -0.37-16.02) more classes than females, the difference did not reach statistical significance (p = 0.061).

The overall dropout rate in the programme was 24.5%, with reasons for dropout outlined in table 3.9. Participants who dropped out of the study during the first 4 weeks had significantly higher DBP than participants still engaged in the programme. The WEMWBS and MCS was lower in participants who dropped out at any time over the course of the 10 weeks, though this was not evident in the first 4 or 8 weeks. There was no significant difference in the proportion of participants who dropped out of the CAD and OCD during the first 4, 8 and 10 weeks. The proportion of men and women who dropped out during the first 4, 8 and 10 weeks was not significantly different. There was no significant difference in age, distance to the MCEP, education status, marital status, or employment status between participants who dropped out by week 4, 8 or 10 and those who were still attending the MCEP at 10. Comparisons between attenders and those who dropped out by weeks 4, 8 and 10 are outlined in tables 3.12 to 3.17.

Table 3.8 Rates of initiation, attendance, and dropout during the first 4, 8, and 10 weeks

| | Sample Size | Initiation | Attendance | Dropout during 4wks | Dropout during 8wks | Dropout during 10wks |
|---|---|---|---|---|---|---|
| | n | n (%) | % | n (%) | n (%) | n (%) |
| Full sample | 194 | 184 (94.8) | 60.74±27.06 | 22 (12.0) | 40 (21.7) | 45 (24.5) |
| **Gender** | | | | | | |
| Male | 116 | 112 (96.6) | 64.03±2.56 | 12 (10.7) | 21 (18.8) | 25 (22.3) |
| Female | 78 | 72 (92.3) | 56.20±3.27 | 10 (13.9) | 19 (26.4) | 20 (27.8) |
| **Intervention group** | | | | | | |
| CAD | 96 | 93 (96.9) | 64.80±3.09* | 8 (8.6) | 18 (19.4) | 21 (22.6) |
| OCD | 98 | 91 (92.9) | 55.43±2.77 | 14 (15.4) | 22 (24.2) | 24 (26.4) |
| Values for initiation and dropout are presented as n (%); Attendance as mean% ±SD for full sample and estimated marginal mean%±SE for gender and intervention groups | | | | | | |
| * CAD had greater attendance rates than OCD, F (1, 180) = 5.093, p = 0.025, partial $\eta^2$ = 0.03 | | | | | | |

Table 3.9 Reasons for non-initiation and dropout of the MCEP

| | Non-Initiation | | Dropout | |
|---|---|---|---|---|
| Reason | CAD | OCD | CAD | OCD |
| Injury/other health issues | - | 2 | 5 | - |
| Work commitments | 1 | 1 | 1 | 2 |
| Family/personnel commitments | - | - | 2 | - |
| Distance | - | - | 1 | 1 |
| Didn't feel physically/mentally capable | - | - | - | 4 |
| Time didn't suit | 1 | - | - | - |
| Deceased | 1 | - | 1 | 1 |
| Unknown | - | 4 | 11 | 16 |
| Total | 3 | 7 | 21 | 24 |

Table 3.10 Demographics of initiators and non- initiators

| | Initiators | Non- Initiators | Main effects |
|---|---|---|---|
| **Variable** | | | |
| Sample size (n) | 184 | 10 | |
| Age (yr.) | 64.02±9.96 | 61.90±12.39 | t (192) = 0.646, p = 0.519 |
| **Gender** | | | $\chi^2$(1, n=194) = 1.718, p = 0.205 |
| Male | 112 (96.6%) | 4 (3.4%) | |
| Female | 72 (92.3%) | 6 (7.7%) | |
| %M | 61% | 40% | |
| Distance to MCEP (km) | 18.08±15.54 (13.0) | 8.00±5.87 (6.5) | U = 594.0, z = -1.889, p = 0.059 |
| No. of CD | 2.29±1.25 (2.0) | 2.40±1.51 (2.0) | U = 940.5, z = 0.123, p = 0.902 |

Values are expressed as absolute values (percentage) or mean±SD (median), M = male,
MCEP = multi-disease, community-based exercise programme, CD = chronic disease

Table 3.11 Health and fitness characteristics of initiators and non-initiators

| | n | Initiators | n | Non-initiators | Main Effect |
|---|---|---|---|---|---|
| SBP (mmHg) | 172 | 140.08±18.46 | 9 | 143.56±23.29 | t (179) = -0.544, p = 0.587 |
| DBP (mmHg) | 172 | 79.65±9.32 | 9 | 81.22±8.39 | t (179) = -0.497, p = 0.620 |
| RHR (bpm) | 184 | 69.34±12.43 | 10 | 71.70±12.74 | t (192) = -0.584, p = 0.560 |
| Weight (kg) | 184 | 83.85±15.89 | 10 | 76.99±19.23 | t (192) = 1.315, p = 0.190 |
| BMI ($kg/m^2$) | 184 | 29.21±4.95 | 10 | 28.37±5.56 | t (192) = 0.520, p = 0.604 |
| Waist (cm) | 183 | 101.85±13.18 | 10 | 95.80±17.24 | t (191) = 1.391, p = 0.166 |
| Hip (cm) | 166 | 107.01±9.90 (106.0) | 9 | 105.52±11.83 (105.0) | U = 681.5, z = -0.443, p = 0.658 |
| WHR | 166 | 0.95±0.09 | 9 | 0.90±0.11 | t (173) = 1.641, p = 0.103 |
| GripD (kg) | 182 | 29.21±9.46 | 10 | 24.10±9.85 | t (190) = 1.658, p = 0.099 |
| GripND (kg) | 183 | 28.27±9.60 | 10 | 21.05±10.66 | t (191) = 2.304, p = 0.022 |
| 6MWTD (m) | 184 | 473.33±89.79 | 9 | 397.09±128.05 | t (8.39) = 1.765, p = 0.114 |
| S&R (cm) | 176 | 7.86±11.27 | 6 | 11.83±5.85 | t (180) = -0.858, p = 0.392 |
| STS (sec) | 181 | 28.47±7.19 (27.38) | 9 | 33.61±8.91 (33.63) | U = 1122.5, z = 1.913, p = 0.056 |
| WEMWBS | 168 | 53.69±10.24 | 8 | 49.25±11.45 | t (174) = 1.190, p = 0.235 |
| SF-12v2 PCS | 179 | 44.16±9.49 | 10 | 37.17±10.98 | t (187) = 2.249, p = 0.026 |
| SF-12v2 MCS | 179 | 50.87±9.58 | 10 | 47.84±12.48 | t (187) = 0.956, p = 0.341 |

Values are expressed as mean ± SD (median)
SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

Table 3.12 Demographics of attenders and dropout during first four weeks

| | Attenders | Dropout | Main effects |
|---|---|---|---|
| **Variable** | | | |
| Sample size (n) | 162 | 22 | |
| Age (yr.) | 64.30±9.53 | 61.91±12.74 | t (24.30) = -0.850, p = 0.404 |
| Gender, M:F (%M) | 100:62 (62%) | 12:10 (55%) | $\chi^2$(1, n=184) = 0.420, p = 0.517 |
| Distance to MCEP (km) | 17.92±15.56 | 19.23±15.70 | t (182) = 0.369, p = 0.712 |
| No. of CD | 2.30±1.27 (2) | 2.23±1.19 (2) | U = 1813.0, z = 0.137, p = 0.891 |
| **Marital status^** | | | $\chi^2$(2, n=184) = 1.672, p = 0.433 |
| Married/living with partner | 113 (89.0%) | 14 (11.0%) | |
| Separated/divorced/widowed | 34 (89.5%) | 4 (10.5%) | |
| Single | 15 (78.9%) | 4 (21.1%) | |
| **Education^** | | | $\chi^2$(3, n=184) = 2.337, p = 0.506 |
| Some primary school | 22 (84.6%) | 4 (15.4%) | |
| Junior cert or equivalent | 37 (94.9%) | 2 (5.1%) | |
| Leaving cert or diploma | 61 (85.9%) | 10 (14.1%) | |
| Degree or postgraduate | 42 (87.5%) | 6 (12.5%) | |
| **Employment status** | | | $\chi^2$(2, n=184) = 1.336, p = 0.513 |
| Employed or homemaker | 34 (82.9%) | 7 (17.1%) | |
| Unemployed or unable to work* | 40 (88.9%) | 5 (11.1%) | |
| Retired | 88 (89.8%) | 10 (10.2%) | |

Values are expressed as absolute values (percentage) or mean±SD (median), M = male, F = female,
* due to illness, MCEP = multi-disease, community-based exercise programme, CD = chronic disease,
^ Cell count violated (25%)

Table 3.13 Health and fitness characteristics of attenders and dropout during first 4 weeks

| | n | Attenders | n | Dropout | Main Effect |
|---|---|---|---|---|---|
| SBP (mmHg) | 153 | 139.65±17.79 | 19 | 143.53±23.46 | t (170) = 0.863, p = 0.389 |
| DBP (mmHg) | 153 | 79.09±8.96 | 19 | 84.11±11.08 | t (170) = 2.238, **p = 0.026** |
| RHR (bpm) | 162 | 68.97±12.38 | 22 | 72.05±12.76 | t (182) = 1.089, p = 0.278 |
| Weight (kg) | 162 | 83.54±14.80 | 22 | 86.13±22.72 | t (23.48) = 0.521, p = 0.607 |
| BMI | 162 | 29.21±4.62 | 22 | 29.22±7.07 | t (23.50) = 0.009, p = 0.993 |
| Waist (cm) | 162 | 101.43±12.51 | 21 | 105.15±17.57 | t (22.70) = 0.940 p = 0.357 |
| Hip (cm) | 148 | 106.53±8.95 (105.75) | 18 | 110.99±15.51 (108.5) | U = 1133.0, z = -1.034, p = 0.301 |
| WHR | 148 | 0.95±0.09 | 18 | 0.97±0.09 | t (164) = 0.826, p = 0.410 |
| GripD (kg) | 160 | 28.79±9.10 | 22 | 32.22±11.55 | t (180) = 1.600, p = 0.111 |
| GripND (kg) | 161 | 28.02±9.37 (26.5) | 22 | 30.14±11.21 (25.0) | U = 1694.0, z = -0.331, p = 0.741 |
| 6MWTD (m) | 162 | 475.66±91.05 | 22 | 456.17±79.68 | t (182) = -0.955, p = 0.341 |
| S&R (cm) | 154 | 7.76±11.33 | 22 | 8.61±11.05 | t (174) = 0.333, p = 0.739 |
| STS (sec) | 160 | 28.32±7.19 (27.25) | 21 | 29.63±7.19 (30.0) | U = 1477.0, z = -0.899, p = 0.369 |
| WEMWBS | 149 | 54.17±10.11 | 19 | 49.90±10.74 | t (166) = -1.723, p = 0.087 |
| SF-12v2 PCS | 157 | 44.56±9.28 | 22 | 41.30±10.66 | t (177) = -1.518, p = 0.131 |
| SF-12v2 MCS | 157 | 51.15±9.50 | 22 | 48.85±10.07 | t (177) = -1.056, p = 0.293 |

Values are expressed as mean ± SD (median)
SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

Table 3.14 Demographics of attenders and dropout during first 8 weeks

| | Attenders | Dropout | Main effects |
|---|---|---|---|
| **Variable** | | | |
| Sample size (n) | 144 | 40 | |
| Age (yr.) | 64.39±9.43 | 62.68±11.69 | t (53.90) = -0.853, p = 0.397 |
| Gender, M:F (%M) | 91:53 (63%) | 21:19 (52.5%) | $\chi^2$(1, n=184) = 1.503, p = 0.220 |
| Distance to MCEP (km) | 17.88±15.44 | 18.80±16.07 | t (182) = 0.332, p = 0.740 |
| No. of CD | 2.34±1.29 (2) | 2.10±1.11 (2) | U = 3144.0, z = 0.921, p = 0.357 |
| **Marital status** | | | $\chi^2$(2, n=184) = 3.998, p = 0.135 |
| Married/living with partner | 104 (81.9%) | 23 (18.1%) | |
| Separated/divorced/widowed | 28 (73.7%) | 10 (26.3%) | |
| Single | 12 (63.2%) | 7 (36.8%) | |
| **Education** | | | $\chi^2$(3, n=184) = 5.005, p = 0.171 |
| Some primary school | 19 (73.1%) | 7 (26.9%) | |
| Junior cert or equivalent | 35 (89.7%) | 4 (10.3%) | |
| Leaving cert or diploma | 56 (78.9%) | 15 (21.1%) | |
| Degree or postgraduate | 34 (70.8%) | 14 (29.2%) | |
| **Employment status** | | | $\chi^2$(2, n=184) = 0.278, p = 0.870 |
| Employed or homemaker | 31 (75.6%) | 10 (24.4%) | |
| Unemployed or unable to work* | 35 (77.8%) | 10 (22.2%) | |
| Retired | 78 (79.6%) | 20 (20.4%) | |

Values are expressed as absolute values (percentage) or mean±SD (median), M = male, F = female,
* due to illness, MCEP = multi-disease, community-based exercise programme, CD = chronic disease

Table 3.15 Health and fitness characteristics of attenders and dropout during first 8 weeks

| | n | Attenders | n | Dropout | Main Effect |
|---|---|---|---|---|---|
| SBP (mmHg) | 137 | 139.60±17.69 | 35 | 141.94±21.37 | t (170) = 0.669, p = 0.504 |
| DBP (mmHg) | 137 | 79.33±9.08 | 35 | 80.89±10.22 | t (170) = 0.882, p = 0.379 |
| RHR (bpm) | 144 | 68.73±12.39 | 40 | 71.55±12.48 | t (182) = 1.273, p = 0.205 |
| Weight (kg) | 144 | 83.48±14.82 | 40 | 85.17±19.41 | t (52.28) = 0.510, p = 0.612 |
| BMI | 144 | 29.15±4.52 | 40 | 29.42±6.34 | t (50.51) = 0.255, p = 0.800 |
| Waist (cm) | 144 | 101.45±12.39 | 39 | 103.36±15.84 | t (51.26) = 0.696 p = 0.489 |
| Hip (cm) | 133 | 106.35±8.98 (105.5) | 33 | 109.70±12.79 (109.0) | U = 1853.5, z = -1.380, p = 0.168 |
| WHR | 133 | 0.95±0.09 | 33 | 0.95±0.08 | t (164) = -0.083, p = 0.934 |
| GripD (kg) | 142 | 28.80±9.23 | 40 | 30.66±10.26 | t (180) = 1.100, p = 0.273 |
| GripND (kg) | 143 | 27.93±9.47 | 40 | 29.51±10.09 | t (181) = 0.923, p = 0.357 |
| 6MWTD (m) | 144 | 474.46±90.36 | 40 | 469.25±88.74 | t (182) = -0.323, p = 0.747 |
| S&R (cm) | 137 | 7.46±11.38 | 39 | 9.27±10.89 | t (174) = 0.883, p = 0.378 |
| STS (sec) | 143 | 28.25±7.05 (27.3) | 38 | 29.31±7.70 (28.25) | U = 2518.0, z = -0.693, p = 0.488 |
| WEMWBS | 132 | 54.46±9.99 | 36 | 50.86±10.80 | t (166) = -1.880, p = 0.062 |
| SF-12v2 PCS | 140 | 44.31±9.27 | 39 | 43.65±10.37 | t (177) = -0.380, p = 0.705 |
| SF-12v2 MCS | 140 | 51.45±9.27 | 39 | 48.75±10.45 | t (177) = -1.565, p = 0.119 |

Values are expressed as mean ± SD (median)
SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

Table 3.16 Demographics of attenders and dropout during first 10 weeks

| | Attenders | Dropout | Main effects |
|---|---|---|---|
| **Variable** | | | |
| Sample size (n) | 139 | 45 | |
| Age (yr.) | 64.61±9.20 | 62.18±11.93 | t (61.84) = -1.253, p = 0.215 |
| Gender, M:F (%M) | 87:52 (63%) | 25:20 (56%) | $\chi^2(1, n=184) = 0.706$, p = 0.401 |
| Distance to MCEP (km) | 17.81±15.53 | 18.91±15.71 | U = 3020.5, z = -0.345, p = 0.730 |
| No. of CD | 2.31±1.29 (2) | 2.22±1.17 (2) | U = 3198.50, z = 0.238, p = 0.812 |
| **Marital status** | | | $\chi^2(2, n=184) = 2.695$, p = 0.260 |
| Married/living with partner | 100 (78.7%) | 27 (21.3%) | |
| Separated/divorced/widowed | 27 (71.1%) | 11 (28.9%) | |
| Single | 12 (63.2%) | 7 (36.8%) | |
| **Education** | | | $\chi^2(3, n=184) = 4.174$, p = 0.243 |
| Some primary school | 19 (73.1%) | 7 (26.9%) | |
| Junior cert or equivalent | 34 (87.2%) | 5 (12.8%) | |
| Leaving cert or diploma | 53 (74.6%) | 18 (25.4%) | |
| Degree or postgraduate | 33 (68.8%) | 15 (31.3%) | |
| **Employment status** | | | $\chi^2(2, n=184) = 0.458$, p = 0.795 |
| Employed or homemaker | 30 (73.2%) | 11 (26.8%) | |
| Unemployed or unable to work* | 33 (73.3%) | 12 (26.7%) | |
| Retired | 76 (77.6%) | 22 (22.4%) | |

Values are expressed as absolute values (percentage) or mean±SD (median), M = male, F = female,
* due to illness, MCEP = multi-disease, community-based exercise programme, CD = chronic disease

Table 3.17 Health and fitness characteristics of attenders and dropout during first 10 weeks

| | n | Attenders | n | Dropout | Main Effect |
|---|---|---|---|---|---|
| SBP (mmHg) | 133 | 139.08±17.60 | 39 | 143.46±21.02 | t (170) = 1.305, p = 0.194 |
| DBP (mmHg) | 133 | 79.02±8.99 | 39 | 81.77±10.19 | t (170) = 1.627, p = 0.106 |
| RHR (bpm) | 139 | 68.70±12.34 | 45 | 71.31±12.62 | t (182) = 1.226, p = 0.222 |
| Weight (kg) | 139 | 83.23±14.50 | 45 | 85.77±19.64 | t (60.29) = 0.801, p = 0.426 |
| BMI | 139 | 29.07±4.48 | 45 | 29.62±6.23 | t (59.44) = 0.550, p = 0.584 |
| Waist (cm) | 139 | 101.20±12.17 | 44 | 103.92±15.95 | t (59.67) = 1.038 p = 0.303 |
| Hip (cm) | 128 | 106.18±9.06 (105.4) | 38 | 109.83±12.03 (109.0) | U = 1947.0, z = -1.865, p = 0.062 |
| WHR | 128 | 0.95±0.09 | 38 | 0.96±0.09 | t (164) = 0.139, p = 0.890 |
| GripD (kg) | 137 | 28.75±9.07 | 45 | 30.58±10.57 | t (180) = 1.128, p = 0.261 |
| GripND (kg) | 138 | 27.87±9.41 | 45 | 29.50±10.16 | t (181) = 0.987, p = 0.325 |
| 6MWTD (m) | 139 | 474.67±90.77 (489.6) | 45 | 469.16±87.58 (460.0) | U = 3360.0, z = 0.749, p = 0.454 |
| S&R (cm) | 132 | 7.48±11.38 | 44 | 9.00±10.97 | t (174) = 0.772, p = 0.441 |
| STS (sec) | 138 | 28.21±7.12 | 43 | 29.30±7.41 | t (179) = 0.871, p = 0.385 |
| WEMWBS | 127 | 54.61±10.04 | 41 | 50.81±10.46 | t (166) = -2.091, **p = 0.038** |
| SF-12v2 PCS | 135 | 44.40±9.35 | 44 | 43.42±9.98 | t (177) = -0.594, p = 0.553 |
| SF-12v2 MCS | 135 | 51.75±9.20 | 44 | 48.15±10.29 | t (177) = -2.184, **p = 0.030** |

Values are expressed as mean ± SD (median)
SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

### 3.4.5 Predictors of Attendance

The GLM model to predict the percentage of classes attended in the 10 weeks was statistically significant ($F(9) = 4.183$, $p < 0.001$). Gender and baseline MCS independently contributed to the model (Table 3.18). The interaction between marital status and intervention group contributed to the model, as did HGS of the dominant hand and intervention group (Table 3.18 and Table 3.19).

The percentage attendance for males was predicted to be 13.9% greater than females. Percentage attendance was predicted to increase by 0.4% for every 1-point increase in MCS. There is an improvement in attendance of 0.88% in CAD over OCD for every 1 kg increase in HGS in the dominant hand. Pairwise comparison of the interaction effects (Table 3.20) predicted that CAD who were married/living with a partner or who were separated, divorced, or widowed had a predicted attendance rate of 63.3% and 66.7%, respectively, compared to CAD who were single (32.1%).

Table 3.18 Parameter estimates for GLM for predicting percentage attendance – main effects

| | ***B* (SE)** | **95% CI for *B*** | | **df** | **t** | **p** | **partial eta$^2$** | ***R*$^2$** | **$\Delta R^2$** |
|---|---|---|---|---|---|---|---|---|---|
| | | LL | UL | | | | | | |
| Model | | | | | | | | 0.18 | 0.14 |
| Intercept | 56.61 (14.44) | 28.11 | 85.11 | 1, 167 | 3.921 | 0.000 | 0.084 | | |
| Intervention group ref: OCD | -58.52 (17.85) | -93.76 | -23.29 | 1, 167 | -3.279 | 0.001^ | 0.061 | | |
| Gender ref: female | 13.94 (4.54) | 4.98 | 22.90 | 1, 167 | 3.070 | **0.002** | 0.053 | | |
| Marital status ref: single | | | | 2, 167 | | | | | |
| Married/living with partner | -11.51 (7.95) | -27.21 | 4.19 | | -1.447 | 0.150 | 0.012 | | |
| Separated/divorced/widowed | -11.29 (9.12) | -29.29 | 6.72 | | -1.238 | 0.218 | 0.009 | | |
| GripD | -0.71 (0.30) | -1.30 | -0.13 | 1, 167 | -2.401 | 0.017 | 0.033 | | |
| SF-12 MCS | 0.44 (0.21) | 0.03 | 0.85 | 1, 167 | 2.096 | **0.038** | 0.026 | | |
| Intervention group*Marital status | | | | | | | | | |
| CAD*married/living with partner | 42.75 (13.25) | 16.60 | 68.90 | 2, 167 | 3.228 | **0.002** | 0.059 | | |
| CAD*separated/divorced/widowed | 45.98 (15.08) | 16.20 | 75.76 | 2, 167 | 3.048 | **0.003** | 0.053 | | |
| CAD*GripD | 0.88 (0.43) | 0.04 | 1.72 | 1, 167 | 2.063 | **0.041** | 0.025 | | |

B = unstandardised regression coefficient, SE = standard error of the coefficient, CI = confidence interval, LL = lower limit, UL = upper limit, df = degrees of freedom, t = T-statistic, $R^2$ = coefficient of determination, $\Delta R^2$ = adjusted $R^2$, GripD = handgrip of dominant hand, SF-12 = 12-item short form survey, MCS = mental component score

^ not significant on pairwise comparison

Reference category for intervention group is OCD = intervention group is expressed as CAD compared to OCD

Reference category for gender is female = gender is expressed as males compared to females

Reference category for education is degree/postgraduate = all results for education are expressed as comparisons to degree/postgraduate

Reference category for employment status is retired = all results for employment status are expressed as comparisons to retired

Table 3.19 Model effect of GLM regression model for predicting percentage attendance - interaction effects

| | df | F | p | partial eta$^2$ | $R^2$ | $\Delta R^2$ |
|---|---|---|---|---|---|---|
| Model | | | | | 0.18 | 0.14 |
| Intercept | 1, 167 | 10.349 | 0.002 | 0.058 | | |
| Intervention group *Marital status | 2, 167 | 5.613 | **0.004** | 0.063 | | |
| Intervention group * GripD | 1, 167 | 4.255 | **0.041** | 0.025 | | |

df = degrees of freedom, F = F-statistic, $R^2$ = coefficient of determination, $\Delta R^2$ = adjusted $R^2$, GripD = handgrip of dominant hand

Table 3.20 Post hoc pairwise comparison of the estimated marginal mean differences for significant categorical interaction effects

| Effect | Comparison | Mean difference | SE | df | p | CI of difference |
|---|---|---|---|---|---|---|
| Intervention group *Martial status | CAD (married/partner) v CAD (single) | 31.24 | 10.35 | 1 | **0.038** | 0.87 to 61.61 |
| | CAD (S/D/W) v CAD (single) | 34.69 | 11.69 | 1 | **0.045** | 0.38 to 69.01 |

SE = standard error, df = degrees of freedom, p = using Bonferroni correction, CI = confidence interval, S/D/W = separated/divorced/widowed, M = male, F = female

### 3.4.6 Predictors of Dropout

A binomial logistic regression with a logit link function was used to identify predictors of dropout during the first 4, 8 and 10 weeks.

**Prediction of dropout during the first 4 weeks**

The model for prediction of dropout during the first 4 weeks was statistically significant ($\chi^2$ (3) = 8.125, p = 0.043). The model explained 8% of the variance in dropout. Increasing dominant HGS was associated with an increased likelihood of participants dropping out of the programme during the first 4 weeks (table 3.21).

Table 3.21 Logistic regression predicting likelihood of dropout during the first 4 weeks

| Variable | B | SE | Wald | df | p | Odds Ratio | 95% CI for odds ratio |
|---|---|---|---|---|---|---|---|
| Intervention group ref: OCD | 0.762 | 0.494 | 2.380 | 1 | 0.123 | 2.143 | 0.814 to 5.644 |
| Gender ref: female | 0.889 | 0.599 | 2.199 | 1 | 0.138 | 2.432 | 0.751 to 7.874 |
| GripD | -0.069 | 0.029 | 5.551 | 1 | **0.018** | 0.934 | 0.882 to 0.989 |
| Constant | 4.039 | 0.933 | 18.741 | 1 | **0.000** | 56.760 | |

GripD = handgrip of dominant hand
Reference category for intervention group is OCD = intervention group is expressed as CAD compared to OCD
Reference category for gender is female = gender is expressed as males compared to females

**Prediction of dropout during the first 8 weeks**

At 8 weeks, the overall model was not statistically significant ($\chi^2$ (3) = 6.464, p = 0.091). Increasing dominant HGS was associated with an increased likelihood of dropping out of the programme during the first 8 weeks (table 3.22). Males had higher odds of engaging in the programme over the first 8 weeks.

Table 3.22 Logistic regression predicting likelihood of dropout at 8 weeks

| Variable | B | SE | Wald | df | p | Odds Ratio | 95% CI for odds ratio |
|---|---|---|---|---|---|---|---|
| Intervention group ref: OCD | 0.307 | 0.379 | 0.654 | 1 | 0.419 | 1.359 | 0.646 to 2.856 |
| Gender ref: female | 0.896 | 0.458 | 3.829 | 1 | **0.050** | 2.450 | 0.999 to 6.013 |
| GripD | -0.049 | 0.023 | 4.427 | 1 | **0.035** | 0.952 | 0.910 to 0.997 |
| Constant | 2.660 | 0.7171 | 13.757 | 1 | 0.000 | 14.294 | |

GripD = handgrip of dominant hand
Reference category for intervention group is OCD = intervention group is expressed as CAD compared to OCD
Reference category for gender is female = gender is expressed as males compared to females

**Prediction of dropout during the first 10 weeks**

The overall model was not statistically significant ($\chi^2$ (3) = 4.626, p = 0.201). No outcome variables could independently predict dropout at 10 weeks (table 3.23).

Table 3.23 Logistic regression predicting likelihood of dropout at 10 weeks

| Variable | B | SE | Wald | df | p | Odds Ratio | 95% CI for odds ratio |
|---|---|---|---|---|---|---|---|
| Intervention group ref: OCD | 0.250 | 0.362 | 0.479 | 1 | 0.489 | 1.285 | 0.632 to 2.610 |
| Gender ref: female | 0.669 | 0.432 | 2.402 | 1 | 0.121 | 1.953 | 0.838 to 4.553 |
| GripD | -0.042 | 0.022 | 3.549 | 1 | 0.060 | 0.959 | 0.919 to 1.002 |
| Constant | 2.285 | 0.670 | 11.624 | 1 | 0.001 | 9.825 | |

GripD = handgrip of dominant hand
Reference category for intervention group is OCD = intervention group is expressed as CAD compared to OCD
Reference category for gender is female = gender is expressed as males compared to females

## 3.5 Summary of Results

Participants attending a MCEP were more likely to be married/living with a partner, retired, overweight/obese with well-regulated BP. Cardiac patients referred into the MCEP were older and more likely to be male compared to OCD patients. The cardiac patients had better actual and perceived physical and mental health than patients with OCD at induction to the programme. Patients from multiple CD cohorts in the OCD group had similar fitness and perceived HRQoL measurements. There were high initiation rates

in CAD and OCD groups, but CAD were higher attenders. Actual and perceived physical function was lower in non-initiators. Being male, having better mental wellbeing, along with marital status and HGS in CAD were identified as predictors of increased attendance over the 10 weeks. Dropout rate in the first 10 weeks was 24.5%, with almost half occurring in the first 4 weeks. WEMWBS and MCS scores were lower in participants who dropped out at any time point over the 10 weeks, but neither were predictors of dropout. Having a lower HGS was associated with still engaging with the programme at 4 and 8 weeks. Males attended more classes and were more likely to still be attending at 8 weeks.

# Chapter IV

# Study II

# Efficacy of a Multi-Disease, Community-Based Exercise Programme

## 4.1 Introduction

Increasing PA levels or undertaking structured exercise training has a positive impact on both physical and mental health. Increasing PAET is associated with improvements in mortality rates, reduction in hospital admissions, improved physical fitness and psychological wellbeing in individuals with CD including CAD, stroke, MS, COPD, MSK conditions, T2DM and PD (Rietberg *et al.* 2005; Goodwin *et al.* 2008; Lavie and Milani 2011; Brozic *et al.* 2017; Geneen *et al.* 2017; Li *et al.* 2019; Saunders *et al.* 2020; Dibben *et al.* 2021). Consequently, PAET is now used as an adjunct therapy in the treatment of many lifestyle-mediated CDs (Pedersen and Saltin 2015).

In Ireland, structured, hospital-based PAET rehabilitation programmes are available for individuals diagnosed with CVD and pulmonary disease. Internationally, these programmes are delivered by a team of HCPs including exercise physiologists, physiotherapists, nurses, cardiologists, dieticians and/or counsellors (Amatya *et al.* 2019; Saunders *et al.* 2020; Dibben *et al.* 2021; McKeon 2021). The efficacy of PAET interventions for CVD and pulmonary disease is well established. However, opportunities for structured PAET are currently limited for other CD.

With the numbers of individuals living with ≥ 1 CD projected to increase 40% by 2030 (H.S.E. 2020b), the Irish government and the HSE have prioritised the development

of strategies to address this growing burden. A key aim of the 'National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020-2025' (H.S.E. 2020a) is to move away from disease-specific programmes and provide services to support and empower individuals living in the community to manage their CD. It is envisaged that CDM hubs involving cross-disciplinary teams will provide an holistic, multi-faceted model of care for the integrated prevention and management of CD (H.S.E. 2020a). A key priority regarding population health and wellbeing services in the HSE's National Service Plan 2021 is the establishment of a PA pathway for HCPs to refer individuals with ≥ 1CD to appropriate structured PAET programmes within the community (H.S.E. 2020b). Interventions treating individuals with more than one CD or different CDs have been found to be feasible, safe, and effective, with high levels of participant satisfaction (McNamara *et al.* 2016; Barker *et al.* 2018; Kastner *et al.* 2018; Rowley *et al.* 2018).

Many CDs share common risk factors, such as hypertension, dyslipidaemia, sedentary behaviour and obesity (Pedersen and Saltin 2015), display a similar pathogenesis, e.g., chronic inflammation (Furman *et al.* 2019) and endothelial dysfunction (Steyers and Miller 2014) and, result in comparable disease burden in terms of functional impairment (Chou *et al.* 2021) and diminished HRQoL (Booth *et al.* 2012). Many of these common elements are subject to adaptation and improvement with PAET (Pedersen and Saltin 2015; Naviaux 2019).

Multi-disease, community-based exercise programmes provide common exercises/activities (Pedersen and Saltin 2015) designed to allow participants to attend on

a regular basis, or drop in and out when extra support and guidance is required. These programmes involve significantly less monitoring than hospital-based programmes and, because they have no fixed duration (Kehoe *et al.* 2020), could potentially support a lifelong commitment to exercise in a safe and structured environment.

It is unrealistic to rely on HCPs to deliver long-term maintenance PAET programmes for individual CD. Furthermore, the fact that many individuals are experiencing a reduction in the severity of their condition, due to major advances in medical treatment and management of CD, (Christensen *et al.* 2009) reduces the need for the presence of HCP in the delivery of long-term maintenance programmes. These programmes could be delivered by trained exercise specialists thereby reducing the burden on the healthcare system. In addition to providing a structured exercise opportunity for the 70% of individuals with uncomplicated CD (H.S.E. 2020a) as part of the GP structured CDM programme 2023 (D.O.H. 2021b), the MCEP would be an ideal transition for individuals following completion of a hospital-based programme such as CR and PR.

A MCEP was established at the ATU Sligo in the northwest of Ireland in 2016. Participants with a wide range of CD who were deemed suitable were referred by HCPs, primarily cardiologists and physiotherapists. The programme was delivered by clinical exercise instructors. The purpose of this study was to evaluate the effects of participation in a MCEP on selected health indices, functional capacity, and HRQoL.

## 4.2 Aims and Hypotheses

### 4.2.1 Aims

- Evaluate the effect of participation in a MCEP on selected health indices
- Evaluate the effect of participation in a MCEP on functional capacity
- Evaluate the effect of participation in a MCEP on HRQoL

### 4.2.2 Hypotheses

1. Participation in a MCEP will result in significant improvements in selected health indices
2. Participation in a MCEP will result in significant improvements in functional capacity
3. Participation in a MCEP will result in significant improvements in HRQoL

## 4.3 Methodology

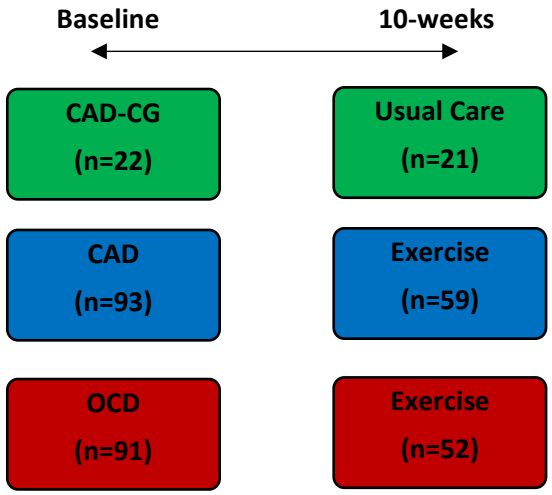
### 4.3.1 Study Overview

A quasi-experimental design was used to evaluate the effects of participation in a MCEP on selected health indices, functional capacity, and HRQoL. Detailed methodology of participant background, induction, the intervention, and outcome measures are described in chapter 3. In summary, participants with a diagnosis of CAD or OCD (including stroke, MS, PD, MSK, IBD and T2DM) were recruited at induction to a MCEP following referral from a HCP.

Prior to the intervention, all individuals completed a battery of health and fitness indices to obtain baseline measurements for resting BP and HR, body composition, CRF, flexibility, and both upper and lower body functional strength. They also completed two health and wellbeing questionnaires, specifically the SF12v2 Health Survey (Ware *et al.* 2010) and the WEMWBS (Stewart-Brown and Janmohamed 2008).

The intervention group completed 10 weeks, two days per week of a MCEP that involved 60 min of a combination of aerobic and resistance training, with an extended warm-up and cool-down as per BACPR guidelines (BACPR 2016). A control group consisted of individuals with CAD (CAD-CG) who had also completed phase III CR but were unable attend the MCEP due primarily to distance to the exercise facility and lack of time. Usual homecare advice was provided to the CAD-CG by the CR team in the hospital. Participants attended a post evaluation session where all health and fitness indices were

repeated. Figure 4.1 illustrates the study design, experimental groups and outcomes measured.




| Outcome Measures |
|---|
| **Health Indices** |
| Weight and height |
| Waist and hip circum. |
| BMI |
| Resting heart rate |
| Resting blood pressure |
| **Functional Capacity** |
| 6MWT |
| Handgrip strength |
| Sit to stand |
| Sit and reach |
| **HRQoL** |
| SF-12v2 health survey |
| WEMWBS |

Figure 4.1 Overview of study design and outcome measures

### 4.3.2 Primary and Secondary Outcome Measures

The primary outcome measure was CRF, measured by the distance covered in the 6MWT. Secondary outcome measures were resting BP and HR, body composition, upper and lower muscular strength, flexibility and HRQoL measurements.

### 4.3.3 Data Analysis

Independent t-tests and Chi square analysis were used to compare differences in demographics, baseline health indices, functional capacities and HRQoL scores between participants who attended and those that did not attend for post testing after 10 weeks of the intervention. Outliers defined as residuals > ±3 SD from the mean were identified by inspection of boxplots. Normality was assessed using the Shapiro-Wilk's normality test and, skewness for each cell of the design and homogeneity of variances was assessed

using the Levene's test. A Welch t-test was reported where homogeneity of variance was violated ($p < 0.05$). If data was highly skewed (> -1.0 or > 1.0), a Mann Whitney U test was conducted as it decreases the risk of committing a type 1 error.

Preliminary analysis of the mean change in outcome measures indicated a high correlation (> 0.6) between waist circumference, hip circumference and WHR. To control for type 1 error, further analysis only included waist circumference. A high correlation was also found between BMI and weight as well as dominant and non-dominant HGS. Further analysis only included BMI and dominant HGS.

A linear mixed model analysis (MMA) was used to examine the effect of the MCEP intervention on the primary and secondary outcome measures. A MMA is a suitable approach to model repeated measures that does not contain complete or balanced data sets (Armstrong 2017). MMA provides the flexibility to model variances and covariance's in addition to mean values (IBM 2021). MMA also allows for the covariance structure that best models the variances and covariances to be appropriately selected. It has less stringent assumptions and increased power to detect treatment effects (Armstrong 2017).

Participants were included in the model as the subject variable and time was treated as repeated measures. Time was also included as a fixed effect along with gender and experimental group. Baseline HGS (dominant) and 6MWTD were included as covariates as they are robust measurements of mobility, functional performance and HRQoL (Jakobsen *et al.* 2010) and, were used to control for heterogeneity within the population. The relevant baseline covariate was excluded for analysis of their respective

outcome measure; i.e., in analysing the impact of the intervention on 6MWTD, only baseline HGS was included as a covariate. All fixed effects, covariates and the interaction effect of time and experimental group were investigated.

The repeated measures component was analysed for several covariance structures including unstructured, autoregressive, compound symmetry (CS), autoregressive heterogenous and compound symmetry heterogenous (CSH). The AIC and BIC was used to evaluate the best-fit covariance structure of the mixed model. If the intercept of the model was not significant, an analysis of the correlation matrix was undertaken to identify highly correlated parameters which were subsequently removed. Covariance parameters were assessed for significance using the Wald statistic with statistical significance set at $p < 0.05$.

In the event of a significant two-way interaction effect between time and experiential group, a one-way ANCOVA comparing the estimated marginal means of the mean differences between baseline (BL), and post intervention (PI) was performed (between group difference). A significant main effect for time was followed with an analysis of the main effect of each experimental group (within group) with estimated marginal means and standard error reported. For all post-hoc analysis, a manual Bonferroni adjustment was made to the statistical significance ($p < 0.0167$). All models were checked for heteroscedasticity, normality, and outliers of errors/residuals.

The ANCOVA output was assessed by visual inspection of the standardized residuals plotted against the predicted values for each group in order to access homoscedasticity within groups. Homogeneity of variance was assessed using the

Levene's test ($p \geq 0.05$). Outputs from the one-way ANCOVA were also checked for univariate outliers in the standardized residuals (≥ ±3SD). Unusual points were further investigated. Finally, before interpreting the one-way ANCOVA, studentized residuals were checked for normal distribution, as assessed by the Shapiro-Wilks test ($p > 0.05$). If any assumptions were violated, data was further investigated. A pairwise comparison was undertaken to establish where the difference in mean change between the groups occurred, with p-values automatically adjusted using the Bonferroni correction.

A number of key primary components of HRPF and psychological measurements of HRQoL were also descriptively analysed to identify the levels of clinically meaningful values in the outcome variables. Participant results for the various dependent variables were classified into 3 group:; i) non-responders who had no change or had a negative response, ii) meaningful change indicated observed improvement in the outcome variable and, iii) MCID referred to participants who recorded a value equal or greater than the identified MCID for that outcome variable (Skelly 2021).

Those achieving MCID were presented according to the intention to treat (ITT) principle and the per protocol (PP) approach. There is validity in both approaches with ITT aiming to assess the effect of assigning PAET to a target population group and PP reports on the effect of adhering to a PAET programme such as an MCEP (Tripepi *et al.* 2020). ITT was expressed as a percentage of those who commenced the programme. PP was expressed as a percentage of those who re-tested PI.

All data analysis was performed using IBM SPSS statistics software (ver. 26). All values were reported as estimated marginal means and standard error.

## 4.4 Results

### 4.4.1 Characteristics of those who attended and did not attend for post testing

Of the initial 206 participants who commenced the MCEP, 59 (63.4%) from the CAD, 52 (57%) from OCD and 21 (95.5%) from the CAD-CG were retested after 10 weeks. Participants who were not post-tested included those who dropped out as outlined in study 1, along with participants who completed the programme but were unable attend for retesting at 10 weeks (13 CAD - 14% and 15 OCD - 16.5%). There were no significant differences in age, gender, distance to the MCEP, number of comorbidities, health indices, functional capacity or HRQoL between individuals who attended the post-test after 10 weeks and those that did not attend in both CAD and OCD as outlined in tables 4.1 to 4.4.

Table 4.1 Demographics of CAD participants who underwent post-testing and those that did not undergo post-testing.

| Variable | Post-tested | Not post-tested | Main effects |
|---|---|---|---|
| Sample size (n) | 59 | 34 | |
| Age (yr.) | 67.37±7.01 (68.0) | 64.88±7.00 (65.5) | U = 843.5, z = -1.274, p = 0.203 |
| **Gender** | | | $\chi^2(1, n=93) = 0.005$, p = 0.946 |
| Male | 43 (63.2%) | 25 (36.8%) | |
| Female | 16 (64%) | 9 (36%) | |
| %M | 73% | 74% | |
| Distance to MCEP (km) | 17.58±14.50 | 17.03±14.90 | t (91) = 0.173, p = 0.863 |
| No. of CD | 2.56±1.36 | 2.62±1.37 | t (91) = -0.199, p = 0.843 |

Values are expressed as absolute values (percentage) or mean±SD (median), M = male, F = female, MCEP = multi-disease, community-based exercise programme, CD = chronic disease

Table 4.2 Demographics of OCD participants who underwent post testing and those that did not undergo post-testing

| Variable | Post-tested | Not post-tested | Main effects |
|---|---|---|---|
| Sample size (n) | 52 | 39 | |
| Age (yr.) | 62.06±9.93 | 60.79±13.90 | t (65.52) = 0.482, p = 0.631 |
| **Gender** | | | $\chi^2(1, n=91) = 0.620, p = 0.431$ |
| Male | 27 (61.4%) | 17 (38.6%) | |
| Female | 25 (53.2%) | 22 (46.8%) | |
| %M | 52% | 44% | |
| Distance to MCEP (km) | 19.65±17.51 | 17.64±15.27 | t (89) = 0.573, p = 0.568 |
| No. of CD | 2.15±1.21 (2.0) | 1.77±0.81 (2.0) | U = 847.5, z = -1.412, p = 0.158 |

Values are expressed as absolute values (percentage) or mean±SD (median), M = male, F = female, MCEP = multi-disease, community-based exercise programme, CD = chronic disease

Table 4.3 Health and fitness characteristics of participants post tested and not post-tested in CAD

| | n | Post-tested | n | Not post-tested | Main Effect |
|---|---|---|---|---|---|
| SBP (mmHg) | 58 | 140.64±17.15 | 32 | 142.44±18.20 | t (88) = -0.466, p = 0.642 |
| DBP (mmHg) | 58 | 78.22±9.76 | 32 | 79.84±9.98 | t (88) = -0.747, p = 0.457 |
| RHR (bpm) | 59 | 64.98±9.85(64.0) | 34 | 64.59±10.18 (62.5) | U = 935.5, z = -0.539, p = 0.590 |
| Weight (kg) | 59 | 83.19±13.91 | 34 | 86.77±15.87 | t (91) = -1.135, p = 0.259 |
| BMI (kg/m$^2$) | 59 | 28.69±4.03 | 34 | 29.86±5.18 | t (56.17) = -1.131, p = 0.263 |
| Waist (cm) | 59 | 100.94±11.93 | 33 | 104.82±13.42 | t (90) = -1.429 p = 0.156 |
| Hip (cm) | 59 | 104.55±7.33 | 21 | 106.62±7.54 | t (78) = -1.101 p = 0.274 |
| WHR | 59 | 0.97±0.09 | 21 | 0.99±0.10 | t (78) = -0.898, p = 0.372 |
| GripD (kg) | 59 | 30.85±8.44 | 34 | 32.10±9.06 | t (91) = -0.672, p = 0.503 |
| GripND (kg) | 59 | 30.24±8.21 | 34 | 30.97±9.04 | t (91) = -0.400 p = 0.690 |
| 6MWTD (m) | 59 | 511.02±70.12 | 34 | 481.56±72.67 | t (91) = 1.926, p = 0.057 |
| S&R (cm) | 58 | 7.70±13.09 | 31 | 10.46±8.23 | t (84.59) = -1.219, p = 0.226 |
| STS (sec) | 59 | 26.37±6.91 (25.78) | 34 | 26.85±4.83 (26.45) | U = 1115.0, z = 0.894, p = 0.372 |
| WEMWBS | 55 | 58.06±8.95 | 28 | 54.25±8.86 | t (81) = 1.836, p = 0.070 |
| SF-12v2 PCS | 57 | 47.01±8.71 | 32 | 46.32±7.88 | t (87) = 0.373, p = 0.710 |
| SF-12v2 MCS | 57 | 53.37±8.96 | 32 | 52.94±8.84 | t (87) = 0.220, p = 0.827 |

Values are expressed as mean ± SD (median)
SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

Table 4.4 Health and fitness characteristics of participants post tested and not post-tested in OCD

| | n | Post-tested | n | Not post-tested | Main Effect |
|---|---|---|---|---|---|
| SBP (mmHg) | 48 | 140.77±17.78 | 34 | 135.91±21.72 | t (80) = 1.112, p = 0.270 |
| DBP (mmHg) | 48 | 79.88±8.19 | 34 | 81.56±9.41 | t (80) = -0.862, p = 0.391 |
| RHR (bpm) | 52 | 72.45±13.35 | 39 | 75.92±12.62 | t (89) = -1.256, p = 0.213 |
| Weight (kg) | 52 | 83.94±16.14 (80.9) | 39 | 82.16±18.47 (77.7) | U = 1708.0, z = -0.690, p = 0.490 |
| BMI ($kg/m^2$) | 52 | 29.43±5.06 | 39 | 29.12±5.91 | t (89) = 0.267, p = 0.790 |
| Waist (cm) | 52 | 100.91±12.67 | 39 | 101.99±15.40 | t (89) = -0.367 p = 0.714 |
| Hip (cm) | 52 | 107.54±10.94 (105.2) | 34 | 110.72±12.27 (109.5) | U = 1039.5, z = 1.374, p = 0.169 |
| WHR | 52 | 0.94±0.09 | 34 | 0.94±0.08 | t (84) = 0.194, p = 0.847 |
| GripD (kg) | 51 | 26.32±9.22 (25.0) | 38 | 27.93±10.64 (25.8) | U = 1039.5, z = 0.585, p = 0.559 |
| GripND (kg) | 51 | 25.50±10.18 (24.0) | 39 | 26.58±10.27 (25.0) | U = 1031.5, z = 0.301, p = 0.763 |
| 6MWTD (m) | 52 | 440.97±101.11 | 39 | 452.26±94.15 | t (89) = -0.543, p = 0.589 |
| S&R (cm) | 50 | 6.81±9.96 | 37 | 7.37±12.12 | t (85) = -0.234, p = 0.815 |
| STS (sec) | 51 | 29.60±7.03 | 37 | 31.76±8.28 | t (86) = -1.320, p = 0.190 |
| WEMWBS | 49 | 51.25±9.94 | 36 | 49.89±11.29 | t (83) = 0.587, p = 0.559 |
| SF-12v2 PCS | 51 | 42.72±9.47 | 39 | 40.13±10.29 | t (88) = 1.239, p = 0.219 |
| SF-12v2 MCS | 51 | 49.49±9.56 | 39 | 47.31±9.93 | t (88) = 1.054, p = 0.295 |

Values are expressed as mean ± SD (median)
SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, WHR = waist-to-hip ratio, GripD = handgrip of dominant hand, GripND = handgrip of non-dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh mental well-being scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score

### 4.4.2 Adverse Events

One participant fell during the post-test session while completing the 6MWT. The participant was a 68 yr. old female with a primary diagnosis of CAD who also suffered with OA. She had attended 10 sessions over the 10 weeks. She received first aid but did not complete the 6MWT. She was able return to exercise when the programme returned. One participant sustained a minor skin laceration that required immediate first aid attention. The incident occurred two weeks into the programme. The participant attended 14 sessions during the 10-week period.

### 4.4.3 Impact of MCEP on Health Indices, Functional Capacity and HRQoL Scores

A CSH covariance structure was found to have the lowest AIC and BIC for SBP, SF-12 PCS and dominant handgrip strength. The variances at BL and PI and the CSH ρ of the error term were found to be significant for all outcome variables (Appendix J).

A CS covariance structure was identified to have the lowest AIC and BIC for DBP, STS, RHR, waist circumference, BMI, S&R, WEMWBS, SF-12 MCS and 6MWD. The CS diagonal and CS covariance of the error term were found to be significant for all outcome variables using the CS covariance structure (Appendix J).

The type III test effects for the interaction of experimental group*time (between group) are outlined in table 4.5 along with the within-group custom contrasts for each outcome measure. The percentage change in health and fitness indices between BL and PI, based on estimated marginal means, are illustrated in figure 4.2.

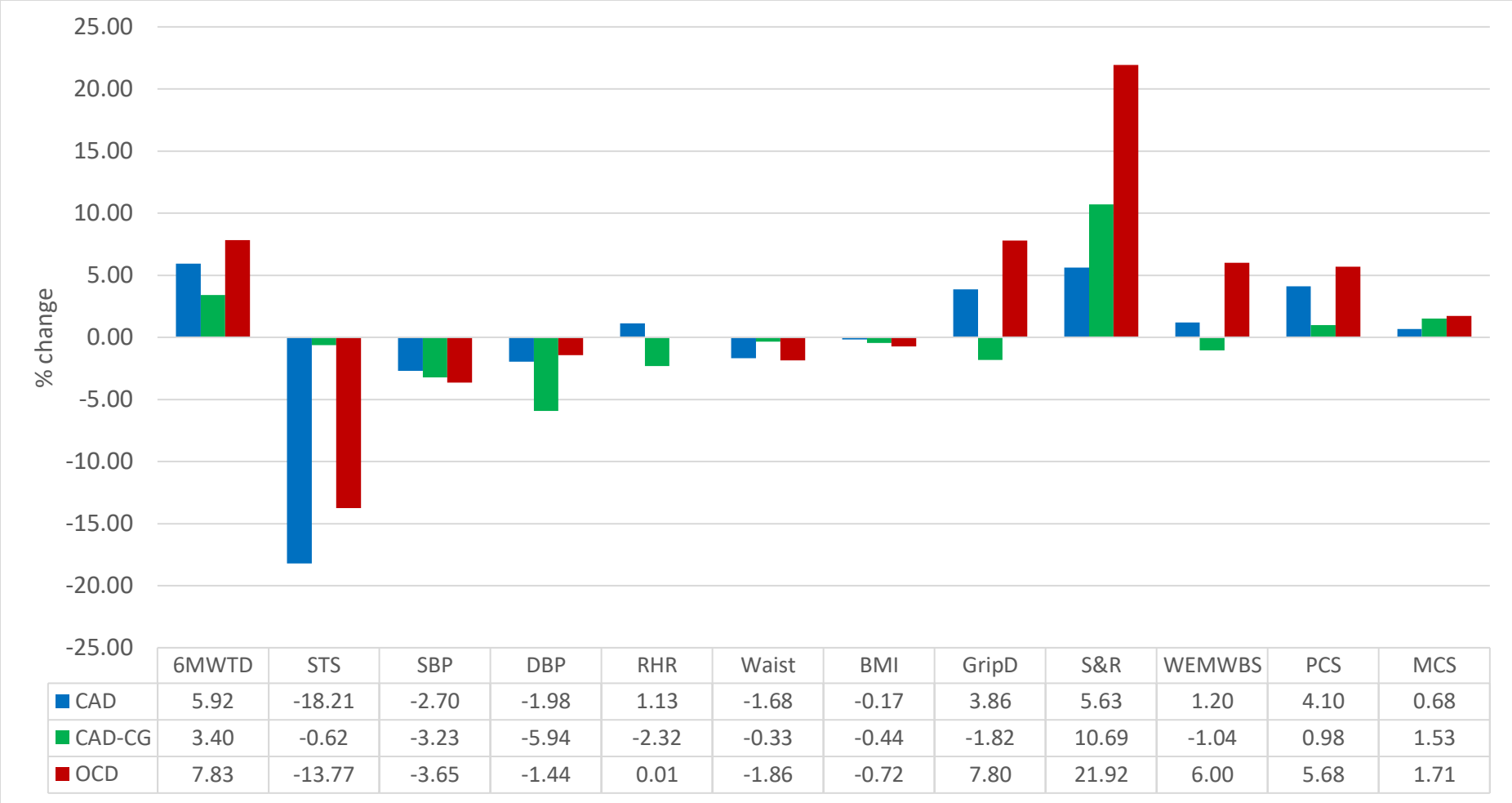
Table 4.5 Analysis of within- and between-group differences between participant health and fitness indices at baseline and post-intervention

| | BL | PI | WG | BL | PI | WG | BL | PI | WG | Group*Time Interaction | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **CAD (n=93)** | **CAD (n= 59)** | **p^** | **CAD-CG (n=22)** | **CAD-CG (n=21)** | **p^** | **OCD (n=91)** | **OCD (n=52)** | **p^** | **df** | **F** | **p*** | **d** |
| SBP (mmHg) | 141.05±2.01 | 137.24±1.97 | 0.055 | 145.30±4.06 | 140.61±3.44 | 0.190 | 137.72±2.10 | 132.70±2.1 | 0.022 | 2, 135.1 | 0.089 | 0.915 | 0.54 |
| DBP (mmHg) | 77.93±1.00 | 76.39±1.16 | 0.149 | 80.99±2.00 | 76.18±2.04 | **0.011** | 81.18±1.03 | 80.01±1.27 | 0.321 | 2, 133.2 | 1.465 | 0.235 | 0.56 |
| RHR (bpm) | 64.75±1.22 | 65.48±1.43 | 0.574 | 67.37±2.42 | 65.81±2.47 | 0.487 | 73.29±1.22 | 73.30±1.50 | 0.993 | 2, 140.3 | 0.395 | 0.674 | 0.77 |
| Waist (cm) | 101.26±1.38 | 99.56±1.43 | **0.011** | 99.20±2.72 | 98.87±2.73 | 0.770 | 100.61±1.37 | 98.74±1.45 | **0.009** | 2, 128.1 | 0.745 | 0.477 | 0.20 |
| BMI (kg/m$^2$) | 29.34±0.54 | 29.29±0.54 | 0.562 | 29.70±1.07 | 29.57±1.07 | 0.400 | 29.12±0.54 | 28.91±0.54 | 0.037 | 2, 125.1 | 0.668 | 0.515 | 0.16 |
| GripD (kg) | 28.50±0.85 | 29.60±0.84 | 0.107 | 30.73±1.70 | 30.17±1.51 | 0.641 | 28.08±0.84 | 30.27±0.87 | **0.003** | 2, 138.3 | 1.978 | 0.142 | 0.26 |
| 6MWTD (m) | 506.90±8.63 | 536.93±9.33 | **0.000** | 519.61±17.22 | 537.29±17.34 | 0.072 | 458.26±8.56 | 494.12±9.4 | **0.000** | 2, 132.1 | 1.241 | 0.293 | 1.00 |
| S&R (cm) | 11.55±1.15 | 12.20±1.22 | 0.362 | 7.95±2.26 | 8.80±2.28 | 0.489 | 6.66±1.09 | 8.12±1.20 | 0.064 | 2, 130.0 | 0.296 | 0.744 | 0.54 |
| STS (sec) | 26.97±0.64 | 22.06±0.72 | **0.000** | 27.52±1.27 | 27.35±1.28 | 0.859 | 28.91±0.65 | 24.93±0.76 | **0.000** | 2, 138.0 | 8.609 | **0.000** | 1.19 |
| WEMWBS | 56.54±1.18 | 57.22±1.32 | 0.504 | 57.53±2.31 | 56.93±2.26 | 0.735 | 51.13±1.13 | 54.20±1.30 | **0.003** | 2, 121.2 | 2.190 | 0.116 | 0.64 |
| SF-12 PCS | 46.06±0.97 | 47.95±0.95 | 0.040 | 45.69±1.90 | 46.14±1.64 | 0.780 | 42.57±0.96 | 44.99±1.00 | **0.013** | 2, 142.7 | 0.564 | 0.570 | 0.47 |
| SF-12 MCS | 53.25±1.01 | 53.61±1.15 | 0.721 | 54.40±1.96 | 55.23±1.99 | 0.623 | 48.44±0.99 | 49.27±1.20 | 0.438 | 2, 134.4 | 0.062 | 0.939 | 0.76 |

Values are presented as estimated marginal means ± standard error, adjusted for the following covariates baseline GripD and 6MWD, significant if ^ $p < 0.017$ and *$p < 0.05$, df = degrees of freedom, F = F statistic, d = Cohen's d effect size

Group*Time Interaction indicates between group differences and was analysed using a linear MMA
WG - Within group differences were analysed using custom contrasts in the linear MMA

SBP = systolic blood pressure, DBP = diastolic blood pressure, RHR = resting heart rate, BMI = body mass index, GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, S&R = sit and reach test, STS = sit to stand test, WEMWBS = Warwick Edinburgh Mental Well-Being Scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score




| | 6MWTD | STS | SBP | DBP | RHR | Waist | BMI | GripD | S&R | WEMWBS | PCS | MCS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CAD | 5.92 | -18.21 | -2.70 | -1.98 | 1.13 | -1.68 | -0.17 | 3.86 | 5.63 | 1.20 | 4.10 | 0.68 |
| CAD-CG | 3.40 | -0.62 | -3.23 | -5.94 | -2.32 | -0.33 | -0.44 | -1.82 | 10.69 | -1.04 | 0.98 | 1.53 |
| OCD | 7.83 | -13.77 | -3.65 | -1.44 | 0.01 | -1.86 | -0.72 | 7.80 | 21.92 | 6.00 | 5.68 | 1.71 |

Figure 4.2 Percentage change in health and fitness indices between BL and PI

**Systolic Blood Pressure**

The final parameter estimates for the fixed effects of the final model of choice for SBP are shown in table 4.6. There was no significant group x time interaction effect. There was a significant main effect for time. SBP decreased significantly between BL and PI in OCD (5.02 ± 2.17 mmHg). Following adjustment for multiple comparisons, the decrease in SBP was no longer significant.

Table 4.6 Parameter estimates of main fixed effects for SBP

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 149.80 | 6.69 | 162.17 | 22.407 | 0.000 | (136.60 to 163.00) |
| Gender ref: female | 3.95 | 2.73 | 160.49 | 1.451 | 0.149 | (-1.43 to 9.34) |
| Experimental group ref: OCD | | | | | | |
| CAD | 4.54 | 2.95 | 140.15 | 1.538 | 0.126 | (-1.30 to 10.37) |
| CAD-CG | 7.91 | 4.18 | 132.77 | 1.892 | 0.061 | (-0.36 to 16.18) |
| Time ref: time point 2 | 5.02 | 2.17 | 143.42 | 2.317 | **0.022** | (0.74 to 9.30) |
| GripD at BL | -0.07 | 0.15 | 172.19 | -0.475 | 0.636 | (-0.35 to 0.22) |
| 6MWTD at BL | -0.04 | 0.01 | 158.02 | -2.558 | **0.011** | (-0.06 to -0.01) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**Diastolic Blood Pressure**

The final parameter estimates for the fixed effects of the final model of choice for DBP are shown in table 4.7. There was no significant group x time interaction effect. There was a significant main effect for experimental group. DBP decreased significantly between BL and PI in CAD-CG (4.82 ± 1.87 mmHg). The custom contrasts between CAD and OCD showed a difference at BL (-3.25 ± 1.45 mmHg, df 238.5, t = -2.237, p = 0.026) and PI (-3.62 ± 1.73 mmHg, df 298.9, t = -2.087, p = 0.038) indicating that DBP was significantly lower in CAD at both time points. Following adjustment for multiple comparisons, the difference in DBP was no longer significant.

Table 4.7 Parameter estimates of main fixed effects for DBP

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 72.76 | 3.63 | 189.13 | 20.037 | 0.000 | (65.59 to 79.92) |
| Gender ref: female | 2.67 | 1.47 | 178.42 | 1.821 | 0.070 | (-0.22 to 5.56) |
| Experimental group ref: OCD | | | | | | |
| CAD | -3.62 | 1.73 | 298.92 | -2.087 | **0.038** | (-7.03 to -0.21) |
| CAD-CG | -3.83 | 2.46 | 270.29 | -1.560 | 0.120 | (-8.67 to 1.00) |
| Time ref: time point 2 | 1.17 | 1.18 | 143.43 | 0.995 | 0.321 | (-1.16 to 3.50) |
| GripD at BL | 0.08 | 0.08 | 185.43 | 1.004 | 0.317 | (-0.08 to 0.23) |
| 6MWTD at BL | 0.01 | 0.01 | 176.96 | 1.005 | 0.316 | (-0.01 to 0.02) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**Resting Heart Rate**

The final parameter estimates for the fixed effects of the final model of choice for RHR are shown in table 4.8. There was no significant group x time interaction effect. In addition, there were no significant within-group differences between BL and PI. There was a significant main effect for experimental group. The custom contrasts between CAD and OCD identified a significant difference in RHR at BL (-8.55 ± 1.75 bpm, df 252.4, t = -4.892, p = 0.000) and PI (-7.83 ± 2.09 bpm, df 317.7, t = -3.748, p = 0.000). This was also evident between CAD-CG and OCD at BL (-5.92 ± 2.76 bpm, df 254.8, t = -2.145, p = 0.033) and PI (-7.50 ± 2.94 bpm, df 285.3, t = -2.553, p = 0.011). This was due to a higher RHR in OCD than both CAD groups at BL and PI.

Table 4.8 Parameter estimates of main fixed effects for RHR

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 77.66 | 4.35 | 204.81 | 17.861 | 0.000 | (69.09 to 86.23) |
| Gender ref: female | 1.38 | 1.78 | 192.06 | 0.772 | 0.441 | (-2.14 to 4.89) |
| Experimental group ref: OCD | | | | | | |
| CAD | -7.83 | 2.09 | 317.72 | -3.748 | **0.000** | (-11.93 to -3.72) |
| CAD-CG | -7.50 | 2.94 | 285.28 | -2.553 | **0.011** | (-13.27 to -1.72) |
| Time ref: time point 2 | -0.01 | 1.39 | 151.40 | -0.009 | 0.993 | (-2.76 to 2.73) |
| GripD at BL | -0.09 | 0.09 | 198.16 | -0.929 | 0.354 | (-0.27 to 0.10) |
| 6MWTD at BL | -0.01 | 0.01 | 188.75 | -0.568 | 0.571 | (-0.02 to 0.01) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**Waist Circumference**

The final parameter estimates for the fixed effects of the final model of choice for waist circumference are shown in table 4.9. There was no significant group x time interaction effect. There was a significant main effect for gender and time. There was a significant decrease in waist circumference between BL and PI in both CAD (1.69 ± 0.65 cm) and OCD (1.87 ± 0.71 cm). Females, irrespective of time point and experimental group, had a lower waist circumference (7.10 ± 2.14 cm, df 195.3, F = 11.026, p = 0.001) than men.

Table 4.9 Parameter estimates of main fixed effects for waist circumference

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 111.15 | 5.15 | 198.06 | 21.568 | 0.000 | (100.99 to 121.32) |
| Gender ref: female | 7.10 | 2.14 | 195.28 | 3.321 | **0.001** | (2.89 to 11.32) |
| Experimental group ref: OCD | | | | | | |
| CAD | 0.82 | 2.07 | 238.94 | 0.397 | 0.692 | (-3.26 to 4.90) |
| CAD-CG | 0.13 | 3.15 | 216.22 | 0.043 | 0.966 | (-6.08 to 6.35) |
| Time ref: time point 2 | 1.87 | 0.71 | 130.04 | 2.637 | **0.009** | (0.47 to 3.27) |
| GripD at BL | 0.07 | 0.11 | 196.26 | 0.622 | 0.535 | (-0.15 to 0.29) |
| 6MWTD at BL | -0.04 | 0.01 | 194.32 | -3.455 | **0.001** | (-0.06 to -0.02) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**Body Mass Index**

The final parameter estimates for the fixed effects of the final model of choice for BMI are shown in table 4.10. There was no significant group x time interaction effect. There was a significant decrease in BMI between BL and PI in OCD (0.21 ± 0.10 $kg \cdot m^2$). The decrease in BMI was no longer significant following adjustment for multiple comparisons.

Table 4.10 Parameter estimates of main fixed effects for BMI

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 32.92 | 2.03 | 198.18 | 16.210 | 0.000 | (28.91 to 36.92) |
| Gender ref: female | -0.46 | 0.85 | 197.79 | -0.541 | 0.589 | (-2.13 to 1.22) |
| Experimental group ref: OCD | | | | | | |
| CAD | 0.38 | 0.78 | 203.83 | 0.489 | 0.625 | (-1.16 to 1.92) |
| CAD-CG | 0.67 | 1.22 | 200.45 | 0.544 | 0.587 | (-1.75 to 3.08) |
| Time ref: time point 2 | 0.21 | 0.10 | 125.37 | 2.105 | 0.037 | (0.01 to 0.40) |
| GripD at BL | 0.03 | 0.04 | 197.92 | 0.586 | 0.558 | (-0.06 to 0.11) |
| 6MWTD at BL | -0.01 | 0.004 | 197.70 | -2.203 | **0.029** | (-0.02 to -0.001) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**Dominant Handgrip Strength**

The final parameter estimates for the fixed effects of the final model of choice for dominant HGS are shown in table 4.11. The group x time interaction effect was not statistically significant. There was a significant main effect for both gender and time. Muscle strength (2.19 ± 0.73 kg) improved significantly between BL and PI in OCD. Males, irrespective of time point and experimental group had a stronger handgrip score (10.26 ± 1.05 kg, df 185.4, F = 95.625, p = 0.000) than females.

Table 4.11 Parameter estimates of main fixed effects for dominant HGS

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 12.67 | 2.82 | 182.36 | 4.492 | 0.000 | (7.11 to 18.24) |
| Gender ref: female | 10.26 | 1.05 | 185.36 | 9.779 | **0.000** | (8.19 to 12.33) |
| Experimental group ref: OCD | | | | | | |
| CAD | -0.66 | 1.23 | 168.77 | -0.537 | 0.592 | (-3.10 to 1.77) |
| CAD-CG | -0.10 | 1.78 | 146.56 | -0.055 | 0.956 | (-3.61 to 3.41) |
| Time ref: time point 2 | -2.19 | 0.73 | 145.55 | -2.988 | **0.003** | (-3.64 to -0.74) |
| 6MWTD at BL | 0.03 | 0.01 | 181.84 | 4.427 | **0.000** | (0.01 to 0.04) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**Six-Minute Walk Test**

The final parameter estimates for the fixed effects of the final model of choice for 6MWTD are shown in table 4.12. There was no significant group x time interaction. There was a significant main effect for gender, time, and experimental group. There was a significant increase in 6MWTD between BL and PI in CAD (30.04 ± 5.83 m) and OCD (35.87 ± 6.21 m). The custom contrasts between CAD and OCD indicated a significant difference at BL (48.64 ± 12.15 m, df 220.4, t = 4.004, p = 0.000) and PI (42.81 ± 13.27 m, df 279.4, t = 3.226, p = 0.001). This was also evident between CAD-CG and OCD at BL (61.35 ± 19.40 m, df 220.6, t = 3.162, p = 0.002) and PI (43.16 ± 19.94 m, df 240.3, t = 2.165, p = 0.031). These differences were because both CAD groups covered a greater 6MWTD at BL and PI compared to OCD. Following adjustment for multiple comparisons, the difference between CAD-CG and OCD in 6MWDT was no longer significant PI. Females, irrespective of time point and experimental group, covered a greater distance in the 6MWT than men (50.03 ± 13.14 m, df 200.6, F = 14.502, p = 0.000).

Table 4.12 Parameter estimates of main fixed effects for 6MWTD

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 425.31 | 18.62 | 219.89 | 22.840 | 0.000 | (388.61 to 462.01) |
| Gender ref: female | -50.03 | 13.14 | 200.61 | -3.808 | **0.000** | (-75.93 to -24.13) |
| Experimental group ref: OCD | | | | | | |
| CAD | 42.81 | 13.27 | 279.37 | 3.226 | **0.001** | (16.69 to 68.93) |
| CAD-CG | 43.16 | 19.94 | 240.28 | 2.165 | **0.031** | (3.89 to 82.44) |
| Time ref: time point 2 | -35.87 | 6.21 | 135.76 | -5.772 | **0.000** | (-48.16 to -23.58) |
| GripD at BL | 3.15 | 0.68 | 202.60 | 4.664 | **0.000** | (1.82 to 4.49) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, BL = baseline

**Sit and Reach Test**

The final parameter estimates for the fixed effects of the final model of choice for S&R are shown in table 4.13. There was no significant group x time interaction or any within group differences identified between BL and PI. There was a significant main effect for gender and experimental group. The custom contrasts between CAD and OCD found a significant difference at BL (4.89 ± 1.59 cm, df 214.2, t = 3.069, p = 0.002) and PI (4.09 ± 1.72 cm, df 264.8, t = 2.379, p = 0.018) indicating that CAD performed better in the S&R test at BL and PI. Females, irrespective of time point and experimental group, had better flexibility (11.44 ± 1.53 cm, df 195.7, F = 55.796, p = 0.000) than males.

Table 4.13 Parameter estimates of main fixed effects for S&R

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 13.84 | 1.41 | 257.13 | 9.837 | 0.000 | (11.07 to 16.61) |
| Gender ref: female | -11.44 | 1.53 | 195.66 | -7.470 | **0.000** | (-14.46 to -8.42) |
| Experimental group ref: OCD | | | | | | |
| CAD | 4.09 | 1.72 | 264.83 | 2.379 | **0.018** | (0.70 to 7.47) |
| CAD-CG | 0.68 | 2.58 | 231.48 | 0.264 | 0.792 | (-4.40 to 5.76) |
| Time ref: time point 2 | -1.45 | 0.78 | 134.19 | -1.865 | 0.064 | (-3.00 to 0.09) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
Covariates were removed due to high correlation with intercept

**Sit to Stand Test**

Preliminary analysis identified a single extreme outlier (>8 SD) that violated most of the assumptions for a linear MMA. This value was subsequently removed. The final parameter estimates for the fixed effects of the final model of choice for STS are shown in table 4.14. There was a significant group*time interaction. Post hoc analysis (Table 4.15) of the mean change between BL and PI found that the improvement in STS was greater in CAD (-4.95 ± 0.61 sec) and OCD (-3.69 ± 0.70 sec) than CAD-CG (0.05 ± 1.05 sec).

There was a significant main effect for experimental group and time. There was a significant decrease in STS performance in both CAD (4.91 ± 0.58 sec) and OCD (3.99 ± 0.63 sec) between BL and PI. Custom contrasts between CAD and CAD-CG identified no difference in STS at BL (-0.55 ± 1.38 sec, df 240.7, t = -0.401, p = 0.689). In contrast, there was a difference between the two groups PI (-5.28 ± 1.43 sec, df 263.9, t = -3.692, p = 0.000). Although performance in the STS improved significantly in OCD following their participation in the MCEP, they were still slower than the CAD at BL (-1.94 ± 0.92 sec m, df 235.0, t = -2.106, p = 0.036) and PI (-2.86 ± 1.06 sec, df 303.1, t = -2.705, p = 0.007). Following adjustment for multiple comparisons, the difference was only significant PI.

Table 4.14 Parameter estimates of main fixed effects for STS

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 42.86 | 2.33 | 208.18 | 18.397 | 0.000 | (38.26 to 47.45) |
| Gender ref: female | 0.93 | 0.96 | 195.07 | 0.968 | 0.334 | (-0.96 to 2.82) |
| Experimental group ref: OCD | | | | | | |
| CAD | -2.86 | 1.06 | 303.07 | -2.705 | **0.007** | (-4.95 to -0.78) |
| CAD-CG | 2.42 | 1.52 | 264.29 | 1.595 | 0.112 | (-0.57 to 5.41) |
| Time ref: time point 2 | 3.99 | 0.63 | 146.26 | 6.376 | **0.000** | (2.75 to 5.22) |
| GripD at BL | -0.03 | 0.05 | 199.86 | -0.668 | 0.505 | (-0.13 to 0.07) |
| 6MWTD at BL | -0.04 | 0.01 | 197.83 | -7.425 | **0.000** | (-0.05 to -0.03) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

Table 4.15 STS pairwise comparison for the mean change between BL and PI

| Experimental group | Mean Difference | SE | p | C.I. |
|---|---|---|---|---|
| CAD – CAD-CG | -4.901 | 1.191 | **0.000** | (-7.791 to -2.010) |
| CAD – OCD | -1.258 | 0.957 | 0.573 | (-3.580 to 1.065) |
| OCD – CAD-CG | -3.643 | 1.317 | **0.020** | (-6.840 to -0.446) |

F (2, 123) = 8.497, p = 0.000, partial $\eta^2$ = 0.12
Based on estimated marginal means

**Warwick Edinburgh Mental Well-Being Scale**

The final parameter estimates for the fixed effects of the final model of choice for WEMWBS are shown in table 4.16. There was no significant group x time interaction. There was a significant main effect for time. There was a significant improvement (3.08 ± 1.03) between BL and PI in perceived mental health in OCD. Custom contrasts indicated higher perceived mental health in CAD compared to OCD at BL (5.41 ± 1.65, df 217.9, t = 3.274, p = 0.001) and between CAD-CG and OCD at BL (6.40 ± 2.62, df 237.9, t = 2.447, p = 0.015). Perceived mental health scores between CAD and OCD and between CAD-CG and OCD were not significantly different PI.

Table 4.16 Parameter estimates of main fixed effects for WEMWBS

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 50.84 | 4.13 | 191.97 | 12.301 | 0.000 | (42.69 to 58.99) |
| Gender ref: female | 0.52 | 1.73 | 186.99 | 0.299 | 0.765 | (-2.89 to 3.93) |
| Experimental group ref: OCD | | | | | | |
| CAD | 3.01 | 1.87 | 278.89 | 1.609 | 0.109 | (-0.67 to 6.70) |
| CAD-CG | 2.72 | 2.65 | 245.25 | 1.028 | 0.305 | (-2.50 to 7.94) |
| Time ref: time point 2 | -3.08 | 1.03 | 124.35 | -2.977 | **0.003** | (-5.12 to -1.03) |
| GripD at BL | -0.03 | 0.09 | 190.66 | -0.335 | 0.738 | (-0.21 to 0.15) |
| 6MWTD at BL | 0.01 | 0.01 | 184.15 | 0.963 | 0.337 | (-0.01 to 0.03) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**SF-12 Physical Component Score**

The final parameter estimates for the fixed effects of the final model of choice for PCS are shown in table 4.17. There was no significant group x time interaction. There was a significant main effect for both experimental group and time. Perceived physical health improved significantly between BL and PI in CAD (1.88 ± 0.91) and OCD (2.42 ± 0.97). Following adjustment for multiple comparisons, the improvement in perceived physical health was no longer significant in CAD. Based on custom contrasts PCS values were significantly higher in CAD- IG than OCD at BL (3.49 ± 1.38, df 209.8, t = 2.523, p = 0.012) and PI (2.95 ± 1.39, df 157.7, t = 2.122, p = 0.035). Following adjustment for multiple comparisons, the difference in PCS between CAD and OCD was no longer significant PI.

Table 4.17 Parameter estimates of main fixed effects for SF-12 PCS

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 32.48 | 3.18 | 184.91 | 10.214 | 0.000 | (26.21 to 38.76) |
| Gender ref: female | 1.21 | 1.32 | 184.55 | 0.918 | 0.360 | (-1.39 to 3.80) |
| Experimental group ref: OCD | | | | | | |
| CAD | 2.95 | 1.39 | 157.67 | 2.122 | **0.035** | (0.20 to 5.70) |
| CAD-CG | 1.14 | 1.96 | 146.47 | 0.583 | 0.560 | (-2.72 to 5.01) |
| Time ref: time point 2 | -2.42 | 0.97 | 151.14 | -2.500 | **0.013** | (-4.33 to -0.51) |
| GripD at BL | -0.04 | 0.07 | 192.70 | -0.537 | 0.592 | (-0.17 to 0.10) |
| 6MWTD at BL | 0.03 | 0.01 | 176.45 | 4.098 | **0.000** | (0.01 to 0.04) |

Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

**SF-12 Mental Component Score**

The final parameter estimates for the fixed effects of the final model of choice for MCS are shown in table 4.18. There was no significant group x time interaction or any within-group differences between BL and PI. There was a significant main effect for experimental group. Custom contrasts indicated a higher MCS in CAD than OCD at BL (4.82 ± 1.43, df 242.1, t = 3.360, p = 0.001) and PI (4.34 ± 1.67, df 307.4, t = 2.596, p = 0.010). Similarly, there was a higher MCS between CAD-CG and OCD at BL (5.96 ± 2.24, df 242.4, t = 2.665, p = 0.008) and PI (5.96 ± 2.36, df 272.5, t = 2.522, p = 0.012).

Table 4.18 Parameter estimates of main fixed effects for SF-12 MCS

| Parameter | Estimate | SE | df | t | p | C.I. |
|---|---|---|---|---|---|---|
| Intercept | 50.76 | 3.59 | 201.34 | 14.154 | 0.000 | (43.69 to 57.83) |
| Gender ref: female | 0.42 | 1.47 | 190.26 | 0.284 | 0.777 | (-2.48 to 3.31) |
| Experimental group ref: OCD | | | | | | |
| CAD | 4.34 | 1.67 | 307.44 | 2.596 | **0.010** | (1.05 to 7.64) |
| CAD-CG | 5.96 | 2.36 | 272.45 | 2.522 | **0.012** | (1.31 to 10.61) |
| Time ref: time point 2 | -0.83 | 1.07 | 144.75 | -0.778 | 0.438 | (-2.94 to 1.28) |
| GripD at BL | -0.05 | 0.08 | 195.44 | -0.697 | 0.487 | (-0.21 to 0.10) |
| 6MWTD at BL | -0.0002 | 0.01 | 185.87 | -0.030 | 0.976 | (-0.02 to 0.01) |

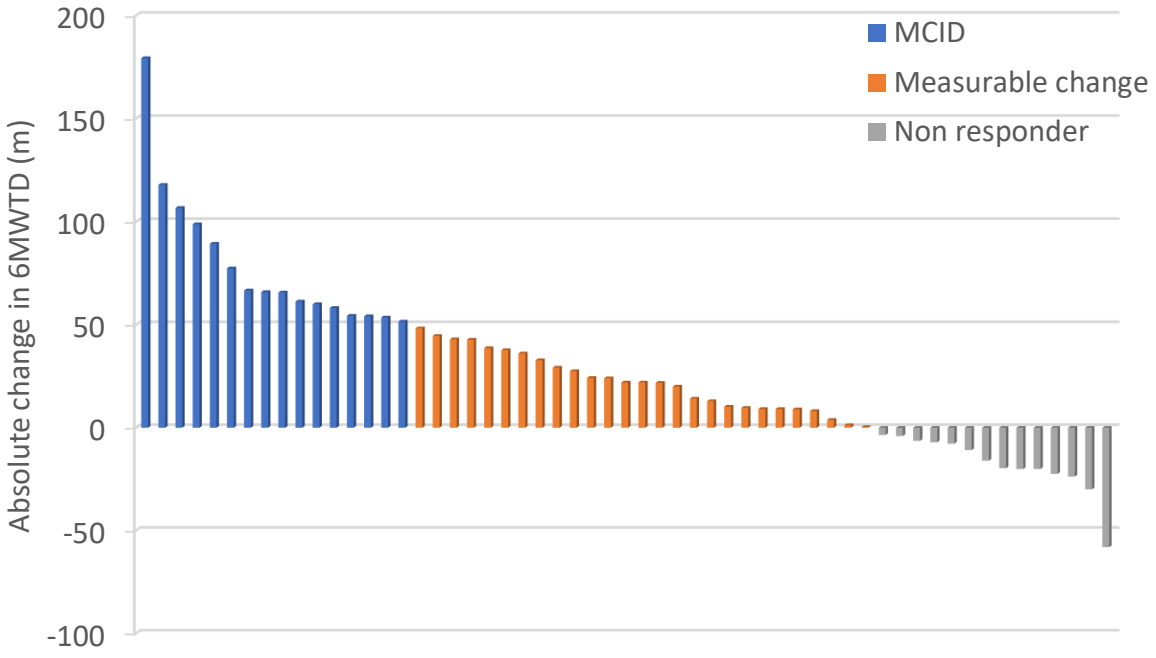
Reference category for intervention group is OCD, intervention group is expressed as CAD compared to OCD and CAD-CG to OCD
Reference category for gender is female, gender is expressed as males compared to females
Reference category for time is time point 2, time is expressed as time point 1 compared to time point 2
GripD = Handgrip of dominant hand, 6MWTD = 6-minute walk test distance, BL = baseline

### 4.4.4 Clinically Meaningful Differences

**Six-Minute Walk Test**

A total of 57 CAD, 51 OCD and 21 CAD-CG completed the 6MWT at BL and PI. A clinically meaningful improvement (≥ 50m) was achieved in 28%, 31% and 14% in CAD, OCD and CAD-CG, respectively (Figure 4.2), while 47%, 49% and 48% achieved a measurable change (≥0.01 m).

**a.**



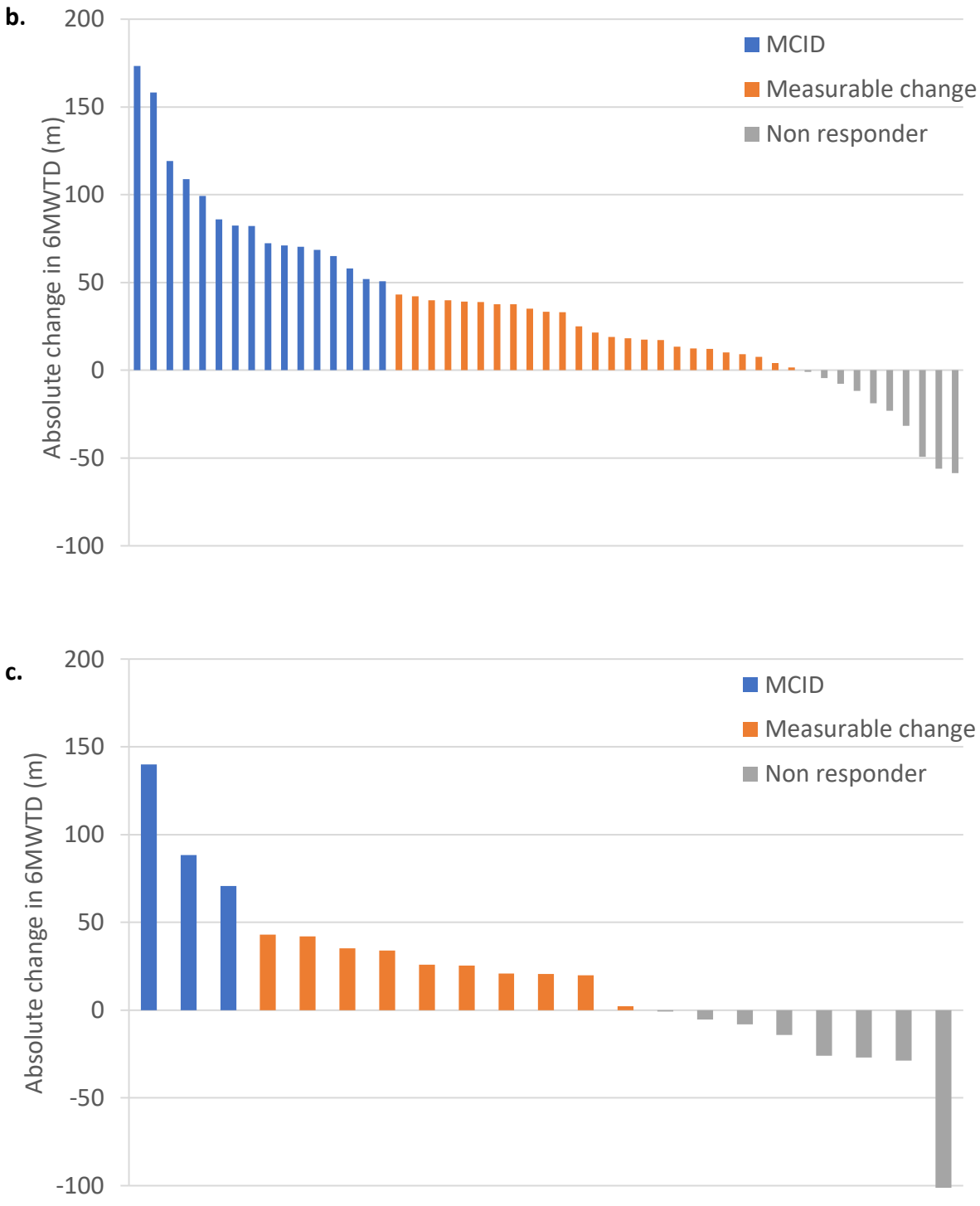
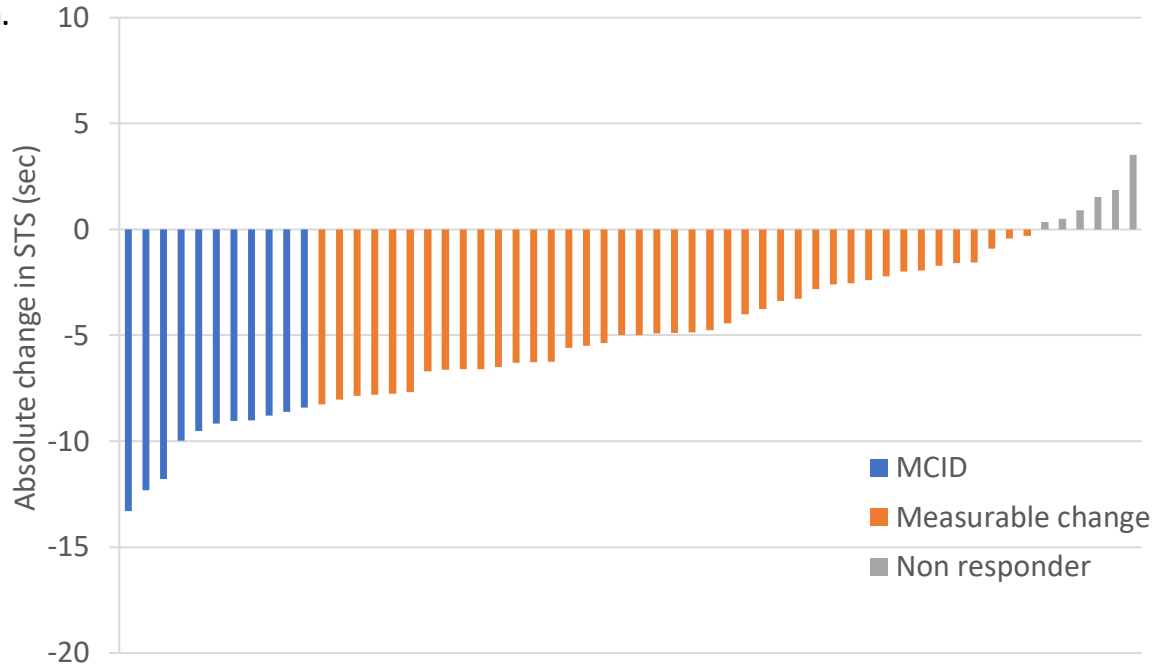



Figure 4.3 Absolute change in 6MWTD between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**Sit to Stand Test**

A total of 58 CAD, 50 OCD and 21 CAD-CG completed the STS at BL and PI. A clinically meaningful decrease (≥8.4 sec) was achieved in 19%, 16% and 0% in CAD, OCD and CAD-CG, respectively (Figure 4.3), while 71%, 62% and 48% achieved a measurable change (≥0.1 sec).

**a.**



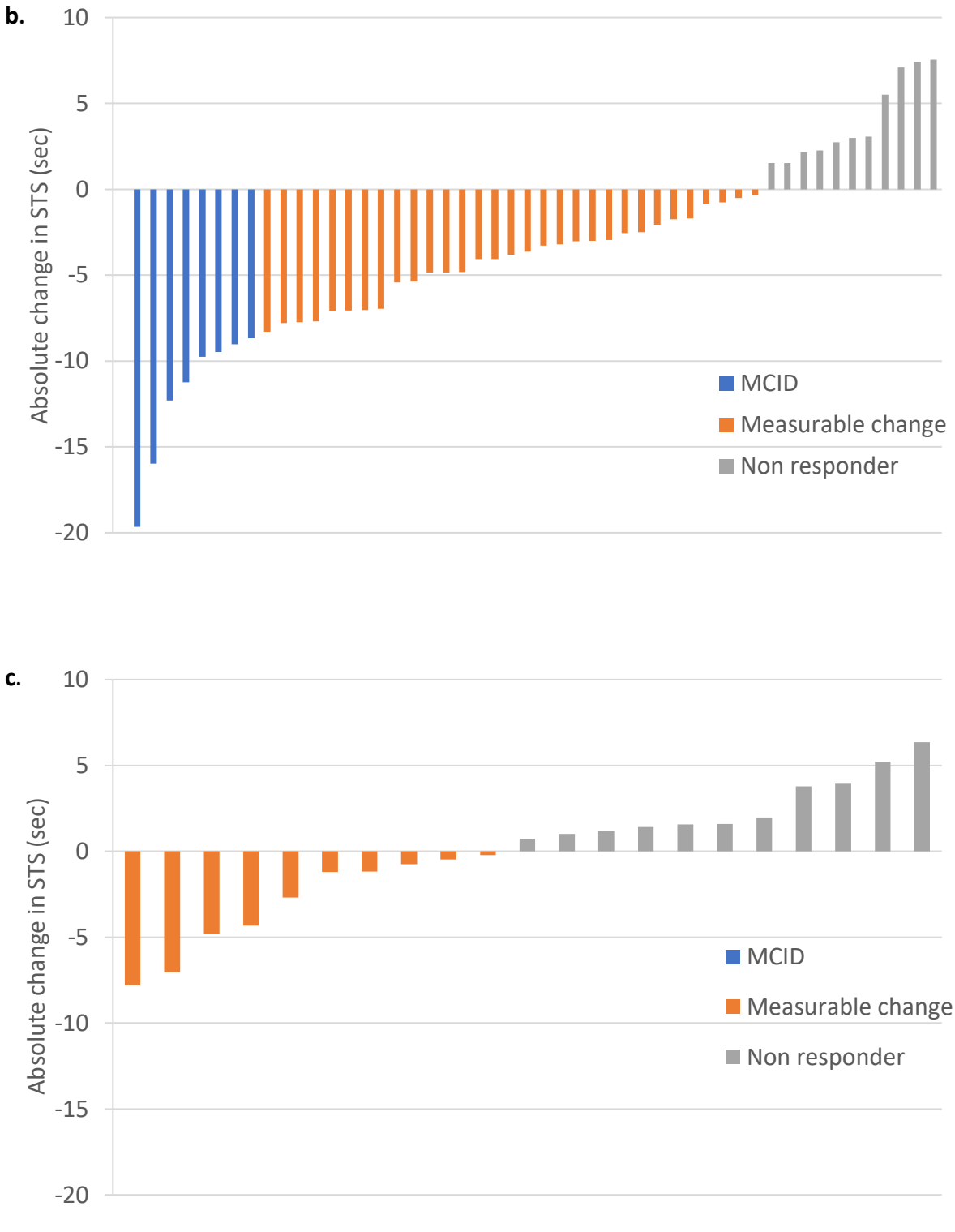
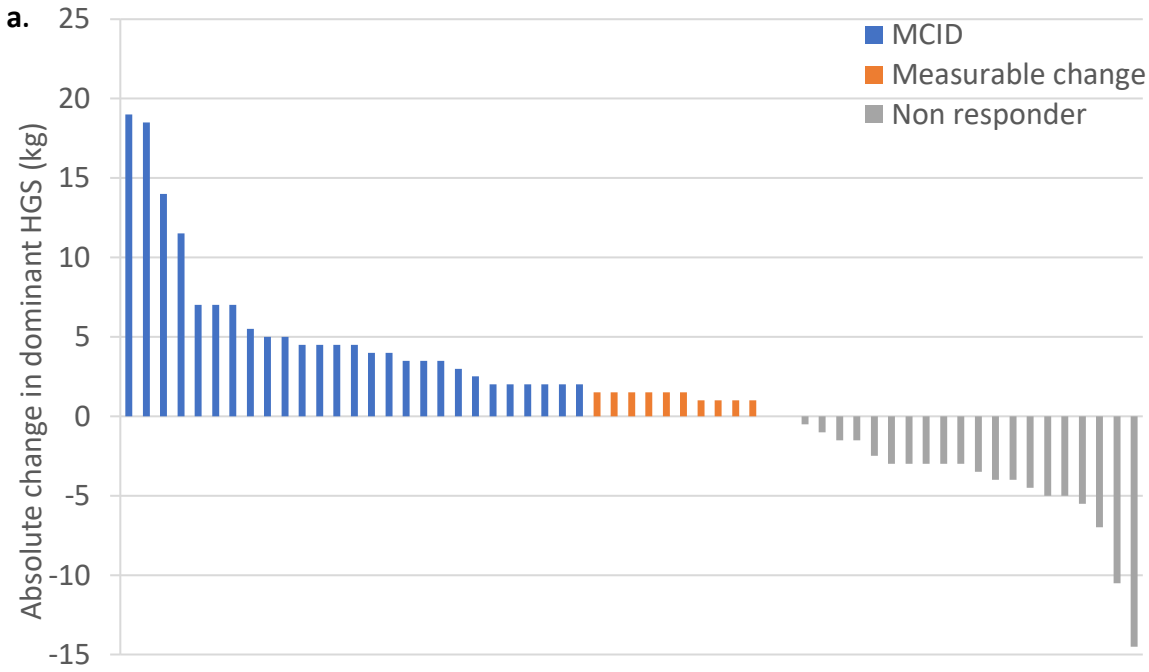



Figure 4.4 Absolute change in STS between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**Dominant Handgrip Strength**

A total of 59 CAD, 50 OCD and 21 CAD-CG completed HGS test in the dominant hand at BL and PI. A clinically meaningful improvement (≥1.64 kg) was achieved in 46%, 58% and 24% in CAD, OCD and CAD-CG, respectively (Figure 4.4), while 17%, 8% and 0% achieved a measurable change (≥0.1 kg).



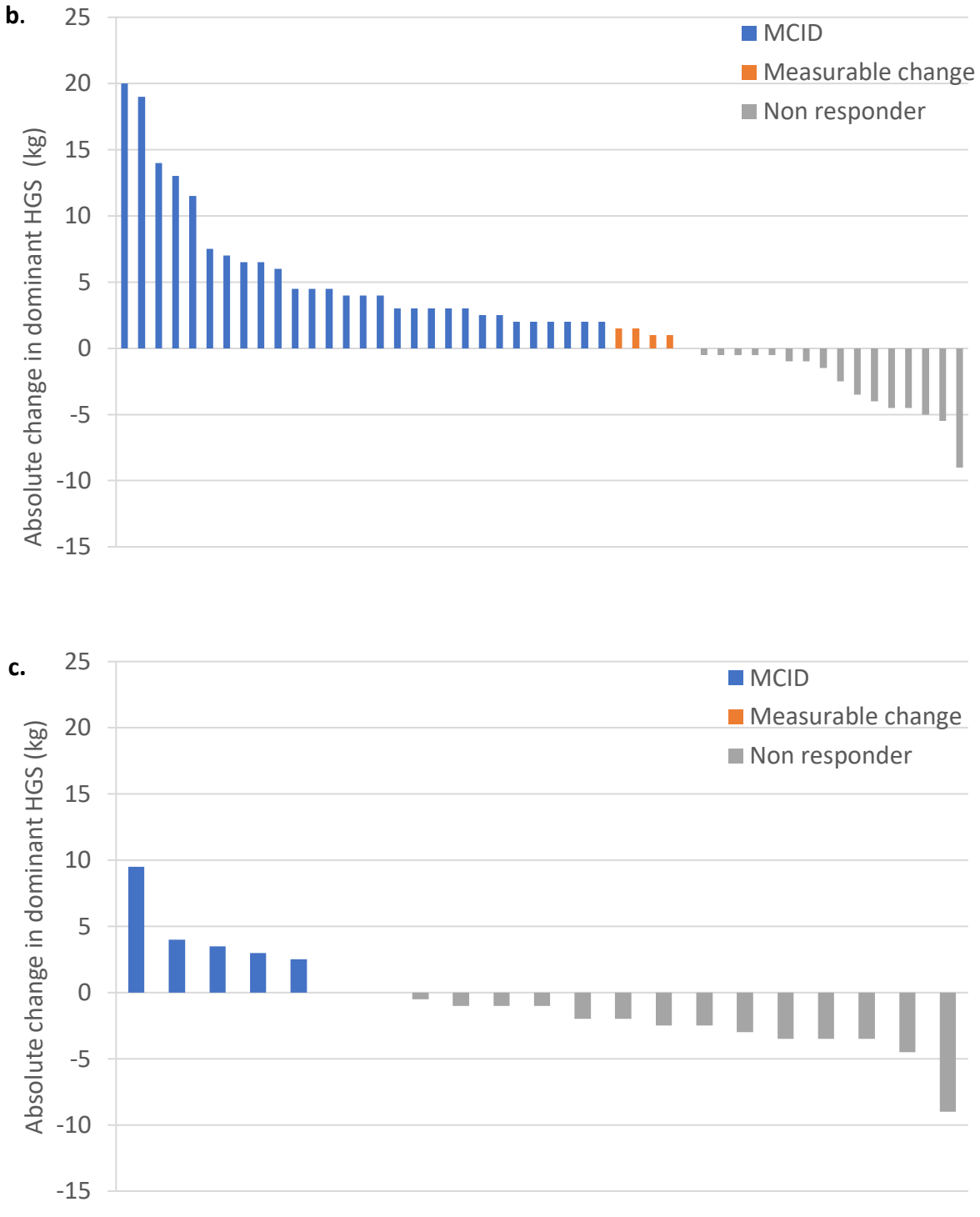
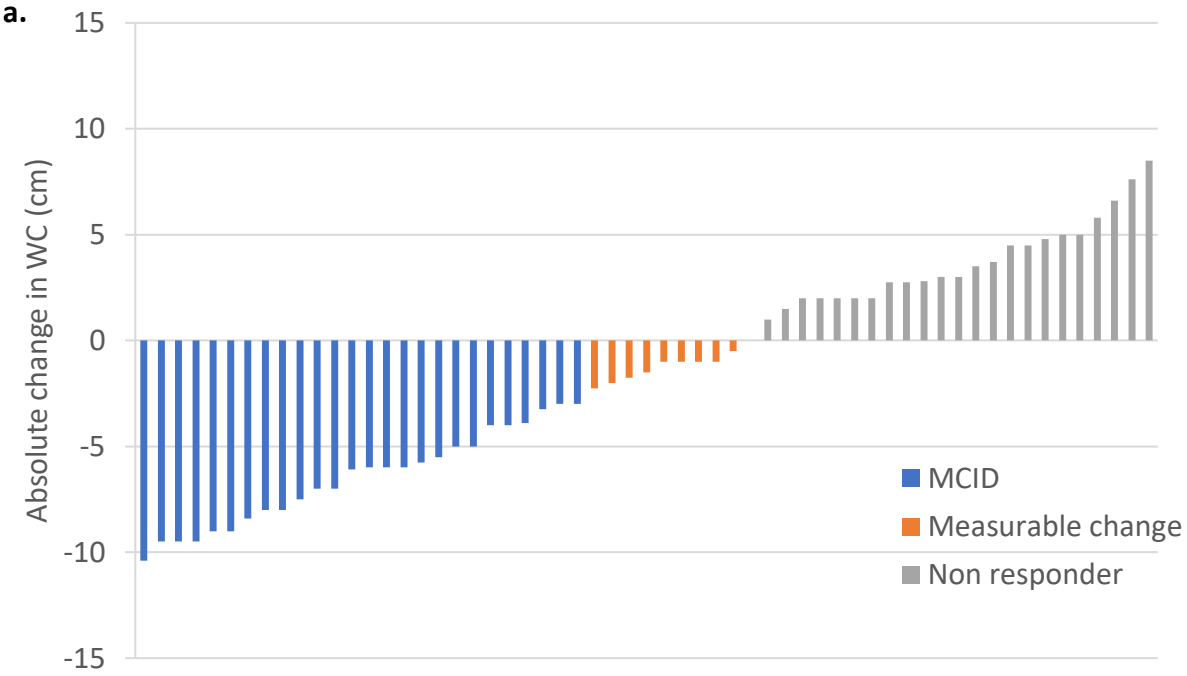



Figure 4.5 Absolute change in dominant HGS between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**Waist Circumference**

A total of 59 CAD, 51 OCD and 21 CAD-CG had a valid BL and PI measurement for waist circumference. A clinically meaningful decrease (≥ 3.0 cm) was achieved in 44%, 37% and 29% in CAD, OCD and CAD-CG, respectively (Figure 4.5), while 15%, 31% and 19% achieved a measurable change (≥0.1 cm).

**a.**



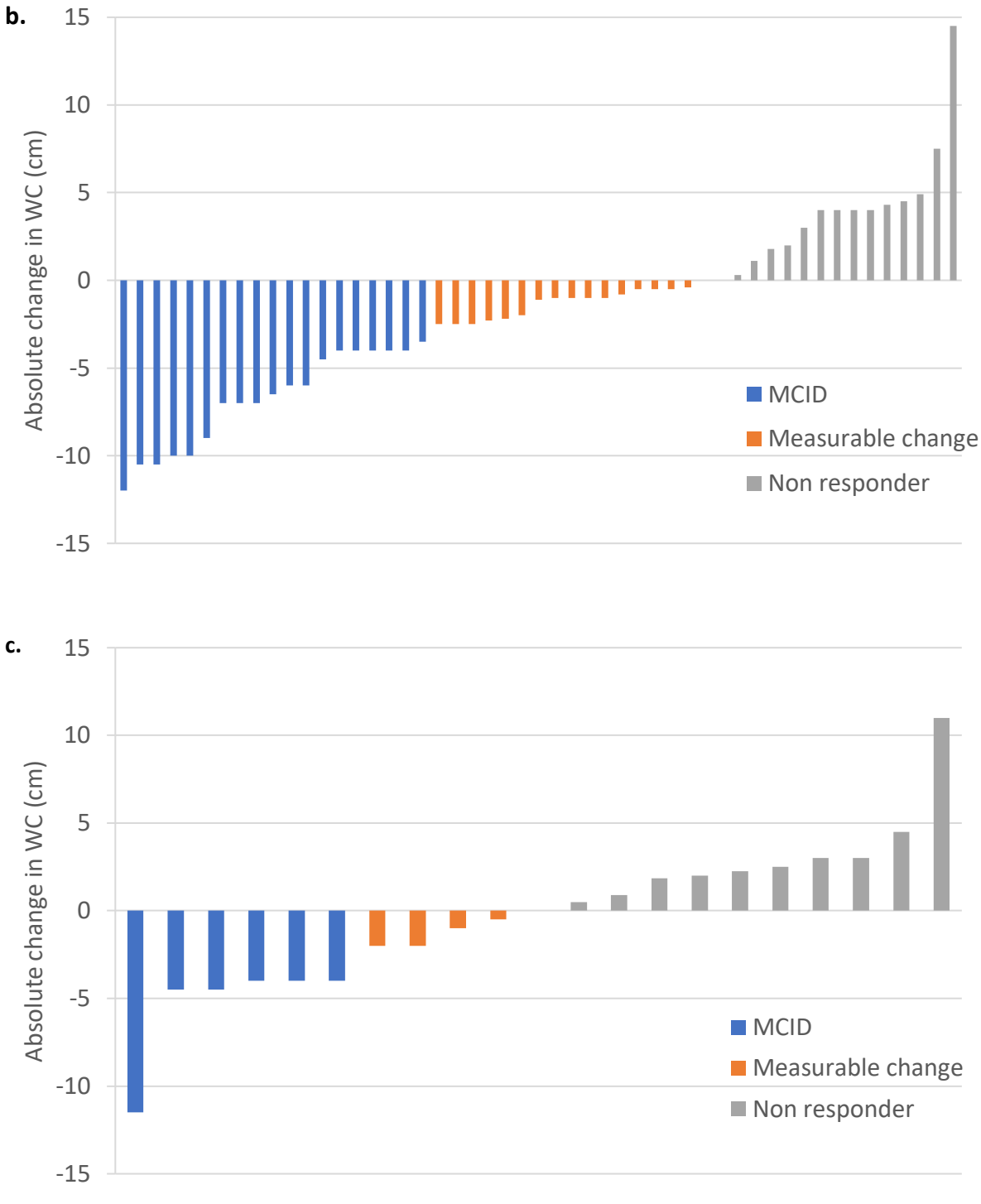
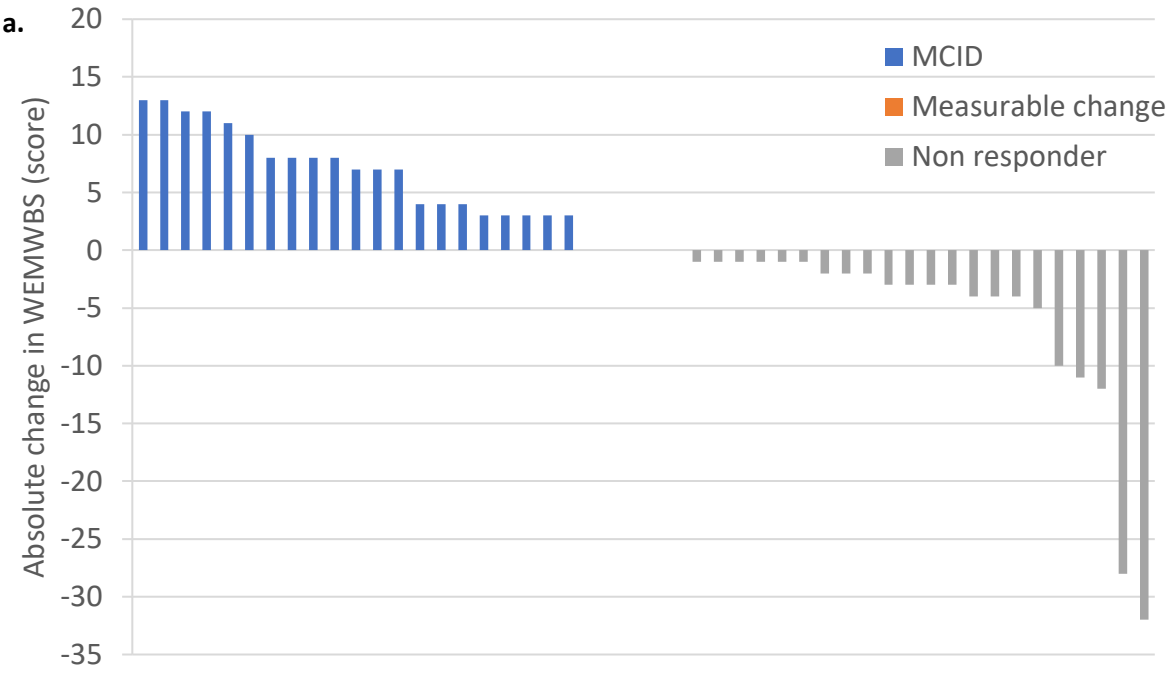



Figure 4.6 Absolute change in waist circumference between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**Warwick Edinburgh Mental Well-Being Scale**

A total of 48 CAD, 47 OCD and 16 CAD-CG had a valid BL and PI WEMWBS completed. A clinically meaningful improvement (≥3.0 points) was achieved in 44%, 49% and 6% in CAD, OCD and CAD-CG, respectively (Figure 4.6), while 0%, 13% and 13% achieved a measurable change (≥0.1 point).

**a.**



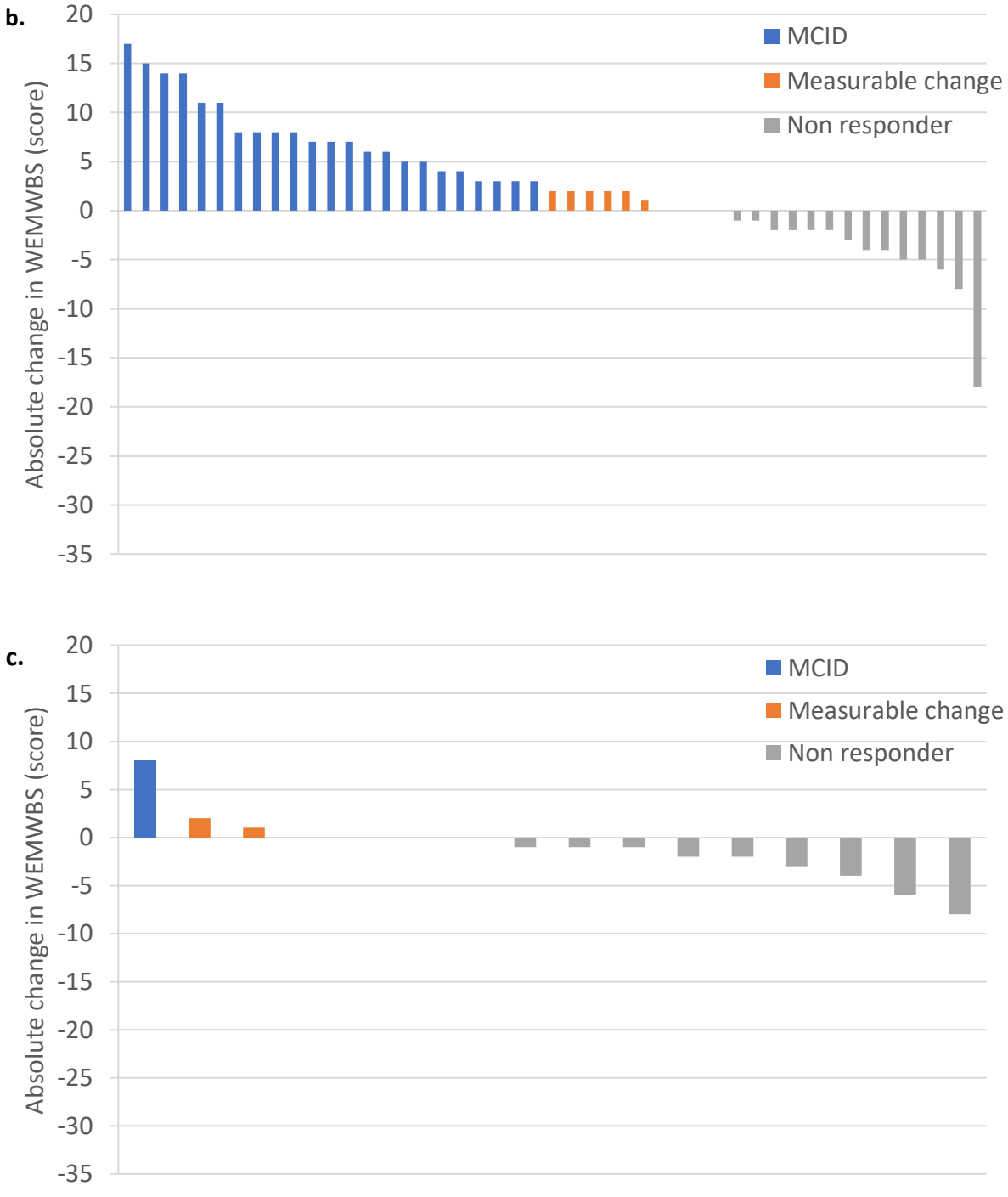
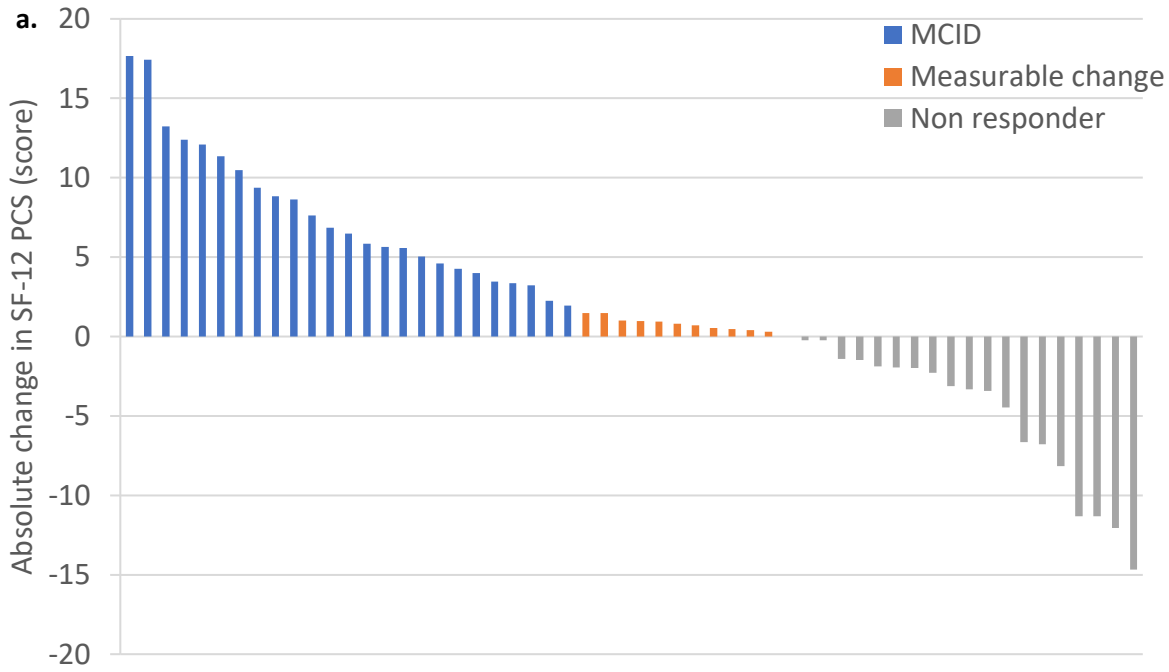



Figure 4.7 Absolute change in WEMWBS between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**SF-12 Physical Component Score**

A total of 56 CAD, 49 OCD and 21 CAD-CG had a valid BL and PI SF-12 PCS score. A clinically meaningful improvement (≥1.8 points) was achieved in 45%, 49% and 43% in CAD, OCD and CAD-CG, respectively (Figure 4.7), while 20%, 14% and 10% achieved a measurable change (≥0.1point).



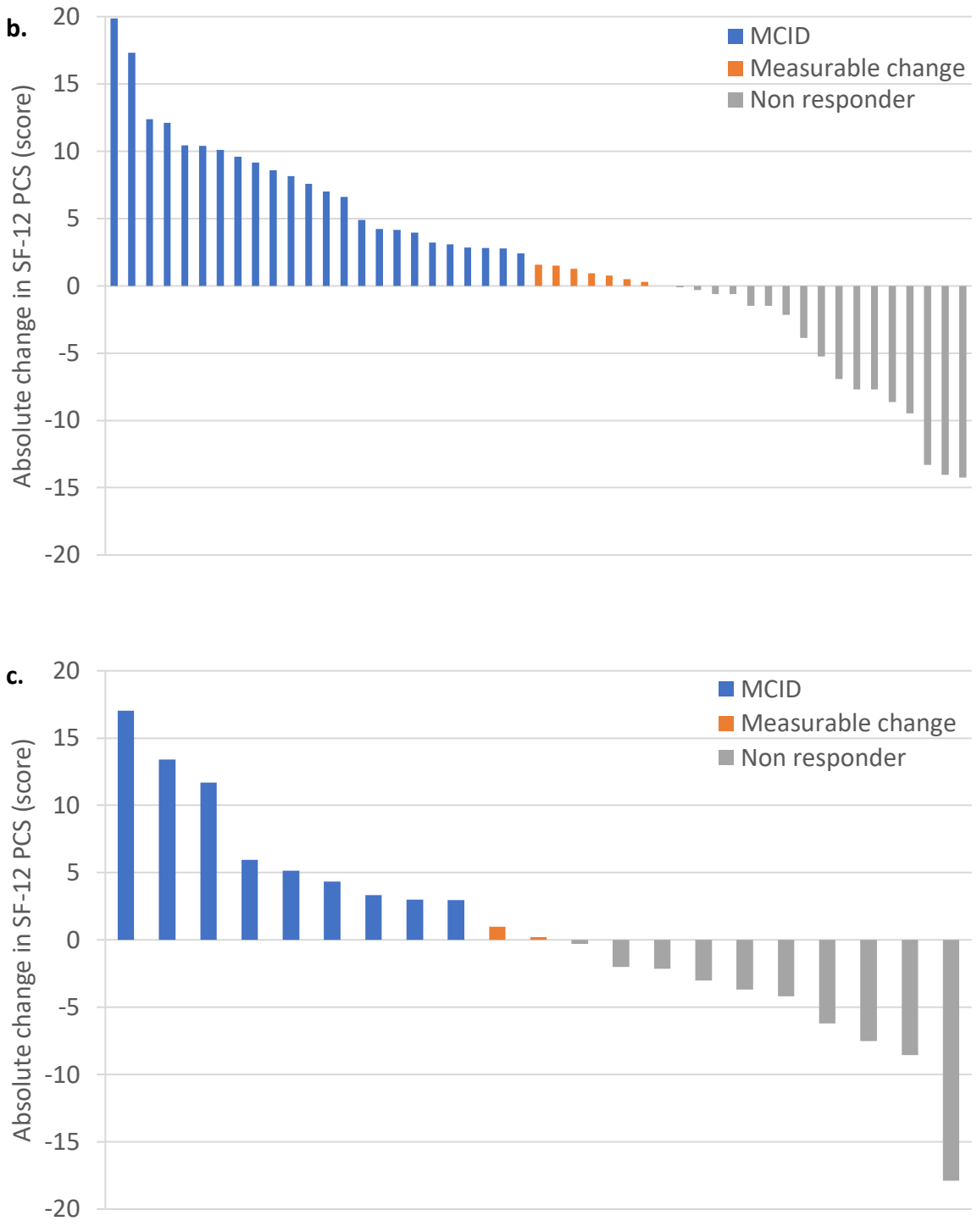
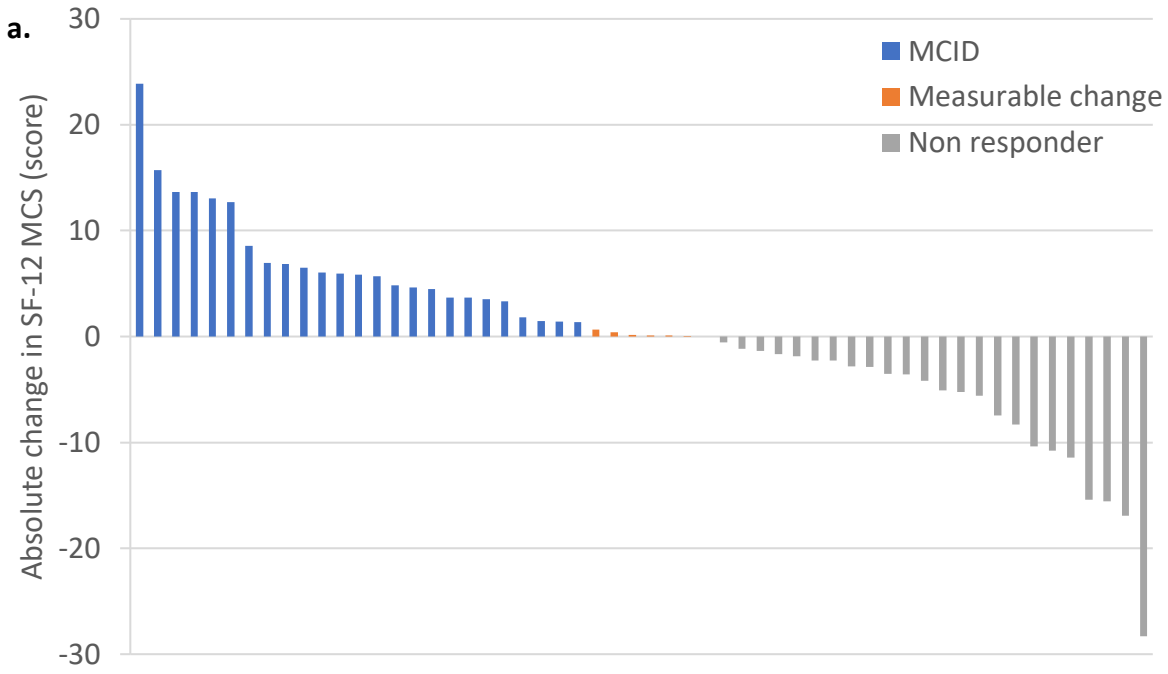



Figure 4.8 Absolute change in SF-12 PCS between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**SF-12 Mental Component Score**

A total of 56 CAD, 49 OCD and 21 CAD-CG had a valid BL and PI SF-12 MCS score. A clinically meaningful improvement (≥1.13 points) was achieved in 45%, 41% and 33% in CAD, OCD and CAD-CG, respectively (Figure 4.8), while 11%, 10% and 10% achieved a measurable change (≥0.1 point).



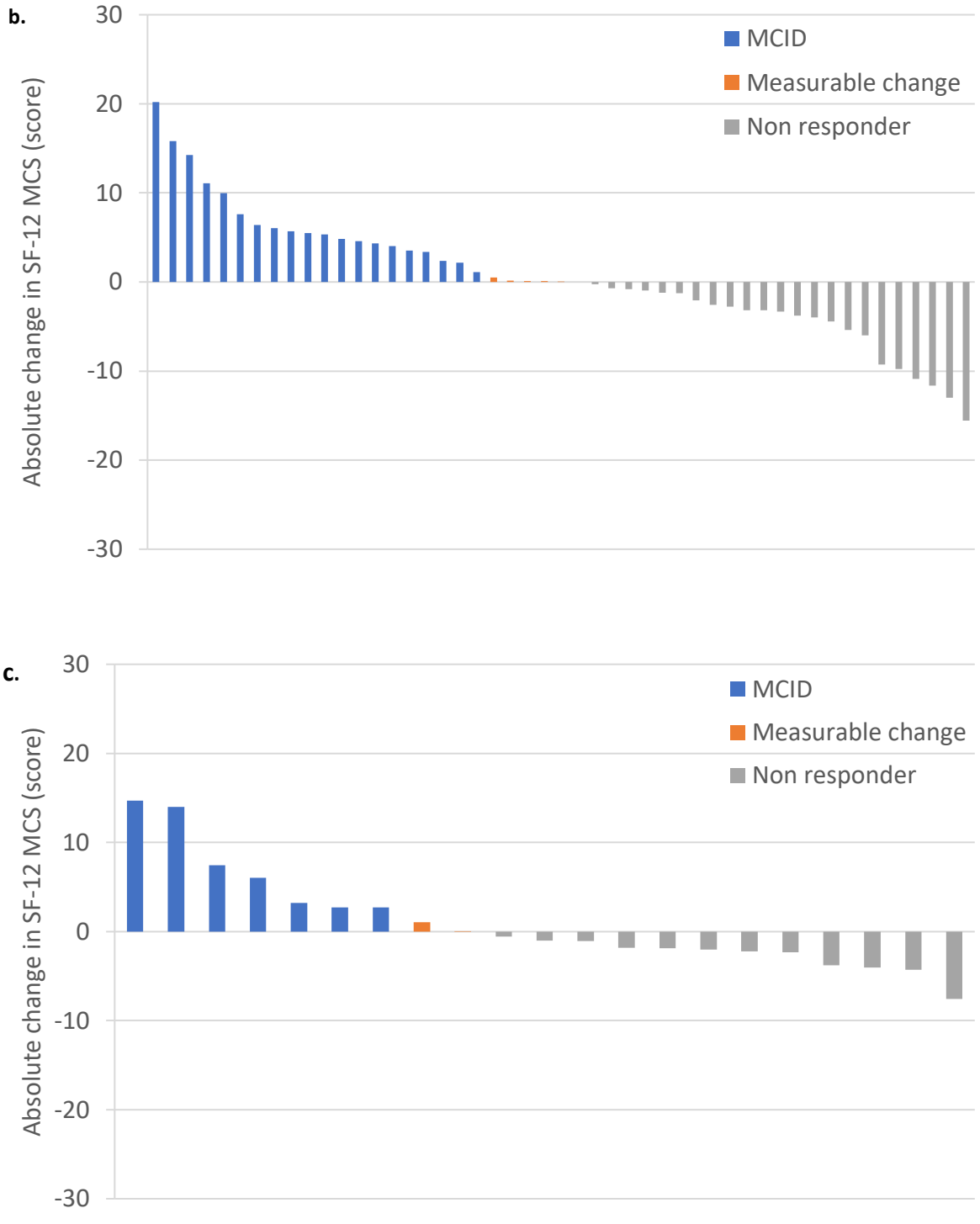
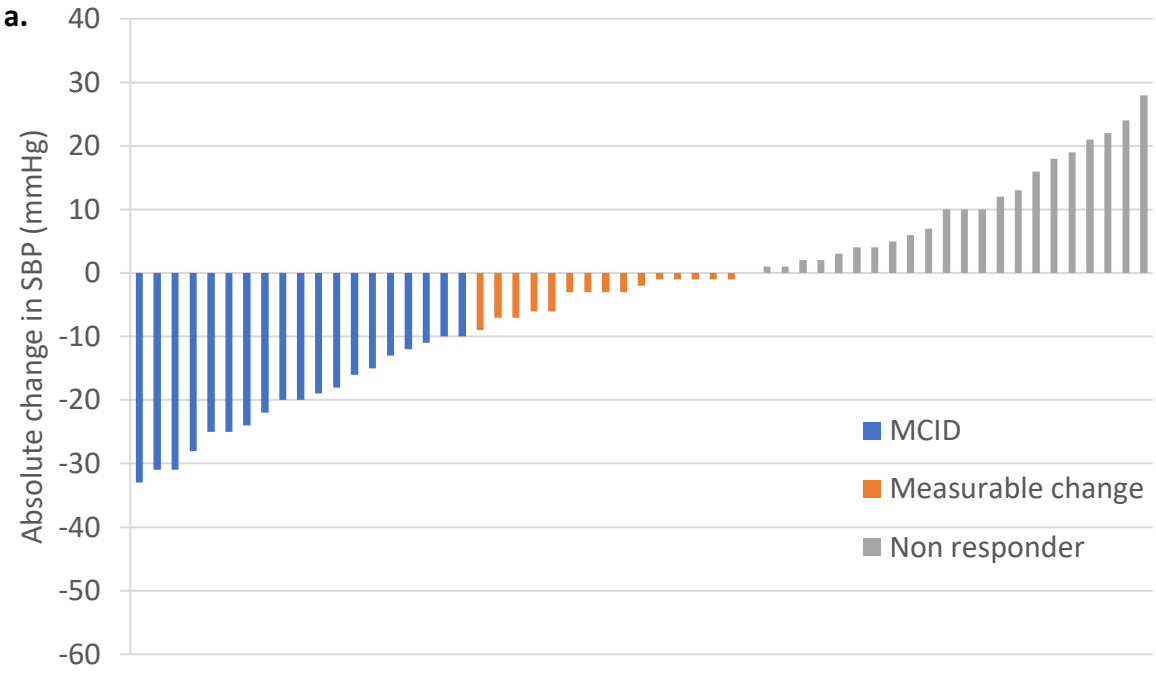



Figure 4.9 Absolute change in SF-12 MCS between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**Systolic Blood Pressure**

A total of 57 CAD, 47 OCD and 20 CAD-CG had a BL and PI SBP measurement. A clinically meaningful decrease (≥10.0 mmHg) was achieved in 33%, 38% and 30% in CAD, OCD and CAD-CG, respectively (Figure 4.9), while 26%, 26% and 35% achieved a measurable change (≥0.1 mmHg).



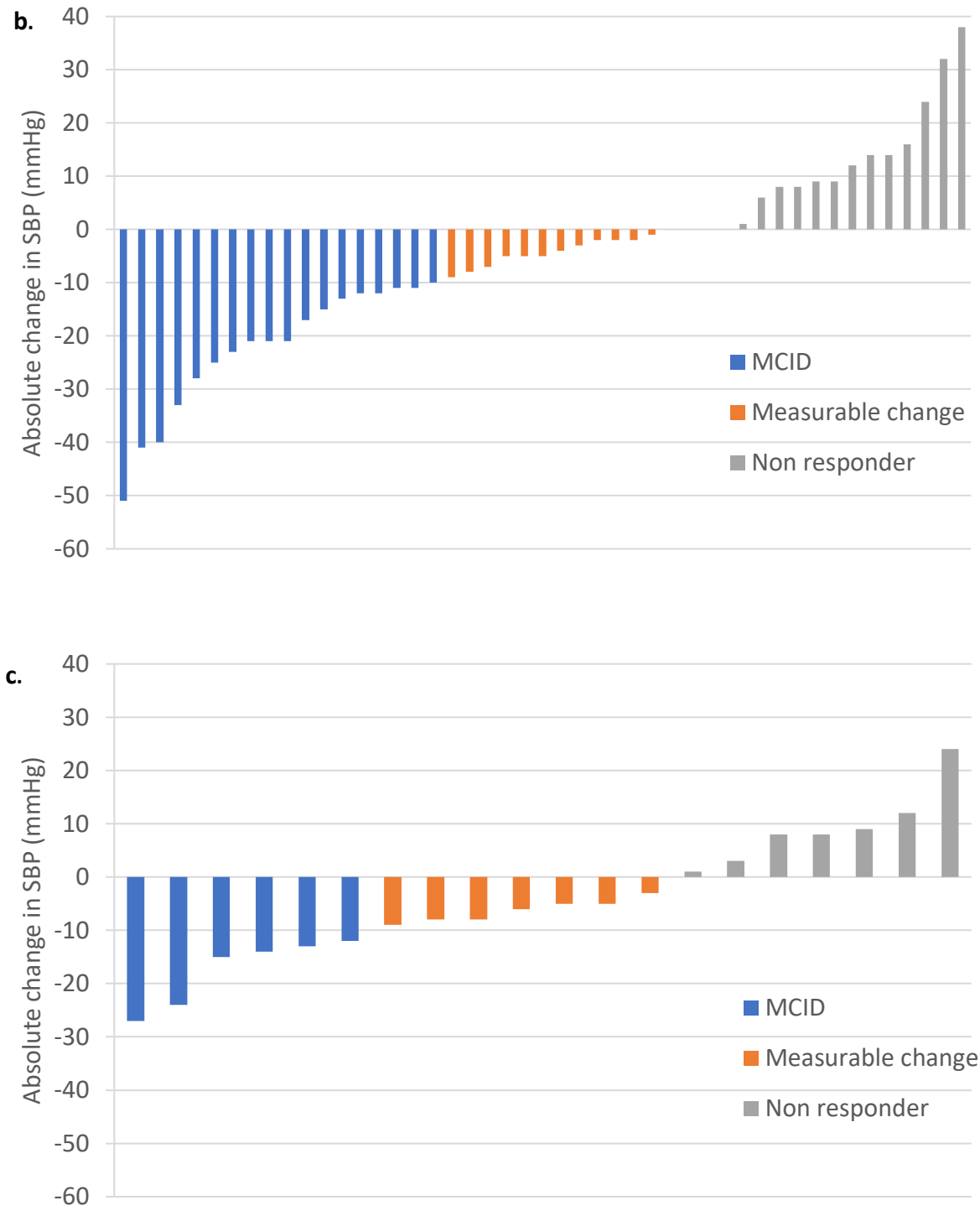
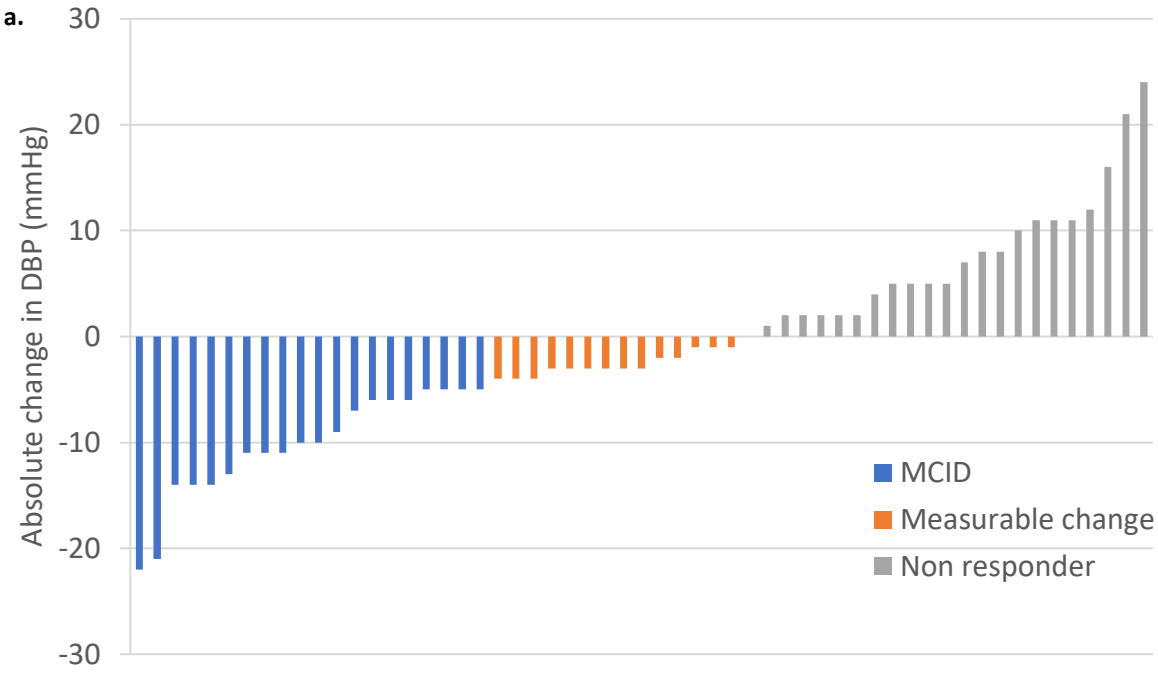
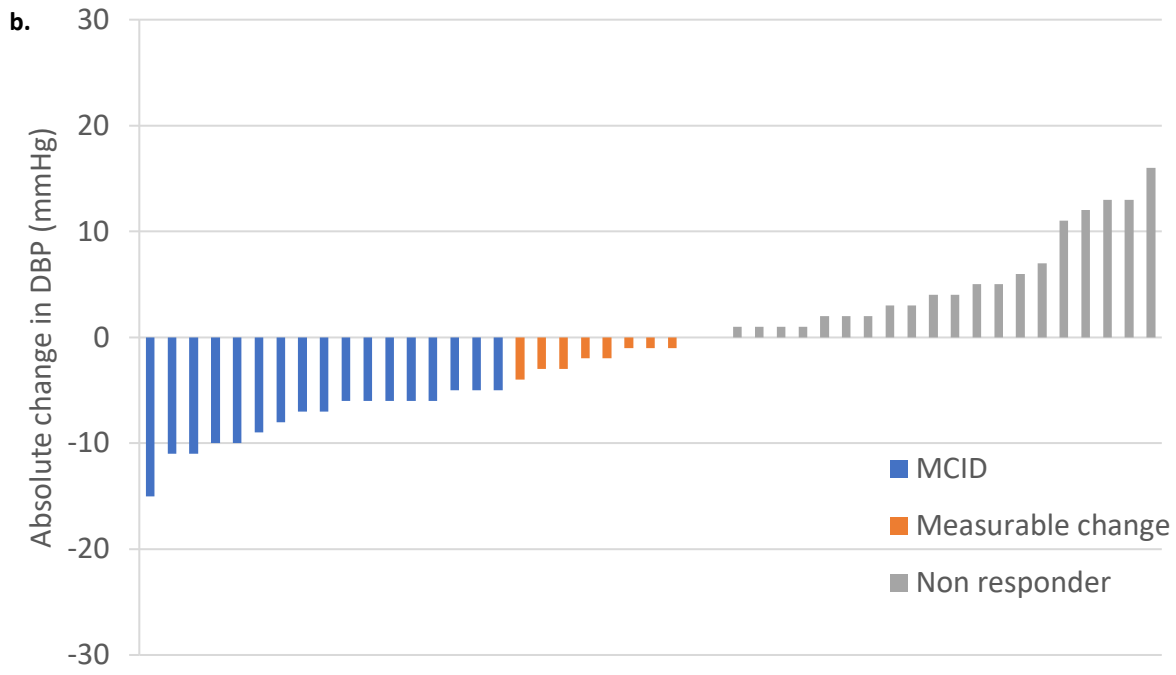



Figure 4.10 Absolute change in SBP between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

**Diastolic Blood Pressure**

A total of 57 CAD, 47 OCD and 20 CAD-CG had a BL and PI DBP measurement. A clinically meaningful decrease (≥5.0 mmHg) was achieved in 35%, 36% and 45% in CAD, OCD and CAD-CG, respectively (Figure 4.10), while 25%, 17% and 20% achieved a measurable change (≥0.1 mmHg).





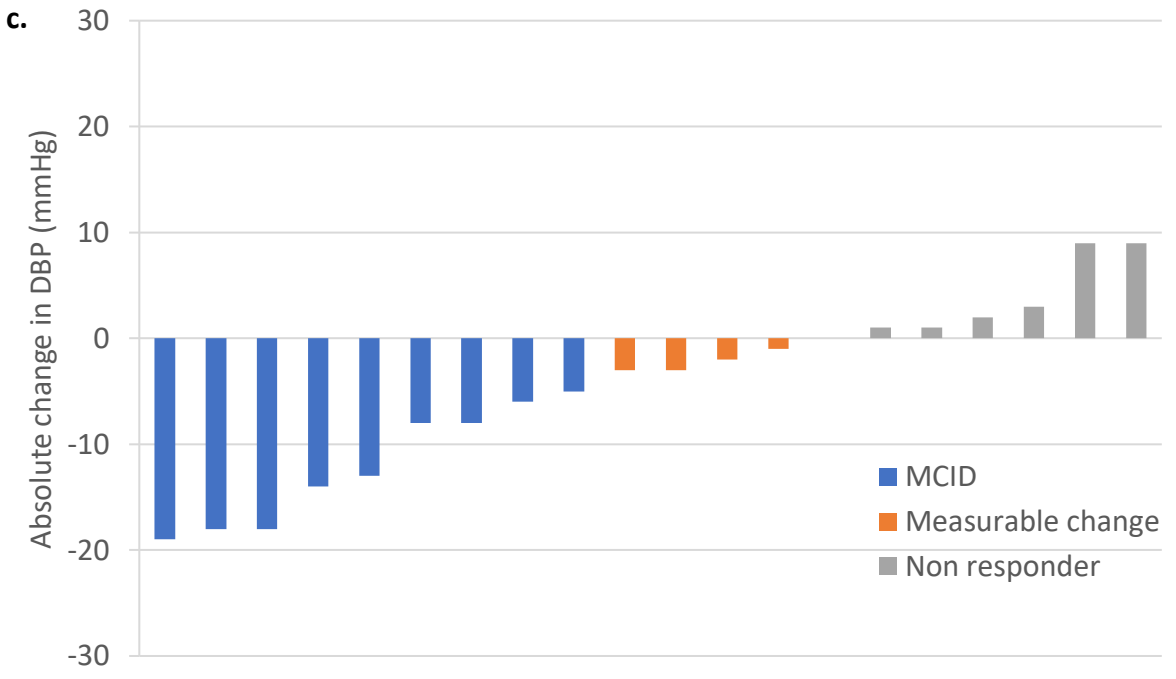




Figure 4.11 Absolute change in DBP between BL and PI for participants in a. CAD b. OCD and c. CAD-CG

### 4.4.5 MCID expressed according to Intention to Treat and Per Protocol

Those achieving MCID in key primary components of HRPF and psychological measurements of HRQoL are reported according to ITT and PP in table 4.19.

Table 4.19 Percentage achieving MCID in each experimental group expressed according to ITT and PP

| | ITT* | | | PP^ | | |
|---|---|---|---|---|---|---|
| | **CAD** | **OCD** | **CAD-CG** | **CAD** | **OCD** | **CAD-CG** |
| 6MWTD (m) | 17 | 18 | 14 | 28 | 31 | 14 |
| STS (sec) | 12 | 9 | 0 | 19 | 16 | 0 |
| GripD (kg) | 29 | 32 | 23 | 46 | 58 | 24 |
| Waist (cm) | 28 | 21 | 27 | 44 | 37 | 29 |
| WEMWBS | 23 | 25 | 5 | 44 | 49 | 6 |
| SF-12 PCS | 27 | 26 | 41 | 45 | 49 | 43 |
| SF-12 MCS | 27 | 22 | 32 | 45 | 41 | 33 |
| SBP (mmHg) | 20 | 20 | 27 | 33 | 38 | 30 |
| DBP (mmHg) | 22 | 19 | 41 | 35 | 36 | 45 |

ITT = intention to treat, PP = per protocol, 6MWTD = 6-minute walk test distance, STS = sit to stand test, GripD = Handgrip of dominant hand, WEMWBS = Warwick Edinburgh Mental Well-Being Scale, SF-12 = 12-item short form survey, PCS = physical component score, MCS = mental component score, SBP = systolic blood pressure, DBP = diastolic blood pressure

*ITT was expressed as a percentage of those who commenced the programme, CAD = 93, OCD = 91 and CAD-CG = 22.
^PP was expressed as a percentage of those who re-tested PI, maximum number in each group was CAD = 59, OCD = 52 and CAD-CG = 21, this denominator varied due to missing data

## 4.5 Summary of Results

There were no serious adverse events reported in any CD cohort taking part in the MCEP. Participation in the MCEP was associated with significant improvements in CRF, lower body muscle strength and waist circumference in both CAD and OCD. There was also a significant improvement in upper body muscle strength, perceived physical (SF-12PCS) and mental well-being (WEMWBS) in the OCD. There was a significant decrease in DBP found the

CAD-CG, but no other outcome variable improved significantly in the control group. Although there were significant improvements identified within each intervention group, lower body muscle strength was the only outcome variable to report a significant improvement between the experimental groups indicting the overall intervention efficacy of a MCEP was demonstrated, primarily, in muscle fitness.

In agreement with the statistical improvements outlined above, there was a higher percentage of individuals adhering to the MCEP (PP) who reported a clinically meaningful improvement in CRF, and lower muscle strength compared to the control group. However, statistical improvements and clinically meaningful improvements did not always agree. There was a significant improvement in upper body strength and perceived mental wellbeing (WEMWBS) at 10 weeks in OCD only. However, a similar percentage of participants in CAD and OCD had a clinically meaningful change in both upper body strength and perceived mental wellbeing.

When comparing ITT to PP, there was still a higher percentage of individuals who commenced the MCEP (ITT) who reported a clinically meaningful improvement in lower muscle strength and perceived mental wellbeing compared to control group. The beneficial effect in other key components of HRPF was reduced with little difference between experimental groups.

# Chapter V

## Study III

## Patient perspective of their experience of early transition from hospital-based CR and participation in a MCEP

### 5.1 Introduction

PAET is well established as an effective intervention in the management of CD and is associated with many beneficial health outcomes (Pedersen and Saltin 2015; Piepoli *et al.* 2019). Approximately, 268,000 people in Ireland live with CVD, of which 67,000 have CAD (Wilkins *et al.* 2017). Multifaceted, fixed-duration (6 - 12 weeks), hospital-based phase III CR is an important component of the multidisciplinary approach to the management of patients with various presentations of CVD (Pesah *et al.* 2017; Irish Heart Foundation 2018). These programmes are delivered by HCP and incorporate strategies to optimise cardiovascular risk reduction, promote adoption and adherence to healthy behaviours and an active lifestyle with the aim of reducing the risk of a recurring event, increasing survival and improving HRQoL (I.A.C.R. 2021).

Following completion of hospital-based CR, PA levels can decline, with only 25 - 40% maintaining exercise six months post CR (Bellg 2003) resulting in the loss of many of the health-related benefits achieved in response to participation in the programme (Willmer and Waite 2009). Long-term maintenance programmes (such as phase IV CBCR programme) can

act as a vehicle to maintain exercise behaviour (Fletcher and McBurney 2016) and, those who transition into CBCR have been shown to have better health outcomes (Willmer and Waite 2009). It is estimated that only 5-20% of eligible CR patients attend CBCR programmes (Ozemek and Squires 2021) at 6 months.

Limited studies have focused on the facilitators of adherence to maintenance CBCR (Thow *et al.* 2008; Martin and Woods 2012; Dunn *et al.* 2014; Hardcastle *et al.* 2015). These studies identified the social nature of the programme, support provided by instructors and exercising alongside people with similar health problems as powerful motivators for participating in long-term CBCR. Participants also valued the support and encouragement given by family and friends. The group-based exercise sessions and routine associated with a scheduled exercise time (Martin and Woods 2012; Hardcastle *et al.* 2015) along with the novel exercises giving a new dimension to their PA (Martin and Woods 2012) and, the enjoyment they received from taking part in the class (Thow *et al.* 2008; Martin and Woods 2012; Dunn *et al.* 2014; Hardcastle *et al.* 2015) were also strong facilitators of participation in CBCR. Other factors that influenced long-term exercise maintenance was the importance of being able to spend time with family, being able to travel and being able maintain independence (Hardcastle *et al.* 2015). Ability to avoid ill health was also evident, indicating that health was perceived to be in their control (Thow *et al.* 2008; Martin and Woods 2012; Dunn *et al.* 2014; Hardcastle *et al.* 2015).

Perceived physical and psychological benefits have also been identified as key facilitators to long-term exercise maintenance. Improvement in psychological wellbeing was evident through participants acknowledging a sense of accomplishment, improved mood and mentally 'feeling better' (Dunn *et al.* 2014; Hardcastle *et al.* 2015; Horwood *et al.* 2015). Participants perceived many physical and functional benefits that allowed them to perform ADL and maintain their independence (Thow *et al.* 2008; Hardcastle *et al.* 2015; Horwood *et al.* 2015).

Many studies refer to factors such as lack of knowledge, lack of social support, poor health, and lack of medical support as barriers to long-term exercise maintenance. However, these are primarily barriers to initiating as opposed to sustaining exercise (Bellg 2003). To our knowledge, only two studies (Dunn *et al.* 2014; Horwood *et al.* 2015) have examined barriers to adherence, and both identified travel and lack of appropriate locations/time, other health problems e.g., arthritis and illness, time constraints such as family responsibilities, work commitments and weather as key barriers.

The vast majority of previous studies that examined the facilitators of adherence to maintenance CBECR involved participants who were attending for between 12 months (Martin and Woods 2012; Dunn *et al.* 2014; Horwood *et al.* 2015) to >24 months (Thow *et al.* 2008; Hardcastle *et al.* 2015), and were in true "maintenance" stage of change in terms of their exercise behaviour. There is value in understanding participants' motivations for and

barriers to adhering to the exercise programmes at different time points (2008), particularly in the early transition into CBCR when dropout is highest (Carmody *et al.* 1980).

Uptake to maintenance CBCR and other CD programmes in Ireland is hindered by the inadequate availability of appropriate services (Lavin *et al.* 2005; I.A.C.R. 2020). Internationally, the majority of supervised CBCR and CD specific programmes are delivered by either HCPs such as physiotherapists (Kwan *et al.* 2016; Ong *et al.* 2016), GPs (Zhang *et al.* 2018) or a multidisciplinary team including cardiologists, physiotherapists, CR nurses, exercise physiologists and other allied health professionals (Seki *et al.* 2008; Dunn *et al.* 2014). Since most long-term exercise maintenance programmes have comparable designs and, target similar components of fitness irrespective of the CD (Desveaux *et al.* 2014), there is scope to establish a MCEP which would be a more efficient delivery model and could be used as an alternative to CBCR. MCEP provide a safe and effective exit route from hospital-based programmes (McNamara *et al.* 2016) and are likely to support the habituation of exercise (Fletcher and McBurney 2016) and maintenance of associated health benefits (Clark *et al.* 2011). Patients have expressed how the community setting promotes a sense of 'normality' within the rehabilitation experience, distinguishing exercise as a normal behaviour as opposed to a treatment for their condition (McNamara *et al.* 2016). Engaging the patient's perspective on their experience of such programmes could improve and optimise the rates of enrolment, effectiveness, and level of adherence (Bombard *et al.* 2018).

The purpose of the present study was to explore the CAD patient's perspective of their experience of early transition and participation in a MCEP.

## 5.2 Aims

The aims of this study were to explore

- CAD patient experiences of the early transition from Phase III CR to participation in a MCEP
- The dimensions that facilitate and hinder PA engagement in individuals with CAD
- Perceived benefits to participation in a MCEP among individuals with CAD

## 5.3 Methodology

### 5.3.1 Participants

Adults with established CAD who had completed hospital-based CR at Sligo University Hospital (SUH) and, who did not require the presence of a physician or other appropriately trained HCP to undertake a supervised exercise programme (chapter III) were referred by the senior cardiac physiotherapist at the hospital to a MCEP at the ATU Sligo. Some of the participants had completed their hospital-based phase III CR prior to the MCEP being established, but were subsequently referred, while others were referred directly following completion of their hospital-based CR. Participants were informed of the aims of the research study and provided with a plain language participant information leaflet and given the opportunity to ask questions. Participants provided written informed consent prior to participation. Ethical approval was obtained from SUH Research Ethics Committee (Ref No. 579). A total of 51 patients were referred and commenced the MCEP between May 2016 and September 2017. At 10 weeks, 31 participants were still attending the ATU MCEP and were invited to attend a focus group to discuss their experience of the programme.

### 5.3.2 Multi-Disease, Community-Based Exercise Programme

An overview of the MCEP is outlined in chapter III.

### 5.3.3 Focus Groups

Four focus groups and a single interview (due to work commitments) were conducted with four to eight participants (mixed gender) per group. The focus groups aimed to obtain

participant opinions/experiences of participating in the ATU MCEP within the first 10 weeks. A topic guide was developed based on Braun and Clarke (2013) to guide focus group discussions. The topic guide is outlined in Appendix K. Topics included the journey to the MCEP, experience of the programme, the exercise class, factors that facilitated participation in the programme, perceived benefits of the MCEP setting and recommendations for exercise programme improvements. Discussions were not limited to these areas and, opportunity was provided for the exploration of other/wider topics identified by participants. The interview followed the same topic guide.

Focus groups and the interview were conducted by two trained independent researchers who had not been involved in the delivery of the MCEP. One acted as the moderator who introduced the session and followed the topic guide, while the second researcher was the assistant moderator and manually recorded the key points. The focus group sessions were approximately 45 min in duration. To ensure the setting was familiar to the participants, the meeting took place in a meeting room located in the same building at ATU Sligo where the exercise classes were delivered. The focus group sessions and interview were digitally recorded and transcribed verbatim.

### 5.3.4 Authors' experience with MCEPs

There was differing involvement of the researchers who analysed the data in relation to their experience of MCEPs. JRM has a background in exercise physiology. She was involved in the setting-up and, in the day-to-day running of the MCEP. She was not in involved in

conducting the focus groups but assisted with data analysis. Although not a participant of the MCEP, she represented an 'insider' perspective (Hayfield and Huxley 2015) due to her closeness to the day-to-day running of the programme. Researcher MMcM represented an 'outsider' perspective (Hayfield and Huxley 2015). She was not involved in the delivery of the MCEP and has expertise in public health/health promotion and qualitative research methods. In the later phases, BK and SH contributed to the analysis. BK has expertise in establishing and running MCEPs. SH has a wealth of experience and expertise in qualitative design and analysis. Neither BK nor SH had direct involvement in the day-to-day running of the MCEP at ATU or with any aspect of the data collection. Both were deemed to contribute an 'outsider' and more independent perspective. The advantage of having both an insider and outsider perspective was that it strengthened the study design (Thompson and Wilkie 2021) giving a more reflective and varied viewpoint during analysis.

### 5.3.5 Data Analysis

Data was inductively analysed following the six phases of reflexive thematic analysis as outlined by Braun and Clarke (Braun and Clarke 2012; Braun and Clarke 2021). In the first phase, both researchers (JRM and MMcM) *familiarised* themselves with the transcripts by manually listening back to the audio tapes and, going through the assistant moderators' notes to fill in any apparent gaps or correct any errors in transcribing. In the second phase, transcripts were discussed jointly to *generate representative codes*. The *initial themes* generated in phase 3, were further *reviewed and developed* in phase 4 following in-depth discussions between the researchers. At this point in time, another perspective was provided

to give a fresh viewpoint (BK). *Refining, defining, and naming* of the themes was undertaken in phase 5 to ensure that they correctly reflected the transcripts. The thematic analysis report (phase 6) was drafted (JRM), discussed and revised (JRM, MMcM, BK), with key quotations, where appropriate, selected (JRM) for each theme.

## 5.4 Results

### 5.4.1 Participant Characteristics

Four focus groups and a single interview were conducted. They were attended by 24 participants (63% male) in total. Characteristics of participants involved in the focus groups/interview are presented in table 5.1.

Table 5.1 Participant characteristics

| **n** | **24** |
|---|---|
| Age (yr.) | 65.5±6.12 |
| Gender, M:F | 15:9 |
| BMI (kg/m$^2$) | 29.3±4.7 |
| Cardiac history | |
| Myocardial infarction | 13 (54%) |
| Percutaneous coronary intervention with stenting | 16 (67%) |
| Coronary artery bypass graft | 4 (17%) |
| Percutaneous coronary intervention without stenting | 3 (13%) |
| Valve replacement | 5 (21%) |
| Absolute values (percentage) or mean ± standard deviation | |

### 5.4.2 Focus Groups

Data analysis identified four major themes relating to participants' perceptions of their initiation of and their early participation in a MCEP during the first three months. The overall themes were i) moving from fear to confidence, ii) drivers of engagement, iii) challenges to maintaining exercise adherence, and iv) life beyond their illness. A table of themes, subthemes and supporting quotes are in appendix L.

**Theme 1 - Moving from Fear to Confidence**

The overall focus of this theme was 'moving from fear to confidence'. It contained three subthemes: fear and uncertainty, need for continuity, and increase in confidence.

**Subtheme 1.1- Fear and Uncertainty**

Despite undertaking 10 weeks of supervised exercise in a hospital setting and being advised upon discharge from the hospital programme to continue to exercise, many of the participants expressed fear and uncertainty in exercising independently.

Participants knew they should be active, but many described feelings of fear, they were '*afraid*' or '*nervous'* to exercise *'Yes, fear is the thing, in case we over do it.*' (P3 FG1). They were fearful of exercising independently in case it would exacerbate their condition or overexert themselves and induce symptoms of their condition *'I was wondering would it bring on the pain, the angina I had… I didn't know where I was going'* (P6 FG1) and *'once this* [the cardiac event] *happened, I was afraid to walk'* (F3 FG3) with many clearly recalling their period of ill health.

Participants seemed unaware of how to exercise independently following the hospital-based programme: '*sure, I wouldn't know what I needed to do'* (M3 FG4) *'I wouldn't have known about the warm up or the cool down.'* (P9, FG2). This included uncertainty in their ability to exercise independently *'Well, I thought I mightn't be able to do much, or I*

*wouldn't be able to manage it* [exercise]*'* (M1 FG4) and *'I felt after it [hospital-based CR] finished I didn't know where to go' (M1 FG3).*

**Subtheme 1.2 - Need for Continuity**

There was a strong sense from participants that they wanted to maintain their exercise after the hospital-based CR programme, but that they needed guidance and direction to help them overcome their fears. There was a desire and perceived need for follow-on supervised exercise opportunities *'...it was something we were waiting for, all of us.'* (P1 FG1).

Many were informed of the programme during their hospital-based CR and were referred directly *'It was pretty much straight forward, she* (senior physio) *just told us in the rehab class, and we came down here'* (M1 FG3). They referred to the continuity with the hospital-based CR programme. *'The continuity and the link between the hospital and yourselves* [the programme] *is critical, it's really important.'* (M3, FG4).

Participants reported receiving significant reassurance from having access to consult medical personnel if they '*felt a wee pain'* or had a particular worry. Many acknowledged that the medical staff were not always on site but were happy with the link between the programme and medical support at SUH '*You've a back-up really… It's knowing you can get back to them'* (F2, FG3) and it was enough to know it was there if they needed it '*We've got that link. We don't want to lose that support now that we have it.*' (M1, FG3). They felt supported that they could bring their worries to the staff who would act accordingly. For

some participants, participation in the MCEP was in response to their second cardiac event and commented on '*there was nothing'* there after their first experience of CR in the hospital.

There was evidence of some participants being active without the programme, mainly walking or cycling. Many mentioned that they had never previously exercised in a gym or completed circuit type training. The programme provided them with the knowledge, skill, and confidence to perform other activities; *'you learn how to do exercises.' (F1 FG4)*:

*'You'd walk all right, but you wouldn't do the exercises* [circuit]' (F2 FG 3)

*'You see those gym things, I would have never walked into a gym, I had never been in a gym…… Everyone seemed to like the gym, you would feel really awkward going in, you wouldn't know what you were doing before that. At least now when I sit down, I know what I'm supposed to be doing.' (P10, FG2)*

**Subtheme 1.3 - Increase in Confidence**

The delivery by clinical exercise professionals, with referrals and support from the hospital physiotherapists and nurses, was an essential aspect to the programme for participants *'The combination of all of them was very beneficial.'* (P3, FG1) that lead to a sense of confidence and trust in the programme over other exercise opportunities.

The clinical exercise instructors were viewed positively in delivering the classes '…*you trusted the staff that were looking after us, you knew that they were not going to put you in harm's way, they are there to take care of you.'* (P7 FG1). Participants recognised that the

instructors gradually progressed the programme and gave them confidence they were exercising to a level they could manage.

> '*They do 3 stages* [show you 3 levels] *of what you can do …. you're not being pushed into working flat out, you do what you can.'* (M2 FG4)

Through participation in the MCEP, there was a noticeable improvement in exercise confidence. The MCEP broadened their awareness and capability of the different components of an exercise session that went beyond walking and, gave them the confidence to carry out these exercises *'We thought we couldn't do* [the exercises] *and now we can do everything.'* (F2 FG3). Participants described increased confidence to self-monitor their own exercise intensity.

> *'More confidence anyway in yourself you know – you were afraid to do anything in case you were doing too much or too little you know so you have that confidence that you know you able to do a lot more.'* (F2 FG3)

> *'I have to say I feel better …. because I'm more confident in myself'* (P6 FG1)

For many, this sense of empowerment extended to increased confidence to exercise independently, at home or in a gym. After just three months, many of the participants felt they had now overcome their initial fears of unsupervised exercise and could exercise independently without fear of negative consequences.

'*my daughter has a treadmill at home, and I was afraid to go on it, but I go on it now you know'* (F2 FG4)

*'Before I wouldn't know what exercises to do or anything like that and it's great to be able to do them at home, now that I understand what I should and shouldn't do'* (F1 FG4)

*'Some of us are coming back here next week* [outside of the programme] *and we are just going to go the gym.*' (P1 FG1)

**Theme 2 - Drivers of Engagement**

The overall theme of 'drivers of engagement' contains three subthemes: importance of scheduled exercise, social connections, and enjoyment. The subthemes cover a variety of factors that motivated patients to engage with the exercise programme and appeared to facilitate adherence.

**Subtheme 2.1 - Importance of Scheduled Exercise**

Many of the participants lacked the motivation to exercise, admitting they were not inclined to exercise at home or by themselves*: 'I would have done none* [exercise]*, literally none.' (P9, FG2).* The programme created an opportunity for participants to maintain their exercise beyond the hospital setting with many indicating that they would not exercise independently *'you will not do it at home, you will not do it by yourself.' (P1 FG1) and 'If we hadn't this* [the programme] *we'd be home sitting on the couch.' (F1 FG4)*.

*'You see what happens is you go and have heart problems and you get it sorted out and you go to the cardiac rehab up in Sligo hospital, which is very good. You get hooked up to machines and everything but then you get sent home and you're told carry on walking with this and within a month you go back to your normal self and you're not doing anything.' (P1 FG1)*

The scheduled nature of the exercise programme of two set times and days per week was deemed important for adherence *"You know you had two dates in the week you had to meet and otherwise you might have done nothing.'* (P8, Int. 1) *and 'The discipline part of it is fantastic that you make yourself come twice a week'* (F2, FG3). The scheduled exercise seemed to foster commitment that may be otherwise lacking: *'at least them 2 days, that you are sure of doing your exercise …. those 2 days you're committed, you know what you're doing and you're going to go…… some of us but not all mightn't be as good at doing it at home.'* (F2, FG4)

**Subtheme 2.2 - Social Connections: 'I'm not as bad as I thought'**

The social connections appeared to motivate engagement with the exercise programme and, for some, started before they ever entered the programme. Although many engaged with the programme initially because they were referred through the hospital, many in the latter focus groups were also influenced by positive feedback from current participants *'anyone I talked to recommended it highly.'* (F1, FG4) and *'I heard about this from my sister-*

*in-law so I rang up to see could I join* up' (M3 FG3). They appeared to value their recommendation and felt it encouraged their attendance at the programme.

Once attending, participants particularly enjoyed the social nature of the programme. It encouraged them to continue to participate and was one of the main drivers of exercise engagement. Participants described the sense of a collective reason for being there, i.e., a medical reason. Be it a similar condition to their own or another chronic condition, either way they felt *'everyone's in the same boat'* (M2 FG4) or '*all on the same wavelength'* (F1 FG4). This made participants *'more comfortable'* (P4 FG1) being part of the programme and helped them form social bonds.

> *'And then the social aspect of it too. In the rehab programme in the hospital, once you are finished with it, you are gone out the door straight away. This is nicer where you get to meet a few people, and I can talk to people who have similar issues and on similar medications to myself.'* (P8, INT 1)

> *'I felt this was great because we bounce off each other, meet people with the same situations that we have all been through and psychologically it was a chance to meet other people, talk…'* (M1 FG3)

> *'…. fantastic therapy …… you come down here and you think everyone has had stents put in but it's not, people have had different problems and you just start talking to people and it makes people at ease more…'* (M4 FG3)

There was evidence of social comparison influencing their belief in their ability. Some felt *'put at ease'* by comparing their medical history with other members of the group and some viewed it rather light-heartedly.

*'I'm not as bad as I thought I was* [laughing] *I've only 2 stents...'* (M3 FG3)

*'...we were counting who had the more stents at this stage you know we found out there's always someone better or worse than you'* (M1, FG3)

This social comparison gave them more confidence in their own ability to participate in the exercise classes. There was a sense that if others with a similar [or even worse] condition to themselves could exercise then they could to. *'...well, if they can do it so can I.'* (P2 FG1).

As new people entered the programme, it became clear that their own ability had improved from when they started as they again compared themselves to the new entrants. They also talked about offering support to new people and encouraging them to stick with it and, that they would gradually progress.

*'You see new people coming in now and they aren't able to do what we can do, and we were once them…. and we see them kind of struggling and we say don't try to do what we are doing because you won't be able for it …'* (M1 FG3)

The main component of the programme that fostered the social support was the post-class cup of tea *'it's the social gathering as well.'* (M1 FG3). It provided an opportunity for

conversations about their medical conditions and other unrelated topics *'…the chat can be about anything.'* (M2 FG4).

The importance of the social support and the camaraderie they got from each other was evident from all participants to the extent that one called it the '*centre piece of this whole thing*.' (M3 FG4).

*'It was the motivational encouragement you got from others* [in the group]*'* (FG1 P3)

**Subtheme 2.3 - Enjoyment**

Enjoyment in the programme appeared to foster motivation and exercise engagement. Most participants talked about the exercise as being 'enjoyable' and 'fun' with some even surprised that they found it to be fun. *'We had fun too, a lot of laughter and that's very important too'* (P3 FG1) and *'…we actually have fun…. who would associate P.E. and fun!*' (M3 FG4). The circuits session, in particular, was associated with fun '*we have great fun down there* [circuit class]*'* (F1 FG3)/ *'The wit and the banter that goes on – makes it for everybody'* (M2 FG3).

Participants enjoyed exercising to music. Many participants described how music was a key motivational aspect of the class. Music added meaning and made the exercise easier and more interesting.

*'… try to do an exercise and no music, it's totally different, meaningless.'* (F2 FG3)

*'Yes, the music and the exercise yes and it makes it more interesting.'* (M1 FG4)

*'If the music is off there's something wrong.'* (M2 FG4)

Many expressed a preference for more gym sessions *'I thought the gym was the best'* (P12 FG2) and '*bit more of the gym and wee bit less of the circuit training'* (P2 FG1) indicating they '*found the gym more challenging'* (F2 FG3). Others expressed an interest for the circuits *'I liked all the different exercises, and we were not long doing them…. The time went around quicker.'* (P6 FG1) while others liked the combination of both *'I liked the combination of the circuit training and the gym.'* (P10 FG2). Essentially a desire for variety was evident '*vary it and give you a bit more interest, you know….'* (P2 FG1) with some even suggesting new alternatives such as making use of the athletics track or jiving class.

**Theme 3 - Challenges to Maintaining Exercise Adherence**

As positive as the programme appeared to be, it was not without its challenges. This theme focuses on the 'challenges to maintaining exercise adherence' with barriers and dependency as its subthemes.

**Subtheme 3.1 - Barriers**

The primary barrier to attending the programme was the timing of the classes clashing with family '*I couldn't do it all the time because I was babysitting'* (P12, FG2), '*clashed with dropping off kids and grandkids'* (F1, FG4) and work *'I hadn't the time to do it all the time because I was working.'* (P10, FG2), '*Can't see myself having the time to do it.'* (P8, Int. 1) commitments. Although most preferred an early morning time slot, concerns were expressed

about the dark winter mornings and the early awaking time for those who had a distance to travel.

**Subtheme 3.2 - Dependency**

A key enabler of the MCEP was the availability of medical oversight and for most that was enough. However, for some participants there was a risk it was breeding medical dependency. For the first inducted group, medical personnel from the hospital were always on site. This was viewed as being regular feature of the programme and valued by participants.

> *It* [medical support] *was automatically there, we had the support, and it was always at the back of your mind, they are there and that is great.* (P2, FG1)

From the second inducted group onwards, the medical personnel were only on site on certain weeks. Participants seemed to miss the reassurance from the presence of medical personnel '*I thought that was very good to have somebody professional like herself here all the time, I know with staff shortages but if for future references that we could have someone here professional all the time'* (M1 FG3) with them looking for the medical staff to '*regularly to be here'* (M2 FG3).

The monitoring before and during the classes provided further reassurance of a safe exercise environment. Many participants noted the opportunity to have their BP monitored as part of the pre-exercise health check giving them confidence, they were safe to exercise

*'It reassures you that you're ok for it.*' (F1, FG4) or getting their pulse checked during the class through random heart rate measurements to ensure they were training in the correct training zone *'they monitor you, they come around and take a heart rate.'* (F1, FG4) and *'you can actually see them going around to each individual and they pick out somebody who's under stress and bring them out and measure their heart rate.'* (M3 FG4). While participants saw this as a positive addition to the programme, it could indicate an over-medicalisation of exercise and create a dependency on the instructors/programme.

> *'Getting your blood pressure taken … it keeps you focused on it, otherwise when would you have it taken…. it's nice to know you're plodding along nicely.'* (F4, FG3)

Despite the increase in their self-efficacy to exercise that was evident for many, it appears others may not exercise by themselves, while others went further expressing concern in relation to losing the support of the programme. One participant feared what would happen to them if the programme stopped and the impact on their health '*I hope it continues this year so that I don't land up in hospital'* (P6, FG1). Another person referred to when there was a break in the programme, how they really missed it and felt themselves *'slip back'* (M3 FG4).

**Theme 4 - Life Beyond their Illness**

There was a sense of 'moving forward'. The programme was giving participants something to look forward to and providing many benefits that were making an impact on their day-to-day living and they wanted to maintain this positive trajectory.

*'Absolutely beneficial, in every way. It was something we looked forward to and was excited to see who was going to take part after all, we are delighted…. We have really enjoyed it; we have got the bug…wonderful experience.'* P3 FG1

Many talked about the programme/instructors making them feel normal again and that they were no longer defined by their condition '*Well, that's in the background* [being a patient], *it's gone*.' (F2 FG4). They no longer felt they were a patient but a participant in an exercise class.

*'.. they don't treat us as recovering patients, and you're no longer a patient. That's a huge thing …. All from different backgrounds …. and it's by being targeted normally that you're well able to do this….* (M3 FG 4)

Participants associated being part of the programme with many physical benefits. Many referred to the progress they made in the first 10 weeks; not only progress in their ability to complete the exercises in the class *'when I started …. I wouldn't have been able to do a fraction of those things that we are able to do now'* (F2 FG3) but also in activities or tasks outside of the class *'I've my walk down from an hour to 50min'* (M1 FG3). There were consistent references to walking 'further' and 'more comfortably' *'Well for me I have had dreadful angina when walking and that seems to have improved immensely*.' (P3 FG1).

Participants also referred to the mental health benefits.

*'it does something to your mind, it focuses it, it is very positive.'* (P6 FG1)

*'Physically you feel better but even mentally you feel better'* (P10 FG2)

*'There is a real feel-good factor about it…. good inner feeling.'* (M3 FG3)

Their confidence, courage, energy, and outlook on life had improved in just 10 weeks and there was a realisation that there was a life beyond their illness *'…the illness isn't the end of the road…'* (M2 FG3).

**5.5 Summary of results**

The overarching theme was a transition from fear to exercise confidence following participation in the MCEP. The predominant drivers of exercise engagement were social support, enjoyment, and routine or scheduling. There was a strong sense of a need for a structured, follow-on exercise programme. The move from the hospital setting to a MCEP appeared to be a smooth transition with high satisfaction expressed by participants. They expressed reassurance provided by the link between the hospital and community provider. Physical, psychological, and social benefits were described. A novel finding that emerged from this study was that participation in the MCEP could be viewed as a double-edged sword. Undoubtedly the programme provided an outlet to encourage continued exercise beyond the hospital setting. There were, however, indications that some participants were dependant on the exercise programme and were less likely to exercise independently. This could potentially hinder their ability to achieve the daily recommended PA. A further novel finding was the evident use of social comparison against other CAD participants and individuals with other CD to provide favourable valuations of performance and increased exercise confidence.

# Chapter VI

# Discussion

Currently almost 50% of men and women in Ireland over the age of 50 are living with ≥ 1 CD (H.S.E. 2021b), with this number predicted to increase by 40% by 2030 (H.S.E. 2020b). The most recent National Framework for the Integrated Prevention and Management of CD 2020-2025' (H.S.E. 2020a) places greater emphasis on facilitating individuals to manage their CD in the community. One of the key aims of the National framework is to move away from disease-specific programmes, in preference of broader, more inclusive intervention programmes that cater for multiple CD.

PAET is well established as an adjunct therapy in the management of many CD (Pedersen and Saltin 2015). An integrated MCEP could be a resource-efficient strategy for providing exercise to individuals with a CD who do not requires medical supervision. Most CD-specific exercise programmes have comparable designs (Desveaux *et al.* 2014) with a combination of aerobic and resistance training recommended (Pedersen and Saltin 2015).

## Baseline Characteristics

A MCEP was established at ATU Sligo with the goal of delivering supervised exercise classes for individuals with a range of CD. The MCEP was a collaboration with SUH, who referred suitable individuals to the MCEP on a thrice-yearly format. While many participants were referred from hospital-based setting (CAD), many others had not taken part in a previous structured exercise programme (OCD) and may therefore present with a lower

functional capacity and other health-related indices than CR patients. The first aim of this PhD was to describe and compare baseline health and fitness indices of individuals referred to a MCEP. There was a significant difference in many actual and perceived physical and mental health at baseline between patients who had completed hospital-based CR and patients being referred through non-hospital-based programmes.

According to the ACSM, the most effective exercise prescription for an individual is one that is most helpful in achieving behavioural change (Garber *et al.* 2011). Exercise prescription in the setting of a MCEP can be challenging. In general, exercise prescription involves identifying a range of PA options that are effective in improving fitness and health while ensuring that risk is minimised and, optimising the conditions for a sustained behavioural change (Ekkekakis 2009). Factors related to the individual such as exercise history, current fitness levels, exercise preferences and symptoms relevant to the CD need to be considered when prescribing PAET.

Factors that have been found to impact uptake and attendance to CBCR such as level of education, employment status, distance to MCEP, and marital status were similar in both CAD and OCD, and between experimental groups. Participants attending this MCEP were more likely to be married/living with a partner, retired, overweight/obese with well-regulated BP. However, compared to OCD, participants in CAD were older and currently prescribed PPI, had a greater number of CDs, and a higher prevalence of hypertension, rheumatic conditions and T2DM. There were also more men than women in CAD than OCD.

The CAD group had a lower RHR, higher WHR, greater muscle strength, muscle endurance and aerobic endurance and, better self-reported health indicating that participants entering the MCEP from hospital-based structured programmes do have higher actual and perceived physical and mental wellbeing, with the exception of flexibility. Flexibility is the most common overlooked component of fitness (Gummelt 2015) and evidently not a focus of hospital-based CR. The range in age, body composition and fitness levels should ideally be taken into account when deciding on the frequency, intensity, time and type of exercise. Similarly, among OCD, those with inflammatory bowel disease had a greater number of CD than neurological and MSK. Stroke participants lived closer to the MCEP than T2DM, and the WHR was lower in patients with bowel disease than those with stroke.

There is a need to balance physiological effectiveness of PAET with enjoyment and pleasure to ensure that adherence is sufficient to maintain or positively affect desired biological outcomes. Prescribed exercise that is perceived as unpleasant or uncomfortable may negatively impact enjoyment and long-term adherence (Rose and Parfitt 2007). Conflicting opinions in terms of level of difficulty have been reported by patients attending a CBEP following completion of a hospital-based CR. Some participants indicated that the exercise was not challenging enough while others felt that the instructors were pushing them too much (Clark *et al.* 2011). Accommodating exercise preferences was still a challenge despite the fact that all participants had completed a hospital-based CR programme and, were therefore likely to be somewhat similar in terms of functional capacity (Clark *et al.*

2011). Preference for exercising alongside people of similar capabilities has been expressed among a group of individuals living with chronic pain (Dnes *et al.* 2021).

Exercise intensity is a crucial component of exercise prescription and has a major influence on the extent to which exercise participation can lead to health and fitness benefits. Standard exercise prescription procedures based on the titration of exercise intensity, to elicit a predetermined HR, $\dot{V}O_2$, RPE, caloric expenditure or blood lactate level, may be perceived as unpleasant or uncomfortable which may negatively impact enjoyment (Ekkekakis *et al.* 2011). The ATU MCEP used a circuit training format that could easily accommodate a large group of individuals. Participants were encouraged to exercise at an intensity ranging from 11 (light) to 14 (between somewhat hard and hard) on the 6 to 20-point Borg RPE scale. These RPE values equate to the normal perceptual preference range of most individuals (Moyna *et al.* 2001; Rose and Parfitt 2012).

An individual's perception of physical exertion can be viewed as a psychophysiological construct that represents the integration of multiple sensory inputs between external stimuli arising from physical work and internal responses reflecting physiological functions and situational and dispositional factors (Noble and Robertson 1996). The use of effort perception to self-regulate exercise intensity may encourage the development of intrinsic motivation, a central element in promoting adherence to exercise, and increase enjoyment and participation levels. Johnson *et al.,* (2006) found that 86% of adult women involved in aerobic exercise used effort perception exclusively to determine exercise intensity. This is

not surprising considering that exertional feedback is commonly used to regulate the pace of many daily activities. This is often done without conscious awareness. Allowing individuals participating in the MCEP to titrate their exercise intensity within the normal perceptual preference range is likely to have promoted enjoyment while accommodating a wide range of intensity preferences. In addition, the use of effort perception to self-regulate exercise intensity may have also helped participants to adjust their work rate to account for improvements in fitness.

HRQoL is a measure of an individual's perceived physical and mental health (CDC 2021). Generic questionnaires, such as the WEMWBS and the SF-12 Health Survey, have the advantage of being able to compare HRQoL across different CDs (Megari 2013). The impact of living with a CD and advancing age has been associated with lower perceived physical and mental health, with the impact usually greater for perceived physical health (Alonso *et al.* 2004; Sansgiry *et al.* 2008). This study found a higher perceived physical and mental wellbeing among patients coming from structured hospital-based CR indicating a need for greater support and encouragement for individuals referred to the MCEP without prior participation in a supervised exercise programme.

With the exception of WHR, there was no significant group difference in any of the other measurements of body composition. Almost 9 out of every 10 participants in each experimental group were classified as overweight or obese with the average waist circumference >105 cm in males and >96 cm in females. Gluteal fat increases the friction on

clothing and skin, the chafing creates sores, making it more painful to walk. In addition, many overweight and obese individuals may find exercise difficult due to lower extremity arthritis and low exercise tolerance. Variations in levels of body weight may also influence self-regulated exercise intensity. For example, self-regulated walking speed was found to be significantly lower, with RPE and both absolute and relative HR significantly higher in obese than the non-obese group adults (Hills *et al.* 2006). In contrast, Browning et al., (2006) found no difference in the preferred walking speed between class II obese and normal-weight men and women. The preferred walking speed corresponded to the speed that minimised the gross energy cost per distance. As excess body weight, particularly in the abdominal region, is related to higher risk of CD (Liguori *et al.* 2021) ideally, a combination of exercise and dietary advice is required to reduce obesity levels in individuals with CD.

Despite significant differences in perceived and actual physical and mental health at baseline, initiation rates were very high in both CAD (97%) and OCD (93%), indicating a high interest in a MCEP in the region. The rate of uptake is much higher than previously reported for similar exercise programmes. The high initiation rates may be related to nature of the referral pathway. All patients were referred through a cardiologist, GP, physiotherapist, or nurse. Pavey *et al.,* (2012) found that uptake to an ERS was much lower following referral by letter (28-35%) compared to face to face (58-100%). Initiation rates of 65% to ERS in the UK have been reported following referral (James *et al.* 2008). Interestingly, referral from a GP was more likely to lead to initiation of an ERS compared to other HCP such as dieticians,

psychiatrists, smoking cessation offices and healthy lifestyle coordinators. The high level of uptake indicates the referral pathway used for this MCEP is a good model going forward.

Despite the statistically significant difference in age between CAD and OCD, both cohorts on average were in their early 60s, indicating that the MCEP based at ATU Sligo appealed to an older cohort who were more likely to be retired. The fact that the MCEP was scheduled during midweek mornings may be a barrier to participation in the MCEP among younger men and women who are still working. The difference in gender profile between CAD and OCD cohorts align with latest prevalence rates. Fewer females than males in Ireland are living with CAD (Wilkins *et al.* 2017), whereas females have a similar or higher prevalence of stroke (Wilkins *et al.* 2017), OA (French *et al.* 2016), MS (O'Connell *et al.* 2017) and IBD (Dahlhamer *et al.* 2016).

Not surprisingly, levels of prescribed medication for hypertension were high in both CAD cohorts resulting in BP in both OCD and CAD being well regulated and a lower RHR in the CAD. Participants with a pre-session resting BP >180/90 mmHg were not allowed to participate in an exercise class. Most instances of elevated BP were due to participants forgetting to take their medication in the morning. On rare occasions, some of participants required a change in BP prescription. This highlights the importance of pre-exercise BP screening and, the importance to continually remind participants of the need to take their medication according to GP instructions. The significantly higher use of PPI in the CAD population is concerning considering a recent publication linking long-term use of PPI to

increased risk of MI due to their deleterious effect on endothelial function (Ariel and Cooke 2019).

**Efficacy**

The second major aim of the present PhD was to assess the efficacy of participating in a MCEP. Participation in the MCEP resulted in significantly greater improvement in lower body muscle strength in CAD, and OCD, compared to CAD-CG. There was no significant difference in any of the other fitness indices or HRQoL between CAD, OCD and CAD-CG at 10 weeks. There were however significant within-group differences in both intervention groups compared to baseline that were not evident in the control group. In just 10 weeks of participating in the MCEP, individuals with CAD and OCD had significantly improved CRF and waist circumference. Individuals with OCD also improved upper body muscle strength and HRQoL.

CRF relies on the integrative function of a number of physiological processes including right and left ventricular function, ventricular-arterial coupling, pulmonary ventilation and diffusion, peripheral muscle oxygen utilisation, and vascular health (Ross *et al.* 2016). Incidence rates for many CD such as CVD, respiratory disease, dementia, metabolic disorders, and cancers is inversely related to CRF (Myers *et al.* 2002; Lee *et al.* 2011; Ross *et al.* 2016; Steell *et al.* 2019). Although cardiopulmonary exercise testing allows for the most accurate and standardised quantification of CRF, it is not always feasible or readily available (Ross *et*

*al.* 2016). Submaximal performance tests like the 6MWT can provide valuable information and, although not as accurate, can be used to estimate levels of CRF (Nolen-Doerr *et al.* 2018).

The 6 - 8% improvement in 6MWTD in both CAD and OCD is smaller than previously reported for CD-specific CBEPs of similar duration (van de Port *et al.* 2012; Zhang *et al.* 2018). Baseline 6MWTD of CAD and OCD was however 36% and 25 - 46% higher, respectively in the present study, compared to studies that reported greater improvements in 6MWTD (Table 6.1). Individuals with lower baseline 6MWTD (<400 m) are more likely to have greater improvements (Minnella *et al.* 2016). Where 6MWTD was similar at baseline (Zernicke *et al.* 2016), improvements over the same timeframe are consistent with previous research. There is potential for a 'ceiling' effect for individuals with a higher (> 450m) baseline 6MWTD (Frost *et al.* 2005) as the linear relationship between $VO_2$max and 6MWTD is lost as they are closer to their maximal walking speed (Puente-Maestu *et al.* 2018). This needs to be investigated further and if evident then an alternative test like the ISWT or the 12min Cooper should be considered. Maintaining or improving CRF provides protection against all-cause and CV mortality (Lee *et al.* 2011). Although the percentage improvement in 6MWTD in the intervention groups was ≤ 8%, it is worth noting that almost one-third of CAD and OCD that adhered to the MCEP achieved a MCID of ≥ 50 m. A MCID represents a change that is meaningful and worthwhile to the patient and is often more relevant to the clinician and the patient (Copay *et al.* 2007).

Table 6.1 Improvements in 6MWDT following 10-12 weeks of exercise training among individuals with specific CD

| | **Location** | **Condition** | **Baseline 6MWD** | **% Improvement** |
|---|---|---|---|---|
| Current study | Community | CAD/OCD | 506m/454m | 6%/8% |
| (Zhang *et al.* 2018) | Both | CAD | 324m | 27% |
| (van de Port *et al.* 2012) | Community | Stroke | 339m | 22% |
| (Gordon *et al.* 2013) | Community | Stroke | 247m | 18% |
| (Zernicke *et al.* 2016) | Home | MSK (RA) | 581m | 5% |

Greater levels of muscular fitness have been shown to have a beneficial effect on CVD risk factors, CVD events and all-cause mortality (Katzmarzyk and Craig 2002; Garber *et al.* 2011). Despite a combination of aerobic and resistance training being considered optimal for individuals with ≥1CD (Pedersen and Saltin 2015), muscle fitness is not always prioritised when prescribing exercise for individuals with CD (Loudon *et al.* 1999; Johnson *et al.* 2009; Gordon *et al.* 2013; Ong *et al.* 2016; Varas *et al.* 2018; Zhang *et al.* 2018). The components of ATU Sligo MCEP reflected the current evidence-based literature and included both aerobic and resistance exercises (Pedersen and Saltin 2015).

The positive impact of the resistance exercise component is exemplified by the 14 - 18% increase in lower body muscle strength in both intervention groups. Furthermore, 19% of CAD and 16% of OCD had a MCID in lower body muscle strength following their participation in the 10-week MCEP compared to none of the participants in CAD-CG. It is important to note that lower body muscle strength decreased in 52% of CAD-CG. This novel finding suggests that participants discharged from phase III CR may continue to exercise aerobically but are unlikely to focus on muscle fitness indicating a key benefit to participating in a MCEP is to ensure muscle fitness is incorporated into the weekly activity of individuals

with a CD. The improvements in lower body muscle strength are consistent with previous studies that have included resistance exercises in exercise programmes involving CAD, stroke and MSK patients (Pang *et al.* 2005; Izawa *et al.* 2006; Seki *et al.* 2008; Zernicke *et al.* 2016). In contrast, no improvement in lower body muscle strength have been found in programmes that are exclusively aerobic in nature (Izawa *et al.* 2006; Globas *et al.* 2012).

HGS is a commonly used and reliable measure of overall muscle strength, with reduction in HGS indicative of age-related muscle loss and frailty (Sousa-Santos and Amaral 2017). Below normal HGS is a significant predictor of future health, morbidity, and mortality (Sayer and Kirkwood 2015). Although the relative increase in HGS was lower in both OCD and CAD compared to lower body strength, a higher number of participants in both experimental conditions achieved a MCID. Interestingly, 46% of participants in CAD achieved a MCID despite the fact that the average change in HGS did not reach statistical significance. The larger, and statistically significant, increase in HGS in OCD compared to CAD is probably due to their lower baseline values. The higher baseline HGS in CAD reflects the fact that they had participated in a structured hospital-based CR programme prior to commencing the MCEP. However, participating in the MCEP continues to provide further meaningful improvements in HGS. Improvements in upper body strength has been found in OCD groups such as neurological (6 - 8%), bowel disease (8%) and T2DM (47%) (Elsworth *et al.* 2011; Gallé *et al.* 2019; Jones *et al.* 2020).

In contrast to BMI, waist circumference decreased in both OCD and CAD compared to baseline. It is not unusual for some measurements of body composition to improve while others remain unchanged (Seki *et al.* 2008; Mendes *et al.* 2017; Noites *et al.* 2017; Gallé *et al.* 2019). Importantly, reduced levels of abdominal obesity and waist circumference have been associated with a lower risk of CVD and cancer mortality irrespective of changes in BMI (Zhang *et al.* 2008). Due to the association of obesity-related health risk to abdominal obesity, a reduction in waist circumference may be more desirable than a reduction in BMI when monitoring body composition (Liguori *et al.* 2021).

Although flexibility is not a significant predictor of mortality, it has been shown to be a predictor of independent living and maintaining HRQoL (Katzmarzyk and Craig 2002). Flexibility, when combined with resistance exercises, may enhance postural stability and balance, and reduce the risk of falls (Garber *et al.* 2011). Although joint flexibility decreases with aging, improvements can be achieved after 3 - 4 weeks of regular stretching at least 2 - 3 times a week (Garber *et al.* 2011). Stretching exercises were included as part of the MCEP cool-down and, although there were no significant improvements in flexibility as measured by the S&R test, baseline levels were maintained. Improvements in flexibility likely require a more intensive period of static and dynamic stretching (Seki *et al.* 2008; Mendes *et al.* 2016).

Exercise interventions improve HRQoL in both healthy individuals and those with CD (Mitchell and Barlow 2011). There is an accumulating body of evidence demonstrating improved psychological and/or physical wellbeing following completion of a range of disease-

specific CBEP (Loudon *et al.* 1999; Foley *et al.* 2003; Johnson *et al.* 2009; Elsworth *et al.* 2011; Globas *et al.* 2012; Beauchamp *et al.* 2013; Gordon *et al.* 2013; Pinto *et al.* 2013; Amin *et al.* 2014). The present study found no difference in HRQoL between those who participated in the MCEP or the control group.

The WEMWBS score, which assesses an individual's state of wellbeing, was significantly higher at baseline in both CAD and CAD-CG than OCD. This difference may be due in part to the fact that participants in both CAD and CAD-CG had completed in a medically supervised hospital-based CR programme. There was, however, no group difference in the WEMWBS score at 10 weeks due to a significant improvement in OCD only. The level of improvement in the WEMWBS score in OCD was similar to a previous study that had comparable baseline scores and exercise intervention (Maheswaran *et al.* 2012). Despite no significant improvement in the WEMWBS in the CAD, 44% had a clinically meaningful improvement (>3 points) over the 10-week intervention, which is similar to the 50% improvement in the OCD and, much higher than those in the CAD-CG (6%).

The SF-12v2 Health Survey derives a mental and emotional wellbeing score (MCS) and a perceived physical functioning score (PCS) (Linde et al., 2009). There was no effect of participation in the MCEP on mental wellbeing as measured by the MCS component of the SF-12 among any of the experimental groups. There is conflicting evidence for the impact of CBEP on the SF-12 MCS. Some CBEP have found a positive improvement in MCS (Foley *et al.* 2003; Pinto *et al.* 2013) while others have reported change (Elsworth *et al.* 2011; Gordon *et*

*al.* 2013; Christle *et al.* 2017). Importantly, there was no decrease in mental wellbeing following participating in the MCEP.

Consistent with previous research, the PCS was consistently lower than the MCS at baseline and after the intervention (Alonso *et al.* 2004; Sansgiry *et al.* 2008). There was a significant improvement in PCS in OCD following the 10-week intervention and, a trend towards a significant improvement in the CAD group. Individuals in OCD, who were less likely to be commencing the MCEP following a structured exercise programme, had a significant improvement in perceived physical and mental wellbeing compared to CAD.

The MCID for the key components for HRPF outlined above were based on PP analysis. Although prone to bias and overestimating the treatment effect (Tripepi *et al.* 2020), PP analysis provides an estimate of the benefit of participants partaking in the MCEP when compliance is maintained. The use of ITT approach investigates the effect of assigning PAET to a target population where realistically there will be drop out in a real-world programme such as this MCEP. Both approaches have validity in reporting their results. The effect may, however, be underestimated using the ITT approach as it assumes those that didn't post-test reported no MCID. While the majority of those that didn't post-test did drop out of the programme it also included a group that completed the programme but were not available for re-testing.

**Adherence**

A third aim of the present PhD was to assess the adherence rates and predictors of adherence during the first 10 weeks of the MCEP. The average attendance during the 10-week MCEP block was 61%. Participants in CAD attended significantly more classes (65%) than OCD (55%). Intervention group was not however a predictor of attendance in a multivariate model. Attendance at the MCEP was lower than previously reported for both CD-specific programmes and other MCEP where the rates ranged from 70% to 94% (Sørensen *et al.* 2008; van de Port *et al.* 2012; Beauchamp *et al.* 2013; Moore *et al.* 2015; McNamara *et al.* 2016). The majority of these programmes were however, delivered by HCPs. Although the presence of HCPs may foster higher attendance rates, they are not a feasible long-term option for delivering a MCEP.

Overall, male gender and better mental wellbeing were identified as predictors of attending a higher number of classes. Being single and having a higher HGS predicted low and high attendance respectively in CAD. Marital status was not however a predictor of adherence in OCD. A higher attendance by males has been consistently reported in both short and long-term CBCR programmes (Dohnke *et al.* 2010; Mandic *et al.* 2015). In contrast, females were more likely to attend a CBEP for older people with and without CD (Killingback *et al.* 2017). The fact that attendees were predominantly female may have encouraged higher attendance.

That fact that mental wellbeing was a predictor of attendance is particularly important considering that HRQoL measures are significant predictors of short and long-term mortality (Brown *et al.* 2015). Individuals with lower baseline (induction) mental health scores should be closely monitored and provided with more individualised support to encourage attendance. Collaboration between the MCEP and other specialities to provide support structures to improve mental wellbeing may also be an avenue to explore.

Marital status has also been shown to be a predictor of attendance to both CBCR and CBEP (Mandic *et al.* 2013; Killingback *et al.* 2017). However, in the present study, the association between marital status and attendance was only evident in the CAD group. The CAD cohort may have a larger family support structure that may encourage higher attendance. Interestingly, individuals who were separated, divorced, or widowed were also high attenders indicating having a partner was not critical to achieving a high attendance. Functional ability has been found to be a predictor in certain disease-specific CBEP and to be associated with long-term engagement in PA among MS and stroke patients (Tiedemann *et al.* 2012; Ploughman *et al.* 2015). In the present study, better functional ability assessed using HGS predicted attendance in CAD but not in OCD.

The dropout rate in ATU Sligo MCEP was 25%, which compares favourably to an ERS that reported 42% had stopped attending at 13 weeks (Tobi *et al.* 2012). Almost 50% of the dropout in the ATU MCEP occurred in the first 4 weeks. Strategies to improve adherence and reduce dropout especially in the first 4 weeks are warranted. The fact that mental wellbeing

was significantly lower among dropouts over the course of the 10 weeks indicates the importance of measuring this construct at baseline in order to identify individuals at risk and intervene appropriately.

In a multivariable model, individuals who had a lower upper body muscle strength and were male were less likely to drop out during the 10-week MCEP. In contrast, Soohyun *et al.,* (2012) found low levels of aerobic fitness but not gender to be a predictor of dropout from a 6-month exercise programme among individuals with T2DM. Similar to the present study, Dohnke *et al.,* (2010) found that males were more likely to still be attending a CBCR at 6 months compared to females. Although the present study found gender and muscle fitness to impact dropout over the 10 weeks, the model explained only 8% of the variance.

Females were less likely to attend and more likely to drop out of the ATU Sligo MCEP. Females are more likely to identify themselves as homemakers (Adelmann *et al.* 1993) indicating that they may have greater external commitments than males. Family commitments was identified by females in the focus groups as a key barrier to attending the MCEP. Future studies should address the factors influencing female attendance in MCEP, and in a particular address the barriers to attendance.

There was evidence from the focus groups that some of the participants perceived themselves as having a higher functional capacity compared to new programme entrants. Preference for exercising alongside people with similar physical capabilities has been expressed in a group of individuals living with chronic pain (Dnes *et al.* 2021). There may be

a need to introduce a short-term, entry level MCEP to allow participants with greater levels of baseline deconditioning to undertake a more individualised programme prior to progressing to an established MCEP. Providing an option for an entry level programme may improve exercise self-efficacy and promote higher adherence. This could be beneficial for those who have not participated in a structured hospital-based programme or who fail to meet minimum fitness level that is deemed appropriate for participating in a MCEP.

**Patient Perspective**

The final aim of this PhD was to explore CAD patients' experience regarding their transition from hospital-based CR to participation in a MCEP and to identify the dimensions that both facilitated and hindered PA engagement. The four key themes that emerged from the focus groups were i) moving from fear to confidence, ii) drivers of engagement, iii) challenges to maintaining exercise adherence and iv) life beyond their illness.

A key finding was that patients experienced a transition from *fear to confidence* in the early weeks attending the ATU Sligo MCEP. Fear of exercise has previously been reported by individuals with CD as a barrier to initiating independent exercise (Rogerson *et al.* 2012). Despite understanding the importance of continuing to undertake regular exercise following participation in hospital-based CR, participants were fearful and uncertain of what type(s) of exercise to undertake, the quantity of exercise required and, were fearful of exercising independently. The circuits and resistance training appeared to be the key activities in which participants lacked confidence. It is likely that participants were not taught to be

independently physically active on leaving hospital-based CR or that they did not feel safe exercising independently.

The continuity between hospital-based CR and the MCEP was viewed as important. The fact that some participants were concerned about how their health would be impacted if the MCEP ceased, supports the potential role of a long-term step-down MCEP with less involvement of HCPs. For most participants, the MCEP appeared to reduce this concern and gave them the confidence to exercise both in a class setting and independently. Importantly, participants felt more comfortable to be exercising alongside others '*in the same boat,* a phrase that has also been reported in other studies (Martin and Woods 2012; Hardcastle *et al.* 2015).

The importance of the link between the MCEP and the hospital-based CR programme gave participants confidence in transitioning to and attending the MCEP. Participants felt that the direct link between the hospital-based CR programme and the supervised ATU Sligo MCEP set it apart from a regular gym or community exercise class. The importance of the link between community and hospital setting to ensure smooth transition into the community setting has been previously reported (Clark *et al.* 2011; Martin and Woods 2012). The link between hospital-based exercise programme and MCEP is not evident in many of the long-term studies implying this link may be only viewed as being important in the early stages of attending a MCEP.

Notwithstanding the benefits of continuity and reassurance highlighted by participants attending the MCEP, there is some concern that the MCEP may be over medicalising exercise through regular BP and HR monitoring and may not be supporting a transition to more independent PA and long-term exercise engagement. Over-medicalisation of exercise could breed dependency on such supervision and monitoring. For some participants, there were signs that the dependency had just moved from the hospital to the community setting. This could be problematic considering that all adults with a CD including CVD, are recommended to accumulate at least 150 - 300 min of moderate intensity aerobic exercise each week. In addition, they should complete muscle -strengthening and functional balance activities on two or more days per week (Dempsey *et al.* 2021). Considering that the MCEP programme is delivered twice a week, participants who only complete the programme and fail to undertake any other exercise are unlikely to achieve the recommended daily PA guidelines. There is therefore a need to encourage, educate, and empower MCEP participants to increase their PA levels outside of class time.

For the majority of MCEP participants, there was a noticeable increase in exercise confidence along with evidence of increased self-efficacy to exercise at home. Many of the participants commented that the MCEP made them feel 'normal' again. They no longer identified themselves as patients, but as participants in an exercise class. Many of the participants had moved from a fear of exercise to confidence in their ability to exercise. McNamara *et al.,* (2016) also found that exercising in a community setting promoted a sense of normality to the exercise environment.

Consistent with previous research focusing on long-term exercise maintenance for individuals with a cardiac condition, this study found that scheduled exercise classes, social connections and enjoyment were the primary motivators and drivers of exercise engagement. The scheduled exercise classes fostered a commitment and routine with several reporting a lack of motivation to exercise independently. The provision of routine and structure has been previously shown to be a key enabler to maintaining a regular exercise habit (Martin and Woods 2012; Hardcastle *et al.* 2015). In some instances, participants reported that exercise was part of their weekly routine and that they did not schedule other commitments that would prevent them from attending classes (Martin and Woods (2012). Hardcastle *et al.,* (2015) also found the discipline and routine was important with participants believing that the other class members expected them to come resulting in a 'sense of duty' to attend.

Consistent with previous research, the social nature of the programme and social support from fellow participants was a key driver of continued engagement in long-term exercise maintenance (Thow *et al.* 2008; Martin and Woods 2012; Dunn *et al.* 2014; Hardcastle *et al.* 2015). This study highlights that the social aspect is developed very early. Social support was fostered through chatting over a cup of tea at the conclusion of each class.

A novel finding of the present study is the evident harnessing of social comparison whereby participants appeared to take comfort in and took confidence from knowing they were not in the worst position. They were comparing their condition and exercise ability to

others who were worse or better off than them. This social comparison appeared to influence their perception of their ability to exercise. The behavioural change technique (BCT) of 'facilitate social comparison' has rarely been used in exercise interventions, and usually involves explicitly drawing attention to others' performance to elicit comparisons. Williams and French (2011) found higher PA effect sizes were achieved when interventions included the BCT of 'facilitate social comparison' along with five other BCTs (i.e., provide information on consequences of the behaviour, action planning, reinforcing effort or progress towards behaviour, provide instruction, and time management). It may be the case that social comparison works in tandem with modelling to increase self-efficacy in terms of observing similar individuals and favourably comparing one's performance to that of others. Participants who engaged with social comparison compared themselves favourably to others and, this in turn increased confidence to exercise and exercise engagement.

Enjoyment was the final driver of exercise engagement, which is consistent with previous research (Thow *et al.* 2008; Hardcastle *et al.* 2015). Similar to Thow *et al.,* (2008), participants expressed surprise at finding exercise fun, indicating past experiences led them to believe exercise was not an enjoyable experience. Although many expressed a preference for the gym-based exercise, in the belief that the gym environment challenged them more, the consensus appeared to be that the circuit session was more fun. Therefore, appealing to everyone and achieving the right balance is a challenge to the MCEP instructors. Music added to the enjoyment and was described as a key motivational aspect of the class which has

previously been noted as an important aspect of programme design (Killingback *et al.* 2017) in group exercise classes for older people.

There was an important distinction between the circuit-based exercises and using the cardiovascular equipment in the gym or doing the dance moves. Some of the participants indicated that using the cardiovascular equipment in the gym and dance was on a different level compared to the circuit-based class. Many participants expressed a preference for the gym-based exercise, which is contrary to previous research in similar populations. Research undertaken by Killingback *et al.,* (2017) reported that older people and individuals with CD expressed a preference for a non-gym environment. They viewed gyms as boring or isolating. A systematic literature review of the barriers to ERS, which are similar to MCEPs, reported that the participants found the gym to be an intimidating environment unless activities were scheduled during off-peak hours (Morgan *et al.,* (2016). Previous studies appeared to use the gym for individual exercise prescription while other gym members where present. In the present study, participants were introduced to the gym as part of a group. Perhaps dedicated gym hours for the older adult may encourage greater enjoyment and adherence to gym-based training.

Participants identified family and work commitments as key barriers to continued participation in the MCEP. Similar findings have been observed previously (Dunn *et al.* 2014; Horwood *et al.* 2015). Although distance wasn't viewed as a barrier for those in the focus group, it was mentioned as a reason for dropout by some of the other participants. Barriers

such as cost and other health problems that were reported as barriers in other studies (Rogerson *et al.* 2012; Dunn *et al.* 2014; Horwood *et al.* 2015), did not appear to hinder PA engagement.

Previous research found that patients could identify many perceived physical, psychological, and social benefits following long-term attendance at a CBCR (Thow *et al.* 2008; Horwood *et al.* 2015). Many of the perceived physical, psychological, and social benefits were evident in the first 10 weeks, indicating that attending a MCEP is a viable option for individuals with one or more CD.

**Thesis Limitations**

There were several limitations to this research. The control group was not a randomised control group, consisting of individuals who were interested in the MCEP but were unable to attend due to time constraints or distance to the MCEP. As the study setting was community-based, intentionally withholding access to the service to allow for a RCT was not considered ethically appropriate. Furthermore, the control group only included individuals with CAD which questions their appropriateness for determining efficacy of the MCEP for both CAD and OCD. Future studies should try to include other CD cohorts in the control group.

As participants attended a single MCEP in Sligo, Ireland, the study findings may not be applicable in other locations. The fact that the study only comprised individuals who met the

inclusion criteria and who HCPs deemed suitable for participating in a MCEP, limits the generalisability of this study to all individuals with a CD.

PA levels in both the intervention group and control group were not recorded. PA undertaken outside of the MCEP could also have influenced the health and fitness indices of all three experimental groups over the 10-week period.

All participants in the focus groups had completed the first 10 weeks of the MCEP with full intentions of continuing and may be a somewhat biased sample. Only individuals with a cardiac history were included in the focus groups, which limits the interpretation of the qualitative results to a single CD. Finally, despite participants being informed that their responses would be anonymous, they were aware that these results would be seen by programme coordinators, and this may have further biased their responses.

**Recommendations for Future Research**

- **Engage patients and HCP in the development stage of MCEP**

Although many key CD cohorts were included in this study there were many other CD that require a similar exercise programme. Whether they can all be accommodated under the one umbrella still requires further research. It is likely that a one size will not fit all but that a suite of opportunities to either exercise independently or group classes catering for different levels of ability need to be developed and evaluated. Engaging the patients in the development stage could enhance service development and delivery (Bombard et al. 2018).

- **Objectively measure PA and sedentary behaviour external to the MCEP**

This study reported that some individuals were likely not to exercise independently outside of the MCEP. Recording PA levels and sedentary behaviour over the course of a week, ideally objectively using accelerometers, could provide beneficial information of activity levels of the control group and activity level of the intervention group outside of scheduled classes. Previous research has found that individuals with a CD have lower weekly PA levels (Brawner *et al.* 2016). In fact, one study reported that individuals with CD that participated in a CBEP did so at the expense of other weekly activities reducing other activities rather than adding to their activity levels (Elsworth *et al.* 2011).

- **Use focus groups to explore the perspective of patients with a range of CD**

All participants in the focus group had a cardiac history and therefore were a homogenous group suitable for assessing in the focus group and were, also, the predominant group in the MCEP. However, there were participants with other CD engaging with the MCEP. Future research should explore their perspective of participating in a MCEP.

- **Examine other clinical measurements relevant to each CD**

This study showed that a MCEP could effectively improve various health and fitness indices. Despite an array of dependant variables being analysed there are other clinical measurements which would be relevant to both patients and HCPs and could focus on the mechanisms of how a MCEP may enhance patients' lives. Future work should include data

on key clinical measurements such as selected blood profiling (LDL-C, HDL-C, TG, anti-inflammatory markers), complete blood count (white blood cells, red blood cells, platelets, red cell distribution width, mean corpuscular volume, mean platelet volume, neutrophil to lymphocyte ratio, monocyte to HDL ratio, platelet to lymphocyte ratio) and vasculature changes (endothelial function). Many of these are now being used as indices of health (Lassale *et al.* 2018; Haybar *et al.* 2019; Park *et al.* 2021) and may be beneficial biomarkers in detection, or predicting the prognosis, of different CDs in future studies (Ferrucci and Kohanski 2022).

- **Examine the relationship between depression and anxiety in individuals with a CD on programme uptake, adherence, and efficacy**

This study assessed the impact of partaking in a MCEP on perceived physical and mental wellbeing demonstrating a positive impact. Future work should also assess levels of depression and anxiety in individuals with a CD taking part in a MCEP. Depression and anxiety are common comorbidities in many CD (Boing *et al.* 2012; DeJean *et al.* 2013) and it has been established as an independent risk factor for predicting mortality and specifically cardiac morbidity (Freedland and Carney 2013). The relationship between depression and anxiety on programme uptake, adherence, and efficacy in a MCEP warrants further research.

- **Explore the reasons why individuals dropped out of the programme in order to develop effective strategies to promote adherence**

Valuable information was obtained on individuals attending a MCEP, but future work should explore individuals that dropped out of the programme. This could be done through inviting participants back to complete the series of baseline induction tests and comparing outcomes to those that continued to attend the MCEP. Exploring their reasons for drop out through questionnaire or focus group would also help understand their reasons for drop out, highlighting any issues within the programme that can be adjusted or changed to increase engagement with the MCEP. It could help the MCEP providers to develop and support people at risk of dropping out and in doing so reduce dropout.

- **Assess the impact of integrating nutrition counselling into the delivery of a MCEP**

With the high levels of overweight and obese individuals with CD a multidimensional approach needs to be considered and evaluated. Future work should assess the integration of nutrition and/or exercise counselling into the delivery of a MCEP.

- **Long-term follow-up of attendance, dropout, efficacy, and patient perspectives**

As this is an ongoing maintenance MCEP further evaluation should be conducted on attendance, drop out, efficacy and patients' perspective at longer timepoints. This will help direct resources and supports to gain maximum benefit.

**Conclusion**

Despite the wide range of initial physical abilities, the present study demonstrated that MCEPs are safe for patients with a range of CD. Referral to the MCEP through a HCP was effective. Participation in an integrated MCEP facilitated exercise maintenance and helped to maintain or improve actual and perceived physical and mental wellbeing, beyond the hospital setting for CAD patients. The MCEP was also effective in improving CRF, lower and upper body strength, waist circumference and perceived physical and mental wellbeing for low-risk individuals with OCD who had been referred directly by a HCP and had not participated in a hospital-based programme. However, the only component of fitness that improved over and above the control group was lower body muscle strength indicating that a MCEP is primarily effective in improving muscle fitness.

Females and individuals with lower mental wellbeing were less likely to attend and more likely to drop out, indicating these cohorts should be closely monitored and supported especially in the first 4 weeks when dropout is highest. Although participation in the ATU Sligo MCEP resulted in significant physical and mental health benefits, some individuals may be less likely to exercise independently, resulting in them not meeting their PA guidelines and not maximising the health benefits of exercise. A MCEP provides an ideal platform to educate, support and facilitate PAET in individuals with CD and help reduce the growing burden of CD in Ireland.

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## Appendices

### Appendix A National Exercise Referral Framework Guidelines

**NATIONAL EXERCISE REFERRAL FRAMEWORK INCLUSION CRITERIA TEMPLATE; CATEGORIES A AND B**

**GENERAL CRITERIA FOR REFERRAL TO THE SERVICE**

- Clinically stable
- Able to monitor and regulate the intensity of their activity
- Able to recognize their optimum level of exercise intensity
- Able to acknowledge the importance of and demonstrate a commitment to modifying risk-related behaviour
- Able to sit in any seat independently (time unlimited)
- Ambulant and able to mobilize more than 5 m with or without a walking stick,
- independently or supervised
- Adequate communication strategies for those with aphasia to allow participation

**WITH REGARD TO GROUP B PATIENTS**

Patients with functional capacity levels 1-2 may attend community-based elements of the service (i.e., walking groups etc) while patients with functional level 3-4 are advised to attend (initially at least) centres (i.e., community gyms) with supervised options.

**Functional Level 1**: Illness diagnosed, but not interfering in any with normal activities
**Functional Level 2**: Can carry out all normal activities, but with symptoms
**Functional Level 3:** Can carry out some but not all normal daily activities (independently), because of symptoms
**Functional Level 4**: Can carry out very few normal daily activities independently, because of symptoms

**Note:** The listing below is to provide general guidelines. It may not be complete and clinical judgement may always be applied in deciding where to refer patients.

| Condition | Group A | Group B |
|---|---|---|
| **Cardiovascular Disease** | • Stable angina<br>• Stable chronic heart failure<br>• Stable valvular heart disease<br>• Implanted cardiovertor defibrillator with history of cardiac arrest | • Post non-recent (> 2months) percutaneous coronary intervention (with or without prior cardiac event) ><br>• Post non-recent (>6 months) cardiac surgery<br>• Permanent pacemaker |

| | | |
|---|---|---|
| | • Pre cardiac transplant without absolute contraindications<br>• Post cardiac transplant<br>• Stable cardiomyopathy<br>• Stable cardiac arrhythmia<br>• NYHA Risk Stratification 2-3<br>• Post recent (i.e., < 2 months) percutaneous coronary intervention (with or without prior cardiac event)<br>• Post recent (<6 months) cardiac surgery<br>• Severe arterial hypertension (i.e., systolic BP of >170mm Hg and/or a diastolic of BP of >100mm Hg) at rest<br>• Post-myocardial infarction (to hospital-based Phase 3 Rehabilitation)<br>• Long Q-T syndrome | • Those identified as suitable for transfer to Phase IV by Phase III assessment and risk stratification<br>• Hypertension (systolic BP of >140 mmHg and <170 mmHg, diastolic BP >95 mmHg and <100 mmHg)<br>• Post Myocardial infarction on referral from Phase 3 Programme<br>• Implanted cardiovertor defibrillator without history of cardiac arrest |
| **Rheumatology** | Rheumatoid Arthritis (or other connective tissue disease) with lung involvement or associated significant cardiovascular disease | Rheumatological conditions not included in Category A |
| **Pulmonary Disease** | • COPD GOLD Stage 3-4<br>• Any patient using supplemental oxygen<br>• Any patient with Pulmonary fibrosis<br>• Any patient with pulmonary hypertension<br>• Any patient pre or past lung transplant<br>• Any patient with lung cancer (pre or post treatment)<br>• Severe unstable asthma<br>• Unexplained multifactorial dyspnea<br>• Cystic Fibrosis | Established pulmonary disease significantly affecting (or likely to affect) Quality of Life |

| | | |
|---|---|---|
| **Diabetes** | • Recent (within past 6 months) documented cardiovascular disease event (e.g., infarction) or procedure (i.e., stenting)<br>• Established autonomic neuropathy<br>• Documented hypoglycaemia unawareness<br>• History of recurrent severe hypoglycaemia<br>• Recent (within past year) laser or intra vitreal injection treatment of eye complications | • Type 1 or Type 2 diabetes, excluding those categories listed in group A.<br>• Pre-diabetes, i.e., impaired fasting glucose (fasting plasma glucose **≥**5.55 mmol/L and ≤6.94 mmol/L) or impaired oral glucose tolerance test (2h values in oral glucose tolerance test ≥7.77 mmol/L and ≤11.04 mmol/L) |
| **Stroke** | No specific stroke related requirement for high support, once period of stroke evolution / resolution has passed | Most stroke patients could attend low support centres |
| **Neurological conditions** | Autonomic dysfunction, autonomic neuropathy or multi-system atrophy with risk of exercise induced autonomic collapse<br>Severe or atypical Parkinson's (falls risk) | Chronic Neurological conditions impacting on QoL and not listed in Category A |
| **Orthopaedic** | Moderate to severe OA with co-morbidities | Moderate to severe OA which is impacting on QoL |
| **Mental wellness** | • Significant panic disorder<br>• Long Q-T syndrome (related to use of some neuroleptic medication) | Most mental illness patents who are mentally stable and willing to participate could attend low support centres |
| **Renal Disease** | Chronic or end stage kidney disease (GFR below 30mls /min with either<br>○ Cardiac co-morbidity<br>○ Hb <10g/dl (not corrected by EPO) | Chronic or end stage renal disease without cardiac comorbidity or anaemia uncorrected by EPO |

**Exclusion Criteria**

- <18 years of age
- Currently physically active (i.e., ≥30 min of moderate physical activity on 5 d/week)

**Absolute Contraindications to Exercise[1]**

- A recent significant change in the resting ECG suggesting significant ischaemia, recent myocardial infarction (within 2 days) or other acute cardiac event
- Unstable angina
- Uncontrolled cardiac dysrhythmias causing symptoms or hemodynamic compromise
- Symptomatic severe aortic stenosis
- Uncontrolled symptomatic heart failure
- Acute pulmonary embolus or pulmonary infarction
- Acute myocarditis or pericarditis
- Suspected or known dissecting aneurysm
- Acute systematic infection, accompanied by fever, body aches, or swollen lymph glands

**Relative contraindications to exercise***

- Left main coronary stenosis
- Moderate stenotic valvular heart disease
- Electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia)
- Severe arterial hypertension (i.e., systolic BP of >200mm Hg and/or a diastolic of BP of >110mm Hg) at rest
- Tachydysrhythmia or bradydysrhythmia
- Hypertrophic cardiomyopathy and other forms of outflow tract obstruction
- Neuromuscular, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
- High-degree atrioventricular block
- Ventricular aneurysm
- Uncontrolled metabolic disease (e.g., diabetes, thyrotoxicosis, or myxedema)
- Chronic infectious disease (e.g., mononucleosis, hepatitis, AIDS)
- Mental or physical impairment leading to inability to exercise adequately
- Relative contraindications can be superseded if benefits outweigh risks of exercise. In some instances, these individuals can be exercised with caution and/or using low-level end points, especially if they are asymptomatic at rest.

1. American College of Sports Medicine. ACSM's Guidelines for Exercise testing and Prescription, 9th edition. Lippincott Williams & Wilkins, Philadelphia, 2013.

**Appendix B Participant Information Leaflet and Consent Form**

## Information Sheet for MedEx@ITSligo Programme

### Introduction

Hello and first of all, thank-you for expressing your interest in taking part in our programme and the evaluation study attached to it. You have been invited to take part in an exercise programme aimed at improving your physical health and wellbeing. This information sheet has been written for you, to clearly explain what will be involved, how and where the programme will take place and why we are piloting and evaluating this programme. Please read the sheet carefully to ensure that you understand all the information. If there are any questions, please feel free to contact us at any time. All contact details are provided at the end of the last page.

The programme and the evaluation of same has been designed by staff from IT Sligo (ITS), specialised fitness instructors and physiotherapists from Sligo University Hospital (SUH) who specialise in cardiovascular physiotherapy. The ITS staff and fitness instructors specialise in the area of exercise science and exercise for rehabilitation purposes The programme is being evaluated by ITS staff, students and SUH staff. All of the activity sessions taking place in the in the Knocknarea Arena conducted by fitness instructors qualified in exercise for chronic conditions.

### What is involved in the Programme?

You will be required to attend the Knocknarea Arena (located on the ITS campus), for an exercise class that lasts about one hour on two separate mornings for ~10 weeks with an option to continue after that.

At each session, you will be required to undertake a quick check on your health first. This will involve a measure of your pulse and blood pressure and answering a couple of questions about your health, to let us know if there have been any changes since the last session. If your pulse and blood pressure are very high, we will be recommending you not to exercise on that particular day and ask you to consult your GP as regards continuing with the programme.

But presuming you will be good to go, you start your class which will be a combination of exercises designed to improve your breathing and circulation systems and also tone your muscles and develop strength. The fitness instructors have designed the classes following recommended guidelines for cardiac rehabilitation and will be present for the entire session. The sessions will last for 20 minutes initially and build up to 30 minutes over the 10 weeks

with an extended warm-up and cool down as per recommended guidelines. You are encouraged to work at your own pace, keep the legs moving and push yourself as you feel fitter. The general effort level the class will strive for is 'moderate', 11-14 on the rate of perceived exertion scale that goes from 6-20. But remember, everybody's 'moderate' is different!

We will organise light refreshments for afterwards, so feel free to stay and have a chat to your fellow participants and instructors.

**Evaluating the Programme – The Research Study**

As the programme is new, ITS want to find out what works well and what needs tweaking as we go along, with a view to developing and expanding the programme to offer it to more people like you. So with your agreement, we want to conduct some research to evaluate the programme.

What this means for you is that on the first day and the last day of the 10-week programme we will be asking you to take part in some health & fitness tests. This process will take about 2 hours in total for the whole group, including verbal introduction, completing all forms and questionnaires and doing all of the fitness tests. We will then compare your test scores from the beginning with test scores taken at the end of the exercise programme to see if scores improved. We are more concerned at looking at the average scores of the whole group for changes following the programme than to focus on anyone's individual scores.

The tests which you will be asked to complete and what each measure is outlined in the table below. The questionnaires are in your welcome pack, and we encourage you to fill these in in advance of the Induction session as honestly as possible. However, if you need any assistance, please bring them with you and our staff will answer your queries.

| The Test | What it Measures | What you have to do |
|---|---|---|
| **6 Minute Walk Test (6MWT)** | This test measures the *efficiency of your circulation and breathing systems* to work together with your leg muscles and endure 6minutes of walking. | The test simply requires you to walk as far as you can in 6 minutes, so the faster you walk, the further you get! |
| **Body mass Index (BMI)** | This is a measure of your *body fat levels* | This involves measuring your height and your weight and using a simple equation to calculate BMI. |
| **Waist-to-Hip-Ratio (WHR)** | This is another test of body fat but it focuses on *where body fat is being stored* on the body. | This is also another calculation, assessing the relationship of your waist measurement to your hip |

| | | |
|---|---|---|
| | | measurement. It therefore involves measurement of the narrowest waist circumference and the widest hip circumference. |
| **Strength Grip Test** | This simple test measures the strength of your 'gripping' muscles in your arms and is commonly used to assess *strength*. | It involves squeezing the handle of a piece of equipment called a 'grip-strength dynamometer' as hard as you can. |
| **Sit to Stand Test** | This test measures your lower body muscle strength in your legs. | It involves standing up and sitting down 10 times as fast as you can. |
| **Sit & Reach Test** | This tests the *flexibility* of the back of your upper legs and your lower back. | You sit on a mat and reach forward along a measurement scale as far as you can. It is basically like trying to touch your toes from a seated position. |
| **SF-12v2** | Complete a 7-question paper and pencil survey, which asks you about your health and well being | |
| **Warwick Edinburgh Mental Well-being Scale (WEMWBS)** | Complete a 14-question paper and pencil survey, which asks you about your mental well-being. | |
| **Blood Pressure & Pulse Check** | Pre-test *Blood Pressure, Pulse checks* will also be recorded. | |
| **Your Opinions / Levels of Satisfaction** | We may offer you the opportunity to participate in a focus group and/or complete a customer satisfaction survey during the programme to *tell us what you think* and give us *your suggestions* for programme development.<br><br>The focus group will be conducted by 2 members of the research team and a maximum of 10 participants. It will be scheduled to last a maximum of 1 hour. The purpose is to generate a group discussion on the experience of participants in the programme, from which we can ascertain pros, cons and recommendations to what we are running directly from yourselves. It will be recorded on an audio recorder and typed up with no use of real names. You can request a copy of the typed transcript if you wish from the lead researcher using the details at the bottom of this leaflet. | |

**Medical Information about your Health**

A certain amount of information regarding your health and medical history will be transferred on the referral form completed by either, your referring GP / Physiotherapist / Consultant including; your date of birth, main diagnosis and a list of any other medical problems, details of any prescribed medications and allergies, if applicable and relevant comments regarding anything the medical professional feels the exercise professional should know to take care of you in classes e.g. specific exercise recommendations, recent procedures, complications, notes, etc. . The information on this form is considered by the principal researcher and the fitness instructor before you commence the programme, in the interests of your safety on the programme. Please feel free to request a copy of the referral form to satisfy yourself as regards the specific information being transferred.

**Photographs, Videos, Audio Recordings**

From time to time, we may take photos and/or videos of sessions in action for promotional purposes only. If you are not happy to be included in these, please let a member of the research team know.

Also, the focus group where we ask for your feedback and opinions on programme development is likely to be recorded. The purpose of this is so that a transcript of the meeting can be typed up to accurately reflect everyone's views. We will be happy to send you a copy of the transcript to verify you agree that your contributions are reflected as you intended. No real names will be used in the typed transcript or subsequent reporting of experiences.

**Confidentiality**

All personal information and results from the study are treated as highly confidential. All final results are anonymised, this means that names or any other information that could identify you as a participant are removed after the initial testing period with researchers. All personal information collected is legally protected under both the Data Protection Act and the Institute of Technology Sligo confidentiality agreement. You have the right to access all personal information at any time throughout the study and after its completion. All information is stored securely on the IT Sligo campus and access to this information is given only to those directly involved in the study. All hard copy (written) information is kept securely in a locked filing cabinet in a secure office and all electronic data (computer) is password protected. No information is taken off the IT Sligo campus. Results may potentially be published in scientific journals or be presented at medical conferences; however, no participant can be identified as all data is anonymised at this stage.

**Do I have the right to opt out of the study?**

Yes. Your participation in the programme and evaluation study is entirely voluntary. You have the right to cease involvement in the study at any time you wish, without having to provide a reason, although we would love to know why you choose to leave, so if you are happy to tell us, please do – it might help us make positive changes to the programme!

**Potential Benefit of Participating in the Programme**

Physical activity participation has already been proven to benefit functional fitness. Exercise is increasingly being focused on as an adjunct therapeutic intervention which aims to improve health care and rehabilitation because it is relatively cheap and accessible, has few side effects and has many other benefits to holistic health. Some of the positive health indices exercise has been linked to are; increased energy levels, better mood, better sleep to name but a few. At present in Sligo, options for supported community-based exercise programmes are limited, so involvement in this programme offers the support of likeminded participants and fitness instructors with specialist training in exercise for chronic disease. Thus, to gather the backing to develop more opportunities such as this, it is vital that evaluation research studies such as this one take place. Very little research has taken place involving community-based exercise programmes in Ireland.

**Potential Risks**

Engaging in any exercise poses a small risk, typically of muscle or skeletal injury. However, it is generally considered that even in people with cardiac illness, the benefits of carefully planned exercise outweigh the risks and the incidence of cardiac related events during exercise are very rare, especially among regular exercisers. The programme and its evaluation study have a rigorous design to ensure that all potential risks are kept to a minimum. Participants will be monitored at all times during the sessions. Any unlikely problem which participants may have during the exercise sessions will be dealt with immediately, with the utmost professionalism and confidentiality. Fitness instructors and researchers are trained in Occupational First Aid and use of the Defib., both of which are conveniently located on site.

**Results**

Upon completion of the study, all results will be sent to you by letter or by email if you request them.

**Researchers Contact details**

**Name:** Ms Joanne Regan

| | |
|---|---|
| **Job Title:** | Principal Researcher |
| **Phone number:** | 087 2020413 |
| **Email:** | regan.joanne@itsligo.ie |
| **Address:** | Dept. Life Science, Institute of Technology Sligo,<br>Ash Lane, Sligo F91 YW50. |

**Informed Consent Form**

MedEx@ITSligo Programme

1. I confirm that I have been referred by my health professional for the above programme.

2. I confirm that I have read the programme information sheet, understand what is involved, and what will be required of me.

3. I confirm that I understand both the risks and the benefits of participating in this programme and have had any questions answered to my satisfaction.

4. I give my permission for my health professional to give the required details of my health status and medical history to the study research team on the referral form.

5. I consent to the use of photographs or videos of the exercise sessions which I may be present in, for programme promotional purposes.

6. I consent to being audio recorded if I participate in a focus group gathering participant feedback on the programme.

7. I understand that no identifiable results will be circulated/published as a result of my participation and that my identity and data will remain confidential.

8. I understand that I have the right to withdraw from the programme or the evaluation study at any time without reason.

9. I have had time to consider whether to participate in this programme and the associated evaluation research.

Given all of the above, my signature below indicates that I volunteer to participate in MedEx@ITSligo Programme and be part of the evaluation research.

| _____ | _____ | |
|---|---|---|
| Name of Participant (print) | Date | Signature |
| _____ | _____ | |
| Name of Principle Researcher | Date | Signature |

**Appendix C Participant Information Leaflet and Consent Form for Control Group**

## Information Sheet for MedEx@ITSligo Programme

## Evaluation of Fitness Parameters following Usual Care Cardiac Rehabilitation Advice

### Introduction

Hello and first of all, thank-you for expressing your interest in taking part in our study. You have been invited to take part in a study aimed at tracking various fitness parameters following completion of your **Phase III cardiac rehabilitation**. This information sheet has been written for you, to clearly explain what will be involved, how and where the evaluation will take place and why we are evaluating your progress. Please read the sheet carefully to ensure that you understand all the information. If there are any questions, please feel free to contact us at any time. All contact details are provided at the end of the last page.

The tests used in evaluation of your fitness indices has been designed by staff from IT Sligo (ITS), specialised fitness instructors and physiotherapists from Sligo University Hospital (SUH) who specialise in cardiovascular physiotherapy. The ITS staff and fitness instructors specialise in the area of exercise science and exercise for rehabilitation purposes. The programme is being evaluated by ITS staff, students and staff from SUH.

### Evaluating your Fitness – The Research Study

What this means for you is that following completion of Phase III Cardiac Rehab you will be invited to complete a battery of health and fitness test. This process will take about 2 hours in total for the whole group, including verbal introduction, completing all forms and questionnaires and doing all of the fitness tests. You will be given advice from the Cardiac Rehabilitation team how to continue and maintain your fitness and then 10 weeks later you will be invited back to complete the battery of tests again. We will then compare your test scores from the beginning with test scores taken at the end of the specified time period. We are more concerned at looking at the average scores of the whole group for changes than to focus on anyone's individual scores.

The tests which you will be asked to complete and what each measures is as follows :

| The Test | What it Measures | What you have to do |
|---|---|---|
| **6 Minute Walk Test (6MWT)** | This test measures the *efficiency of your circulation and breathing systems* to work together with | The test simply requires you to walk as far as you can in 6 minutes, so the faster you walk, the further you get! |

| | | |
|---|---|---|
| | your leg muscles and endure 6minutes of walking. | |
| **Body mass Index (BMI)** | This is a measure of your *body fat levels* | This involves measuring your height and your weight and using a simple equation to calculate BMI. |
| **Waist-to-Hip-Ratio (WHR)** | This is another test of body fat but it focuses on *where body fat is being stored* on the body. | This is also another calculation, assessing the relationship of your waist measurement to your hip measurement. It therefore involves measurement of the narrowest waist circumference and the widest hip circumference. |
| **Strength Grip Test** | This simple test measures the strength of your 'gripping' muscles in your arms and is commonly used to assess *strength*. | It involves squeezing the handle of a piece of equipment called a 'grip-strength dynamometer' as hard as you can. |
| **Sit to Stand Test** | This test measures your lower body muscle strength in your legs. | It involves standing up and sitting down 10 times as fast as you can. |
| **Sit & Reach Test** | This tests the *flexibility* of the back of your upper legs and your lower back. | You sit on a mat and reach forward along a measurement scale as far as you can. It is basically like trying to touch your toes from a seated position. |
| **SF-12v2** | Complete a 7-question paper and pencil survey, which asks you about your health and well being | |
| **Warwick Edinburgh Mental Well-being Scale (WEMWBS)** | Complete a 14-question paper and pencil survey, which asks you about your mental well-being. | |
| **Blood Pressure & Pulse Check** | Pre-test *Blood Pressure, Pulse checks* will also be recorded. | |
| **Your Opinions / Levels of Satisfaction** | We may offer you the opportunity to participate in a focus group and/or complete a customer satisfaction survey during the programme to *tell us what you think* and give us *your suggestions* for programme development.<br><br>The focus group will be conducted by 2 members of the research team and a maximum of 10 participants. It will be scheduled to last a | |

| | |
|---|---|
| | maximum of 1 hour. The purpose is to generate a group discussion on the experience of participants in the programme, from which we can ascertain pros, cons and recommendations to what we are running directly from yourselves. It will be recorded on an audio recorder and typed up with no use of real names. You can request a copy of the typed transcript if you wish from the lead researcher using the details at the bottom of this leaflet. |

**Medical Information about your Health**

A certain amount of information regarding your health and medical history will be transferred on the referral form completed by either, your referring GP / Physiotherapist / Consultant including; your date of birth, main diagnosis and a list of any other medical problems, details of any prescribed medications and allergies, if applicable and relevant comments regarding anything the medical professional feels the Exercise Professional should know to take care of you in testing. If blood pressure or heart rate are outside recommended guidelines you will be asked to attend your GP and the Physiotherapists from SUH may also contact your GP with any concerns. The information on this form is considered by the principle researcher before you commence the battery of tests, in the interests of your safety on the study. Please feel free to request a copy of the referral form to satisfy yourself as regards the specific information being transferred.

**Photographs, Videos, Audio Recordings**

From time to time we may take photos and/or videos of sessions in action for promotional purposes only. If you are not happy to be included in these, please let a member of the research team know. Also the focus group where we ask for your feedback and opinions on programme development is recorded. The purpose of this is so that a transcript of the meeting can be typed up to accurately reflect everyone's views. We will be happy to send you a copy of the transcript to verify you agree that your contributions are reflected as you intended. No real names will be used in the typed transcript or subsequent reporting of experiences.

**Confidentiality**

All personal information and results from the study are treated as highly confidential. All final results are anonymised, this means that names or any other information that could identify you as a participant are removed after the initial testing period with researchers. All personal information collected is legally protected under both the Data Protection Act and the Institute of Technology Sligo confidentiality agreement. You have the right to access all personal

information at any time throughout the study and after its completion. All information is stored securely on the IT Sligo campus and access to this information is given only to those directly involved in the study. All hard copy (written) information is kept securely in a locked filing cabinet in a secure office and all electronic data (computer) is password protected. No information is taken off the IT Sligo campus. Results may potentially be published in scientific journals or be presented at medical conferences; however no participant can be identified as all data is anonymised at this stage.

**Do I have the right to opt out of the study?**

Yes. Your participation in the evaluation study is entirely voluntary. You have the right to cease involvement in the study at any time you wish, without having to provide a reason, although we would love to know why you choose to leave, so if you are happy to tell us, please do – it might help us make positive changes to the study!

**Potential Benefits**

Physical activity participation has already been proven to benefit functional recovery post cardiac event. Exercise is increasingly being focused on as an adjunct therapeutic intervention which aims to improve cardiac health care and rehabilitation because it is relatively cheap and accessible, has few side effects and has many other benefits to holistic health. Some of the positive health indices exercise has been linked to are; increased energy levels, better mood, better sleep to name but a few. The benefit to taking part in this study is we will track various fitness indices for a period of 10 weeks following successful completion of Phase III cardiac rehabilitation.

**Potential Risks**

Engaging in any fitness test poses a small risk, typically of muscle or skeletal injury. However, it is generally considered that even in people with cardiac illness, the benefits of carefully planned exercise testing outweigh the risks and the incidence of cardiac related events is very rare, especially among regular exercisers. The evaluation study has a rigorous design to ensure that all potential risks are kept to a minimum. Participants will be monitored at all times during the testing sessions. Any unlikely problem which participants may have during the fitness tests will be dealt with immediately, with the utmost professionalism and confidentiality. Fitness instructors and researchers are CPR trained to HSE standards and trained in the use of the Defibrillator which is conveniently located onsite.

**Results**

Upon completion of the study, all results will be sent to you by letter or by email if requested.

**Researchers Contact details**

**Name:** Ms Joanne Regan
**Job Title:** Principal Researcher
**Phone number:** 087 2020413
**Email:** regan.joanne@itsligo.ie
**Address:** Dept. Life Science, Institute of Technology Sligo,
Ash Lane, Sligo F91 YW50.

**Information Sheet for MedEx@ITSligo Programme**

**Evaluation of Usual Care Cardiac Rehabilitation Advice**

1. I confirm that I have been referred by my health professional for the above study.

2. I confirm that I have read the study evaluation information sheet, understand what is involved, and what will be required of me.

3. I confirm that I understand both the risks and the benefits of participating in this study and have had any questions answered to my satisfaction.

4. I give my permission for my health professional to give the required details of my health status and medical history to the study research team on the referral form.

5. I consent to the use of photographs or videos of the testing sessions which I may be present in, for promotional purposes.

6. I consent to being audio recorded if I participate in a focus group gathering participant feedback on the programme.

7. I understand that no identifiable results will be circulated/published as a result of my participation and that my identity and data will remain confidential.

8. I understand that I have the right to withdraw from the evaluation study at any time without reason.

9. I have had time to consider whether to participate in this evaluation research.

Given all of the above, my signature below indicates that I volunteer to participate in this study and be part of the evaluation research.

| _____ | _____ | _____ |
|---|---|---|
| Name of Participant (print) | Date | Signature |
| _____ | _____ | _____ |
| Name of Principle Researcher | Date | Signature |

# Induction Questionnaire

The following questionnaire is designed to gather information on your health and wellbeing. Your responses are both for **research** purposes and for **reports to your medical team** and will be treated in the strictest confidence.

- While many of the questions may appear quite similar, there are subtle differences between them, and you should treat each one as a separate question.
- The best approach is to answer each question fairly quickly and focus on each item separately.
- It is important to answer ALL the questions.
- Your answers are strictly confidential so try to answer all questions as honestly as you can.
- This is not a test, so there is no pass/fail.

## Thank you

**Please PRINT all information in CAPITALS**

**Q1.** **First Name**_____**Q2** **Surname**____
_____

**Q3** **Date of Birth**_____/_____/_____ (day/month/year)

For Official Use Only: ID Number:_____ Date:_____

**Q5** **Gender** (Please tick (✓) one box): Male ☐ (1) Female ☐ (2)

**Q6 What is your marital status**
(Use "✓" to indicate your answer)

Married ..... ☐ (1)

Living with partner ..... ☐ (2)

Single (never married) ..... ☐ (3)

Separated ..... ☐ (4)

Divorced ..... ☐ (5)

Widowed ..... ☐ (6)

**Q7 What is the highest level of education you have completed?** (Use "✓" to indicate your answer)

Some primary (not completed) ..... ☐ (1)

Intermediate/junior/group certificate or equivalent... ☐ (2)

Leaving certificate or equivalent..... ☐ (3)

Diploma/certificate..... ☐ (4)

Primary degree..... ☐ (5)

Postgraduate/ higher degree ..... ☐ (6)

None..... ☐ (7)

Don't know ..... ☐ (8)

**Q8 How would you describe your present principle status?** (Use "✓" to indicate your answer)

| | |
|---|---|
| Working for payment or profit…… | 1 ☐ |
| Looking for first regular job…… | 2 ☐ |
| Unemployed…… | 3 ☐ |
| Student or pupil…… | 4 ☐ |
| Looking after home or family…… | 5 ☐ |
| Retired from employment…… | 6 ☐ |
| Unable to work due to permanent sickness or disability…… | 7 ☐ |
| Other…… | 8 ☐ |

**Q9 What is (was) your occupation in your main job?**

Write in your main occupation? _____

**Q10 Sometime in the future we may want to contact you to follow up on this research. Would that be OK?** (Please tick (✓) one box):

Yes ₁☐ No ₂☐

## SECTION 1

**Q1. Who referred you to this project?**

(Use "✓" to indicate your answer)

Hospital Consultant
Please list:_____ 1☐

General practitioner (GP)
Please list:_____ 2☐

Phase III Cardiac Rehab (SUH) 3☐

Other
Please list:_____ 4☐

## SECTION 2

**Q1**. Please indicate which chronic condition(s) you have (tick all that apply).

| | |
|---|---|
| None …… | ☐ 1 |
| Heart Disease *Type of heart disease* _____ | ☐ 2 |
| Peripheral arterial disease/claudication…… | ☐ 3 |
| Chronic bronchitis, emphysema or COPD……..…… | ☐ 4 |
| Asthma…… | ☐ 5 |
| Other lung disease *Type of lung disease*_____ | ☐ 6 |
| Cancer *Specify type*_____ | ☐ 7 |
| Type 2 diabetes…… | ☐ 8 |
| Type 1 diabetes…… | ☐ 9 |
| Depression…… | ☐ 10 |
| Anxiety or other emotional mental health condition…… | ☐ 11 |
| Arthritis or other rheumatic disease *Specify type*_____ | ☐ 12 |
| Other chronic condition *Please specify*_____ | ☐ 13 |

**Appendix E Referral Form**

## Referral Form for Category B[1] MedEx Centre

**Patient Details**

Name: _____ DOB: _____ Gender : M / F

Tel: _____ Mob: _____

Address: _____

NOK Name: _____ NOK Tel: _____

**Referrer Details**

Consultant Name: _____ Hospital: _____

GP Name: _____ Tel: _____

Address: _____

**Illness Details**

**Main Diagnosis**

_____

**Other medical problems (comorbidities)**

1_____

2_____

3_____

4_____

5_____

**Medications**

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

**Allergies**

_____

_____

**Relevant comments (e.g. recent procedures, complications, exercise capacity, specific recommendations or concerns)**

_____

_____

_____

**Participation in MCEP**

I confirm that this patient: (Please ✓ only one box)

☐ clear to participate in the MCEP Programme

☐ unclear to participate and require further medical screening

**Signed (Consultant/GP): _____ Date: _____**

[1]Please refer and utilise the inclusion and exclusion criteria for a category B NERF centre when referring patients

# Physical Fitness Tests

**Hand Grip Strength**

Exclusion criteria: Participants with swelling, inflammation, sever pain or recent injury to their hand/wrist within the last 6months

1. This test is conducted standing but if this is not possible the participant may sit upright on a chair.
2. Ask the participant to indicate their dominant hand and record this
3. Set the gripping hand width to a comfortable width to ensure the participant can rest the middle piece of the four fingers on the handle of the **hand grip dynamometer**
4. Instruct the participant to keep their upper arm tight against their trunk and the forearm at a 90-degree angle (Note if the dynamometer is too heavy for the participant, they can hold their forearm with their free hand OR if necessary, a table can be used for arm support ensuring the forearm remains at a tight angle to the upper arm – take note of any deviations)
5. Make sure the dial is moved back to “0” before each attempt
6. Instruct the participant to squeeze the handle with maximum force for ~3sec
7. Record the value on the reading scale using kg
8. Allow the participant ~30sec rest between each effort – alternating between dominant and non-dominant hand allows this if the hand grip does not need to be adjusted
9. The score is recorded as the best of the 3 trials

**6 Minute Walk Test**

*Prior to test*

*Using a **measuring tape** set out **2 small cones** 20m apart indoors with a **chair at each end**; have a stopwatch and **data collection sheet** ready*

Participant should sit at rest in a chair for at least 10min before test starts. Prior to testing educate the participant on the test. This may include:

"The object of this test is to cover as much ground as possible in 6min. You will walk back and forth around the two cones. During the test you may become breathless. You may become breathless. You can slow down or stoop and rest as necessary"

1. Bring the participant to the starting line (you stand near the starting line but do not walk with the participant)
2. Start the stopwatch when the participant leaves the starting line
3. Each time the participant reaches the starting cone (i.e., 40m completed) record this with a tick on the data collection sheet
4. The following standard encouragement should be given
   After 1min*, "You are doing well. You have 5min to go"*

   After 2min*, "Keep up the good work. You have 4min to go."*

   After 3min*, "You are doing well. You are halfway there"*

   After 4min*, "Keep up the good work. You have only 2min left"*

   *After 5 min; "You are doing well. You have one minute to go"*

   *After 5:45; "In a moment I'm going to tell you to stop. When I do, just stop right where you are and I will come to you"*

   After 6min*, "Stop"*

   ***NOTE*** Do not use other words of encouragement 9or body language to speed up). If the participant stops during the test and needs a rest say, "*You can rest if you would like, do you need a chair, then continue walking whenever you feel like able*". Do not stop the timer. If the participant stops before the 6min are up and refuses to continue, note the distance, time, and reason for stopping prematurely.

5. Mark the stop where they finish with a cone
6. Measure the distance covered in the final partial lap and calculate the total distance walked rounding to the nearest meter

**Sit and Reach Flexibility**

Before taking this measure ask the participant to take off their shoes

1. The **sit and reach box** is placed on a **mat**
2. Instruct the participant to sit on the mat with soles of the feet (no shoes) flat against the sit and reach box
3. Instruct the participant to extend their arms out in front of them, placing one hand on top of the other
4. Instruct the participant to reach forward *in a slow and controlled movement* toward the box as much as possible *without bending the knees* keeping the arms and fingers fully extended
5. The participant must hold this position for 2 seconds
6. Record the score using the most distal point on the box contacted by the fingertip. **NOTE**: If the participant cannot reach the box, using a **ruler** record the distance between their fingertips and the bottom of the box. This is recorded as a negative figure (e.g. -3cm)
7. This test is performed 3 times, allowing 30seconds break between each effort
8. The score recorded is the best of the 3 attempts

**Sit to Stand Strength**

You require a **chair** (~45cm in height) and a **stopwatch**

1. Demonstrate and give a verbal description of the test
2. Instruct the participant to sit on the chair with arms crossed on their chest for the duration of the test with legs placed flat on the floor, parallel to each other and approximately a foot apart. The participant should have their back against the chair.
3. The participant should be prompted not to bounce off the chair when moving from the seated to standing position and that legs should be fully straightened on each stand
4. Commence the test with the verbal cue "*Ready? Go*"
5. Participants should be instructed to stand up and sit down 10 times as quickly as possible
6. The time commences once the instructor says "*Go*" and is ceased when the participant sat back down with back against the chair for the tenth time
7. No encouragement is given during the test
8. Performance is recorded in seconds using the stopwatch
9. The test is repeated following at least 2min rest
10. The score is recorded as the best of the two trials

**Height and Weight**

Before measuring height or weight ensure that the participant has removed their footwear and any heavy clothing

*Height*

1. Place the blue base of the **stadiometer** on an even surface
2. Slot the white slats into the base ensuring that they are in the right order
3. Slide the blue height marker down the slats
4. Instruct the participant to stand on the blue base with their back to the scale
5. Instruct the participants to stand up straight, looking straight ahead
6. Instruct the participant too take a deep breath
7. Ensure the participants head is in the Frankfurt plane (straight line through opening of ear and lower orbital socket)
8. Slide the marker down until it rests on their head
9. Take not of the measurement in cm given between the two arrows

*Weight*

1. Place the **scales** ensuring that they are placed on an even surface
2. Ensure the scales are level by checking the bubble is in the centre of the circle
3. Add a set weight to check for accuracy (e.g., 10kg weight)
4. Step on the scales to turn it on and step off, wait for the dial to read 0.0 and ensure it is reading in kg
5. Ask the participant to step on the scale and stand still
6. Record the measurement in kg

**Waist and Hip Circumference**

1. Ask the participant to stand with their feet together and arms by their side
2. Instruct the participant to take a few deep breaths before taking the measurement to avoid abdominal tension. Measurements should be taken at the end of normal expiration
3. Measure the waist circumference at approximately the midpoint between the last palpable rib and the top of the iliac crest
4. Measure the hip circumference around the widest portion of the buttocks.
5. Take the measurement twice
6. If measurements are within 1cm of each other, an average should be calculated (cm) but if the difference exceeds 1cm, repeat the measure

# Your Health and Well-Being

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

**For each of the following questions, please tick the one box that best describes your answer.**

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

| Excellent | Very good | Good | Fair | Poor |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

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 Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | ☐ 1 | ☐ 2 | ☐ 3 |
| b Climbing several flights of stairs | ☐ 1 | ☐ 2 | ☐ 3 |

**3. During the <u>past 4 weeks</u>, how much of the time 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>?**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a <u>Accomplished less</u> than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b Were limited in the <u>kind</u> of work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**4. During the <u>past 4 weeks</u>, how much of the time 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)?**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a <u>Accomplished less</u> than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b Did work or other activities <u>less carefully than usual</u> | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**5. During the <u>past 4 weeks</u>, 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 |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**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 | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a Have you felt calm and peaceful? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b Did you have a lot of energy? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c Have you felt downhearted and low? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**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 with friends, relatives, etc.)?**

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

***Thank you for completing these questions!***

## Appendix H Warwick Edinburgh Mental Well-Being Scale

**Below are some statements about feelings and thoughts.**

Please tick (√) the box that best describes your experience of each over the **last 2 weeks**

| STATEMENTS | None of the time | Rarely | Some of the time | Often | All of the time |
|---|---|---|---|---|---|
| I've been feeling optimistic about the future | 1 | 2 | 3 | 4 | 5 |
| I've been feeling useful | 1 | 2 | 3 | 4 | 5 |
| I've been feeling relaxed | 1 | 2 | 3 | 4 | 5 |
| I've been feeling interested in other people | 1 | 2 | 3 | 4 | 5 |
| I've had energy to spare | 1 | 2 | 3 | 4 | 5 |
| I've been dealing with problems well | 1 | 2 | 3 | 4 | 5 |
| I've been thinking clearly | 1 | 2 | 3 | 4 | 5 |
| I've been feeling good about myself | 1 | 2 | 3 | 4 | 5 |
| I've been feeling close to other people | 1 | 2 | 3 | 4 | 5 |
| I've been feeling confident | 1 | 2 | 3 | 4 | 5 |
| I've been able to make up my own mind about things | 1 | 2 | 3 | 4 | 5 |
| I've been feeling loved | 1 | 2 | 3 | 4 | 5 |
| I've been interested in new things | 1 | 2 | 3 | 4 | 5 |
| I've been feeling cheerful | 1 | 2 | 3 | 4 | 5 |

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## Appendix I Post hoc analysis of baseline categorical and continuous variables

### Post Hoc tests of categorical variables at baseline

**Calculation for standard error and pooled variance**

SE1 and SE2 = taken from parameter estimates table (see below)

n1/n2 = sample size of each group

SD1 = SE1*√(n1-1)

SD2 = SE2*√(n2-1)

$S1(2) = SD1^{2}*(n1-1)$

$S2(2) = SD2^{2}*(n2-1)$

Sp(2) = (S1(2) + S2(2))/(n1+n2-2)

SE = √Sp(2)/(n1-1) + Sp(2)/n2-1)

**Calculating t value and p value**

Use B1 and B2 from parameter estimates table (^calculate absolute difference)

T value^ = B2-B1/SE

Use T.DIST in excel to calculate t distribution

p value = 1-t dist

| **Post hoc test for Gender** | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | **Bonferroni Correction** | | | | | | |
| SE1 | 0.31 | | B1 | 1.11 | | 0.05 | 0.017 | | | | | |
| SE2 | 0.55 | | B2 | 1.35 | | **NOTE** Must use Bonferonii correction for α | | | | | | |
| | | | t value | 0.33 | | | | | | | | |
| SD1 | 2.98 | | t dist | 0.63 | | | | | | | | |
| SD2 | 2.51 | | p value | 0.370 | | | | | | | | |
| n1 | 96 | | | | | | | | | | | |
| n2 | 22 | | | | | | | | | | | |
| S1(2) | 845.62 | | | | | | | | | | | |
| S2(2) | 132.19 | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Sp(2) | 8.43 | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | 0.09 | | | | | | | | | | | |
| | 0.40 | | | | | | | | | | | |
| | 0.49 | | | | | | | | | | | |
| SE | 0.70 | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| **Post hoc test using a generalized linear model with a logit link function used to specify group differences for dichotomus dependant variables** | | | | | | | | | | | | |
| Parameter Estimates | | | | | | | | | | | | |
| Parameter | B | Std. Error | 95% Wald Confidence Interval | | Hypothesis Test | | | | | | | |
| | | | Lower | Upper | Wald Chi-Square | df | Sig. | | | | | |
| (Intercept) | -0.123 | 0.2024 | -0.519 | 0.274 | 0.367 | 1 | 0.545 | | | | | |
| [ResearchGr1=1] | 1.113 | 0.3061 | 0.513 | 1.713 | 13.218 | 1 | 0.000 | | | | | |
| [ResearchGr1=2] | 1.346 | 0.5475 | 0.273 | 2.42 | 6.047 | 1 | 0.014 | | | | | |
| [ResearchGr1=3] | 0a | . | . | . | . | . | . | | | | | |
| (Scale) | 1b | | | | | | | | | | | |
| Dependent Variable: Gender | | | | | | | | | | | | |
| Model: (Intercept), ResearchGr1 | | | | | | | | | | | | |
| a Set to zero because this parameter is redundant. | | | | | | | | | | | | |
| b Fixed at the displayed value. | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| **NOTE** The GLM compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2 | | | | | | | | | | | | |

Post hoc test for Education

| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | **Bonferroni Correction** | |
|---|---|---|---|---|---|---|---|
| SE1 | 0.47 | | B1 | -1.22 | | 0.05 | 0.004 |
| SE2 | 1.10 | | B2 | 0.90 | | **NOTE** Must use Bonferonii correction for α | |
| | | | t value | 1.89 | | | |
| SD1 | 4.55 | | t dist | 0.97 | | | |
| SD2 | 5.05 | | p value | 0.031 | | | |
| n1 | 96.00 | | | | | | |
| n2 | 22.00 | | | | | | |
| S1(2) | 1968.25 | | | | | | |
| S2(2) | 536.52 | | | | | | |
| | | | | | | | |
| Sp(2) | 21.59 | | | | | | |
| | | | | | | | |
| | 0.23 | | | | | | |
| | 1.03 | | | | | | |
| | 1.26 | | | | | | |
| SE | 1.12 | | | | | | |

**Post hoc test using a multinomial logesitic regression model with a logit link function used to specify group differences between multiple dependant variables**

Parameter Estimates

| Edu.a | | B | Std. Error | Wald | df | Sig. | Exp(B) | 95% Confidence Interval for Exp(B) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Lower Bound | Upper Bound |
| Some primary | Intercept | -1.135 | 0.383 | 8.774 | 1 | 0.003 | | | |
| | [ResearchGr1=1] | 1.086 | 0.494 | 4.826 | 1 | 0.028 | 2.963 | 1.124 | 7.809 |
| | [ResearchGr1=2] | 1.135 | 1.465 | 0.6 | 1 | 0.439 | 3.111 | 0.176 | 54.967 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| Intermediate/Junior, | Intercept | -0.499 | 0.307 | 2.634 | 1 | 0.105 | | | |
| | [ResearchGr1=1] | 0.713 | 0.425 | 2.811 | 1 | 0.094 | 2.039 | 0.887 | 4.69 |
| | [ResearchGr1=2] | 2.578 | 1.104 | 5.452 | 1 | 0.02 | 13.176 | 1.513 | 114.764 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| Leaving Cert / Diplon | Intercept | 0.452 | 0.242 | 3.496 | 1 | 0.062 | | | |
| | [ResearchGr1=1] | -0.129 | 0.375 | 0.119 | 1 | 0.73 | 0.879 | 0.421 | 1.832 |
| | [ResearchGr1=2] | 2.033 | 1.069 | 3.62 | 1 | 0.057 | 7.636 | 0.94 | 62.005 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |

a The reference category is: Degree / Post Grad.

b This parameter is set to zero because it is redundant.

**NOTE** The MLR compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2

Parameter Estimates

| Edu.a | | B | Std. Error | Wald | df | Sig. | Exp(B) | 95% Confidence Interval for Exp(B) | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Lower Bound | Upper Bound |
| Intermediate/Junior, | Intercept | 0.636 | 0.412 | 2.38 | 1 | 0.123 | | | |
| | [ResearchGr1=1] | -0.374 | 0.508 | 0.54 | 1 | 0.462 | 0.688 | 0.254 | 1.864 |
| | [ResearchGr1=2] | 1.443 | 1.138 | 1.609 | 1 | 0.205 | 4.235 | 0.455 | 39.401 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| Leaving Cert / Diplon | Intercept | 1.587 | 0.366 | 18.817 | 1 | 0 | | | |
| | [ResearchGr1=1] | -1.215 | 0.467 | 6.766 | 1 | 0.009 | 0.297 | 0.119 | 0.741 |
| | [ResearchGr1=2] | 0.898 | 1.103 | 0.662 | 1 | 0.416 | 2.455 | 0.282 | 21.334 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| Degree / Post Grad | Intercept | 1.135 | 0.383 | 8.774 | 1 | 0.003 | | | |
| | [ResearchGr1=1] | -1.086 | 0.494 | 4.826 | 1 | 0.028 | 0.337 | 0.128 | 0.889 |
| | [ResearchGr1=2] | -1.135 | 1.465 | 0.6 | 1 | 0.439 | 0.321 | 0.018 | 5.679 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |

a The reference category is: Some primary.

b This parameter is set to zero because it is redundant.

**NOTE** The MLR compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Post hoc test for Employment Status | | | | | | | | | |
| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | | **Bonferroni Correction** | | |
| SE1 | 0.42 | | B1 | -1.07 | | | 0.05 | 0.006 | |
| SE2 | 0.66 | | B2 | -0.36 | | | **NOTE** Must use Bonferonii correction for α | | |
| | | | t value | 0.74 | | | | | |
| SD1 | 4.13 | | t dist | 0.77 | | | | | |
| SD2 | 3.02 | | p value | 0.230 | | | | | |
| n1 | 96.00 | | | | | | | | |
| n2 | 22.00 | | | | | | | | |
| S1(2) | 1622.48 | | | | | | | | |
| S2(2) | 192.10 | | | | | | | | |
| | | | | | | | | | |
| Sp(2) | 15.64 | | | | | | | | |
| | | | | | | | | | |
| | 0.16 | | | | | | | | |
| | 0.74 | | | | | | | | |
| | 0.91 | | | | | | | | |
| SE | 0.95 | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| **Post hoc test using a multinomial logesitic regression model with a logit link function used to specify group differences between multiple dependant variables** | | | | | | | | | |
| Parameter Estimates | | | | | | | | | |
| Principle_Stat.a | | B | Std. Error | Wald | df | Sig. | Exp(B) | 95% Confidence Interval for Exp(B) | |
| | | | | | | | | Lower Bound | Upper Bound |
| Working / Homemaker / Student | Intercept | -0.583 | 0.255 | 5.238 | 1 | 0.022 | | | |
| | [ResearchGr1=1] | -0.482 | 0.364 | 1.755 | 1 | 0.185 | 0.618 | 0.303 | 1.26 |
| | [ResearchGr1=2] | 0.583 | 0.536 | 1.184 | 1 | 0.276 | 1.792 | 0.627 | 5.121 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| Unemployed / Unable work due to illness | Intercept | -0.327 | 0.236 | 1.929 | 1 | 0.165 | | | |
| | [ResearchGr1=1] | -0.843 | 0.358 | 5.537 | 1 | 0.019 | 0.43 | 0.213 | 0.869 |
| | [ResearchGr1=2] | -0.484 | 0.645 | 0.562 | 1 | 0.454 | 0.616 | 0.174 | 2.184 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| a The reference category is: Retired. | | | | | | | | | |
| b This parameter is set to zero because it is redundant. | | | | | | | | | |
| | | | | | | | | | |
| **NOTE** The MLR compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2 | | | | | | | | | |
| | | | | | | | | | |
| Parameter Estimates | | | | | | | | | |
| Principle_Stat.a | | B | Std. Error | Wald | df | Sig. | Exp(B) | 95% Confidence Interval for Exp(B) | |
| | | | | | | | | Lower Bound | Upper Bound |
| Unemployed / Unable work due to illness | Intercept | 0.256 | 0.272 | 0.886 | 1 | 0.347 | | | |
| | [ResearchGr1=1] | -0.361 | 0.424 | 0.727 | 1 | 0.394 | 0.697 | 0.304 | 1.598 |
| | [ResearchGr1=2] | -1.067 | 0.66 | 2.616 | 1 | 0.106 | 0.344 | 0.094 | 1.253 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| Retired | Intercept | 0.583 | 0.255 | 5.238 | 1 | 0.022 | | | |
| | [ResearchGr1=1] | 0.482 | 0.364 | 1.755 | 1 | 0.185 | 1.619 | 0.794 | 3.301 |
| | [ResearchGr1=2] | -0.583 | 0.536 | 1.184 | 1 | 0.276 | 0.558 | 0.195 | 1.595 |
| | [ResearchGr1=3] | 0b | . | . | 0 | . | . | . | . |
| a The reference category is: Working / Homemaker / Student. | | | | | | | | | |
| b This parameter is set to zero because it is redundant. | | | | | | | | | |
| | | | | | | | | | |
| **NOTE** The MLR compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2 | | | | | | | | | |

Post hoc test for PPI Medication

| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | **Bonferroni Correction** | |
|---|---|---|---|---|---|---|---|
| SE1 | 0.36 | | B1 | 1.27 | | 0.05 | 0.017 |
| SE2 | 0.52 | | B2 | 1.38 | | **NOTE** Must use Bonferonii correction for α | |
| | | | t value | 0.14 | | | |
| SD1 | 3.48 | | t dist | 0.56 | | | |
| SD2 | 2.36 | | p value | 0.443 | | | |
| n1 | 89.00 | | | | | | |
| n2 | 22.00 | | | | | | |
| S1(2) | 1064.28 | | | | | | |
| S2(2) | 117.15 | | | | | | |
| | | | | | | | |
| Sp(2) | 10.84 | | | | | | |
| | | | | | | | |
| | 0.12 | | | | | | |
| | 0.52 | | | | | | |
| | 0.64 | | | | | | |
| SE | 0.80 | | | | | | |

**Post hoc test using a generalized linear model with a logit link function used to specify group differences for dichotomus dependant variables**

Parameter Estimates

| Parameter | B | Std. Error | 95% Wald Confidence Interval | | Hypothesis Test | | |
|---|---|---|---|---|---|---|---|
| | | | Lower | Upper | Wald Chi-Square | df | Sig. |
| (Intercept) | -1.451 | 0.2869 | -2.013 | -0.889 | 25.579 | 1 | 0 |
| [ResearchGr1=1] | 1.383 | 0.3568 | 0.684 | 2.083 | 15.035 | 1 | 0.000 |
| [ResearchGr1=2] | 1.269 | 0.5154 | 0.258 | 2.279 | 6.058 | 1 | 0.014 |
| [ResearchGr1=3] | 0a | . | . | . | . | . | . |
| (Scale) | 1b | | | | | | |

Dependent Variable: MedPPI

Model: (Intercept), ResearchGr1

a Set to zero because this parameter is redundant.

b Fixed at the displayed value.

**NOTE** The GLM compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2

Post hoc test for HTN

| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | **Bonferroni Correction** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| SE1 | 0.33 | | B1 | 0.82 | | 0.05 | 0.017 | | | | |
| SE2 | 0.50 | | B2 | 1.24 | | **NOTE** Must use Bonferonii correction for α | | | | | |
| | | | t value | 0.56 | | | | | | | |
| SD1 | 3.24 | | t dist | 0.71 | | | | | | | |
| SD2 | 2.28 | | p value | 0.288 | | | | | | | |
| n1 | 96.00 | | | | | | | | | | |
| n2 | 22.00 | | | | | | | | | | |
| S1(2) | 1000.17 | | | | | | | | | | |
| S2(2) | 109.63 | | | | | | | | | | |
| | | | | | | | | | | | |
| Sp(2) | 9.57 | | | | | | | | | | |
| | | | | | | | | | | | |
| | 0.10 | | | | | | | | | | |
| | 0.46 | | | | | | | | | | |
| | 0.56 | | | | | | | | | | |
| SE | 0.75 | | | | | | | | | | |

**Post hoc test using a generalized linear model with a logit link function used to specify group differences for dichotomus dependant variables**

Parameter Estimates

| Parameter | B | Std. Error | 95% Wald Confidence Interval | | Hypothesis Test | | |
|---|---|---|---|---|---|---|---|
| | | | Lower | Upper | Wald Chi-Square | df | Sig. |
| (Intercept) | -1.425 | 0.2555 | -1.926 | -0.924 | 31.102 | 1 | 0 |
| [ResearchGr1=1] | 0.824 | 0.3329 | 0.172 | 1.477 | 6.13 | 1 | 0.013 |
| [ResearchGr1=2] | 1.243 | 0.4986 | 0.265 | 2.22 | 6.211 | 1 | 0.013 |
| [ResearchGr1=3] | 0a | . | . | . | . | . | . |
| (Scale) | 1b | | | | | | |

Dependent Variable: ComorbidityHTN

Model: (Intercept), ResearchGr1

a Set to zero because this parameter is redundant.

b Fixed at the displayed value.

**NOTE** The GLM compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Post hoc test for Rheumatic Conditions | | | | | | | | | | | |
| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | **Bonferroni Correction** | | | | | |
| SE1 | 0.42 | | B1 | -0.01 | | 0.05 | 0.017 | | | | |
| SE2 | 0.82 | | B2 | 1.14 | | **NOTE** Must use Bonferonii correction for α | | | | | |
| | | | t value | 1.17 | | | | | | | |
| SD1 | 4.13 | | t dist | 0.88 | | | | | | | |
| SD2 | 3.76 | | p value | 0.122 | | | | | | | |
| n1 | 96.00 | | | | | | | | | | |
| n2 | 22.00 | | | | | | | | | | |
| S1(2) | 1620.18 | | | | | | | | | | |
| S2(2) | 296.53 | | | | | | | | | | |
| | | | | | | | | | | | |
| Sp(2) | 16.52 | | | | | | | | | | |
| | | | | | | | | | | | |
| | 0.17 | | | | | | | | | | |
| | 0.79 | | | | | | | | | | |
| | 0.96 | | | | | | | | | | |
| SE | 0.98 | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| **Post hoc test using a generalized linear model with a logit link function used to specify group differences for dichotomus dependant variables** | | | | | | | | | | | |
| Parameter Estimates | | | | | | | | | | | |
| Parameter | B | Std. Error | 95% Wald Confidence Interval | | Hypothesis Test | | | | | | |
| | | | Lower | Upper | Wald Chi-Square | df | Sig. | | | | |
| (Intercept) | -2.291 | 0.3498 | -2.977 | -1.606 | 42.915 | 1 | 0 | | | | |
| [ResearchGr1=1] | 1.136 | 0.4237 | 0.306 | 1.967 | 7.194 | 1 | 0.007 | | | | |
| [ResearchGr1=2] | -0.011 | 0.82 | -1.618 | 1.596 | 0 | 1 | 0.989 | | | | |
| [ResearchGr1=3] | 0a | . | . | . | . | . | . | | | | |
| (Scale) | 1b | | | | | | | | | | |
| Dependent Variable: ComorbRheumatic | | | | | | | | | | | |
| Model: (Intercept), ResearchGr1 | | | | | | | | | | | |
| a Set to zero because this parameter is redundant. | | | | | | | | | | | |
| b Fixed at the displayed value. | | | | | | | | | | | |
| | | | | | | | | | | | |
| **NOTE** The GLM compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2 | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Post hoc test for T2DM | | | | | | | | | | | |
| **Calculating SE and pooled variance** | | | **Calculating t value and p value** | | | **Bonferroni Correction** | | | | | |
| SE1 | 0.50 | | B1 | 0.43 | | 0.05 | 0.017 | | | | |
| SE2 | 0.85 | | B2 | 1.19 | | **NOTE** Must use Bonferonii correction for α | | | | | |
| | | | t value | 0.68 | | | | | | | |
| SD1 | 4.86 | | t dist | 0.75 | | | | | | | |
| SD2 | 3.91 | | p value | 0.250 | | | | | | | |
| n1 | 96.00 | | | | | | | | | | |
| n2 | 22.00 | | | | | | | | | | |
| S1(2) | 2247.23 | | | | | | | | | | |
| S2(2) | 320.88 | | | | | | | | | | |
| | | | | | | | | | | | |
| Sp(2) | 22.14 | | | | | | | | | | |
| | | | | | | | | | | | |
| | 0.23 | | | | | | | | | | |
| | 1.05 | | | | | | | | | | |
| | 1.29 | | | | | | | | | | |
| SE | 1.13 | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| **Post hoc test using a generalized linear model with a logit link function used to specify group differences for dichotomus dependant variables** | | | | | | | | | | | |
| Parameter Estimates | | | | | | | | | | | |
| Parameter | B | Std. Erro | 95% Wald Confidence Interval | | | Hypothesis Test | | | | | |
| | | | Lower | Upper | | Wald Chi-Square | df | Sig. | | | |
| (Intercept) | -2.73 | 0.4214 | -3.556 | -1.904 | | 41.98 | 1 | 0 | | | |
| [ResearchGr1=1] | 1.194 | 0.499 | 0.216 | 2.172 | | 5.723 | 1 | 0.017 | | | |
| [ResearchGr1=2] | 0.427 | 0.853 | -1.244 | 2.099 | | 0.251 | 1 | 0.616 | | | |
| [ResearchGr1=3] | 0a | . | . | . | | . | . | . | | | |
| (Scale) | 1b | | | | | | | | | | |
| Dependent Variable: ComorbType2 | | | | | | | | | | | |
| Model: (Intercept), ResearchGr1 | | | | | | | | | | | |
| a Set to zero because this parameter is redundant. | | | | | | | | | | | |
| b Fixed at the displayed value. | | | | | | | | | | | |
| | | | | | | | | | | | |
| **NOTE** The GLM compares RG1 to RG 3 and RG2 to RG 3 and then the calculation above (pooled variances) is used to compare RG1 to RG2 | | | | | | | | | | | |

**Post Hoc tests of categorical variables at baseline**

NOTE: If equal variance use Bonferroni/If unequal variances use Games-Howell

| Dependent Variable | | (I) ResearchGr1 | (J) ResearchGr1 | Mean Difference (I-J) | Std. Error | P value | 95% Confidence Interval | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | LL | UL |
| Age | Bonferroni | CAD-IG | CAD-CG | 3.581 | 2.278 | 0.352 | -1.91 | 9.08 |
| | | | OCD-IG | 4.844* | 1.384 | 0.002 | 1.5 | 8.18 |
| | | CAD-CG | CAD-IG | -3.581 | 2.278 | 0.352 | -9.08 | 1.91 |
| | | | OCD-IG | 1.263 | 2.273 | 1.000 | -4.22 | 6.75 |
| | | OCD-IG | CAD-IG | -4.844* | 1.384 | 0.002 | -8.18 | -1.5 |
| | | | CAD-CG | -1.263 | 2.273 | 1.000 | -6.75 | 4.22 |
| | Games-Howell | CAD-IG | CAD-CG | 3.581 | 1.861 | 0.15 | -1.01 | 8.18 |
| | | | OCD-IG | 4.844* | 1.4 | **0.002** | 1.53 | 8.16 |
| | | CAD-CG | CAD-IG | -3.581 | 1.861 | 0.15 | -8.18 | 1.01 |
| | | | OCD-IG | 1.263 | 2.087 | 0.818 | -3.8 | 6.32 |
| | | OCD-IG | CAD-IG | -4.844* | 1.4 | **0.002** | -8.16 | -1.53 |
| | | | CAD-CG | -1.263 | 2.087 | 0.818 | -6.32 | 3.8 |
| RHR (bpm) | Bonferroni | CAD-IG | CAD-CG | -2.1468 | 2.6644 | 1.000 | -8.576 | 4.283 |
| | | | OCD-IG | -8.8533* | 1.6187 | 0.000 | -12.759 | -4.947 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CAD-CG | CAD-IG | 2.1468 | 2.6644 | 1.000 | -4.283 | 8.576 |
| | | | OCD-IG | -6.7065* | 2.6593 | 0.037 | -13.124 | -0.289 |
| | | OCD-IG | CAD-IG | 8.8533* | 1.6187 | 0.000 | 4.947 | 12.759 |
| | | | CAD-CG | 6.7065* | 2.6593 | 0.037 | 0.289 | 13.124 |
| | Games-Howell | CAD-IG | CAD-CG | -2.1468 | 1.8374 | 0.478 | -6.612 | 2.318 |
| | | | OCD-IG | -8.8533* | 1.6657 | **0.000** | -12.79 | -4.917 |
| | | CAD-CG | CAD-IG | 2.1468 | 1.8374 | 0.478 | -2.318 | 6.612 |
| | | | OCD-IG | -6.7065* | 2.0233 | **0.004** | -11.575 | -1.838 |
| | | OCD-IG | CAD-IG | 8.8533* | 1.6657 | **0.000** | 4.917 | 12.79 |
| | | | CAD-CG | 6.7065* | 2.0233 | **0.004** | 1.838 | 11.575 |
| WHR | Bonferroni | CAD-IG | CAD-CG | 0.01241 | 0.02205 | 1.000 | -0.0408 | 0.0657 |
| | | | OCD-IG | .03730* | 0.01391 | **0.024** | 0.0037 | 0.0709 |
| | | CAD-CG | CAD-IG | -0.01241 | 0.02205 | 1.000 | -0.0657 | 0.0408 |
| | | | OCD-IG | 0.02488 | 0.02177 | 0.763 | -0.0277 | 0.0775 |
| | | OCD-IG | CAD-IG | -.03730* | 0.01391 | **0.024** | -0.0709 | -0.0037 |
| | | | CAD-CG | -0.02488 | 0.02177 | 0.763 | -0.0775 | 0.0277 |
| | Games-Howell | CAD-IG | CAD-CG | 0.01241 | 0.01983 | 0.807 | -0.0359 | 0.0607 |
| | | | OCD-IG | .03730* | 0.01419 | 0.025 | 0.0037 | 0.0709 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CAD-CG | CAD-IG | -0.01241 | 0.01983 | 0.807 | -0.0607 | 0.0359 |
| | | | OCD-IG | 0.02488 | 0.01918 | 0.406 | -0.022 | 0.0718 |
| | | OCD-IG | CAD-IG | -.03730* | 0.01419 | 0.025 | -0.0709 | -0.0037 |
| | | | CAD-CG | -0.02488 | 0.01918 | 0.406 | -0.0718 | 0.022 |
| GripD (kg) | Bonferroni | CAD-IG | CAD-CG | -3.25 | 2.169 | 0.407 | -8.484 | 1.984 |
| | | | OCD-IG | 4.6219* | 1.3245 | **0.002** | 1.426 | 7.818 |
| | | CAD-CG | CAD-IG | 3.25 | 2.169 | 0.407 | -1.984 | 8.484 |
| | | | OCD-IG | 7.8719* | 2.169 | **0.001** | 2.638 | 13.106 |
| | | OCD-IG | CAD-IG | -4.6219* | 1.3245 | **0.002** | -7.818 | -1.426 |
| | | | CAD-CG | -7.8719* | 2.169 | **0.001** | -13.106 | -2.638 |
| | Games-Howell | CAD-IG | CAD-CG | -3.25 | 1.9857 | 0.245 | -8.129 | 1.629 |
| | | | OCD-IG | 4.6219* | 1.337 | 0.002 | 1.463 | 7.781 |
| | | CAD-CG | CAD-IG | 3.25 | 1.9857 | 0.245 | -1.629 | 8.129 |
| | | | OCD-IG | 7.8719* | 2.0445 | 0.001 | 2.873 | 12.871 |
| | | OCD-IG | CAD-IG | -4.6219* | 1.337 | 0.002 | -7.781 | -1.463 |
| | | | CAD-CG | -7.8719* | 2.0445 | 0.001 | -12.871 | -2.873 |
| GripND (kg) | Bonferroni | CAD-IG | CAD-CG | -4.1065 | 2.2235 | 0.198 | -9.472 | 1.259 |
| | | | OCD-IG | 5.4027* | 1.3508 | **0.000** | 2.143 | 8.662 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CAD-CG | CAD-IG | 4.1065 | 2.2235 | 0.198 | -1.259 | 9.472 |
| | | | OCD-IG | 9.5093* | 2.2192 | **0.000** | 4.154 | 14.864 |
| | | OCD-IG | CAD-IG | -5.4027* | 1.3508 | **0.000** | -8.662 | -2.143 |
| | | | CAD-CG | -9.5093* | 2.2192 | **0.000** | -14.864 | -4.154 |
| | Games-Howell | CAD-IG | CAD-CG | -4.1065 | 1.8294 | 0.078 | -8.588 | 0.375 |
| | | | OCD-IG | 5.4027* | 1.3736 | 0.000 | 2.157 | 8.648 |
| | | CAD-CG | CAD-IG | 4.1065 | 1.8294 | 0.078 | -0.375 | 8.588 |
| | | | OCD-IG | 9.5093* | 1.9329 | 0.000 | 4.812 | 14.207 |
| | | OCD-IG | CAD-IG | -5.4027* | 1.3736 | 0.000 | -8.648 | -2.157 |
| | | | CAD-CG | -9.5093* | 1.9329 | 0.000 | -14.207 | -4.812 |
| SIXMWT (m) | Bonferroni | CAD-IG | CAD-CG | -21.76694 | 20.96085 | 0.901 | -72.3481 | 28.8142 |
| | | | OCD-IG | 58.53101* | 12.7665 | 0.000 | 27.7238 | 89.3382 |
| | | CAD-CG | CAD-IG | 21.76694 | 20.96085 | 0.901 | -28.8142 | 72.3481 |
| | | | OCD-IG | 80.29795* | 20.94069 | 0.000 | 29.7654 | 130.8305 |
| | | OCD-IG | CAD-IG | -58.53101* | 12.7665 | 0.000 | -89.3382 | -27.7238 |
| | | | CAD-CG | -80.29795* | 20.94069 | 0.000 | -130.8305 | -29.7654 |
| | Games-Howell | CAD-IG | CAD-CG | -21.76694 | 20.87572 | 0.557 | -73.483 | 29.9491 |
| | | | OCD-IG | 58.53101* | 12.69971 | **0.000** | 28.5099 | 88.5521 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CAD-CG | CAD-IG | 21.76694 | 20.87572 | 0.557 | -29.9491 | 73.483 |
| | | | OCD-IG | 80.29795* | 22.06172 | **0.003** | 26.2202 | 134.3757 |
| | | OCD-IG | CAD-IG | -58.53101* | 12.69971 | **0.000** | -88.5521 | -28.5099 |
| | | | CAD-CG | -80.29795* | 22.06172 | **0.003** | -134.3757 | -26.2202 |
| WEMWBS | Bonferroni | CAD-IG | CAD-CG | -0.183 | 2.5412 | 1.000 | -6.321 | 5.955 |
| | | | OCD-IG | 6.2334* | 1.4774 | **0.000** | 2.665 | 9.802 |
| | | CAD-CG | CAD-IG | 0.183 | 2.5412 | 1.000 | -5.955 | 6.321 |
| | | | OCD-IG | 6.4164* | 2.5265 | **0.036** | 0.314 | 12.519 |
| | | OCD-IG | CAD-IG | -6.2334* | 1.4774 | **0.000** | -9.802 | -2.665 |
| | | | CAD-CG | -6.4164* | 2.5265 | **0.036** | -12.519 | -0.314 |
| | Games-Howell | CAD-IG | CAD-CG | -0.183 | 2.3789 | 0.997 | -6.119 | 5.753 |
| | | | OCD-IG | 6.2334* | 1.4774 | 0.000 | 2.741 | 9.726 |
| | | CAD-CG | CAD-IG | 0.183 | 2.3789 | 0.997 | -5.753 | 6.119 |
| | | | OCD-IG | 6.4164* | 2.4386 | 0.036 | 0.367 | 12.466 |
| | | OCD-IG | CAD-IG | -6.2334* | 1.4774 | 0.000 | -9.726 | -2.741 |
| | | | CAD-CG | -6.4164* | 2.4386 | 0.036 | -12.466 | -0.367 |
| PCS | Bonferroni | CAD-IG | CAD-CG | 0.00208 | 2.15929 | 1.000 | -5.2094 | 5.2135 |
| | | | OCD-IG | 5.94173* | 1.32408 | **0.000** | 2.7461 | 9.1374 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | CAD-CG | CAD-IG | -0.00208 | 2.15929 | 1.000 | -5.2135 | 5.2094 |
| | | | OCD-IG | 5.93965* | 2.14853 | **0.019** | 0.7542 | 11.1251 |
| | | OCD-IG | CAD-IG | -5.94173* | 1.32408 | **0.000** | -9.1374 | -2.7461 |
| | | | CAD-CG | -5.93965* | 2.14853 | **0.019** | -11.1251 | -0.7542 |
| | Games-Howell | CAD-IG | CAD-CG | 0.00208 | 1.88907 | 1.000 | -4.6322 | 4.6363 |
| | | | OCD-IG | 5.94173* | 1.33615 | 0.000 | 2.7846 | 9.0988 |
| | | CAD-CG | CAD-IG | -0.00208 | 1.88907 | 1.000 | -4.6363 | 4.6322 |
| | | | OCD-IG | 5.93965* | 1.96189 | 0.012 | 1.1555 | 10.7238 |
| | | OCD-IG | CAD-IG | -5.94173* | 1.33615 | 0.000 | -9.0988 | -2.7846 |
| | | | CAD-CG | -5.93965* | 1.96189 | 0.012 | -10.7238 | -1.1555 |
| MCS | Bonferroni | CAD-IG | CAD-CG | -1.02244 | 2.20386 | 1.000 | -6.3414 | 4.2966 |
| | | | OCD-IG | 4.90274* | 1.35141 | **0.001** | 1.6411 | 8.1644 |
| | | CAD-CG | CAD-IG | 1.02244 | 2.20386 | 1.000 | -4.2966 | 6.3414 |
| | | | OCD-IG | 5.92518* | 2.19287 | **0.022** | 0.6327 | 11.2177 |
| | | OCD-IG | CAD-IG | -4.90274* | 1.35141 | **0.001** | -8.1644 | -1.6411 |
| | | | CAD-CG | -5.92518* | 2.19287 | **0.022** | -11.2177 | -0.6327 |
| | Games-Howell | CAD-IG | CAD-CG | -1.02244 | 1.8865 | 0.851 | -5.6392 | 3.5943 |
| | | | OCD-IG | 4.90274* | 1.36922 | 0.001 | 1.6677 | 8.1378 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | CAD-CG | CAD-IG | 1.02244 | 1.8865 | 0.851 | -3.5943 | 5.6392 |
| | | OCD-IG | 5.92518* | 1.94189 | 0.011 | 1.1936 | 10.6567 |
| | OCD-IG | CAD-IG | -4.90274* | 1.36922 | 0.001 | -8.1378 | -1.6677 |
| | | CAD-CG | -5.92518* | 1.94189 | 0.011 | -10.6567 | -1.1936 |

* The mean difference is significant at the 0.05 level

No. of comorbidities - due to non-normality of data and highly skewed a Kruskal-Wallis was ran

Pairwise Comparisons of ResearchGr1

| Sample 1-Sample 2 | Test Statistic | Std. Error | Std. Test Statistic | Sig. | Adj. Sig.[a] |
|---|---|---|---|---|---|
| OCD-IG-CAD-CG | 17.387 | 14.149 | 1.229 | 0.219 | 0.657 |
| OCD-IG-CAD-IG | 25.369 | 8.612 | 2.946 | 0.003 | **0.010** |
| CAD-CG-CAD-IG | 7.982 | 14.176 | 0.563 | 0.573 | 1.000 |

Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions are the same.

Asymptotic significances (2-sided tests) are displayed. The significance level is .05.

[a] Significance values have been adjusted by the Bonferroni correction for multiple tests.

STS - due to non-normality of data and highly skewed a Kruskal-Wallis was ran

Pairwise Comparisons of ResearchGr1

| Sample 1-Sample 2 | Test Statistic | Std. Error | Std. Test Statistic | Sig. | Adj. Sig.[a] |
|---|---|---|---|---|---|
| CAD-CG-CAD-IG | 1.399 | 14.499 | 0.096 | 0.923 | 1.000 |

| | | | | | |
|---|---|---|---|---|---|
| CAD-CG-OCD-IG | -39.526 | 14.528 | -2.721 | 0.007 | **0.020** |
| CAD-IG-OCD-IG | -38.127 | 8.901 | -4.284 | 0.000 | **0.000** |

Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions are the same.

Asymptotic significances (2-sided tests) are displayed. The significance level is .05.

[a] Significance values have been adjusted by the Bonferroni correction for multiple tests.

## Appendix J Covariance parameters

Estimates of covariance parameters for compound symmetry and compound symmetry heterogenous covariance structures

| Variable | Parameter | Estimate | SE | Wald Z | p | C.I. |
|---|---|---|---|---|---|---|
| SBP | Var: Time 1 | 327.591 | 34.288 | 9.554 | 0.000 | (266.833 to 402.185) |
| | Var: Time 2 | 220.089 | 29.799 | 7.386 | 0.000 | (168.791 to 286.978) |
| | CSH ρ | 0.539 | 0.066 | 8.133 | 0.000 | (0.397 to 0.656) |
| DBP | CS diagonal | 35.223 | 4.541 | 7.757 | 0.000 | (27.359 to 45.348) |
| | CS covariance | 43.475 | 7.509 | 5.790 | 0.000 | (28.759 to 58.192) |
| RHR | CS diagonal | 53.208 | 6.686 | 7.958 | 0.000 | (41.592 to 68.067) |
| | CS covariance | 69.080 | 11.325 | 6.100 | 0.000 | (46.883 to 91.277) |
| Waist circ. | CS diagonal | 12.748 | 1.610 | 7.920 | 0.000 | (9.953 to 16.327) |
| | CS covariance | 140.184 | 15.104 | 9.281 | 0.000 | (110.581 to 169.788) |
| BMI | CS diagonal | 0.239 | 0.030 | 7.900 | 0.000 | (0.186 to 0.306 |
| | CS covariance | 23.332 | 2.363 | 9.875 | 0.000 | (18.701 to 27.962) |
| GripD | Var: Time 1 | 60.190 | 6.039 | 9.967 | 0.000 | (49.445 to 73.270) |
| | Var: Time 2 | 46.090 | 5.739 | 8.032 | 0.000 | (36.110 to 58.829) |
| | CSH ρ | 0.720 | 0.042 | 17.152 | 0.000 | (0.627 to 0.790) |
| 6MWTD | CS diagonal | 999.894 | 125.51 | 7.966 | 0.000 | (781.809 to 1278.814) |
| | CS covariance | 5252.772 | 596.94 | 8.799 | 0.000 | (4082.782 to 6422.761) |
| S&R | CS diagonal | 15.118 | 1.910 | 7.914 | 0.000 | (11.801 to 19.366) |
| | CS covariance | 89.074 | 10.088 | 8.830 | 0.000 | (69.302 to 108.846) |
| STS | CS diagonal | 10.313 | 1.289 | 7.998 | 0.000 | (8.072 to 13.177) |
| | CS covariance | 22.916 | 3.093 | 7.409 | 0.000 | (16.854 to 28.979) |
| WEMWBS | CS diagonal | 26.437 | 3.591 | 7.362 | 0.000 | (20.257 to 34.501) |
| | CS covariance | 74.175 | 9.839 | 7.539 | 0.000 | (54.891 to 93.459) |
| SF-12 PCS | Var: Time 1 | 75.726 | 7.631 | 9.924 | 0.000 | (62.154 to 92.260) |
| | Var: Time 2 | 53.061 | 6.696 | 7.925 | 0.000 | (41.435 to 67.949) |
| | CSH ρ | 0.591 | 0.057 | 10.305 | 0.000 | (0.467 to 0.692) |
| SF-12 MCS | CS diagonal | 30.049 | 3.852 | 7.801 | 0.000 | (23.374 to 38.631) |
| | CS covariance | 49.659 | 7.516 | 6.607 | 0.000 | (34.928 to 64.390) |

**Appendix K Topic Guide for Focus Group**

Topic guide followed by the moderator in each focus group

| Topic | Typical Questions • Probes |
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| **Journey to MCEP** | What was your initial perception of coming down to the MedEx programme?<br>When the programme was suggested to you, how did the idea strike you?<br>• What influenced you to join the programme?<br>• Did you have a clear understanding what you were signing up for?<br>• What aspects might have worried or concerned you? |
| **Experience of the programme** | Now that you are here what has been your experience of the programme?<br>Looking at all aspects, the programme design, the referral from the hospital, the social side, the education talks |
| **The exercise class** | What aspects did you like/dislike?<br>Suitability of classes<br>Looking at the running, structure, content of the exercise class |
| **Factors that facilitated participation in the programme** | What has helped your participation in the programme?<br>Who has helped?<br>• What did the person/people do to support you that made it effective?<br>Were there any supports that were good/you think are needed?<br>• At what stage do you feel support is needed most and why?<br>• Are there more ways that people referred to the programme could be supported?<br>Any barriers you felt you had to overcome? |
| **Perceived benefits of the MCEP setting** | What effect do you think the programme has had on you?<br>• Social/Mental/Physical<br>• Any changes in amount of PA you partake in weekly? |
| **Recommended improvements** | What improvements would you suggest to this programme?<br>• Consider referral process/ the classes/ the talks/ the gatherings/ the initial assessments/ any other factors. |

**Appendix L Table of Themes, Subthemes and Supporting Quotes**

| Theme | Subtheme | Supporting Quotes |
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| Moving from Fear to Confidence | Fear and Uncertainty | '*I've been lacking confidence in doing exercises …. I was wondering would it bring on the pain, the angina I had… I didn't know where I was going'* (P6 FG1)<br>'*Fear is the worst thing because you are on your own and you are just wondering am I able to do it or am I not able to do it* [exercise]*'* (P7, FG1)<br>*'Yes, fear is the thing, in case we over do it.*' (P3 FG1)<br>'*we were afraid to do anything'* (F1 FG3) (a number more agreeing in the background)<br>*'I think we all had that feeling that we were afraid to do anything'* (F3 FG3)<br>*'once this* [the cardiac event] *happened, I was afraid to walk – there was weeks I didn't go out because I thought oh no….'* (F1 FG3)<br>*'when you have a major episode in life, quite a lot gets stolen away from you. You live with the trauma of what you have gone through …. We were all nervous about what you go through.'* (M3 FG4)<br>*'thing for me is.... you have these operations in hospital, and I'm just talking about myself, but you have this pity for yourself.' (*P6 FG1)<br>*'You're coming out of hospital; you're painted as dead'* (M2 FG4)<br>*'Before I wouldn't know what exercises to do or anything like that.'* (F1 FG4)<br>*'Well, I thought I mightn't be able to do much, or I wouldn't be able to manage it* [exercise]*'* (M1 FG4)<br>*'I want to be able to use a chain saw again and to chop wood again, I really wasn't fit for it.' (*M3 FG4)<br><br>*'sure, I wouldn't know what I needed to do'* (M3 FG4)<br>'*I felt after it* [hospital-based CR] *finished I didn't know where to go'* (M1 FG3)<br>'*you're down doing the exercise in the rehab* [hospital] *and when that was over that was it, you were gone'* (M4 FG3).<br>*'I would never have warmed up before. I would have just started walking with a lot of pain in my shins. So, I thought that was great.'* (P10, FG2)<br>*'I wouldn't have known about the warmup or the cool down.'* (P9, FG2) |

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| | Need for Continuity | *'...it was something we were waiting for, all of us'* (P1 FG1)<br><br>*'they (hospital) rang me up and sent me out a letter and so I'm doing it now.'* (P12 FG2)<br>*'I did the CR programme in the hospital, and they had mentioned it up there.' (P8 INT 1)*<br>*'They (the hospital) told me about it' (F1 FG4)*<br>*'Audrey (senior physio) would have told us about it now' (F4 FG3)*<br>*'It was pretty much straight forward, she (senior physio) just told us in the rehab class, and we came down here' (M1 FG3)*<br><br>*'If you were worried [medical person] was there to reassure us.'* (P3, FG1)<br>*'It's having someone you know and who knows you'* (M3, FG2).<br>*'The continuity and the link between the hospital and yourselves* [the programme] *is critical, it's really important.'* (M3, FG4)<br>*'You've a back-up really, any problem you just talk to …. and they refer you back. It's knowing you can get back to them' (F2, FG3)*<br>*'We've got that link. We don't want to lose that support now that we have it.' (M1, FG3)*<br><br>*'You'd walk all right but you wouldn't do the exercises* [circuit]' (F2 FG 3)<br>*'I was told to get out walking and that didn't really suit me as I was a bit of a crock so I got on a bicycle and I found that a great alternative, I can do that 3 -4 days a week and then 2 days here so as you said the discipline of getting up and getting out' (M3 FG3)*<br>*'otherwise I wouldn't go to the gym myself… I was delighted to get the chance'* (F2, FG4)<br>*'It was the first time I have been to the gym and had to use the machines and not be afraid.'* (F2 FG4)<br>'*Also, you learn how to do exercises. Before I wouldn't know what exercises to do or anything like that and it's great to be able to do them at home now that I understand what I should and shouldn't do.*' (F1 FG4)<br>*'You see those gym things, I would have never walked into a gym, I had never been in a gym…… Everyone seemed to like the gym, you would feel really awkward going in, you wouldn't know what you were doing before that. At least now when I sit down, I know what I'm supposed to be doing.'* (P10, FG2)<br>*'You certainly wouldn't have had the confidence to go in and use those machines* [before the programme]' (P7, FG1) |

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| | Increase in Confidence | *'The combination of all of them was very beneficial.' (P3, FG1)*<br>*'It was a team effort' (P7, FG1)*<br><br>*'…you trusted the staff that were looking after us, you knew that they were not going to put you in harm's way, they are there to take care of you.' (P7 FG1)*<br>*'They do a 3 stage of what you can do yourself, you're not being pushed into working flat out, you do what you can' (M2 FG4)*<br>*'they [the instructors] are very good at that and they also tell us not to overdo it – gives you direction.' (M1 FG3)*<br>*'they were always reassuring us that if we had any problems, to stop. Not to overdo it.' (P1 FG1)*<br>*'The instructors encouraged you, but you weren't pushed. If you weren't able to do something, that was ok.' (P9, FG2)*<br>*'They step out in front of us, and we do it, then they walk around and look back to see what we are doing and see are you doing the right thing.' (F2 FG4)*<br><br>*'We thought we couldn't do* [the exercises] *and now we can do everything….'* (F2 FG3)<br>*'More confidence anyway in yourself you know – you were afraid to do anything in case you were doing too much or too little you know so you have that confidence that you know you able to do a lot more.'* (F2 FG3)<br>*'I have to say I feel better …. because I'm more confident in myself'* (P6 FG1)<br>'*my daughter has a treadmill at home, and I was afraid to go on it, but I go on it now you know*' (F2 FG4)<br>*'Before I wouldn't know what exercises to do or anything like that and it's great to be able to do them at home, now that I understand what I should and shouldn't do'* (F1 FG4)<br>*'Some of us are coming back here next week* [outside of the programme] *and we are just going to go the gym.*' (P1 FG1) |
| Drivers of Engagement | Scheduled Exercise | *'I would have done none [exercise], literally none.' (P9, FG2).*<br>*'It's fantastic, just fantastic. Because you will not do it at home, you will not do it by yourself.' (P1 FG1)*<br>*'Well, I have an exercise bike, I used to try but not much……. And the longer you leave it, the less you are inclined to do something. It [the programme] was great……..you come in and do a class and you walk out the door and feel completely different, instead of sat at home giving out to yourself for not doing it.' (P10, FG2)* |

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| | | *'You wouldn't do it otherwise; you wouldn't do it at home' (F1 FG3)*<br>*'If we hadn't this [the programme] we'd be home sitting on the couch.' (F1 FG4)*<br>*'You see what happens is you go and have heart problems and you get it sorted out and you go to the cardiac rehab up in Sligo hospital, which is very good. You get hooked up to machines and everything but then you get sent home and you're told carry on walking with this and within a month you go back to your normal self and you're not doing anything.' (P1 FG1)*<br><br>*'You know you had two dates in the week you had to meet and otherwise you might have done nothing.' (P8, Int. 1)*<br>*'The discipline part of it is fantastic that you make yourself come twice a week' (F2, FG3)*<br>*'at least them 2 days, that you are sure of doing your exercise …. those 2 days you're committed, you know what you're doing and you're going to go…… some of us but not all mightn't be as good at doing it at home.' (F2, FG4)* |
| | Social Connections | *'I heard about this from my sister-in-law so I rang up to see could I join up' (M3 FG3)*<br>*'Anyone I talked to recommended it highly.' (F1, FG4)*<br>*'I know of a girl who already was coming to this session …. That's where I heard about it first …. Then I asked … about it'* (F2 FG4)<br>'*Participant X was present. He went through it, and he advised me to do it.'* (M3 FG4)<br><br>*'everyone's in the same boat' (M2C FG4)*<br>*'all on the same wavelength' (F1C FG4)*<br>*'We are more comfortable talking with each other.' (P4 FG1)*<br>*'And then the social aspect of it too. In the rehab programme in the hospital, once you are finished with it, you are gone out the door straight away. This is nicer where you get to meet a few people, and I can talk to people who have similar issues and on similar medications to myself.' (P8, INT 1)*<br>*'I felt this was great because we bounce off each other, meet people with the same situations that we have all been through and psychologically it was a chance to meet other people, talk…' (M1B FG3)*<br>*'…. fantastic therapy …… you come down here and you think everyone has had stents put in but it's not, people have had different problems and you just start talking to people and it makes people at ease more…' (M4 FG3)*<br>*'I'm not as bad as I thought I was [laughing] I've only 2 stents...' (M3 FG3)* |

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| | | *'...we were counting who had the more stents at this stage you know we found out there's always someone better or worse than you' (M1, FG3)*<br>*'...well, if they can do it so can I.' (P2 FG1)*<br>*'You see new people coming in now and they aren't able to do what we can do, and we were once them…. and we see them kind of struggling and we say don't try to do what we are doing because you won't be able for it …' (M1 FG3)*<br>*'…the chat can be about anything.' (M2 FG4).*<br>*'After my open-heart surgery, I had a problem with the stitches down where the wound was and a lot of the vest that you buy have a hem which was rubbing against the wound irritating it. And I discovered [through talking to someone during the tea and chat] if I turned it inside out it made a big difference, and it was ages, absolute torture trying to figure it out.' (FG1 P7)*<br>*'And we talk among ourselves about what we're eating and what we're not eating and what suits us and what doesn't and it's the social gathering as well.' (M1 FG3)*<br>*'centre piece of this whole thing.' (M3 FG4)*<br>*'It was the motivational encouragement you got from others [in the group]' (FG1 P3)* |
| | Enjoyment | *'We had fun too, a lot of laughter and that's very important too' (P3 FG1)*<br>*'…we actually have fun…. who would associate P.E. and fun!' (M3 FG4)*<br>*'there's a great fun aspect to it also – we have great fun down there [circuit class]' (F1 FG3)*<br>*'The wit and the banter that goes on – makes it for everybody' (M2 FG3)*<br><br>*'… try to do an exercise and no music, it's totally different, meaningless.' (F2 FG3)*<br>*'Yes, the music and the exercise yes and it makes it more interesting.' (M1 FG4)*<br>*'If the music is off there's something wrong.' (M2 FG4)*<br><br>*'I thought the gym was the best' (P12 FG2)*<br>*'I liked getting back into the gym. Before that it was circuit training in here [the studio], which was grand but after a few times doing it.... maybe if there was a wee bit more of the gym and wee bit less of the circuit training …. vary it and give you a bit more interest, you know…. It's not like we didn't like the circuit training classes it's just if they were a bit more mixed.' (P2 FG1)*<br>*'I liked the combination of the circuit training and the gym.' (P10 FG2)*<br>*'I liked all the different exercises and we were not long doing them….The time went around quicker.' (P6 FG1)*<br>*'I'd like a little bit more variety into it' (F4 FG3)* |

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| | | *'vary it and give you a bit more interest, you know….' (P2 FG1)* |
| Challenges to Maintaining Exercise Adherence | Barriers | *'Ideally, I would, but once I go back in September, I can't see it happening. Can't see myself having the time to do it.'* (P8, Int. 1)<br>*'The only negative thing is that I hadn't the time to do it all the time because I was working.'* (P10, FG2)<br>'*I couldn't do it all the time because I was babysitting*' (P12, FG2)<br>'*Yeah, the group* [hospital CR] *that I was in were interested but it just didn't suit their work.'* (P9, FG2)<br>*'We lost a lot of people because it clashed with dropping off kids and grandkids*' (F1, FG4)<br>*'As it's ongoing, as the year gets darker it's very early in the morning'* (F2, FG4)<br>*'there's one man that comes from Enniscrone and he'd have to leave at 7 o'clock to be here. Wouldn't it be terrible if he'd to drop out because of this, I'd imagine other people dropping out too*' M3 FG4 |
| | Dependency | *It* [medical support] *was automatically there, we had the support, and it was always at the back of your mind, they are there and that is great.* (P2, FG1)<br>*'she (senior physio) was there, you know on hand, to say I got a wee pain here what's this all about, am I doing too much, am I going too quick, too slow, can I do more, and I thought that was very good to have somebody professional like herself here all the time, I know with staff shortages but if for future references that we could have someone here professional all the time to talk to that if we weren't feeling 100% that she could give us directions'* (M1 FG3)<br>'*Yes regularly to be here*' (Requesting medical presence) (M2 FG3)<br>'*You've a back-up really, any problem you just talk to …. and they refer you back. It's knowing you can get back to them'* (F2, FG3)<br>'*We've got that link. We don't want to lose that support now that we have it.'* (M1, FG3)<br>*'If there was subliminal support every week, I'd be happy enough. Just to know that it's there.'* (P8, Int. 1)<br>*'you can actually see them going around to each individual and they pick out somebody who's under stress and bring them out and measure their heart rate.*' (M3 FG4)<br>*'It* [blood pressure monitoring*] reassures you that you're ok for it.*' (F1, FG4)<br>*'Getting your blood pressure taken … it keeps you focused on it, otherwise when would you have it taken…. it's nice to know you're plodding along nicely.'* (F4, FG3)<br>*'they monitor you, they come around and take a heart rate.'* (F1, FG4) |

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| Life Beyond their Illness | | *'Absolutely beneficial, in every way. It was something we looked forward to and was excited to see who was going to take part after all, we are delighted…. We have really enjoyed it; we have got the bug…wonderful experience.' P3 FG1*<br><br>*'.. they don't treat us as recovering patients, and you're no longer a patient. That's a huge thing …. All from different backgrounds …. and it's by being targeted normally that you're well able to do this…. (M3 FG 4)*<br>*'That [their condition] would rarely come up. Very, very rarely.' (F1 FG4)*<br>*'Well, that's in the background [being a patient], it's gone.' (F2 FG4)*<br><br>*'when I started …. I wouldn't have been able to do a fraction of those things that we are able to do now' (F2 FG3)*<br>*'I'm fitter than I ever was!' (F1 FG4)*<br>*'I've my walk down from an hour to 50min' (M1 FG3)*<br>*'Well for me I have had dreadful angina when walking and that seems to have improved immensely.' (P3 FG1)*<br>*'What improved for me was my knees, they were very stiff, and they have improved unbelievably. And I noticed my back is stronger, my back used to get tired at night and now I completely forgot about it. Now it does not bother me, it's strong, it does not get tired at night.' (P6 FG1)*<br>*'We do feel motivated now and also more energized. I think our mobility, and everything has improved because of it.' (P3 FG1)*<br><br>*'it does something to your mind, it focuses it, it is very positive.' (P6 FG1)*<br>*'Physically you feel better but even mentally you feel better' (P10 FG2)*<br>*'There is a real feel-good factor about it…. good inner feeling.' (M3 FG3)*<br><br>*'…the illness isn't the end of the road…' (M2 FG3)* |