An ecologically valid assessment of the exercise is medicine hypothesis

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DECLARATION

I certify that this work has not been accepted in substance for any degree, and is not concurrently being submitted for any degree other than that of Doctor of Philosophy being studied at the University of Greenwich. I also declare that this work is the result if my own investigations except where otherwise identified by references and that I have not plagiarised the work of others.

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ABSTRACT

Widespread physical inactivity and resultant increases in cardiovascular and metabolic disease is a serious public health concern in the developed World. Unsurprisingly, the vast majority of research evidence suggests that physical activity is an effective intervention in addressing this state of affairs. An apparently strong case exists for the widespread clinical prescription of physical activity (PA). The application of PA in both preventative and remedial health is often termed ‘exercise is medicine’.

Whilst on the basis of a large volume of laboratory data there is some consensus regarding the optimal delivery of health related PA, there is an apparent discrepancy between data emanating from laboratory and/or clinical studies and those emanating from real world interventions. In short, real world interventions do not appear to be as effective in promoting health as laboratory research suggests should be the case. This situation is compounded by a relative paucity of peer reviewed research studies reporting real world PA research, and furthermore by even less clinically relevant data. On this basis, a clear picture of the degree of translation from laboratory to the field is not yet possible. It is however not unreasonable to argue that the setting of the vast majority of research studies investigating the exercise is medicine hypothesis - that is laboratories, hospitals and clinics – might theoretically limit the translation of these findings to real world public health settings, and on that basis, more real world research is warranted.

In Chapters 1 and 2 of this thesis the above arguments are developed into a case for a large scale ecologically valid translational study to investigate the effects of exercise on clinically relevant health variables. Chapter 3 presents the results of a pilot study that assessed the comparative effectiveness of structured PA (STRUC), unstructured PA (FREE), and PA counselling (PAC), among sedentary individuals in a community fitness centre setting. Significant improvements were observed in cardiovascular risk factors in all three groups, with no significant between-group differences.

Chapters 4, 5 and 6 report data from a large scale, ecologically valid, longitudinal (48 week), multi-centre (n=26) investigation comparing the three interventions above with a measurement only condition. Participants were 1146 previously sedentary individuals. The ecological validity of the exercise is medicine hypothesis was tested from a clinical (Chapter 4) and behavioural (Chapter 5) perspective. Survey data pertaining to factors influencing the effectiveness of the interventions are explored in Chapter 6.

Data suggest that the baseline health status of participants mediated effects over time, with participants most at risk of cardiovascular disease experiencing clinically significant improvements in health (e.g. VO_2max: STRUC High -7.52% vs Low 32.03% (P=0.005), FREE High -4% vs Low 24.31% (P=0.023), PAC High -8.19 vs Low 35.8% (P=0.007), COM High -5.22% vs Low 8.17% (P=0.663). These effects differed by condition. Improvements in body composition and VO_2max following STRUC are consistent with previous laboratory findings. However, behavioural data indicate a stark contrast between retention rates observed in the current study and those reported elsewhere in laboratory studies (STRUC 34%, FREE 34%, PAC 29%, COM 31%). Post intervention survey data suggest that engaging with previously sedentary and/or low fitness participants within a fitness facility is challenging, and that as a consequence necessary levels of communication and motivation can be difficult to maintain.

Overall data highlight several factors that differ between laboratory research and real world practice. These collectively potentially reduce the ecological validity of the exercise is medicine hypothesis. It is suggested that more real world research is warranted to better identify factors that might both mediate and moderate the relationship between physical activity and health.

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ABBREVIATIONS

Expansion	Abbreviation	Expansion	Abbreviation
Coronary Heart Disease	CHD	Metabolic Equivalence of Task	METs
Low Density Lipoprotein	LDL	Metabolic Syndrome	MetS
High Density Lipoprotein	HDL	Body Mass Index	BMI
Triglyceride	TG	Activated Protein Kinase	AMPK
Very Low Density Lipoprotein	VLDL	Mammalian Target Rapamycin	mTOR
Total Cholesterol	TC	National Institute of Clinical Excellence	NICE
Physical Activity	PA	General Practitioner	GP
Milligrams per Decilitre	mg/dl	Physical Activity Counselling	PAC
Millimoles per Litre	mmol/L	Body Mass	BM
Heart Rate max	HRmax	Fat Mass	FM
Maximal Cardiorespiratory Fitness	VO2max	Fat Free Mass	FFM
Heart Rate reserve	HRreserve	Body Fat Percentage	BF%
Repetition Max	RM	Systolic Blood Pressure	SBP
Moderate Intensity	MOD	Diastolic Blood Pressure	DBP
High Intensity	HIGH	Resting Heart Rate	RHR
Type Two Diabetes	T2D	Chest Press	CP
Homeostasis Model Assessment	HOMA	Aerobic Exercise	AE
Glucose Transporter Type Four	GLUT4	Resistance Training	RT
Glycated Haemoglobin	HbA1c	Combined Aerobic and Resistance Training	COM

PUBLICATIONS/CONFERENCE PRESENTATIONS

Peer reviewed publications

Beedie, C., Mann, S., & Jimenez, A. (2014). Community Fitness Center-Based Physical Activity Interventions: A Brief Review. Current sports medicine reports, 13(4), 267-274

Mann, Beedie & Jimenez (2014). Differential effects of aerobic exercise, resistance training and combined exercise modalities on cholesterol and the lipid profile: review, synthesis and recommendations. Sports Medicine, 44(2), 211-221.

Mann, S., Beedie, C., Balducci, S., Zanuso, S., Allgrove, J., Bertiato, F., & Jimenez, A. (2014). Changes in Insulin Sensitivity in Response to Different Modalities of Exercise: a review of the evidence. Diabetes/metabolism research and reviews, 30(4), 257-268.

Conference communications

Mann, Beedie & Jimenez (2014), Changes in cardiovascular risk of previously sedentary individuals resulting from four gym-based exercise programmes. American College of Sports Medicine Annual Meeting. Orlando, USA. **Poster Presentation**

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Mann, Allgrove & Jimenez (2012). The effect of 12 week fitness centre based; physical activity counselling and exercise, upon cardiovascular risk factors. International Congress on Physical Activity and Public Health. Sydney, Australia. **Poster Presentation**

1. Introduction

1.1. Background

One of the prime responsibilities of a government is to maintain, if not improve, the health of its population. In the developed world, the incidence of communicable diseases that require the control of infection have been dramatically reduced through large scale immunisation programmes and the increased ability of hospitals and doctors to treat such conditions as they arise. Non-communicable diseases however are on the increase throughout the developed world [1]. Non-communicable diseases are non-transmissible amongst people and therefore require very different methods of prevention to communicable diseases. Non-communicable diseases, such as cardiovascular diseases, cancers, respiratory disorders and diabetes are often long in duration and slow in progression. They therefore require chronic care programmes and long courses of medication that place large financial burdens upon societies and their respective health care programmes [2].

According to the World Health Organisation [3] non-communicable diseases kill more than 36 million people each year. Cardiovascular diseases account for 17.3 million of these deaths – significantly more than any other non-communicable disease (this is followed by Cancer at 7.6 million). The most widely cited, significant and modifiable behavioural risk factors for non-communicable disease are tobacco smoking, diet, alcohol abuse and physical inactivity [4]. It was proposed by the World Health Organisation [5] that the reduction of these risk factors must be seen as a priority if we as a society are going to be able to reduce harm and reduce the financial and medical burden non-communicable diseases place upon us.

In England the incidence of coronary heart disease is projected to rise from 2.4 million in 2010 to 2.8 million in 2020 [6]. Likewise the incidence of Diabetes is expected to increase from 3.1 Million (2010) to 4.6 Million in 2030 as a result of changing age and ethnic structures in the population, as well as the growing prevalence of obesity in the United Kingdom (UK) [7].

As part of the aforementioned governmental responsibility, initiatives have been launched in the UK to counteract tobacco smoking, poor dietary habits, excessive alcohol consumption and sedentary lifestyles – as recommended by the World Health Organisation [5]. For example, tobacco companies have been banned from sponsoring sporting events, advertising on television and in the mass media. All tobacco packing must carry health warnings and is required to be hidden behind screens in supermarkets and alike. Tobacco smoking has been banned in public places such as restaurants, coffee shops and pubs. All of the above have been implemented by different UK governments but for the same reason – to remove the attraction of smoking and make it more difficult to do so in comfort [8]. In response to such measures the number of people smoking has fallen from 39% of the population (1980) in England to 21% in 2011 [9]. Furthermore, it is reported that between April 2011 and March 2012 400,955 people stopped smoking – a five percent improvement over the same period the previous year (383,548) [10].

In a response to increases in obesity and caloric intake over the previous 20 years measures have been taken by governmental departments, agencies and public bodies to address the nutritional, factor i.e. excessive energy intake, associated with increases in obesity [11-13]. Measures have included healthy cooking lessons for overweight children and their parents in schools, 'traffic lighting' on food packaging and the calorific values of meals in restaurants being detailed on their menus. All have aimed to increase the awareness of healthy diets and their implications for health [14]. In 2012 it was found that 80% of consumers claimed to follow a healthy diet – an increase of 10% from 2004 [15]. The same report found that between 2004 and 2012 the understanding of what a healthy diet was had increased. 95% of respondents rated fresh fruit and vegetables as important, 87% a balanced diet and 74% drinking enough fluid – this was an increase of 20%, 24% and 26% respectively compared with the same questions in 2004.

In the UK large-scale media campaigns – as part of the Change 4 Life initiative [14] - have focused upon the dangers of excessive alcohol intake. In addition minimum pricing per unit of alcohol has been implemented in Scotland [16] and has been proposed in England as a method of limiting the availability of cheap alcohol [17]. Data from the 2011 General Lifestyle Survey [18] suggests that there has been a sustained and steady downward trend in alcohol consumption over time. The proportion of men who drank alcohol in the seven days prior to the questionnaire fell from 72% to 66% between 2005 and 2011 (decrease from 57% to 54% in women). Those drinking alcohol upon five or more days of the week also fell – from 22% to 16% in men and 13% to 9% in women [19].

Worldwide physical activity levels have decreased over the last 50 years [20, 21]. In an attempt to provide clear guidance regarding the volume of physical activity required to promote good health, the UK Chief Medical Officer [22] published physical activity guidelines (five times 30 minutes physical activity each week). These have been extensively publicised through the Change 4 Life campaign and Sport England (non-departmental public body tasked with the promotion of sport). Furthermore regional/local campaigns and promotions have been run by individual clinical commissioning groups and local fitness facilities to encourage increased physical activity. The latest Active People Survey published by Sport England [23] (covering the period April 2012 – April 2013) indicated that 15.3 million people completed a sporting / exercise session lasting 30 minutes once a week [23]. This is an increase of 1.4 million compared with 2005/6. Furthermore, the British Heart Foundation Physical Activity Statistics Report [24] indicated that the proportion of adults achieving the recommended levels of physical activity increased in England between 1997 and 2008 (32% to 39% in men and 21% to 29% in women). The same report highlighted however that there is a large discrepancy in activity levels reported by self-report questionnaire and those measured objectively via accelerometer. Among males, whilst 39% reported meeting the recommended activity levels, of those measured objectively only 6% did so. Among females these figures were 29% and 4% respectively.

Cardiorespiratory fitness is an indicator of one's physical activity levels [25-27]. Data from the aerobics centre longitudinal study (n>50,000) [26] suggest that low cardiorespiratory fitness is the largest attributable factor to all-cause mortality, larger than tobacco smoking and obesity. Alcohol intake was not reported. This suggests that non-smokers, as well as people of what is considered a healthy weight, are at an increased risk of non-communicable disease if physically inactive.

Despite the measures detailed above, non-communicable diseases continue to rise in the UK. The fact that in the most recent survey only 6% (male) and 4% (female) of monitored adults (n=1305) met the physical activity recommendations of the Chief Medical Officer would suggest that the initiatives aimed at reducing physical inactivity have not been effective. Considering the data revealing low cardiorespiratory fitness to be a greater risk to all-cause mortality than obesity and smoking [26], this can only increase the significance of inactivity as a public health concern.

1.2. Physical inactivity

A sedentary (inactive) lifestyle is associated with increased incidence of cardiovascular disease, some cancers and psychological disorders [28]. Bull et al [29] classified inactivity as follows; Level 1 exposure (inactive) – doing no or little physical activity at work, at home, for transport or in discretionary time, and Level 2 exposure (insufficiently active) – doing some physical activity but less than 150 minutes moderate intensity physical activity, or 60 minutes of vigorous intensity physical activity a week accumulated across work, home, transport or discretionary domains. These classifications were adopted in the United Kingdom by the Chief Medical Officer [22] and the United States by the American College of Sports Medicine [30].

Physical inactivity has become an important and highly significant issue in public health [31]. Rütten et al [31] proposed five factors that have influenced this process: 1) Physical inactivity is a key lifestyle component relating to the obesity epidemic and rise in non-communicable diseases. 2) There is a stable and increasing prevalence of physical inactivity. 3) The advent of the concept that physical activity can be used to improve health. 4) The multiple and varying causes and ecological models of physical inactivity. 5) The multiple types and combinations of interventions designed to promote physical activity / eradicate physical inactivity. An examination of these five factors is presented below.

1.2.1 Physical inactivity and non-communicable disease

Cardiovascular diseases account for the highest proportion of non-communicable diseases worldwide. Risk factors for cardiovascular disease are both modifiable (tobacco smoking, unhealthy diet, physical inactivity, hypertension, dyslipidaemia, impaired fasting glucose and obesity) and non-modifiable (age, gender and family history). Physical inactivity has been shown to contribute to hypertension, dyslipidaemia, impaired fasting glucose and obesity [32], all of which can be prevented by increases in physical activity [33-38].

Cardiorespiratory fitness and physical activity are inversely associated with the development of hypertension in young adults (n=4618) [39]. It is reported that incidence of hypertension (classified as a blood pressure reading above 140/90mmHg) was inversely associated with baseline fitness and self-report physical activity levels in 4618 participants over a 20 year examination period when data were adjusted for age, sex, race and baseline smoking status [39]. Further, a meta-analysis of 93 trials involving 5223 participants found that exercise training was able to significantly reduce systolic and diastolic blood pressure [38]. Objectively measured (accelerometer) lifestyle physical activity levels revealed a significant ($p<0.001$) and negative association with dyslipidaemia [40]. An equally significant but positive association was found between time spent sedentary and dyslipidaemic symptoms i.e. cholesterol levels.

Impaired fasting glucose or pre-diabetes is signified by a chronic elevation in blood glucose levels despite the secretion of insulin or when fasting. This is a response to a decrease in insulin sensitivity and a pre-cursor of type two diabetes [41]. A positive energy balance, caused by low levels of energy expenditure i.e. low physical activity, and a high calorific diet can result in raised levels of sugars in the blood and impaired fasting glucose. Time spent sedentary (measured via accelerometer) was positively associated with fasting plasma glucose levels ($p<0.001$) in a mixed age cohort (n=878) [42].

A positive energy balance also leads to an accumulation of excess body fat – classified as obesity when one's body mass index (height divided by weight squared) reaches 30kg/m^2. Moderate to vigorous physical activity was consistently and inversely associated with obesity, regardless of sedentary behaviours, according to data from the National Health Examination Survey (n=5083) [43].

The evidence presented above, linking physical inactivity with four modifiable risk factors of cardiovascular disease, demonstrate its contribution to the major non-communicable disease in turn affecting populations in both developed and developing nations.

1.2.2 Stable and increasing prevalence of physical inactivity

Despite initiatives designed to increase physical activity levels across populations, such as the Global Strategy for Diet, Physical Activity and Health [44], Change for Life (UK) [14] and A 2020 Vision for Healthy People (USA) [45] – physical inactivity levels have remained relatively stable in developed nations. Although the Active People Survey [23] reports slight decreases, the objective (accelerometer) data collected in the British Heart Foundation Physical Activity Statistics Report [24] suggests this is inaccurate. Additionally in Europe for example 60% of those surveyed said they never or very rarely played sport while only 27% engaged in regular physical activity [46]. In the United States between 1997-2007 numbers reporting leisure time physical activity levels meeting the 30 minutes 5 times per week guidelines fell in all cohorts except those with college degrees [47]. Developing nations such as Brazil, India and Thailand are seeing physical inactivity increases due to rapid economic and social development e.g. urbanisation, motorisation, industrialisation and increase in disposable income [48].

Perhaps the greatest public health concern regarding physical inactivity is in fact that people are becoming increasingly aware of the ramifications and expectations around physical activity but not changing their behaviour. This only highlights the importance of more effective and better targeted interventions.

1.2.3 Health enhancing physical activity

There is an ever increasing and arguably indisputable body evidence that physical activity and exercise are effective in the prevention and management of cardiovascular conditions. Pedersen and Saltin [49] presented the evidence for prescribing exercise therapy in the treatment of the four modifiable risk factors of cardiovascular disease - insulin resistance, dyslipidaemia, hypertension and obesity – concluding that there is strong (Category A) evidence for the positive effect of exercise upon the pathogenesis, symptoms specific to the diagnosis, and physical fitness or strength and quality of life of those with all four conditions (barring quality of life in those with dyslipidaemia which was associated with moderately strong evidence). More recently research has shifted from the general effectiveness of physical activity / exercise interventions to optimising the mode, frequency, intensity and duration of activity interventions [50]. There is currently however no accepted consensus and as a consequence exercise prescriptions are difficult to administer and outcomes difficult to predict [51].

1.2.4 Multiple causes and ecological models of physical inactivity

The multiple and diverse nature of the mechanisms that underpin physical inactivity make it difficult for public health interventions to successfully increase physical activity. Barriers to physical activity can be found throughout the socio-ecological spectrum (individual, interpersonal, organisational, community and public policy), and successful interventions will need to address all levels [52].

Over 15 years ago Dunn et al [53] and Sallis & Owen [54] described some of the barriers to physical activity; lack of time, lack of social support, bad weather, lack of knowledge, age, educational attainment, attitudes and availability of infrastructure and facilities.

Many of these barriers continue to limit increases in physical activity. A review [55] of qualitative studies investigating participation in sport and physical activity in 2006 found that cost, poor access to facilities and unsafe environments were cited as reasons for not participating in physical activity schemes. More specifically adults revealed that anxiety and confidence issues prevented them attending General Practitioner referral schemes. Those that did attend were often unable to relate to their physical activity / exercise leaders.

The 2007 Health Survey for England [56] revealed that men and women differ in their rationale regarding physical inactivity but that both rationales relate to time. 45% of inactive men cited work commitments as the primary reason for inactivity while 37% of women revealed a lack of leisure time. Respondents claim that more available leisure time (49%), some external motivation (40%), their own ill health (36%) and advice from a doctor or nurse (29%) would encourage them to do more physical activity.

1.2.5 Multiple types and combinations of interventions to promote physical activity

The task of tackling physical inactivity has been approached in many ways – ranging from societal level mass media campaigns [14] to individual counselling sessions in community settings [57]. There is however no clear, evidence based, strategy that has emerged from over 20 years of research – in fact many of the interventions have failed to deliver substantial increases in physical activity [58] or deliver clinically significant reductions in cardiovascular risk [59].

There are examples of interventions that have increased the physical activity levels of participants from a whole host of different demographics in different countries [60]. The findings from a collection of evidence based interventions were collated by Heath et al [60], who concluded that in children and adolescents' physical activity could be effectively increased though school-based initiatives. In adults however it is suggested that physical activity interventions should link and apply individual, behavioural, social, environmental and policy level considerations, something very difficult to achieve and hard to sustain [60].

1.3 Physical activity and types of exercise

The terms ''physical activity'' (PA) and 'exercise'' are often used interchangeably in the literature. However it is suggested that the two terms denote two different concepts [61]. ''PA'' refers to any bodily movement produced by skeletal muscles that results in an expenditure of energy (expressed in kilocalories), and which includes a broad range of occupational, leisure and daily activities. ''Exercise" instead refers to planned or structured PA, performed for a reason, which can be aerobic (AE), resistance training (RT) or the two combined (COM). AE involves cardiorespiratory endurance exercises such as jogging, running and cycling [61], RT is strength developing exercise utilising external resistance or one's own body weight [61], and COM combines the two.

The Physical Activity Guidelines Advisory Committee Report [50] highlighted the need to design a programme that will provide appropriate exercise in order to attain maximal benefit at the lowest level of risk. However, despite a large number of related publications, a comprehensive overview of optimal modes, intensities and frequencies of exercise in the context of the four modifiable risk factors of cardiovascular disease (lipid profile, insulin sensitivity, body composition or blood pressure) has yet to be published by any of the agencies involved.

1.4 Implications for research

The evidence presented above suggests overwhelmingly that physical inactivity is a very relevant and pressing public health concern. It is a leading cause of cardiovascular disease and is directly associated with modifiable risk factors of cardiovascular health. There is however very strong evidence that PA and exercise are effective in the amelioration, management and prevention of, dyslipidaemia, impaired fasting glucose, obesity and hypertension [31-36].

This evidence, divided by mode of exercise (AE, RT & COM), is systematically reviewed later in the thesis. The findings are extensive and demonstrate beyond reasonable doubt the potential effectiveness of exercise in preventing, managing and treating modifiable risk factors of cardiovascular disease.

Initiatives such as ‘Exercise is Medicine’ [62] have been operational since 2008 in the US and built upon such evidence. The notion of exercise as medicine is however unfounded. Exercise has yet to be subjected to the rigorous clinical trial process required for a medicine (i.e., a drug) to be licenced and recommended for public use. Pre-marketing and post discovery drugs move through the three phases of a clinical trial [63]. The first phase involves confirming the drug’s safety in small experimental cohorts (n=20-80). This is followed by phase two which investigates whether the new drug is effective when compared to placebo or more effective than currently available medications (n>300). Finally phase three tests the drug in large diverse populations to examine its safety and effectiveness (n>1000). If a new drug passes these three phases it can be marketed to the public. Post marketing studies (phase four) then determine to what extent the drug works in the real world i.e. additional factors that may limit or increase a drug’s effectiveness can be observed, factors that it would not be possible to observe in controlled laboratory environments. The requirement of these studies, and the need to set them in community environments is well recognised [64]. There is a fundamental difference between phase three clinical trials and phase four post marketing studies that include patient characteristics, the setting, and the manner of drug use [65].

A robust evidence base for the prescription of exercise in the prevention and management of cardiovascular disease is described below – meeting the criteria set forth in the first three phases of the clinical trial process. Theoretically therefore the ‘prescription’ of specific frequency, intensity, time and type (FITT) of exercise via anything from GP Referral through to publicity/awareness campaigns should impact on public health. However, such interventions have proven largely unsuccessful [20, 59, 66]. In the real world we cannot be confident this dose will be achieved or will not be offset by external factors e.g. poor diet or increased sedentary behaviours. Post marketing studies of exercise as medicine must be set in local community facilities and be delivered in a way that replicates real world delivery if the criteria that distinguish between phases three and four of clinical trials are to be met [65]. Research meeting these criteria is systematically reviewed below.

Such research could be considered translational in that it attempts to transfer basic scientific discoveries into clinical applications and ultimately public health improvements [67]. Translational research provides the interface between basic science and public health outcomes [68], while ecologically valid research protocols offer the potential for answers to real world problems [69], in this instance the ever increasing prevalence of inactivity related disease [1]. Chapters 3, 4, 5 and 6 seek to translate the best practices identified in the literature review into real world, public health outcomes.

2. Review of literature

2.2 Community based intervention

2.2.1 Introduction

Despite the large and ever increasing body of evidence that demonstrates the effectiveness of physical activity and exercise in prevention, management and treatment of non-communicable disease [49], and the implementation of initiatives such as the Global Strategy for Diet, Physical Activity and Health [44], Change for Life (UK) [14] and A 2020 Vision for Healthy People (USA) [45], inactivity related diseases continue to increase in prevalence and public health interventions are failing to deliver clinically relevant outcomes [20, 59, 66].

Exercise referral is an example of a nationwide scheme that, according to academic literature, has not delivered an increase physical activity levels or improve clinical outcomes in participants [59]. Exercise referral is the practice of referring a person from primary care to a qualified exercise professional to develop a tailored programme of physical activity [70]. This provides patients with access to facilities (usually a community fitness centre) and expertise (usually an exercise professional) that can help them to make short term increases in activity levels and long term behavioural changes. It also gives exercise professionals the opportunity to monitor and prescribe the intensity, frequency and duration of exercise undertaken in their care and to provide nutrition and lifestyle advice during the sessions. Thus ‘exercise as medicine’, delivered within community fitness centres, does not seem to be increasing physical activity levels or generating health outcomes. Exercise referral is arguably the area of physical activity that is most closely aligned with traditional medical practice, that is a that is a problem is diagnosed, an appropriate type, dose and frequency of treatment is prescribed, and the patient’s response is monitored – yet even in this quasi-clinical setting exercise is proving far less effective than either the laboratory or the physiological theory suggests should be the case. There is a gap between the theoretical expectation and the real world reality. Such an expectation has however been generated as a result of laboratory or clinic based research and not translational or ecologically valid research.

A systematic literature search was conducted to identify all published fitness centre based investigations of relationships between exercise and health. The aim was determine how much research has been conducted and published investigating the translation of laboratory based research into real world public health outcomes.

2.2.2 Fitness centre based research

Recent reports (e.g., European Health and Fitness Association, 2010), have called on fitness centres to become 'community hubs for PA promotion and exercise'. Exercise referral schemes, whereby patients are referred by their General Practitioner (GP) to programmes within local fitness centres, have been proposed as an effective way of promoting PA and managing chronic conditions [71]. There is however uncertainty as to the effectiveness of such schemes [59] specifically whether they are an efficient use of resources for sedentary people with or without a medical diagnosis [59]. GP referral schemes have not yet led to significant improvements in health conditions or long term behaviour changes [66] or to increases in PA levels [58].

Given the evidence presented in major reviews [49, 71, 72] and in position stands issued by professional bodies [30, 37] there is little doubt among researchers, policy makers, and practitioners that PA can lead to improvements in health and a reduction in risk factors. However, on the basis of the evidence above, there appears to be a problem in converting the findings of research into large scale interventions that make real impacts in public health.

The translation of evidence based research findings into practice that is effectively, appropriately and widely implemented has been described as one of the greatest challenges facing health promotion and disease prevention [73, 74]. It has been hypothesised that the controlled environments in which much research into PA and health is conducted reduces its transferability into community settings [75], and that if more research was conducted in real world environments, the resultant data would have more relevance to, and application in, public health. Hohmann & Shear [76] suggest that the setting of research should be generalizable to its delivery setting in the real world and that participants must be representative of those most in need of the 'treatment' being proposed. Community based intervention trials test a treatment intervention but in the context of community based delivery i.e. the way in which such interventions would be accessed in the real world. These trials, in order to provide meaningful information for community clinical practice must take into account many factors that are controlled for, or perhaps are not considered, in traditional clinical trials e.g. changes in diet or sedentary behaviours. The real world delivery of PA interventions is often by community fitness centres.

The aim of this section is to assess the evidence for the impact of community fitness centre interventions on inactivity-related diseases in adults.

2.2.3 Search methodology

Article selection criteria are presented in Table 1. PubMed searches were conducted for search terms detailed in Tables 2 & 3. Articles were screened by title, then by abstract and finally by a full reading of the paper if required. Papers were only included if the PA intervention was delivered in or from a community fitness centre. Examples of articles excluded are those in which the intervention was administered from locations such as clinical research units [77] human performance laboratories [78] clinical centres [79] outpatient clinics [80] university medical centre's [81, 82] biomedical research centres [83] university research centres [84] or the applied physiology section of a university exercise facility [85]. Papers were also excluded if not in English [86, 87] or if the target cohort were children [88]. The inclusion of Dunn et al [53], conducted within the Cooper Fitness Centre and linked with the Cooper Institute and Clinic, hosts of many large and widely cited studies in PA [27, 89] was borderline. The facility in question is however run as a community fitness facility, in a similar way to the The Ohio State University Center for Wellness and Prevention (Graffagnino et al,.[75]) – also a borderline inclusion.

Table 1 Fitness centre based research article selection criteria

Fitness Centre Based Research: Selection Criteria
• Article Published between 01/01/1975 – 22/01/2013
• Physical Activity / Exercise intervention located / delivered from a community Fitness Centre
• Measurement Pre & Post intervention
• Clinically relevant measures of health

Table 2 Articles located during initial searches – Title & Abstract

Fitness Centre Based Research: Search Results		
Search Terms	**Papers Located**	**Relevant Papers**
Fitness Centre & Insulin Sensitivity	0	0
Fitness Centre & Blood Pressure	0	0
Fitness Centre & Cholesterol	0	0
Fitness Centre & Obesity	3	2

Table 3 Articles located during secondary searches – All Fields

Fitness Centre Based Research: Search Results			
Search Terms	**Papers Located**	**Relevant Papers**	**Final Papers**
Fitness Centre & Insulin Sensitivity	171	1	1
Fitness Centre & Blood Pressure	373	8	5
Fitness Centre & Cholesterol	208	4	2
Fitness Centre & Obesity	473	9	3

2.2.4 Research examining fitness centre based physical activity delivery

Searches for matches in the Title and Abstract only (Table 2.) located only three articles [90-92] Suchánek et al [90] focused on gene polymorphism and falls outside the public health spectrum in this case. Both Jolly et al [91] and Boyce et al [92] however reported relevant findings. Searches were widened to include all fields and 1225 articles were located. The number of articles implementing community based PA / exercise interventions from fitness centres was still limited – only 11 met the selection criteria (Table 1). This evidence is presented below and detailed in Table 4.

It is evident that few articles document research conducted in community fitness facilities. Of 1225 articles identified only 22 were relevant, or required reading to identify the setting of the intervention. However, the 11 articles described below provide an insight into the evidence base for community based interventions.

Jolly et al [91] compared several commercial and primary care weight loss programmes in the UK, each of 12 weeks duration, on a sample of 740 overweight men and women. Programmes included the commercially available products 'Weight Watchers', 'Slimming World' and 'Rosemary Conley' (group based diet and fitness classes), and GP and Pharmacy-led counselling sessions. A comparison group was provided with vouchers for 12 weeks access to a local fitness facility. Primary outcome variables were weight loss at 12 weeks and at 12 month follow up. All interventions resulted in significantly reduced weight at 12 weeks, and all barring the GP and Pharmacy-led counselling maintained this reduction at 12 months. Only Weight Watchers was associated with a significant increase in PA and decrease in body mass than the comparison group.

PA levels and body mass reduction / gain were also the key focus of the investigation by Boyce et al [92]. The investigation monitored staff during the first eight months of working in a call centre. Questionnaire data relating to weight, height, PA levels/habits, and body part discomfort were collected from 393 employees. The study highlighted substantial weight gains (68% gained an average of 0.9kg/month), which in fact may have been greater than reported due to the under-reporting associated with self-report data, especially the obese [93]. Perhaps counter-intuitively it was reported that fitness centre members in the sample experienced significantly greater BMI and weight gains over the period than non-members (the authors make no reference to rates of fitness centre attendance or usage).

Mathieu et al [94] designed and piloted a 10 week exercise programme for health and exercise professionals who want to help those at risk of, or already with, Type 2 Diabetes (T2D). The programme involved one weekly supervised exercise session and an individual home-based training session, and was conducted with 39 participants with T2D (29 completed the study with no controls). Supervised sessions included a 15 minute lecture on health improvements tips before 60 minutes PA and finally a 15 min review of the previous week. Aerobic, resistance and flexibility training were all covered in both the supervised and home-based sessions. PA levels were self-reported by telephone. Significant increases in PA were reported at 10 weeks and maintained at 6 month follow-up. Aerobic capacity, grip strength, HDL cholesterol, body weight, waist circumference and systolic blood pressure all improved between baseline and 10 weeks (but were not measured at six months). These data highlight the benefits of one session a week with an exercise professional who is able to initiate and monitor behaviour change. Improvements in metabolic risk factors however are significant and suggest a tangible training effect.

A similar process was implemented by Kreuzfeld et al [95] with long-term unemployed workers (n=119). Participants were referred by a job training centre and attended a lecture on the benefits of a healthy lifestyle alongside physical training in a fitness studio. A combined endurance and strength training protocol was conducted in groups of 12 twice a week for eight weeks. Following the structured training period, participants were able to continue exercising free of charge, but on a self-guided basis. Significant improvements in physical fitness, blood pressure and body composition were reported following the initial intervention. Significant reductions in depression and chronic backache were reported by over 50% of participants (two factors that are often linked with long term unemployment). All improvements were maintained at six months, although no further improvements were made.

Dunn et al [53] compared PA counselling (PAC), aimed at increasing PA levels and improving dietary and lifestyle choices, with a supervised structured exercise programme. All participants (n=235) lived within 10 miles of the Cooper Fitness Centre (Texas, USA), and were recruited via posters, newspaper adverts etc. It was reported that PAC and the structured exercise programme were equally effective at improving cardiorespiratory fitness, total cholesterol levels and blood pressure after six months.

Van Roie et al [96] reported that both lifestyle counselling and structured exercise interventions improved cardiovascular risk factors to similar extents in elderly participants over an 11 month period (n=186). Cardiorespiratory and muscular fitness however improved to greater levels with structured exercise. Structured exercise was not only supervised, but the fitness centre was only open to study participants, arguably decreasing its potential for replication outside of a research environment. It was hypothesised that observed improvements would subside in the 12 months following the intervention in participants who completed the exercise programme but be maintained in the lifestyle counselling group, and this was found to be the case at 12 month follow-up [97]. After 23 months however both groups still showed improvements from baseline. These data once again demonstrate the potential of such interventions, but also suggest the difficulties associated with maintaining improvements derived from supervised and structured environments following such interventions.

Brehm et al [98] implemented a 12 month structured exercise intervention with a 12 month follow up in a German sports club (n=157). The structured programme involved one 90 minute class per week incorporating exercise, games, relaxation techniques and general health and fitness information. Adherence was 84% (n=117) over the first 12 months and at the 12 month follow up 80% of these were still active within the sports club. Participants had been offered a continuation of the programme or other similar activities upon completion of the first year and consequently had the opportunity to maintain their activity levels in a familiar environment. Previously exercise referral schemes have been criticised for not providing participants with a clear exit pathway, and consequently activity has ceased and behaviour change is limited [59]. There is a strong chance that the positive effects of the initial 12 months on behaviour, fitness, cardiovascular risk factors and mental health will have been maintained in those still engaged, although this was not examined.

Graffagnino et al [75] reported a study in which a community medical wellness facility within a hospital hosted an intervention aimed at reducing body weight and other cardiovascular risk factors. Participants were asked to pay an enrolment fee of $350 and $130 per month for the duration of the intervention (six months), and had access to exercise physiologists and dieticians for 10 minute sessions each week for counselling and dietary advice. After six months mean body mass was reduced by 7.3% in men and 4.7% in women, whilst significant reductions in fasting blood lipids and glucose levels were observed. Furthermore, significant correlations between percentage weight loss, the number of sessions attended with experts and the number of times the exercise facility was used were evident. Although this investigation was conducted in a community facility it was very expensive, and even with the availability of expert advice, the dropout rate was very high – 53% of the 418 participants – suggesting a lack of sustained behaviour modification.

Tworoger et al [99] reported an intervention aimed at post-menopausal women (n=173) achieving five sessions of moderate intensity exercise (60-75% HRmax) per week for one year. For the first three months participants attended three supervised sessions a week and completed a further two at home. For the final nine months this was reduced to between one and three supervised sessions per week with the remainder of the five completed at home. PA levels increased throughout the intervention with those reporting at least 225 minutes of exercise per week reporting greater improvements in sleep quality (primary outcome) than those completing less than 180 minutes. PA data were collected via daily activity logs. A mean improvement in cardiorespiratory fitness of 12% suggests a large training effect. Therefore there was undoubtedly a positive impact on health, suggesting that initial high supervision and gradual handover may be an effective method for initiating behaviour change.

Nishijima et al [100] approached supervision slightly differently in the Sapporo Fitness Club Trial. Participants (n=561) attended eight individually supervised exercise sessions spread throughout the six month intervention period. Other than these sessions participants were asked to attend the fitness centre two to four times each week on their own. 2.6 sessions per week were averaged by participants. Supervised sessions consisted of bicycle exercise at 40% predicted VO_2 peak combined with resistance training (two set of 20 repetitions). Each exercise session lasted 60-90 minutes. Reductions were demonstrated in all primary outcomes - systolic blood pressure, LDL cholesterol and glycated haemoglobin, although only systolic blood pressure was reduced to a significantly greater extent than controls. Significant between-group differences were observed in changes in body weight, waist circumference, diastolic blood pressure, and triglycerides. Dropout rate was only 11% i.e. 249 of 281 participants completed the exercise intervention, an impressive percentage considering the limited supervision.

A commercial fitness programme (Bally Total Fitness) was compared with unstructured fitness centre use (controls), in a study by Kaats et al [101]. Body composition was the primary outcome variable. Small between-group differences were reported in body mass, however there was a significant difference between fat mass reductions – the fitness programme resulting in a 6.1 pound fat loss compared to 0.9 pounds in the control condition – while fat-free mass increased significantly in those following the fitness programme.

Table 4 Details and main findings of fitness centre based research

Lead Author (year)	Sample Size	Sample Characteristics	Study Type	Delivery Location	Intervention	Outcome Measure	Effect
Jolly (2011) [91]	740	Overweight men & women	RCT	Primary care / community groups inc. Fitness Centre, Birmingham, United Kingdom	Commercially available weight loss programmes, fitness centre access & primary care	Body Weight	Commercial = 2.3kg greater loss than primary care (p=0.004). All groups stat sig* decrease ranging from – Weight Watchers (4.4kg) – general practice (1.4kg). FC use = 2.01kg.
Boyce (2008) [92]	393	Call centre employees	Pre - Post	Call centre – South Eastern USA	Questionnaires repeated after 8 months – no direct intervention	Body Weight, PA levels, fitness centre membership & injuries	Weight gain over 8 months – 5.1kg*.PA associated with non-weight gain. Fitness centre members (6.3kg) increased weight more than non-members (4.3kg)*
Mathieu (2008) [94]	39	Type 2 diabetic / insulin resistant / family history of type 2 diabetes	Pre - Post	Sports Centre – Montreal, Canada	10 week individualised home based programme including 1 supervised PA session per week that included a lecture.	PA levels, aerobic capacity, strength, dynamic balance, anthropometry & CV risk factors	Increase in; PA (effect size – 0.55), strength (0.31), aerobic capacity (0.28), dynamic balance (0.28). Reduction in; body fat (0.58) & resting heart rate (0.48).
Kreuzfeld (2013) [95]	119	Unemployed workers	Pre - Post	Lectures – Training Centre PA – Fitness Centre Rostock, Germany	3 month intervention. Lectures to enhance individual health competence. 2 weekly group exercise sessions combining endurance and resistance training.	Physical fitness, blood pressure, body composition, depression & back pain	Reduction in; blood pressure (systolic p=0.016, diastolic p<0.01), body fat % (p=0.017), depression (p=0.028). Increase VO_2max (p=0.002). Back ache reduced 50%*.
Dunn (1997) [53]	235	Sedentary adults	Quasi - Experimental	Cooper fitness centre, Texas, USA	6 month - Structured gymnasium based exercise programme in comparison with lifestyle physical activity counselling.	Lipid profile, blood pressure, body composition & maximal METs	Mean change – (STRUC) vs (LIFE). Total Cholesterol (mmol/L) - -0.3* vs -0.2*. LDL Cholesterol(mmol/L) - -0.2* vs -0.1*. SBP (mm/Hg) - -1.8* vs -3.2*. DBP (mm/Hg) - -2.2* vs -2.2*. BF% - -1.7* vs 1.4*. max

							METs (kcal/kg/hr) – 1.1* vs 0.4*.
Van Roie (2010) [96]	186	Sedentary older adults	RCT	Specific location not reported – Leuven, Belgium	11 month – Structured gymnasium based exercise in comparison with home based PA programme and control.	Functional performance, cardio respiratory and muscular fitness & CV risk.	Mean change – (STRUC) vs (LIFE). VO_2 (ml/kg/min) – 4.5* vs 3. Time to exhaustion (sec) – 68.7* vs 33.8. Static Strength (Nm) – 17.1* vs 7.1. Dynamic Strength (Nm) – 6.2* vs 1.6. SBP (mmHg) - -4.9 vs -9.3*. DBP (mmHg) – -5.5* vs -6.4*. TOT (mg/dL) - -15.6 vs -4.1. LDL (mg/dL) -2.8 vs -12.
Brehm (2005) [98]	157	Sedentary adults	RCT	Sports club – Erlangen, Bavaria. Germany	12 months – 7 sequence exercise following FITT recommendations in comparison with active and non-active controls. Intervention group divided into High, Low and No risk.	Blood Pressure, Blood Glucose, Cholesterol and BMI.	Intervention: High Risk: Mean Reductions; SBP: -19.83* (mmHg), DBP: -19.50* (mmHg), GLU: -17.25* ($mgdL^{-1}$), Total Cholesterol: -37.88* ($mgdL^{-1}$), LDL: -26.12* ($mgdL^{-1}$), TRI: -114* ($mgdL^{-1}$), BMI: -0.45* (kg/m^2).
Graffagnino (2006) [75]	418	Overweight / obese adults	Pre - Post	Medical wellness facility, Columbus, Ohio. USA	6 months – access to exercise physiologists and dieticians – ability to exercise at home or at centre.	Body weight, cholesterol, blood glucose.	Mean change: Total Cholesterol: -12.1mg/dL*, LDL: -9.6mg/dL*, HDL: -1.7mg/dL*, TRI: -21.7mg/dL*, GLU: -3.6mg/dL*.
Tworoger (2003) [99]	173	Post-menopausal overweight / obese women, not receiving hormone replacement therapy	Quasi - Experimental	Exercise training facility, Seattle, Washington. USA	1 year – moderate intensity (60-75% HRmax). Aim 5 times per week. 1st 3 months – 3 supervised exercise sessions and 2 at home. 2nd 9 months – 1-3 sessions in facility the remainder at home.	Sleep quality / amount, VO_2max & BMI.	225 minutes exercise per week associated with less trouble sleeping when compared with less than 180 minutes. 12% increase in VO_2max*. BMI reduced by 0.3kg/m^2*.
Kaats (1998) [101]	200	Healthy (no underlying chronic conditions). Male & female	RCT	Bally's Total Fitness – Huntington Beach / Long Beach, California, USA	EX: Micro and Macro dietary supplements provided. Exercise 3 times per week: 5 minute warm up, 30	Body composition and lipid profile.	Mean change – EX vs CON. Body weight (lbs) - -1.7 vs 0.1. Body Fat (lbs) – 6.1 vs 0.9. Fat Free Mass (lbs) 4.5 vs 0.8. Percentage decrease – EX vs

					minutes AE & 2 sets of RT – supervised.		CON. TOT – 6.5 vs no change. LDL – 11.1 vs 0.7.
Nishijima (2007) [100]	561	40-89 years. 2 of 3 conditions – Hypertension, Hyperlipidemia, Glucose Intolerance	RCT	Sapporo Fitness Centre, Sapporo, Japan	EX: 6 months – 8 individualised training sessions with an exercise professional. 2-4 fitness centre sessions unsupervised (mean =2.6).	Primary Outcomes – LDL, SBP & HbA1c. Secondary included hsCRP and VO_2peak.	Mean change – EX vs CON. SBP (mmHg) - -8.3 vs 6.17. LDL (mg/dL) - -3.99 vs -1.65. HbA1c (%) - -0.023 vs -0.035. hsCRP (log transformed) - -0.111 vs -0.039. VO_2peak (ml/kg/min) – 2.42 vs 0.35. (no pre/post p value reported).

RCT = Randomised controlled trial, STRUC = Structured exercise intervention, LIFE = Lifestyle intervention, SBP = Systolic blood pressure, DBP = Diastolic blood pressure, MET = Metabolic equivalent of task, Ex = Exercise condition, CON = Control condition, TOT = Total cholesterol, LDL = Low density lipoprotein, HDL = High density lipoprotein, TRI = Triglycerides, BMI = Body mass index. * = P<0.05 - all comparisons pre-post intervention.

2.2.5 Discussion

The articles above provide insights into the effectiveness of community PA interventions. Interventions are generally reported as successful, and several common themes emerge. For example, it is evident that supervised PA is associated with desirable outcomes. However, whilst many of the studies report interventions that begin with supervision, moving to a less supervised and more client-autonomous model, the data of Nishijima et al [100] suggests that spreading the supervision throughout the process may maintain engagement. Additionally the presence of post-programme follow up sessions may increase retention and maintain PA levels. Lifestyle and home based interventions such as those by Van Roie et al [96] and Tworoger et al [99] increased PA over extended periods, reduced cardiovascular risk and increased cardiorespiratory fitness.

There are however issues with the reliability of several of the studies. PA data collected via questionnaire or telephone calls has the potential to be influenced by a number of sources of bias/error, for example, participants' perceptions of what the researchers want to hear. This can often be controlled for, however the lack of control groups in many studies is notable and renders it problematic to attribute effects exclusively to intervention. The unreliable nature of self-report PA was emphasised in the British Heart Foundation 2012 report [24], suggesting that whilst 39% of males reported meeting recommended levels of PA, only 6% actually did so (in females the figures were 29% and 4% respectively). Related to this, the false reporting of other data, for example body weight, is common [93].

Participants who volunteer for PA interventions are often motivated to change, arguably aiding in the success of interventions (noted by Dunn et al [53]). Whilst this could positively impact upon engagement with any intervention, it may limit the degree of generalizability to less motivated cohorts, for example GP referral patients. Likewise, the reliability of questionnaire-based analysis is a function of the sample that respond, a sample often characterised by certain psychosocial traits (for example, people motivated to exercise might also be more motivated to respond to the survey). An example of typical response rates was provided by Boyce et al [92] who distributed over 1100 surveys but were met with a response rate of only 33%.

Body mass is a measurement reported widely in the studies above. It is however a crude measure that may mask clinically significant changes in lean/fat mass associated with, for example, strength training [102]. Body composition analysis might have provided more clinically relevant information. Additionally and related to this, there are example of questionable logic/ad-hoc hypotheses regarding body mass gains, for example Boyce et al [92] suggested that observed weight gain in their study might have resulted from resistance training, despite the fact that the level of muscle gain in question – almost 1kg per month - would be challenging to achieve and require high levels of resistance training.

2.2.6 Conclusions

The studies above highlight several factors, the paucity of published research in this area (in comparison with the 350 articles that are reviewed in the laboratory based literature review below), the lack of clinically relevant data, and a reliance upon self-report that provides little categorical insights into the effectiveness of public health interventions.

Kaats et al noted in 1998 that although almost every fitness / athletic club offers weight loss and fitness programmes, very few provide information relating to their effectiveness, which is arguably still the case today. Such information might exist but remain unpublished as the result of commercial factors or publication bias. However, it is likely that in the majority of cases the tools of measurement and the controls required for rigorous programme evaluation are simply not common place in fitness centres. Worst still, such rigorous evaluation is often not seen as worthwhile. From a public health perspective however this type of information could be crucial. The programmes described above are often the first port of call for many individuals wishing to begin exercising. It is essential therefore that what is being delivered demonstrates tangible and clinically relevant benefits to consumers.

Little research has examined the delivery of public health interventions from community centres. This might hamper the administration of public health and exercise referral interventions aimed at increasing PA and managing / preventing the onset of inactivity related disorders. It is not feasible to expect the same results found within highly controlled laboratory environments in programmes delivered by community centres; in fact data above suggest that attempts to replicate such controlled environments in the community might limit the effectiveness of interventions. It is imperative that there is an improvement in the measurement and evaluation of real world PA initiatives.

2.3 Physical activity counselling

Community based physical activity interventions have struggled to make a clinically significant and sustained impact upon public health [59]. Previous data highlight the need for interventions designed to be delivered flexibly and with the ability to incorporate physical activity and exercise into daily lifestyle activities [103-105]. Additionally it seems there is a requirement for a physical activity promotion intervention designed for those patients not wishing to exercise in a fitness centre environment but who do need to increase their physical activity levels [53, 54, 60].

Behavioural counselling services have been shown to be effective in smoking cessation [106], reducing the alcohol intake of adults whose drinking levels are deemed as risky [107] and weight loss through improved dietary intake [108]. It is important to rigorously test the implementation of counselling interventions in promoting behaviour change however. Data has suggested that in adult populations without a known diagnosis of hypertension, type two diabetes, dyslipidaemia or cardiovascular disease behavioural counselling interventions delivered in primary care to promote a healthy diet or increase physical activity the benefit can be small and the delivery of such an intervention may take away the opportunity to provide other, potentially more effective services. Physical activity counselling (PAC) has been proposed as such an intervention for increasing physical activity [57] although the most effective mode of delivery and setting for counselling has been debated in recent literature. This is presented below.

2.3.1 Research into physical activity counselling

Exercise professionals were integrated into primary care by Fortier et al [109] to provide physical activity counselling to a sedentary cohort. Participants (n=120) were randomised between one of two interventions; an intensive counselling condition that involved a brief counselling session at baseline and six subsequent patient centred physical activity counselling sessions over a three month period, or a control condition that received the initial brief counselling session at baseline but no further interaction with the exercise professionals. Physical activity (via questionnaire and accelerometer) and body composition were measured at six, thirteen and twenty-five weeks. Adherence was reported at 81.7% across the whole investigation and 88.5% in the intensive counselling group, suggesting continual engagement over the 25 week intervention period. Physical activity was reported to be significantly higher at six and thirteen weeks in those receiving the intensive counselling programme than control. This was however measured via questionnaire - physical activity measured directly via accelerometer revealed no differences between the groups. Counselling did however elicit significantly greater reductions in body fat percentage and total fat mass at weeks thirteen and twenty-five. This reveals that if no changes in physical activity were made then wider lifestyle and behavioural changes may have been elicited by the counselling intervention – leading to improvements in body composition. This investigation reveals three significant factors about the implementation of physical activity counselling and its evaluation. Firstly that 88.5% of those randomised into the counselling condition were still part of the process at twenty-five weeks, suggesting that the counselling was meeting participant needs and was engaging to them. Secondly, that there were differences between physical activity measured via questionnaire and accelerometer. Without direct assessment of physical activity it would have been assumed that it had increased significantly more than the control group – which was shown not to be the case in the reported accelerometer data. Future research should objectively measure physical activity levels to ensure no misrepresentation, unless supported by physiological data such as cardiorespiratory fitness that is directly associated with physical activity levels. Thirdly, that although physical activity levels may not have differed significantly between the groups when directly measured (accelerometers may have provided a significant intervention themselves), there may be additional behavioural changes associated with counselling as opposed to measurement alone – as represented by changes in body composition. These data suggest that physical activity counselling may present an effective community intervention to increase physical activity if incorporated into primary care. Although the authors note that a multi-centre, long term intervention and follow up is warranted.

The cost associated with integrating a physical activity counsellor in to a primary health care team was investigated by the same research team [110]. It is reported that the costs associated are much lower than many other physical activity promotion interventions. The research team hope that demonstrating this competitive cost base should encourage additional research the effectiveness and feasibility of such schemes.

McPhail and Schippers [111] present a perspective on physical activity counselling from medical professionals. General practitioners (GP's) are presented as a potentially powerful influence on those who do not meet minimum physical activity levels. It is thought that they have the scope to reach and influence large, relevant (sedentary) proportions of the population. Further to this GP's are a respected source of information, from which people expect to receive advice and are therefore receptive to it. Despite this however GP's and other front line health professionals are not routinely practicing physical activity promotion, especially not delivering specific guidelines or recommendations. The authors cite a lack of time and a lack of self-efficacy in improving physical activity levels for reasons that this is not routinely practiced. Additionally, although GP's are seen as experts in many areas of medicine, exercise and physical activity are not generally perceived as medical disciplines and consequently other professionals may be able to make a more significant contribution to physical activity promotion e.g. exercise professionals [109, 110]. It has been hypothesised that medical professionals should identify suitable community interventions to refer physically inactive patients too. By outsourcing in this way

GP's can reduce time with each patient and be confident that inactive patients are seeing those with the confidence and self-efficacy to increase activity levels.

One such community intervention was trailed in Scotland by Fitzsimons et al [112]. Participants (n=79) were randomised between a walking intervention with minimal intervention and one with assisted with physical activity counselling. Physical activity counselling was administered by a member of the academic research team and involved moving participants through the transtheoretical model of behaviour change using goal setting, barrier identification and enhancing self-efficacy. Data reported reveal that pedometer based walking interventions, that have often shown short term effects, can be maintained over 48 weeks. Physical activity levels increased in both intervention groups without statistically significant differences between the interventions. Physical activity levels increased by 28% in those receiving the counselling intervention and only 16% in the pedometer only intervention, suggesting that although these differences were not statistically significant there were differences in physical activity level increases and also that this investigation may have been under powered. There were further trends suggesting that the counselling intervention reduced time spend sedentary and improved anthropometric measures to a greater degree than the pedometer alone. The replicabilty of this data however could be questioned due to the academic involvement and setting within a University. It is not beyond reason to suggest that people will behave differently when asked to report to an exercise professional or health care provider than to an academic institution. Further the knowledge that your physical activity data will be analysed and assessed even if you are not part of an intervention such as counselling will have had an effect upon participants, this is not a phenomenon that would be repeated if for example pedometers were provided by health care professionals as an independent intervention to sedentary populations.

Bock et al [113] completed a systematic review of community interventions aiming to increase physical activity levels. Data from 55 studies and 20,532 participants reveal that one half of studies have positive impacts upon physical activity outcomes. The authors summarise that community based interventions are generally effective, but divide their analysis into subgroups by mode of delivery. Face to face counselling / group sessions are shown to be more effective than exercise / walking sessions and pedometer based interventions. Furthermore public mass-media campaigns are shown to have very little effect, while telephone, web and multi-component interventions had a good mean positive impact upon changes in physical activity levels but very large confidence intervals. This suggests that the effectiveness varies greatly within groups and what may be very effective for some people will have a negative impact on others. It is concluded that community physical activity promotion interventions are most effective when they involve personal contact for information delivery, and when that information is tailored both in terms of the information presented and delivery mode. Both of these factors, recommended by Bock et al, for optimal increases in physical activity, can be incorporated into physical activity counselling.

2.3.2 Conclusions

Information such as that presented above has resulted in a call to action regarding physical activity counselling to be published in the British Journal of Sports Medicine [57]. Joy et al, suggest that by linking patients to community resources and specifically health and fitness professionals, healthcare professionals may be able to provide a key strategy in the fight against inactivity. Additionally if physicians are presented with the methods and support they need to counsel patients if required. This should begin with connecting the fitness industry with the healthcare industry. Eventually however programmes should be developed to educate physicians and encourage them to be active and consequently increase their self-efficacy in counselling others.

To summarise, the literature presented above demonstrates the potential effectiveness of physical activity counselling as an intervention suited to those needing to increase their physical activity levels. Research has highlighted increases in physical activity levels, increases in adherence to interventions and wider physiological improvements associated with a counselling intervention. It has been concluded that such interventions are most effective when personalised and communication and recommendations are tailored to meet the requirements of the participant. Although physicians and health care professionals would seem to command the most respect and have the greatest access to relevant populations, constraints upon their time - along with expertise and confidence in this area – renders them potentially ineffective in this area (on population level). Outsourcing such a role to health and fitness, and exercise professionals may be a more viable and effective option.

Evidence based interventions are required to provide feasible and clinically relevant community physical activity interventions into which healthcare professionals can refer patients. This can only be achieved if the research that is conducted is designed to make it replicable in community settings and by exercise professionals or alike, and not academics.

Physical activity counselling has the potential to provide a viable alternative to traditional physical activity and exercise interventions in patients disinclined to participate in fitness centre based exercise or requiring behavioural changes [57, 114]. Multi centre, longitudinal and community based research is required to assess the feasibility and effectiveness of physical activity counselling delivered by exercise professionals in improving physical activity levels and supporting physiological measurements.

2.4 Modifiable cardiovascular risk factors

Translational research should aim to harness knowledge from basic sciences to produce new treatments and recommendations [68]. The present research aimed to address this issue and develop the testing of physical activity and exercise interventions delivered in the real world i.e. what in drug discovery and development would constitute the final stages of clinical trials.

The Physical Activity Guidelines Advisory Committee Report [50] highlighted the need to design a programme that will provide appropriate exercise in order to attain maximal benefit at the lowest level of risk. Based upon an extensive review of the current literature exercise recommendations are presented for the prevention, management and treatment of the four modifiable risk factors of cardiovascular disease outlined by the World Health Organisation [5] and the American College of Sports Medicine [32]; dyslipidaemia, impaired fasting glucose, obesity and hypertension. These evidence based recommendations are then incorporated into an exercise programme for implementation in local community fitness centres, in comparison with general (unstructured) fitness centre based exercise.

Although it is unfeasible to suggest such data will translate directly into public health, it is possible to generate evidence based best practices from the existing literature and translate them into an intervention for delivery within community fitness facilities. It is hypothesised that such an intervention, incorporating evidence based exercise recommendations, would generate improvements in cardiovascular and to a greater extent than traditional exercise practices.

2.4.1 Lipid profile

2.4.1.1 *Introduction*

The term 'lipid profile' describes the varying levels of lipids in blood, the most commonly reported being low-density lipoprotein cholesterol (LDL cholesterol), high-density lipoprotein cholesterol (HDL cholesterol) and triglycerides (TG). High levels of LDL cholesterol indicate surplus lipids in the blood that in turn increase the risk of cardiovascular complications. HDL cholesterol transports lipids back to the liver for recycling and disposal; consequently high levels of HDL cholesterol are an indicator of a healthy cardiovascular system [115]. TG in plasma are derived from fats eaten in foods or other energy sources. An excess of TG in plasma is positively and independently associated with cardiovascular disease [116]. Very low-density lipoprotein cholesterol (VLDL cholesterol) – which is generally less frequently reported in the literature - has been shown to positively correlate with TG and be independently associated with cardiovascular risk, even in those individuals expressing normal LDL cholesterol levels [117].

The most commonly used measure of cholesterol is arguably 'total cholesterol' (TC), a measure that includes LDL cholesterol and HDL cholesterol. However, given the different effects of LDL cholesterol and HDL cholesterol on health, TC can be a misleading metric. More sensitive measures report, for example, the ratio of TC:HDL cholesterol, or non-HDL cholesterol (i.e. in the latter all cholesterol variables positively associated with cardiovascular diseases [118]).

There is a direct relationship between chronically elevated cholesterol levels (dyslipidaemia) and coronary heart disease (CHD) [119]. In a meta-analysis of 170,000 participants [34], it was reported that reductions in LDL cholesterol decreased the incidence of heart attacks and ischaemic strokes. It is also reported that individuals with elevated TC levels – above 200mg/dL (5.172mmol/L) – have approximately twice the risk of CHD as those with optimal levels (<180mg/dL/ 4.66mmol/L) [120]. The US Centers for Disease Control and Prevention suggested that this is the case with 71 million US adults, equating to 33.5% of the population [121]. The prevalence of elevated TC is even higher in Europe, where 54% of adults aged 25 and over have TC levels above the recommended levels [122].

For over ten years the link between high cholesterol and ischaemic heart disease has been evident. Data from 2003 [123] attributed one third of all cases of ischaemic heart disease globally to high cholesterol levels. Whilst age-adjusted prevalence of high cholesterol in the United States decreased from 26.6% (1988-1994) to 25.3% (1994-2004), recent data [124] suggest that the use of pharmacological cholesterol-lowering substances increased from 11.7% to 40.8% of the adult population during this period. It has long been recognised that reductions in serum cholesterol can reduce CHD risk, for example, reductions of around 0.6mmol/L can reduce the incidence of ischaemic heart disease by 54% at the age of 40 years reducing to 19% at 80 years [125]. Reduction in TC is therefore still considered the "gold standard" in preventative cardiovascular medicine [126]. This highlights the importance of interventions aimed at reducing serum cholesterol levels. Furthermore, the advantage of early intervention has been demonstrated; long term exposure to 1mmol/L lower LDL cholesterol was associated with a 55% reduction in CHD risk, while treatment with statins starting in later life required a threefold reduction in LDL cholesterol to achieve the same magnitude risk reduction [127].

Pedersen and Saltin [49], citing thirteen meta-analyses, reported improvements in lipid profile following exercise. They described this as Category A evidence that exercise can have a positive effect on the pathogenesis, symptomatology and physical fitness of individuals with dyslipidaemia. In addition, Aadahl et al [35] reported a physical activity (PA) intervention based on lifestyle consultations in 1,693 sedentary men and women aged between 33 – 64 years. Participants taking lipid lowering medication were excluded from the analysis. At three-year follow-up a significant positive association was observed between self-reported 24-hour PA and HDL cholesterol (p=0.0001), whilst a significant negative association was reported between PA and TG levels (p=0.0001). Overall, data suggested a dose-response relationship between increases in PA and improvements in TG and HDL cholesterol in previously sedentary populations. Five year follow-up of a subsequent study (Aadahl et al [128]) reported significant associations between PA and improvements in TC (p=0.006), LDL cholesterol (p=0.007), TG (p=0.02) and HDL cholesterol (p=0.01) among 4039 participants aged between 30 and 60 years, although significant improvements in HDL cholesterol levels were found in men only.

Whilst the mechanisms underlying the effect of exercise on the lipid profile are unclear, exercise appears to enhance the ability of skeletal muscles to utilise lipids as opposed to glycogen, thus reducing plasma lipids [129]. Mechanisms may include increases in lecithin-cholesterol acyltransferase (L-CAT) – the enzyme responsible for ester transfer to the HDL cholesterol [130] that has been shown to increase following exercise training [131], and increases in lipoprotein lipase activity, although data in this instance is inconsistent [132] and may depend upon the total energy expenditure. Ferguson et al [133] reported that 1,100kcal of energy expenditure is required to elicit increases in HDL cholesterol that coincide with significant increases in lipoprotein lipase activity. The process of cholesterol removal is known as ‘reverse cholesterol transport’. This process removes cholesterol from circulation for disposal as a result of increases in L-CAT and reductions in cholesterol ester transfer protein (CETP) (enzyme responsible for the transfer of HDL cholesterol to the other lipoproteins) following acute and chronic exercise [134]. This increased enzymatic activity increases the ability of the muscle fibres to oxidise fatty acids originating from plasma, VLDL cholesterol or TG [135]. This process is conceptualised in Figure.1.

Kesaniemi et al [136] reviewed 51 papers describing PA interventions and reported a mean increase in HDL cholesterol of 4.6%. Effects on LDL cholesterol and TG were reported as inconsistent. The authors concluded that the most likely PA-induced improvement in lipid profile is an increase in HDL cholesterol.

A recent review by the European Society of Cardiology (ESC) [51] briefly summarised the short and long term effects of AE and RT in normolipidaemic subjects and hyperlipidaemic patients. The ESC concluded that it has not been established how much exercise is required in order to improve lipid profile and reduce cardiovascular risk. In fact the authors of a recent meta-analysis [137] highlight the lack of evidence for training programmes that optimally improve cardiovascular risk, drawing particular attention to the effects of AE, RT and COM on cardiovascular risk factors.

This section aims to synthesise the current published evidence regarding the impact of AE, RT and COM on cholesterol levels. Following the review, evidence-based recommendations for best practice are presented.

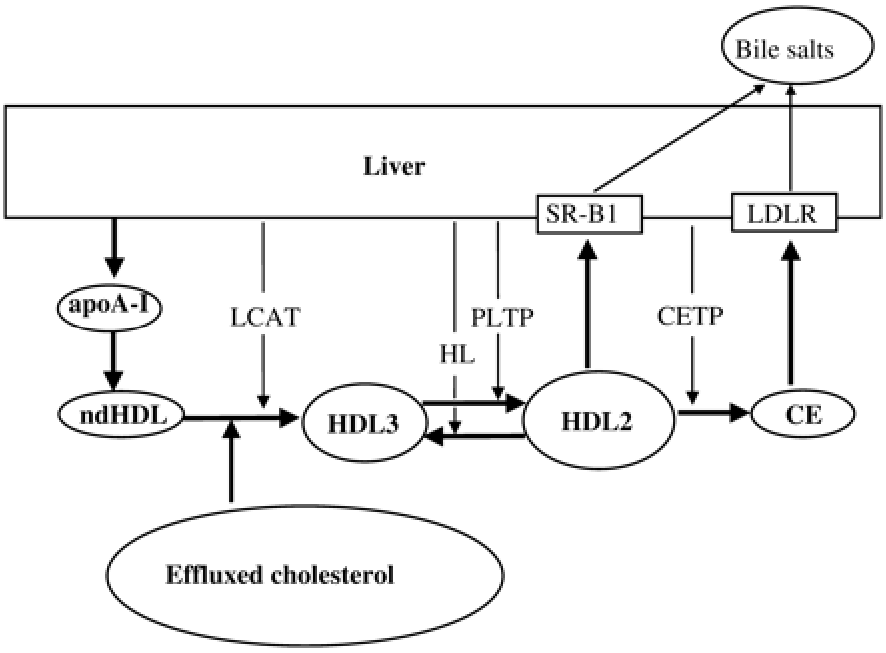

Figure 1 Reverse cholesterol transport pathway

Pathway delivers free cholesterol from macrophages or other cells to the liver or intestine for excretion. Process regulated by enzymes such as lecithin-cholesterol acyltrans (LCAT) and cholesterol ester transfer protein (CETP). HDL = HDL cholesterol, apoA-1 = apolipoprotein A-1, PLPT = phospholipid transfer protein, HL = hepatic lipase, CE = cholesteryl esters, LDL-R = low density lipoprotein receptor, ndHDL = nascent discoidal high density lipoprotein. [138] by permission of Oxford University Press.

2.4.1.2 *Research examining the effects of various types of exercise on the lipid profile*

The characteristics and findings of all included studies are also presented in Table 5.

2.4.1.2.1 Aerobic Exercise

AE involves cardiorespiratory endurance exercises such as jogging, running and cycling [61]. Leon and Sanchez [139] conducted a meta-analysis of 51 interventions involving 12 weeks or more of AE (n=4700). It was reported that on average HDL cholesterol increased by 4.6% while TG levels fell by 3.7% and LDL cholesterol by 5%. TC remained unchanged although the HDL cholesterol: LDL cholesterol ratio improved considerably, suggesting that the increased intensity and structure normally associated with AE has a more consistent impact upon TG and LDL cholesterol than moderate levels of PA. Studies subsequent to or not included in this meta-analysis are reported below.

It was suggested in the introduction that HDL cholesterol is the component of the lipid profile most likely to improve as the result of PA. This is supported by evidence relating to AE presented by Banz et al [140], who reported a 13% increase in HDL cholesterol (29.8 – 33.7mg/dL; $p<0.05$) following a relatively short 10 week protocol - training three times a week at 85% maximal heart rate (HR_{max}) (from the second week onwards) for 40 minutes on ski style exercise equipment. The authors reported that HDL cholesterol was the only component of lipid profile to improve. Nybo et al [141] reported that the TC:HDL cholesterol ratio was the only component of lipid profile significantly improved by 150 minutes of exercise a week at 65% maximal aerobic capacity (VO_2max) in previously untrained participants (3.41 – 2.92; $p<0.05$). This investigation compared a prolonged (150min/wk) AE protocol with an intense interval running protocol (40min/wk) (n=36). No improvements in lipid profile were reported following the intense interval programme. The authors consequently suggested that training volume as opposed to training intensity is the key to improving in lipid profile. Furthermore, these authors suggested that there may be a relationship between body fat – which was only lowered in the prolonged group – and cholesterol levels, whereby a volume sufficient to elicit changes in fat mass is required to favourably alter lipid profile.

When the intensity of AE is increased during continuous effort, the effects upon HDL cholesterol appear to become more consistent. Dunn et al [53] investigated the effects of a six month AE training programme that progressed from 50 – 85% maximum aerobic power for 20 – 60 minutes three times a week and reported a significant decrease in TC (-0.3 mmol/L; $p<0.001$) as well as TC:HDL cholesterol ratio (-0.3; $p<0.001$). In this case the intervention period was relatively long and the intensity relatively high. In a 16 week study, LeMura et al [142] reported significant reductions in plasma TG (1.4 – 1.2mmol/L; $p<0.05$) and increases in HDL cholesterol (1.4 – 1.8mmol/L; $p<0.05$) after training three times a week at 70-75% HR_{max} for 30 minutes for the first eight weeks, progressing to four times at 85% HR_{max} for 45 minutes thereafter. Data suggested that shorter term interventions will be effective also if training volume is high enough. Increasing the frequency of training to four times per week may have elicited the additional benefits seen by LeMura et al in comparison with Banz et al (three training sessions per week). Further LeMura et al observed a 13% reduction in body fat percentage (26.4 – 22.9%; $p<0.05$), suggesting the additional volume of training generated an additional metabolic response, a parameter not reported by Banz et al.

Kraus et al [143] investigated the impact of increasing the volume and intensity of AE upon lipid profile among 111 sedentary overweight participants, all with mild to moderate dyslipidemia. Participants were allocated to either six months in a control group or eight months in one of three AE groups. The three groups were; high intensity/high volume (jogging the calorific equivalent of 20 miles per week at an intensity of 65-80% peak aerobic capacity (VO_2peak), high intensity/low volume (jogging the calorific equivalent of 12 miles per week at an intensity of 65-80% VO_2peak), and moderate intensity/low volume (walking the calorific equivalent of 12 miles per week at an intensity of 40-55% $VO2_{peak}$). It was reported that the high intensity/high volume training combination resulted in the greatest improvements in 10 of 11 lipid variables (LDL cholesterol: 130.1 – 128.2mg/dL; $p<0.05$, HDL cholesterol: 44.3 – 48.6mg/dL; $p<0.05$, TG: 166.9 – 138.5mg/dL; $p<0.05$). These data suggest that in relation to AE both total energy expenditure and intensity are factors in lipid reduction.

O'Donovan et al [144] controlled training volume to directly assess the impact of training intensity. 64 previously sedentary men were randomly allocated to either a control group, a moderate intensity exercise group (60% VO_2max) or a high intensity group (80% VO_2max). Both exercising groups completed three 400kcal sessions per week for 24 weeks. By setting the session volume in calories, the overall training volume was controlled. Participants were instructed to maintain their dietary habits. It was reported that significant lipid profile improvements occurred only in the high intensity group, with TC (6.02 – 5.48mmol/L), LDL cholesterol (4.04 – 3.52mmol/L) and non HDL cholesterol (4.58 – 4.04mmol/L) all decreasing significantly ($p<0.05$).

Evidence suggests that a moderate intensity exercise programme will be effective in increasing HDL cholesterol. This will have a positive impact upon atherosclerosis (hardening of artery walls through plaque and fat accumulation [126]) via HDL cholesterol facilitated removal of LDL cholesterol. To directly reduce LDL cholesterol and TG levels however, the intensity of aerobic exercise must be increased, something that may not be possible in individuals with limited exercise capacity or other risk factors.

2.4.1.2.2 Resistance Training

Theoretically RT (strength developing exercise utilising external resistance or one's own body weight [61]) may be a more accessible form of exercise for less mobile groups as well as providing an alternative to aerobic training for more mobile individuals [145]. Prabhakaran et al [146] investigated the effect of 14 weeks RT in premenopausal women (n=24). RT was at an intensity of 85% of one maximal repetition (85%1RM), where one maximal repetition is the maximal load that can be lifted once for a given exercise [147]. Participants were randomised to either RT or to a non-exercising control. Supervised exercise sessions lasted between 40-50 minutes and were completed three times weekly. Significant ($p<0.05$) decreases in TC (4.6 - 4.26mmol/L) and LDL cholesterol (2.99 - 2.57mmol/L) were observed, along with lowered body fat (27.9% - 26.5%). Acute changes in lipid profile following different intensities of RT were examined by Lira et al [134]. Untrained males (n=30) were randomised to intensity groups at baseline. Measures of cholesterol were collected at time points of one, 24, 48 and 72 hours following RT at intensities of 50%, 75%, 90% and 110% (in the later scenario in the eccentric phase only, performance was assisted during the concentric phase). Total training volume was equalised between the groups to ensure that RT intensity was the factor being assessed. TG clearance was significantly ($p<0.05$) greater following 50% (-14.6mg/dL) and 75% (-10.7mg/dL) 1RM compared with 90% (+9.5mg/dL) and 110% (+12.1mg/dL) at 72 hours. Further, increases in HDL cholesterol were significantly greater following 50% and 75% 1RM compared to 110% ($p=0.004$ and 0.03 respectively). The authors concluded that low to moderate intensity RT results in greater benefit to lipid profile than high intensity RT, although the mechanisms underlying this difference are unclear. It is speculated that the reduction in TC is a result of the exchange of cholesterol ester between tissues and lipoproteins to HDL cholesterol (Figure.1), however the way this differs between 50%, 75%, 90% and 110% 1RM warrants further investigation.

Vatani et al [148] examined the effects of various intensities of RT on lipid profile over six weeks. Healthy male participants (n=30) were randomised to either a moderate intensity RT programme (Mod) (45-55% 1RM) or a high intensity RT programme (High) (80-90% 1RM).

Both groups were supervised during training sessions and attended three sessions per week. Significant ($p<0.05$) reductions in LDL cholesterol (Mod:-13.5mg/dL vs High:-12.1mg/dL), TC (Mod:-12.2mg/dL vs High:-11.3mg/dL), and the ratio of TC to HDL cholesterol (Mod:-0.38 vs High:-0.47) were found in both groups, with no significant differences between the two intervention groups reported. Significant increases in HDL cholesterol however were only observed in the high intensity group (+5.5mg/dL). This is perhaps surprising considering that previous research indicates that increased HDL cholesterol is likely to be the first lipid profile response to exercise, even at low intensities of activity [136]. This study once again demonstrated the limited additional benefit of increasing the intensity of resistance training when equalising the training load by reducing the sets and repetitions completed to compensate for the increased weight being lifted. In addition the authors reported no significant changes in lipoprotein lipase activity following the exercise training intervention – surprising considering the changes in lipid profile elicited. This would however be dependent upon the time taken between the final exercise session and the blood sample collection (normally longer than 24 hours), due to the acute response of lipoprotein lipase (increases have previously been shown to only be maintained for 48 hours following a 1,500kcal exercise session and not 1,300kcal or below [133], levels unlikely to be attained in this exercise intervention). Thus although levels are unchanged at post intervention testing, lipoprotein lipase should not be ruled out as a mechanism.

Fett et al [149] incorporated RT into circuit training sessions in which no specific weight was specified but in which specific time was allocated to each exercise. Sessions lasted 60 minutes and were completed three times a week for one month and four times a week for the second month. Significant reductions were reported in TC (203 – 186mg/dL; $p<0.01$) and TG (122 – 91mg/dL; $p<0.05$), further adding to the speculation that the volume of movement involved may be as/more important as the amount of weight lifted.

2.4.1.2.3 Combined Training

The evidence presented above demonstrates the effectiveness of both AE and RT in controlling and improving cholesterol levels through various modes, frequencies, intensities and durations of exercise, in different populations. There is limited literature that has examined the two modalities combined, although a recent review by Tambalis et al [150] suggests that although some combination protocols have been effective in lowering LDL cholesterol and increasing HDL cholesterol, others have not.

Shaw et al [135] examined the effect of a 16 week moderate intensity COM protocol in previously untrained but otherwise healthy young men (n=28). The protocol lasted 45 minutes and combined AE at 60% HR_{max} with RT (two sets of 15 repetitions) at 60% 1RM. It was reported that LDL cholesterol significantly reduced following the COM training (4.39 – 3.23mmol/L; $p<0.05$), although the improvements were not significantly different to those achieved by 45 minutes AE alone (3.64 – 2.87mmol/L; $p<0.05$). It can therefore be concluded that no additional LDL cholesterol reduction resulted from combining the modes of exercise. However, this investigation did demonstrate that RT might successfully compensate for reductions in AE. Further, the authors suggested that additional physiological systems benefited from RT making it potentially more effective.

Yang et al [151] reported a study investigating relationships between exercise, cholesterol and arterial stiffness in obese middle aged women (n=40, body mass index (BMI)>25kg/m^2, age 30-60 years). The experimental protocol consisted of 45 minutes AE at an intensity of 60-75% HR_{max} at 300kcal per session and 20 minutes RT at 100kcal per session five times a week over a 12 week period. Reductions were observed in TC (5.2 – 4.2mmol/L; p=0.655), LDL cholesterol (3.2 – 2.6mmol/L; p=0.172), TG (3.0 – 2.5mmol/L; $p<0.001$), and in arterial stiffness measured via brachial-ankle pulse wave velocity (1286 – 1195cm/s; $p<0.001$). While no controls were included in this study, these data suggested the potential clinical significance of reductions in cholesterol, that is, the reduction in arterial stiffness all too often associated with heart attacks and strokes.

Ha and So [152] combined 30 minutes AE at 60 – 80% maximal heart rate reserve (maximal heart rate – heart rate at rest) ($HR_{reserve}$), with 30 minutes RT between 12-15 repetition maximum in 16 participants aged between 20 and 26 years for 12 weeks. The intervention significantly reduced waist circumference, body fat percentage and blood pressure when compared to non-exercising controls. Lipid profile improved in the exercising condition (TC: 180.29 – 161mg/dL, LDL cholesterol: 112.14 – 103.57mg/dL, TG: 97.14 – 50.43mg/dL), although changes did not reach statistical significance when compared with controls. The authors suggested that the age of the study cohort was too young to find the clinical and significant effects shown by previous research in predominantly elderly or middle aged participants.

Table 5 Main characteristics and findings of studies examining the effects of various types of exercise on the lipid profile

Author (year)	n	Design	Intervention	Measure	Effect		p-value
Banz (2003) [140]	26	Quasi-experimental	AE 10 weeks 3 sessions per week 85% HR_{max} 40 minutes	TC	↑	4.1mg/dL	Not reported
				HDL cholesterol	↑	3.9 mg/dL	p<0.05*
				LDL cholesterol	↑	3.4 mg/dL	Not reported
Nybo (2010) [141]	36	RCT	AE (prolonged) 12 weeks 150 min/week 65% VO_2max	TC	↓	0.3mmol/L	Not reported
				HDL cholesterol	↑	0.1mmol/L	Not reported
				LDL cholesterol	↓	0.1mmol/L	Not reported
				TC:HDL	↓	0.49	p<0.005*
			AE (intense interval) 12 weeks 40min/week HR>95% during sprints	TC	↓	0.1mmol/L	Not reported
				HDL cholesterol	/	0mmol/L	Not reported
				LDL cholesterol	↓	0.1mmol/L	Not reported
				TC:HDL	↓	0.08	Not reported
Dunn (1997) [53]	235	Quasi-experimental	AE 24 weeks 3 sessions per week 50-85% max aerobic power 20-60minutes	TC	↓	0.3mmol/L	p<0.001*
				HDL cholesterol	/	0mmol/L	p=0.54
				LDL cholesterol	↓	0.2mmol/L	p<0.001*
				TC:HDL	↓	0.3mmol/L	p<0.001*
LeMura (2000) [142]	48	RCT	AE 16 weeks 3 sessions per week 70-75% HR_{max} (weeks 1-8) 85% HR_{max}	TC	↓	0.3mmol/L	Not reported
				HDL cholesterol	↑	0.4mmol/L	p<0.005*

			(weeks 8-16) 30 minutes (weeks 1-8) 45 minutes (weeks 8-16)	LDL cholesterol	↓	0.2mmol/L	Not reported
				TG	↓	0.2mmol/L	$p<0.005$*
				TC:HDL	↓	1	Not reported
Kraus (2002) [143]	111	RCT	AE 24 weeks 65-80% VO_2peak Jogging Calorific equivalent of 20 miles per week	TC	↑	0.4mg/dL	Not reported
				LDL cholesterol	↓	1.9mg/dL	$p<0.005$*
				HDL cholesterol	↑	4.3mg/dL	$p<0.005$*
				TG	↓	28.4mg/dL	$p<0.005$*
O'Donovan (2005) [144]	64	RCT	AE (MOD) 24 weeks 3 sessions per week 60% VO_2max 400kcal per session	TC	↑	0.3mmol/L	Not reported
				LDL cholesterol	↑	0.17mmol/L	Not reported
				HDL cholesterol	↑	0.08mmol/L	Not reported
				nonHDL cholesterol	↑	0.23mmol/L	Not reported
				TG	↑	0.12mmol/L	Not reported
			AE (HIGH) 24 weeks 3 sessions per week 80% VO_2max 400kcal per session	TC	↓	0.54mmol/L	$p<0.005$*
				LDL cholesterol	↓	0.52mmol/L	$p<0.005$*
				HDL cholesterol	↓	0.01mmol/L	Not reported
				nonHDL cholesterol	↓	0.54mmol/L	$p<0.005$*
				TG	↓	0.05mmol/L	Not reported
Prabhakaran (1999) [146]	24	RCT	RT 14 weeks 3 sessions per week 85% 1RM	TC	↓	0.42mmol/L	$p<0.005$*
				LDL cholesterol	↓	0.42mmol/L	$p<0.005$*
				HDL cholesterol	↑	0.07mmol/L	Not reported
				TG	↓	0.16mmol/L	Not reported
				LDL cholesterol :HDL cholesterol	↓	0.42mmol/L	$p=0.057$
				TC:HDL cholesterol	↓	0.54mmol/L	$p<0.005$*

Vatani (2011) [148]	30	RCT	RT (MOD) 6 weeks 3 sessions per week 45-55% 1RM	HDL cholesterol	↑	2.3mg/dL	Not reported
				LDL cholesterol	↓	13.5mg/dL	p<0.005*
				TG	↓	11.4mg/dL	Not reported
				TC	↓	12.4mg/dL	p<0.005*
				TC:HDL cholesterol	↓	0.38mg/dL	p<0.005*
			RT (HIGH) 6 weeks 3 sessions per week 80-90% 1RM	HDL cholesterol	↑	5.5mg/dL	p<0.005*
				LDL cholesterol	↓	12.1mg/dL	p<0.005*
				TG	↑	0.1mg/dL	Not reported
				TC	↓	11.3mg/dL	p<0.005*
				TC:HDL cholesterol	↓	0.47mg/dL	p<0.005*
Fett (2009) [149]	50	Quasi-experimental	RT Circuit training 8 weeks 3 sessions per week (1-4) 4 sessions per week (4-8) 60 minutes	TC	↓	17mg/dL	p<0.01*
				LDL cholesterol	↓	11mg/dL	Not reported
				HDL cholesterol	↓	6mg/dL	Not reported
				TC:HDL cholesterol	↓	0.2mg/dL	Not reported
				TG	↓	31mg/dL	p<0.05*
Shaw (2009) [135]	28	RCT	COM 16 weeks 3 sessions per week AE – 60% HR_{max} RT – 60% 1RM 45 minutes	LDL cholesterol	↓	2.16mmol/L	p<0.05*
Yang (2011) [151]	40	Pre-post	COM 12 weeks 5 sessions per week AE – 300kcal RT – 100kcal	TC	↓	1mmol/L	p=0.655
				LDL cholesterol	↓	0.6mmol/L	p=0.172
				TG	↓	0.5mmol/L	p<0.01*
Ha (2012) [152]	16	RCT	COM 12 weeks	TG	↓	46.71mg/dL	p<0.05*

			3 sessions per week AE – 60-80% HRreserve RT – 12-15 rep maximum AE – 30 minutes RT – 30 minutes	HDL cholesterol	↓	3.71mg/dL	Not reported
				TC	↓	19.29mg/dL	p<0.05*
				LDL cholesterol	↓	8.57mg/dL	p<0.05*

RCT = randomised controlled trial, TC = total cholesterol, LDL cholesterol = low density lipoprotein cholesterol, HDL cholesterol = high density lipoprotein cholesterol, TG = triglycerides, TOT:HDL cholesterol = total cholesterol to high density lipoprotein cholesterol ratio, VLDL cholesterol = very low density lipoprotein cholesterol, PA = physical activity, AE = aerobic exercise, RT = resistance training, COM = combined aerobic and resistance training, Mod = moderate intensity training programme, High = high intensity training programme, HR = heart rate, HR_{max} = maximal heart rate, $HR_{reserve}$ = heart rate reserve, rep = repetition, RM = repetition maximum, VO_2max = maximal aerobic capacity, max = maximum, ↑ = increase, ↓ = decrease, / = no change. *Represents significant (p<0.05) interaction or pre – post change in change in cholesterol level. All comparisons are to baseline.

2.4.1.3 *Exercise recommendations for the improvement of the lipid profile*

Based upon the data above relating to the effect of exercise on cholesterol levels, exercise recommendations have been formulated (Table 6). Interventions that have demonstrated particular effectiveness, that is higher intensity AE [144] and moderate intensity RT [134] have been incorporated. Previous evidence has highlighted a dose response relationship between activity levels and increases in HDL cholesterol [35], therefore the exercise recommendations are to be considered a minimum. These evidence-based recommendations should aid in the prescription and delivery of interventions designed to reduce cholesterol levels.

Table 6 Exercise recommendations for the improvement of the lipid profile

Patient group	Exercise recommendations
Healthy	Increase PA to more than 30 minutes a day 5 times a week [35, 128]. Prolonged moderate intensity AE – 70-80% $HR_{reserve}$ [150] combined with low intensity RT – 50% 1RM [134].
Elevated cholesterol (dyslipidemia)	Increase PA to more than 30 minutes a day 5 times a week [35, 128]. Prolonged moderate intensity AE – 70-80% $HR_{reserve}$ [150] progressing to 85% HR_{max} [53, 142] combined with moderate – high intensity RT – 75-85% 1RM [134, 146]
Elevated cholesterol (dyslipidemia) and limited mobility (disabled, elderly populations etc.)	Increase PA as much as is feasible [35, 128]. RT progressing from 50% - 75% in major muscle groups [134] – can be incorporated into circuit sessions and maintained at a moderate intensity [149].

2.4.1.4 *Conclusions*

Data above provide some support for the proposal that PA and exercise can be utilised to improve cholesterol levels. Regular PA has been shown to increase HDL cholesterol while maintaining, and theoretically offsetting increases in, LDL cholesterol and TG. There appears to be a linear dose-response relationship between activity level and HDL cholesterol concentration. More intense activity however is required to elicit reductions in LDL cholesterol and TG. AE at high intensities appears to be effective at improving lipid profile, the effects surpassing those of PA by initiating the clearance of plasma LDL cholesterol and TG. The dose-response relationship between lipid profile and energy expenditure seems to transcend the mode of exercise. Increases in calorific expenditure associated with AE (via increased intensity and/or duration) were shown to positively influence lipoprotein lipase activity, HDL cholesterol levels

[133], and lipid profile [143]. During RT it has been shown consistently that the increased volume of movement via increased sets and/or repetitions, has a greater impact upon lipid profile than increased intensity (e.g. via high weight low repetition training) [134, 149].

Prolonged moderate intensity AE should be recommended as a starting point for those previously sedentary or new to exercise. RT presents a viable alternative to AE or an effective intervention independently. High intensities (>85% 1RM) were shown to be no more effective than moderate intensities (50-85% 1RM). The addition of RT to AE will supplement – and possibly enhance - the effects on lipid profile, although there is limited literature comparing the three modes of exercise, rendering definitive statements problematic. There will however be no reduction in effect, and the additional physiological and psychological systems impacted may elicit additional benefits when combining AE and RT.

Data reviewed confirm the benefits of regular PA on cholesterol levels. Such knowledge should aid in the prevention and management of dyslipidemia while reducing the risk of heart attacks, strokes and coronary artery disease. Having considered the baseline condition of their patients, clinicians should encourage as much PA as possible whilst, where feasible highlighting the additional impact or appropriateness of AE and/or RT and COM to obtain the optimal benefits in their patients.

2.4.2 Insulin sensitivity

2.4.2.1 *Introduction*

Diabetes is responsible for over one million amputees worldwide each year, is a major cause of blindness, and is the largest cause of kidney failure in the developed world [153]. The prevalence of Type 2 Diabetes (T2D) is alarming. In 2010, 285 million people worldwide were classified as suffering with the disease, a figure that is expected to rise to 438 million by 2030 [154]. Latest available figures indicate that 8.3% of the US population [155] and 5.1% of the UK population have the disease [156]. In 2010, the estimated cost of treatment in the UK was £3.5 billion per year [157], with US costs estimated at $174 Billion in 2007 [155].

T2D is characterised by elevated glucose levels in circulating blood, caused by impairment in glucose tolerance following the development of insulin resistance and relative insulin deficiency. Insulin resistance / reduced insulin sensitivity impair the ability of the muscle cells to take up and store glucose and triglycerides. This results in higher levels of glucose and triglycerides circulating in the blood. In a healthy individual, insulin is secreted in response to these rising levels. However, if this does not occur, or has little effect, blood glucose levels increase, leading to T2D as recognised by the American Diabetes Association [41]. This level of impaired glucose control is regarded as a major risk factor of cardiovascular disease [32].

The gold standard measure of insulin sensitivity is ascertained via a hyperinsulinemic euglycemic clamp – this is however highly invasive and time consuming [158]. As a consequence other, validated, methods of data collection are often used to predict or indirectly measure insulin sensitivity, these include – glycated haemoglobin (HbA_{1c}) levels in both normoglycaemic [159] and hyperglycaemic patients [160], the Oral Glucose Tolerance Test [161], homeostatic model assessment (HOMA) [162] and finally, a calculation using glycaemic and insulin levels upon fasting [158].

A positive energy balance, indicating more energy being ingested than expended, results from low levels of physical activity (PA) and a high calorific diet, resulting in raised levels of glucose and triglycerides in the blood. The muscular contractions associated with PA have the ability to increase glucose uptake via increased glucose transporter type four (GLUT 4) production and increased insulin signalling within skeletal muscle – thus increasing insulin sensitivity [163]. Using PA to maintain or increase insulin sensitivity in individuals at risk of T2D may help to reduce its incidence and lower the economic burden T2D places upon societies.

A sedentary lifestyle has been associated with increased levels of HbA_{1c} [164]. HbA_{1c} indicates average plasma glucose concentration over time, with higher levels indicating poor blood glucose control and decreases in insulin sensitivity that are associated with T2D [165] ($\geq$ 6.5% is accepted as a criterion for diagnosis of T2D [164]). It has been reported that lifestyle modifications inclusive of a PA programme are at least as effective in treating T2D as any single pharmacological agent [36], and increased levels of PA are associated with significantly delaying the onset of T2D. Further, changes in insulin sensitivity occur independently of changes in body weight [166]. This suggests that PA might function to decrease hepatic and muscle insulin resistance and increase glucose disposal through a number of mechanisms not necessarily associated with body weight. Such mechanisms might include increased post-receptor insulin signalling and increased glucose transporter proteins [166]. Although it has previously been shown that there is a positive relationship between T2D and obesity [167], these results suggest that the association is the result of the sedentary behaviour associated with both conditions, as opposed to one being a direct cause of the other. These findings could influence the way in which T2D is managed and prevented; that is, hypothetically basing recommendation on the promotion of weight loss alone in the absence of PA might be unproductive.

Chomistek et al [168] found that males who completed greater levels of vigorous PA (>6METS) - as detailed in the Health Professionals Follow-Up Study (n=18,225) - exhibited lower levels of HbA_{1c}. Furthermore, those reporting that they completed more than three hours of vigorous PA per week had a 22% lower risk of myocardial infarction, for which lower HbA_{1c} is a potential mediator. Larsson et al [169] found an inverse association ($P<0.05$) between self-report leisure time PA and insulin resistance (n=1745 – Swedish participants aged 30-74 years) while Dwyer et al [170] reported that by increasing daily step count over a five year period insulin sensitivity, measured via Homeostatic Model Assessment (HOMA) could be increased (n=592 – mean age 51.4 (males) 50.3 years (females)). The authors attribute this improvement to reductions in body mass index and waist-to-hip ratio. Further, and perhaps most significantly there was a linear relationship between daily step count and improvements in insulin sensitivity. Those sedentary individuals able to alter their behaviour to meet 10,000 steps-per-day increased insulin sensitivity three-fold compared to a similar person who increased to only 3000 steps [170]. These data suggest a dose response relationship between PA and insulin sensitivity.

The evidence above suggests that PA can maintain (i.e. prevent decreases in) insulin sensitivity. There may be a dose-response relationship between the volume [170] and energy expenditure [168] of PA and improvements in insulin sensitivity. This would suggest that an increase in volume and intensity of PA might elicit greater improvements in insulin sensitivity. This would essentially entail an increase in PA meeting the minimum number of METs/week.

In relation to T2D and PA, recent reports by the American College of Sports Medicine (ACSM) [41] and the Physical Activity Guidelines Advisory Committee [50] highlight the need to design a programme that will provide appropriate exercise in order to attain maximal benefit at the lowest level of risk. However, despite a large number of related publications - PubMed searches post-1965 (01/10/2012) for ‘insulin sensitivity exercise’ and ‘insulin sensitivity PA’ located 5329 and 4895 articles respectively (it is noted that many articles will appear in both searches) - the optimal modes, intensities and frequencies of exercise in this context are unknown.

This section synthesises the current published evidence regarding the effectiveness of AE, RT and COM on improving insulin sensitivity. From this synthesis, evidence-based recommendations for exercise in the improvement of insulin sensitivity are presented.

Research examining the effects of various types of exercise on insulin sensitivity

2.4.2.1.1 Aerobic Exercise

Lehman et al [171] reported that there was absolutely no alteration in HbA_{1c} following a 13 week intervention incorporating 90 minute sessions of AE three times a week at an intensity averaging 50-70% VO_2max in participants with well established (7.8 years) T2D. The exercise intervention did however protect against HbA_{1c} increases reported in the control group suggesting that although significant improvements could not be made the management of blood glucose did improve. Similar participants (T2D average 7.1 years) were recruited by Ronnemaa et al [172] who reported significant reductions in HbA_{1c} following AE at an intensity of 70% VO_2max for 45 minutes six times per week for eight weeks – indicating that an increased frequency of exercise training will reduce HbA_{1c} even in those with long standing T2D. Mourier et al [173] also elicited a significant decrease in HbA_{1c} in T2D participants following an intervention lasting 10 weeks. The intensity of AE was set at 75% VO_2peak and participants completed three 55 minute sessions a week. Raz et al [174] replicated these findings i.e. a significant reduction in HbA_{1c} in participants without T2D with an intervention also incorporating 55 minute AE sessions three times each week, although at a lower intensity of 65% VO_2max – the intervention did last two weeks longer however.

Kohno et al [175] reported that within hospitalised hypertensive patients significant reductions in plasma insulin were observed following exercise involving only a 3 minute warm up, a 6-minute cycle at 75% VO_2max and a 3-minute cool down, performed four times daily for 3 weeks. This improvement has added significance as decreases in insulin sensitivity lead to a greater retention of magnesium and as a consequence increases in blood pressure [175], although could only be feasibly replicated in highly controlled environments such as hospitals due to the high frequency of exercise training.

Magkos et al [176] demonstrated that in excess of one hour of moderate intensity exercise at 60% VO_2max was required to improve whole body basal insulin sensitivity. The same authors identified a curvilinear relationship between energy expenditure and insulin sensitivity in single bouts of exercise in recreationally active, non–obese men, whereby those expending the most energy saw the greatest benefits, providing further indications that insulin sensitivity is related to energy expenditure.

Van Dijk et al [177] investigated whether there was any benefit in exercising daily when compared to every other day if energy expenditure was controlled. No significant between-group differences were observed in reductions in fasting blood glucose (both were significantly improved by the intervention). Participants were asked to cycle for either 60 minutes every other day at 50% maximal exertion or 30 minutes every day, thus the energy expenditure was controlled between the two groups. This suggests that although energy expenditure is critical, everyday exercise may not elicit additional benefits over exercise every two days, whilst allowing time for recovery and presenting a far more palatable public health message.

High intensity exercise has been presented as an effective and time efficient way of improving insulin sensitivity [178]. Babraj et al [178] implemented a protocol that consisted of 4-6 30sec cycle sprints three times a week. This was shown to increase insulin sensitivity by 23% in young participants (mean age = 21±2) of normal weight (mean BMI = 23.7±3.1 kg/m^2) in just two weeks. It must be noted however noted that this type of exercise may not be appropriate for some populations who may be at risk from such high levels of exertion.

This is a factor considered by Hood et al [179] who designed a protocol for older, sedentary and overweight participants (mean age = 45±5, mean BMI = 27±5 kg/m^2) that consisted of 6 sessions of 10 x 1 minute cycles at 60% peak power separated by 1 minute rest intervals. GLUT 4 protein content increased by 260% whilst insulin sensitivity improved by 35% after two weeks of training (3 sessions per week). A combination of low intensity cycling and 2 all-out sprints increasing from 10sec to 20sec improved insulin sensitivity by 28% after 6 weeks of training [180]. Metcalfe et al reported that the average rate of perceived exertion score for each session was 13 and that adherence was 97%, an important consideration when designing public health interventions.

These studies suggest that customising interval training for differing individuals/populations may present a practical and time efficient strategy for improving glycemic control. When all out exercise in not feasible i.e. in the elderly or new to exercise, the intensity can be lowered to 60% maximal and duration increased to 1 minute and still be effective [179].

Yfanti et al [181] investigated whether antioxidant supplementation in healthy physically active men (n=21) could enhance the effects of aerobic endurance training upon insulin sensitivity. It was found that following 12 weeks of training 5 times a week, insulin-stimulated glucose uptake increased by 17.2% in the supplementation group. The placebo group improved by 18.9%. Whilst these data suggest no beneficial effects of antioxidant supplementation upon insulin sensitivity, clear effects of exercise were evident. In all participants these improvements were augmented by significant increases in GLUT 4, Hexokinase II and Protein Kinase B (Akt) which play key roles in glucose metabolism. Vind et al [182] propose similar mechanisms for the improvements in insulin-mediated glucose disposal observed following an aerobic training programme consisting of 10 weeks training on a stationary cycle 4-5 times a week at approximately 65% VO_2max. Subjects were obese, the experimental group with T2D (n=26) and normoglycemic controls. Significant improvements were observed in both groups (~20%), but the glucose disposal rates of the diabetic patients remained 38% lower than their non-diabetic counterparts. This suggests that although insulin sensitivity was increased, 10 weeks is not long enough to improve glucose disposal to non-T2D levels.

Not all aerobic training programmes are associated with improvements in insulin sensitivity. Mujumdar et al [183] implemented a 6 month programme that involved progressive marathon running training (6 miles per week increasing over time to 55) that did not significantly alter HOMA insulin resistance scores in middle-aged untrained participants. Given the findings above and elsewhere this is surprising, and might suggest either a chance outcome or even hint at publication bias in the area (i.e. there may be other unpublished data also suggesting a nul effect. This is of course speculative). Either way, the findings in question warrant replication.

Bacchi et al [184] compared supervised AE (3 times a week over 4 months at 60-65% HRreserve) to RT (3 times a week over 4 months 70-80% 1RM – 9 exercises covering all major muscle groups), both significantly reduced HbA_{1c}. Effects did not differ between groups but were predicted by baseline HbA_{1c} levels, subsequent increases in cardiorespiratory fitness (CRF) and reductions in truncial fat. These findings are at odds with those of Totsikas et al [185] who reported that improvements in insulin sensitivity were more likely in those with the highest CRF at baseline - and therefore likely poorer glycemic control - following a lifestyle intervention. The authors provide little detail of the mechanisms that support this finding other than that the intervention was only part supervised and that the participants with the greatest CRF were more compliant to exercise recommendations.

Jorge et al [186] found AE to be less effective than RT or COM in a comparative study. Although T2D patients who completed 60 minutes of cycling at an intensity relative to lactate threshold 3 times a week for 12 weeks were able to significantly lower fasting plasma glucose.

Based upon the evidence presented in this section, it can be concluded that AE is effective in improving insulin sensitivity at a variety of intensities and to differing degrees. Significant improvements can be elicited by interval training (high intensity exercise separated by rest intervals) [178, 179] as well as continuous effort [176]. As one study suggests however there may be other training interventions that are as effective or even more effective at improving insulin sensitivity which could include RT and COM.

2.4.2.1.2 Resistance Training

Honkola et al [187] implemented RT within a circuit training session twice a week for 22 weeks – each session lasting 45 minutes and incorporating 2 sets of 12-15 repetitions. It was reported that there were no alterations in HbA_{1c} levels. Similarly to Lehman et al [171] participants had well established T2D (average 8 years). Once again there was an increase in HbA_{1c} found in the control group however – suggesting that glycemic control was improved if not overall HbA_{1c} levels.

Dunstan et al [188] investigated the effect of circuit weight training at 55% 1RM in 27 adults (mean age 51 years) 3 times a week for 8 weeks. The training programme elicited significant strength improvements in all exercises (demonstrating training effect) along with improvements in glucose and insulin levels following a 12 hour fast when compared to controls [188]. Dunstan et al [189] followed this work with an investigation incorporating a higher intensity RT - 75-80% 1RM - in older participants with T2D (n=36 aged between 60-80 years) for an increased duration of 26 weeks. Both RT and the control group incorporated a weight loss programme. HbA_{1c} was reduced to a significantly greater extent following RT at both 13 and 26 weeks. There was no difference between body weight and fat mass reduction between groups. RT increased lean mass however, while it was reduced following the weight loss programme alone. This data further strengthens the argument that weight loss interventions to reduce the risk of T2D are flawed unless attempts are made to maintain muscle mass via RT. 80% 1RM was also the training intensity employed by Castaneda et al [190] in elderly T2D subjects (n=62 mean age 66 years) 3 times a week over a shorter intervention period of 16 weeks. HbA_{1c} was again significantly reduced with muscular glycogen stores increased, suggesting greater insulin action; no such changes were evident in the control group.

Cauza et al [191] compared the effects of a four month hypertrophic strength training programme with endurance training at 60% VO_2max upon measures of insulin sensitivity. Participants had T2D and trained on three non-consecutive days of the week. The RT group reduced HbA_{1c} by 8.3% and significantly reduced blood glucose levels and insulin resistance. No such improvements were found in the AE training group.

Maximal RT (5 sets 3-4 repetitions at 60-85% 1RM) was compared with Endurance RT (3 sets 12-15 repetitions at 45-65% 1RM) by Hansen et al [192].The intervention lasted 4 months and all subjects had impaired glucose tolerance at baseline. It was observed that both interventions decreased insulin resistance but by differing mechanisms. Maximal RT increased muscular glucose uptake capacity, whilst Endurance RT increased the insulin sensitivity of the muscles. Kwon et al [193] investigated the effectiveness of low intensity resistance training (40-50% 1RM) and was unsuccessful at improving insulin sensitivity tested via the insulin tolerance test in overweight participants with T2D. The training was conducted over a 12 week period, with exercise 3 times per week suggesting that the intensity was the determinant factor and that intensities of over 50% are required to generate a significant response unless supplemented with increases in sets and repetitions [192].

Brooks et al [145] investigated the effects of 16 weeks RT - 60-80% 1RM (weeks 1-8) and 70-80% 1RM (weeks 10-14) compared with conventional care in 62 T2D community dwelling individuals over the age of 55 years. Insulin sensitivity (measured via HOMA and HbA_{1c}) and muscle quality i.e. the strength per unit of muscle mass, were both significantly improved compared with controls.

Possible mechanisms by which insulin action increases with exercise have been attributed to increased expression of GLUT4 and other signalling proteins [194]. Holten et al [194] investigated the mechanisms behind improvements in insulin sensitivity in subjects with T2D by employing a RT intervention (weeks 1+2 50% 1RM, weeks 3-6 70-80% 1RM – 3 sessions per week) in one leg only. Muscle biopsies taken post-intervention showed increases in GLUT4 and various insulin signalling protein activity levels in the trained leg only. This suggests that the improvements in insulin action were a result of local physiological adaptation. That adaptations occurred locally has implications for the use of RT as a method of increasing insulin sensitivity; it implies that large muscle groups should be trained to stimulate the greatest improvements, and furthermore that improvements will be greater if more muscles are activated.

Further mechanisms and inhibitors to resistance training upon insulin sensitivity were found when Layne et al [195] compared RT subjects with and without the Metabolic Syndrome (MetS). Eight weeks RT elicited improvements in both strength and stamina in all subjects. Insulin sensitivity however was only improved significantly in those without MetS. Layne et al attribute these differences to changes in GLUT 4 levels which increased 67% in non-MetS sufferers compared with 36% in the MetS group. Further; muscle 5 adenosine monophosphate-activated protein kinase (AMPK) rose 43% in non-MetS and only 8% in MetS. Conversely muscle mammalian target of rapamycin (mTOR) was higher in the MetS suffers than non-MetS, suggesting that the higher activation of mTOR inhibited the training-related increases in AMPK in those suffering from MetS which would have increased GLUT 4 and Hexokinase II levels and in turn increased glucose uptake by the muscles [195].

The evidence presented above suggests that resistance training is effective in improving insulin sensitivity when the intensity is above 50% 1RM and that adaptations are made locally in the trained muscles.

2.4.2.1.3 Combined Training

By combining AE and RT it may be possible to obtain greater increases in insulin sensitivity than with either AE or RT alone. This was the case when AE, RT and COM and their impact upon muscle insulin signalling in T2D patients was investigated [186]. Jorge et al [186] investigated the effect of a 7 exercise RT circuit incorporating large muscle groups completed 3 times a week over 12 weeks, finding it to improve Insulin Resistance Index (IRI) scores by 65%. The addition of AE to the RT circuit elicited significantly greater improvements however – a 90% improvement in IRI scores.

Tessier et al [196] combined AE at 60-79% HRmax and RT (two sets of 20 repetitions) into sessions lasting 60 minutes, three times a week for 16 weeks. Significant improvements were reported in the Oral Glucose Tolerance Test (OGTT). Balducci et al [197] investigated 30 minutes of AE at 40-80% heart rate reserve and 30 minutes of RT 40-60% 1RM (reassessed every three weeks) when completed 3 times a week by sedentary individuals. After 1 year significant reductions in fasting blood glucose were observed, decreasing by 36mg/dl. This suggests that in previously sedentary individuals combining AE and RT, even at low intensities, can have positive outcomes, although the intervention period was particularly long.

A COM intervention lasting only four months was employed by Tokmakidis et al [198] with female T2D post-menopausal subjects. The frequency and intensity of exercise employed was higher than that of the previously cited study – two AE sessions per week beginning at 60-70% heart rate max and increasing to 70-80% after two months and two RT sessions a week at 60% 1RM (3 sets of 12 repetitions). HbA_{1c} levels decreased by 12.5%, whilst glucose tolerance improved by 38%.

Schrauwen et al [199] investigated an even shorter 12 week intervention with obese but non T2D subjects (mean BMI = 29.9±0.01kg/m^2). The intervention combined 30 min AE at 55% VO_2max and RT at 75% 1RM (2 sets x 8 repetitions, following 8 repetitions at 55% warm up) and was completed three times a week. Fasting blood glucose concentrations were lowered from 6.3±0.2 to 5.7±0.2mmol/L and HbA_{1c} levels significantly improved. These findings suggest that positive effects can be observed following relatively short intervention periods (≥ 12 weeks) when incorporating both aerobic and resistance training in the same exercise session.

The three modes of exercise training assessed in this chapter were compared by Sigal et al [200] in a randomised controlled trial involving participants ranging in age from 39-70 years old. In this investigation the COM group completed the full AE and RT programmes (AE. 15-20 min 60% HR max progressing to 45 min 75% HR max 3 times a week RT. 2/3 sets at max weight lifted 7-9 times 3 times a week) and consequently the training volume was far greater than in the other groups. This was reflected in the results which showed that although all three training modes were effective in lowering HbA_{1c}, the COM approach was the most effective, supporting the previously established dose response relationship between PA volume and insulin sensitivity improvements [201].

In a more recent study Larose et al [202] correlated HbA_{1c} with increases in cardiorespiratory fitness. The COM training programme elicited an increase in VO_2peak and ventilatory threshold, and consequently significantly decreased HbA_{1c} levels. AE and RT also elicited positive effects on glucose control independently, although these effects were smaller than the COM training programme. However, as with the previous study, it is not possible to compare the respective effects of each programme independently since the COM group employed the full AE and RT programmes which would have increased the overall volume performed. On the basis of the dose-response relationship between exercise volume and insulin sensitivity it can come as little surprise that the effects were greater in conditions in which the overall volume of exercise was greater [170].

The Italian Diabetes and Exercise Study (IDES) [203] demonstrated the effectiveness of a combined protocol compared with PA alone in 606 sedentary subjects with T2D and MetS. Subjects were randomised into one of two groups, a control group who received counselling only or an exercise group who completed aerobic and resistance training in a structured environment twice weekly for 12 months. HbA_{1c} levels were observed to be lower in the exercise group along with several other markers of cardiovascular health. Although the counselling-only group increased their PA to the recommended dosage of 5 times 30 minutes PA a week, there was no significant impact upon HbA_{1c} or cardiovascular health profile. This suggests that greater levels of PA are required to improve the health status of individuals with MetS than is currently recommended [204] and that a supervised, structured combined exercise programme will be effective if administered properly.

The evidence above suggests the potentially substantial effect that combining aerobic and resistance training might have upon insulin sensitivity in both healthy and T2D individuals. These data do not indicate however whether it is the volume of exercise or the modality that affects insulin sensitivity and glycaemic control. Further to this, there is an inconsistency between the way exercise sessions are structured, i.e. some studies incorporate AE and RT into the same session [197, 199, 203], whilst others place the different modalities in different exercise sessions [198, 200, 202]. A similar problem is evident in relation to the order in which the different exercises are completed when combined. Further large scale studies, controlling the volume of AE, RT and COM exercise programmes are required, along with investigations into the differing effect of AE and RT in different orders and structured together or separately before definitive statements can be made.

2.4.2.2 *Exercise recommendations for the improvement of insulin sensitivity*

Based upon the exercise detailed in the research above and the effect of this exercise on insulin sensitivity, exercise recommendations have been formulated (Table 7). Interventions that have demonstrated particular effectiveness i.e. high intensity AE [178] and COM [203] have been incorporated, whilst where particular intensities have been compared the most effective have been recommended [205]. The evidence presented for PA suggests a dose-response relationship between volume of activity and improvements in insulin sensitivity, therefore the established minimum amounts (30 minutes of PA five times weekly) recommended by the ACSM [204] are proposed as a minimum. These evidence based PA / exercise recommendations should aid in the prescription and delivery of exercise as a measure to prevent and manage to T2D.

Table 7 Exercise recommendations for the improvement of insulin sensitivity

Patient Group	Exercise recommendations
Healthy (Insulin Sensitivity Maintenance)	Increase PA to more than 30 minutes per day 5 times a week [41, 201]. Include high intensity aerobic exercise (>75%VO_2) [178] three times a week combined with strength training in all major muscle groups [194] at 70% 1RM [191] twice a week separated by more than 24 hours [177].
With Type 2 Diabetes (Insulin Sensitivity Improvement)	Increase PA to more than 30 minutes per day 5 times a week [41, 201]. Include long duration (>1hour) moderate intensity (60% VO_2max) [176] aerobic training three times a week combined with low intensity & high repetition resistance training (50-60% 1RM) [193] in all major muscle groups [194] twice a week separated by more than 24 hours [177].
Those with Type 2 Diabetes and Limited Mobility (Disabled, Elderly Populations etc.)	Increase PA as much as is feasible [201]. Include low intensity aerobic exercise (40-80% HR reserve) / PA [197] combined with resistance training at low intensity 50-55% 1RM [193, 205] in all major muscle groups [194] three times a week separated by more than 24 hours [177].

2.4.2.3 *Conclusions*

This section supports the proposal that PA is beneficial in improving metabolic control in general and in improving insulin sensitivity specifically.

Regular leisure time PA can maintain insulin sensitivity and improve glycemic control in those with T2D. There may be a dose response-relationship between the intensity and duration of PA and improvements in insulin sensitivity, in which case the progression to higher levels of systematic PA (i.e. exercise) may elicit greater benefits.

AE appears effective in improving insulin sensitivity even though there is not presently evidence to suggest that those benefits transcend those of lifestyle PA unless high intensities are implemented. Interval training has been shown to be particularly effective at both moderate and high intensities, prescribed according to the participant’s ability to meet demands of the exercise.

Evidence suggests that RT is effective, most likely due to an increase in muscle GLUT4 and in various insulin signalling protein activity levels in the trained muscles. RT seems to be effective at intensities above 50% of 1 RM, a fact that is reflected in the recommendations for exercise training in subjects with T2D presented in this section.

It appears that combining AE and RT is the most efficient training strategy in improving insulin sensitivity.

2.4.3 Body composition

2.4.3.1 *Introduction*

High levels of body fat are positively associated with metabolic conditions including type 2 diabetes and cardiovascular diseases [206]. Obesity – classified as having a body mass index (BMI) of over 30kg/m^2 [207] is increasing in prevalence throughout the developed and developing world. Latest World Health Organisation data suggest that worldwide obesity levels have nearly doubled since 1980 [208].

Obesity can be an indicator of a poor lifestyle and two of the core risk factors of non-communicable disease – poor diet and a physically inactive lifestyle (it is noted that there are various genetic, disability and ethnic factors that may cause obesity).

Physical exertion increases the energy requirements of the body. Providing this is not replaced by further calories the body will be in a negative energy balance and body fat will be lost [49]. The greater the physical exertion the more energy will be required and the greater the negative energy balance will become.

Significant reductions in blood pressure have been shown with reductions in obesity levels [209-211], along with reductions in LDL cholesterol and triglyceride concentrations [209, 212, 213]. This evidence suggests that making steps towards a healthy body composition might have beneficial effects upon cardiovascular health. A Cochrane Library Review [214] assessing the impact of 43 randomised controlled trials using 3476 subjects concluded that exercise is an effective method for promoting weight loss.

2.4.3.2 *Research examining the effects of various types of exercise on body composition*

2.4.3.2.1 Physical Activity

The volume of physical activity required to elicit reductions in body fat is a matter of some debate in the literature. Schoeller et al [215] concluded that 80 minutes per day of moderate PA or 35 minutes per day of vigorous PA added to a sedentary lifestyle was suitable reach weight loss targets (23±9kg) in middle aged women (n=32 mean age 38±7years, mean BMI 24±3kg/m^2). Similarly Jakic & Otto [216] conclude in a review of existing literature that 200-300 minutes per week may be required to elicit significant health and body composition improvements. Blair et al [217] suggest that RT and flexibility training will help prevent weight re-gain following PA induced weight loss.

The most recent American College of Sports Medicine position stand regarding weight loss [218] proposed a Category A evidence statement that physical activity comprising of 150 to 250 minutes per week, equating to an energy expenditure of between 1200 and 2000kcal per week will prevent weight gain. To elicit weight loss of five to seven kilogrammes more than 225 to 420 minutes of physical activity will be required.

Ross & Jansen [219] conducted a meta-analysis of 33 studies investigating exercise induced weight loss on total and/or abdominal fat. It was revealed that energy expended per week is positively related to reductions in total adiposity in a dose-response manner. Additionally physical activity with an energy expenditure of over 2200kcal/week is required to elicit significant reductions in adipose tissue – equating to approximately 45-60 minutes of moderate intensity PA upon most days of the week.

Aadahl et al [35] demonstrated a significant inverse relationship between 24 hour physical activity levels and waist to hip ratio (p=0.002) in a cross section analysis of a population based intervention study (n=1693 mean age 50.8 years – range 33 - 64). Aadahl et al [128] followed this cross sectional analysis with a full report including measurements from 4039 participants over a five year period. It was reported that changes in physical activity were significantly associated with changes in body weight and waist circumference in both men and women.

It was concluded in the Physical Activity Guidelines Advisory Committee Report in 2009 [50] that ample evidence exists for a positive dose-response relationship between the volume of activity and the total and regional fat loss as a result. Such evidence suggests that a progression from general lifestyle based physical activity to a structured form of exercise of increased intensity and duration will elicit greater effects on body composition.

2.4.3.2.2 Aerobic Exercise

Wu et al [220] completed a meta-analysis of 18 randomised controlled trails comparing dietary interventions and dietary interventions coupled with aerobic exercise and their impact upon body weight and body mass index. It was reported that mean decreases in body weight were 1.14kg greater when exercise was incorporated into the intervention. There is also a strong chance that additional physiological adaptations will have occurred as a result of the exercise training.

McTiernan et al [221] reported a 12 month randomised controlled trial (n=202) in which the exercising group were asked to complete 60 minutes exercise on six days of the week divided between supervised and home based programmes. Exercising participants averaged a mean of 370 minutes per week (men) and 295 minutes per week (women) - significantly improving their body composition in comparison with controls. Fat mass was reduced 1.9kg (women – control = +0.2kg) and 3kg (men – 0.2kg).

Similar improvements were reported by Sykes et al [222] who compared two 8 week programmes; one of which involved 5 exercise sessions a week expending 400kcal (2000 per week) and the other only 2 sessions expending 1000kcal (also 2000 per week), no significant differences were found between the groups with both significantly reducing body weight, BMI, body fat and waist circumference. These results suggest the calorific requirement of an exercise may be more important than the frequency of sessions when creating a weight loss.

Van Pelt et al [223] report that that women involved in regular aerobic exercise will stave off age-associated increases in body weight. Inverse correlations were noted between fat mass and exercise volume and VO_2max. Friedenreich et al [224] demonstrate a 2kg body fat loss in post-menopausal woman of normal to obese baseline weight in comparison with a control group following a yearlong intervention study during which they were encouraged to perform 45minutes of moderate – vigorous aerobic exercise five times a week, Three of these sessions were supervised and on average participants trained 3.6 days of the week. A linear trend was observed between the amount of aerobic exercise completed and the body fat lost. Data support the dose response relationship between activity and improvements in body composition, although it does suggest exercising five times a week may be unachievable, especially when only three sessions are supervised.

Additional literature provides examples of the widely varying styles of aerobic exercise will decrease WHR and body fat percentage (obesity). These include long duration low intensity jogging [149], high intensity short duration running [225] and step aerobics [226]. Thus it seems the way in which energy is expended is unimportant in comparison with the energy demands of the activity.

The evidence presented above highlights the large variety of AE interventions able to impact upon obesity levels and improve body composition, those most effective have been incorporated into the exercise recommendations made in Table 8.

2.4.3.2.3 Resistance Training

Skeletal muscle is the primary metabolic target organ for glucose and triglyceride disposal and is an important factor in the regulation of resting metabolic rate [227], key factors in the accumulation of excess body fat that leads to obesity.

Substantial evidence suggests that resistance training can effectively alter body composition in men and women [228]. A review published by the American Heart Association [229] states that there is good evidence that resistance training reduces total fat mass in men and women, independent of caloric restriction, as well as that resistance training is an effective way of reducing visceral adipose tissue in older men and women.

However, an ACSM Position Stand [37] provides a category A evidence statement that ‘resistance training will not promote clinically significant weight loss’ due to its low energy expenditure and fat usage in relation to aerobic exercise, along with its tendency to increase lean body mass. It is recognised however that this increase in muscle mass will subsequently increase resting metabolic rate and aid in the prevention of weight regain. A review into the effectiveness of resistance training in obesity by Strasser & Schobersberger [227] identified seven investigations in which significant decreases in fat mass were associated with similar increases in lean body mass resulting in no change in body weight, although they also suggest that resistance training is an effective alternative to improve body composition and maintain reductions in fat mass.

Banz et al [140] compared a resistance training group to an aerobic group, finding that after ten weeks of training significant decreases in waist hip ration were found in both groups with no significant differences between the two. However the resistance group demonstrated a significant difference in body fat and a significant increase in fat free mass, that was not apparent in the aerobic group.

A further study involving overweight adolescents [230] found that a 12 week resistance training program significantly improved strength and lead to significant decreases in body fat percentage. As an aside it was also reported that attractive body adequacy and global self-worth were significantly improved from pre-test to post-test, indicating that there may be additional benefits found when resistance training.

2.4.3.2.4 Combined Training

Evidence presented above suggests that both aerobic and resistance training are effective in reducing body fat and improving body composition. Wong et al [231] investigated the impact of incorporating sessions with an ACSM exercise specialist into physical education lessons. A control group continued with their usual physical education lessons whist the intervention group completed two additional 45-60 minute COM circuit training sessions. Significant reductions in BMI and body fat percentage, and increases in lean mass were found in the intervention group in comparison with the control group. This study highlights the effects of a well-designed combination programme, and its potential benefits to obesity in adolescents.

Stensvold et al [102] compared aerobic interval training to resistance and a combination of the two, finding that all three protocols were equally effective in reducing waist circumference. Seo et al [232] however reported that in middle aged women combining a walking programme with resistance training was more effective than combining walking with further aerobic training, leading to significant reductions in body fat and waist circumferences. These two studies provide slightly conflicting evidence, although it could be hypothesised that the addition of resistance training to an aerobic programme might be effective with low intensity aerobic but perhaps less so when the intensity increases. It will however likely always aid in the preservation of muscle mass and consequent maintenance of resting metabolic rate. This concept could be put to best use in those populations where intense aerobic exercise is not possible such as the elderly or less mobile.

A long term (12 month) and high volume (45 minutes moderate AE and two sets of moderate intensity RT five days a week) was investigated by Irwin et al [233]. It was reported that body weight, body fat, intra-abdominal fat and subcutaneous abdominal fat all significantly decreased following the intervention in previously overweight, post-menopausal women (n=173). A shorter 21 week intervention in which participants were randomised between aerobic, resistance, combination training and a control group, Sillanpaa et al [234] concluded that both aerobic endurance training and resistance training and their combination are effective in modifying body composition by increasing lean mass. Changes in lipid metabolism are more related to aerobic training than to resistance training. This same study group subsequently reported that in older men (40-65) a combination training intervention is more effective than either mode alone in optimising body composition and physical fitness [235].

2.4.3.3 *Exercise recommendations for the improvement of body composition*

Based upon the exercise detailed in the research above and the effect of this exercise on body composition, exercise recommendations have been formulated (Table 8).

Table 8 Exercise recommendations for the improvement of body composition

Patient group	Exercise recommendations
Healthy body fat levels	PA of 150-250 minutes per week to avoid weight gain [37], including; high levels of aerobic exercise at varying intensities i.e. high intensity interval / low intensity jogging [223] combined with strength training [227].
Obese	PA of more than 300 minutes per week [37, 128], including high duration low intensity aerobic exercise increasing in intensity with training 3 times a week, plus low weight high rep resistance training at 60% 1RM [234] twice a week separated by more than 24 hours [227].
Less Mobile	Increase PA to more than 30 minutes 3-5 times a week [37, 128] combined with resistance training in large muscle groups with low weight and high repetitions 50-60% 1RM 3 times a week [234, 235].

2.4.3.4 *Conclusion*

The evidence presented above demonstrates the effectiveness of increasing physical activity levels in improving body composition and reducing obesity levels. Evidence suggests a dose response relationship between changes in physical activity and improvements in body composition. Resistance training has a role in increasing calorific expenditure as well as increasing the resting metabolic rate of individuals. A combination of aerobic exercise and resistance training will increase the energy expenditure elicited during an intervention and promote increases in lean mass and thus resting metabolic rate. This will not only increase the chances of body composition changes but also their maintenance.

2.4.4 Blood pressure

2.4.4.1 *Introduction*

Hypertension is a highly prevalent and dangerous condition, effecting large proportions of society. Subjects with a blood pressure of 140/90mmHg or higher for over a period of a week may be classified as hypertensive, the case in 1 Billion people worldwide, 74.5 Million in the US and 16 Million in the UK [236]. The ACSM Position Stand entitled ‘Exercise and Hypertension’

[33] provides conclusive evidence for the benefits of exercise in the treatment of hypertension and its ability to lower blood pressure in normotensive persons.

The mechanisms, related to exercise, credited with eliciting such positive effects upon blood pressure are numerous but include neurohumoral, vascular and structural adaptations [49]. A reduction in systolic blood pressure of as little as 3mmHg will reduce the risk of coronary heart disease by 5-9%, strokes by 8-14% and all-cause mortality by 4% [227], thus there is great significance to the slightest improvements in blood pressure that can be made.

The relationship between physical activity and blood pressure is examined in an evidence-based symposium [136] comprising of 51 studies, involving 4700 subjects. It is concluded that there is 'Category A' evidence to indicate that physical exertion at around 50% maximal exertion will induce significant reductions in blood pressure. It is unclear however whether there are additional benefits to more intense activity. The Inter99 study [128] investigated the benefits of increasing physical activity over a five year period in 4039 Danish men and women. A significant inverse relationship is reported between self-report physical activity levels and diastolic blood pressure Similarly, the Physical Activity Guidelines Report [50] provides evidence for the positive effects of progressive training programmes upon blood pressure. The recommended intensity of activity is however higher than general physical activity. The report concludes that training programmes including 40 minutes of moderate to high-intensity exercise training 3-5 times a week, that involves more than 800 MET minutes of aerobic exercise per week appear to have reproducible effects on blood pressure reduction [50].

2.4.4.2 *Research examining the effects of various types of exercise on blood pressure*

2.4.4.2.1 Aerobic Exercise

A meta-analysis [237] of 44 randomised controlled trials investigated the impact of dynamic or endurance exercise interventions on blood pressure levels in otherwise healthy hypertensive and normotensive participants. All of the interventions included in the analysis lasted four weeks or longer and training intensities varied between 43-87% VO_2max.The frequencies of training varied also varied between the interventions. No dose response relationship was reported between the amount and intensity of exercise and its' impact upon blood pressure levels. The exercise intervention did however significantly improve mean resting blood pressure levels. Blood pressure decreased 3/2mmHg in normotensive, and 7/6mmHg in hypertensive participants. This analysis supports the beneficial impact of AE on blood pressure but provides no information regarding optimal intensities and frequencies of training. It was however concluded that training at 40-50% VO_2max was no less effective than training at 70% in reducing resting blood pressure. These findings are supported by Kelley et al [238], who report 4% and 5% decreases in systolic and diastolic pressures respectively in hypertensive participants, and 2% and 1% in those with normal blood pressure levels. Data was collected from 47 clinical trials (n=2543). A previous meta-analysis by Halbert et al [239] that included 29 studies (n=1533) concluded that exercise interventions had a small but clinically significant effect upon resting blood pressure, and that training at intensities above 70% maximal effort had no additional impact.

The meta-analysis' above suggest that moderate intensity aerobic exercise will reduce blood pressure. This is supported by Cornelissen et al [240] who reported aerobic exercise at 33% of heart rate reserve was just as effective as 66%. Such low intensities of exercise may have an effect in reducing the blood pressure of hypertensive patients; it should be considered however that hypertensive patients may also be at increased risk from other cardiovascular risk factors. Therefore exercise interventions may have to include higher intensity AE to impact upon wider cardiovascular risk factors e.g. lipid profile.

Individual studies have used differing intensities, frequencies and durations of AE in creating exercise interventions. These have elicited different blood pressure responses. These include low intensity jogging for 60 minutes three times a week [149], and AE at 50-85% maximal aerobic power for 20-60min three times a week [53]. Both studies significantly decreased both systolic and diastolic blood pressure.

Mean arterial pressure was significantly decreased by high intensity interval training in normotensive overweight adolescents (4x4min 90% maximal heart rate separated by three minutes at 70% maximal heart rate twice a week for three months) [225], whilst significant reductions in both systolic blood pressure and mean arterial pressure were found in hospitalised hypertensive patients following a three minute warm up, six minutes cycling at 75%VO_2max followed by a 3minute cool down when completed 4 times daily for 3weeks [175].

The evidence presented above suggests that aerobic exercise is effective in reducing blood pressure in both normotensive and hypertensive participants. The optimal training conditions however remain elusive. There is no common consensus regarding the optimal intensity, frequency and type of AE in reducing blood pressure. It does seem that there is no direct benefit to blood pressure when training at high intensities, although high intensity interval training did elicit a positive response. In order to widen the impact of an exercise intervention to other cardiovascular risk factors however it may be necessary to increase the training intensity.

2.4.4.2.2 Resistance Training

The ACSM position stand on hypertension concludes that 'Resistance training performed according to ACSM guidelines reduces blood pressure in normotensive and hypertensive adults' [33].

A meta-analysis [241] of 11 studies (n=320) found 2-4% decreases in blood pressure using progressive resistance training interventions at differing intensities and durations. It was concluded that progressive RT was effective in reducing blood pressure, although no comment was made regarding the most effective training intensities. A more recent meta-analysis [242] supports these findings. Data from 12 studies (n=341) reports mean reductions of 3.5/3.5mmHg following a RT intervention. In this instance it is concluded that moderate intensity RT could become part of a non-pharmacological intervention to prevent and control high blood pressure.

The evidence is currently limited regarding the effects of resistance training upon blood pressure. The limited evidence suggests effectiveness at moderate intensities although further research is warranted. RT may provide an option for those clinical groups who find AE difficult to complete, a factor considered in the evidence based exercise recommendations made in Table 9.

2.4.4.2.3 Combined Training

Combining AE and RT it may be possible to elicit greater improvements in blood pressure than either component alone. The literature examining this is limited, although the three studies presented below suggest it may be effective.

Twelve weeks of step aerobics lasting 40 minutes was compared with 25 minutes of step aerobics and 15 minutes of RT by Kraemer et al [243]. It was reported that diastolic blood pressure improved by 5.8mmHg following AE alone and 6.7mmHg when combined with RT. Both reductions are clinically and statistically significant however it can be noted that the COM intervention was the most effective.

As has previously been mentioned the ability to supplement AE with RT may be particularly helpful in elderly and less mobile populations for whom long duration AE may be difficult. Stewart et al [244] investigated the impact of a COM intervention comprising of 50% 1RM RT and 45 minutes AE (60-90% HRmax) (three training sessions per week for six months). Blood pressure decreased 5.3/3.7mmHg (mean) in participants (n=104) all aged between 55 and 75 years. Walking programmes are often suggested as an effective means for the elderly to stay active and maintain health. Seo et al [245] investigated their impact alone, and combined with RT. Walking and aerobics were completed at 60-80% HRreserve three times a week for 12 weeks, compared with walking and RT (50-70% 1RM). Only the intervention incorporating RT significantly reduced blood pressure. Data suggest the addition of RT may increase the effectiveness of AE interventions.

2.4.4.3 *Exercise recommendations for the improvement of blood pressure*

Based upon the evidence reviewed above, exercise recommendations have been made for different demographics in Table 9.

Table 9 Exercise recommendations for the improvement of blood pressure

Patient group	Exercise recommendations
Normotensive	Increase PA to more than 30 minutes 5 times a week [22], including; Moderate Aerobic Exercise (50-70% VO_2max) 3 times a week [240] [237] Combined with Resistance Training at 70-80% 1RM [242] twice weekly, separated by more than 24 hours [147].
Hypertensive	Increase PA to more than 30 minutes 5 times a week [22], including; Aerobic Exercise (50-70% HR reserve) 3 times a week Combined with Resistance training at 60-70% 1RM twice weekly [240] [237], separated by more than 24 hours [147].
Limited Mobility	Increased PA as much as possible [22] including Resistance Training [246] Involving Large Muscle Groups at 50-60% 1RM [147].

2.4.4.4 *Conclusions*

The evidence presented above demonstrates the effectiveness of increasing physical activity levels in reducing blood pressure in both normotensive and hypertensive individuals. Conversely with other cardiovascular risk factors there does not seem to be a relationship between the dose of exercise and the improvements made. Moderate intensity activity was shown to be as effective as higher intensities, although to positively impact wider physiological and cardiovascular systems more intense exercise may be required.

2.4.5 Summary of findings

The evidence presented above supports the notion that exercise can be used to prevent and manage the four modifiable risk factors of cardiovascular disease as outlined by the World Health Organisation [5] and American College of Sports Medicine [32]. There is conclusive and substantial laboratory based evidence that cholesterol, insulin resistance, blood pressure and body fat levels will be reduced following an exercise intervention. Exercise of varying intensity, duration and frequency have all been shown to be effective for different components of cardiovascular risk, although data suggest a dose-response relationship between the volume of exercise and improvements made. Additionally by combining AE and RT the widest range of physiological systems are affected and greatest effects elicited.

It could therefore be argued, that the hypothesis that exercise is medicine is both internally and externally valid. There is a consistent causal correlation between exercise behaviours and improvements in cardiovascular health. Additionally, the results of the studies above could be generalised to other situations and cohorts i.e. if the same programme was implemented and wider behaviours repeated, similar findings would be expected. What is not known however is the ecological validity of the exercise is medicine hypothesis. It is not known whether the evidence based exercise recommendations generated above, from an extensive literary base, will translate when delivered in the real world. In the real world members of the public do not attend a laboratory to exercise, nor are they monitored by researchers. In the real world members of the public attend community fitness centres and are monitored by exercise professionals. The following chapters will investigate this translation.

3. Pilot study

3.2 Introduction

Physical inactivity has been described as the ‘biggest public health problem of the 21st century’ [26]. To be physically inactive is to complete less than 30 minutes of moderate intensity physical activity 5 times a week [204]. Data suggest that physical inactivity is associated with all-cause mortality [26], non-insulin dependent diabetes mellitus [165] and cardiovascular disease [247].

As a consequence of widely reported low levels of physical activity, researchers have sought to identify barriers to physical activity. Key amongst those reported are; lack of social support, lack of knowledge, lack of access to facilities, a dislike of vigorous exercise and the perception that the only other option to physically inactivity is structured gymnasium exercise – an intimidating prospect / environment for many [53]. Clearly many of these barriers are psychological/behavioural in nature, and potentially amenable to counselling interventions such as physical activity counselling (PAC).

PAC is the process of encouraging individuals or groups to partake in more physical activity. The PAC practitioner aims to identify why the individual is inactive and to provide both the means and motivation for that person to become more active. A recent meta-analysis of 13 studies investigating PAC [114] suggested that PAC delivered by primary health care services using interview and telephone conversation elicited a small to medium positive effect on physical activity levels after 12 months. The same study identified that it took on average 12 counselling sessions for an individual initially classified as inactive to achieve recommended physical activity levels. The 5 A’s counselling method (Ask, Advise, Assess, Assist and Agree) has been proposed as an effective method of physical activity counselling [248] but is yet to be trialled when delivered by exercise professionals within fitness centres. There are 5852 fitness centres in the UK and 90% of the population live within 2 miles of one of them [249]. On the basis of the above data, such centres could provide a platform for community PAC interventions aimed at increasing physical activity in the community.

It is reasonable to suggest however that PAC does not fit within the prevalent service model in UK fitness centres; that is the provision of facilities, equipment and products that enable members to exercise freely in terms of mode, frequency and intensity (this shall be termed ‘unstructured’, although it is recognised that many people exercising freely do so in a structured manner). In this model, fitness staff generally provide support, knowledge and a structured exercise programme only if specifically requested by the individual member (what will be termed ‘structured exercise’), or on a generic and unsupervised basis via media such as workout cards, posters etc.

There is little evidence relating to the relative effectiveness of structured and unstructured exercise undertaken in community fitness centres. Furthermore, whilst PAC has been successfully delivered by exercise professionals in a primary care setting its delivery from within a fitness centre is yet to be investigated, and it has yet to be compared directly with a competing physical activity intervention. In fact the lack of community based research in this area may be directly impacting upon the replicabilty of research findings derived in clinical or academic environments [75]. Subsequently there is a need for translational research, delivered in a setting generalisable to that of real world delivery, to investigate the effectiveness of such interventions [73, 74, 76].

The present study aimed to assess the effectiveness of three competing interventions, unstructured exercise, structured exercise, and PAC, on modifiable cardiovascular risk factors in a previously physically inactive cohort. Comparisons were made between groups to identify the intervention most effective in increasing activity and reducing cardiovascular risk within.

The following hypotheses were made:

1. The structured exercise programme, incorporating evidence based exercise recommendations (Chapter 2), would be associated with greater increases in the volume and intensity of physical activity and exercise completed than either unstructured exercise or PAC.
2. Cardiovascular risk will be reduced to a greater extent in participants completing the structured exercise programme than either unstructured exercise or PAC.
3. There will be significant reductions in cardiovascular risk in all participants.

3.3 Methods

3.3.1 Subjects

Untrained male (n=32 mean age=42.95±5.67 years) and female (n=73 mean age=42.95±4.1 years) participants were recruited after responding to either a local newspaper article or to letters sent to eligible fitness centre members (Impulse Leisure, Essex, United Kingdom). Participants were recruited on a ‘first come first served’ basis to avoid the biasing of data collected i.e. only selecting those volunteers most at need, or within whom it could be predicted the greatest benefits may be elicited. Participants had to meet the following selection criteria; aged between 35 and 45 years, free from chronic disease, untrained (i.e. had not attended a fitness centre for more than 30 days and not currently part of a structured exercise programme), and knowing of no reason limiting their ability to participate in physical activity and / or exercise. Participants received a detailed explanation of the study and provided written informed consent. The study was approved by the University of Greenwich Research Ethics Committee. Participants were recruited for either 12 weeks PAC (n=18) or 12 weeks fitness centre based exercise (n=87). Those recruited for fitness centre based exercise were randomised into unstructured (FREE) (n=44) or structured (STRUC) (n=43) exercise. Participants were recruited separately i.e. for either fitness centre based exercise or PAC - where all activity would be completed outside of the fitness centre, to replicate the choice that would be faced by anybody entering a PA promotion scheme in the real world. The recruitment target for the PAC condition was 20 participants and based upon what was deemed achievable in a working fitness centre. Given the current investigation is a pragmatic pilot study no power analysis was completed, instead available resource dictated sample size. This was determined based upon the number of clients an exercise professional could be expected to manage, following conversations with fitness centre staff and management. Baseline assessments were carried out immediately pre and post the 12 week intervention period and comprised the following:

Anthropometric Measurements / Body Composition

Body mass (BM) and height were measured and body mass index (BMI) calculated. Body composition was measured using air displacement plethysmography (Bod Pod, Life Measurements, Concord, CA) providing results for fat mass (FM), fat free mass (FFM) and body fat percentage (BF%) [250, 251]

Blood Pressure and Resting Heart Rate

Systolic (SBP), and diastolic blood pressure (DBP), and resting heart rate (RHR) were measured using a commercially available blood pressure monitor (Omron Healthcare, Japan) following a 15 minute period of inactivity.

Cholesterol

Total cholesterol (TC), low density lipoprotein (LDL), high density lipoprotein (HDL), triglycerides (TG) and TC to HDL ratio (TC:HDL) were measured via finger prick blood analysis (Cholestech LDX, Hayward, CA) [252, 253].

Cardiorespiratory Fitness

Predicted maximal aerobic capacity (VO_2max) was measured sub-maximally via the Modified Blake Protocol [254, 255] using a Fitmate Pro (Cosmed, Rome, Italy) [256, 257].

Muscular Strength & Flexibility

Predicted one repetition maximum (1RM), a measure of resistance training completed, for chest press (CP), *latissimus dorsi* pull down (LPD) and leg press (LP) (Technogym, Cessana, Italy) were obtained by gauging the maximal weight that could be lifted successfully for between 5 and 15 repetitions. This was the placed into the Brzycki equation [258] to predict the 1RM.

Flexibility in both right (FlexR) and left (FlexL) legs was measured using a Technogym (Cessana, Italy) Posterior Flexibility Machine, which was able to measure maximal hamstring extension.

Physical activity

Following the health assessment all participants were provided with a previously validated [259] Technogym MyWellness Key (Cessana, Italy). This device is an accelerometer able to measure participant's movement, provide continuous feedback in the form of 'moves' completed, and to set individualized, progressive daily targets on the basis of previous performance. The key was positioned in the exercise machines at the fitness centre, allowing workouts to be set (STRUC) and monitored. The key also allowed participants to track their progress online or in the fitness facility and log any exercise / PA that was completed when the key could not be worn or placed into equipment, such as free weights, cycling or swimming. Instructions were given that the key be worn by participants from all three groups during waking hours and any additional exercise / PA be logged.

Using the Technogym MyWellness Key it is possible to estimate the amount of movement completed and the time taken to complete it. Consequently it is possible to estimate the Metabolic Equivalence of the Task (MET). This provides a measure of the energy cost elicited by physical activities whereby 1 MET is equal to the predicted resting metabolic rate of an individual and increases in energy expenditure are measured as multiples of this figure. The availability of such information provides insight into the amount and intensity of physical activity being completed.

3.3.2 Experimental conditions

PAC: (n=18 (5 male 13 female) mean age=44.5±4.96) underwent 12 weeks of PAC delivered from within a fitness centre. Participants had no access to the facilities of that centre. Participants were met bi-weekly and counselling followed the 5 A's method; Ask, Advise, Assess, Assist and Agree [248], with the aim being to increase the physical activity completed by participants. Progress was monitored via the Technogym MyWellness key which allowed both researchers and participants to identify weak areas, for example a particular day of the week being associated with inactivity on a regular basis - leading to discussions regarding how the participant could modify their behaviour accordingly. The progressive, individual targets being set were used to ensure progression over the full 12 week period.

FREE*:* (n=44 (13 male 31 female) mean age=42.5±4.89 years) had access to all fitness centre facilities including the gym floor (cardiovascular, strength and flexibility equipment), group classes and swimming pool. Generic advice was provided based upon participant requirements and health check results; however no structured exercise programme was administered. Progress was monitored via the Technogym MyWellness Key and the targets used to maintain progression.

STRUC*:* (n=43 (12 male 31 female) mean age=43.39±4.27 years) were provided with a structured exercise programme, devised based upon the exercise recommendations presented in Chapter 2, (Figure 2) that comprised a combination of aerobic exercise, resistance training and stretching. Participants in the STRUC group were asked to complete the programme three times during each week, upon non-consecutive days, equating to 36 exercise sessions in total. The exercise programme was individualised and based upon the VO_2max and strength predictions found during the health assessment.

	Aerobic Exercise	
Baseline VO_2max level	Mesocycle 1 Weeks 1 - 6	Mesocycle 2 Weeks 7 - 12
Less than 40 ml/kg/min	W1: 20 minutes at 60% HRmax W2: 25 minutes at 60-65% HRmax W3: 25 minutes at 60-65% HRmax W4: 30 minutes at 65-70% HRmax W5: 30 minutes at 65-70% HRmax W6: 20 minutes at 60% HRmax	W7: 20 minutes at 70% HRmax W8: 25 minutes at 70-75% HRmax W9: 25 minutes at 70-75% HRmax W10: 30 minutes at 70-75% HRmax W11: 30 minutes at 70-75% HRmax W12: 20 minutes at 60% HRmax
Exercise Equipment	Bike + Cross Trainer	Cross Trainer + Treadmill
More than 40 ml/kg/min	W1: 20 minutes at 70% HRmax W2: 25 minutes at 70-75% HRmax W3: 25 minutes at 70-75% HRmax W4: 30 minutes at 75-80% HRmax W5: 30 minutes at 75-80% HRmax W6: 20 minutes at 70% HRmax	W7: 20 minutes at 75% HRmax W8: 25 minutes at 75-80% HRmax W9: 25 minutes at 75-80% HRmax W10: 20 minutes at 80-85% HRmax W11: 20 minutes at 80-85% HRmax W12: 20 minutes at 70% HRmax
Exercise Equipment	Bike + Cross Trainer	Cross Trainer + Treadmill
	Resistance Training	
Exercises	Mesocycle 1 Weeks 1 - 6	Mesocycle 2 Weeks 7 - 12
1. Leg press 2. Chest press 3. Low row 4. Hamstrings curl	W 1: 1 set 8-10RM. 1 minute recovery W 2: 2 sets 15RM. 2 minute recovery W 3 - 5: 4 sets 10RM. 2 minute recovery W 6: 1 set 8-10RM. 1 minute recovery	W 7: 4 sets 10RM. 2 minute recovery W 8 - 11: 4 sets 8RM. 2 minute recovery W12: 1 set 8-10 RM. 1 minute recovery
Muscle group	**Flexibility**	
1. Lumbar 2. Shoulder 3. Quadriceps 4. Hamstrings 5. Calf	10’’ to 30’’ per exercise: 2 - 3 sets To be completed during the recovery time between sets during resistance exercise	

Figure 2 Structured exercise programme - pilot study

3.3.3 Contact between participants and research team

Participants had contact with the research team throughout the intervention period, this took the form of a 10 minute face to face meeting (meet) or a brief telephone call (call) during which the meetings were arranged. As previously explained PAC occurred bi-weekly throughout the process. Table 10 provides details of the contact structure.

Table 10 Contact between participants and research team

	Group		
Week	PAC	FREE	STRUC
0	Baseline Testing	Baseline Testing	Baseline Testing
2	PAC	Call	Call
4	PAC	Meet	Meet
6	PAC	Call	Meet*
8	PAC	Meet	Meet
10	PAC	Call	Call
12	End line Testing	End line Testing	End line Testing

* Mesocycle 2 uploaded to MyWellness Key by member of research team or fitness centre staff; this resulted in a brief consultation and took the place of a telephone conversation.

3.3.4 Statistics

All data were evaluated for normality of distribution and homogeneity of variance before testing the hypotheses that cardiovascular risk factors would be improved by the interventions but to differing extents. Where non-normality of distribution was identified LOG transformation was performed.

Main effects of group (PAC, FREE and STRUC), time (pre and post intervention) and group time interactions were assessed using mixed design analysis of variance (ANOVA). Alpha was set at $P \leq .05$. Where main effects were identified Bonferonni corrections were used to complete post-hoc comparisons.

3.4 Results

3.4.1 Compliance

All participants who reported for post intervention testing were included in the statistical analysis (n=97 representing 92% retention). Figure 3 displays STRUC compliance data organised by the amount of workouts completed (100% = 36), this is possible as participants completed on average 98.7% of the programme allocated when attending the fitness facility. Also displayed are the amount of times FREE used the gym facility.

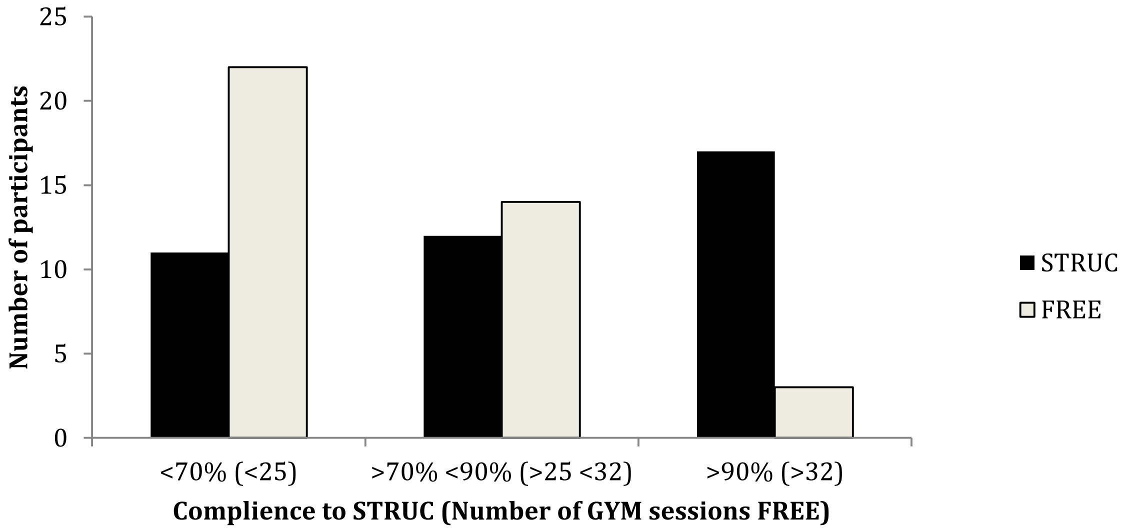

Figure 3 Number of STRUC participants completing differing percentages of the structured exercise programme and number of gym sessions completed by FREE

3.4.2 Weekly Metabolic Equivalent of Tasks (METs)

Figure 4 demonstrates the estimated increase in METs across the 12 week intervention period. The main effect of the interventions was a significant increase in estimated METs expended pre-post (i.e. week 1 and week 12) by all three groups. No significant differences between groups were observed at week 12. Weekly METs increase almost linearly in STRUC with a strong correlation between week number and METs expended (r=0.91 P<0.01), whilst in PAC and FREE there is no significant correlation in either.

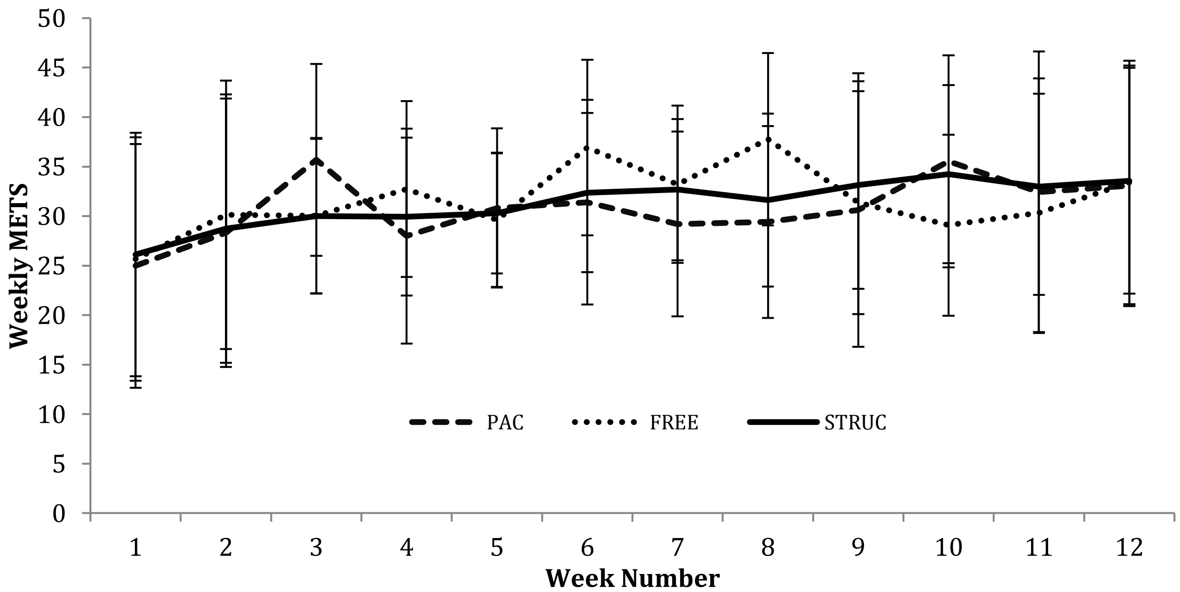

Figure 4 Weekly metabolic expenditure

3.4.3 Health assessment

The results of the health assessment and associated statistical analysis are presented in Table 11.

Table 11 Within and between group analysis of cardiovascular and physiological variables

Dependant variable (unit)	Pre (SD)	Post (SD)	Group P value	Main Effects Pre.Post P value	Time*Group Effect P value
SBP (mmHg)					
PAC (14)	132 (13.64)	129.29 (12.03)			
Free (39)	130.1 (15.76)	125.46 (14.07			
Struc (38)	137 (13.24)	130.82 (12.48)			
Overall			0.24	0.001	0.668
DBP (mmHg)					
PAC (14)	79.64 (10.24)	80.14 (7.99)			
Free (39)	74.31 (9.43)	74.33 (8.95)			
Struc (38)	82.84 (9.99)	79.08 (10.79)			
Overall			0.001	0.137	0.014
FFM (kg)					
PAC (18)	52.42 (8.63)	52.83 (8.95)			
Free (38)	51.97 (10.13)	52.29 (9.93)			
Struc (40)	52.36 (10.1)	52.56 (10.68)			
Overall			0.964	0.046	0.842
TC (mmol/L)					
PAC (18)	4.97 (0.73)	4.68 (0.8)			
Free (39)	4.46 (0.89)	4.35 (0.76)			
Struc (40)	4.85 (0.83)	4.82 (0.76)			
Overall			0.02	0.007	0.19
TG (mmol/L)					
PAC (18)	1.75 (0.8)	1.41 (0.55)			
Free (39)	1.51 (0.97)	1.3 (0.78)			
Struc (40)	1.83 (1.44)	1.71 (1.16)			
Overall			0.095	0.062	0.737
TC:HDL					
PAC (18)	4.6 (1.84)	3.83 (0.92)			
Free (39)	3.49 (1.17)	3.39 (1.21)			
Struc (39)	3.95 (1.59)	3.95 (1.55)			
Overall			0.12	0.005	0.014

VO_2 (ml/kg/min)					
PAC (18)	31.07 (7.8)	33.91 (6.51)			
Free (35)	37.86 (8.32)	38.14 (8.33)			
Struc (39)	34.42 (7.12)	35.14 (7.46)			
Overall			0.03	0.056	0.765
CP (kg)					
PAC (17)	40.93 (16.37)	41.84 (19.7)			
Free (39)	43.77 (21.58)	48.45 (23.85)			
Struc(40)	39.01 (20.46)	48.89 (20.17)			
Overall			0.54	<0.001	0.005
BM (kg)					
PAC(18)	86.54 (16.78)	84.84 (16.78)			
Free (39)	79.87 (16.66)	78.49 (16.4)			
Struc (40)	85.09 (18.49)	83.34 (18.42)			
Overall			0.92	<0.001	0.656
FM (kg)					
PAC (18)	34.32 (13.37)	32.06 (13.77)			
Free (38)	28.48 (11)	26.73 (11.09)			
Struc(40)	32.85 (12.16)	30.85 (12.08)			
Overall			0.029	<0.001	0.639
LDL (mmol/L)					
PAC (18)	2.9 (0.5)	2.76 (0.67)			
Free (35)	2.48 (0.8)	2.48 (0.72)			
Struc (36)	2.77 (0.82)	2.69 (0.72)			
Overall			0.035	0.139	0.751
HDL (mmol/L)					
PAC (18)	1.25 (0.51)	1.27 (0.31)			
Free(39)	1.331 (0.38)	1.39 (0.39)			
Struc (40)	1.32 (0.43)	1.34 (0.38)			
Overall			0.464	0.173	0.625
BF%					
PAC (18)	38.62 (9.06)	36.7 (9.93)			
Free (39)	34.61 (8.31)	32.97 (8.75)			
Struc (40)	37.71 (8.39)	36.15 (8.95)			
Overall			0.034	<0.001	0.801
RHR (bpm)					
PAC (14)	80 (12.94)	71.71 (15.44)			

Free (39)	71.03 (10.1)	66.9 (10.37)			
Struc (39)	78.54 (13)	73.13 (10.66)			
Overall			0.001	<0.001	0.26
LPD (kg)					
PAC (17)	50.94 (13.32)	56.5 (13.96)			
Free (39)	54.68 (19.92)	61.15 (23.54)			
Struc (40)	52.08 (16.25)	60.82 (19.9)			
Overall			0.564	<0.001	0.005
LP (kg)					
PAC (17)	91.49 (26.24)	126.18 (38.23)			
Free (39)	89.92 (24.83)	135.5 (50.98)			
Struc (38)	92.81 (29.03)	140.11 (58.49)			
Overall			0.652	<0.001	0.68

Significant decreases pre-post intervention were observed in BM, FM, BF%, SBP and TC, while FFM significantly increased, with no statistical differences between the groups (Table 11). There was a significant group effect in DBP however which improved significantly in STRUC only.

3.5 Discussion

The main findings of the present study are that over 12 weeks fitness centre based PAC and two gym-based exercise interventions appear equally effective in decreasing cardiovascular risk factors in middle aged adults free from chronic disease. Significant improvements were observed in blood pressure, resting heart rate, body composition, muscular strength and flexibility. Cholesterol results were inconsistent whilst VO_2 max tended to increase although not significantly.

The improvements found in cardiovascular risk factors are not surprising and in line with previous research [49]. The additional information this study provides however is evidence for the potential role of fitness centres as hubs for community interventions aimed at increasing physical activity and improving cardiovascular health, even if the people involved do not actually use the exercise facilities on the gym floor or in other areas of the fitness centre.

The lack of a significant difference between the groups in all markers barring DBP, TC:HDL, LPD and LP was perhaps surprising. It was hypothesised that the STRUC condition would be associated with significantly greater improvements in dependant variables than PAC due to the likely higher intensity and volume of exercise and due to the periodisation of the STRUC condition, when in fact although the intensity of exercise was higher in STRUC the overall volume was similar. Several factors might explain this finding, the most obvious being that the study was conducted over too short a period of time. Participants were physically inactive at baseline and therefore even a small increase in physical exertion will likely have resulted in improvements in the dependant variables [260]. Furthermore, the significant increases in metabolic expenditure represented in the increases in METs over the 12 week period were not significantly different between the groups. This may help to explain not only the improvements seen in cardiovascular health markers but also the fact that the improvements did not differ significantly between the groups (it has been reported that there is a dose-response relationship between improvements in cardiovascular risk factors and energy expended [217, 218].

Figure 4 however highlights different patterns in MET increases over time by condition. FREE was particularly erratic with spikes in energy expenditure during contact weeks. PAC increased dramatically at the beginning of the process before decreasing and remaining consistent (albeit at a level greater than baseline), before gradually increasing again at week 8 when it was emphasised that the process was reaching its conclusion. STRUC on the other hand followed a far more consistent and steady increase, consistent with the exercise programme set. The erratic nature of the increase in energy expenditure observed in PAC and FREE directly impacted upon the correlation values calculated ($r = 0.28$ & 0.12) both of which demonstrate non-significant correlations between the week of the intervention and the energy expended, making further increases hard to predict. A strong correlation between week and energy expenditure in STRUC ($r= 0.91$) suggests that if the intervention period were to be increased, weekly METs would also continue to increase. This furthermore suggests that over a longer period of time greater health benefits might be observed in the STRUC group compared to other groups. Of course, given a relatively small sample and unequal allocation to treatment (only 18 participants undergoing PAC compared to 39 and 40 in FREE and STRUC respectively), the study might have been underpowered. The unequal sample is a consequence of conducting pragmatic research within a working community fitness centre. Initially 20 participants were targeted for the PAC intervention (two failed to attend initial health check) – this was pre-determined due to the time required to deliver the PAC sessions and preparation for them. This was calculated at 10 hours spread over two weeks (15 minutes delivery, 15 minutes preparation for 20 participants delivered bi-weekly) a time that following consultation with fitness centre staff and management it was agreed would be achievable in a working fitness centre. Although it is noted that this impacts upon comparisons between groups, one of the main aims of the investigation (as a pilot study) was to identify whether fitness centre based PAC was feasible, effective, and of interest to members of the community – all of which it was shown to be. It should be noted however that the recruitment of participants, although completed with relative ease, was met with initial scepticism and seen as a method of selling fitness centre membership by some. The time taken and community perceptions are two factors that should be considered during future research.

The fact that the PAC group were recruited from a different cohort to the other groups and displayed different characteristics at baseline i.e. higher FM and lower VO_2max (although non-significant) may have impacted upon the results. There is potential that improvements will be quicker and easier to attain when baseline characteristics indicate higher cardiovascular risk [50, 61, 218]. This was shown to be the case in DBP where although STRUC was the only of the three groups to reduce significantly it was also the group that displayed the highest baseline readings (significant difference between groups). Participants were recruited separately i.e. for either fitness centre based exercise or PAC - where all activity would be completed outside of the fitness centre, to replicate the choice that would be faced by anybody entering a PA promotion scheme in the real world e.g. theoretically somebody averse to fitness centres would not enter / be receptive to either of the exercising interventions. As has previously been stated the idea of exercising within a fitness centre could prove intimidating for many and could be a factor in the high dropout rates from - and limited effectiveness of - exercise referral schemes [59]. PAC delivered from within the fitness centre however may begin to remove these barriers and could become an intermediary step for practitioners to recommend before fitness centre based exercise is prescribed. The implication of this research to application is that fitness centre based PAC is a potentially effective community based intervention to increase physical activity levels in a previously physically inactive cohort and improve modifiable risk factors of cardiovascular health.

3.6 Conclusions

The main findings of this investigation are that all 3 interventions increased the physical activity levels of participants resulting in significant increases in weekly METs that did not differ between groups. Significant improvements were found in SBP, BM, FM, FFM, TC, BF%, RHR, LP, and flexibility across all three groups. Significant differences were however found between groups in CP and LPD with STRUC showing significantly greater improvements; this may have impacted upon DBP which only improved significantly in STRUC.

This study was limited by its short duration as a longer intervention period may have elicited greater differences between groups as implied by correlations between the week of the intervention and energy expended, as well as the differences in baseline measurements between those recruited for PAC and those randomised between exercise groups. Further research will extend this pilot study over longer intervention periods and include a comparison group receiving no intervention other than measurement to determine any measurement effect.

4. Study 1: The impact of community fitness centre based physical activity interventions on risk factors of cardiovascular disease

4.2 Introduction

The pilot study detailed previously suggests that community fitness centre based interventions have the potential to reduce cardiovascular risk in previously sedentary participants aged between 35 and 45 years. That no significant differences between the three intervention groups were observed might be the result of a number of factors ranging from low power, differences in participants' cardiorespiratory fitness levels at baseline, or the fact that a short term intervention moving from a sedentary lifestyle to a more active one, regardless of the mode activity or exercise, will likely have elicited improvements in health.

The pilot study highlighted several future research considerations. It demonstrated that it is feasible to conduct research from within community fitness centres i.e. to recruit participants, collect clinically relevant data, and deliver effective physical activity / exercise interventions relatively economically whilst maintaining high ecological validity. The study was however limited by a lack of a control condition, appropriate for a pilot study informing the feasibility of such an investigation, but limiting the conclusions that can be drawn. Increases in physical activity and improvements in cardiovascular risk factors may have been attributable to other external facts such as seasonal factors (improved weather resulting in greater organic levels of activity) or wider societal influences. Further, the short (12 week) intervention period meant that the longer term effects of the interventions could not be properly investigated. Factors such as retention within the interventions and the effectiveness of different interventions within different sub-samples of the study cohort e.g. health status when beginning a programme, are key components of an ecologically valid investigation. These are factors that have not been fully investigated in the current exercise is medicine literature.

The current investigation aimed to create an ecologically valid study that would represent and investigate the real world delivery of physical activity interventions from community fitness centres. In addition to the factors outlined above that limited the pilot study and previous exercise is medicine research, the delivery and evaluation of physical activity and exercise interventions by researchers automatically limits their replicabilty outside of a research environment [261]. It has been stated that behavioural intervention studies completed in community settings external validity is limited by a lack of representativeness in the sample population and intervention delivery, and consequently generalisability is reduced [262].

Addressing this issue will help the transition of efficacy research findings into effectiveness trials in clinical and service delivery settings [263]. Relating this concept to the current investigation, a researcher may have a significant interest in delivering a successful project, and as a consequence will dedicate time and resource to ensure its delivery. Such time and resource is not always available to those delivering initiatives in the real world and therefore the retention levels and adherence to exercise programmes demonstrated in the literature may not be deliverable in community fitness centres and as a consequence their clinical effect may be limited.

Therefore, to ensure the ecological validity of an investigation that sought to examine the degree to which laboratory research supporting the exercise is medicine hypothesis translates into the real world, the current investigation was hosted by fitness centres and delivered by exercise professionals who recruited participants, collected all data and delivered the interventions. Interventions lasted 48 weeks and participants were offered an exercise pathway, and randomised between a structured exercise programme and unstructured fitness centre use, or a physical activity pathway, and randomised between fitness centre based physical activity counselling and a comparison group that received no intervention other than measurement at baseline, 24 and 48 weeks.

Although pilot data suggested that over 12 weeks there were no differences between changes physical activity levels between the interventions, and as a result cardiovascular risk was reduced to the same extent. It is predicted that over 48 weeks differences between interventions will be magnified and cardiovascular risk affected accordingly i.e. significant differences between fitness centre based exercise interventions and lifestyle physical activity orientated interventions. Additionally it is predicted that the interventions effectiveness will be increased / impaired by the baseline health status of participants i.e. those at greatest risk of cardiovascular disease will see the greatest improvements. This investigation also offered the opportunity to assess the impact of different fitness centre provision models upon retention within interventions. It was hypothesised that the structured exercise programme would demonstrate better retention levels than the unstructured fitness centre use as a result of the progressive programme to be implemented, whilst the physical activity counselling intervention would retain participants more effectively than measurement alone as a result of the rapport build between the exercise professional and participant receiving the counselling.

In this ecologically valid investigation comparing the effectiveness of three modes of physical activity delivery from community fitness centres, the following hypotheses were tested:

1. A structured exercise programme would elicit greater improvements in cardiovascular health than unstructured fitness centre based exercise, physical activity counselling or a measurement only comparison intervention over 48 weeks.
2. Improvements in cardiovascular health would be mediated by baseline health condition i.e. those at greatest risk would see greater benefit than those with the lowest risk as determined by level of dependant variable.
3. Retention within the 48 week interventions would be greater in the structured exercise programme and physical activity counselling interventions than unstructured fitness centre use and the measurement only comparison condition.

Hypotheses one and two, that is the impact of the interventions upon cardiovascular risk factors, are detailed below. Hypothesis three and additional factors that influence retention are explored in Chapter 5. A follow up questionnaire aimed at gathering information to support that presented in Chapters 4 and 5 is then presented in Chapter 6.

4.3 Methods

4.3.1 Recruitment of fitness centres

To understand how findings from this investigation will translate in the real world it was essential that it be hosted by working community fitness centres representing; the public and private sectors, a range of locations throughout the United Kingdom, and operators ranging from independent facilities to large international chains. Likewise the exercise professionals selected by each operator to deliver the investigation in their facility, although never pre-determined by the research team, had to range in; age, experience, qualification level and position within the organisation.

Fitness operators were invited to apply to take part in this investigation. As part of the application they were asked to provide details of the centre being proposed e.g. the number of members, previous experience delivering public health initiatives, and a strategy for recruiting sedentary participants. Further, two exercise professionals were to be proposed and their details (age, experience, qualification level etc.) provided. Operators were informed that they could submit no more than three applications.

In total 29 applications were received. No centres were rejected from the process. Any selection process on behalf of the research team would have reduced the ecological validity of the investigation, by limiting its application to only those centres meeting the criteria employed by the researchers. What the application process demonstrated however was a certain degree of commitment from the facilities i.e. they were willing to complete an extensive application form and commit two members of staff for two full days of training with the researcher.

Two facilities decided not to take part in the investigation following staff training as they felt unable to fully commit to the process. Details of the facilities that begun the investigation are provided below.

Table 12 Details of the fitness centres hosting the investigation

Operator	**Region**	**Town**	**Sector**	**Size of operator – classified by number of sites**
Active Nation	South West	Abingdon	Public	Small / Medium
Active Nation	North	Chorley	Public	Small / Medium
Active Nation	Midlands	Lincoln	Public	Small / Medium
Aquaterra	London	Highbury	Public	Small / Medium
DC Leisure	London	New Malden	Public	Large
DC Leisure	South West	Taro	Public	Large
DC Leisure	Midlands	Harbourne	Public	Large
Doncaster Culture & Leisure Trust	North	Doncaster	Public	Small / Medium
Edinburgh Leisure	Scotland	Leith Victoria	Public	Small / Medium
Edinburgh Leisure	Scotland	Gracemount	Public	Small / Medium
Edinburgh Leisure	Scotland	Ainslee	Public	Small / Medium
ESPH	London	Dulwich	Private	Independent
EZE Fitness	Midlands	Derby	Private	Small / Medium
EZE Fitness	Midlands	Redditch	Private	Small / Medium
EZE Fitness	North	Scarborough	Private	Small / Medium
Fitness First	London	London	Private	Large
Fitness First	London	London	Private	Large
Fitness First	South West	Bristol	Private	Large
HALO Leisure	South West	Hereford	Public	Small / Medium
Life Leisure	North	Stockport	Public	Small / Medium
North Lanarkshire Leisure	Scotland	Motherwell	Public	Small / Medium
Pent Valley Leisure	South East	Folkestone	Public	Independent
Pontefract Squash and Leisure Club	North	Pontefract	Private	Independent
The Club Company	South East	East Grinstead	Private	Small / Medium
The Club Company	South East	Hildenborough	Private	Small / Medium
The Club Company	South East	Earls Colne	Private	Small / Medium
Topnotch	South East	Colchester	Private	Small / Medium

4.3.2 Training of exercise professionals

Training days were organised by region and delivered by the researcher. Training was delivered over two days with exercise professionals required to attend both days. All exercise professionals were deemed able to deliver the research following the training. The following topic areas were covered:

- Introduction and background to research
- The study design and research questions
- Participant selection criteria and recruitment strategies
- Data collection and rationale for each measure
  - Anthropometric measurements
  - Body composition
  - Blood pressure
  - Cholesterol levels
  - Cardiorespiratory fitness
- Intervention delivery and communication structure
  - Structured programme design
  - Unstructured fitness centre based exercise
  - Physical activity counselling

4.3.3 Participants

Following training exercise professionals, in conjunction with their centre and operator, were tasked with recruiting 80 participants (40 to be entered into the exercise pathway and 40 the physical activity pathway).To estimate the real world likelihood of success for a preventative intervention it has been suggested that participant recruitment should occur with minimal enticement e.g. payments, and replicate real world recruitment techniques [264]. Furthermore participants should be asked post intervention why they decided to participate in the intervention [264]. This is part of the follow up detailed in Chapter 6.

It was decided to ask each facility to recruit 80 participants based upon the time allocated to each centre to complete data collection (each centre had a 21 day window to collect baseline, 24 and 48 week data), following consultation with fitness centre operators and based on the experiences of the researcher during the pilot study. Exercise professionals were instructed that participants should meet the following selection criteria:

- Aged between 30 and 55 years
- Sedentary i.e. not completing any form of regular exercise or currently meeting the physical activity recommendations of the chief medical officer (150 minutes each week)
- Taking no medication that will impact upon cardiovascular risk e.g. statins

The age range was selected to represent a population that may have previously been active and are becoming increasing sedentary, in addition to the fact that it is between these ages that recreational sports participation drops and in which work and family commitments tend to take on greater significance than maintaining physical activity levels. This is also an age range that has limited risk of an adverse event associated with increased physical activity [32]. Participants received a detailed explanation of the study and provided written informed consent. The study was approved by the University of Greenwich Research Ethics Committee.

4.3.4 Study design

The following schematic demonstrates the journey of participants through this investigation. In short however, participants meeting the selection criteria above were offered the choice of increasing physical activity levels via fitness centre based exercise, or lifestyle based physical activity. This decision arguably (and partially) mimics the decision taken by people in the real world i.e. they understand or are told that increasing their physical activity levels will benefit their health and have a choice in how to do so. For some the opportunity to attend a fitness centre will be a positive and motivating experience. For others however this could present a barrier to behaviour change, and they would be better suited to lifestyle oriented behaviour changes. Having chosen either a fitness centre or lifestyle based intervention participants were then randomised into one of two intervention groups. Data was collected at baseline, 24 and 48 weeks, with the interventions (detailed below) delivered throughout this 48 week period. An online follow up questionnaire was then circulated to exercise professionals and participants. This aimed to gather insight into the feasibility of such interventions and factors that influenced retention.

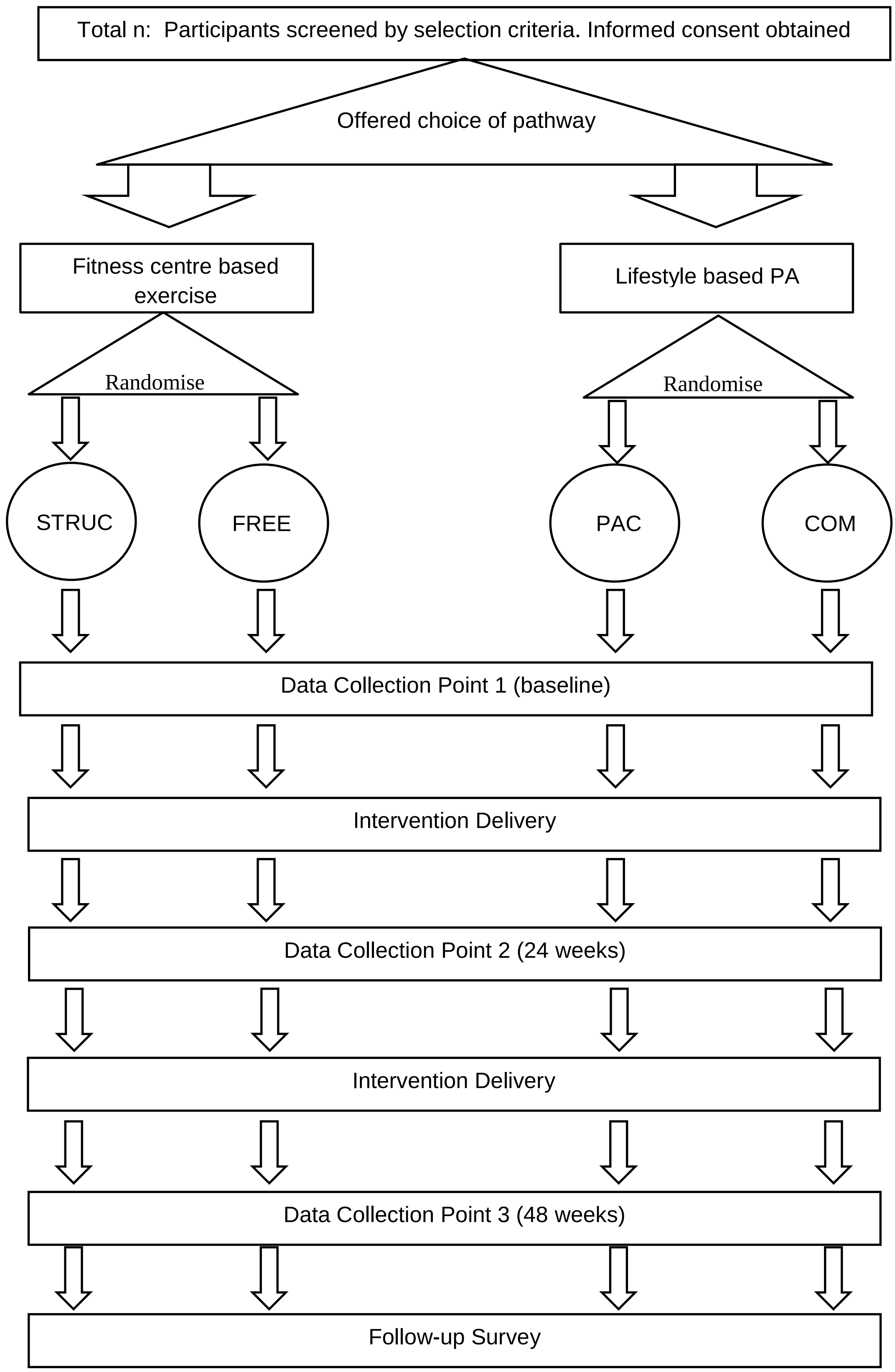

Figure 5 Study design schematic

4.3.5 Interventions

The four interventions are described below:

Structured exercise programme (STRUC): Participants had access to all fitness centre facilities and received an individualised exercise programme to follow. The programme combined aerobic and resistance training and was created following an extensive review of the existing literature (as detailed in Chapter 2). The intensity of training was based upon calculations of one repetition maximum and cardiorespiratory fitness during data collection. This was re-assessed following 24 week data collection. Exercise professionals were instructed to meet STRUC participants once a month to discuss their programme, the intervention generally and to maintain motivation. The full programme is detailed below (Figure 6):

		Mesocycle 1	**Mesocycle 2**	**Mesocycle 3**	**Mesocycle 4**
Aerobic Exercise		Weeks 1 - 12	Weeks 13 - 24	Weeks 25 - 36	Weeks 37 - 48
Baseline VO_2max	<40 ml.kg.min	60% HRmax 20 minutes	65-70% HRmax 30 minutes	75% HRmax 30 minutes	80% HRmax 20 minutes
	>40 ml.kg.min	70% HRmax 30 minutes	75% HRmax 30 minutes	85% HRmax 20 minutes	85-90% HRmax 20 minutes
Resistance Training	Basic Exercises Leg press Chest press Lat pull down Hamstring curl	Weeks 1-3 1 set 8-10 reps Weeks 3-5 2 sets 15 reps Weeks 6-8 3 sets 12 reps Weeks 9-12 4 sets 12 reps	Weeks 13-16 4 sets 10 reps Weeks 17-24 3 sets 15 reps	Weeks 25-27 4 sets 10 reps Weeks 28-36 3 sets 12 reps	Weeks 37-39 3 sets 6 reps Weeks 40-48 4 sets 10 reps

Figure 6 Structured exercise programme

Unstructured fitness centre based exercise (FREE): Participants had access to all fitness centre facilities but received no structured programme to follow. Exercise professionals were instructed to meet with FREE participants once each month to discuss the intervention generally and to maintain motivation. Exercise professionals were able to answer any questions presented by the participants and recommend training modes, exercise classes or activities. Exercise professionals were however not permitted to recommend or prescribe any specific exercise programme.

Physical activity counselling (PAC): Participants did not have access to any fitness centre facilities. Exercise professionals were instructed to meet participants once each month and deliver counselling sessions. These counselling sessions were to be structured according to the 5 A's model and delivered within the fitness centre in a location deemed appropriate by the exercise professional such as a coffee shop or private office.

Comparison (COM): Participants did not have access to any fitness centre facilities. Exercise professionals were instructed have no contact with participants during the intervention period. The only contact between exercise professionals and the participants was to arrange data collection at 24 and 48 weeks.

What are represented by these three interventions are models of provision that could be adopted by community fitness centres. A summary of the proposed communication between the exercise professionals and participants in each group is presented in Table 13:

Table 13 Communication between participant and exercise professional

Group	**STRUC**	**FREE**	**PAC**	**COM**
Communication	Every 4 weeks Discuss programme	Every 4 weeks Discuss intervention	Every 4 weeks Counselling	Every 24 weeks Data collection

4.3.6 Data collection

Clinically relevant measures of cardiovascular risk were collected at baseline, 24 and 48 weeks. These included body composition, blood pressure, lipid profile and cardiorespiratory fitness.

4.3.6.1 *Body composition*

Measures of body composition; body fat mass (kg), lean mass (kg) and body fat percentage (%) were collected via bio-impedance (Bodystat 1500, Bodystat, Isle of Man, UK).

4.3.6.2 *Blood pressure*

Blood pressure readings were collected following body composition analysis. Systolic and diastolic blood pressures (mmHg) were measured using a commercially available blood pressure monitor (Omron Healthcare, Japan). Three readings were collected and the mean value reported. Mean arterial pressure (MAP) was estimated via the following calculation MAP=DBP+0.33(SBP-DBP).

4.3.6.3 *Lipid profile*

Lipid profile (total cholesterol, low density lipoprotein (LDL) cholesterol (mmol/l), high density lipoprotein (HDL) cholesterol (mmol/l), total to HDL cholesterol ratio and non HDL cholesterol (mmol/l)) was measured via finger prick blood analysis (Cholestech LDX, Alere, UK).

4.3.6.4 *Cardiorespiratory fitness*

Maximal aerobic capacity (VO_2max) was predicted using a sub-maximal treadmill protocol (Modified Blake Protocol [254, 255]). Briefly, participants were asked to walk on a treadmill at a speed between 3.6kph and 5.6kph depending on ability for three minutes. At the end of this this initial three minute period the gradient of the treadmill was increased by one percent each minute. During this process participants were asked to rate their perceived exertions on the OMNI (1-10) scale. The test was stopped when participants indicated their perceived exertion level was above six (hard) and / or their heart rate reached 150bpm. Throughout the test oxygen consumption was monitored via direct gaseous analysis (Fitmate Pro, COSMED, Italy [256, 257]) and using the relationship with heart rate, predicted VO_2max was extrapolated. This was an automated procedure and required no calculation by the exercise professional.

4.3.6.5 *Data collection procedure*

Data were collected following randomisation at baseline. Participants were asked to note their dietary intake for the day leading up to data collection. This was collected by exercise professionals and participants were asked to replicate this at the subsequent 24 and 48 weeks data collection points. Exercise professionals were instructed to ensure that each data collection appointment was booked for the same time of day each time. These measures were put in place to limit changes in dependant variables that would not be attributable to the intervention. A follow-up questionnaire was circulated following 48 week data collection to all participants who completed baseline testing.

4.3.7 Statistics

To test hypothesis one; that greater reductions in cardiovascular risk would be elicited following STRUC than FREE, PAC or COM, the following procedure was followed. To equalise data percentage change in risk factors between baseline and 48 weeks were calculated. These were compared between groups in a one-way ANOVA.

To test hypothesis two; that improvements in cardiovascular health would be mediated by baseline health condition i.e. those at greatest risk would see greater benefit than those with the lowest risk as determined by level of dependant variable, the following procedure was followed. Participants in each intervention group (STRUC, FREE, PAC and COM) were divided into quartiles based upon the baseline level of the dependant variable (high, moderately high, moderately low and low). The mean percentage change in each subgroup was compared in a one-way ANOVA and post-hoc comparisons between the high and low quartiles completed [265-267].

All data were analysed in accordance with intention to treat analysis [268, 269] i.e. the initial intervention participants were assigned and not the intervention they eventually received. Therefore, no consideration was given to the number of workouts completed or counselling sessions attended, and no participants were excluded. Reporting for data collection was considered compliance. Alpha was set at <0.05 in each ANOVA and 0.017 for post-hoc comparisons between sub groups in hypothesis two (application of bonferroni correction – alpha of 0.05 divided by number of comparisons being made, in this case three).

4.4 Results

One way ANOVA's of percentage change between baseline and 48 weeks revealed no significant differences between the four groups for any of the dependant variables examined over the 48 week interventions. Thus the hypothesis that STRUC would elicit significant greater improvements in cardiovascular risk factors than FREE, PAC and COM can be rejected. All data, main effects and results of statistical analysis are presented in Table 14.

Table 14 Cardiovascular risk - main findings and statistical analysis

N=366 – STRUC 109, FREE 111, PAC 71, COM 75							
Dependant Variable	Pre (Baseline)	SD	Post (48 weeks)	SD	Mean Percentage Change	Degrees of Freedom	One way ANOVA % Change P value
VO_2 (ml/kg/min)							
STRUC	34.84	8.29	36.47	8.11	7.53		
FREE	37.91	10.09	38.80	10.14	5.54		
PAC	36.45	9.86	35.32	8.37	6.83		
CON	39.28	11.32	38.66	10.58	-0.91		
Group						225	0.438
BF% (%)							
STRUC	29.16	8.19	27.85	8.97	-4.66		
FREE	29.98	9.86	29.46	9.21	-0.59		
PAC	31.35	8.75	30.35	8.57	-2.63		
CON	29.78	7.19	29.82	7.56	0.99		
Group						279	0.216
BF (kg)							
STRUC	24.37	10.03	23.07	10.37	-4.4		
FREE	23.51	10.42	23.29	10.38	-0.93		
PAC	24.51	9.86	23.89	9.14	-0.42		
CON	24.56	13.54	23.09	9.27	-0.63		
Group						346	0.308
LM (kg)							
STRUC	55.3	13.26	55.92	12.35	2.61		
FREE	47.21	18.24	46.99	17.98	1.39		
PAC	49.59	19.05	50.59	19.5	2.42		
CON	49.24	19.11	47.37	18.87	-2.64		
Group						327	0.151
SBP (mmHg)							
STRUC	125	13	123	12	-0.72		
FREE	125	13	124	14	-0.07		
PAC	128	14	127	13	-0.76		
CON	127	17	125	16	-0.92		
Group						343	0.935
DBP (mmHg)							
STRUC	80	9	78	9	-1.71		
FREE	77	9	77	9	0.23		
PAC	80	11	79	10	-0.41		
CON	77	9	75	9	-1.84		
Group						338	0.56
TC (mmol/L)							
STRUC	4.87	0.86	4.78	0.84	-0.45		
FREE	4.58	0.91	4.59	0.83	1.28		
PAC	4.83	0.95	4.85	0.1	1.22		
CON	4.7	0.88	4.83	0.99	3.16		
Group						346	0.385
LDL (mmol/L)							
STRUC	2.69	0.73	2.81	0.65	6.82		
FREE	2.41	0.89	2.58	0.75	13.22		
PAC	2.69	0.69	2.79	0.68	5.97		

CON	2.55	0.8	2.77	0.75	10.34		
Group						287	0.371
HDL (mmol/L)							
STRUC	1.4	0.44	1.35	0.41	-1.05		
FREE	1.35	0.45	1.3	0.39	0.23		
PAC	1.39	0.43	1.38	0.46	-0.41		
CON	1.39	0.47	1.41	0.45	-1.84		
Group						339	0.35
TCHDL							
STRUC	3.71	1.2	3.77	1.07	3.56		
FREE	3.62	1.37	3.74	1.34	10.37		
PAC	3.84	1.5	3.94	1.54	3.76		
CON	3.69	1.49	3.83	1.64	5.79		
Group						320	0.288
nonHDL							
STRUC	3.48	0.85	3.53	0.84	2.48		
FREE	3.18	0.93	3.23	0.85	3.94		
PAC	3.47	1.03	3.46	0.96	2.23		
CON	3.3	0.96	3.35	1.04	3.21		
Group						326	0.946

One-way ANOVA’s comparing the percentage change between baseline and 48 weeks of quartiles within groups, based upon the baseline level of each dependant variable, revealed significant effects in VO_2, MAP, BF, TC:HDL and LDL cholesterol. Post-hoc pairwise comparisons reveal a significant difference between the high and low subgroups in VO_2 (STRUC, PAC), BF (PAC), MAP (STRUC, FREE, PAC), TC: HDL (STRUC, FREE), and LDL (STRUC, PAC, COM). This suggests that the baseline measure did impact on the effectiveness of the interventions. This was confirmed by significant correlations, r ranging from 0.27 to 0.6, between baseline level and percentage change at 48 weeks in at least one of the groups in VO_2, BF, BF%, LM, MAP, TC: HDL and LDL cholesterol.

Table 15 demonstrates the effect of each intervention on each dependant variable, classified by intervention subgroup. Results suggest that dependant variables were affected differently by interventions. Table 16 highlights within which sub-groups positive or negative effects were found. Some interventions positively affected different proportions of the cohort whilst there were negative effects in others. Significant correlations between baseline level and percentage change suggest these effects are not random. Table 17 shows the actual levels of the dependant variables that distinguish the sub-groups and highlights those that were positively affected by the interventions. Trends suggest that STRUC positively impacted upon wider proportions of the cohort than FREE, PAC and COM. Thus the hypothesis that changes in cardiovascular risk factors would be mediated by baseline level, and that those at greatest risk would see the greatest benefits can be accepted. Specific findings are presented below.

***Body composition* -** positive effects were observed across the whole cohort (FM & BF%) in those completing STRUC, and three quartiles in those receiving PAC. In the FREE and COM conditions positive effects were only found in those in the highest BF% and FM quartiles.

***Lipid profile* -** TC: HDL only improved in the most at risk quartile of participants in all groups. In LDL cholesterol however positive effects were extended to 50% of the participants in those who completed STRUC and PAC interventions.

***Mean arterial pressure* -** mild positive effects were observed in the measurement only condition in 75% of the cohort; this was limited to 50% in the other three interventions. There is a strong correlation between baseline condition and changes made.

***Cardiorespiratory fitness* -** different percentiles of the cohort in each intervention received positive effects. STRUC saw 75% of participants receive a benefit, FREE – 50% and PAC – 25%.

Table 15 Comparison of the percentage change between baseline and 48 weeks of within group quartiles & post hoc comparisons between high and low sub-groups

Dependant Variable		One Way ANOVA – P Value	High vs Low percentage change		Pairwise comparison High vs Low
			High	Low	
Cardiorespiratory Fitness	STRUC	0.001	-7.52	32.03	P=0.005*
	FREE	0.003	-4	24.31	P=0.023
	PAC	0.003	-8.19	35.8	P=0.007*
	COM	0.131	-5.22	8.17	P=0.663
Body Fat Mass	STRUC	0.577	-7.23	-1.03	P=1
	FREE	0.263	-4.05	5.11	P=1
	PAC	0.005	-10.12	9.34	P=0.002*
	COM	0.207	-7.67	8.47	P=0.349
Body Fat Percentage	STRUC	0.875	-6.51	-2.99	P=1
	FREE	0.11	-5.55	7.85	P=0.101
	PAC	0.173	-5.8	2.66	P=0.378
	COM	0.368	-6.86	4.71	P=0.814
Lean Mass	STRUC	0.305	0.12	8.03	P=0.625
	FREE	0.219	-2.57	8.09	P=0.364
	PAC	0.156	0.24	0.96	P=1
	COM	0.584	-3.19	0.52	P=1
Mean Arterial Pressure	STRUC	0.001	-9.34	4.86	P<0.00*
	FREE	0.003	-4.64	5.62	P=0.002*
	PAC	0.001	-4.25	5.62	P=0.001*
	COM	0.027	-5.19	3.61	P=0.021
Total:HDL Cholesterol	STRUC	0.001	-12.46	14.25	P<0.00*
	FREE	0.001	-11.12	36.6	P<0.00*
	PAC	0.066	-7.98	10.36	P=0.123
	COM	0.014	1.96	17.01	P=0.157
LDL Cholesterol	STRUC	0.001	-4.5	16.83	P=0.013*
	FREE	0.001	-5.59	42.9	P<0.00*
	PAC	0.001	-4.18	29.43	P=0.004*
	COM	0.007	-1.36	35.25	P=0.016*

* Denotes statistically significant difference between High and Low sub-groups where alpha was set at 0.017 following manual Bonferroni correction.

Table 16 Positive, negative or no effect over 48 week intervention classified between group and within group quartiles

Dependant Variable	Group	High	Mod High	Mod Low	Low
Cardiorespiratory Fitness	STRUC	X	✓	✓	✓
	FREE	X	X	✓	✓
	PAC	X	X	X	✓
	COM	X	X	X	✓
Body Fat Mass	STRUC	✓	✓	✓	✓
	FREE	✓	X	X	X
	PAC	✓	✓	X	X
	COM	✓	✓	X	X
Body Fat Percentage	STRUC	✓	✓	✓	✓
	FREE	✓	-	X	X
	PAC	✓	✓	✓	X
	COM	✓	X	X	X
Lean Mass	STRUC	✓	X	✓	✓
	FREE	X	X	X	✓
	PAC	-	-	✓	✓
	COM	X	X	X	✓
Mean Arterial Pressure	STRUC	✓	✓	X	X
	FREE	✓	✓	X	X
	PAC	✓	✓	X	X
	COM	✓	✓	✓	X
Total to HDL Cholesterol Ratio	STRUC	✓	X	X	X
	FREE	✓	X	X	X
	PAC	✓	X	X	X
	COM	X	✓	X	X
LDL Cholesterol	STRUC	✓	✓	X	X
	FREE	✓	X	X	X
	PAC	✓	✓	X	X
	COM	✓	X	X	X

✓ = positive effect, X = negative effect, - = no effect

Table 17 Classification of within group quartiles highlighting positive effects

VO_2 (ml/kg/min)	Low	Mod Low	Mod High	High
STRUC	<28	28-33	33-41	>41
FREE	<28	28-34	34-42	>42
PAC	<27	27-33	33-43	>43
COM	<29	29-36	36-42	>42
Fat Mass (kg)	Low	Mod Low	Mod High	High
STRUC	<17	17-21	21-30	>30
FREE	<16	16-21	21-29	>29
PAC	<17	17-22	22-29	>29
COM	<16	16-21	21-26	>26
Body Fat Percentage (%)	Low	Mod Low	Mod High	High
STRUC	<23	23-30	30-34	>34
FREE	<23	23-27	27-36	>36
PAC	<25	25-30	30-36	>36
COM	<25	25-30	30-36	>36
Lean Mass (kg)	Low	Mod Low	Mod High	High
STRUC	<45	45-53	53-63	>63
FREE	<42	42-50	50-60	>60
PAC	<41	41-49	49-64	>64
COM	<41	40-48	48-63	>63
Mean Arterial Pressure	Low	Mod Low	Mod High	High
STRUC	<87	88-96	96-101	>101
FREE	<87	88-95	95-100	>100
PAC	<90	90-97	97-103	>103
COM	<85	86-92	92-98	>98
Total:HDL Cholesterol	Low	Mod Low	Mod High	High
STRUC	<2.7	2.8-3.4	3.4-4.2	>4.2
FREE	<2.6	2.6-3.2	3.2-4.4	>4.4
PAC	<2.6	2.6-3.4	3.4-4.5	>4.5
COM	<2.7	2.7-3.3	3.3-4.6	>4.6
LDL Cholesterol (mmol/L)	Low	Mod Low	Mod High	High
STRUC	<2.14	2.14-2.51	2.51-3.09	>3.09
FREE	<1.85	1.85-2.37	2.37-2.92	>2.92
PAC	<2.14	2.14-2.65	2.65-3.05	>3.05
COM	<1.96	1.96-2.38	2.38-3.16	>3.16

Note: Highlighted quartiles indicate a mean positive effect.

4.5 Discussion

The main findings of this investigation were that over a 48 week intervention period STRUC, FREE, PAC and COM elicited statistically similar reductions in cardiovascular risk at the group level. Changes in cardiovascular risk factors were however mediated by the baseline status of participants, and different effects were observed in different quartiles of the cohort depending on the intervention completed.

Although there were no statistically significant differences in the changes observed between the interventions, there were noticeable differences in the percentage change generated. In VO_2 for example there were mean clinically relevant improvements in STRUC (7.5%), FREE (5.5%) and PAC (6.8%), whilst a 0.9% reduction is reported in the COM group. Similar trends can be observed in BF% (STRUC improved 4.7%, FREE 0.59%, PAC 2.6%, while COM increased by 0.6%) and LM (STRUC improved 2.6%, FREE 1.4%, PAC 2.4%, while COM decreased 2.6%).

These effects when taken as a whole are however influenced by the impact of baseline status on each dependant variable. That is, data could be influenced by the fact that in those participants 'healthy' at baseline there was a negative response to the interventions. Although a repeat of analysis containing only those participants meeting the ACSM sedentary criteria i.e. the lowest 20^{th} percentile of normative values [32] (detailed in Table 18) revealed no differences in the statistical outcomes i.e. one way ANOVAs.

Table 18 ACSM sedentary classifications

Age Range (years)	VO_2 (ml/kg/min) Male	VO_2 (ml/kg/min) Female
30-39	36.7	29.9
40-49	34.6	28
50-59	31.1	25.5

Results for cholesterol reported above are inconsistent with the literature. A major review and meta-analysis [150] investigating the impact of exercise interventions on lipid profile suggests that the mean changes to be expected range between 4-34% improvement in LDL cholesterol, 3.5-23% improvement in HDL cholesterol, and 10-25% improvement in total cholesterol. The present investigation there is a negative mean impact of each intervention upon each component of lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, TC: HDL and nonHDL cholesterol, with the exception of STRUC on total cholesterol (-0.45%) and FREE on HDL cholesterol (0.2%), both of which are negligible effects. The data reported by Tambalis et al [150] was collected in clinical, laboratory based trials where non-compliant participants were removed from the analysis. Additionally the intensities of exercise prescribed would have been monitored and enforced in a way not possible in this ecologically valid investigation, or in a working fitness centre environment. As is highlighted in the exercise recommendations provided for lipid profile in Chapter 2 the intensity of exercise is a significant factor in the clearance of LDL cholesterol [144] and although the STRUC programme did incorporate intensities that meet these recommendations there is no way of determining whether this was completed. Previous literature does however suggest that general increases in physical activity will be met by increases in HDL cholesterol [128]. This is not supported by data from this investigation. Although there were increases in VO_2, an indicator of ones' physical activity levels, these were not associated with changes in HDL cholesterol (non-significant correlation, r=0.09).

Results reported above for body composition are however more consistent with findings elsewhere. A literature search for other 48 week / one year interventions revealed three other investigations. The findings from which (BF% and BF) are presented below along with data from the current investigation (Table 19).

Table 19 Findings from 48 weeks interventions in current literature - body composition

Dependant Variable	Friedenreich et al [224]	Campbell et al [270]	Rokling-Andersen et al [271]	STRUC	FREE	PAC
Body Fat %	42.2 – 40.2 -4.7%	47.2 – 44.02 -1.5%	24.9 – 23.9 -4%	29.16 – 27.85 -4.7%	29.98 – 29.46 -0.59%	31.35 – 30.35 -2.63%
Body Fat (kg)	30.9 – 28.5 -7.8%	Not reported	22.4 – 21.4 -4.5%	24.37 – 23.07 -4.4%	23.51 – 23.29 -0.93%	24.51 – 23.89 -0.42%

Participants in the STRUC condition, completing an exercise programme based upon the literature reported in Chapter 2, saw improvements in body composition that are similar to that in clinical research and delivered in semi-supervised exercise settings. Improvements in FREE and PAC groups are however less substantial. Data suggest that by leaving participants or clients to select their own exercise patterns in a traditional fitness centre model i.e. buying a membership and attend a facility, it may not be possible to replicate the findings reported elsewhere. A programme designed based upon such literature may be as effective however. In fact, the participants included in analysis by Friedenreich et al [224] and Campbell et al [270] had substantially higher BF and BF% levels at baseline than those in the current investigation. Therefore, given the already established relationship between baseline body composition and improvements made over 48 weeks in this investigation, it could be hypothesised that the effect may actually be greater in this community based intervention than those conducted in the clinical settings. Of the 48 week investigations cited above, only Campbell et al report VO_2max, finding an average increase of 13.8% compared with 7.53% mean increase in the STRUC condition. Once again however the baseline VO_2max reported by Campbell et al was 14ml/kg/min lower than in the current investigation (20.7 ml/kg/min compared with 34.84 ml/kg/min).

Data suggest that the ecological validity of the exercise is medicine hypothesis is low when lipid profile is the dependant variable, or the cardiovascular risk factor being targeted. Conversely however when body composition or cardiorespiratory fitness are being targeted a structured, progressive exercise programme may be able to replicate laboratory based findings in the real world. This does not seem to be the case with FREE or PAC however.

The way in which different subgroups were affected by the interventions has implications for their future delivery. More importantly data has the ability to predict positive outcomes in participants when recommending the interventions i.e. if a participants VO_2max was known at baseline and it was above 33ml/kg/min it could be predicted that STRUC would be required to generate a positive impact, whilst PAC would be effective for those below 28ml/kg/min. Similarly in body composition, STRUC generated positive changes in in all subgroups, PAC 75% and only those 25% most at risk saw benefits following the FREE condition.

4.6 Conclusions

Over the 48 week intervention period there were statistically similar reductions in cardiovascular risk factors, although changes were mediated by the baseline health status of participants. When this is considered different effects were observed in different quartiles of the cohort depending upon the intervention completed.

Improvements in cardiorespiratory fitness and body composition where most substantial, clinically relevant, and effected the greatest percentage of the cohort in the STRUC condition. Effects on blood pressure and cholesterol levels (lipid profile) were inconsistent and did not meet the expectation set out in the current, laboratory based, literature. Conversely however improvements in body composition and cardiorespiratory fitness following STRUC supported those predicted by the literature that influenced the creation of the exercise programme.

These data suggest that the ecological validity of the exercise is medicine hypothesis is limited to those risk factors that do not require control over the volume or intensity of exercise completed. Where a dose-response relationship exists between amount of physical activity completed and improvements made, the ecological validity, and ability to translate findings from the laboratory to real world intervention, is high.

5. Study 2: Adoption, retention and attrition associated with community fitness centre based physical activity interventions

5.2 Introduction

The following chapter presents an analysis of Hypothesis 3, that retention at 48 weeks would be greater in the structured exercise programme and physical activity counselling interventions than unstructured fitness centre use and the measurement only condition. Retention is defined as presenting for data collection at the 48 week point and is expressed as a percentage value, for example, 75% retention indicates that 75% of participants completed the intervention (the flip side of retention is attrition, also expressed as a percentage, in the above example attrition would be 100 - 75% = 25%). The role of biosocial factors such as age, gender, baseline cardiorespiratory fitness (VO_2) and body composition (BF%) in retention and attrition are investigated. Such analyses may aid in the provision of future community based physical activity interventions, supplemented by data presented in Chapter 4.

Chapter 4 discussed the ecological validity of the exercise is medicine hypothesis. The importance of such findings are directly related to retention within such interventions i.e. although there may be a potentially positive effect, public health benefits will be negligible if engagement is low. Thus, the ecological validity of the exercise is medicine hypothesis is impacted by the ability to replicate laboratory findings within, amongst others, the service delivery setting [262, 263], in this instance community fitness centres.

Current literature reports that mean retention within exercise referral schemes lasting between 8 – 24 weeks is 49% when studied as a product of randomised controlled trials (n=6) and 43% in observational studies (n=16) [104]. This is in contrast with previous fitness centre based research (Table 20) that reports overall retention levels similar to those presented in the current laboratory based literature. For example the 48 week fitness centre based intervention authored by Brehm et al [98] reports retention of 84%. This arguably compares favourably with the three 48 week laboratory based interventions discussed in Chapter 4 i.e. 97% [224], 94% [270] and 84% [271]. Psychological models have been used to examine behaviour changes such as the adoption and maintenance of a physically active lifestyle e.g. the Health Belief Model [272] suggests that those most aware of their own health problems and the perceived benefits of physical activity are more likely to become active. Factors specific to exercise that have been reported to influence retention within real world fitness centre based initiatives have included anxiety, a lack of self-confidence, and a failure to relate with physical activity / exercise leaders [55]. Physical activity counselling has been proposed as not only a means of utilising the expertise of exercise professionals in a wider context [114], but also of removing what is often perceived as the intimidatory aspect of attending exercise classes or the gym floor itself. PAC has however yet to be systematically delivered from fitness centres themselves, only in traditional primary care settings (GP surgeries) [109], where retention was reported as 81.7% for the 25 week intervention.

Table 20 Retention level in previous fitness centre based research

Lead Author	Length of intervention	Retention percentage
Jolly [91]	12 weeks	56%
Mathieu [94]	10 weeks	74%
Kreuzfled [95]	12 weeks	79%
Dunn [53]	24 weeks	94%
Van Roie [96]	44 weeks	93%
Brehm [98]	48 weeks	84%
Graffagnino [75]	24 weeks	47%
Nishijima [100]	24 weeks	89%

The present study will compare the adoption, retention and attrition associated with three potential models of physical activity provision available to community fitness centres and a comparison group receiving no intervention. The role of biosocial factors such as age, gender, baseline VO_2 and body composition in maintenance and attrition are investigated.

5.3 Methods

The recruitment of fitness centres, training of exercise professionals, and recruitment of participants is as per that presented in Study 1 (Chapter 4).

5.3.1 Study design

Figure 5 presents the journey of participants through this investigation. In short however, participants meeting the selection criteria above were offered the choice of increasing physical activity levels via fitness centre based exercise, or lifestyle based physical activity. Having chosen either a fitness centre or lifestyle based intervention participants were then randomised into one of two intervention groups i.e. structured or unstructured exercise (fitness centre based exercise), or, physical activity counselling or a measurement only comparison group (lifestyle based intervention). Data was collected at baseline, 24 and 48 weeks, with the interventions (detailed below) delivered throughout this 48 week period.

5.3.2 Interventions

The four interventions have been described in Chapter 4. A short summary is however provided below:

Structured exercise programme (STRUC): Participants had access to all fitness centre facilities and received an individualised exercise programme to follow (designed to meet the exercise recommendations presented in Chapter 2). Exercise professionals were instructed to meet STRUC participants once a month to discuss their programme, the intervention generally and to maintain motivation. The full programme is detailed below in Figure 6.

Unstructured fitness centre based exercise (FREE): Participants had access to all fitness centre facilities but received no structured programme to follow. Exercise professionals were instructed to meet with FREE participants once each month to discuss the intervention generally and to maintain motivation.

Physical activity counselling (PAC): Participants did not have access to any fitness centre facilities. Exercise professionals were instructed to meet participants once each month and deliver counselling sessions. These counselling sessions were to be structured according to the 5 A's model and delivered within the fitness centre in a location deemed appropriate by the exercise professional such as a coffee shop or private office.

Comparison (COM): Participants did not have access to any fitness centre facilities. Exercise professionals were instructed have no contact with participants during the intervention period. The only contact between exercise professionals and the participants was to arrange data collection at 24 and 48 weeks.

What are represented by these three interventions are models of provision that could be adopted by community fitness centres. A summary of the proposed communication between the exercise professionals and participants in each group is presented in Table 13.

5.3.3 Data collection

Participants reporting for baseline data collection were considered 'recruited' and were on that basis included in all subsequent analyses. Similarly those participants reporting for data collection at the 48 week point were considered 'retained'. Participant's age, gender, body composition and cardiorespiratory fitness were recorded at both baseline and 48 weeks. These procedures are outlined below.

5.3.3.1 *Body composition*

Measures of body fat percentage (%) were collected via bio-impedance (Bodystat 1500, Bodystat, Isle of Man, UK).

5.3.3.2 *Cardiorespiratory fitness*

Maximal aerobic capacity (VO_2max) was predicted using a sub-maximal treadmill protocol (Modified Blake Protocol [254, 255]). Briefly, participants were asked to walk on a treadmill at a speed between 3.6kph and 5.6kph depending on ability for three minutes. At the end of this this initial three minute period the gradient of the treadmill was increased by one percent each minute. During this process participants were asked to rate their perceived exertions on the OMNI (1-10) scale. The test was stopped when participants indicated their perceived exertion level was above six (hard) and / or their heart rate reached 150bpm. Throughout the test oxygen consumption was monitored via direct gaseous analysis (Fitmate Pro, COSMED, Italy [256, 257]) and using the relationship with heart rate, predicted VO_2max was extrapolated. This was an automated procedure and required no calculation by the exercise professional.

5.3.3.3 *Data collection procedure*

Data were collected following randomisation at baseline. Participants were asked to note their dietary intake for the day leading up to data collection. This was collected by exercise professionals and participants were asked to replicate this at the 48 week data collection point. Exercise professionals were instructed to ensure that each data collection appointment was booked for the same time of day each time. These measures were put in place to limit changes in dependant variables that would not be attributable to the intervention.

5.3.4 Statistics

To test Hypothesis 3; that retention within the 48 week interventions would be higher in STRUC and PAC than FREE and COM, the following procedure was followed. Those participants reporting for data collection at 48 weeks were considered 'retained'. The percentage of participants reporting for 48 week data collection across the whole cohort was calculated and used to predict retention levels in each intervention group, assuming retention to be exactly the same in each i.e. if retention across the whole cohort was 50%, it was predicted that this would be the same for each intervention group – providing predicted values for Chi-Squared analysis. These predicted values were compared with observed values in a Chi-Squared test with alpha set at $P<0.05$, whereby a significant result would indicate a difference between the intervention groups and cause the null hypothesis to be rejected. Post-hoc comparisons between the groups were completed by calculating standardised residuals (z score) between expected and observed values in each intervention group, in which instance the critical value was set at +/- 1.96 (to correspond with alpha set at 0.05), signifying significantly higher (+) or lower (-) retention than predicted if retention was equal between groups. Odds ratios were then calculated to compare directly between the groups. This process was followed in accordance with previous such research [273-275].

The same statistical procedure was followed to examine how age, gender, baseline VO_2 and body composition impacted upon retention within the investigation as a whole, by presenting baseline data as quartiles (and classifying as groups). This process was repeated for within group analysis.

5.4 Results

5.4.1 Recruitment and retention

A target of 2080 participants was projected and funded at the outset of the project. A total of 1146 participants were recruited. This equates to 55% of the initial target. These were divided between the exercise pathway (n=648) and the physical activity pathway (n=498). At 48 weeks a total of 366 participants were still involved in the interventions / reported for data collection. A schematic of the participant pathway is presented in Figure 7.

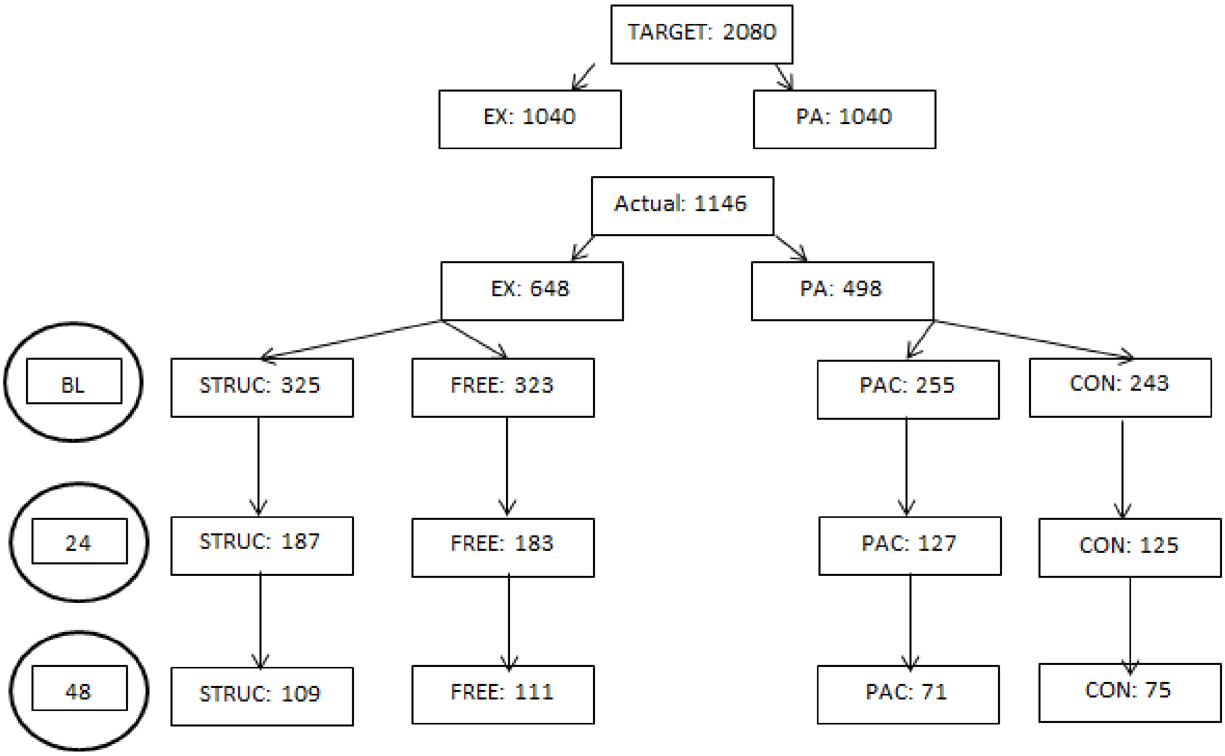

Figure 7 Recruitment and retention

Chi-Square analysis revealed no significant difference in retention between the intervention groups (P=0.31). Therefore the hypothesis that retention would be greater in STRUC and PAC than FREE and COM can be rejected. There was however a significant difference in pathway choice between fitness centre based exercise and lifestyle based physical activity (P<0.001 – when predicting allocation to be equal, in comparison with observed values).

5.4.2 Biosocial predictors of retention

5.4.2.1 *Whole cohort*

More females participants were recruited than male (61% vs 39%), although analysis suggests gender had no impact upon retention across the whole cohort (P=0.838). Similarly data suggest that neither baseline VO_2 or BF% significantly impacted on retention (P=0.244 and 0.462 respectively). However a significant association between baseline age and retention was observed (P=0.047), with eldest quartile of participants (z = 2.4) 38% more likely to complete the 48 week intervention than the youngest (z = -0.94). Data are presented in Table 21.

Table 21 Chi Square analysis and standardised residual scores - whole cohort

Whole Cohort		Standardised residual – z score			
Biosocial factor	Chi Square (P value)	High	Mod High	Mod Low	Low
VO_2	0.244	1.04	-0.31	0.73	-1.56
BF%	0.462	-0.31	1.46	-0.42	-0.42
AGE	0.047*	2.40*	0.00	-1.15	-0.94
		Male		Female	
Sex	0.838	-0.16		0.13	

5.4.2.2 *Within group analysis*

Age: There was a significant association between baseline age and retention within the PAC intervention (P=0.027) (Table 22). Data suggest the eldest participants are twice as likely to complete the 48 weeks intervention as the youngest (z = 2.36 vs -0.94), according to the odds ratio. A non-significant trend is observed in STRUC (z = High 1.35 vs Low -1.35). Data are presented in Table 23.

Table 22 Chi Square analysis - within group impact of age

Age	Intervention Group			
	STRUC	FREE	PAC	COM
Chi Square (P Value)	0.282	0.543	0.027*	0.530

Table 23 Standardised residual (z) scores - within group impact of age

Standardised residual (z)	**High**	**Mod High**	**Mod Low**	**Low**
STRUC	1.35	0.38	-0.19	-1.35
FREE	1.13	-0.38	-0.38	-0.76
PAC	2.36*	-1.65	0.00	-0.94
COM	0.23	0.92	0.00	-1.15

Gender: Data reveal no significant association between gender and retention within any intervention group. All data are presented in Tables 24 and 25.

Table 24 Chi Square analysis - within group impact of gender

Sex	Intervention Group			
	STRUC	FREE	PAC	COM
Chi Square (P Value)	0.547	0.248	0.808	0.401

Table 25 Standardised residual (z) scores - within group impact of gender

Intervention Group	Male	Female
	Standardised Residual (z)	Standardised Residual (z)
STRUC	0.49	-0.36
FREE	-0.88	0.74
PAC	0.19	-0.15
COM	-0.71	0.45

Cardiorespiratory fitness: Data reveal no statistically significant association between baseline VO_2 values and retention (data presented in Table 26). A non-significant trend in both STRUC and PAC was however evident. These trends suggest that a fitter participant at baseline is more likely to complete STRUC (z = 1.15) and less likely to complete PAC (z = -1.65), whilst a less fit participant is less likely to complete STRUC (z = -2.12) and more likely to complete PAC (z = 0.71). All data are presented in Table 27.

Table 26 Chi Square analysis - within group impact of baseline VO_2

VO_2	STRUC	FREE	PAC	COM
Chi Square (P Value)	0.087	0.536	0.126	0.530

Table 27 Standardised residual (z) scores - within group impact of baseline VO_2

Standardised residual (z)	**High**	**Mod High**	**Mod Low**	**Low**
STRUC	1.15	0.77	0.38	-2.12*
FREE	0.76	-0.38	0.76	-0.94
PAC	-1.65	1.41	-0.71	0.71
COM	-0.23	0.92	0.00	-1.15

Body composition: Data reveal a significant association between baseline BF% and retention in STRUC (P=0.044) and COM (P=0.023), data are presented in Table 28. Although there are no significant post-hoc comparisons in COM, STRUC data suggest that those with the highest baseline BF% are significantly less likely to be retained within STRUC (z=-2.31). This seems to represent the fact that, based on the odds ratio, the odds of participants dropping out of the intervention were twice (2.13) those of with the lowest BF%. Data are presented in Table 29.

Table 28 Chi Square analysis - within group impact of baseline BF%

BF%	Intervention Group			
	STRUC	FREE	PAC	COM
P Value	0.044*	0.878	0.943	0.023*

Table 29 Standardised residual (z) scores - within group impact of baseline BF%

Standardised residual (z)	**High**	**Mod High**	**Mod Low**	**Low**
STRUC	-2.31*	1.35	0.19	0.96
FREE	0.19	-0.76	0.19	0.19
PAC	0.24	-0.47	0.24	0.24
COM	0.00	2.52	-1.15	-1.38

5.5 Discussion

Overall, data indicate that allocation to treatment did not impact upon retention. Retention within the specific interventions (STRUC 34%, FREE 34% and PAC 29%) is similar to the mean reported in exercise referral schemes lasting between 8 – 24 weeks, that is 49% in randomised controlled trials (n=6) and 43% in observational studies (n=16) [104]. This is in stark contrast with the previously outlined 48 week intervention studies that were completed in laboratory settings where retention levels are reported as 97% [224], 94% [270] and 84% [271]. These data highlight a substantial difference between data collected within a laboratory and that collected in a working fitness centre environment. This is a factor that has the potential to undermine and limit the use of exercise as medicine. If commissioning bodies cannot be confident that the literature supporting the exercise is medicine hypothesis will translate into real world community settings, whether in terms of the magnitude of clinical effect or of the number of people completing the interventions, their support will be withdrawn. In the same way that in post marketing (Phase Four) clinical trials, if it is found that in practice patients do not take a medicine, or there are additional, unwanted side effects the medicine is withdrawn [63] from the market. This argument is supported by the fact that recruitment in the current investigation met 55% of the initial target, which compounded with the overall retention figure suggests that only 18% of the targeted population received the full intervention.

The retention levels reported in the current investigation are also low in comparison with the previous fitness centre based research reported in Chapter 2 and presented in Table 20, and the pilot study presented in Chapter 3 (in which retention was 92% of n=105 participants). It seems the fundamental difference is the delivery mechanism i.e. in both the exercise referral schemes and the current investigation there was no direct researcher involvement with intervention delivery or data collection. Consequently the way in which physical activity interventions would be / are delivered in the real world is better represented in the current investigation and data has greater real world replicabilty. This does however highlight both a limitation of current real world physical activity programmes, and a principle difference between research oriented schemes and those delivered within communities. More research is required to investigate the behavioural differences i.e. retention and activity completed, between community led interventions and those lab based studies presented in the scientific literature. Data from the current investigation suggests that these factors may limit the success of physical activity interventions and thus limit the ecological validity of the exercise is medicine hypothesis.

The examination of the biosocial factors that may have impacted upon retention in the current investigation does however provide insight that could influence the future delivery / recommendation of physical activity interventions. Across the whole cohort lowest retention was observed in the lowest quartile for fitness i.e. those arguably most in need of the intervention, and also the group that (amongst those retained) demonstrated the greatest benefits. This lack of sustained behaviour change can be examined via the Transtheoretical Model of Behaviour Change, a model that assesses the readiness of a person to adopt a new behaviour [276]. The person moves between stages from pre-contemplation, where the new behaviour is not even being thought about, through contemplation (recognising the current behaviour may present an issue), preparation, action, maintenance and finally termination where a new behaviour has been adopted [276]. Those with the highest baseline fitness levels, and therefore arguably the highest physical activity levels when entering the intervention [277], may have already successfully completed the preparation and action stages of the model – that is they had planned to adopt exercise and had taken action, even if only the purchasing of some training shoes - and seen the intervention as a way of continuing this process. Conversely those participants with the lowest fitness levels may have been in pre-contemplation or perhaps more likely contemplation (given the fact that they entered the intervention and therefore aware that a problem may exist), and failed to move into preparation or action.

That more female participants were recruited than male is consistent with previous work [104]. Recent research suggests that ability to make exercise part of a routine, intrinsic motivation, and psychosocial commitments are key drivers that contribute to increases in middle-aged female participation in physical activity and exercise [278]. Similarly the literature suggests that retention in such interventions will be improved the older participants become [279], a trend observed in the current investigation. The Health Belief Model [272] may help to explain this trend. The health belief model posits that those most aware of health problems and perceived benefits of actions to reduce them are more likely to adopt such behaviours [272], and therefore the older one becomes the more aware of health risks they become and more likely to adopt positive behaviours such as increases in physical activity [280]. Both research [103], and the Health Belief Model would suggest that those participants who see themselves most at risk of cardiovascular disease are those more likely to adhere to interventions. In this instance however body fat percentage, arguably the most widely recognised risk factor of cardiovascular disease [281], had no impact upon retention across the whole cohort, and in fact significantly reduced retention within STRUC. It could be predicted however that those participants may have the lower self-efficacy [55], less intrinsic motivation [278], and generally more averse to the fitness centre environment – specifically the gym floor that houses the equipment required for STRUC [53]. It is noted however that there may be differences between the measured body fat percentage, and the level of body fat that is perceived by the participant [282] i.e. low fat mass compared to height, but high compared to lean body mass, that may have mediated this proposed effect.

Within group analysis can provide guidance for future recommendations and influence best practice, especially when combined with the cardiovascular risk data presented in Chapter 4. Data suggest that in the STRUC condition fitter participants at baseline were more likely to maintain engagement. STRUC was also the intervention that had a positive effect on the fittest participants VO_2 levels, as well as those most at risk i.e. lowest baseline VO_2 quartile. Conversely however PAC had the higher retention in the least fit participants, the only quartile upon which the intervention also had a positive effect on VO_2 levels. Data would suggest therefore that those participants with higher fitness levels when entering an intervention should be recommended STRUC as they are less likely to see benefit or be retained in PAC, whilst those who are sedentary when entering will be unsuited to STRUC and more likely to be retained and see benefit in PAC.

5.6 Conclusion

Data suggest that individuals with higher VO_2 levels at commencement may be more likely to be retained within fitness centre based exercise interventions, and consequently such interventions may not meet the requirements of those most at need. This is emphasised by the STRUC intervention where trends suggest a decrease in retention with lower levels of baseline body composition and fitness levels. PAC may provide a means of increasing retention in those with the lowest fitness levels, and also those who according to the cardiovascular risk data will see the greatest benefit.

6. Study 3: Delivery and participation perspectives associated community fitness centre based physical activity interventions

6.2 Introduction

Data presented in Chapters 4 and 5 provide some insight into the degree to which the extensive literature presented in Chapter 2 translates into the real world. Data suggest that although there are positive health benefits associated with physical activity and exercise interventions, these health benefits do not completely mirror those reported in the literature. The impact i.e. reduction in cardiovascular risk, is reduced and less consistent, only effecting sub-groups of the cohort. Chapter 5 suggests however that a more fundamental difference between the current literature and data reported in the current investigation is the retention of participants within the interventions. Although some biosocial factors that may have impacted upon retention are presented in Chapter 5, a more in depth analysis is required that considers the view of both the exercise professionals delivering the intervention and the participants completing it. Such analysis may add to the conclusions drawn in Chapters 4 and 5 and provide additional information that can influence the delivery of future health community based physical activity interventions.

In an attempt to maintain the ecological validity of the current investigation and to ensure the generalisability of any conclusions, interviews or questionnaires were not conducted during the 48 week intervention (that is, the research protocol observed standard operating procedure at the sites involved). Any attempt to conduct such analysis might have altered the behaviours of participants [283], and consequently influenced the dependant variables being investigated i.e. cardiovascular risk factors and retention. As a result a survey designed for completion following the 48 week intervention was sent to all participants, including those not reporting for data collection.

As has been detailed previously the fundamental difference between the current investigation and the literature presented in Chapter 2, both previous fitness centre based research and that which formed the exercise recommendations presented and implemented in the current investigation, is in both the delivery of interventions and collection of data by practitioners as opposed to by researchers. Consequently information provided by the exercise professionals with reference to recruitment of participants, data collection and intervention delivery, completed within a working fitness centre environment is of great significance to the future delivery of such initiatives. Questions provided to exercise professionals and participants at the end of the 48 week intervention are presented below, and their findings discussed in context with the physiological and behavioural data presented previously.

6.3 Methods

The recruitment of fitness centres, training of exercise professionals, recruitment of participants, and interventions delivered is as per that presented in Study 1 (Chapter 4).

6.3.1 Data collection

Surveys were delivered and completed electronically via Survey Monkey (www.surveymonkey.net). The link required to complete the participant questionnaire was sent to the exercise professionals, who were then instructed to forward it onto the participants. The researcher did not hold direct contact information for participants. Questionnaires aimed to elucidate factors that may have impacted upon the outcomes of the interventions, such as improvements in cardiovascular risk factors and retention.

6.3.1.1 *Exercise professionals*

The questions sent to exercise professionals are presented in Table 30. The full survey, including the response options is presented in Appendix 1.

Table 30 Survey questions sent to exercise professionals

When your site was applying to host part of the investigation, how were you approached to take part?
Which training days did you attend?
To what extent do you feel the training you received prepared you to deliver the investigation?
You were asked to recruit participants who were inactive, is this a population you deal with on a regular basis?
How did you find attempting to recruit inactive participants for the investigation?
Do you feel you were successful in recruiting sedentary participants?
Do you believe your fitness centre is appropriately set up to cater for sedentary populations?
Did you feel confident delivering the health checks?
In your opinion did participants enjoy receiving such health checks within a fitness centre?
In your opinion did the measurement at the beginning, half way though, and at the end of the intervention aid in the retention and performance of participants?
What, if any, aspects of the health check would you implement within your fitness centre?
Did you feel comfortable delivering the structured exercise programme?
Did you feel comfortable delivering the general (unstructured) fitness centre use?
Did you feel comfortable delivering the physical activity counselling intervention?
What factors do you think have stopped participants in this investigation attending your facility?
How often did you communicate with participants following the structured exercise programme?
How often did you communicate with participants completing the general (unstructured) fitness centre use?
How often did you communicate with the participants receiving the physical activity counselling intervention?
In your opinion is it feasible and appropriate to deliver physical activity counselling from within a fitness centre?

6.3.1.2 *Participants*

The questions sent to participants are presented in Table 31. The full survey, including the response options is presented in Appendix 2.

Table 31 Survey questions sent to participants

Which category below includes your age?
In which town / city was the fitness centre you attended?
How were you approached to take part in the investigation?
What made you want to take part?
Which programme were you assigned to?
Do you have any comments about the way your health check/s were delivered?
Do you think the delivery of clinical testing within a fitness centre was appropriate?
How would you rate the communication with the exercise professionals at your centre?
How often did you communicate with your exercise professional?
Was the programme / intervention you received appropriate for your needs?
Were you satisfied with the results you achieved at your 24 week health check?
Did these results influence your decision to continue with the programme / intervention?
What other factors influenced your decision to continue with the programme / intervention?
Did you feel fitter / healthier as a result of taking part in this investigation?

6.4 Results

6.4.1 Exercise professionals

Response rate to the survey was very low (19%). Of the 63 exercise professionals that attended training with the researcher and who subsequently delivered the investigation, 12 provided responses.

Data gathered from exercise professionals (n=12) revealed the following:

- To what extent do you feel the training you received prepared you to deliver the investigation?
  - 66.7% (8) - very much so
  - 25% (3) - to a certain extent
  - 8.3% (1) - somewhat.
- 100% (12) of responders suggested they were confident delivering 'health checks' and that participants enjoyed / were comfortable receiving them
- Inactive participants are a population that the exercise professionals deal with on a regular basis (75% - 9).
- Only 8.3% (1) found it easy to recruit sedentary participants, 58.3% (7) found the experience mixed, 16.7% (2) challenging and 16.67% (2) very challenging.
- 58.3% (7) of exercise professionals suggested they were successful in recruiting sedentary participants.
- 91.7% (11) of exercise professionals believe their fitness centre is appropriately set up to cater for sedentary populations.
- 63.7% (7) of exercise professionals believed that measurement positively influenced retention within the interventions.
- The Table 32 below summarises findings regarding intervention delivery:

Table 32 Exercise professional - intervention delivery (n=12)

	Comfortable delivering?		Contact with participants?				
Intervention	**YES**	**NO**	**Weekly**	**Bi-weekly**	**Monthly**	**Bi-monthly**	**At fitness centre**
STRUC	72.8%	27.3%	0%	0%	33.3%	11.1%	55.6%
FREE	90.9%	9.1%	0%	11.1%	55.6%	0%	33.3%
PAC	72.8%	27.3%	0%	0%	100%	0%	0%

- Exercise professionals indicated that; demotivation (4), boredom (6), lack of benefits (4), not achieving goals (4), lack of interaction with peers (3) and lack of interaction with exercise professional (4), were reasons for participants leaving the intervention.
- 80% (10) of exercise professionals believe it is feasible to deliver PAC from community fitness centres.
- The data in Table 33 suggests that results achieved at 24 weeks influenced retention within the interventions.

Table 33 Exercise professional - impact of 24 week results on 48 week retention (n=12)

Q. Which of the following do you agree with most strongly?	Percentage agreeing
A1. Positive changes between baseline and 24 weeks increased the likelihood that participants would continue with the intervention - increased motivation	72.7%
A2. Positive changes between baseline and 24 weeks decreased the likelihood that participants would continue with the intervention - decreased motivation as aims achieved	18.2%
A3. Negative changes between baseline and 24 weeks increased the likelihood that participants would continue with the intervention - increased motivation	18.2%
A4. Negative changes between baseline and 24 weeks decreased the likelihood that participants would continue with the intervention - decreased motivation	45.5%

6.4.2 Participants

Response rate to the survey was very low (4%). Of the 1146 participants that were recruited and allocated to a treatment 44 provided responses.

Data gathered from participants (n=44) reveals the following:

- The decision to take part in the investigation was motivated by a desire to improve health in 46.2% (20) of responders. 43.6% (19) said that the free health check was a motivation, 17.5% (8) took part to increase physical activity levels, 7.7% (3) to improve psychological wellbeing, and 5.1% (2) because of the offer of free fitness centre membership.
- 97.7% (43) of participants approved of clinical testing within a fitness centre environment.
- Communication with exercise professionals was rated excellent by 45.5% (20) of responders, good by 38.6% (17), satisfactory by 16.6% (7), un-satisfactory by 2.3% (1), and poor by 2.3% (1).

- 6.8% (3) of responders only attended the first health check, 20.5% (9) attended at baseline and 24 weeks, 20.5% (9) attended at baseline and 48 weeks, while 52.3% (23) attended all three.
- Table 34 highlights which intervention group responders were allocated to:

Table 34 Participants - intervention group allocated (n=44)

Group	**STRUC**	**FREE**	**PAC**	**COM**	**Didn't know**
Percentage of responders	29.6%	34.1%	11.4%	18.2%	6.5%

- Table 35 details level of communication with exercise professionals during the intervention period:

Table 35 Participants - communication with exercise professional (n=44)

Communication	Very often – once a week	Often – Bi-weekly	Once a month	Not very often – every couple of months	Sparingly – only to arrange health check
Percentage of responders	11.9%	16.7%	28.6%	19.1%	23.8%

- Responses suggest that achieving positive results at 24 weeks was a major motivator for continued participation. Responses are presented in Table 34.

Table 36 Participants - impact of 24 week results on 48 week retention (n=44)

Q. Which of the following do you agree with most strongly?	**Percentage agreeing**
A1. Achieving positive outcomes at 24 weeks made me more likely to continue with the programme / intervention	70.5%
A2. Achieving positive outcomes at 24 weeks made me less likely to continue with the programme / intervention	9.1%
A3. Negative outcomes at 24 weeks made me more likely to continue with the programme / intervention	9.1%
A4. Negative outcomes at 24 weeks made me less likely to continue with the programme	11.4%

- Motivators for retention are presented in Table 35.

Table 37 Participants - factors motivating participation (n=44)

Enjoyment	Positive outcomes	Negative outcomes	Rapport with EX Profs	Prospect of better health	Feeling fitter / healthier	Psychological wellbeing
29.3%	43.9%	2.4%	24.4%	48.8%	61%	36.6%

- 71.4% (31) of responders felt fitter / healthier as a result of the intervention they received.

6.5 Discussion

Data from the post intervention survey provide some insight into the motivators for recruitment into the interventions and retention within them. However response rates from both practitioners and participants were extremely low and it is therefore problematic to generalise from these, specifically as there may be substantial response bias. Results from the participant survey (n=44) suggest that improving health (46.2% - 20) and the offer of a free service i.e. not membership for a facility, but the intervention and health checks (43.2% - 19) were the prime motivators for taking part. This supports the Health Belief Model [272] proposed as a motivator for recruitment and retention in Chapter 5, whereby those most aware of health problems and perceived benefits of actions to reduce them are more likely to adopt health enhancing behaviours such as physical activity.

Although many exercise professionals found it difficult to engage sedentary participants. Only 58.3% (7) suggested they were successful and 33.3% (4) said that the experience was either challenging or very challenging. This is reflected in the baseline cardiorespiratory scores of many of the participants (mean 35.5 ± 10.25ml/kg/min) and the fact that 35.4% (15) of participants responding to the questionnaire were approached to take part in the investigation whilst in the fitness centre. This undermines the selection criteria set by the researcher, that is that participants should have been sedentary when entering the intervention, and highlights an issue presented by asking exercise professionals to recruit participants within the community. This is supported by the unequal allocation between the fitness centre based exercise pathway, and lifestyle based physical activity pathway. Participants were not excluded from the investigation following data collection if, for example, they were too fit, to replicate the way in which such an intervention would be delivered in the real world. Additionally it was noted in the cardiovascular risk factor data that when excluding those not meeting the sedentary criteria set forth by the ACSM there were no changes in the statistical outcomes. This is a factor that may have influenced retention within the intervention however. Data in Chapter 5 suggest that the more active a participant (as indicated by fitness levels) at baseline, the better chance of them being retained within the intervention, and as a consequence if only sedentary participants were recruited retention may have been even lower. This may partially explain the findings from exercise referral literature where retention is similar to the current investigation although across a timeframe of only 8-24 weeks [104], and where participants are recruited directly from primary care and already with increased cardiovascular risk.

Although communication was rated as excellent or very good by 84.1% (36) of participants responding to the questionnaire, this is not necessarily indicative of the wider cohort as 72.7% (32) of the responders completed the full 48 week intervention. Thus this view may not be shared by those who dropped out. Furthermore despite instruction to communicate with participants once a month (barring COM where exercise professionals were instructed to only communicate with participants to arrange data collection), this was not completed. There are varying perspectives on the intervention delivery, revealed in the exercise professional survey. This is perhaps reflective of the wider consumer experience in this industry, and something that limits the ecologically validity of the exercise is medicine hypothesis i.e. the success if an exercise programme or intervention is reliant upon it being delivered to the specification provided. This is the primary concern of a researcher delivering an intervention in a laboratory or clinical setting, but can be seen as a distraction or inconvenience for a working exercise professional.

The consumer experience may have been impacted by the level of communication received by participants. 42.9% (19) of responding participants said they had contact with their exercise professional every couple of months or only to arrange the health checks. Considering that only 18.18% (8) of responders were in the COM group (where this level of communication was instructed), this is a large subgroup that was not receiving regular communication.

Factors that positively influenced retention included feeling fitter and healthier (61% - 27), the prospect of future health benefits (48.8% - 21) and positive changes in health (43.9% - 19). Additionally 36.6% (16) of responders suggested improved psychological wellbeing was a motivator for continuing with the interventions, despite only 7.7% (4) suggesting this was a reason for joining in the first place. Thus it may have been an unexpected benefit for many.

It seems that in both recruitment and retention, health is a determining factor. Seeing improvements in health at 24 weeks was a significant factor in the decision to complete the full 48 week intervention according to 70.5% (31) of responders. On the other hand 11.4% (5) suggested that negative outcomes at 24 weeks impacted their decision to drop out (significant when one considers only 20.5% (9) of those responding to the questionnaire dropped out between the 24 and 48 week data collection points). This was a trend observed by the exercise professionals also; 72.7% (9) of who thought that positive outcomes at 24 weeks positively influenced retention, and 45.5% (5) said that in their opinion negative outcomes at 24 weeks negatively influenced retention. It is hard to gauge what other factors influenced participants dropping out of the investigation as the majority of those completing the questionnaire completed the intervention also (73% - 32). From the exercise professionals perspective however, boredom with the programme / intervention was the most widely provided reason for drop-out. This highlights the importance of keeping interventions continually engaging.

6.6 Conclusions

Data suggest improving health was the primary motivator for recruitment to the current investigation, although exercise professionals found it difficult to engage with and recruit sedentary participants. Communication between the exercise professional and participant was not as regular as instructed by the researcher and may have affected retention within the interventions. This suggests another significant difference between laboratory based, or researcher led research and this ecologically valid investigation. That is that within such research the communication with participants, along with exercise prescribed, is well structured, something it does not seem to be possible in working fitness centres – limiting the ecological validity of the exercise is medicine hypothesis when removed from a structured environment.

7. General discussion

Physical inactivity is associated with increased incidence of cardiovascular disease and other metabolic conditions, and as a result has been recognised as an important and highly significant public health issue [31]. Physical activity and exercise programmes have been shown to be highly effective in the prevention, management and treatment of four modifiable risk factors of cardiovascular disease – dyslipidaemia, insulin resistance, obesity and hypertension [49]. The optimal 'prescription' i.e. mode, intensity, frequency and duration, of exercise however remains uncertain, although evidence based recommendations are presented in Chapter 2. The way in which these recommendations, and the wider research presented in Chapter 2, translate into interventions to be delivered in the real world is open to debate.

In addition to the translation of optimal modes, intensities, frequencies and durations of exercise into real world public health interventions, there is a requirement to develop physical activity programmes that meet the needs of those averse to the fitness centre environment, specifically exercise classes and the 'gym floor' [55]. Physical activity counselling has been proposed as such an intervention [57]. The pilot study detailed in Chapter 3 compared physical activity counselling, with unstructured fitness centre based exercise, and a structured exercise programme the design of which was based upon the conclusions and recommendations made in Chapter 2. Results suggested that all three programmes elicited significant increases in physical activity levels and significant improvements in cardiovascular risk factors, although there were no differences observed between the three intervention groups. Although this study was limited by its short duration and lack of a comparison condition, it did confirm the feasibility of delivering and evaluating such interventions within a working fitness centre environment. In addition, and importantly, it also confirmed that the collection of clinically relevant data, such as cholesterol levels, cardiorespiratory fitness, and body composition, was possible within such an environment.

Following this pilot study a larger (n=1146), ecologically valid, multi-centre (n=26), longitudinal (48 week) investigation (Studies 1, 2 and 3) was completed. To ensure the ecological validity of this investigation it was hosted by fitness centres and delivered by exercise professionals who recruited participants, collected all data and delivered the interventions. Interventions lasted 48 weeks and participants were offered an exercise pathway, and randomised between a structured exercise programme and unstructured fitness centre use, or a physical activity pathway, and randomised between fitness centre based physical activity counselling and a comparison group.

Two key concepts, both crucial to the success of a public health intervention, were investigated; the most effective style of intervention for improving cardiovascular risk in previously sedentary, middle aged adults, and the retention within these interventions. These data are supported, and to a certain extent triangulated, by a follow up questionnaires completed by exercise professionals who delivered the investigation and participants that completed it.

Data reveal that over the 48 week intervention period there were statistically similar reductions in cardiovascular risk factors between the intervention groups, although changes were mediated by the baseline health status of participants. Improvements in cardiorespiratory fitness and body composition were most substantial, clinically relevant, and effected the greatest percentage of the cohort in those completing the structured exercise programme. These improvements met the expectations presented in the literature and suggest that findings from the laboratory based research presented in Chapter 2 are replicable in an ecologically valid environment. Effects on blood pressure and cholesterol levels (lipid profile) were inconsistent however and did not meet expectations.

The type of intervention received did not impact retention rates. Although retention was low in comparison with laboratory based 48 week interventions and previous fitness centre based research, it was similar to that observed in GP exercise referral schemes. The primary difference being direct researcher involvement, that is when interventions are delivered by those same people that would deliver them in real world settings (in this instance exercise professionals), retention is dramatically reduced in comparison with those delivered by researchers. This seems to be a primary limitation in the translation of evidence based interventions into real world settings, and consequently limits the ecological validity of the exercise is medicine hypothesis. Data from Chapter 6 suggests that an influencing factor in this discrepancy is the communication between the exercise professional and participant that, outside of a structured environment, was not as regular as planned or indeed desirable.

Data from this investigation will aid in the recommendation of future physical activity interventions. Data would suggest that those participants with higher fitness / physical activity levels when entering an intervention should be recommended a structured exercise programme as they are less likely to see benefit or be retained in a counselling intervention, whilst those who are sedentary when entering will be unsuited to a structured programme and more likely to be retained and see benefit in physical activity counselling.

Overall, while there can be no doubt that in controlled environments exercise can effectively and consistently be used to treat, manage and prevent risk factors of cardiovascular disease, there is some doubt that these findings translate when delivered in real world settings. Data from the current investigation suggests that physical activity interventions, delivered by exercise professionals from within community fitness centres, do not replicate the findings from the existing literature. Specifically, by removing the control of exercise volume and engagement with participants the beneficial physiological effects of the interventions are limited and retention reduced. It could therefore be concluded that the ecological validity of the exercise is medicine hypothesis is low. This conclusion must however be caveated by the fact that an expectation to replicate laboratory findings in community fitness centres would be flawed. What is demonstrated in this present investigation is the potential of such interventions to improve the health of participants completing the interventions, specifically those with the highest risk of cardiovascular disease. Future research must now develop and inform practices aimed at increasing engagement and delivering clinically relevant improvements in health within local communities.

7.2 Conclusions, limitations and future directions

Physical inactivity is a very real and pressing public health concern. There is very strong evidence that physical activity is effective in the amelioration, management and prevention of, dyslipidaemia, impaired fasting glucose, obesity and hypertension. The findings are extensive and demonstrate beyond reasonable doubt the potential effectiveness of exercise in preventing, managing and treating modifiable risk factors of cardiovascular disease. A lack of published and peer reviewed community based research, and the lack of clinically relevant data in what has been published, suggests however that whilst the exercise as medicine *hypothesis* is legitimate, evidence for the effectiveness of exercise as medicine in the real world is not as strong as laboratory data would suggest it could be or as policymakers suggest it should be. To use a perhaps tenuous analogy, the medicine works but insufficient people are taking it, and even among those that are, too many are not taking a sufficiently large dose or for long enough. In talking of exercise as a medicine, a link with clinical trials of drugs is legitimate. No matter how effective a drug is demonstrated in the clinical phase, if patients don't take it - as the result for example of inconvenience, side effects or perceived low effectiveness - it is not considered an effective intervention by practitioners and policymakers alike and will not be commissioned.

The research presented is however limited by the fact that data relating to fitness centre attendance and engagement with the physical activity counselling programme is lacking. Data would have provided insight into where any additional activity was completed, whether different demographics attended facilities more than others, and whether greater engagement with an exercise professional elicited greater increases in physical activity levels. Further limitations include a lack of insight gathered from fitness facility management teams and wider staff, along with any additional financial costs that were placed upon facilities due to their involvement with the investigation. Such analysis in future may add to the debate around the feasibility of such real world investigations.

Exercise has demonstrated its effectiveness in the laboratory but the research must now move to a new phase in which it does so consistently in the field. Borrowing from a previous discussion of translational research, 'post marketing' studies of exercise as medicine must be set in local community facilities and be delivered in a way that replicates real world delivery if the criteria that distinguish between phases three and four of clinical trials are to be met [65].

Furthermore, such research must improve upon designs that rely on crude measures such as body mass or unreliable methods such as self-report physical activity levels, and must embrace new measurement opportunities and technologies. Increasingly it is only this evidence that will convince practitioners and policy makers that the interventions they prescribe, recommend, or commission will make a clinically relevant impact when delivered in the real world. These concepts should be translated into other ecologically valid settings, namely, work place initiatives aimed at increasing employee health and wellbeing, GP exercise referral schemes, and programmes designed to increase the physical activity levels of children. The development of practices via the translation of evidence based initiatives that have been rigorously tested and refined in the real world may present the next phase in the fight against inactivity related disease.

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Appendices

Appendix 1 - Exercise Professional Survey

Introduction

Firstly we, the research team, would like to thank you for your efforts in managing this project within your facility. We really appreciate the effort and dedication shown through this process, and you have helped to generate some interesting and important findings.

This survey forms the final part of the investigation and will provide valuable feedback that will influence the design of future physical activity interventions, research projects and recommendations for best practice.

We would really appreciate it if you could spend five minutes completing the following questionnaire and answering as honestly as you can. Please note that at no point will it be possible to trace answers to individuals.

PAGE 2 - Selection & Training

These first few questions will give us some insight into how you were selected to take part in this investigation and your thoughts about the training received.

1. When your site was applying to host part of the investigation, how were you approached to take part?

- You asked to be involved and were selected over others who also wanted to take part
- You asked to be involved
- You were asked to be involved by your manager and agreed
- You were told to be involved

2. Which training days did you attend?

- Kent / Essex
- London
- Bristol
- Birmingham
- Leeds
- Scotland

3. To what extent do you feel the training you received prepared you to deliver the investigation?

- Not at all
- Not really
- Somewhat
- To a certain extent
- 5. Very much so

PAGE 3 - Recruitment

These questions will give us some insight into how you felt about the recruitment process and any factors that may have hindered / improved it.

4. You were asked to recruit participants who were inactive, is this a population you deal with on a regular basis?

- Yes
- No

5. Please add any additional comments if you have any

6. How did you find attempting to recruit inactive participants for the investigation?

- Very challenging
- Challenging
- Mixed
- Relatively easy
- Very easy

7. Please add any additional comments if you have any

8. Do you feel you were successful in recruiting sedentary participants?

- Yes
- No

9. Please add any additional comments if you have any

10. Do you believe your fitness centre is appropriately set up to cater for sedentary populations?

- Yes
- No

PAGE 4 - Health Checks

These next questions will give us an idea about how you felt delivering the health checks and how they were received by the participants.

11. Did you feel confident delivering the health checks?

- Yes
- No

12. In your opinion did participants enjoy receiving such health checks within a fitness centre?

- Yes
- No

13. Please add any additional comments if you have any

14. In your opinion did the measurement at the beginning, half way though, and at the end of the intervention aid in the retention and performance of participants?

- Yes
- No

15. If yes, in what way?

16. What, if any, aspects of the health check would you implement within your fitness centre?

- Body composition
- Cholesterol
- Blood pressure
- VO_2 max

PAGE 5 - Interventions

Please provide some comment on how you felt delivering each intervention and any specific points you want to make about each.

17. Did you feel comfortable delivering the structured exercise programme?

- Yes
- No

18. Please provide any comments you have about the delivery of the structured exercise programme - e.g. delivery, effectiveness, retention

19. Did you feel comfortable delivering the general (unstructured) fitness centre use?

- Yes
- No

20. Please provide any additional comments about general (unstructured) fitness centre use - delivery, effectiveness, retention

21. Did you feel comfortable delivering the physical activity counselling intervention?

- Yes
- No

22. Please provide any additional comments about the physical activity counselling intervention - delivery, effectiveness, retention

PAGE 6 - Retention

23. What factors do you think have stopped participants in this investigation attending your facility?

- Demotivation

- Boredom
- Lack of benefits
- Achieving goals
- Lack of interaction with peers
- Lack of interaction with exercise professionals
- Other (please specify)

24. How often did you communicate with participants following the structured exercise programme?

- Weekly
- Bi-weekly
- Once a month
- Bi-monthly
- When they attended the facility
- Other (please specify)

25. How often did you communicate with participants completing the general (unstructured) fitness centre use?

- Weekly
- Bi-weekly
- Once a month
- Bi-monthly
- When they attended the facility
- Other (please specify)

26. How often did you communicate with the participants receiving the physical activity counselling intervention?

- Weekly
- Bi-weekly
- Once a month
- Bi-monthly
- When they attended the facility
- Other (please specify)

27. In your opinion is it feasible and appropriate to deliver physical activity counselling from within a fitness centre?

- Yes
- No

28. Please add any additional comments if you have any

29. Do you think a participants results at 24 weeks influenced their retention between 24 and 48 weeks?

- Yes

- No

30. Please add any additional comments if you have any

31. Which of the following statements do you agree with most strongly?

- Positive changes between baseline and 24 weeks increased the likelihood that participants would continue with the intervention - increased motivation
- Positive changes between baseline and 24 weeks decreased the likelihood that participants would continue with the intervention - decreased motivation as aims achieved
- Negative changes between baseline and 24 weeks increased the likelihood that participants would continue with the intervention - increased motivation
- Negative changes between baseline and 24 weeks decreased the likelihood that participants would continue with the intervention - decreased motivation

PAGE 7 - Final Comments

Please use this opportunity to provide any other observations or comments you have about the investigation that may help us to understand the findings and inform future intervention.

32. Please provide any comments below

Appendix 2 – Participant Survey

Introduction

Firstly we, the research team, would like to thank you for your participation in this investigation. We hope that it was a rewarding experience and one that has been of benefit to you.

As a final part of the process we would like you to complete the following survey about your experience. This will help us to understand the findings and design physical activity programmes in the future. This will take around three minutes to complete, although you are of course free to add detail to your answers if you wish.

Thank you.

PAGE 2 - Background

The following questions are designed to give us an idea of why you decided to take part in the investigation, the type of facility you attended and which programme you were assigned to.

1. Which category below includes your age?

- 30-35
- 36-40
- 41-45
- 46-50
- 51 or older

2. In which town / city was the fitness centre you attended?

3. How were you approached to take part in the investigation?

- Contacted by telephone
- Contacted by email
- Approached in the fitness centre
- Approached outside the fitness centre
- Referred by a friend
- Responded to advertising
- Other (please specify)

4. What made you want to take part?

- Become more physically active
- Improve health
- Offer of free services inc. health check
- Offer of free fitness centre membership
- Psychological benefit
- Other (please specify)

5. Please provide any additional comments if you have any

6. Which programme were you assigned to?

- Structured exercise programme
- Unstructured fitness centre use
- Physical activity counselling
- Measurement only
- I don't know

PAGE 3 - Health Check and Exercise Professional

These next questions will tell us what you think about the health checks you received and the quality of your communication with the exercise professionals at your centre.

7. How many health checks did you attend?

- One - First one only
- Two - First one and 24 weeks
- Two - First one and 48 weeks
- Three - First one, 24 weeks and 48 weeks

8. Do you have any comments about the way your health check/s were delivered by the exercise professional?

9. Do you think the delivery of clinical testing within a fitness centre was appropriate?

- Yes
- No

10. Please provide any additional comments if you have any

11. How would you rate the communication you had with the exercise professionals at your centre?

- 1 - Poor and un-motivating
- 2 - Un-Satisfactory
- 3 - Satisfactory
- 4 - Good
- 5 - Excellent and motivating

12. Please provide any additional comments if you have any

PAGE 4 - Programme

These next few questions will give us an insight into how you found the programme you were assigned. Please answer as honestly as you can.

13. How often did you communicate with your exercise professional?

- Very often (once a week)
- Often (once every two weeks)
- Once a month
- Not very often (once every couple of months)
- Sparingly (only to arrange health checks)

14. Was the programme / intervention you received appropriate for your needs?

- Yes
- No

15. Were you satisfied with the results you achieved at your 24 week health check?

- Yes
- No
- N/A

16. Did these results influence your decision to continue with the programme / intervention?

- Yes
- No
- N/A

17. Which of the statements below do you agree with more strongly than the others?

- Achieving positive outcomes at 24 weeks made me more likely to continue with the programme / intervention
- Achieving positive outcomes at 24 weeks made me less likely to continue with the programme / intervention
- Negative outcomes at 24 weeks made me more likely to continue with the programme / intervention
- Negative outcomes at 24 weeks made me less likely to continue with the programme

18. What other factors influenced your decision to continue with the programme / intervention?

- Enjoyment
- Positive results
- Negative results
- Rapport with exercise professional
- The prospect of future health benefits
- Feeling fitter and healthier

- Improved psychological wellbeing
- N/A

19. What other factors influenced your decision to leave the intervention / programme?

- Boredom
- Positive results
- Negative results
- Lack of rapport with exercise professional
- Did not see future health benefits being achieved
- Did not feel fitter and healthier
- Decrease in psychological wellbeing
- N/A
- Other (please specify)

20. Did you feel fitter / healthier as a result of taking part in this investigation?

- Yes
- No

PAGE 5 – Conclusion

Thank you for taking the time to complete this survey. The responses you have provided will help us to develop better programmes and interventions in the future.

21. Please take this opportunity to provide any additional comments or opinions you have regarding the investigation, its delivery or the results.