PROMOTING AND MAINTAINING PHYSICAL ACTIVITY IN PEOPLE WITH TYPE 2 DIABETES

by

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ABSTRACT

The benefits of regular, frequent physical activity and exercise for the management of Type 2 diabetes are well documented. Current American College of Sports Medicine (ACSM) guidelines for physical activity recommend that people should aim to accumulate at least 30 minutes of moderate intensity physical activity 5 days a week or 20 to 60 continuous minutes of moderate to high intensity exercise, 3 to 5 days a week. Around 80 percent of people with Type 2 diabetes do not achieve these guidelines. To date, research that addresses the promotion of physical activity in people with Type 2 diabetes has been limited. The successful results of a pilot study evaluating the effectiveness of exercise consultation to promote physical activity in people with Type 2 diabetes over 5 weeks led to the development of this PhD. This thesis builds on the foundations of the pilot study and evaluates the effectiveness of this intervention over 12 months in people with Type 2 diabetes.

Accurate assessment of habitual physical activity is of key importance to this research to examine the true effect of the exercise consultation on physical activity. Accelerometers have become a popular objective method for physical activity measurement. Studies investigating the validity of accelerometers have been restricted to children and young adults. Prior to the main PhD research a further pilot study was conducted to investigate the accuracy of the Computer Science and Applications (CSA) uniaxial accelerometer to measure physical activity in people with Type 2 diabetes. 13 people with Type 2 diabetes (8M 5F, mean age 54.2±6.5yrs, BMI 33.4±4.1) were recruited. Participants walked at a slow, normal and brisk pace and performed other daily living activities (e.g. stair climbing, hoovering, carrying loaded shopping bags and pushing a loaded shopping trolley at the normal walking pace). During each activity steady state oxygen uptake (Vo_2ml/kg/min) was measured using a portable breath by breath system (Cosmed K4b^2) and activity counts/min were recorded using CSA accelerometers worn at the waist, ankle and wrist.

The results of this study demonstrated oxygen uptake and activity counts at all accelerometer placements significantly increase as walking speed increased ($p<0.05$). Oxygen uptake for carrying the bags and pushing the loaded shopping trolley were similar, and significantly higher than normal walking ($p<0.01$). Compared to normal walking, activity counts when carrying the bags were significantly higher and activity

counts when pushing the cart were significantly lower ($p<0.05$). Results were similar at all accelerometer placements. Ankle counts were consistently higher than wrist and waist counts for all activities except vacuuming when wrist counts were highest. No significant differences were found between wrist and waist counts for all activities except vacuuming. It was concluded from the results of this study that changes in oxygen uptake during daily living activities are not always reflected by changes in activity counts. To accurately assess physical activity in people with Type 2 diabetes several methods should be used.

The primary aim of the main study was to evaluate the effectiveness of exercise consultation for promoting and maintaining physical activity over 12 months in people with Type 2 diabetes. Secondary aims were to investigate changes from baseline to 6 and 12 months in a number of physiological, biochemical and quality of life variables. 70 inactive people with Type 2 diabetes (35M 35F, mean age 57.6±7.9yrs, BMI 34.6±6.8) were given standard exercise information and randomised to receive an exercise consultation intervention (experimental group n=35) or not (control group n=35). Exercise consultation, based on the transtheoretical model, combines motivational theory and cognitive behavioural strategies into an individualised intervention to promote and maintain physical activity. Exercise consultations were delivered at baseline and 6 months and support phone calls were given 1 and 3 months after each exercise consultation. Changes from baseline to 6 and 12 months were assessed in a) physical activity (7-day recall, accelerometer, stage and processes of exercise behaviour change and cardiorespiratory fitness), b) physiological (body mass index and blood pressure), c) biochemical (glycaemic control, lipid profile, fibrinogen and microalbuminuria) and d) quality of life (Short form-36 and Well-being questionnaire).

Results recorded illustrated between group differences in minutes of moderate activity and total accelerometer counts per week at 6 and 12 months ($p<0.01$). The experimental group increased minutes of moderate activity and total accelerometer counts from baseline to 6 months ($P<0.01$), with no significant decrease from 6 to 12 months ($P>0.05$). From baseline to 12 months a significant increase was recorded in the experimental group for minutes of moderate activity ($p<0.01$), but not total accelerometer counts per week ($p=0.7$). The control group recorded a decrease in accelerometer counts per week from baseline to 12 months ($p=0.03$).

At 6 and 12 months significantly more experimental participants, compared to controls,

were meeting ACSM physical activity guidelines (6M χ^2=22.0, p<0.01, 12M χ^2=15.2. P<0.01) and a greater proportion reported being in an active stage (action or maintenance) of exercise behaviour change (6M χ^2=26.4, p<0.01, 12M χ^2=19.9, p<0.01). Significant between group differences were recorded for the frequency of using behaviour change processes self-liberation, counter conditioning & reinforcement management (p<0.05) at 6 months and all processes (p<0.01), except dramatic relief & stimulus control at 12 months. Experimental participants significantly increased their use of the processes self-liberation, counter conditioning & reinforcement management (p<0.01) from baseline to 6 months and the processes self-liberation, counter conditioning, reinforcement management & helping relationships (p<0.01) from baseline to 12 months. The control group recorded no significant changes in the frequency of using any processes of exercise behaviour change.

Analyses of change in exercise testing variables illustrated an increase in total exercise duration and peak gradient from baseline to 6 months (p<0.01) in the experimental group, with no significant decrease from 6 to 12 months (p>0.05). The control group recorded a significant decrease in oxygen uptake from baseline to 6 and 12 months (p<0.05). Significant between group differences were recorded for the change in systolic blood pressure, HbA_{1c} and fibrinogen from baseline to 6 months (p<0.05) and in total cholesterol from baseline to 12 months (p=0.03). In both quality of life questionnaires on most sub-scales the experimental group recorded small to moderate positive effect size scores from baseline to 6 and 12 months. In comparison the control group recorded small to moderate negative effect size scores from baseline to 6 and 12 months. A significant between group difference of the change from baseline to 12 months in the physical functioning score on the SF-36 was recorded (p<0.01). At 6 months a greater number of experimental participants reported an improvement in health recorded by the Short form-36 questionnaire (p=0.04).

The greater improvements in all physical activity outcomes in the experimental group, compared to controls, demonstrated that the exercise consultation intervention was more effective than standard exercise information for promoting and maintaining physical activity behaviour change over 12 months in people with Type 2 diabetes. Participants receiving the exercise consultation intervention also experienced improvements in glycaemic control and a number of cardiovascular risk factors. Exercise consultation requires minimal resources and with training could be conducted by any member of the

multidisciplinary diabetes team. This research provides the evidence base for an innovative addition to current diabetes management.

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DECLARATION

I declare that I composed the work submitted in this thesis and that all data were collected and analysed by myself. Neither the thesis nor the original work contained therein has been submitted to this or any other institution for a higher degree.

[redacted] Signed [redacted] Date

ALISON F KIRK

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ABBREVIATIONS

ACSM	American College of Sports Medicine
ADA	American Diabetes Association
AH	Adrienne Hughes
BMI	Body Mass Index
CDC	Centres for Disease Control and Prevention
CSA	Computer Science and Applications
DLW	Doubly Labelled Water
DNA	Deoxyribonucleic acid
HbA_{1c}	Glycosylated haemoglobin
HDL-C	High Density Lipoprotein-Cholesterol
HR	Heart Rate
IDDM	Insulin-Dependent Diabetes Mellitus
LDL-C	Low Density Lipoprotein-Cholesterol
MI	Myocardial Infarction
NHS	National Health Service
NIDDM	Non-Insulin-Dependent Diabetes Mellitus
PAL	Physical Activity for Life
PET_{CO2}	End-Tidal Carbon Dioxide Partial Pressure
PET_{O2}	End-Tidal Oxygen Partial Pressure
RER	Respiratory Exchange Ratio
RPE	Rate of Perceived Exertion
SF-36	Short Form-36
SIGN	Scottish Intercollegiate Guidelines Network
SMI	Silent Myocardial Infarction
SPAQ	Scottish Physical Activity Questionnaire
UKPDS	United Kingdom Prospective Diabetes Study
Vco_2	Carbon Dioxide Output
V_E	Minute Ventilation
V_E/V_{CO2}	Ventilatory Equivalent for Carbon Dioxide,
V_E/V_{O2}	Ventilatory Equivalent for Oxygen,
Vo_2max	Maximal Oxygen uptake

Vo_2peak	Peak Oxygen Uptake
WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION

The aim of this chapter is to provide an introduction to this thesis. The study population is described including definitions and classifications of diabetes, associated complications and current prevalence. The need for behaviour change in this population is explained and limitations that exist within the current literature described. Overall this chapter outlines why the research was conducted.

DEFINITION, DIAGNOSIS AND CLASSIFICATION OF DIABETES

Diabetes Mellitus is a metabolic disorder characterised by chronic hyperglycaemia (raised blood glucose level) resulting from a deficiency of, and/or, insensitivity to, the hormone insulin. Diabetes is suspected by the presence of symptoms such as excessive thirst, urination, unusual weight loss, extreme tiredness and blurred vision and is diagnosis by measurements of abnormal blood glucose levels[1]. In 1999 the World Health Organisation (WHO)[1] developed new diagnostic criteria for the range of blood glucose indicative of diabetes. These are as follows: random venous plasma glucose ≥ 11.1mmol/L; or fasting plasma glucose ≥ 7.0mmol/L; or plasma glucose ≥ 11.1mmol/L at two hours after a 75g oral glucose load (oral glucose tolerance test (OGTT)). The new criteria include a decrease in fasting plasma glucose from 7.8mmol/L to 7.0mmol/L. This change occurred as a result of new research associating poor glycaemic control with the development of diabetic complications.

Although there are a number of different types of diabetes the two main forms are Type 1 and Type 2 diabetes. Type 1 diabetes, previously referred to as insulin-dependent diabetes mellitus (IDDM), occurs as a result of an autoimmune response which is directed at the pancreas and causes the insulin producing cells, known as beta cells, to be destroyed. The result is an absolute deficiency of insulin. Type 1 diabetes is less common than Type 2 diabetes, accounting for approximately 10 percent of all people with diabetes[2]. This condition develops most frequently in children and young adults and is generally diagnosed before age 30. The symptoms of Type 1 diabetes develop rapidly and patients require insulin to survive. Adjustments in lifestyle including diet and physical activity are also important in Type 1

diabetes.

Type 2 diabetes, previously referred to as non-insulin-dependent diabetes mellitus (NIDDM) involves variable degrees of defective insulin secretion as a result of beta cell dysfunction and insulin resistance. The WHO defines insulin resistance as insulin sensitivity, under hyperinsulinemic euglycaemic clamp conditions, below the lowest quartile for the population under investigation[3]. This form of diabetes constitutes approximately 85 percent of all people with diabetes and is most commonly diagnosed in adults over the age of 40. Type 2 diabetes is increasingly appearing in children and young adults as a result of an increase in childhood obesity and/or decrease in physical activity[4,5]. The symptoms of Type 2 diabetes appear more gradually and as a result a diagnosis may not be made for some years. It has been suggested that there may be as many people with undiagnosed Type 2 diabetes as there are diagnosed cases[2]. People with Type 2 diabetes need to adjust their diet and lifestyle and may also need to take oral hypoglycaemic tablets and or insulin to control blood sugar levels.

COMPLICATIONS OF DIABETES

Prolonged exposure to raised blood glucose levels damages tissues throughout the body. Microvascular complications, which are specific to diabetes, include: damage to eyes (diabetic retinopathy), which can lead to visual impairment and blindness; damage to kidneys (diabetic nephropathy), which can lead to progressive renal failure; and damage to nerves (diabetic neuropathy). Damage to lower limb nerves, can lead to loss of sensation in the feet, increasing the risk of foot ulcers and lower limb amputations. Damage to other nerves can lead to a variety of further complications including postural hypotension, abnormal sweating, gastrointestinal problems and erectile dysfunction.

In terms of macrovascular complications, compared to non diabetic populations, people with Type 2 diabetes have a two to four fold higher risk of cardiovascular disease[6]. This is the leading cause of mortality in this population, with up to 75 percent of deaths being due to cardiovascular disease[2]. Haffner and colleagues[6] reported that people with Type 2 diabetes, without prior myocardial infarction (MI), have as high a risk of a new MI as a non diabetic person who has already had an MI. In view of the excessive cardiovascular disease in this population, diabetes has been described as "a state of premature cardiovascular death"[7].

In 1998 the United Kingdom Prospective Diabetes Study (UKPDS)[8] reported that

improvements in glycaemic control led to clear reductions of microvascular complications, but only borderline reductions in macrovascular complications. This highlights the importance of incorporating interventions in diabetes management designed to improve cardiovascular disease risk factors as well as interventions to improve glycaemic control. Treatment of hypertension is particularly important, having been shown to decrease both macrovascular and microvascular complications[9].

PREVALENCE

In 1997 Amos and colleagues[10] estimated the current global prevalence of diabetes and made projections for the year 2000 and 2010 using published prevalence rates in addition to current and projected age distributions and developments in economic state. In 1997 124 million people were estimated to have diabetes, representing approximately 2.1 percent of world population. 97 percent of this total had Type 2 diabetes. The prevalence of diabetes is rapidly increasing and it is estimated that a total of 151 million people will have diabetes by the year 2000, this figure increasing to 221 million by the year 2010. In the year 2000 in the United Kingdom the projected prevalence of Type 2 diabetes was 1,864,400. It is estimated that this figure will increase by over one million by the year 2010[10]. The prevalence of Type 2 diabetes increases rapidly with age and is higher in ethnic groups, being six times more common in people with South Asian descent and up to three times more common amongst those of African and African-Caribbean origin[10].

Type 2 diabetes is a serious burden to health care resources. It is estimated that Type 2 diabetes costs Britain's National Health Service (NHS) £2 billion a year, approximately 4.7 percent of total NHS expenditure. An additional £36 million is estimated to be spent on related social services and private health costs. The high cost is largely caused by treatment of complications of diabetes, which increases overall spending for an affected patient more than five fold[11].

Clearly effective methods for managing Type 2 diabetes and in particular preventing associated complications will substantially reduce the costs of this condition. A number of large scale studies have estimated the cost of diabetes throughout the world[11-14]. The total expense is likely to be significantly underestimated as a result of the high number of undiagnosed cases and the misclassification of the cause of complications. The rising prevalence of Type 2 diabetes and the associated drain on the NHS makes this condition one of the most challenging health

problems of the 21st Century.

PHYSICAL ACTIVITY AND PREVENTION OF TYPE 2 DIABETES

An increasing sedentary way of life, greater prevalence of obesity and an ageing population are largely to blame for the current epidemic of Type 2 diabetes [15-17]. Dr Bill Burr proposed an alternative definition of Type 2 diabetes, describing it as "a deficiency state, the deficiency being that of physical activity"[17]

Obesity and physical inactivity are established risk factors for Type 2 diabetes[18]. A number of studies have indicated that changes in lifestyle, including diet and physical activity, can delay the onset of Type 2 diabetes[19-21]. These studies have been criticised for methodological weaknesses such as lack of randomisation. Two multi-centre randomised controlled trials with good methodology confirmed previous findings that changes in lifestyle can prevent or delay the development of Type 2 diabetes in people at a high risk for the disease. In the Finish Diabetes Prevention Study, published in 2001, Tuomilehto and colleagues[22] randomly assigned 522 men and women to an intervention group that received regular, detailed, individualised advice on physical activity and diet or control group who received standard care. All participants had impaired glucose tolerance, an intermediate category between normal glucose tolerance and overt diabetes which is associated with an annual rate of progression to diabetes of one to ten percent[23]. Participants were followed for an average of 3.2 years. At one-year-follow-up the intervention group recorded significantly greater self-reported improvements in diet and physical activity, body composition, glycaemic control, lipid profile and blood pressure. Analysis of progression to Type 2 diabetes showed that the cumulative incidence of diabetes was 58 percent lower in the intervention group compared to the control group.

Results from the Diabetes Prevention Study[24] in 2002 in the United States, parallel those of the Finish study, although with greater power, involving 3234 men and women with impaired glucose tolerance. Half of these participants were from a racial or ethnic minority group. All participants received standard diet and exercise information and were randomly assigned to a placebo group, a pharmacological intervention (850 mg of metformin twice daily) or an individualised lifestyle intervention. Results demonstrated the lifestyle intervention to be significantly more effective at preventing or delaying Type 2 diabetes than treatment with metformin. The effects were similar in men and women and in all racial and ethnic groups. The

incidence of diabetes was reduced by 58 percent with the lifestyle intervention and by 31 percent with metformin, as compared to the placebo group. Both these studies highlight the importance of modification in lifestyle as an effective strategy to prevent or delay the onset of Type 2 diabetes.

PHYSICAL ACTIVITY AND MANAGEMENT OF TYPE 2 DIABETES

The beneficial effects of physical activity and exercise for the management of Type 2 diabetes has been well established for many years. Early recommendations were based on observations that exercise improved blood glucose measurements. A recent meta-analysis[25] of controlled clinical trials investigating the effect of exercise on glycaemic control concluded that exercise significantly reduced glycosylated haemoglobin (HbA_{1c}) values by 0.66 percent. This reduction is clinically significant and is noted to be only slightly less that the difference between conventional and intensive glucose lowering therapy in the UKPDS[8], which significantly reduced the development of diabetic microvascular complications. The majority of the studies used in this meta-analysis investigate the effect of exercise on glycaemic control over a short period (up to 3 months). The difficulty is in maintaining this difference over a long enough period to reduce the development of diabetic complications.

It has become increasingly recognised that Type 2 diabetes is part of a cluster of cardiovascular risk factors that constitute what is now referred to as "the metabolic syndrome". Proposed components of the metabolic syndrome include insulin resistance, glucose intolerance, central obesity, hypertension, dyslipidemia and a hypercoagulable state[3]. Frequent, regular physical activity and exercise favourably affects nearly all proposed components of the metabolic syndrome.

Physical activity is also an important determinant of quality of life in people with Type 2 diabetes[26-28]. Higher levels of physical activity are associated with a better quality of life[26-28] and programmes of physical activity have been shown to improve quality of life and wellbeing[29,30].

PHYSICAL ACTIVITY PROMOTION IN DIABETES

Promotion of physical activity in Type 2 diabetes management is generally inadequate. People with Type 2 diabetes report receiving the least amount of support, education and encouragement for physical activity compared to any other aspect of diabetes management. Any

and colleagues[31] demonstrated that although 75% of people with diabetes were told to exercise, only about 20% received written instructions and advice. In comparison 73% were given written instructions and advice about diet. Health professionals are confused about how to promote physical activity to people with Type 2 diabetes. Marsden[32] reported that health professionals admit to putting exercise last on the agenda in diabetes management largely because they do not understand or have the knowledge of the possible value that exercise could have for their patients. Perhaps it is not surprising that the majority of people with Type 2 diabetes are inactive and attempts to become more active are often met with failure[33,34]. The publication of two multi-centre randomised controlled trials[22,24] demonstrating the strong protective effects of physical activity combined with diet for people at risk of Type 2 diabetes has led to a slowly growing interest in physical activity and exercise for the prevention and management of Type 2 diabetes. If increased physical activity and improved diet can substantially reduce or delay the incidence of Type 2 diabetes, what are the long term effects in the management of Type 2 diabetes?

CHANGING BEHAVIOUR

People with Type 2 diabetes who become regularly physically active can potentially gain several improvements in health including better diabetes control, fewer diabetes complications and a better quality of life. Furthermore a more active population of people with Type 2 diabetes could reduce health care burden and expenditure. Given the current epidemic nature of Type 2 diabetes and the extensive benefits of physical activity for the management of Type 2 diabetes, physical activity should be a major therapeutic strategy for the diabetes care team. The question of the best way to promote physical activity in this population remains unanswered. The majority of studies investigating the effects of physical activity on Type 2 diabetes have incorporated structured exercise programmes. These programmes are expensive and time consuming[35] and therefore inappropriate for an already stretched NHS. These programmes often target a highly motivated, selected group of people and experience high drop out rates[36]. There is a need to increase the evidence base concerning how to promote physical activity to this population[37].

PHYSICAL ACTIVITY PROMOTION

In 1995 the American College of Sports Medicine (ACSM) and Centres for Disease Control and prevention (CDC) developed new physical activity guidelines which focused on maintaining and improving health. These guidelines recommend accumulating 30 minutes of moderate intensity physical activity most days of the week[38].These guidelines are potentially more accessible to the whole population, including people with Type 2 diabetes. Closely linked to the introduction of these guidelines was the development of lifestyle physical activity interventions as a break away from the traditional structured exercise programme. These interventions are often based on a theoretical framework and focus on creating an individually tailored physical activity prescription and developing cognitive behavioural strategies to help people become and stay active.

Lifestyle interventions have been shown to be as effective as structured exercise programmes for improving physical activity and health outcomes and may be more effective for maintaining long term adherence[39,40]. Lifestyle interventions address important barriers to physical activity participation and are a promising strategy for attracting sedentary individuals to physical activity.

Physical activity counselling is an approach often used in lifestyle interventions. Physical activity counselling is often based on the transtheoretical model of behaviour change and involves a one to one discussion with an individual, incorporating a number of evidence based strategies to promote and maintain physical activity. A number of randomised controlled trials provide strong support for the use of physical activity counselling for promotion of physical activity in the general population[41-45]. A pilot study in people with Type 1 diabetes demonstrated physical activity counselling to be effective for promoting physical activity over one month[46].

PILOT RESEARCH

A critical review of the literature investigating methods of physical activity promotion in people with Type 2 diabetes was conducted. Conclusions from this literature review were used in the development of the Scottish Intercollegiate Guidelines Network (SIGN) on lifestyle management of diabetes[37]. General conclusions were that physical activity interventions should be tailored to stage of exercise behaviour change, include the development of cognitive

behavioural skills and techniques and provide ongoing support.

A pilot study[29] was conducted prior to this PhD research. This study investigated the effectiveness of physical activity counselling for promoting physical activity over 5 weeks in people with Type 2 diabetes. 26 sedentary people with Type 2 diabetes were randomly assigned to receive an exercise consultation and standard exercise information (experimental) or standard exercise information alone (control). Changes from baseline at 5 weeks were assessed in a) stage of exercise behaviour, b) physical activity levels, (Scottish Physical Activity Questionnaire and CSA accelerometer) c) quality of life (SF-36 Health Survey and 22-Item Well-Being Questionnaire). Results demonstrated that more experimental participants increased their stage of exercise behavior compared to controls (χ^2=5.4, P=0.02). A significant between group difference was recorded for the change in activity counts per week from baseline to 5 weeks (98% CI = 60 673 to 710 827). The experimental group recorded a 4% increase in total activity counts/week, the control group recorded a 9% decrease. The number of participants taking part in sport or leisure activity increased by 55 % (6/11) in the experimental group and decreased by 6% (1/12) in controls. Positive changes were evident in the experimental group, compared to controls, in both quality of life questionnaires. It was concluded from this study that exercise consultation was more effective, than a standard exercise leaflet, in stimulating physical activity behaviour change in the short-term.

This pilot study only assessed the effectiveness of the exercise consultation for promoting physical activity in the short term. The longer-term effectiveness of this intervention and the resultant effects on physiological, biochemical and quality of life variables in this population has not been studied.

AIM OF PHD RESEARCH

The primary aim of this research was to evaluate the longer term effectiveness of exercise consultation, compared to standard exercise information, for promoting and maintaining physical activity in a group of people with Type 2 diabetes. Secondary aims were to assess changes from baseline to 6 and 12 months in physiological, biochemical and quality of life variables.

VALUE OF RESEARCH

Physical activity counselling allows people with diabetes to work with health professionals to develop safe and suitable ways to increase physical activity, individualised to personal needs and lifestyle. If successful at improving and maintaining physical activity, it is anticipated that physical activity consultations could be incorporated routinely into diabetic management. A more physically active diabetic population could potentially demonstrate a better management of diabetes including improved glycaemic control, reduced likelihood of complications, reduced cardiovascular risk factors, and improved quality of life. These benefits may reduce the need for medication and treatment and therefore reduce the cost implication of the disease. Physical activity counselling offers a low cost, minimal resource intervention that could be incorporated, with appropriate training, into standard diabetes care. If successful, this research will provide the evidence base for an innovative addition to standard diabetes care.

OVERVIEW OF THESIS

The research in this thesis investigates the effectiveness of exercise consultation for promoting physical activity in people with Type 2 diabetes. Chapter two provides a critical review of the literature relevant to this thesis and is in three sections. Section one reviews physical activity in Type 2 diabetes, section two reviews physical activity promotion and section three reviews methods of physical activity measurement. Chapter three describes a pilot study conducted to assess the accuracy of the CSA accelerometer to measure physical activity in people with Type 2 diabetes. Chapter four presents the aims and methods of the randomised controlled trial investigating the effectiveness of exercise consultation for promotion and maintenance of physical activity in people with Type 2 diabetes. Chapter five describes baseline characteristics of the participants in this study. Chapters six and seven present the results and discussion of changes in primary and secondary outcome measures. Finally chapter eight contains a summary and conclusions, including study limitations and areas for future research.

CHAPTER TWO

LITERATURE REVIEW

This chapter provides a critical review of literature relevant to this thesis. The first section begins by defining key phrases and terms and then explores the effects of physical activity and exercise on Type 2 diabetes, the current level of physical activity participation in this population and physical activity recommendations. The second section reviews literature on physical activity promotion including theories of behaviour change and physical activity interventions. Finally methods for assessing physical activity are critically reviewed. The literature was reviewed using Web of Science, Medline and Embase databases using keywords and phrases appropriate to the section being searched. Keywords and phrases included were physical activity, exercise, Type 2 diabetes, glycaemic control, cardiovascular disease, physical activity measurement, physical activity promotion. Searches were also carried out on key authors identified from reviews, for example Professor S Blair, Professor N Mutrie, Dr B Marcus and Dr D Bassett, and appropriate web sites (Diabetes UK, American Diabetes Association, American College of Sports Medicine).

SECTION ONE

DEFINITION OF KEY TERMS

Physical activity has been defined as "any bodily movement produced by the contraction of skeletal muscles that results in an increase in energy expenditure"[47]. Physical activity is performed in everyday life in a number of different situations including leisure time, housework and occupational. Everyone performs physical activity but the amount, frequency and kind of activity is a matter of personal choice. Physical activity has three dimensions; frequency (times per week), duration (minutes per week) and intensity (light, moderate, heavy)[47]. Light intensity is classified by the ACSM[48] as 30 to 49 percent of maximal oxygen uptake, moderate intensity as 50 to 74 percent of maximal oxygen uptake and heavy exercise as 75 to 84 percent of maximal oxygen uptake. As discussed later these dimensions are key features in physical activity and exercise recommendations for health and fitness.

Physical fitness is defined as a set of attributes (e.g. cardiorespiratory fitness, muscular strength and flexibility) that people have or achieve that relates to the ability to perform physical

activity[49]. Physical fitness is mainly determined by physical activity behaviour, although genetic contributions play a variable role[50].

Exercise is a category of leisure time physical activity that is planned, structured and repetitive and is done to improve or maintain one or more components of physical fitness[51]. Aerobic exercise improves the efficiency of the aerobic energy-producing systems and involves large muscle groups in dynamic activity. Resistance exercise is often specific to the area of the body being trained and can be dynamic or static in nature. Resistance exercise improves strength, power and muscular endurance.

PHYSICAL ACTIVITY, EXERCISE AND TYPE 2 DIABETES

Metabolic control

Acute effects

The increased metabolic demands that accompany physical activity and exercise requires an increase in fuel mobilisation from storage sites and an increase in fuel oxidation in the working muscle. Fuel mobilisation and utilisation during exercise are controlled by a precise endocrine response. Generally, in normal healthy individuals arterial insulin levels reduce and levels of glucogon, cortisol, epinephrine and norepinephrine levels increase. This precise endocrine response ensures arterial glucose levels change very little during exercise up to a moderate intensity.

Few studies have evaluated the acute metabolic response to exercise in people with Type 2 diabetes. During mild to moderate exercise most people with Type 2 diabetes exhibit decreases in blood glucose levels[52,53]. This response often persists in to the post exercise period[54]. The reason why blood glucose levels decrease during mild to moderate exercise remains controversial. Earlier studies attribute the decrease to an inadequate exercise associated increase in hepatic glucose production coupled to a normal increase in muscle glucose utilisation[52]. The reduced rise in glucose production is suggested to be due to the failure of insulin to fall during exercise, as it does in people without diabetes and/or to the hepatic effects of hyperglycaemia present in people with Type 2 diabetes[52]. In more recent studies a greater increase in glucose utilisation and a decrease in plasma insulin levels has been described[53].

In contrast to moderate intensity exercise, short-term high intensity exercise has shown to increase blood glucose levels during and for up to one hour after exercise. This rise in blood glucose has been associated with an exaggerated counter regulatory hormone response[55].
Several studies have demonstrated that acute exercise increases insulin sensitivity[52].
Improvements in insulin sensitivity have been demonstrated after light[56], moderate[57] and heavy exercise[57]. The effect of an acute bout of exercise on insulin action is lost within a few days[58].
However, a single bout of exercise has been shown to restore insulin sensitivity to the same level as in the trained state[58]. Health et al[58] illustrated that trained individuals lose much of their enhanced sensitivity to insulin within a few days of exercise termination.
Most studies investigating the effects of acute exercise on glucose levels and insulin resistance in people with Type 2 diabetes have used relatively small study groups, controlled by diet or oral antidiabetic therapy. Further research with larger and more diverse diabetic populations is required to fully understand the effects of acute exercise in people with Type 2 diabetes.

Long-term effects

HbA_{1c} is a measure of long-term (3-month) glycaemic control and is expressed as a proportion of HbA_{1c} to total haemoglobin. Studies investigating the effect of physical activity and exercise on HbA_{1c} are described in Table 1. The majority of studies report reductions in HbA_{1c} after physical activity of variable type, duration and intensity. Most studies incorporate structured, supervised physical activity interventions with no theoretical framework or education on cognitive behavioural strategies. Studies that include a control group often report a decrease in HbA_{1c} in the experimental group and an increase in the control group[63,65,66,60]. A recent meta-analysis[25] concluded that compared to control conditions, exercise interventions lasting at least 8 weeks significantly reduced HbA_{1c} with a mean difference of 0.66%. Interventions combining diet and exercise produced slightly greater improvements with a mean difference of 0.76%.
A favourable effect of frequent exercise on hypoglycaemic medication has also been documented[71,72]. Fujinuma et al[71] investigated the effect of 3 to 4 weeks of supervised exercise in 78 people with Type 2 diabetes. Compared to a non exercising control group, a significantly greater number of participants in the exercise group discontinued or reduced their insulin dose.

Table 1: Effects of physical activity and exercise on HbA_{1c} in people with Type 2 diabetes

Study	Design	Subjects	Intervention	Exercise intensity/duration	Changes in HbA_{1c} (%)
Agurs-Collins et al, 1997[59]	RCT	64 M/F, 55-79yrs	3 months of 1wk diet counselling & exercise (phase 1)followed by 6 bi-week sessions 6-months (phase2) total	Unsupervised moderate intensity 30 minutes + one structured class	Phase 1&2 (Exp – sig↓ Cont NC)[1]
Honkola et al, 1997[60]	Non randomised	38 M/F. 62yrs	Supervised resistance training, 5 months	2 x wk moderate intensity, medium -high resistance	(Exp – NC, Cont - sig↑)[1] (Sig between group difference of change)[2]
Ishii et al, 1998[61]	Non randomised	17 M only, 46yrs	Supervised resistance training, 5 weeks	5 x wk, moderate intensity, medium -high resistance	No within or between group changes
Khan & Rupp, 1995 [62]	RCT	39 M/F 50yrs	Unsupervised aerobic exercise, 15 weeks	5 x wk, 50% V_{O2}max, 50 minutes	No within or between group changes
Lehmann et al, 1995[63]	RCT	29 M/F, 54yrs	Supervised & non-supervised aerobic exercise, 3 months	3 x wk, 60% V_{O2}max, 40 minutes	(Exp – NC, Cont - sig↑)[1]
Lightenberg et al 1997[64]	RCT	58 M only, 62yrs	Supervised aerobic exercise, 12 week (phase 1), non-supervised 14 week (phase 2)	3 x wk, 70% V_{O2}max, 1 hour	(Exp NC. No mention of control)[1]
Mourier et al, 1997[65]	RCT	24 M/F, 45yrs	Supervised aerobic exercise, 8 weeks	2 x wk, 75% V_{O2}max, 45 minutes	(Exp - sig↓, Cont – NC)[1]. (Sig between gp diff of change)[2]

Raz et al, 1994[66]	RCT	40 M/F, 56yrs	Supervised aerobic exercise, 12 weeks	3 x wk, 65% V_{O2}max, 1 hour	(Exp - sig↓, Cont – NC)[1]. (Sig between gp diff of change)[2]
Trovati et al, 1984[67]	Non randomised	5 M only 54yrs	Unsupervised aerobic exercise, 6 weeks	7 x wk, 55% V_{O2}max, 1 hour	(Exp - sig↓)[1] No control
Uusitupa, 1996[68]	RCT	86 M/F, 52yrs	Diet & unsupervised exercise, 1-year	Written & oral instructions encouraged 3-4 x wk aerobic exercise for 30-60 minutes.	No within or between group changes
Vanninen et al, 1992[69]	RCT	78 M/F, 53yrs	Diet & unsupervised exercise, 1 year	4 x wk, 124bpm HR, 45minutes	No within or between group changes in exercise groups
Walker et al, 1999[70]	Non randomised	31 F only, 58yrs	Unsupervised walking, 12 weeks	5 x wk, 1 hour, self selected walking pace	(Exp - sig↓)[1]. No control

RCT = randomised controlled trial, V_{O2}max = maximal oxygen uptake, HR = heart rate, HbA_{1c} = glycosylated haemoglobin, [1] = within group changes, [2] = between group changes, NC = no change, ↓ = decrease, ↑ = increase, Exp = experimental group, Cont = control group, M = male, F = female.

Of the 56 people allocated to the exercise group, ten participants discontinued insulin injections and 36 reduced the number of insulin injections per day.

The majority of research investigating the effect of exercise on glycaemic control in people with Type 2 diabetes has used structured, supervised exercise programmes with relatively short term follow-up periods (up to 3 months). A non randomised study by Walker et al[70] recently demonstrated that with correct education and encouragement an unsupervised exercise programme could also be carried out successfully and lead to significant improvements in HbA1c.

Improvements in glucose concentration usually deteriorate within 72 hours of the last exercise session in people with Type 2 diabetes[58]. Improved glycaemic control over prolonged periods of frequent exercise participation is suggested to be largely due to the cumulative effects of individual exercise bouts as opposed to the long-term adaptations to physical activity training[73,58]. As a result people with Type 2 diabetes should participate in frequent exercise to sustain the glucose lowering effects of exercise.

Not all studies have reported improvements in glycaemic control with physical activity. Skarfors et al[74] studied the long-term effects of physical activity in a group of men over 60 years with Type 2 diabetes. Exercise training incorporated supervised exercise sessions, twice weekly at 75 percent of maximal oxygen uptake for 45 minutes. At 2-year follow-up significant improvements in maximal oxygen uptake were demonstrated, but no accompanying beneficial effects were shown in metabolic variables when compared to controls. Similar findings have been reported by Ligtenberg et al[64].

The results of these studies suggest that exercise could be more effective for improving glycaemic control during earlier stages of diabetes. Consistent with this suggestion Barnard et al[75] demonstrated that the effect of exercise and diet on glycaemic control was related to treatment of diabetes, the effect of diet and exercise interventions being greatest in those participants receiving no medication or oral hypoglycaemic agents, compared with participants taking insulin. These results stress the need for an early emphasis on lifestyle modification in the management of people with Type 2 diabetes.

Cardiovascular disease and mortality

Cardiovascular disease is the leading cause of death in people with Type 2 diabetes. Haffner et al[6] reported that people with Type 2 diabetes without prior myocardial infarction have as high a risk of death from coronary heart disease as non diabetics with a previous history of myocardial infarction. Many people with Type 2 diabetes are obese, physically inactive with a low cardio-respiratory fitness and a large number have hypertension, dislipidemia and an altered fibrinolytic system. Several reviews have highlighted the potential for physical activity to improve both glycaemic control and cardiovascular risk factors[76-80].

Physical activity and mortality

Physical inactivity has been established as an important risk factor for the development of cardiovascular disease[81]. In observational studies an inverse association between increased physical activity levels and cardiorespiratory fitness and lower risk for cardiovascular disease and all-cause mortality is well established in the general population[82-84]. A similar relationship has been described in people with Type 2 diabetes[85-87]. In a prospective cohort study Wei and co workers[85] followed 1263 men with Type 2 diabetes for an average of 12 years. After adjustment for age, baseline cardiovascular disease, fasting plasma glucose level, high cholesterol, overweight, smoking status, high blood pressure and family history of cardiovascular disease, men with low cardiorespiratory fitness had an adjusted risk for all cause mortality of 2.1, compared with fit men. Kohl et al[88] demonstrated a similar inverse relationship between cardiorespiratory fitness and all-cause mortality in 8715 men with variable levels of glycaemic control. Kohl concluded that although risk of death increases with higher glycaemic status the adverse impact of hyperglycaemia on mortality appears to be reduced with increased fitness.

A recent study[86] which incorporated repeated measurements of physical activity over a 14-year follow-up provided evidence of an inverse relationship between increased physical activity levels and lower risk for cardiovascular disease in 5125 women with Type 2 diabetes. The results of this study illustrated that women who spent at least 4 hours per week performing moderate or vigorous exercise had an approximately 40 percent lower risk for cardiovascular disease than those were inactive. It should be noted that all studies to date investigating the relationship between physical activity, cardiorespiratory fitness and mortality have been

observational in design and could be confounded by limitations such as behaviour change in other health habits during follow-up. The consistent findings, however, provide strong evidence of an inverse association between increase physical activity levels and cardiorespiratory fitness and lower risk for cardiovascular disease and all-cause mortality.

Blood lipids and lipoproteins

Dyslipidaemia is often present in people with Type 2 diabetes and this is associated with increased morbidity and mortality from coronary heart disease[89]. Typical dyslipidaemia in people with Type 2 diabetes is increased concentrations of triglycerides and decreased concentrations of high density lipoprotein–cholesterol (HDL-C)[90]. The Scottish Intercollegiate Guidelines Network (SIGN) recommend treatment of dyslipidaemia in people with Type 2 diabetes with the recommended target of total cholesterol <5.0mmol/l[90].

Physical activity is associated with favourable effects on blood lipids. A systematic review[91] of randomised controlled trials investigating blood lipid response to exercise in the general population, published in 2001, concluded that moderate to hard intensity aerobic exercise training improves blood lipid profile, although there were marked variations in the observed responses. The most common observed lipid change was a significant increase in HDL-C. Reductions in low density lipoprotein–cholesterol (LDL-C), triglyceride and total cholesterol are observed less frequently.

Studies investigating the effect of physical activity and exercise on plasma lipids in people with Type 2 diabetes are outlined in Table 2. Variations also occur in the response of blood lipids to exercise in people with Type 2 diabetes. Studies which show significant changes tend to use structured, high intensity exercise programmes, incorporate younger people and combine diet and physical activity. In contrast to the general population the most common observed lipid change in response to exercise in people with Type 2 diabetes appears to be a significant decrease in triglycerides.

Lehmann et al[63] investigated the effect of an individualised, moderate intensity aerobic exercise programme in people with Type 2 diabetes. Once weekly exercise was performed under supervision and participants were encouraged to include a further three exercise sessions a

Table 2: Effects of physical activity and exercise on plasma lipid in people with Type 2 diabetes

Study	Design	Subjects	Intervention	Exercise intensity/duration	Change in lipid profile
Agurs-Collins et al, 1997[59]	RCT	64 M/F 55-79yrs	12 weeks of 1wk diet counselling & exercise followed by 6 biweek sessions	exercise 30minutes structured 1wk (first 3 months) encourage to include further 2 session/wk	No within or between group changes
Barnard et al, 1994[75]	Non randomised	652 M/F 59yrs	Diet & exercise 26 days	no details	(Exp - sig ↓ TC, LDL-C & Triglycerides, Sig ↑ HDL-C)[1]. No control
Dunstan et al, 1998[92]	RCT	55 M/F 53yrs	4 groups 1. Fish/moderate ex 2. Fish/light ex 3. No fish/moderate ex, 4. No fish/light ex	Moderate ex - 3xwk, 60% V_{O2}max, 30minutes. Light ex - 10 light cycle + stretch	(Exp - moderate ex gp – sig ↓ Triglycerides & ↑ HDL-C)[1]
Halle et al, 1999[93]	Non randomised	34 M only 49yrs	Diet exercise and education 4 weeks	5xwk, 70% HRmax, 30 minutes + 2hour hike/1week	(Exp - sig ↓ TC, LDL-C, Triglycerides, HDL-C NC)[1] No control
Honkola et al, 1997[60]	Non randomised	38 M/F 62yrs	Resistance training 5months	moderate intensity, medium - high resistance	(Exp - sig ↓ TC, LDL-C & triglycerides, Cont – sig ↑ HDL-C)[1]. (Between gp diff in triglycerides)[2]

Khan & Rupp, 1995[62]	RCT	39 M/F 50yrs	Unsupervised aerobic exercise 15 weeks	5 x wk, 50% V_{O2}max, 50 minutes	No within or between group changes
Lehmann et al, 1995[63]	RCT	29 M/F 54yrs	Supervised & non-supervised aerobic exercise, 3 months	3 x wk, 60% V_{O2}max, 40 minutes	(Exp – sig ↑ HDL-C & ↓ triglycerides. LDL-C & TC NC, Cont – NC)[1]
Lehmann et al, 2001[94]	Non randomised	16 M/F 54yrs	Supervised aerobic exercise + exercise education 3 months	3 x wk, 60% HRmax, 40 minutes	(Exp – Sig ↑ HDL-C, sig ↓ Triglycerides, TC & LDL-C NC. Cont NC)[1]
Lightenberg et al 1997[64]	RCT	58 M/F 62yrs	Supervised aerobic exercise, 12 week (phase 1), non-supervised 14 week(phase 2)	3 x wk, 70% V_{O2}max, 1 hour	(Sig between gp diff for change in TC)[2] (Phase 1 only)
Raz et al, 1994[66]	RCT	40 M/F 56yrs	Supervised aerobic exercise 12 weeks	3 x wk, 65% V_{O2}max, 1hour	(Between gp diff in Triglycerides)[2]
Skarfors et al 1987[74]	Non randomised	16 M only 59yrs	Supervised aerobic exercise, 2 years	2 x wk, 75% V_{O2}max, 45minutes	No within or between group changes
Taniguchi et al 2000[95]	Non randomised	15 M/F 60yrs	Unsupervised aerobic & resistance exercise 12 days	Daily, 7,000 steps	(Exp - Triglyceride sig↓, TC & HDL NC)[1] No control
Uusitupa, 1996[68]	RCT	86 M/F 40-64yrs	Diet & exercise 1-year	Written & oral instructions encouraged 3-4xwk aerobic exercise for 30-60 minutes. Monitored by exercise log	(Exp – sig ↑ HDL-C & ↓ triglycerides. Cont NC)[1]

Vanninen et al, 1992[69]	RCT	78 M/F 53yrs	Diet & unsupervised exercise 1 year	4 x wk, 124bpm HR, 45minutes	(Exp – F=sig ↑ HDL-C & ↓ TC. M=sig↓ Triglycerides)[1] (Between gp diff in TC in F only)[2]
Walker et al, 1999[70]	Non randomised	31 F only 58yrs	Unsupervised walking only 12 weeks	5 x wk, 1 hour	(Exp - sig ↓ TC, LDL-C & HDL-C NC)[1]. No control

RCT = randomised controlled trial, VO_2max = maximal oxygen uptake, TC = Total cholesterol, LDL-C = low-density lipoprotein-cholesterol, HDL-C = high-density lipoprotein-cholesterol, [1] = within group change, [2] = between group change, NC = no change, ↑ = increase, ↓ = decrease, M = male, F = female, Sig = p>0.05, Exp = experimental group, Cont = control group, gp = group.

week through goal setting, self monitoring and social support. At 3 month follow-up participants in the experimental group recorded a 20 percent reduction in triglyceride and a 23 percent increase in HDL-C. These effects occurred independent of changes in body weight and glycaemic control, which did not change during the study.

The effect of resistance training on cardiovascular risk factors has been demonstrated. Honkola et al[60] evaluated the effect of an individualised, progressive resistance training programme on lipid profile in people with Type 2 diabetes. A moderate intensity, high volume, low resistance supervised resistance training programme was carried out twice weekly for 5 months. At follow-up the experimental group recorded significant reductions in total cholesterol, LDL-C and triglycerides. Total cholesterol fell by 12 percent, LDL-C by 14 percent and triglycerides by 20 percent. Body weight did not change significantly in the experimental group, but increased in the control group. This study could be criticised for a lack of randomisation and as a result the majority of men participated in the experimental group and women in the control group. The variability in responsiveness of blood lipids to exercise may be caused by potential confounding factors include stability of diet, and exercise prescription and adherence.

Blood pressure and hypertension

Hypertension is more prevalent in diabetic populations than in non-diabetic populations[96] Around 40 percent of people with Type 2 diabetes have arterial hypertension (<140/90mmHg)[97]. Hypertension is positively related to risk of cardiovascular death, with a progressive increase in risk with rising systolic blood pressure[98,99]. In the UKPDS Hypertension in Diabetes Study[9] tight blood pressure control in people with hypertension and Type 2 diabetes significantly reduced the development and progression of diabetic complications and risk of death related to diabetes. In this study a significant number of participants required three or more hypotensive agents to control blood pressure. A target blood pressure of below 140/80mmHg is currently recommended by SIGN in people with Type 2 diabetes[90].

Increased physical activity is a generally accepted lifestyle measure for the management of hypertension. In 2001 a systematic review concluded that there was good evidence from randomised controlled trials that dynamic regular physical activity (3-5 times/week, 30-60 minutes, 40 to 70 percent of maximal oxygen uptake) reduces blood pressure[100]. Baseline blood pressure has been noted as an important determinant of blood pressure response to physical

activity. A more pronounced effect has been demonstrated in people with existing hypertension than in people with normal blood pressure[100]. It could be suggested therefore that people with Type 2 diabetes, a population with a high prevalence of hypertension could gain important significant reductions in blood pressure in response to regular physical activity.

A small number of studies have examined the impact of physical activity on blood pressure in people with Type 2 diabetes[63,75,101,102]. In a randomised controlled trial Lehman and co-workers[63] recorded significant reductions in systolic (138±16 to 128±15mmHg) and diastolic (88±10 to 77±6mmHg) blood pressure after a 3 month individualised, moderate intensity aerobic exercise programme in people with Type 2 diabetes. As noted this magnitude of reduction in blood pressure in extremely beneficial for people with Type 2 diabetes, significantly reducing the risk of both microvascular and macrovascular complications. If this degree of reduction can be maintained long term it may allow tight blood pressure control with a smaller number of hypotensive agents. Bernard and co-workers[75] evaluated the effect of a 4-week diet and aerobic exercise programme in 652 people with Type 2 diabetes. Both systolic and diastolic blood pressure were significantly reduced, and of the 319 participants initially taking antihypertensive drugs, 34 percent had their medication discontinued. A criticism of this study is the absence of a control group. In contrast to these two studies Leon et al[102] recorded no change in blood pressure in 50 men with Type 2 diabetes after 3 months of vigorous intensity aerobic exercise. More research is required to establish the true effect of regular frequent physical activity on blood pressure in people with Type 2 diabetes.

Obesity and weight Loss

Around 80 to 90 percent of people with Type 2 diabetes are obese and this constitutes an important obstacle to successful long term diabetes management[103]. The combination of obesity, particularly central obesity, with Type 2 diabetes is associated with a greater cardiovascular risk[104]. There is some evidence that people with diabetes are less successful in maintaining long term weight loss than people without diabetes[105]. Obese people with Type 2 diabetes often face extra impediments to weight loss such as the weight promoting effect of a number of diabetes treatments.

A five to ten kilogramme, or five to ten percent reduction in weight which is maintained can provide several health benefits for people with Type 2 diabetes including improvements in insulin sensitivity and glycaemic control, blood pressure, lipid profile and quality of life[106-111]. In observational research weight loss has been associated with increased life expectancy in people with Type 2 diabetes[112]. Lean and colleagues[112] demonstrated that after correcting for pre-existing risk factors, weight loss within the first year of diagnosis was associated with an improved prognosis. On average, each kilogram of weight loss over the first year from diagnosis was associated with about three to four months increased survival. Williamson and colleagues[104] demonstrated that intentional weight loss in 4,970 overweight people with Type 2 diabetes was associated with a 25 percent reduction in total mortality and a 28 percent reduction in cardiovascular disease and diabetes related mortality over a 12 year follow-up period.

Studies investigating the effect of physical activity on body composition in people with Type 2 diabetes are detailed in Table 3. Individualised exercise programmes that incorporate behavioural strategies such as social support and goal setting and interventions which combine diet and exercise appear to be the most successful in promoting and maintaining weight loss. Regular physical activity has been shown to be an important component of long term weight loss maintenance[111,107]. Kayman and co workers[107] compared people who were successful in achieving long-term weight loss with people who lost weight and regained it. Of the successful weight losers, 83 percent reported exercising three or more times a week for at least 30 minutes, compared with only 34 percent of weight regainers.

Cardiorespiratory fitness

Low cardiorespiratory fitness has been directly associated with a higher risk for cardiovascular disease and all cause mortality in the general population[82-84] and in people with Type 2 diabetes[85-87].

Maximal oxygen uptake (Vo_2max) is the classic measure of cardiorespiratory fitness and describes the highest oxygen uptake obtainable by an individual for a given form of exercise despite increased effort and work rate. Several studies have demonstrated that people with Type 2 diabetes have a reduced oxygen consumption at sub-maximal[116,117] and maximal exercise when compared with healthy age matched controls[118-120].

Table 3: Effects of physical activity and exercise on body weight and composition in people with Type 2 diabetes

Study	Design	Subjects	Intervention	Exercise intensity/duration	Changes in body composition
Agurs-Collins et al, 1997[59]	RCT	64 M/F 55-79yrs	12 weeks of 1wk diet counselling & exercise followed by 6 bi-week sessions, 3 & 6-month follow-up	exercise 30minutes structured 1wk (first 3 months) encourage to include further 2 session/wk	(Sig diff for the change in body weight between gps at 3&6months)[2] (F only)
Barnard et al, 1994[75]	Non randomised	652 M/F 59yrs	Diet & exercise intervention, 26-day follow-up	no details	(Exp - sig ↓ body weight)[1]. No control
Dunstan et al, 1998[113]	RCT	27 M/F 53yrs	Resistance type exercise training, 8 week follow-up	3 x wk moderate intensity, medium -high resistance	(Exp - sig ↓ in body weight. Cont – NC)[1].
Glasgow, 1992[114]	RCT	102 M/F >60yrs	Diet & exercise self management intervention, 6-month follow-up	Individualised education plus 2 supervised walking sessions	(Exp – sig ↓ body weight. Cont – NC)[1].
Halle et al, 1999[93]	Non randomised	34 M only 49yrs	Diet & exercise, 4week follow-up	5 x wk, 70% HR max, 30 minutes + 2hour hike/1week	(Exp - sig ↓ body weight & BMI)[1]. No control
Honkola et al, 1997[60]	Non randomised	38 M/F 62yrs	Resistance type exercise training, 5 month follow-up	2 x wk moderate intensity, medium -high resistance	(Exp – sig ↓ body weight. Cont – NC)[1]. (Significant between group difference of change in body weight)[2]

Ishii et al, 1998[61]	Non randomised	17 M only 46yrs	Resistance type exercise training, 5 week follow-up	5 x wk, moderate intensity, medium -high resistance	No within or between group changes
Khan & Rupp, 1995[62]	RCT	39 M/F 50yrs	Unsupervised aerobic exercise, 15 week follow-up	5 x wk, 50% V_{O2}max, 50 minutes	(Exp – sig ↓ body fat, body weight NC. Cont – NC)[1]. (No between gp diff)[2]
Lehmann et al, 1995[63]	RCT	29 M/F 54yrs	Supervised & non-supervised aerobic exercise, 3 month follow-up	3 x wk, 60% V_{O2}max, 40 minutes	(Exp – sig ↓ waist-hip & body fat, body weight NC' Cont – NC)[1].
Lehmann et al, 2001[94]	Non randomised	16 M/F 54yrs	Supervised aerobic exercise + exercise education, 3 month follow-up	3 x wk, 60% HRmax, 40 minutes	(Exp – sig ↓ hip ratio, % body fat & Lean body mass. NC in body weight, Hip circumference. Cont NC)[1]
Mourier et al, 1997[65]	RCT	24 M/F	Supervised aerobic exercise, 8 week follow-up	2 x wk, 75% V_{O2}max, 45minutes	(Exp - sig ↓ abdominal fat, body weight NC. Cont – NC)[1]. (Sig between gp diff in abdominal fat)[2].
Rogers et al, 1988[115]	Non randomised	10 M only 53yrs	Supervised and unsupervised exercise, 7 day follow-up	7days, 60 minutes, 60% HRmax	(Exp - body weight NC)[1]. No control group
Skarfors et al 1987[74]	Non randomised	16 M only 59yrs	Supervised aerobic exercise, 2 year follow-up	2 x wk, 75% V_{O2}max, 45minutes	No within or between group changes

Taniguchi et al 2000[95]	Non randomised	15 M/F 60yrs	Unsupervised aerobic & resistance exercise, 12 day follow-up	7,000 steps daily	(Exp - BMI NC)[1]. No control
Uusitupa, 1996[68]	RCT	86 M/F 40-64yrs	Diet & exercise, 1-year follow-up	Written & oral instructions encouraged 3-4xwk aerobic exercise for 30-60 minutes. Monitored by exercise log	(Exp – sig ↓ body weight Cont – NC)[1].
Vanninen et al, 1992[69]	RCT	78 M/F 40-64yrs	Diet & unsupervised exercise intervention, 1-year follow-up	4 x wk, 124bpm HR, 45minutes	(Both Exp & Cont groups sig ↓ BMI)[1] (both groups increase physical activity)
Walker et al, 1999[70]	Non randomised	31 F only 58yrs	Unsupervised walking only, 12 week follow-up	5 x wk, 1 hour	(Exp - sig ↓ BMI, body fat (upper body & android region))[1]. No control group

RCT = randomised controlled trial, V_{O2}max = maximal oxygen uptake, HRmax = maximal heart rate, sig = significant ($p<0.05$), [1] = within group change, [2] = between group change, NC = no change, ↓ = decrease, ↑ = increase, Exp = experimental group, Cont = control group, M = male, F = female.

The causes of this impaired exercise capacity are unknown. A strong inverse association between cardiorespiratory fitness and development of Type 2 diabetes has been demonstrated[85]. This raises the possibility that reduced cardiorespiratory fitness may contribute to the development of Type 2 diabetes and could potentially serve as a marker for individuals at high risk. There is also evidence to suggest that central (cardiac)[118,121] and peripheral factors[122,123] may be involved. In comparison to lean and weight matched controls Regensteiner et al[118] reported that people with Type 2 diabetes had lower oxygen uptake and heart rate kinetics at constant exercise workloads below the lactate threshold. Roy et al[121] described an autonomic influence of reduced cardiac parasympathetic nervous system activity in people with Type 2 diabetes. Reduced oxidative and increase glycolytic enzyme activity[123] and an increased number of mitochondia deoxyribonucleic acid (DNA) deletions[122] in skeletal muscle have also been reported in people with Type 2 diabetes.

Several studies have reported improvements in Vo_2 max as a result of exercise training in people with Type 2 diabetes[120,124,62,64]. Ligtenberg et al[64] found significant improvements in Vo_2 max in elderly people with Type 2 diabetes after 6 weeks of moderate intensity supervised exercise. After 15 weeks of individualised exercise at 40 to 60 percent of Vo_2 max Khan et al[62] reported significant improvements in Vo_2 max. Brandenburg et al[120] demonstrated that an individually prescribed moderate intensity exercise programme significantly improved Vo_2 max in previously sedentary women with uncomplicated Type 2 diabetes. Despite beginning with the lowest Vo_2 max participants with Type 2 diabetes recorded the greatest improvements in Vo_2 max after exercise training compared to lean or overweight control.

Coagulation

Vascular hemostasis results from a regulated interaction of coagulation and fibrinolytic systems. In a normal situation these systems are in dynamic equilibrium. Any imbalance between the systems leads to a tendency to bleed or to an increased thrombogenesis.

Fibrinogen promotes platelet aggregation and is a key determinant of blood viscosity. Epidemiological studies show that increased fibrinogen level is an independent risk factor for cardiovascular disease and mortality[125,126]. Elevated levels of fibrinogen are found in people with Type 2 diabetes[127]. An inverse association between increased fibrinogen levels and lower

physical activity levels and/or cardiorespiratory fitness has been found in cross sectional studies in the general population[128] and in people with Type 2 diabetes[129].

A limited number of studies have investigated the effect of regular, frequent physical activity on plasma fibrinogen. Results are inconsistent in both the general population and in people with Type 2 diabetes. Schneider and colleagues[127] investigated the effect of a 6 week exercise programme on fibrinogen concentration in 16 sedentary men with Type 2 diabetes. Although baseline fibrinogen concentration was elevated and cardiorespiratory fitness increased by eight percent after training, no significant change was observed in fibrinogen concentration. In contrast Hornsby and co workers[130] observed in an uncontrolled trial that 12 to 14 weeks of exercise of a similar duration and intensity significantly improved cardiorespiratory fitness and reduced fibrinogen concentration in people with Type 2 diabetes. Furthermore Vanninen and co workers[129] reported a significant decline in fibrinogen after 12 months of intensified diet and exercise education in sedentary people with newly diagnosed Type 2 diabetes. Differences in exercise protocol, training status, subject health, and the methods used for the assessment of plasma fibrinogen are likely to be responsible for the inconsistency in results.

Quality of life and well-being

Diabetes has generally been associated with a poorer quality of life and well being. Several studies have reported higher levels of depression [131-133] and anxiety[134] in people with Type 2 diabetes and it has been suggested that these states could be associated with poorer glycaemic control[133,134]. The favourable effects of exercise on quality of life and wellbeing have been extensively reported in the general population[135]. Only a few studies have investigated the association between physical activity and quality of life in people with Type 2 diabetes.

In a 2 year observational study Stewart et al[26] demonstrated higher levels of physical activity to be associated with overall better psychological functioning and well-being in people with both Type 1 and Type 2 diabetes. Glasgow et al[27] investigated the association between quality of life and the demographic, medical and self-management characteristics of 2,800 people with diabetes. Results revealed exercise participation to be the only significant self-management behaviour predictive of enhanced quality of life.

A small number of studies have investigated the effect of physical activity on quality of life in people with Type 2 diabetes. Tessier and colleagues[136] assessed the effect of supervised aerobic

and resistance exercise in 45 elderly people with Type 2 diabetes. At 16 week follow-up no significant changes were recorded in quality of life. In the pilot study[29] conducted for this research significant improvements were shown in quality of life after a 5 week intervention designed to promote physical activity. Lightenberg et al[30] also recorded significant improvements in quality of life in 51 elderly people with Type 2 diabetes after 6 weeks of supervised exercise training three times a week for one hour at 60 to 80 percent of Vo_2max. At the end of the supervised exercise period participants were advised to continue training at home without supervision. A follow-up was conducted 14 weeks after the supervised exercise period. At this follow up although Vo_2 max remained significantly higher than the control group, quality of life scores returned to baseline level. These results could suggest that social support achieved during supervised group exercise is an important factor for the enhanced psychological well being apparent after exercise training. The development of social support through family or friends should therefore receive high priority when developing individualised unsupervised exercise programmes.

Additional benefits of physical activity in Type 2 diabetes

Regular physical activity and exercise hold numerous additional health benefits which are well documented in the U.S department of health and human services surgeon general report on physical activity and health[135]. Additional benefits include:

- Better muscle strength, healthier joints and bones
- Maintained ability to live independently
- Reduced occurrence of falling and fractured bones
- Reduced risk of developing certain cancers (particularly colon)
- Control of joint swelling and pain associated with arthritis
- Enhanced self esteem and confidence

PHYSICAL ACTIVITY PARTICIPATION IN TYPE 2 DIABETES

Physical activity participation

Despite the potential benefits of physical activity and exercise in the management of Type 2 diabetes, it is estimated that only 20 to 30 percent of people with Type 2 diabetes do enough activity to achieve these benefits[34,33,137]. This percentage of participation in physical activity is similar to the general population, although research suggests that people with diabetes experience a significantly greater frequency of relapse from physical activity programmes[34]. The greatest number of people with diabetes report low adherence to exercise recommendations, compared to other diabetes self care behaviours[31]

Variables associated with physical activity behaviour

Limited research has examined variables associated with physical activity behaviour in people with diabetes. Hays and Clark[33] reported higher levels of education and younger age to be significantly associated with greater physical activity participation in people with Type 2 diabetes. Krug et al[34] also reported an association between physical activity participation and age. In contrast Krug et al reported that older people with Type 2 diabetes were more likely to exercise than younger people. Swift et al[138] found older age and greater time since diagnosis to be associated with how long people with Type 2 diabetes had maintained regular physical activity. These findings could be related to the health belief model[139]. This model proposes that adherence with a health behaviour depends on the perceived severity of illness threat, perceptions of vulnerability to illness if no action is taken and the belief that the effectiveness of the behaviour outweighs barriers to making the change. Increasing age and duration of diabetes with the onset of diabetes complications may influence perceived susceptibility and severity of diabetes and may explain why people with Type 2 diabetes delay initiating an exercise program until a later age.

Self-efficacy (a person's confidence in their ability to perform a behaviour) has been identified as an important predictor of exercise participation in people with Type 2 diabetes. Kingery et al[140] examined the relationship of self-efficacy in predicting diabetes self care behaviour including diet, exercise and glucose testing in people with Type 2 diabetes. Exercise self-efficacy proved to be a moderate predictor of exercise participation. Of the three self care behaviours participants rated themselves lowest on exercise self efficacy. These findings are

consistent with a study conducted by Padgett et al[141] who also showed that people with Type 2 diabetes report the lowest self efficacy for exercise compared to diet, medication and general diabetes management. These findings highlight the importance of physical activity interventions designed to enhance self efficacy for improving exercise adherence in people with Type 2 diabetes.

Other cognitive variables which have been shown to be associated with exercise participation in people with Type 2 diabetes include perceived benefits to physical activity participation[142], performance and outcome expectations[140], motivation and physical activity knowledge[33]. Wilson et al[142] reported that people with Type 2 diabetes perceive the greatest belief in the effectiveness of medication therapies of diabetes management, but report the lowest belief in the effectiveness of exercise. This highlights the need to explain the rationale behind the effectiveness of exercise in the management of Type 2 diabetes. Perceived benefits of exercise among people with Type 2 diabetes include improving diabetes control and managing weight[138]. Reported barriers include physical discomfort from exercise, a fear of hypoglycaemia, being too overweight to exercise, and lack of support[138,142]. The identification of perceived barriers to physical activity participation and education on how to overcome them could significantly enhance adherence to physical activity.

Low motivation to participate in physical activity is a major factor associated with poor physical activity participation and drop out in healthy individuals[143]. In a study by Hays and Clark[33] people with Type 2 diabetes who reported fewer motivational barriers for physical activity were more likely to report higher levels of physical activity. These findings suggest effective methods for enhancing motivation should be included in the promotion of physical activity in people with Type 2 diabetes. Goal setting and self-monitoring of progress are important sources of self-motivation. Martin et al[144] found that flexible exercise goals set by the individual in comparison to goals set by an instructor significantly improved adherence to an exercise programme and long term maintenance of physical activity following completion of the programme.

Physical activity knowledge has been shown to correlate poorly with physical activity behaviour in the general population[145]. Similar findings have been reported in people with diabetes[146]. Guion et al[146] recently assessed knowledge of exercise in people with Type 2 diabetes. Results demonstrate only 38 percent of respondent knew the current physical activity

recommendations. Consistent with previous research, a weak relationship was present between knowing physical activity recommendations and actual reported physical activity participation. Similar findings have been reported from other health behaviours suggesting that awareness of desired health practices is not sufficient for bringing about the adoption of health behaviour change.

Social support has been consistently correlated with physical activity participation in the general population[147]. People with Type 2 diabetes report the least amount of social support for exercise, compared to other diabetes self care behaviour[142]. Lack of social support is one of the most frequently cited barriers to exercise participation among people with Type 2 diabetes[138]. Ary and colleagues[31] reported that although 76 percent of people with Type 2 diabetes are advised to exercise regularly only 21 percent receive instructions about the most beneficial type and amount. In comparison 76 percent of people with Type 2 diabetes receive dietary instructions. A study by Marsden[32] reported that people with Type 1 diabetes indicated that they did not receive adequate education, support or encouragement for physical activity.

To develop effective methods for promoting physical activity in people with Type 2 diabetes these variables associated with physical activity behaviour such as motivation, support and performance and outcome expectations should be targeted and interventions developed to meet personal needs.

PHYSICAL ACTIVITY RECOMMENDATIONS

Physical activity recommendations for the general population

Traditional guidelines from the ACSM for exercise prescription result from research about the quality and quantity of exercise required to improve or maintain cardiorespiratory fitness. These guidelines recommend 20 to 60 minutes of moderate to high intensity endurance exercise (60 to 90 percent of maximum heart rate or 50 to 85 percent of maximum oxygen uptake) performed 3 to 5 days a week[73]. Changes in health do not necessarily parallel improvements in cardiorespiratory fitness. A review of physiological, epidemiological and clinical evidence outlined that participation in moderate intensity activity, which may not improve cardiorespiratory fitness, had potential to improve health. In view of this new research the ACSM and CDC developed additional exercise guidelines focusing on improving health. These guidelines recommend accumulating 30 minutes of moderate intensity physical activity (60 to

79 percent of maximum heart rate or 50 to 74 percent of maximum oxygen uptake) most days of the week[38].

These guidelines appear more acceptable to the whole population[148,149]. A recent study assessing participation in these two guidelines in an obese population reported that the newer physical activity recommendations were met by twice as many of obese participants (34%) as the traditional recommendations (17%)[148].

Physical activity recommendations for people with Type 2 diabetes

It is generally recommended that people with Type 2 diabetes follow the above guidelines[76]. The ACSM recently published a position statement outlining additional physical activity recommendations for people with Type 2 diabetes[76]. These guidelines recommend that people with Type 2 diabetes with no significant complications or limitations achieve a minimum cumulative total of 1000Kcal.wk^{-1} in aerobic activity to facilitate weight management and achieve health related benefits. The addition of a well balanced resistance training programme is recommended to improve and maintain muscular strength and body composition.

In view of research demonstrating that favourable changes in glucose tolerance and insulin sensitivity deteriorate within 72 hours of physical activity participation frequent physical activity is important for people with Type 2 diabetes. The guidelines encourage participation in physical activity on at least three non-consecutive days. A low to moderate intensity of physical activity (40 to 70 percent of maximum oxygen uptake) is recommended to achieve these metabolic improvements. The guidelines stress that the intensity of physical activity performed should be a comfortable level of exertion which minimises risk and maximises health benefits and most importantly enhances the likelihood of adherence to the physical activity programme. It should be noted that the ACSM/CDC[38] recommend that to achieve health related benefits, such as improvements in weight, blood pressure and lipid profile, physical activity should be performed at a minimum intensity of 50 percent of maximum oxygen uptake on, most, if not every day of the week.

If no contraindications to exercise exist, the type of exercise a person with diabetes performs is generally a matter of personal preference. Most research documenting the benefits of physical activity for people with diabetes incorporate aerobic activity such as walking[70], cycling[67],

rowing[120] or swimming[75]. Recent research with circuit type resistance exercise has been shown to improve glucose utilisation and plasma lipid profile associated with increasing muscle mass[60]. It is recommended that people with Type 2 diabetes perform physical activity for a cumulative duration of 30 minutes per day. When weight loss is the primary goal the duration should to be incrementally increased to one hour[150]. For previously sedentary people with no formal history of exercise an initial low intensity of exercise is recommended with a gradual progressive increase in activity. To prevent musculoskeletal injuries a proper warm-up and cool-down period should be included.

Most people, including those with diabetes can undertake exercise with a high level of safety. Exercise however is not with out risk and the recommendation that people with diabetes participate in physical activity is made on the basis that the benefits outweigh the risks. The American Diabetes Association (ADA) in collaboration with the ACSM developed a position statement on exercise in the management of Type 1 and 2 diabetes[77]. These guidelines aim to minimise the possible risks of exercise for people with diabetes and recommend particular attention is paid to appropriate screening, programme design, monitoring and patient education when developing an exercise programme.

The guidelines recommend that people with diabetes have a medical evaluation to screen for the presence of micro and macrovascular complications that could potentially deteriorate as a result of participation in exercise. Identification of existing complications will assistance in the development of an individualised exercise prescription with minimal risk to the patient. It is also recommended that an exercise tolerance test is conducted prior to participation in moderate to high intensity exercise if a person with diabetes is at a high risk for underlying cardiovascular disease. This risk is based on the presence of one of the following criteria:

- age greater than 35 years
- Type 2 diabetes of greater than 10 years duration
- Type 1 diabetes of greater than 15 years duration
- presence of any additional risk factor for coronary artery disease
- presence of microvascular disease (retinopathy or nephropathy, including microalbuminuria)
- peripheral vascular disease or autonomic neuropathy

This recommendation has been developed in view of the higher prevalence of silent ischaemia[151] in people with diabetes. Silent myocardial infarction (SMI) has a reported prevalence ranging from 5 to 20 percent in diabetic populations[151]. Variations in reported prevalence probably occur due to differences in populations studied, screening techniques used and diagnostic criteria. Janand-Delenne and colleagues[151] recently conducted a cross sectional study to estimate the prevalence of SMI in a diabetic population and to determine a high risk population. 203 asymptomatic people with Type 1 and Type 2 diabetes were screened using either an exercise test (positive test = ≥ 1mm ST segment depression), thallium myocardial scintography, or both and confirmed by coronary angiography. The total prevalence of angiographically confirmed SMI was 4.8 percent (2.3% in males, 7.4% in females) in people with Type 1 diabetes and 12.1 percent (20.9% in males, 3.4% in females) in people with Type 2 diabetes. Male gender and the presence of retinopathy, peripheral artery disease and a family history of coronary artery disease were predictive factors for SMI in people with Type 2 diabetes.

It is important to note that the recommendation of pre-participation exercise screening in people with diabetes is not currently followed in the United Kingdom. If resources are available this test can provide valuable information. The exercise test can be used to evaluate ischaemia, arrhythmia, abnormal hypertensive response to exercise or abnormal orthostatic responses during or after exercise. The test will also provide information about aerobic capacity, specific precautions that may need to be taken and heart rate or perceived exertion that could be used to prescribe activities.

Physical activity prescription for people with diabetic complications

An area of ongoing concern is the possible adverse effect of physical activity on existing complications of diabetes. It has been suggested that people with diabetes complications are often told to refrain from exercise for fear of deterioration of the condition and development of further complications[152]. This leads to further compromise of physical and cardiovascular conditioning. It is important to develop exercise prescriptions for individuals with diabetes complications that will result in improved participation in normal activities and psychosocial well being while minimising risk of further deterioration.

Retinopathy

Retinopathy is a disorder of the retina that can result in impairment or loss of vision. In theory physical activity and exercise could have a potential detrimental effect on diabetic retinopathy by raising systolic blood pressure. At present there is evidence of no association between physical activity participation and development or progression of diabetic retinopathy. In the Wisconsin epidemiological study of diabetic retinopathy[153] higher levels of physical activity in women were associated with a reduced risk of having proliferative diabetic retinopathy and no association was found in men. It is possible in this study that people with diabetic complications were less likely to participate in exercise. Bernbaun et al[154] assessed the effects of a 12 week moderate intensity exercise programme in participants with multiple diabetes complications including retinopathy. No deterioration of retinopathy was reported and significant improvements were recorded in exercise tolerance, glycaemic control and insulin requirements. Activities such as walking, swimming, low impact aerobics and cycling are encouraged for people with retinopathy. Strenuous anaerobic exercise, exercise involving valsalva-type manoeuvres or jarring movements and activities that lower the head below the waist may be contraindicated[155].

Peripheral Artery Disease

Peripheral artery disease is caused by atherosclerosis of blood vessels that supply the legs and arms. Research evaluating the effects of physical activity on peripheral artery disease in people with Type 2 diabetes is limited. A number of studies evaluating the effects of physical activity for non-diabetic people with peripheral artery disease have reported improvements in symptoms. Haitt et al[156] demonstrated that 12 weeks of exercise training for people with peripheral artery disease improved peak exercise performance, delayed the onset and progression of claudication pain during exercise and improved walking ability. Interval training (e.g. 3 minute walk, 1 minute rest), swimming, stationary cycling and chair exercises are recommended activities for people with peripheral artery disease[155].

Peripheral Neuropathy

Peripheral neuropathy is defined as any disease of the peripheral nerves, usually causing weakness and numbness. Limited research has evaluated the effects of physical activity for people with peripheral neuropathy. Complications of peripheral neuropathy, with the development of the insensate foot, and foot abnormalities indicate weight bearing exercise particularly prolonged walking, running or step exercise should be undertaken with care or avoided. The repetitive stress and pressure from these types of exercise could lead to ulceration and fractures. To minimise the risk of injury, non-weight bearing exercise such as cycling, rowing, swimming and chair exercises should be encouraged. For people with neuropathy performing weight-bearing exercise emphasis of foot care and decreasing foot pressure by proper footwear is important[155].

Autonomic neuropathy

Autonomic neuropathy is a condition affecting the autonomic nervous system and is associated with a reduced aerobic capacity[157] and an increased risk of an adverse cardiovascular events or sudden death during exercise[62]. Hilstead et al[157] demonstrated people with autonomic neuropathy have a reduced Vo_2 max and impaired heart rate response to exercise in comparison to people with no autonomic neuropathy. Impaired heart rate response to exercise makes the use of heart rate to measure exercise intensity inappropriate for people with autonomic neuropathy. It is recommended that subjective perceptions of intensity using for example the rate of perceived exertion (RPE) scale should be used instead[158]. Blood pressure response during exercise and with changes in posture may be abnormal and ventilatory reflexes impaired in people with autonomic neuropathy. Tantucci et al[159] found people with diabetic autonomic neuropathy had an increased respiratory rate and alveolar ventilation in response to sub-maximal incremental exercise, in comparison to both people without diabetic autonomic neuropathy and healthy controls. Activities that cause rapid changes in body position, heart rate or blood pressure should be avoided. Water exercises and semi-recumbent cycling are recommended for those with orthostatic hypotension since the semi-recumbent posture and the pressure of water surrounding the body will help to maintain blood pressure[160].

Nephropathy

Nephropathy is a disease of the kidneys. During and immediately after acute exercise albuminuria excretion rate increases. This effect has been associated with the rise in systolic blood pressure during exercise[161]. No evidence is available to suggesting this acute effect leads to renal impairment in the long term. With a cohort of 372 people with Type 2 diabetes Calle-pascual et al[162] evaluated the effect of regular physical activity on the appearance of microalbuminuria. Results demonstrated presence of normoalbuminuria is related to higher levels of physical activity when corrected for blood pressure, duration of diabetes and glycaemic control. The higher the activity levels the higher the prevalence of normoalbuminuria. At present it is generally recommended that people with nephropathy should avoid high intensity strenuous physical activity but light to moderate intensity activity is safe and should be encouraged in this patient group[163].

SUMMARY OF SECTION ONE

A substantial amount of evidence supports the hypothesis that regular, frequent physical activity and exercise can provide important health benefits for people with Type 2 diabetes. Unfortunately only a small percentage of this population do enough physical activity to achieve these benefits. People with Type 2 diabetes experience several barriers to physical activity participation and report a greater frequency of relapse from physical activity programmes than the general population. Effective interventions to promote physical activity need to address these barriers and tailor programmes to the motivational and disease characteristics of the individual.

SECTION TWO

PHYSICAL ACTIVITY BEHAVIOUR CHANGE

A number of theoretical models have been proposed and used in an attempt to explain physical activity behaviour. Models include: the health belief model[164] and protection motivation theory[165] which both propose that health behaviour change is related to the potential to protect against disease and improve health, the self efficacy theory[166] which centres behaviour change round a person's confidence in their ability to successfully perform a behaviour, and the theory of reasoned action[167] and theory of planned behaviour[168] which both examine a persons intention to perform or not perform a behaviour.

Transtheoretical model of behaviour change

The transtheoretical model of behaviour change, originally developed to explain and predict negative behaviours has been applied to physical activity[169]. This model treats behaviour change as a dynamic process rather than an "all or nothing" phenomenon, suggesting individuals move through stages. Three factors are hypothesised to mediate the process of behaviour change. These are an individual's self efficacy for change, the decisional balance of perceived pros and cons of change and the processes individuals use to modify behaviour. The transtheoretical model therefore includes four components: the stages of change, the processes of change, decisional balance and self efficacy.

Stages of exercise behaviour change

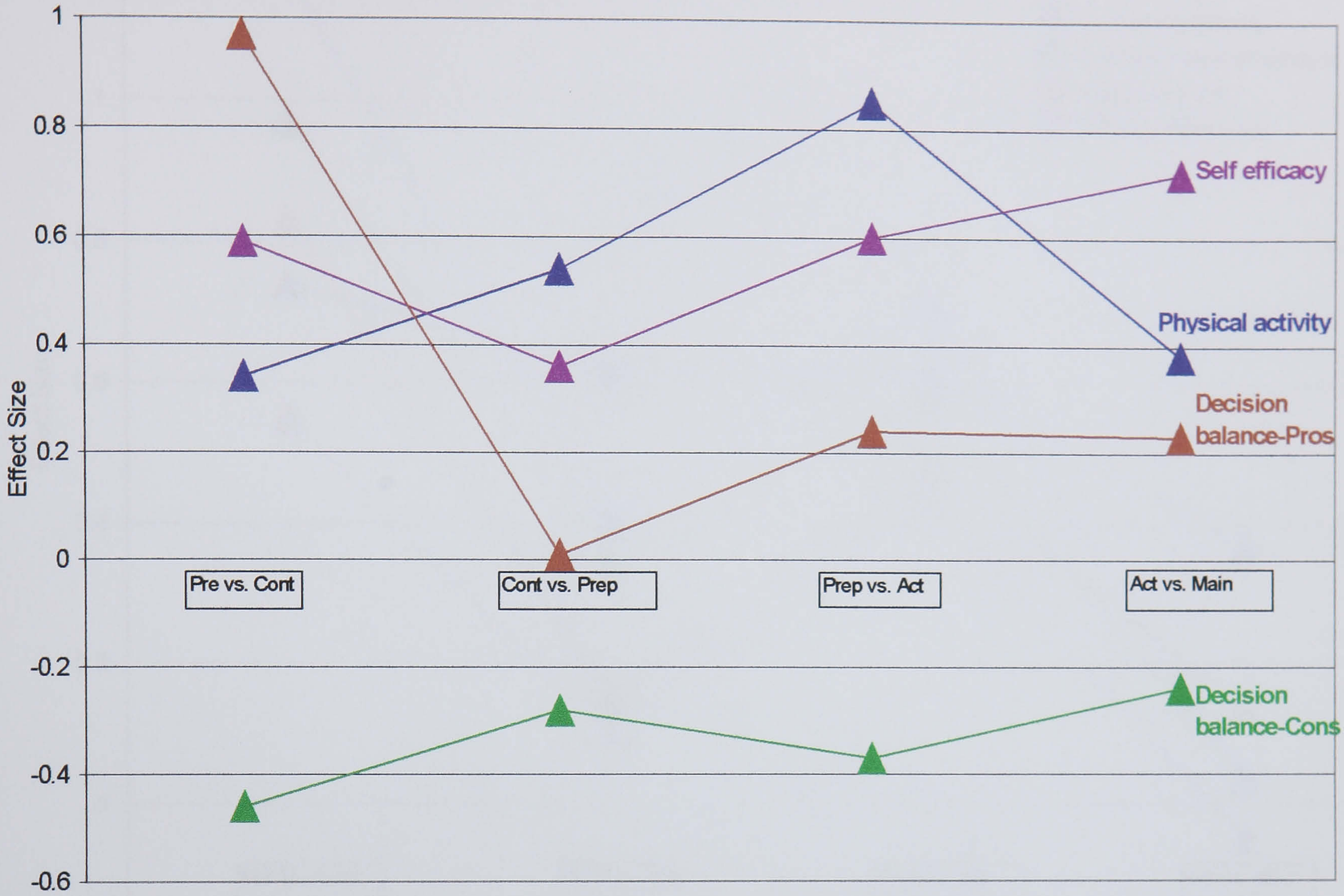
The transtheoretical model suggests that during behaviour change individuals move through five stages labelled pre-contemplation, contemplation, preparation, action and maintenance. In application to physical activity pre-contemplation includes people who do no physical activity and do not intend to start in the next 6 months. Contemplators do no physical activity but intend to start in the next 6 months. People in a preparation stage participate in some physical activity, but not enough to meet current physical activity guidelines[48]. People in an action stage are achieving current guidelines but only began in the last 6 months, whereas maintainers have been meeting current physical activity guidelines for 6 months or longer.

Termination is the final stage of behaviour change. This stage has been defined as "the stage in which there is no temptation to engage in the old behaviour and 100% self efficacy in all

previously tempting situations"[169]. There is controversy over whether this stage exists in physical activity behaviour change, as a result this stage is often ignored in applications to physical activity. Progression from one stage to another is not always linear, at any point individuals can relapse back one or a number of stages. In view of the progressive and regressive nature of behaviour change it has been suggested that an additional relapse stage should be included in the stages of exercise behaviour change model[170].

A number of studies have investigated the relationship between stage of behaviour change and physical activity behaviour in the general population. Marcus and colleagues reported an increase in minutes of moderate and vigorous intensity activity with advancing stage[171]. Cardinal[172] reported a similar relationship using two valid physical activity 7 day recall questionnaires and a measure of predicted cardiorespiratory fitness. The relationship between stage of change and physical activity behaviour in people with Type 2 diabetes has only recently been investigated. Mau et al[173] reported stage of change and movement in stage of change to be related to current physical activity behaviour and changes in physical activity behaviour respectively in people with or at risk for diabetes. A meta-analysis[174]of 71 published reports examined the relationship of transition in stage of change and level of physical activity, in addition to the three hypothesised mediators of change (decision balance, self-efficacy and the processes of change). Analyses were conducted using effect size estimates which represents the difference in mean scores divided by the pooled standard deviation. The reported relationship for all components is illustrated in Figures 1, 2 and 3[174]. In Figure 1 the greatest change in level of physical activity occurs from preparation to action, the point at which people begin to meet the physical activity guidelines.

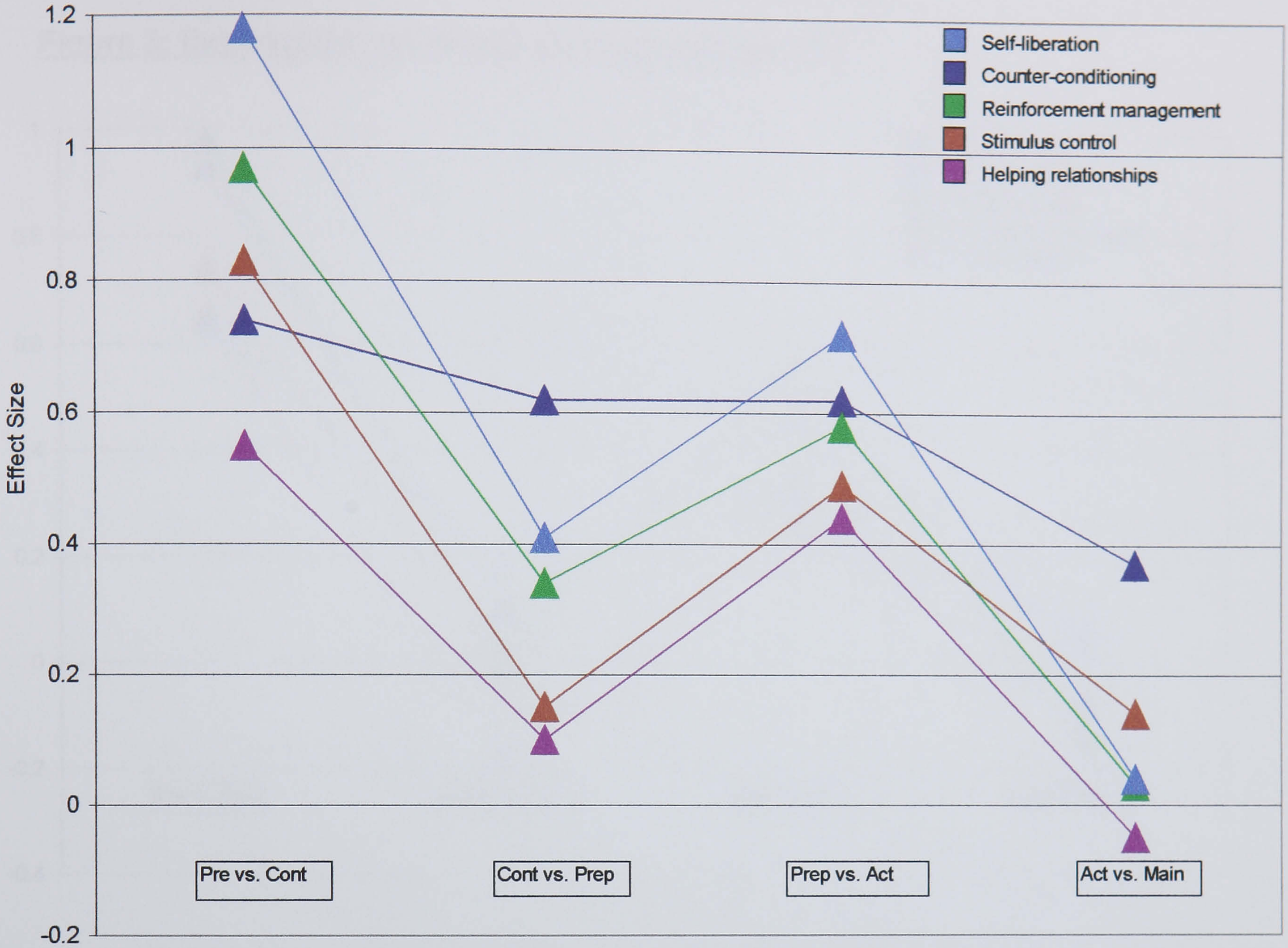
Figure 1: Physical activity, self efficacy, decision balance by stage transition[174]



Key - Pre = Pre-contemplation, Cont = Contemplation, Prep = Preparation, Act = Action, Main = Maintenance

Description - This graphs represents the relationship of transition in stage of change (i.e. movement from, for example pre-contemplation to contemplation) and change in level of physical activity, decision balance (pros and cons) and self-efficacy. The data used to develop the graph was taken, with kind permission from the authors of a published meta-analysis incorporating 71 studies[174]. Effect size data are plotted (triangle marker) representing the difference in mean scores divided by the pooled standard deviation. The connecting lines are present only to link each marker to the appropriate variables. They do not represent the flow of the relationship.

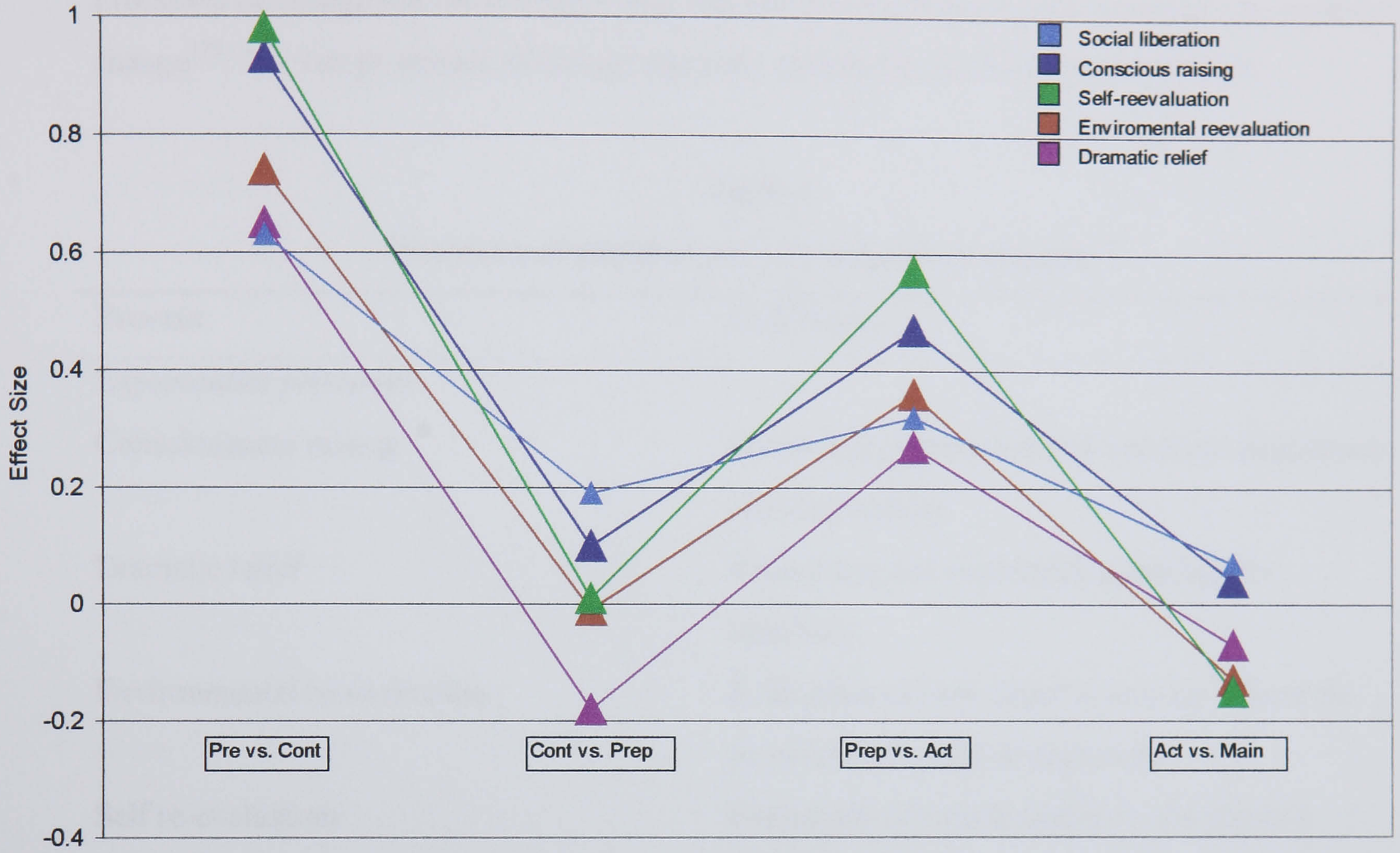
Figure 2: Behavioural processes by stage transition[174]



Key - Pre = Pre-contemplation, Cont = Contemplation, Prep = Preparation, Act = Action, Main = Maintenance

Description - This graphs represents the relationship of transition in stage of change (i.e. movement from, for example pre-contemplation to contemplation) and change in behavioural process use. The data used to develop the graph was taken, with kind permission from the authors of a published meta-analysis incorporating 71 studies[174]. Effect size data are plotted (triangle marker) representing the difference in mean scores divided by the pooled standard deviation. The connecting lines are present only to link each marker to the appropriate variables. They do not represent the flow of the relationship.

Figure 3: Experiential processes by stage transition[174]



Key - Pre = Pre-contemplation, Cont = Contemplation, Prep = Preparation, Act = Action, Main = Maintenance

Description - This graphs represents the relationship of transition in stage of change (i.e. movement from, for example pre-contemplation to contemplation) and change in frequency of experiential process use. The data used to develop the graph was taken, with kind permission from the authors of a published meta-analysis incorporating 71 studies[174]. Effect size data are plotted (triangle marker) representing the difference in mean scores divided by the pooled standard deviation. The connecting lines are present only to link each marker to the appropriate variables. They do not represent the flow of the relationship.

Processes of exercise behaviour change

Processes of change are the strategies and techniques people use to move through the stages of change[175]. The ten processes of change and their definitions are illustrated in Table 4.

Table 4

Processes of physical activity behaviour change[175]

Process	Definition
Experiential processes	
Consciousness raising	Increasing information and understanding about physical activity
Dramatic relief	Expressing and experiencing feelings for inactivity
Environmental re-evaluation	Evaluation of how physical activity affects the physical and social environments
Self re-evaluation	Evaluation of values related to the physical activity
Social liberation	Awareness, availability, and acceptance of physical activity in society
Behavioural processes	
Counter conditioning	Substituting situations of inactivity for more active options
Helping relationships	Trusting, accepting and using the support of others during physical activity behaviour change
Reinforcement management	Strengthening of successful attempts at becoming more active
Self-liberation	Commitment and self efficacy for physical activity behaviour change
Stimulus control	Control of situations that have a negative impact on physical activity behaviour change

The ten processes of change can be classified as either experiential or behavioural. The frequency of using of each process of change is related to an individual's stage of change. Marcus *et al*[175] evaluated the stages and processes of exercise behaviour change in 1,172 healthy adults. Participants in a pre-contemplation stage of change used each of the ten processes significantly less than participants in any other stage of change. The frequency of using experiential processes increased from pre-contemplation to action participants, followed by a decline in use by participants in a maintenance stage. The frequency of using behavioural processes increased steadily from pre-contemplation to action participants and remained steady for maintenance participants. The relationship between stage transition and change in process use reported in the Marshall and Biddle meta-analysis[174] of the transtheoretical model is illustrate in Figure 2 and 3. The greatest change in use across all processes occurred from pre-contemplation to contemplation, followed by preparation to action.

It has been suggested that the use of experiential processes are more important in the earlier stages of behaviour change, and the behavioural processes are more important for those in later stages[176]. Marcus and colleagues[176] investigated change in process use in relation to change in stage of exercise behaviour. 314 participants completed the stages and processes of behaviour change questionnaires at baseline and 6 month follow-up. Participants were categorised as: stable-sedentary (participants who remained in either pre-contemplation or contemplation at both assessments); stable-active (participants who remained in preparation, action or maintenance at both assessments); adopters (participants who progressed from pre-contemplation or contemplation to a higher stage) and relapsers (participants who regressed from preparation, action or maintenance to a lower stage). The two groups who remained stable in stage of exercise behaviour (stable-sedentary and stable-active) from baseline to follow-up demonstrated little change in process use. Adopters significantly increased the frequency of using all processes, except social liberation, and relapsers significantly decreased the frequency of using all behavioural processes and the experiential process "dramatic relief". This study demonstrates the importance of experiential and behavioural process use in physical activity behaviour change. In particular behavioural processes appear to be important for relapse prevention. This is consistent with the 6-month findings of project prime, a large randomised controlled trial comparing a physical activity counselling intervention, delivered by

mail or telephone. This study demonstrated that although changes in cognitive and behavioural processes of change could predict achieving current ACSM guidelines only behavioural processes could predict maintenance of these guidelines[177].

Decision balance

The third component of the transtheoretical model is decisional balance. Originally Janis & Mann[178] subdivided decision making into benefits and costs to self and others and approval or disapproval by self or others. In recent years a simpler two component structure has been used in which the benefits and costs or pros and cons of behaviour change are evaluated.

The benefits and costs of behaviour change have varying levels of importance during each stage of behaviour change. In pre-contemplation the costs of becoming more physically active outweigh the benefits, in preparation the benefits and costs are in balance and in action and maintenance the benefits outweigh the costs[179,174]. This relationship of decision balance to stage transition is reported in the meta-analysis by Marshall and Biddle[174]and is illustrated in Figure 1. Similar to the processes the most pronounced effect size is seen from pre-contemplation to contemplation.

These findings suggest that increasing perceived benefits and reducing perceived costs of physical activity should enhance behaviour change. In a randomised controlled trial Nigg et al[180] examined the effect of a decision balance intervention on attendance at a fitness centre. 153 people were randomly assigned to a control (non intervention), placebo (smoking decision balance intervention) or experimental condition (physical activity decision balance intervention). Attendance rates were assessed for 4 weeks before randomisation and for 8 weeks after. Findings illustrate the physical activity decision balance intervention to be effective in maintaining exercise participation, whereas the control and placebo groups experienced a significant decline in attendance over the 8 week period.

Self-efficacy

Self-efficacy is integrated into the transtheoretical model from Bandura's self efficacy theory[166] and describes a person's confidence in their ability to carry out behaviour change. Self efficacy in physical activity behaviour change can apply in a number of situations such as confidence in ability to overcome barriers to physical activity or to achieve activity goals. Self efficacy is a

strong determinant of exercise behaviour in the general population[181] and in people with Type 2 diabetes[140]. People with Type 2 diabetes report the lowest self efficacy scores for exercise than any other diabetes self care behaviour such as diet or blood glucose monitoring[140,141].

Self efficacy increases with advancing stage of behaviour change[174]. Marcus and colleagues[182] examined the ability of a self efficacy measure to differentiate individuals according to stage of change. 1063 participants completed stage of change and self efficacy questionnaires. Results showed self efficacy scores differentiated participants at different stages with pre-contemplators scoring lowest and maintainers scoring highest. Similar findings have been reported by Mutrie and Caddell in a British population[170]. The results of a recent meta-analysis[174], illustrated in Figure 1, show the relationship between stage transition and change in self efficacy to be non linear, with the smallest effect size occurring in the transition from contemplation to preparation.

Application of the Transtheoretical model

A large amount of research supports the use of the transtheoretical model for physical activity behaviour change. Several studies have used the transtheoretical model as a theoretical framework for physical activity promotion interventions[183-187]. In a 6 week community intervention self help manuals tailored to stage of exercise behaviour change resulted in significant increases in physical activity levels[183]. Two similar studies which incorporated randomised controlled designs also concluded stage matched manual to be more effective than standard manuals for promoting physical activity behaviour change[184,185]. The majority of these studies however involve middle aged healthy adults. Few studies have incorporated individuals with chronic diseases, such as diabetes. The ACSM position statement on exercise and Type 2 diabetes highlights the use of the transtheoretical model for promoting physical activity in this population. The transtheoretial model includes a number of mediators, such as self efficacy and perceived advantages and disadvantages of behaviour change, which are reported as being important for physical activity participation in people with Type 2 diabetes. Further research is required to fully assess the application of the transtheoretical model and all its components for physical activity research in people with Type 2 diabetes.

PHYSICAL ACTIVITY INTERVENTIONS

Physical activity is a recommended component of good diabetes management. Limited research is available to guide the promotion of physical activity in this population. The majority of research examining the effects of physical activity on diabetes management has used structured exercise programmes in which one exercise mode applies to all participants. Early physical activity interventions in the general population also incorporated structured exercise programmes implementing traditional ACSM exercise recommendations of a minimum of 3, 20 minutes of continuous, moderate to vigorous intensity exercise sessions a week. These programmes often target a small number of highly motivated people who are followed for a short time period. The majority of programmes have no theoretical basis and often experience a high drop out rate[36,74,188].

In recent years lifestyle physical activity interventions have emerged. These interventions are often based on theoretical models of behaviour change such as the transtheoretical model and are closely linked with the new physical activity recommendations of accumulating 30 minutes of moderate intensity physical activity on most, preferably all days of the week. Lifestyle interventions address important barriers such as time and accessibility, and are a promising strategy for attracting sedentary individuals to increase physical activity. Two recent studies compared structured exercise programmes to a lifestyle approach and reported that the lifestyle approach was as effective as structured exercise programmes in improving physical activity and health outcomes, including body weight and cardiorespiratory fitness[39,40].

Project active[39] randomly assigned 235 participants to either a structured exercise programme or lifestyle physical activity counselling programme. The structured exercise group followed traditional ACSM guidelines for improving cardiorespiratory fitness[73]. Participants were given a free 6 month supervised gym based programme and were then encouraged to remain a paying member. The lifestyle physical activity counselling group followed the newer ACSM guidelines for improving and maintaining health[38]. Lifestyle participants met for group discussions focusing on cognitive and behavioural strategies and techniques to assist the adoption and maintenance of a physically active lifestyle. Initially participants met weekly for 4 months, then bi-weekly from 4 to 6 months. Meetings were then decreased at 6 month intervals to monthly then bi-monthly and finally tri-monthly.

At 6 months both groups significantly increased physical activity levels and cardiorespiratory

fitness (structured group improved significant more in cardiorespiratory fitness than lifestyle group). Both groups experienced similar and significant improvements in total cholesterol, HDL-C, diastolic blood pressure and percentage body fat. From 6 to 24 months both groups reported significant decreases in physical activity levels and cardiorespiratory fitness (cardiorespiratory fitness decreased significantly more in the structured group). Diastolic blood pressure was significantly reduced and HDL-C significantly increased in both groups. Significant group differences were recorded in body composition with the lifestyle group experiencing significant reductions in body fat and no change in body weight and the structured group experiencing an significant increase in body weight and no change in body fat. From baseline to 24 months physical activity levels, cardiorespiratory fitness, blood pressure and percentage body fat were significantly higher than at baseline in both groups. The structured group also maintained a significant reduction in total cholesterol, LDL-C, and HDL-C.

This study has been criticised for not employing a randomised controlled design since no true control group was included. Furthermore both interventions are intensive and expensive with the initial cost of the lifestyle and structured interventions being $46.53 and $190.24 per month respectively[35]. This may limit their potential for implementation into other settings. This study highlights the important health benefit of an active living approach to physical activity promotion and supports the development of cognitive and behavioural strategies for physical activity promotion and maintenance.

Hillsdon et al[189] conducted a systematic review of randomised controlled trials evaluating physical activity promotion interventions in the general population. The review concluded that home based, unsupervised interventions were more successful than facility based, group programmes and that moderate intensity physical activity which could be incorporated into existing lifestyle, and interventions which provided frequent professional contact achieved better adherence. Dishman and Buckworth[190] reported similar findings in a meta-analysis of 127 physical activity promotion studies. This meta-analysis also concluded the use of behaviour modification strategies in physical activity promotion intervention to be important.

Two recent approaches to physical activity promotion which are based on the transtheoretical model and incorporate behaviour modification strategies organised into a systematic individualised intervention are motivational interviewing and physical activity counselling. Both interventions have been applied in the general population and more recently in people with

Type 2 diabetes.

Motivational interviewing

Motivational interviewing was originally developed as a treatment for addictive behaviours and is described as "a directive, client centred counselling style for helping clients examine and resolve ambivalence about behaviour change"[191]. During motivational interviewing conflicting feelings concerning a particular behaviour are explored. Using reflective listening and open-ended questions an individual is encouraged to express self-motivational statements, problem-solve their own barriers to change and formulate personal goals. A strong emphasis of the intervention is personal responsibility for change. Motivational interviewing is generally aimed at people in pre-contemplation and contemplation stages of change, where ambivalence to change is at its greatest.

Motivational interviewing has recently been applied to physical activity behaviour change. A randomised pilot study examined the effectiveness of adding motivational interviewing strategies to a behavioural weight control programme for women with Type 2 diabetes[192]. Participants who received motivational interviewing strategies demonstrated significantly better attendance, submitted more self-monitoring diaries, monitored their blood glucose more often and achieved better glucose control following treatment. Self reported frequency of exercise and recording of caloric intake also improved although not significantly.

Harland et al[193] investigated the effectiveness of brief or intensive motivational interviewing, with or without financial incentive to promote physical activity in the general population. The proportion of participants reporting increased physical activity at 12 weeks was significantly greater in all intervention groups compared with controls. The proportion of participants increasing their activity did not differ between groups receiving brief or intensive motivational interviewing. However, a greater proportion of participants who received a combination of financial incentives and intensive motivational interviewing increased their physical activity compared to other intervention groups.

Reported short-term increases in physical activity at 12 weeks were not maintained at 1 year regardless of the intensity of intervention. The authors concluded "brief interventions to promote physical activity are of questionable effectiveness". These conclusions have been highly criticised and should be interpreted with caution. Dunn stated that "a shift of 20 to 30

percent of sedentary people meeting minimum physical activity guidelines would be a major public health achievement"[39]. In this study, 26 percent of the intervention group and 23% of the control group had increased physical activity at 1 year. It is unclear whether they were meeting the 1995 ACSM/CDC physical activity guidelines[48]. The increase in physical activity in the control group may have been a result of receiving a component of motivational interviewing involving feedback of results. Several additional limitations are inherent in this study and it is clear that further research is required to accurately assess the effectiveness of motivational interviewing on promotion and maintenance of physical activity.

Physical activity counselling

Physical activity counselling[194] is similar to motivational interviewing and incorporates reflective listening, reviewing current behaviour, decisional balancing, social support and the development of realistic personal goals. There are several important differences between these two interventions. Motivational interviewing is aimed at individuals in pre-contemplation or contemplation stages of behaviour change. Miller states that motivational interviewing is most effective to "start the process of change" and additional strategies are required to "make the change"[191]. Physical activity counselling, in comparison is aimed at individuals in contemplation and preparation stages of behaviour change; individuals who are ready to change physical activity behaviour. Physical activity counselling has a core element of giving advice, where as during motivational interviewing the counsellor plays a passive role and encourages the participant to present their own arguments and strategies for change.

A number of randomised controlled trials have investigated the effectiveness of a physical activity counselling process in middle and older aged adults of the general population. Details of these studies are outlined in Table 5. Research comparing the effectiveness of fitness assessment, exercise consultation and physical activity information alone demonstrated that at 1 year post intervention only those participants receiving an exercise consultation reported significantly more physical activity than at baseline. In addition exercise consultation was the preferred intervention among sedentary members of the general public[201].

A number of studies have reported the effectiveness of physician based physical activity counselling[41-45]. Calfas et al[42] investigated the effect of brief physician led physical activity counselling, compared to standard information on promoting physical activity. Consistent

Table 5: Physical activity counselling interventions

Author	Design	Design	Population	Outcomes	Results	Comments
Activity Counselling trial writing group[195,196, 197]	RCT	2 intensities of physical activity counselling compared to usual care	874 sedentary healthy adults	7DPAR, BP, lipids, plasma insulin, cardiorespiratory fitness, fibrinogen, body composition, diet, smoking, HR variability, mood, self efficacy, QOL, cost effectiveness. *6 & 24 month follow-up*	*Women*-counselling & assistance group similar sig increases in CRF at 6 & 24 month compared to controls. PA increases in all groups at 6 months, but significantly more in counselling group. PA declines in all group to 24 months. Men No intervention effect	2 intensities of intervention equal in effectiveness in women. In men neither intervention was more effective than routine care.
Calfas (PACE trial) 1996 [198,42]	Quasiexperimental	Brief physician physical activity counselling vs standard care	212 healthy adults (mostly female)	PACE assessment score, 3 walking habits questionnaires, 7DPAR, caltrac *4 weeks*	Intervention effect on 5/6 PA outcomes.	Only ST follow-up, No clinical variables measured. Consistent results note intervention highly effective in ST
Graham-Clarke 1994[44]	RCT	Comparison of lifestyle counselling (videos), Lifestyle counselling (videos +	758 healthy adults	Diet, PA, SOEBC, smoking, perceived health	Sig increase in energy expenditure in all group. No difference between groups. Sig higher	Even minimal routine care intervention increases energy expenditure. Could suggest face to face contact

		self help manual)), usual care			number of routine care participants progressed in SOEBC	is important
Goldstein 1999[43]	RCT	Brief physician counselling vs usual care	355 older adults	SOEBC & PA levels *6 week & 8 month follow-up*	Intervention effect at 6 weeks in SOC. Not maintained at 8 months. No effect on PA	Suggested more intensive, sustained intervention required for older adults
Stevens[199]	RCT	Comparison of physical activity consultation(experimental) and posted information on leisure centre(control)	714 healthy adults	PA behaviour *8 Month follow-up*	Intervention effect on PA behaviour	High drop out rate
Loughlan 1997[200]	RCT	Exercise consultation, fitness assessment and PA information only	179 healthy adults (mostly female)	Amended 7DPAR 1,3 & 6 month follow-up	All groups increase PA (peaks at 1 month and declines to a level higher than baseline at 6 months) preparers in exercise consultation group more likely to maintain PA	Even giving information in a supportive environment is effective. Exercise consultation may be more effective in maintaining
Lowther	RCT	Exercise consultation,	370 healthy	SPAQ	All groups sig increase in	Suggests exercise

2000[201]		fitness assessment and PA information only	adults	*1,3,6 & 12 month follow-up*	PA at 1 month & maintained at 3 months. Increase comparable across groups. Only fitness assessment & exercise consultation maintained to 6 months and only exercise consultation to 12 months	consultation most successful intervention for long term PA adherence
Marcus 1997[45]	sequential comparison group design	Brief physician physical activity counselling vs usual care	44 sedentary healthy older adults mostly female	PASE, SOEBC *6 week follow-up*	Counselling perceived as feasible by physicians. Greatest increase in physical activity from participants receiving the most counselling messages	
Norris 2000[202]	RCT	As above uses PACE materials. 1/3 of intervention receive booster phone calls 2, 3, 4 months	847 healthy adults	PACE assessment, SOEBC, SF-36, PASE, PA index, behavioural determinants (self	PASE assessment sig improved in experimental group. No intervention effect on physical activity levels, SF-36 or	Participants quite active at baseline

				efficacy, social support, decision balance) *6month follow-up*	behavioural determinants. No effect of booster calls	
Project Prime[203]	RCT	Comparison of delivery method 1. By person, 2. By telephone & mail compared to usual care	378 healthy sedentary adults	7DPAR, cardiorespiratory fitness, BP, fasting plasma glucose, cholesterol, body composition, POC	Results not published yet.	
Steptoe 1999[41,204]	Cluster RCT	Stage of change tailored brief physician behaviour counselling vs standard care	883 sedentary with 1 or more modifiable CV risk factor	BMI, lipids, BP, smoking, diet, PA. *4 & 12 months*	Favourable changes in experimental group physical activity, diet & smoking. Systolic BP only CV risk factor to improve in experimental group.	Brief behavioural counselling improved health behaviour but did not really affect CV risk factors

SPAQ = Scottish Physical Activity Questionnaire, RCT = randomised controlled trial, 7DPAR = 7-day physical activity recall, CV = cardiovascular, PA = physical activity, BP = blood pressure, SOEBC = stage of exercise behaviour change, BMI = body mass index, ST = short term, POC = processes of change.

findings were recorded with five out of the six physical activity measures recording significant higher physical activity levels from baseline to 4 weeks follow-up in the experimental group compared to controls. In a similar large randomised controlled trial Steptoe et al[41] evaluated the effectiveness of including brief, nurse led behavioural counselling on healthy behaviour and cardiovascular risk factors in people with one or more modifiable cardiovascular risk factor. The intervention targeted three health behaviours (smoking, diet and physical activity). Compared to controls, participants receiving behavioural counselling recorded favourable improvements in diet, physical activity and smoking habits from baseline at 4 and 12 months. No significant difference were found in cardiovascular risk factors.

Physical activity for life (PAL)[43] is a randomised controlled trial investigating the effectiveness of brief physician-delivered physical activity counselling compared to usual care to promote physical activity in older healthy adults. 355 sedentary older adults from 24 primary care medical practices were randomly assigned to a physical activity counselling or control group. Changes in stage of behaviour and physical activity levels were assessed from baseline at 6 weeks and 8 months. Results at 6 weeks showed that a significantly greater number of the intervention group had progressed in stage of change compared to controls. This effect was not maintained at 8 months and the intervention did not produce any significant changes in physical activity levels. The author suggested that a more intensive, sustained intervention may be necessary to promote and maintain physical activity among older adults.

In general consistent findings from these studies provide strong support for the use of a physical activity consultation process in physical activity promotion in the general population. A number of studies have concluded that long term support is required to maintain physical activity behaviour[43,200]. The intensity of this support remains debatable and the topic of ongoing research[195]. Furthermore in an attempt to reach a larger number of people alternative methods for delivery of physical activity counselling, such as by mail or telephone, or internet are also under investigation[203].

The characteristics of physical activity counselling make it an attractive intervention for promoting physical activity in people with Type 2 diabetes. In theory certain activities could be contraindicated for people with Type 2 diabetes because of the presence of diabetic complications. This highlights the need for an individualised physical activity intervention that can take account of existing complications. Individualised physical activity advice has been

shown to be more effective than routine group advice at increasing physical activity behaviour in people with Type 2 diabetes[205,206]. Physical activity counselling is based on the transtheoretical model and therefore takes in to account a person's motivational readiness for physical activity behaviour change. Interventions employing stage matched strategies have shown to be more effective than non stage matched intervention at promoting physical activity. Physical activity counselling incorporates an educational component. This component will be particularly important for people with Type 2 diabetes for providing education on the metabolic effects of exercise and therefore avoiding unnecessary risk and barriers.

Current research provides modest support for the use of physical activity counselling for people with diabetes. A study of 34 people with Type 1 diabetes showed significant improvements in physical activity levels at 30 days using exercise consultation[46]. The pilot study[29] conducted for this study demonstrated improvements in physical activity at 5 weeks in people with Type 2 diabetes. Both these studies incorporate small patient numbers and relatively short follow-up periods. Further research is required to assess the long-term effectiveness of physical activity counselling in diabetic populations.

SUMMARY OF SECTION TWO

The transtheoretical model has been extensively used as a valid and reliable model for assessment of readiness to change physical activity behaviour and as a theoretical framework for interventions. This model includes a number of mediators that are reported as being important for physical activity participation in people with Type 2 diabetes. Traditional structured exercise programmes have been unsuccessful for maintaining physical activity behaviour change in people with Type 2 diabetes. Physical activity counselling has proven successful for promoting and maintaining physical activity behaviour change in the general population over periods of up to 2 years. Physical activity counselling offers numerous advantages for promoting physical activity in people with Type 2 diabetes and has shown to be successful for increasing physical activity levels over the short term (5 weeks). There is a need to assess the effectiveness of this intervention for promoting and maintaining physical activity behaviour in the longer term.

SECTION THREE

PHYSICAL ACTIVITY MEASUREMENT

The primary aim of this study was to evaluate the effect of exercise consultation on physical activity. Accurate assessment of physical activity behaviour is therefore important to establish the true effect of the intervention.

Physical activity is a complex behaviour that is multidimensional and can vary in type, intensity, duration, frequency and intermittency. Measurement of these dimensions of physical activity is important in order to relate behaviour to current physical activity recommendations. Physical activity can be performed in a number of settings including leisure, housework and occupational. Inclusion of physical activity performed in all settings is required to establish a clear picture of habitual physical activity.

Methods of measurement

Numerous methods of physical activity measurement have been developed. LaPorte[207] reported that more than 30 different methods have been used in population studies of physical activity. The large number of methods for physical activity measurement reflects the multidimensional, complex nature of physical activity and the difficulty of its measurement. Techniques for assessment of physical activity can be grouped into six general categories: behavioural observation, diaries and questionnaires, physiological markers (heart rate and cardiorespiratory fitness), calorimetry, doubly labelled water and motion sensors.

When selecting appropriate methods for physical activity assessment it is important to consider how valid, reliable and practical a method is. Validity studies assess how well a method measures what it is designed to measure. Validation of methods for measuring physical activity is complicated by the lack of an accurate criterion to which methods can be compared. Limitations in all methods of physical activity measurement have been identified. Doubly labelled water is often used as the "gold standard" method, however this method is only suitable for comparisons of total energy expenditure from physical activity and can not be used to assess individual components of physical activity such as time spent in moderate intensity activity. The doubly labelled water method is expensive and as a result intercorrelation of various methods is often carried out. Reliability is the ability of a method to provide the same results under the same conditions. This is often tested using repeated measurements of activity,

known as test-retest reliability. High reliability is important in a study that is investigating the effect of an intervention to ensure that changes in physical activity are due to the intervention and not variation of the method of measurement.

Behavioural observation

Assessing physical activity by direct observation is one of the earliest methods of physical activity measurement. This method has been used mostly as a validation criterion or with small children, when other assessment methods are unsuitable. The validity and reliability of this technique has improved over the years with advances in technology, including the use of video cameras and digital recording systems. Behavioural observation is time consuming and expensive and therefore not suitable for use in even moderately large groups. Furthermore observations are confined to relatively short periods which may not reflect habitual physical activity and people often alter activity when being observed.

Diaries and questionnaires

The diary method of assessing physical activity involves recording activity periodically and varies in complexity from detailed recordings every minute to gross categories recorded daily. Physical activity diaries are inexpensive and do not involve long-term recall, however they require co-operation and conscientiousness from participants and data processing can be time consuming if a large volume of data is involved. Also normal habitual physical activity may change as participants make their own recordings.

In 1997 the ACSM produced a supplement describing more than 30 physical activity questionnaires[208]. There are a wide variety of questionnaires each measuring different dimensions of physical activity with different degrees of complexity and length. Different questionnaires and scoring protocols yield different information about participation in current physical activity guidelines[209].

Recognised benefits of questionnaires to assess physical activity include their ability to collect data from a large number of people at a low cost, they are unobtrusive and unlikely to alter behaviour and can assess all dimensions of physical activity. There are, however, a number of limitations. Inaccurate recall is a consistent problem. This is particularly true for women[210], older people[211] and people who are sedentary[212] or overweight[213,214]. Studies have also reported

poorer accuracy in reporting moderate compared to vigorous activity[215,210]. A review by Tudor-Locke and Myers[216] identified problems of floor effects in measuring physical activity by questionnaire in physically inactive people. The authors highlight that many questionnaires do not capture low to moderate intensity accumulated physical activity and suggests that motion sensors are more appropriate for measuring physical activity in inactive populations.

The Stanford 7-day physical activity recall[217] has been selected for use in this study. This questionnaire has important advantages for the purposes of this study. This questionnaire characterises patterns of leisure and work related physical activity in terms of intensity, frequency and duration. This can be related to the current ACSM physical activity guidelines. It can be interview or self administered in a reasonable time period and is appropriate for evaluating changes in physical activity behaviour. This questionnaire has been extensively used in a wide variety of populations, including people with Type 2 diabetes[218,219]. A number of studies have used this questionnaire to evaluate the effects of interventions to promote physical activity [220,39,203,195,198]. The extensive use of this questionnaire will allow comparison of results across studies using different physical activity interventions and study populations.

The validity and reliability of this questionnaire has been studied extensively. Modest reliability has been demonstrated from the 7-day physical activity recall questionnaire using a test-retest design requiring completion of the questionnaire on two separate occasions. Repeatability has been tested over 1 week ($r=0.80$)[212], 2 weeks ($r=0.67$)[217] and 1 month ($r=0.34$)[210]. In general as the time between questionnaire completion increases the reliability decreases.

Patterson[221] outlined that test-retest reliability which does not cover the same time period is confounded by true variability in physical activity. A 7-day recall should therefore be repeated within 7 days of initial completion to include overlapping days. Patterson also questioned the use of correlation coefficients obtained from Pearson product moment correlation tests. These tests were used in the majority of the above studies These test do not detect trends. For example a ten-fold increase in physical activity from day one to two could occur, but if the order remained the same the correlation would be perfect (e.g. equal one). Lowther et al[222] tested the reliability of the Scottish Physical Activity Questionnaire (SPAQ), a modified version of the Stanford 7 day recall. During this study participants completed the SPAQ on a Monday and the following Wednesday. Each questionnaire therefore measured four identical days. Agreement between the two questionnaires was assessed by coefficient of repeatability,

recommended by Bland and Altman[223] for assessing agreement between two measures. Results revealed a high agreement and no significant difference between the two questionnaires. the mean difference being 3.09±26.5 minutes.

The validity of the Stanford 7-day physical activity recall has been extensively studied including comparisons with doubly labelled water[224-226], heart rate[224], motion sensors[226,210,227], peak oxygen uptake[226], physical activity records[226,225,210] and questionnaires[227,228]. In comparison with physical activity records Richardson and colleagues[210] demonstrated a higher association in men for total (r=0.58 to 0.66) and very hard activity (r=0.44 to 0.60) than women for total (r=0.32 to 0.33) and very hard activity (r=0.06 to 0.20). Physical activity recorded from the Caltrac accelerometer was associated with total physical activity on the 7-day recall in men (r=0.54) but not women (r=0.20). Similar associations were reported for peak Vo_2ml/kg/min. These intercorrelations of different methods of physical activity measurement illustrate interesting gender differences. This study however could be criticised for using Spearman partial correlation tests and not coefficients of repeatability as recommended for assessing agreement between two measures[223].

A limited number of studies have compared the Stanford 7-day recall with the doubly labelled water method. Using recommended statistics for investigating the agreement between two measures[223], Conway an co-workers[225] reported a significant difference between physical activity energy expenditure determined by 7 day physical activity recall and doubly labelled water. The 7 day physical activity recall overestimated energy expenditure by 30.6 percent. Racette and colleagues[224] reported similar results in a population of obese women measured before and during a 12 week weight reduction programme. In this study the 7 day recall over estimated energy expenditure significantly by 36.3 percent during weight maintenance and non-significantly by 15.8 percent during weight reduction. Leenders and co-workers[226] reported a much smaller non significant 5 percent difference between physical activity energy expenditure determined from the physical activity recall and doubly labelled water. A small number of studies have compared energy expenditure determined by other questionnaires and doubly labelled water. Starling and colleagues[229] reported the Minnesota Leisure Time Physical Activity questionnaire significantly underestimated energy expenditure by 50 to 60 percent and the Yale Physical Activity survey by one to nine percent. Using a combination of the Minnesota Leisure Time Physical Activity questionnaire and Tecumseh Occupational Activity, Conway et

al[230] reported a one to nine percent overestimation of energy expenditure.

Physiological markers

Two physiological markers used to monitor physical activity are heart rate and cardiorespiratory fitness. The rationale for the use of heart rate monitoring to measure physical activity is based on the linear relationship between heart rate (HR) and oxygen consumption (Vo_2)[231]. HR monitoring is frequently used to assess physical activity, particularly in children, due to the ability to provide a continuous, indirect, objective measure of physical activity patterns. It is relatively inexpensive, simple to use, robust and versatile in a wide variety of field settings. Although there is a strong linear relationship between HR and Vo_2 at moderate to vigorous intensities, increasing error is introduced at lower intensities[232]. HR is affected by factors other than activity such as emotional stress, temperature and food intake. HR response to physical activity varies by cardiorespiratory fitness, medication, body posture and active muscle group. Freedson & Miller [233] noted that the individual nature of the HR/Vo_2 relationship makes it necessary to establish regression equations for each subject at several types and intensities of activity.

Several methods have been used for assessing data from HR monitoring such as minutes above a certain HR[234], NET HR (activity HR minus resting HR)[234] and HR FLEX [231]. HR FLEX [231] has been established in view of the nonlinearity between HR and energy expenditure at lower HR and is an estimation of the HR at which the linear assumption does not hold. HR FLEX is taken as the mean of the highest HR at rest and the lowest HR on exercise. Below this point, energy expenditure is assumed to be equal to rest, above this point it is estimated from the slope and intercept of the line between energy expenditure and exercise HR. Westerterp[235] reviewed validation studies of the HR FLEX method with doubly labelled water as the criterion measure. The review concluded there was no significant difference between energy expenditure estimated from FLEX HR and measured by doubly labelled water. Individual differences were large ranging from –17 to +52 percent.

Livingstone and co workers[236] highlighted limitations of the HR FLEX method. HR/Vo_2 relationships are specific to activities performed and established under controlled laboratory conditions are unlikely to represent the cardiorespiratory dynamics of free living activities. The development of individual HR/Vo_2 relationships will be time consuming, making the application

of this method to large population studies limited. The assumption that one HR provides a physiological distinction between rest and exercise is questionable.

Physical activity and cardiorespiratory fitness are closely related[50]. Physical fitness is mainly determined by physical activity, although genetic contributions play a part[50]. Increases in physical activity generally produce increases in physical fitness, although the amount of adaptation in fitness to standard physical activity training varies and is under genetic control[50]. In a review of studies investigating the response to standardised training Bouchard and Rankinen[237] reported wide variation in response ranging from almost no gain to 100 percent increase.

Similar to physical activity behaviour there is a strong inverse relationship between high physical fitness and lower risk of cardiovascular and all cause morbidity and mortality[238]. Some studies suggests the relationship is stronger for cardiorespiratory fitness compared to physical activity levels[238]. This may be due to limitations in assessment. Cardiorespiratory fitness can be directly and accurately assessed during a graded exercise test. Measurement of physical activity is generally less accurate, often using questionnaires.

Vo_2 max is the classic measure of cardiorespiratory fitness and defines the highest oxygen uptake obtainable by an individual for a given form of exercise despite increased effort and workrate. A plateau in oxygen uptake is often used to determine if Vo_2max has been achieved. People with medical conditions often reach their limit of tolerance during an incremental exercise test without demonstrating a plateau in oxygen uptake. As a result the term peak oxygen uptake (Vo_2 peak) is often used.

Lactate threshold is the level of exercise (measured in units of oxygen consumption) above which aerobic energy production is supplemented by anaerobic production. Assessment of lactate threshold provides a measure of submaximal endurance capacity. This may be a more appropriate variable to assess in relatively inactive populations that rarely exert themselves beyond light to moderate intensity activity.

Lactate concentration can be measured directly in the blood and indirectly by non-invasive measurements of respiratory variables. Wasserman and McIlroy[239]described the concept of detection of the lactate threshold by measurement of respiratory variables. Lactic acid is produced during anaerobic energy production, a reaction accompanied by H^+, which undergo immediate bicarbonate buffering. This results in an increase in carbon dioxide output (Vco_2). At

work rates above the lactate threshold Vco_2 increases more rapidly than Vo_2 because carbon dioxide generated by bicarbonate buffering of lactic acid is added to the metabolic production of carbon dioxide production. This is the basis of the V-Slope technique for measuring the lactate threshold. As illustrated in Figure 4[239] when Vco_2 and Vo_2 are plotted against each other the relationship consists of two slopes. The intercept of these two slopes is the lactate threshold. Values obtained using this method have shown to closely match those obtained during direct measurements with blood lactate[240,241].

As the work rate increases during a progressive exercise test the linear pattern of V_{CO2} and minute ventilation (V_E) seen below the lactate threshold changes to a curvilinear pattern above the lactate threshold, while Vo_2 continues to increase relatively linearly. Therefore V_E/Vo_2 and $PETo_2$ increase where as V_E/Vco_2 and $PETco_2$ remain constant. These changes are illustrated in Figure 5 and can be used in accompaniment with the V-Slope technique to estimate the lactate threshold. When the work rate is increased above the lactate threshold ventilatory compensation occurs and causes an increase in V_E/Vco_2 and decrease in $PETco_2$ while V_E/Vo_2 and $PETo_2$ continue to rise.

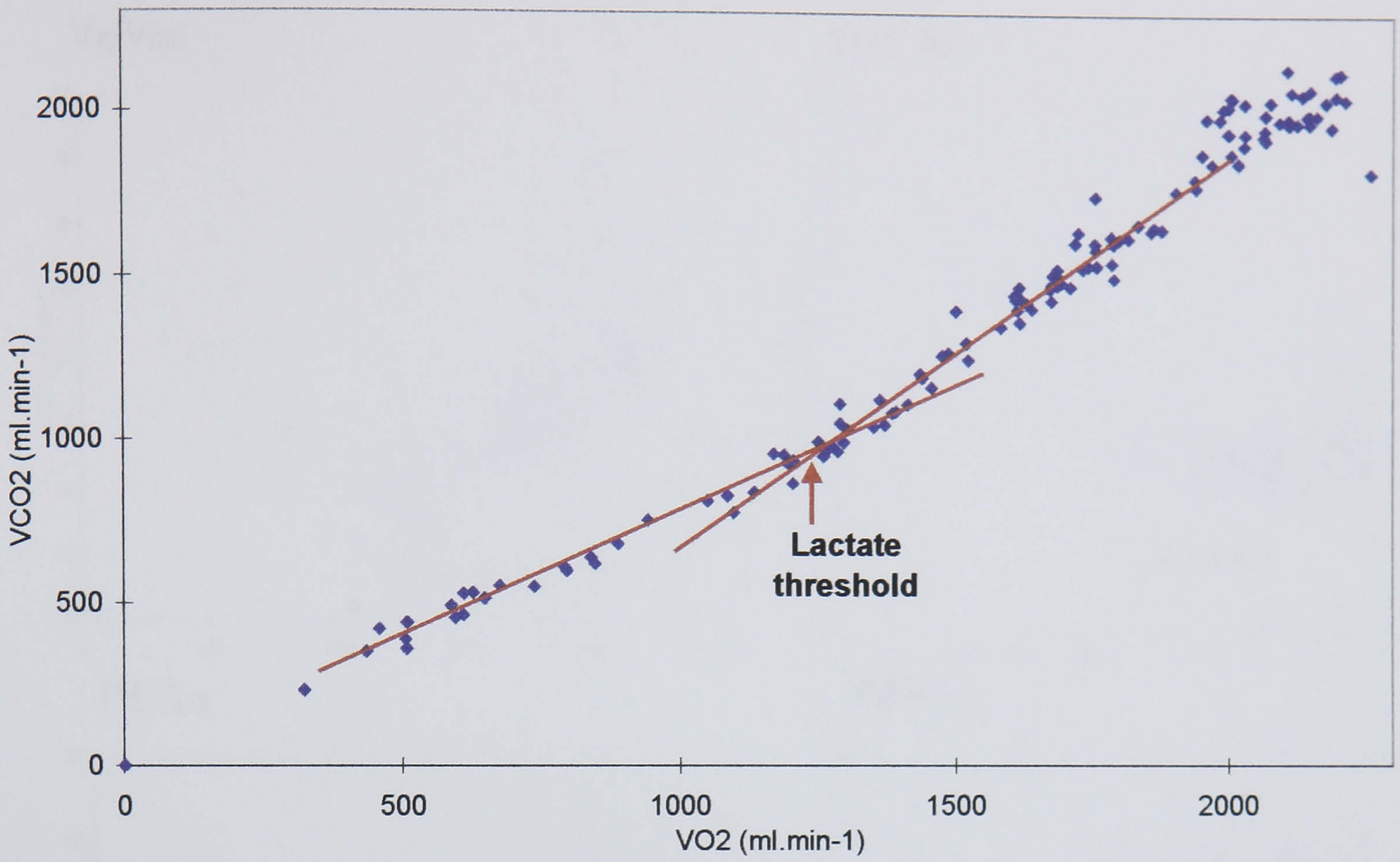
Calorimetry

Whole body calorimetry is described as the most precise laboratory based method for measuring total energy expenditure[242] and estimates energy expenditure by directly measuring oxygen uptake and carbon dioxide production. Measurements can be conducted using either a whole room calorimeter or a metabolic cart. This technique is expensive and has limited application to population based studies as it does not assess individuals in a free-living situation.

Doubly Labelled Water (DLW)

The DLW method involves subjects ingesting a quantity of water with known hydrogen and oxygen isotope concentrations. Urine samples for isotope measurement are collected before and several times after ingestion of the solution. Isotope abundance in the urine is then measured and related to carbon dioxide production. Total carbon dioxide production can then be converted to total daily energy expenditure. Energy expenditure during physical activity can be determined indirectly by subtracting resting metabolic rate and the thermic effect of food from total daily energy expenditure.

Figure 4: The V-Slope technique[239]

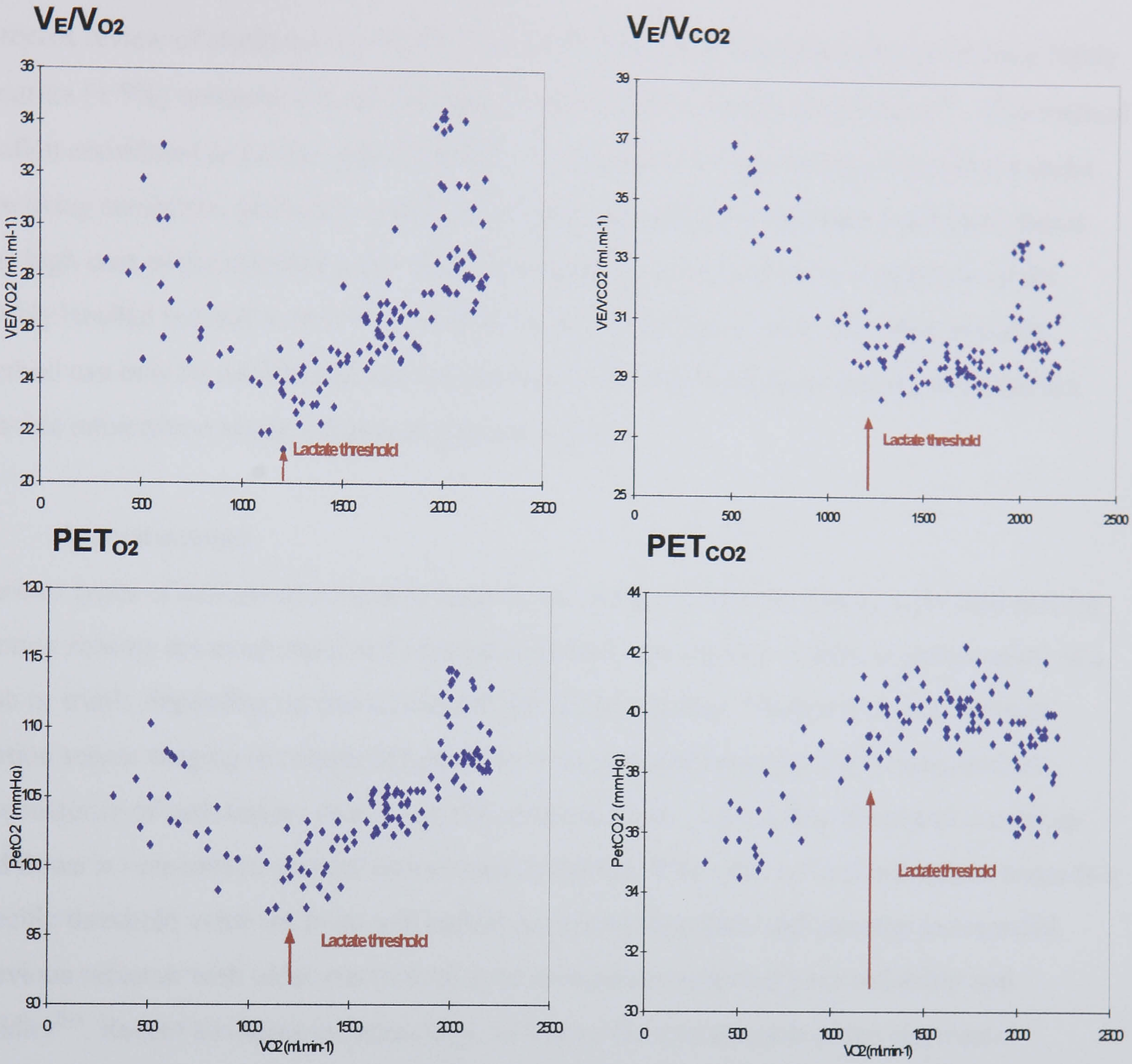


Key - VO2 = oxygen uptake, VCO2 = carbon dioxide output

The V-Slope technique

A non invasive technique allowing detection of the onset of lactic acidosis. Above the lactic threshold, the increase in lactic acid production causes an acceleration of the rate of Vco_2 relative to Vo_2. When Vco_2 and Vo_2 are plotted against each other the relationship consists of two slopes. The intercept of these two slopes is the lactate threshold.

Figure 5: Ventilatory equivalent method[239]



Key - Vo_2 = oxygen uptake, Vco_2 = carbon dioxide output, PET_{CO2} = End-Tidal Oxygen Partial Pressure , PET_{O2} = End-Tidal Oxygen Partial Pressure, V_E/V_{CO2} = Ventilatory Equivalent for Carbon Dioxide, V_E/V_{O2} = Ventilatory Equivalent for Oxygen

Ventilatory equivalent method

The ventilatory equivalent method is often used in accompaniment with the V-Slope techniques to estimate the lactate threshold. As work rate increases during a progressive exercise test the linear pattern of V_{CO2} and minute ventilation (V_E) seen below the lactate threshold changes to a curvilinear pattern above the lactate threshold, while Vo_2 continues to increase relatively linearly. Therefore V_E/Vo_2 and $PETo_2$ increase where as V_E/Vco_2 and $PETco_2$ remain constant.

A recent review of studies using the DLW method concluded this techniques provides a highly accurate (± 5%) measure of total daily and physical activity energy expenditure[243]. This method is often considered to be the 'gold standard' for estimation of total energy expenditure under free living conditions and is often used as the criterion method to evaluate other instruments. The high cost of the stable isotopes and sophisticated analysis limits the application of the doubly labelled method to relatively small groups. Furthermore the doubly labelled water method can only be used to indicate the average level of daily physical activity and does not provide information about patterns of physical activity.

Motion sensors

Various types of motion sensors have been developed to objectively measure physical activity. Motion sensors are mechanical and electronic devices that pick up motion or acceleration of a limb or trunk, depending on the attachment site of the monitor. There are several types of motion sensor ranging in complexity and cost from pedometers to triaxial accelerometers. The majority of pedometers operate on the same principle. A horizontal lever arm moves up and down in response to vertical movements of the hip. When the vertical movement exceeds a specific threshold value the lever arm makes an electrical contact and one step in recorded. Previous research with older mechanical style pedometers reported poor reliability and validity[244]. Recent advances in technology, including the introduction of the electronic pedometer, combined with greater quality control in manufacturing has improved the reliability and validity of pedometers. Bassett et al[245] investigated the accuracy of five commercially available electronic pedometers, reported acceptable results for most monitors, with the Yamax Digi-Walker 500 (Yamax Inc, Tokyo, Japan) demonstrating the highest reliability and validity. During field-based evaluations along a 4.88km pavement, the Digi-Walker measured the number of steps and distance to within 1% of actual values.

Pedometers are generally small, inexpensive and easy to use, therefore very useful for large scale trials. They can provide feedback, making them useful as motivational tools with the ability to influence physical activity behaviour. Their use for measuring habitual physical activity has several limitations. Pedometers have a restricted data storage capacity limiting their use for assessment of activity over extended periods. Pedometers are not sensitive to changes in speed. Bassett et al[245] reported that at slow walking speeds pedometers tend to underestimate

distance. This inaccuracy results from smaller vertical movements of the hip which are below the specific threshold value and are therefore not recorded. Similarly at faster speeds the pedometers also underestimate distance. This is due to a lengthening of stride. Another limitation is that pedometers do not contain an internal clock, therefore it is not possible to determine the intensity or duration of activity performed. This limitation makes it difficult to determine the number of steps per day required to meet existing physical activity guidelines. Literature from Japan[246,247] has recommended a goal of 10,000 steps/day however there is no evidence to support that recommendation at this time.

Although pedometers report reasonable accuracy for measuring walking activities, research demonstrates they are less accurate for measuring free living activities. Based upon comparison with a 7-day physical activity recall interview the Yamax Digiwalker 500 significantly underestimated energy expenditure for physical activity by 48 percent[248]. Bassett and co workers[249] reported similar results with the newer Yamax pedometer (Yamax SW-701). Pedometers are designed to measure vertical movement at the hip during walking. Activity with little or no vertical movement of the hip therefore will not be recorded. In conclusion although the limitations of pedometers make them less suitable for assessing habitual physical activity patterns, they are potentially useful tools for walking interventions.

Acceleration of the body occurs in response to muscular forces and thus energy expenditure. Accelerometers provide an objective measure of dynamic physical activity measured by bodily acceleration. The uniaxial accelerometer is a more complex instrument than the pedometer. These devices record the magnitude of accelerations from a single axis (usually vertical). Monitors are small and have an internal clock allowing the assessment of patterns of activity over extended time periods. Several uniaxial accelerometers are commercially available. As a result of the favourable size, ease of use, durability and large memory capacity the CSA accelerometer (Computer Science and Applications, Shalimar, Florida) is often the most preferred accelerometer for field studies. This monitor has the further advantage of being designed and validated to be worn at the hip, wrist or ankle.

The reliability and validity of the CSA accelerometer to measure physical activity and estimate energy expenditure has been tested in children and young adults under laboratory and free living conditions. Melanson and Freedson[250] reported high reliability (r=0.93 to 0.99) for the CSA monitor at all attachment sites using a test-retest design requiring healthy young adults to

repeat the same activity protocol (treadmill walking and running) on two separate occasions. Inter-instrument reliability has also shown to be high (r=0.87 to 0.99)[251,252] in tests requiring participants to wear two monitors attached at the same site, at the same time.

Melanson and Freedson[250] assessed the validity of the CSA monitor worn at all three sites during treadmill walking and running in young adults using energy expenditure assessed by indirect calorimetry as the criterion measure. Activity counts from the monitors at all sites significantly increased with increasing speed. Significant linear correlations between activity counts, energy expenditure and Vo_2 were recorded at all monitors sites (ankle EE=0.66, Vo_2=0.77, hip=0.80, Vo_2=0.82, wrist EE=0.81, Vo_2=0.89). Melanson and Freedson[250] reported that the CSA did not discriminate change in treadmill gradient and no relationship was found between activity counts, energy expenditure and Vo_2 for changes in treadmill gradient.

A number of models have been developed to estimate energy expenditure ($Kcal.min^{-1}$) from CSA activity counts[250,252]. Melanson and Freedson[250] developed three energy expenditure prediction models using one (wrist), two (wrist & hip) and three (wrist, hip & ankle) monitors. Cross validation of estimated energy expenditure and actual energy expenditure, assessed by indirect calorimetry, demonstrated no significant difference for all three monitor sites. Activity counts measured at the wrist, wrist & hip and wrist, hip & ankle explained 82, 85-89 and 92 percent respectively of the variance in energy expenditure. Multiple monitors therefore slightly improved estimations of energy expenditure during treadmill walking and running, however whether this small improvement warrants the extra cost and subject burden associated with wearing multiple monitors is questionable. Prediction models published by Melanson[250] and Trost[252] have both been developed from laboratory based treadmill walking and running. In view of the more complex and diverse nature of free living activity the relationship between activity counts and energy expenditure in a controlled laboratory setting are unlikely to reflect the relationship under free living conditions.

The accuracy of the CSA monitor to measure physical activity and estimate physical activity energy expenditure in free living conditions has been studied using doubly labelled water(DLW) as the criterion measure[226]. Activity counts were significantly correlated to physical activity energy expenditure measured by DLW. However, compared to DLW measurements of physical activity energy expenditure, the CSA monitor significantly underestimated physical activity energy expenditure by 40 to 55 percent. Hendlemen et al[253] developed individual energy

expenditure equations during indoor track walking. These equations were then applied to free living activities. Results demonstrated the metabolic costs of all free-living activities were significantly underestimated by 30 to 57 percent from the equations using both the CSA and Tritrac accelerometers. These studies demonstrate that there are limitations to the use of accelerometers in predicting energy expenditure in free living conditions. The primary limitation is that the relationship of activity counts with energy expenditure differs depending on the type of physical activity performed, therefore no single regression equation can be used to accurately predict energy expenditure. Furthermore accelerometers do not detect the added energy cost of activities related to muscular loading, upper body movements, added loads and graded or soft surfaces. Accelerometers cannot be used during swimming or other water activities.

Acknowledging the limitations of estimating energy expenditure from accelerometer counts, a number of studies[254], have proposed the use of activity count cut points to classify activity into intensity ranges. This method could then be used to determine the amount of time spent at a specific levels of intensity. Similar to the limitations of predicting energy expenditure from activity counts the activity count cut points corresponding to specific intensity levels will depend on the type of activity performed. The application of activity count cut points developed from controlled laboratory treadmill walking and running to free living conditions is questionable.

Triaxial accelerometers measure accelerations in the vertical, horizontal and mediolateral axis. These monitors are larger than uniaxial accelerometers and more expensive. In general triaxial accelerometers offer similar features as uniaxial monitors, although accelerations are recorded for each individual axis and for all axis combined. The Tritrac R3D (Hemokinetics,Inc, Madison, WI) is the most commonly used triaxial accelerometer. The reliability and validity of the Tritrac R3D worn at the waist has been investigated in a number of studies[253,248,255-263]. Kochersberger et al[255] reported a high test-retest reliability (r=0.97) during treadmill walking in an elderly population. Limitations in interinstrument reliability have been reported[258,257]. Meijer et al[264] reported the difference in activity counts between two triaxial accelerometers during treadmill walking to be as much as 22 percent. This difference is higher than the 3 percent difference reported by Fairweather et al[251] from the CSA uniaxial accelerometer.

As human movement is multidirectional a triaxial accelerometer might be expected to capture a greater proportion of free living activity than a uniaxial accelerometer. Bouten et al[265] supports

this theory reporting that during sedentary activities, including sitting, writing, arm work and standing 67 percent of the variance in energy expenditure could be explained by activity counts from the x, y and z-axis. When activity counts from only the x-direction were considered energy expenditure was underestimated by 60 percent. A number of studies have demonstrated a high interaccelerometer agreement and a similar degree of error between the CSA, uniaxial accelerometer and Tritrac-R3D, triaxial accelerometer[248,255,253,263], suggesting that triaxial measurements are not superior to uniaxial measurements of physical activity.

In a comparison with energy expenditure measured by indirect calorimetry during physical activity in a field setting, Hendleman et al[253] reported similar correlations between measured and estimated energy expenditure from both the CSA (r=0.59) and Tritrac-R3D (r=0.62) accelerometers. Correlations between the two accelerometers were high (r=0.93). Leenders et al[226] compared physical activity measurement in free living conditions over 7 days using the 7-day physical activity recall, CSA and Tritrac-R3D accelerometers. Activity counts from the CSA were highly correlated with the Tritrac-R3D (r=0.91). Furthermore analysis of variance demonstrated no significant difference between time spent in light, moderate and very/very hard activities determined by the 7 day physical activity recall, CSA and Tritrac-R3D accelerometers. It is interesting to note that this study used activity counts from the CSA and Tritrac-R3D, which correlated well with the 7-day recall. Previous studies[261] using energy expenditure estimated from accelerometer counts have demonstrated poorer correlations with the 7 day recall. This suggests that converting activity counts to energy expenditure is not the best approach and using activity counts is more appropriate.

When comparing the CSA and Tritrac-R3D it is important to note that the Tritrac is larger and reports have been made of the monitor being bulky and obtrusive to wear. The CSA is smaller and can be worn underneath clothes, making it less conspicuous in addition to limiting extraneous movement. In a field setting, compliance is an important issue. This may make the size of the CSA accelerometer more appealing.

Time frame for measurement

A large amount of research has focused on improving methods of physical activity measurement. A further important consideration when measuring habitual physical activity is the time frame required to provide an accurate estimate of normal habitual physical activity.

"The pattern of activity for each individual is different, and within individuals the pattern of activity is likely to vary from day to day, weekday to weekend, week to week and season to season". Sallis et al (1985)[217]

As outlined in this quote by Sallis physical activity levels in free living humans are variable. These variations are important when considering the number of days and timing of physical activity measurement. Mathews and collegues[266] recently investigated sources of variation in self reported physical activity and estimated the number of days of measurement required to provide an acceptable measure of normal physical activity habits. Day to day variation was the principle source of variance in total physical activity (50-60 percent), with variance in day of week and season being evident, but smaller in comparison (6-15 percent). Overall variance declined with age and was lower in women compared to men and occupational compared to non-occupational activity. 7-10 days of self reported data in men and 14-21 days in women were required to provide an acceptable measure of habitual physical activity. This estimate is based on a healthy, although varied population. A similar time period was reported by Baranowski and co-workers[267] with a group of 174 high school teachers. Gretebeck and Montoye[268] reported that using objective measures of physical activity (pedometers and accelerometers) 6 days (including weekend days) of accelerometer data were needed to adequately describe the activity patterns of middle aged men. Subjects used in these studies are unlikely to be representative of all populations. Populations with less between day variability, for example sedentary or elderly populations, are likely to require a smaller monitoring time frame.

The reliability of self reported physical activity declines with age[266] and recall of activity has been reported to decline over 7 days[269]. Multiple days of recording increase participant burden and may affect behaviour. Working on the principle that error in physical activity measurement increases variance, increasing the reliability of physical activity measurement should reduce variance in recorded physical activity behaviour. Combining methods of physical activity measurement may increase the reliability and validity of the estimate and thus reduce the number of days required.

Although noted to be less variable than day to day variance, seasonal effects on physical activity should also be considered[266]. Seasonal effects on physical activity are likely to differ across countries. Ideally, when assessing the effects of a physical activity intervention, measurements should be included which assess physical activity during the same seasonal period.

SUMMARY OF SECTION THREE

Despite the abundance of available methods of physical activity measurement there is currently no single "gold standard" method that can simultaneously and accurately measure all dimensions of physical activity. Subjective and objective methods have different limitations for measuring physical activity. The advantages of objective methods often compensate for the disadvantages of subjective methods. This outlines the benefits of combining these methods to measure physical activity. The CSA accelerometer offers several advantages for measuring free living activity. The accuracy of the uniaxial CSA accelerometer for measuring free living activity is better than the pedometer and about the same as the triaxial Tritrac accelerometer. The CSA accelerometer has the advantage over the Tritrac of being smaller and less obtrusive to wear. The validity of the CSA accelerometer to measure physical activity under laboratory and free living conditions has established in children and young adults. Limited research has determined the validity of the CSA accelerometer in older people.

CHAPTER THREE

STUDY ONE

A PILOT STUDY

THE VALIDITY OF THE CSA ACCELEROMETER TO MEASURE PHYSICAL ACTIVITY IN PEOPLE WITH TYPE 2 DIABETES[270]

AIM

This pilot study was conducted to investigate the validity of the CSA accelerometer to measure walking and daily living activities in people with Type 2 diabetes. Originally a secondary aim of the study was to establish a relationship between accelerometer activity counts and oxygen uptake with the view to developing activity count cut points related to intensity categories in people with Type 2 diabetes. This conversion would allow the results from the CSA accelerometer to be related to current physical activity guidelines[48]. Initial results of the research, in addition to subsequent studies published after the pilot led to the conclusion that relating activity counts to oxygen uptake and developing activity count cut points has many limitations. Analyses for the secondary aim of this pilot study was not conducted and it was concluded that the results from the CSA accelerometer would be better analysed using the raw activity counts.

METHODOLOGY

<u>Participants</u>

13 people with Type 2 diabetes (8M 5F, age 54.2±6.5yr, BMI 33.4±4.1) were recruited from diabetes outpatient clinics at the Royal Alexandra Hospital in the West of Scotland. Type 2 Diabetes Mellitus was defined according to established criteria[1]. Patients with concurrent medical conditions contraindicated to the exercise associated with the study were excluded. The ethical committee of Argyll and Clyde Health Board approved the study and all patients provided written informed consent before participating (see Appendix A and B).

Procedure

All participants completed two visits for study assessment.

Visit one: Total duration 60 minutes

Participants performed a symptom limited peak treadmill exercise test using an incremental protocol. This test was used to screen patients prior to participation and to determine peak aerobic capacity and therefore intensity of activities performed. The protocol consisted of a three minute warm-up during which the speed was increased to achieve a brisk walking pace at a zero percent gradient. This speed varied among participants and once achieved was then maintained throughout the test. After the three minute warm-up phase the gradient of the treadmill was increased by 1 to 2 percent (depending on individual capacity) to the limit of tolerance. During the test oxygen uptake (Vo_2ml/kg/min), carbon dioxide output (Vco_2ml/min), minute ventilation (V_E ml/min) and respiratory exchange ratio ($RER=Vco_2/Vo_2$) were continuously measured using the Cosmed $K4b_2$ telemetry system. Peak oxygen uptake was calculated by averaging the final 30 seconds of exercise.

Visit two: Total duration 90 minute

Participants walked at a slow, normal and brisk pace and performed other daily living activities (e.g. stair climbing, hoovering, carrying loaded shopping bags and pushing a loaded shopping cart at the normal walking pace). Walking activities were performed using a ten-metre shuttle walk course[271,272]. All activities were performed at a self-selected pace. The selected pace of activities was held constant by a metronome (stairclimbing and vacuuming) or an audio signal played on a tape cassette (walking activities). The range of walking speeds was as follows: slow 2.44km/h^{-1}, normal 3.27 to 3.60km/h^{-1} and brisk 4.11 to 4.97km/h^{-1}. The order in which each activity was performed was randomised. Each activity was performed for six minutes or until a steady state oxygen uptake was reached. Activities were separated by an adequate period to allow pulmonary gas exchange indexes to return to a resting state. During each activity, steady state Vo_2ml/kg/min was measured using a portable breath by breath system (Cosmed $K4b^2$) and activity counts (AC/min) were recorded using accelerometers (CSA Inc.) worn on the waist, ankle and wrist.

Outcomes measures

Indirect calorimetry

Oxygen uptake, measured by the Cosmed $K4b_2$ telemetry system was used as the reference criterion. The Cosmed $K4b_2$ is a lightweight (550g) portable breath by breath gas exchange system which has been previously validated[273,274]. The system is composed of a soft face mask to sample exhaled air and a sensor system to measure ventilation, oxygen and carbon dioxide concentrations in expired air. A bi-directional digital turbine fixed to the face mask measures flow and volume. The system also contains a polar heart rate monitor in addition to a transmitter and receiver unit and rechargeable battery that are all attached to a chest harness. The $K4b_2$ system was calibrated before each assessment according to manufacturers instructions. Steady state Vo_2ml/kg/min for each activity was calculated by averaging the final two minutes of exercise.

Accelerometry

The CSA accelerometer (Computer Science and Applications, Shalimar, FL) is a small (5.1, 4.1, 1.5cm), lightweight (70gm) activity monitor which provides an objective measure of dynamic physical activity measured by bodily acceleration. The CSA monitor measures movement using a vertical uniaxial piezoelectric bender which, when displaced, generates a signal proportional to the force acting on it. Generated signals are compiled developing an activity count that is stored over a defined period. During this study activity monitors were secured firmly using velcro straps to the participants dominant hip, wrist and ankle. Monitors were programmed to collect activity counts at one minute intervals. On completion of the daily living activities the accelerometers were downloaded and an average activity count per minute for each activity was calculated.

An external timepiece was used to synchronise the accelerometer internal clock with the $K4b_2$ software programme.

Data analysis

Data is presented as mean (± standard deviation). Data with variations from a normal distribution is presented as median (interquartile range). Minitab (version 13.3) was used to analysed data. Statistical analyses were performed by paired t-tests or non parametric equivalent tests. A Bonferroni correction was applied to control for Type 1 errors as a large number of comparisons were conducted.

RESULTS

Walking activity

Table 6 illustrates the Vo_2ml/kg/min and activity counts/min recorded during each walking speed and Table 7 shows the 98% CI for the results of the pairwise statistical comparisons used to analyse the difference in Vo_2 (ml/kg/min) and activity counts/min at each walking speed results. The results demonstrate that Vo_2ml/kg/min significantly increased as walking speed increased. A similar pattern of results was recorded for activity counts at all accelerometer placements.

Table 6

Mean Vo_2 (ml/kg/min) and median activity counts/min at different walking speeds

Walking speed	Mean Vo_2 (ml/kg/min)	% of peak	Median CSA Ankle	Median CSA Waist	Median CSA Wrist
Slow	9.3±0.8	36.4	4716 (4134,5192)	1151 (982,1262)	1888 (1383,1916)
Normal	10.8±1.0	42.3	6825 (5855,7832)	1901 (1754,2173)	2780 (2218,3547)
Brisk	16.2±2.6	62.6	8404 (7175,9653)	3991 (2842,4247)	2897 (3505,6423)

Table 7

98%CI from pairwise comparison tests of the difference in Vo_2 (ml/kg/min) and activity counts/min at each walking speeds

Comparison	Vo_2ml/kg/min 98%CI	CSA Ankle 98%CI	CSA Waist 98%CI	CSA Wrist 98%CI
Slow-Normal	0.9,2.2	1584,2083	676,982	834,1513
Slow-Brisk	5.1,8.8	2944,4351	2090,3094	1924,4329
Normal-Brisk	3.9,6.8	1275,2444	1299,2171	853,3097

Daily living activity

The Vo_2 (ml/kg/min), percentage of peak Vo_2 and activity counts/min for all activities of daily living are detailed in Table 8.

Table 8

Mean Vo_2ml/kg/min, percentage of peak Vo_2 ml/kg/min and activity counts for activities of daily living

Activity	Mean Vo_2 (ml/kg/min)	% of peak Vo_2	Median CSA Ankle	Median CSA Waist	Median CSA Wrist
Stairs	18.4±2.7	71.4	6679	2078	3095
Hoover	9.4±1.3	36.5	235	227	1684
Trolley	11.9±0.9	46.6	6376	1602	725
Shopping	12.3±1.1	48.2	7395	1967	2805

Oxygen uptake for carrying the bags and pushing the loaded shopping trolley was similar, and significantly higher than normal walking (98%CI Bags-normal 1.1,2.0, Trolley-normal 0.7,1.6). Compared to normal walking, activity counts recorded at the ankle and waist when carrying shopping bags were significantly higher (98%CI Ankle 248,595, Waist 41,238) and activity counts at all placement sites when pushing the shopping trolley were significantly lower (98%CI Ankle –959,-248, Waist –353,-143, Wrist –2879,-1059).

Monitor placement

Ankle counts were consistently higher then wrist and waist counts for all activities except hoovering when wrist activity counts were highest. No significant differences were found between wrist and waist activity counts for all activities except hoovering (98%CI 765,4095).

DISCUSSION

In this pilot study oxygen uptake and activity counts, at all accelerometer placements, significantly increased as walking speed increase. This finding is consistent with previous research in children[252] and young adults[250] and indicates that the CSA accelerometers are sensitive to changes in walking speed in a range of difference populations, including people with Type 2 diabetes. Again consistent with Melanson and colleagues[250] activity counts recorded at the ankle were consistently higher than activity counts recorded at other placement sites. In this study this was true for all activities except hoovering, which is primarily an arm activity.

Analyses of activity counts and oxygen uptake during daily living activities led to the conclusion that oxygen uptake during daily living activities is not always reflected by changes in activity counts. Oxygen uptake was significantly higher when pushing or carrying a load. Activity counts when carrying shopping bags at a normal walking pace were also significantly higher than walking at a normal pace without shopping bags. In contrast activity counts when pushing a loaded shopping trolley were significantly lower. This finding highlights an inability of the CSA accelerometer to detect increased oxygen uptake required when pushing or lifting objects. From this finding it becomes clear that the relationship of activity counts to oxygen uptake is different depending on the type of physical activity performed. The relationship of activity counts to oxygen uptake will also be dependent on individual fitness. For example the same activity performed by a person with a high level of fitness and by a person with a low level of fitness will record the same activity counts with different a different oxygen uptake.

Relating activity counts to oxygen uptake has a number of limitations and therefore the analyses for the secondary aims of this pilot study were not conducted. It was concluded that the results from the CSA accelerometer would be better analysed using the raw activity counts.

Despite the limitations of the CSA accelerometer highlighted from the pilot study, these devices have a number of advantages over other methods of physical activity measurement. The main advantage is their ability to store movement data for long periods of time to be recalled later. This eliminates many of the problems associated with subjective recall physical activity questionnaires. Many of the advantages of the objective accelerometer method of measuring physical activity compensate for the disadvantages of subjective methods such as recall

questionnaires. For this reason it would be beneficial to include both subjective and objective methods for measurement of free living activity.

CHAPTER FOUR

STUDY TWO

EFFECTIVENESS OF EXERCISE CONSULTATION TO PROMOTE AND MAINTAIN PHYSICAL ACTIVITY IN PEOPLE WITH TYPE 2 DIABETES

The benefits of regular physical activity in the management of Type 2 diabetes are well documented. Unfortunately the majority of this population do not do enough activity to achieve these benefits[34,33,137]. Research is required to determine how to promote physical activity to this population. Exercise consultation[194], based on the transtheoretical model of behaviour change, combines motivational theory and cognitive behavioural strategies into a systematic individualised intervention to promote and maintain physical activity behaviour. Randomised controlled trials in the general population with intermediate to long term follow-up (6-24 months) have demonstrated effective physical activity promotion with exercise consultation interventions[274,39]. In a pilot study exercise consultation was effective for increasing short-term (1-month) physical activity in people with Type 2 diabetes[29].

AIM

The primary aim of this study was to assess the effectiveness of exercise consultation for the promotion and maintenance of physical activity over 12 months in people with Type 2 diabetes. Secondary aims were to assess changes in physiological, biochemical and quality of life variables from baseline to 6 and 12 months.

METHODOLOGY

Participants

223 suitable people with Type 2 diabetes were invited to participate in this study. These people were identified from diabetes outpatient clinics at the Royal Alexandra Hospital in the West of Scotland. The gender, age and BMI of these people were recorded from patient records. From this group 74 people volunteered to participate in the study. Reasons given Type 2 Diabetes

Mellitus was defined according to established criteria[1] and controlled by diet, hypoglycaemic agents or insulin. All participants were selected to be in either a contemplation or preparation stage of exercise behaviour change i.e. they reported not meeting current physical activity guidelines but intended to become more active[171]. Exclusion from participation occurred if any of the following applied: age over 75 years, severe immobility, amputation, symptomatic claudication, severe peripheral or autonomic neuropathy (vibration threshold greater than 20 volts), severe retinopathy, blindness or severe visual impairment, uncontrolled hypertension. Patients requiring further cardiological investigation on the basis of the screening exercise test were also excluded. The ethical committee of Argyll and Clyde Health Board approved the study and written informed consent was obtained before study participation (see Appendix C and D).

Procedure

Figure 6 illustrates the experimental design of the study. Participants made six to eight visits for study assessment.

Visit one: Total duration 60 minutes.

Participants were instructed to remain on normal diabetes therapy during all procedures carried out during the 12 month period of research. At the start of visit one all participants were interviewed and information was collected on a variety of variables including demographic details, medical history (casenote documentation of hypertension, retinopathy, myocardial infarction, microalbuminuria and current medication), cigarette/cigar smoking and socio-economic status. Socio-economic status was established using new socio-economic classifications published by the steering committee of the Economic and Social Research Council (ESRC)[275] and categorised using the three class model into managerial/professional, intermediate and workings class. Body weight and height were measured and body mass index (BMI) was calculated as weight (Kg)/height $(m)^2$. Participants were then asked to perform a peak exercise test. This test was used to screen participants for silent ischaemic heart disease prior to randomisation and to assess cardiopulmonary fitness. Participants were then given both the Medical Outcomes Survey Short Form-36[276] and Well-being Questionnaire[277] to be completed and handed in at visit two, a CSA Inc physical activity monitor[250] to be worn for approximately 7 days and a sample bottle to provide a urine sample 24-hours prior to visit two.

Figure 6

Experimental design of study

Recruitment

(September 2000 - September 2001)

Sampled population (n=223), patients consented (n=74)

Baseline assessment - Visit 1

Personal details, medical history, BMI & medication

Peak exercise test

Accelerometer (CSA Inc) worn for seven-days

2 quality of life questionnaires

24-hour urine sample completed prior to visit two

Baseline assessment - Visit 2

Seven-day physical activity recall

Stage & processes of exercise behaviour change questionnaire

Blood pressure, Fasting blood sample

Randomised *(n=70)* Not randomised *(n=4)*

Because of positive test *(n=2)*, hypertension *(n=1)* too active *(n=1)*

Visit 3 - Exercise consultation & standard exercise leaflet *(n=35)*	Standard exercise leaflet alone *(n=35)*
One & three-month phone call	One & three-month phone call
Six month assessment *(March 2001 – March 2002)* Repeat baseline visit one, two & three *(n=32)*	**Six month assessment** *(March 2001 – March 2002)* Repeat baseline visit one, two & three (n=31)
Six month exercise consultation & standard exercise leaflet	Six month standard exercise leaflet alone
Seven & nine-month follow-up phone call	Seven & nine-month follow-up phone call
One year assessment *(September 2001 – September 2002)* Repeat baseline visit one and visit two *(n=30)*	**One year assessment** *(September 2001 – September 2002)* Repeat baseline visit one and visit two *(n=29)*

Visit two: Total duration 60 minutes

Approximately 7 days after visit one participants returned for visit two. During this visit blood pressure was measured and a fasting blood sample was taken to measure full lipid profile, glycaemic control and fibrinogen. The stage and processes of exercise behaviour change questionnaires[171,175] and 7 day physical activity recall questionnaire[217] were completed. All participants received standard exercise information and were randomly assigned to the experimental or control group.

Visit three: Total duration 30 minutes

Only participants assigned to the experimental group returned for visit three. During this visit participants received an exercise consultation.

Follow up

All outcome measures taken at baseline were repeated after 6 and 12 months. The experimental group received a further exercise consultation at 6 months.

Randomisation

The process of randomisation involved the development of computer-generated tables of random numbers. A blinded research assistant (AH) marked paper with 'control' or 'experimental' by assigning odd numbers to the control condition and even numbers to the experimental condition. The marked paper was then transferred to white envelopes. This was done in four blocks to ensure there was an even number of participants in each group if recruitment targets were not met. These envelopes were then allocated to participants at visit two and were opened by the principle researcher after all baseline outcome measures had been taken

Intervention

Exercise Consultation

The exercise consultation intervention consisted of two individual counselling sessions, one at baseline and one 6 months after baseline. Each lasted around 30 minutes. Supporting phone calls were given 1 and 3 months after each exercise consultation. For the experimental group

these phone calls involved a discussion of previously set activity targets, experienced benefits, barriers and cost of becoming more active and relapse prevention. To maintain equal contact time between the experimental and control group phone calls were also given to participants in the control group. These phone calls involved discussions about topics unrelated to exercise for example the weather, holidays, diabetic and general health.

Exercise consultations were conducted in accordance with the guidelines published by Loughlan and Mutrie[194]. Baseline exercise consultations were designed to initiate activity, incorporating stage specific strategies for people in either a contemplation or preparation stage of exercise behaviour change. Strategies used focused on enhancing motivation, overcoming barriers and developing an appropriate activity plan. A copy of the basic exercise consultation sheet is included in Appendix E. Consultations were individualised to personal needs, therefore the strategies and format used varied from person to person. In general, baseline consultations started with the completion of a decision balance table, involving weighing up the perceived pros and cons of becoming more physically active. This often involved an explanation of the effectiveness of physical activity in the management of Type 2 diabetes. The overall aim of the decision balance table was to encourage people to perceive more pros than cons for becoming more physically active. Barriers to physical activity were then discussed. The most frequently cited barriers to physical activity for people with Type 2 diabetes are physical discomfort from exercise, fears of low blood sugar reactions, being too overweight to exercise and lack of support[138,142]. This section therefore often included a discussion of suitable activities, establishing social support and ways to avoid low blood sugars. Physical activity status was established including a summary of the previously completed 7 day physical activity recall and accelerometer recordings. The discrepancy between physical activity status and current physical activity recommendations[48] was outlined. Past and potential new activities were then discussed to establish likes and dislikes. The final stage of the consultation involved developing physical activity goals. These goals were time phased into short-term (1 month), intermediate term (3 months) and long term (6 months).

After the initial consultation a number of participants had progressed to a higher stage of exercise behaviour change. The exercise consultation given at 6 months focused more on relapse prevention and improving long term maintenance of a physically active lifestyle. Relapse prevention strategies involved identifying situations that may have a negative impact on

behaviour change, such as a busy work schedule or holidays, and developing ways to prevent relapse during these high risk situations such as time management or cues to get back to an activity plan after holidays. A number of strategies used in baseline consultations were also incorporated into the 6 month consultation. Experienced benefits, costs and barriers were discussed and current physical activity status was reviewed. Time phased (1, 3 and 6 month) physical activity goals were again developed.

Standard Exercise Information

Standard exercise information was given to both the experimental and control group participants. This was a general information leaflet on diabetes and exercise, currently used for diabetes management. The leaflet was titled "Exercise and your Diabetes"[278], published by Boehringer Mannheim and approved by Diabetes UK. The leaflet covered the following topics; Why should I exercise?, How much exercise should I do?, How to get started, Will exercise affect my diabetes?

Primary outcome measures

Physical activity levels

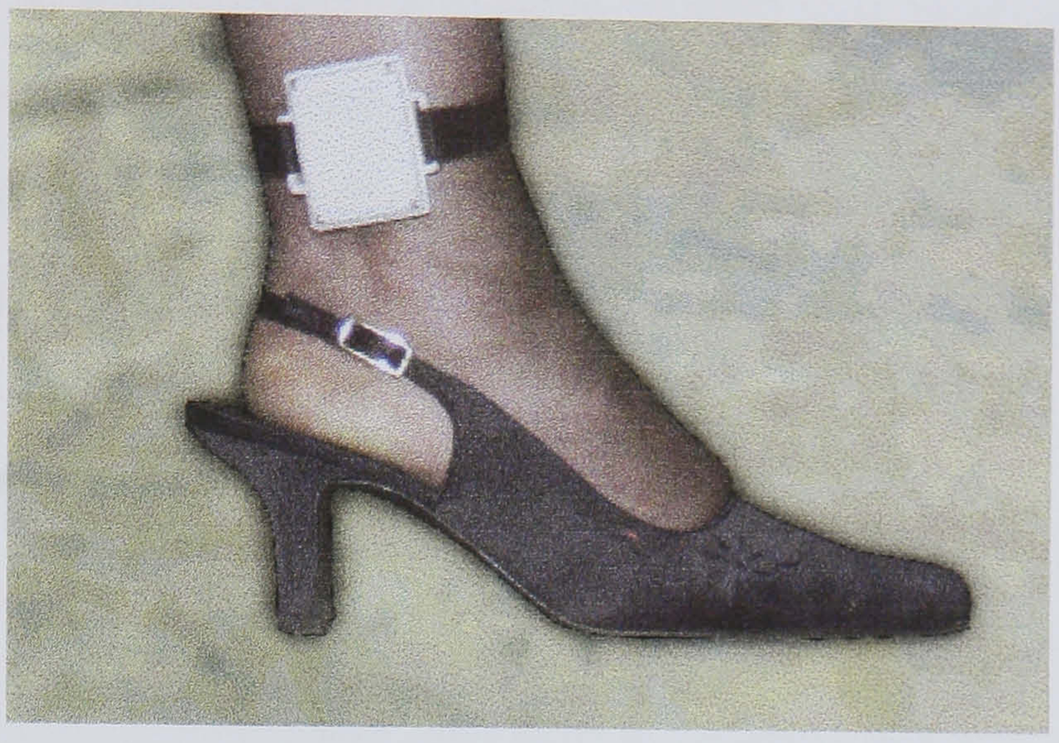
Physical activity levels were assessed over the same 7 consecutive days using objective and subjective measurements.

The CSA accelerometer[250] (Computer Science and Applications, Shalimar, Florida) illustrated in Figure 7 is a small, lightweight monitor that provides an objective assessment of dynamic physical activity measured by bodily acceleration. The CSA monitor measures movement using a vertical uni-axial piezoelectric bender which, when displaced, generates a signal proportional to the magnitude of acceleration during bodily movement. Signals are sampled at a rate of 10 samples per second and are summed to develop an activity count that is stored over a user-defined period (epoch). Activity counts therefore represent the sum of accelerations during bodily movement and the higher the intensity of activity the higher the activity count. The CSA monitors are designed to detect accelerations ranging in magnitude from 0.005 to 2.00G, with frequency response from 0.25 to 2.5HZ. These parameters allow for measurement of normal human movement and not high frequency vibrations encountered in activities such as driving or lawn mowing. Monitors can store data continuously for up to 6 weeks and can be worn at the

hip, ankle or wrist.

Figure 7

Picture of the Computer Science and Applications (CSA) accelerometer



During this study monitors were secured firmly using velcro straps to participant's right ankle. Most studies have used the hip as an attachment site, however during pilot work[29] participants reported that monitors secured at the hip were obtrusive and moved more, often turning upside down. Participants were carefully instructed, verbally and in writing (see Appendix F), on how to attach the monitors and were asked to wear the monitors for at least 7 days during all waking hours except bathing or during water activities. Some participants wore the monitor for longer than 7 days however only 7 days of activity counts were totalled and used for data analyses. Participants were also asked to record the time the monitor was attached and removed each day and any problems experienced with the monitor. Monitors were pre-programmed to collect activity counts at 1 minute interval. When returned monitors were downloaded and a total activity count for the previous 7 day period was calculated.

The Stanford 7 day physical activity recall[217] was used as a subjective measure of physical activity levels. This questionnaire involves a structured interview following a standard set of questions. The same investigator conducted all interviews. Participants were asked about time spent each day in moderate, hard, very hard and strength and flexibility activities. Time spent in light intensity activity was obtained by subtracting the number of hours spent in sleep and all intensities of activity from the total hours for the week. Participants were asked at the end of the questionnaire if the recorded week was representative of a typical week in terms of physical activity.

Behaviour change

Stage of exercise behaviour change was assessed by asking participants to read a definition of regular physical activity. Regular physical activity was defined as "exercising at a moderate to vigorous intensity 3 or more times a week for at least 20 minutes"[73] or "accumulating 30 minutes or more of moderate intensity physical activity 5 or more days a week"[38]. Participants then indicated which statement, described in Table 9, best represented their current physical activity status.

Table 9

The stages of exercise behaviour change

Stage of exercise behaviour change	Description
Pre-contemplation	I am not regularly physically active and do not intend to be so in the next 6 months
Contemplation	I am not regularly physically active but am thinking about becoming so in the next 6 months
Preparation	I do some physical activity but not enough to meet the description of regular physical activity given above
Action	I am regularly physically active but only began in the last 6 months
Maintenance	I am regularly physically active and have been so for longer than 6 months

Marcus et al[182] demonstrated the reliability of the stages of change questionnaire, reporting a Kappa index of 0.78 over a 2 week period. Concurrent validity of the questionnaire has been demonstrated by its significant association with the 7 day recall physical activity questionnaire[171]. The stage of exercise behaviour change questionnaire has also been shown to be significantly related to instruments measuring self efficacy[182] and decision balance[179].

Processes of exercise behaviour change were assessed by a 40-item questionnaire developed and validated by Marcus and colleagues[175]. The ten processes have been previously illustrated and defined in Table 4. Participants were asked to rate the frequency of using each process over the past month on a 5-point Likert scale (1=never to 5=repeatedly). There is limited research evaluating the reliability and validity of this questionnaire. Marcus et al[175] reported good internal reliability across all sub-scales of the questionnaire, alpha coefficients ranged from 0.62 (social liberation) to 0.89 (self-reevaluation). Similar findings were reported by Rodgers et al[279] in three different populations of varying age.

Cardiorespiratory fitness

Cardiorespiratory fitness was measured during a peak exercise test. To avoid hypoglycaemic reactions participants were asked to check blood glucose levels and have a light meal 2 hours before the exercise test. Participants were also asked to avoid smoking and drinking tea or coffee for 2 hours before their appointment and vigorous exercise the day before the appointment. A brief familiarisation was conducted prior to each peak exercise test.

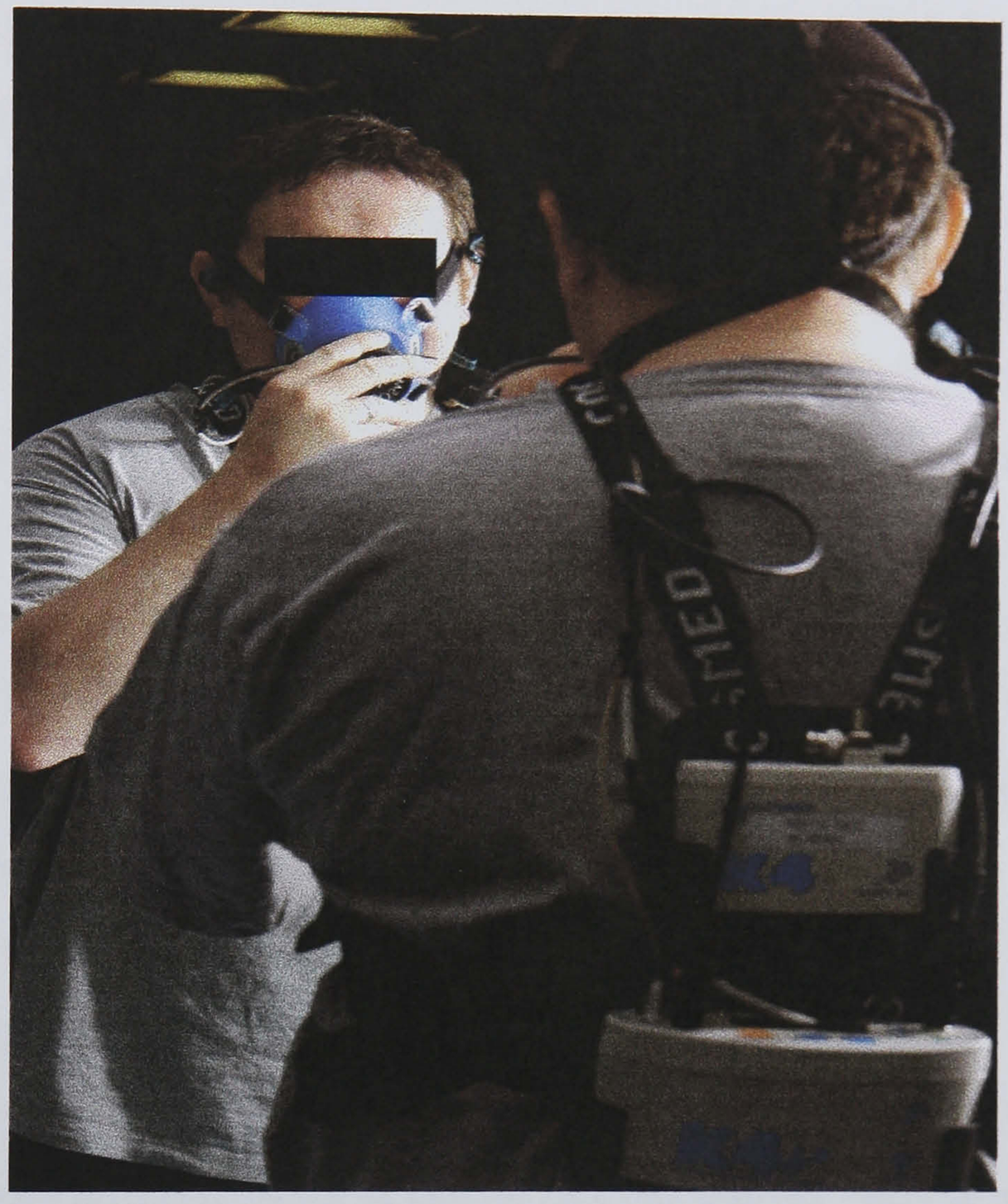
Peak exercise tests were performed on a motorised treadmill using an incremental protocol. In view of the poor functional capacity of the majority of people with Type 2 diabetes a new protocol[280] was developed with experts in the field of exercise testing in clinical populations[281]. This protocol was individualised, developed to obtain an optimal exercise duration of 8 to 12 minutes[282]. Participants were initially asked to walk at a normal to brisk speed for 3 to 5 minutes (depending on fitness). Once a suitable speed was obtained this remained constant for the duration of the test. The treadmill gradient was then increased between a half and two percent each minute (depending on fitness) to the limit of tolerance. Tests were terminated on report of limiting symptoms of angina, fatigue or breathlessness or in the event of significant ECG changes (ST depression $\geq$ 2mm), significant arrhythmia or a fall in blood pressure. Heart rate (12 lead) and blood pressure (cuff sphygmomanometer) were monitored continuously.

Expired gases were sampled and analysed using the Cosmed $K4b_2$ portable metabolic system. The Cosmed $K4b^2$ metabolic system is illustrated in Figure 8. This system is lightweight (550g) and portable. During exercise tests the cosmed portable unit was placed on the back of participants using a harness. This unit contains the oxygen and carbon dioxide analysers, sampling pump, transmitter, barometric sensors and electronics and is powered by a battery

also placed on the harness. The system also contains a polar heart rate monitor and a facemask, covering the mouth and nose, held securely by a head cap with adjustable straps.

Figure 8

Picture of the Cosmed K4b^2 portable metabolic system



A bi-directional, digital turbine fixed to the facemask measures respiratory flow and volume. Respiratory flow rotates the turbine blade. Rotations of the blade are measured in revolutions per second. The flowmeter measures airflow rate and calculates the volume of expiratory air and the number of expiratory cycles per minute. Concentrations of expired oxygen and carbon dioxide are sampled by an analyser connection in the turbine unit that is connected to the portable unit via a nafion tube. Following a 45 minute warm up, the $K4b_2$ was calibrated before each test according to manufacturers specifications. Validation studies of the Cosmed K4b^2 using the Douglas bag method[273] and metabolic cart[283,284] as criterion measures have demonstrated the Cosmed $K4b_2$ to be an accurate system for metabolic gas analysis.

Data from each exercise test was downloaded to an excel spreadsheet and basic graphs were drawn. During each exercise test any action causing abnormal breathing patterns, such as talking, coughing or sneezing were recorded in addition to the corresponding time. Any extreme outliers in the data corresponding with these actions were removed. Total exercise duration, peak gradient and reason for termination were recorded. Analysis of each test included an assessment of aerobic, cardiovascular and ventilatory function.

Aerobic function was measured by peak values for Vo_2 (ml/kg/min), Vo_2 (ml/min) and respiratory exchange ratio ($RER = V_{CO2}/V_{O2}$), calculated by averaging the last 30 seconds of exercise. Lactate threshold (LT) was estimated as the Vo_2 at which a breakpoint in the Vco_2-Vo_2 relationship was first evident (V-slope technique) in addition to an increase in V_E/V_{O2} and PET_{O2} with no increase in V_E/V_{CO2} or decrease in PET_{CO2}[285,240]. Cardiovascular function was measured by peak heart rate which was taken as the highest heart rate recorded during the test and peak oxygen pulse (V_{O2}/HR), calculated by averaging the last 30 seconds of exercise. Heart rate at the Vo_2 point of lactate threshold was also determined. Ventilatory function was measured by peak ventilation (V_E), calculated by averaging the last 30 seconds of exercise and the respiratory rate and tidal volume at the Vo_2 point of lactate threshold.

Secondary outcome measures

Physiological

Body mass index (BMI) was calculated as weight (Kg)/height$(m)^2$. Blood pressure was measured from the left arm in the seated position with an automatic blood pressure monitor (Omron 705CP, OMRON Healthcare, Japan). This system has been validated in clinical trials and meets the criteria of both the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS). Three blood pressure measurements were taken and the average value recorded.

Biochemical

A blood sample was taken between 900 and 1100h after a 12 hour overnight fast and abstinence from alcohol and strenuous activity the day before the blood sample, and abstinence from smoking or drinking tea or coffee on the morning of the sample. Participants were rested for at least 20 minutes before blood samples were collected and blood was sampled with

minimal venous occlusion. Blood samples were taken to assess (a) Glycaemic control (HbA_{1c}). (b) Full lipid profile (total cholesterol, HDL-C, LDL-C and triglycerides) and (c) Fibrinogen. A 24-hour urine sample was completed to assess microalbumin. The biochemistry and haematology departments at the Royal Alexandra Hospital in Paisley carried out all biochemical analyses. All samples were analysed immediately after being taken and no samples were stored and analysed at a later date.

HbA_{1c} is a measure of the attachment of glucose to haemoglobin, expressed as the percentage of haemoglobin that is glycated (normal non-diabetic reference range is 4-6%). Since the lifespan of an erythrocyte is about 10 days, HbA_{1c} is a measure of average glycaemia over half this time period, i.e. over 60 days. HbA_{1c} was determined from a prepared haemolysate, measured by latex inhanced turbidimetric immunoassay[286]. Total cholesterol, HDL-C and triglycerides were measured directly using enzymatic methods[287] and LDL-C was calculated using the Friedewald formula[288]. Plasma fibrinogen was measured by the Clauss method[289]. Microalbumin was determined by automated immunopreciptin analysis and diagnosed when the urinary albumin excretion rate was between 30 and 300 mg/24h[290].

Quality of life

Somatic symptoms of depression and anxiety in the general population, such as appetite or weight loss or tiredness, frequently included in quality of life scales are often similar to the somatic symptoms of hyperglycaemia, hypoglycaemic or chronic complications of diabetes. From correspondence with experts[291] in the field of quality of life assessment in people with diabetes it was concluded that both a generic and disease specific questionnaire should be used to assess quality of life in this study. The SF-36 version 2 was chosen as the generic questionnaire as it has demonstrated a high level of reliability and validity across a wide range of disabilities and conditions including a number of studies with diabetic populations. The Well-being Questionnaire was selected as it was developed specifically for people with diabetes. This questionnaire is relatively short and measures both positive and negative aspects of mood. Pilot research demonstrated both questionnaires to be appropriate for use in this study.

Both questionnaires were self-administered. Participants were asked to complete each questionnaire with regards to their health over the past month.

The SF-36 version 2[276] is a 36-item questionnaire that evaluates eight dimensions of health. These dimensions are physical functioning, social functioning, limitations in usual role activities due to physical health problems, limitations in usual role activities due to emotional health problems, bodily pain, general health perception, energy/vitality and mental health. A single item is also included assessing perceived change in health. Scores for each dimension are obtained by reverse scoring, where necessary, and summing responses. Raw scores can then be transformed in to a scale from 0 (worst possible health state measured by the questionnaire) to 100 (best possible health state).

The original SF-36 has been extensively used over a wide range of populations including a number of patient groups[292,293]. This questionnaire has demonstrated a high level of validity[294,295] however internal reliability on some dimensions has been questioned[292]. The SF-36 version 2 incorporates content and layout alterations intended to improve internal reliability and reduce standard deviations, ceiling and floor effects. All eight dimensions of the SF-36 version 2 have demonstrated good internal reliability. Alpha coefficients, an indicator of inter-item correlation, range from 0.8 (for general health perception) to 0.95 (for role-physical)[276]. These values are higher than those reported in similar studies using the original SF-36[292]. The SF-36 version 2 has also shown to have appropriate construct validity[276].

The Well-being Questionnaire[277] contains 22 items measuring four sub-scales of depression, anxiety, energy and positive well being. The questionnaire focuses on cognitive symptoms of mood and avoids items relating to somatic symptoms such as fatigue or loss of appetite as these may be due to physical condition rather than mood. Scores for each sub-scale are obtained by reverse scoring where necessary and summing responses. A higher score on each sub-scale indicates more of the mood described by the sub-scale label. A general well-being total score is obtained by summing the sub-scale scores after reversing the scores on the depression and anxiety sub-scales.

Recent research has evaluated the validity and reliability of the Well-being Questionnaire. Hirsch et al[296] demonstrated good internal reliability on most sub-scales (0.77 - 0.92), except depression (0.57). Bradley[277] reported similar results, although a higher alpha coefficient was reported for the depression sub-scale (0.70). The questionnaire has also shown to be sensitive to change and reports appropriate construct validity[296,277].

Statistical analysis

Estimation of sample size

Statistical power was calculated using the difference in the mean change in physical activity counts/week between the experimental and control groups at 30 days obtained from previous pilot work[29]. There will be a 90 percent power of detecting a true 23 percent difference in counts/week (baseline mean=1813893, mean difference=409780, SD=444779) with a minimum of 25 patients in each group given a significance level of 5 percent. 35 patients will be recruited in each group to allow for dropout from the study.

Analysis

Data was analysed using Minitab (version 13.30) and SPSS (version 11). Two-sample t-tests were used to assess whether baseline measured variables were similar between the experimental and control group and confirm successful randomisation. A Bonferroni correction was applied to control for Type 1 errors as a large number of comparisons were conducted.

To analyse the effect of the exercise consultation intervention on both primary and secondary outcomes repeated measures analyses of variance models were used. Where appropriate covariate adjustments for baseline effects of gender and body mass index were applied. Significant main effects were followed up with Bonferroni multiple comparisons for repeated measures. Significant interaction effects were also followed up by analysing the between group difference of the change in variables from baseline to 6 months and baseline to 12 months using two-sample t-tests or non-parametric equivalent test.

For the repeated measures analyses, tests were conducted for homogeneity of covariance using a Mauchly sphericity test. Where the data failed this test ($p<0.05$), the analysis of variance was modified to make it more conservative by conducting a Green-house Geisser analysis (i.e the epsilon-corrected averaged F)[297]. To test for normality in the analysis of variance and t-tests, data was graphed in box-plots and a series of Anderson-Darling tests were performed. Variables with non normal distributions (7 day physical activity recall variables) were transformed using the square root before analysis. The data were also analysed using the last-observation-carried-forward (LOCF) method. This involved replacing missing values with

results obtained at baseline or 6 months. Study drop out was minimal. At 6 months 3 experimental and 4 control participants had dropped out of the study and at 12 months 5 experimental and 6 control participants had dropped out of the study. Analysis of this data was used to determine if there was any significant response bias caused by study drop out. Categorical data is reported as a proportion and was analysed using Chi-square or Fishers exact tests. For all statistical analyses $p<0.05$ was considered to be statistically significant.

Effect size statistics were used to further investigate changes in scores on the quality of life and well-being questionnaires. These statistics have been recommended for determining changes in scores on health status measures[298]. Effect size was calculated by taking the difference between the mean scores at time one and time two and dividing by the standard deviation of the time one score. An effect size of 1.00 is therefore equivalent to a change of one standard deviation in the sample. For this study an effect size was calculated from baseline to 6 months and from baseline to 12 months. As higher scores on the SF-36 questionnaire indicate better quality of life, a negative effect score will indicate an improvement in health. On the Well-being questionnaire a higher score indicates a greater expression of the defined sub-scale. For sub-scales depression and anxiety a positive effect score reflects improved well-being and for sub-scales energy, well-being and total a negative effect score reflects improved well-being.

CHAPTER FIVE

STUDY TWO

BASELINE CHARATERISTICS

RESULTS

Recruitment characteristics

223 suitable people with Type 2 diabetes were invited to participate in this study. This sampled group consisted of 130 males and 93 females with a mean age of 57.8±8.9yrs and BMI of 33.0±6.4. 74 people volunteered to participate in the study. Reasons given for declining study participation included: lack of time; already participating in a drug trial; already active (wrong stage of change) not interested and employment. The recruitment group included 37 males and 37 females with a mean age of 57.6±7.8yrs and mean BMI of 34.6±6.8. Two-sample t-tests revealed no significant difference between the sampled and recruited group for age and BMI (95%CI age -1.9,2.5yrs, BMI –3.4,0.3) and a chi-square test demonstrated no significant difference in sex (χ^2=1.6,df=1, p=0.2).

Baseline participant characteristics

70 people completed baseline assessments and were randomised into either the experimental or control group. Four people were excluded from randomisation. One patient was already regularly physically active and reported being in a maintenance stage of exercise behaviour change. One patient had uncontrolled hypertension and was referred for further treatment and two patients had a positive exercise test (>2mm ST segment depression) with no previous documented evidence of coronary heart disease and were referred for further investigation.

The demographic and medical characteristics of participants in the experimental and control group are shown in Table 10. To test for differences between the experimental and control groups at baseline two-sample t-tests (continuous data) and chi-square or fisher exact tests (categorical data) were conducted on all measured outcomes. No significant differences were recorded confirming successful randomisation.

Table 10

Baseline demographic and medical characteristics of participants by group.

Variable	Experimental	Control	Difference between group
	Mean±SD or total number		95%CI or χ^2 result
Demographic			
Age (yrs)	56.7±6.8	58.4±8.9	CI -5.5,2.1, p=0.4
Male/female	20F	15F	χ^2=1.4, p=0.2
Duration of diabetes (yrs)	5.3±3.5	6.8±4.6	CI –3.4,0.5, p=0.1
Employed	13	11	χ^2=0.3, p=0.6
Socio-economic category			
Managerial/professional	12	11	χ^2 = 0.08, p=0.8
Intermediate	10	11	χ^2 = 0.08, p=0.8
Working	13	13	χ^2 = 0, p=1.0
Medical			
Regular smoker (>1cigarette or cigar/day)	17	16	χ^2=0.06, p=0.8
HbA_{1c} (%)	8.3±1.3	8.8±1.5	CI –1.4,0.3, p=0.2
Body mass index (kg/m^2)	35.4±7.8	33.7±5.7	CI -1.5,5.0, p=0.1
Evidence of:			
Hypertension(<140/90 or on medication)	19	20	χ^2=0.06, p=0.8
Retinopathy	6	10	χ^2=1.3, p=0.3
Previous MI	7	6	χ^2=0.09, p=0.8
Microalbuminuria (n=54)	5	9	χ^2=1.2, p=0.3
Diabetic therapy			
Diet	5	2	χ^2=1.4, p=0.2
Oral hypoglycemic only	9	5	χ^2=0.2, p=0.6
Insulin only	9	14	χ^2=1.2, p=0.3
Combination therapy (oral therapy & insulin)	12	14	χ^2=2.8, p=0.1

Other Medication			
Aspirin	17	21	χ^2=0.9, p=0.3
Beta-blocker	8	8	χ^2=0.08, p=0.8
Statin	15	16	χ^2=0.06, p=0.8

SD = standard deviation, CI = confidence interval, MI = myocardial infarction, HbA_{1c} = glycosylated haemoglobin, df = degrees of freedom, $p<0.05$ = significant difference.

Baseline physical activity

As a whole the recruited group (n=70) reported participating in a median of 45 minutes of moderate activity per week (IQ range 0,132 minutes). No hard, very hard or strength and flexibility activity was reported. Mann-Whitney tests illustrated no significant differences in reported minutes of moderate activity between male and female participants (95%CI –50,10 minutes). To assess differences in self-reported physical activity by age, BMI and diabetes duration, participants were categorised as being either above or below the mean value. Mann-Whitney tests were conducted to analyse any differences. No significant effects of age (95%CI -65.0,2.0 minutes), BMI (95%CI –0.04,105.0 minutes) or diabetes duration (95%CI -15.0,20.0 minutes) were recorded.

At baseline 23% (16/70) of participants were meeting ACSM/CDC 1995 guidelines of at least 30 accumulated minutes of moderate physical activity five or more days a week[38]. 1% (1/70) was meeting the ACSM 1990 exercise guidelines of at least 20 minutes of continuous moderate to vigorous intensity activity three times a week[73]. At baseline the proportion of participants by group meeting either guideline was similar (experimental 7/35, control 10/35, χ^2=0.7, df=1, p=0.4). These people were not excluded from the study as although there self reported minutes of activity were equivalent to meeting the guidelines, they reported themselves to be in either a contemplation or preparation stage of exercise behaviour change and not to be meeting the guidelines.

Total activity counts recorded by the CSA accelerometer at baseline were 2,908,974. Total activity counts recorded were similar in male and female participants (95%CI –256880,867238 counts/week). To assess differences in total activity counts by age, BMI and diabetes duration participants were categorised as being either above or below the mean value. Two-sample t-tests were conducted to analyse any differences. No significant effects of age (95%CI -

691011,457507 counts/week) or diabetes duration (95%CI -891290,262947 counts/week) were recorded, but there was a significant effect of BMI (95%CI 515175,1536106 counts/week). Participants with a BMI above the mean value of 34.6 recorded significant lower total activity counts/week than participants with a BMI below the group mean.

The mean peak oxygen uptake for the whole group was 20.3 ± 5.6 ml/kg/min. Two-sample t-tests revealed peak oxygen uptake to be significantly higher in male than female participants (95%CI 3.2,8.0 ml/kg/min). To assess differences in oxygen uptake by age, BMI and diabetes duration participants were categorised as being either above or below the mean value. Two-sample t-tests were conducted to analyse any differences. No significant effects of age (95%CI -1.7,3.8ml/kg/min) or diabetes duration (95%CI -3.2,2.3ml/kg/min) were recorded, but there was a significant effect of BMI (95%CI 0.36,5.71ml/kg/min). Participants with a BMI above the mean value of 34.6 recorded significant lower peak Vo_2ml/kg/min than participants with a BMI below the group mean.

At baseline 57% (40/70) of the recruited group were in a contemplation stage of exercise behaviour change and 43% (30/70) were in a preparation stage. The number of participant at each stage was similar for males and females (contemplation 21M, 19F, preparation 18M, 12F, χ^2=0.4, df=1, p=0.5). Compared to participants in the preparation stage of exercise behaviour change, participant in the contemplation stage were significantly younger (95%CI –7.4,-0.1yrs), although they had a similar duration of diabetes (95%CI –30.0,11.0 months).

DISCUSSION

Of the 223 people invited to participate in this study, 74 were recruited, giving a recruitment rate of 33 percent. The mean age, gender and BMI of the recruited group was similar to the total sample invited to participate, confirming a representative group of people were recruited in terms of these variables.

At baseline the recruited group, as a whole, reported participating in a median of 45 minutes of moderate intensity activity per week and no hard, very hard or strength and flexibility activity per week. Self-reported levels of physical activity were similar by age, gender, BMI and duration of diabetes, although were widely variable with inter-quartile ranges often totalling 150 minutes. At baseline a number of participants reported minutes of physical activity

equivalent to meeting the current ACSM/CDC physical activity guidelines[73,38]. These people were not excluded from participation in the study as they reported themselves to be in either a contemplation or preparation stage of exercise behaviour change and therefore perceived themselves not to be meeting the ACSM/CDC guidelines. This discrepancy could be explained by an overestimation of self-reported physical activity. Previous research has documented that obese and sedentary adults are particularly prone to overestimating both the amount and intensity of physical activity[212,213].

It is hard to comment on the baseline total activity counts recorded for 7 days by the CSA accelerometer. Comparison with previous research is difficult as the majority of studies attached the monitors to the right hip. In the pilot study[270] for this research that investigated the validity of the CSA accelerometer to measure walking and daily living activities, activity counts recorded at the ankle were consistently higher than activity counts recorded at the hip. It is therefore inappropriate to compare activity counts recorded from different sites. Previous pilot research[29] investigating the effect of exercise consultation in people with Type 2 diabetes over 5 weeks used the hip as the attachment site for accelerometers. Participants in this study reported that monitors were obtrusive and moved a lot, often turning upside down. As a results the monitor attachment site for this research was changed to the ankle.

A number of studies have converted activity counts recorded from the CSA accelerometer into energy expenditure or physical activity intensity categories. These conversions have a number of limitations (documented in literature review) and were not used in this study. In a study measuring physical activity in active participants of cardiac rehabilitation Hughes[299] recorded a mean total activity count for 7 days of 4,344,079±1,811,935 from CSA accelerometers worn at the ankle. This is much higher than the 2,908,974±1,187,066 recorded at baseline in the present study. The participants of cardiac rehabilitation were relatively active and were attending two structured exercise sessions a week in addition to being encouraged to exercise at home.

At baseline the recruited group recorded low levels of cardiorespiratory fitness (peak Vo_2 20.3±5.6ml/kg/min). Values recorded for peak Vo_2ml/kg/min are comparable with values recorded in chronic stable heart failure patients (peak Vo_2 =19.7ml/kg/min)[300] and are consistent with previous research in people with Type 2 diabetes[119]. Regensteiner et al[119] recorded a mean peak oxygen uptake and oxygen uptake at lactate threshold of

21.5±5.8ml/kg/min and 1224±172.3ml/min respectively in a slightly younger group (mean age 50±7yrs) of people with Type 2 diabetes. Peak oxygen uptake was significantly higher in males than female participants and in participants with a lower BMI. These findings are also consistent with previous research[301].

Participants in this study were selected to be in either a contemplation or preparation stage of exercise behaviour change. The concept of targeting people in contemplation and preparation stages of change has been criticised[302]. It has been argued that this is an easy target group, which has more chance of successful change. Furthermore it has been questioned whether it is ethical to target people who are most likely to change and ignore sections of the population who may be in greatest need for behaviour change interventions[302]. Under restrictions of time and as a result a limited sample size it was thought important to target a homogenous group of people in terms of intentions to change physical activity. If people in all stages of exercise behaviour change had been included a larger sample would have been required to allow subgroup analyses of change in outcome measures related to stage as change in physical activity levels would likely differ across stage. There is strong evidence that a dose response relationship exists between physical activity and health[303] with the greatest health gain occurring when the least active people become moderately active. People in a contemplation or preparation stage of exercise behaviour change are not achieving current ACSM/CDC physical activity guidelines of accumulating 30 minutes of moderate physical activity a week[38]. Promoting higher levels of physical activity in this group will result in a greater health gain than targeting people in an action or maintenance stage of change as these people are already achieving current ACSM/CDC physical activity guidelines[38]. Similar to people in a contemplation and preparation stage of exercise behaviour change, people in a pre-contemplation stage are not achieving current physical activity guidelines[38]. This group however has no intention to change physical activity behaviour and therefore a different physical activity intervention would be required.

CHAPTER SIX

STUDY TWO

EFFECT OF EXERCISE CONSULTATION ON PHYSICAL ACTIVITY OUTCOMES

RESULTS

Primary outcome measures

Physical activity levels

The 7-day recall records the minutes spent in six activity categories: sleep; light; moderate; hard; very hard and strength and flexibility activity. The data collected for most of the activity categories did not form a normal distribution. Before analysis the data was transformed using the square root. A series of two-way analyses of variance (time x group) with repeated measures (time) were conducted to assess any differences. A total of 27 experimental participants and 28 control participants had complete 7-day recall data sets.

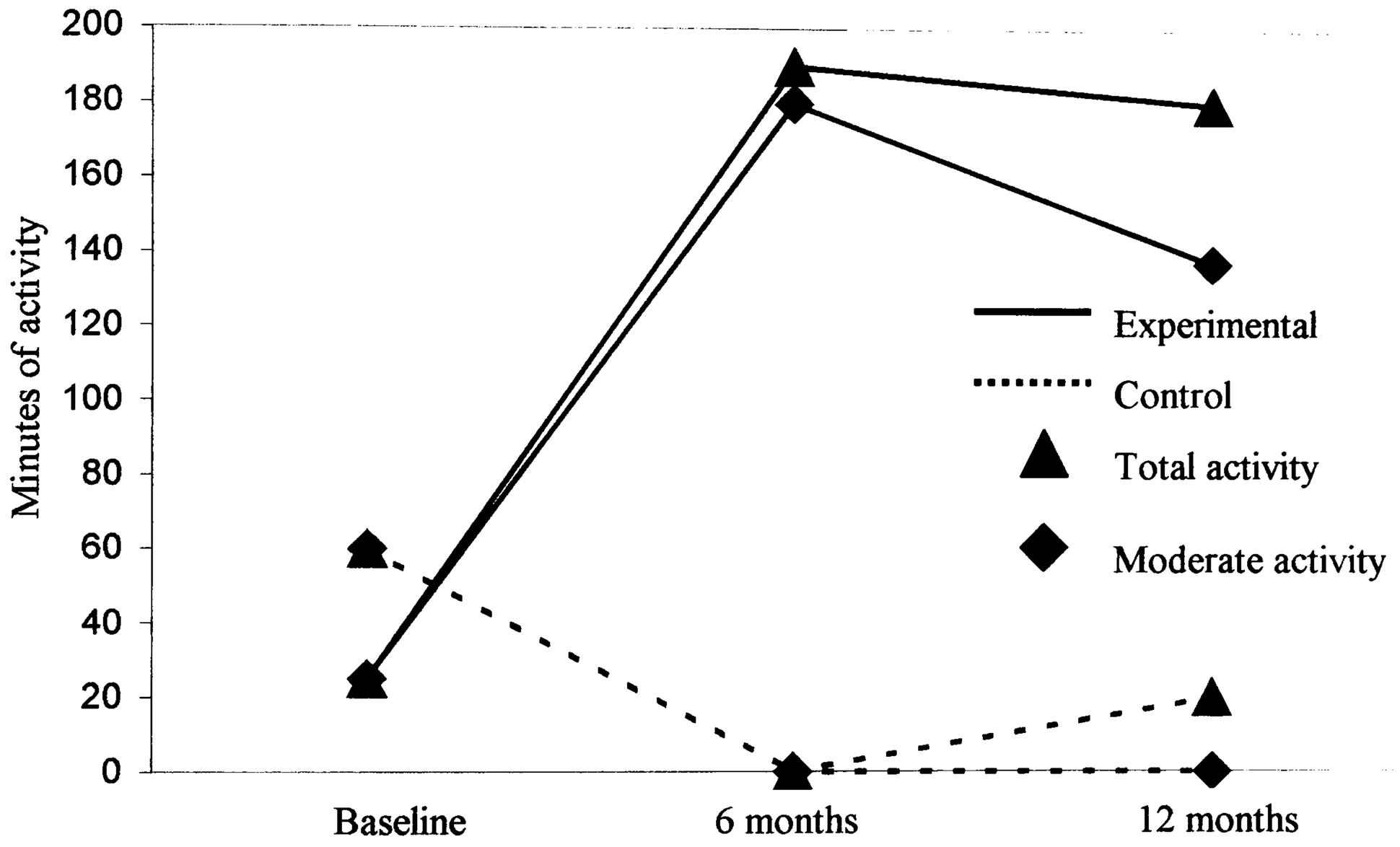
Analysis of the moderate intensity activity category demonstrated significant main effects of time ($F_{2,51} = 3.1$, $p=0.05$), group ($F_{1,51} = 10.3$, $p=0.002$) and the interaction of group and time ($F_{2,51} = 18.2$, $p<0.001$). Bonferroni multiple comparisons for repeated measures illustrated that the experimental group significantly increased the minutes of moderate activity recorded from baseline to 6 and 12 months (95%CI 6M 10.4,119.7 minutes, 12M 4.9,98.6 minutes) with no significant decrease recorded from 6 to 12 months (95%CI –23.7,8.1 minutes). The control group recorded no significant changes from baseline at either 6 or 12 months (95%CI 6M –46.9,0.53 minutes, 12M –38.3,1.93 minutes). Significant between group differences were recorded at 6 and 12 months (95%CI 6M –148.4,-20.5 minutes, 12M –132.7,-15.0 minutes). The changes in recorded minutes of moderate activity in each group are illustrated in Figure 9.

Only a small number of participants took part in hard, very hard, and strength and flexibility activities. These categories were combined with moderate activity and analysed separately as total activity. Similar to moderate activity significant main effects of time ($F_{2,51} = 6.2$, $p=0.003$), group ($F_{1,51} = 16.7$, $p<0.001$) and the interaction of time and group ($F_{2,51} = 7.5$, $p=0.008$) were recorded. Bonferroni multiple comparisons illustrated that the experimental group recorded a significant increase in total minutes of activity from baseline to 6 and 12 months (95%CI 6M

22.2,145.3 minutes, 12M 14.1, 123.2 minutes), with no significant decrease from 6 to 12 months (95%CI –21.4,7.4 minutes). The control group recorded no significant changes from baseline at either 6 or 12 months (95%CI 6M –44.0,0.3 minutes, 12M –35.7,1.5 minutes). Significant between group differences were recorded at 6 and 12 months (95%CI –161.7,-38.6 minutes, 12M –164.6,-30.9 minutes). The changes in total minutes of activity are illustrated in Figure 9.

Figure 9

Median minutes of moderate and total activity at baseline, 6 and 12 months by group



No significant main effects of time ($F_{2,51} = 1.63$, p=0.2), group ($F_{1,51} = 0.28$, p=0.6), or the interaction of time and group ($F_{2,51} = 0.17$, p=0.84) were recorded for the calculated minutes of light activity. For the minutes of recorded sleep there was no significant main effect of group ($F_{1,51} = 3.6$, p=0.06) or the interaction of time and group ($F_{2,51} = 0.86$, p=0.4) but there was a significant main effect of time ($F_{2,51} = 4.0$, p=0.02). Follow-up multiple comparison analyses revealed the whole group significantly increased the total time spent sleeping from baseline to 12 months (95%CI 0.02,7.31 minutes).

Significant between group differences were recorded for the change from baseline to 6 months

and baseline to 12 months in minutes of moderate activity and total activity (95%CI 6M moderate 100.0,220.0 minutes, total 120.0, 245.0 minutes, 12M moderate 65.0,195.0 minutes, total 95.0,220.0 minutes). No significant between group differences were recorded for sleep and light activity (95%CI 6M sleep –319.9,205.0 minutes, light –229.9,300.2 minutes, 12M sleep –294.9,215.1 minutes, light –295.1,235.0 minutes).

Two-way analysis of variance tests were also conducted on an intention to treat basis. The same values of significance were obtained suggesting no significant response bias caused by study drop out.

The data recorded from the 7-day recall questionnaire was related to the current ACSM and CDC physical activity guidelines[73,38]. Participants who were achieving at least three, 20 minute sessions of continuous moderate to hard intensity activity a week were categorised as meeting ACSM 1990 guidelines[73]. Participants who were achieving a minimum of 150 accumulated minutes of moderate intensity activity per week were categorised as meeting the ACSM/CDC 1995 guidelines[38]. The number of participants by group meeting each ACSM guideline is illustrated in Table 11. The categories were combined into meeting or not meeting either guidelines and analysed using Chi square tests. The results revealed that there was no significant difference in the number of participants meeting the guidelines between the groups at baseline (χ^2 =0.7, df=1, p=0.4), but there was a significant difference at 6 (χ^2 = 22.0, df=1, p<0.001) and 12 months (χ^2 = 15.2, df=1, p<0.001). At both 6 and 12 months more experimental, compared to control, participants were meeting current physical activity guidelines.

Table 11

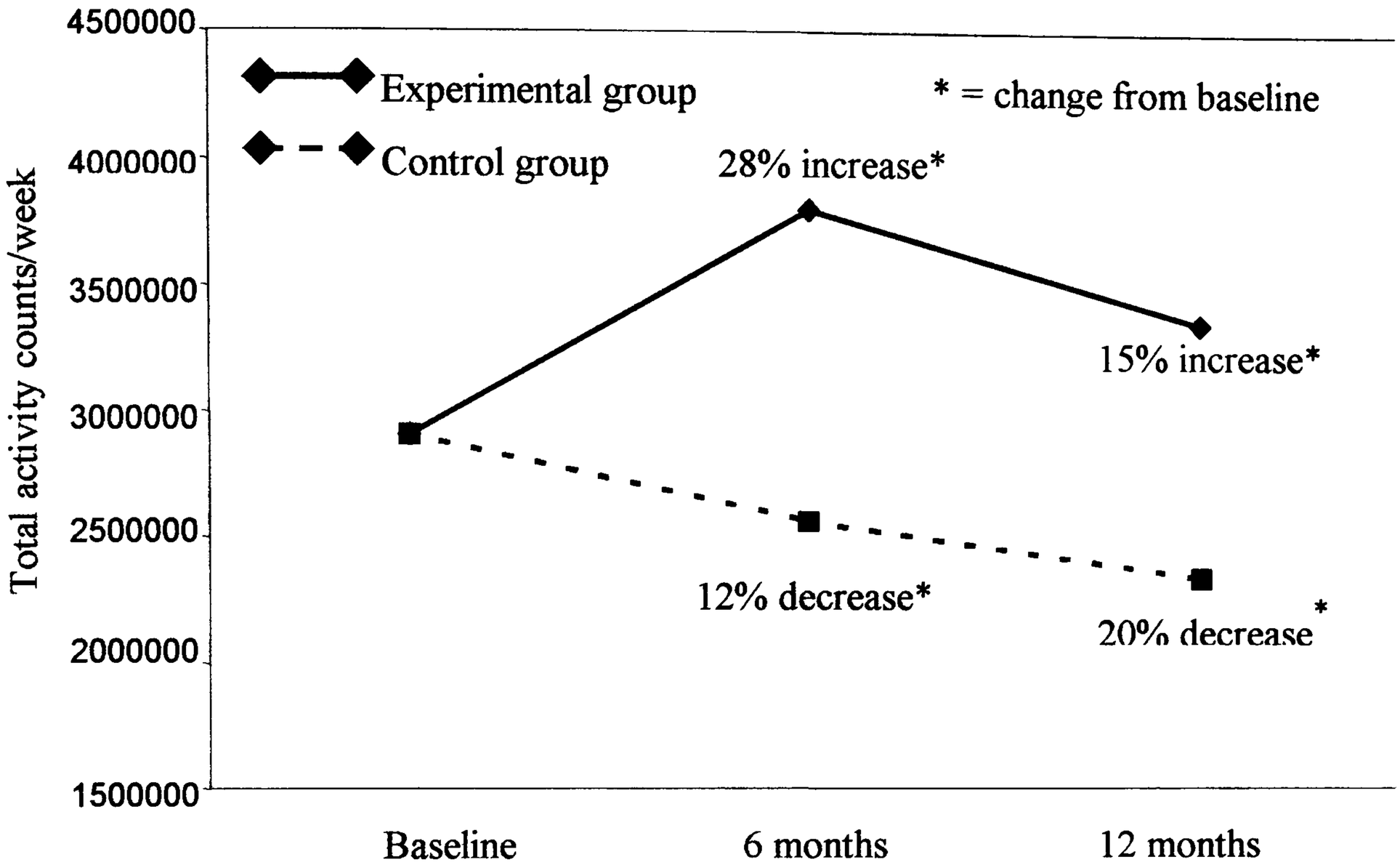
Number of participants meeting the ACSM 1990 and 1995 physical activity and exercise guidelines at baseline, 6 and 12 months by group.

Guidelines	Baseline		6 months		12 months	
	Experimental *(n=35)*	Control *(n=35)*	Experimental *(n=30)*	Control *(n=30)*	Experimental *(n=28)*	Control *(n=28)*
ACSM 1990	1	0	8	0	8	0
ACSM 1995	6	10	14	4	9	3

Figure 10 shows the total activity counts recorded by the CSA accelerometer at baseline, 6 and 12 months. A repeated measures (time), two-way analysis of variance (time x group) with covariate adjustment for baseline BMI was conducted to assess any differences. A total of 25 experimental participants and 27 control participants had complete accelerometer data sets. There was no significant main effect of time ($F_{2,49}$=3.02, p=0.06), but there were significant main effects of group ($F_{1,49}$=34.9, p<0.01) and the interaction of group and time ($F_{2,49}$=10.0, p<0.01). Bonferroni multiple comparisons for repeated measures were conducted to determine where the differences were. The results illustrated that the experimental group significantly increased total activity counts/wk from baseline to 6 months (95%CI 188427,1422725 counts/wk), with no significant decrease from 6 to 12 months (95%CI –1040090,262202 counts/wk). The change from baseline to 12 months did not reach significance (95%CI –217743,1051007 counts/wk). The control group recorded no significant change in total activity counts/wk from baseline to 6 months (95%CI –932741,266054 counts/wk) or 6 to 12 months (95%CI -966683,295248 counts/wk), although a significant decrease was recorded from baseline to 12 months (95%CI –1292285,-45837 counts/wk). Significant between group differences were recorded at 6 and 12 months (95%CI 6M –1786768,-491490 counts/wk, 12M –1771560,-400245 counts/wk). Significant between group differences for the change from baseline to 6 months (95%CI 594501,1723539 counts/wk) and from baseline to 12 months (95%CI 488465,1792253 counts/wk) were also recorded. This analysis was also conducted on an intention to treat basis. The same values of significance were obtained suggesting no significant response bias caused by study drop out.

Figure 10

Total activity counts/week at baseline, 6 and 12 months by group.



Behaviour change

Table 12 illustrates the number of participants in each stage of exercise behaviour change at baseline, 6 and 12 months by group. A total of 26 experimental participants and 28 control participants had complete stage of change data sets. Chi-square analysis revealed no significant difference between the experimental and control group at baseline (χ^2=0.2, df=1, p=0.6) with a significant difference between the groups at 6 and 12 months (6M χ^2=26.4, df=2, p<0.001, 12M χ^2=19.9, df=4, p=0.001). At both 6 and 12 months a greater number of experimental compared to control participants were in higher stages of exercise behaviour change.

Table 12

Number of participants in each stage of exercise behaviour change by group at baseline, 6 and 12 months

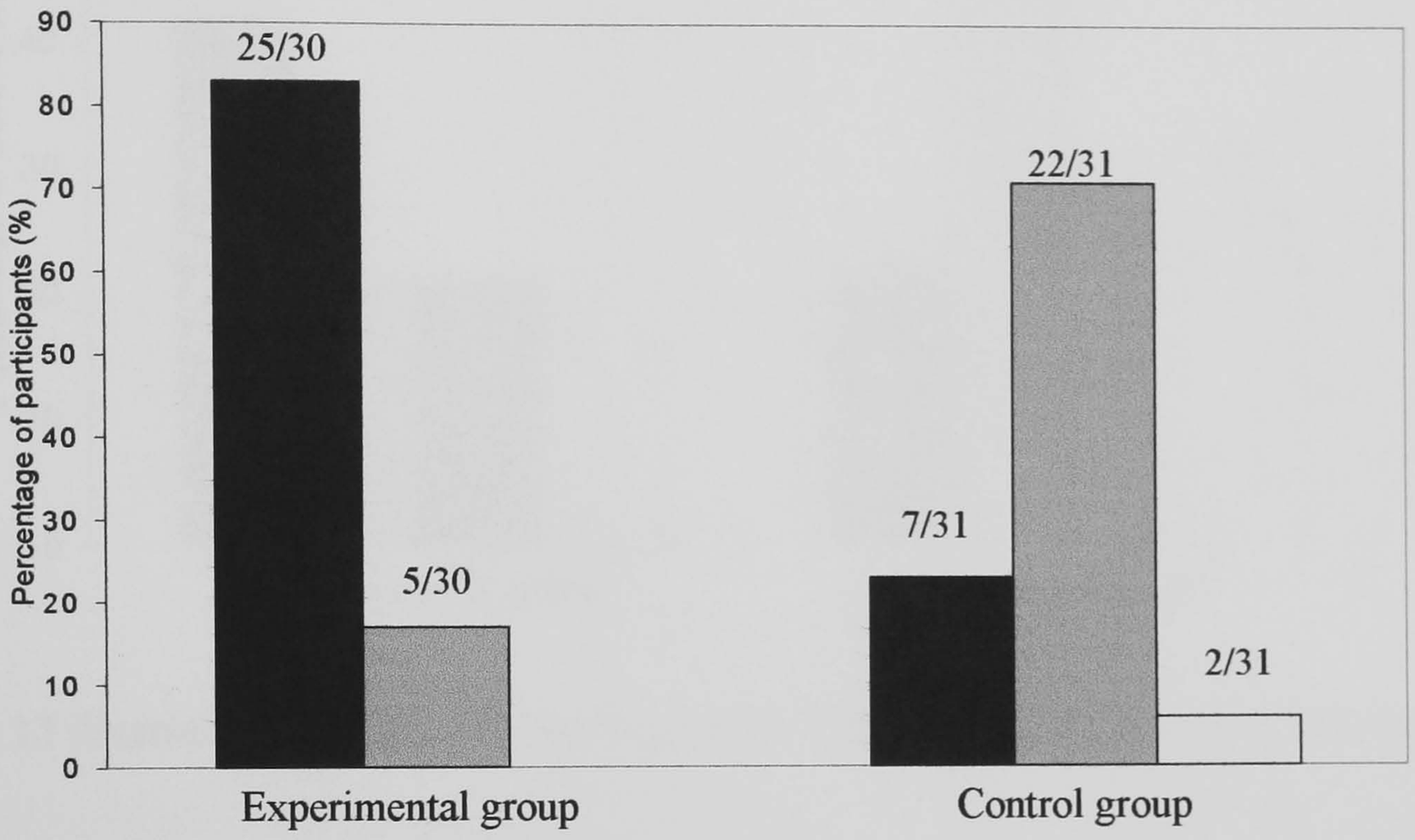
Stage	Baseline		6 months		12 months	
	Experimental	Control	Experimental	Control	Experimental	Control
Pre-contemplation	0	0	0	0	0	1
Contemplation	21	19	1	14	2	15
Preparation	14	16	11	16	8	9
Action	0	0	17	1	5	1
Maintenance	0	0	0	0	11	2

Changes in stage of exercise behaviour change from baseline to 6 and 12 months were categorised into progression, no change or regression in stage. From 6 to 12 months the no change category was further subdivided into a no change-active category (i.e. participants who had progressed to, and remained in, an active stage of change) and a no change-inactive category (i.e. participants who had remained in a non active stage of change). The percentage of participants at 6 and 12 months by group in each category of change is illustrated in Figure 11. Chi-square analysis revealed these changes in stage of exercise behaviour change to be significantly different between the experimental and control group (baseline to 6 months $\chi^2=21.7$, df=1, $p<0.001$, baseline to 12 months $\chi^2=9.3$, df=1, $p<0.001$, 6 to 12 months $\chi^2=10.9$, df=3, $p=0.01$).

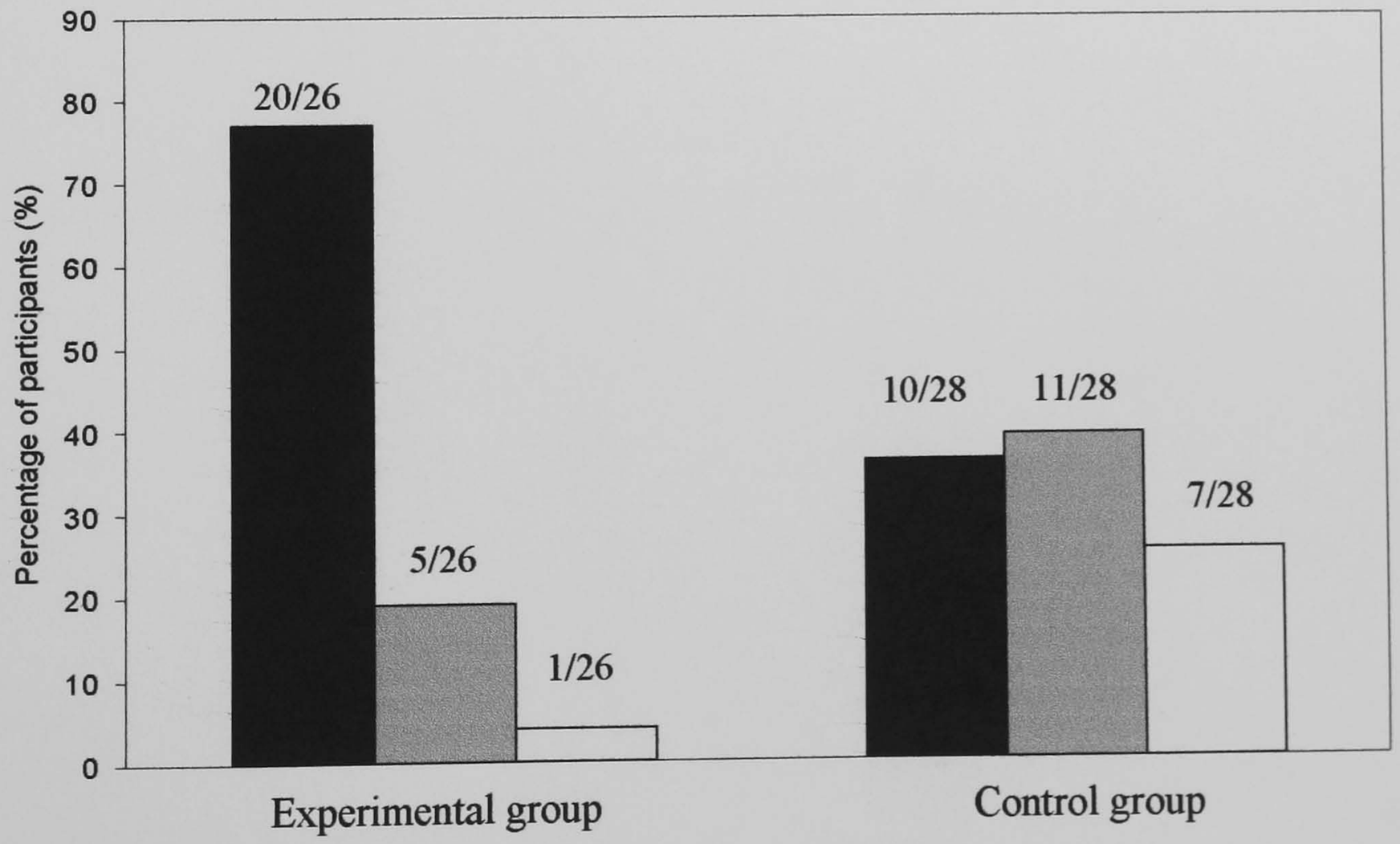
Figure 11

Movement in stage of exercise behaviour change by group

Change from baseline to six months



Change from baseline to twelve months



Change from six to twelve months

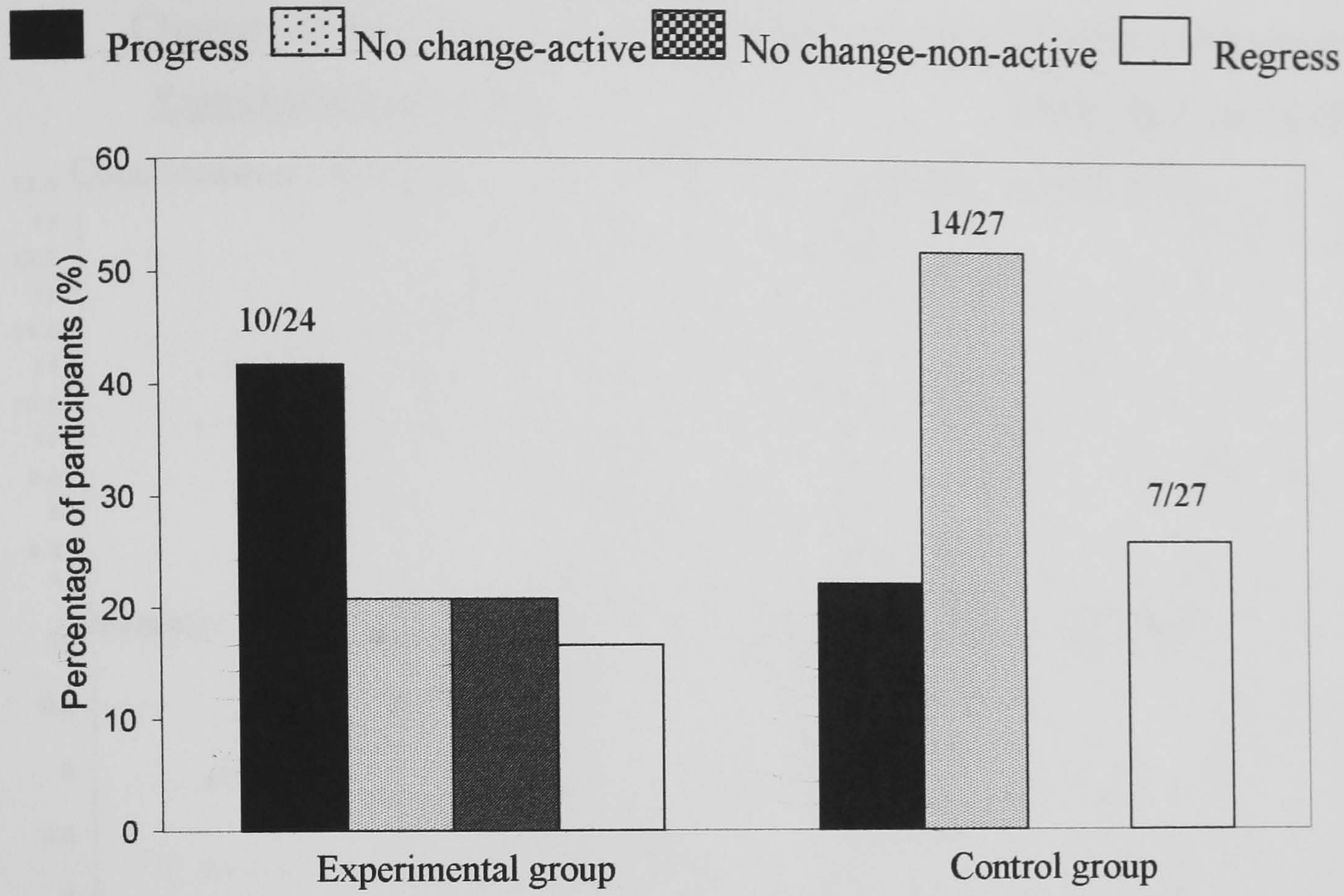
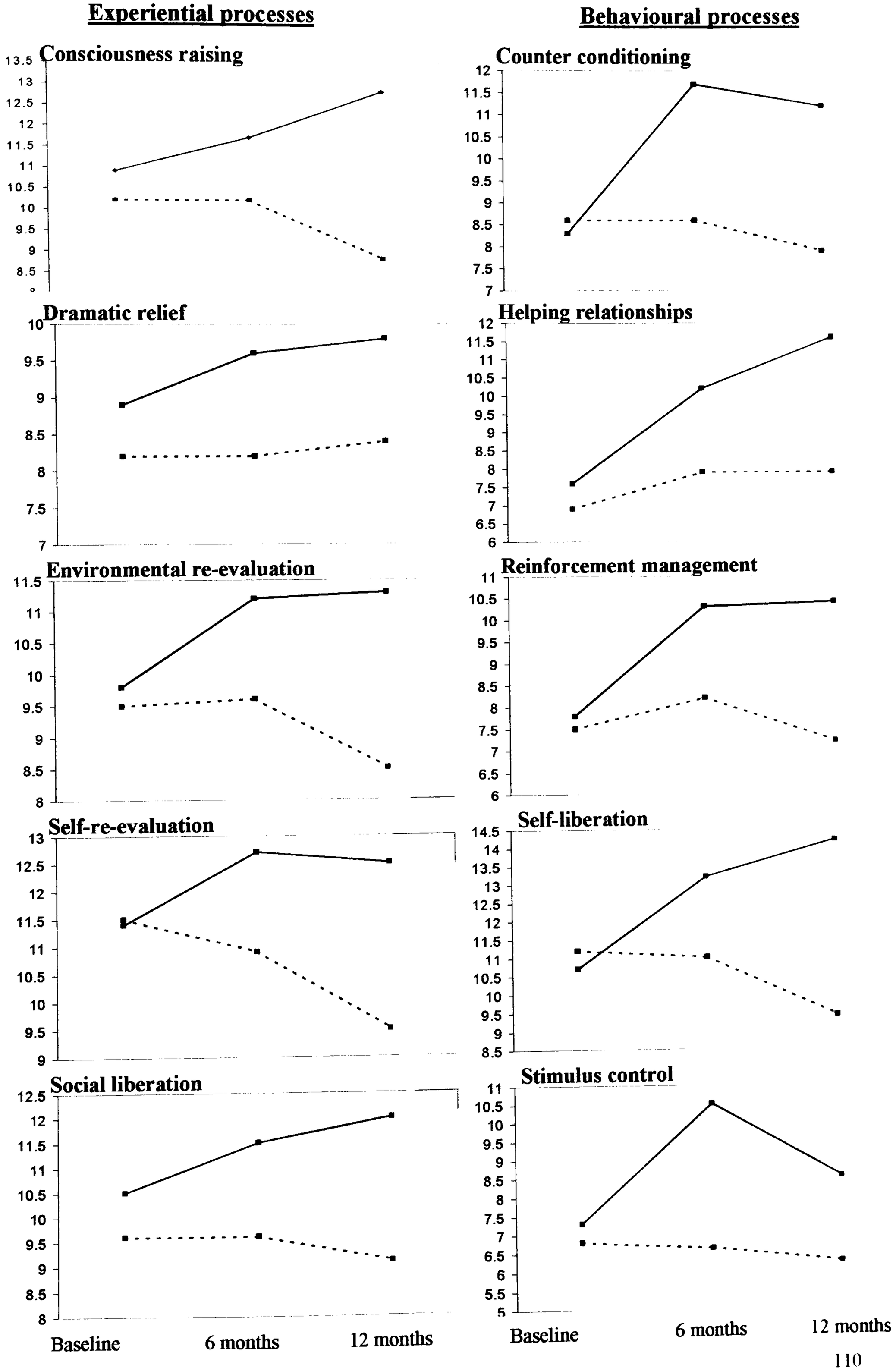


Figure 12 illustrates the change in the frequency of using each process of behaviour change

Figure 12

Changes in the frequency of using each process of exercise behaviour change



Repeated measures analyses for multiple variables (MANOVAs) were conducted to assess changes over time and between groups. A total of 26 experimental participants and 25 control participants had complete processes of change data sets. Analyses of the experiential processes revealed no significant effect of time ($F_{2,49} = 0.2$, $p = 0.6$), but a significant effect of group ($F_{1,49} = 4.6$, $p = 0.04$) and the interaction of time and group ($F_{2,49} = 10.4$, $p = 0.002$) for the conscious raising process. Multiple comparisons analyses illustrated a significant between group difference at 12 months (95%CI – 6.1,-2.1). No significant effect of group ($F_{2,49} = 1.46$, $p = 0.2$), time ($F_{2,49} = 0.65$, $p = 0.5$) or the interaction of group and time ($F_{2,49} = 0.45$, $p = 0.6$) were recorded for the dramatic relief process. No significant main effects of time ($F_{2,49} = 1.1$, $p = 0.3$) or group ($F_{1,49} = 2.7$, $p = 0.1$) were recorded for the environmental re-evaluation process, but there was a significant main effect of the interaction of time and group ($F_{2,49} = 3.0$, $p = 0.05$). Bonferroni multiple comparisons for repeated measures illustrated a significant between group difference for the use of this process at 12 months (95%CI–4.8,-0.67). No significant main effect of time ($F_{2,49} = 1.41$, $p = 0.2$) or group ($F_{1,49} = 2.7$, $p = 0.1$) were recorded for the self re-evaluation process, but there was a significant main effect of the interaction of time and group ($F_{2,49} = 4.24$ $p = 0.02$). Bonferroni multiple comparisons illustrated a significant between group difference for the use of this process at 12 months (95%CI–5.1,-0.86). Analyses of the social liberation process revealed no significant main effect of time ($F_{2,49} = 0.63$, $p = 0.5$) or the interaction of time and group ($F_{2,49} = 2.13$ $p = 0.1$), but a significant effect of group ($F_{1,49} = 4.2$, $p = 0.05$). Bonferroni multiple comparisons illustrated a significant between group difference for the use of this process at 12 months (95%CI–4.89,-0.80).

Analyses of the behavioural processes revealed significant main effects of time ($F_{2,49} = 5.09$, $p = 0.008$), group ($F_{1,49} = 6.06$, $p = 0.02$) and the interaction of time and group ($F_{2,49} = 7.59$ $p = 0.001$) for the counter conditioning process. Multiple comparisons illustrated a significant increase in the use of this process from baseline to 6 and 12 months. (95%CI 6M 1.15,5.47, 12M 0.65,5.0). Furthermore there was a significant between group difference for the use of this process at 6 and 12 months (95%CI 6M –5.28,-0.91, 12M –5.42,-1.05). Significant main effects of time ($F_{2,49} = 8.70$, $p < 0.001$), group ($F_{1,49} = 8.1$, $p = 0.006$) and the interaction of time and group ($F_{2,49} = 3.10$ $p = 0.05$) were recorded for the helping relationships process. Bonferroni multiple comparisons for repeated measures illustrated a significant increase in the use of this process from baseline to 12 months. (95%CI 1.43,6.58). Furthermore there was a

significant between group difference for the use of this process at 12 months (95%CI –6.34,-1.1). Analyses of the reinforcement management process revealed significant main effects of time ($F_{2,49}$ = 10.44, p < 0.001), group ($F_{1,49}$ = 5.76, p = 0.02) and the interaction of time and group ($F_{2,49}$ = 7.79 p = 0.001). Bonferroni multiple comparisons illustrated a significant increase in the use of this process from baseline to 6 and 12 months (95%CI 6M 1.0,4.08, 12M 1.03,4.12). There was a significant between group difference for the use of this process at 6 and 12 months (95%CI 6M –3.71,-0.59, 12M –4.74,-1.63). Results from the self liberation process illustrated significant main effects of time ($F_{2,49}$ = 3.3, p = 0.04), group ($F_{1.49}$ = 8.0, p = 0.007) and the interaction of time and group ($F_{2,49}$ = 17.0, p < 0.001). Bonferroni multiple comparisons illustrated a significant increase in the use of this process from baseline to 6 and 12 months. (95%CI 6M 0.64,4.59, 12M 1.60,5.55). There was a significant between group difference for the use of this process at 6 and 12 months (95%CI 6M –4.26,-0.28, 12M –6.82,-2.83). No significant effects of time ($F_{2,49}$ = 1.37, p = 0.3), group ($F_{2,49}$ = 3.6, p = 0.06) or the interaction of time and group ($F_{2,49}$ = 1.44, p = 0.2) were recorded for the stimulus control process.

In summary significant between group differences were recorded for the frequency of using behaviour change processes self-liberation, counter conditioning & reinforcement management at 6 months and all processes, except dramatic relief & stimulus control at 12 months. Experimental participants significant increase there use of processes self-liberation, counter conditioning & reinforcement management from baseline to 6 months and processes self-liberation, counter conditioning, reinforcement management & helping relationships from baseline to 12 months. In comparison the control group recorded no significant changes. Significant between group differences were recorded from baseline to 6 months for processes self-liberation (98%CI 0.84,5.6), counter conditioning (98%CI 1.3,5.6) and self re-evaluation (98%CI 0.2,4.6). Significant differences from baseline to 12 months were recorded for processes consciousness raising (98%CI 0.9,5.9), self-liberation (98%CI 3.3,7.8), Environmental re-evaluation (98%CI 0.3,4.5), helping relationships (98%CI 0.2,6.2), counter conditioning (98%CI 0.8,5.9), self re-evaluation (98%CI 0.5,5.3) and reinforcement management (98%CI 1.2,4.5).

The analysis conducted to assess changes in the frequency of using each process of change was also carried out on an intention to treat basis. The same values of significance were obtained

suggesting no bias caused by study drop out.

Cardiorespiratory fitness

Table 13 shows the cardiorespiratory fitness outcome variables by group at baseline, 6 and 12 months. A series of repeated measures (time) two-way analyses of variance (time x group) with covariate adjustments for gender and BMI were conducted to investigate differences over time and between groups. A total of 28 experimental participants and 29 control participants had complete exercise test data sets.

Table 13

Exercise testing variables by group at baseline, 6 and 12 months

Variable	Group	Baseline	6 months	12 months
			Mean (±SD)	
Exercise duration (mins)	Experimental	9.42±3.3	12.03±3.4	11.44±3.5
	Control	10.36±4.4	9.54±5.2	9.56±5.3
Peak gradient (%)	Experimental	8.38±4.6	11.8±5.0	11.6±6.0
	Control	9.2±5.7	8.8±6.2	8.8±6.2
Aerobic function				
Vo_2 (ml/Kg/min)	Experimental	20.1±5.9	21.0±5.2	20.2±4.9
	Control	20.6±5.5	18.7±5.4	17.8±5.8
Vo_2 (ml/min)	Experimental	1925±684	1996±540	1899±629
	Control	1956±600	1763±626	1799±603
Vo_2 at LT (ml/min)	Experimental	1156±329	1255±317	1178±289
	Control	1217±322	1209±255	1142±215
Vo_2 at LT (%peak)	Experimental	61.2±9.9	63.6±9.1	63.8±12.2
	Control	61.9±9.7	65.5±10.0	63.1±12.0

Cardiovascular function				
Whole group				
Peak HR (bpm)	Experimental	129.9±23.9	134.5±19.5	136.2±17.2
	Control	133.5±24.4	129.8±23.5	132.0±21.8
Vo_2/HR (ml/bpm)	Experimental	14.9±4.8	15.3±4.7	14.5±4.4
	Control	14.3±3.9	13.5±3.8	13.6±3.6
HR at Vo_2pt (bpm)	Experimental	97.2±13.2	94.8±15.8	94.9±16.6
	Control	100.9±18.1	98.4±14.9	98.1±12.8
HR at Vo_2pt LT (bpm)	Experimental	102.0±15.0	103.6±16.5	101.5±17.0
	Control	106.8±18.9	104.5±13.1	102.5±13.5
Without Beta-blockers				
Peak HR (bpm)	Experimental	137.4±21.3	140.0±17.3	141.4±13.9
	Control	138.9±21.6	134.1±20.6	133.0±21.6
Vo_2/HR (ml/bpm)	Experimental	14.1±3.9	14.5±3.9	14.0±4.1
	Control	13.4±3.3	12.9±3.3	12.7±3.2
HR at Vo_2pt (bpm)	Experimental	105.0±15.7	103.0±10.6	100.5±11.3
	Control	101.5±13.1	98.0±13.8	100.7±13.0
HR at Vo_2pt LT (bpm)	Experimental	110.7±15.9	108.0±10.1	105.5±12.3
	Control	107.1±14.7	106.9±14.7	107.2±12.3
Ventilatory function				
Peak VE (ml/min)	Experimental	57.7±22.7	60.6±20.2	56.4±20.6
	Control	58.2±18.1	56.0±22.0	53.8±18.5

VE at Vco_2pt (ml/min)	Experimental	24.9±5.2	25.6±5.4	25.3±5.5
	Control	26.9±4.9	25.8±4.5	26.0±4.5
F at Vco_2pt (breaths/min)	Experimental	24.0±5.4	23.1±6.6	23.8±6.1
	Control	23.6±4.4	23.7±4.4	23.4±3.7
VT at Vco_2pt (L)	Experimental	1.07±0.27	1.18±0.33	1.11±0.33
	Control	1.17±0.25	1.12±0.25	1.14±0.24

SD = standard deviation, Vo_2 = oxygen uptake, Vo_2 at LT = oxygen uptake at lactate threshold, Vo_2 at LT (%peak) = oxygen uptake at lactate threshold as a percentage of peak oxygen uptake, HR = heart rate, Vo_2/HR = oxygen pulse, HR at Vo_2pt = heart rate at a given point of oxygen uptake, HR at Vo_2pt LT = heart rate at the oxygen uptake point of lactate threshold, VE = ventilation, VE at Vco_2pt = ventilation at a given point of carbon dioxide output, F at Vco_2pt = respiratory frequency at a given point of carbon dioxide output, VT at Vco_2pt = tidal volume at a given point of carbon dioxide.

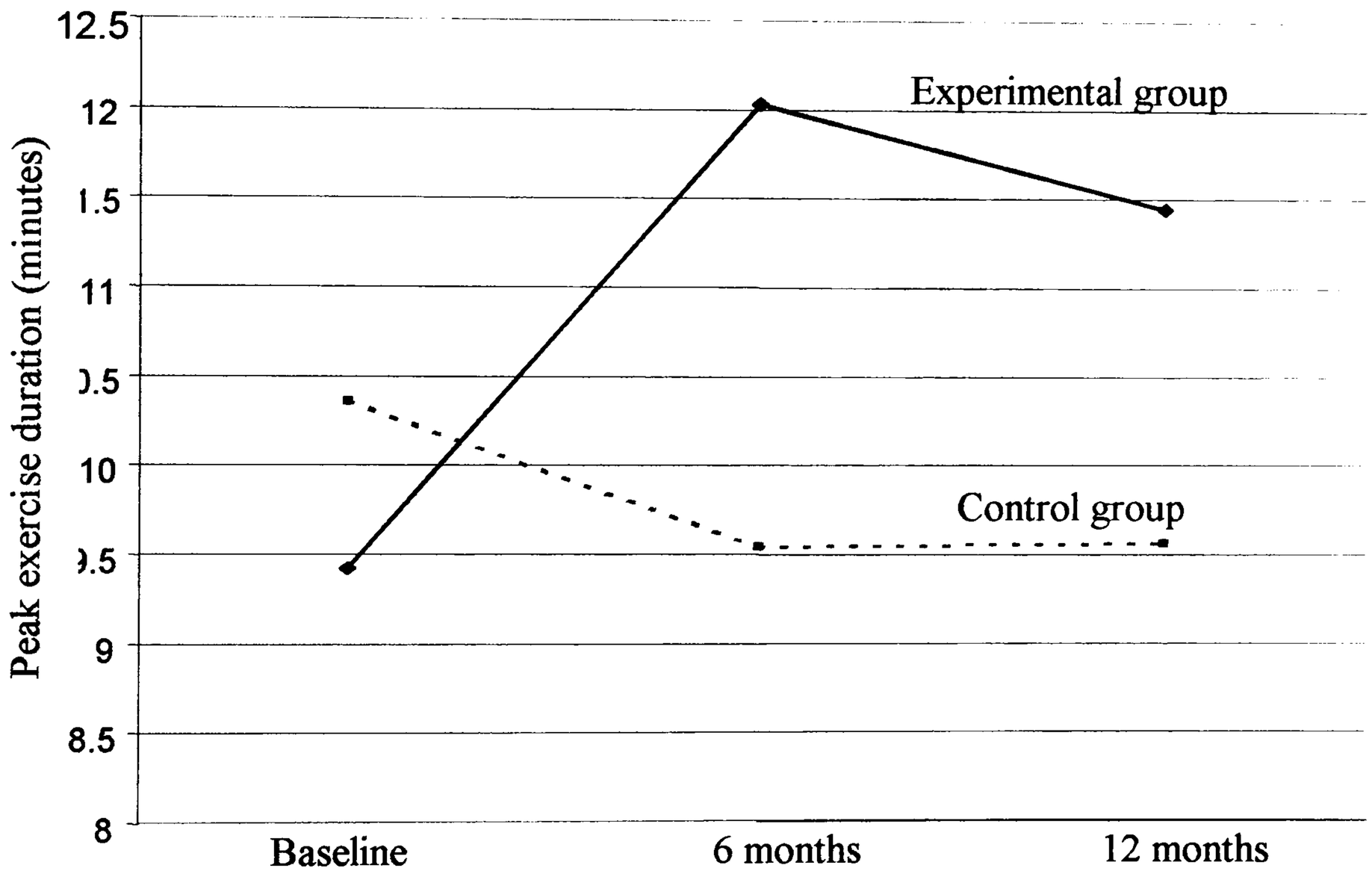
Peak exercise duration achieved during the exercise test by group at baseline, 6 and 12 months is illustrated in Figure 13. Analyses of total exercise duration revealed there was no significant main effect of group ($F_{1,53}$=1.23, p=0.27) or time ($F_{2,53}$ =3.08, p=0.06) but there was a significant main effect for the interaction of group and time ($F_{2,53}$=4.75, p=0.01). Follow-up Bonferroni multiple comparisons for repeated measures showed that total exercise duration increased significantly from baseline to 6 months in the experimental group (95%CI 0.24,3.20mins) with no significant decrease from 6 to 12 months (95%CI –2.02,1.04mins). The change in total exercise duration from baseline to 12 months did not reach significance (95%CI -0.07,2.57mins). The control group recorded no significant changes. The difference between the experimental and control group for total exercise duration did not reach significance at 6 or 12 months (6M – 95%CI –3.02,0.06mins, 12M –2.38,0.39mins). The difference between the experimental and control group for the change in total exercise duration, was significant from baseline to 6 months (95%CI 0.57,2.51mins) and from baseline to 12 months (95%CI 0.08,3.25mins).

Analyses of the peak gradient achieved at the end of the exercise test illustrated significant main effects for time ($F_{2,52}$ = 6.98, p=0.001) and the interaction of group and time ($F_{2,52}$ = 4.97, p=0.009), but no significant main effect of group ($F_{1,52}$ = 2.53, p=0.11). Follow-up Multiple

comparisons showed that the experimental group achieved a significantly higher peak gradient at 6 and 12 months compared to baseline (95%CI 6M 0.57,4.0%, 12M 0.83,4.3%) with no significant decrease in peak gradient from 6 to 12 months (95%CI –1.5,2.1%). The control group recorded no significant changes. At 6 and 12 months post intervention the experimental group achieved a significantly higher peak gradient than the control group (95%CI 6M –3.8,-0.1%, 12M –4.0,-0.3%). The difference between the experimental and control group for the change in peak gradient was significant from baseline to 6 months (95%CI 0.94,4.08%) and baseline to 12 months (95%CI 0.6,4.37%).

Figure 13

Peak exercise duration by group at baseline, 6 and 12 months



Analyses of aerobic function variables illustrated no significant main effect of group for peak oxygen uptake ($F_{1,53}$ = 1.13, p=0.3), but there was a significant main effect of time ($F_{2,53}$ = 7.69, p=0.001) and the interaction of time and group ($F_{2,53}$ = 2.94, p=0.05). Bonferroni multiple comparisons for repeated measures illustrated a significant decrease in the control group for peak oxygen uptake from baseline to 6 months (95%CI -353.6,-35.9ml/min). Oxygen uptake corrected for body weight (Vo_2ml/kg/min) was analysed separately. Similar results were

obtained with significant main effects for time and the interaction of time and group being recorded (time $F_{2,53} = 8.5$, $p<0.001$, interaction $F_{2,53}=2.97$, $p=0.05$). Follow-up multiple comparisons illustrated a significant decrease in Vo_2ml/kg/min from baseline to 6 and 12 months (95%CI 6M –3.3,-0.04ml/kg/min, 12M –4.0,-0.61ml/kg/min). No significant main effects of time, group or the interaction of time and group were recorded for oxygen uptake at lactate threshold (time $F_{2,44} = 2.85$, $p=0.06$, group $F_{1,44} = 0.06$, $p=0.8$, interaction $F_{2,44} = 1.25$, $p=0.3$),or oxygen uptake at lactate threshold as a percentage of peak oxygen uptake (time $F_{2,44} = 2.18$, $p=0.13$, group $F_{1,44} = 0.13$, $p=0.7$, interaction $F_{2,44} = 0.13$, $p=0.7$). No significant between group differences were found for the change from baseline to 6 months and baseline to 12 months on any aerobic function variables.

Analyses of cardiovascular function variables revealed no significant main effect of time, group or the interaction of time and group for peak heart rate (time $F_{2,53} = 0.26$, $p=0.8$, group $F_{1,53} = 0.51$, $p=0.5$, interaction $F_{2,53} = 1.26$, $p=0.3$), oxygen pulse (Vo_2/HR) (time $F_{2,42} = 2.2$, $p=0.1$, group $F_{1,42} = 1.15$, $p=0.3$, interaction $F_{2,42} = 1.24$, $p=0.3$), heart rate at a given point of oxygen uptake (time $F_{2,37} = 1.72$, $p=0.2$, group $F_{1,37} = 0.58$, $p=0.5$, interaction $F_{2,37} = 0.95$, $p=0.4$) or heart rate at the oxygen uptake point of lactate threshold (time $F_{2,35} = 2.29$, $p=0.1$, group $F_{1,35} = 1.8$, $p=0.2$, interaction $F_{2,35} = 1.12$, $p=0.3$). In view of the effects of beta-blocker medication on heart rate this analyses was also carried out separately for participants not on beta-blocker medication. Similar results were obtained although the analyses of oxygen pulse revealed a significant effect of group ($F_{1,33} = 15.97$, $p<0.01$) with Bonferroni multiple comparisons for repeated measures illustrating that the significant difference occurred at 6 months when the experimental group recorded a significantly greater oxygen pulse that the control group (95%CI –2.86,-0.01ml/bpm). Separate analyses were not conducted for the group on beta-blockers as numbers were small and the dose and timing of beta-blocker medication was not controlled for during the study. No significant between group differences were found for the change from baseline to 6 months and baseline to 12 months on any cardiovascular function variables.

Analyses of ventilatory function variables illustrated no significant main effects of group ($F_{1,49} = 0.7$, $p=0.4$) or the interaction of group and time ($F_{2,49} = 0.50$, $p=0.5$) for peak ventilation but there was a significant main effect of time ($F_{2,49} = 4.9$, $p=0.009$). Bonferroni multiple comparisons for repeated measures illustrated that there was a significant decrease in peak

ventilation in the whole group from baseline to 12 months (95%CI –7.8,-0.9ml/min). No other significant main effects for time, group or the interaction of time and group were recorded for ventilation at a given Vco_2 point (time $F_{2,48} = 0.1$, p=0.7, group ($F_{1,48} = 0.3$, p=0.7), interaction $F_{2,48} = 0.13$, p=0.7), peak tidal volume (time $F_{2,48} = 1.48$, p=0.2, group $F_{1,48} = 0.01$, p=0.9, interaction $F_{2,48} = 1.78$, p=0.2) or peak respiratory frequency (time $F_{2,48} = 1.4$, p=0.3, group $F_{1,48} = 0.001$, p=0.9, interaction $F_{2,48} = 0.03$, p=0.9). The change in tidal volume from baseline to 6 months was the only significant between group difference of the change recorded (95%CI 0.01,0.15L).

DISCUSSION

Primary outcome measures

Physical activity levels

The changes in the primary outcome measures of this study demonstrated that the exercise consultation intervention was more effective in promoting and maintaining physical activity, than a standard exercise leaflet, in people with Type 2 diabetes.

In this study both subjective and objective methods of physical activity measurement were used. There are limitations to using either method alone and often the advantages of objective methods compensate for the disadvantages of subjective methods and vice versa. This outlines the benefits of using both subjective and objective methods to measure physical activity.

Participants receiving the exercise consultation intervention reported significant increases from baseline at 6 and 12 months in minutes of moderate and total (moderate + hard + very hard + strength and flexibility) activity. From baseline to 6 months the experimental group recorded a median increase of 120 and 153 minutes of moderate and total activity respectively and from baseline to 12 months a median increase of 100 and 130 minutes of moderate and total activity respectively. In comparison the control group recorded no significant changes. At both 6 and 12 months the experimental group were participating in significantly more moderate and total activity compared to the control group.

In general, the results from the CSA accelerometer parallel the results of the 7-day recall and this adds strength to these findings. The experimental group recorded a significant 28% increase in total counts from baseline to 6 months with no significant decrease from 6 to 12

months, although the change from baseline to 12 months failed to reach significance. The change from baseline to 12 months however did represent a 15% increase. The control group recorded no significant changes from baseline to 6 months and a significant decrease from baseline to 12 months. Significant between group differences were recorded at 6 and 12 months.

The changes in physical activity in this study identify a number of important points for discussion. Significant increases in the experimental group from baseline to 6 months were recorded from both measures of physical activity. A limited number of studies in people with Type 2 diabetes have evaluated the effects of physical activity interventions beyond 6 months. The majority of studies evaluate the effects over shorter periods (up to 3 months). Agurs-Collins and colleagues[59] reported the 3 and 6 month effects of a diet and exercise programme for older African-American people with Type 2 diabetes. The intervention involved weekly diet and exercise counseling sessions for 3 months followed by 6 biweekly sessions. Physical activity increased significantly from baseline to 3 months, however this significant change was not maintained at 6 months.

In the general population a number of studies have reported significant increases in physical activity with both structured exercise progammes and lifestyle physical activity counselling interventions[200,201,195,203,199,39]. Project Prime[203], a 4 year randomised controlled trial comparing physical activity counselling, delivered by person or by mail and telephone reported change in minutes of physical activity measured by the same 7-day recall questionnaire used in this study. To date only changes from baseline to 6 months have been reported. The two physical activity counselling groups, delivered by person or by mail and telephone reported significant increases of 187 and 164 minutes of moderate activity per week respectively. Theses changes in minutes of physical activity are higher in comparison to those recorded in this study. This difference could be a result of the more complex and intensive intervention used in Project Prime.

A number of studies that use the 7 day recall to evaluate changes in self reported physical activity as a result of an intervention have converted minutes of physical activity into energy expenditure[39,195,203]. Converting minutes of physical activity into energy expenditure has a number of limitations such as variation in individual performance of activities. Analysing the change in self reported physical activity enables the data to be related to the current ACSM/CDC physical activity

guidelines[48], which quantifies physical activity in minutes. In this study at 6 months 73% of the experimental group, compared to 13% of the control group were meeting the ACSM/CDC guidelines[48]. These figures are comparable with the results of Project Active[39]. Project Active compared the effectiveness of a structured exercise intervention to a lifestyle physical activity counseling intervention over 6 and 24 months. At 6 months 78% of the lifestyle group and 85% of the structured group participants were meeting or exceeding the ACSM/CDC guidelines[48]. One of the key findings of this study was that increases in physical activity in the experimental group were in general maintained at 12 months. In comparison to baseline, self reported minutes of moderate and total activity were significantly higher at 12 months and 61% of experimental participants, compared to 11% of controls, were meeting or exceeding the ACSM/CDC guidelines[48]. Although physical activity counts were not significantly higher at 12 months they were significantly higher than the control group. In the experimental group no significant decrease from 6 to 12 months was recorded in minutes of moderate or total activity recorded from the 7-day recall. Although a trend towards a decrease from 6 to 12 months was recorded in total activity counts from the accelerometer, this does not reach significance. This difference in pattern between 6 and 12 months between the two physical activity measurement methods could be explained by either an inaccurate recall from the questionnaire or a change in compliance with wearing the accelerometer.

Limited research has evaluated the effectiveness of physical activity interventions in people with Type 2 diabetes over 12 months. Vanninen et al[69] investigated the effect of a 1 year diet and exercise intervention in people with Type 2 diabetes. No significant differences in physical activity levels were recorded between the experimental and control group at 12 months. In a similar study Uusitpua[68] reported similar findings with no significant changes being recorded in physical activity after 12 months of oral and written instructions for exercise. In both these studies experimental participants were simply encouraged to do more physical activity and suitable types of physical activity were explained. Neither intervention had a theoretical base, provided structured exercise or developed cognitive behavioural techniques.

In the general population a number physical activity interventions have been evaluated over the longer term (up to 24 months)[39,203,195,41,201,199]. Project Active[39] reported that at 24 months only 20% of participants in both the structured and lifestyle intervention groups were meeting or exceeding the ACSM/CDC physical activity guidelines[48]. Similar results were reported from the

Activity Counseling Trial[195]. This trial compared the effectiveness of two physical activity counseling interventions, which differed in the type and frequency of contact with health professionals. At 24 months only 25.5% of participants in the most intensive intervention group were meeting or exceeding the ACSM/CDC physical activity guidelines[48]. The percentages of participants at 24 months meeting the guidelines in these studies are much lower than the percentage recorded at 12 months in the present study. This difference could be explained by differences in the timing of assessments (Activity counseling trial - 24 months, present study 12 months) or the characteristics of the study population. The Activity Counseling Trial involved the general population, in comparison the present study involved people with Type 2 diabetes. Steptoe et al[41] reported significant increases in physical activity at 4 and 12 months after brief behavioural counselling in sedentary adults. Similarly Stevens et al[199] reported significant higher levels of physical activity 8 months after a brief exercise consultation and the development of a 10 week personalised physical activity programme. In a randomised controlled trial comparing fitness assessment, exercise consultation and standard exercise information, Lowther et al[201] showed that only participants in the exercise consultation group reported significantly higher levels of physical activity at 12 months. Comparison of these studies is difficult due to different counselling techniques and varied methods being used to measure physical activity.

In a number of physical activity intervention studies positive changes have also been reported in the control group[201,200,195]. Lowther et al[201] reported a significant increase in physical activity from baseline to 6 months in the control group who received a physical activity booklet and exercise vouchers. Similarly in the Activity Counselling Trial[195] the male participants of the control group who received brief physician advice about physical activity recorded significant improvements in cardiorespiratory fitness at 6 months. It has been suggested that even giving physical activity information in a supportive environment can be effective for promoting physical activity in the general population. In comparison to these studies the control group in this study reported no significant changes in physical activity at any time point and no significant change in total accelerometer counts were recorded from baseline to 6 months, with a significant decrease from baseline to 12 months. A significant decrease was also recorded in the pilot study evaluating the effectiveness of the exercise consultation at 5 weeks[29]. This highlights that simply giving people with Type 2 diabetes information about physical activity in a supportive environment is not effective.

The standard exercise information used in this study was a general leaflet on diabetes and exercise, currently used in diabetes management[278]. The leaflet covers the following topics: Why should I exercise?, How much exercise should I do?, How to get started, Will exercise affect my diabetes? The leaflet is not tailored to stage of exercise behaviour change and does not provide information to encourage the use of cognitive behavioural strategies for changing physical activity behaviour. The decrease in physical activity recorded in the control group in this study could be explained by a true decrease in physical activity, a lower compliance with wearing the accelerometers during follow-up or an increase in motivation following recruitment into a physical activity study, followed by a regression to the norm over the follow-up period.

Behaviour change

Movement in stage of exercise behaviour change recorded in the pilot study[29], evaluating the effectiveness of the exercise consultation at 5 weeks, was similar to the movement in stage recorded in this study at 6 months. Both studies categorised movement in stage into progression (increase one or more stages), no change (no change in stage) and regression (decrease one or more stages). In the pilot study[29] at 5 weeks 82% of the experimental group had progressed and 18% reported no change. 33% of the control group progressed, 50% reported no change and 17% regressed. In the main study at 6 months 83% of the experimental group had progressed and 17% reported no change. 23% of the control group had progressed, 71% reported no change and 6% had regressed. At 5 weeks 55% of experimental participants in the pilot, compared to 8% of controls reported being in an active stage (action or maintenance) of behaviour change. In this study at 6 months 59% of experimental participants, compared to 3% of controls reported being in an active stage. Project Active[304] reported 78% of the lifestyle physical activity counselling group to be in an active stage at 6 months. This percentage is slightly higher than the percentage recorded in this study at 6 months. The lifestyle physical activity counselling intervention used in Project Active was much more complex and intensive and this may explain this difference. In Project Active the intervention used involved 26 group meetings over 12 months in which cognitive behavioural strategies were discussed. Participants also received monthly stage tailored manuals and activity calendars. The intervention used in the present study is relatively minimal in comparison, involving two individual consultations and four supporting phones calls over 12 months.

In this study the percentage of participants who reported being in an active stage is maintained at 12 months, with 61% reporting being in an active stage. The stage distribution of the lifestyle physical activity counselling group in Project Active at 24 months is not reported, however it is documented that only 20% are meeting or exceeding the ACSM/CDC physical activity guidelines[48]. The positive movement in stage of exercise behaviour change complements the increase in physical activity reported by the 7 day recall and CSA accelerometer.

A large amount of change is recorded in this study for the frequency of using the ten processes of exercise behaviour change. From baseline to 6 months a large number of the experimental group (17/29) move from a contemplation or preparation stage into an action stage. In a meta-analysis conducted by Marshall and Biddle[174] movement from a preparation stage into an action stage was associated with the second largest change in processes use. The largest change in process use occurred during the transition from pre-contemplation to contemplation. In this study from baseline to 6 months in the experimental group the frequency of using all processes increased, although only the three behavioural processes of self-liberation, counter conditioning and reinforcement management reached significance. In Marshall and Biddle's meta-analysis these three processes recorded the largest effect size for change in frequency of use during transition from preparation to action. This suggests that increasing the frequency of using these three processes is particularly important to encourage people to progress from inactive to active stages of exercise behaviour change. Physical activity interventions for people in inactive stages of exercise behaviour should focus strongly on these three processes.

From 6 to 12 months in this study the experimental group record no significant changes in the frequency of using any processes. During this time period a number of people (11/24) report movement from action to maintenance. In the meta-analysis by Marshall and Biddle[174] it was reported that movement from action to maintenance is generally associated with only small changes in the frequency of process use (effect size up to 0.2). Analysis of changes in the frequency of using the processes of exercise behaviour change from baseline to 12 months in the experimental group show significant increases in all processes except dramatic relief and stimulus control. It is difficult to relate these changes to stage transition as over this time period a number of transitions have been made. The changes in processes use in the experimental group of this study suggest that nearly all processes are important for adoption and maintenance of physical activity in people with Type 2 diabetes. Interventions to promote and

maintain physical activity in people with Type 2 diabetes should therefore incorporate ways to encourage people to increase the frequency of using all ten identified processes of behaviour change.

The control group in this study recorded no significant changes in the frequency of using any processes of exercise behaviour change. There are a couple of trends that are important to mention. From baseline to 6 months the use of all processes is relatively stable and this can be associated with the fact that the majority of the control group (22/31) reported no change in stage over this time period. From 6 to 12 months there is a decrease in the frequency of using six of the ten processes of exercise behaviour change. During this time period a number of control participants (7/27) reported a regression in stage. In a study investigating the relationship between the stages and processes of exercise behaviour change Marcus and colleagues[176] reported no change in stage to be associated with no change in processes use and regression in stage to be associated with a decrease in process use.

In theory, the exercise consultation is proposed to develop the ten identified processes important for physical activity behaviour change to encourage progression through the stages of exercise behaviour change and thus increase adoption and maintenance of physical activity. The results of this study can be related directly to this theory. Participants receiving the exercise consultation intervention recorded significant increases in the frequency of using three out of ten and eight out of ten processes from baseline to 6 months and baseline to 12 months respectively. This group also reported positive movement in stage of exercise behaviour change at both 6 and 12 months and levels of physical activity were significantly increased from baseline to 6 months and maintained at 12 months.

Cardiorespiratory fitness

A significant difference was recorded between the experimental and control group for the change in total exercise duration and gradient recorded during the peak exercise test. From baseline to 6 months the experimental group recorded a significant mean increase of two minutes and 21 seconds in total exercise duration and 3.4 percent increase in peak gradient. From baseline to 12 months a significant mean increase of 3.2 percent in peak gradient was recorded. Although the change from baseline to 12 months in peak exercise duration in the experimental group did not reach statistical significance, an increase of two minutes and two

seconds was recorded and this could be considered clinically significant[305]. The control group recorded no statistically or clinically significant changes. It is difficult to compare these changes to other studies as different exercise protocols have been used.

A significant decrease in peak oxygen uptake from 20.6 to 17.8ml/kg/min was recorded in the control group. The small increase in body weight recorded in the control group from baseline to 6 and 12 months could be related to this change in peak Vo_2ml/min/kg. However analysis of peak Vo_2ml/min, not corrected for body weight, revealed similar results with a significant decrease in the control group and no change in the experimental group. This decrease therefore could be a result of either a decrease in motivation during the exercise test from baseline to both 6 and 12 months follow-up or a true decrease in peak oxygen uptake as a result of the progressive nature of Type 2 diabetes (24). There was little change from oxygen uptake at lactate threshold, indicating no decline in sub-maximal cardiorespiratory fitness. Only small decreases from baseline in total exercise duration and peak gradient were recorded. This suggests there may have been a true decrease in peak Vo_2ml/kg/min in the control group with more anaerobic work being done above the lactate threshold.

Previous studies in people with Type 2 diabetes have reported similar changes in oxygen uptake, with significant decreases in control participants over 6 and 24 months[64,74]. Lightenberg et al[64] reported a decrease in peak oxygen uptake from 20.8 to 18.2ml/kg/min over 6 months in the control group of people with Type 2 diabetes who received an educational programme with no instructions about exercise. Skafors et al[74] recorded a decrease in peak oxygen uptake from 30.2 to 26.7ml/kg/min in the control group of people with Type 2 diabetes who received standard care. No details are given about the content of standard care. The changes in Vo_2ml/min/kg recorded by Lightenberg et al[64] are similar to the changes recorded in this study. The characteristics of both study participants are similar. In the study by Skafors et al[74] the baseline peak Vo_2ml/min/kg recorded is much higher than the peak Vo_2ml/min/kg recorded in this study and by Lightenberg et al[64]. The participants of the study by Skafors et al[74] were younger, had a lower body weight and a relatively short duration of diabetes (mean 2.3 years). In the experimental group despite a significant increase in total exercise duration no significant changes in peak Vo_2ml/kg/min were recorded. There are a number of possible reasons for this. From baseline to 6 months there were small increases in peak oxygen uptake and oxygen uptake at lactate threshold. This may have been sufficient to significantly increase exercise

duration and peak gradient. However this cannot explain the change from baseline to 12 months in which there was relatively no change in either peak oxygen uptake or oxygen uptake at lactate threshold. Similar to the control group the changes from baseline to 12 months in the experimental group suggest that a greater amount of work was being done anaerobically above the lactate threshold.

Other significant changes in exercise testing variables were a between group difference in oxygen pulse at 6 months in the group not on beta-blockers, a between group differences of the change from baseline to 6 months in tidal volume and a decrease over the study period in minute ventilation in the whole group.

The significant between group difference in oxygen pulse at 6 months occurs as a result of a small increase in oxygen pulse in the experimental group and a small decrease in the control group. This significant between group difference is only recorded in the group not on Beta-blockers. The lack of significant change in the group on Beta-blockers is probably due to the actions of the drug. Beta-blockers prevent stimulation of the beta-adrenergic receptors at the nerve endings of the sympathetic nervous system decreasing the activity of the heart by reducing heart rate and contractile force. Peak oxygen pulse is the quotient of peak oxygen uptake and peak heart rate. The controlling effects of Beta-blockers on peak heart rate may have prevented any significant change in oxygen pulse. The timing and dose of Beta-blocker medication was not controlled for in this study.

Oxygen pulse is a measure of oxygen extraction by the tissues of the body from the oxygen carried in each stroke volume and is therefore equal to the product of stroke volume (SV) and arterial-mixed venous oxygen content difference ($C(a\text{-}v)O_2$). In the control group the small decrease in peak oxygen pulse is related to a significant decrease in peak oxygen uptake with only a small decrease in peak heart rate. In the experimental group the small increase in peak oxygen pulse is related to a small increase in peak oxygen uptake with relatively no change in peak heart rate. The significant between group differences of the change from baseline to 6 months in tidal volume indicates an improvement in ventilatory function. This change is not maintained to 12 months. The decrease over the study period in minute ventilation in the whole group could be related to anxiety levels with study participants becoming more comfortable with the exercise testing procedures and personnel over the study period.

In general improvements in all outcome measures of physical activity in the experimental group. compared to controls, demonstrate that exercise consultation was more effective for promoting and maintaining physical activity in people with Type 2 diabetes than a standard exercise information leaflet.

CHAPTER SEVEN

STUDY TWO

EFFECT OF EXERCISE CONSULTATION ON PHYSIOLOGICAL, BIOCHEMICAL AND QUALITY OF LIFE OUTCOMES

RESULTS

Secondary outcomes

Physiological outcomes

A two-way analysis of variance (time x group) with repeated measures (time) was conducted to assess differences between the groups in BMI over the study period. A total of 27 experimental participants and 28 control participants had complete data sets for BMI. There was no significant main effect of time ($F_{2,53} = 1.6$, p=0.2), group ($F_{1,53} = 0.05$, p=0.8) or the interaction of time and group ($F_{2,53} = 1.5$, p=0.2). There was no significant differences between the experimental and control group for the change in BMI from baseline to 6 or 12 months (95%CI 6M –1.7,0.3, 12M –1.9,0.1). This analysis was repeated on an intention to treat basis. The same values of significance were obtained suggesting no significant response bias caused by study drop out. Changes in body weight were categorised into an increase, no change, decrease and decrease equivalent to greater than or equal to 5kg or 5% of body weight. Chi-square analyses demonstrated no significant between groups differences for the number of participants achieving this reduction (6M χ^2=0.21, df=2, p=0.9, 12Mχ^2=0.19, df=3, p=0.9). There were no significant between group differences at baseline, 6 or 12 months for the number of participants on Orlisat (weight loss medication) (baseline χ^2=1.9, df=1, p=0.16, 6M χ^2=1.9, df=1, p=0.16, 12M χ^2=0.26, df=1, p=0.60).

A total of 28 experimental participants and 27 control participants had complete data sets for blood pressure. Two-way analyses of variance (time x group) with repeated measures (time) revealed no significant main effect of time ($F_{2,53} = 0.3$, p=0.7), group ($F_{1,53} = 0.9$, p=0.3) or the interaction of time and group ($F_{2,53} = 2.7$, p=0.08) for changes in blood pressure. The difference between the experimental and control group for the change in systolic and diastolic blood pressure from baseline to 6 and 12 months however revealed a significant between group

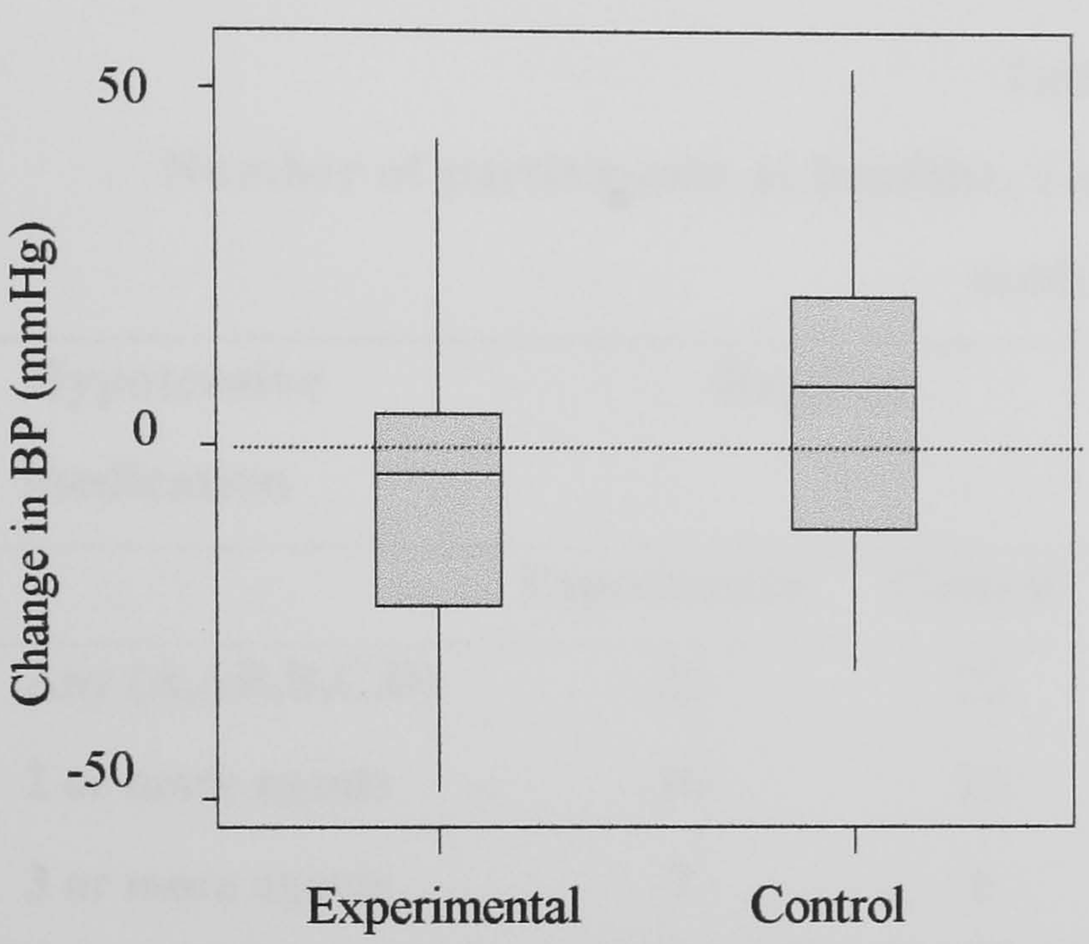
difference for the change in systolic blood pressure from baseline to 6 months (95%CI –24.7,-2.0mmHg). No significant differences were recorded for the between groups difference of the change in diastolic blood pressure from baseline at 6 or 12 months (95%CI 6M –9.8,1.7, 12M –15.2,1.4mmHg) or the change in systolic blood pressure from baseline to 12 months (95%CI –24.7,0.1mmHg). Figure 14 illustrates these changes in blood pressure from baseline at 6 and 12 months by group. This analysis was repeated on an intention to treat basis. The same values of significance were obtained suggesting no significant response bias caused by study drop out. Blood pressure was also categorised at baseline, 6 and 12 months into meeting the current SIGN guidelines of below 140/80 or not[90]. Chi square analyses revealed a greater number of experimental participants were meeting this guideline at 6 and 12 months (6M χ^2=4.8, df=1, p=0.03, 12M χ^2=6.4, df=1, p=0.01).

Figure 14

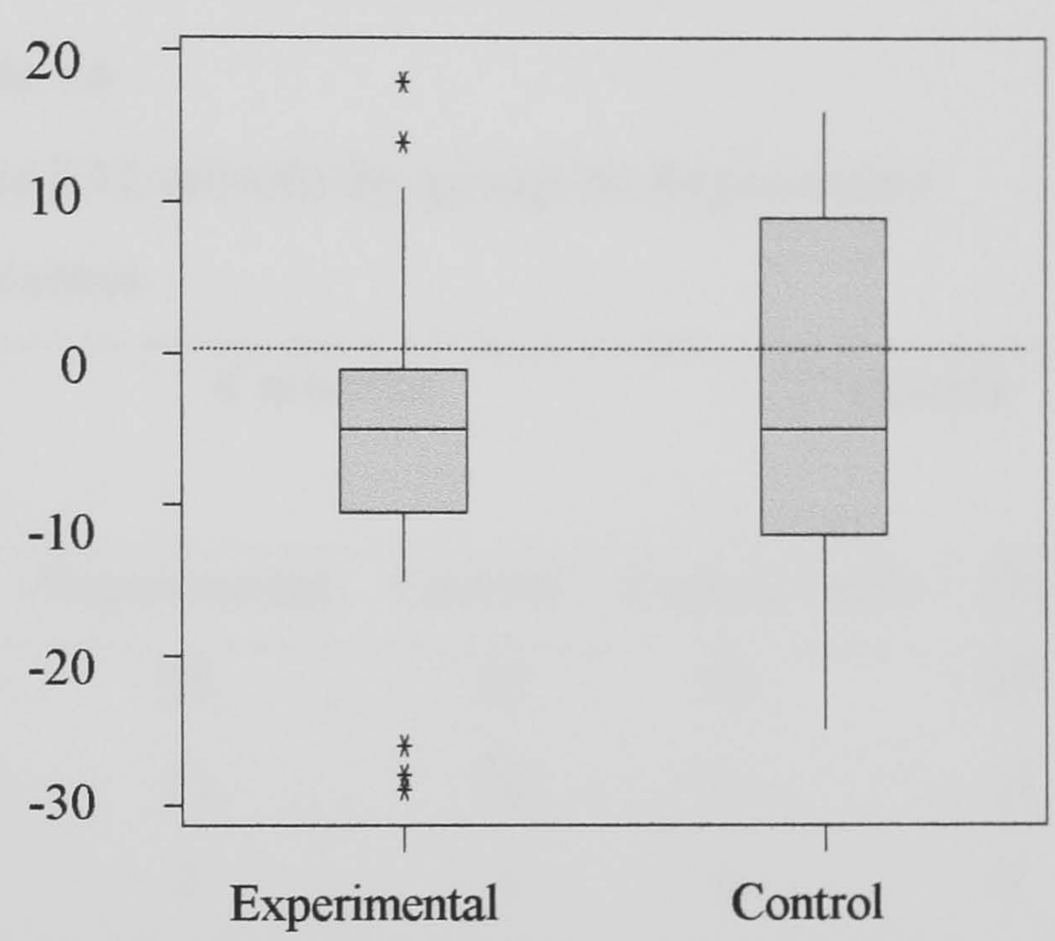
Change in blood pressure by group from baseline at 6 and 12 months

Baseline to 6 months

Systolic blood pressure

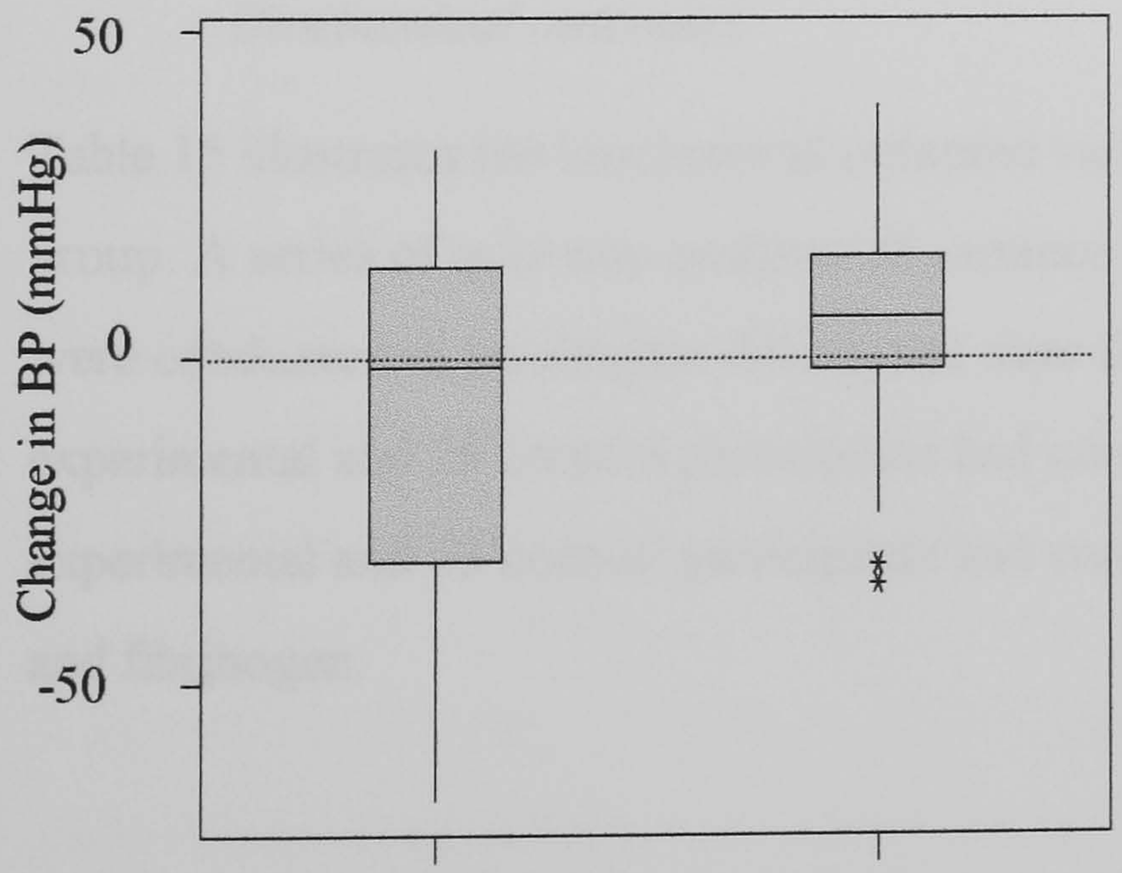


Diastolic blood pressure



Baseline to 12 months

Systolic blood pressure



Diastolic blood pressure

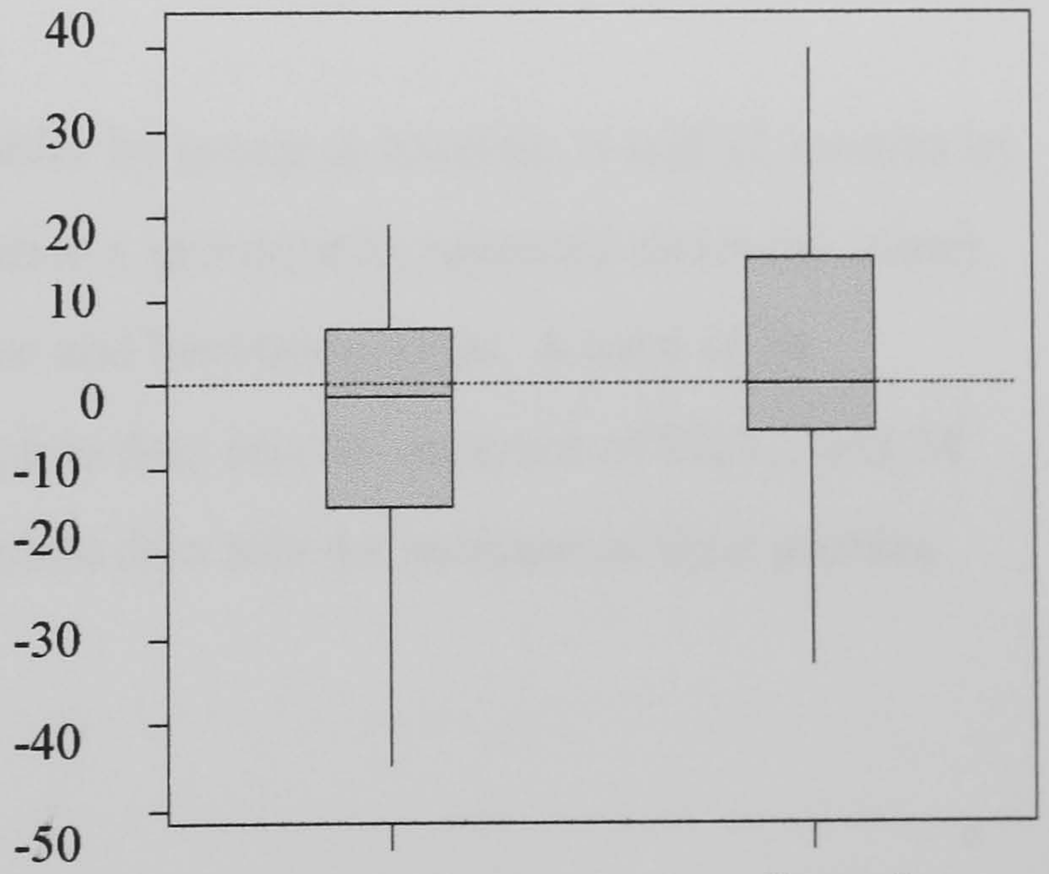


Table 14 illustrates the number of participants at baseline, 6 and 12 months by group on hypotension medication. Chi-square analyses revealed no significant between group differences at baseline ($\chi^2 = 0.06$, df=2, p=0.9) , 6 ($\chi^2 = 0.2$, df=2, p=0.9) or 12 months ($\chi^2 = 0.7$, df=2, p=0.7) in the number of participants on different levels of hypotensive medication.

Table 14

Number of participants at baseline, 6 and 12 months by group on hypotensive medication

Hypotensive medication	Baseline		6 months		12 months	
	Experimental	Control	Experimental	Control	Experimental	Control
Any (A,AB,B,C,D)	22	22	23	22	18	19
2 or more agents	10	10	13	10	9	11
3 or more agents	7	6	7	6	5	3

A = Ace inhibitor, AB = Alpha blocker, B = beta blocker, C = Ca channel blocker, D = Diuretic

Biochemical outcomes

Table 15 illustrates the biochemical outcome variables by group at baseline, 6 and 12 months by group. A series of two-way analyses of variance (time x group) with repeated measures (time) were conducted to investigate differences over time and between groups. A total of 26 experimental and 25 control participants had complete data sets for analyses of HbA_{1c} and 24 experimental and 23 control participants had complete data sets for analyses of lipid profiles and fibrinogen.

Table 15

Biochemical variables by group at baseline, 6 and 12 months

Variable	Group	Baseline	6 months	12 months
			Mean ±SD	
HbA_{1c} (%)	Experimental	8.3±1.4	8. 0±1.5	8.1±1.6
	Control	8.8±1.4	9.2±1.2	9.1±1.5
Cholesterol	Experimental	4.69±1.0	4.63±1.0	4.51±1.0
(mmol/l)	Control	4.62±0.8	4.72±0.8	4.74±0.7
HDL-C	Experimental	1.14±0.3	1.19±0.3	1.18±0.3
(mmol/l)	Control	1.11±0.3	1.14±0.3	1.15±0.3
LDL-C	Experimental	2.56±0.8	2.53±0.9	2.47±0.9
(mmol/l)	Control	2.52±0.6	2.59±0.5	2.54±0.6
Triglycerides	Experimental	1.97±1.0	2.17±1.6	2.18±1.2
(mmol/l)	Control	2.21±1.4	2.29±1.3	2.41±1.0
Fibrinogen	Experimental	310.7±73.0	307.1±69.2	318.4±71.3
(mg/dl)	Control	312.4±56.8	333.9±74.6	331.8±65.4

HbA1c = Glycosylated haemoglobin, HDL-C = High density lipoprotein-cholesterol, LDL-C = Low density lipoprotein-cholesterol, SD = standard deviation

No significant main effect of time ($F_{2,49} = 0.2$, p=0.9) or the interaction of time and group ($F_{2,49} = 2.1$, p=0.1) was recorded for HbA_{1c}, but there was a significant effect of group ($F_{1,49} = 6.6$, p=0.01). Follow-up Bonferroni multiple comparisons for repeated measures showed that the mean HbA_{1c} was significantly different between the groups at 6 and 12 months (95%CI 6M 0.49,1.9%, 12M 0.22,1.7%) This analyses was repeated on an intention to treat basis. The same values of significance were obtained suggesting no significant response bias caused by study drop out. There was a significant difference between the experimental and control group for the change in HbA_{1c} from baseline to 6 months (-1.23,-0.07%). No significant difference was found for the change from baseline to 12 months. (95%CI –1.32,0.5%).

Table 16 illustrates diabetes therapy by group at baseline, 6 and 12 months. Chi-square analyses

revealed no significant between group differences at baseline (χ^2 = 3.7, df=3, p=0.3), 6 (χ^2 = 3.6, df=3, p=0.3) or 12 months (χ^2 = 1.8, df=3, p=0.6). Changes in insulin dose were categorised into increase, no change or decrease in dose and analysed using chi-square. The results revealed no significant differences between the experimental and control group from baseline to 6 months (χ^2 = 1.7, df-2, p=0.4) and from 6 to 12 months (χ^2 = 1.4, df=2, p=0.5). Differences in mean insulin dose by group at baseline, 6 and 12 months were also analysed using two-sample t-tests. There was no significant between group differences recorded at any time point (95%CI baseline –42.9,8.4 units, 6M –31.9,22.6 units, 12M –42.5,9.1 units).

Table 16

Diabetes therapy by group at baseline, 6 and 12 months

Diabetes therapy	Baseline		6 months		12 months	
	Experimental	Control	Experimental	Control	Experimental	Control
Diet	5	2	4	2	4	2
Oral hypoglycaemic	9	5	10	5	8	6
Insulin	9	14	8	12	7	11
Combination*	12	14	9	12	9	9

* = Combination of insulin and oral hypoglycaemic diabetes therapy

No significant main effect of time, group or the interaction of time and group were recorded for total cholesterol, HDL-C, LDL,C, or triglycerides (Time TC $F_{2,45}$ = 0.2, p=0.8, HDL-C $F_{2,58}$ = 2.0, p=0.1, LDL-C $F_{2,52}$ = 2.7, p=0.08, Trigs $F_{2,45}$ = 0.89, p=0.4, Group $F_{1,45}$ = 0.1, p=0.7, HDL-C $F_{1,58}$ = 0.2, p=0.7, LDL-C $F_{1,52}$ = 0.05, p=0.8, Trigs $F_{1,45}$ = 0.35, p=0.6, Interaction TC $F_{2,45}$ = 2.2, p=0.1, HDL-C $F_{2,58}$ = 0.12, p=0.9, LDL-C $F_{2,52}$ = 0.94, p=0.4, Trigs $F_{2,45}$ = 0.1, p=09). This analysis was repeated on an intention to treat basis. The same values for significance were obtained suggesting no significant response bias caused by study drop out. The difference between the experimental and control group for the change in each variable from baseline to 6 months and baseline to 12 months was also analysed. The only significant difference recorded was the change in total cholesterol from baseline to 12 months (95%CI -0.73,-0.04mmol/L).

Analysis of fibrinogen revealed a significant main effect of time ($F_{2,57}$ = 3.7, p=0.3) and the interaction of time and group ($F_{2,57}$ = 3.0, p=0.05), but no significant main effect of group ($F_{1,57}$ = 0.69, p=0.4). Follow-up Bonferroni multiple comparisons for repeated measures showed that at 6 months the experimental and control group were significantly different (95%CI 5.09,48.50mg/dl). The difference between the experimental and control group for the change in fibrinogen was significant from baseline to 6 months (95%CI –57.2,-4.3 mg/dl) but not 12 months (95%CI –40.4,8.7 mg/dl). This analysis was repeated on an intention to treat basis. The same values of significance were obtained suggesting no significant response bias was caused by drop out from the study.

The number of participants at baseline, 6 and 12 months with evidence of microalbuminuria (albumin excretion rate of 20 to 300mg/24 hours) measured by a 24 hour urine test is illustrated in Table 17. A total of 19 experimental and 17 control participants had complete data sets for analyses of microalbuminuria.

Table 17

Number of participants at baseline, 6 and 12 months, by group with evidence of microalbuminuria

	Baseline		6 months		12 months	
	Experimental	Control	Experimental	Control	Experimental	Control
Microalbuminuria	5	9	2	6	2	5
Normoalbuminuria	21	19	17	15	14	13

Microalbuminuira = albumin excretion ratio of 20 – 300mg/24hours, Normoalbuminuria = albumin excretion ratio of <20mg/24hours

Chi-square analyses revealed no significant between group differences for the number of people with evidence of microalbuminuria at baseline (χ^2 = 1.2, df=1, p=0.3), 6 (χ^2 = 2.0, df=1, p=0.2), or 12 months (χ^2 = 1.2, df=1, p=0.3).

Table 18 illustrated the number of participants, by group, at baseline, 6 and 12 months on cardiovascular medication. Chi-square analyses revealed no significant between groups differences at baseline, 6 or 12 months.

Tables 18

Number of participants, by group, at baseline, 6 and 12 months on cardiovascular medication.

Drug	Baseline		6 months		12 months	
	Experimental	Control	Experimental	Control	Experimental	Control
Betablocker	8	7	8	6	7	6
Aceinhibitor	15	17	17	16	14	15
Ca Channel Blocker	9	8	6	3	3	4
Alpha blocker	5	3	5	2	4	1
Diuretic	10	6	10	7	8	8
Statin	15	14	18	11	17	11
Asprin	15	19	18	20	19	16
Anticoagulent	0	0	0	0	1	0
Nitrate	2	4	3	5	3	1

Ca = calcium

Quality of life outcomes

In addition to group comparisons change in quality of life and well-being scores were also compared using effect size statistics. Cohen[306] defined an effect size of 0.2 as small, one of 0.5 as moderate and one of 0.80 or greater as large.

Table 19 shows the Short-form-36 sub-scale scores and effect size by group at baseline, 6 and 12 months. A total of 27 experimental and 27 control participants had complete data sets for analyses of the Short-form-36 health survey.

Table 19

Short-form-36 sub-scale percentage scores and effect size by group at baseline, 6 and 12 months

Scale	Group	Baseline mean ± SD	6 month mean± SD	12 month mean ± SD	Effect size B-6M	Effects size B-12M
Physical functioning	Experimental	58.0 ± 30.3	66.2 ± 25.0	68.0 ± 24.3	-0.27	-0.33
	Control	69.8 ± 24.2	64.9 ± 24.6	59.8 ± 22.3	0.20	0.41
Role physical	Experimental	67.7 ± 32.4	72.3 ± 21.1	75.9 ± 20.6	-0.14	-0.26
	Control	80.5 ± 25.1	70.3 ± 30.2	71.5 ± 28.8	0.41	0.35
Role mental	Experimental	83.1 ± 27.1	80.2 ± 29.2	84.9 ± 21.1	0.11	-0.07
	Control	83.1 ± 23.3	73.6 ± 29.8	80.7 ± 25.8	0.41	0.10
Social functioning	Experimental	72.2 ± 29.4	79.8 ± 21.4	81.4 ± 27.2	-0.26	-0.31
	Control	85.0±20.5	76.4 ± 26.3	74.6 ± 25.6	0.42	0.51
Mental health	Experimental	71.1 ± 17.7	77.0 ± 20.4	77.3 ± 20.5	-0.33	-0.35
	Control	73.3 ± 18.2	75.1 ± 17.6	74.7 ± 16.6	-0.10	-0.08
Energy	Experimental	50.0 ± 20.8	56.1 ± 17.5	57.1 ± 20.8	-0.29	-0.34
	Control	58.0 ± 19.0	59.4 ± 19.5	57.2 ± 17.4	-0.07	0.04
Pain	Experimental	65.2 ± 28.3	68.6 ± 21.6	64.6 ± 25.3	-0.12	0.02
	Control	73.3 ± 23.0	70.4 ± 26.3	67.8 ± 25.5	0.13	0.24
Health perception	Experimental	48.5 ± 19.2	50.5 ± 21.5	55.3 ± 21.8	-0.10	-0.35
	Control	57.6 ± 15.4	57.1 ± 20.3	53.0 ± 17.7	0.03	0.30

SD = standard deviation, B-6M = baseline to 6 months, B-12M = baseline to 12 months

By Cohen's definition the magnitude of the effect size for the change from baseline to 6 months and baseline to 12 months on most sub-scales for both the experimental and control group was small to moderate. In the control group from baseline to 6 months six out of eight of the sub-scale scores show small to moderate decreases, indicating poorer quality of life. In comparison in the experimental group seven out of eight sub-scale scores show small to moderate increases, indicating better quality of life. This pattern is similar for the effects sizes calculated from baseline to 12 months.

In view of the skewed distribution of the SF-36 scores it is recommended that median values are used for data analyses [307]. Changes in SF-36 scores were analysed using Mann-Whitney test for between group analyses and Wilcoxon Signed Rank tests for within group analyses. A significant between group difference was recorded at 6 months in the sub-scale measuring limitations in usual role activities due to emotional health problems (98%CI 0.01,24.99%). The between group difference of the change in physical functioning was also significant (98%CI 5.00,30.00%).

The SF-36 also contains one health transition item, "compared to 3 months ago, how would you rate your health in general now?" The responses to this question by group are shown in Table 20. Fishers exact tests revealed the number of participants in each response category to be similar at baseline and 12 months, but significantly different at 6 months. (Baseline $\chi^2 = 1.02$, df=4, p=0.91, 6M $\chi^2 = 9.92$, df=4, p=0.04, 12M $\chi^2 = 4.84$, df=4, p=0.18).

Tables 20

Participant response to change in health sub-scale on the SF-36 questionnaire at baseline, 6 and 12 months by group.

Response	Group	Baseline %	6 months %	12 months %
Much worse	Experimental	3 (1/35)	0 (0/31)	0 (0/28)
	Control	0 (0/35)	0 (0/30)	0 (0/28)
Somewhat worse	Experimental	6 (2/35)	13 (4/31)	7 (2/28)
	Control	6 (2/35)	14 (4/30)	11 (3/28)
About the same	Experimental	80 (28/35)	58 (18/31)	61 (17/28)
	Control	83 (29/35)	80 (24/30)	78 (22/28)
Somewhat better	Experimental	8 (3/35)	29 (9/31)	21 (6/28)
	Control	8 (3/35)	3 (1/30)	11 (3/28)
Much better	Experimental	3 (1/35)	0 (0/31)	11 (3/28)
	Control	3 (1/35)	3 (1/30)	0 (0/28)

Table 21 shows the Well-being questionnaire scores and effect size by group at baseline, 6 and 12 months. A total of 28 experimental and 27 control participants had complete data sets for analyses of the well-being questionnaire. In comparison to Cohen's definitions the magnitude of the effect size for the change in well-being scores from baseline to 6 and 12 months for all sub-scales in both groups is small. In the experimental group changes from baseline to 6 and 12 months on all four sub-scales and the total well-being score indicate an increase in well-being. In comparison, in the control group changes from baseline to 6 and 12 months on three sub-scales and the total wellbeing score indicate a decrease in well-being.

Table 21

Well-being questionnaire scores and effect size by group at baseline, 6 and 12 months.

Scale	Group	Baseline mean± SD	6 month mean ± SD	12 month mean ± SD	Effect size B-6M	Effect size B-12M
Depression	Experimental	4.3 ± 3.0	4.0 ± 3.0	3.8 ± 3.1	0.10	0.17
	Control	3.5 ± 3.1	3.9 ± 3.6	4.3 ± 3.4	-0.13	-0.26
Anxiety	Experimental	5.1 ± 3.5	4.7 ± 3.4	4.3 3.3	0.11	0.23
	Control	4.7 ± 3.2	4.7 ± 4.0	5.4 ± 3.5	0	-0.22
Energy	Experimental	6.7 ± 3.3	6.9 ± 2.5	7.3 ± 2.6	-0.06	-0.18
	Control	6.9 ± 2.3	6.5 ± 3.5	7.3 ± 2.6	0.17	-0.17
Well-being	Experimental	12.2 ± 3.6	12.5 ± 3.1	12.5 ± 3.1	-0.08	-0.08
	Control	13.1 ± 3.6	12.1 ± 4.5	11.8 ± 4.3	0.28	0.36
Total	Experimental	45.8 ± 10.8	46.8 ± 10.1	47.6 ± 9.7	-0.09	-0.17
	Control	47.8 ± 10.5	46.3 ± 13.6	47.1 ± 10.3	0.14	0.07

SD = standard deviation, B-6M = baseline to 6 months, B-12M = baseline to 12 months

This data was also analysed using repeated measures analyses for multiple variables (MANOVA). No significant main effect of time, group or the interaction of time and group were found for any wellbeing score (Time depression $F_{1,53}$=1.1,p=0.4, anxiety $F_{1,53}$=1.6,p=0.2,energy $F_{1,53}$=1.1, p=0.4, positive well-being $F_{1,53}$=0.7, p=0.5, total well-being $F_{1,53}$=0.7, p=0.5, Group, depression $F_{2,53}$=2.1,p=0.1, anxiety $F_{2,53}$=0.2, p=0.7,energy $F_{2,53}$=0.6,

p=0.4, positive well-being $F_{2,53}$=0.4, p=0.5, total well-being $F_{2,53}$=2.3, p=0.1, Interaction depression $F_{1,53}$=1.1, p=0.4, anxiety $F_{1,53}$=2.2, p=0.1,energy $F_{1,53}$=0.02, p=0.9, positive well-being 1.2, p=0.3, total well-being $F_{1,53}$=0.4, p=0.7).

The difference between the groups for the change from baseline to 6 months and baseline to 12 months in Well-being scores was also analysed using two sample t-tests. The only significant between groups difference recorded was for the change in anxiety from baseline to 12 months (98%CI –2.37,0.14). The experimental groups recorded small decrease in anxiety (98%CI –2.16,0.31), in comparison the control group recorded a small increase (98%CI –0.99,1.53).

DISCUSSION

Secondary outcomes measures

Physiological outcomes

Although no significant between or within group changes were recorded in BMI over the study period, changes recorded were in the expected direction. The experimental group recorded relatively small decreases over the 12 month study period (baseline to 6 months –0.04kg/m^2, baseline to 12 months 0.01kg/m^2) and the control group recorded moderate increases (baseline to 6 months 0.67kg/m^2, baseline to 12 months 0.91kg/m^2). These changes occurred despite no significant between or within group changes in weight loss medication (Orlisat). No significant between groups differences were recorded for the number of people achieving a greater than or equal to five kilogramme weight loss or 5% reduction in body weight. The majority of studies reporting improvements in BMI and body weight in people with Type 2 diabetes have combined diet and physical activity. In addition most of these studies evaluate the effect of the intervention over a short period (up to 3 months). The lack of significant change in BMI in this study could be a result of the longer follow-up or lack of combined dietary intervention. The lack of significant change in BMI is consistent with the findings of a meta-analysis conducted in 2001[25] that investigated the effect of exercise on BMI in people with Type 2 diabetes. The meta-analysis showed no significant greater change in BMI when exercise conditions were compared to control conditions. Project Active[39], a 2 year randomised controlled trial, compared the effectiveness of a structured exercise intervention to a physical activity

counselling intervention in the general population. The only significant change recorded in body weight was a decrease in the structured exercise group from baseline to 6 months. No significant changes were recorded from baseline at 6 or 24 months in the physical activity counselling group.

There was a significant between group difference for the change in systolic blood pressure at 6 months. The experimental group recorded a decrease of 7.7mmHg, the control group recorded an increase of 5.6mmHg. Similar changes were recorded for the change in systolic blood pressure from baseline to 12 months (experimental – 8.2mmHg, control + 4.14mmHg), although these changes failed to reach significance. Although no significant changes in diastolic blood pressure were recorded, the changes were generally in the expected direction. The experimental group recorded small decreases (baseline to 6 month –5.6mmHg, baseline to 12 months –4.5mmHg), the control group recorded little change (baseline to 6 month –1.5mmHg, baseline to 12 months +2.5mmHg). These changes occurred despite no significant changes in anti-hypertensive medication.

A recent systematic review [100] concluded there was good evidence that regular, moderate physical activity reduces blood pressure in the general population. This review also highlighted baseline blood pressure to be an important determinant of blood pressure response to physical activity. A more pronounced effect being shown in people with existing hypertension than in people with normal blood pressure. This could suggest that people with Type 2 diabetes, a population with a high prevalence of hypertension, could gain significant reductions in blood pressure in response to regular moderate physical activity. Only a small number of studies have investigated the effect of regular physical activity on blood pressure in people with Type 2 diabetes. Lehmann et al[63] reported significant reductions in systolic (138±16 to 128±15mmHg) and diastolic blood pressure (88±10 to 77±6mmHg) after a 3 month moderate intensity aerobic exercise program in people with Type 2 diabetes. These improvements are slightly better than those recorded in this study. This difference could be due to the shorter follow-up, the supervised nature of the physical activity intervention or the type of activity undertaken. The type of activity included in the study by Lehmann et al[63] was mostly structured, continuous moderate exercise. In comparison in this study the activity undertaken varied and in a number of cases involved unstructured, accumulated physical activity.

A reduction in blood pressure is particularly important in people with Type 2 diabetes. The UKPDS[9] demonstrated tight blood pressure control in people with hypertension and Type 2 diabetes significantly reduces the development and progression of diabetic complications and risk of death related to diabetes. A target blood pressure of below 140/80 is currently recommended by SIGN[90] for people with Type 2 diabetes. In this study a significantly greater number of experimental participants was meeting this guideline at 6 and 12 months. In the UKPDS study a large number of people required three or more hypotensive agents to control blood pressure. The degree of reduction in blood pressure in this study, if maintained long term, may allow tight blood pressure control with a smaller number of hypotensive agents.

Biochemical outcomes

Analyses of changes in glycaemic control showed a significant between group difference at 6 and 12 months. The experimental group recorded a mean decrease in HbA_{1c} of 0.26% and 0.27% from baseline to 6 and 12 months respectively, indicating an improvement in glycaemic control. The control group recorded a mean increase in HbA_{1c} of 0.15% and 0.34% from baseline to 6 and 12 months respectively, indicating a deterioration in glycaemic control. These changes occurred despite no significant between group changes in diabetes therapy. These improvements in HbA_{1c} are consistent with the findings of a meta-analysis conducted by Boule in 2001[25]. The meta-analysis reviewed studies investigating the effect of exercise on HbA_{1c} in people with Type 2 diabetes and demonstrated an overall mean difference in HbA_{1c} of 0.66% between exercise and control conditions.

The difference between the control and experimental group in HbA_{1c} in this study is clinically significant[25] and is close to the difference between conventional and intensive glucose lowering therapy in the UKPDS[8]. In the UKPDS[8] this difference was related to a significant reduction in the development and progression of diabetes complications. It should be noted that in the UKPDS this difference was maintained for a median of 10 years.

The only significant difference in lipid profile recorded in this study was a significant between group difference of the change in total cholesterol from baseline to 12 months. Throughout the study no changes were recorded in triglycerides in either group with small changes in total cholesterol, LDL-C and HDL-C. In the experimental group from baseline to 12 months total cholesterol decrease by 7% (4.87 to 4.55mmol/L), LDL-C by 4% (2.56 to 2.47mmol/L) and

HDL-C increased by 5% (1.14 to 1.20mmol/L). In comparison the control group recorded no changes (TC 4.74 to 4.78mmol/L, LDL 2.52 to 2.54mmol/L, HDL-C 1.11 to 1.11mmol/L). A number of studies have reported changes in lipid profile after exercise in people with Type 2 diabetes[63,64,70,69]. Studies that show the greatest improvements tend to use moderate to high intensity structured exercise programmes[64,63] or incorporate an intervention that combines diet and physical activity[75,69,68]. Furthermore the majority of studies incorporate only a short-term follow-up (up to 3 months). Studies including a longer follow-up in general show little improvement in lipid profile. Skafors et al[74] reported no significant changes in lipid profile after a 2 year supervised moderate to vigorous aerobic exercise programme.

From previous research the most common observed lipid change in response to exercise in people with Type 2 diabetes appears to be a significant decrease in triglycerides. Lehmann et al[63] demonstrated a 20% reduction in triglycerides (2.81 to 2.24mmol/L) after a 3 month moderate intensity aerobic exercise programme. Lehmann et al[63] reported a baseline level for triglycerides of 2.81mmol/L. This is much higher than the baseline level recorded in this study (2.1mmol/L). The mean baseline level of most lipids recorded in this study met the current targets recommended by SIGN[90] and this could explain the relatively small changes recorded.

At 6 and 12 months more experimental participants, than controls were on a statin. Although this difference is not statistically significant it cannot be overlooked as a potential reason for the greater improvements in lipid profile recorded in the experimental group in this study.

Limited research has investigated the effect of regular physical activity on plasma fibrinogen in people with Type 2 diabetes. Results from previous research are inconsistent. Schneider and colleagues[127] observed no significant changes in fibrinogen after 6 weeks of moderate to high intensity aerobic exercise. In comparison Hornsby et al[130] demonstrated significant reductions in fibrinogen after 12 to 14 weeks of similar exercise. In this study a significant between group difference was recorded in fibrinogen at 6 months. From baseline to 6 months the experimental group recorded a mean 5mg/dl decrease and the control group recorded a 25.8mg/dl increase. This significant difference recorded at 6 months was not maintained at 12 months follow-up. From baseline to 12 months follow-up the experimental and control group recorded an increase of 10.7mg/dl and 26.6mg/dl respectively. It is difficult to compare the results of this study to previous research. None of the previous studies in people with Type 2 diabetes include a true control group and in the present study the significant difference recorded at 6 months is largely

the result of an increase in fibrinogen in the control group.

Albuminuria excretion rate increases during and immediately after acute exercise and this is associated with the rise in systolic blood pressure during physical activity and exercise[161]. There is currently no evidence suggesting this acute effect of physical activity and exercise leads to renal impairment in the long term. In people with Type 2 diabetes the presence of microalbuminuria is associated with increased cardiovascular disease and all cause mortality[308]

In an observation study Calle-Pascual et al[162] demonstrated higher levels of physical activity to be related to a higher prevalence of normoalbuminuria. In this study there was no significant difference at baseline, 6 or 12 months for the number of participants with evidence of microalbuminuria, defined as an albumin excretion rate of 20 to 300mg/24hours.

Quality of life outcomes

The SF-36 version 2 health survey and Well-being questionnaire were used in this study to measure quality of life. Over the 12 months study period small changes in quality of life were recorded. Jenkinson et al[276] reported normative data for the SF-36 version 2 health survey in the United Kingdom. This data was generated from a large scale survey, the Third Oxford Health and Lifestyles survey. Normative data is provided separately for those people reporting a long-standing illness. Table 22 shows a comparison of the median SF-36 version 2 scores from this study with the normative mean SF-36 version 2 scores for the general population and people reporting long standing illness. In comparison to the normative data for people reporting long standing illness six out of eight of the scores from this study are higher. In particular for sub-scales measuring social functioning, role limitations due to emotional problems and mental health which are also higher than the normative data for the general population. Similar high quality of life scores on the SF-36 were recorded in the pilot study for this research, which evaluated the effectiveness of the exercise consultation over 5 weeks[29]. This ceiling effect could explain the lack of significant change recorded in both the present study and in the pilot study evaluating the effectiveness of exercise consultation in people with Type 2 diabetes at 5 weeks.

Table 22

Comparison of study SF-36 scores with reported normative SF-36 scores for the general populations and people with long-standing illness.

Scale	General population	Longstanding illness	Study sample
	Mean ± SD		Median IQ range
Physical functioning	88.0±19.7	79.4±24.3	70.0 (45.0,85.0)
Social functioning	82.8±23.2	75.1±26.9	93.4 (59.4,100.0)
Role – physical	87.2±22.0	77.6±27.7	87.3 (50.0,100.0)
Role – mental	85.8±21.2	80.4±25.1	100 (75.0,100.0)
Mental health	71.9±18.2	67.3±19.7	75.0 (55.0,90.0)
Energy/vitality	58.0±19.6	51.2±20.7	56.0 (44.0,64.5)
Pain	78.8±23.0	67.1±25.6	72.4 (52.6,89.0)
General health	71.1±20.4	60.8±22.0	57.0 (40.0,65.0)

SD = standard deviation, IQ = interquartile range

On the SF-36 questionnaire a significant between group difference was recorded for the change from baseline to 12 months in the sub-scale measuring physical functioning. Interestingly the baseline values recorded for this sub-scale are below both normative values for the general population and people reporting a long standing illness. From baseline to 6 months a greater number of experimental participants reported an improvement in health. Although only a few changes were recorded in the SF-36 questionnaire, the changes recorded were in the expected direction. In general in the experimental group small to moderate positive changes from baseline to 6 and 12 months were recorded. In comparison in the control group small to moderate negative changes were recorded. The lack of significant changes could be related to the high quality of life scores recorded at baseline.

Comparison of changes in quality of life in this study with previous studies is difficult. Different questionnaires are used and only a small number of studies have examined the effect of physical activity on quality of life in people with Type 2 diabetes. Tessier et al[136] reported no significant changes in quality of life, measured by a modified version of the Diabetes Quality of Life

Questionnaire, after a 16 week progressive aerobic and resistance training programme in older (>65yrs) people with Type 2 diabetes. In comparison Lightenberg et al[30] recorded significant improvements in quality of life in 51 elderly (mean age 64.2yrs) people with Type 2 diabetes after an intensive 6 week supervised exercise programme. This study used the same Well-being questionnaire used in the present study. Baseline values for each sub-scale were similar for both studies. At 6 weeks follow-up Lightenberg et al[30] recorded significant improvements in the experimental group for total wellbeing, anxiety, positive well-being and energy. In comparison in this study the only significant change recorded was a significant between group difference of the change from baseline to 12 months in anxiety levels. Lightenberg et al[30] however reported that Well-being scores had returned to baseline in a follow-up conducted 14 weeks after the supervised exercise had stopped. The pilot study for this research[29], evaluating the effectiveness of the exercise consultation at 5 weeks examined changes in quality of life using the SF-36 and Well-being questionnaire. Similar baseline values were recorded for both questionnaires. In the pilot study the only significant changes recorded were a significant change in the experimental group in SF-36 sub-scales measuring energy and mental health.

CHAPTER EIGHT

SUMMARY AND CONCLUSIONS, IMPLEMENTATION, LIMITATIONS AND FUTURE RESEARCH

Summary and conclusions

Extensive evidence demonstrates the benefits of physical activity for the management of Type 2 diabetes[76]. Unfortunately the majority of people with Type 2 diabetes do not do enough physical activity to achieve these benefits[33]. To date research that addresses how to promote physical activity to people with Type 2 diabetes has been limited. Exercise consultation[194] holds many advantages as an intervention for promoting physical activity in people with Type 2 diabetes. It provides an individualised physical activity plan tailored to motivational and personal characteristics. Cognitive behavioural strategies are developed and education provided to improve long term adherence to physical activity behaviour change. Furthermore the exercise consultation is a relatively minimal intervention that could realistically be incorporated into current diabetes care. Exercise consultation has shown to be successful for promoting and maintaining physical activity behaviour change in the general population over periods up to 2 years[201,39]. Pilot research has shown this intervention to be effective for increasing physical activity over the short term (up to 5 weeks) in people with Type 2 diabetes[29]. The research in this thesis evaluates the effectiveness of the exercise consultation for promoting and maintaining physical activity over the longer term (1 year). The resultant effects of this intervention on physiological, biochemical and quality of life variables are also assessed.

The results of this research demonstrate that the exercise consultation intervention was more effective for promoting and maintaining physical activity behaviour change than a standard exercise information leaflet in people with Type 2 diabetes. The intervention also had a favourable effect on several physiological, biochemical and quality of life variables. The results from a number of primary and secondary outcome measures demonstrated standard care to be associated with a deterioration. These results provide a strong evidence base for incorporating exercise consultation as an innovative addition to current diabetes care.

Limitations of study

Limitations of this research are generally related to time constraints of doctorate study. The exercise consultation was only evaluated over a 12 month period. Further research is required to determine the longer term effectiveness of this intervention in people with Type 2 diabetes. 70 people were recruited in to this study. As only a small number of participants dropped out of the study adequate power was achieved to detect true changes in most variables. Unfortunately there was insufficient power to investigate any gender differences. In the Activity Counselling Trial, a randomised controlled trial evaluating the effectiveness of physical activity counselling compared to advice only in the general population, gender differences were recorded. For women the physical activity counselling group recorded significantly higher values for cardiorespiratory fitness compared to the advice only group at 24 months. In men no significant differences were recorded. In the present study there was no indication of any gender differences however a larger sample size would be required to investigate this fully.
All procedure of this research, including randomisation, conducting interventions and evaluating outcomes measures, were conducted by the same researcher. It was therefore not possible for the researcher to be blinded to group allocation. In an attempt to control any influence of knowing group allocation standard procedure manuals for collecting outcome measures were developed. During the exercise tests the Cardiac Clinical Scientific Officer, who was blinded to group allocation, was responsible for giving the participant encouragement. Furthermore as most participants came from the same community it is possible that interventions were discussed and compared. Unfortunately there is no way of controlling for this in a free living sample.

Exercise consultation: Implementation into practice

The results of this study demonstrate exercise consultation to be effective intervention for promoting and maintaining physical activity behaviour change in people with Type 2 diabetes. Consideration needs to be given to how this intervention can be implemented into practice. The exercise consultation is a minimal intervention that could realistically be incorporated into current diabetes care. It is a relatively inexpensive intervention in terms of time, resources and personnel. Initial consultations take around 30 minutes to deliver and follow-up interventions

tend to be shorter. Asking people to complete some of the tasks before the consultation i.e. physical activity habits, decision balance table could reduce this time. The only resources required are the materials for the exercise consultation and a quite room in which to conduct the consultation. The exercise consultation could potentially be conducted by a number of people. An ideal candidate would be an exercise specialist with skills in cognitive behavioural counselling. This individual would require additional training in diabetes care. Any member of the multidisciplinary diabetes care team could also be trained to conduct exercise consultations. These individuals are likely to have some training in cognitive behavioural counselling, although additional training in physical activity and exercise would be required. In 2002 the Greater Glasgow Health Board and NHS Argyll and Clyde developed a training resource targeted at people whose work could affect physical activity[309]. The training resource includes sections on supporting behaviour change, considerations for special groups and health effects of physical activity. This would be an ideal resource for training individuals to conduct exercise consultations in clinical settings. Exercise consultations could potentially be delivered in other ways such as by post, telephone or computerised. Additional research would be required to determine if these methods of delivery are as effective as a personal approach.

Future research

In reviewing current literature on physical activity and exercise in people with Type 2 diabetes a number of important future areas of research were identified. Studies investigating the acute effect of physical activity and exercise on glucose concentration in people with Type 2 diabetes have generally been restricted to small groups of people controlled by diet or oral hypoglycaemic agents. Further research with larger more diverse populations, including ethnic minority groups, are required to fully understand the effects of acute physical activity and exercise in people with Type 2 diabetes. The improvement in glycaemic control with regular, frequent physical activity and exercise over periods up to 6 months are only slightly less that the improvements with intensive glucose lowering therapy in the UKPDS[8], which led to significant reductions in the development and progression of microvascular complications over 15 years. The question of what the long term effects of regular physical activity and exercise on

microvascular complications remains unanswered and this is an important area for future research

Improvements in blood pressure are particularly important for people with Type 2 diabetes[9]. There is good evidence that regular, frequent physical activity and exercise can improve blood pressure in the general population. More research is required in people with Type 2 diabetes. A number of studies report improvements in cardiovascular risk factors after regular, frequent physical activity and exercise in people with Type 2 diabetes[76]. In addition in observational research an inverse association has been established between increased physical activity and cardiorespiratory fitness and decreased cardiovascular disease and all-cause mortality[85-87]. A long-term study is required to determine the effects of regular, frequent physical activity and exercise on cardiovascular disease and all-cause mortality in people with Type 2 diabetes. The ongoing Look AHEAD study[310] being conducted in the United States will shed some light on this issue. This is a multicentre randomised controlled trial comparing the effectiveness of a lifestyle behaviour change intervention with standard diabetes support and education for promoting weight loss and maintenance. The resultant effects on cardiovascular and all-cause mortality will be assessed. The study aims to enrol 5,000 people with Type 2 diabetes over a 2.5 year period starting in June 2001. Participants will be followed up for a total period of up to 11.5 years.

Limited research is available describing how to promote physical activity to people with Type 2 diabetes. Further research is required with more diverse populations including ethnic minority groups. The success of the intervention used in this study provides the foundations for additional research with this intervention. A number of questions need to be answered: Can exercise consultation in people with Type 2 diabetes maintain physical activity behaviour change for longer than 12 months? Are continuous exercise consultations required? Is a personal approach to the exercise consultation required, or could this intervention be delivered successfully by post, telephone or World Wide Web?

The most effective time to deliver the exercise consultation should also be investigated. Should it be delivered at diagnosis of Type 2 diabetes or would this result in information overload? Furthermore are there any other strategies that could be added to the exercise consultation to make it more effective? Pedometers are possible additional strategies that have recently been introduced as motivational tools into physical activity and weight management programmes.

The increased frequency of relapse from physical activity behaviour change in people with Type 2 diabetes needs to be investigated further. Does this occur throughout all stages of exercise behaviour change and can it be associated with changes in the progression of Type 2 diabetes such as moving to insulin or developing complications. Finally this study targeted individuals in a contemplation and preparation stage of exercise behaviour change. Future research needs to identify ways to target people in other stages of exercise behaviour change.

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LREC 01/00

1st February 2000

Dr Paul MacIntyre
Consultant Physician and Cardiologist
Argyll and Clyde Acute Hospitals NHS Trust
Royal Alexandra Hospital
Corsebar Road
PAISLEY
PA2 9PN

Dear Dr MacIntyre

VALIDATION OF AN ACCELEROMETER TO ESTIMATE EXERCISE INTENSITY DURING VARIOUS WALKING SPEEDS AND ACTIVITIES OF DAILY LIVING IN A GROUP OF PEOPLE WITH TYPE 2 DIABETES

Thank you for complying with the conditions set out in my last letter dated 21st January 2000.

I confirm that there is no objection on ethical grounds to the proposed study and I write to give you approval to proceed on the understanding that:-

a. All patients recruited to the study will be interviewed by the Clinician responsible for the conduct of the trial or a member of the Clinical Team who will obtain consent. This will not be delegated to an external agency.

b. You will notify the Medical Director of any hospital whose facilities you may use during the conduct of the study.

c. You submit a progress report to this Committee one year from the date of this letter.

In reaching the decision, the following documents were reviewed:-

Protocol
LREC Application Form
Patient Information Sheet/Consent Form
GP Letter
C.V.

A list of Committee members present at meeting held on 19th January 2000 is appended.

Yours sincerely

J.J. Morrice F.R.C.S.
Chairman

ARGYLL & CLYDE HEALTH BOARD

ETHICS COMMITTEE

FORM OF INFORMATION AND CONSENT FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Brief Title of Protocol

Monitoring exercise intensity during various walking speeds and daily living activities in a group of Type 2 diabetes patients.

Patient's Summary

We invited you to take part in a study to monitor exercise intensity during various walking speeds and daily living activities in a group of Type 2 diabetes patients.

If you agree to take part, you will be asked to visit the RAH on 2 separate occasions. You will remain on your normal medication throughout the duration of the study.

Visit 1: Total Duration 45 minutes

During this visit your height and weight will be measured. We will then assess your exercise performance by asking you to walk on a treadmill and measuring the amount of oxygen that you use. During the exercise test, we will monitor your heart rate using an ECG and measure your blood pressure using an inflation cuff. In addition, we will ask you to wear a lightweight monitor (about the size of a videotape) which will be secured to your chest using an elastic strap. You will be breathing through a mask, which will cover your nose and mouth. The monitor and mask will allow us to measure your breathing during the test. You will be asked to keep exercising until you can no longer continue. You will be able to stop the test at any time if you experience any ill effects. The supervising doctor will stop the test if you develop chest pain or you have any changes on the ECG.

Visit 2: Total Duration 2 hours

During visit 2, we will ask you to wear a small device (about the size of a matchbox) which will be secured to your right hip and ankle using a velcro strap. This will record your movements during the various activities. Similar to visit 1, you will be requested to wear the monitor and mask to measure your breathing. You will be asked to walk up and down a 10m course identified by 1 cone at each end. This will be performed at 4 different speeds (slow, normal, brisk and brisker) for 6 – 8 minutes each time. You will be able to stop the test at any time if you experience any ill effects. You will receive a rest period (approximately 10 minutes) between each walking test. Following a further rest period, you will be asked to carry out the following activities: pushing a shopping trolley, stacking cans onto a shelf, carrying 2 loaded shopping bags, vacuuming a section of rug, stair climbing, and cycling on an exercise bike. You will be able to choose the speed at which you perform these activities, which will be maintained for 3 – 6 minutes.

If you do not wish to participate, it will not affect your current or future medical treatment in anyway. You are free to withdraw from the study at any point without providing any explanation and with no obligation. Should you decide to take part your GP will be informed. It should be noted that your participation in this study may not be of direct benefit to you, but could help in the development of treatment for the benefit of future patients. The only people who will have access to your results will be

those involved in the testing and analysis of the data. It is possible that the results of this study will be published in a medical journal. Although your own results will be part of any publication your identity will not be disclosed at any point. If you are, or are likely to become pregnant, you should not participate in this study.

If you have any questions about the study or need to contact us for any reason, please use any of the following means:

Alison Kirk, Research Assistant, L5 North, Royal Alexandra Hospital, Corsebar Rd, Paisley 0141 580 4628 or 0141 339 8855 ext 0884

Dr Paul MacIntyre, Consultant Cardiologist, L5 North, Royal Alexandra Hospital, Corsebar Rd, Paisley 0141 580 4628

Dr Miles Fisher, Consultant Diabetologist, L4, North, Royal Alexandra Hospital, Corsebar Rd, Paisley 0141 580 4440

Consent:

I,.....

give my consent to the research procedures described above, the nature, purpose and possible consequences of which have been described.

Signed:.....

Date: .....

Witness.....

Date: .....

0141 842 7266
Elizabeth Hutchenson
0141 842 7308

LREC 5/99

4th July 2000

Dr Paul MacIntyre
Consultant Physician and Cardiologist
Argyll and Clyde Acute Hospitals NHS Trust
Royal Alexandra Hospital
Corsebar Road
PAISLEY
PA2 9PN

Dear Dr MacIntyre

PHYSIOLOGICAL, PSYCHOLOGICAL AND MEDICAL EFFECTS OF INCREASING PHYSICAL ACTIVITY IN PEOPLE WITH TYPE 2 NON INSULIN DEPENDENT DIABETES MELLITUS (NIDDM) PATIENTS

Many thanks for submitting an amendment to the above protocol. The committee reviwed this on the 5th July, 2000 and are happy to grant approval.

A list of Committee members present at meeting held on 19th January 2000 is appended.

Yours sincerely

J.J. Morrice F.R.C.S.
Chairman

DIABETIC CLINIC & ADULT MEDICINE

EXERCISE AND TYPE 2 DIABETES

FORM OF INFORMATION

Title of Research
Physical activity levels in people with Type 2 diabetes.

Summary
We invite you to take part in a study looking at physical activity in people with Type 2 diabetes. This study will allow you to learn more about the benefits of physical activity and will provide regular medical check-ups over one year as part of your diabetes management.

If you agree to take part, you will be asked to visit the *Royal Alexandra Hospital* between 6 and 8 times over the course of 1 year. These visits will last 30 to 60 minutes only. The details of each visit are described in more detail below.

Visit 1: Total duration 1hour.
During visit one you will be asked to complete a personal health questionnaire and your weight and height will be measured. You will also be asked to perform an exercise test, which will last around 10 minutes. We will measure your exercise performance by asking you to exercise on a treadmill and measuring the amount of oxygen you use. During the test, we will monitor your heart rate using an ECG and measure your blood pressure by an inflation cuff. We will measure your breathing during the exercise test by asking you to breathe through a mouthpiece. You will be asked to keep exercising until you can no longer continue. The test will also be stopped if you develop chest pain or if there are changes on the ECG. At the end of the exercise test you will be given a sample bottle and asked to complete a urine sample, 24-hours before your second visit. You will also be given a small monitor about the size of a 50p piece, which you will be asked to wear on your ankle. This will record the amount of physical activity you do. The researcher will show you how to attach the monitor and instruct you to wear it during all waking hours (except during bathing or other water activities) for 7 days immediately after the first visit.

You will be asked to return for visit 2 one week after your first visit.

Visit 2: Total duration 30 minutes.
During this visit, a blood sample will be taken from your arm. A fasting blood sample is required, therefore you will be asked to refrain from eating for 12 hours before your visit. Breakfast will be provided after you have given the sample. During this visit you will return the activity monitor and the researcher will ask you about your physical activity during the previous 7 monitored days. You will also be asked to complete a questionnaire about your present exercise habits.

You may be asked to return for a third visit within 7 days after visit 2.

Visit 3: Total duration 30 minutes.
This visit involves a discussion with the research assistant on exercise. You will also receive a telephone call phone call 1-month after this visit.

Six and 12 months after visit 3, you will be asked to return to the Royal Alexandra Hospital where the procedures carried out during visits 1, 2 and 3 will be repeated. Visit 3 will not be repeated at 1 year.

Final Points to Note
If you do not wish to participate, it will not affect your current or future medical treatment in anyway. You are free to withdraw from the study at any point without providing any explanation and with no obligation. Should you decide to take part your GP will be informed. The only people who will have access to your results with be those involved in the testing and analysis of the data. It is possible that the results of this study will be published in a medical journal. Although your own results will be part of any publication your identity will not be disclosed at any point. If you are, or are likely to become pregnant, you should not participate in this study. If you are harmed by taking part in this research, there is no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health complaints mechanism is available to you

If you have any questions about the study or need to contact us for any reason, please use any of the following means:

Alison Kirk, Research assistant, L5 North, RAH, Paisley. 0141 580 4628 or 0141 330 2830

Dr Miles Fisher, Consultant Diabetologist:: L4, RAH, Paisley. 0141 580 4433

Dr Paul MacIntyre, Consultant Cardiologist: L5 North, RAH, Paisley. 0141 580 4628

Consent:

I,.....

give my consent to the research procedures described above, the nature, purpose and possible consequences of which have been described.

Signed:.....

Date: .....

Witness.....

Date: .....

EXERCISE CONSULTATION

Decision Balance Table

Gains	Losses
1. *Improve diabetes control*	1. *Time*
2. *Lose weight*	2. *Money*
3. *Feel fitter*	

- Go through benefits of physical activity. Attempt to overcome perceived losses (time management, low cost activities)

Barriers to physical activity

Barriers	Strategies to overcome barriers
1. *Physical discomfort from exercise*	1. *Individual exercise prescription avoid exercise which causes discomfort*
2. *Frightened of having hypos*	2. *Education on how to avoid hypos*
3. *Too overweight to exercise*	3. *Prescribe non-weight bearing exercise. Possible initial home based exercise programme to enhance confidence*
4. *Lack of support*	4. *Seek out social support (family & friends)*

- Assess current/past physical activity status
- Go through current ACSM & ACSM/CDC physical activity guidelines
- Look at potential activities

Physical activity goal setting

1-month	3-months	6-months
1. *Walk back from work (5-10minutes) at least 3 days/week.*	1. *Increase walking to accumulate at least 30 minutes/day, 5 days/week*	1. *Complete sponsored 3km walk*

- Address issues of relapse prevention *(indoor activities for wet days, ways to get back to exercise after holidays)*
- Discuss effects of exercise & diabetes *(avoiding hypo's, foot care)*

ACTIVITY MONITOR INFORMATION

- The activity monitor is **not waterproof**, however, small water splashes will not cause any damage. You will have to take the monitor off to bathe, swim or shower. Please record the time your remove and re-attach the monitor on the back of this sheet.

- The activity monitor should be worn on your ankle above your ankle bone. Use the strap provided, and **make sure the arrow is pointing upward**.

- **Wear the monitor during all waking hours, except when bathing.** Leave the monitor in place until you go to bed. When you take the monitor off record the time on the back of this sheet. On waking in the morning, reattach the monitor to your ankle immediately. Record the time of reattachment on the back of this sheet. Continue wearing the monitor in this manner every day until your next visit.

- **FRAGILE** As these top-of-the-range monitors are expensive, you are asked to take very good care of them.

- Please record any day and time the physical activity monitor is not worn on the back of this sheet.

If you have any questions,

contact Alison Kirk on 0141 580 4628/5096.

Thank you for your time and co-operation in our study

Record for Physical Activity Monitors

Please be as accurate as possible with this record

SLEEPING

Day	Time monitor was removed	Time monitor was attached
Example Tuesday	*10.00pm*	*9.00am*

BATHING OR SWIMMING

Day	Time monitor was removed	Time monitor was attached

ANY OTHER PROBLEMS WITH THE ACTIVITY MONITOR

Day	Reason	Time removed	Time attached
Example Saturday	*Forgot to put it on in the morning (please try not to forget)*	*10.00pm on Friday*	*2.00pm on Saturday*