THE PSYCHOLOGICAL AND PHYSIOLOGICAL EFFECTS OF PHYSICAL ACTIVITY AND FITNESS IN CHILDREN WITH TYPE 1 DIABETES

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This thesis is dedicated to the memory of my friend and colleague Phil Deeks.

Abstract

Maintenance of blood glucose control and psychological well being are both important health outcomes for children with Type 1 diabetes. Diabetes management, the balance of insulin, diet and exercise, interacts with all aspects of these children's health, however, to date the effects of exercise in this interaction are poorly understood. This is particularly so with regard to the effects of exercise on psychological health. The aims of the present study were to investigate the effects of physical activity and fitness on the psychological and physiological health of children with Type 1 diabetes. The hypotheses were 1) that higher levels of physical activity and fitness would be positively associated with both greater psychological well-being and lower HbA_{1c}, 2) that increasing physical activity would increase psychological health and lower HbA_{1c}.

Participants were aged 9-15 years, diabetes duration more than 2 years. There were 39 participants in phase one. Physiological data collected were physical activity, aerobic fitness, sum of skinfolds, BMI and HbA_{1c}. Psychological questionnaires used were the physical self perception profile for children, the self efficacy for diabetes scale and the diabetes quality of life for youths questionnaire. Physical self esteem and quality of life were significantly associated with both greater fitness and higher physical activity. There were no significant associations between HbA_{1c} and either fitness or physical activity.

Phase two was a randomised controlled trial to evaluate a 12 week physical activity intervention. Thirty-nine children were recruited to this phase, 27 experimental and 12 control, of these 14 experimental and 7 control children completed the study. Data were collected as in phase one. When differences between the groups at time 1 were taken into account the only significant effect of the intervention was an increase in the BMI of the experimental group. There were increases in the hypothesised direction for aerobic fitness, perceived sports competence and perceived condition competence. Skinfold thickness and self efficacy for diabetes decreased significantly in both groups, strength competence increased significantly in both groups. There was no significant effect on HbA_{1c}. Sample size was small and therefore the results must be treated cautiously due to the possibility of Type 2 error.

It was concluded that both physical activity and fitness showed positive associations with psychological variables but that a physical activity intervention programme did not lead to significant increases in these variables. It is suggested that an intervention programme that incorporated physical activity and an educational or cognitive component would have a greater effect on the outcomes studied.

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Description of Type 1 diabetes and the concepts in this study

This chapter begins by giving a brief explanation of the physiology and symptoms of the chronic disease Type 1 diabetes, followed by a description of its management, long term outcomes, epidemiology and aetiology. A model of health which can explain the interrelated nature of physical well being, psychological well being and disease management in people with Type 1 diabetes is then discussed. The chapter goes on to provide a rationale for, and description of, the psychological and physiological constructs which are measured in the present study, these are HbA_{1c}, quality of life, self efficacy, self esteem, physical activity, exercise and physical fitness.

1.1: Physiology of Type 1 diabetes

The condition Type 1 diabetes has affected people for thousands of years. This is known because the symptoms of untreated Type 1 diabetes were recorded in writings from ancient times in China, Egypt and India. The name diabetes comes from Greek. Diabetes means a siphon, or to run through, and referred to the excess urine which was passed by people with the condition. The name was first used by Aretaeus of Cappodocia around 100 AD. He described the condition as 'a mysterious affection melting down of flesh and limbs into urine, life is short, disgusting and painful, thirst unquenchable, death inevitable' (Kelnar, 1995, pg 123).

Type 1 diabetes is now known to be an autoimmune disease. Beta cells in the pancreas, the site of insulin production in the body, are destroyed over a period of weeks or months by the immune system. Insulin facilitates the uptake of glucose from the blood into cells, where it can be used immediately for energy or stored as glycogen, protein or adipose tissue. When insulin levels are low or deficient in the blood stream stored substrates are mobilised and tissue uptake of glucose is inhibited. In its healthy state the body is able to closely control the level of glucose in the bloodstream around a set point. Insulin plays an important role in this regulation, so when the body cannot produce its own insulin this homeostatic mechanism is disrupted.

In the early stages of insulin deficiency beta cells begin to be destroyed and hyperglycaemia occurs. Hyperglycaemia causes the kidneys to expel excess blood glucose. This increased glucose has an osmotic effect leading to an increased flow of urine and eventual dehydration. As insulin deficiency becomes more severe fat metabolism, which is inhibited in the presence of insulin, occurs. However, fat cannot be metabolised fully without the by-products of glucose combustion and stops with the formation of acidic ketones. High concentrations of ketones result in Diabetic Ketoacidosis, a potentially life threatening condition. Ketoacidosis displays symptoms similar to those of hyperglycaemia but in addition nausea, vomiting and lethargy often occur, and in the most serious cases it can lead to coma or death. Nowadays these symptoms are rare, occurring most often where diagnosis is delayed.

1.2: Treatment and outcomes

Treatment for Type 1 diabetes is a complex self management regimen consisting of injection of insulin alongside regulation of diet and exercise. The amount of insulin administered, the amount of energy consumed in the diet, and the amount of energy used in physical activity have to be balanced to maintain the desired blood glucose level. When insulin is produced internally it is finely adjusted by the body to maintain blood sugars within a healthy range. People with Type 1 diabetes have to maintain this balance consciously by balancing energy intake in their diet, expenditure in physical activity and amount of insulin injected. Blood glucose levels can be monitored using a blood glucose monitor, these are pocket sized machines which measure the blood glucose level of a drop of blood, usually from a fingerprick. It is recommended that people with diabetes test their blood glucose several times a day and adjust their diabetes regimen accordingly, by for example eating more or less carbohydrate or injecting more or less insulin. Insulin is typically injected two or more times a day. If blood sugars go out of the 'normal' range hypoglycaemia, hyperglycaemia or ketoacidosis can occur. Therefore the treatment regimen for Type 1 diabetes is complex and continuous for a lifetime.

Longer term complications such as retinopathy (disease of the retina arising from degeneration of its small arteries), neuropathy (disorder of the peripheral nerves) and nephropathy (disease of the kidney as a result of damage to its small blood vessels) can occur. A multicentre, randomised controlled trial examined whether maintaining blood glucose concentrations close to the normal range could decrease the frequency and severity of these complications (Diabetes Control and Complications Trial (DCCT, 1993). A total of 1441 patients were recruited from 29 centres between 1983 and 1989, and followed for an average of 6.5 years. Criteria for study entry were that participants were aged 13 to 39 years, had been diagnosed with diabetes for at least one year, and had no hypertension, hypercholesterolemia, severe diabetic complications or medical conditions. Participants were randomly assigned to a treatment or control group. The treatment group participated in intensive diabetes therapy which involved administering insulin 3 or more times daily and adjusting this dependent on self monitoring of blood glucose results, diet and exercise. The control group received conventional diabetes therapy which involved 1 or 2 insulin injections a day, self monitoring of blood glucose or urine and education about diet and exercise. Average blood glucose levels were assessed by measuring HbA_{1c}, a measure of average blood glucose levels over the previous three months (see section 1.6.2). A statistically significant difference between the HbA_{1c} values of the conventional and intensive therapy groups was maintained after baseline ($p<0.001$).

The cumulative risk of retinopathy was 52% lower in the intensive therapy group. Microalbuminuria developed in fewer participants in the intensive therapy group than the conventional group, the risk reduced by 38.5%. The risk of albuminuria was also reduced. The development of clinical neuropathy was also reduced in the intensive therapy group. The age of the participants meant the number of macrovascular events was low but intensive therapy reduced the risk factors for macrovascular disease compared to conventional therapy. However, there were negative events associated with intensive therapy, the intensive group reported approximately three times as many episodes of severe hypoglycaemia as the conventional group, and had increased weight gain compared to the conventional group.

Secondary analyses showed that the risk for developing retinopathy increased as mean HbA_{1c} increased and similarly that the risk of severe hypoglycaemia increased as mean HbA_{1c} decreased. However, no target HbA_{1c} level to maximise benefits while reducing the risks was recommended. The main recommendation from the study was that most patients with Type 1 diabetes be treated with closely monitored intensive regimens, with the goal of maintaining their glycaemic status as close to the normal range as safely possible. They note however that the risk-benefit ratio may be less favourable in children under 13 years of age.

The data from the DCCT were re-examined to see whether the findings were the same for the younger participants, those aged 13 to 17 at study entry (DCCT, 1994). The number of adolescent participants was 195, at study entry 41% of these were 13 or 14, 47% were 15 or 16, and 12% were 17 years old. The data showed that intensive therapy delayed or slowed the progression of diabetic retinopathy and reduced the risk for the development of microalbuminuria for these adolescents. Both the direction and magnitude of these effects was similar to those in the entire DCCT cohort. However mean HbA_{1c} values were higher in both the intensively and conventionally treated adolescents than the corresponding adult groups. Rates of hypoglycaemia were also higher in adolescents on intensive treatment than the corresponding adult group, despite having higher HbA_{1c} levels. This suggests maintaining good control is more difficult for adolescents than adults but that it has the same benefits of preventing or delaying the onset of secondary complications.

1.3: Epidemiology and Aetiology

Standardised collection and analysis of epidemiological data of Type 1 diabetes started in the late 1970's and three international studies have allowed worldwide variation in incidence to be assessed. These have found that the present day incidence of Type 1 diabetes varies quite widely.

The EURODIAB ACE study prospectively identified newly diagnosed cases of Type 1 diabetes in children up to 15 years old in 24 regions of Europe during 1989 and 1990. Most regions had incidence rates between 6 and 9 per 100,000 per year. In general eastern and south-western Europe recorded low rates whereas northern Europe recorded generally high rates (Green et al., 1992).

A wider review of epidemiological data from around the world was carried out for the WHO multinational project group (WHO, 1992; Karvonen et al., 1993). Again variations in incidence were found between geographic areas, the lowest incidences were found in Asia, followed by Oceania, South and North America and the highest rates were in Europe. Actual incidence rates varied from 0.6 per 100,000 in Korea and Mexico to 35.5 per 100,000 in Finland. The largest intracontinental variation was found within Europe. Neither study found support for a correlation between incidence and latitude or average yearly temperature although a difference in incidence was found between northern and southern hemispheres. A more recent review of the worldwide literature found results were similar to those of Karvonen et al. (1993). Incidence varied from 0.5 per 100,000 per year in Peru, to 30.3 per 100,000 per year in Finland, a 60-fold difference between those countries with the highest and lowest incidence rates.

Onkamo et al. (1999) also analysed changes in incidence over time. A statistically significant increase was found in 24 of the 37 studies, and a further 12 showed an upwards tendency in incidence which was not significant. The global annual increase in incidence was 3.0% from 1960 to 1996 showing a highly significant increasing trend. When this data is used to predict future trends it is estimated that the incidence of Type 1 diabetes globally will be 40% higher in 2020 than it was in 1998.

As yet the exact aetiology of Type 1 diabetes is not known. Detailed epidemiological studies alongside genetic studies are helping to unravel the cause but as yet there is still some way to go. There are several sources of evidence for an environmental factor in causation. One is the occurrence of epidemics of Type 1 diabetes, these have been reported, mainly during the mid 1980's, with an increase in incidence of between 3-5% (WHO, 92). Also age of onset of the disease appears to differ by region, in general the incidence rates were lowest in the 0-4 years age group and highest in the 10-14 years age group. Onset of Type 1 diabetes shows seasonal variation with a reduction of cases in the warm summer months (Laron, 1999; Karvonen et al., 1993).

There is also evidence for some genetic component. Studies of first degree relatives of people with Type 1 diabetes show that the cumulative risk of developing Type 1 diabetes by the age of 30 is 3-10% compared to less than 1% for the general population (Diabetes Epidemiology Research International Group, 1988). The WHO study looked at incidence, risk factors and mortality associated with childhood Type 1 diabetes and found that it aggregated in families (WHO, 1992). Genetic studies have identified genes within the HLA region of chromosome 6 which have been linked to increased susceptibility to Type 1 diabetes (Dahlquist, 1998).

Studies of migrant populations and monozygotic twins have been used to determine the genetic versus the environmental component of the causation of Type 1 diabetes. If a migrant population retains the prevalence of their native country it is evidence of a genetic cause but if they take on the occurrence rate of the country they have moved to this is evidence for an environmental cause. A review of migrant studies (Serrano-Rios et al., 1999) concluded that Type 1 diabetes is caused by both genetic and environmental factors. Studies of monozygotic twins have found a 36% concordance rate for Type 1 diabetes providing further evidence of some environmental component (Olmos et al., 1988). Overall the results of this research suggest that Type 1 diabetes is a multifactorial disorder in which genetic susceptibility is necessary but not sufficient for its development. Viruses, toxins, psychosocial factors and nutritional intake have been implicated as potential triggers but conclusive evidence has yet to be found.

The previous section summarised very briefly some of the research into the epidemiology and aetiology of Type 1 diabetes. It is through understanding this that the eventual goal of research into Type 1 diabetes, its prevention or cure, will come about. However, at the present time this goal is still some way off and as has been described the incidence of the disease is increasing. Even if a method of preventing development of Type 1 diabetes is found in the near future there will already be a large number of people with the disease for whom it is necessary to provide treatment. The aim for this group of people must be to provide treatment that allows them to live with the best possible quality of life. This means that research into the management of this disease is crucial.

Section 1.2 explained the treatment regimen used to manage Type 1 diabetes, this involves people with Type 1 diabetes constantly balancing the amount of insulin injected with diet and exercise to maintain blood glucose levels as close to those in people without Type 1 diabetes as possible. The complex and demanding nature of this regimen means that it interacts with both physical and psychological wellbeing.

The following section discusses a model which can describe the health of people with Type 1 diabetes and capture the interrelatedness of health and diabetes management.

1.4: A model of health for people with Type 1 diabetes

Understanding what is meant by health and having a conceptual model of this helps to ensure that care provided by medical professionals and health workers results in the best health outcome for each individual. It is increasingly becoming accepted that psychological health should be included within this concept in addition to physical well being and this is leading to a shift in the way health is understood and in some instances the way illnesses are treated. This is particularly relevant when the health of people with a chronic disease is considered. These people by definition will always have imperfect physical health but the treatment they receive for their disease may differ if its effect on their psychological health is considered alongside its effect on their physical health, rather than solely treating physical well-being. Concepts of health and existing models that explain them will be explored here in relation to the health of people with the chronic illness Type 1 diabetes. A model is required which explains the interrelated nature of physical well-being, psychological well-being and disease management.

Two widely known conceptions of health that have influenced medicine and research into this area are the medical model and the definition of the World Health Organisation (WHO). The medical model defines health as the absence of disease or disability. Health is modelled on a linear scale with healthy at one end and ill at the other. It is an intuitively appealing model and fits many common lay conceptions of health. In some situations, however, the classification of healthy or unhealthy on a linear scale, which an individual would be given according to this model, does not seem appropriate. For example, a person who is physically disabled following a car accident but who has adapted to her new physical abilities and is living a full and productive life within certain limitations would be classified as unhealthy by the medical model as she has a disability but would be viewed by some people as healthy. Similarly an individual who has no identifiable disease but who is continually unhappy, anxious and lonely would be classified as healthy but some people would not consider them so. An individual with Type 1 diabetes would be classified as ill by this model because they have a disease. Their ability to manage this disease and their psychological health would not be taken into account in this classification. The model has also been criticised for being too narrow because it does not consider social or economic factors such as poor housing or unemployment, which influence health without necessarily causing physical symptoms of disease. Measurements of health using this model are actually measures of the negative deviation away from a state of health or in other words measures of ill health. This may be appropriate for those who are severely ill but this is only a small percentage of the population. A measure of positive health would be more informative about the majority of the population.

An important step towards measuring positive health instead of, or in addition to, ill health was made when the WHO defined health in its 1946 constitution as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO, 1946). This increased discussion about wider issues of health than absence of illness and overcame some of the criticisms which had been put forward about the medical model. It did not however provide an operational definition, as 'complete physical, mental and social well being' is too vague a concept to be quantified and so is difficult to measure. It has been questioned whether a state of 'complete physical, mental and social well-being' is actually attainable or whether it is an idealistic state. Even if it is attainable only a very small proportion of the population would reach it, and so be considered healthy, at any one time. These would be physically fit young adults with a large social network who were mentally well adjusted. A further criticism of the definition is that it does not include emotional or spiritual aspects of health. In fact providing an operational definition of positive health has proven difficult. Bowling looked for common ideas between the various theories of positive health and concluded 'there is now a broad agreement that the concept of positive health is more than the mere absence of disease or disability and implies 'completeness' and, 'full functioning' or 'efficiency' of mind and body and social adjustment. Beyond this there is no one accepted definition' (Bowling, 1997, p 5).

Although both of these models are widely known, have helped to direct research into health and have led to advances in medicine, the criticisms which have been made of each show that neither fully captures all that is meant by the concept of health as it is used in everyday conversation. A person with Type 1 diabetes would be classified as ill by both models whereas these people themselves, and their families, mostly do not see things as simply as this. The classification of health on one continuum restricts this classification and means that the contribution of psychological well being and other non physical concepts to overall health cannot be considered. The criticisms of these and other unidimensional or vaguely defined concepts of health have led some more recent authors to suggest that it is a concept with various definitions no one of which can be seen to be more correct than the others.

Studies in medical anthropology in the 1970's were informative in developing this view. They provided rich and detailed theory bases from a variety of cultures which were used to study explanations for health and illness. As a result of these analyses it began to be recognised that 'explanatory systems differ intraculturally as well as interculturally; that within any society or community there will operate a number of sympatric systems, which co-exist and compete in dynamic interplay, varying in the extent to which they are culturally sanctioned and endorsed' (Rogers 1991, p.17). This view is shared by Seedhouse who argues from a philosophical and historical perspective that health has a variety of meanings and the one which is used at any one time depends on the context, the user or both these factors. He also argues that there must be a common factor to all definitions of health. The rationale for this is that 'if the idea of health is not to be meaningless, if the word 'health' is not to mean anything one wants it to mean, then it must be possible to display some limit to the sense of the word' (Seedhouse, 1986, p25). After considering four theories of health, medical, sociological, humanist and idealist he defines this common factor as: 'In general, the provision of the conditions necessary for the achievement of some biological and chosen potentials, and of conditions which enable people to work towards the achievement of other biological and chosen potentials is the goal of all approaches. Much of the provision of suitable conditions is achieved by the removal of obstacles' (Seedhouse 1986, p.29). By chosen potentials he is referring to the fact that there are an infinite number of possibilities available to us as we go through life but that it is not possible to achieve them all and each individual has to choose which to work towards. By obstacles he is referring to negative influences on health for example a lack of education, poor housing conditions or smoking.

The wellness model has more recently become popular as a model of health. It accommodates the idea that health is more than the absence of disease and is conceptually less vague than the WHO definition. It views health as consisting of five interrelated domains; physical, mental, social, spiritual and emotional. It is the integration of these domains which is considered to determine wellness. There are a very large number of ways in which they can be integrated depending on the goals a person has chosen and the obstacles they encounter. Various models have been proposed to explain how these dimensions interrelate. Two which provide different ways to visualise this interaction are explained here.

Greenburg (1985) provides a clear explanation of how health and illness can be conceptualised as existing at the same time, a problem for both the medical and WHO models. He considers the health illness continuum to actually be a series of tiny dots rather than one continuous line. Each of these dots is composed of the five components of health (see figures 1.1 and 1.2).

Figure 1.1: The magnified health – illness continuum (from Greenburg, 1985)

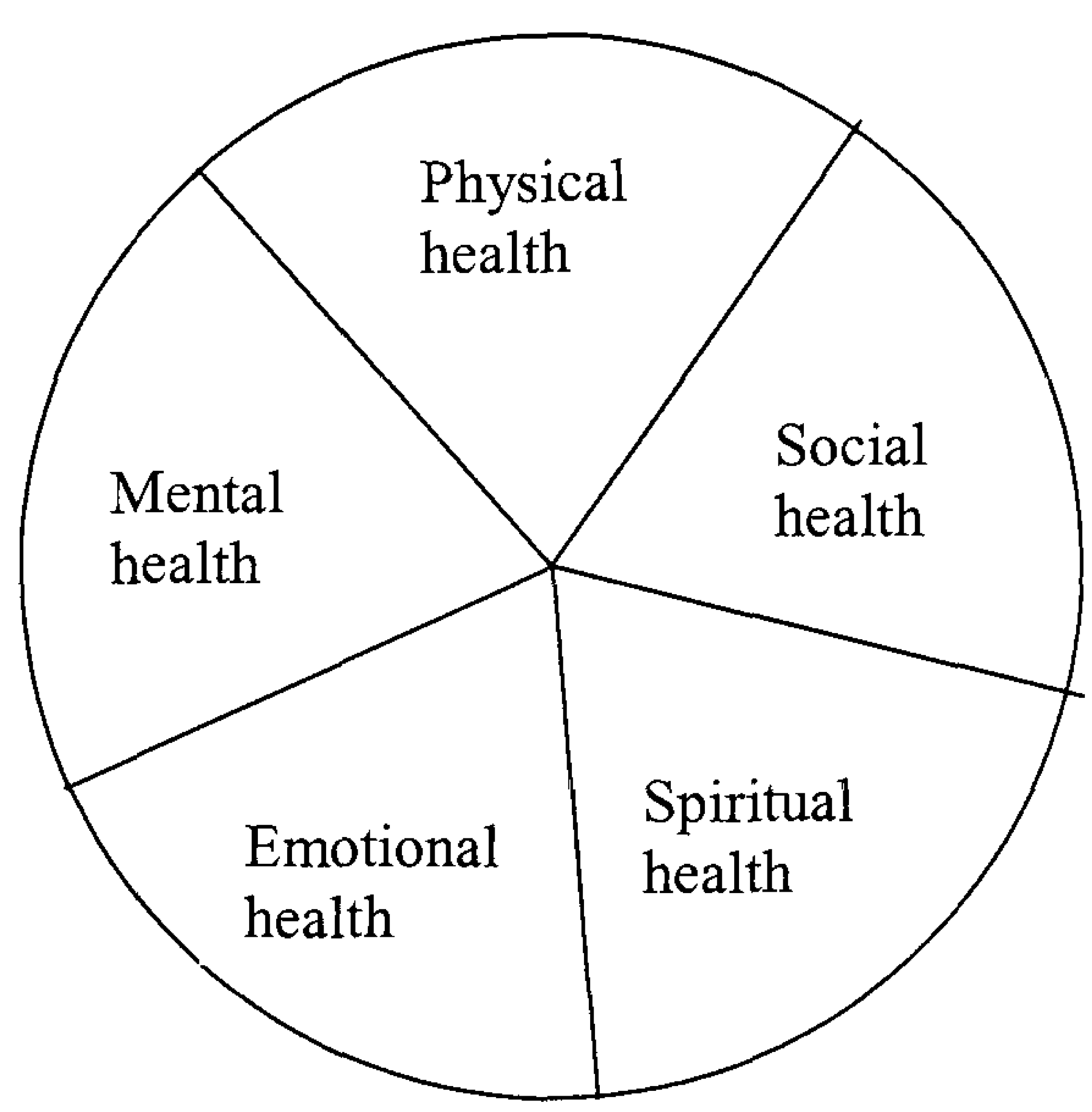

Figure 1.2: A single health – illness continuum dot (from Greenburg, 1985)

Wellness is the integration of these five components at any level of health or illness. So using this model a person can be well regardless of whether they are ill or healthy. This initially seems contradictory as wellness is a positive state and illness a negative state, however, it makes sense in terms of a person's potential for health. Certain illnesses, for example Type 1 diabetes, limit a person's potential for health. but within this limitation there is potential for variability. One person may become depressed, withdraw from social situations, and unfit. Whereas another person may interact well with family and friends, express their emotions appropriately, maintain their physical fitness, do well at school, and sense how they fit in to the 'grand scheme of things'. This second person, by enhancing all five components of health, near to their potential, is achieving wellness in spite of having Type 1 diabetes. These two people with Type 1 diabetes have the same condition and the same level of health on the health-illness continuum but behave very differently.

The model considers the balance of attention given to each domain and their integration to be important to achieving high level wellness. A person may focus so much on one component of health that the others suffer, e.g. a person who socialises to the detriment of physical fitness and academic success. A person with a high level wellness is able to integrate all of the components of health into their lifestyle. Here the analogy of the health-illness spectrum being comprised of a series of dots is useful again. If equal attention is given to each of the components of wellness they occupy an equal proportion of the dot and it is symmetrical which leads to a smooth ride through life (figure 1.2). If attention is focused on one area more than others this leads to asymmetry and a bumpy ride (figure 1.3).

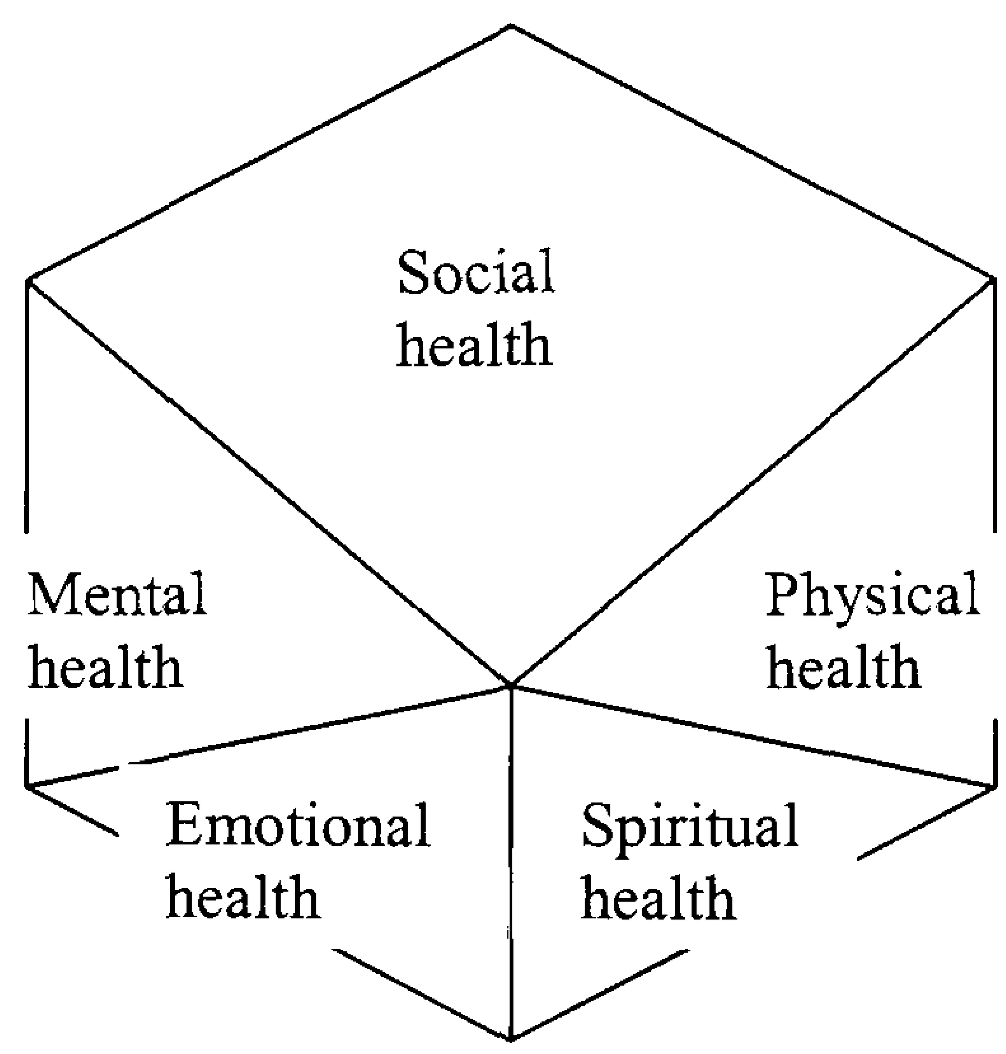

Figure 1.3: An assymetric dot on the health – illness continuum (From Greenburg, 1985)

Eberst (1984) provided a different and original way to conceptualise the interrelated nature of the components of wellness. He used the analogy of a Rubik's cube, each side of the cube represented one component of wellness (figure 1.4), in this model the sixth side represented vocational health. Each component of health is comprised of several subelements, which are represented by the nine subelements of each side of the cube. The interrelated nature of the components of health is represented by the fact that moving one subelement in the cube causes changes in many of the other subelements, including those on other faces (i.e. other components of health). The highest state of wellness is represented by each side having all nine subelements the same colour. However the 4.3 x 10^{19} possible arrangements of all the subelements represent the many different ways in which people can reach their own individual state of wellness. In reality it is very unlikely that anyone will be able to attain their 'perfect health' condition or in terms of Eberst's analogy people will have a number of different coloured subelements in each of their dimensions of health. In Greenburg's model focussing on one component of health to the detriment of others caused assymetry to the wellness spectrum and a bumpy ride through life. Ebert's model represents this by the fact that focussing solely on making all the subelements on one side of the cube the same colour will result in the other five sides becoming very mixed up.

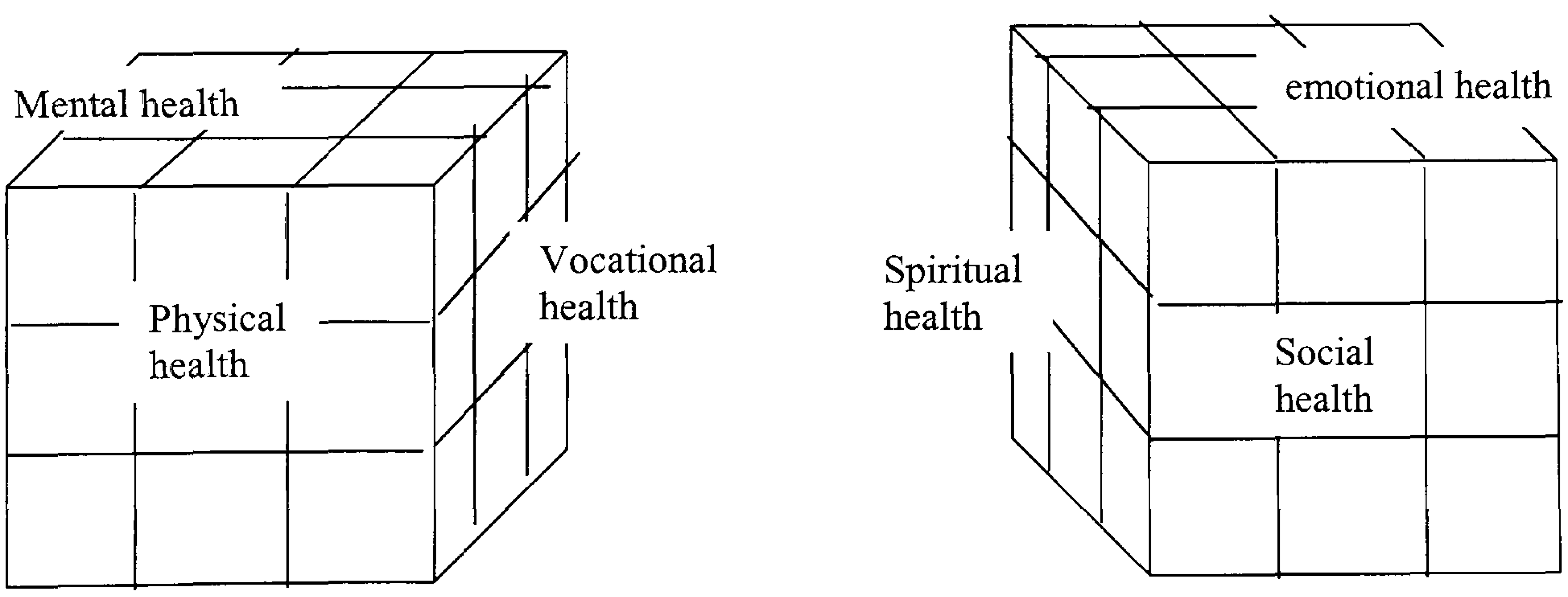

Figure 1.4: The 'Cube' model of health (from Eburst, 1984)

These two ways of conceptualising the wellness model are similar in that wellness consists of at least five dimensions, these are interrelated and high level wellness occurs when equal attention is given to each dimension. The wellness model allows

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the scenarios mentioned previously (e.g. someone who is physically disabled but lives a full and productive life within certain limitations) to be understood and explained. When applied to people with Type 1 diabetes it means social, emotional, mental and spiritual well being are considered to be as important as physical health. This agrees with people's self reported feelings that they are well although they have Type 1 diabetes.

Applied to the management of Type 1 diabetes it leads to shift in focus from a purely physiological perspective to one in which the effect of diabetes management on each of the domains of health is considered as is the interaction between these domains. Klepac (1996) considered the management of Type 1 diabetes in relation to a wellness perspective. She felt the nature of diabetes management, i.e. the extent to which the individual with diabetes is personally involved in this, means that it will affect all components of health, not only physical health. For example emotions may affect eating patterns which in turn may affect blood glucose levels. Following this framework an individual's diabetes management plan should be integrated within a personal wellness plan so that the two are not in conflict. For example if a diabetes management plan interferes with social and emotional health (e.g. by preventing participation in desired activities), adjustments should be made to try to modify this negative interaction (e.g. by altering insulin dose or timing of meals) to restore balance to the wellness state. Klepac says that 'ideally, management of diabetes with attention to all health components can strengthen the state of wellness' (Klepac, 1996, p227). In this model empowerment (the patient in collaboration with a healthcare professional, making their own individual healthcare decisions based on personal goals and lifestyle factors) and self efficacy (a patient's confidence level to perform desired activities to achieve personal goals, such as following an exercise programme) are interrelated with wellness. They help people with Type 1 diabetes to attain and maintain high levels of wellness. Figure 1.5 is a representation of this model, it shows how a person with diabetes considers the impact of diabetes on each of the five areas of health and in addition considers strengths or weaknesses in any health component, due to self efficacy or empowerment, that may influence diabetes management.

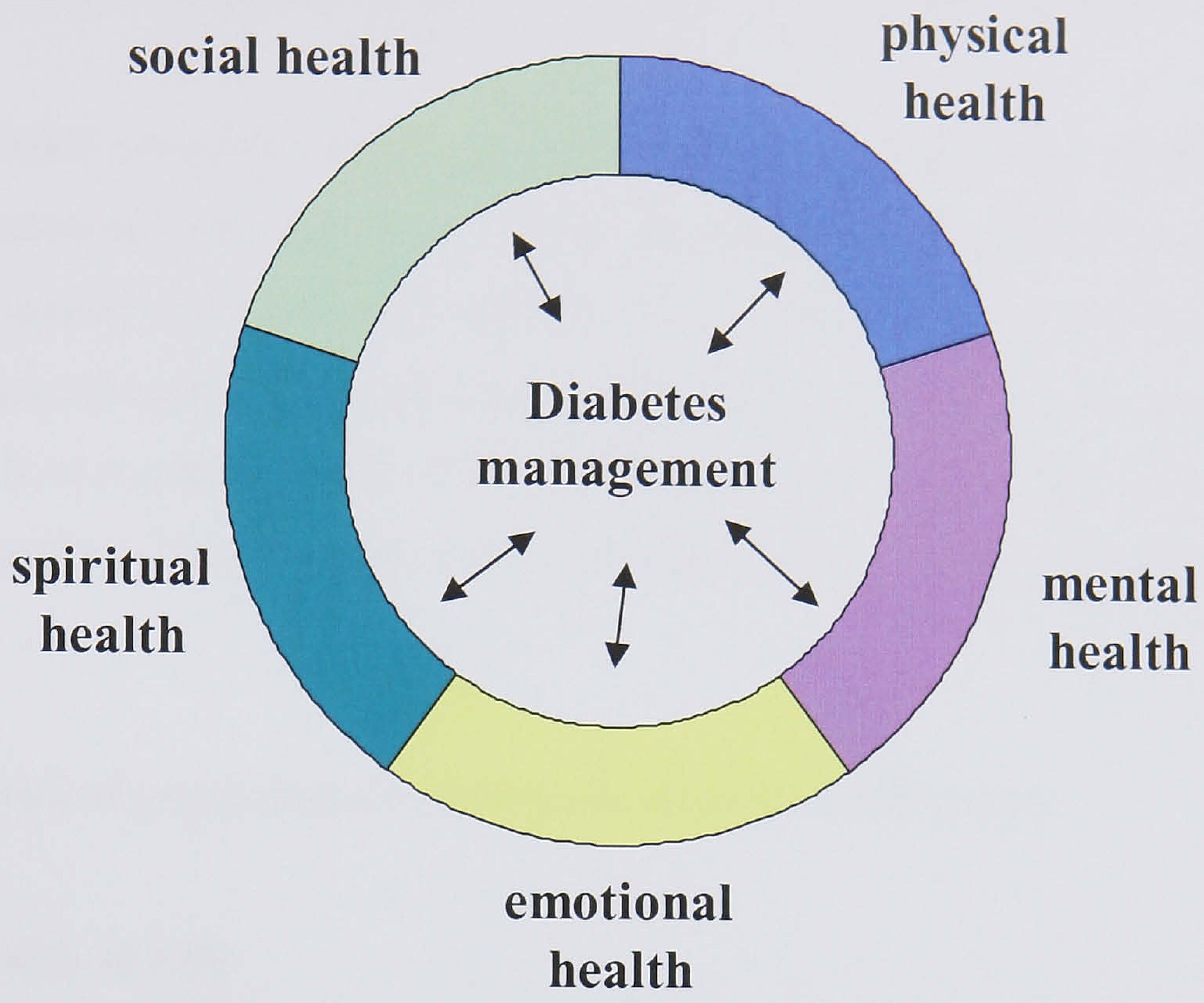

Figure 1.5: The web of wellness and diabetes management (Klepac, 1996)

The word health derived from the word for whole and was originally associated with wholeness. Up until approximately 200 years ago health was considered to be a soundness of body, mind and spirit. With the growth of professional medicine around this time this view changed to one that health was a state of biological normality which could be achieved by external intervention (Seedhouse, 1986). The philosophy of wholeism 'emphasises the synergistic nature of health, man and society, where all the component parts act together in synergy creating a whole which is greater than the sum of its parts' (Cribb and Dines, 1993, p18). This fits in with the wellness model of health. It emphasises the interactive nature of the constituent parts of health, for example the mind body link and the link between health and environment. Wholeism also suggests that there is a balance between these various parts and emphasises the importance of equilibrium in life. Seedhouse discussed the change in the way health had been conceptualised up until that time by saying 'there has been a move from health which required personal action to health which can be imposed or acquired-health as a commodity' (Seedhouse, 1986, p15). It appears that the discussion has gone full circle and theories emphasising the interrelatedness of various components of health and the importance of autonomy and choice are again being put forward.

Wellness itself is not defined in a way that allows it to be measured. Therefore quality of life is assessed in this thesis, as it is a multidimensional measure of how an individual perceives their health. Self esteem is also measured, as it is one of the most widely used indicators of psychological health. In addition self efficacy is included, the possible importance of this to diabetes management was highlighted in the previous section. These constructs are explained in more detail in the following section.

1.5: Analysis of psychological constructs assessed in this study

1.5.1: Quality of Life

The term quality of life is used in many different ways in everyday language. To some people it is about happiness, others material wealth, still others relationships with family or friends (Eiser and Morse, 2001). Also, personal definitions and perceptions of quality of life differ over time and between cultures. For example in some countries quality of life is determined by basic needs such as running water and sufficient food whereas in most Western countries these are taken for granted and quality of life is thought of in terms of social and psychological factors. Likewise in the scientific study of quality of life there are a number of approaches used to conceptualise it. These are the philosophical approach, the economic approach, the sociological approach, the psychological approach and the medical approach (Lindstrom & Koehler, 1991). The psychological and medical approaches are the most relevant to this study. The psychological approach defines a person with high quality of life as someone with high self esteem who is able to make decisions, is happy and fulfilled. This ideal state may not be achieved by many people but the nearer a person is to achieving their life goals the better their quality of life will be. The medical approach emerged as a result of advances in medical care and the increasing number of people living with chronic diseases. It is necessary in these cases to ensure treatment makes patients feel better and quantity of survival is not considered as the only end point of treatment.

Health related quality of life draws on all five approaches and refers specifically to the impact of health and illness on the individual's quality of life. In a review of the assessment of health related quality of life in children and adolescents it stated 'health related quality of life refers to the subjective and objective impact of dysfunction associated with an illness or injury, medical treatment, and health care policy' (Spieth & Harris, 1996, p 176). In other words it is concerned with the areas of functioning that are directly affected by an illness or its treatment. As this study is investigating the effects of having Type 1 diabetes on the quality of life of children it is health related quality of life that will be assessed. However, for ease of reference the term quality of life will be used to mean health related quality of life for the remainder of the thesis.

The areas of functioning that are included in the above definition have to be defined for it to be operational. It is generally agreed that it is a multidimensional construct following the World Health Organisation's (1946) definition of health, referred to earlier (Bullinger and Ravens-Sieberer, 1995; Eiser and Morse, 2001), however, it is not so widely agreed what these dimensions are. In their review of quality of life assessment Spieth and Harris (1996) consider that there are four core quality of life domains: disease state and physical symptoms, functional status, psychological functioning and social functioning. Whereas another review, considered quality of life had five components: physical, emotional, mental, social and behavioural, i.e. the components of well-being as described earlier (Bullinger and Ravens-Sieberer, 1995). Within each domain there are objective and subjective perspectives. The objective component refers to what the individual can do and the subjective component refers to the meaning of this to the individual. The subjective component means that two people with the same objective health status can report very different subjective quality of life in a similar way to Greenburg's (1985) model of wellness. A good quality of life exists when hopes are matched and fulfilled by experience (Eiser and Morse, 2001).

Considering a different aspect of the operationalisation of quality of life assessment in children Bullinger and Raven-Sieberer (1995) state that there are three dimensions to quality of life assessment in children. The first relates to the specificity of the assessment, disease specific and generic assessment methods have been developed.

Disease specific measures are most likely to provide information that is clinically relevant (Spieth and Harris, 1996). The main disadvantage to using disease specific measures is that they are not comprehensive and do not allow comparison of dysfunction across illness groups. However as this study is focussed on children with Type 1 diabetes and comparison with other chronic conditions is not required a disease specific measure was most appropriate. The second dimension relates to the type of assessment to use; questionnaire, interview or observation. Spieth and Harris concluded the questionnaire method is usually favoured as it is more economical to use and has psychometric quality criteria i.e. reliability, validity and sensitivity. A questionnaire method will be used in this study. The third dimension considers who assesses the quality of life of children. Their review found that 50% of studies of quality of life in children since 1964 used parents' assessments of child well-being and another 40% used clinical staff's assessments (Spieth and Harris, 1996). There is limited data on adult–child concordance in quality of life assessment but Eiser and Morse (2001) reviewed what is available. They found limited evidence that parent–child concordance is greater for observable behaviours such as physical functioning than for non observable functioning such as emotion or social quality of life. There was insufficient data to conclude whether parents over or under estimate their child's quality of life. There was also little literature examining to what extent concordance is affected by age, gender or illness status. Concordance seemed to be greater for parents with chronically sick children compared to healthy children. However, as Speith and Harris said, the essence of quality of life assessment is the self rating method. In this study children were asked to rate their own quality of life.

Despite these difficulties that surround measuring and quantifying quality of life a strong rationale can be made for measuring it. In a very broad sense the two outcomes that matter in paediatric medicine are the quantity and the quality of a child's life. Therefore these outcomes should be used to evaluate clinical practice; i.e. the focus should be on symptoms and behaviours that improve quality or quantity of life. Also in research, outcomes should be chosen which reflect improved quality or quantity of life. Measurement of quality of life as an outcome of research is even more important where, as is the case in this study, there are no implications for survival of a new treatment or an intervention. Taking a child's perspective on the intervention will give a broader picture of its effects compared to more traditional outcome indicators such as HbA_{1c}. Children may have a different view of long term outcomes or the secondary complications of treatment than their parents or doctors. This again highlights the need to assess quality of life following an intervention or change in treatment as children may not respond in the same way as doctors or researchers predict. In addition measuring quality of life is in line with recent Government reports which emphasise the importance of involving children in their own healthcare and taking their views into account (House of Commons Health Committee, 1997).

These differences in the definition of quality of life have led to a range of measurement instruments being developed. In the present study a self completed diabetes specific questionnaire was used. This was designed for children and adolescents to complete. It allowed the children's own perspectives on their quality of life related to diabetes to be accessed.

1.5.2: Self efficacy

The theory of self efficacy was first proposed by Albert Bandura as a theoretical framework, in which the concept of self efficacy was assigned a central role, for analysing changes achieved in fearful or avoidant behaviour (Bandura, 1977). Although this was 25 years ago, the theory remains similar today to when it was first proposed. Bandura's principal assumption in his theory was psychological procedures, whatever their form, serve as a means of creating and strengthening expectations of personal efficacy. Efficacy expectations are distinguished from outcome expectations; the latter is defined as a person's estimate that a given behaviour will lead to certain outcomes, the former is the conviction that one can successfully execute the behaviour required to produce the outcomes. This distinction is seen in people who believe a particular behaviour will produce certain outcomes but doubt their own ability to perform these behaviours, thus the belief does not influence their behaviour.

People's efficacy expectations influence whether they initiate and persist with coping behaviours. Those with stronger efficacy beliefs are more likely to initiate and persist in coping behaviours than those with weak efficacy beliefs. In addition people tend to fear and avoid situations that they feel exceed their coping skills. These behaviours can affect future efficacy beliefs; by persisting in behaviours and eventually achieving the desired outcome efficacy can be reinforced, whereas by ceasing coping efforts prior to succeeding, self debilitating expectations and fears are be retained (Bandura, 1977). Bandura added that although perceived self efficacy influences behaviour in the way just described, behaviour is also determined by skills possessed and incentives. However, if a person has the appropriate skills and incentives, efficacy expectations are a major determinant of their choice of activities, how much effort they will expend, and of how long they will sustain effort in dealing with stressful situations.

Efficacy expectations, as defined by Bandura (1977) vary on three dimensions; magnitude, strength and generality. If tasks were ordered in level of difficulty high magnitude expectations would extend to the most difficult ones, whereas low magnitude expectations may only include the simpler tasks. Weak expectations are more easily extinguished by failure or disconfirming experiences than strong expectations. Generality refers to the extent to which efficacy is specific to a particular behaviour or generalised to a range of behaviours. However, no one self efficacy belief will generalise across all domains of functioning, individuals express a wide range of efficacy beliefs across a variety of domains of functioning. For example people who are confident they can exercise regularly may not be confident they can maintain a healthy diet (Maibach & Murphy, 1995). Bandura proposed four sources of efficacy expectations; performance accomplishments, vicarious experience, verbal persuasion and emotional arousal. Of these performance accomplishments are the most influential on efficacy as they are based on personal mastery experiences.

In a series of experiments Bandura provided evidence for this theory. He showed that self efficacy expectations accounted for: variation in behavioural changes produced by different modes of treatment; behavioural variations displayed by individuals receiving the same treatment; and predicted performance successes at the level of individual tasks during and after treatment. Further studies have shown that people were more influenced by how they interpreted performance successes than by performance successes per se. That is, that perceived self efficacy was a better predictor of subsequent behaviour than was performance attainment during treatment (Bandura, 1982).

The importance of self efficacy can be seen by the ways it affects human functioning. It has four main processes through which it affects functioning: choice of behaviour, effort expenditure and persistence, thought patterns, and emotional reactions (Maibach & Murphy, 1995). Some of these have been mentioned earlier when discussing Bandura's theory of self efficacy. In relation to children with Type 1 diabetes these four processes all interact with diabetes management. For example self efficacy for maintaining desired average blood glucose levels may influence the effort expenditure and persistence with which a child adheres to their treatment regimen. Similarly self efficacy in their ability to maintain blood glucose control whilst participating in certain behaviours, for example hill walking or eating out with friends, may influence their decision to participate in these or not. Further studies have confirmed that self efficacy plays a central role in behavioural interventions (Maibach and Murphy, 1995). They give two reasons for this, firstly, diverse behavioural influences (e.g. social, educational, motivational) operate, at least in part, by increasing self efficacy beliefs. Secondly, efficacy beliefs are dynamic and subject to influence in many different ways.

Maibach and Murphy (1995) go on to consider methods of assessing self efficacy and the development of scales. They conclude that there can be no single all purpose approach measure of self efficacy. Scales to measure it have to be tailored to specific domains of functioning and there are no standard sets of domain specific self efficacy items that are applicable to all people in all situations. This is because efficacy judgements are a function of both the specific behaviours and situational contexts in which they occur, and these vary from population to population. Therefore in this study a diabetes specific measure of self efficacy was used to assess self efficacy for management of Type 1 diabetes. This measure had been developed to be appropriate to children's management of their diabetes.

1.5.3: Self esteem

In 1890 James was one of the earliest writers to define the self, and as will be discussed here several of his key ideas survive as main themes of self psychology today. He distinguished between the concepts of I and Me. The Me, he defined as the 'empirical person' and the I as the 'judging thought' (James, 1890, p.371). In other words the I-self was the subjective self and the Me-self was the objective or empirical self as it was the object of the I-self's creation. This Me became known as the self concept and has received most attention in the field of self psychology (Harter, 1996). James considered that the Me-self could be subdivided into the constituents of the self as known, the three major constituents were the material self, the social self and the spiritual self. In addition James considered these dimensions had a hierarchical structure, the material self was lowest, followed by the social self with the spiritual self at the highest level.

Another idea that remains important today was of the role of pretensions. That is that people may well not be able to fulfil all the potential roles they would wish to in their life. Therefore they must decide which roles are important to them and focus on these. Being poor at something a person had no pretensions to be good at would not be detrimental to their self esteem. James suggested that self esteem represented a ratio of successes to pretensions. So if a person's perceived successes were equal to or greater than their pretensions for success they would enjoy high self esteem. In contrast if pretensions exceeded successes, so a person was unsuccessful in things they aspired to be good at, they would experience low self esteem (James, 1890).

Later authors have distinguished, within the Me-self, between self esteem and self concept. Self esteem is generally thought of as the evaluative component of the self concept (Gergen 1971). Fox distinguished between self concept and self esteem as follows: 'self concept refers to self description where individuals build up a multifaceted picture of themselves from identity statements such as 'I am female', 'I am a mother', or 'I am a provider''. 'Self esteem is concerned with the evaluative element of self concept where individuals formulate a judgement of their own worth.' (Fox, 1990, p.2). In this definition the judgement of worth is dependent on the individual's own values not moral or societal ones. So, for example, in someone who aspires to be a gang member high self esteem may come from the ability to carry out gang crimes.

Self esteem is one of the most widely used psychological constructs in both the academic literature and the media. It is often used as an indicator of mental health and many see it as the best indicator of the well being of the self system, low self regard accompanies clinical depression and high self regard is a sign of functioning well

(Fox, 1997). In these cases self esteem is seen as accompanying mental states. Theories also suggest that it is an initiator and mediator of human behaviour (Campbell, 1984), in other words we do things in order to maximise our potential to feel good about ourselves. So, self esteem can be considered to play a dual role in the understanding of human behaviour and well being.

Although James (1890) originally discussed a multidimensional self he also brought in the concept of a global, or overall, self esteem. It was this global self esteem that was initially taken up by researchers and it was not until the late 1970's and 1980's that further empirical work revealed that people, including children, do make different evaluative judgements across various domains. This led to the conclusion that the self concept is multifaceted (Harter, 1996). The general acceptance of that conclusion has been a major advancement for self esteem theory (Fox & Corbin, 1989). This does not preclude, however, the idea that a global self esteem construct exists alongside these domains.

Some of the evidence that self esteem is multidimensional was provided by Harter. She found empirical evidence that from the age of 7 to 8 years children develop domain specific evaluations of their competence or adequacy in addition to a more global concept of their self worth as a person (Harter, 1982; Harter, 1985). She then developed a Self Perception Profile for Children that incorporated the most relevant of the above domains. These were scholastic competence, athletic competence, social acceptance, physical appearance and behavioural competence. A measure of global self esteem was included too (Harter, 1985). Initial studies with the profile showed that in order to understand the relationship between the individual domains and global self esteem it was necessary to consider the importance of success in these domains (Harter, 1993). This referred back to another of James's ideas from 1890. Harter found that two children with similar scores on each of the domains might have very different global self esteem. When the importance of success in each of these domains was examined it was seen that the child with high global self esteem attributed low importance to the domains she was less competent in, whereas the child with low global self esteem attributed high importance to all the domains, i.e. those she was competent in and those she was less competent in. In general Harter found that the more importance ratings exceed perceived adequacy or competence, across all the domains, the lower one's self worth (Harter, 1993).

In addition to research into the elements of self esteem there has been interest in the organisational structure of these elements. Shavelson et al. (1976) identified seven features that were critical to their definition of the self concept construct. Among these was the fact that it was organised hierarchically. They considered that perceptions of personal behaviour in specific situations were at the base of the hierarchy, inferences about the self in broader domains, (e.g. social, physical, and academic) were in the middle of the hierarchy and a global, general, self concept was at the apex. In this model the apex of the hierarchy, global self-concept, is stable, as one descends the hierarchy self concept becomes increasingly situation specific and so less stable. Changes in self perceptions at the base of the hierarchy may be strengthened or weakened by changes at higher levels. Similarly, changes in global self concept may occur as a result of changes in situation specific instances at the base of the hierarchy, although a large number of specific instances would have to change to result in a change in global self concept.

One of the domains of self esteem which has received empirical support is the physical self. The structure of this domain has been examined with an instrument developed by Fox and Corbin (1989) to test the dimensionality and hierarchical structuring of the physical self concept. This produced empirical evidence to support the multidimensional and hierarchical nature of the physical self concept (Fox and Corbin, 1989). The importance of this domain to overall self esteem is highlighted by Fox (1997, p.112) when he says 'in Western societies at least, the body, its appearance, its capabilities and its capacity to portray messages about and on behalf of the self, has recently been thrust into greater prominence'. As this study focused on the effects of physical activity and fitness for children with Type 1 diabetes the physical self concept is of particular interest. Therefore a version of Fox and Corbin's scale, adapted for use with children (Whitehead, 1995), was used.

1.6: Analysis of physiological measures

In addition to the psychological constructs just explained the present study measures physical activity, fitness and glycated haemoglobin. This section gives brief explanations of these terms.

1.6.1: Physical activity, Exercise and Physical fitness

These are three interrelated terms, definitions as given by the Health Education Authority are as follows. Physical activity is defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure'. Exercise is a subset of physical activity, it is defined as 'planned, structured, and repetitive bodily movement done to improve or maintain physical fitness'. Physical fitness is 'a set of attributes that people have or achieve that relates to the ability to perform physical activity' (Health Education Authority, 1998, p2). Specific forms of physical activity which young people might participate in are walking, bicycling, and playing actively, i.e. unstructured activities. Sport is a subcategory of physical activity that includes 'activities that are structural, organised, rule governed, competitive and involve gross motor actions' (Armstrong and Welsman, 1997, pg 100). Forms of exercise might include participating in organised sports or dancing, and working at a job that has physical demands.

1.6.2: Glycated Haemoglobin

Glycated haemoglobin testing is a way to assess average blood glucose levels over approximately the previous three month period. It is the main clinical outcome measure of Type 1 diabetes management, and its importance in relation to long term outcomes for people with Type 1 diabetes was shown in the Diabetes Control and Complications Trial (DCCT, 1993), see section 1.2.

The blood is composed of plasma (55%) and formed elements (45%) of these formed elements 99% are red blood cells and 1% white blood cells and platelets. Each red blood cell contains approximately 250 million haemoglobin molecules (Wilmore and Costhill, 1994). Glycated haemoglobin is a term for linkages formed between haemoglobin and various sugars. The reaction between glucose and haemoglobin A (HbA) is an example of nonenzymatic glycation that is slow, continuous and irreversible (Goldstein, 1995). Red blood cells are freely permeable to glucose and therefore within each red blood cell glycated haemoglobin is formed from HbA at a rate which is proportional to the concentration of glucose circulating in the blood, the higher the concentration of glucose the more HbA that is glycated. Mature red blood cells have an average lifespan of four months, therefore the level of glycated haemoglobin that is in a blood sample provides a glycemic history of the previous four months. However, glycated haemoglobin is a weighted measure of average blood glucose, more recent past events contribute relatively more to the result than earlier events. Average blood glucose levels during the 90 to 120 days preceding the blood sampling contribute on about 10% to the final result. Therefore glycated haemoglobin is usually considered to be a measure of average blood glucose over the previous three months.

Some glycated haemoglobins have different electrical charges from HbA, they are called 'fast haemoglobins' as they migrate more quickly than HbA when placed in an electric field. The 'fast haemoglobin' that is present in the highest concentrations, and that is most important with respect to diabetes is HbA_{1c}. HbA_{1c} refers to HbA that has joined with glucose at a particular site in the molecule. It is reported as the percent HbA_{1c}, i.e. the ratio of the concentration of HbA_{1c} compared to the concentration of total haemoglobin. The proportion of total haemoglobin that is HbA_{1c} is approximately 3-6% in people without diabetes but can be 15% or more in people with poorly controlled diabetes (Goldstein, 1995). Other forms of 'fast haemoglobin' are HbA_{1a} and HbA_{1b} , together these three forms are termed HbA_1. Levels of HbA_{1c} are generally 2-3% lower than HbA_1 (Hampson et al., 2001). The various terms that are used to describe haemoglobin that has reacted with sugars are summarised in table 1.1.

Table 1.1: Glycated haemoglobin terminology.

Term	Description
HbA	The major form of unmodified haemoglobin.
GHb	A general term for glucose bound nonenzymatically to haemoglobin
HbA_1	GHb species that are more negatively charged forms of HbA. They include HbA_{1a}, HbA_{1b}, and HbA_{1c}, also called the 'fast haemoglobins'.
HbA_{1c}	A specific GHb. The form of 'fast haemoglobin' that is present in the highest concentration and which is most important in with respect to diabetes.

2

Literature Review

This literature review begins by examining studies of the psychological effects of Type 1 diabetes in children. This literature is extensive so the review is focused on studies which have examined levels of psychological well being over time or in relation to non diabetic control groups, and studies looking at associations between psychological well being and metabolic control. Self esteem, self efficacy and quality of life are particular focuses. The literature on psychological well being specifically in relation to exercise in children with Type 1 diabetes is sparse, and is reviewed together with the literature on exercise in relation to HbA_{1c}. Intervention studies in children with Type 1 diabetes are then considered. Psychosocial interventions and exercise interventions are both reviewed; there are no studies which have looked at the psychosocial outcomes of exercise interventions. Thus the literature on adults with Type 1 diabetes and non diabetic children is used to provide a context and rationale for the present study.

2.1: Psychological well being in children with Type 1 diabetes

Three large scale longitudinal studies have been conducted looking at psychological outcomes for children from the time they were diagnosed with Type 1 diabetes over a period of 2, 9 and 10 years (Jacobson et al., 1997a; Grey et al., 1995; Kovacs et al., 1990). Two of the studies included a non diabetic control group (Jacobson et al., 1997a, Grey et al., 1995).

Jacobson et al. (1997a) compared 57 children with Type 1 diabetes (aged 9 to 16 years) with a control group of 54 age matched children with an acute medical problem within one year of the start of the study. The children were assessed initially, then yearly for four years, then after 7 and 10 years. In terms of psychological adjustment there was no difference between the groups in level of psychiatric symptoms reported, the only significant differences were found on the Harter Perceived Competence Scale at 10 years follow up. The group with diabetes had significantly lower global self worth, and lower perceived competence in sociability, physical appearance, being an adequate provider and humour subscales. The lowered level of self esteem may be an early indicator of depressive symptoms in later years, particularly as global self worth was significantly lower. However, developmental changes in self esteem cannot be inferred from this study as the Coopersmith Self Esteem Inventory was used at previous assessments and differences between the groups may have been present but not picked up by the alternative measure.

Several other factors were investigated by Jacobson et al. (1997b). Adjustment to diabetes improved over time. Social relationships were assessed, specifically relationship patterns, close relationships and loneliness were measured using self report measures. The participants with diabetes reported fewer friends overall but the groups were similar with regard to the number of close, intimate friends and romantic partners. However, some between group differences were found, the group with Type 1 diabetes experienced significantly less trust and overall sense of closeness in their social relationships. This may reflect the finding from Harter's questionnaire that this group had lower perceived competence in social relationships. On the other measures, however, the study found that children, adolescents and young adults who develop diabetes between 9 and 16 years have similar patterns of psychological and social development to people without chronic illness.

A similar, but shorter, study was carried out by Grey et al. (1995). They followed 89 children with Type 1 diabetes, aged 8 to 16 years, over the first two years since diagnosis, and 53 of their peers without diabetes over the same time period. Psychological well being was assessed using the Child and Adolescent Adjustment Profile, the Self Perception Profile for Children, the State-Trait Anxiety Inventory for Children, the Children's Depression Inventory and the Current Health Scale (completed by parents). Two years post diagnosis there were no significant differences between the groups or changes over time in perceived competence or anxiety. This is in line with Jacobson et al.'s studies (1997a; 1997b). In Grey's study the group with diabetes did have significantly greater depression scores two years post diagnosis and greater dependency and withdrawal on the Child and Adolescent Adjustment Profile. As the Self Perception profile was the only common measurement tool between Grey and Jacobson's studies it is not possible to compare the results for the other variables. It may be that there were subtle differences in the psychological well being of children with Type 1 diabetes compared to their non diabetic peers that the psychiatric screening measures used by Jacobson et al. (1997a) at two years post diagnosis did not pick up.

The third study was conducted by a group the University of Pittsburgh (Kovacs et al., 1990; Kovacs et al., 1992; Goldston et al., 1995; Kovacs et al., 1995), 95 children, aged 8 to 13 years, newly diagnosed with Type 1 diabetes were followed for up to 9 years. Children were aged between 8 and 13 years at recruitment. Children were initially assessed 2 to 3 weeks after discharge from hospital and 3 to 4 times in the first year after diagnosis, in subsequent years assessments were less frequent, between 1 and 3 per year. At each assessment a research clinician interviewed the child and at least one parent about their lives, the child's psychiatric symptoms and diabetes care. A diagnosis of non compliance with medical treatment was given if the child showed serious and persistent negligence in at least two areas of diabetic management. HbA_1 values were recorded as a measure of metabolic control. Children also completed four inventories; the children's depression inventory, the revised children's manifest anxiety scale, the Coopersmith self esteem inventory and the issues in coping with Insulin Dependent Diabetes Mellitus-child version scale.

Children's ratings of depression, anxiety and self esteem revealed that they did not perceive themselves as having any problems. Initially children reported problems after diagnosis but these had decreased to normal levels after 10 months. Psychological ratings over the first 6 years from diagnosis with diabetes were examined, they showed levels of depression, anxiety and self esteem initially after diagnosis were strong predictors of later levels. Additionally, as disease duration increased girls reported somewhat increased anxiety, whereas boys' anxiety decreased. Self esteem scores were high throughout the study and were not affected by negative medical events such as rehospitalization and poor metabolic control. Children found diabetes management tasks harder to do the longer they had had diabetes. Children who reported more depression and anxiety reported diabetes management to be harder (Kovacs et al., 1990).

When more severe psychological disorders were examined a similar pattern was found: those who initially showed more psychological problems following diagnosis with diabetes also had more difficulties later (Kovacs et al. 1995). Adjustment disorders were most common straight after diabetes onset but all children recovered from these initial diagnoses. However, over a five year period from diabetes onset 27% of the participants had a new episode of a specific psychiatric disorder, most commonly major depression (10%) and conduct disorder (7%). Those children who had developed adjustment disorder following diagnosis were at greater risk of developing psychiatric disorders.

Noncompliance with diabetes care was associated with both greater risk for rehospitalization and poorer metabolic control. Participants had a 45% chance of developing noncompliance at some point over the 9 year study period. Adolescence was a high risk period for it developing. Noncompliance was therefore shown to have negative consequences and to be fairly common. There were no significant relationships between social competence at onset of diabetes, self esteem, initial family functioning, psychiatric disorder at diabetes onset and non compliance. Self esteem did show a non significant trend, indicating that higher self esteem may facilitate compliant behaviours (Kovacs et al., 1992). Further analyses with this cohort found that youths who experienced high stress were at greater risk for serious non-compliance which can in turn lead to a worsening of diabetic control (Goldston et al., 1995). Higher impact of life event was also found to be significantly associated with higher HbA_1.

In summary these studies suggest that young people with Type 1 diabetes have largely similar psychosocial development to their healthy peers but at the same time are at greater risk for psychiatric disorders. The different study designs and measurement instruments used make it difficult to synthesise these findings. It is likely that children's response to diabetes is not uniform and some experience more psychological problems than others.

Qualitative methods take a more in-depth approach than the quantitative ones in the studies reviewed so far, and so are able to pick up these individual differences. They may help to clarify whether some children with Type 1 diabetes experience psychological problems that were not detected by the methods that have been described.

Two such studies that were carried out in the UK are discussed here. Both used semi-structured interviews alongside quantitative measurements. Lloyd et al. (1992) studied the education and employment experiences of 40 young adults (aged 16 to 25) with Type 1 diabetes and 40 age and sex matched controls. Details of educational qualifications and an employment record were also obtained. The two groups showed no differences in level, type or number of qualifications obtained or in employment experiences. However, 61% of those who had had diabetes while at school reported that they had experienced problems in relation to their disease. These were in relation to physical education, perceived change in attitudes towards them, and lack of understanding by teachers or other pupils. The group with diabetes were also significantly less likely to feel competent with regard to their educational performance compared to controls. Both these factors were associated with educational achievement. Those who felt less competent were significantly less likely to have obtained examinations at 18 years than those who felt more competent, and only one of those who experienced problems at school obtained any further or higher qualifications. Although this study was on a slightly older age range and educational experiences were reported retrospectively, which may affect their validity, it showed that older adolescents with Type 1 diabetes had lowered self esteem compared to their non diabetic peers, supporting the findings of Jacobson et al. (1997a). The fact that this has been found using both quantitative and qualitative methodologies shows convergent evidence and gives more validity to the finding.

The second study examined emotional and behavioural difficulties in 21 children, aged 6 to 16 years, with Type 1 diabetes compared to their siblings and peers (Gardner, 1998). Parents and teachers completed Conners rating scales, which assess behaviour. Parents of children with diabetes rated their children with diabetes significantly higher than their healthy siblings for 5 subscales, conduct disorder, anxious shy, restless/disorganised, psychosomatic and hyperactive/immature. No significant difference was found when parents' ratings for children with diabetes were compared with parents' ratings for non diabetic peers of these children. Teachers ratings showed much less difference, the only significant effect was on the hyperactivity/immature scales on which children with diabetes were rated higher than their peers but not their siblings. The differences in behaviour reported by parents between children with diabetes and their siblings suggest this is an important area to address. However, it may be that parents have a perceptual bias and tend to overestimate the problems of their child with diabetes relative to a well sibling. Semi-structured interviews focusing on whether the children experienced difficulties in their life and the degree to which these were related to diabetes suggested that more of the children with diabetes and their siblings experienced problems in their lives than their healthy peers and that these problems were commonly diabetes related. Problems mentioned touched on themes of identity, autonomy and family stress. The data from parents and teachers were different from those previously described as they were not the children's own self reports. They suggest children with diabetes may show more behavioural problems at home than their siblings. Thus overall there are indications from a number of studies of a greater than average amount of psychological morbidity associated with having Type 1 diabetes.

The review now turns to other research that has investigated associations between metabolic control, diabetes regimen adherence and self efficacy, quality of life and self esteem.

Self efficacy

Both general self efficacy and self efficacy related to the diabetes regimen have been investigated in children and adolescents with Type 1 diabetes. Given the nature of the self care regimen in diabetes, it would seem reasonable to suggest that belief in one's ability to carry out self care tasks i.e. self efficacy for diabetes, would be important for adherence to this regimen.

Havermans and Eiser (1991) compared health efficacy and health locus of control in a group of 61 children with Type 1 diabetes and 85 non diabetic children, mean age was 11.50 and 11.57 years respectively. Non diabetic children obtained higher self efficacy scores on the personal responsibility sub-scale than those with diabetes, suggesting they have stronger beliefs in their own ability to carry out self care tasks. This may reflect the greater complexity which having diabetes brings to general self care tasks. In terms of locus of control children with diabetes expressed less reliance on powerful others but firmer beliefs in personal control with no differences on belief in chance compared with healthy children. Young non diabetic children expressed most beliefs in powerful others and older diabetic children the least. This suggests that as children with diabetes get older they believe that they have more control over their own health compared to non diabetic children, again possibly due to having to manage their diabetes.

Other studies have investigated diabetes specific self efficacy. Griva et al. (2000), looked at the role of self efficacy and illness perceptions in metabolic control and diabetic regimen adherence in 64 patients aged 15 to 25 with Type 1 diabetes. Measures were: illness perceptions, a generalised and a diabetes specific self efficacy scale, and a self report measure of adherence. Higher diabetes specific self efficacy was significantly associated with higher generalised self efficacy, fewer perceived consequences and more perceived control of diabetes. Generalised self efficacy, but not diabetes specific self efficacy, differed between patients who reported good and poor adherence to exercise recommendations. Two multiple regression analyses were conducted, one to find the variables which best account for adherence and the other to find the variables which best account for HbA_{1c}. In the first analysis only perceived control contributed significantly to the equation, accounting for 39% of the variance in adherence. Four variables contributed significantly to HbA_{1c}, diabetes self efficacy contributed the most (29.9% of the variance) followed by perceived consequences of diabetes, identity beliefs and lastly generalised self efficacy. Thus the link between self efficacy and metabolic control was stronger than the link between self efficacy and adherence. Griva et al. (2000) suggested that self efficacy beliefs may affect metabolic control directly through the physiological effects of stress or anxiety.

An earlier study by Littlefield et al. (1992) also looked at factors, including self efficacy, in relation to adherence in 193 children aged 13 to 18 with Type 1 diabetes. The measures used were different to those of Griva et al. (2000), they developed adherence and diabetes self efficacy scales for the study. The Rosenberg self esteem questionnaire, Children's Depression Inventory and a question on eating binges were also used. Correlations between the variables found lower self efficacy was significantly associated with more depression and lower self esteem, suggesting these factors may be related. A multiple regression analysis found self efficacy, depression and bingeing behaviour contributed significantly to adherence (self esteem was left out due to its high correlation with depression). Self efficacy contributed the largest proportion of variance in adherence, 20%. HbA_{1c} was not used as the outcome of a regression analysis but higher adherence was significantly associated with lower HbA_{1c}. This contrasts with Griva's study that found only perceived control over diabetes significantly contributed significantly to the variance in adherence. It seems likely that this is due to the different scales used to measure self efficacy and adherence. Griva's study looked specifically at intentional non adherence, i.e. choosing not to follow their diabetes regimen as opposed to forgetting to follow it, or remembering it wrongly. These two studies are cross sectional so causality cannot be inferred but both show diabetes related self efficacy is related to metabolic control in children and young people with Type 1 diabetes, either directly or through treatment regimen adherence. Longitudinal studies are needed to investigate the causality of this relationship, which may well be bi-directional.

Given that self efficacy is now known to be a strong predictor of children's adherence to medical treatments for chronic illnesses, including diabetes, Ott et al. (2000) moved one stage beyond the above studies to look at the process of enhancing self efficacy for treatment adherence. They examined two processes by which self efficacy may influence adherence; mastery experience and social persuasion. The first was defined as the child's personal responsibility for their diabetes treatment, by administering treatment children would be expected to learn that self management can be attained and so develop self mastery and self efficacy. The second, social persuasion, was defined by parental support and encouragement for adherence. One hundred and sixty one families with children aged 11 to 18 years participated. They completed a range of self report questionnaires. In general the children reported, and were reported by their parents, to be fairly adherent to their diabetes treatment regimen. They reported exercising for at least 20 minutes a day on an average of 5.2 days a week (how exercise was defined is not reported). Older children in the study reported higher self efficacy for diabetes and that they assumed more responsibility for their treatment and received less parental supportive behaviours. Again higher self efficacy for diabetes was significantly associated with greater reported adherence to diabetes treatment and also to assuming more responsibility for treatment. Self efficacy was found to be a mediator for mastery experience but not for social persuasion. That is the relation between assuming personal responsibility for treatment and children's adherence to treatment was explained by perceived self efficacy. Perceived self efficacy was a better predictor of adherence than ability to carry out management tasks. Therefore understanding how to increase perceived self efficacy could have implications for adherence.

Following the DCCT it is acknowledged that for people with Type 1 diabetes maintaining good metabolic control prevents or delays onset of secondary complications associated with diabetes and is therefore a very important outcome. However psychological well being is also an important outcome in its own right, as described in the section on the wellness model. A number of studies have examined whether metabolic control and psychological well being are related or independent outcomes. This has implications for treatment and interventions. The studies described above have shown an association between self efficacy for diabetes and metabolic control. That is a fairly specific aspect of psychological well being which is quite focussed perceived ability to perform tasks of diabetes management. Quality of life is a broader measure of self reported well being as is global self esteem.

Quality of life

Grey et al. (1998a) assessed a range of psychological variables and HbA_{1c} in 52 adolescents aged 13 to 20 years, diagnosed with Type 1 diabetes for at least one year, at the start of an intervention, which is described later. HbA_{1c} was not significantly associated with quality of life for diabetes, depression, self efficacy for diabetes, coping, family behaviours or family adaptability and cohesion. The finding that self efficacy for diabetes was not associated with HbA_{1c} was in contrast to the studies described previously. This reflect a difference in this sample. The lack of associations between HbA_{1c} and all the psychological variables measured suggests low HbA_{1c} by itself does not indicate treatment success for adolescents with Type 1 diabetes and psychological variables should be considered separately. There were significant associations between the psychological variables. Multiple regression analyses were carried out to find the impact of variables on quality of life, (quality of life was divided into three sub-scales; impact of diabetes, satisfaction with life and worry about diabetes) Depression was the most consistent variable associated with quality of life. Analyses were carried out separately for the three quality of life sub-scales. Depression and the degree of upset with coping with diabetes accounted for 48% of the variance in the impact of diabetes, depression and self efficacy accounted for 45%

of the variance in satisfaction with life, and depression and rebellious coping strategies accounted for 43% of the variance in worry about diabetes.

Ingersoll and Marrero (1991) also found no association between the Diabetes Quality of Life Measure for Youths and HbA_{1c} with a sample of 74 children and adolescents, aged 10 to 21 years, with Type 1 diabetes. However, better self rated health (using a single item measure) was significantly associated with lower HbA_{1c} values.

In contrast to these findings Guttmann Bauman et al. (1998) found that HbA_{1c} was significantly associated with quality of life, assessed using the same instrument as Grey et al. (1998a) and Ingersoll and Marrero (1991). Their sample consisted of 69 patients with Type 1 diabetes, aged 10 to 20 years, diagnosed with diabetes for at least one year. HbA_{1c} was assessed using the value taken at the time the questionnaire was completed and the mean value over the preceding 12 months. Number of acute events, defined as visits to A&E or hospital admissions was also used as a measure of metabolic control. All three measures of metabolic control were significantly correlated with total score on the diabetes quality of life scale, mean HbA_{1c} over the past year was most strongly correlated. Mean HbA_{1c} was also significantly correlated with the satisfaction with life and impact of diabetes but not with reported worries about diabetes. Number of acute events was significantly correlated with worries about diabetes. A difference between Bauman's study and those reported above is that HbA_{1c} over the previous year is used. As the quality of life instrument does not specify a time frame it may be that people respond to it to indicate their quality of life over the previous 12 months or longer.

A study by Hoey et al. (2001) aimed to clarify these contrasting findings, 2101 children, with Type 1 diabetes, aged 10 to 18, from Europe, North America and Japan participated. Time since diagnosis with diabetes was not specified. HbA_{1c} was measured and children completed the Diabetes Quality of Life for Youths scale. Higher HbA_{1c} was significantly associated with greater impact of diabetes, more worries about diabetes and less satisfaction with life and lower overall health perception. This large international study had greater power than the studies by Grey et al. (1998a), Ingersoll and Marrero (1991) and Guttmann Baumann et al. (1998) and is more likely to accurately reflect the association between HbA_{1c} and quality of life in children with Type 1 diabetes. The study of Hoey et al. (2001) was cross sectional so cause and effect relations could not be determined but as both quality of life and HbA_{1c} are important outcomes for treatment it is recommended that both are assessed regularly at least until the causal relationship is known.

Self esteem

The longitudinal study by Kovacs et al. (1992) suggests high self esteem may facilitate compliance with the diabetes regimen, Jacobson et.al. (1997a) found some aspects of self esteem were lower in children with Type 1 diabetes compared to their healthy peers 10 years following diagnosis with diabetes. These studies suggest maintaining high self esteem is important for children with Type 1 diabetes. As described below it has also been closely associated with depression and other psychological variables in these children, as it is in children generally (Battle, 1987; Battle et al., 1988). Similar to quality of life, self esteem appears not to be associated with metabolic control, although it has been linked to adherence to the diabetes treatment regimen.

Lernmark et al. (1999) investigated associations between psychological functioning, metabolic control and adaptation to diabetes in 62 children aged 9 to 18 years, diagnosed with Type 1 diabetes for at least two years. They assessed depression using the Children's Depression Inventory, self esteem using a questionnaire developed in Sweden called 'I think I am', and fear using the Fear Schedule for Children. Two adaptation scales were used, one focussed on emotional adaptation and the other on more practical aspects of adaptation, these were analysed together. As in Guttmann Bauman et al.'s study (1998) average HbA_{1c} over the past year was taken as a measure of metabolic control. Low self esteem was significantly associated with both depression and fear, however only fear was significantly associated with metabolic control. There were significant associations between psychological functioning and adaptation; greater depressive symptoms, lower self esteem and more fear were associated with poorer adaptation to diabetes. Two regression analyses were conducted, the first showed adaptation was the only significant variable to predict metabolic control, when adaptation was broken down into its components only blood glucose monitoring significantly predicted HbA_{1c}, accounting for 26% of the variance. A second regression found depression and metabolic control significantly predicted adaptation, together accounting for 40% of the variance in adaptation. When the participants were split into a 'depressed' and 'non depressed' group, those with more depression also showed significantly lower self esteem, significantly worse adaptation, and significantly higher HbA_{1c}.

A further study looked at self esteem, using the Harter questionnaire, and behavioural disturbance, using the Achenbach Child Behaviour Checklist, in 91 children, aged 8 to 15, with Type 1 diabetes (Hoare and Mann, 1994). Using Achenbach's recommended score, 65, to indicate a clinically significant problem 20% of the children were rated as withdrawn and 25% with somatic problems, 15% or fewer of the children were scored with clinically significant problems on the other subscales. A regression analysis found that duration of treatment and male gender contributed most to the variance in Achenbach scores, HbA_{1c} had no significant association. On the Harter questionnaire global self worth and appearance sub-scales showed the strongest association. The Harter and Achenbach scores were all negatively correlated, showing that the lower the child's own rating of their self esteem the more behaviourally disturbed the child was rated by their parent.

The relationship between psychological variables and HbA_{1c} was further investigated by Rothbaum et al. (1992), this study also included measures of symptom reporting. Thirty-four children aged 7 to 18 participated, duration since diagnosis with Type 1 diabetes was not specified. Children completed the Children's Depression Inventory, the Rosenberg Self Esteem Scale, a measure of mood and reported their somatic symptoms. HbA_{1c} measurements were collected, both at the time the questionnaires were completed and 3-4 months prior to this. Self esteem, depression and positive mood were not found to be related to HbA_{1c}. Negative mood and somatic symptoms were associated with HbA_{1c} at the time the questionnaire was completed but not 3 months prior to this. There were significant associations between the psychological variables; those with less depression also reported more positive self concept and a more positive mood.

Bennett-Murphy et al. (1997) looked at adherence in a slightly different way; by examining the role of cognitive appraisals in predicting adherence behaviour. They were interested in explaining the variability in health and psychological outcomes among people with a chronic illness. The study used the transactional stress and coping model, which views the presence of an illness as a potential stressor to which the adolescent and family system must adapt. The measure of adherence behaviour used was checking blood sugar. The role of primary stress appraisals, and secondary appraisals including attributional style, self esteem and locus of control were examined in relation to checking blood sugar. Forty children aged 12 to 18 participated, all had been diagnosed with Type 1 diabetes for at least 6 months. Hierarchical multiple regression conducted with adherence behaviour as the dependent variable found demographic variables and family functioning accounted for 44% of the variability in adherence. When appraisal processes were included self esteem related to physical appearance entered the model first, accounting for 16% of the variability in adherence behaviour, perceived control when ill accounted for 10% of variance and attributional style for negative events accounted for 6% of variance. Therefore cognitive appraisals accounted for variability in adherence behaviour beyond that explained by demographic and family functioning variables and secondary appraisals about self appeared to be more critical for good adherence than did stress appraisals about diabetes management. This suggests perceived physical appearance may have consequences for adherence in children with Type 1 diabetes, although causality cannot be assumed and it may be that adherence leads to better perceived physical appearance. The study did not include a measure of metabolic control. It is interesting to note that the perceived physical appearance subscale of Harter's Self Perception scale was one of the sub-domains found to be rated lower by young people with Type 1 diabetes than a healthy control group 10 years after diagnosis with diabetes (Jacobson et al., 1997a).

A study by Hanson et al. (1987) investigated whether the link between metabolic control and stress is direct or indirect and whether this association is mediated by either self esteem or parental control with 104 adolescents, mean age 14.5, and their parents; duration since diagnosis with Type 1 diabetes was not specified. Measures used were: average of HbA_{1c} values at clinic visits during the previous year; adherence (diet, insulin adjustment, hypoglycaemia, glucose testing and foot care); adolescent-family inventory of life events and changes to assess stress; perceived competence scale for children which assesses four domains (cognitive, social, physical and general self esteem) and the social competence scale of the Child

Behaviour Checklist; and diabetes family behaviour checklist to assess parental support. A multiple regression analysis found both stress and regimen adherence had a direct significant association with metabolic control. A further multiple regression analysis found that the negative association between stress and metabolic control was significantly buffered by self esteem. Adolescents under high stress with low self esteem had relatively poor metabolic control, whereas high levels of stress were not linked with poor metabolic control in adolescents with high self esteem. Parental support was not associated with HbA_{1c} directly or by buffering the effect of stress. Self esteem was also significantly correlated with adherence. This study suggests the importance of self esteem to metabolic control and regimen adherence and suggests a mechanism through which this association may occur.

Summary

This section examined associations between metabolic control, self efficacy, self esteem and quality of life. Self efficacy was found to be associated with both HbA_{1c} and adherence to diabetes management. There are contrasting data as to whether HbA_{1c} is associated with quality of life, however, the strongest evidence found that greater quality of life was significantly associated with lower HbA_{1c} (Hoey et al., 2001). As in children generally, significant associations were found between self esteem and depression. Self esteem was associated with adherence to diabetes management although there were contrasting data on the association between HbA_{1c} and self esteem. This review now turns to the relationship of exercise to metabolic control.

2.2: Exercise in children with Type 1 diabetes and its relationship with HbA_{1c}

Several studies have been reviewed which have examined the association of adherence to treatment regimen for diabetes with metabolic control and psychological variables (Griva et al., 2000; Ott et al., 2000; Bennett-Murphy et al., 1997; Littlefield et al., 1992; Hanson et al., 1987). Of these only the studies by Griva et al. and Ott et al. specified that they included exercise in their assessment of adherence.

A study which did assess physical activity relation to HbA_{1c} was conducted by Hanson et al. (1996) with 256 youths aged 4 to 20 years diagnosed with Type 1 diabetes for >10 months. HbA_{1c}, physical activity, diet and a self care adherence interview were recorded three times during one year. The self care adherence interview included items on general dietary behaviours, insulin adjustment, glucose testing and hypoglycaemia preparedness. Physical activity was assessed using the 7 day physical activity recall interview and a 3 day physical activity log, diet was assessed using a 24 hour dietary recall and a 3 day dietary log. Partial correlation coefficients, controlling for age and disease duration found the Self Care Adherence Interview was significantly related to HbA_{1c} at all three time periods. Nutritional quality of the overall diet was significantly associated with glycaemic control at two time points. Physical activity was not associated significantly with glycaemic control at any time point.

Bennett Johnson et al. (1986) developed a 24 hour recall interview about diabetes management behaviour, including exercise, using 168 patient aged 6 to 19 years, diabetes duration more than 1 year, and their parents. Participants and one parent were interviewed three times over a two week period. Factor analysis of the responses grouped the 13 adherence measures into 5 independent factors: exercise, injection, diet type, testing/eating frequency and diet amount. This suggested compliance with recommended treatment was not a general characteristic and patients may be adherent in one aspect but not in others. The exercise factor included exercise duration, type and frequency. The mean number of minutes of physical activity reported per day was 21. Analysis by age and gender showed older girls spent significantly less time exercising than the rest of the sample. The 16-19 year olds exercised significantly less frequently than 6-12 year olds, 13-15 year olds also exercised less frequently than the 6-12 year olds, but not significantly so. The oldest age group also engaged in the least strenuous exercise. These patterns of physical activity were similar to those of children and young people in the general population (Health Education Authority, 1998).

In a further study, using the same 24 hour recall interview Bennett Johnson et al. (1990) investigated whether adherence to the diabetes regimen was associated with metabolic control. There were 78 patient-parent pairs and interviews were conducted

3 times over a 3 month period. At the beginning and end of this period HbA_{1c} and glycosylated serum protein, a measure of blood glucose levels over the preceding one to two weeks, were measured. Multiple regression techniques were used to assess adherence- metabolic control relationships. Calories consumed was the only adherence measure that showed any predictive power for HbA_{1c} or glycosylated serum protein.

Loman and Galgani (1996) measured the habitual physical activity level of adolescents with Type 1 diabetes and looked at whether this was associated with HbA_{1c}. They used a convenience sample of 30 adolescents aged 12-17 years, diagnosed with diabetes for at least one year. Physical activity was assessed using the 7 Day Physical Activity Recall. Twenty percent of the sample reported moderate activity for 30 minutes or more daily and 10% reported engaging in vigorous activity for at least 20 minutes three times a week. Overall the sample reported participating in moderate physical activity for an average of 5.75 hours a week and vigorous physical activity for 0.83 hours a week. These levels were about half those reported in a large U.S. study of physical activity (Ross and Gilbert, 1985). This may be related to the children having diabetes, or may be due to the small sample size and the population sampled. The sample was divided into adolescents who were consistently active and those that were not, based on the 7 day recall data, there was no significant difference in HbA_{1c} values for these two groups. However, it is not reported when the HbA_{1c} values were taken in relation to the physical activity assessment or whether there was any association when correlation analyses were conducted for the whole sample.

Thus in summary the few studies that have looked at this area have found no association between habitual physical activity or exercise habits and metabolic control. These studies have all assessed physical activity using self report measures of physical activity assessment. These are practical for large scale studies but have been shown to be less valid than physiological measurements or observation (Armstrong and Welsman, 1997). However, no one method of physical activity assessment has been shown to be completely valid and reliable (the different methods of physical activity assessment are discussed further in chapter 3). Therefore the lack of an association may be due to inaccuracies in assessment of physical activity. If an alternative method of physical activity monitoring, or a combination of several methods as recommended by Armstrong and Welsman (1997) was used it may produce a different finding. These studies that have assessed physical activity or exercise were carried out in the USA. The author could trace no study that assessed the physical activity levels of children with Type 1 diabetes in the UK.

Some information on the physical activity of children in the general population is available for the UK. The Health Education Authority's review concluded 'most young people accumulate 30 minutes or more of moderate intensity physical activity on most days of the week. Some young people are very active whereas others are inactive, boys are more active than girls from an early age, and both boys and girls reduce their physical activity as they mature' (Health Education Authority, 1998, pg 5). An analysis of heart rate monitoring of 743 British children over three twelve hour periods found most accumulate at least 30 minutes of moderate intensity physical activity every day but that significant numbers seldom experience 10 minutes or longer of sustained moderate intensity physical activity (Armstrong and Welsman, 1997). Atkins (1998) found a similar pattern for 51 Liverpool schoolchildren aged 9 to 13 years. He reported a mean of 56 minutes per day of moderate intensity physical activity (above 139 beats per minute) but that very few of these children achieved 10 minutes or longer of sustained activity at this level.

Following the above review the Health Education Authority produced recommendations for children's physical activity participation (Health Education Authority, 1998). These were firstly, that all young people should participate in physical activity of at least moderate intensity for one hour a day, those who currently do little activity should participate in physical activity of at least moderate intensity for at least half an hour per day. Secondly, it was recommended that at least twice a week some of these activities should help to enhance muscular strength, flexibility and bone health. This document is targeted at young people in general, however, as little research has investigated the effects of habitual physical activity for young people with Type 1 diabetes there are no physical activity guidelines specifically for this group. It may be that these guidelines are also appropriate for children and young people with Type 1 diabetes, but there are a number of factors (e.g. the effects of physical activity on blood glucose levels and the increased risk for cardiovascular disease) which mean further research specific to this group should be conducted.

2.3: Long term outcomes of physical activity in people with Type 1 diabetes

LaPorte et al. (1986) conducted a survey to evaluate the relationship of physical activity to severe retinopathy, macrovascular disease and mortality, using 671 participants, average age 29 years, from the longitudinal Pittsburgh Insulin Dependent Diabetes Mellitus Morbidity and Mortality Study. Physical activity was assessed using the Harvard Alumni survey of physical activity, and recall of participation in team sports during high school or college. Participation in school sports was not significantly associated with severe retinopathy. Participation in school sports was, however, negatively associated with macrovascular disease among men, but not women. Mortality figures showed that 25 years after diagnosis with diabetes men who had not participated in school sports were more likely to die than those who had participated, but this was not statistically significant. A difficulty with this study was that it was retrospective so it is hard to determine whether only healthy individuals become active or whether activity makes people healthier. However the same pattern of associations was present when data were analysed for individuals whose severe complications developed after the age of 20 years, suggesting that the choice of participation in physical activity occurred before the onset of diabetes complications. The sex difference, that physical activity was beneficial for men but not women may be due to the low number of women who participated in team sports when this sample was at high school. The findings may well be different if the same study was repeated today. There was no evidence that physical activity participation was associated with long term risk of microvascular disease, macrovascular disease or death.

Kriska et al. (1991) conducted further analyses on the same sample as above, clinicians assessments of retinopathy, neuropathy and nephropathy were included rather than self report as well as measures of glycosylated haemoglobin. Typical of the general population, leisure physical activity declined with age and was greater in males than females. Higher current levels of physical activity were associated with reduced occurrence of diabetic complications. It is possible that the associations reflected the fact that those with complications were limited in the amount of exercise they could do, however, logistic regression models showed physical activity in the school years was significantly associated with nephropathy and neuropathy but not retinopathy when controlling for disease duration. This suggests that physical activity may play a protective role in the development of some complications related to diabetes.

The same group of individuals were followed prospectively for a further 6 years after the assessments already discussed. During the follow up period 54 individuals had died, an 11-fold excess compared to the general population. Participation in team sports at school was not significantly related to mortality risk for males or females. There was, however, a strong inverse relation between reported kilocalorie expenditure in 1981 and mortality. When those in the lowest quintile of physical activity were compared to those in the highest quintile there was a 6-fold increase in mortality in males and a 4-fold increase in females. This association remained significant in both males and females, although less strongly in females, when the confounding effects of other mortality risk factors were removed. The optimal 'protection' against death was associated with activity levels above 2000 kcal energy expenditure per week. Physical activity in 158 of the individuals with Type 1 diabetes was compared with one of their siblings without diabetes. Individuals with diabetes were as active as their healthy siblings, when those who reported limitations due to diabetes complications were removed (Moy et al., 1993) Again, these are associations and do not necessarily imply causation.

This longitudinal study provided data that higher levels of physical activity in childhood are associated with reduced risk for complications related to diabetes and mortality risk factors later in life. Mortality was also associated with physical activity level six years previously. However it was not possible to infer causation from the data as no intervention was applied.

2.4: Psychosocial intervention studies

As the above relationships between psychological variables, metabolic control and adherence were identified during cross sectional studies causality cannot be inferred. A number of intervention studies have been carried out to investigate methods of improving psychological well-being, metabolic control and causal relationships

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between variables. The intervention methods that have been examined are wide ranging, as are the outcome measures used.

A systematic review of educational and psychosocial interventions for adolescents with Type 1 diabetes was recently published (Hampson et al., 2001). Inclusion criteria for this review were that: the paper referred to Type 1 diabetes; the age range of the participants was between 9 and 21 years; and that there was a psychosocial or educational intervention, or discussion of such an intervention. They found considerable gaps in the current literature about educational and psychosocial interventions in young people with Type 1 diabetes. Low sample size was one problem although this is difficult to overcome, except with multicentre trials, due to the prevalence of the disease. The nature of the interventions that have been studied was varied but it is noticeable that the number of interventions that used exercise was low. Similarly the outcome measures used to assess these interventions were varied, glycated haemoglobin was most common, followed by psychosocial measures. A range of psychological questionnaires have been used, which alongside the range of interventions, made it difficult to directly compare the effects of different interventions. Self management behaviours have not commonly been assessed. However, as a link between adherence to diabetes management and HbA_{1c} has been shown cross-sectionally (Littlefield et al., 1992; Hanson et al., 1987) this is an important area of investigation.

In their review Hampson et al. (2001) used effect sizes to allow the effects from several studies which used different measurement units of the same outcome to be combined. They noted that the method has limitations due to the differences among the studies being combined, and therefore recommended that the results should be treated with caution. Effect sizes were only calculated for the studies with the most rigorous design, RCTs with a randomised control group, of which there were 16. The mean effect size for glycated haemoglobin outcomes was 0.33, and median effect size 0.18, these represent changes in HbA_{1c} of 0.6 and 0.3% respectively. The mean effect size for psychosocial outcomes was 0.37, median 0.36. These are both considered small to medium effect sizes by the convention adopted in the behavioural sciences (Cohen, 1988).

One meta analysis and one review of psychological and psychosocial interventions for children with chronic health conditions have been published (Kibby et al., 1998; Bauman et al., 1997), however they do not focus specifically on children with Type 1 diabetes. Kibby et al. looked at intervention studies between 1990 and 1997 which had investigated the effectiveness of psychological interventions with chronically ill children up to 18 years old. Seven of the 42 studies included focussed on children with Type 1 diabetes. Overall the meta-analysis found that psychological interventions were effective with an effect size of 1.12 as well as maintenance of treatment gains for at least 12 months post-treatment. Bauman et al. (1997) reviewed psychosocial interventions for children with chronic health conditions between 1979 and 1993. Fifteen studies fitted their eligibility criteria, of these none focussed specifically on Type 1 diabetes. This may be due to one of the eligibility criteria being that sample size was a minimum of 15 in both the experimental group and a comparison group, many intervention studies for children with diabetes have smaller sample sizes than this. Effect sizes were not calculated but the overall conclusion was that 'when examined against conventional scientific criteria, there was reasonably convincing evidence of efficacy in 10 of the 15 studies included in the final review' (Bauman et al., 1997, p 249).

A study by Satin et al. (1989) which used a multi-family group intervention and parent simulation of diabetes was found to have a larger effect size for GHb than any of the other studies reviewed by Hampson et al. (2001). The study included 32 adolescents with Type 1 diabetes, mean age 14.6 years. They were divided into three groups, a multi-family group who received 6 weekly sessions to discuss diabetes management and attitudes towards diabetes. A second group who received this plus parent simulation of diabetes using saline injections and a management regimen, 'taught' by the adolescents. The third was a control group who received standard care. Three months after the intervention HbA_1 values for adolescents in the parent simulation group had significantly decreased compared to the other two groups ($p < 0.05$). Six months after the intervention there was no significant difference in HbA_1 values between the three groups, although those who undertook the parent simulation with smaller group sessions did still have significantly lowered HbA_1. It is surprising, given the effectiveness that this intervention showed after three months, that further similar studies have not been reported.

The only intervention study included in the review by Hampson et al. (2001) for which positive effect sizes were calculated for both GHb and psychosocial outcomes, i.e. GHb decreased and psychosocial outcomes improved, was one carried out by Grey et al. (2000; 1999; 1998b). This was a prospective randomised controlled trial with 77 children aged 12 to 20 diagnosed with diabetes for more than one year, to examine whether a behavioural programme of coping skills training in combination with intensive diabetes management leads to improved metabolic control and psychosocial outcomes. Both groups received intensive diabetes management during the 12 month study and in addition coping skills training was given to the experimental group. This involved role-playing various social situations, emphasising social problem solving, social skills training, cognitive behaviour modification and conflict resolution. HbA_{1c} was significantly lower in the group receiving cognitive skills therapy compared to the control group after 3 months, this difference was maintained at 6 and 12 months. The cooping skills training group also had significantly greater increases in diabetes self efficacy and medical self efficacy than the control group at 12 months and reported significantly less negative impact on quality of life at 3, 6 and 12 months. Results suggest that cognitive skills training is beneficial for HbA_{1c}, self efficacy and quality of life and that this beneficial effect increases over time. Grey et al. (2000) suggest this shows the importance of teaching adolescents the skills to manage their own lives as well as those to manage their diabetes and its treatment.

A behavioural intervention similar to that of Grey et al. (2000; 1999; 1998b) was conducted by Mendez and Belendez (1997) to increase treatment adherence and improve stress management in 37 children aged 11 to 18 with Type 1 diabetes. The study design was not as strong as that of Grey, sample size was smaller, the control group was not randomly assigned, and there were no criteria for duration since diagnosis with diabetes. Severity of daily hassles and social skills uneasiness decreased significantly after the 12 week intervention and had decreased further at follow up 13 months later. Response likelihood in social interaction relating to diabetes increased straight after the intervention, but this was not maintained at follow up. Metabolic control was no different immediately following the intervention or at follow up. The difference from the significant reduction in HbA_{1c} found by Grey et al.

may well be because Mendez and Belendez used average of two weeks' blood glucose tests rather than HbA_{1c}, which is a more accurate measure of overall metabolic control. Self reported exercise did not increase following the intervention even though the reported frequency of adherence barriers to exercise decreased. However, it was not reported that exercise participation was a main component of the intervention and it would be expected that an intervention that focussed on this aspect of management would have more effect on it as an outcome. It is difficult to compare the findings of Mendez and Belendez and Grey et al.'s studies further as they used different outcome measures. Hampson et al. (2001) found this was a problem generally in the literature surrounding psychosocial interventions for adolescents with Type 1 diabetes.

In summary there are few quality studies of psychosocial interventions for children with Type 1 diabetes. It is difficult to synthesise the findings of those that have been conducted as they use different outcome measures. However, there is some evidence that psychosocial interventions are effective at reducing HbA_{1c} and improving psychological well being in children with Type 1 diabetes. This review now examines exercise intervention studies in children with Type 1 diabetes.

2.5: Exercise intervention studies

Studies for children with Type 1 diabetes that have focussed on exercise participation have generally asked the children to participate in an exercise programme over a period of weeks, the duration, intensity and setting of these interventions vary. Hampson et al. (2001) identified five educational or psychosocial interventions which included some mention of exercise, in each of these studies exercise was included in relation to educational outcome measures rather than psychosocial outcomes. Other exercise intervention studies have been carried out which do not include educational or psychosocial aspects.

The majority of these studies were based in laboratories and so would be difficult to implement on a large scale but one study was reported which used a home based exercise intervention (Marrero et al., 1988). In this 10 children aged 12 to 14 years, duration of diabetes 1-11 years, who did not previously participate in exercise were included. These children had one group session where they were taught the objectives of aerobic exercise and how to adjust insulin and diet to compensate for exercise. Peak VO_2 was determined using a cycle ergometer. They also learnt an exercise routine in two sessions which they were then given on a videocassette and were asked to do a 45 minute workout at least 3 times a week for twelve weeks. At the end of the 12 weeks HbA_1 values were significantly decreased and peak VO_2 values were significantly increased, 7 of them by more than 5% which was the threshold criterion set for improvement. Fitness of these children was initially well below the average range for this age group. These findings are very encouraging both because they suggest that participating in increased exercise over a 12 week period can decrease HbA_1 and increase peak VO_2, and because this is achieved using a home based relatively low cost intervention. However, this is a small study with a pre-post test design so the findings must be interpreted cautiously. An increase in fitness has been found consistently in similar studies but improved metabolic control has not.

The earliest reported studies of exercise intervention in children and adolescents with Type 1 diabetes were conducted in the 1960's by Larsson et al.. He trained 6 boys with Type 1 diabetes and 6 healthy control boys for 1 hour a week for 5 months. peak VO_2 increased in both groups, but was consistently lower for the boys with diabetes compared to the control group. Metabolic control of the boys with diabetes, assessed using glycosuria levels, was unchanged throughout the study (Larsson et al., 1964). More recent studies have used stronger methodologies, randomised controlled trials and quantified exercise programmes. However, sample sizes are still typically small, ranging from 15 to 32 participants in total.

Campaigne et al. (1984) carried out an exercise intervention study on children with Type 1 diabetes, aged 5 to 11 years, which did significantly reduce HbA_1 and increase aerobic fitness. Children were randomly allocated to experimental (n= 9) and control groups (n= 10), the experimental group participated in 30 minute activity sessions three times a week for 12 weeks, the control group did not. The sessions were designed to increase heart rate to $\geq$ 160 beats per minute, and this was achieved on average for 20 minutes per session. They found peak VO_2 increased significantly in the experimental but not the control group following the intervention. Both HbA_1 and fasting blood glucose decreased significantly in the experimental group with no significant change in the control group.

Another exercise intervention study was conducted on 22 children with Type 1 diabetes, aged 9 to 15 years, mean age 11 years (Dahl-Jorgensen et al., 1980). Fourteen children participated in training for one hour, twice a week, for 5 months. Training consisted of mainly group training activities rather than intensive individual training. The remaining 8 children acted as controls and did not participate in any exercise programme. Groups were not selected randomly; only cooperative children were selected for participation in the exercise programme. HbA_1 values decreased significantly during the exercise programme in the exercise group. There was no significant change in HbA_1 in the control group. There was no significant effect for aerobic fitness, the peak VO_2 values of the exercise group did not change compared to the control group. However, peak VO_2 values were within the normal range for this age group.

A similar intervention as that of Campaigne et al. (1984) was conducted with older participants, aged 15 to 16 years (Landt et al., 1985). There were 15 participants in total, with diabetes diagnosed for more than one year. Nine participants were randomly assigned to the experimental group, they participated in 45 minute exercise sessions three times a week for 12 weeks, and 6 to the control group, they continued with their normal activity routine. As in the previous reported studies peak VO_2 increased significantly in the experimental but not the control group. The actual peak VO_2 levels reported for the whole group prior to the intervention were lower than those typical of this age group. However, in contrast to the studies by Campaigne et al. (1984) and Dahl-Jorgensen et al. (1980) there was no significant change in HbA_1 values in either the experimental or control groups. There was an increase in insulin sensitivity of the experimental group, despite no decrease in overall metabolic control. The authors speculated that exercise may improve glycaemic control provided there is additional adjustment of insulin and diet.

Another exercise intervention study compared the effect of an 8 week supervised exercise programme to being given an outline of a recommended exercise programme and instructed as to the importance of regular exercise (Stratton et al., 1987). Sixteen children aged 15 years with Type 1 diabetes, were randomly assigned to the experimental (supervised exercise) or control group (exercise recommendations). Comparisons before and after the intervention found a significant increase in fitness in the experimental but not the control group. There was no significant change in sum of skinfolds in either group. Analysis of glycaemic control found no significant change in HbA_1 in either group. The experimental group did, however, show a significant decline in glycosylated serum albumin, which is a more sensitive measure of blood glucose levels than HbA_1, changes can be seen more quickly than with HbA_1. It may be that the 8 week intervention was too short for changes in HbA_1 to be apparent.

A further study which found no significant reduction in HbA_1 following a structured exercise programme was conducted by Rowland et al. (1985). Fourteen children, aged 9 to 14, duration of diabetes 0.5 to 9.5 years, participated in 1 hour exercise sessions, 3 times a week, for 12 weeks. Exercise consisted of running and swimming with intensity monitored so that heart rate was at least 60% of heart rate reserve. Prior to the exercise programme children's parents indicated they participated in an average amount of routine physical activity. Subjects acted as their own controls in a 12 week period prior to the intervention. The exercise programme increased children's aerobic fitness, shown by average increase of 9% in peak VO_2. Pre-training values were lower than published norms for children. There were no significant changes in HbA_1. The authors did not report any assessment of psychological well being but suggested children with Type 1 diabetes may benefit from the enjoyment and improved feelings of self worth provided by participation in physical activity.

A study on older male adolescents with Type 1 diabetes, aged 17 to 19 years, diagnosed with diabetes for at least 2 years, looked at the effects of aerobic circuit exercise training on fitness, glucose regulation and lipid/cholesterol levels. Ten boys with Type 1 diabetes mean age 17.2 years, and 11 male controls without diabetes mean age 19.4 years, participated in exercise training 3 times a week for 12 weeks. In contrast to the majority of other studies reported here (Huttunen et al., 1989; Marrero et al., 1988; Landt et al., 1985) which found young people with diabetes to have lower peak VO_2 values than the general population, but similarly to Dahl-Jorgensen et al. (1980), peak VO_2 values of boys with diabetes were not significantly different from those of the control participants before or after training. Peak VO_2 increased significantly in both groups. The control group was significantly stronger before and after training. HbA_{1c} decreased significantly. The reduction was greatest for those with initially poorer control and blood lipid profiles improved in participants with Type 1 diabetes (Mosher et al., 1998).

None of the above studies included a control group with Type 1 diabetes that spent the equivalent amount of time participating in the study. Therefore it could be argued that when non exercising controls with Type 1 diabetes were used results were due to the increased amount of care and attention given to the experimental group rather than the content of the intervention. Huttunen et al. (1989) conducted a study to address this issue. They assigned 32 children with Type 1 diabetes, aged 8 to 16 years, to either an experimental or control group by forming age and sex matched pairs and randomly assigning one from each pair to each group. Children in the experimental group participated in exercise sessions for 45 minutes, once a week, for 13 weeks. The control group participated in an equivalent number of sessions but did activities which did not require physical effort. Peak VO_2 was assessed, as in the previous studies it increased significantly in the experimental but not the control group. Values for the whole group prior to the intervention were again low compared to children in the general population. In contrast with previous studies HbA_{1c} increased in both groups, significantly so in the experimental group. The question of whether increased attention being focussed on the experimental group caused an improvement in glycaemic control was not answered from this data. What it did suggest was that exercising once a week for 3 months was not sufficient to cause an improvement in glycaemic control.

Exercise training studies carried out on adults with Type 1 diabetes have generally found an increase in peak VO_2 but no improvement in glycaemic control over a 12 week, or longer, period (Lehmann et al., 1997; Campaigne and Gunnarsson, 1988; Wallberg-Henrikson et al., 1986; Zinman et al., 1984). One study on young adults, mean age 25 years, found a reduction in HbA_{1c} as a result of an exercise training programme (Peterson et al., 1980), levels fell by 40% during a 10 month, 3 times a week, exercise programme. However, it was not possible to determine the effect of the exercise alone in this study as training began at the same time as the participants changed their insulin dose and started self monitoring their blood glucose.

It is difficult to tease out the factors that are important to improving glycaemic control from these small studies, which are all slightly different in their methodology and outcome measures. Campaigne and Lampman (1994) reviewed exercise training studies for children and adolescents and suggested that those with poor control of diabetes prior to intervention showed greater improvement than those with fair control. She also suggested exercise interventions may be more effective at improving metabolic control in young children diagnosed with diabetes for a short duration (about 5 years). However this is contradicted by Mosher et al. (1998) who found a significant decrease in HbA_{1c} in boys aged 17 to 19, with good metabolic control. During puberty insulin sensitivity decreases disturbing blood glucose control, it may be that exercise interventions are less likely to improve metabolic control during this period than before or after it. However, the literature on exercise interventions in adults with Type 1 diabetes has found no clear evidence of improvements in metabolic control following training (Campaigne and Lampman, 1994). It is interesting that the one study which did show an improvement (Peterson et al., 1980) was with young adults, aged 16 to 34 years, mean age 25 years. Possibly exercise interventions can improve metabolic control in young adults. Several authors point to the fact that participants consume more calories during the exercise intervention, and suggest this alteration of diet may counteract the effect of exercise in lowering blood glucose. Any effect on metabolic control seems to be independent of the effect on aerobic fitness as all but one of the above studies showed an increase in peak VO_2.

Increased insulin sensitivity and improved blood lipid profiles (Lehmann et al., 1997; Campaigne and Gunnarsson, 1988) have been shown in adults, as well as in the studies previously reviewed on children and adolescents, suggesting exercise decreases cardiovascular disease risk factors in both adults and children. This is alongside the increase in aerobic fitness following participation in an exercise intervention programme, found by all but one of the studies reviewed. As people with Type 1 diabetes are at increased risk for macrovascular disease (American Diabetes Association, 2002), these benefits are particularly valuable promoting exercise as an important component of treatment, regardless of whether or not it reduces HbA_{1c}.

To the author's knowledge there are no published exercise intervention studies which have looked at psychological outcomes following an exercise intervention. This is despite the suggestion by Rowland et al. 17 years ago that participation in physical activity may provide increased feelings of self worth for children with Type 1 diabetes (Rowland et al., 1985).

2.6: Physical activity and exercise in relation to psychological well being

The dearth of research on physical activity and exercise in relation to psychological well being in children and adolescents with Type 1 diabetes is particularly surprising given the findings in the literature on both adults with Type 1 diabetes and healthy children. This is described below in detail, but overall shows physical activity is linked to psychological well being in both adults with Type 1 diabetes and children in the general population. The lack of research is also surprising given the large literature that is based around the psychological aspects of Type 1 diabetes in children in relation to the other two aspects of diabetes management, insulin and diet. The gap in the literature has been commented on by Mutrie in a chapter reviewing the therapeutic effects of exercise on the self. In relation to both Type 1 and Type 2 diabetes she wrote:
'Given the wealth of literature on these psychological issues in diabetes and the standard recommendation that exercise should be part of treatment, it is astonishing to note that neither the psychological benefits of exercise for diabetics nor patient exercise education has been researched' (Mutrie, 1997, p. 297).

A small study has investigated adolescents' beliefs about exercise. Loman and Galgini (1996) developed an exercise belief instrument that asked about perceived benefits, facilitators and barriers related to exercise. The sample in the study was 30 adolescents aged 12 to 17 with Type 1 diabetes, they completed the instrument twice, two weeks apart. The majority of the group strongly agreed or agreed that exercise made them feel good, was a way to have fun with other people, made their blood sugar easier to control, was encouraged by their families, and that a close friend exercised regularly. Thus, the study suggested that young people with diabetes feel exercise is beneficial for their psychological well being, but this was not tested empirically. It is interesting that only 7% of the sample noted insulin reactions as a barrier to exercise, the most frequently cited barriers were weather, lack of time and that exercise is hard work. This suggests reasons for not exercising are similar to those of adolescents in general, rather than due to having diabetes.

A longitudinal study on adults investigated the effects of physical activity on psychological well being for people with a range of chronic illnesses, including Type 1 diabetes (Stewart et al., 1994). Patients were recruited if they visited one of the participating clinicians during a 9 day period, with one of 7 chronic illnesses, and were over 18 years old. 1758 patients were recruited altogether, the number with Type 1 diabetes was not specified. At baseline physical activity was assessed using a self report questionnaire, measures of total time spent exercising, total time spent walking, and perceived level of physical activity were analysed. Thirteen measures of functioning and well being, relating to physical and mental health, were assessed at baseline and again two years later. Regression analyses between the three physical activity measures and the various functioning and well being measures found that all but one of the significant coefficients were in the direction indicating that more physical activity was associated with better health. The majority of significant associations were with the total time spent exercising measure. Data were analysed separately for each illness. Participants were divided into high or low activity groups and differences in functioning and well being two years later were examined. Of those with Type 1 diabetes participants in the high activity group rated themselves with better health on measures of physical functioning, energy/fatigue, psychological distress/well being, anxiety and depression. They rated themselves with worse health on the measure of pain severity. Measures of disease and comorbidity, verified by a health examination, were used to try to control for the confounding factor that people who were more physically active were healthier to begin with. Overall this suggests that participation in more physical activity may predict better functioning and psychological well being two years later in adults with Type 1 diabetes.

A further paper has been published which suggests aerobic exercise may be beneficial to people with Type 1 diabetes by reducing stress. Vasterling et al. (1988) summarised the influence of stress on diabetes as having three effects, directly by altering blood glucose levels, indirectly by affecting adherence to treatment regimens, and by increasing risk of cardiovascular disease. They suggested that as aerobic exercise can reduce both physiological responses to stressors, and anxiety and depression, it may be beneficial to people with diabetes in two ways. Firstly, because reducing stress may improve psychological well being and secondly, because reducing stress is associated with improved metabolic control and decreased risk of cardiovascular disease. However this hypothesis was not tested experimentally.

Research has been undertaken with children and adolescents in the general population which has investigated whether there is a link between physical activity and psychological health. Calfas and Taylor (1994) conducted a comprehensive review of the psychological effects of physical activity in adolescents. The psychological variables focussed on were depression, anxiety, stress, self esteem, self concept, hostility, anger, intellectual functioning, and psychiatric disorders. Articles which investigated one or more of these variables, and physical activity or exercise were identified. Selection criteria were that participants were aged between 11 and 21 and that the study design was randomised controlled, prospective observational or cross sectional observational. They identified 15 studies that met these criteria on healthy adolescents and 5 on adolescents with psychological problems or diagnosed psychological illnesses. Eight of the 11 studies that investigated anxiety/stress found physical activity was associated with reductions in anxiety and stress. Nine of the 10 studies which addressed self esteem, self concept or self efficacy found a positive relationship or experimental effect. Nine of 11 studies that addressed depressed mood also found a positive relationship or experimental effect. The evidence regarding hostility/anger was inconsistent. They noted that overall there was a lack of research in this area and that there were methodological problems with the data reviewed. Problems were that the number of controlled studies was small, many studies have small samples, psychological variables were measured using a variety of tools making synthesis of results difficult, and assessing physical activity accurately was problematic. However, there was no evidence that physical activity created any psychological harm in adolescents. They also looked at the intensity, duration and frequency of physical activity most likely to produce psychological benefits. Overall high intensity aerobic activity had greater benefits than low intensity activity. The average duration of studies that had significant effect of psychological health was 106 minutes per week (range 60 – 125 mins per week), and the average duration of these studies was 12.8 weeks (range 1 – 20 weeks). They recommended that adolescents participate in aerobic activity, at 70% of their maximum heart rate, three times a week, for 60 minutes per week in total.

Data from the 1986 follow up of the 1970 British Cohort Study, a longitudinal study of all children born over a 7 day period during 1970, were analysed to look at associations between participation in physical activity and psychological well being. This is a large data set of 5161 adolescents, representative of the UK population. Participants were all aged 16 years. Measures used were the General Health Questionnaire, which has been used to assess mental health in community samples, and the Malaise inventory, which lists psychological and somatic symptoms. Physical activity was assessed by asking how often during the previous year the adolescents had participated in a range of team and individual sports or vigorous recreational activities. Adolescents were also asked about participation in non-vigorous recreational activities e.g. snooker, darts. Analyses showed fewer psychological symptoms were reported by adolescents who engaged in more sport and vigorous activity. Conversely, more psychological symptoms were reported by adolescents who engaged in non-vigorous physical activities. Greater participation in vigorous activities was associated with lower risk of emotional distress, independently of gender, social class, illness during the previous year and use of hospital services (Steptoe and Butler, 1996). This was a cross-sectional data set therefore causal relationships between psychological symptoms and physical activity cannot be inferred.

The importance that young people themselves attach to physical activity as a way of improving the way they feel is highlighted by a large scale survey of 1634 boys and girls between 13 and 14.5 years old in Glasgow, called Howie Feel (Gordon & Grant, 1997). This was intended to give young people an opportunity to express how they were feeling on a particular day and to describe positive and negative influences on these feelings. They were asked to write down three things that make them happy and 24% of respondents included physical activity, boys were more likely to write this than girls, 40% versus 10%. A small percentage of these, 4%, thought it was important to do well at sport, for the others participating in sport was sufficient to make them happy. When they were asked to list three things that made them feel good about themselves 28% listed winning or achieving at sports whilst participating in sport in itself was not listed here.

A meta-analysis of self esteem and physical activity was undertaken by Gruber (1986). Twenty seven controlled experimental studies within the last 20 years and so suitable were included in the meta-analysis, all but two of these were on preadolescent children. Overall it was found that participation in directed play and physical education programmes positively influenced the development of self concept as the average scores of those in the experimental groups exceeded the scores of 66% of those in the control groups. Therefore the most benefit was gained by those with initially lowest self esteem. The type of activity engaged in was also looked at, physical fitness and aerobic activities were shown to be much more effective at increasing psychological variables than perceptual motor development, sports skills or dance, mime and creative movement programmes.

The Health Education Authority recently carried out a review of available evidence in order to define the position regarding physical activity and young people. The policy framework produced following this review (Health Education Authority, 1998) included improved psychological well being, increased self esteem, and moral and social development, as some of the benefits of physical activity for current and future well being. Other stated benefits were reducing incidence of people who are overweight and reducing obesity, reducing chronic disease risk factors and improving skeletal health. The Health Education Authority report is targeted at young people in general. It does, however, highlight young people with diabetes as a priority group for further investigation of targeted strategies to increase physical activity.

In summary, the literature about physical activity and exercise in relation to psychological well being is limited, both in quantity and quality, particularly for younger children. However, these studies consistently show that for children in the general population there is a link between participation in higher levels of physical activity and greater psychological health. There is also no evidence of physical activity causing negative psychological effects. This association may also exist in children with Type 1 diabetes. However, this cannot be assumed as there are additional factors for children with Type 1 diabetes, for example, living with a chronic disease and the effect of exercise on blood glucose levels, which may reduce this association.

2.7: Rationale for study

To summarise, the literature on psychological well being of children with Type 1 diabetes suggests that this group is at increased risk of developing psychiatric disorders and that less severe psychological deficits may develop over time. This is not a universal finding though, those children who have psychological problems initially after diagnosis are more likely to develop problems later. Following the DCCT good control of blood glucose levels is known to be associated with prevention or delay of secondary complications related to diabetes. Better psychological health has been associated with good metabolic control, although this appears to be true for some but not all aspects of psychological health. Quality of life is one aspect of psychological health which has mostly been found to be independent of metabolic control, as it is an important outcome in its own right it shows psychological outcomes of treatment should be assessed in addition to HbA_{1c}. Intervention studies show psychological and educational interventions typically result in increases in psychological well being and small reductions (0.3 to 0.6%) in HbA_{1c}.

No association between habitual physical activity and metabolic control have been found. Exercise intervention studies on children with Type 1 diabetes have produced equivocal findings with respect to their effect on HbA_{1c}, some have found reductions and some no change or an increase. Reduction in risk factors for cardiovascular disease have been found more consistently by these studies. Further evidence for the long term benefits of physical activity was shown by a large longitudinal study which found significant reduction in mortality and morbidity for people who participated in sport at school compared to those who did not and that physical activity level was associated with mortality 6 years later. The actual levels of physical activity in children with Type 1 diabetes are not well established but limited data from the US and research on the general population in the UK suggest they are below the recommended guidelines.

It is accepted that physical activity is beneficial for the psychological health of children in the general population and some evidence that it is associated with better psychological well being in adults Type 1 diabetes. No studies have investigated this in children with Type 1 diabetes, although several authors have suggested it may be have a beneficial effect. If this is true increasing physical activity could be used as an intervention to improve psychological health in this population. Physical activity is not an intervention focused on a particular psychological variable and could be expected to improve several aspects of health as defined by the wellness model. This model emphasises the importance of all the aspects of health, physical, psychological, social, mental and spiritual, to overall wellness. The use of exercise as an intervention also emphasises the interrelatedness of the various aspects of diabetes management as increasing exercise also affects insulin and diet requirements. Thus, the lowered psychological health and established benefits of physical activity for physical health mean increasing physical activity could potentially be very beneficial for children with Type 1 diabetes and justifies research into this area.

2.8: Aims, objectives and hypotheses of the study

Aims

1. To establish baseline data for level of physical activity, fitness, glycaemic control and psychological variables in children with Type 1 diabetes.

2. To assess the effect of increasing physical activity on fitness, glycaemic control and psychological health in children with Type 1 diabetes.

Objectives

i. To measure physical activity, aerobic fitness, body composition, self esteem, quality of life, self efficacy and HbA_{1c} of children with Type 1 diabetes.

ii. To investigate associations between physical activity, aerobic fitness, body composition, psychological health, and HbA_{1c} in children with Type 1 diabetes.

iii. To measure the effect of a 12-week physical activity intervention programme on the aerobic fitness, body composition, quality of life, self esteem, self efficacy and HbA_{1c} of children with Type 1 diabetes.

Hypotheses

1. There would be a positive association between higher levels of physical activity, fitness and glycaemic control in children with Type 1 diabetes.

2. There would be a positive association between higher levels of physical activity, fitness and psychological health in children with Type 1 diabetes.

3. Increasing physical activity would lead to higher fitness, greater psychological health and improved glycaemic control in children with Type 1 diabetes.

3

Rationale for Measures Used: Phase One

Chapter one gave a rationale for and description of the psychological and physiological constructs that were measured in the present study, these were HbA_{1c}, quality of life, self efficacy, self esteem, physical activity and physical fitness. Chapter two reviewed the literature that is related to the psychological and physiological effects of physical activity and fitness in children with Type 1 diabetes and stated the hypotheses, aims and objectives of the present study. The questionnaires and procedures used to take these measurements are described in this chapter along with data on their validity and reliability. Where there was more than one possible method of measurement the rationale for using the method chosen is explained.

3.1: Psychological inventories

Quality of life, self efficacy and self esteem were assessed using three separate self report questionnaires. In order for meaningful data to be collected it is important that psychological questionnaires are both valid and reliable.

The reliability of a questionnaire is the extent to which people give the same response when answering it on different occasions given that the variable being assessed has remained constant. It is also to what extent different raters would agree on a rating for the same individual. Internal consistency, a type of reliability for questionnaires, refers to the extent to which items of a domain or scale assess the same dimension. It is normally measured using Cronbach's Alpha, a statistical assessment of the correlation between items within a dimension, i.e. whether items within a scale correlate positively and so can be said to measure the same thing (Nunnally, 1978).

Validity is the extent to which a scale measures what it is purports to measure. Types of validity are construct, predictive and content. Construct validity or the extent to which an instrument is a good representation of the construct is central to the evaluation of any measure and represents the key distinction between behavioural measurement as a scientific science from non scientific approaches (Eiser and Morse. 2001). Factor analysis is one way of establishing construct validity. Evidence from an independent source that the instrument is measuring what it is supposed to is another source of construct validity; it is usually examined by looking at correlations between the new measure and a gold standard. However, in some areas, for example quality of life, there is no accepted gold standard measure. In these cases Bradley (1996) suggests clear hypotheses about expected similarities and differences between the new measure and other variables can be tested, or changes in the measure following an intervention designed to improve the variable it assesses can be investigated.

Sensitivity to change is an important quality of instruments particularly in interventions, where sensitive instruments require smaller sample sizes. Disease specific measures are more likely to be sensitive to change than generic ones as they select items that are important to the respondent (Bradley, 1996).

The development, validity, reliability, and sensitivity where known, of the specific questionnaires used to assess quality of life, self efficacy and self esteem are now discussed.

3.1.1: Quality of life

The questionnaire used to measure quality of life in the present study was the disease specific Diabetes Quality of Life for Youths questionniare (DQOL-Y) (Ingersoll and Marrero, 1991). This was developed from the Diabetes Quality of Life questionnaire that was created for use in the Diabetes Control and Complications Trial to address patient perceived burden of the trial (DCCT, 1988), see section 1.2. It was adapted by adding items relating to school life and peers and removing the items that were of limited relevance to the lives of children.

The scale was validated with a sample of 74 children, age range was 10.8-21.8 years, mean 16 years (Ingersoll and Marrero, 1991). In the revised instrument items divided into three scales, satisfaction with life (26 items), disease impact (26 items) and disease related worries (13 items). Items in these sub-scales were each rated on 5 point Likert scale. In addition an overall self rating of health was added, this was a one item question asking 'compared to other children your age would you rate your health as excellent, good, fair or poor? Internal consistency was assessed, Cronbach's

Alpha for the sub-scales was satisfaction (0.85), impact (0.83) and worries (0.82). They were not independent, for example children who reported greater disease impact also had lower life satisfaction. Scores were not related to age. The only gender difference found was that girls were more likely to report worries than boys.

The version of the DQOL-Y used in the present study was the most recent version of this instrument at its start (Ingersoll, 1998, personal communication). It was slightly modified compared to the instrument published by Ingersoll and Marrero (1991). One adjustment was that on the worry sub-scale an additional option of 'does not apply' was added, this was scored zero. Secondly, the item 'how often does your diabetes keep you from driving a car or using a machine (for example a typewriter)?', was removed from the impact sub-scale. See appendix 1 for questionnaire.

Since its development this scale has been used in a study by Guttmaun-Bauman et.al. (1998) with a sample of 69 children aged 10-20. They found similar internal reliability using Cronbach's Alpha coefficients as Ingersoll and Marrero (1991): satisfaction = 0.88, impact = 0.88, worries = 0.82. The scale has also been used by Grey et al. (1998a; 1998b; 1999; 2000), although validity and reliability data were not published in these papers.

No studies have been published using the DQOL-Y in children with Type 1 diabetes in the UK. However, the scale has been shown to have sound validity and reliability in child populations and was therefore appropriate to use in the present study.

3.1.2: Self Efficacy

The theory of self efficacy first proposed by Bandura (1977) and its effect on children and adolescents' ability to manage their diabetes was reviewed in section 1.5.2. Grossman and colleagues developed a scale to measure this concept in order to examine it further (Grossman et al., 1987). They defined diabetes self efficacy as 'the perceptions or expectations held by persons with diabetes about their personal competence, power and resourcefulness for successfully managing their diabetes. ...... In other words the construct focuses on youngsters' estimates of their own ability to cope with their illness' (Grossman et al., 1987, pg 324). The scale was developed to evaluate youngsters' perceptions of their personal ability or power in diabetes and related situations. Based on Bandura's conception of self efficacy it assesses both the magnitude and generality of these beliefs. This is achieved through three sub-scales which assess differing levels of generality, they are termed self efficacy for diabetes specific situations, self efficacy for medical situations and self efficacy for general situations.

The scale was developed through consultations with medical staff which generated a pool of 40 items relating to areas of concern and demands facing adolescents with Type 1 diabetes. These were then presented to three paediatric/adolescent diabetologists who were asked to judge independently the relevance and representativeness of the items for their patient population. In the final instrument there were 35 items in total (SED-T): 24 to assess diabetes specific self efficacy (SED-D); 5 to assess medical self efficacy (SED-M); and 6 to assess general self efficacy (SED-G).

Grossman et al. (1987) tested the validity and reliability of the scale with a sample of 68 children, 34 boys and 34 girls aged 12-16 years in the USA. Reliability was assessed using the Kuder Richardson co-efficient alpha, all were acceptable (SED-T $\alpha = 0.90$, SED-D $\alpha = 0.92$, SED-M $\alpha = 0.70$, SED-G $\alpha = 0.60$). The sub-scales were derived conceptually rather than by factor analytical methods, independent factors were therefore not predicted or tested for. Validity was assessed by its association with other scales. The total SED score and the scores for the sub-scales were significantly associated with both the Children's locus of Control Scale ($r= 0.31 - 0.45$, $p< 0.01$) and the Coopersmith Self Esteem questionnaire ($r= 0.32 - 0.46$, $p< 0.01$). Associations with metabolic control were also evaluated. HbA_{1c} measurements were not available, instead four other measures including blood glucose and urine glucose levels were combined. SED-T and SED-D were significantly associated with blood glucose levels ($p< 0.05$), higher self efficacy was associated with lower blood glucose. These associations provided some evidence of validity. T tests between scores for boys and girls found no significant differences. Responses to the SED scale were tested for social desirability, no significant associations were found between the total SED score and a measure of social desirability, or between the sub-scale scores and this measure.

Havermans and Eiser (1991) used this scale with a group of 61 British children with Type 1 diabetes aged 9-15 years. They extended Grossman et al.'s (1987) work by using factor analysis to examine the underlying structure of the scale and also assessed validity by looking at associations with the health locus of control scale and a health efficacy scale, developed for the study. Havermans and Eiser's paper said that the SED scale was modified to make it appropriate for a British sample. The scale they used contained 22 items 'largely taken from the Diabetes Self Efficacy scale and made appropriate for an English sample' (pg 300). These items were rated on a 5-point scale.

As the participants for this study were British children aged 9-15 years it was initially decided to use the version of the scale developed by Havermans and Eiser. However it was not possible to obtain a copy of this version from the authors when this present study was being planned. Also there were no other studies published using this version of the scale whereas two papers using the original version had been published (Grey et al., 1998a, Grey et al., 1998b). As Grossman et al. (1987) did not state how the items were divided into the three sub-scales the method used by Grey was also used in this study (Grey, 1998, personal communication). Following Havermans and Eiser (1991) the researcher made some adjustments to update the scale and make it appropriate for a British sample. The word 'shot' was changed to 'injection' and 'acetones' to 'ketones', two items which referred to monitoring glucose in the urine were removed from the scale as this test is not done regularly anymore. This left a total of 33 items which were divided into sub-scales as follows: SED-D 22 items; SED-M 6 items, SED-G 6 items.

As Havermans and Eiser (1991) did not specify that they had included items in their scale which were suitable for younger children it was considered that the original scale would be valid with 9-15 year olds. There has been variation in published studies as to whether items are rated on a 5 or a 6 point Likert scale. In this study a 6 point scale was used in order to minimise neutral judgements. The scale was labelled from 'very sure I can't', to 'very sure I can', the items were scored so that high numbers related to high self efficacy. See appendix 1 for questionnaire.

3.1.3: Physical self esteem

Self esteem is composed of several domains that can be measured separately, see section 1.5.3, one of these is physical self esteem.

The Physical Self Perception Profile (PSPP) was developed by Fox and Corbin (1989) to measure physical self esteem. Four independent sub-domains of the physical self were identified; sports competence, attractive body competence, physical strength competence and physical condition competence. A physical self worth (PSW) subscale was developed to act as a generalised outcome of perceptions in the four sub-domains of the physical self. Relationships between the PSW, other sub-domains of the PSPP and global self worth (GSW) show this to be the case, it explains much of the co-variance among the sub-domain scores and mediates their relationship with global self esteem.

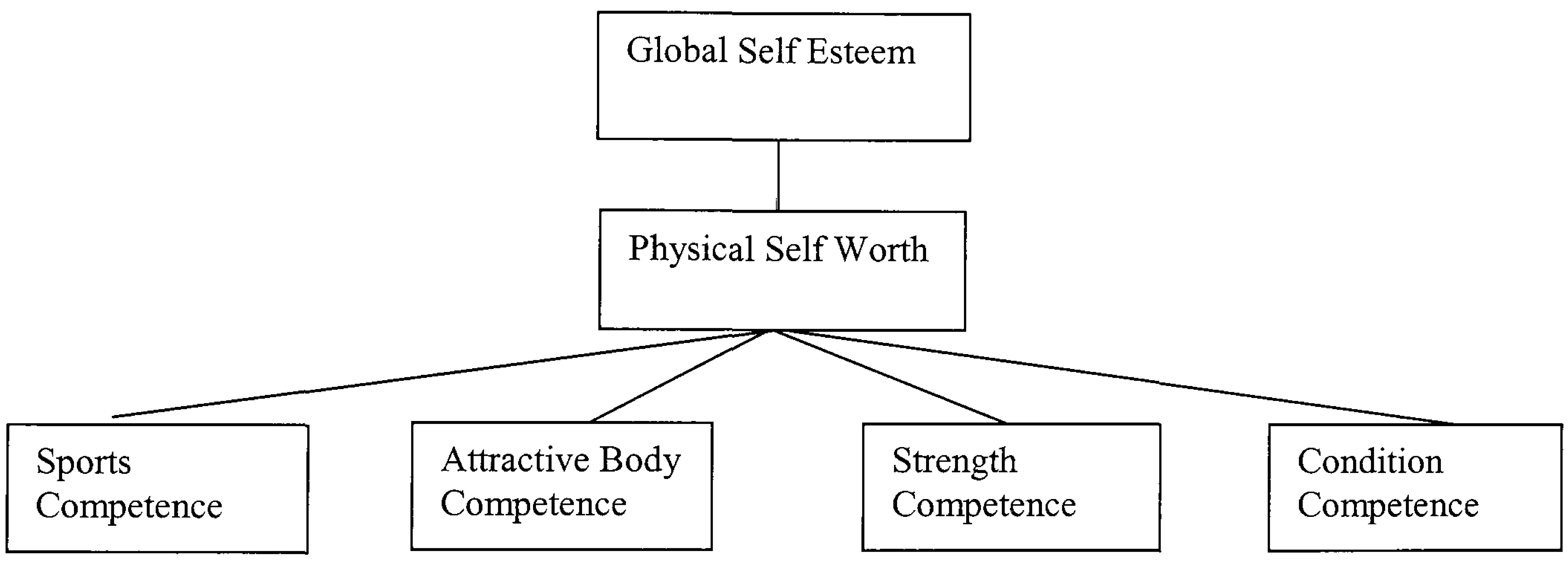

Figure 3.1: Hypothesised hierarchical organisation of self perception (adapted from Fox and Corbin, 1989)

A modified version of Fox and Corbin's scale, called the Physical Self Perception Profile for Children (PSPP-C) was used in the present study (Whitehead, 1995), see appendix 1 for questionnaire. This was developed for use with a younger age group. In the PSPP-C the sport/athletic competence sub-scale was taken from Harter's self perception scale, as it was almost identical to Fox's scale and already validated for children. Items to measure the other three sub-domains (body adequacy, condition and strength competence), the PSW and the GSW were adapted from the PSPP. This involved rewording several of the items. All the sub-scales had six items and used a structured alternative format designed to minimise social desirability responses. In this format two alternatives are presented to the children. For example:

Some kids do very well at all kinds of sports	BUT	other kids don't feel that they are very good when it comes to sports

The children then have to choose which statement applies to them and tick the appropriate box to indicate whether it is 'really true for me' or 'sort of true for me'.

Whitehead (1995) examined the validity of the PSPP-C with a sample of 459 children aged 12-13 years. The factor structure of the subscales was supported. Principal components analysis showed all had eigenvalues >1 and explain an average of 60.1% (boys) and 66.6% (girls) of the variance. The hierarchical structure was tested using regression analysis and supported, 0.64 (girls) and 0.70 (boys) of the variance in PSW was explained by scores on the subscales. The body subscale explained the greatest proportion of the variance. Concurrent and construct validity was supported by comparison with physical fitness scores and fitness classifications. Internal reliability was high (alpha coefficients ranged from 0.8 to 0.9). Descriptive statistics for scales showed gender differences on almost every scale, where these were significant girls scored lower than boys. There were no significant differences between 12 and 13 year olds' overall scores.

Further validation of the PSPP-C with different populations has been carried out. Welk et al. (1995) studied 542 boys and girls aged 13-18 (87% were 16 or younger) from the U.S.A. who participated in a variety of sports. Overall the scale's validity with this population was confirmed. The athletes scored higher than non-athletic populations, showing the scale can discriminate between these populations. There were significant differences between the mean scores of boys and girls on all four sub-domains and PSW, girls scored lower than boys.

Eklund et al. (1997) conducted a confirmatory factor analysis on the combined data sets of Whitehead (1995) and Welk et al. (1995). He found all items strongly loaded on designated factors (average factor loading 0.71). He also found correlations between variables that were not present in Fox and Corbin's PSPP. It is suggested this may be because concepts of self are less differentiated at a young age.

Biddle et al. (1993) tested the validity of the PSPP-C on a sample of British boys and girls, 130 twelve year olds and 322 fifteen year olds. Internal reliability, assessed with Cronbach's Alpha showed each subscale had adequate internal reliability for the younger age group (0.77-0.87) but less so for the older age group (0.63-0.72). In contrast to the data from US studies confirmatory factor analysis did not support a four factor solution although four subdomains could be detected. The hierarchical structure was supported, correlations were stronger between subdomains and PSW and between PSW and GSW than between GSW and subdomains. Subscales were more highly intercorrelated than for the US children suggesting British children may be less good at discriminating between sub-domains, or differentiate them in a different way. Criterion validity was found; there were positive correlations between a physical fitness test and physical self perception scores. Descriptive statistics showed that, as with US samples, boys had higher physical self perceptions than girls but global self worth scores were similar. The instrument was further tested on a British sample by Hagger and Ashford (1998). Using confirmatory factor analysis on a sample of 240 children aged 13-14, they found limited support for the multidimensional, hierarchical model.

On balance there is evidence to support the psychometric properties of this instrument with U.S. and British children. The present study was the first to use it with a group of children with Type 1 diabetes.

3.2: Physical Activity Assessment

As stated in section 1.6.1 physical activity is defined as any bodily movement produced by skeletal muscle that results in energy expenditure. Exercise is structured, repetitive physical activity which results in the improvement or maintenance of one or more of the components of physical fitness (Health Education Authority, 1998). Assessment of physical activity is a problematic area. Ideally intensity, frequency and duration of activities should be monitored, and if habitual physical activity is being assessed day to day variation should be taken into account. Measurement techniques can be divided into four categories; self/proxy report, observation, motion sensor monitoring, and physiological analyses. Each has advantages and disadvantages, these are briefly explained here for the most common measurement techniques.

Self/proxy report:

Self report is the most commonly used physical activity measure in children. Examples of self report methods include retrospective questionnaires, interview administered recall, activity diaries and mail surveys. Children can be asked directly, or their parents and/or teachers questioned. The advantages of using self/proxy reports are that the cost is low, they can be used easily with a large number of subjects and it is possible to collect a variety of physical activity variables over time. The main disadvantage is the validity of the data obtained. This is due to the cognitive demands of the recall and the more intermittent nature of children's activities, which makes them difficult to recall accurately.

Observation:

The advantage of assessing physical activity using observation is that it is reliable and, so long as observers are trained appropriately, accurate. There are several recording techniques available. Difficulties with observation are firstly that it is unclear to what extent the presence of observers alters the subject's behaviour, and secondly it is very time consuming and therefore expensive.

Motion sensors:

These traditionally measured movement and data were calculated using physical translocation of the body. More recently accelerometers, which also measure the intensity of movement have largely replaced movement counters. The Tritrac is a triaxial accelerometer and measures movement in three planes. It was developed to try to capture sporadic activity patterns, such as those of children, more accurately. The device is about the size and weight of a pocket calculator and can be placed in a pouch worn round the waist. Early trials suggest the device has promising validity, heart rate and Tritrac data both correlated highly with direct observation scores, but further evaluation is needed (Welk et al., 1998). Problems with using the Tritrac are both in terms of time and expense.

Physiological analyses:

There are three types of these: i) energy intake ii) doubly labelled water and iii) heart rate monitoring.

i) Energy intake analysis works on the principle of conservation of energy, energy expenditure (physical activity) can be quantified in terms of energy intake, taking changes in body mass into account. It is problematic for many of the reasons self reported physical activity measures are, it relies on accurate recall of food intake over a period of days. It is also not possible to estimate the frequency, intensity or duration of physical activity from this data.

ii) Doubly labelled water uses two naturally occurring isotopes of water to estimate oxygen consumption and therefore energy expenditure. This is an accurate measurement of energy expenditure however it is not practical in large scale studies of physical activity due to the cost and equipment necessary. Also, as with measures of energy intake the frequency, intensity and duration of physical activity is not known.

iii) Heart rate can be monitored using telemetry systems which are socially acceptable, allow freedom of movement and should not alter the child's normal physical activity pattern. Systems are available which record minute by minute heart rates over 30 hours with fairly good accuracy (see section 3.1.1 for further details). This makes it a practical method for large scale studies. The main difficulty with using this method is that there are factors other than physical activity which also alter heart rate, such as metabolism and emotional state. Also, heart rate can change very rapidly in response to activity and systems which record the average heart rate every minute may miss some very brief periods of physical activity. Heart rate data can be used to provide information on intensity and duration of physical activity by recording time above a specified threshold heart rate. Armstrong and Welsman (1997, p 111) recommends 'in comparison with other forms of physiological analysis heart rate monitoring is the most suitable single method for use in large-scale physical activity studies with children'.

Having reviewed the main methods of physical activity monitoring it can be seen that there is no single perfect measure. The weak relationships found between measurement methods on the same subjects may in part be accounted for by the fact that the various techniques measure different dimensions of physical activity. As all methods of physical activity assessment in children have deficiencies ideally a combination of methods should be used. (Armstrong and Welsman, 1997).

In the present study two techniques were used to assess physical activity; heart rate monitoring and self report. These were chosen as the best methods in terms of the validity and reliability of the data they would collect which were also practical in terms of cost and time.

3.2.1 Heart rate monitoring:

Polar Sports Tester systems were used to monitor heart rate (Polar, Sportstester, Kempele, Finland). These consist of a lightweight transmitter which is attached to the child's chest using either an elasticated belt or 50 mm diameter Skintact foam ECG electrodes. The transmitter picks up the child's heart rate and transmits a signal via radiowaves to a receiver which is worn on the wrist. The receiver records average heart rate over 5, 15 or 60 second periods and can store data for up to 2hrs 48mins, 8hrs25mins or 33hrs40mins respectively. In order to obtain the maximum recording time the 60 second interval was used in this study. It is a waterproof and shockproof system so can be worn during all normal activities without altering usual physical activity patterns. After the monitoring period data is downloaded from the receiver to a PC using a Polar interface.

A series of studies were carried out by Treiber et al. (1989) to investigate the validity of the Polar Sports Tester with children. In the first study they monitored heart rate using a Polar Sports Tester and an electrocardiograph during a maximum exercise test on 48 children aged 10 years. Correlation coefficients between the two instruments were high (r=0.97-0.99) and the mean values were quite similar, showing validity of the Sports Tester. The second study compared the two methods with younger children (mean age 5.8 years) during a maximal exercise test with 5 year olds and again found the Sports tester to be valid. In the third study 14 children aged 7-9 years participated in a variety of activities designed to elicit a range of heart rates and upper and lower body movements. Again the two methods produced very similar heart rate data. The investigators concluded that the Sports Tester could accurately assess heart rate during a variety of exercises involving many forms of body movement. They also noted additional benefits to using the system in field work. Firstly, only small amounts of data were lost due to malfunction (e.g. electrode detachment due to sweating, body movement) and there were no differential losses for different exercise types. Secondly, children readily tolerated it and many enjoyed wearing it.

Another way data can be lost, not mentioned by Treiber et al. (1989) is due to interference in the radio signal between the transmitter and receiver. This can occur during field studies when the equipment is worn near to electric fields (e.g. when in a motorised vehicle) or when two or more monitors are recording in close proximity of one another. As children will not be wearing the monitors near to each other in the present study the latter should not cause problems. It is not possible to avoid other types of interference from occurring, but it can be recognised from the heart rate trace and removed from the analysis.

Children's resting heart rates vary. If they are known, along with maximum heart rate individual thresholds can be calculated to estimate the amount of time children spent above the same relative intensity of physical activity. Atkins (1998) suggest heart rate monitoring during sleep to be a useful, socially acceptable method of obtaining basal heart rate values directly. Therefore in this study heart rate was recorded during one night.

Bar-Or (1983) recommended that to obtain a true picture of habitual physical activity a minimum monitoring period of three days was required. Armstrong has carried out a large scale study to monitor physical activity of children, aged 11 to 16, using heart rate monitors (Armstrong et al., 1990b). In this children were monitored during three school days and one Saturday. Both boys and girls were less active on Saturdays than during the week but this was not statistically significant. In the present study a researcher visited each child in their home after waking and before they left for school to fit the heart rate monitor. As children were spread out geographically across the city only one or two children could be monitored on a week day. On weekend days two or three children could be monitored as there was a wider time period over which the children reported waking up than during the week. Therefore two week days were monitored for each child plus two weekend days.

Time of year is a possible confounding factor in physical activity studies, as the weather and number of hours of daylight can effect activity levels. The data in this study were collected between February and September, with the majority being collected during the spring and summer. In the study referred to above Armstrong monitored children throughout the school year. He checked for seasonal differences by monitoring 24 children repeatedly during the summer and autumn terms and found no significant differences (Armstrong et al., 1990a). Therefore time of year was not expected to be a significant confounding factor in this study.

3.2.2: Self Report Physical Activity Questionnaire

Several self report measures of physical activity have been developed for use with children. These have been developed to meet various research objectives and vary in the specificity with which mode, duration, intensity, and frequency are assessed. They also vary in the period of time covered by the report and whether the data are reported as ratings, activity scores with arbitary units, time, calories expended, or other summary scores (Sallis, 1991). Several reviews of the various measures have been written (Sallis, 1991; Sallis et al., 1993; Cale, 1994). From these it can be seen that it is important to select a measure appropriate to the objectives of the study and which has been shown to be valid and reliable with the population being studied.

In the present study the 7-Day Physical Activity Recall Questionnaire (7-Day PAR) (Sallis et.al., 1985) was used, see appendix 2 for questionnaire. This provided data on physical activity patterns by asking for recall over the previous week. Measures which ask for recall on only the previous day provide more valid data (Sallis et al., 1993), however, measuring physical activity over 7 days is in line with the recommendations of Bar-Or (1983). A measure of physical activity over a period longer than 7 days was not chosen as they tend to assess duration, intensity and frequency less precisely (Sallis, 1991). Sallis et al. (1993) assessed the test-retest reliability, and the validity of the 7 Day PAR measure against heart rate monitoring, for 102 children aged 10 to 17 years. Test re-test reliability data was more accurate for the older children but reasonably reliable in the youngest (r= 0.11-0.36 in 10 years olds, r= 0.65-0.75 in 17 year olds). Reliability decreased as the time between when the activity was being recalled and when the activity took place increased. Males were more reliable than females (males: r=0.61-0.69, females: r= 0.25-0.41). Reports of very hard activity were well validated by heart rate data (periods of ≥ 10 minutes above 140 and 160 beats per minute). Correlation co-efficients increased with age (r= 0.29–0.72) but were significant in all age groups, indicating 10 year olds can report vigorous activities with reasonable accuracy.

The 7-Day PAR collects data through interviews administered by an interviewer, who records the activity recalled by the participant on an interview schedule. In the present study interviews were conducted following the guidelines set out in the Project GRAD Seven-Day Physical Activity Recall Interviewer's Manual (Sarkin et al., unpublished). This was developed in order to make the interview as structured and consistent across interviewers as possible therefore increasing agreement among interviewers and limiting interviewer bias. It drew on accumulated experience of approximately 75 interviewers in studies carried out in San Diego.

3.3: Fitness Parameters

Physical fitness is comprised of several components, these are defined in table 3.1 (Armstrong and Welsman, 1997, pg 101). The components measured in the present study were aerobic fitness and body fatness.

Table 3.1: The components of physical fitness

Aerobic fitness	The ability of the cardiac, circulatory, and pulmonary systems to supply fuel and to eliminate waste products during exercise.
Muscular strength	The ability of a muscle group to exert force against a resistance in one maximal effort.
Muscular endurance	The ability of a muscle group to perform repeated contractions against a light load for an extended period of time.
Flexibility	The range of motion around a joint
Body fatness	Percentage of body mass that is fat.

3.3.1: Body Composition

This refers to the body's chemical composition. The body is composed of various chemical components e.g. mineral, water, carbohydrate, protein and fat, and various anatomical ones e.g. bone, organs, muscle and adipose tissue. It can also be divided more simply into fat mass and fat free mass. Fat mass is often discussed in terms of relative body fat, which is the percentage of the total body mass that is composed of fat. Fat free mass refers to all body tissue that is not fat. Some fat is necessary for normal functioning of the body but high levels, i.e. obesity, are undesirable as they are associated with increased morbidity and mortality.

Assessment of body fat as a percentage of body composition is complex and there are various methods available. Most field techniques are validated against densitometry. This involves measuring the density of the body, defined as the mass divided by the volume. Volume is measured by hydrostatic weighing, weighing underwater. Body density is then converted into an estimate of relative body fat using standard equations. However, in the paediatric population the method has problems due to the variation in density of fat free mass and fat (Claessens et al., 2000). In addition the method has practical difficulties in its use with children. Therefore this method was not used in the present study.

Body mass index (BMI) is a frequently used standard to measure obesity. It is defined as mass divided by stature squared ($kg^{-1}m^{2}$). However, it is not possible to distinguish between fat mass and fat free mass using this so it is not an accurate estimate of body fatness. This is particularly the case for children and adolescents as body mass and height are affected by natural growth and biological development, for example increase in BMI in adolescent boys may reflect the development of muscle and bone rather than an increase in fat. However, as the data is quick and non-invasive to collect and there is normative data available, BMI was measured in the present study.

Skinfold measurements are also relatively quick and non-invasive to take. They are widely used to estimate body fatness. In general the skinfold thickness is measured at one or more sites on the body and the values are entered into an equation to estimate relative body fat. However, there are limitations to the use of the method with children and adolescents. These relate to: the body density of children; the accuracy of the existing equations; and variability in the density of fat free mass, distribution of subcutaneous fat, and ratio of internal to external fat stores (Claessens et al., 2000). To minimise these problems of converting skinfolds to percentage body fat, sum of skinfolds by itself can be used, this provides a useful indicator of children and adolescents' subcutaneous fatness (Armstrong and Welsman, 1997). This measure was used in the present study.

3.3.2: Aerobic Fitness

Maximal oxygen uptake (VO_{2max}) has traditionally been considered the 'gold standard' criterion of aerobic fitness, this is defined as the highest rate of oxygen consumption during maximal or exhaustive exercise. There is a relationship between oxygen consumption and fitness due to the fact that the body requires oxygen in order to produce energy and that increased energy is required during exercise. Training can increase VO_{2max} by increasing the rate at which systems can provide oxygen to cells and the rate at which cells catabolise fuels. Similarly, a period of prolonged inactivity, such as bed rest, can decrease VO_{2max}. Various factors other than training also effect VO_{2max} for example age, sex, body size and genetic factors. The influence of these was reduced by the method of analysis.

The most commonly used criterion for determining that VO_{2max} has been reached in adults is called the VO_2 plateau. This is when VO_2 remains steady despite increasing physical effort. However, only a minority of children reach a VO_2 plateau during an exercise test to exhaustion (Armstrong et al., 1996b). The most commonly applied criterion with children is an increase in VO_2 of ≤ 2.0 $mlkg^{-1}min^{-1}$ for a 5-10% increase in exercise intensity. This lack of a plateau has led to the term peak VO_2 being used for the highest oxygen uptake achieved during a test to voluntary exhaustion rather than VO_{2max}, to avoid implying an oxygen plateau has been reached. As a result of reviewing several studies Armstrong concluded 'the weight of evidence indicates that peak VO_2 measured using a jogging or running protocol is as reliable in young people as VO_{2max} is in adult groups (Armstrong and Welsman, 1997, pg 28). Therefore in this study demonstration of a peak in oxygen uptake alongside signs of maximal effort was taken as a maximal VO_2 value.

Choice of protocol

One of the general recommendations for the assessment of peak VO_2 is that participants should perform rhythmic exercise that requires a large muscle mass. Two types of exercise that are commonly used to assess peak VO_2 in children are treadmill running and cycle ergonometry. A treadmill test is more likely to be likely to be terminated by the respiratory or cardiovascular system than a cycle test, as it engages a larger muscle mass. (Shephard, 1984) Another advantage to using a treadmill protocol with children is that they may find it difficult to maintain the required pedal rhythm on a cycle and may slacken pace, particularly in the latter stages of the test, making it difficult to elicit a peak VO_2. These limitations led to the recommendation that the treadmill is the most appropriate mode of exercise for paediatric testing (Armstrong and Welsman, 2000a), this was the method used in the present study.

It is important to use a standardised protocol throughout the study because this affects performance. The range of ages, body sizes and fitness levels in the paediatric population make it difficult to specify generalised protocols. Two popular treadmill protocols are the Bruce and the Balke. In the Bruce protocol both the speed and grade increase every minute or every two minutes. In the Balke protocol the treadmill is set at a constant speed and the grade increases every minute. Adapted versions of the protocols have been used and different ones developed depending on the information required and the characteristics of the participants. In research settings a modified Balke protocol is the most common treadmill method (Rowland, 1993).

Rowland (1993) made several general recommendations for treadmill tests. The duration should not be too long or boredom can prevent maximal effort, on the contrary a very short overly intense test can be intimidating to an unfit child. He suggested the optimal duration was 8–12 minutes. Steep slopes should be avoided as these may make the child feel insecure, as should high speeds, which might limit performance in children with short stride length. Increasing only the speed or the grade at one time minimises the adaptive changes that the child needs to make. Stages should be long enough to allow levelling of physiologic values in response to an increased workload, three minutes is generally considered sufficient time (Rowland, 1993). The greater the increase in gradient the greater the increase in workload.

Therefore in the present study, a modified version of the Balke protocol was used, in which grade was increased by 2.5% every three minutes.

Criteria for termination of peak VO_2 test

The termination of maximal exercise tests with children is usually dictated by the point of voluntary exhaustion. This is a subjective criterion, defined as when the young person is unable or unwilling to continue exercising despite strong verbal encouragement. (Armstrong and Welsman, 2000a) Visible signs of intense effort, such as unsteady gait, hyperpnoea, sweating, facial flushing and grimacing, can be used as confirmation that maximal effort has been reached in young subjects.

Objective criteria can be used as confirmatory markers that the child has performed to their maximum. In the absence of a VO_2 plateau secondary criteria are used, these are heart rate, respiratory exchange ratio (RER), and blood lactate. All three of these have limitations in their use with children due to variation between individuals that lead to difficulties in specifying generalised criteria for the determination of maximal effort.

Heart rate:

Heart rate is a simple yet informative cardiovascular measure. It reflects the amount of work the heart has to do to meet the increased energy demands of the body when it is engaged in activity. Resting heart rate averages 60 to 80 beats per minute but varies considerably. With exercise heart rate increases rapidly, in proportion to exercise intensity, until near the point of exhaustion when it begins to level off. This levelling off indicates individuals are approaching their maximum heart rate, the highest heart rate value they achieve during an all out effort to the point of exhaustion. It is a highly reliable value that remains constant from day to day and changes only slightly from year to year. There is considerable variation between children's maximum heart rates, a range of 185 to 225 beats per minute have been recorded at peak VO_2 (Armstrong et al., 1996b).

In the present study a levelling off of heart rate was taken as one of the secondary criteria that peak VO_2 had been reached.

Respiratory Exchange Ratio (RER)
RER is the ratio of carbon dioxide released to oxygen consumed during nutrient metabolism. It allows an estimate of the type of food (carbohydrate, fat or protein) that is used during metabolism to be made, as the amount of oxygen used during metabolism depends on the type of fuel being oxidised. The RER for carbohydrate is 1.0, i.e. the amount of oxygen required to metabolise one molecule of carbohydrate is the same as the amount of carbon dioxide produced. Metabolising fats requires more oxygen per molecule than the amount of carbon dioxide that is produced, which means the RER is less than 1, it is 0.71.

During a progressive exercise test to exhaustion with adults, RER is typically around 0.8 during the initial stages rising to exceed 1.0 at VO_{2max}. Armstrong and Welsman (1997) reviewed the published literature and noted that values ranging from 0.99 to 1.1 have been reported at peak VO_2. Due to this he recommended that a single specific RER criterion for determining that peak VO_2 has been reached should be used with caution.

In the present study RER was calculated but used as a guide alongside the other termination criteria to determine whether maximal effort had been reached during a test.

3.4: HbA_{1c}

Haemoglobin A_{1c} is a compound present in the blood which provides a measure of the average blood glucose level over the previous two to three months and thus provides an indication of blood glucose control over this period. There is an association between lower HbA_{1c} values and delay or prevention of secondary complications associated with diabetes (DCCT, 1993). Therefore HbA_{1c} is an important treatment outcome and is routinely used to assess children's treatment regimens in outpatient clinics. See section 1.6.2 for further description about HbA_{1c}.

In people without diabetes HbA_{1c} is present at a concentration of between 4 and 6% (Brown, 1998,). Brown states that in terms of assessing blood glucose in people with Type 1 diabetes in general, an HbA_{1c} of 6-7% may be classed as acceptable, a value of 7-8% as less than ideal and a result greater than 8% would indicate poor control

(Brown, 1998). However analyses from the DCCT show that this figure is not realistic for the adolescents, they find it harder to maintain such tight blood glucose control, as explained below.

When the results of the DCCT were analysed for the 195 adolescent participants, i.e. participants aged 13-17 years at study entry, separately to the 1246 adult participants, some differences in HbA_{1c} were found. The main finding of lower HbA_{1c} values being associated with a reduction in risk for the development and progression of secondary complications remained true. There was a continuously decreasing risk of having a sustained three step progression in retinopathy with decreasing HbA_{1c} (DCCT, 1993). However, there was a difference in absolute HbA_{1c} levels between adults and adolescents. Adolescents found it more difficult to achieve and sustain blood glucose control than adults when using an intensive treatment regimen, mean HbA_{1c} of $8.06 \pm 0.13\%$ was achieved by adolescents compared to $7.12 \pm 0.03\%$ by adults. There were similar differences between adults and adolescents using conventional treatment, mean HbA_{1c} for adolescents was $9.76 \pm 0.12\%$ compared to a mean of $9.02 \pm 0.05\%$ in the adult sample. These differences were significant at $p < 0.001$ (DCCT, 1994). The value of 8.0% HbA_{1c} was used as a threshold to compare well controlled patients versus others, in a large cross sectional study of 2579 French children aged 1 to 19 years with diabetes duration > 1 year. The investigator's rationale for using this threshold was that it was that it was the mean HbA_{1c} value obtained following maximal therapeutic efforts in a carefully selected and motivated group of young patients with compliant families (Rosilio et al. 1998). 8.0% also appears to be an approximate threshold beyond which the risk of microangiopathy increases more rapidly (DCCT, 1993).

Values were assessed using a DCA 2000 Analyser and a reagent kit for this machine. The volume of blood required by this analyser is just 1μL, which can be obtained by fingerprick or venipuncture. In this case fingerprick samples were taken. Immediately prior to analysis a glass capillary is filled and inserted into the reagent cartridge. This is then placed in the analyser and the test result is displayed with in six minutes.

Each DCA 2000 system is calibrated by the manufacturer. After this it automatically self-adjusts during power-up and each assay. If it is unable to make appropriate adjustments the machine displays an error message. The reagent cartridges are analysed by the manufacturers before they are released and the values for calibration parameters are encoded on a card which is read by the machine before the analysis is carried out. Two DCA 2000 quality controls (one normal and one abnormal) are run for each new lot number of reagent kits and thereafter one per 10 cartridges. The machine will automatically indicate whether the control result is within or out-of-limits.

Specific performance characteristics of Bayer DCA 2000 analysers and DCA 2000 HbA_{1c} reagent kits (Bayer, 1996), show within run precision for normal and abnormal control samples and correlations between the DCA 2000 system and ion exchange high performance liquid chromatography, the method commonly used prior to the DCA 2000 system. For 21 duplicated runs the average within run standard deviation was 0.13 (2.6% of the control value) for the normal range of HbA_{1c} and 0.37 (3.2% of the control value) for the abnormal range of HbA_{1c}. Between run standard deviation was 0.06 (1.2% of the control value) for the normal range of HbA_{1c} and 0.31 (2.6% of the control value) for the abnormal range of HbA_{1c}. Correlation coefficients between the two measurement methods were 0.98 for venous samples and 0.97 for capillary samples. These show high reliability and validity for the DCA 2000 analyser and that variation between machines should be minimal. Therefore the use of separate DCA analyser machines by the two clinics in phase one of the study was not considered to increase the variability of the results.

3.5: Summary of measures used

To summarise this chapter, the measures used in the present study were as follows:

Psychological inventories
Diabetes Quality of Life for Youths Questionnaire (Ingersoll and Marrero, 1991)
Self Efficacy for Diabetes Questionnaire (Grossman et al., 1987)
Physical Self Perception Profile for Children (Whitehead, 1995)

Physical activity assessment

Heart rate monitoring

7-Day physical activity recall questionnaire (Sallis et al., 1985)

Fitness parameters

Body mass and stature

Skinfold measurements

Peak VO_2

Blood glucose control

HbA_{1c}

4

Methods: Phase One

The aim of phase one was to establish baseline date for level of physical activity, fitness, glycaemic control and psychological variables in children with Type 1 diabetes. In this chapter the data collection procedures followed during phase one are described. The methods used to score the psychological questionnaires and calculate sub-scale values are also explained, as are the procedures used to convert physiological values into data that could be used in statistical calculations.

4.1: Ethical approval

Ethical approval for the study was sought from two local research ethics committees, relating to two NHS trusts, and the university ethics committee. Approval for both phases of the study was given by the university and one local research ethics committee. Approval for the first phase of the study was given by the other local research ethics committee. This committee requested that data from the first phase of the study be analysed and presented to the committee in order for them to decide whether continuing with phase two would be justified. See appendix 3 for letters of ethical approval.

All three committees requested that informed consent be obtained in writing from parents or guardians of the participants and that informed assent be obtained in writing from the participants themselves. Assent rather than consent was required as the participants were under 16 years of age. Additionally information documents were required which gave essential information about the study in an impartial manner and which were written in simple, non technical scientific language. One information sheet was required for the parents or guardians of the participants and one for the participants themselves. The three ethics committees approved the same consent forms, assent forms and information sheets, see appendix 4 for these.

4.2: Study population

There were two eligibility criteria for inclusion in this study. The first was that children had been diagnosed with Type 1 diabetes two or more years prior to entry into the study. The second was that children were aged between 9 and 15 years at entry to the study. The reason for the first of these criteria was that the usual pattern of insulin production after the onset of Type 1 diabetes is a gradual decline in level of production. It can take up to two years from diagnosis of the condition for insulin secretion to stop completely. This period is known as a 'honeymoon period'. Exogenous insulin is needed to control blood glucose levels during this period, however, the dose required is often lower and good control easier to obtain than once insulin production has stopped completely. As one of the outcome variables of this study is HbA_{1c} it was considered necessary to exclude children in this period so that changes in internal insulin production would not be a confounding factor in the analysis. Age was used as an eligibility criterion due to its effect on psychological and physiological outcome variables. Nine years was used as a lower cut off threshold as the questionnaires used in this study had been previously tested for validity and reliability with children aged nine and above. 15 years was used as an upper threshold as children are transferred to the adult clinic at 16 and treatment is transferred to a different diabetes team. It was also used because the intention of the study was to investigate the effects of physical activity and fitness in a young population who had not had diabetes for a long enough duration to develop secondary complications that would prevent participation in vigorous physical activity.

4.3: Recruitment

All children and their parents or guardians who attended the diabetes clinics at either of the two participating hospitals between February and June 1999 and who fitted these inclusion criteria were approached. The study was explained to them verbally and an information sheet was given to both the child and parent or guardian. Those who agreed to take part in the study returned signed consent forms, either at the clinic or in postage paid envelopes. Consent was obtained from each child's parent or guardian and assent was obtained from the children themselves. Eighty-three children and their parents or guardians were asked if they would like to take part in the study. Forty-six children and their parents or guardians gave consent to participate, seven subsequently dropped out. Therefore the number of participants was 39, a 47% recruitment rate.

4.4: Physical activity assessment and analysis protocol

Three researchers were involved in collecting heart rate data. Each participant was visited in their home on two consecutive school day mornings before they left to go to school. The monitor was attached to the participant who was instructed not to touch it during the day. The recording interval was set to 60 seconds, which gave a recording period of 33 hours 40 minutes. A telephone number to contact the researcher was left with the family and they were asked to telephone if there were any problems with the monitor. If they telephoned the problem could be determined. The most common problem was that the monitor had fallen off or lost contact with the skin and stopped recording. Instructions for restarting the monitor could be given over the telephone. On the first evening the child removed the monitor before they went to bed. The following day the same researcher returned, collected the previous day's monitor and attached a new one. This was again worn throughout the day. On the second evening the researcher returned, approximately 12 hours after the morning visit, to collect the monitor.

The following weekend the researcher visited the participant's house again on the Saturday morning between 9am and 11am. A monitor was again attached to the child. They were instructed to keep it on for the full recording period of the receiver, i.e. 33hours 40minutes. This was so that an overnight recording was obtained. During sleep the monitor sometimes fell off and so stopped recording. The participant was asked to check the receiver was still recording in the morning. They were shown and left instructions how to restart it if it had stopped. The researcher returned on the Sunday evening, between 6.30pm and 8.30pm to collect the monitor.

Due to the population being spread throughout Merseyside it was only possible to visit one or at most two children per week day in the time available before they left for school and two or three on weekend mornings. This meant that the time span over which the data was collected was from February to September 1999. If 4 full days of data were not collected due to either the receiver not recording properly or the transmitter falling off children were asked if they would be happy to wear the monitor for another day or days. If they were happy to the above procedures were repeated. One participant did not want to wear the monitor for any extra days.

When the researcher visited the child's house to collect the fourth day's heart rate data they interviewed the child using 7 Day PAR questionnaire (Sallis et al., 1985). The interviews were conducted with the child, in the case of the younger participants their parents assisted with recall. The interview took approximately 15 minutes and followed the guidelines set out in the interviewer's manual (Sarkin et al., unpublished). The interviewee was asked to recall periods of activity of 5 minutes or longer over the past 7 days that had made them feel as tired as walking at a brisk pace or more tired. Activity was divided into moderate, hard or very hard. These intensities were defined as: moderate activity makes you feel as tired as you do when walking at a brisk pace; hard activity makes you feel more tired than walking but less tired than running; very hard activity makes you feel as tired as when you are running. The interviewee decided the intensity of each activity they recalled. Activities were recorded by the interviewer separately for the morning, afternoon and evening of each day, using a standard interview schedule.

4.4.1: Physical activity data analysis

4.4.1.1: Analysis of data from heart rate monitors

Data from the heart rate monitors were downloaded onto a PC using an interface and Polar software. This plotted heart rate as a graph of heart rate (beats per minute) against time (minutes). A complete data set consisted of two traces of approximately 12 hours and one trace of 32 hours 40 minutes. Some of the data sets however, were not complete. There were three main reasons for this: a) the transmitter either became disconnected from the electrodes or the electrodes became detached from the skin and the recording stopped; b) the child pressed the buttons on the watch and stopped the recording; c) the system malfunctioned due to low battery and the data file was lost. Data files were included in the analysis if they were 8 hours duration or longer. This length was chosen because it would include the school day and activity getting to and from school.

Using the criteria of 4 data files of ≥ 8 hours duration per child as a complete data set 18 (47%) of the children had complete data sets. The number of files ≥ 8 hours duration collected for each participant is shown in the table below.

Table 4.1: Number of heart rate data files ≥ 8 hours duration for each participant.

Number of data files ≥ 8 hours per participant	Number of participants
5 data files ≥ 8 hours	2
4 data files ≥ 8 hours	16
3 data files ≥ 8 hours	11
2 data files ≥8 hours	8
1 data files ≥ 8 hours	2

To allow comparison between subjects the average number of minutes of physical activity per participant per day was calculated. This is referred to as 'average number of minutes of physical activity per day' for the rest of the thesis. All participants with one or more data files were included in further analyses. Although including participants with fewer than four files reduced the validity of the results, as physical activity is known to vary from day to day, it was considered that the increased information that was gained from including 39 participants outweighed the reduction in validity of the results.

Within the data files of 8 hours of longer there were some short periods of interference. As explained in section 2.2.1 these were caused by interference in the radio signal between the transmitter and the receiver. There were also occasional zero readings caused by the transmitter becoming detached from the skin for a short period of time. These were called missing data points as opposed to the end of a data file if the monitor continued recording afterwards without having to be restarted.

Criteria for removing data points were as follows:

1) Interference caused very high heart rates to be recorded. As can be seen in figure 4.1 the trace rises in one minute from a steady value to greater than 225 beats/min and then returns to the steady state. The points at this very high level were removed.

2) Values of zero beats/minute were the result of no data point being recorded. This can also be seen in figure 4.1. The recording went from a steady state heart rate to zero the next minute and then back to the steady state again on the next non zero value. The zero values were removed.

Figure 4.1: Graph of heart rate (beats/min) against time (mins)

Physical activity was calculated as cumulative number of minutes above threshold heart rate levels. These were calculated as a percentage of the difference between maximum heart rate, at the point of running to exhaustion during the VO_{2max} test, and minimum heart rate during sleep. Minimum heart rate during sleep was defined as the lowest value recorded for 5 continuous minutes. This difference is known as maximum heart rate reserve (MHRR).

The formula used to calculate threshold heart rate values was:

X % MHRR = X (HR max – HR min) + HR min

The thresholds used and the levels of physical activity they represented were as follows:

50% MHRR = moderate activity e.g. light jogging or fast walking;

60% MHRR = hard physical activity;

75% MHRR = very hard physical activity e.g. fast or prolonged running.

These thresholds were the same as those used by Stratton (1996), who stated that 50% MHRR resembles moderate activity heart rates (140 beats per minute) reported in previous studies. Sixty and 75% MHRR represented vigorous physical activity with heart rates greater than those previously recommended for promoting health and fitness. These thresholds relate to different heart rate values in each individual but in this age group the values were in the range 135 to 148 (50% MHRR), 148 to 158 (60% MHRR) and 168 to 174 (75% MHRR) beats per minute.

A range of activities could elicit these threshold heart rate levels, e.g. swimming slowly or cycling on flat ground may elicit 50% MHRR. Heart rate may also be raised by stress or anxiety. This had to be taken into consideration when the validity of the data was assessed, however there is no gold standard measure of physical activity with each method having its limitations.

The numbers of minutes above these three thresholds in each data file were summed. This was done using a function of the Polar software. On the heart rate/time graph a reference line was set at the threshold heart rate. Parts of the heart rate curve above this line were then highlighted. Sections with interference were omitted as mentioned previously. The programme then summed the number of minutes that were highlighted representing time above the threshold. The average number of minutes per day spent in moderate (between 50 and 60% MHRR), hard (between 60 and 75% MHRR), and vigorous (above 75% MHRR) physical activity was calculated for each participant. In addition the total number of minutes per day spent in moderate or higher intensity activity was calculated for each participant.

4.4.1.2: Analysis of self report physical activity data

Data from the physical activity recall questionnaire were entered into a spreadsheet with duration of physical activity in the morning, afternoon and evening of each of the seven days. Times were recorded to the nearest 0.25 hours. The duration of physical activity in the morning, afternoon and evening of each of these days was summed and then these totals were summed to find the total volumes of moderate, hard and very hard physical activity each child participated in over the seven days. To make the data comparable to those from the heart rate monitors the total volumes of moderate, hard and very hard physical activity over 7 days were divided to find the average volumes per day.

4.5: Laboratory data collection and analysis protocol

Aerobic fitness, body composition and psychological well-being were measured during one visit by the participants to the study laboratory. Each visit lasted for 1.5 to 2 hours. On arrival the child and their parent or guardian were greeted, shown around the laboratory and shown the equipment they would be using during their visit. Between one and three participants were in the laboratory at any one time. To ensure participants spent as little time as possible waiting between measures the order that the data were collected in varied

4.5.1: Psychological questionnaires

4.5.1.1: Completion of questionnaires

The Diabetes Quality of Life for Youths (DQOL-Y), the Self Efficacy for Diabetes (SED) and the Physical Self Perception Profile for Children (PSPP-C) questionnaires were printed in one booklet. All three questionnaires were completed by the participants. Each questionnaire included written instructions and in addition the booklet stated that there were no correct answers and that we were interested in their opinions not other people's. The researcher went through the instructions on how to complete each of the questionnaires with the children to ensure they were clear about these. The children were told that if they had any questions or did not understand something while they were filling in the questionnaires to ask the researcher.

4.5.1.2: Scoring of psychological data

DQOL-Y:

A modified version of Ingersoll and Marrero's (1991) questionnaire was used in this study. The 56 data items were grouped into 3 sub-scales. These were labelled satisfaction with life, disease impact and disease related worries. In addition there was a single question about overall health rating. The satisfaction and impact sub-scales were rated on 5 point Likert-scales, the worry sub-scale on a 6 point Likert-scale, and the overall health rating on a 4 point Likert-scale. Low scores represented high quality of life for the satisfaction, impact and worry sub-scales. The overall health rating was scored in the reverse direction, a high score represented high quality of life.

However, studies in the existing literature used the version published by Ingersoll and Marrero (1991). To make the data easily comparable to published data the scores on the satisfaction scale were reversed during the analysis so that a score of 5 was converted to 1, 4 to 2 etc. Data were recomputed using SPSS. The worry scale was not directly comparable to the literature as it has an additional option of zero for each item, which increased the range of the scale from 11 to 55 to 0 to 55. It has not been reported in the literature but item 7 of the impact scale ('how often do you feel good about yourself?') is in the reverse direction to the other items on that scale (e.g. 'how often do you feel restricted by your diet?'). Therefore in the analysis scores for item 7 were reversed so that a response of 'never' scored 5 and a response of 'all the time' scored 1.

Therefore as data are presented in chapter 5 on the satisfaction sub-scale low scores represent low satisfaction and low quality of life. On the impact and worry sub-scales low scores represent low impact and worry and high quality of life. On the overall health question a high score represents high quality of life.

SED:

There were a total of 33 items in this questionnaire, these were divided into 3 sub-scales the SED-diabetes (22 items), the SED-medical (6 items) and the SED-general (6 items). All the items were scored on a 6 point Likert-scale. The scale was labelled from 'very sure I can't', to 'very sure I can', the items were scored so that high numbers related to high self efficacy. The total score for each sub-scale was the sum of all its items. In addition a total self efficacy for diabetes (SED-T) score was obtained by summing the responses on all 33 items in the SED.

PSPP-C:

There were 6 sub-scales in this questionnaire: general self worth (GSW), physical self worth (PSW), sport competence, condition competence, attractive body competence and strength competence. All had six items. In each item the children had four choices, which were scored on a 4 point Likert-scale. On each item a high score represented high self esteem and a low score low self esteem. The total score for each sub-scale was the sum of the 6 items it contained. To make the data easily comparable to the majority of published data each of the total sub-scale scores was divided by 6 to give scores within the range 1 to 4.

4.5.2: Body Composition

4.5.2.1: BMI

Stature was measured using a free standing measure. Children wore light clothing with their shoes and socks off. They stood with their heels, buttocks and shoulder blades touching the vertical scale and with their arms relaxed. The measuring arm was brought down to rest firmly on their head. The measurement was taken to the nearest 5mm.

Children were weighed using a balance scale. This was checked for accuracy before every measuring session by making sure that when all the weights were on '0' the arm of the scale balanced in mid air. Children wore shorts or tracksuit trousers, and a T-shirt, with shoes and socks off. Body mass was recorded to the nearest 50g.

BMI was calculated from stature and body mass using the formula:

BMI = mass (kg) / stature (m) ^{2}

4.5.2.2: Sum of skinfold measurements

Harpenden skin callipers (British Indicators Ltd, Birmingham, UK) were used to take skinfold measurements. All measurements were taken in triplicate on the left hand side of the body. Five sites were measured, these were biceps, triceps, subscapular, suprailiac and calf.

Using skinfold measurements to estimate total body fatness in this age group produces inaccurate results but sum of skinfolds in itself is a useful indicator of children and adolescent's subcutaneous fatness, see section 3.3.2. Therefore data are presented as sum of 5 skinfold measurements.

4.5.3: Aerobic fitness

4.5.3.1: Data collection protocol

Blood glucose measurement

Due to the effect acute exercise is known to have on blood sugar levels the children tested their blood glucose, using their own monitor, before beginning the peak VO_2 test, to check it was within the safe limits specified by the ethics committee. These limits were that blood glucose level was between 4mmol and 16mmol. If blood glucose was 4mmol or lower at this point the participants would eat or drink a high energy snack and test their blood glucose level again after about 10 minutes, if it had risen to above 4mmol they would then perform the test. If it had not risen they would have another snack, wait, and then test their blood glucose again until it was above 4mmol. High energy drinks and snacks were available if children required them at any point while they were in the laboratory.

If blood glucose was above 16mmol the participant would test for ketones. If these were present they would not perform the test that day. Another appointment would be arranged if possible. To try to avoid this happening in the letter sent to participants before their visit to the laboratory, they were asked to test for ketones on the morning of the day of their visit and to telephone to arrange another appointment if ketones were present. If blood glucose was above 16 mmol. but ketones were not present the participants were allowed, if they wished, to begin the familiarisation stage of the test and measure their blood glucose again after a gentle warm up. If at this point blood glucose was still above 16mmol the test would not be performed. If blood glucose had fallen to below 16mmol the test would be performed but the participant would test their blood glucose after every 3 minutes of running and if it rose again the test would be stopped.

Familiarisation and warm up:

The procedure for the peak VO_2 test was fully explained to the participants. They were then fully familiarised with the treadmill and mouthpiece. This phase continued until the participant was able to jog on the treadmill without holding the hand rails and insert the mouthpiece into their mouth whilst jogging.

The participants then performed a 3 minute warm up, this consisted of jogging on the treadmill. Participants wore a heart rate monitor whilst on the treadmill and the warm up aimed to increase heart rate to 70% of their age related maximum heart rate (220 beats per minute – age). Intensity was set by varying the speed of the treadmill.

Test protocol:

Speed was set 1 km/hr faster than that which had elicited a heart rate of 70% of the child's age related maximum during the warm up. The test was run in a series of 3 minute stages. The first stage had a gradient of 0%. On stage 2 the gradient was increased to 2.5%, the gradient was increased by a further 2.5% on each successive stage. The speed remained constant throughout the test.

A discontinuous protocol was used, i.e. the child stopped running briefly between each stage. This was necessary to allow finger prick blood samples to be taken for lactate, and if necessary blood glucose analysis. The participants were told that they should work as hard as possible during the test but that they should signal when they could not continue. The experimenters also watched out for indications that the test should be terminated, these were Visible signs of intense effort, such as unsteady gait, hyperpnoea, sweating, facial flushing and grimacing.

Expired gas was collected during the last 30 seconds of each stage and for the final 30 seconds of the test, even if full 3-minute stage was not completed. Expired gas was collected into meteorological balloons (Cranlea Medica, Electronic, Birmingham, England). For these 30 seconds subjects expired through a low-resistance paediatric face mask (Hans Rudolph, Kansas City, USA) which were attached to the balloons via 5cm-diameter plastic tubing. Expired gases were analysed for concentrations of oxygen and carbon dioxide using dry gas analysers (Servomex 470A and 1400, Servomex, Crowborough, England).

Analysers were calibrated using gases of known concentration (O_2 15.1 to 20.9%; CO_2 1.19 to 6.03%) Expired gas concentrations were determined to the nearest 0.01%. Gas volumes were determined by the manual evacuation of the metabolic balloon through a mechanical dry gas meter (Harvard dry gas meters, Edenbridge, England). Dry gas meters were calibrated using a 350 litre Tissot spirometer (Tissot, Warren and Collins, Braintree, England).

4.5.3.2: Analysis of peak VO_2 data

The following data were entered into an EXCEL macro, which calculated VO_2 in $ml^{-1}kg^{-1}min^{-1}$: volume of expired gas collected in 30 seconds, temperature of this gas, percentage O_2 in sample, percentage CO_2 in sample. The humidity, temperature and pressure in the room at the time of the test were also entered.

4.6: HbA_{1c} data collection protocol

HbA_{1c} values were taken from clinic records. Each time the child visited the outpatient clinic for a routine appointment their HbA_{1c} was measured. This was approximately every 3 months, although some children attended more frequently and others less frequently. The value used in this study was the next measurement taken in clinic after the heart rate monitoring took place. However, where this was more than 3 months after the heart rate monitoring the previous measurement was used if this was within 6 weeks. If neither of these criteria applied, no HbA_{1c} value was included. As heart rate monitoring took place over several days the middle date between the first and last day was used to judge which HbA_{1c} measurement to include.

5

Results: Phase One

There were two hypotheses for phase one of the study. Firstly, that there would be a positive association between levels of physical activity, fitness and glycaemic control in children with Type 1 diabetes. Secondly, that there would be a positive association between higher levels of physical activity, fitness and psychological health in children with Type 1 diabetes.

The objectives were:

i. To measure physical activity, aerobic fitness, body composition, self esteem, quality of life, self efficacy and HbA_{1c} of children with Type 1 diabetes.
ii. To investigate associations between physical activity, aerobic fitness, body composition, self esteem, quality of life, self efficacy and HbA_{1c} in children with Type 1 diabetes.

In this chapter the study sample is described first, then descriptive statistics are presented for each of the variables measured, finally associations between variables are investigated.

5.1: Gender, age and duration since diagnosis with Type 1 diabetes

There were 39 participants in the study. Of these 21 (54%) were boys and 18 (46%) were girls.

The mean age of the whole group was 12.8 years (95% confidence interval (C.I.) 12.1 to 13.5; minimum 9.2 years, maximum 16.3 years. The number of children of each age can be seen in figure 5.1. The reason two participants aged 16 years were included was that the age criterion for inclusion into the study was that children were aged between 9 and 15 years on the day they agreed to participate in the study. However, the ages given here were for the day each child visited the laboratory to do the fitness tests and complete the psychological questionnaires.

The mean length of time, in years, since the participants had been diagnosed with Type 1 diabetes was 5.8 years (95% C.I. 4.8 to 6.8; minimum 2.3 years, maximum 13.3 years). The descriptive statistics for age and duration since diagnosis with Type 1 diabetes, divided by gender, are shown in table 5.1.

Frequency	Stem &	Leaf
5	9 .	12244
4	10 .	2379
5	11 .	12445
6	12 .	014557
7	13 .	0567899
4	14 .	0045
6	15 .	012556
2	16 .	03

Stem width: 1 year

Each leaf: 1 child

Figure 5.1: Stem and leaf diagram showing distribution of ages in years.

Table 5.1: Descriptive statistics for age and duration since diagnosis.

	Number	Mean Age (years (95% C.I.))	Mean duration since diagnosis with diabetes (years (95% C.I.))
All participants	39	12.8 (12.1 – 13.5)	5.8 (4.8 – 6.8)
Boys	21	12.6 (11.6 – 13.7)	5.4 (4.0 – 6.8)
Girls	18	12.9 (11.9 – 14.0)	6.1 (4.6 – 7.7)

There was no significant difference between the boys and girls with respect to age ($t = -0.53$, $p = 0.60$), although the girls had a slightly higher mean age, 12.9 years compared to 12.5. There was also no significant difference between boys and girls in the length of time since diagnosis with Type 1 diabetes ($t = -0.71$, $p = 0.48$).

5.2: Levels of psychological well being, physical activity, fitness and HbA_{1c}.

In this section descriptive data on each of the measured variables (quality of life, self efficacy, self esteem, physical activity, sum of 5 skinfolds, BMI, peak VO_2 and HbA_{1c}) are reported in turn. These data are reported as means and 95% confidence intervals for the whole group and for boys and girls separately. Differences between the results of boys and girls were tested for significance using independent groups t tests. For each of these calculations Levene's test was calculated to test for the equality of group variances. Where these were significantly different the adjusted t value was reported. Associations of each variable with age and duration since diagnosis with Type 1 diabetes were calculated using Pearson Product Moment correlation coefficients (written as Pearson correlation coefficients for the remainder of the chapter). One of the criteria for using parametric tests is that data are interval or ratio. However, Clarke-Carter (1997) states that 'if a variable is ordinal but has sufficient levels – say 20 or more – then, as long as the other parametric assumptions are fulfilled it is considered legitimate to conduct parametric tests on the data. A common example of this is when the score has been produced from a multi-item Likert scale' (Clarke-Carter, 1997, p 204). Therefore in the present study the parametric Pearson test was used with both the ordinal data from the psychological questionnaires and the interval data from the physiological measurements, provided the other parametric assumptions were fulfilled.

These other parametric assumptions were firstly, that the sample was representative of the population to which the inference was made. Secondly, variables being correlated had a normal distribution. Thirdly, for every value of x the distribution of y scores had an approximately equal variability i.e. the assumption of homoscedasticity. Lastly there was a linear relationship between x and y. The first assumption was fulfilled by the sampling method, all eligible children, from two diabetes clinics, were invited to participate in the present study. Histograms were examined to check the normality of the sample distribution. Outliers, defined as >3 standard deviations above the mean (Munro, 1997), were identified. Where these were found the researcher decided whether they were due to errors in the data collection or coding or represented actual values. If they were due to errors data were either corrected or removed. For outliers that represented actual values, or for which the explanation was unknown, data were analysed once including outliers in the analysis and once excluding them. Where the results of these two analyses were not similar the distribution free Kendall's tau-b non-parametric test was used in place of the Pearson.

5.2.1: Quality of Life

The Diabetes Quality of Life for Youths Questionnaire (DQOL-Y) was used to assess this variable. The range and mid-point of its four sub-scales are shown in table 5.2.

Table 5.2: Range, midpoint and meaning of the DQOL-Y questionnaire sub-scales.

Variable	Range of sub-scale	Mid-point	Meaning of high score	Meaning of low score
Satisfaction with life	17-85	51	High satisfaction with life	Low satisfaction with life
Disease impact	22-110	66	Diabetes has high impact on life	Diabetes has low impact on life
Disease related worries	0-55	27.5	Many disease related worries	Few disease related worries
Overall health rating	1-4	2.5	Positive rating of health	Negative rating of health

Data were only included here if a response was given for each of the items in a sub-scale. If there were missing data items, the score for the sub-scale they were missing from was not reported for that child. There was one outlying data point this was in the satisfaction with life sub-scale, 1 child reported satisfaction with life as 35, more than 3 standard deviations below the mean value. The researcher had no reason to consider that this response was due to measurement or coding error, so it was included in the descriptive statistics and further analyses were conducted both including and excluding it.

Table 5.3: Descriptive statistics for the DQOL-Y questionnaire.

Variable	Sub-group	Mean	95% confidence interval.	Number
Satisfaction with life (Satisfaction)	All	68.00	64.32 – 71.68	35
	Boys	68.17	61.60 – 74.73	18
	Girls	67.82	63.90 – 71.74	17
Disease impact (Impact)	All	48.66	43.98 – 53.34	29
	Boys	48.60	41.27 – 55.93	15
	Girls	48.71	41.95 – 55.48	14
Disease related worries (Worry)	All	16.65	14.05 – 19.24	34
	Boys	14.65	11.13 – 18.17	17
	Girls	18.65	14.71 – 22.58	17
Overall health rating (Health rating)	All	3.17	2.95 – 3.39	36
	Boys	3.22	2.86 – 3.59	18
	Girls	3.11	2.82 – 3.40	18

Overall quality of life was reported to be good, scores were towards the positive end of each sub-scale's range. Boys reported slightly better quality of life than girls for all four sub-scales, but an independent groups t tests found none of these were significant (Satisfaction $t = 0.09$, $p = 0.93$; Impact $t = -0.03$, $p = 0.98$; Worry $t = -1.61$, $p = 0.12$; Health rating $t = 0.50$ $p = 0.62$). Excluding the outlying data point did not alter this result.

Pearson correlation coefficients were calculated between the satisfaction, impact and worries DQOL-Y sub-scales, age and duration since diagnosis with Type 1 diabetes. As the overall health rating was a one item sub-scale with four levels the non-parametric Kendall's tau correlation was used, as recommended by Munro (1997). The correlation between age and overall health rating was significant, younger children tended to rate their overall health higher than older children ($r = -0.28$, $p = 0.04$). There were no other significant associations between the DQOL-Y scores and age or duration since diagnosis with Type 1 diabetes. Excluding the outlying data point did not alter these associations.

Correlation coefficients between the sub-scales showed that the satisfaction, impact and worry sub-scales were significantly associated with each other, see table 5.4 for r and p values. These are presented excluding the outlying data point, but correlations were still significant when this was included.

Table 5.4: Pearson correlation co-efficients between sub-scales of the DQOL-Y questionnaire

	Disease impact	Disease related worries
Satisfaction with life	$r = -0.57^{**}$ $p < 0.01$ $n = 28$	$r = -0.58^{**}$ $p < 0.01$ $n = 32$
Disease impact		$r = 0.71^{**}$ $p < 0.01$ $n = 28$

$^{*}p < 0.05$ $^{**}p < 0.01$

The DQOL-Y scale had previously been validated with 10 to 21 year olds, there were 5 children aged 9 in the present study. When the above calculations were repeated with data from these children excluded the significance of the results remained the same as reported with the whole data set.

5.2.2: Self Efficacy

Data were collected using the Self Efficacy for Diabetes questionnaire (SED). The range, mid-point and meaning of each sub-scale is shown in table 5.5.

Table 5.5: Range, midpoint and meaning of the SED questionnaire sub-scales.

Variable	Range	Mid-point	Meaning of high score	Meaning of low score
Total self efficacy	33-198	115.5	high self efficacy (3 sub-scales combined)	low self efficacy (3 sub-scales combined)
Diabetes self efficacy	22-132	77	high diabetes self efficacy	low diabetes self efficacy
Medical self efficacy	5-30	17.5	high medical self efficacy	low medical self efficacy
General self efficacy	6-36	21	high general self efficacy	low general self efficacy

The means and 95% confidence intervals are presented in table 5.6 for the total score (sum of all 33 items) plus the 3 sub-scales. These are presented for the group as a whole and for boys and girls separately. Participant's scores were only included if they responded to all the items in a sub-scale, if any items were left blank no data were reported for that sub-scale. This was the reason the number of participants varies for the different sub-scales. There was one outlier on the general self efficacy sub-scale, this child reported general self efficacy more than 3 standard deviations below the mean. The researcher had no reason to consider that this response was due to measurement or coding error so it was included in the descriptive statistics and further analyses conducted both including and excluding it.

Table 5.6: Descriptive statistics for the SED questionnaire.

Variable	Sub-group	Mean	95% C.I.	Number
Total self efficacy	All	150.05	141.22 – 158.88	31
(SED-T)	Boys	147.41	133.12 – 161.70	16
	Girls	152.87	141.05 – 164.69	15
Diabetes self efficacy	All	101.36	95.58 – 107.14	32
(SED-D)	Boys	100.09	90.97 – 109.22	16
	Girls	102.63	94.47 – 110.78	16
Medical self efficacy	All	21.00	19.20 – 22.80	35
(SED-M)	Boys	20.50	17.81 – 23.19	18
	Girls	21.53	18.89 – 24.17	17
General self efficacy	All	28.03	26.16 – 29.90	36
(SED-G)	Boys	27.39	23.95 – 30.83	18
	Girls	28.67	26.80 – 30.54	15

All the sub-scales had a mean above the mid-point, showing children were sure they could do more of the tasks than they could not. Analysis by gender showed girls had higher self efficacy than boys for the total self efficacy score and all three sub-scales. An independent samples t test between the scores for boys and girls showed that none of these differences were significant at $p < 0.05$ (SED-T $t = 0.62$, $p = 0.54$; SED-D $t = 0.44$, $p = 0.66$; SED-M $t = 0.58$, $p = 0.57$; SED-G $t = 0.69$, $p = 0.50$). Excluding the outlying data point did not alter these results.

Pearson correlation co-efficients were calculated between the total self efficacy score, the three sub-scales, age, and duration since diagnosis with Type 1 diabetes. The outlying data point was excluded, as it would have undue influence on the outcomes. There were significant associations between age and two of the self efficacy sub-scales, the older children had higher self efficacy for diabetes (SED-D $r = 0.42$, $p = 0.02$) and medical self efficacy (SED-M $r = 0.38$, $p = 0.02$) and higher total self efficacy (SED-T $r = 0.46$, $p < 0.01$). Including and excluding the outlying data point on the general self efficacy sub-scale affected the associations, therefore Kendall`s tau-b was calculated. This showed no significant association between general self efficacy and age or duration since diagnosis with Type 1 diabetes.

Correlation co-efficients calculated between the sub-scales of the SED showed there were significant associations between these, see table 5.7. Children who rated themselves low on one sub-scale tended to rate themselves low on the other two sub-scales as well. Data are presented without the outlying data point but associations were still significant when it was included.

Table 5.7: Pearson correlation co-efficients between the sub-scales of the SED questionnaire

	SED-M	SED-G
SED-D	r= 0.65** p< 0.01 n = 31	r= 0.58** p< 0.01 n = 31
SED-M		r= 0.36* p= 0.03 n = 34

*p < 0.05 ** p < 0.01

5.2.3: Self Esteem

Data were collected using the Physical Self Perception Profile for Children (PSPP-C). Data were only included where participants had answered all six items on the sub-scale. Where there were missing data no value was reported for the sub-scale, but the remaining sub-scales from that participant were reported provided these were complete. There were no outliers.

The range for each sub-scale was 1 to 4. 1 corresponded to low self esteem and 4 to high self esteem, 2.5 was the midpoint on the scale. Global self worth (GSW) was rated highest out of the six sub-scales (mean 3.01 (95% CI 2.73 – 3.29)) i.e. it was rated higher than the sub-scales more specific to physical self esteem. The sub-scale measuring overall physical self worth (PSW) had a mean score of 2.64 (2.39 – 2.90), just above the midpoint between high and low self esteem. The four components of PSW had mean scores of, in order from highest to lowest; condition (2.89 (2.68 –

3.11), strength (2.82 (2.60 – 3.03)), sport (2.77 (2.52 – 3.02)), body (2.44 (2.17 – 2.71)). Descriptive statistics are presented in table 5.8.

Table 5.8: Descriptive statistics for the PSPP-C.

Variable	Sub-group	Mean	95% C.I.	Number
Global Self Worth (GSW)	All	3.01	2.73 – 3.29	33
	Boys	3.12	2.74 – 3.49	17
	Girls	2.90	2.44 – 3.35	16
Physical Self Worth (PSW)	All	2.64	2.39 – 2.90	32
	Boys	2.77	2.42 – 3.12	16
	Girls	2.51	2.11 – 2.91	16
Sport Competence (Sport)	All	2.77	2.52 – 3.02	33
	Boys	2.70	2.28 – 3.11	17
	Girls	2.84	2.53 – 3.16	16
Condition Competence	All	2.89	2.68 – 3.11	34
(Condition)	Boys	2.98	2.72 – 3.24	18
	Girls	2.79	2.42 – 3.17	16
Attractive Body	All	2.44	2.17 – 2.71	34
Competence (Body)	Boys	2.67	2.31 – 3.03	18
	Girls	2.18	1.77 – 2.58	16
Strength Competence	All	2.82	2.60 – 3.03	34
(Strength)	Boys	2.82	2.46 – 3.19	18
	Girls	2.81	2.56 – 3.07	16

When the data were divided by gender the boys scored themselves higher than the girls on all but the sport sub-scale. Independent samples t tests between the mean scores for the boys and the girls found no significant difference between the two groups on any of the sub-scales ($p > 0.05$). However the difference in scoring for the body sub-scale approached significance ($t=1.92$, $p=0.06$) with the girls on average reporting lower scores than the boys.

Calculation of Pearson correlation coefficients between the sub-scales, age and duration since diagnosis with diabetes showed the only significant association was between age and condition competence, older children tended to rate their condition as lower ($r= - 0.42$, $p= 0.01$).

Correlation co-efficients calculated between the sub-scales of the PSPP-C showed that PSW was significantly correlated with all four of its sub-domains (sport, condition, body, strength) and with GSW. Although GSW was significantly correlated with PSW it was only significantly correlated with one of the sub-domains of PSW, attractive body competence. Details of the correlation co-efficients between all the PSPP-C sub-scales are given in table 5.9.

The PSPP-C also included a perceived importance scale. This had four sub-scales that measured the importance children attached to the sport, condition, attractive body and strength competence. Each sub-scale had a range of 2 – 8, high scores represented high importance and low scores low importance. Table 5.10 presents descriptive data from the perceived importance profile of the PSPP-C for the sample as a whole, and for boys and girls separately. There were no outlying data points.

Table5.9: Pearson correlation co-efficients between the sub-scales of the PSPP-C.

	Condition	Body	Strength	PSW	GSW
Sport	r= 0.60** p< 0.01 n = 33	r= 0.53** p< 0.01 n = 33	r= 0.58** p< 0.01 n = 33	r= 0.64** p< 0.01 n = 31	r= 0.31 p= 0.09 n = 32
Condition		r= 0.51** p< 0.01 n = 34	r= 0.49** p< 0.01 n = 34	r= 0.34* p= 0.01 n = 32	r= 0.07 p= 0.72 n = 33
Body			r= 0.38* p= 0.03 n = 34	r= 0.88** p< 0.01 n = 32	r= 0.62* p< 0.01 n = 33
Strength				r= 0.45 p= 0.01* n = 32	r= 0.31 p= 0.08 n = 33
PSW					r= 0.73** p< 0.01 n = 31

* p< 0.05 ** p< 0.01

Table 5.10: Descriptive statistics for the perceived importance profile of the PSPP-C.

Variable	Sub-group	Mean	95% C.I.	Number
Sport Competence importance	All	2.38	2.05 – 2.71	33
	Boys	2.56	2.13 – 2.98	18
	Girls	2.17	1.61 – 2.73	15
Condition Competence importance	All	2.74	2.42 – 3.06	33
	Boys	2.67	2.19 – 3.14	18
	Girls	2.83	2.36 – 3.31	15
Attractive Body Competence importance	All	2.61	2.28 – 2.93	33
	Boys	2.58	2.18 – 2.99	18
	Girls	2.63	2.05 – 3.22	15
Strength Competence importance	All	2.48	2.16 – 2.81	33
	Boys	2.67	2.25 – 3.08	18
	Girls	2.27	1.71 – 2.82	15

Girls rated condition and attractive body competence as more important than boys and boys rated sport and strength competence as more important than girls. Independent groups t tests conducted between the scores for boys and girls found these differences were not significant (sport $t= 1.20$, $p= 0.24$; condition $t= -0.52$, $p= 0.61$; body $t= -0.15$, $p= 0.88$; strength $t= 1.25$, $p= 0.22$).

As these sub-scales consisted of two items and had a possible range of 2 to 8, the non parametric Kendall's tau-b correlation was used. There were no significant associations between these sub-scales and duration since diagnosis with Type 1 diabetes. Age was significantly associated with the importance attached to condition competence, older children tended to rate it as less important ($r= -0.29$, $p= 0.02$), there were no other significant associations with age.

5.2.4: HbA_{1c}

Mean HbA_{1c} values and their standard deviations are listed below for the group as a whole, and boys and girls separately in table 5.11. There were no outlying data points.

Table 5.11: Descriptive statistics for HbA_{1c}.

Variable	Sub-group	Mean HbA_{1c} (%)	95% C.I.	Number
HbA_{1c}	All	9.70	9.15 – 10.24	39
	Boys	9.62	8.87 – 10.39	21
	Girls	9.77	8.89 – 10.63	18

Figure 5.2 plots HbA_{1c} values against age for boys and girls separately. As the graph suggests there was no significant association between age and HbA_{1c} ($r = 0.17$, $p = 0.30$). Nor was there a significant difference between the HbA_{1c} values of boys and girls ($t = -0.27$, $p = 0.79$). A second Pearson Product Moment correlation between HbA_{1c} and duration since diagnosis with Type 1 diabetes found no significant association ($r = -0.21$, $p = 0.22$).

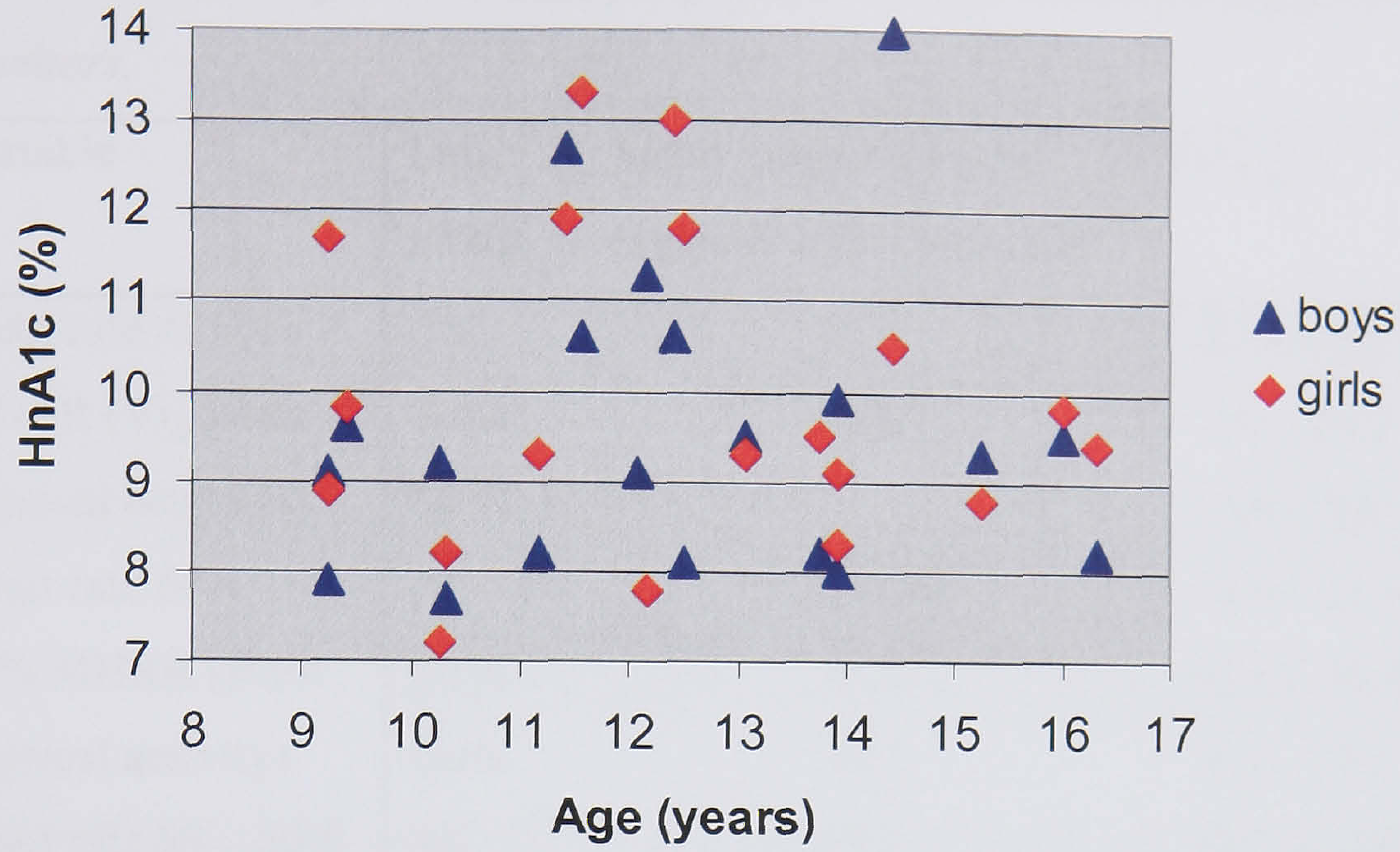

Figure 5.2: Distribution of HbA_{1c} according to age and gender

5.2.5: Physical activity

There were three outlying data points. Two of these were for vigorous physical activity, values for two children were more than three standard deviations above the mean. The third outlier was for moderate physical activity, one child had a value that was more than three standard deviations greater than the mean. These three values were considered valid after examination of the raw data and were therefore included in the descriptive statistics in table 5.12.

Table 5.12: Descriptive statistics for physical activity measured using heart rate monitors.

Variable	Sub-group	Mean number of mins physical activity per day	95% C.I.	Number
Heart rate >75% MHRR (Vigorous physical activity)	All	9.31	5.5 – 13.1	39
	Boys	13.6	7.0 – 20.3	21
	Girls	4.3	2.6 – 5.9	18
Heart rate 60% - 75% MHRR (Hard physical activity)	All	17.9	14.0 – 21.8	39
	Boys	21.0	15.1 – 26.9	21
	Girls	14.3	9.3 – 19.3	18
Heart rate 50 – 60% MHRR (Moderate physical activity)	All	27.8	22.7 – 33.0	39
	Boys	28.4	22.0 – 34.8	21
	Girls	27.2	18.1 – 36.3	18
Total physical activity: i.e. heart rate > 50% MHRR	All	55.1	44.4 – 65.8	39
	Boys	63.0	47.2 – 78.8	21
	Girls	45.8	31.3 – 60.2	18

The mean number of minutes per day spent doing physical activity of moderate or greater intensity was 55.1 (44.4 – 65.8) minutes. The mean volume of moderate physical activity was 27.8 (22.7 – 33.0) minutes, the mean volume of hard physical activity was lower (17.9 (14.0 – 21.8) minutes), and the mean volume of vigorous physical activity lower still (9.3 (5.5 – 13.1)). These values are presented graphically in figure 5.3. When data were examined by gender it could be seen that boys were more active than girls. Independent groups t tests between mean values for boys and girls showed the difference for vigorous physical activity was significant ($t= 2.7$, $p= 0.01$), the other differences were not. Removing the outlying data points did not alter this result.

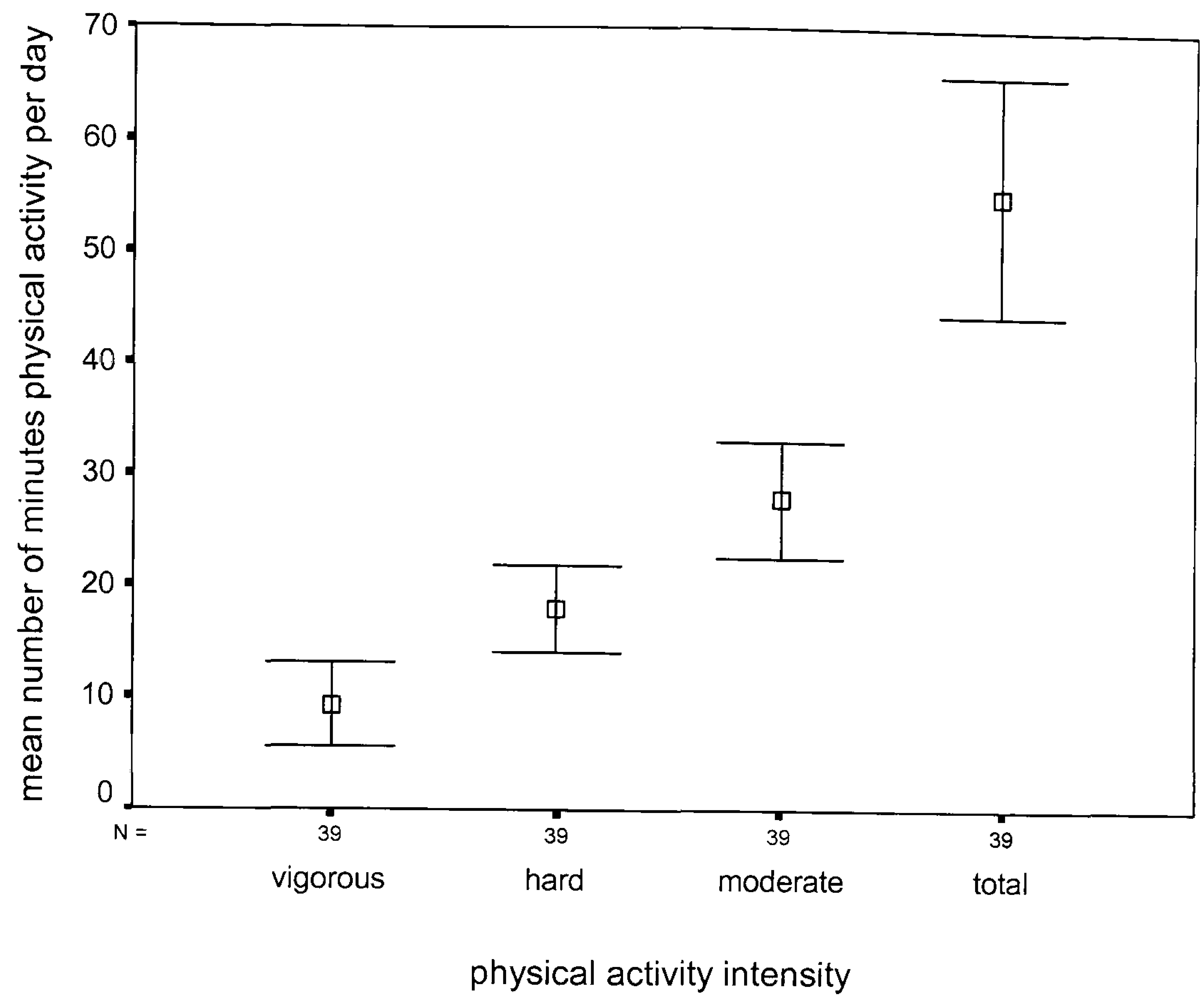

Figure 5.3: Graph showing mean physical activity levels and 95% confidence intervals for moderate, hard, vigorous and total physical activity.

Pearson correlation coefficients were calculated between the three mean physical activity levels, age and duration since diagnosis with Type 1 diabetes. These found age was significantly correlated with vigorous, hard and total physical activity, in all three cases physical activity decreased as age increased (vigorous $r = -0.39$, $p=0.02$; hard $r=-0.44$, $p < 0.01$; total physical activity $r = -0.32$, $p<0.05$). Duration since diagnosis with Type 1 diabetes was not significantly associated with any of the levels of physical activity. Data are presented with outlying data points removed, but they remained significant when these were included.

Seventeen (44%) of this sample participated in moderate or greater intensity physical activity for at least 60 minutes per day and so met the Health Education Authority's (1998) optimal physical activity target. This is that all young people should participate in physical activity of at least moderate intensity for one hour a day. Twenty-nine (74%) of the sample participated in at least 30 minutes of moderate or greater intensity physical activity per day and therefore met the Health Education Authority's initial physical activity target. This is that young people who currently do little activity should participate in physical activity of at least moderate intensity for at least half an hour a day.

5.2.5.2: Self report physical activity data

The 7 Day PAR was used to collect data. The definitions for categorising physical activity into moderate, hard or very hard were:
Moderate physical activity - walking at a brisk pace or any other activity that makes you feel as tired as this;
Hard physical activity - any activity which is more tiring than walking at a brisk pace but less tiring than running;
Very hard physical activity - running or any other activity that makes you feel as tired as this.

Data are presented as average number of minutes of self reported physical activity per day, see table 5.13. There were two outlying data points. One of these was considered to be due to inaccurate data collection, working as a shop assistant had been classified as hard physical activity, and therefore all self reported physical activity data were removed for that participant. The other outlier was for very hard physical activity, a value more than three standard deviations above the mean was reported. Consultation with the original data and with heart rate data suggested it was valid and it was therefore included in the descriptive data.

Table 5.13: Descriptive statistics for physical activity measured using a self report questionnaire.

Variable	Sub-group	Mean number of mins physical activity per day	95% C.I.	Number
Very hard physical activity	All	12.1	4.5 – 20.7	22
	Boys	17.9	3.4 – 32.3	12
	Girls	6.2	0.6 – 11.8	10
Hard physical activity	All	22.4	12.0 – 32.8	22
	Boys	25.5	7.3 – 43.8	12
	Girls	18.6	7.5 – 29.8	10
Moderate physical activity	All	45.4	29.7 – 61.0	22
	Boys	51.8	26.8 – 76.8	12
	Girls	37.7	16.3 – 59.1	10
Total (sum of moderate, hard and very hard)	All	80.4	62.6 – 98.1	22
	Boys	95.2	68.9 – 121.5	12
	Girls	62.6	40.0 – 85.2	10

Boys reported more moderate, hard and very hard physical activity than girls. Independent samples t tests found these differences were not significant (moderate $t= 0.92$ $p=0.37$, hard $t= -0.68$ $p= 0.51$, very hard $t= 1.66$ $p= 0.12$, total $t= 2.04$ $p= 0.06$). This remained the same when the outlying data point was excluded.

Pearson correlation coefficients calculated between self reported physical activity and age showed non significant associations with moderate ($r= 0.15$ $p= 0.51$) and hard ($r= -0.41$ $p= 0.06$) physical activity and a significant association with very hard physical activity ($r= -0.60$ $p< 0.01$). The correlation between total physical activity and age was also not significant ($r= -0.38$ $p= 0.08$). There were no significant associations between duration since diagnosis with Type 1 diabetes and average number of minutes of self reported physical activity per day. Data are reported with outliers excluded, but the significance of the results remained the same when they were included.

The two methods used to assess physical activity were assessing the same dimension, therefore a positive association between them would be evidence of concurrent validity. Correlation coefficients calculated using Pearson's coefficient correlations showed self reported very hard activity was significantly associated with time spent in hard and very hard physical activity as measured by heart rate monitors. Self reported hard physical activity was also significantly associated with time spent in very hard physical activity as measured by heart rate monitors. Self reported moderate physical activity was not significantly associated with time spent above any of the three heart rate thresholds, see table 5.14 for details of the correlation coefficients.

Outliers that were considered valid data points were not removed in the above calculations. This was because the two measures were recorded over the same period of time and therefore unusual physical activity patterns would be recorded by both.

Table 5.14: Pearson correlation co-efficients between physical activity measured by self report and using heart rate monitors.

		50-60% MHRR	60-75% MHRR	>75% MHRR
Self report	r	- 0.30	- 0.25	- 0.17
moderate	p	0.18	0.27	0.45
physical activity	n	22	22	22
Self report hard	r	- 0.12	0.04	0.47*
physical activity	p	0.59	0.88	0.03
	n	22	22	22
Self report very	r	0.04	0.52 **	0.63 **
hard physical	p	0.88	0.01	< 0.01
activity	n	22	22	22

$^*p < 0.05$ $\quad$ $^{**} p < 0.01$

5.2.6: Body composition data

5.2.6.1: BMI

BMI was calculated from height and body mass using the formula:

BMI = weight (kg) / height (m) ^{2}

Descriptive data are presented in table 5.15, there were no outlying data points.

Table 5.15: Descriptive statistics for BMI.

Variable	Sub-group	Mean ($kg^{-1}m^2$)	95% C.I.	Number
BMI	All	20.89	19.47 – 22.30	33
	Boys	19.11	17.81 – 20.42	17
	Girls	22.77	20.40 – 25.14	16

On average the boys had lower BMI values than the girls. An independent samples t test showed this difference was significant ($t= -2.9$, $p< 0.01$). Pearson correlation coefficients found age was significantly correlated with BMI, older children tended to have higher BMI values ($r= 0.43$ $p= 0.01$). There was no significant association between duration since diagnosis with Type 1 diabetes and BMI ($r= -0.02$ $p= 0.90$).

5.2.6.2: Sum of 5 skinfold measurements

The measurements summed were as follows:

Sum of 5 skinfolds = sum of bicep, tricep, subscapular, suprailliac and calf

Descriptive data are shown in table 5.16, there were no outlying data points. Girls had greater levels of subcutaneous fat than boys, an independent samples t test showed this was significant ($t= -2.78$ $p= 0.01$). The 95% confidence interval of the mean for girls was more than double that of the boys, i.e. there was greater variation in levels of subcutaneous fat in girls than in boys.

Table 5.16: Descriptive statistics sum of skinfold measurements.

Variable	Sub-group	Mean (mm)	95% C.I.	Number
Sum of 5 skinfolds	All	67.90	56.25 – 79.55	33
	Boys	53.62	45.15 – 62.09	17
	Girls	83.08	62.20 – 103.97	16

Pearson correlation coefficients showed there was no significant association between age and sum of 5 skinfolds. However it approached significance, older children tended to have higher levels of subcutaneous fat. ($r= 0.33$ $p= 0.07$). Figure 5.4 shows that older girls tended to have particularly high levels of body fat. There were no significant associations between duration since diagnosis with Type 1 diabetes and sum of skinfold measurements.

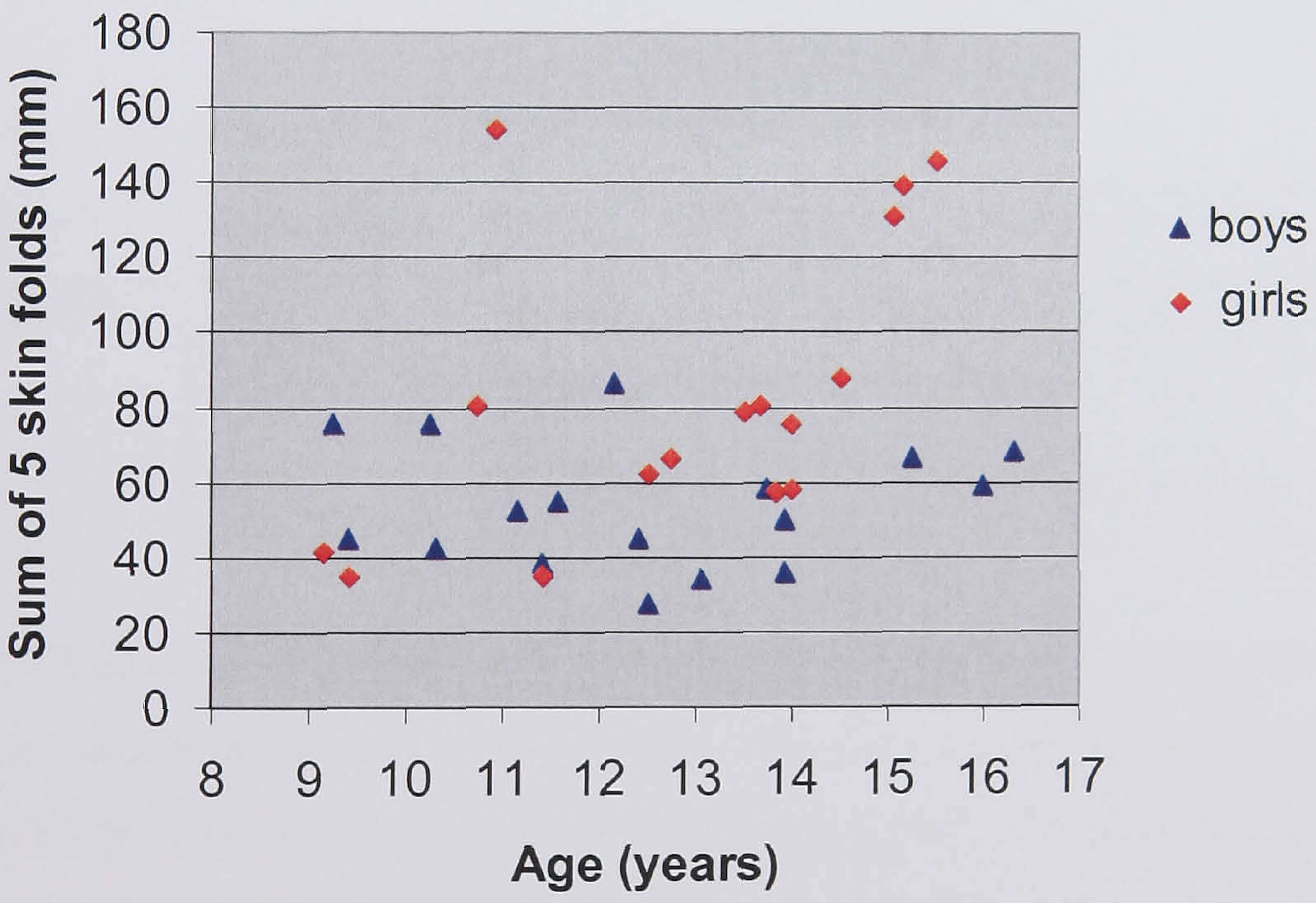

Figure 5.4: graph showing sum of 5 skinfold measurements against age for boys and girls separately.

BMI and sum of skinfold measurements were measuring the same parameter of fitness and so would be expected to correlate highly as was the case ($r= 0.87$, $p< 0.01$).

5.2.6.3: Peak VO_2

Data are presented in table 5.17 for 15 children. This was because the remaining tests were carried out using an automatic gas analysis system, an aerosport gas analyser. This was easier to operate and more comfortable for the children to use. In initial tests to check the validity of this system, using adults, it appeared to be comparable to the Douglas bag system. However, further tests before phase two of the study showed an error with part of the system, which analysed concentration of CO_2, which had not been previously identified. It was considered that this would have also been affecting the system during phase 1 and therefore these data were removed.

Two further data points were removed, these were peak VO_2 values of 10.27 and 10.48 $ml^{-1}kg^{-1}min^{-1}$. These values would signify clinically unfit children and as this was not the case for either of these participants the results were considered to be invalid. Of the remaining 15 data points, none were outliers.

Table 5.17: Descriptive statistics for peak VO_2.

Variable	Sub-group	Mean ($ml^{-1}kg^{-1}min^{-1}$)	Standard deviation	Number
peak VO_2	All	35.80	30.91 – 40.69	15
	Boys	34.97	27.75 – 42.18	9
	Girls	37.05	28.04 – 46.06	6

The mean peak VO_2 value for girls was greater than that for boys but this was not a significant difference ($t= -0.43$ $p= 0.67$). Pearson correlation coefficients showed no significant association between peak VO_2 and age ($r= 0.40$, $p= 0.14$). There was also no significant association between duration since diagnosis with Type 1 diabetes and peak VO_2.($r= 0.18$, $p= 0.28$).

5.2.7: Associations between measures of physical activity and fitness

The associations between physical activity, measured using heart rate, sum of 5 skinfold measurements, BMI, and peak VO_2 were examined. As physical activity and sum of 5 skinfolds were significantly associated with age, partial correlations, controlling for age, were carried out for these variables. No significant associations were found between the three intensities of physical activity and the three measures of fitness. Neither was there a significant association between sum of 5 skinfold measurements or BMI and peak VO_2.

5.3: Investigation of hypotheses

In this section data were examined in relation to the hypotheses of the study. Section 5.3.1 reports calculations that tested whether higher levels of physical activity and fitness were associated with greater psychological well being in children with Type 1 diabetes. In section 5.3.2 the hypothesis that higher levels of physical activity and fitness would be associated with lower HbA_{1c} values in the same group was investigated.

Associations between variables were tested using correlation coefficients. The number of data points used in each correlation varied because the outlying data points, described in section 5.2, were excluded in the reported data. As self report data and heart data both assessed physical activity and were shown to be significantly associated, see section 5.2.5.2, only heart rate physical activity data are used in this section.

5.3.1: Examination hypothesis 1: higher levels of physical activity and fitness would be associated with greater psychological well being.

Pearson Product Moment correlation coefficients between the sub-scales of the physical self perception profile and measurements of physical activity and fitness are presented in table 5.18. Physical self esteem, and two of its sub-scales, were significantly correlated with sum of 5 skinfolds , higher adiposity was associated with lower physical self esteem ($r= -0.48$, $p<0.01$; body $r=-0.54$, $p<0.01$; condition $r=-0.46$, $p<0.01$). Figure 5.5 shows the association between physical self worth and sum of 5 skinfolds in more detail as a scattergram.

Table 5.18: Pearson correlation coefficients between sub-scales of the PSPP-C and measures of physical activity and fitness.

		Sum of 5 skinfolds	**BMI**	**Peak VO_2**	**Moderate P.A.**	**Hard P.A.**	**Vigorous P.A.**
GSW	r	- 0.13	- 0.10	0.61*	- 0.19	- 0.07	0.10
	p	0.48	0.59	0.02	0.30	0.71	0.58
	n	30	30	14	32	33	31
PSW	r	- 0.48**	- 0.43*	0.74**	- 0.09	0.10	0.18
	p	< 0.01	0.02	<0.01	0.64	0.58	0.34
	n	29	29	13	31	32	30
Body	r	- 0.54**	- 0.52**	0.51	0.04	0.21	0.31*
	p	< 0.01	< 0.01	0.07	0.81	0.24	0.05
	n	31	31	14	33	34	32
Condition	r	- 0.46**	- 0.49**	0.23	0.10	0.28	0.24
	p	< 0.01	< 0.01	0.42	0.57	0.11	0.18
	n	31	31	14	33	34	32
Strength	r	- 0.01	0.08	0.42	0.14	0.03	0.04
	p	0.94	0.68	0.14	0.44	0.86	0.84
	n	31	31	14	33	34	32
Sport	r	- 0.26	- 0.19	0.63*	0.08	0.08	-0.12
	p	0.17	0.31	0.02	0.67	0.65	0.51
	n	30	30	14	32	33	31

*p < 0.05 ** p < 0.01

Vigorous physical activity had a significant association with body adequacy competence (r= 0.31, p= 0.03). Non of the other sub-scales were significantly associated with physical activity. When the same calculation was performed with the outlying physical activity data included the result was similar, the only significant association between physical activity and the sub-scales of the PSPP-C was for body adequacy competence and vigorous physical activity, the r value was slightly greater (r= 0.38, p= 0.03).

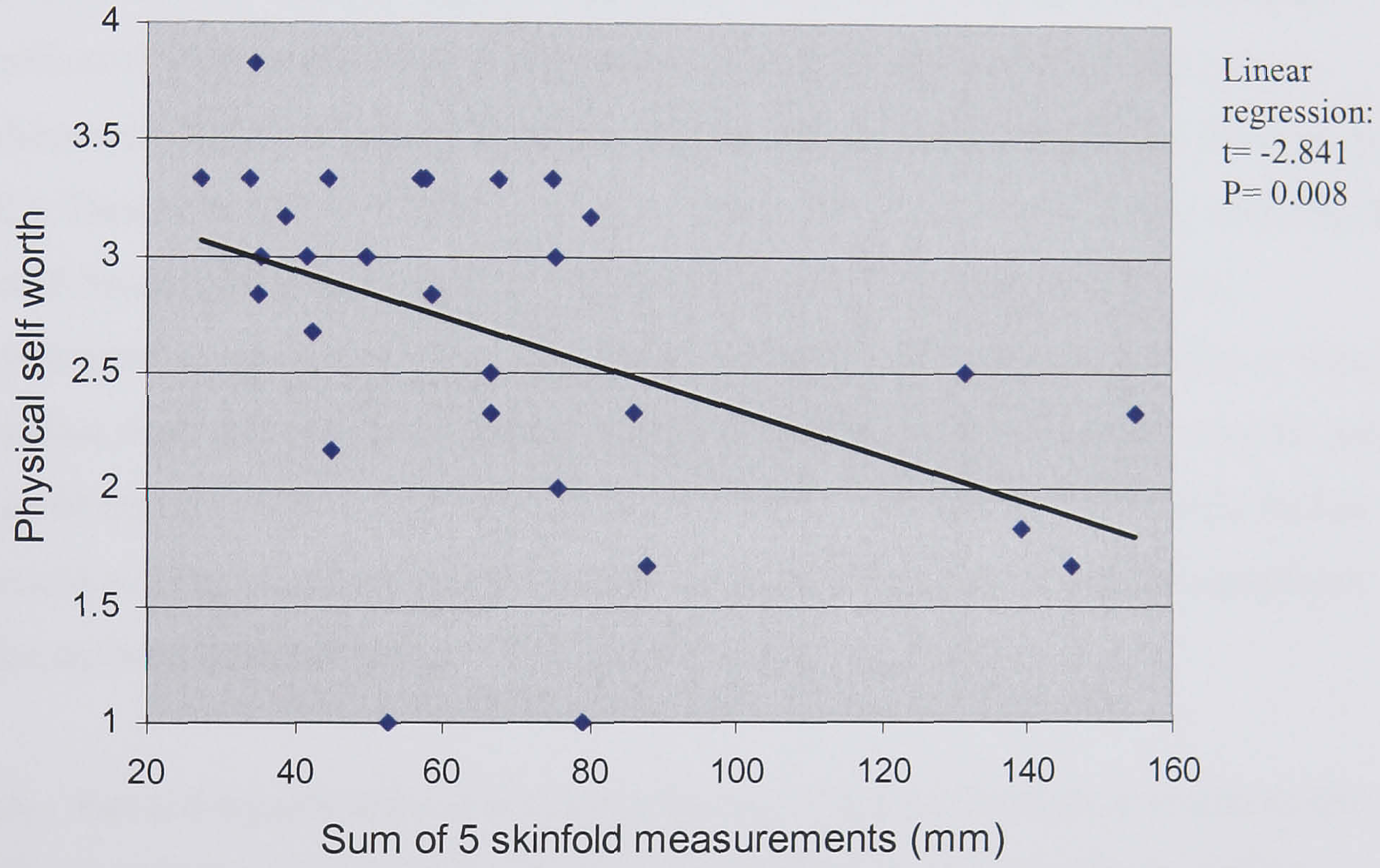

Figure 5.5: Scattergram showing the association between sum of 5 skinfolds and physical self worth

Two of the SED sub-scales and the total SED score were significantly associated with age, therefore partial correlations, controlling for age, were conducted with those physical activity and fitness variables that also had a significant association with age. The SED sub-scales and the SED total score were not significantly associated with the physical activity or fitness variables. This result was the same both when outliers were included and excluded.

Calculations between the DQOLY and physical activity and fitness variables showed BMI was significantly associated with the disease related worries sub-scale ($r= 0.36$, $p< 0.05$), children with higher BMI had more disease related worries. Vigorous physical activity was also significantly associated with the worry sub-scale but only when outliers were excluded. Munro (1997) suggested that when this happens an analysis that is resistant to outliers should be used. Kendall's tau-b showed a significant association between vigorous physical activity and disease related worries ($r= 0.27$, $p= 0.03$). Those children who participated in more vigorous physical activity had fewer disease related worries. Satisfaction with life and peak VO_2 were also significantly correlated using Pearson's product moment coefficient, but only if outliers were removed. Kendall's tau-b showed a significant association ($r= 0.51$, $p= 0.01$). Those children with higher aerobic fitness had greater satisfaction with life. The overall health rating was significantly associated with age therefore partial correlations, controlling for age, were used between it and physical activity or fitness variables that were also associated with age. Vigorous physical activity was the only variable significantly associated with overall health rating ($r=0.37$, $p=0.03$), higher physical activity was associated with better health rating, this remained significant when outliers were excluded.

HbA_{1c} was not significantly associated with any of the psychological measures ($p > 0.05$) when Pearson correlations were conducted both with and without outliers.

5.3.2: Examination of hypothesis 2: greater physical activity and fitness would be associated with lower HbA_{1c}

Pearson's Product Moment correlation coefficients between HbA_{1c} and physical activity and fitness variables are presented in table 5.19. Outlying data points were excluded.

Table 5.19: Pearson correlation coefficients between HbA_{1c} and physical activity and fitness variables.

	HbA_{1c}		
	Pearson Correlation (r)	Significance (p)	n
Moderate physical activity	0.18	0.29	38
Hard physical activity	- 0.12	0.46	39
Vigorous physical activity	- 0.32	0.05	37
BMI	0.03	0.86	33
Sum of 5 skinfolds	0.08	0.67	33
peak VO_2	0.25	0.38	15

The association between vigorous physical activity and HbA_{1c} approached significance when the outlying data points were removed ($r= -0.32$, $p= 0.05$), those children with lower HbA_{1c} participated in more vigorous physical activity. However, it was non-significant when these were included and the distribution free Kendall's tau correlation calculated ($r= -0.15$, $p= 0.20$). The r values suggested that although non significant, vigorous physical activity accounted for more of the variance in HbA_{1c} than hard or moderate physical activity. These associations can be seen in figures 5.6 and 5.7.

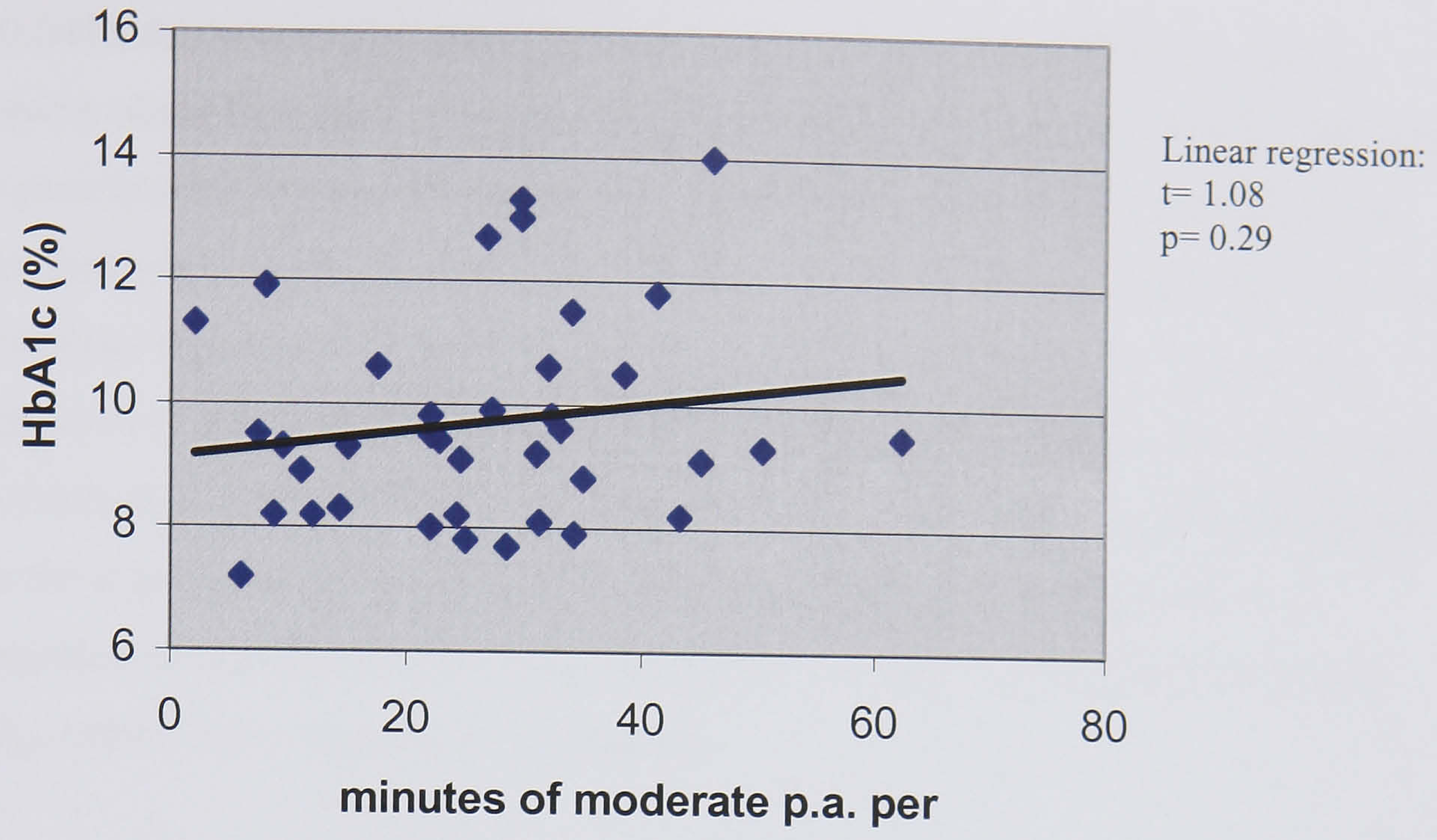

Figure 5.6: Scattergram showing the association between HbA_{1c} and moderate physical activity

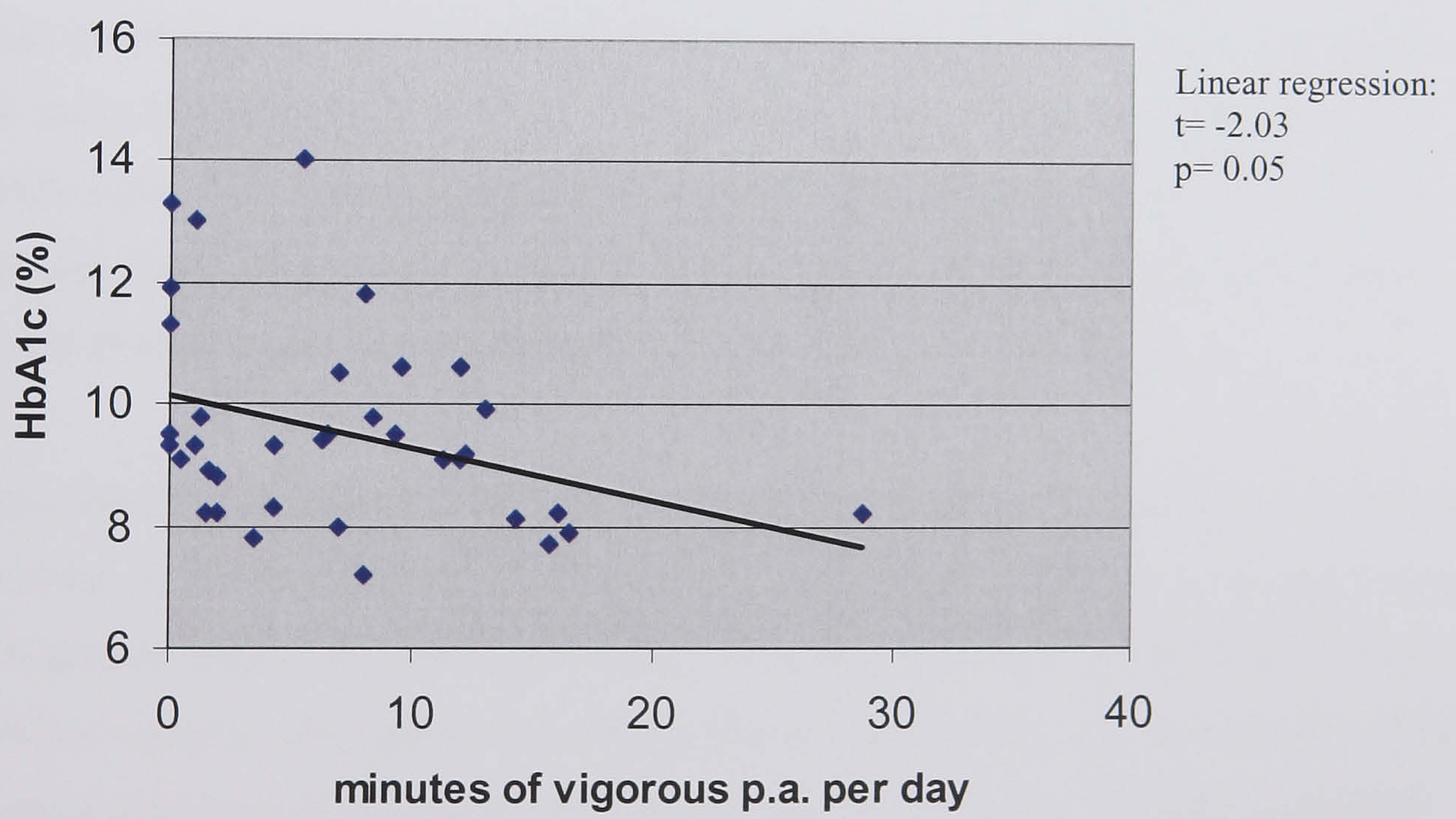

Figure 5.7: Scattergram showing the association between HbA_{1c} and vigorous physical activity.

This result was different to that reported in the conference presentation to the North American Society of Pediatric Medicine (Edmunds et al., 2001), where a significant association between vigorous physical activity and HbA_{1c} was reported (r= -0.33, p= 0.048), this was calculated using a Spearman correlation coefficient, due to concerns about the data meeting parametric assumptions. Statistical advice following this presentation has recommended that Pearson correlation coefficients should be calculated and where parametric assumptions are not met the Kendall's tau is a more appropriate distribution free test. Therefore Pearson correlation coefficients are reported here. The difference between the three calculations when outlying data points are removed is small, but Pearson and Kendall's tau correlation coefficients are just over the significance level, p=0.05 in both cases. Therefore the association is interpreted here as a non-significant trend between vigorous physical activity and HbA_{1c} rather than a significant association.

5.4: Summary of main findings in Phase One

To summarise the results, the sample of children in the present study reported positive diabetes quality of life and self efficacy for diabetes. Their physical self esteem was again generally high, the sub-scale rated lowest was the attractive body competence sub-scale. Physical activity levels approached the target level recommended by the Health Education Authority to maintain health, however, vigorous physical activity was low. There was a large range in the BMI and sum of skinfold data, older girls tended to have high values. Mean peak VO_2 was 35.8 $ml^{-1}kg^{-1}min^{-1}$.

There were significant associations between physical self esteem and all three fitness variables, sum of 5 skinfolds, BMI and peak VO_2, higher self esteem was associated with greater fitness. The only association of physical activity with the PSPP-C was between vigorous physical activity and attractive body adequacy competence, greater physical activity was associated with higher body competence. The disease related worries and overall health rating sub-scales of the DQOL-Y were also significantly associated with vigorous physical activity, greater physical activity was associated with better quality of life. The satisfaction with life sub-scale was significantly associated with aerobic fitness, again, greater satisfaction was associated with higher fitness.

Due to the number of correlation coefficients calculated it is possible that significant associations found were the result of Type 1 error. A Bonferoni adjustment was not used because, although this would have reduced the likelihood of Type 1 error, it would have increased the possibility of Type 2 error to such an extent that no significant results would have been found. As this was an exploratory study in an area where there is no previous research, it was felt it was important to report trends in the data, in order to give future studies with greater power and indication of which areas may be interesting to examine.

When outlying data points were removed there was no significant association between lower HbA_{1c} and greater vigorous physical activity, although a non-significant trend in this direction was evident. None of the other physical activity or fitness variables showed significant associations with HbA_{1c}.

6

Discussion: Phase One

The study was divided into two parts; this chapter is a discussion of the findings of phase one that were presented in chapter 5.

The hypotheses of phase one were:

1. There would be a positive association between higher levels of physical activity, fitness and glycaemic control in children with Type 1 diabetes.
2. There would be a positive association between higher levels of physical activity, fitness and psychological health in children with Type 1 diabetes.

There were two objectives:

i. To establish baseline data for level of physical activity, fitness, HbA_{1c} and psychological variables in children with Type 1 diabetes.
ii. To investigate associations between physical activity, fitness, psychological health and HbA_{1c} in these children.

The first section of this chapter relates to objective one, it examines the descriptive statistics for each of the measures used: Diabetes Quality of Life Youth Scale (DQOL-Y) (Ingersoll and Marrero, 1991); Self Efficacy for Diabetes scale (SED) (Grossman et al., 1987); Physical Self Perception Profile for Children (PSPP-C) (Whitehead, 1995); heart rate monitors; the 7 Day Physical Activity Recall (7 Day PAR) (Sallis et al., 1985); peak VO_2 test; sum of skinfold measurements; and HbA_{1c}. The sample in the present study is then compared to either children with Type 1 diabetes, children in the general population, or both, depending on what data is available for the measure. Limitations of the data are discussed. The second section of the chapter relates to objective two that was to investigate associations between the variables in order to test the hypotheses of phase one of the study. Implications of the findings for the second phase are discussed in the third section of the chapter. Implications for further research and for practice are discussed for the study as a whole at the end of chapter 10.

6.1: Descriptive Baseline data

Physical activity

For the group as a whole the mean time per day that children spent in moderate or higher intensity physical activity, defined in this study as above 50% maximum heart rate reserve (MHRR), was 55 minutes. This was an encouraging mean level of moderate physical activity when considered in relation to the Health Education Authority's current recommendations for promoting health enhancing physical activity with young people age 5 to 18 (Health Education Authority, 1998, see section 2.2). The primary recommendation is that 'all young people should participate in physical activity of at least moderate intensity for one hour per day. Young people who currently do little activity should participate in physical activity of at least moderate intensity for at least half an hour a day'. It is recommended that the activity can be performed continuously or accumulated throughout the day, to take into account children's sporadic activity patterns. Therefore on average the children with diabetes in this study appeared to be approaching the Health Education Authority's primary physical activity target.

The Health Education Authority's secondary recommendation is 'at least twice a week, some of these activities should help to enhance and maintain muscular strength and flexibility, and bone health.' The rationale for this is that participation in strength and weight bearing activities is positively associated with bone and mineral density and is believed to be related to a reduced long-term risk of osteoporosis. It was more difficult to use heart rate data to interpret whether this recommendation was met than the primary one, but it would relate to some extent to participation in more vigorous physical activity. For heart rate data hard physical activity was defined as heart rate between 60 and 75% MHRR and vigorous physical activity as heart rate greater than 75% MHRR. Using these thresholds the mean time per day spent in hard physical activity was 18 minutes, vigorous physical activity was less frequent; children spent an average of 9 minutes per day doing this. These data suggest children may be participating in some weight bearing physical activity but a different method of physical activity assessment, e.g. an assessment of type of physical activity, would be necessary to clarify this.

Self report physical activity data were also collected, using the 7 day physical activity recall interview. Children reported participating in an average of 45 minutes per day of moderate physical activity (activity equivalent to walking at a brisk pace), 22 minutes of hard physical activity (equivalent to activity more tiring than walking but less tiring than running), and 12 minutes per day of very hard physical activity (activity equivalent to running). The total amount of physical activity reported, equivalent to brisk walking or more tiring, was 80 minutes per day.

Self report measures of physical activity and physical activity measured by heart rate, assess different dimensions of physical activity and so may not be expected to correlate highly (see section 3.2). However, a previous study by Sallis found self reported very hard physical activity, assessed using the 7 day PAR, was significantly associated with physical activity assessed as time spent above heart rate thresholds of 140 and 160 beats per minute. He did not report associations with the less vigorous physical activity because heart rates lower than 140 beats per minute are more likely to be affected by emotional factors (Sallis et al., 1993).

Positive associations between heart rate and self report data in this study would support their validity. Pearson correlation co-efficients between the two sets of data showed a significant positive association between self reported very hard physical activity and both hard ($r=0.52$, $p< 0.01$) and very hard physical activity ($r=0.63$, $p< 0.01$) measured using heart rate monitors. This suggests that the 60% MHRR threshold corresponded to what the children described as very hard physical activity, defined as running or any other activity which makes you feel as tired as this. Therefore the self reported very hard physical activity in the present study was considered a valid measure of physical activity. Self reported hard physical activity was also significantly associated with time spent above 75% MHRR, but not time spent between 60 and 75% MHRR. This suggested that children may have been inaccurate in their categorisation of physical activity intensity. Moderate physical activity was not significantly associated with heart rate data, this related to lower heart rate thresholds which, as Sallis et al. (1993) suggested, are more likely to be affected by emotional factors. Therefore self report very hard physical activity was considered to be a valid measure of physical activity but self report hard and moderate data were treated more cautiously.

Data on the physical activity patterns of children with Type 1 diabetes are very limited. However, physical activity patterns of young people in the UK, Europe and North America have been documented by large national surveys. It is difficult to compare data from these surveys due to different methodologies in the data collection and analyses, but consistent age and gender related trends are clear. A review of a number of these national studies found boys to be more active than girls, and younger children tend to be more active than adolescents. Gender differences are evident early in childhood but they are greater in older children and adolescents (Armstrong and Welsman, 1997).

The data from this study followed the same trends. Boys were on average more active than girls (mean 63 minutes compared to 46 minutes respectively). Analysis by age showed that physical activity decreased as age increased. Although the mean physical activity level approached that recommended by the Health Education Authority further analysis revealed that 29 children (74%) participated in at least 30 minutes moderate physical activity per day but only 17 (44%) participated in 60 minutes physical activity per day. Analysis by gender and age showed older girls had particularly low physical activity levels.

These physical activity levels were very similar to those reported by Atkins (1998) for a sample of 51 Liverpool schoolchildren aged 9 to 13. He reported a mean of 56 cumulative minutes per day above 139 beats per minute (equivalent to 55% MHRR), 40 minutes per day above 60% MHRR and 10 minutes per day above 75% MHRR. Therefore it would seem that children with Type 1 diabetes have very similar physical activity levels to their healthy peers and that physical activity trends over time and between genders are also typical of this age group

The physical activity level of this sample differed from that of the only other study which has reported physical activity levels of children with Type 1 diabetes (Loman and Galgini, 1996). They reported that children with Type 1 diabetes, aged 12 to 17 years, participated in approximately half the total amount of exercise participated in by the general population. In contrast the present study found that levels of moderate physical activity were similar to those of the general population. Loman and Galgini's

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data were collected on a sample of 30 children from the US, using the 7 day PAR instrument. The contrasting findings of these two studies could be due to both having small samples and therefore data that are not typical of the population. Alternatively the results may reflect differing physical activity patterns of children with Type 1 diabetes in the UK and the USA.

Body fatness

Obesity is defined as BMI greater than $30kg^{-1}m^2$ and overweight as BMI greater than 25 $kg^{-1}m^2$ (Department of Health, 1995). Using these definitions in the present sample 5 children (13%) were overweight and two (5%) of these were obese. These five were all girls. Compared to normative data for over 1000 Liverpool schoolchildren aged 9 to 14 (Stratton, 1999) twenty-one (55%) of the children with Type 1 diabetes in the present study had BMI above the 75th percentile for of the equivalent age. When analysed by gender this was 8 (40%) of the boys and 12 (69%) of the girls.

However, during puberty growth can confound BMI. Twisk (2000, p 256) recommended that 'results obtained with BMI as the indicator for body fatness should be interpreted cautiously; especially in children and adolescents, because in this particular population the variables concerned are also influenced by natural growth and biological development.' He suggests results obtained from skinfold measurements are more accurate. As above data were compared with normative data for sum of the same 5 skinfold measurements for over 1000 Liverpool schoolchildren aged 9 to 14 (Stratton, 1999). Eighteen (45%) of the children in the present study had skinfold thickness above the 75th percentile for their healthy peers of the same age. A greater number of girls than boys were overfat, 7 (31%) of boys compared to 11 (59%) of girls. Twenty five percent of these girls were above the 95th percentile.

This represented a high proportion of children who were overweight and overfat. Given the immediate and long term negative consequences of childhood and adolescent obesity e.g. high blood pressure, lipid disorders and increased risk for coronary heart disease, it was an important finding. Correlation co-efficients between age and BMI showed significant associations, older children tended to have higher BMI. There was a similar non-significant trend with skinfold thickness, older children tended to have higher skinfold thickness. The scattergram of this distribution (figure

5.4) showed that overfatness and overweight particularly affected the 14 and 15 year old girls.

This confirmed previous findings with children with Type 1 diabetes (Tylleskar et al., 2001; Du Caju et al., 1995; Gregory et al., 1992; Campaigne et al., 1984). Of these three studies only Gregory et al. (1992) assessed body composition using skinfold thickness measurements and bioelectrical impedence methods. The sample (35 boys and 33 girls, mean age 12.6 years, range 6 to 18 years) was similar to the one reported in this study. They found that when weight was expressed as a percentage of the median for age and sex, pubertal boys and girls had greater percentage weights than those in pre-puberty. However, when groups were divided into pre-pubertal boys, pre-pubertal girls, pubertal boys and pubertal girls the only group that had significantly higher percentage body fat than the others was pubertal girls ($p<0.001$), representing a 40% increase in percentage body fat compared to pre-pubertal girls. No significant changes occurred in boys. The study did not have a control group but, compared to the 1990 Census of the Dietary and Nutritional Survey of British Adults a higher proportion of pubertal girls than young British women aged 16 - 24 as a whole had percentage body fat above 30% (57% and 29% respectively). Tylleskar et al. (2001) retrospectively examined records of 8 girls with Type 1 diabetes from age 10 to around 18 years. They again found that BMI increased during puberty and the adolescent period, the longer follow up time showed that BMI was still rising at the end of this period. An interesting finding from this study was that elevated BMI at 10 years of age had a predictive value for both the risk of developing high BMI/obesity in late adolescence and increased HbA_{1c} levels in late adolescence. Gregory et al. (1992) speculated that to prevent excess body fat in girls with Type 1 diabetes the focus should be on limiting dietary energy intake and increasing energy expenditure. The findings of Tylleskar et al. suggested that interventions to lower body fat may be most beneficial prior to the onset of puberty.

Increased exercise alongside healthy eating is recommended as a way to reduce body fat. This is more complicated in children with Type 1 diabetes than for children in general because dietary intake, amount of insulin injected and exercise have to be balanced to maintain desired blood glucose levels. If sufficient food is not consumed compared to the insulin injected, blood glucose can fall below desired levels causing hypoglycaemia. If too much food is consumed or too little insulin injected blood glucose levels can rise above desired levels causing hyperglycaemia. Exercise increases the uptake of glucose from the blood to the cells in the same way it does in people without diabetes. However, people with diabetes are unable to suppress the level of insulin in the blood during exercise as it is not produced internally, which means that they can suffer hypoglycaemia if either extra food is not consumed or the amount of insulin injected not reduced. On the other hand if there is insufficient insulin, glucose cannot be taken up into the cells and hyperglycaemia can occur. However, if these factors are taken into account, and the appropriate adjustments to the treatment regimen made, increasing physical activity alongside healthy eating would be expected to have the same effect on body fat in children with diabetes as children in general. It may be particularly beneficial in older girls, identified with high levels of body fat and low levels of physical activity.

Aerobic fitness

Peak VO_2 has been investigated in the general population of children and in children with Type 1 diabetes. In general boys have higher peak VO_2 values than girls; the difference increases with age. peak VO_2, expressed in $L.min^{-1}$ increases with age but peak VO_2 expressed in relation to mass ($ml.kg^{-1}.min^{-1}$), the unit used in this study, does not. Typical levels of peak VO_2 in children are between 40 and 55 $ml.kg^{-1}.min^{-1}$ in children aged 8 to 15 years, 50 $ml.kg^{-1}.min^{-1}$ for boys and 35 to 45 ml. $kg^{-1}.min^{-1}$ for girls (Armstrong and Welsman, 2000b). Members of the European Pediatric Work Physiology group considered that low mass related peak VO_2, in the absence of other health related problems, may constitute a health risk. They proposed risk levels of 35 $ml.kg^{-1}.min^{-1}$ for boys and 30 $ml.kg^{-1}.min^{-1}$ for girls (Bell et al., 1986).

Data from the present study showed that in contrast to the norm girls had higher peak VO_2 than boys (37 $ml.kg^{-1}.min^{-1}$, compared to 35 $ml.kg^{-1}.min^{-1}$). However, this was not a significant difference when examined using a t-test ($p= 0.671$) and is likely it was due to the small number of peak VO_2 values. Due to technical difficulties values of only 9 boys and 6 girls were analysed. These mean levels approached those described above as constituting a health risk, but were not unexpected given the high levels of body fat in the present sample. Several previous studies reviewed by Armstrong have found significantly lower values of mass related peak VO_2 to be consistently reported in overweight young people with typical values of 29 to 36 $ml.kg^{-1}.min^{-1}$ (Armstrong and Welsman, 1997).

Studies that have examined the aerobic fitness of children and adolescents with Type 1 diabetes in comparison with the general population give contradictory findings. Several studies have confirmed the findings of the present study and found aerobic fitness, assessed using a peak VO_2 test, to be lower than that of children in the general population. Huttunen et al. (1989) reported a mean peak VO_2 value of 40.2 ± 7.2 ml.min-1.kg-1 for 32 children with Type 1 diabetes aged 8 to 16 years. Landt et al. (1985) reported a mean peak VO_2 value of 37.8 ml.min-1.kg^{-1} in 15 children with Type 1 diabetes aged 15 to 16 years. Also Marrero et al. (1988), Fremion et al. (1987) and Rowland et al. (1985) reported peak VO_2 of children with Type 1 diabetes to be lower than the average for healthy children the same age. However, other studies have found peak VO_2 to be similar to population norms (Campaigne et al., 1984; Mosher et al., 1998; Dahl Jorgensen et al., 1980).

Data for healthy Liverpool schoolchildren, collected in the same laboratory that was used in the present study, showed they had higher mean peak VO_2 values (Atkins, 1998). He found boys had a mean peak VO_2 of 46.5 ml.min-1.kg^{-1} and girls 44.5ml.min-1.kg^{-1} . Therefore the children in the present study with Type 1 diabetes had lower aerobic fitness than their healthy peers. Whether this was a result of high levels of body fat, having Type 1 diabetes, or a combination of these, could not be determined from these data.

Psychological variables

i) Quality of Life

Several studies have reported descriptive data for the quality of life scale used in the present study, the Diabetes Quality of Life for Youths questionnaire (DQOL-Y). However, these varied in how they analysed questionnaire's sub-scales, which meant it was not possible to compare directly between studies. One other factor that complicated the comparison of the present data with that from previous studies was the scoring of the worry sub-scale. Ingersoll was approached by the present author prior to the beginning of the study and provided the author with a revised version of the scale. This used a 6 rather than the original 5 point Likert scale for the worry sub-scale, an option labelled 'does not apply' was added. This version of the DQOL-Y was used in the present study and also used by Guttmann-Bauman et al. (1998) but the majority of studies presenting data from the DQOL-Y have used the version published by Ingersoll and Marrero (1991). What can be examined regardless of the direction of the scores and the range of the scale is the score in relation to the median value for the scale.

In the present study the mean score for each sub-scale showed positive quality of life. A large international study with data from 2101 children aged 10 to 18 years similarly found that children tended to rate themselves positively for these four sub-scales (Hoey et al., 2001). Grey et al. (2000, 1999, 1998a, 1998b) found adolescents generally reported their quality of life as good, using the DQOL-Y, they reported high satisfaction, moderate impact and relatively low worries. Therefore the group of children in the present study appear to be typical of children with Type 1 diabetes in general in terms of their perceived level of quality of life.

In the present study correlation coefficients calculated between the three sub-scales found significant associations between the satisfaction, impact and worry sub-scales (satisfaction x impact $r= 0.59$, satisfaction x worry $r= 0.63$, impact x worry $r= 0.82$. $p<= 0.001$). Children who were less satisfied with their lives also found diabetes had a greater impact on their lives and had more worries related to diabetes. These associations between the sub-scales were similar to those reported in by Ingersoll and Marrero (1991) in their paper which described the psychometric properties of the DQOL-Y. This supports the validity of the DQOL-Y with the present study group.

There was a tendency, in the present study, for boys to rate their quality of life higher than girls for the satisfaction, impact and worries sub-scales and for the overall health rating, but not significantly so. This finding was in a similar direction to previous studies although less strong. Hoey et al. (2001) looked at the scores for the four sub-scales by gender and found that in general girls reported lower quality of life than boys. She found this was significant for disease related worries in girls older than 12 years and for overall health rating. Ingersoll and Marrero (1991) also found girls significantly more likely to report worries related to diabetes than boys ($p < 0.05$) but no other significant gender effects.

There are contradictory results in the literature with regard to the relation of diabetes quality of life to age and duration since diagnosis with Type 1 diabetes. In the present study age was significantly related to the overall health rating, younger children rated their health higher than older children, but the other three sub-scales were not significantly related to age. Hoey et al. (2001) also found overall health rating was lower in older children. Additionally they found worries increased with age, satisfaction with life decreased with age, and impact of diabetes was not related to age. Ingersoll found age had no significant effect on quality of life. In the present study there were no significant associations with duration since diagnosis with diabetes and any of the sub-scales. Ingersoll and Marrero (1991) found duration since diagnosis with diabetes was significantly associated with impact of diabetes ($p < 0.05$), Hoey et al. found it was not.

The study by Hoey et al. had a larger sample size (2101) than either the study by Ingersoll or the present study. The significant associations found in the present study matched those of Hoey although Hoey found further associations that were not replicated in the present study. This may be a result of Type 2 error in the present study. The rigorous study by Hoey et. al included data from 17 countries and reported that variation between centres for the satisfaction sub-scale was highly significant suggesting cultural effects may be important. More detailed analysis of Hoey's data set would clarify this further. In addition differences in the findings may be due to the age range of the samples, Ingersoll's sample had a maximum age of 21.8 years and a mean of 16 years, Hoey's had an age range of 10 to 18 years, the present study had an age range of 9 to 15 years with a mean age of 12.7 years. As was described in chapter 3 the DQOL-Y has been validated with 10 to 21 year olds and the present study included five 9-year old children. However, overall health rating remained the only sub-scale significantly associated with age when data from 9 year olds were excluded.

Hoey et al. (2001) commented that there are insufficient published data for the DQOL-Y to anchor particular score levels of the worry sub-scale to concepts such as excessive worry about diabetes or insufficient worry about the necessary aspects of good clinical management of diabetes treatment. Similarly further research is needed to establish what scores on the disease impact and satisfaction with life sub-scales are associated with changes in disease management or other psychological variables e.g. depression or anxiety. This information would make the DQOL-Y a more useful tool clinically and academically.

The present study found no association between HbA_{1c} and quality of life. The wellness model suggests that both are important to overall health regardless of whether they are associated with one another. Previous studies have contradictory findings as to whether the two variables are associated or not. Both Ingersoll and Marrero (1991) and Grey et al. (1998a) found no association between quality of life and HbA_{1c}, Guttmann-Bauman et al. (1998) and Hoey et al. (2001) found that better quality of life was reported by children with better metabolic control. Of these studies the one by Hoey et al. had the largest sample size, 2101 compared to 74, 52 and 69 respectively, and therefore is the least likely to have been affected by Type 1 or Type 2 error. It is possible that there is a weak association between the two variables, which only a large study is likely to detect.

ii) Self Efficacy

There are three factors that make it difficult to compare of the data collected using the Self Efficacy for Diabetes Scale in this study with that collected in previous studies. Firstly, some studies have used a five item response scale (Grey, 1998a, Grey 1998b, Havermans and Eiser, 1991). Others have used a six-item response scale; Howells et al. (2002), Grossman et al. (1987). This alters the range of the scale and means scores are not directly comparable. Secondly, studies differ in whether they analyse data by dividing the items into sub-scales or summing them into a total score. In the paper describing the development of the SED scale it did not state which items were in which sub-scale (Grossman et al., 1987). Following a personal communication with Dr Grey the present study divided items in the same way that Grey et al. did in a series of published papers (Grey et al., 2000; Grey et al., 1999; Grey et al., 1998b). Some papers have reported data as a total score (Howells et al., 2002; Grey et al., 1998a). Thirdly, some studies have altered or the wording of certain items to make them appropriate to the study population (Havermans and Eiser, 1991). The present study removed two items from the diabetes subscale because they refer to measuring glucose in the urine, a procedure that has been superseded.

Taking the above into consideration the mean scores from previous studies could only be compared to see whether scores were roughly similar to the present study. In addition associations between sub-scales and with age, gender etc. were examined to look at the external validity of the present data. In general studies show that children with Type 1 diabetes rate themselves highly on the Self Efficacy for Diabetes scale (Howells et al., 2002; Grey et al., 1999; Grey et al., 1998b), this is similar to the children in the present study. The mean values in the present study were: total self efficacy 150 ± 24; diabetes self efficacy 101 ± 16; medical self efficacy 21 ± 5; general self efficacy 28 ± 6. The range of the sub-scales was: 33 to 198; 22 to 132; 5 to 30; and 6 to 36 respectively.

In their paper discussing the development of this scale Grossman et al. (1987) presented data on its psychometric properties. Factor analysis was not reported, as the sub-scales were devised conceptually, but they reported significant intercorrelations among the sub-scales that were also found in the present study. Correlation coefficients showed children who rated themselves as having low diabetes self efficacy also rated themselves as having low medical self efficacy ($r = 0.62$, $p < 0.001$) and low general self efficacy ($r = 0.65$, $p < 0.01$). Those who reported low medical self efficacy also reported low general self efficacy ($r = 0.43$, $p = 0.01$). The two studies were also similar in reporting no significant differences between the scores of boys and girls. Grossman et al. (1987) did not analyse their data by age so it cannot be seen whether they also found older children reported greater self efficacy.

In the present study there was a clear association between age and self efficacy, older children tended to have higher self efficacy for diabetes. This may be because children are given greater autonomy for managing their diabetes as they get older. There were no significant associations between duration of time since diagnosis with Type 1 diabetes and self efficacy. It may be expected that there would be an association, again as children who have been diagnosed for longer have had longer to learn to manage their treatment themselves. The data suggest, however, that age is more critical to reported ability to manage diabetes than is duration since diagnosis with diabetes.

There are not presently threshold levels of self efficacy that are known to be associated with management or clinical difficulties in children with Type 1 diabetes, this would be very useful but further studies need to be carried out to establish them. Studies have found self efficacy to be associated with adherence to treatment regimens (Ott et al., 2000; Littlefield et al., 1992) and with HbA_{1c} (Ott et al., 2000; Griva et al., 2000; Littlefield et al., 1992). The present study differed from these by finding no significant association between self efficacy and HbA_{1c}, adherence was not assessed in the present study. It was similar, however, to a study by Grey et al. (1998a) that also found no association between HbA_{1c} and self efficacy. The present study included a younger age group than the above studies and as HbA_{1c} increases with age (Mortensen et al., 2002) it may be that this confounded the association in the present study. Alternatively the difference may be due to the smaller sample size of the present study, 39 children, and that of Grey et al., 52 children, compared to the studies where an association between self efficacy and age was found, 193 children in the study by Littlefield et al. (1992), 161 in the study by Ott et al. (2000) and 64 in the study by Griva et al. (2000).

iii) Self esteem

Unlike the quality of life for diabetes scale and the self efficacy for diabetes scale, the physical self perception profile for children (PSPP-C) was developed for use with children in the general population and data has been collected on groups of children, both in the US and the UK. This was the first study to use the PSPP-C specifically with a population of children with Type 1 diabetes, therefore the data are compared to those for children in the general population.

The PSPP-C models self esteem using a hierarchical structure, the sport, condition, body and strength sub-scales are components of physical self worth (PSW) which is itself a component of global self worth (GSW), for more details see section 2.1.3. All six subscales have the same range, 1 to 4. The overall mean scores showed that GSW was reported to be higher than any of its components, 3.01. A mean value of 2.64 was reported for physical self worth (PSW), the four components of PSW were scored, in order from highest to lowest: condition competence (2.89), strength competence (2.82), sport competence (2.77), attractive body competence (2.44). These were similar to the means reported by Whitehead (1995) for a group of 459 7th and 8th grade U.S. children (aged 12 to 13 years): GSW 3.08 ± 0.68, PSW 2.96 ± 0.65, condition 2.90 ± 0.67, strength 2.73 ± 0.64, sport 2.85 ± 0.70, attractive body 2.59 ± 0.72. Biddle et al. (1993) reported descriptive data for 452 British children aged 12 and 14; the mean values were GSW 2.93 ± 0.63, PSW 2.75 ± 0.54, condition 2.79 ± 0.54, strength 2.60 ± 0.54, sport 2.69 ± 0.58, attractive body 2.53 ± 0.58. Both Whitehead and Biddle's studies found attractive body competence and PSW to be higher than in the present study. The self perception profile (Harter, 1982) also measures self esteem using a multidimensional approach, the physical appearance sub-scale of this instrument was the only dimension of self esteem that differed between a group of children with Type 1 diabetes and a healthy control group in a longitudinal study (Jacobson et al., 1997a). The physical appearance sub-scale and the attractive body sub-scale measure similar aspects of self esteem; the present study together with Jacobson's suggest children with Type 1 diabetes have lowered self perceptions of their physical attractiveness compared to healthy children. However, global self esteem is similar to that of children in general.

Correlation coefficients calculated in the present study between sub-scales of the PSPP-C support the factor structure reported by Whitehead (1995). The condition, strength, sport and body sub-scales correlated more strongly with PSW ($r=0.34$, $r=0.45$, $r=0.64$, $r=0.88$) than with GSW ($r=0.07$, $r=0.31$, $r=0.31$, $r=0.62$). GSW and PSW were significantly correlated $r=0.62$. Also in agreement with Whitehead (1995), of the four sub-domains of PSW the attractive body sub-scale was the most strongly associated with both PSW and GSW.

Work investigating the construct of self esteem and its determinants has found that physical appearance contributes more to overall global self worth than any of its other determinants, these being social acceptance, scholastic competence, athletic competence and behavioural conduct. This importance of physical appearance has been shown to apply to young children through to adults (Harter, 1999). The scale used in this study was different to those developed by Harter in that it focussed on physical self perceptions rather than all the components of self esteem. However the global self worth scale was the same as that used by Harter. Within the PSPP-C the body adequacy sub-scale was the most specific to physical appearance. It differed from the physical appearance scale of Harter in that it concentrated on the appearance of one's body rather than facial or other aspects of physical attractiveness. The inter-relationships between the sub-scales of the PSPP-C suggested that physical appearance was very important to this sample too.

Previous authors validating the PSPP-C have found significant gender differences, boys rated their physical self perceptions higher than girls (Whitehead, 1995; Biddle et al., 1993). Similarly Raudsepp & Liblik (2002) found boys reported significantly higher competence for sport, condition, strength and physical self worth in a sample of 280 children aged 10 to 13. Crocker et al. (2000) found boys reported significantly higher competence for sport and strength with 466 children aged 10 to 14 years. In the present study the same trend was found, boys rated their self perceptions higher than the girls for five of the six sub-scales, sport was rated higher by girls. However, independent sample t tests did not find these differences to be significant. The difference between boys' and girls' body self perceptions was greatest and approached significance ($t= 1.92$, $p= 0.06$). The reason that a significant difference between the physical self perceptions of boys and girls was not found in the present study may be that the sample size was smaller, 32 compared to over 200. A smaller sample size meant that significant differences were more likely to be missed due to chance. The finding that girls self perceptions of sport competence were higher than boys is highly unusual. The most likely explanation is that this result was due to the sample size, and not representative of children with Type 1 diabetes in general.

In this sample (age range 9 to 15 years) age was only significantly associated with the condition sub-scale, older children tended to report low levels of condition. Fitness data showed the older children tended to have greater body fat and take part in less physical activity, which gave external validity to the finding. However, in a previous study Whitehead (1995) found no significant differences between 7th and 8th grade data (12 to 13 years old). Biddle et al. (1993) presented data from 12 and 15 year olds, the means for the older age group were generally lower but he did not report whether the differences were significant.

As with the DQOL and SED scales the scores for the PSPP-C showed no association with duration since diagnosis with Type 1 diabetes.

Compared to children in the general population this study found that children with Type 1 diabetes had lowered self perceptions related to body attractiveness competence and overall physical self perceptions. Global self esteem was not lowered in this group of children compared to children in general. The construct of physical self esteem was similar in children with Type 1 diabetes as in children in general.

HbA_{1c}

The mean HbA_{1c} value for the participants was 9.75 ± 1.68%. This was very close to the mean value of 9.76 ! 0.12% that was reported for the conventionally treated group of adolescents in the DCCT trial (DCCT, 1994). Rosilio et al. (1998) reviewed 13 major studies of glycaemic control in children with Type 1 diabetes and reported mean HbA_{1c} values between 6.6 and 9.85% (mean ages were between 10.3 and 16.8 years and mean diabetes duration 3 to 7.7 years). Therefore the mean HbA_{1c} for the children in the present study was within the range found by large scale cross sectional surveys of HbA_{1c}. It was, however, towards the upper end of the range of values reported, and above the threshold value of 8% beyond which the risk of developing microangiopathy increases more rapidly (DCCT, 1993).

HbA_{1c} and age were not significantly associated in the present study ($r = 0.13$, $p = 0.43$). In contrast Rosilio et al. (1998) found a significant positive correlation ($r = 0.30$) between age and HbA_{1c}. Also a large international study by Hoey et al. (2001) found HbA_{1c} was significantly higher in older children ($p<0.05$). Diabetes duration and HbA_{1c} were also found to not be significantly associated in the present study ($r= -0.21$, $p= 0.21$). Again this is contrary to Rosilio et al. (1998) who found that diabetes duration had a significant regression co-efficient with HbA_{1c} ($R_c = 0.14$) and Hoey et al. (2001) who found a significant negative association between number of years since diagnosis with diabetes and HbA_{1c}. The reason significant associations were not found in the present study may be that the sample size was smaller than the other two studies.

Analysis by gender showed that on average girls had slightly higher HbA_{1c} values than boys, 9.87 ± 1.72% compared to 9.63 ± 1.67%, but this difference was not statistically significant. Hoey et al. (2001) found girls had significantly higher HbA_{1c} than boys, the present data followed the same trend but was not significant, again probably due to the smaller sample size. Although Rosilio et al. (1998) also found a non significant trend for girls to have higher HbA_{1c} than boys with a sample of 2579 children.

The group of children with Type 1 diabetes in the present study had HbA_{1c} values within the range typical of children with diabetes. They were higher than some reported mean HbA_{1c} values for children and typical of the values reported for older children. The DCCT found the same mean value for a group of children aged 13 to 17 years (DCCT, 1994), Rosilio et al. (1998) found that HbA_{1c} values tended to be greater than 9% in children aged over 11 years. Despite the difficulty of maintaining average blood glucose below 8% during puberty this is the level that is recommended to lower the risk of developing microangiopathy (DCCT, 1993). Therefore one of the aims of the second phase of the study was to lower HbA_{1c}.

6.2: Associations between variables

Hypothesis one

The first hypothesis of phase one was that higher levels of physical activity and fitness would be associated with better psychological health. Of the three psychological variables measured in the present study, physical self esteem, self efficacy for diabetes and diabetes quality of life, only physical self esteem had been previously studied in relation to physical activity and fitness. Higher physical self esteem had been found to be significantly associated with higher levels of physical activity and fitness in the general population (Raudsepp & Liblik, 2002; Raudsepp et al., 2002; Crocker et al., 2000; Whitehead, 1995; Biddle et al., 1993).

In the present study the only significant association between moderate, hard or vigorous physical activity and the sub-scales of the PSPP-C was between vigorous physical activity and attractive body competence ($r=0.31$, $p < 0.05$). Higher vigorous physical activity levels were associated with greater attractive body competence. This association was in agreement with the hypothesis. However, there is a possibility that it was the result of Type 1 error rather than an actual association. This is because a large number of correlations were carried out on the data set and there is a possibility that a significant association was found by chance. A Bonferroni correction factor could have been applied to reduce the possibility that this would occur but in the present study this would have increased the possibility of Type 2 error to such an extent that it would have been unlikely to find any significant associations.

This finding was in contrast to the two studies in the literature that have examined the relationship between children's physical self perceptions and physical activity (Raudsepp et. al., 2002; Crocker et al., 2000). These both found that physical activity was significantly associated with physical self worth and its four sub-domains. Neither study included the global self worth sub-scales. The contrasting result may reflect differences in the association between physical activity and physical self perceptions in children with Type 1 diabetes. However, it is also possible that it is due to the accuracy with which physical activity can be measured in children. In the present study heart rate monitors were used to assess physical activity, this is an objective assessment method but does have limitations, see section 2.2. In addition the present study had a smaller sample size than those of Raudsepp and Crocker, which included 253and 466 children respectively. Therefore significant differences were less likely to be found.

Correlation coefficients between sum of skinfolds (body fatness) and the sub-scales of the PSPP-C found significant negative associations with physical self worth ($r=-0.48$, $p<0.01$), and two of the four sub-domains of physical self worth, (attractive body competence $r=-0.54$, $p<0.01$ and condition/stamina competence $r=-0.46$, $p<0.01$). In each case lower body fatness was associated with higher self esteem. There were no significant associations between body fatness and global self worth. Associations between the PSPP-C sub scales and BMI were similar to those with body fatness. BMI was significantly associated with physical self worth ($r=-0.43$, $p=0.02$), attractive body competence ($r=-0.52$, $p<0.01$) and condition competence ($r= -0.49$, $p<0.01$). This would be expected, and is evidence of convergent validity, as BMI and skinfold thickness were measures of the same dimension of physical fitness. peak VO_2 showed significant positive associations with GSW ($r= 0.61$, $p= 0.02$), PSW ($r= 0.74$, $p< 0.01$) and sport competence ($r= 0.63$, $p= 0.02$). In each case greater peak VO_2 was associated with higher psychological well being. Raudsepp and Liblik (2002) found body fatness was significantly associated with attractive body competence in boys and girls. They also found a measure of aerobic fitness, the endurance shuttle run, was significantly associated with physical self worth, and all of the sub-scales for boys and all but the attractive body subscale for girls, the strongest associations were reported for the sport competence sub-scale. Body fatness was more influential to the physical self perceptions of the present sample of children than in previous studies. This may be due to the present sample having higher mean body fat than their healthy peers.

Physical activity was less strongly associated with physical self esteem than were body fatness and aerobic fitness. Nevertheless vigorous physical activity had a significant positive association with attractive body competence. Participation in physical activity in the general population is postulated to help weight loss and increase muscle tone and stamina, the present data showed a similar trend. The present data were cross sectional and therefore only revealed associations between variables, however, it is interesting to speculate on the causation of these. It could be argued that increasing the level of vigorous physical activity that children with Type 1 diabetes participate in may increase aerobic fitness and lead to a reduction in body fat that in turn would lead to an increase in PSW and consequently GSW. However, it is also possible that having higher physical self competence would predispose children to participate in more physical activity and become fitter. The exercise intervention in phase two of the present study aimed to give a better understanding of this relationship, by increasing physical activity to see whether physical self perceptions rose.

Associations between moderate, hard or vigorous physical activity and the sub-scales of the SED or the DQOL-Y questionnaires found vigorous physical activity was significantly associated with the disease related worries ($r=-0.27$, $p=0.03$) and the overall health rating ($r=0.40$, $p=0.02$) sub-scales of the DQOL-Y. There were no significant associations with the sub-scales of the SED. These associations were in the hypothesised direction, higher physical activity levels were associated with better quality of life. Peak VO_2 was significantly associated with and the satisfaction sub-scale of the DQOL-Y ($r= 0.51$, $p= 0.01$). BMI was significantly associated with disease related worries ($r=0.36$, $p=0.05$). Again this association was in the hypothesised direction, higher aerobic fitness and lower BMI were associated with better quality of life. The same limitations as discussed for associations with the PSPP-C stand for these associations. Therefore it is possible that because of the sample size associations were missed, or significant associations that were found were chance. Also, measuring physical activity accurately is notoriously difficult and subtle associations may have been missed because of inaccuracies in the measurement of physical activity. These data suggest that they may be affected by error because there is no evidence of convergent validity in the associations of the fitness variables, disease related worries were significantly associated with BMI but not with skinfold thickness.

It was encouraging that there was no evidence that high levels of physical activity were associated with lower psychological well-being. There was one significant association that was contrary to the hypothesis, between higher BMI and higher total self efficacy. Although studies on the general population suggest this would not be the case for physical self perceptions self efficacy for diabetes and diabetes quality of life have not been studied in relation to physical activity or fitness previously. Because participating in exercise requires children with Type 1 diabetes to make adjustments to their diabetes regimen prior to and after exercise it is possible that self efficacy for diabetes would be associated with physical activity and fitness in a positive or negative way. Similarly for quality of life, children may feel diabetes has greater impact on their lives if they are having to adjust their diabetes regimen in order to participate in physical activity or they may feel more satisfied with their lives because they participate in physical activity.

In summary, high body fatness was associated with low physical self esteem but not associated with global self esteem, quality of life or self efficacy. Psychological variables that focus on diabetes were not affected by body fatness. Children with high body fat may protect their global self esteem by giving less importance to physical factors, as has been postulated by Harter (1999). Aerobic fitness was positively associated with global self worth, physical self worth and satisfaction with life. Vigorous physical activity was significantly associated with attractive body competence, disease related worries and an overall health rating, higher physical activity was associated with better psychological health. Therefore the hypothesis that higher levels of physical activity and fitness would be associated with better psychological health was partially supported. Higher levels of fitness were associated with greater psychological well being in some dimensions, particularly physical self esteem. Participation in vigorous physical activity was associated with higher attractive body self competence, fewer disease related worries and better overall rating of health.

Hypothesis two

The second hypothesis in phase one was that higher levels of physical activity and fitness would be associated with lower levels of HbA_{1c}. The correlation co-efficient calculations found no significant associations between HbA_{1c} and physical activity or measures of physical fitness, thus finding no support for the hypothesis. When outlying physical activity data points were removed the association between vigorous physical activity and HbA_{1c} approached significance ($r = -0.32$, $p=0.05$), participation in more vigorous physical activity was associated with lower HbA_{1c}. However, the distribution free Kendall's tau correlation showed no significant association. HbA_{1c} is affected by many factors and therefore it is unlikely that any one by itself will show a significant association. The association that was found should be treated cautiously due to the small sample size and low levels of vigorous physical activity.

The finding agrees with those from previous similar studies. Two studies have investigated whether there is a relationship between habitual physical activity and HbA_{1c}, Hanson et al. (1996) and Loman and Galgini (1996) see section 2.2, neither found a significant association. These studies used different thresholds of physical activity to define physical activity level than in the present study. They reported associations between HbA_{1c} and moderate to vigorous physical activity as reported by the participants. The present study defined physical activity levels using thresholds of maximum heart rate reserve. The threshold that showed the strongest association with HbA_{1c} in the present study was 75% MHRR. This related to more intense physical activity than the threshold level used by Loman and Galgini (1996), and Hanson et al. (1996). Therefore it is suggested that although moderate physical activity shows no association with HbA_{1c}, more intense physical activity may have a negative association with HbA_{1c}.

Loman and Galgini (1996) and Hanson et al. (1996) both used a self report measure of physical activity whereas the present study used heart rate monitoring. In the present study no significant associations were found between self reported physical activity and HbA_{1c}. No previous study has reported associations between physical activity assessed using heart rate monitoring and HbA_{1c} therefore a direct comparison of the findings cannot be made.

Reducing HbA_{1c} is a main aim of clinical treatment, as this has been shown to delay or prevent secondary complications (DCCT, 1993). Although the present study found no significant association, the trend towards an association between higher vigorous physical activity and lower HbA_{1c} was encouraging and worthy of further investigation due to the potential implications for diabetes management.

Summary

In the introduction diabetes management was discussed in terms of the wellness model. This states that wellness is composed of several interrelated dimensions, physical, mental, emotional, social and spiritual, which all contribute to overall well-being. It shifts the focus of diabetes management from a physiological perspective to one in which the effect of management on each of the above domains is considered. In terms of this model, both the finding that some aspects of psychological well being are associated with fitness, and that HbA_{1c} may have an association with vigorous physical activity are important findings in their own right. In the present study HbA_{1c} was not associated with psychological well being. There are conflicting findings in the literature on this point, some studies finding significant associations (Hoey et al., 2001; Griva et al., 2000) and some no significant associations (Grey et al., 1998a; Niemcryk et al., 1990). In terms of the wellness model both physical and psychological measures should be considered as important treatment outcomes whether or not they are associated with each other.

Together the analyses of associations between psychological variables, physical activity and fitness and between HbA_{1c}, physical activity and fitness showed that vigorous physical activity was particularly important for this population. Attractive body adequacy was significantly associated with vigorous physical activity but not hard or moderate physical activity. Similarly disease related worries and an overall health rating were significantly associated with vigorous but not moderate physical activity. HbA_{1c} showed a non-significant trend with vigorous physical activity but no trend with less intense physical activity.

Whether physical activity is related to aerobic fitness is still unclear for children and adolescents. No significant associations were found in the present study. A review of the evidence was undertaken by Morrow and Freedson (1994). They identified 20 appropriate studies from which they concluded there is typically a small to moderate relationship, about $r = 0.16$. However, not all of these studies reported any relationship. Armstrong also reviewed the evidence on this subject and concluded: '…the simple explanation for the lack of relationship between habitual physical activity and aerobic fitness probably lies in the low level of physical activity of most young people. The vast majority of children and adolescents rarely experience physical activity of sufficient intensity and duration to increase peak VO_2 …' (Armstrong and Welsman, 1997, p 124).
As it has been recommended that physical activity at an intensity of 75% MHRR is necessary to increase aerobic fitness (Morrow and Freedson, 1994), it is probably the case that levels of physical activity of sufficient intensity to increase aerobic fitness are too low in this population for any association to be measurable. Alternatively it could be due to the difficulties inherent in measuring physical activity accurately.

This emphasis on vigorous physical activity is different from the recommendation of the Health Education Authority, which recommends 60 minutes of moderate physical activity per day to maintain current and future well being. The effects of physical activity for children with Type 1 diabetes have not been researched thoroughly. It is possible that the effects of physical activity are different in children with Type 1 diabetes, for example that psychological and physiological benefits are gained at higher or lower volumes or intensities, due to the way that insulin, diet and physical activity interact. The data suggest that this is the case, and that vigorous physical activity is particularly important.

In terms of informing the development of the second phase of the study, a physical activity intervention, phase one repeatedly found that hard and vigorous physical activity were more strongly associated with psychological well-being and HbA_{1c} than moderate physical activity. Therefore the exercise sessions in the intervention were designed to include high intensity exercise. The study sample was found to have lower aerobic fitness, higher adiposity, lower attractive body competence and lower physical self worth than norms for healthy peers. The second phase of the study investigated the causality of associations between variables by increasing physical activity to see what effect it had on the other variables that were measured in phase one.

7

Rationale for measures used: Phase Two

The third hypothesis of the study was that increased physical activity and fitness would lead to improved psychological health and lower HbA_{1c}. This was tested in the second phase of the study using a randomised controlled trial of an exercise intervention programme. The goals of the programme were to increase physical activity, fitness and psychological health, and to reduce HbA_{1c} levels.

The four main points that have to be specified when designing any exercise programme are exercise frequency, duration, intensity and type. The literature and findings from phase one of this study were examined to decide on the specifications for this exercise programme. In general it can be said that the literature is not conclusive about how frequency, intensity, type and duration affect the programme outcomes, and less is known for children than for adults. This literature is summarised in the following section, firstly the effect of exercise frequency, duration, intensity and type on aerobic fitness are discussed, then their effect on psychological health, and finally on HbA_{1c}. The specifications of this study are then described. This is followed by a rationale for the experimental design and data collection methods where these were different from in phase one.

7.1: Effect of exercise frequency, intensity, type and duration on intervention outcome measures

7.1.1: Aerobic fitness

Sady (1986) and Rowland et al. (1985) published reviews on the effects of cardiorespiratory training on aerobic fitness in children. They both concluded that, although the literature is lacking high quality studies on the effect of training regimens on children's aerobic fitness, the evidence indicated that the recommendations of the American College of Sports Medicine to promote aerobic fitness in adults were also appropriate to promote aerobic fitness in children. These are that continuous, rhythmic exercise using large muscle groups (e.g. jogging, cycling, swimming) occurs 3-5 days a week, at an intensity of 60-90% heart rate reserve, for 15 to 60 minutes a session. Rowland (1985) compared the training regimens of studies with children that resulted in increased VO_{2max} with those that did not. He found that 6 out of 9 studies that met the American College of Sports Medicine guidelines reported increased VO_{2max}, whereas none of the studies where these guidelines were not met reported increased VO_{2max} values.

In a more recent review Welsman and Armstrong (1998) agreed with the earlier recommendations for exercise type and frequency. They stressed however the importance of rest between training sessions and recommended a minimum of 24 hours rest between each session to ensure the replenishment of energy stores and the development of muscle mass. Exercise duration was refined to sessions of 20 to 40 minutes and intensity to 80-90% of maximum heart rate. This is a high level of intensity and they added that intensity must be increased gradually so that it continually produces improvements in performance but does not make exercise unduly uncomfortable or painful. Welsman and Armstrong (1998) and Sady (1986) noted that improving the cardiopulmonary fitness of young, prepubertal, children is problematic and suggest that there may be a maturational training threshold. A separate review by Armstrong and Welsman (1997) of the evidence surrounding the effects of exercise intervention programmes on the fitness of children and young people concluded that the optimum intensity of exercise for the promotion of aerobic fitness remained to be established. However, from the evidence available he recommended that to induce an increase in aerobic fitness, exercise at 80-90% of maximal heart rate should be participated in for 20 –30 minutes at a time. The current guidelines therefore recommend that high intensity exercise is necessary to promote increased aerobic fitness in children.

Phase one of the present study did not find a significant association between fitness and physical activity. However this was in line with the published literature (Armstrong et al., 1990b; Armstrong et al., 1996b). In a review of the literature Armstrong and Welsman (1997) suggested several reasons for this: that any relationship that does exist is likely to be a complex one; that there is an as yet unquantified genetic component to peak VO_2; and the low level of physical activity that the majority of children experience. This last reason was very relevant to the present study.

In addition to the training regimen of an exercise intervention study the duration of the regimen has to be specified. Exercise interventions of varying duration have been used in studies examining the effect of exercise training on fitness in children. Armstrong and Welsman (1997) reviewed the better controlled studies of training with children aged 8 to 15 years and reported the duration of these varied from 6 to 14 weeks. They recommended that to induce an increase in aerobic fitness in boys and girls an exercise prescription of specified frequency, intensity and type should be followed for not less than 12 weeks. Studies that have lasted more than 6 months have found the analysis complicated by the effects of growth and maturation (Sady, 1986).

7.1.2: Psychological well-being

There is evidence that participation in physical activity is associated with positive psychological well being in children and young people in the general population, and that exercise intervention can increase psychological well being, see section 2.6. However, the frequency, intensity, duration and type of activity necessary to increase psychological well being are less clear.

The effect of exercise intensity has been examined by studies comparing two differing exercise programmes. In general more intense physical activity appears to have a more beneficial effect on psychological well being than less intense physical activity. MacMahon and Gross (1988) compared the psychological and physical effects of an aerobic exercise programme (sustained exercise for 40 minutes three times a week) to one of limited physical exertion (activities designed to avoid elevated heart rates). The study was carried out on 98 boys, mean age 16.3 years, in a juvenile detention centre, which meant that differences in activity and lifestyle outside of the exercise programme were minimised. However, changes in psychological well being may have been different to those which would occur in the general population due to the boys being detained and separated from their families. After three months the boys who had participated in the aerobic programme showed significantly greater improvement in mood ($p < 0.05$), improved self concept ($p = 0.06$), and significantly improved cardiovascular physical fitness ($p < 0.01$) compared to the control group. The psychological impact of the programme was independent of the effect on cardiovascular physical fitness.

Norris et al. (1992) also investigated the impact of exercise intensity on psychological health. They assigned 80 children, mean age 16 years, to four groups; high intensity exercise (70-75% maximum heart rate), moderate intensity exercise (50-60% maximum heart rate), flexibility training and a control group. The training programmes lasted for 10 weeks and ran twice a week for 25-30 minutes each session. Before and after the programme the children completed self report measures of life events, seriousness of illness, subjective stress levels, anxiety, depression and hostility. Blood pressure and heart rate before and after exercise were also measured. Participants in the high intensity group showed the expected increases in fitness, as measured by resting heart rate and recovery after a step test. None of the other groups showed consistent improvement with regard to aerobic fitness. For the psychological measures the high intensity group had significantly lower perceived stress scores following training than the other three groups ($p < 0.05$). Also the high intensity group had significantly lower scores for anxiety than the moderate intensity group following training ($p<0.05$). There were no effects for the other variables studied. These results suggest that aerobic training can improve psychological well being in adolescents but that high intensity training, at 70-75% maximum heart rate reserve, is necessary to achieve these benefits.

Calfas and Taylor (1994) reviewed 20 studies of young people aged 11 to 21 that focussed on physical activity or exercise alongside depression, anxiety, stress, self esteem, self concept, hostility, anger, intellectual functioning or psychiatric disorders. Studies that compared high to moderate intensity activity groups, or aerobic to flexibility activity groups, found greater improvement on psychological variables for the more aerobic or active conditions. A meta analysis conducted by Gruber (1986) similarly found that physical fitness and aerobic activities were much more effective at increasing psychological variables than perceptual motor development, sports skills or dance, mime and creative movement programmes. See section 2.6 for further details of these papers.

No studies examining the effect of duration and frequency of physical activity participation on psychological health were found. However, as a result of their literature review Calfas and Taylor (1994) made recommendations for the intensity, frequency and duration of exercise participation. These were that adolescents should participate in physical activity three times a week, for 60 minutes a week in total, at 70% maximum heart rate. Type of exercise was not specified. These recommendations were qualified by the statement that due to the small number of studies, and the methodological flaws that these had, it was difficult to make specific recommendations for physical activity regimens. Those that they made were based on the available adolescent, child and adult literature, and expert opinion.

In agreement with this literature, phase one of the present study found that in children with Type 1 diabetes vigorous physical activity was more strongly associated with aspects of self esteem than moderate physical activity. In particular time spent in physical activity above 75% maximum heart rate reserve showed a significant positive correlation coefficient with attractive body adequacy competence (<0.05).

The time scale over which changes in psychological variables can be expected is also not clearly defined. In the review by Calfas and Tayor (1994) the average duration of studies that showed a significant positive effect on psychological health was 12.8 weeks, but the range was very large, from 1 to 20 weeks.

7.1.3: HbA_{1c}

The importance of HbA_{1c} as a clinical outcome measure for people with Type 1 diabetes was shown by the DCCT (1993), see section 1.2. An explanation of the measure glycated haemoglobin and in particular HbA_{1c} was given in section 1.6.2, very simply it is a measure of the average blood glucose level over the previous three months. So, in order to detect a change in HbA_{1c} as a result of the exercise programme this would have to be at least twelve weeks duration. Therefore a main criterion for deciding the duration of the intervention programme was that it would allow changes in HbA_{1c} to be observed.

The literature examining the effect of physical activity interventions on HbA_{1c} in children with Type 1 diabetes is limited, see section 2.4, and does not compare the effect of intensity, frequency, duration or type of exercise on HbA_{1c}. Phase one of the present study found that vigorous physical activity was more strongly associated with HbA_{1c} than moderate physical activity. Time spent in physical activity above 75%

maximum heart rate reserve had a negative correlation coefficient with HbA_{1c} that approached significance (r= -0.32, p=0.05), i.e. those children who participated in more vigorous physical activity tended to have lower HbA_{1c} values.

7.2: Exercise frequency, duration, intensity and type specifications in this study

The evidence described in the previous section was used in the design of the present study. The exercise sessions were therefore designed to include high intensity activity. Activities were mainly aerobic with the aim being to increase heart rate above 75% maximum heart rate reserve for as much of the session as possible. This was the threshold found to be significant for children with Type 1 diabetes in phase 1. In addition, if 200 beats per minute is used as an average maximum heart rate in children, 75% maximum heart rate reserve is roughly comparable to 80-90% maximum heart rate, the intensity recommended in the current literature to increase aerobic fitness in children (Welsman and Armstrong, 1998; Armstrong and Welsman, 1997). The duration of each session was one hour in total, this included a warm up and cool down period. Therefore the duration of activity at the above intensity was planned for 20 to 40 minutes per session. Data from phase one showed that the majority of this population participated in very low levels of vigorous physical activity. Therefore, in line with the advice of Welsman and Armstrong (1998), the exercise intensity during the sessions and duration of time spent working at high intensities was increased gradually over the period of the exercise programme.

The exercise intensity and duration of the sessions was monitored using training heart rate. Heart rate telemetry systems, as described in section 2.2.1, were used to record heart rate during the sessions. This information allowed the actual intensity and duration of the sessions to be assessed, it also allowed the intensity and duration of the sessions at the three different centres to be compared.

The frequency of the sessions was two times a week for the first eight weeks of the programme increasing to three times a week for the last four weeks. This frequency was initially lower than that recommended for both increasing aerobic fitness and psychological well being. However, it was decided that to reduce the drop out rate from the programme an exercise routine should be established, at the lower frequency of two times a week initially, and then increased. It was felt that this was necessary due to the low levels of physical activity participation found during phase 1, which showed that these children did not exercise regularly, together with the time commitment required to participate in the exercise programme.

There is general consensus that exercise requiring rhythmic movement of the large muscle groups, e.g. running, swimming, skipping and cycling, is the type of exercise most likely to increase aerobic fitness (Armstrong and Welsman, 1997). There are no recommendations for the most effective type of exercise to increase psychological well being or lower HbA_{1c}. As one of the aims of this exercise programme was to increase aerobic fitness the activities were mainly of the type just described. Aerobic exercises were mixed with some anaerobic exercise to increase muscle strength. All exercises were run as games or fun type activities to increase enjoyment and maintain participation.

The design of the programme was based on a very successful physical activity scheme called Kids EXCEL (Enjoy eXercise Create an Enhanced Lifestyle) which has been running in Sefton since 1994 (Stratton and Sweeney, 1998). The aim of this scheme is to promote physical activity and exercise, as opposed to sport, with children aged 7-12 years. By 1999 it was running in 48 primary schools borough wide and had an average attendance of 813 children per week. It aims to give children the opportunity to enjoy exercise in a fun orientated, non competitive manner. Through a variety of activities children improve their cardiovascular fitness and learn about the working body. The rationale behind the scheme is that by learning how the body works and adapts to exercise, the children gain an understanding of the positive effect exercise can have on their lives. It is hoped that this knowledge will give them the desire to maintain an active lifestyle as they get older. Some of the participants in the present study were older than 12 years, for these children the ethos of the EXCEL programme was followed with the activities adapted as necessary to suit this age group. For example circuit training, exercise bikes and treadmills were offered.

The main criteria used to determine the duration of the exercise programme was that it was of sufficient duration that any change in blood glucose control would be detectable in HbA_{1c} values. The duration needed for this is 12 weeks, this is the same as that recommended by Fox (1997) to increase aerobic fitness and the mean duration of exercise studies found to increase psychological well being (Calfas and Taylor, 1994). Therefore the exercise programme ran for 12 weeks for each participant. As the programme began during the school summer holidays an extra three week period was added to allow all participants to complete 12 weeks, even if they were away from the city on holiday at the beginning of the programme. The total duration of the exercise programme was therefore 15 weeks.

7.3: Experimental design

The experimental design used to investigate the effects of an exercise intervention programme on children with Type 1 diabetes was a randomised controlled trial. A definition of randomised controlled trials is given by Friedman at al. (1998, p 43) as 'comparative studies with an intervention and a control group; the assignment of the participant to a group is determined by the formal procedure of randomisation'. The advantages of using a randomised controlled trial, as opposed to another design, are: that they tend to produce groups that are initially comparable on the outcome variables to be assessed; that the validity of statistical calculations on the data is guaranteed; and that randomised controlled trials also remove the potential of bias in the allocation of participants to the intervention or control group (Friedman at al., 1998).

A critical look at alternative methodologies shows why randomised controlled trials have become generally accepted as the most reliable method of conducting clinical research. Studies that do not use a control group tend to overestimate the benefit of an intervention compared to properly controlled trials. The use of historical controls has the problem that the two groups may differ on variables other than the intervention, due to either patient selection or changes in the experimental environment (Pocock, 1983). This means that it is very difficult to obtain a reliable assessment of treatment efficacy from such trials. Another methodology is to use non randomised concurrent controls, this means that the clinician referring a patient or the experimenter know what group a person would be assigned to if they were entered into the trial. This can cause a selection bias in the groups if this knowledge influences whether a person is entered into the trial or not.

Ethical considerations must be taken into account in the design of any randomised controlled trials. It is likely to be the case that an intervention is being tested because it is thought to be superior to the present treatment method. Therefore a decision has to be taken as to whether it is justifiable to withhold this treatment from some of the study participants. This is a decision for individual clinicians to make but it has been found several times that the expected benefits of a new treatment are not found to be fulfilled by a randomised controlled trial. In the case of the present intervention the randomised controlled trial was justified ethically because exercise is available to everyone and widely recommended as part of a healthy lifestyle. The intervention made exercise more easily accessible to the participants in the experimental group and encouraged them to take part but those in the control group were not prevented from doing exercise in the community or at school.

7.4: Physical activity assessment

It was decided to use the self report measure of physical activity to assess habitual physical activity in phase 2 of the study. Although heart rate monitoring has greater validity and reliability it has limitations for a study of this type. One of these limitations is that it is very time consuming to administer for this population of children due to the large geographical area over which they live. As was explained in the chapter 3, this geographical separation meant that only one or two children could be visited per day, which increased the time needed for data collection. It was also more commitment on the part of the children to wear a heart rate monitor for four days than to recall their physical activity in an interview lasting 10-15 minutes. In addition it is inevitable that data are lost during any heart rate monitoring due to problems with the heart rate monitors. The intensity of the exercise intervention in the present study may well have caused additional problems for heart rate monitoring. In terms of the aims of the study, in phase one, one of the aims was to establish physical activity level in this population, therefore it was important to collect data which were as valid and reliable as possible. In phase two the emphasis was on increasing fitness, measuring psychological health and HbA_{1c} rather than assessing habitual physical activity level.

Data from phase one showed that self reported very hard physical activity was significantly correlated with hard, and very hard physical activity, recorded by heart rate monitors ($p< 0.01$). Self reported hard physical activity was also significantly correlated with very hard physical activity, recorded by heart rate monitors ($p<0.05$). Therefore it was considered that the 7 Day PAR was sensitive enough to detect differences between experimental and control groups, and between genders, in vigorous and to a lesser degree hard physical activity.

7.5: HbA_{1c} data collection

Participants were from 3 clinics, all assessed HbA_{1c} using DCA 2000 analyser machines. High validity and reliability have been found for these machines (Bayer, 1996), see section 3.4. Therefore the use of data from three clinics was not considered to increase variability in the study data.

7.6: Exploratory Interviews

Following the exercise intervention programme a small number of exploratory interviews were conducted with some of the participants to obtain a consumer perspective on the programme. An additional reason for conducting these was that during the course of the intervention the researcher came to the view that the standard questionnaires being used were not accessing all aspects of the children's experience. She felt that this qualitative data would be useful to look at the experience of the exercise programme from the participants' perspectives. See appendix 5 for interview schedule.

The method used was semi-structured interviews. Interviews vary according to the amount of control that is exerted by the interviewer during the interview and to the degree of structure. Semi structured interviews are based around an interview guide, a written list of questions and topics that need to be covered, but interviewees' responses to these questions shape the order and structure of the interview. The interviewer also has the discretion to follow a lead on a particular topic that the interviewee mentions, even if it is not in the interview guide. Bernard (2000) recommended that this is the best interview methodology to use when you have only one chance to interview a person. In this study it was desired that data were based around specific areas and therefore the semi-structured method was appropriate.

When conducting interviews a specific type of relationship is set up. This is different from a normal conversation as the interviewer has most of the control over the interaction. Esterberg (2002) described an interview as two individuals coming together to create meaning about a particular topic. The traditional view of the interviewer-interviewee relationship as the interviewer being neutral and revealing very little about themselves meant that the majority of the power in the relationship remained with the interviewer. The more modern view, introduced largely by the feminist movement, that the interviewer brings something of themselves to the interview and can reveal things about themselves to the interviewee reduces this imbalance somewhat. However, Eder and Fingerson (2002) reminded us that the interviewer must be particularly sensitive to this imbalance of power when interviewing children. In this study the interviewer was known to the children being interviewed from the previous three month exercise programme. The interviews were also conducted in the children's own homes, with their parents present if they wished, to try to make the children feel comfortable with the situation.

Although being known to the children was an advantage in terms of making the children feel comfortable to express their views and opinions, it may have caused a deference or acquiescence effect. This is when interviewees tell you what they think you want to know, so not to offend you (Bernard, 2000). It may have affected this study if the children reported what they thought the interviewer wanted to hear about the exercise programme rather than what they really felt. However, they were asked to express their honest opinions. In addition it was felt that the benefit of knowing the children and having built up a relationship with them over the previous three months would outweigh the possible deference effect.

Triangulation is the term use to mean bringing different kinds of evidence to bear on a problem. The rationale is that while each form of evidence has its own strengths and weaknesses, using multiple methods allows the researcher to balance these strengths and weaknesses. Although in the present study interviews were used in an exploratory way, rather than as an integral part of the research design, the data were used to compare to the quantitative data previously described.

7.7: Summary of measures used

To summarise this chapter in phase 2 the measures used to collect data at times 1 and 2 were as follows:

- *Psychological inventories*
  Diabetes Quality of Life for Youths Questionnaire (Ingersoll and Marrero, 1991)
  Self Efficacy for Diabetes Questionnaire (Grossman et al., 1987)
  Physical Self Perception Profile for Children (Whitehead, 1995)

- *Fitness parameters*
  Body mass and stature
  Skinfold measurements
  Peak VO_2

- *Physical activity assessment*
  7-Day physical activity recall questionnaire (Sallis et al., 1985)

- *Blood glucose control*
  HbA_{1c}

- *Semi-structured interviews*

The intervention used was a 12 week randomised controlled exercise intervention with 1 hour sessions twice a week for the first 8 weeks increasing to 3 times a week for the last 4 weeks.

8

Methods: Phase Two

8.1: Ethical approval

Ethical approval for the second phase of the study had previously been obtained from one Local Research Ethics Committee and The University Ethics Committee, see phase one. A report on the findings from phase one was submitted to the second Local Research Ethics Committee and they gave approval to continue with the second phase of the study. In order to increase the number of participants, approval to carry out phase two of the study was sought and obtained from a third research ethics committee, which related to a third NHS trust within the North West area. See appendix 3 for letters of ethical approval.

As in phase one, all the committees requested that informed consent be obtained in writing from parents or guardians of the participants, and that informed assent be obtained in writing from the participants themselves. Assent rather than consent was required as the participants were under 16 years of age. Additionally information documents were required which gave essential information about the study in an impartial manner and which were written in simple, non-technical or scientific language. One information sheet was required for the parents or guardians of the participants, and one for the participants themselves. The same consent forms, and assent forms and information sheets were approved by the three ethics committees (see appendix 6 for copies of these forms).

8.2: Study Population

Eligibility criteria for inclusion in the study were that children were aged 9 to 15 years and had been diagnosed with diabetes for two years or longer at the first data collection, time 1. These were the same criteria as were used in phase one and the rationale for using them was described in section 4.3.

8.3: Sample Size

Sample size was calculated to ensure that the study would have the ability to detect intervention effects of clinical importance between the experimental and control groups. Sample size is too small if statistical power is such that clinically important effects are likely to be missed. Above a certain sample size there is only a very small increase in power for a large increase in participant numbers. The greater the effect of the intervention the smaller the sample size required to demonstrate statistical significance.

The main clinical outcome variable used in diabetes management is HbA_{1c}, therefore this was the variable used to calculate sample size. A consultant paediatric diabetologist from one of the participating hospitals advised that a 1% change in HbA_{1c} is the minimum clinically relevant difference for this variable.

A statistician calculated the sample size necessary to detect this 1% change in HbA_{1c} using the following values which were obtained from analysis of data from phase one of this study:
significance level $\alpha = 0.05$
mean $HbA_{1c} = 9.75\%$
standard deviation of mean $HbA_{1c} = 1.68$.
Sample sizes were calculated for a two tailed test. The sample size necessary to detect a 1% change in HbA_{1c} with a power of 0.80 was 46 participants per group. The statistician recommended that this is the conventional power level used in studies of this type.

8.4: Recruitment

Children were recruited from the diabetes clinics at the three hospitals where ethical approval had been obtained. At each hospital recruitment was carried out in conjunction with the diabetes medical team there. In particular the diabetes nurse specialists assisted with recruitment.

The diabetes nurse specialists at each clinic identified the children who fitted the inclusion criteria for the study from their database. They then sent out a letter, parent and participant information sheets, which had been approved by the local research ethics committee, to the parents of these children. The letters were sent from each hospital by the nurses so that none of the research team had access to patient's names and addresses. The researcher and the appropriate diabetes nurse signed the letters. They had a reply slip attached which the parent or child was asked to return indicating whether they were interested in finding out more details about the project and including their address and telephone number if they were happy for the research team to contact them directly. A stamped addressed envelope was included. This letter was sent out during June. Four weeks later a second letter was sent out by the diabetes nurses from the first two hospitals, reminding people who were interested but had not yet sent back a reply slip to do so. This was sent to all the parents of children previously identified as fitting the inclusion criteria who had not replied to the first letter. Again parent and participant information slips were included as was a stamped addressed envelope. At the same time as this letter was sent out a confirmation letter was sent to those who had replied telling them the research team had received their reply slip and would be in contact soon.

Fifty-four replies were received saying they would like further information about the study and 17 were received saying they were not interested in finding out more about the study. This was less than the number estimated to be necessary by the sample size calculations. However, as a preliminary hypothesis generating study it was decided to continue with the intervention. In addition, the literature review found that intervention studies with children with Type 1 diabetes typically had small sample sizes. More than half of the psychosocial intervention studies on adolescents with Type 1 diabetes, included in a systematic review of the area, had fewer than 40 participants in total and no randomised controlled trials have previously been conducted in the UK (Hampson et al., 2001). Previous exercise intervention studies had sample sizes ranging from 15 to 32. Therefore a sample size of 54 was larger than any previous published randomised controlled trial of an exercise intervention with children with Type 1 diabetes at the time of carrying out the study.

The optimal design is one with equal numbers of participants in the experimental and control groups (Welkowitz et al., 2000). In this study it was considered that due to the high level of commitment demanded by the intervention both for the participants and their families drop out from the experimental group should be expected. Participants were therefore assigned to the experimental and control groups with a ratio of 3:2 respectively with the expectation that this would result in equal group sizes for analysis following higher drop out from the experimental than the control group.

8.5: Randomisation Process

Once recruitment to the study was completed randomisation was carried out. As the intervention was group based all the children began at the same time. The method of randomisation used was simple randomisation. The names of all the children who had replied saying they were interested in finding out more about the study were listed alphabetically and given numbers. Where two siblings had both volunteered for the study they were given the same number to ensure that they would end up in the same group, this was done for pragmatic reasons to make it easier for the families to participate. Six siblings from three families participated in total, therefore the numbers were from 1 to 51. A random numbers table was used to create a sequence of numbers between 1 and 51. The order of the numbers on the random numbers table was used to assign participants to each group. Participants whose numbers corresponded to the first numbers from the random numbers table were assigned to the experimental group until 34 had been assigned to this group. Participants with the remaining numbers were assigned to the control group. Thirty-four children were assigned to the experimental group and 20 to the control group.

Randomisation was carried out at this stage of the study rather than after the first laboratory measurements had been taken because final plans had to be made for running the intervention and these were dependent on the locations the experimental group lived. It was also felt that it was necessary to give the children and their families some advanced notice of whether they would be taking part in the exercise sessions, again due to the commitment involved.

8.6: Contact procedures

Pre Intervention

The children and their parents who had returned positive reply slips were contacted by telephone. The study was explained to them in more detail at this point and any questions were answered. Points explained on the telephone included the randomisation process and the fact that both groups were equally important for the findings of the study. They were then told which group they had been assigned to and if this was the experimental group they were given information about the exercise programme. This included information about locations, dates, travelling expenses and friends participating. Of the 54 families who had expressed an interest in participating in the study 39 agreed to participate at this stage. Reasons for not participating were the distance from their home to the laboratory, the time commitment involved, and for those in the experimental group the distance from their house to the exercise centre. Therefore the actual number in the experimental and control groups was 27 and 12 respectively.

For those families who agreed to participate an appointment was then made, with the children's parents or guardians, for them to visit the laboratory at I.M. Marsh campus of Liverpool John Moores University to participate in the pre-intervention testing. This was carried out during the school summer holidays so appointments were made for either mornings or afternoons during week or weekend days to suit the families. Parents were told testing for each child took approximately 2 hours. If the child and their parents were interested in participating but transport was a barrier every effort was made to overcome this. Where possible transport was provided by one of the researchers or shared lifts between participants were arranged. Where parents drove to the laboratory they were offered reimbursement of petrol expenses.

Following this telephone conversation a letter confirming the time of the appointment, a contact telephone number, what to bring plus instructions for getting to the laboratory were sent out to the parent and child. Children were asked to bring with them; shorts and T Shirt, their blood glucose monitor, and any snacks or drinks they wanted in addition to those available in the laboratory. Also included with this letter were a consent form for the parent/guardian to complete, an assent form for the participant to complete.

Post intervention testing

The post intervention testing was carried out immediately following the exercise programme. Appointments were made with the intervention group during the final exercise sessions, parents of participants in the control group were contacted by telephone. The testing was carried out during three weeks in November and December on Saturdays, Sundays and evenings during the week. As in the pre intervention testing every effort was made to overcome transport to the laboratory being a barrier to participation. Letters were sent out giving directions and information about what to bring if the parent requested them.

Participants who had been in the experimental group were given their final reward of a £10 gift voucher after the lab visit. Participants who had been in the control group were given a baseball cap with the STEPS 2000 logo on it to thank them for taking part. The children were not told about these rewards until they were part way though the study.

8.7: Laboratory protocol and data analysis (pre and post intervention)

The protocol described for Phase 1 of the present study (see section 4.5) was repeated. In addition children completed the 7-Day Physical Activity Recall Questionnaire. This was completed during the physical activity data collection of phase one of the present study (see section 4.4 for protocol).

Two experimenters who did not know whether the children were in the experimental or control group carried out the peak VO_2 tests at times 1 and 2. This was the test where it was most likely that experimenter knowledge of the child's group would influence the results was the peak VO_2 test, through differential levels of encouragement.

8.8: HbA_{1c} Data Collection Protocol

In order to analyse change in HbA_{1c} over the exercise intervention period it was intended to record values during the laboratory visits before and after this. However it was not possible to do this for every child due to a world wide shortage of DCA 2000 reagent kits which meant there were very few available for non clinical testing. An agreement was reached with the diabetes team at the main hospital in the study that if the child had not had an HbA_{1c} measurement taken at the out-patient clinic within the last six weeks, a blood sample would be taken while he or she was in the laboratory. This was taken from a fingerprick and stored in a heparin coated test tube below 25°C. These were taken to the hospital laboratory once a week where they were analysed using the same machines as during the outpatient clinic. A senior biochemist advised that using this method blood could be stored for up to one week without affecting the HbA_{1c} value. If children had had a measurement taken at the outpatient clinic within the six weeks prior to their laboratory visit this value was used.

8.9: Exercise programme

8.9.1: Intervention protocol

It was decided that in order to give the study an identity a logo should be designed for it. The version decided on was LJMU STEPS 2000 which was an acronym for Liverpool John Moores University Sports, Training and Exercise Programme Study, 2000. This was printed on all correspondence about the project to participants and their parents. In addition it was used on signs at the exercise class venues, and T-shirts were printed with the logo for the instructors to wear during exercise sessions (Liverpool John Moores University, 2000).

The participants in this study were spread over a wide geographical area due to the prevalence of Type 1 diabetes, estimated to be 1.25 per thousand children under 16 years in the UK (Department of Health, 2001). In order to make participation possible for as many people as possible sessions were run in three centres around Liverpool. Travel expenses to and from these centres were reimbursed. The sessions were free to the participants and also for siblings or friends who were welcome to come along to the sessions too. The sessions were similar in all three of these centres and the instructors moved between centres.

At the beginning of the intervention each participant was given a STEPS 2000 passport (Liverpool John Moores University, 2000). This contained: a record to fill in at each session attended; details of a reward scheme which ran alongside the activity programme; a home monitoring diary of insulin dosage and blood glucose levels and enjoyment rating of the session to be completed on each exercise session day; guidelines on exercise and diabetes; space to keep a points total related to the reward scheme.

The record of sessions attended was stamped by the instructor after each session. There were 28 stamps to collect which corresponded to doing two sessions a week for eight weeks and then three sessions a week for four weeks. The home monitoring diary was designed to be similar to the diaries of blood glucose levels which are given to the children by their diabetes team to complete. They filled in the type and number of units of insulin taken, and the times of day it was taken. Blood glucose levels, measured by the children using their own blood glucose monitors, were to be entered before the session, after the session, before bed that evening and before breakfast the next morning. The measurements before and after exercise were taken at the sessions. There was space for the children to write any 'key events' or comments, as they felt appropriate. There was also space for them to rate their enjoyment of the session using a happy, straight mouthed or sad face. The aim of this diary was for the children's well-being and education. Taking frequent blood glucose measurements is one of the recommendations to prevent hypo or hyperglycaemia occurring. Additionally it was educational. By keeping a written record of blood glucose levels and insulin injections the children were able to see how exercise affected their blood glucose levels and so alter their diet or insulin based on this to improve control.

The reward scheme that ran alongside the exercise programme was designed to maintain participation and reduce the drop out rate. It was based on a points system. Points were collected for each session attended and for each completed diary record. The number of points awarded for each session increased during the programme from 50 during the first week to 300 during week 12. Twenty points were awarded for each completed diary entry. There were four stages at which prizes were awarded. The prizes awarded were: a baseball cap with the STEPS 2000 logo on it at 600 points; a T-shirt, again with the STEPS 2000 logo printed on it, at 1600 points; a £5 cinema voucher or book token at 3400 points; and a £10 gift voucher for HMV, Wade Smith or Top Shop at 5700 points. The back page of the passport contained a table where points accumulated so far could be recorded. Prizes could then be claimed when the appropriate number of points had been collected.

The guidelines on exercise and diabetes were written in conjunction with the three participating diabetes teams. The points these covered were: eating extra carbohydrate, testing blood glucose regularly, what to do if blood sugar is below 5mmol/l or above 17mmol/l, to drink plenty of water, and reducing insulin if required in consultation with the diabetes team. The last paragraph stated that these were only guidelines and had been left vague as everybody reacts differently to exercise but to contact one of their diabetes team with any specific questions. In addition the diabetes nurse specialists were advised which children were participating in the exercise programme.

The instructors for the exercise sessions were 2nd or 3rd year students on the PE teacher training course at Liverpool John Moores University. These students received a training day run by one of the researchers. This included a talk from a diabetes nurse specialist about diabetes in children that covered what to be aware of during exercise sessions to help prevent hypo or hyperglycaemia occurring, and what to do if a child did have a hyperglycaemic or hypoglycaemic episode during a session. The researcher then gave an explanation of the aims and objectives of the project. The students were taken through an example session and given further suggestions of games and activities. The information covered in the session was given to them to take away in an information pack.

High energy snacks and drinks were available at each session for the children if they needed them. There were also ketone sticks available so that children could check their urine for ketones if their blood sugar levels were high before beginning exercise. The instructors kept a record of the attendance at each session.

8.9.2: Monitoring of exercise session intensity

Heart rate monitoring occurred at 15 of the sessions, at each of these two children wore heart rate monitors, set to record heart rate at 5 second intervals, for the duration of the session. Twenty-six data files were recorded successfully.

As in phase 1, heart rate data were analysed to find the number of minutes spent above the thresholds 50, 60 and 75% maximum heart rate reserve (MHRR), see section 4.4.2.1 for further details of heart rate data analysis. Maximum heart rate reserve is the difference between maximal and resting heart rate, plus the resting heart rate,

e.g. 75% MHRR = 0.75 (max heart rate – resting heart rate) + resting heart rate.

Maximum heart rates were taken from the children`s heart rate at maximal exertion at the end of the peak VO_2 test. In two cases this was not recorded and an estimated maximum of 200 beats per minute was used, following the recommendation of Stratton (1996). In phase 1 sleeping heart data were recorded for each child. This information was not recorded in phase 2 as 24 hour heart rate monitoring was not conducted. Therefore standard resting heart rate values were used in the calculation of MHRR, values recommended by Stratton (1996) were used.

8.10: Control group

The control group were asked to visit the laboratory once during the summer holidays and again 12 weeks later, in November or December. They completed the same tests as the intervention group did in the laboratory. In between their visits they were asked to continue participating in the same activities that they would normally do. Due to the design of the study it was unavoidable that the participants in the control group would know about the exercise programme.

8.11: Exploratory Interviewing

Five of the participants in the exercise group were interviewed after completion of the programme using a semi structured interview schedule, see appendix 5 for schedule. The sample was selected purposively. That is the researcher decided on the purpose she wanted the respondents to serve and interviewed people who would fulfil this purpose. There was no overall sampling design to decide how many of each type of informant should be included (Bernard, 2000). Participants were selected to include both boys and girls and both the older and younger age range of the study. Three girls and two boys were interviewed, ages were 9, 12, 13, 13 and 14.

9

Results: Phase Two

The hypothesis for this phase of the study was that increasing physical activity would lead to higher fitness, greater psychological health and improved glycaemic control in children with Type 1 diabetes. Following the results of phase one the focus was particularly on the effect of vigorous physical activity.

The objective was to measure the effect of a 12-week physical activity intervention programme on the aerobic fitness, body composition, quality of life, self esteem, self efficacy and HbA_{1c} of children with Type 1 diabetes.

In this chapter age, gender and duration since diagnosis with Type 1 diabetes are described for the whole sample. Those who completed the study are then compared to those who did not, to see if they differed on any of the measured variables at time 1 (first data collection, pre intervention). Descriptive data at time 1, for only those who completed the study, are then presented, for both the experimental and control groups, these are examined to see if the groups were equal at time 1. Descriptive data at times 1 and 2 (second data collection, post intervention), again for only those who completed the study, split into control and experimental groups are then presented. This is followed by analysis of variance calculations (group x time) to assess whether there were any significant changes in the measured variables between times 1 and 2.

9.1: Gender, age and duration since diagnosis with Type 1 diabetes

There were 39 participants in phase two of the study. Ten of these children had participated in phase one. Twenty-seven children were assigned to the experimental group and 12 to the control, more participants were assigned to the experimental than control group to allow for drop out. The experimental group had more girls than boys (18 girls, 9 boys) whereas the control group had more boys than girls (8 boys, 4 girls)

The mean age of the whole sample at time 1 was 12.6 years (95% confidence interval (C.I.) 12.0 – 13.2; range 9.2 to 15.8 years). The mean age of the experimental group was 12.8 (95% C.I. 12.0 – 13.6; range 9.2 to 15.8 years), and the mean age of the control group was 12.2 (95% C.I. 11.2 – 13.1; range 9.6 to 14.4 years). This difference was not statistically significant using an independent groups t test ($t = 0.93$, $p = 0.34$).

The mean duration since diagnosis with Type 1 diabetes for the whole sample was 6.3 (95% C.I. 5.0 – 7.6; range 0.5 to 12.8 years). The mean duration since diagnosis was similar in the experimental and control groups, experimental mean 6.4 (95% C.I. 4.8 – 8.0; range 0.5 to 11.1 years), control mean 6.3 (95% C.I. 3.3 – 9.2; range 1.8 to 12.8 years). An independent groups t test showed these means were not significantly different ($t = 0.05$, $p = 0.96$).

One of the criteria for inclusion in the study was that participants had been diagnosed with Type 1 diabetes for 2 years or longer; two of the participants did not meet this criterion. One had been diagnosed for 1.75 years. He had a brother who had been diagnosed for over two years, both expressed an interest in participating and it was felt that as both boys would be attending the laboratory and exercise sessions anyway (if randomised to the experimental group) it was worthwhile collecting data from them both. The second participant had been diagnosed with diabetes for 6 months, this was not realised by the experimenters until the girl had begun participating in the exercise programme. At this point it was explained to the girl and her mother that her data may not be used in the final analysis and they were given the choice whether to continue or not, she chose to continue participating and data were collected at time 2. Due to the sample size being smaller than that calculated, data for both these participants were included in the analyses but in each case they were examined to check whether they were outlying data points.

9.2: Comparison between those who completed the study and those who dropped out.

The study was designed with the expectation that there would be a greater drop out from the experimental group than the control group and more participants were assigned to the experimental than the control group. However drop out occurred in both the control and experimental groups. Drop out from the control group was defined as attending the laboratory for testing at time 1 but not returning at time 2. Drop out from the experimental group was defined as attending less than 50% of the exercise sessions or not returning at time 2.

9.2.1: Drop out from the experimental group

Twenty-seven children were randomly assigned to the experimental group, of these 26% completed all 28 sessions, and a further 19% completed 27 sessions. The frequency table below, table 9.1, shows the number of sessions attended by each of the 27 participants.

Table 9.1: Number of exercise sessions attended by children in the experimental group.

Number of sessions attended	Frequency (number of children)	Percent (%)	Cumulative percent (%)
28	7	25.9	25.9
27	5	18.5	44.4
26	1	3.7	48.1
17	1	3.7	51.8
10	1	3.7	55.5
8	2	7.4	62.9
3	1	3.7	66.6
1	4	14.8	81.4
0	5	18.5	100.0

Fourteen of the 27 children in the experimental group (52%) completed more than 50% of the exercise sessions and so fulfilled the first criterion for study completion. All of these children who completed more than 50% of the sessions returned at time 2 for testing and so fulfilled both criteria for study completion. In addition 6 of the children who did not complete more than 50% of the sessions did attend the laboratory for testing at time 2 but the data are not included in the following analyses. The rationale for not including them in analyses was that they would have confounded the results. The children attended less than half of the intervention programme and therefore any effects that it had on the measured variables would have been reduced in these children. Some of the children attended zero or one exercise session but it was considered that counting them as control participants may have introduced bias into the groupings by selecting children non-randomly into the control group. For example these children may be less motivated children, or from less motivated families, and hence control diabetes less well, which would contaminate the control group.

To examine whether the children who participated in the exercise programme differed from those who dropped out, the data collected at time 1 for the 14 children who completed more than 50% of the sessions were compared to those for the children who completed less than 50% of the sessions. Independent groups t tests were conducted between the scores for these two groups. Data were examined for outlying data points, more than 3 standard deviations above or below the mean (Munro, 1997). Where these were present, and considered true values i.e. not due to error, calculations were conducted with and without them, where significance of results varied a distribution free, non parametric test, was conducted.

The results showed the two groups did not differ significantly with respect to age or duration since diagnosis with diabetes. Five of the 9 boys dropped out and 8 of the 18 girls dropped out. Of all the outcome variables measured there were two significant differences, these were for the sport competence sub-scale of the PSPP-C and aerobic fitness. The group who attended more than 50% of the exercise sessions had lower aerobic fitness and lower sport competence than the group who attended less than 50% of the sessions. Table 9.2 gives the mean values for these variables. A full list of the means and t test results for all the measured variables is given in appendix 7.

Table 9.2: Descriptive statistics for the variables on which children who completed the exercise programme differed significantly from those who dropped out at time 1

Variable	**Attended ≥ 14sessions**			**Attended < 14 sessions**			**t**	**p**
	Mean	95% C.I.	N	Mean	95% C.I.	N		
Sport competence	2.52	2.10 – 2.95	14	3.09	2.76 – 3.42	13	-2.25	<0.05
Peak VO_2	30.23	26.56 – 33.89	14	38.70	32.05 – 45.34	12	-2.54	<0.05

9.2.2: Control group

Completion of the study by the control group was defined as attending the laboratory for testing at both times 1 and 2. Twelve children attended at time 1 and of these 7 returned at time 2. As with the experimental group, data collected at time 1 for those who completed the study were compared with data for those who did not. Outliers were dealt with as above. Independent groups t tests were performed between the groups who completed the programme and the group who did not.

There were no significant differences between the ages or duration since diagnosis with diabetes of the children who returned at time 2 and those who did not. When the data for the measured variables were compared there were no significant differences between the participants' scores on any of the sub-scales of the psychological questionnaires, measures of fitness, HbA_{1c}, very hard or hard physical activity. The only variable that differed significantly between the two groups was self reported moderate physical activity, those who returned at time 2 reported significantly lower moderate physical activity than those who did not. However, phase one found that self reported moderate physical activity did not correlate significantly to physical activity measured by heart rate and therefore its validity was unclear. Self reported hard and very hard physical activity had greater validity and in phase two these showed no significant difference between those who completed the study and those who dropped out.

There were small numbers in these analyses and therefore there is the possibility that significant differences were missed due to Type 2 error. However, an examination of the mean values for the two groups, suggested mean values were similar. A full list of the means and t test results for all the measured variables is given in appendix 7.

9.3: Levels of psychological well being, HbA_{1c}, fitness and physical activity at time 1

Only the children who completed the study were included in the analysis of variance calculations that tested the hypothesis of phase two. Therefore in this section describing data in the experimental and control groups at time 1, only data for children who completed the study were included.

Data are presented on each of the measured variables at time 1. For each variable the mean value for the experimental and control groups and for the group as a whole are presented. The variables measured were quality of life, self efficacy, self esteem, HbA_{1c}, BMI, body fatness, peak VO_2 and physical activity. The groups were divided randomly to try to avoid the possibility of there being systematic differences between the two groups at time 1. To test whether this was the case and the groups did not differ on the measured variables at time 1 independent groups t tests were performed between the scores for the two groups at time 1. In each t test, Levene's test of equality of variance was carried out and where it was significant the adjusted t and p values were reported. Data were screened for outliers, the procedure was described in 9.2.1.

The measures used were the same as in phase 1, brief details of the analysis of each of the variables is given here, for a more detailed description of the analysis refer back to sections 4.4 - 4.6.

9.3.1: Age, gender and duration since diagnosis with Type 1 diabetes

The mean age and duration since diagnosis with diabetes of the participants who completed the study is given in table 9.3. These did not differ significantly between the experimental and control groups. There was an unequal gender distribution, 4 boys and 10 girls in the experimental group and 5 boys and 2 girls in the control group. Therefore for variables where the results of phase one suggested there may be gender differences, possible gender effects on the present results were examined.

Table 9.3: Descriptive statistics for age and duration since diagnosis with Type 1 diabetes.

Variable	Experimental			Control			t	p
	Mean	95% C.I.	n	Mean	95% C.I.	n		
Age	12.3	10.9 – 13.6	14	12.0	10.6 – 13.4	7	0.77	>0.05
Duration since diagnosis with diabetes	6.0	3.1 – 8.9	14	6.9	2.4 – 11.6	7	-0.47	>0.05

9.3.2: Quality of life

The satisfaction sub-scale of the Diabetes Quality of Life for Youths Questionnaire (DQOL-Y) had a possible range of 17 to 85, a high score represented high life satisfaction. The impact sub-scale had a possible range of 22 to 110, a high score indicated diabetes had a high impact on life and therefore low quality of life. The worry sub-scale had a possible range of 0 to 55, a high score indicated a high level of worry about diabetes and therefore low quality of life. On the one item global health rating a high score represented high quality of life. The means and 95% confidence intervals reported by the experimental and control groups on the DQOL-Y are presented in table 9.4. There were no outliers.

Table 9.4: Descriptive statistics for the DQOL-Y questionnaire at time 1

Variable	Experimental			Control			t	p
	Mean	95% C.I.	n	Mean	95% C.I.	n		
Satisfaction with life (Satisfaction)	71.08	65.78 – 76.38	13	70.67	62.77 – 78.57	6	0.10	>0.05
Disease impact (Impact)	44.33	39.52 – 49.14	12	47.14	42.07 – 52.22	7	-0.86	>0.05
Disease related worries (Worry)	18.14	12.31 – 23.98	14	21.17	7.69 – 34.65	6	-0.57	>0.05
Overall health rating (Health)	3.31	3.02 – 3.60	13	3.17	2.38 – 3.96	6	0.50	>0.05

Table 9.4 shows that differences between the scores of the two groups were small, and an independent groups t test showed that there were no significant differences between the experimental and control groups for diabetes quality of life at time 1.

9.3.3: Self efficacy

In this questionnaire high scores represented high self efficacy and low scores represented low self efficacy. The possible range of each sub-scale was as follows: total self efficacy 33 to 198; diabetes self efficacy 22 to 132; medical self efficacy 5 to 30; and general self efficacy 6 to 36. The means and standard deviations of the experimental and control group at time 1 on the Self Efficacy for Diabetes questionnaire are presented in table 9.5. There were no outliers. The data showed that the control group had higher mean values than the experimental group for total self efficacy, and all three sub-scales, at time 1. However, independent groups t tests between the groups for each of the sub scales showed these differences were not significant.

Table 9.5: Descriptive statistics for the SED questionnaire at time 1

Variable	**Experimental**			**Control**			**t**	**p**
	Mean	95% C.I.	n	Mean	95% C.I.	n		
Total self efficacy	142.27	125.86 – 158.69	11	148.29	129.31 – 16.26	7	-0.54	>0.05
Diabetes self efficacy	95.55	82.69 – 108.40	11	101.71	89.21 – 114.22	7	-0.74	>0.05
Medical self efficacy	18.50	16.06 – 20.94	14	19.86	14.72 – 24.99	7	-0.63	>0.05
General self efficacy	26.00	22.71 – 29.29	14	26.71	21.49 – 31.94	7	-0.27	>0.05

9.3.4: Self esteem

The possible range of each sub-scale was 1 to 4, one corresponded to low self esteem and 4 to high self esteem. Data for the PSPP-C are presented in table 9.6. There were no outlying data points. Global self worth (GSW) was scored highest of the six sub-scales by both groups. Overall the control group had higher self esteem than the experimental group at Time 1, the mean score for each sub-scale was greater in the control group, see table 9.6. Independent groups t tests showed only the sport competence sub-scale was scored significantly differently by the experimental and control groups, the control group rated their sport competence higher than the experimental group.

Comparison with phase one data found the present control group rated all 6 sub-scales higher than the phase one sample. In phase one boys rated their self esteem as higher than girls for all but the sport competence sub-scale. This suggested the control group have high self esteem for a group of children with Type 1 diabetes. This may in part be due to the control group containing more boys than girls and the experimental group more girls than boys. However, the data from phase one suggested this was not the reason for the significant difference in sport competence between groups.

Table 9.6: Descriptive statistics for the PSPP-C at time 1

Variable	**Experimental**			**Control**			**t**	**p**
	Mean	95% C.I.	n	Mean	95% C.I.	n		
Global self worth	3.35	3.01 – 3.68	14	3.38	2.83 – 3.93	7	-0.13	>0.05
Physical self worth	2.87	2.45 – 3.29	13	3.11	2.79 – 3.44	7	-0.88	>0.05
Sport competence	2.52	2.10 – 2.95	14	3.22*	2.79 – 3.44	6	-2.17*	<0.05
Condition competence	2.72	2.27 – 3.17	13	3.24	2.78 – 3.70	7	-1.65	>0.05
Attractive body competence	2.53	1.95 – 3.10	13	2.81	2.39 – 3.23	7	-0.74	>0.05
Strength competence	2.75	2.38 – 3.12	14	2.95	2.38 – 3.53	7	-0.69	>0.05

In table 9.7 high scores represented a rating of high importance, the possible range of each sub-scale was 1 to 4. There were no outliers. Independent groups t tests showed that there were no significant differences between the ratings on any of the perceived importance profile sub-scales.

Table 9.7: Descriptive statistics for the Perceived Importance Profile of the PSPP-C at time 1.

Variable	**Experimental**			**Control**			**t**	**p**
	Mean	95% C.I.	n	Mean	95% C.I.	n		
Sport competence importance	1.96	1.53 – 2.39	14	2.75	1.89 – 3.61	6	-2.10	0.05
Condition competence importance	2.50	2.22 – 2.78	13	3.00	2.26 – 3.74	6	-1.87	>0.05
Attractive body importance	2.75	2.30 – 3.20	14	2.64	1.65 – 3.63	7	0.26	>0.05
Strength competence importance	1.96	1.75 – 2.18	14	2.57	1.84 – 3.30	7	-1.94	>0.05

9.3.5: HbA_{1c}

The number of participants for whom HbA_{1c} data were available was greater than for the other variables as this was collected at hospital outpatient visits and so was available for control participants who did not return to the laboratory at time two.

Of the two participants with diabetes duration less than 2 years, see section 9.1, one dropped out and was therefore not included in this analysis, the other completed the study. As the reason for the inclusion criteria of diabetes duration more than 2 years was that HbA_{1c} values may be affected by residual insulin production in the first two years post diagnosis, the data for this participant were also excluded from the present analysis of change in HbA_{1c}.

Mean HbA_{1c} values at time 1 are described for the experimental and control groups in table 9.8. There were no outliers. An independent groups t test showed that the mean

HbA_{1c} values in the experimental group (9.5%) and the control group (9.0%) were not significantly different.

Table 9.8: Descriptive statistics for HbA_{1c} at time 1

Variable	Experimental			Control			t	p
	Mean (%)	95% C.I.	n	Mean (%)	95% C.I.	n		
HbA_{1c}	9.54	8.79 – 10.29	14	8.99	8.08 – 9.91	12	0.68	>0.05

9.3.6: Body composition data

BMI

BMI was calculated from height and body mass using the formula:

BMI = weight (kg) / height (m^2)

Table 9.9: Descriptive statistics for BMI at time 1

Variable	Experimental			Control			t	p
	Mean ($kg^{-1}.m^2$)	95% C.I.	n	Mean ($kg^{-1}.m^2$)	95% C.I.	n		
BMI (overall)	20.38	18.86 – 21.90	14	20.11	18.23 – 21.96	7	0.24	>0.05

At time 1 the experimental group had higher mean BMI than the control group 20.38 $kg^{-1}.m^2$ compared to 20.11 $kg^{-1}.m^2$, independent groups t tests showed this difference was not significant. There were no outlying data points.

Phase one found that boys had significantly lower BMI values than girls, 19.1 compared to 22.8 $kg^{-1}.m^2$. Analysis of the present data also showed this trend, mean BMI was higher for girls than boys in both the experimental (girls 21.1 $kg^{-1}.m^2$, boys 18.6 $kg^{-1}.m^2$) and control (girls 20.9 $kg^{-1}.m^2$, boys 19.8 $kg^{-1}.m^2$) groups. The direction of the difference between BMI values for the experimental and control groups as a whole may reflect this given the gender distribution, more girls than boys in the experimental group and more boys than girls in the control group.

Sum of 5 skinfold measurements

The measurements summed were as follows:

Sum of 5 skinfolds = sum of bicep, tricep, subscapular, suprailliac and calf

Data for one participant were excluded from analysis. This was because the difference between values for sum of 5 skinfolds at time 1 and time 2 (time 1: 39.2mm, time 2: 84.6mm) was greater than would be expected over a 12 week time period, and was therefore considered to be due to measurement error. Descriptive statistics are presented in table 9.10.

Table 9.10: Descriptive statistics for sum of skinfold measurements at time 1.

Variable	Experimental			Control			t	p
	Mean (mm)	95% C.I.	n	Mean (mm)	95% C.I.	n		
Sum of 5 skinfolds	63.30	50.69 – 75.94	13	55.93	30.03 – 81.83	7	0.52	>0.05

These show that the experimental group had greater mean skinfold measurements than the control group. There were no outlying data points. An independent groups t test showed that this difference was not significant.

As for BMI the non significant difference between the two groups may reflect the gender distribution. Phase one showed that girls had higher mean skinfold measurements than boys (83.1 and 53.6 mm respectively, p= 0.07). The present data showed the same trend, in the experimental group mean skinfold measurement was 72.7mm for girls and 42.3mm for boys. In the control group it was 61.4mm for girls and 53.7mm for boys.

9.3.7: Aerobic fitness (peak VO_2)

Peak VO_2 was calculated as $ml^{-1}kg^{-1}min^{-1}$. Descriptive statistics for the experimental and control groups at time 1 are presented in table 9.11. There were no outlying data points.

Table 9.11: Descriptive statistics for peak VO_2 at time 1

Variable	Experimental			Control			t	p
	Mean ($ml^{-1}kg^{-1}min^{-1}$)	95% C.I.	n	Mean ($ml^{-1}kg^{-1}min^{-1}$)	95% C.I.	n		
Peak VO_2	30.23	26.56 – 33.89	14	46.10	39.49 – 52.72	7	-5.19	<0.01

These data show that the mean peak VO_2 value was greater in the control group, 46.10 $ml^{-1}kg^{-1}min^{-1}$ than in the experimental group, 30.23 $ml^{-1}kg^{-1}min^{-1}$. An independent groups t test showed that this difference was significant.

Data from phase one showed girls had greater peak VO_2 than boys (35.0 and 37.1 $ml^{-1}kg^{-1}min^{-1}$ respectively). However, this was an unusual finding, generally boys have greater peak VO_2 than girls. Examination of the present data by showed that in the control group boys had a higher mean peak VO_2 value than the girls (47.3 and 43.2 $ml^{-1}kg^{-1}min^{-1}$ respectively). However, in the control group the girls had higher mean peak VO_2 than the boys (30.7 compared to 29.0 $ml^{-1}kg^{-1}min^{-1}$ respectively).

9.3.8: Physical activity

Data for one participant were removed, this was because very high vigorous physical activity was reported (62 minutes per day). Examination of the raw data showed three hours of continuous very hard physical activity were reported, this was considered to be an overestimation of time spent in continuous very hard activity and therefore data were removed. There were no outlying data points. Descriptive data for physical activity collected using the 7-Day PAR are presented in table 9.12.

Table 9.12: Descriptive statistics for habitual physical activity at time 1

Variable	Experimental			Control			t	p
	Mean (minutes per day)	95% C.I.	n	Mean (minutes per day)	95% C.I.	n		
Moderate physical activity	33.63	14.14 – 52.31	13	21.12	9.37 – 32.87	7	1.02	>0.05
Hard physical activity	16.15	8.67 – 23.64	13	30.92	3.89 – 57.94	7	-1.28	>0.05
Very hard physical activity	4.29	0.51 – 8.06	13	17.45	7.45 – 27.45	7	-3.48	<0.01
Total (sum of moderate, hard and very hard)	54.06	33.24 – 74.89	13	69.49	37.58 – 101.40	7	-0.95	>0.05

The data show that the control group reported participating in more hard and very hard physical activity per day than the experimental group. Independent groups t tests between the experimental and control group data showed that the difference between groups for very hard physical activity was significant, the control group reported participating in more very hard physical activity than the experimental group.

Analysis by gender showed in the experimental group boys reported higher very hard physical activity than girls (17.7 and 4.7 minutes per day respectively), however in the control group girls reported more very hard physical activity than boys (15.2 and 9.3 minutes per day respectively). In phase one heart rate data found boys participated in significantly more vigorous physical activity than girls, self report data showed the same trend but the values were not significant.

9.3.9: Summary: Comparability of groups at time 1

The aim of randomisation was to avoid bias in the assignment of children to the experimental and control groups. The above comparisons found that the mean age of the two groups and the mean duration of time since diagnosis with Type 1 diabetes did not differ significantly between the two groups. Comparisons of scores on the sub-scales of the SED and DQOL-Y found no significant differences between the mean scores on these. The sport competence sub-scale of the PSPP-C was scored significantly higher by the control than the experimental group, the other sub scales did not differ significantly. The physiological data showed no significant difference between the mean HbA_{1c} values of the two groups or between mean BMI or body fat values. There were, however, two variables that differed significantly between the two groups these were aerobic fitness and self reported very hard physical activity, these were both greater in the control group. The two groups had small numbers and therefore there is the possibility that Type 1 or Type 2 errors occurred.

It was possible that unequal gender distribution between groups affected the results, there were more girls than boys in the experimental group and more boys than girls in the control group. Phase one found girls tended to have lower self esteem, higher BMI, higher skinfold thickness and participate in less physical activity than boys. Differences between groups are in the direction these gender differences would predict. However, the significant group differences for sport competence and aerobic fitness were not predicted by gender differences in phase one.

9.4: Children's heart rates during exercise sessions

Heart rate monitoring was used at a sample of the sessions to allow the intensity of the exercise sessions to be assessed. Fifteen sessions were monitored, at the majority of these sessions two children wore monitors giving a total of 26 data files. Each session was 60 minutes duration in total, including time for blood glucose monitoring etc.

The mean number of minutes per session spent above the MHRR thresholds described above are shown in table 9.13.

Table 9.13: Mean number of minutes per session spent above thresholds of MHRR

Heart rate (% of MHRR)	Mean time above threshold (mins)	95% C.I. (mins)	n
> 75	13.8	10.2 – 17.5	26
60 – 75	9.6	7.8 – 11.4	26
50 – 60	6.8	5.4 – 8.2	26
≥ 50 i.e. total	30.2	25.0 – 35.5	26

Sixteen files were recorded at centre 1, 9 at centre 2 and 1 at centre 3, the different numbers reflects the fact that there were different numbers of children attending the sessions at each centre. Figure 9.1 shows the mean number of minutes above heart rate thresholds at each of these centres, see appendix 8 for data table.

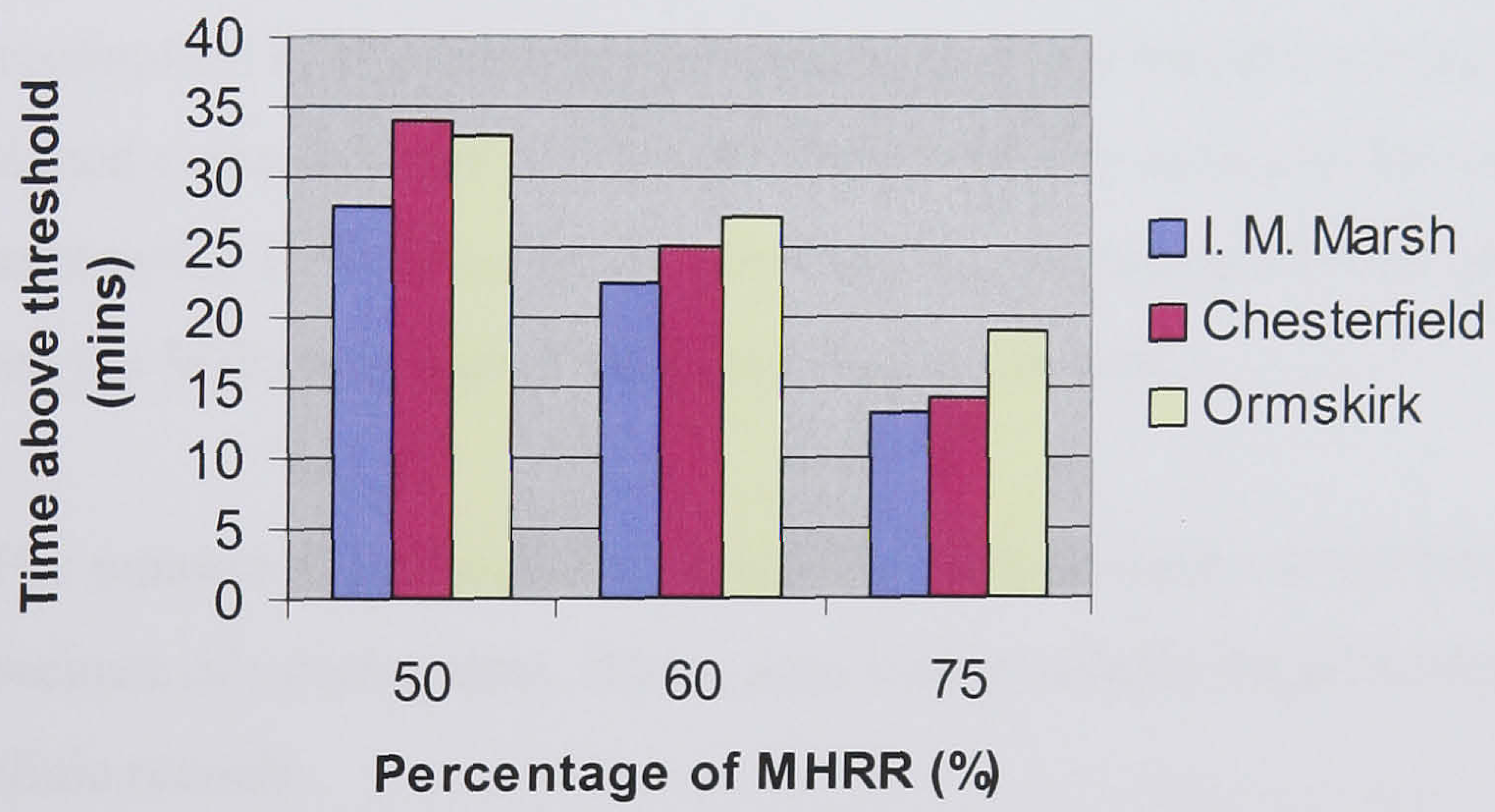

Figure 9.1: Mean number of minutes above 50, 60 and 75% MHRR at each of the centres.

9.5: Differences between groups at time 1 and time 2

To test the hypotheses that increasing physical activity would lead to higher fitness, greater psychological health and lower HbA_{1c} in children with Type 1 diabetes a series of two way (group x time) between and within subjects ANOVA calculations were used. In these calculations only those children who completed the study were included, therefore the groups were the same as described in section 9.3, fourteen in the experimental and 7 in the control. The rationale for using this test with the data from the psychological questionnaires, obtained using Likert scales, was described in section 5.2. For sport competence and peak VO_2 variables, where there was a significant difference between the experimental and control groups at time 1, ANCOVA was conducted instead of ANOVA to test for changes as a result of the intervention correcting for differences at time 1. Physical activity data were only analysed for the control group, a repeated measures t test was used. Data for the experimental group were not analysed because some of the group participated in the intervention exercise sessions during the 7 days prior to laboratory testing and some did not.

Sample size differed between groups, therefore Levene's statistic was used to test whether variances were equal or not. The null hypothesis that group variances were equal in the population was tested, where this was significant, indicating the assumption of homogeneity of variance was not met the non parametric Wilcoxon signed ranks test was performed. Data were also screened for outlying data points, see section 9.2.1. Where significance differed depending whether they were included or not the Wilcoxon signed ranks test was again used.

The number of participants included in each analysis varied between variables because of missing data. HbA_{1c} data were available for all control participants from clinic records.

A Bonferroni correction factor was not used. This was an exploratory study with small sample size and using the Bonferroni correction factor would have increased the chance of Type 2 errors so that effects of the study may have been missed. However, due to the increased chance of Type 1 errors data are interpreted cautiously in the discussion in chapter 10.

Data are presented for each variable in turn, ANOVA tables are presented for the variables that showed significant changes. For the remaining tables see appendix 9.

9.5.1: Psychological variables

Self esteem

Table 9.14: Descriptive statistics for the PSPP-C at times 1 and 2

	Group	Mean time 1 (95% C.I.)	Mean time 2 (95% C.I.)	n
Global self	E	3.35 (3.01 - 3.68)	3.21 (2.95 - 3.48)	14
worth	C	3.38 (2.83 - 3.93)	3.29 (2.68 - 3.89)	7
Physical self	E	2.87 (2.45 – 3.30)	2.95 (2.41 – 3.48)	13
worth	C	3.12 (2.79 – 3.45)	3.29 (3.01 – 3.56)	7
Sport	E	2.49 (2.03 – 2.94)	2.88 (2.46 – 3.30)	13
competence	C	3.22 (2.80 – 3.65)	3.17 (2.71 – 3.62)	6
Condition	E	2.72 (2.27 – 3.17)	2.96 (2.51 – 3.41)	13
competence	C	3.24 (2.78 – 3.70)	3.17 (2.75 – 3.58)	7
Attractive body	E	2.53 (1.95 – 3.10)	2.67 (2.11 – 3.22)	13
competence	C	2.81 (2.39 – 3.23)	2.90 (2.54 – 3.27)	13
Strength	E	2.75 (2.38 – 3.12)	3.00 (2.63 – 3.37)	14
competence	C	2.95 (2.38 – 3.53)	3.17 (2.86 – 3.47)	7

The mean score in the experimental group increased between time 1 and time 2 for all the sub-scales except global self worth, which decreased. In the control group three of the sub-scales were scored higher on average at time 2 compared to time 1 and three were scored lower. The significance of these differences was tested and is reported in the following section for each sub-scale of the PSPP-C.

Global self worth

The ANOVA calculation found no significant interaction between the groups over time, i.e. that the intervention had no significant effect on GSW compared to the control condition ($F_{(1,19)} = 0.05$, $p= 0.82$). There was also no significant difference between the scores at times 1 and 2 ($F_{(1,19)} = 1.85$, $p= 0.19$) or between GSW in the experimental and control groups ($F_{(1,19)} = 0.05$, $p= 0.83$). Levene's test of equality of error variances was non significant, time 1 $F_{(1,19)} = 0.13$, $p= 0.73$, time 2 $F_{(1, 19)} = 0.29$, $p = 0.60$.

Physical self worth

The Levene's test of equality of error variances showed a significant difference at time 1 ($F_{(1,18)} = 4.71$, $p= 0.04$) and time 2 ($F_{(1,18)} = 6.34$, $p= 0.02$). Therefore the Wilcoxon Signed Ranks test was performed. This found no significant difference between PSW scores at time 1 and time 2 in the experimental group ($z= -0.79$, n-ties = 12, $p= 0.43$) or the control group ($z= -1.06$, n-ties = 6, $p= 0.29$). The Wilcoxon Signed Ranks test does not assess interaction between the groups over time, however the mean values show PSW increased slightly between times 1 and 2 in both groups which suggests there was no interaction.

Sport competence

Due to the significant difference between the scores of the experimental and control groups at time 1 for sport competence a one way between group analysis of covariance was conducted on this variable. This compared the scores for the two groups at time 2 adjusted for the scores at time 1. The independent variable was intervention group (experimental or control) and the dependent variable was sport competence scores at time 2. Children's sport competence scores at time 1 were used as the covariate in this analysis. Preliminary tests were checks were carried out to ensure there were no violations of the assumptions of normality, linearity, homogeneity of variances or homogeneity of regression slopes. After adjusting for pre-intervention scores there was no significant difference between the scores for the two groups at time 2 for sport competence, $F_{(1,16)}= 0.86$, $p= 0.37$, eta squared = 0.05.

Although the mean values suggested that the sport competence of the experimental group increased more than the control group (see figure 9.2) this was not significant in the ANCOVA calculation.

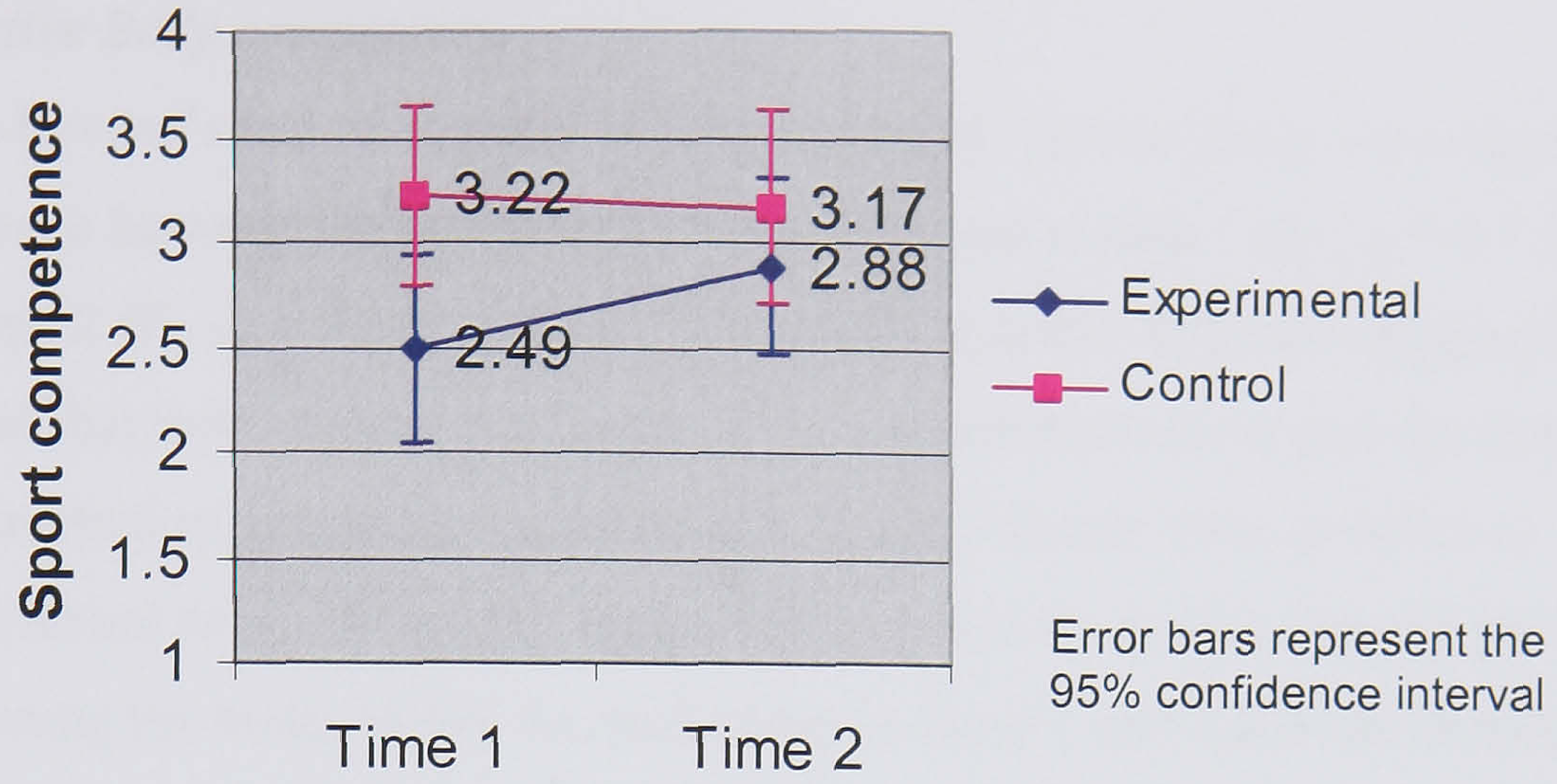

Figure 9.2: Interaction plot between time and group for sport competence

Condition competence

The Levene's test of equality of error variances found there was a significant difference in the error variance of the two groups at both time 1 ($F_{(1,18)} = 4.55$, p= 0.05) and time 2 ($F_{(1,18)} = 5.50$, p= 0.03). Therefore the Wilcoxon Signed Ranks test was performed. No significant differences were found between the scores at time 1 and time 2 for the experimental or the control group. However, the difference between the scores of the experimental group approached significance (z= -1.79, n-ties = 10, p= 0.07). Data for the control group were: z= -0.55, n-ties = 4, p= 0.58. The direction of the change in reported condition competence is shown in figure 9.3. This shows that condition competence of the exercise group increased over the study period whereas that of the control group decreased slightly.

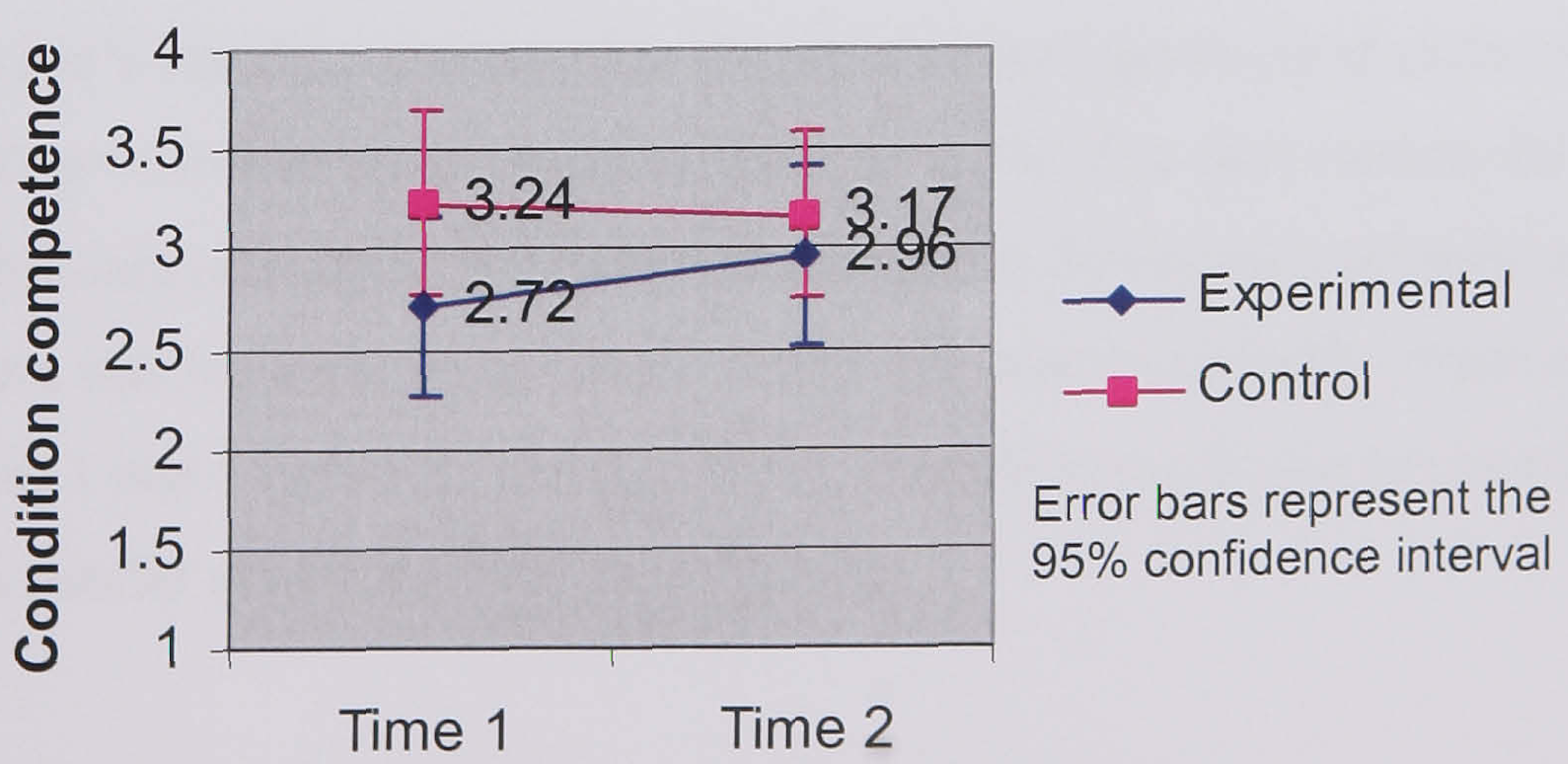

Figure 9.3: Interaction plot between time and group for condition competence

Attractive Body competence

Again Levene's test of equality of error variances showed there was a significant difference between the two group's error variances at time 1 ($F_{(1,18)} = 0.7.87$, p= 0.01) and time 2 ($F_{(1,18)} = 6.63$, p= 0.02). The non parametric Wilcoxon Signed Ranks test showed that there was no significant difference between the scores for either the experimental or control group at times 1 and 2. The data were as follows: experimental z= -1.28, n-ties= 10, p= 0.20; control z= -0.54, n-ties= 5, p= 0.59). Examining the mean values for each group at times 1 and 2 showed that there was a slight increase in body competence in both the experimental and control groups between times 1 and 2 which suggested the intervention did not cause an interaction between time and group.

Strength competence

Table 9.15: two way ANOVA calculations for strength competence

Source	Type III sum of squares	df	Mean square	F	Significance
Time	0.503	1	0.503	4.499	0.047
Time * Group	2.976E-03	1	2.976E-03	0.027	0.872
Error (time)	2.124	19	0.112		
Intercept	328.707	1	328.707	537.287	0.000
Group	0.318	1	0.318	0.519	0.480
Error (group)	11.624	19	0.612		

Levene's equality of error variance test was not significant at either time 1 ($F_{(1,19)} = 0.50$, p= 0.49) or time 2 ($F_{(1,19)} = 2.07$, p= 0.17). The intervention did not cause a significant interaction between time and group for strength competence (p= 0.87). There was however a significant overall increase in strength competence between times 1 and 2 ($p<0.05$), see figure 9.4. strength competence increased in both groups, to a similar extent, over the study period.

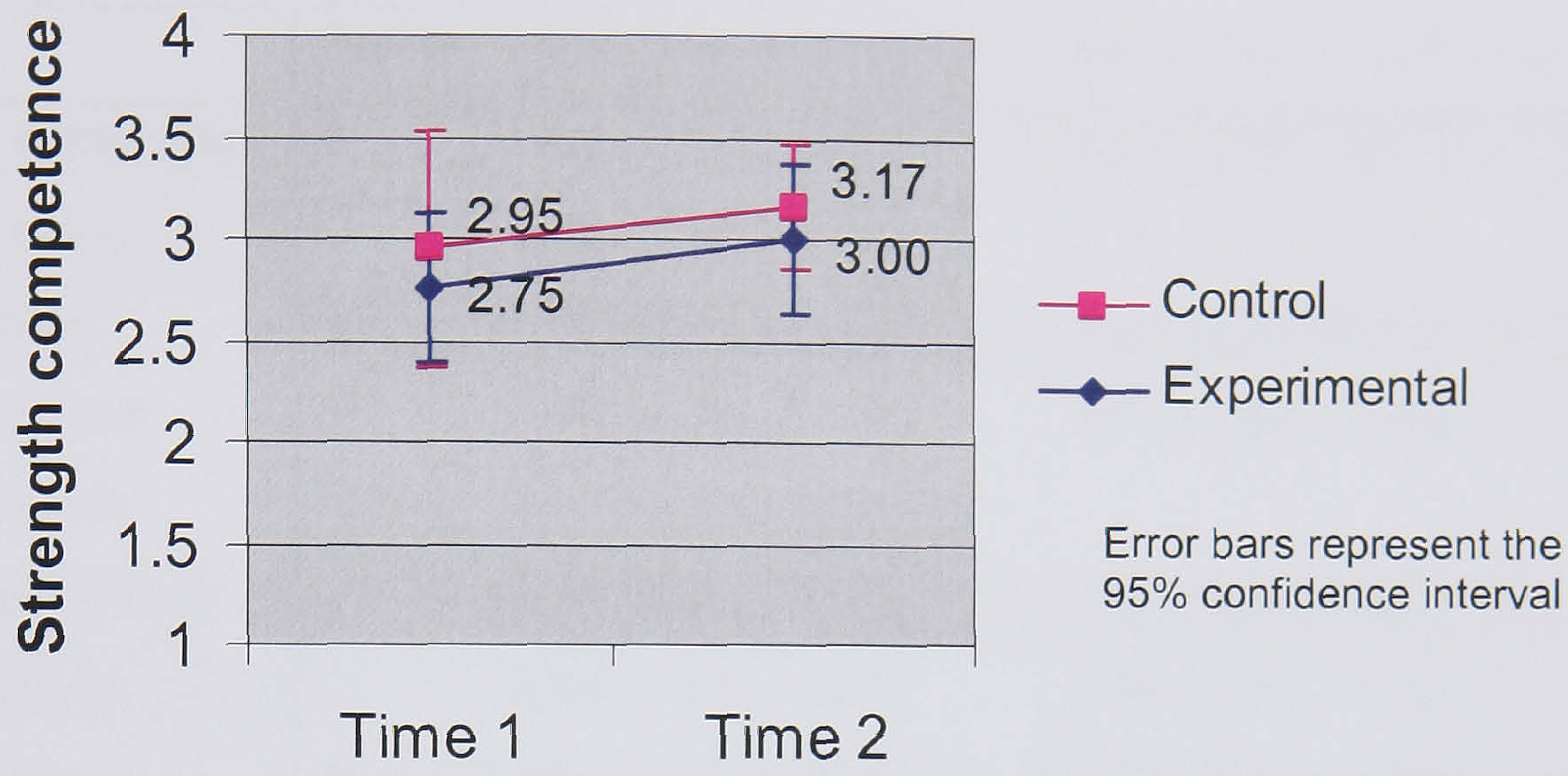

Figure 9.4: Interaction plot between time and group for strength competence

Perceived importance profile

Table 9.16 shows the mean values and 95% confidence intervals for the four sub-scales of the perceived importance profile of the PSPP-C. Overall there was greater change between the mean values at time 1 and time 2 in the experimental group than the control group. The experimental group rated all four sub-scales higher, i.e. more important, following the intervention compared to before. The control group rated two sub-scales the same at times 1 and 2, one slightly lower and one slightly higher.

Table 9.16: Descriptive statistics for the Perceived Importance PSPP-C at times 1 and 2

	Group	Mean time 1 (95% C.I.)	Mean time 2 (95% C.I.)	n
Sport competence	E	1.96 (1.53 – 2.39)	2.43 (2.09 – 2.77)	14
importance	C	2.75 (1.88 – 3.61)	2.75 (1.95 – 3.55)	6
Condition	E	2.50 (2.22 – 2.78)	2.92 (2.54 (3.31)	13
competence	C	3.00 (2.26 – 3.74)	2.67 (1.88 – 3.46)	6
importance				
Attractive body	E	2.75 (2.30 – 3.20)	2.86 (2.44 – 3.27)	14
importance	C	2.64 (1.65 – 3.63)	2.64 (2.13 – 3.16)	7
Strength	E	1.96 (1.75 – 2.18)	2.54 (2.11 – 2.97)	14
competence	C	2.57 (1.84 – 3.30)	2.79 (2.26 – 3.31)	7
importance				

Sport competence importance

Levene's test of equality of error variances was non significant at times 1 ($F_{(1,18)}$ = 0.31, p= 0.58) and 2 ($F_{(1,18)}$ = 0.62, p= 0.44). The ANOVA calculation found that there was no significant interaction between time and group ($F_{(1,18)}$ = 1.23, p= 0.28. The difference between the scores for the experimental and control groups approached significance ($F_{(1,18)}$ = 4.10, p= 0.06). The mean values show that this was due to the experimental group initially rating sport competence importance lower than the control group (1.96 and 2.75 respectively). At time 2 the experimental group mean increased to 2.43 whereas the control group mean did not change. There was no significant difference between the scores at time 1 and time 2 ($F_{(1,18)}$= 1.23, p= 0.28).

Condition competence importance

Table 9.17: two way ANOVA calculation for PIP condition

Source	Type III sum of squares	df	Mean square	F	Significance
Time	1.653 E-02	1	1.653 E-02	0.061	0.808
Time * Group	1.174	1	1.174	4.314	0.053
Error (time)	4.628	17	0.272		
Intercept	252.438	1	252.438	527.969	0.000
Group	0.122	1	0.122	0.255	0.620
Error (group)	8.128	17	0.478		

Levene's test of equality of error variances found no significant difference between the groups at time 1 ($F_{(1,17)} = 1.14$, p= 0.30) or time 2 ($F_{(1,17)} = 0.42$, p= 0.53). The ANOVA calculation, table 9.17, showed that the interaction between time and group for condition competence importance approached significance (p= 0.05). This was due to an increase in condition competence importance by the experimental group (2.50 to 2.92) and a decrease by the control group (3.00 to 2.67), see figure 9.5. The change over time for the group as a whole and the difference in scores between groups was not significant.

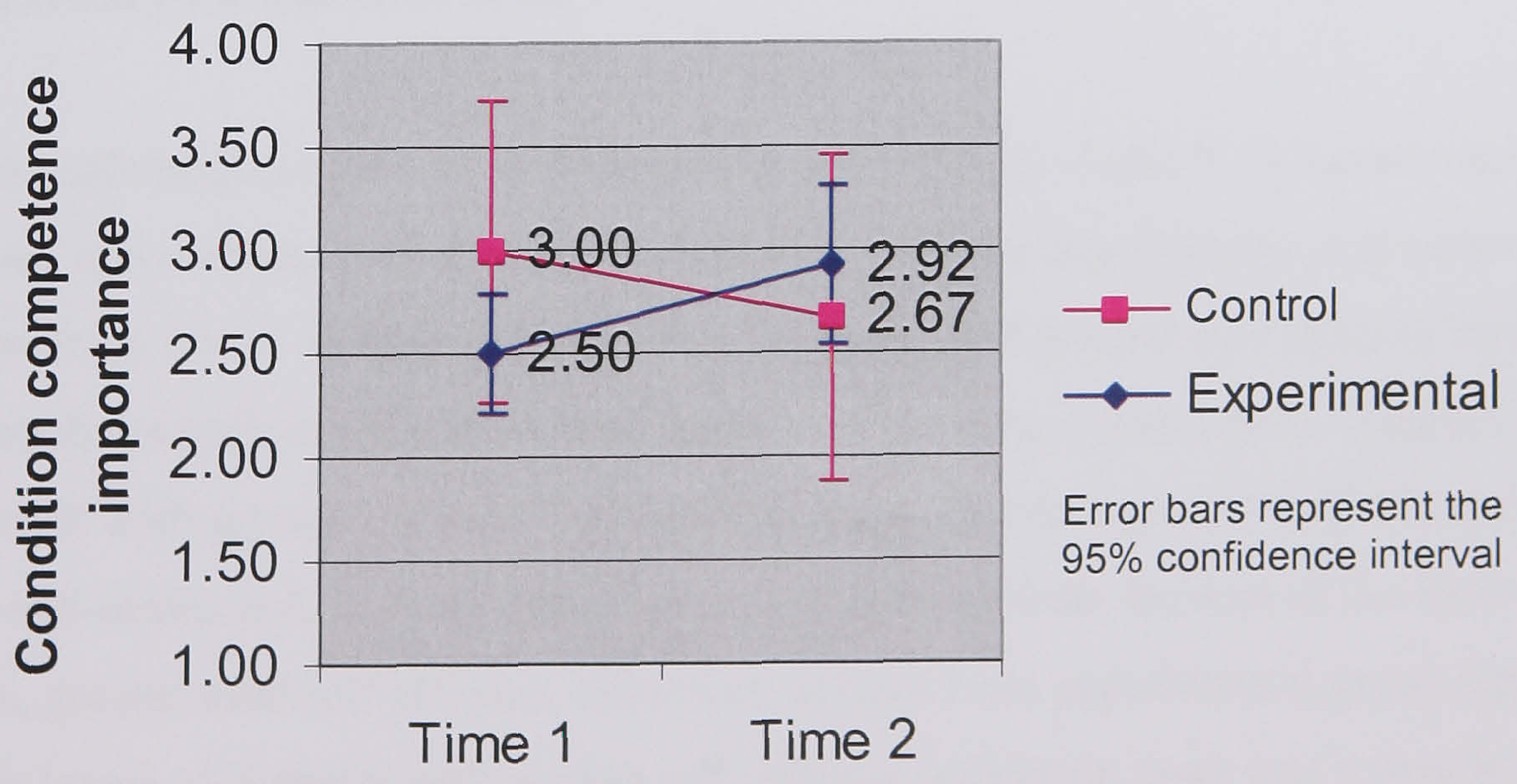

Figure 9.5: Interaction plot between time and group for the perceived importance profile of condition competence

Attractive body importance

Levene's test of equality of error variances found no significant difference between the groups at time 1 ($F_{(1,19)} = 1.37$, $p = 0.26$) or time 2 ($F_{(1,19)} = 0.51$, $p = 0.48$). The ANOVA calculation showed that there was no significant interaction between time and group in attractive body importance as a result of the intervention ($F_{(1,19)} = 0.12$, $p = 0.73$). There was also no significant change over time ($F_{(1,19)} = 0.12$, $p = 0.73$) or between the experimental and control groups ($F_{(1,19)} = 0.24$, $p = 0.63$).

Strength competence importance

Levene's test of equality of error variances showed there was a significant difference between the experimental and control groups at time 1 ($F_{(1,19)} = 9.52$, $p < 0.01$). Therefore the Wilcoxon Signed Ranks test was performed for this sub-scale. This found there was a significant difference between the PIP strength scores for the experimental group at times 1 and 2 ($z = -2.64$, n-ties = 13, $p < 0.01$). There was also a significant difference between the scores of the control group at times 1 and 2 ($z = -2.38$, n-ties = 7, $p = 0.02$). The mean values show that this was due to an increase in strength competence importance, in the experimental group from 1.96 to 2.54, and in the control group from 2.57 to 2.79.

Self Efficacy for Diabetes Scale

In this scale high scores represented greater self efficacy. Table 9.18 shows total self efficacy and diabetes self efficacy decreased in both the experimental and control groups from time 1 to time 2. Medical self efficacy and general self efficacy increased in both the experimental and control group between time 1 and time 2. Changes were similar in both groups. At time 1 the control group reported greater self efficacy on all three sub-scales and, as total self efficacy was derived from the sum of the three sub-scales, greater total self efficacy. However, at time 2 the experimental group reported higher levels of diabetes and general self efficacy indicating there was a time by group interaction for the experimental group. The significance of these differences between groups at times 1 and 2, and interactions were tested experimentally, and are reported in the following section.

Table 9.18: Descriptive statistics for the SED questionnaire at times 1 and 2

	Group	Mean time 1 (95% C.I.)	Mean time 2 (95% C.I.)	n
SED total	E	143.7 (125.6 – 161.8)	140.3 (118.8 – 161.8)	10
	C	150.0 (127.0 – 173.0)	142.2 (120.7 – 163.6)	6
SED diabetes	E	96.3 (82.0 – 110.6)	90.4 (74.63 – 106.2)	10
	C	101.7 (89.2 – 114.2)	89.7 (75.2 – 104.3)	7
SED medical	E	18.5 (16.1 – 20.9)	19.6 (16.8 – 22.5)	14
	C	19.9 (14.7 – 25.0)	20.3 (16.0 – 24.6)	7
SED general	E	26.0 (22.7 – 29.3)	28.5 (25.1 – 31.9)	14
	C	27.7 (21.9 – 33.5)	28.2 (23.6 – 32.7)	6

Total self efficacy for diabetes

Levene's test of equality of error variances was non significant at time 1 ($F_{(1,14)}$ = 0.64, p= 0.44) and time 2 ($F_{(1,14)}$ = 1.06, p= 0.32). The ANOVA calculation showed that there was no significant interaction between the experimental and the control groups from time 1 and 2 for self reported total self efficacy ($F_{(1,14)}$= 0.42, p= 0.53). There was also no significant change in total self efficacy over time ($F_{(1,14)}$= 2.67, p= 0.13) or difference between the experimental and control groups ($F_{(1,14)}$= 0.10, p= 0.75).

Diabetes Self Efficacy

Levene's test of equality of error variances was non significant at time 1 ($F_{(1,15)}$ = 3.82, p= 0.07) and time 2 ($F_{(1,15)}$ = 1.85, p= 0.19). The ANOVA calculation showed there was a significant change in diabetes self efficacy for the group as a whole between times 1 and 2, see table 9.19. The mean values showed that this was due to diabetes self efficacy decreasing in both the experimental and control groups. Participating in the intervention did not alter diabetes self efficacy significantly compared to in the control group and there was no significant difference in the diabetes self efficacy of the two groups. Figure 9.6 shows the change in diabetes self efficacy over time. It can be seen that diabetes self efficacy decreased in both groups between times 1 and 2 and that the decrease was greater in the control group.

Table 9.19: Two way ANOVA calculation for diabetes self efficacy

Source	Type III sum of squares	df	Mean square	F	Significance
Time	659.67	1	659.67	8.93	0.009
Time * Group	76.61	1	76.61	1.04	0.325
Error (time)	1108.45	15	73.90		
Intercept	294373.09	1	294373.09	67.31	0.000
Group	46.03	1	46.03	0.073	0.791
Error (group)	9448.907	15	629.93		

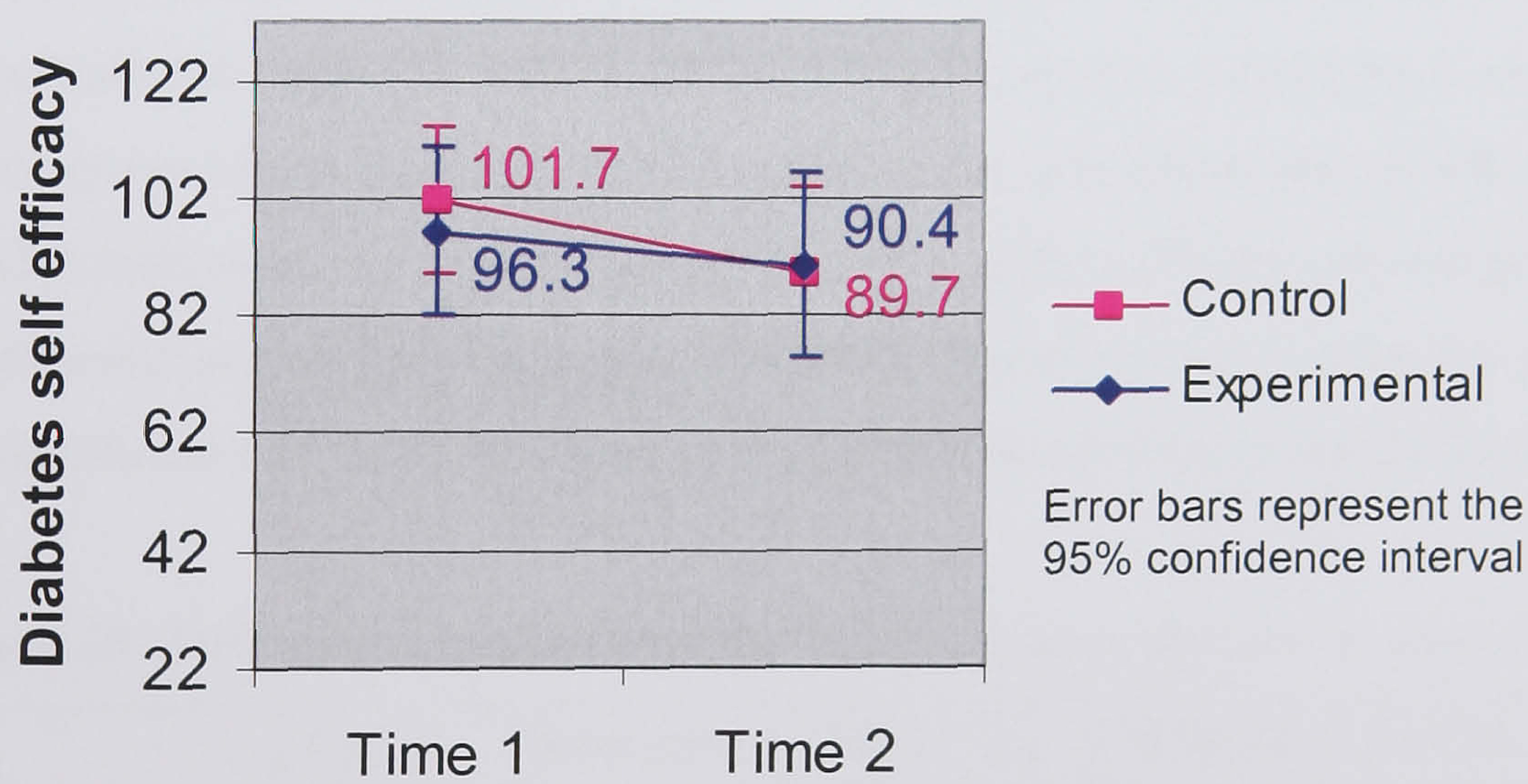

Figure 9.6: Interaction plot between time and group for diabetes self efficacy

Medical self efficacy

Levene's test of equality of error variances was non significant at time 1 ($F_{(1,19)} = 1.0$, $p= 0.33$) and time 2 ($F_{(1,19)} = 0.33$, $p= 0.57$). The ANOVA calculation found medical self efficacy did not change significantly in the experimental compared to the control group ($F_{(1,19)} = 1.19$, $p= 0.65$). There was also no significant change in medical self efficacy over time ($F_{(1,19)}= 1.04$, $p= 0.32$) or significant difference between groups ($F_{(1,19)}= 0.23$, $p= 0.64$).

General Self Efficacy

Levene's test of equality of error variances found no significant difference between the scores at time 1 ($F_{(1,18)} = 0.01$, $p = 0.95$) or time 2 ($F_{(1,18)} = 1.17$, $p = 0.29$). The ANOVA calculation showed that participating in the intervention did not change general self efficacy significantly between times 1 and 2 compared to the control group ($F_{(1,18)} = 0.74$, $p = 0.40$). There was also no significant change over time ($F_{(1,18)} = 1.66$, $p = 0.22$) or between groups ($F_{(1,18)} = 0.07$, $p = 0.79$)

Diabetes Quality of Life for Youths questionnaire

In contrast to the scores on the PSPP-C and the SED the experimental group rated their quality of life slightly better than the control group at time 1 on all four sub-scales. Both groups reported diabetes had more impact on their lives and that they worried more about their diabetes at time 2 than time 1. The experimental group rated their satisfaction with life decreased slightly between time 1 and time 2 whereas the control group reported slightly greater satisfaction with life at time 2. The single item overall health rating did not change from time 1 to time 2 in the control group; the experimental group rated their overall health as better at time 2 compared to time 1. The significance of these data was examined and is reported in the following section.

Table 9.20: Descriptive statistics for the DQOL-Y questionnaire at times 1 and 2

	Group	Mean time 1 (95% C.I.)	Mean time 2 (95% C.I.)	n
DQOLY	E	71.08 (65.78 – 76.38)	70.92 (64.95 – 76.89)	13
satisfaction	C	70.67 (62.77 – 78.57)	72.17 (61.60 – 82.73)	6
DQOLY	E	44.33 (39.52 – 49.14)	49.33 (44.20 – 54.46)	12
impact	C	47.14 (42.07 – 52.22)	52.00 (39.36 – 64.64)	7
DQOLY	E	18.14 (12.31 – 23.98)	19.29 (13.23 – 25.34)	14
worry	C	21.17 (7.69 – 34.65)	22.00 (8.37 – 35.63)	6
DQOLY	E	3.31 (3.02 – 3.60)	3.54 (3.22 – 3.85)	13
health	C	3.17 (2.38 – 3.96)	3.17 (2.74 – 3.60)	6

Satisfaction with life

Levene's test of equality of error variances showed no significant difference between the experimental and control groups at time 1 ($F_{(1,17)} = 0.18$, p= 0.67) or time 2 ($F_{(1,17)} = 0.03$, p= 0.87). The ANOVA calculation found there was no significant interaction between time and group for satisfaction with life, i.e. participating in the intervention did not effect satisfaction with life significantly compared to the control group ($F_{(1,17)} = 0.16$, p= 0.69). There was also no significant change in satisfaction with life over time ($F_{(1,17)}$= 0.11, p= 0.75) or significant difference between satisfaction with life in the two groups ($F_{(1,17)}$= 0.01, p= 0.92).

Diabetes Impact

Levene's test of equality of error variances found no significant differences between the experimental and control groups at time 1 ($F_{(1,17)} = 0.75$, p= 0.40) or time 2 ($F_{(1,17)} = 1.49$, p= 0.24). As with the satisfaction with life sub-scale, there was no significant interaction between time and group for diabetes impact ($F_{(1,17)} = 0.00$, p= 0.98). The difference in diabetes impact at times 1 and 2 for the group as a whole approached significance ($F_{(1,17)} = 3.59$, p= 0.08). The mean values showed that impact was greater, indicating lower quality of life, for both groups at time 2 compared to time 1. There was no significant difference between diabetes impact in the two groups ($F_{(1,17)} = 0.69$, p= 0.42.

Diabetes Related Worries

Levene's test of equality of error variances found no significant difference between the scores of the experimental and control groups at time 1 ($F_{(1, 18)} = 0.24$, p= 0.63) or time 2 ($F_{(1, 18)} = 0.20$, p= 0.66). The ANOVA calculation found that participating in the intervention group did not effect diabetes related worries significantly differently from being in the control group ($F_{(1,18)} = 0.01$, p= 0.92), see table 9.21. There was also no significant change in diabetes related worries over time for the groups as a whole ($F_{(1,18)} = 0.44$, p= 0.52) or between the experimental and control groups ($F_{(1,18)} = 0.30$, p= 0.59).

Table 9.21: Two way ANOVA calculation for diabetes related worries

Source	Type III sum of squares	df	Mean square	F	Significance
Time	8.201	1	8.201	0.439	0.516
Time * Group	0.201	1	0.201	0.011	0.918
Error (time)	336.274	18	18.682		
Intercept	13640.744	1	13640.744	60.045	0.000
Group	69.144	1	69.144	0.304	0.588
Error (group)	4089.131	18	227.174		

Overall Health Rating

This sub-scale was rated on an ordinal scale from 1 to 4, following the recommendation of Munro (1997) the data were analysed using the non-parametric Wilcoxon Signed Ranks test instead of ANOVA.

This test showed that there was no significant difference between the scores of the experimental group at times 1 and 2 ($z= -1.34$, n-ties = 5, $p= 0.18$) or the control group at times 1 and 2 ($z= 0.00$, n-ties = 2, $p= 1.00$). Participating in the intervention did not lead to a significant change in the children's overall rating of their health.

Summary of psychological data

The previous section examined the effect of a 12 week physical activity intervention programme on the self esteem, self efficacy and quality of life of children with Type 1 diabetes compared to a control group who did not participate in an intervention programme. It showed that the intervention had no significant effect on the children's quality of life either positively or negatively. There was also no significant effect on the children's self efficacy for diabetes as a result of the intervention. However, diabetes self efficacy decreased significantly in both groups between time 1 and time 2. The PSPP-C showed that the intervention had no significant effect on the children's global self worth or overall physical self worth compared to the control group. Sport competence and condition competence did show a greater increase in the experimental group compared to the control group. There was a greater increase in condition competence in the experimental group ($p= 0.07$) than the control group ($p= 0.58$).

Sport competence was analysed using ANCOVA to control for the significant difference between the two groups at time 1, this found the effect of the intervention on sport competence was not significant. There was a significant increase in strength competence for the group as a whole ($p<0.05$) however as the scores for both the experimental and control groups increased this could not be said to be due to the intervention. The increase in sport and condition competence was matched by an increase in the importance that the experimental group rated sport competence and condition competence as having. The sport competence importance rating increased from 1.96 to 2.43 in the experimental group and was constant at 2.75 in the control group. The interaction between time and group for condition competence importance neared significance ($p= 0.05$), it increased in the experimental group and decreased in the control group. Strength competence importance also increased but in both the experimental ($p<0.01$) and control ($p= 0.02$) groups.

HbA_{1c}

The descriptive statistics in table 9.22 show that the mean HbA_{1c} value was higher in the experimental group than the control group at time 1. At time 2 this difference had decreased due to a slight decrease in the mean HbA_{1c} of the experimental group and a slight rise in the mean HbA_{1c} of the control group.

Table 9.22: Descriptive statistics for HbA_{1c} at times 1 and 2

	Group	Mean (%) time 1 (95% C.I.)	Mean (%) time 2 (95% C.I.)	n
HbA_{1c}	E	9.48 (8.67 – 10.28)	9.24 (8.18 – 10.30)	13
	C	8.99 (8.07 – 9.91)	9.19 (8.16 – 10.23	12

A two way ANOVA calculation was carried out to assess whether the above changes in HbA_{1c} were significant. The results of this are shown in table 9.23, there were no significant changes in HbA_{1c}. This is an important variable clinically and therefore even though the change was not significant the interaction plot is presented, figure 9.7, to display the data in more detail.

Table 9.23: Two way ANOVA calculations for HbA_{1c}

Source	Type III sum of squares	df	Mean square	F	Significance
Time	4.615E-03	1	4.615E-03	0.005	0.944
Time * Group	0.600	1	0.600	0.661	0.424
Error (time)	20.855	23	0.907		
Intercept	4247.928	1	4247.928	1092.418	0.000
Group	0.883	1	0.883	0.227	0.638
Error (group)	89.437	23	3.889		

Levene's test of equality of error variances found no significant difference between the groups at time 1 ($F_{(1,23)} = 0.62$, p= 0.44) or time 2 ($F_{(1,23)} = 0.07$, p= 0.80).

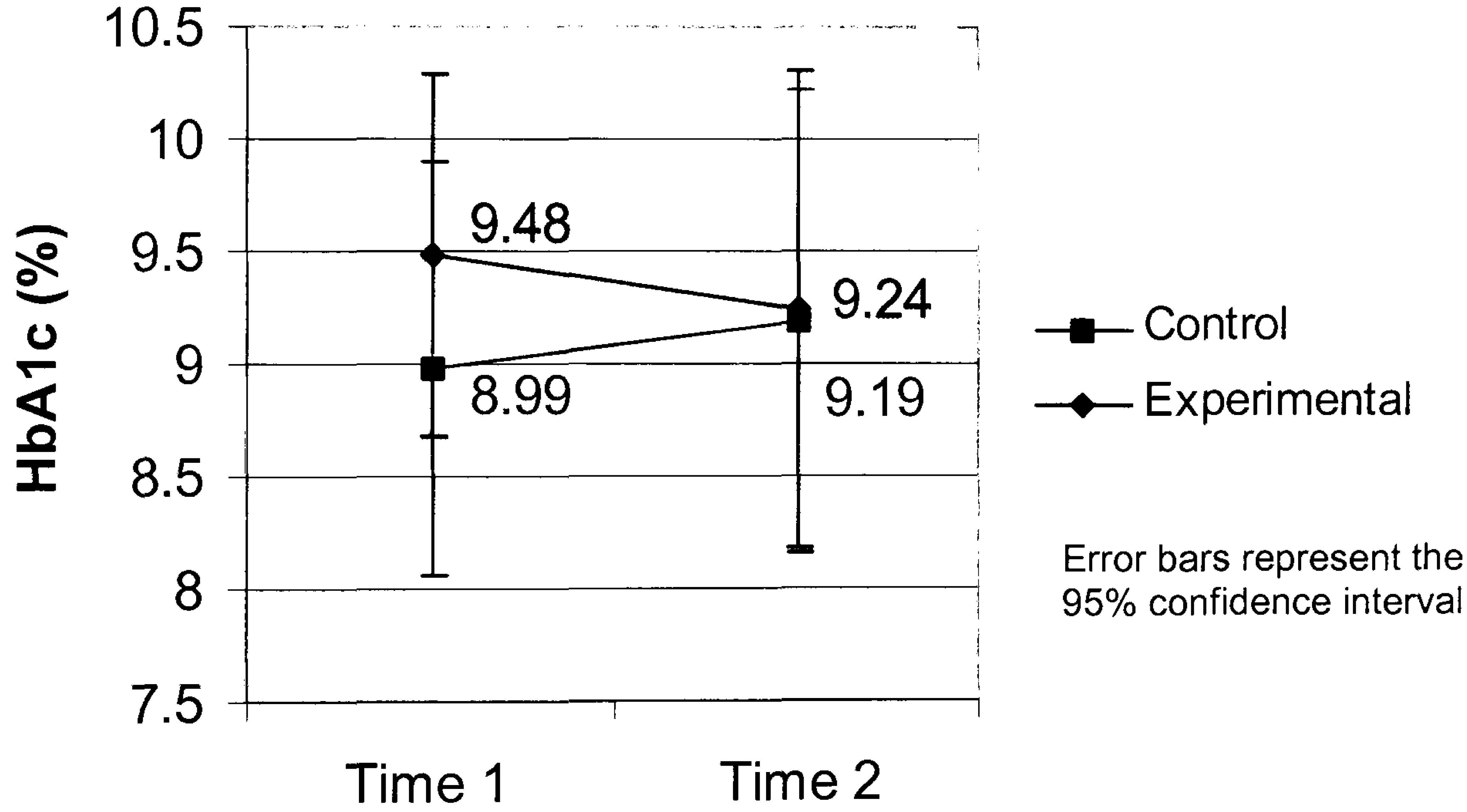

Figure 9.7: Interaction plot between time and group for HbA_{1c}

Body composition data

BMI

Table 9.24 shows that for the experimental group BMI was greater at time 2 than time 1. In the control group BMI was slightly lower at time 2 than time 1.

Table 9.24: Descriptive statistics for BMI at times 1 and 2

	Group	Mean ($kg^{-1}.m^2$) time 1 (95% C.I.)	Mean ($kg^{-1}.m^2$) time 2 (95% C.I.)	N
BMI	E	20.38 (18.86 – 21.90)	20.97 (19.29 – 22.65)	14
	C	20.11 (18.26 – 21.96)	20.07 (18.42 – 21.72)	7

A two way ANOVA calculation was carried out to investigate whether the above changes in BMI were significant (table 9.25). This showed that the interaction between time and group was significant, figure 9.8 shows that this was due to BMI increasing in the experimental group and remaining stable in the control group. The increase in BMI between times 1 and 2 was also significant when the group was analysed as a whole.

Table 9.25: Two way ANOVA calculation for BMI

Source	Type III sum of squares	df	Mean square	F	Significance
Time	0.729	1	0.729	3.801	0.066
Time * Group	0.915	1	0.915	4.773	0.042
Error (time)	3.644	19	0.192		
Intercept	15513.447	1	15513.447	1230.583	0.000
Group	3.228	1	3.228	0.256	0.619
Error (group)	239.525	19	12.607		

Levene's test of equality of error variances found no significant differences between the groups at time 1 ($F_{(1,19)} = 0.36$, p= 0.56) or time 2 ($F_{(1,19)} = 1.35$, p= 0.26).

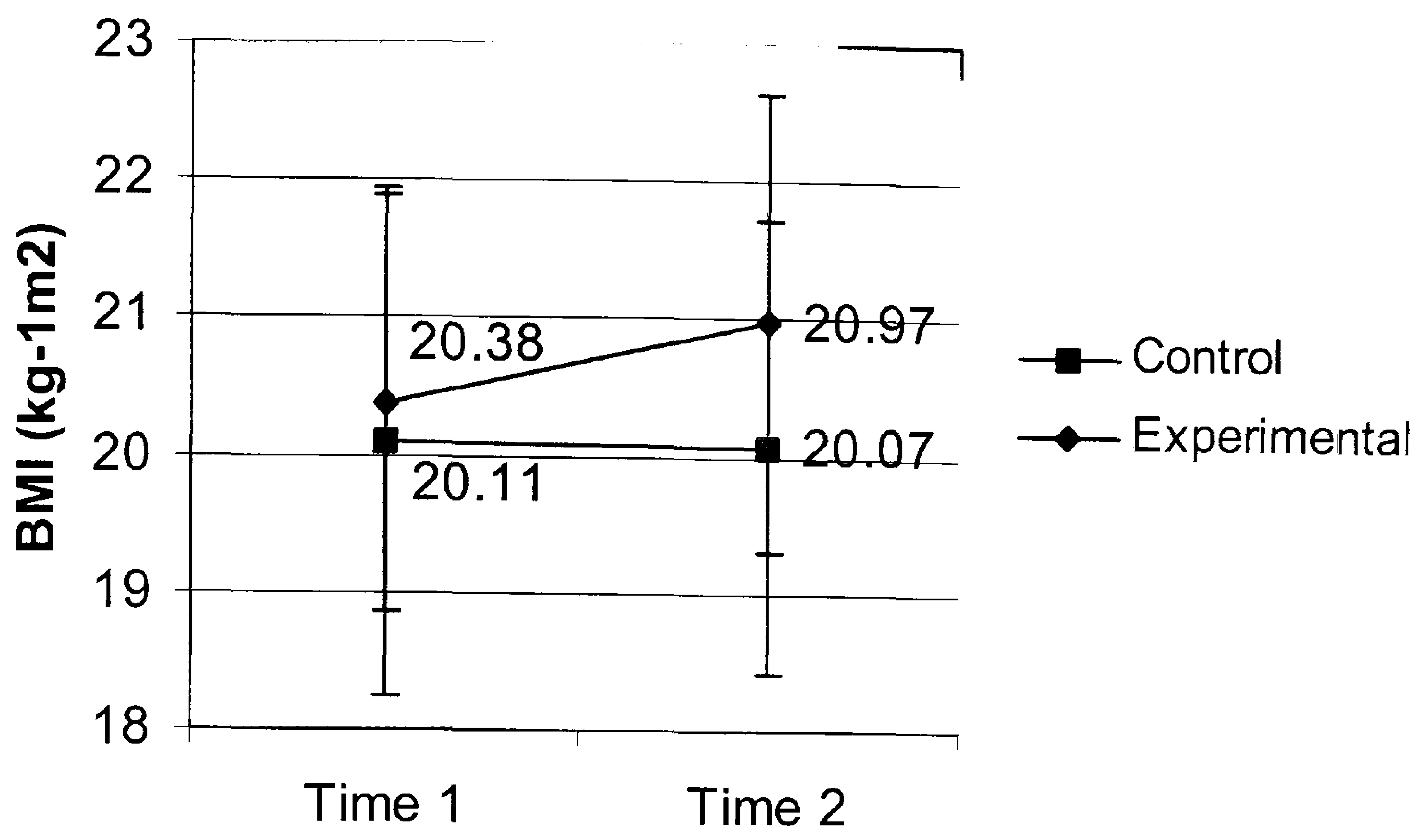

Figure 9.8: Interaction plot between time and group for BMI

Sum of 5 skinfold measurements

Table 9.26 shows that sum of 5 skinfold measurements decreased in both the experimental and control groups between time 1 and time 2 this decrease was greater in the control than the experimental group.

Table 9.26: Descriptive statistics for sum of 5 skinfold measurements at times 1 and 2

	Group	Mean (mm) time 1 (95% C.I.)	Mean (mm) time 2 (95% C.I.)	N
Sum of 5 skinfold measurements	E	63.32 (50.69 – 75.94)	59.39 (48.75 – 70.02)	13
	C	55.93 (30.03 – 81.83)	50.64 (33.02 – 68.26)	7

A two way ANOVA calculation found that the decrease in body fat between times 1 and 2 approached significance for the group as a whole (p= 0.05). There was no significant interaction between time and group and no significant difference between the values for the two groups, see table 9.27. Figure 9.9 shows the change in mean body fat between times 1 and 2.

Table 9.27: Two way ANOVA calculation for sum of 5 skinfold measurements

Source	Type III sum of squares	df	Mean square	F	Significance
Time	193.182	1	193.182	4.376	0.051
Time * Group	4.186	1	4.186	0.095	0.762
Error (time)	794.585	18	44.144		
Intercept	119587.863	1	119587.863	143.080	0.000
Group	591.911	1	591.911	0.708	0.411
Error (group)	15044.636	18	835.813		

Levene's test of equality of error variances found no significant difference between the groups at time 1 ($F_{(1,18)} = 1.11$, $p = 0.31$) or time 2 ($F_{(1,18)} = 0.30$, $p = 0.59$).

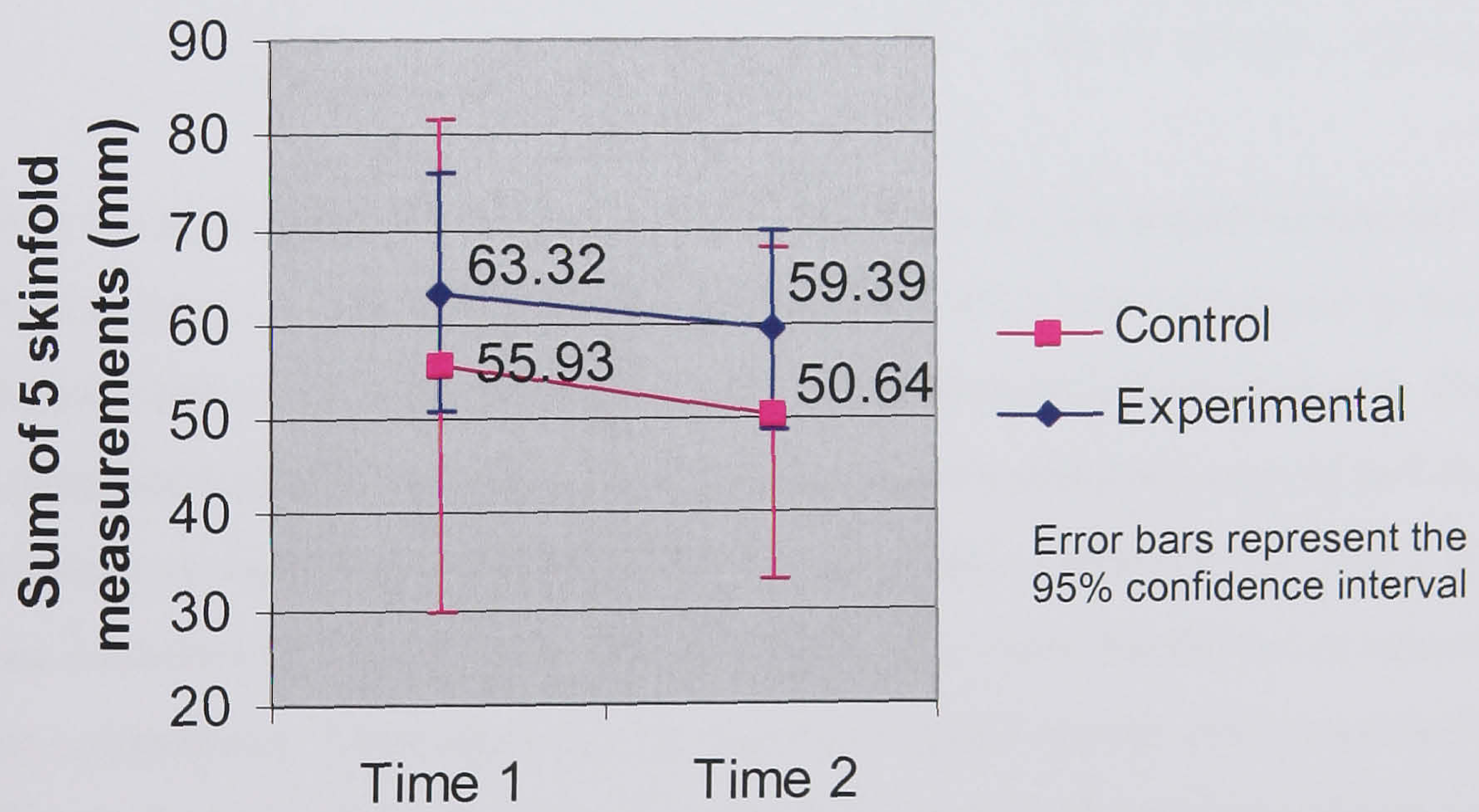

Figure 9.9: Interaction plot between time and group for sum of 5 skinfold measurements

Aerobic fitness (peak VO_2)

At time 2 incomplete data were collected for one participant from the experimental group, so that a peak VO_2 value could not be calculated.. Therefore data for this participant were excluded from this analysis.

Table 9.28 shows that at time 1 the control group had greater aerobic fitness than the experimental group. Between time 1 and time 2 mean aerobic fitness increased by 8.27 $ml^{-1}kg^{-1}min^{-1}$ in the experimental group whereas in the control group there was only a very slight increase of 0.34 $ml^{-1}kg^{-1}min^{-1}$.

Table 9.28: Descriptive statistics for peak VO_2 at times 1 and 2

	Group	Mean ($ml^{-1}kg^{-1}min^{-1}$) time 1 (95% C.I.)	Mean ($ml^{-1}kg^{-1}min^{-1}$) time 2 (95% C.I.)	n
Peak VO_2	E	31.07 (27.61 – 34.53)	39.34 (34.83 – 43.85)	13
	C	46.10 (39.49 – 52.72)	46.44 (39.23 – 53.65)	7

Due to the significant difference between the scores for the experimental and control groups at time 1, a one way between groups ANCOVA was carried out to test for a difference between the two groups at time 2, adjusted for scores at time 1. The independent variable was intervention group (experimental or control) and the dependent variable was peak VO_2 at time 2. Children's peak VO_2 at time 1 was used as the covariate in this analysis. Preliminary checks were conducted as reported for sport competence. After adjusting for pre-intervention scores, there was no significant difference between the two intervention groups on post intervention scores for the peak VO_2 test, $F(1,17) = 0.61$, $p= 0.44$, eta squared = 0.04.

Although the mean values showed that there was a larger increase in peak VO_2 for the experimental but not the control group (see figure 9.10) the ANCOVA found that individual differences between participants' values meant that this was not statistically significant.

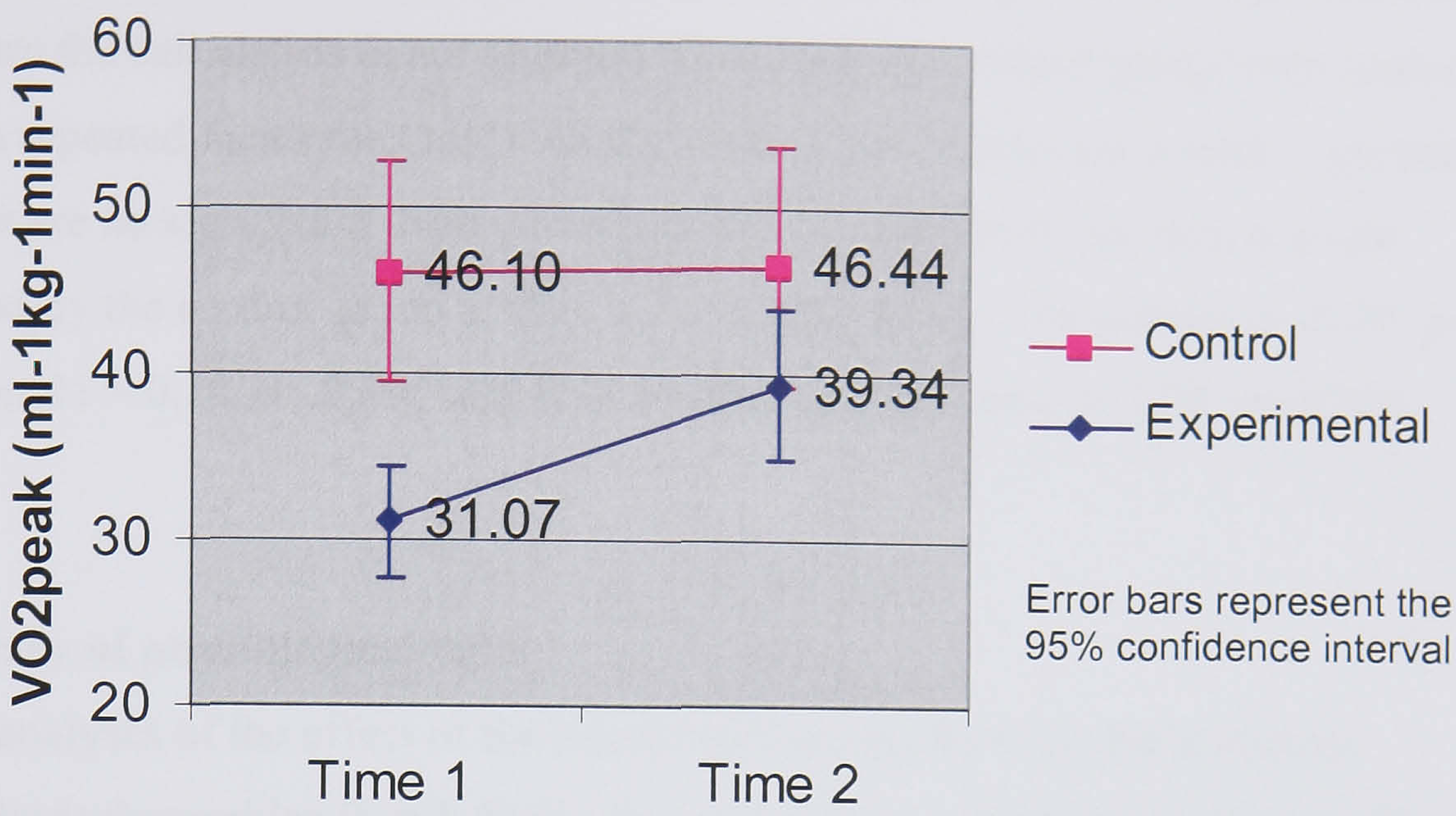

Figure 9.10: Interaction plot between time and group for peak VO_2

Physical activity

Table 9.29: Descriptive statistics for mean physical activity per day at times 1 and 2

	Group	Mean (mins per day) time 1 (95% C.I.)	Mean (mins per day) time 2 (95% C.I.)	n
Moderate physical activity	E	32.30 (14.90 – 49.69)	18.80 (10.57 – 27.02)	14
	C	21.12 (9.37 – 32.87)	22.65 (12.76 – 32.55)	7
Hard physical activity	E	17.60 (10.05 – 25.15)	32.30 (22.29 – 42.31)	14
	C	30.92 (3.89 – 57.94)	29.39 (14.40 – 44.38)	7
Very hard physical activity	E	8.42 (-1.16 – 17.99)	13.93 (4.89 – 22.97)	14
	C	17.45 (7.45 – 27.45)	6.74 (-2.45 – 15.92)	7
Total physical activity	E	58.32 (37.12 – 79.53)	65.02 (52.37 – 77.67)	14
	C	69.49 (37.58 – 101.40)	58.78 (44.13 – 73.43)	7

The main reason for collecting data on physical activity level was as an indicator of whether the activity level of the control group changed between times 1 and 2. Data were collected on both the control and experimental groups but some of the experimental group were still participating in the intervention activity sessions during the recall period and some were not. This would have been a confounding factor in comparisons of physical activity in the experimental group at time 1 and time 2 and therefore the calculation is not reported. Data from the control group were analysed using a repeated measures t test with the physical activity levels at time 1 and time 2. There were no significant differences between the amount of physical activity reported by the control group at time 1 compared to time 2 (moderate $t= -0.29$, $p= 0.78$; hard $t = 0.14$, $p= 0.89$; very hard $t= 2.00$, $p= 0.09$; total $t= 1.08$, $p= 0.32$).

Summary of physiological data

These analyses of the effect of the intervention programme on the measured physiological variables found, firstly that there was no significant change in the HbA_{1c} of the experimental group compared to the control group. There was a slight interaction in the direction hypothesised, mean HbA_{1c} decreased in the experimental group over time and increased in the control group. There was a significant effect on BMI, this increased significantly in the experimental group and remained stable in the control group. At the same time skinfold measurements decreased in both groups from time 1 to time 2 ($p= 0.051$). There was no significant difference between the peak VO_2 scores for the experimental and control groups at time 2 when differences at time 1 were controlled for. However, the mean peak VO_2 of the experimental group increased by 8.27 $ml^{-1}kg^{-1}min^{-1}$, the control group remained virtually unchanged with an increase of 0.34 $ml^{-1}kg^{-1}min^{-1}$. The non significant result was due to individual differences in change between time 1 and time 2, along with a small sample size. The physical activity of the control group was not significantly different at time 1 compared to time 2.

9.6: Exploratory interview data

The five interviews with children from the experimental group were analysed to identify the themes. The two main themes were: the children's perspective on the STEPS 2000 programme as consumers, and how participating in the STEPS 2000 programme had affected them. These were broken down further; the consumer perspective theme was divided into the children's enjoyment of the activities and the impact of being in a group with other children with diabetes. The second theme was broken down into the effect of participating in the STEPS 2000 programme on their fitness, psychological self and diabetes management. Each of these themes is reported in turn in the following section. The responses of the children are summarised first followed by illustrative quotations where appropriate.

Interviewees were selected purposively, see section 8.11, their characteristics were as follows:

C1: boy aged 9 years

C2: boy aged 14 years

C3: girl aged 12 years

C4: girl aged 13 years

C5: girl aged 13 years

Consumer perspective

Content of sessions

All five children said they liked some of the activities, their preferred activities varied. Child 1 liked playing games, the other boy, Child 2, said he preferred doing circuit training and rope climbing, he said he was too fast for the other children when playing games. In one of the centres cardiovascular equipment was available for the children to use. Sessions in this centre were divided between time on the machines and time in the games hall playing games and doing circuits. Child 2 did not attend this centre, the other 4 had and the comments on using the equipment were mixed. Two of the girls liked using it and would have preferred to spend longer on the machines. One suggested the group could be split into age groups and the older children could spend longer in the gym. The third girl found using the gym repetitive and would have preferred to play more games.

Exercising in a group with other children with diabetes

The children were asked how they felt about exercising in a group with other children with diabetes. Child 1 was very positive about being in a group with other children with diabetes felt he made friends with the other children with diabetes during the programme. Child 3, Child 4 and Child 5 felt it was less important that there were other children with diabetes at the exercise sessions and did not see this as a reason for participating in them. They still had positive comments about the fact that there were other children with diabetes there however, these varied and are given below. Child 2 felt that it did not make any difference being with other people with diabetes.

Quotations

Interviewer: '... in the STEPS session there were other, it was along with other children who had diabetes rather than when you do football probably you're the only one who has diabetes there, how did you feel about that? Was that a good thing or a bad thing or was it not important?

C1: I don't mind

Interviewer: Is it any better or worse than in other groups of say PE at school?

C1: Better, better

Interviewer: Why would you say that?

C1 'Cause non of them are diabetics except me so they don't really understand it when I tell them so I'd rather be with diabetic people'.

C3 ' It was a good thing (being with other children with diabetes) because if I forgot glucose tablets or something the instructors would have them.'

C4 'Yer I mean I would have been just as happy if there were no other diabetics in the room except me cause I'm not that kind of person. I don't consciously think all the time oh I'm different because I'm diabetic...'

C4 'because there was everybody else getting their monitors out to check their BM and so in a way it didn't make me feel as if I was the only one.'

C5 '... it was better with people who like had diabetes and that because then if you were to have a hypo or something you wouldn't feel as stupid or something...'

Interviewer: '...how did you feel about being with other children who had diabetes doing the exercise, did that make any difference?

C2: No, I felt fine being around other people

Interviewer: It wasn't a bad thing, was it a good thing at all? Like if you went to another football session, or something normally, how would it compare, or would it not make any difference?
C2: It wouldn't make any difference.'

Effect on interviewees of participating in STEPS 2000

Effect of STEPS 2000 participation on fitness
All five children mentioned that they felt their fitness increased during the STEPS 2000 programme and that they found the sessions tiring.

Interviewer: 'and how hard did you find the sessions, how tiring were they?
C1:'Some of them were really hard, some of them were hard and some of them were quite easy.'

C2: 'At first I was really tired but I started, like I started not going tired as fast.'

C2: 'I felt I could do more of the dips, the ones where you have to hold on the bar and go down. And I was the first to get to the top of the ropes.'

C3: 'I can run a bit faster now'

C3: 'I'm not at the back (in PE) anymore'

Interviewer: 'And did you notice you got any improvements in fitness out of it then?'
C4: I think so, I think so cause we have, at the end of term we have, it's called the bleep test ..... and I've improved on that...'

C4: '...I lost a little bit of weight but then I put it back on again...'

C4 'Umm, I don't know, I was probably, I was probably fitter at the end um I suppose yer probably I was stronger at the end.'

C5: 'When we did those circuit training they made me ache like mad but erm yer it got easier as you went along cause you were used to it....'

Interviewer: 'What way did you notice you were fitter?

C5: 'I don't know I just had more energy and I was like willing to do more things like in PE I was getting really into things and like now, before I, I don't know whether this is the fitness thing but before with PE I like hated it and now I quite enjoy PE now like hockey and that I get really into it and so I think I've benefited maybe cause like I'm getting better at PE and things.'

Effect of STEPS 2000 participation on psychological well being

Two of the children said they had noticed no differences in how they felt about themselves during the programme, the other three children said they had noticed positive changes.

Interviewer: 'Do you feel maybe any difference in how much energy you've got or

C2: Yer, I've got more energy

Interviewer: Do you have less because you're tired or do you have more because you've been doing exercise?

C2: I think more because I've been exercising.'

C5 : I don't know I just think because I'd started, I'd never really, because I'd not made an effort and that and then now doing all these fitness like things I'd learned that PE's not just about like, it's hard to explain. It's like before I'd just think oh PE's all about competition and like it'd be horrible and now I just think well it's better because you got to, I don't know it's just because like the fitness thing I'd have more energy and I'd be like raring to go and that and so like I'd enjoy PE more because it'd like make me feel good about myself cause I'd think well I've done loads, exercise and I'd worked really hard and burnt off a few calories as well so I don't know, it's really hard to explain.'

C5: '... it made you feel like you, like you know like if you go to the gym or you've gone for a swim cause you think I've burnt some calories off today and stuff like that well your cause I mean you'd just be sitting doing nothing in school so you might as well and like you did these sessions you just felt better because well I've done something today, I've not just sat around....'

Effect of STEPS 2000 participation on diabetes management

All 5 children found the exercise affected their blood glucose levels. Four out of the five mentioned they experienced at least one hypoglycaemic episode at night after an exercise session. Two of these felt they could prevent these by eating more after exercise or reducing insulin. Three said they sometimes reduced insulin dose on exercise days.

Three of the children said their blood glucose level usually went lower after exercise but sometimes it went higher. Two said they thought it was a bit easier to control their blood glucose levels while they were doing the programme, two felt it was not any different from before the programme.

Interviewer: 'Did you feel that overall your control was different?

C5: Yer, well no not , but um say I had my tea then I'd like eat my pudding or whatever and then sometimes I'd have like hypos in the night because you know when your blood sugar doesn't react immediately does it, it like takes a while to, so sometimes I'd have hypos during the night but not loads, yes so it did affect my control a bit but not like

Interviewer: Did you learn to stop them after a while or did they just sort of happen

C5: Yer, I just sort of took lower insulin or erm, ate a snack before I went so I knew I'd be alright during the fit ness and then like my mum would bring me snack or something to have if I felt a bit after the fitness then and then I'd have my tea and eat a good proper tea and then I wouldn't have them in the night then, so yer.'

Effect of having diabetes on the exercise you do

Three of the children said they were not worried or apprehensive about the effect of exercise on their blood glucose levels. None of the children said they did worry or that having diabetes would prevent them from doing any kind of exercise that they wanted to.

9.7: Summary of main findings in Phase Two

Of the 39 children who started the study, 14 in the experimental and 7 in the control group completed it. Those who completed it in the experimental group had significantly lower sports competence and aerobic fitness than those who did not. None of the other variables differed in either group. Experimental and control groups were assigned randomly to try to avoid bias, at time 1 there were no significant differences between groups for the majority of the variables. However, the control group had significantly greater sports competence, higher aerobic fitness and participated in more vigorous physical activity. During the exercise sessions children spent an average of 14 minutes in vigorous physical activity and 23 minutes in hard or vigorous physical activity per session. Sessions were initially 2, increasing to 3, times a week.

There was a non-significant interaction between groups over time for sport competence when group differences at time 1 were taken into account, it increased in the experimental group and decreased in the control group. Condition competence increased in the experimental group ($p= 0.07$) but not the control group. Strength competence increased significantly in both groups ($p<0.05$). Overall physical self esteem and global self esteem did not change. The importance attached to certain sub-scales of physical self esteem also increased. The importance attached to condition competence increased over time in the experimental compared to the control group ($p=0.05$), the importance attached to strength competence increased significantly in both groups over time. In contrast diabetes self efficacy decreased significantly in both groups over time, medical and general self efficacy did not change. There were no significant changes in diabetes quality of life. HbA_{1c} did not change significantly, it decreased slightly in the experimental group and increased slightly in the control group. There was a significant interaction in BMI, it increased significantly in the experimental group compared to the control group over time. Skinfold thickness decreased significantly over time in both groups. There was also a non-significant interaction for aerobic fitness when differences at time 1 were taken into account, it increased in the experimental group over time and remained stable in the control group. The physical activity of the control group was not significantly different at time 2 compared to time 1. Five exploratory interviews found children felt positive about exercising with other children with diabetes, particularly the youngest child, age 9 years. All felt their fitness had increased during the programme, supporting the physiological data. Nocturnal hypoglycaemia was identified as an issue during the study.

Therefore the data showed some trends in the direction predicted by the hypotheses of phase two, increasing physical activity led to non-significant increases aerobic fitness and some aspects of physical self esteem. However, diabetes self efficacy decreased in both groups and the intervention had no effect on diabetes quality of life. HbA_{1c} was not significantly reduced by participating in the intervention.

10

Discussion: Phase Two

The hypotheses for the second phase of the study were that increasing physical activity would lead to higher fitness, greater psychological health and lower HbA_{1c} in children with Type 1 diabetes. This chapter discusses whether these hypotheses were supported, firstly whether an increase in fitness occurred in the children who participated in the activity programme compared to those who did not and secondly whether there were changes in psychological health and HbA_{1c}. The chapter also examines whether the data from phase two support those from the first phase of the study, which examined associations between the same variables as were measured in phase two. The findings of the study are compared to those from previous exercise intervention studies and psychological interventions in the literature. The limitations of the study are discussed in the second section of the chapter. The last section deals with recommendations resulting from this research study firstly for further research in this area and secondly for practice.

10.1: Comparison of Phase One and Phase Two data

Phase one of the study found the quality of life and diabetes self efficacy of children with Type 1 diabetes were generally good. Comparison of the mean scores from phases one and two showed that the two groups rated their diabetes quality of life similarly. The participants in phase two tended to rate the sub-scales of the self efficacy for diabetes questionnaire lower than the phase one group, however these differences were small given the large variance in the scores. Phase one found that children with Type 1 diabetes had lowered physical self perception and attractive body competence compared to non diabetic children. In phase two physical self perceptions were closer to those for the reported for non diabetic children (Whitehead, 1995; Biddle et al., 1993). Attractive body competence was rated lowest out of all the sub-scales in both phases.

In phase one there was a high proportion of children who were overweight and overfat. In phase two mean BMI and sum of skin folds were both lower than in phase one, of those who completed the study one girl had a BMI greater than 25 $kg^{-1}m^2$, and one boy and 5 girls had skinfolds greater than the 75th percentile of Liverpool schoolchildren in general. The experimental group had higher BMI and higher body fat than the control group, i.e. values closer to those found in phase one. In addition to having greater BMI and body fat than their peers without diabetes, the children in phase one had lower peak VO_2. In phase two similarly low peak VO_2 values were found in the experimental group, the control group had a mean value very similar to those for healthy Liverpool schoolchildren (Atkins, 1998), 46.1 and 46.5 $ml^{-1}kg^{-1}min^{-1}$ respectively. In phase one children were found to accumulate similar levels of physical activity per day as their peers without diabetes (Atkins, 1998). Moderate physical activity levels approached 60 minutes per day, the recommended level set by the Health Education Authority (1998) but vigorous physical activity was low, average of 9 minutes per day. In phase two only self report physical activity data were available, overall levels of hard and very hard physical activity were similar to in phase one, the control group reported higher levels than the experimental group. Therefore even though they were selected randomly the control group in phase two of the study appear to have been a particularly fit and active group of children with Type 1 diabetes. It may have been advisable to use stratified random sampling, so that groups were better matched initially on key outcome measures, see section 10.7.

10.2: Effects of the intervention on fitness

Comparisons of peak VO_2 in the two groups after the intervention, controlling for differences between groups at time 1, showed that there was no significant difference in peak VO_2 at time 2. However, comparison of the mean values for each group showed that peak VO_2 increased in the experimental group from 31.1 (95% C.I. 27.6 – 34.5) $ml^{-1}kg^{-1}min^{-1}$ to 39.3 (34.8 – 43.9) $ml^{-1}kg^{-1}min^{-1}$, which was an increase of 8.3 $ml^{-1}kg^{-1}min^{-1}$ or 26.6%. Whereas in the control group it remained virtually unchanged (time 1: 46.1 (39.5 – 52.7) $ml^{-1}kg^{-1}min^{-1}$, time 2: 46.4 (39.2 – 53.7) $ml^{-1}kg^{-1}min^{-1}$), which is 0.3 $ml^{-1}kg^{-1}min^{-1}$, or 0.7%. This non significant result despite a large change in the mean values was the result of individual variation in values between times 1 and 2. One problem may have been that the reliability of the measurements was not high.

This may have been due to termination of the peak VO_2 test before children reached their actual peak VO_2 threshold. This is a problem generally in peak VO_2 studies with children, section 3.3.2 discussed end point criteria. In all tests in the present study the participant displayed visible signs of intense effort, such as unsteady gait, sweating, facial flushing, grimacing, at the end point of the test. These were described by Armstrong and Welsman (1994) as signs to use to confirm that maximal effort had been reached. However, examination of RER values showed that not all children had achieved values of ≥ 1.00, which is recommended by Armstrong and Welsman (2000a) as a valuable physiological indicator of near maximal effort in young people. Therefore within subject reliability may have been affected because children did not reach their peak VO_2 threshold. The sample size of the study was small, particularly in the control group, 7 participants, therefore the possibility of Type 2 error has to be considered in interpreting this result.

The literature on exercise training studies with children generally reports increases in peak VO_2, but this is not a consistent finding. Of the exercise intervention studies on children with Type 1 diabetes reviewed in chapter two all but one found a significant increase in VO_{2max}, the largest increase was shown by Larsson et al. (17.1%, 1964), the second largest was 11.1% (Marrero et al., 1988), the average increase was 10.4 $ml^{-1}kg^{-1}min^{-1}$. Intensity, frequency and duration of the exercise interventions varied between studies. Those that included exercise 3 times a week at a specified heart rate threshold resulted in increases in peak VO_2, however, the study by Larsson et al. (1964) consisted of gymnastics for one hour once a week, with no heart rate threshold specified. Mahon (2000) reviewed 28 exercise training studies that have been carried out on healthy children aged 8 to 13 years. Nine of these had no significant effect on peak VO_2, those studies that used more rigorous training programmes did consistently report increases in peak VO_2.

Although non significant when controlling for differences at time 1, the increase of 26.6% in peak VO_2 of the experimental group was a substantial gain in aerobic fitness and suggests that the intervention did have some effect on the aerobic fitness of the experimental group. Practice effects, children becoming accustomed to the apparatus on the second laboratory visit and therefore recording a higher value, are another source of error in peak VO_2 testing. However, these would have been evident in both groups equally so this is unlikely to be the cause of the increase in the experimental group. In addition the experimenters who carried out the tests were unaware of the group each child was in.

Recommended training thresholds to increase aerobic fitness in children were defined as 20 to 40 minutes at 80 to 90% of maximum heart rate (equivalent to 75% MHRR), three to five times a week (Welsman and Armstrong, 1998). Heart rate data recorded at a random selection of exercise sessions during the present study showed children spent an average of 14 minutes per session with heart rate greater than 75% MHRR, 9 minutes per session with heart rate between 60% and 75% MHRR and 7 minutes per session with heart rate between 50 and 60% MHRR. Overall this was an average of 30 minutes of activity of moderate or greater intensity per session. Sessions were 2 times a week for the first 8 weeks and increased to 3 times per week for the last 4 weeks of the programme. Fourteen minutes above 75% MHRR is below the threshold recommended to increase peak VO_2 but it is also recommended that intensity should be increased gradually. Physical activity data reported at time 1, prior to the start of the intervention, showed children in the experimental group participated in an average of 4 minutes per day of very hard physical activity (equivalent to running) and 16 minutes per day of hard physical activity (more intense than walking but less intense than running). These initially low levels of aerobic fitness and vigorous physical activity in the study population would suggest the intervention would increase their aerobic fitness.

Examination of the children who completed the study and those who dropped out from the experimental group showed that one of the two variables that they differed on significantly was aerobic fitness. Those who completed the study had significantly lower aerobic fitness than those who did not (30.2 and 38.7 $ml^{-1}kg^{-1}min^{-1}$ respectively). Therefore the intervention appears to have appealed to those children who were initially less fit. As this was the group most at risk for cardiovascular disease it was encouraging from a health perspective. However, there were other factors that affected participation, for example parental support particularly in relation to transport to the sessions and time due to participation in other activities.

Body composition was assessed using both BMI and sum of 5 skin fold measurements. The results showed that there was a significant interaction between time and group for BMI. The interaction plot (figure 9.7) showed this was due to an increase of $0.59kg^{-1}m^2$, from 20.38 to $20.97kg^{-1}m^2$, in the experimental group and very little change in the control group, a decrease of 0.04 $kg^{-1}m^2$ from 20.11 to $20.07kg^{-1}m^2$. BMI does not differentiate between fat mass e.g. adipose tissue, and fat free mass e.g. muscle. Muscle is denser than fat and it may be that the increase in BMI in experimental group was due to an increase in muscle in this group.

A previous study with children with Type 1 diabetes found an increase in muscle mass following an exercise intervention. Landt et al. (1985) used hydrostatic weighing with a group of 15 males and females aged 15 to 16 years, before and after an exercise intervention programme, and found lean body mass increased by 1.94 ± 0.9 kg in the experimental group and by 0.04 ± 0.7 kg in the control group. This finding gives support to the suggestion that the increase in BMI in the present study was due to an increase in lean body mass rather than an increase in fat mass.

A significant interaction of body fat over time, with a decrease in the experimental group compared to the control group, would add further support to this hypothesis. Sum of 5 skin fold measurements showed body fat did decrease in the experimental group between times 1 and 2, the mean decrease was 4mm (from 63mm to 59mm). However, body fat also decreased in the control group over the same time period, the decrease was 5mm (from 56mm to 51mm). The decrease over time approached significance ($p=0.05$) but there was no significant interaction between the groups, therefore it could not be concluded that participating in the intervention caused this change. This finding was different to the one controlled exercise intervention study that reported sum of skin fold measurements, this included 16 children, aged 15 years, with Type 1 diabetes (Stratton et al., 1987). He found a non significant interaction between the experimental and control group for sum of 6 skin fold measurements, following an 8-week intervention. However, the age group differed from that in the present study and this may have been the reason for the different finding.

One possible explanation for the decrease in skin folds in both groups in the present study was maturation. The age group of the present study was 9 to 15 years so some of the children could have been going through a growth spurt during the intervention phase and this could have resulted in reduction in mean body fat. Examination of height and body mass data showed mean height of both groups increased by 2cm between time 1 and time 2. Mean body mass of the experimental group increased by 2.5kg whereas the mean body mass of the control group increased by 1.4kg. The height of both groups increased by a similar amount and the skin fold thickness of both groups decreased by a similar amount, but the body mass of the experimental group increased by 2.5kg compared to 1.4kg in the control group. This therefore supports the hypothesis that the increase in BMI seen in the experimental group was due to an increase in muscle mass rather than an increase in fat mass.

Data from phase one found girls had greater BMI and skin fold thickness than boys. The gender distribution between the groups in the present study was such that there were more girls than boys in the experimental group and more boys than girls in the control group. Analysis by gender showed that in phase 2, again, girls had higher BMI and body fat than boys. However there was no clear pattern of change linked to gender. This may have been due to the small numbers in each cell when participants were divided by group and gender.

10.3: Effects of the intervention on psychological well being

This phase of the study investigated the effect of increasing physical activity on self esteem, self efficacy and quality of life of children with Type 1 diabetes. In phase one associations between these psychological variables, fitness and physical activity were examined using cross sectional data. These found higher global self esteem was significantly associated with higher aerobic fitness, higher physical self esteem was significantly associated with lower skin folds, lower BMI and higher aerobic fitness. Greater attractive body competence and condition competence, sub-scales of physical self esteem, were also significantly associated with lower skin folds and lower BMI. The body sub-scale was also significantly associated with vigorous physical activity. Self efficacy for diabetes was not significantly associated with fitness variables or physical activity. There were some significant associations of quality of life with fitness and physical activity data. Children who reported greater satisfaction with life had higher aerobic fitness. Those with more disease related worries had greater BMI values and lower vigorous physical activity, also the children's overall health rating was positively associated with vigorous physical activity. The intervention study was designed to be of sufficient intensity to increase physical fitness and the previous section showed that this was achieved for aerobic fitness. Therefore the result of phase one predicted that self esteem would be positively affected by participation in the intervention programme. It was expected that quality of life may show some positive associations with higher fitness and physical activity but self efficacy was not expected to be affected. The effect of the intervention on self esteem is discussed first, followed by self efficacy and quality of life.

Self esteem

Comparisons of the scores of the experimental and control groups before and after the intervention found that participating in the intervention had no significant effect on the children's global or overall physical self worth. Given that phase one found a significant association between greater aerobic fitness and greater global and physical self worth, and that aerobic fitness increased significantly in the experimental group in phase two, one might have expected that there would have been a significant effect. However, examination of the sub-scales of physical self worth showed that the intervention did have some non-significant effects in the hypothesised direction. It may be that the 12 week intervention was too short a period of time to show significant effects on self esteem.

The sport and condition competence sub-domains of physical self worth showed differential changes in the experimental and control groups. Both sub-scales increased in the experimental group, indicating greater competence after the intervention, and decreased slightly in the control group. For condition competence the increase between the mean score at time 1 and time 2 approached significance ($p=0.07$) in the experimental group whereas the decrease in the control group was not significant ($p=0.58$). This increase in condition competence brought the level in the experimental group towards that of the control group. Sport competence increased from 2.49 to 2.88 in the experimental group whereas it decreased slightly from 3.22 to 3.17 in the control group. As the two groups differed significantly at time 1 an ANCOVA analysis was carried out which found there was no significant difference between the scores at time 2 when scores at time 1 were taken into account. As with aerobic fitness, this non-significant result could be due to within subject variability. The sample size meant that there was the possibility of Type 2 error occurring. Given these non-significant trends in the hypothesised direction it would be interesting to investigate whether continued participation in vigorous physical activity resulted in further gains in sport and condition competence beyond the level of the control group. These increases in sport and condition competence in the group who participated in the intervention were very encouraging, particularly as this group had low competence in these areas before the intervention.

Perceived attractive body competence showed no significant change as a result of the intervention, the scores increased slightly in both groups. Phase one found that greater attractive body competence was significantly associated with lower body fat, lower BMI and greater vigorous physical activity. The analysis of fitness data in phase two showed that skin fold thickness was not decreased in the experimental group beyond that which occurred due to maturation in both groups. The experimental group did show an increase in BMI, compared to no change in the control group, which it was suggested above was due to increased muscle mass. The present data suggested this was not perceived as increasing attractive body competence. Whitehead (1995) showed that, out of the four sub-domains of physical self worth, attractive body competence had the strongest association with physical self worth. Therefore the fact that attractive body competence did not change following the intervention may have been the reason that a change in overall physical self worth did not occur.

Strength competence increased significantly between time 1 and time 2, however, this was in both the intervention and control group, so could not be attributed to participation in the intervention. The most likely explanation for this change was maturation, increases in strength occur during puberty. Examination of the height data showed that mean increase in height over the intervention period was 2 cm in both groups, this supports the hypothesis that a number of the participants were going through puberty during the study. However, no objective measure of strength was taken so it not possible to say whether there were real as well as subjective gains in strength over this time.

Analysis of the experimental and control groups by gender resulted in small numbers in each cell, so data must be treated cautiously. However in the experimental group girls showed greater increases in all four physical self worth sub-scales than boys, in fact boys scores at time 2 were slightly lower at time 2 than time 1 for condition, body and strength competence. In the control group this trend was not evident.

Calfas and Taylor (1994) reviewed the literature in relation to the psychological effects of physical activity for adolescents and found a general positive relationship, particularly for self esteem, self concept and self efficacy. However, few studies have investigated the effect of participating in an exercise programme on the physical self perceptions of children. One recent study that did this looked at the effect of daughters and mother's exercising together over a 12-week period (Ransdell et al., 2001). Fourteen girls aged 11 to 17 years and their mothers participated in one activity and one theoretical session per week, there were no controls. Aerobic capacity did not increase significantly for daughters. The PSPP was used rather than the version adapted for children, but both have similar sub-scales. Changes reported were similar, but stronger than those in the present study, the daughters' sports competence, strength competence and physical condition increased significantly, significant changes did not occur in attractive body competence or overall physical self worth. Asci et al. (1998) conducted a randomised controlled trial to investigate the effect of participation in an exercise programme 3 times a week for 8 weeks on physical self perceptions in 45 girls aged 19 to 28. Again, the PSPP rather than the version adapted for children was used. There were no significant increases in physical self perceptions but greater increases in physical self perceptions occurred in females in the experimental group than the control group. This group was older than in the present study and this may be the reason for the different result. Although the data is limited, these results suggests that the physical self perceptions of children with Type 1 diabetes are affected similarly to those of children without diabetes by an exercise intervention and that the effects are particularly important for females. However, both the present study and Ransdell's study had small sample sizes so caution should be taken generalising to the population from these.

Previous studies have found a significant association between physical self worth and its sub-scales and physical activity (Raudsepp et al., 2002; Crocker et al., 2000). This association was only found for body attractiveness in phase one of the present study, but it is likely this was due to Type 2 error, given the smaller sample size. The causality of this association was not known from these cross-sectional studies. However, the increase in two sub-scales of physical self worth following the present intervention was encouraging as this may lead to continued participation in higher levels of physical activity. This hypothesis was supported by the exploratory interviews that were conducted, one child said she used to hate PE and following the intervention quite enjoyed it. Another child said he had more energy following the exercise programme.

A recent study by Kowalski et al. (2001) examined whether physical self perceptions or social physique anxiety were predictors of physical activity and showed perceived condition competence to be a significant predictor of physical activity levels in young women. The increase in perceived condition competence resulting from the present intervention suggests that perceived condition competence was increased by increasing physical activity; it would be interesting to examine whether the increase in condition competence would be sufficient to motivate continued participation in physical activity. Kowalski et al. (2001) found attractive body competence did not predict physical activity levels. This was also supported by the present study, which did not find an increase in perceived attractive body competence following participation in the intervention. As Kowalski commented this goes against what one might expect given that research has shown young women are particularly motivated to participate in physical activity for body related reasons. One finding of the present study that differed from Kowalski's study was that perceived sport competence increased. It may be that although participating in sport increases competence it does not predict physical activity, or alternatively sport competence may be more important for younger children. Kowalski's study was on young women aged 18 to 24 years and children tend to participate in more sport related activities than this age group.

The importance attached to sport, condition, attractive body and strength competence was greater in the experimental group following the intervention compared to before. Comparisons with the control group showed the importance of sport competence increased, from 1.96 to 2.43, in the experimental group and remained constant in the control group, but that this interaction was not significant. The importance of condition competence was rated higher following the intervention in the experimental group and lower in the control group, this interaction approached significance ($p=0.05$). There was little change in attractive body importance in either group. The importance attached to strength competence increased significantly in both groups. The validity of this perceived importance profile has not been found to be satisfactory with children (Whitehead, 1995; Hagger and Ashford, 1997). Therefore the data were not used to calculate discrepancy scores between competence and importance. However, work with older samples has shown perceptions of importance independently predict activity involvement (Fox and Corbin, 1989). From this perspective the present results were very encouraging as increased importance attached to aspects of physical self esteem may help continued participation in physical activity in the long term.

Self efficacy and quality of life

Phase one found and some significant associations between quality of life and both physical activity and fitness variables, see above for details. There were no significant associations between self efficacy and physical activity or fitness variables. Over the period of the intervention, self efficacy did not change significantly in the experimental group compared to the control group on the diabetes, medical, general or total self efficacy sub-scales. An unexpected finding was that diabetes self efficacy decreased significantly between times 1 and 2 in both the experimental and control groups. Medical and general self efficacy did not follow this trend and were greater in both groups at time 2 than time 1. This increase was greater in the experimental than the control group but none of the differences were significant.

It was unclear why diabetes self efficacy decreased in the control group. The number of participants was small therefore it may be an instance of Type 1 error. Other possible explanations were that it was due to participation in the study, knowledge that they were participating in a research study on diabetes may have put greater emphasis on diabetes control, or to maturation. An increase in mean height between times 1 and 2 suggested some of these children were going through puberty during the intervention. During puberty hormone levels increase which makes diabetes control more difficult to maintain and may have led to a reduced diabetes self efficacy. In a future study with a greater sample size a Bonferroni correction factor could be used to reduce the possibility of type 1 error and this variable should be re-examined. In addition further qualitative interviews could be used in future studies, with members of both the experimental and control group, to explore this unexpected finding in more detail.

The fact that diabetes self efficacy decreased by a similar amount in both groups suggests that it may be some factor external to the intervention that caused this. However, the possibility that the intervention caused the decrease in the experimental group should also be explored. In the exploratory interviews conducted following the intervention four out of five children mentioned that they had episodes of hypoglycaemia at night as a result of the exercise sessions. The severity of these episodes was not defined, in other studies they have been defined as the person losing consciousness (Hoey et al., 2002) or needing assistance with treatment from another person to recover (Grey et al., 1999). It is likely that the episodes in the present study were not so severe, as loss of consciousness was not mentioned. However, it is something which may have impacted on their self efficacy for diabetes and their confidence to maintain desired blood glucose levels. Although, when the interviewees were asked whether they found their blood sugars any easier or more difficult to control during the intervention, two out of the five children felt it was a bit easier, two felt it was no different to before the intervention and one did not comment.

Similarly to self efficacy quality of life did not change significantly for the group who participated in the intervention compared to the group who did not. There were some non-significant changes between time 1 and time 2. However, these were not in the direction that would be predicted from the associations found in phase one. Satisfaction with life decreased in the experimental group and increased in the control group. Diabetes impact increased in both groups, as did worries about diabetes. The overall health was rated higher at time 2 than time 1 in the experimental group and exactly the same at both times by the control group. Of these changes the increase in diabetes impact was the largest change and approached significance (p=0.08). Phase one found no significant association between diabetes impact and physical activity or fitness variables, as the decrease occurred in both the experimental and the control groups it suggested it was due to some factor external to the intervention. This may be same issue that caused a significant decrease in diabetes self efficacy.

It is possible that changes in perceived quality of life occur more gradually than changes in fitness and physical self perceptions. However an intervention study carried out by Grey et al. (2000, 1999, 1998b), which examined the effect of intensive diabetes management with or without coping skills training on quality of life found significant changes after three months. The impact of diabetes was significantly reduced by Grey's intervention after 3 months and the reduction was maintained through the following 9 months. Significant changes in worry or satisfaction did not occur during the whole 9 months. This suggests changes in quality of life in the present study would be observable after three months. However, the present intervention was an exercise intervention and it is possible that changes may occur more slowly for this than more educationally based interventions. A longer study with a follow up data collection could examine this. There is also the implication from these studies that a many pronged intervention that included an educational aspect alongside increased physical activity may have more positive effects for self efficacy and quality of life.

It is encouraging, however, that participating in the intervention did not have a more negative effect on quality of life or self efficacy than being in the control group. Although the hypothesis of the study was that they would increase, it is also possible that the time involved in participating in the intervention may have made children feel diabetes was having a greater impact on their lives or that they were less satisfied with their lives. Similarly changes to diabetes management that were necessary to accommodate the increased exercise they were doing may have decreased their self efficacy to manage their diabetes. Diabetes self efficacy decreased and impact of diabetes on quality of life increased in the experimental group. Future exercise intervention studies should investigate this further as an intervention which increases fitness, with the associated health benefits, but at the detriment of some aspects of psychological well being is not working within the wellness model of health that was discussed in chapter 2. This intervention did not include an educational element beyond the diabetes team's standard care. Given these findings it is suggested that future exercise interventions could focus on diabetes management techniques or goal setting alongside the exercise sessions. It appears that the sessions by themselves did not improve self efficacy or quality of life and may have decreased them, therefore the intervention should also be targeted towards these areas. Previous studies have shown that self efficacy for diabetes can be increased through interventions. Grey et al. (1998b) found diabetes and medical self efficacy increased significantly after three months of coping skills training combined with intensive insulin treatment. Also Howells et al. (2002) showed overall self efficacy for diabetes increased significantly after a 12 month telephone support trial.

10.4: Effects of the intervention on HbA_{1c}

One of the hypotheses of the study was that participation in increased physical activity would lower HbA_{1c}. Data from phase one found no significant association between HbA_{1c} and physical activity or fitness, although there was a non-significant trend for those children who participated in more vigorous physical activity to have lower HbA_{1c} values. In phase two the mean HbA_{1c} of the experimental group at time 1 was greater than that of the control group (9.48% compared to 8.99% respectively). At time 2 the mean HbA_{1c} of the experimental group had decreased by 0.24% to 9.24% and that of the control group had increased by 0.2% to 9.19%. These changes were in the hypothesised direction but were not statistically significant (time by group interaction: $p= 0.42$). The results were also not clinically significant, a 1% reduction in HbA_{1c} would be necessary. The increase in HbA_{1c} in the control group is typical of the seasonal variation in children's HbA_{1c}. Nordfeldt and Ludvigsson (2000) found HbA_{1c} was lowest between May and September and highest between October and December. In the present study time 1 data were collected in July and August and time 2 data were collected in December. It could be speculated that the intervention reversed this increase and actually improved HbA_{1c} by 0.44% from what it would have been in this group had the intervention not occurred. However, this would still not be a clinically significant decrease.

This finding did not support the hypothesis that HbA_{1c} would decrease in the experimental group. However, several previous intervention studies for children with Type 1 diabetes that have used HbA_{1c} as an outcome measure have found changes to

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be small. Hampson et al. (2001) in her review of educational and psychosocial interventions for children with Type 1 diabetes and found the median effect size was equivalent to a decrease of 0.31% in HbA_{1c}. Exercise intervention studies have had mixed results, of 8 exercise intervention trials that assessed HbA_{1c}, see section 2.5, four found a significant decrease, actual HbA_{1c} values decreased by between 0.95% and 1.3% in these studies, three found no significant change and one found a significant increase. These exercise studies differed in their samples and methodologies but there was no clear pattern to differentiate those that led to a decrease in HbA_{1c} and those that did not.

HbA_{1c} is an outcome measure that is affected by and affects a range of factors e.g. physical health (including physical activity levels, infections), psychological health (including self efficacy, self esteem), social health (including peer support and pressure, family support) etc., see chapter 2. Therefore it is very difficult in any one intervention to control all the confounding factors to examine the effect of altering one particular variable. Therefore changes in HbA_{1c} as a result of an exercise intervention might be confounded by other factors. In the present study the main confounding factor would be expected to be diet, as children tended to increase their food intake to avoid having hypoglycaemia before or after exercise. There may also have been social or psychological pressures related to participating in the actual sessions or outwith the sessions (e.g. family or peer interactions).

Two studies that were successful in reducing HbA_{1c} significantly used intensive diabetes treatment. The DCCT was successful in reducing HbA_{1c} in adolescents in a large randomised controlled trial. This used intensive diabetes treatment, with increased attention from the diabetes team. However analysis of the psychological outcomes for this group of adolescents showed that initiation of intensive therapy in early adolescence was associated with increased school dissatisfaction (Madsen et al., 2002). From a wellness perspective this effect of the intervention should be addressed. Grey et al. (2000, 1999, 1998b) have shown that intensive therapy alongside coping skills training results in significant increases in psychological health compared to a control group participating in intensive therapy alone.

10.5: Summary of the effects of the intervention

The intervention caused a significant increase in the BMI of the experimental group compared to the control group. Although muscle mass was not measured directly, it is suggested this was due to an increase in muscle mass of the experimental group. Aerobic fitness increased in the experimental but not the control group. However ANCOVA found no significant difference at time 2 controlling for scores at time 1. This may be because the test re-test reliability of the measure was poor and therefore the data have to be interpreted cautiously. The increase in fitness of the experimental group does, however, concur with findings of the majority of exercise intervention studies both with children with Type 1 diabetes and healthy children. The increases in fitness were encouraging from a health perspective, particularly given the low initial levels of fitness in the experimental group. Physical self perceptions of sport competence and condition competence increased in the experimental compared to the control group, although non-significantly. Analysis by gender suggested the intervention may have increased girls' physical self perceptions more than boys. These effects were encouraging as higher physical self perceptions are associated with greater physical activity, and may therefore lead to long term increases in physical activity. Changes found to occur in both groups, increased strength competence, increased diabetes impact, and decreased skin fold thickness, were most likely due to maturation. Increase in mean height during the study period suggests some of the children were going through puberty during the study. However, there were difficulties in interpretation of data from this intervention, mainly due to the small sample size. This meant that both Type 1 and Type 2 errors were likely to occur and all findings must be treated cautiously as a result.

At the start of the present study the wellness model was discussed. This is a model of how the different domains of health interact. Klepac (1996) adapted this model to suggest that in Type 1 diabetes, diabetes management affects all five domains of health. It was suggested that exercise, as an integral part of diabetes management, affects several of these domains and that by increasing exercise it may be possible to significantly affect more than one domain of health, i.e. both physical and mental health. However, the results of the intervention showed that this was not the case. There are many factors that interact in determining the health of children with Type 1 diabetes and it is likely that a more comprehensive intervention programme, that focuses on several factors that affect health simultaneously, would be necessary to cause significant changes in health. This type of intervention is discussed further in section 10.7.

10.6: Methodological considerations

There were several methodological issues within this study that should be taken into consideration when interpreting the results. These can be grouped into two main areas; sample size and issues to do with the data collection. These limitations are discussed here in section 10.6, for recommendations of changes to future study designs to reduce these limitations see section 10.7.

10.6 1: Sample size

Selecting the appropriate sample size is important because it affects the probability of Type I and Type 2 errors. The power of a study determines the likelihood with which these errors may occur. Power is dependent on three factors: the alpha level, the size of the difference to be detected; and the standard deviations of the two groups. Some variability in the scores was due to factors in the children's lives, beyond the researcher's control, but which nevertheless influenced data by increasing standard deviations.

The appropriate sample size for the intervention was calculated to detect a 1% change in HbA_{1c} with a probability of 80%. The sample size calculated was 46 children per group, 92 children in total. The number of children recruited to the study was less than 92. Fifty-two children agreed to participate and of these 39 attended the first data collection session. The rationale for continuing with the study was explained in section 8.4. This was based on the small sample sizes of previous related studies, and lack of data generally on the psychological effects of exercise on children with Type 1 diabetes. Hence a small exploratory study was warranted.

However, the effect of this smaller sample size was that the power of the study was reduced. Therefore there was an increased chance that a real difference between the two groups would not be detected. The probability of this Type 2 error occurring would have been 20% if 46 children had been recruited to each group. With 20 children per group and alpha still set a 0.05 the power was reduced to 44%, i.e. there was a 56% chance that a real difference between the two groups would not be detected.

Therefore the results of this study must be treated cautiously as there was a greater than 50% chance that Type 2 error occurred. It is possible that there were further effects of the exercise intervention programme that were not detected by this study. However, the findings can be used to generate more specific hypotheses about the effects of exercise on both psychological well being and HbA_{1c}. This is particularly the case for psychological well being which had not been investigated previously.

In addition, when a large number of t tests or ANOVA calculations are carried out on one data set there is an increased risk of Type I errors occurring. A method to protect against this is a Bonferroni correction. This controls the error rate by setting the error rate for each test to the experimentwise error rate divided by the total number of tests. Therefore the significance level is adjusted for the fact that multiple comparisons are being made. In reducing the possibility of Type I errors this method does increase the possibility of Type 2 errors occurring as the two are linked. In this study the Bonferroni correction factor was not used as it would have increased the possibility of Type 2 errors further. In setting the odds with which each type of error will occur researchers always have to make a trade off between protecting against one type of error and the probability of committing the other. In this study there is no existing evidence that exercise is harmful to children with Type I diabetes who have no secondary complications and whose blood glucose levels are within a specified range. Therefore it was not considered necessary to overly protect against the possibility of Type 1 error, i.e. suggesting exercise has effects that it does not. It was considered important not to reduce further the chance of finding effects that exercise does have on children with Type 1 diabetes.

10.6.2: Data collection

There are several issues regarding the data collection that should be discussed here. Firstly issues to do with HbA_{1c} measurements, secondly differences between the experimental and control group at time 1, and thirdly drop out.

HbA_{1c} measurements

Children with Type 1 diabetes generally have their HbA_{1c} measured once every three months at outpatient appointments. In phase one changes in physical activity were not being examined and therefore an HbA_{1c} value within three months of the other data being collected was sufficient. In phase two changes in HbA_{1c} over a three month period were examined and therefore a measure immediately before this and immediately afterwards was the most accurate way of examining changes in HbA_{1c} during this period. This was the method planned for the present study.

However, when the hospital laboratories and the company that supplies HbA_{1c} testing kits were approached about buying kits for the study it was found that there was a world-wide shortage of these kits at that time and they were being issued strictly for medical purposes only. This would continue until a new factory was built in about a year's time. Due to the nature of the research funding and the fact that participants had already been recruited to the study it was not possible to postpone the data collection until testing kits were available and a compromise method had to be found. This was that HbA_{1c} measurements would be taken from children at the time of laboratory testing only if they had not been to the diabetes clinic within the last 6 weeks. If they had the clinic value was used.

The implication of this for the results was that the HbA_{1c} values were not taken exactly three months apart, just before and just after the intervention or control periods. As HbA_{1c} is a measure of average blood glucose over the past 12 weeks the measurements that were taken before the end of the intervention would have been influenced partly by the HbA_{1c} values before the start of the intervention. It was agreed with the hospitals involved that HbA_{1c} tests would be done on children who had not had a test within the last 6 weeks. Therefore the minimum period of exercise included was 6 weeks. HbA_{1c} values actually reflect the blood glucose values over the most recent 6 weeks to a greater extent than the 6 weeks previous to that. The average level of blood glucose in the 30 days immediately preceding the blood sampling contributes roughly 50% to the final result, whereas the 90 to 120 days preceding contribute only about 10% (Goldstein, 1995). Therefore in the children whose HbA_{1c} values were tested 6 weeks into the exercise programme roughly 60 to 70% of these values reflected the period while the children were exercising. In all the other children a greater percentage of the HbA_{1c} value reflected the period over which they were exercising, up to 100% for those tested at the end of the 12-week programme. The same criterion of whether a test had been carried out within the last six weeks was used with the control group. No change was expected in this group however measurements had to be taken at the same time for valid comparisons to be made.

The variation in duration of participation in the exercise programme prior to HbA_{1c} measurement along with the reduced power of the study, caused by the sample size, means that changes in HbA_{1c} as a result of the exercise programme may not have been detected.

Differences between the experimental and control groups at time 1.

The experimental and control groups were assigned randomly using a random numbers table. The idea of this was that systematic bias would be removed and the groups would be evenly matched on the measured variables. However it was possible that due to chance groups would differ on some of the variables, the chance of this happening is reduced as sample size increases. When the two groups were compared at time 1, before the intervention, they did have significantly different mean levels of aerobic fitness, perceived sport competence and very hard physical activity. The scores of the control group were higher in all three cases. Consistent with this the control group also had lower body fat and lower BMI, although these differences were smaller and not significant. Physical activity was only compared for the control group at time 1 and time 2, therefore the difference between the experimental group and the control group at time one did not affect the analyses. For sport competence and aerobic fitness an ANCOVA was used to examine changes between groups over time, group differences at time one were used as the covariate.

One of advantages of using a randomised controlled trial methodology is that it produces groups that are initially comparable on the variables to be assessed (Friedman et al., 1998). However as sample size decreases the possibility of there being differences between the groups due to chance on these variables increases. In this study there were differences between the groups in perceived sport competence, aerobic fitness very hard physical activity and gender. The study investigated change in each of the variables from time 1 to time 2, mean values for the control and experimental groups at each time were compared. Therefore it was still possible to investigate these changes and to look at interaction between the groups over time, i.e. did one increase while the other decreased. However there is the possibility that these differences affected the results, gender differences exist for the fitness variables measured and self esteem, boys tend to have greater fitness and to report higher self esteem. Gender differences were examined in the analysis because of this. It was also possible that the participants in the experimental group showed greater gains in aerobic fitness than would have occurred if the groups had been equal on this variable at time 1. Studies with adults have shown the largest gain is for those with initially the lowest peak VO_2 (Armstrong and Welsman, 1997), although the same has not been found in children.

Drop out rate

It was expected that there would be drop out during the study due to its nature, particularly from the experimental group. One reason for dropping out, and the main reason given to the investigators by participants and their parents, was the time participating in the study involved. The data collection sessions took approximately two hours plus travelling time to get to the laboratory. For those who were involved in the exercise intervention the sessions were two, increasing to three times a week. Travelling distances for the participants were reduced by running sessions in three centres in different parts of Liverpool, but these were not local to all the participants. Every effort was made to help families to get to the laboratory and the exercise sessions but some found they were not able to attend. Another reason for dropping out of the study was not enjoying the first data collection session or the exercise sessions. Anecdotally one or two parents said that this was the reason their child dropped out.

In the exercise group non enjoyment was due to the sessions being too easy or there being too many young children at them. The drop out rate from the control group was greater than had been anticipated.

One effect of the drop out was to reduce the sample size and therefore increase the possibility of Type 2 error further. However, exercise intervention studies with children with Type 1 diabetes typically have small sample sizes, from 15 to 32. This highlights the difficulty of obtaining sufficient participants to run a study of this type with the recommended level of power. Power calculations were based on HbA_{1c} standard deviation from a large international study, and the minimum clinically relevant difference used is relevant to children with Type 1 diabetes in general not just in the present study. Therefore the conclusions drawn from previous exercise intervention studies about change in HbA_{1c} and fitness variables were as prone to Type 2 error as those from the present study, although this was not discussed in any of the papers reviewed. The effects of exercise on the psychological health of children with Type 1 diabetes had not been investigated previously and this study provides exploratory data which can be used to indicate which areas should be investigated further in future larger studies.

The large number of calculations conducted on these data meant that there was also the possibility of Type 1 error occurring. Using a Bonferroni correction factor would have reduced the likelihood of this, however, it would also have increased the possibility of Type 2 error further therefore resulting in no significant findings from the study. It was felt that as an initial hypothesis generating study in an area where there is no previous research it was important to examine trends in the data to provide a starting point for future studies, and that therefore not applying a Bonferroni correction factor was justified.

The drop out from the control group increased the difference in group size between the experimental and the control group. The assumptions of ANOVA are more likely to be violated if group size is uneven, therefore this increased the likelihood that Levene's test would be significant indicating unequal variance.

A further effect was found when those children who dropped out were compared with those who completed the study. In the experimental group those who attended more than 50% of the exercise programme had significantly lower aerobic fitness ($p<0.05$) and sport competence ($p<0.05$). The other measured variables did not differ significantly. This suggested that the exercise programme appealed to those who were initially less fit and had less confidence in their ability at sport. This is encouraging from a health perspective, as this is the group that one might particularly want to target with an exercise intervention. However, from a methodological perspective, this drop out increased the differences between the experimental and control groups and may have affected the results, as described above.

In the control group there were no significant differences on the measured variables between those who dropped out and those who completed the study, except for moderate physical activity, those who dropped out reported significantly more moderate physical activity than those who did not. However, phase one found self reported moderate physical activity was less valid than hard and very hard physical activity and as these did not differ significantly this was not expected to affect the results.

10.7: Recommendations for future research

Due to the limitations discussed in section 10.6 this study must be considered as an exploratory, hypothesis generating study. The data on the effect of increasing physical activity on fitness variables found aerobic fitness increased, this was in agreement with previous studies, although the increase in the present study was greater than that found previously. Therefore the present study added further evidence of health benefits of increased physical activity for children with Type 1 diabetes in terms of reduction of risk factors for cardiovascular disease. The data on skin fold thickness and BMI were affected by maturation. The effect of increased physical activity on these should be investigated further, possibly using a younger sample who had not yet reached puberty. Data on HbA_{1c} were similar to those from previous studies that showed no significant change following an exercise intervention study. However, the literature is equivocal about the effect of exercise intervention programmes on HbA_{1c}, some studies have shown significant decreases, others no significant change. In the present study there were methodological issues in the assessment of HbA_{1c} that made it less likely any change would be detected, see section 10.6.2. This, in addition to the high possibility of Type 2 error present in all studies that have investigated change in HbA_{1c}, make it difficult to come to a firm conclusion about the effect of increasing physical activity on HbA_{1c}.

Therefore it is recommended that a large randomised controlled exercise intervention that has sufficient power to provide conclusive data about the effect on HbA_{1c} should be run. The benefits of increasing physical activity in children with Type 1 diabetes in terms of reducing risk factors for cardiovascular disease would provide an ethically sound rationale for running this programme irrespective of the outcome in terms of HbA_{1c}. The present study recruited from three diabetes outpatient clinics in the North West and was not able to obtain the sample size calculated by power calculations. It is a common issue in intervention studies for children with Type 1 diabetes that sample size is small because the prevalence in children under 16 in the UK is 1.25 per 1000 (Department of Health, 2001). Therefore it is recommended that a multi-centre study is conducted.

Following the unequal groups in the present study it is recommended that stratification is used in further work to avoid this. Gender should be used as one variable, due to the known gender differences in fitness and self esteem. In the present study, due to practical reasons in the planning of the intervention, the study groups had to be decided before the first laboratory testing. If future studies could overcome this issue it is suggested that groups are also stratified on either physical activity level, fitness, or both, as these were shown to be associated with psychological variables in phase one.

This was the first study to investigate the effect of increasing physical activity on the psychological well being of children with Type 1 diabetes. Therefore the psychological variables measured were chosen on the basis of previous exercise intervention studies on children in general and psychological intervention studies in children with Type 1 diabetes. The present study found that the intervention had the most effect on the children's ratings of physical self esteem. There were no significant effects on diabetes self efficacy or diabetes quality of life in the in the experimental group compared to the control group. It may be that a more comprehensive management programme is necessary to affect these variables. It is suggested that this programme should focus on education, coping skills and increasing intrinsic motivation to participate in the exercise, in addition to the activity programme.

One suggestion for the educational aspect of the programme is that is focuses on adjusting diet and insulin to accommodate increased exercise. The interviews conducted with five participants, plus anecdotal comments made by the children's parents during the intervention, highlighted that many of the children and their parents had some difficulties adjusting diet and insulin appropriately to accommodate increased exercise and maintain desired blood glucose levels. This resulted in some of the children suffering nocturnal hypoglycaemia. Although each individual has to develop their own diabetes management strategy there are general principles that can be applied. It is suggested that group sessions with parents could be run prior to the intervention and part way through to discuss management strategies and share experiences. These would have the aims of avoiding night time hypoglycaemia and promoting good blood glucose control. Suggested topics would be the effect of timing of insulin injection relative to exercise on blood glucose levels, suggested snacks and drinks for before, during and after exercise, importance of monitoring blood glucose levels for several hours after exercise. The sessions could be run by a member of the diabetes team, probably a nurse specialist or nutritionist. Children may respond better to similar information given through role play, as in coping skills training discussed below. In the present study written advice was given on the STEPS 2000 passport and participants and their parents were encouraged to ask their diabetes nurse specialist for advice but the findings suggest this was not sufficient.

Grey et al. (1999) have shown that coping skills training in children and youths using intensive diabetes therapy increased diabetes self efficacy and diabetes quality of life significantly compared to a control group using intensive therapy only. The programme included role playing difficult social situations so that appropriate coping skills could be practised. The programme was more effective than others that have used education alone and therefore it is suggested that a similar method be used with children alongside an exercise intervention. Focus groups with children with Type 1 diabetes could be used to discover what social and family situations they find difficult, particularly whether there are any related to exercise.

In this study a reward programme was developed to increase adherence to the programme. Children collected points for each session attended and prizes could be claimed when the appropriate number of points had been collected. However, to promote long term adherence to exercise rather than short term adherence to the programme, intrinsic rewards should be focussed on rather than extrinsic. These could involve goal setting for older children. The interviews carried out for this study showed that children had different reasons for participating and setting personal goals could reflect this. This may also lead to greater change in psychological health if these goals are achieved at the end of the programme. The younger children tended to participate because they found the sessions fun. There was positive feedback about the non-competitive nature of the activities. Possibly the educational aspect of the sessions could be increased for the younger children, to maintain interest with less emphasis on material rewards. Goni and Zulaika (2000) found identifying individual goals, promoting participative and non-competitive games, and using encouragement and verbal reward, during usual P.E. classes over a 6-month period increased children's physical self perceptions compared to standard P.E. classes.

It may be that it takes longer than 12 weeks for participating in increased physical activity to impact on the psychological variables of self efficacy and quality of life. It may be necessary for the person to adapt to participating in physical activity being part of their lifestyle for this to impact on these variables. Therefore a longer exercise intervention study should be run. In addition follow up data should be collected to see whether increased physical activity was maintained and therefore the effects on the other variables measured.

Further qualitative studies should be carried out during future exercise interventions to examine how participation in the study affects children. These should focus particularly on the psychological perspective as to date psychological questionnaires are not specific or sensitive enough to capture fully the psychological effects of an exercise intervention programme. These studies should also include participants who 'drop out' of the study to elicit reasons for this.

In addition, education about avoiding night-time hypoglycaemia and altering the timing of the sessions is recommended. In the present study most of the exercise sessions ran from 5 to 6pm or 6 to 7pm. Night-time hypoglycaemia is a danger of evening exercise for children with Type 1 diabetes and it is suggested that in future programmes exercise sessions are run straight after school or during the day at weekends. This would be important with the exercise programme used in this study as the sessions focused on vigorous physical activity, which causes more change to blood glucose levels than moderate physical activity. Additionally the children in this study were in general not used to vigorous exercise prior to the programme.

This focus on vigorous physical activity was based on the findings from phase one, it was also what was used in previous studies. The advice from the American Diabetes Association (2002) is that vigorous physical activity is safe for people with Type 1 diabetes so long as they do not have any secondary complications. Very few children with Type 1 diabetes have developed secondary complications and therefore vigorous physical activity is safe for the majority of them. It is recommended that the exercise intervention programme should continue to include vigorous physical activity, although due to the low levels of fitness that were found, this should be introduced gradually over the programme.

The fact that the children who started but did not complete this exercise programme tended to be those who were fitter suggested that the programme used in this study appealed to those who were less fit to begin with. In one sense this was encouraging, as this was the group that could benefit most from increasing their physical activity level. However it did suggest that to maintain the interest of the fitter children, so that they complete the study, the programme should provide different options for this group. One of the difficulties with doing this is that the number of children with diabetes in any one area means that the groups will be small. This was the case in the present study even when siblings and friends were invited to join in. However, it seems that it would be necessary to run classes at different levels so that all feel they are improving their fitness. Also, using more circuit type exercises where children can exercise at their own level would allow this, children indicated that they enjoyed these exercises in the interviews. It may be helpful to split the classes by age to allow sessions to be targeted to the children's preferred activities.

A difficulty for the programme was that children travelled quite long distances, mainly transported by their parents. Transport costs were refunded and this helped with parents' willingness to participate but it was difficult for those without access to a car to participate. Running the sessions in more centres would reduce the number of children per centre and so increase the difficulties of small class sizes discussed above. It is suggested that sessions are run in more centres and that these are chosen on the basis of good access by public transport. In addition the sessions should be advertised more widely, possibly in the local school, in areas where there are few children with diabetes. The alternative of children attending local exercise sessions was investigated in the planning of this study. However it was discounted because there would not be enough control over the intensity of the sessions to allow valid comparisons to be made at the end of the intervention, particularly when the aim was to promote vigorous physical activity. In addition in interviews following the study several children said they enjoyed being with, and making friends with, other children with diabetes during the programme. They also felt safe exercising because the instructors knew what to do and would have glucose etc, if they went hypoglycaemic during an exercise session. Also the other children and the instructor would understand if they did have a hypoglycaemic episode during a session so there was less fear of embarrassment.

It should be investigated whether it is cost effective to develop diabetes specific exercise programmes to encourage children with Type 1 diabetes who do not currently exercise to begin doing so, or whether similar gains are obtained from participating in community exercise sessions. This would be important because of the incidence of diabetes, which means children have to travel long distances to come to diabetes specific sessions. Following a large scale study of efficacy there could be additional training provided for coaches in local sessions where children with diabetes would be going.

10.8: Recommendations for practice

The results from this study showed that it was possible to interest those children who were less fit and less competent about their ability to participate in sport to take part in vigorous physical activity. Over a twelve-week period this activity increased their aerobic fitness significantly from a level that would be considered a risk factor for future health problems. Participation in the study also led to increases in some aspects of physical self esteem. The reason that these previously inactive children volunteered to participate in an exercise programme is not entirely clear. Anecdotal evidence suggests the non competitive nature of the exercise sessions, along with confidence that the instructors understood the effects of exercise on diabetes, and that some of the other children had diabetes, were contributing factors.

Children with Type 1 diabetes are particularly at risk for cardiovascular disease risk factors later in life and therefore these results were encouraging. The benefits for physical self esteem would also be important given the contribution of this to global self esteem. Until there is further evidence regarding the benefits of exercise sessions for groups of children with diabetes together, compared to children exercising in local centres where staff are trained about diabetes, it is premature to suggest exercise programmes are set up by every diabetes outpatient clinic. However this study does suggest that with increased encouragement and support, increases in the physical activity of this group can be gained.

Resources should be provided for sports coaches to be educated in how exercise can affect children with Type 1 diabetes, and children and their parents should be made aware of that centres have undergone this training. Possibly diabetes clinics could be the setting for a 'buddy scheme' where children could meet other children with diabetes and arrange to participate in local exercise classes together.

10.9: Conclusions

There was some support for the hypothesis that there would be a positive association between higher levels of physical activity, fitness and psychological health in children with Type 1 diabetes. Higher self esteem, particularly physical self esteem and its sub-domains, were significantly associated with greater aerobic fitness and lower body fat. Higher levels of vigorous physical activity were significantly associated with greater attractive body competence. For quality of life, the satisfaction with life sub-scale was significantly associated with greater fitness, and greater vigorous physical activity was associated with fewer disease related worries and a better overall rating of health. Self efficacy for diabetes was not associated with fitness or physical activity.

The hypothesis that there would be a positive association between higher levels of physical activity, fitness and glycaemic control in children with Type 1 diabetes was not supported. There was, however, a non-significant association between higher vigorous physical activity levels and lower HbA_{1c}.

Hypothesis three that increasing physical activity would lead to higher fitness, greater psychological health and improved glycaemic control in children with Type 1 diabetes was not supported, although there were non-significant trends in the hypothesised direction. The intervention in phase two found BMI increased significantly in the experimental compared to the control group. Aerobic fitness increased in the experimental group compared to the control group, however, this was not significant. There were no significant effects in the experimental group compared to the control group for self esteem, self efficacy or quality of life. There were, however, non-significant increases in sports competence and condition competence in the experimental group. There was no significant change in HbA_{1c}.

The sample sizes in both phases of the study mean this must be treated as hypothesis generating study. A larger multi-centre study is indicated. In addition it is suggested that a more comprehensive intervention that focussed on several aspects of diabetes management concurrently may be more effective at improving health outcomes.

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Appendix 1: Psychological Questionnaires

Diabetes Quality of Life Questionnaire: Youths

A) DIRECTIONS:

Read each statement carefully. Please indicate how **satisfied** or **dissatisfied** you currently are with the aspect of your life described in the statement. Draw an [X] in the box that matches how satisfied or dissatisfied you feel.

[1] = very satisfied
[2] = moderately satisfied
[3] = neither satisfied nor dissatisfied
[4] = moderately dissatisfied
[5] = very dissatisfied.

There are no right or wrong answers to these questions. We want your opinion.

		Satisfied Very				Dissatisfied Very
A1:	How satisfied are you with the amount of time it takes to manage your diabetes?	[1]	[2]	[3]	[4]	[5]
A2:	How satisfied are you with the amount of time you spend getting check ups?	[1]	[2]	[3]	[4]	[5]
A3:	How satisfied are you with the time it takes to determine your blood sugar?	[1]	[2]	[3]	[4]	[5]
A4:	How satisfied are you with your current treatment?	[1]	[2]	[3]	[4]	[5]
A5:	How satisfied are you with the flexibility you have with your diet?	[1]	[2]	[3]	[4]	[5]
A6:	How satisfied are you with the burden your diabetes is placing on your family?	[1]	[2]	[3]	[4]	[5]
A7:	How satisfied are you with your knowledge about your diabetes?	[1]	[2]	[3]	[4]	[5]

SPEAKING GENERALLY

A8:	How satisfied are you with your sleep?	[1]	[2]	[3]	[4]	[5]
A9:	How satisfied are you with your friendships?	[1]	[2]	[3]	[4]	[5]

		Satisfied Very				Dissatisfied Very
A10:	How satisfied are you with your work, school, and household activities?	[1]	[2]	[3]	[4]	[5]
A11.	How satisfied are you with the appearance of your body?	[1]	[2]	[3]	[4]	[5]
A12:	How satisfied are you with the time you spend exercising?	[1]	[2]	[3]	[4]	[5]
A13:	How satisfied are you with your leisure time?	[1]	[2]	[3]	[4]	[5]
A14:	How satisfied are you with life in general?	[1]	[2]	[3]	[4]	[5]
A15:	How satisfied are you with your performance in school?	[1]	[2]	[3]	[4]	[5]
A16:	How satisfied are you with how your classmates treat you?	[1]	[2]	[3]	[4]	[5]
A17:	How satisfied are you with your attendance at school?	[1]	[2]	[3]	[4]	[5]

Compared to others your age, would you say your health is:

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

B) DIRECTIONS:

Read each statement carefully. Please indicate **how often** the following events happen to you. Draw an [X] in the box that matches how often it happens to you:

[1] = Never
[2] = Very seldom
[3] = Sometimes
[4] = Very often
[5] = All the time

There are no right or wrong answers to these questions. We are interested in your honest opinion.

		Never	**Very seldom**	**Sometimes**	**Often**	**All the time**
B1:	How often do you feel pain associated with the treatment of your diabetes?	[1]	[2]	[3]	[4]	[5]
B2:	How often are you embarrassed by having to deal with your diabetes in public?	[1]	[2]	[3]	[4]	[5]
B3:	How often do you feel physically ill?	[1]	[2]	[3]	[4]	[5]
B4:	How often does your diabetes interfere with your family life?	[1]	[2]	[3]	[4]	[5]
B5:	How often do you have a bad night's sleep?	[1]	[2]	[3]	[4]	[5]
B6:	How often do you find your diabetes limiting social relationships and friendships?	[1]	[2]	[3]	[4]	[5]
B7:	How often do you feel good about yourself?	[1]	[2]	[3]	[4	[5]
B8:	How often do you feel restricted by your diet?	[1]	[2]	[3]	[4	[5]
B9:	How often does your diabetes interfere with your exercising?	[1]	[2]	[3]	[4]	[5]
B10:	How often do you miss work, school or household duties because of your diabetes?	[1]	[2]	[3]	[4]	[5]
B11:	How often do you find yourself explaining what it means to have diabetes?	[1]	[2]	[3]	[4]	[5]

		Never	Very seldom	Sometimes	Often	All the time
B12:	How often do you find that your diabetes interrupts your leisure time activities?	[1]	[2]	[3]	[4]	[5]
B13:	How often are you teased because you have diabetes?	[1]	[2]	[3]	[4]	[5]
B14:	How often do you feel that because of your diabetes you have to go to the bathroom more than others?	[1]	[2]	[3]	[4]	[5]
B15:	How often do you find you eat something you shouldn't rather than tell someone that you have diabetes?	[1]	[2]	[3]	[4]	[5]
B16:	How often do you hide from others the fact that you are having an insulin reaction?	[1]	[2]	[3]	[4]	[5]
B17:	How often do you find that your diabetes prevents you from participating in school activities? (for example, a school play, playing a sport)	[1]	[2]	[3]	[4]	[5]
B18:	How often do you find that your diabetes prevents you from going out to eat with your friends?	[1]	[2]	[3]	[4]	[5]
B19:	How often do you feel that your diabetes will limit what job you will have in the future?	[1]	[2]	[3]	[4]	[5]
B20:	How often do you find that your parents are too protective of you?	[1]	[2]	[3]	[4]	[5]
B21:	How often do you find that your parents worry too much about your diabetes?	[1]	[2]	[3]	[4]	[5]
B22:	How often do you find that your parents act like diabetes is their disease, not yours?	[1]	[2]	[3]	[4]	[5]

C) DIRECTIONS:

Read each statement carefully. Please indicate **how often** the following events happen to you. Put an [X] in the appropriate box. If the question is **not relevant** mark the box **'Does Not Apply'**.

[0] = Does not apply
[1] = Never
[2] = Seldom
[3] = Sometimes
[4] = Often
[5] = All the time

There are no right or wrong answers to these questions.

		Does Not Apply	**Never**	**Seldom**	**Some-times**	**Often**	**All the time**
C1:	How often do you worry about whether you will get married?	[0]	[1]	[2]	[3]	[4]	[5]
C2:	How often do you worry about whether you will have children?	[0]	[1]	[2]	[3]	[4]	[5]
C3:	How often do you worry about whether you will not get a job you want?	[0]	[1]	[2]	[3]	[4]	[5]
C4:	How often do you worry about whether you will pass out?	[0]	[1]	[2]	[3]	[4]	[5]
C5:	How often do you worry about whether you will be able to complete you education?	[0]	[1]	[2]	[3]	[4]	[5]
C6:	How often do you worry that your body looks different because you have diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C7:	How often do you worry that you will get complications from your diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C8:	How often do you worry whether someone will not go out with you because you have diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C9:	How often do you worry that teachers treat you differently because of your diabetes?	[0]	[1]	[2]	[3]	[4]	[5]

		Does Not Apply	Never	Seldom	Some-times	Often	All the time
C10:	How often do you worry that your diabetes will interfere with things you do in school? (for example, sports, music, drama)	[0]	[1]	[2]	[3]	[4]	[5]
C11:	How often do you worry that your diabetes causes you not to do things with friends like going on dates or going to parties?	[0]	[1]	[2]	[3]	[4]	[5]

Self Efficacy Scale for Diabetes

Please read the following questions. After each question, please put a **tick** in the circle to show how much you believe you **can** or **cannot** do what is asked *now.*

Scale

Very Sure I **Can't**	1	2	3	4	5	6	Very Sure I **Can**

	1	2	3	4	5	6
1. Be the one in charge of giving my insulin injection to myself.	1	2	3	4	5	6
2. Figure out my own meals and snacks at home.	1	2	3	4	5	6
3. Figure out what foods to eat when I am away from home.	1	2	3	4	5	6
4. Keep track of my own blood sugar levels.	1	2	3	4	5	6
5. Change the amount of times I get insulin when I get a lot of extra exercise.	1	2	3	4	5	6
6. Judge the amount of food I should eat before activities.	1	2	3	4	5	6
7. Figure out how much insulin to give myself when I am sick in bed.	1	2	3	4	5	6
8. Prevent having blood glucose reactions.	1	2	3	4	5	6
9. Avoid or get rid of dents, swelling, or redness of my skin where I get my injections.	1	2	3	4	5	6
10. Talk to my doctor myself and ask for the things I need.	1	2	3	4	5	6
11. Suggest to my parents changes in my insulin dose.	1	2	3	4	5	6
12. Sleep away from home on a class trip or at a friend's house where no one knows about my diabetes.	1	2	3	4	5	6
13. Keep myself free of high blood sugar levels.	1	2	3	4	5	6
14. Avoid having ketones.	1	2	3	4	5	6
15. Change my doctor if I don't like him/her.	1	2	3	4	5	6

Very Sure I **Can't** (1) (2) (3) (4) (5) (6) Very Sure I **Can**

16.	Feel able to stop a blood glucose reaction when I am having one.	1	2	3	4	5	6
17.	Ask for help I need from other people when I feel sick.	1	2	3	4	5	6
18.	Tell a friend I have diabetes.	1	2	3	4	5	6
19.	Play football or other sports that take a lot of energy.	1	2	3	4	5	6
20.	Argue with my doctor if I felt he/she were not being fair.	1	2	3	4	5	6
21.	Prevent blindness and other complications from diabetes.	1	2	3	4	5	6
22.	Tell my boyfriend or girlfriend I have diabetes.	1	2	3	4	5	6
23.	Do things I have been told not to do when I really want to do them.	1	2	3	4	5	6
24.	Get as much attention from others when my diabetes is under control as when it isn't.	1	2	3	4	5	6
25	Easily talk to a group of people at a party when I don't know them.	1	2	3	4	5	6
26	Make a teacher see my point of view.	1	2	3	4	5	6
27.	Show my anger to a friend when he/she has done something to upset me.	1	2	3	4	5	6
28.	Take responsibility for getting my homework and chores done.	1	2	3	4	5	6
29	Regularly wear a medical alert tag or bracelet which says I have diabetes.	1	2	3	4	5	6
30.	Sneak food not on my diet without getting caught.	1	2	3	4	5	6
31.	Believe that I have the ability to have control over my diabetes.	1	2	3	4	5	6
32.	Follow my doctors orders for taking care of my diabetes.	1	2	3	4	5	6
33.	Run my life the same as I would if I didn't have diabetes.	1	2	3	4	5	6

What I Am Like

For each number please **read both** statements and **tick one** of the four boxes. Tick the box which is most like how **you** feel.

EXAMPLE

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
	☐	☐	Some kids would rather play outside in their spare time	**BUT**	Other kids would rather watch T.V.	☑	☐
1.	☐	☐	Some kids do very well at all kinds of sports	**BUT**	Other kids *don't* feel they are very good when it comes to sports	☐	☐
2.	☐	☐	Some kids feel *uneasy* when it comes to doing vigorous physical exercise	**BUT**	Other kids feel *confident* when it comes to doing vigorous physical exercise	☐	☐
3.	☐	☐	Some kids feel that they have a good-looking (fit-looking) body compared to other kids	**BUT**	Other kids feel that compared to most, their body *doesn't* look so good	☐	☐
4.	☐	☐	Some kids feel that they *lack* strength compared to other kids their age	**BUT**	Other kids feel that they are stronger than other kids their age	☐	☐
5.	☐	☐	Some kids are *proud* of themselves physically	**BUT**	Other kids *don't* have much to be proud of physically	☐	☐
6.	☐	☐	Some kids are often *unhappy* with themselves	**BUT**	Other kids are pretty *pleased* with themselves	☐	☐
7.	☐	☐	Some kids wish they could be a lot better at sports	**BUT**	Other kids feel that they are good enough at sports	☐	☐
8.	☐	☐	Some kids have a lot of stamina for vigorous physical exercise	**BUT**	Other kids soon get out of breath and have to slow down or quit	☐	☐
9.	☐	☐	Some kids find it *difficult* to keep their bodies looking good physically	**BUT**	Other kids find it easy to keep their bodies looking good physically	☐	☐
10.	☐	☐	Some kids think that they have stronger muscles than other kids their age	**BUT**	Other kids feel that they have weaker muscles than other kids their age	☐	☐

11.	☐	☐	Some kids *don't* feel very confident about themselves physically	BUT	Other kids feel really good about themselves physically	☐	☐
12.	☐	☐	Some kids are *happy* with themselves as a person	BUT	Other kids are often *not* happy with themselves	☐	☐
13.	☐	☐	Some kids think they could do well at just about any new sports activity they haven't tried before	BUT	Other kids are afraid they might *not* do well at sports they haven't ever tried	☐	☐
14.	☐	☐	Some kids *don't* have much stamina and fitness	BUT	Other kids have *lots* of stamina and fitness	☐	☐
15.	☐	☐	Some kids are *pleased* with the appearance of their bodies	BUT	Other kids wish that their bodies looked in better shape physically	☐	☐
16.	☐	☐	Some kids *lack* confidence when it comes to strength activities	BUT	Other kids are very confident when if comes to strength activities	☐	☐
17.	☐	☐	Some kids are very *satisfied* with themselves physically	BUT	Other kids are often *dissatisfied* with themselves physically	☐	☐
18.	☐	☐	Some kids *don't* like the way they are leading their life	BUT	Other kids *do* like the way they are leading their life	☐	☐
19.	☐	☐	In games and sports some kids usually *watch* instead of play	BUT	Other kids usually *play* rather than watch	☐	☐
20.	☐	☐	Some kids try to take part in energetic physical exercise whenever they can	BUT	Other kids try to *avoid* doing enervated exercise if they can	☐	☐
21.	☐	☐	Some kids feel that they are *often* admired for their good-looking bodies	BUT	Other kids feel that they are *seldom* admired for the way their bodies look	☐	☐
22.	☐	☐	When strong muscles are needed some kids are the *first* to step forward	BUT	Other kids are the *last* to step forward when strong muscles are needed	☐	☐
23.	☐	☐	Some kids are *unhappy* with how they are and what they can do physically	BUT	Other kids are *happy* with how they are and what they can do physically	☐	☐

24.	☐	☐	Some kids *like* the kind of person they are	**BUT**	Other kids often wish they were someone else	☐	☐
25.	☐	☐	Some kids feel the they are *better* than others their age at sports	**BUT**	Other kids *don't* feel they can play as well	☐	☐
26.	☐	☐	Some kids soon have to quit running and exercising because they get tired	**BUT**	Other kids can run and do exercises for a long time without getting tired	☐	☐
27.	☐	☐	Some kids are *confident* about how their bodies look physically	**BUT**	Other kids feel *uneasy* about how their bodies look physically	☐	☐
28.	☐	☐	Some kids feel that they are *not* as good as others when physical strength is needed	**BUT**	Other kids feel that they are among the *best* when physical strength is needed	☐	☐
29.	☐	☐	Some kids have a positive feeling about themselves physically	**BUT**	Other kids feel somewhat negative about themselves physically	☐	☐
30.	☐	☐	Some kids are very *happy* being the way they are	**BUT**	Other kids wish they were *different*	☐	☐
31.	☐	☐	Some kids *don't* do well at new outdoor games	**BUT**	Other kids are *good* at new games right away	☐	☐
32.	☐	☐	When it comes to activities like running, some kids are able to keep on going	**BUT**	Other kids soon have to quit to take a rest	☐	☐
33.	☐	☐	Some kids *don't* like how their bodies look physically	**BUT**	Other kids are *pleased* with how their bodies look physically	☐	☐
34.	☐	☐	Some kids think that they are strong and have good muscles compared to other kids their age	**BUT**	Other kids think they are weaker, *don't* have such good muscles as other kids their age	☐	☐
35.	☐	☐	Some kids wish that they could feel better about themselves physically	**BUT**	Other kids *always* seem to feel good about themselves physically	☐	☐
36.	☐	☐	Some kids are *not* very happy with the way they do a lot of things	**BUT**	Other kids think the way they do things is *fine*	☐	☐

HOW IMPORTANT ARE THESE THINGS TO HOW YOU FEEL ABOUT YOURSELF AS A PERSON?

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
1.	☐	☐	Some kids think it's important to be good at sports	BUT	Other kids *don't* think how good you are at sports is that important	☐	☐
2.	☐	☐	Some kids *don't* think that having a lot of stamina for energetic exercises is very important to how they feel about themselves	BUT	Other kids think that having a lot of stamina for vigorous exercise is *very* important	☐	☐
3.	☐	☐	Some kids think it's *very* important to have a good looking (fit-looking) body in order to feel good about themselves as a person	BUT	Other kids *don't* think that having a good looking body is important at all.	☐	☐
4.	☐	☐	Some kids think that being physically strong is *not* all that important to how they feel about themselves as a person	BUT	Other kids feel that it's *very* important to be physically strong	☐	☐
5.	☐	☐	Some kids *don't* think doing well at athletics is that important to how they feel about themselves as a person	BUT	Other kids feel that doing well at athletics is important	☐	☐
6.	☐	☐	Some kids feel that having the ability to do a lot of running and exercising is *very* important to how they feel about themselves as a person	BUT	Other kids *don't* feel it's all that important to have the ability to do a lot of running and exercising	☐	☐
7.	☐	☐	Some kids *don't* think that having a body that looks in good physical shape is important to how they feel about themselves	BUT	Other kids feel that it's *very* important to have a body that looks in good physical shape	☐	☐
8.	☐	☐	Some kids think that having strong muscles is *very* important to how they feel about themselves	BUT	Other kids feel that it's *not* at all important to have strong muscles	☐	☐

Appendix 2: Physical Activity Questionnaire

7-Day Physical Activity Recall

PAR#: 1 2 3 4 5 6 Participant ____________

Date Interviewer ____________ Today is ________

1. How many days of the last seven did you go to school? _____ days
2. If less than five which days did you not go? ____________
3. Have you missed any time from school in the last seven days? **Yes** **No**
4. If so when? ____________

WORKSHEET

		DAYS						
	SLEEP	1	2	3	4	5	6	7
MORNING	**Moderate**							
	Hard							
	Very Hard							
AFTERNOON	**Moderate**							
	Hard							
	Very Hard							
EVENING	**Moderate**							
	Hard							
	Very Hard							

4a. Compared to your physical activity over the past three months, was last week's physical activity more, less or about the same?
1. More
2. Less
3. About the same

5. Were there any problems with the 7-Day PAR interview? 0. No 1. Yes (If Yes, write comments on back)

6. Do you think this was a valid 7-Day PAR interview? 0. No 1. Yes (If No, write comments on back)

Rounding:	10-22 min. = .25	53-1:07 hr/min. = 1.0
	23-37 min. = .50	1:08-1:22 hr/min. = 1.25
	38-52 min. = .75	

7-Day Physical Activity Recall

Interviewer, please write your comments on the interview below.

5. If you answered 'Yes' on question 5, please explain any problems you had with this interview:

____

____

____

____

6. If you answered 'No' on question 6, please explain why you think this interview was not valid?

____

____

____

____

7. Please descibe activites reported by the subject which you do not know how to classify.

____

____

____

____

8. Please provide any other comments you may have.

____

____

____

____

Appendix 3: Ethical Approval

JMU
Liverpool John Moores University

Ref. edmundss

08 June 1998

Sarah Edmunds
School of Health

Dear Sarah

I am pleased to inform you that the Ethics Committee has now considered your application for approval of the project entitled:

The psycho-physiological effects of exercise on children with Insulin Dependent Diabetes Melitus

and I am happy to confirm that it was approved with no provisos set. The Ethics Committee agreed that this is a very good application.

The Ethics Committee approval is given on the understanding that:

(i) any adverse reactions/events which take place during the course of the project will be reported to the Committee immediately;
(ii) any unforeseen ethical issues arising during the course of the project will be reported to the Committee immediately;
(iii) any change in the protocol will be reported to the Committee immediately.

Please note that ethical approval is given for a period of five years from the date granted and therefore the expiry date for this project will be May 2003. An application for extension of approval must be submitted if the project continues after this date.

I am enclosing form EC5 and would be grateful if you could spare the time to complete the questionnaire and return it to me.

Yours sincerely

MBoyle

Marcellina Boyle
Course Information Co-ordinator
Ethics Committee Secretary
Tel: 0151 231 3365
E-mail: m.boyle@livjm.ac.uk

Enc.

cc: Sheila Glenn (HEA), A H Wallymahmed (HEA), Gareth Stratton (IM Marsh Campus)

Alder Hey

Alder Hey Children's Hospital, Eaton Road, Liverpool L12 2AP
Telephone: 0151-228 4811

ROYAL LIVERPOOL CHILDREN'S N.H.S. TRUST

R&D Office

Ms S Edmunds
Research Student
School of Health
Liverpool John Moores University
79 Tithebarn St
Liverpool
L2 2ER

Our ref: 2R/E/39/98

19 October 1998

Dear Ms Edmunds

RE: APPLICATIONS: R/E/39/98 THE PSYCHOLOGICAL AND PHYSIOLOGICAL EFFECTS OF PHYSICAL ACTIVITY AND FITNESS ON CHILDREN WITH INSULIN DEPENDENT DIABETES MELLITUS

Professor Lloyd has now handed over the Chair of the Research Review Committee to me and so I am writing in relation to your application following today's Research Committee meeting.

Our feeling was that we probably asked you to do two things that are difficult to reconcile. The first is to complete Phase 1 and analyse the data before going on to Phase 2, and the other is to only have Phase 1 as a baseline. The view of the Committee was that you should analyse the data from Phase 1 in part check on the levels of activity among children with Diabetes, and also to see if there is a relationship between exercise and glycaemic control. That of course means that your assessments in Phase 1 will be completed several months or even a year before the baseline for Phase 2, so you will have to have a further baseline assessment.

Regarding the power calculations we are still not sure how these were carried out. We have not had a letter from Dr Simon Kirby which might clarify the situation. What we need to know is what analysis will you be carrying out to establish whether exercise makes a difference and then how was the power calculated. For instance, are you referring to a comparison of means and if so are the means and standard deviations you have used derived from the work by Gareth Stratton. Was this based on general population samples, how similar is it to other research, and so on. Regarding the difference of 1%, the numbers required to detect that sound very low, and the Committee wondered whether this referred to 1mg% in HbA_{1c}.

We are therefore giving you approval for Phase 1 of the study, and once that has gone through the Ethics Committee you are free to get started. We would like you to come back to us once you have the data from Phase 1 on level of exercise in diabetic children and we will give you a rapid response regarding progress to Phase 2. Meanwhile this gives you time to sort out the power calculations. I would suggest that if this letter is not clear regarding our wishes for the power calculation, Dr Kirby should contact Paula Williamson.

Yours sincerely

Professor Jonathan Hill
Chairman, Research Review Committee
& Director of Research

Alder Hey

ROYAL LIVERPOOL CHILDREN'S N.H.S. TRUST

Alder Hey Children's Hospital, Eaton Road, Liverpool L12 2AP
Telephone: 0151-228 4811
R&D Office 252 5673

Our ref: R/E/39/98

20 November 1998

Ms S Edmunds
Research Student
Liverpool John Moores University
79 Tithebarn Street
Liverpool
L2 2ER

Dear Ms Edmunds

RE: APPLICATION R/E/39/98: THE PSYCHOLOGICAL AND PHYSIOLOGICAL EFFECTS OF PHYSICAL ACTIVITY AND FITNESS ON CHILDREN WITH INSULIN DEPENDENT DIABETES MELLITUS

We would like to thank you and your colleagues for attending the recent meeting of the Paediatric Research Ethics Committee.

The Committee endorse the comments already sent to you by the Trust's Research Review Committee and approval for Phase 1 of the study was given.

This approval is subject to a revised parent information document being received and accepted. This document should be amended to contain only Phase 1 of the study and we would also suggest that you include 'travelling expenses will be reimbursed'.

We look forward to hearing from you.

Yours sincerely

Peter Rogan

Peter Rogan
Vice-Chairman
Paediatric Research Ethics Committee

Alder Hey

Alder Hey Children's Hospital, Eaton Road, Liverpool L12 2AP
Telephone: 0151-228 4811

ROYAL LIVERPOOL CHILDREN'S N.H.S. TRUST

Sarah Edmunds
School of Health
Liverpool John Moores University
79, Tithebarne Street
Liverpool
L2 2ER

9.1.99

Dear Sarah,

Application R/E/39/98
The Psychological and Physiological effects of Physical Activity and Exercise on Children with Insulin Dependent Diabetes Mellitus (IDDM)

Thank you for amending both the informaton documents as requested. They both now meet the requirements of the Commiittee and approval for the study is given.

Wishing you every success with your research studies.

Yours sincerely,

Peter Rogan
Vice Chair
Paediatric Ethics Committee

R&D Office, Mulberry House
Direct Line: 0151 252 5673
Fax 0151 252 5285
Email address: Kath.Forrest@RLCH-TR.NWEST.NHS.UK

Alder Hey Children's Hospital, Eaton Road, Liverpool L12 2AP
Telephone: 0151-228 4811

Alder Hey

ROYAL LIVERPOOL CHILDREN'S N.H.S. TRUST

Our ref: 4R/E/39/98

4 May 2000

Ms S Edmunds
Research Student
School of Health
Liverpool John Moores University
79 Tithbarn Street
Liverpool, L2 2ER

Dear Ms Edmunds

RE: APPLICATION R/E/39/98: (Phase 2) THE PSYCHOLOGICAL AND PHYSIOLOGICAL EFFECTS OF PHYSICAL ACTIVITY AND FITNESS ON CHILDREN WITH INSULIN DEPENDENT DIABETES MELLITUS

Thank you for your reply to the comments raised by the Research Review Committee for the above study. Your response to the points raised have been satisfactorily addressed.

The Committee are happy to approve the study and will forward it to the LREC for consideration.

Yours sincerely

MRal

Professor Jonathan Hill
Chairman
pp Research Review Committee

INVESTOR IN PEOPLE

Please ensure all correspondence is addressed to:
Local 'Paediatric' Research Ethics Committee
R&D Office, Mulberry House, RLC NHS Trust, Alder Hey, Eaton Road, Liverpool L12 2AP: Fax: 0151 252 5285
Email address: Kath.Forrest@rlch-tr.nwest.nhs.uk
Chairman, Mr Peter Rogan, MBE, JP
Administrator, Mrs Kath Forrest

Your Ref:

Our Ref:

LIVERPOOL HEALTH AUTHORITY

Direct Dial: 0151 252 5673

Our ref: 1R/E/39/98

25 April 2000

Ms S Edmunds
School of Health
Liverpool John Moores University
79 Tithebarn Street
Liverpool
L2 2ER

Dear Ms Edmunds

RE: APPLICATION R/E/39/98: THE PSYCHOLOGICAL AND PHYSIOLOGICAL EFFECTS OF PHYSICAL ACTIVITY AND FITNESS ON CHILDREN WITH INSULIN DEPENDANT DIABETES MELLITUS (PHASE 2)

Thank you for attending the recent meeting of the Paediatric Research Ethics Committee.

As you are aware the Committee suggested several changes to the parent information document (please see enclosed). We also suggested an assent form and information document for the older children. These documents will need resubmitting on the appropriate headed note paper.

On receipt of the above I will attempt to give you a swift response.

Yours sincerely

Peter Rogan
Chairman
Paediatric Research Ethics Committee

Enc

Liverpool Health Authority
Hamilton House, 24 Pall Mall, Liverpool L3 6AL Tel: 0151 285 2000/0151 236 4747 Fax: 0151 258 1442

Your Ref:

Our Ref:

Please ensure all correspondence is addressed to:
Local 'Paediatric' Research Ethics Committee
R&D Office, Mulberry House, RLC NHS Trust, Alder Hey, Eaton Road,
Liverpool L12 2AP: Fax: 0151 252 5285
Email address: Kath.Forrest@rlch-tr.nwest.nhs.uk
Chairman, Mr Peter Rogan, MBE, JP
Administrator, Mrs Kath Forrest

LIVERPOOL HEALTH AUTHORITY

Direct Dial: 0151 252 5673

Our ref: 2R/E/39/98

10 May 2000

Ms S Edmunds
School of Health
Liverpool John Moores University
79 Tithebarn Street
Liverpool
L2 2ER

Dear Ms Edmunds

RE: APPLICATION R/E/39/98: THE PSYCHOLOGICAL AND PHYSIOLOGICAL EFFECTS OF PHYSICAL ACTIVITY AND FITNESS ON CHILDREN WITH INSULIN DEPENDANT DIABETES MELLITUS (PHASE 2)

Thank you for the revised parent information document, a copy of the patient information document and assent form. These are now satisfactory.

The Committee is agreed that there is no objection on ethical grounds to the study mentioned above.

Approval for the study is given on the understanding that you follow the protocol as agreed and promptly inform the Committee of the following:

(a) any deviation(s) from the protocol
(b) any changes which may increase the risk to the subjects
(c) all adverse drug reactions
(d) any new information which may adversely affect the safety of the subjects or conduct of the trial.

I wish you well with the study and look forward to hearing the results in due course.

As is policy we will contact you in 12 months time for a preliminary/final report.

Yours sincerely

Peter Rogan
Chairman
Paediatric Research Ethics Committee

YOUR REF:
OUR REF: EHA/HCF/C8(B)
DIRECT LINE: (01695) 583080

LANCASHIRE
WEST
HEALTH SERVICES

6 October 1998

Ms S Edmunds
Postgraduate Research Student
School of Health
Liverpool John Moores University
79 Tithbarn Street
LIVERPOOL
L2 2ER

Dear Ms Edmunds

Re: (i) The Psycho-Physiological Effects of Physical Activity on Children with Insulin Diabetes Mellitus

(ii) The Effect of Physical Activity and Fitness on Insulin Dependent Diabetes Mellitus : Microvascular Haemodnyamics and Metabolic Control in Children

I am pleased to advise you that the above two studies were considered and approved by the Ethics Committee on 29 September 1998.

However, with regard to (ii) above, it was felt that the patient information sheet and consent form should be more user friendly and that the former should include a declaration stating patient's care will not be affected if they decline to participate in the Study.

Yours sincerely

Eric H Albery

E H ALBERY
Secretary – West Lancashire Local Research Ethics Committee

POSITIVE ABOUT DISABLED PEOPLE

WEST LANCASHIRE NHS TRUST
ORMSKIRK & DISTRICT GENERAL HOSPITAL
WIGAN ROAD, ORMSKIRK, LANCASHIRE L39 2AZ
SWITCHBOARD: (01695) 577111

ST HELENS & KNOWSLEY LOCAL RESEARCH ETHICS COMMITTEE

C/O C-GARRD
Whiston Hospital
Prescot
Merseyside
L35 5DR

Tel: 0151 430 1218
Fax: 0151 430 1218

Chairman: Dr E Whelan
Administrator: Mrs K Lomax
Vice Chairman: Mr A Massey

20 April 2000

Ms Sarah Edmunds
Research Student
School of Health
Liverpool John Moores University
79 Tithebarn Street
Liverpool L2 2ER

Dear Ms Edmunds

The Psychological and Physiological Effects of Physicial Activity on Children with Insulin Dependent Diabetes Mellitus.
[Ref: 2000/2001 - 01]

Many thanks for attending the meeting of the St Helens and Knowsley LREC on 20th April 2000 where the above study was considered. The Committee agreed that, from an ethical perspective, the study raises no major concerns and therefore **approval** is granted.

Although approval has been granted by the St Helens & Knowsley LREC, you are still required to seek permission from the Management of the NHS Institution(s) in which your research will take place before you begin the study. It is also a requirement that you inform the Trust R&D Manager (Barbara Thompson – C-GARRD) of this study.

As I'm sure you are aware it is a requirement that you keep this Committee informed of the Study's progress and eventual outcome, therefore a copy of your final report would be welcomed.

Yours sincerely

Dr C Littlewood
Acting Chairman – St Helens & Knowsley LREC

cc: Dr Woodhall

Appendix 4: Parent and Child Information Sheets and Consent forms – Phase 1

Liverpool John Moores University

The Psychological and Physiological effects of Physical Activity and Exercise on Children with Insulin Dependent Diabetes Mellitus (IDDM).

A study is being undertaken by: Sarah Edmunds, Denise Roche, Gareth Stratton, A.H.Wallymahmed, Dr. Didi and Ms Sue Kerr

What's the study about?

Your child is being invited to take part in a study which will investigate whether higher levels of physical activity and fitness have benefits for the blood glucose control, psychological health and blood flow just beneath the skin of children with diabetes.

Why do we want to do this study?

Exercise has many benefits that we already know about such as it

- controls body weight
- increases body tone
- improves mood, reduces stress and anxiety

Exercise may help individuals with diabetes even more than it does the general public by reducing how much insulin they need. Exercise is also known to improve the circulation, and lower levels of the 'bad' cholesterol. If the same happens in people with diabetes it would be a major health benefit because of their increased risk for heart disease. The psychological benefits from exercise may also be important as it may help individuals feel better about their diabetes and treatment programme. If exercise does have these positive effects then we may have found a way to stop the circulation deteriorating as your child gets older and to improve and maintain their psychological health.

How are children chosen to be part of the study?

The study will involve children between 9 and 15 years old with IDDM and attending Alder Hey or Ormskirk Hospital Diabetes clinics. Participation in the study is entirely voluntary. If you agree to your child taking part you will be free to withdraw him/her from the study at any stage, or your child can decide to withdraw. Taking part will not affect his/her normal treatment at the Diabetes clinic.

What does taking part in the study involve?

Children who agree to take part will:

- Be interviewed in their home by a researcher at a time convenient for you for 10 to 15 minutes about their physical activity over the last 7 days.

- Have their physical activity monitored using a small, lightweight heart rate monitor (worn as watch) and maybe also a motion analyser (clips on waistband).

  The children will wear monitors for four days. One of the researchers will come to your house for about 5 minutes each morning and evening of the 4 days to set up the monitors and collect the data.

Physical activity diary: The children will be asked to keep a diary of their physical activity and insulin injections over these 4 days.

- Come into the Lab at IM Marsh campus of Liverpool John Moores University for about 2 hours.
  We will first measure their weight, height and body composition. Body composition is calculated using the 'pinch an inch' test, this doesn't hurt at all. We test in 6 places; at the top front and top back of the arm, shoulder blade, side of the waist, thigh and calf.
  Then your child will do a treadmill fitness test. This test usually lasts about 7-10 minutes but the children can stop earlier if they need to. Blood samples will be taken before this test just to check they are OK to exercise and also during the test every three minutes. Heart rate will be monitored continually. This will let us know how hard they are finding the exercise.
  Then they will fill out 3 questionnaires related to living with diabetes.

  A Laser Doppler will be used to measure the blood flow just beneath the skin. It heats a small patch of skin on the forearm slightly and then uses a laser, which you can't see or feel, to monitor the blood flow under the skin.

Please Note: All travelling expenses will be reimbursed.

What are the benefits to your child?

Your child will be given close attention while they are in the study. Monitoring their levels of fitness and physical activity will mean we can give advice on how they could improve on their lifestyle. Also, by measuring the blood flow just beneath the skin, we are able to detect any problems early on, just like the eye screening tests do.

Are there any risks?

There is a risk of hypo or hyperglycaemia when individuals with IDDM exercise but this will be the same as when the children are active at other times. We will have high energy snacks and drinks at the ready if necessary and Hypostop in the lab. The diabetes nurse will advise your child on pre-exercise snacks and glucose monitoring before they begin the study. Often children and adults feel a little apprehensive before they perform a fitness test, but your child can stop at any time if they feel uncomfortable. You are welcome to come with your child to the lab if you want.

Will the information collected be confidential?

Yes. All information collected about individual children will only be available to those involved in the study and only those involved in the study will be able to consult any records. Data will be put onto a computer but all names will be kept separate.

Where can I get more information?

Parents or children can make further enquiries at any time before or during the study to Sarah Edmunds (231 4090) or Denise Roche (231 5223) at Liverpool John Moores University or a member of your Diabetes Team.

Many thanks for taking the time to read this information.

Liverpool John Moores University

The Effects of Physical Activity and Fitness on Children with Diabetes.

Researchers: Sarah Edmunds, Denise Roche, Gareth Stratton, A.H. Wallymahmed, Dr. Didi and Sue Kerr

What's the study about?

You are being invited to take part in our research project. We are trying to find out if how fit you are and how much physical activity you do every day is linked to your blood glucose levels, how you feel about yourself and to the amount of blood that flows just under your skin.

Why is it being done?

We think exercise could be very helpful for people like yourselves with diabetes. It lets your body take up glucose just as your injections of insulin do so it may be a way to stop your diabetes causing more problems as you get older. People who do regular exercise feel healthier and happier than people who don't. We think exercise may help you to feel better about having diabetes and about your treatment.

How are children chosen to be part of this study?

Children between 9 and 15 years old who are in the Alder Hey or Ormskirk diabetes clinics will be asked to take part in the study. You do not have to take part. If you decide you would like to and later want to leave the study you can and we won't ask why. It will not change your normal treatment at the diabetes clinic. **All children taking part will have their travelling costs paid for them.**

What will I do?

1. Sarah or Denise will visit you at home and fill in a questionnaire about the physical activity you did the week before.

2. We will measure your physical activity with a heart rate monitor (which is like a watch) and also one to measure movement (the size of a calculator) for 4 days. Sarah or Denise will come to your house for about 5 minutes each morning and evening to set up the monitors and collect the information. You will be asked to keep a diary of your physical activity on these days.

3. You will visit the Exercise Science Lab at IM Marsh, which is part of Liverpool John Moores University, for about two hours to do some tests for us.

a) We will measure your height and weight. We will also use the 'pinch an inch' test to measure your body fat. We measure at the front and back of the arm, the top and bottom of the leg, the shoulder blade and at the side of the waist. This doesn't hurt.

b) The fitness test will be on a treadmill. We will let you get used to running on it first and take a couple of blood samples, just to check you are OK to exercise before we start any tests. In the test we will ask you to run for 7-10 minutes or as long as you can. Every three minutes we will take blood samples and measure your heart rate.

c) You will be asked to fill in three questionnaires which ask you how you feel about living with Diabetes and about your body.

d) We will measure how much blood is flowing just under your skin by using a laser. You can't see or feel the laser, all you will feel is a small patch of skin on your arm being heated a bit.

Will the study help me?

The information we find out will help you and children with diabetes in the future have better treatment. Finding out your fitness level will help you see where you could improve on things and how. Also, by measuring how good your blood flow is, we are able to spot any problems early on, just like eye screening tests do.

Are there any risks?

You may feel a little worried before you take the fitness test, but you can stop at any time if you want to. There is always a risk of your blood sugar becoming too low or too high when you exercise but we will have snacks and glucose drinks there for you if you need them and will check your blood glucose levels before you start. You can come with your parents if you want to.

Will the information be confidential?

Yes. All the information will be kept private, confidential and secure. Only people involved in the study will be able to look at it.

More information

If you have any questions about the study please ask, Sarah Edmunds (telephone 231 4090) or Denise Roche (telephone 231 5223) or one of your Diabetes Team.

Thank you for reading this information.

Liverpool John Moores University

CONSENT FORM (Parent or Guardian)

The psychological and physiologiacal effects of physical activity and fitness on children with insulin dependant diabetes mellitus

Consent of Parent/guardian

I/we (insert name) .... give permission for my/our child named overleaf whom I have responsibility as parent/ guardian to be included in the physical exercise and fitness study described on this form.

The purpose of the study is to investigate if there is any link between how fit a child with IDDM is, how much physical activity they do, their blood glucose control, their psychological well being and the effectiveness of their microcirculation.

The nature of the study will involve some psychological questionnaires and physiological tests namely; body composition, fitness, activity levels, blood glucose control and blood flow in the microcirculation. It may also include a physical activity programme next year.

The full study has been explained to me in the parent/guardian and patient information sheets.

I understand that my child's participation in the study is entirely voluntary and that I have the right to withdraw my child at any time without stating a reason and without prejudice to his/her treatment. I have also read the explanatory document for parents/ guardians for this study and I understand that I have the right to request further information both in relation to my/our child or to the study from the supervising doctor.

I understand that all information will be treated confidentially.

Signature of parent/guardian .... Date ....

Name of investigator (block capitals) .... Date ....

Signature of investigator ....

Liverpool John Moores University

CONSENT FORM (PARTICIPANT)

The Psychological and Physiological Effects of Physical Activity and Fitness on Children with Insulin Dependent Diabetes Mellitus.

I (insert name) .... agree to take part in the above study.

The details of the study have been fully explained to me verbally and explained in writing.

It has been explained to me that I can stop taking part in this study whenever I please and do not have to give a reason for this.

I understand I can ask for more information about the study from the research team, named on the information sheet, at any point.

Signature of participant ....

Date ....

Name of investigator (block capitals)..

Signature of investigator ....

Date ....

Appendix 5: Interview Schedule

How has taking part in STEPS 2000 affected you?

Has doing exercise regularly effected the management of your diabetes? How?

Is it easier or harder to control your blood sugars when you exercise regularly? In what way?

Have you noticed any changes during the programme?

How does having diabetes affect the exercise you do?

Does having diabetes affect how much exercise you do and what type of exercise this is? In what way?

Do you worry about your blood sugars either before, during or after you exercise?

How did you feel at the start of the programme, how do you feel now?

How do you feel about exercising with other children who have diabetes?

Is it any different to exercising in other groups? (PE at school, team sports)

Is it any better? Is it any worse?

Do you find doing exercise regularly affects how you feel about yourself? In what ways?

Does it affect how happy you feel? Do you feel any more or less happy?

If yes, is this during or after exercise or both?

Do you feel any more or less confident? Why?

About the appearance of your body? Can you explain why?

To take part in sports at school or at STEPS? Can you explain why?

With your friends? Can you explain why?

Do you feel different about any of these things now compared to before STEPS?

Do you feel any more or less stressed?

How often did you feel stressed before STEPS?

Does it change how much control you feel you have over your life?

Do you think having diabetes makes exercise any more important or any less important to how you feel about yourself? Or does it not make any difference? Why?

Has doing exercise regularly effected your friendships at all? If yes, in what way?

Have you become better friends or less good friends with anyone during STEPS?

Have you enjoyed meeting other children who have diabetes or understand what it means to have diabetes or would you prefer not to be in a special group?

How did you feel about the exercise sessions?

What things were really good about them? What things didn't you like?

How tiring did you find them?

Would you now include physical activity in your life

Appendix 6: Parent and Child Information Sheets and Consent Forms – Phase 2

Liverpool John Moores University

The Psychological and Physiological effects of Physical Activity and Fitness on Children with Insulin Dependent Diabetes Mellitus (IDDM).

A study is being undertaken by: Sarah Edmunds, Denise Roche, Gareth Stratton, A.H.Wallymahmed, Dr. Didi and Ms Sue Kerr

What's the study about?

Your child is being invited to take part in a study which will investigate whether increasing physical activity levels and fitness improves the blood glucose control, psychological health and blood flow just beneath the skin of children with diabetes.

Why do we want to do this study?

Exercise has many benefits that we already know about such as it

- controls body weight
- increases body tone
- improves mood, reduces stress and anxiety

Exercise may help individuals with diabetes even more than it does the general public by reducing how much insulin they need. Exercise is also known to improve the circulation, and lower levels of the 'bad' cholesterol. If the same happens in people with diabetes it would be a major health benefit because of their increased risk for heart disease. The psychological benefits from exercise may also be important as it may help individuals feel better about their diabetes and treatment programme. If exercise does have these positive effects then we may have found a way to stop the circulation deteriorating as your child gets older and to improve and maintain their psychological health.

How are children chosen to be part of the study?

The study will involve children between 9 and 15 years old with IDDM and attending Alder Hey, Ormskirk or Whiston Hospital Diabetes clinics. Participation in the study is entirely voluntary. If you agree to your child taking part you will be free to withdraw him/her from the study at any stage, or your child can decide to withdraw. Taking part will not affect his/her normal treatment at the Diabetes clinic.

What does taking part in the study involve?

Children who agree to take part will:

- <u>Come into the Lab</u> at IM Marsh campus of Liverpool John Moores University for about 2 hours.
  We will first <u>measure their weight, height and body composition</u>. Body composition is calculated using the 'pinch an inch' test, this doesn't hurt at all. We test in 6 places; at the top front and top back of the arm, shoulder blade, side of the waist, thigh and calf. We will then measure HbA_{1c} in the same way as in the diabetes clinic.
  Then your child will do a treadmill <u>fitness test.</u> This test usually lasts about 7-10 minutes but the children can stop earlier if they need to. Blood samples will be taken before this test to check they are OK to exercise and also during the test every three minutes. Heart rate will be monitored continually. This will let us know how hard they are finding the exercise.
  Then they will <u>fill out 3 questionnaires</u> related to living with diabetes.

A Laser Doppler will be used to measure the blood flow just beneath the skin. It heats a small patch of skin on the forearm slightly and then uses a laser, which you can't see or feel, to monitor the blood flow under the skin.

- Your child will be asked to keep a diary of their physical activity for the three days before they come to the lab.

We will need to take these measurements twice, about three months apart.

Please Note: Transport will be provided or travelling expenses reimbursed.

- Half the children will be chosen at random. If your child is selected they will be invited to take part in a physical activity programme based on a very successful and popular scheme already running in Sefton. This will run for 12 weeks, there will be two sessions a week for the first eight weeks and three sessions for the last four weeks. They will be held at (insert locations). There are separate classes for 9-12 and 13-15 year olds. Children are welcome to come to the sessions with brothers, sisters and friends. The sessions will be FREE for participants in the study and all travel costs will be reimbursed.

What are the benefits to your child?

Your child will be given close attention while they are in the study. Monitoring their levels of fitness and physical activity will mean we can give advice on how they could improve on their lifestyle. Also, by measuring the blood flow just beneath the skin, we are able to detect any problems early on, just like the eye screening tests do.

Are there any risks?

There is a risk of hypo or hyperglycaemia when individuals with IDDM exercise but this will be the same as when the children are active at other times. We will have high energy snacks and drinks at the ready if necessary in the lab and during exercise sessions. The diabetes nurse will advise your child on pre-exercise snacks and glucose monitoring before they begin the study. Often children and adults feel a little apprehensive before they perform a fitness test, but your child can stop at any time if they feel uncomfortable. You are welcome to come with your child to the lab if you want.

Will the information collected be confidential?

Yes. All information collected about individual children will only be available to those involved in the study and only those involved in the study will be able to consult any records. Data will be put onto a computer but all names will be kept separate.

Where can I get more information?

Parents or children can make further enquiries at any time before or during the study to Sarah Edmunds (231 4090) or Denise Roche (231 5223) at Liverpool John Moores University or a member of your Diabetes Team.

Many thanks for taking the time to read this information.

Liverpool John Moores University

The Effects of Physical Activity and Fitness on Children with Diabetes.

Researchers: Sarah Edmunds, Denise Roche, Gareth Stratton, A.H. Wallymahmed, Dr. Didi and Sue Kerr

What's the study about?

You are being invited to take part in our research project. We are trying to find out if doing more physical activity and becoming fitter improves your blood glucose levels, how you feel about yourself and the amount of blood that flows just under your skin.

Why is it being done?

We think exercise could be very helpful for people like yourselves with diabetes. It lets your body take up glucose just as your injections of insulin do so it may be a way to stop your diabetes causing more problems as you get older. People who do regular exercise feel healthier and happier than people who don't. We think exercise may help you to feel better about having diabetes and about your treatment.

How are children chosen to be part of this study?

Children between 9 and 15 years old who are in the Alder Hey, Ormskirk or Whiston diabetes clinics will be asked to take part in the study. You do not have to take part. If you decide you would like to and later want to leave the study you can and we won't ask why. It will not change your normal treatment at the diabetes clinic. **All children taking part will have their travelling costs paid for them.**

What will I do?

You will visit the Exercise Science Lab at IM Marsh, which is part of Liverpool John Moores University, for about two hours to do some tests for us.

1. We will measure your height and weight. We will also use the 'pinch an inch' test to measure your body fat. We measure at the front and back of the arm, the top and bottom of the leg, the shoulder blade and at the side of the waist. This doesn't hurt. We will measure your HbA_{1c} like the diabetes nurse does in the clinic.
2. The fitness test will be on a treadmill. We will let you get used to running on it first and take a couple of blood samples, just to check you are OK to exercise before we start any tests. In the test we will ask you to run for 7-10 minutes or as long as you can. Every three minutes we will take blood samples and measure your heart rate.
3. You will be asked to fill in three questionnaires which ask you how you feel about living with Diabetes and about your body.
4. We will measure how much blood is flowing just under your skin by using a laser. You can't see or feel the laser, all you will feel is a small patch of skin on your arm being heated a bit.
5. You will be asked to keep a diary of what activity you do for the three days before you visit the lab.

we will ask you do these tests for us TWICE, once in March and again in July.

Half the children in the study will be picked randomly (This is like taking names out of a hat). If you are chosen you will be asked to take part in an activity programme called Kids EXCEL if you are between 9 and 12 years old or Youth EXCEL of you are between 13 and 15 years old. The sessions will be fun and give you a chance to be active. You can come with your friends or your brothers and sisters. There will be two or three sessions a week for twelve weeks with awards and certificates to work towards. The sessions wil be free and we will pay for you to get to them.

Will the study help me?

The information we find out will help you and children with diabetes in the future have better treatment. Finding out your fitness level will help you see where you could improve on things and how. Also, by measuring how good your blood flow is, we are able to spot any problems early on, just like eye screening tests do.

Are there any risks?

You may feel a little worried before you take the fitness test, but you can stop at any time if you want to. There is always a risk of your blood sugar becoming too low or too high when you exercise but we will have snacks and glucose drinks there for you if you need them and will check your blood glucose levels before you start. You can come with your parents if you want to.

Will the information be confidential?

Yes. All the information will be kept private, confidential and secure. Only people involved in the study will be able to look at it.

More information

If you have any questions about the study please ask, Sarah Edmunds (telephone 231 4090) or Denise Roche (telephone 231 5223) or one of your Diabetes Team.

Thank you for reading this information.

Liverpool John Moores University

CONSENT FORM (Parent or Guardian)

The psychological and physiologiacal effects of physical activity and fitness on children with insulin dependant diabetes mellitus

Consent of Parent/guardian

I/we (insert name) .... give permission for my/our child named overleaf whom I have responsibility as parent/ guardian to be included in the physical exercise and fitness study described on this form.

The purpose of the study is to investigate if increasing the amount of physical activity and the fitness levels of children with IDDM improves their blood glucose control, psychological well being and the effectiveness of their microcirculation.

The nature of the study will involve some psychological questionnaires and physiological tests namely; body composition, fitness, activity levels, blood glucose control and blood flow in the microcirculation. It may also involve taking part in a 12 week physical activity programme.

The full study has been explained to me in the parent/guardian and patient information sheets.

I understand that my child's participation in the study is entirely voluntary and that I have the right to withdraw my child at any time without stating a reason and without prejudice to his/her treatment. I have also read the explanatory document for parents/ guardians for this study and I understand that I have the right to request further information both in relation to my/our child or to the study from the supervising doctor.

I understand that all information will be treated confidentially.

Signature of parent/guardian .... Date ....

Name of investigator (block capitals) .... Date ....

Signature of investigator ....

Liverpool John Moores University

CONSENT FORM (PARTICIPANT)

The Psychological and Physiological Effects of Physical Activity and Fitness on Children with Insulin Dependent Diabetes Mellitus.

I (insert name) .... agree to take part in the above study.

The details of the study have been fully explained to me verbally and explained in writing.

It has been explained to me that I can stop taking part in this study whenever I please and do not have to give a reason for this.

I understand I can ask for more information about the study from the research team, named on the information sheet, at any point.

Signature of participant ....

Date ....

Name of investigator (block capitals)...

Signature of investigator ....

Date ....

Appendix 7: Comparison of those children who completed the study with those who dropped out

Experimental group

Completed study = Attended >14 sessions
Dropped out = Attended <= 14 sessions

Variable	Completed study			Dropped out			t
	Mean	95% CI	N	Mean	95% CI	N	
Global self worth	3.35	3.01-3.68	14	3.15	2.76 – 3.54	13	0.81
Physical self worth	2.87	2.45-3.29	13	2.93	2.47 – 3.39	12	0.21
Sport competence	2.52	2.10 – 2.95	14	3.09	2.76 – 3.42	13	-2.25*
Condition competence	2.71	2.27 – 3.17	13	3.13	2.79 – 3.47	13	-1.59
Attractive body competence	2.53	1.95 – 3.10	13	2.55	2.10 – 3.01	13	-0.08
Strength competence	2.75	2.38 – 3.12	14	2.97	2.68 – 3.26	12	-0.98
Sport competence importance	1.96	1.53 – 2.39	14	2.38	1.90 – 2.86	13	-1.42
Condition competence importance	2.50	2.22 – 2.78	13	2.73	2.28 – 3.19	13	-0.95
Attractive body importance	2.75	2.30 – 3.20	14	2.58	2.01 – 3.14	13	0.53
Strength competence importance	1.96	1.75 – 2.18	14	2.31	1.89 – 2.73	13	-1.63
SED total	142.27	125.86 – 158.69	11	143.22	120.74 – 165.70	9	-0.08
SED diabetes	95.55	82.69 – 108.40	11	98.10	83.99 – 112.21	10	-0.30
SED medical	18.50	16.06 – 20.94	14	20.50	16.90 – 24.10	12	-1.03
SED general	26.00	22.71 – 29.29	14	27.83	24.23 – 31.44	12	-0.82

Variable	Completed study			Dropped out			t
	Mean	95% CI	N	Mean	95% CI	N	
DQOLY satisfaction	71.08	65.78 – 76.38	13	66.33	59.45 – 73.22	12	1.21
DQOLY impact	44.33	39.53 – 49.14	12	50.00	42.81 – 57.19	12	-1.44
DQOLY worry	18.14	12.31 – 23.98	14	19.00	15.15 – 22.85	13	-0.26
DQOLY health	3.31	3.02 – 3.60	13	3.31	3.02 – 3.60	13	
HbA_{1c}	9.54	8.79 – 10.29	14	9.55	8.36 – 10.74	13	-0.02
BMI	20.38	18.86 – 21.90	14	21.31	19.41 – 23.22	13	-0.84
Sum of 5 skinfolds	61.59	49.42 – 73.77	14	60.09	48.24 – 71.95	13	0.19
Peak VO_2	30.23	26.56 – 33.89	14	38.70	32.05 – 45.34	12	-2.54*
Moderate physical activity	32.30	14.90 – 49.69	14	29.34	10.56 – 48.12	13	0.25
Hard physical activity	17.60	10.05 – 25.15	14	30.49	4.71 – 56.28	13	-1.08
Very hard physical activity	8.42	-1.16 – 17.99	14	3.79	-2.31 – 9.89	13	0.87
Total physical activity	58.32	37.10 – 79.50	14	63.63	39.56 – 87.69	13	-0.36

* $p < 0.05$

Control group

Completed study = attended lab at time 2
Dropped out = did not attend lab at time 2

Variable	Completed study			Dropped out			t
	Mean	95% CI	N	Mean	95% CI	N	
Global self worth	3.38	3.39 – 4.04	7	3.40	2.90 – 3.90	5	-0.06
Physical self worth	3.12	2.79 – 3.54	7	2.73	2.19 – 3.27	5	1.69
Sport competence	3.22	2.45 – 4.5	6	2.87	2.50 – 3.24	5	1.63
Condition competence	3.24	2.50 – 4.08	7	3.07	2.39 – 3.75	5	0.56
Attractive body competence	2.81	2.29 – 3.21	7	2.60	2.17 – 3.03	5	0.86
Strength competence	2.95	2.17 – 4.16	7	2.90	2.29 – 3.51	5	0.16
Sport competence importance	2.75	1.62 – 3.63	6	2.60	1.58 – 3.62	5	0.30
Condition competence importance	3.00	1.52 – 4.23	6	2.50	1.34 – 3.66	5	1.01
Attractive body importance	2.64	1.52 – 4.23	7	2.30	1.59 – 3.01	5	0.65
Strength competence importance	2.57	1.23 – 4.27	7	2.60	1.92 – 3.28	5	-0.07
SED total	148.29	129.31 – 167.26	7	146.40	126.68 – 166.12	5	0.17
SED diabetes	101.71	89.21 – 114.22	7	98.80	81.70 – 115.90	5	0.37
SED medical	19.86	14.72 – 24.99	7	20.60	14.67 – 26.53	5	-0.24
SED general	26.71	21.49 – 31.94	7	27.00	20.92 – 33.08	5	-0.09

Variable	Completed study			Dropped out			t
	Mean	95% CI	N	Mean	95% CI	N	
DQOLY satisfaction	70.67	62.77 – 78.57	6	69.40	62.51 – 76.29	5	0.31
DQOLY impact	47.14	42.07 – 52.22	7	44.60	33.40 – 55.80	5	0.61
DQOLY worry	21.17	7.69 – 34.65	6	17.00	11.18 – 22.82	5	0.68
DQOLY health	3.17	2.16 – 4.24	6	3.40	2.72 – 4.08	5	
HbA_{1c}	9.11	7.72 – 10.51	7	8.82	6.96 – 10.68	5	0.34
BMI	20.11	18.26 – 21.96	7	19.85	18.08 – 21.63	5	0.24
Sum of 5 skinfolds	55.93	30.03 – 81.83	7	57.20	30.51 – 83.89	5	-0.09
Peak VO_2	46.10	39.49 – 52.72	7	37.95	28.16 – 47.74	5	1.87
Moderate physical activity	21.12	9.37 – 32.87	7	55.29	30.44 – 80.13	5	-3.64**
Hard physical activity	30.92	3.89 – 57.94	7	10.71	0.94 – 20.49	5	1.49
Very hard physical activity	17.45	7.45 – 27.45	7	13.71	-9.37 – 36.80	5	0.44
Total physical activity	69.49	37.58 – 101.40	7	79.71	52.23 – 107.19	5	-0.58

** $p< 0.01$

Appendix 8: Mean number of minutes above heart rate thresholds at each exercise centre

Mean number of minutes children spent with heart rates above 50, 60 and 75% MHRR at each of the exercise centres

Location	% of MHRR	N	Min	Max	Mean	Std. Deviation
I M Marsh	50	16	8	47	27.94	12.09
	60	16	5	47	22.38	11.96
	75	16	2	31	13.25	8.07
Chesterfield	50	9	11	60	34.00	15.17
	60	9	6	46	24.89	14.38
	75	9	0	31	14.22	11.41
Ormskirk	50	1	33	33	33.00	.
	60	1	27	27	27.00	.
	75	1	19	19	19.00	.

Appendix 9: Data tables for variables where there was no significant change following the intervention

Two way ANOVA calculation for Global self worth

Source	Type III sum of squares	df	Mean square	F	Significance
Time	0.119	1	0.119	1.854	0.189
Time * Group	2.976E-03	1	2.976E-03	0.046	0.832
Error (time)	1.223	19	6.438E-02		
Intercept	408.175	1	408.175	741.334	0.000
Group	2.679E-02	1	2.679E-02	0.049	0.828
Error (group)	10.461	19	0.551		

One way ANCOVA calculation for Sport competence

Tests of Between-Subjects Effects
Dependent Variable: sport competence at time 2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	4.00	2	2.00	10.39	0.001	0.57	20.78	0.97
Intercept	0.97	1	0.97	5.02	0.04	0.24	5.02	0.56
Sport competence at time 1	3.67	1	3.67	19.08	0.000	0.54	19.08	0.98
Group	0.17	1	0.17	0.86	0.37	0.05	0.86	0.14
Error	3.08	16	0.19					
Total	175.08	19						
Corrected Total	7.07	18						

a Computed using alpha = .05
b R Squared = .565 (Adjusted R Squared = .511)

Two way ANOVA calculation for Sport competence importance

Source	Type III sum of squares	df	Mean square	F	Significance
Time	0.453	1	0.453	1.232	0.282
Time * Group	0.453	1	0.453	1.232	0.282
Error (time)	6.616	18	0.368		
Intercept	205.524	1	205.524	327.539	0.000
Group	2.574	1	2.574	4.102	0.058
Error (group)	11.295	18	0.627		

Two way ANOVA calculation for Attractive body importance

Source	Type III sum of squares	df	Mean square	F	Significance
Time	2.679 E-02	1	2.679 E-02	0.119	0.734
Time * Group	2.679 E-02	1	2.679 E-02	0.119	0.734
Error (time)	4.295	19	0.226		
Intercept	276.860	1	276.860	276.730	0.000
Group	0.241	1	0.241	0.241	0.629
Error (group)	19.009	19	1.000		

Two way ANOVA calculations for Total self efficacy

Source	Type III sum of squares	df	Mean square	F	Significance
Time	236.60	1	236.60	2.67	0.125
Time * Group	36.85	1	36.85	0.42	0.530
Error (time)	1242.62	14	88.76		
Intercept	622440.05	1	622440.05	508.28	0.000
Group	125.05	1	125.05	0.102	0.754
Error (group)	14	14	1224.60		

Two way ANOVA calculation for Medical self efficacy

Source	Type III sum of squares	df	Mean square	F	Significance
Time	5.762	1	5.762	1.036	0.322
Time * Group	1.190	1	1.190	0.214	0.649
Error (time)	105.714	19	5.564		
Intercept	14300.190	1	14300.190	355.036	0.000
Group	9.333	1	9.333	0.232	0.636
Error (group)	765.286	19	40.278		

Two way ANOVA calculations for General self efficacy

Source	Type III sum of squares	df	Mean square	F	Significance
Time	18.900	1	18.900	1.655	0.215
Time * Group	8.400	1	8.400	0.736	0.402
Error (time)	205.500	18	11.417		
Intercept	25564.233	1	25564.233	500.079	0.000
Group	3.733	1	3.733	0.073	0.790
Error (group)	920.167	18	51.120		

Two way ANOVA calculation for Satisfaction with life sub-scale of DQOLY

Source	Type III sum of squares	df	Mean square	F	Significance
Time	3.720	1	3.720	0.106	0.749
Time * Group	5.614	1	5.614	0.160	0.694
Error (time)	597.596	17	35.153		
Intercept	166530.057	1	166530.057	1238.187	0.000
Group	1.425	1	1.425	0.011	0.919
Error (group)	2286.417	17	134.495		

Two way ANOVA calculation for Diabetes impact sub-scale of DQOLY

Source	Type III sum of squares	df	Mean square	F	Significance
Time	214.782	1	214.782	3.589	0.075
Time * Group	4.511E-02	1	4.511E-02	0.001	0.978
Error (time)	1017.429	17	59.849		
Intercept	82177.449	1	82177.449	856.665	0.000
Group	66.291	1	66.291	0.691	0.417
Error (group)	1630.762	17	95.927		

One way ANCOVA calculation for peak VO_2

Tests of Between-Subjects Effects
Dependent Variable: Peak VO_2 at time 2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	586.19	2	293.10	7.37	0.005	0.46	14.74	0.890
Intercept	108.04	1	108.04	2.72	0.12	0.14	2.72	0.34
Peak VO_2 at time 1	357.26	1	357.26	8.98	0.01	0.35	8.98	0.81
Group	24.41	1	24.41	0.61	0.44	0.04	0.61	0.12
Error	676.23	17	39.78					
Total	36251.54	20						
Corrected Total	1262.42	19						

a Computed using alpha = .05
b R Squared = .464 (Adjusted R Squared = .401)

Paired samples t tests for self reported physical activity (PA) in the control group at times 1 and 2

	Paired Differences mean	Std. Dev.	95% C. I. of the Difference	t	df	p
Moderate PA: time 1 - time 2	-1.53	13.92	-14.41 - 11.34	- 0.291	6	0.781
Hard PA: time 1 - time 2	1.53	28.34	-24.68 - 27.74	0.143	6	0.891
Very hard PA: time 1- time 2	10.71	14.16	-2.38 - 23.81	2.002	6	0.092
Total PA: time 1 – time 2	10.71	26.36	-13.67 - 35.09	1.075	6	0.324

APPENDIX NOT COPIED

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