An Investigation of Eating and Weight Concerns as Predictors of Adherence and Glycaemic Control in Adolescents with Type-1 Diabetes.

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DECLARATION

"I declare that I am the sole author of this thesis and that the work contained herein is my own. This thesis, or any part of it, has not been submitted for any other degree of professional qualification".

Signed.

Shona Murphy

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ABSTRACT

There is evidence to suggest that the development of eating disorders is of particular concern in type-1 diabetes. While there is disagreement as to whether the prevalence of eating disorders is higher in type-1 diabetes or not, the presence of such symptoms appears to have a negative affect on glycaemic control and adherence. The aim of this study was therefore to examine the prevalence of eating and weight concerns in a local population of adolescents with type-1 diabetes, compared to adolescents without type-1 diabetes. This study also aimed to examine whether eating and weight concerns could predict adherence and glycaemic control in adolescents with type-1 diabetes and to investigate the relationships of body mass index (BMI), insulin dose and insulin regimen with eating and weight concerns. The Eating Disorders Examination Questionnaire was used to examine the eating and weight concerns of 12-18 year old adolescents with and without type-1 diabetes, using a cross-sectional design. An adherence questionnaire was also administered to the diabetes group and information regarding HbA1c, BMI and prescribed insulin regimens was obtained from participants' medical files. No significant differences in eating and weight concerns existed between the two groups, although BMI was significantly higher in the diabetes group. Eating and weight concerns were significantly predicted by BMI in the diabetes group and significantly predicted level of adherence. No associations between eating and weight concerns with HbA1c, insulin dose or insulin regimen were found. Reports of eating and weight concerns were low in this sample and they did not appear to impact on glycaemic control. However, more eating and weight concerns were associated with poorer adherence. Higher BMI appeared to be an important factor in the occurrence of these concerns in both males and females. These results are discussed in terms of their potential clinical implications. The limitations of this study, along with suggestions for future areas of research, are also identified.

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INTRODUCTION

1.1 GENERAL INTRODUCTION

Type-1 diabetes is a chronic disease resulting in insulin deficiency. While it can not be cured, it can be managed with a multi-component treatment regimen. However, the daily management of diabetes can be burdensome and as the focus is on self-management, issues of adherence are important. A number of psychosocial factors have been shown to be important to consider in diabetes, due to the impact this condition can have on a person's quality of life and due to the complexities of the treatment regimen.

In this introduction, an overview of diabetes will be given, before type-1 diabetes, its treatment and its management are discussed in more detail. The issues surrounding adherence and other psychological aspects of type-1 diabetes will be addressed, both in general and specifically relating to adolescents. The introduction will then focus on the combination of eating disorder psychopathology with type-1 diabetes. The literature for this review was initially obtained through numerous search-term strings on Psychlit, Medline, Ovid, Cochrane library, British Nursing Index and Pubmed databases, with further articles being obtained through the exploration of various citations.

1.2 DIABETES

1.2.1 Introduction to Diabetes

Diabetes Mellitus is a chronic condition which is characterised by insulin deficiency, insulin resistance or both, leading to high blood glucose levels (hyperglycaemia). Although it can be managed through a complex treatment regimen, the late physical complications of diabetes result in a reduced life expectancy and major health costs. It has been estimated that in 1995, the world-wide prevalence of diabetes in adults was 135 million and this is predicted to increase to 300 million by the year 2025 (King, Aubert and Herman, 1998). Rangasami, Greenwood, McSporran, Smail, Patterson and Waugh (1997) also reported an increase in the prevalence of diabetes in young people under the age of 16 years and estimated an annual incidence rate of 25 cases per 100000 people.

1.2.2 Types of Diabetes

Diabetes can be primary or secondary, although secondary diabetes only accounts for about 1 – 2 % of new cases (Gale and Anderson, 2002). Primary diabetes is divided into type-1 (insulin-dependent diabetes) and type-2 (non-insulin-dependent diabetes). Type-1 diabetes is prominent in childhood, reaching peak incidence around puberty and appears to be caused by the autoimmune destruction of pancreatic cells (Watkins, 2003), resulting in little or no insulin production. Type-2 diabetes arises either due to diminished insulin secretion or increased resistance to the action of insulin (Watkins, 2003) and obesity is present in 80% of individuals

with type-2 diabetes (Gale and Anderson, 2002). Type-2 diabetes tends to have a much later onset than type-1 diabetes, although its prevalence in childhood and adolescence is increasing (Fagot-Campagna, Narayan and Imperatore, 2001).

Secondary diabetes can occur as a result of another chronic illness such as cystic fibrosis. It is therefore distinct from type-1 and type-2 diabetes and requires specific consideration for treatment (Cystic Fibrosis Trust and Solvay Healthcare Ltd, 2000).

Due to clinical and epidemiological distinctions between the different types of diabetes, it is important to treat them separately. This study is therefore only concerned with type-1 diabetes, which will be the focus of the following review.

1.2.3 Pathophysiology of Type-1 Diabetes

Insulin is a hormone produced by the beta-cells of the pancreatic islets of Langerhans and it acts to accelerate the conversion of glucose from the blood into energy stored as glycogen. Normal glucose metabolism is regulated by insulin so that blood glucose levels are closely regulated in the range of 3.5 to 8.0 mmol/L. Following the ingestion of carbohydrate, the level of glucose in the blood rises, leading to a corresponding rapid increase in the release of insulin. This acts to stimulate both the transportation of glucose and its storage (as glycogen) in fat and muscles (Epstein, 1999). Blood glucose levels subsequently fall again and as a result, the body either needs to ingest more carbohydrate, or convert glycogen back in to glucose, mainly through the action of the hormone glucagon. Although insulin levels are low in such a fasting

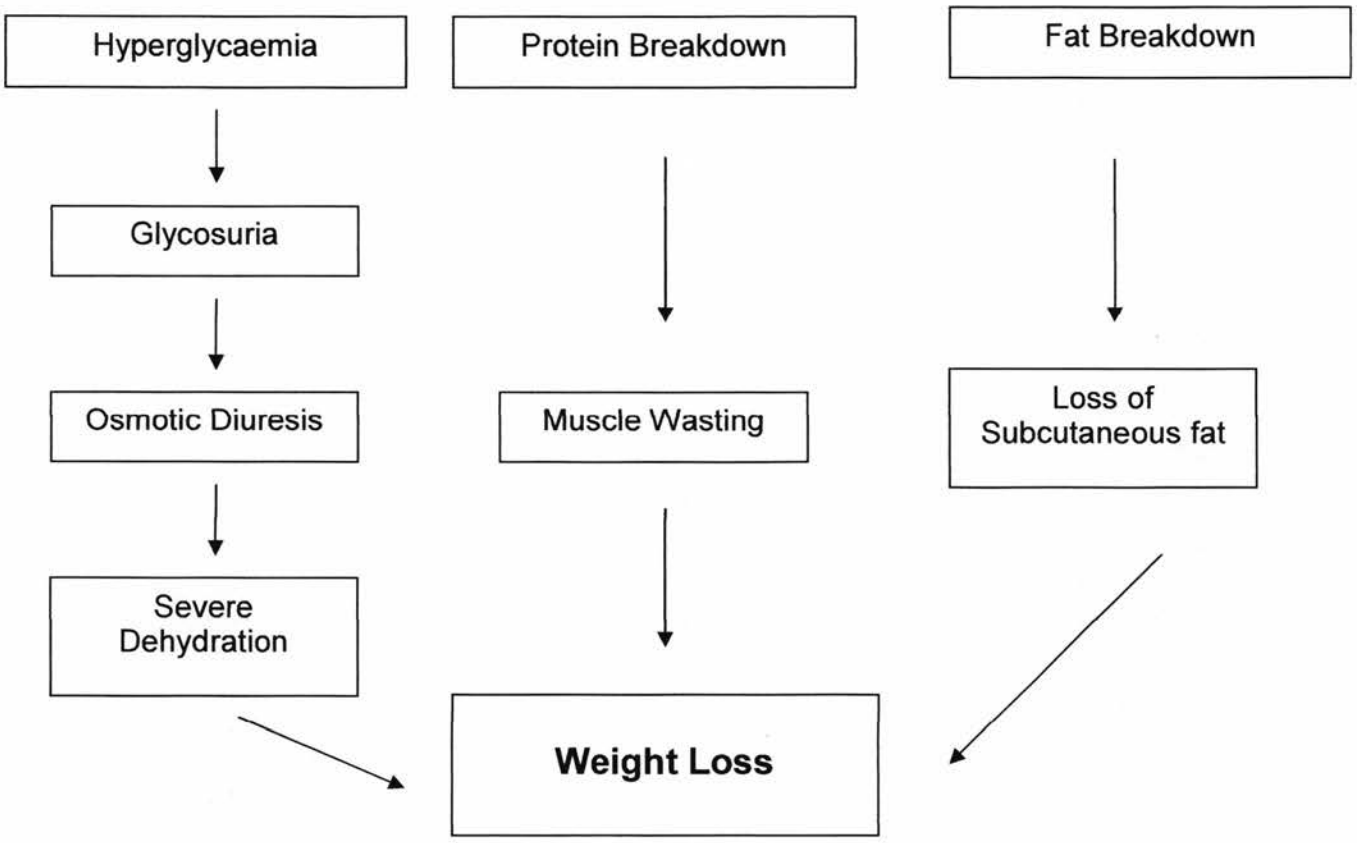
state, insulin continues to modulate the production of glucose from the liver and the breakdown of glycogen. There is therefore a constant level of insulin production by the pancreas in normal metabolism, which peaks with the ingestion of carbohydrate and troughs during fasting.

The lack of insulin production in type-1 diabetes results in impaired glucose homeostasis and hyperglycaemia. In addition to the lack of insulin, it appears that plasma glucagon levels are maintained (or may even increase) in the majority of people with type-1 diabetes (Vander, Sherman and Luciano, 1994). As glucagon acts to convert glycogen stored in cells back into glucose in the blood, this further adds to the hyperglycaemia found in diabetes.

1.2.4 Clinical Symptoms of Type-1 Diabetes

Young people usually present with a two to six week history of an inter-relating triad of symptoms; polyuria (increased urination), polydipsia (increased thirst) and weight loss (Gale and Anderson, 2002). Due to the high levels of glucose in the blood and the inability of the body to store glucose for energy, the excess glucose must be excreted from the body in urine, leading to glycosuria (high urine sugar). As a result, osmotic diuresis takes place, explaining the increase in urination that is found. As a consequence of the extra fluids lost in urine, polydipsia and weight loss also occur. In addition to the loss of fluid, the body is unable to use glucose from carbohydrates for energy and instead, protein and fat stores must be broken down. The different pathways to weight loss in undiagnosed type-1 diabetes are shown in Figure 1.

Figure 1: The Pathways to Weight Loss in Type-1 Diabetes



1.2.5 Treatment of Type-1 Diabetes

There are three main parts to the treatment regimen for type-1 diabetes; exogenous insulin therapy, diet and exercise. Each part contributes to the overall aim of treatment, which is to avoid both high and low levels of blood glucose by keeping levels as near to normal as possible (usually within the range of 4-10 mmol/L). The outcome of treatment is therefore dependent

on self-care behaviour (Mollem, Snoek and Heine, 1996) meaning that the specialist diabetes teams have an important role in patient education and supportive community care.

1.2.5.1 Insulin Therapy

Due to the lack of endogenous insulin production, insulin must be replaced by subcutaneous insulin injections. A number of different insulin preparations and regimens exist and these must be tailored to the individuals' needs and lifestyle (Watkins, 2003).

1.2.5.1a Insulin Regimens

There are three main types of insulin preparation; short-acting insulins, intermediate-acting insulins and long-acting insulins (British National Formulary, 2005). Short-acting insulins have a relatively rapid onset and short duration of action. They include soluble insulin, which begins to work after 30 to 60 minutes and has an overall duration of up to 8 hours. However, this can mean that the effect persists for too long after meals, leading to a risk of hypoglycaemia. Newer human insulin analogues (Insulin Lispro and Insulin Aspart) have a much faster onset and shorter duration of action and overcome this difficulty. They can also be administered directly before meals whereas soluble insulins must be taken in advance of eating to allow for their longer time of onset. Intermediate-acting insulins can be mixed with short-acting preparations, in order to sustain insulin concentration in the blood over a longer period of time. Long-acting insulins have a delayed onset of action and can continue to act for up to 35 hours. Intermediate- or long-acting insulins are particularly used before bedtime to ensure

that night time insulin requirements are met. The exact actions of different types of insulin are dependent on the patient however (British National Formulary, 2005) and so regimens must be considered on an individual basis. Examples of the most common types of insulin regimen are given in Table 1. Intensive Insulin Therapy (IIT: four injections a day or use of an insulin pump) is considered to provide tighter blood glucose control whilst also allowing patients greater flexibility in terms of the timing of meals and the amount of food eaten (Watkins, 2003).

Table 1: Examples of Types of Insulin Regimens for Type-1 Diabetes.

	Number of Insulin Injections Per Day		
	Two	**Three**	**Four**
Breakfast	Mixed soluble and intermediate-acting insulin before meal	Mixed soluble and intermediate-acting insulin before meal	Insulin analogue with meal
Lunch			Insulin analogue with meal
Dinner	Mixed soluble and intermediate-acting insulin before meal	Soluble insulin before meal	Insulin analogue with meal
Bedtime		Intermediate- or long-acting insulin before bedtime	Intermediate- or long-acting insulin before bedtime

1.2.5.1b Replicating Normal Insulin Action

Ideal glycaemic control is usually impossible to achieve because insulin treatment can not reproduce normal insulin production (i.e. a constant baseline of insulin production with a sharp increase following meals). This is due to a number of physiological reasons (Gale and

Anderson, 2002). Firstly, insulin normally has a very small circulation cycle from the pancreas to the liver and so insulin concentration in the liver is high. However, when insulin is injected subcutaneously, it is circulated systemically leading to lower insulin concentrations in the liver than required. Furthermore, the time taken for subcutaneous insulin to reach peak plasma levels is too slow and the absorption rate is variable, especially with longer-acting preparations. Injected insulin also peaks and troughs without providing the baseline concentration found in normal insulin production. This latter difficulty can be overcome with a 'continuous subcutaneous insulin infusion' device (or insulin pump). This is a small device which can be strapped around the waist and delivers a constant basal dose of insulin through a needle inserted in subcutaneous tissue. The patient can then administer additional doses through the pump at mealtimes, as would occur in other IIT regimens. This method of insulin administration can be particularly useful in trying to avoid night time difficulties in control. However, skin infections can occur at the needle site, the device can be inconvenient and if the flow of insulin is broken, the patient has no additional insulin to inject as required.

1.2.5.1c Blood Glucose Monitoring

In order to try to match exogenous insulin as closely as possible to the body's requirements, it is important for patients to regularly check their blood glucose to allow them to adjust their insulin dose accordingly. This can be done by testing finger-prick blood samples using a home monitoring blood glucose meter. Patients should then try to keep a record of their results to allow any patterns of peaks and troughs to be identified and resolved. It is particularly

important for patients to closely monitor their blood glucose levels during deviations from their normal routine, such as when doing extra exercise or when unwell.

1.2.5.1d Additional Consideration with Insulin Therapy

In addition to the type and function of insulin, a number of other factors have to be considered. The rate of insulin absorption varies with local subcutaneous blood flow, meaning that the site of insulin injection is also important. For example, absorption occurs quickly from the abdomen, but is slowest from the thigh. Furthermore, absorption can be affected by factors such as exercise, local massage or high temperatures. The injection site must also be regularly alternated, to prevent the enlargement of fat tissue locally, which would result in a lumpy appearance on the skin and would hinder insulin absorption.

Also of importance is the consideration that insulin therapy leads to weight gain. Not only does insulin increase feelings of hunger, but when circulated systemically (i.e. when injected) it appears to trigger the formation of adipose (fat) tissue. Weight gain has also been specifically acknowledged as a disadvantage to intensive insulin regimens (DCCT Research Group, 1993).

1.2.5.2 Diet

The recommended diet for someone with diabetes is the same as that considered healthy for the normal population. However some important factors must be considered. Carbohydrate intake

should account for approximately 50-55% of calories and should consist of complex carbohydrates rather than simple sugars. This is because complex carbohydrates are absorbed more slowly and gradually, thereby avoiding the sharp increases in blood glucose levels which would occur with refined sugars. The extent to which foods raise blood glucose levels after eating is described as the glycaemic index (Rendell, 2000). Foods with a low glycaemic index, such as complex carbohydrates, produce a smaller rise in blood glucose following ingestion and are therefore recommended in diabetes. It has also been suggested that a high fibre diet in combination with low glycaemic index foods is of additional benefit in lowering postprandial hyperglycaemia (Rendell, 2000).

Patients are usually advised to eat three meals and three snacks a day, which help to buffer the effects of the insulin taken. On many insulin regimens it is important to try to eat the same amount at the same time each day, in order to balance food intake with insulin administration. However with IIT, more flexibility is possible as the amount of insulin taken can be matched to what is being eaten. Alcohol intake must also be carefully considered with respect to insulin requirements and alcoholic binges should be avoided due to the risk of hypoglycaemia.

1.2.5.3 Exercise

Once again, the exercise regimen in diabetes is in line with recommendations for the normal population. Exercise increases glucose transportation within skeletal muscle and therefore has a therapeutic effect on glycaemic control (Shepherd and Kahn, 1999). However, individuals with type-1 diabetes must carefully consider their participation in physical activities. In order

to prevent hypoglycaemia, they must ensure that they increase their carbohydrate intake to counter-balance any energy expended.

1.2.6 Acute Complications in Type-1 Diabetes

1.2.6.1 Diabetic Ketoacidosis (DKA)

Ketoacidosis is associated with insulin deficiency and prolonged hyperglycaemia (Gale and Anderson, 2002). It can occur in previously undiagnosed diabetes, when insulin treatment is interrupted or during an intercurrent illness, whereby blood glucose levels rise. As described, hyperglycaemia leads to osmotic diuresis, loss of fluids and electrolytes and dehydration. When this is prolonged, rapid breakdown of fat molecules with a subsequent increase in circulating fatty acids occurs. These fatty acids are eventually broken down into ketone bodies, which accumulate to produce a state of metabolic acidosis. This can result in vomiting, leading to a further loss of fluids and electrolytes and excess ketones are expelled in the urine. In addition to the features of undiagnosed diabetes, the symptoms of DKA include progressive dehydration, hyperventilation, nausea and vomiting and often, confusion and coma. DKA is therefore considered a medical emergency and if left untreated is invariably fatal.

1.2.6.2 Hypoglycaemia

Hypoglycaemia is the most common complication associated with insulin therapy and occurs when blood glucose levels fall below 3 mmol/L (Gale and Anderson, 2002). It is caused by

an imbalance between the amount of insulin administered, dietary intake and activity. It can result from too much insulin, irregular eating, unusual exertion or alcohol excess. Hypoglycaemia can develop over a few minutes and the symptoms include sweating, tremor, confusion and irritability. It is therefore important that the warning signs can be recognised to allow for rapid treatment. Mild hypoglycaemia can be easily treated with rapidly absorbed carbohydrate such as a sugary drink or sweets. Severe hypoglycaemia can lead to coma and may require intravenous glucose or intramuscular glucagon.

Over time, the occurrence of the warning signs of hypoglycaemia can decline, leaving patients more at risk of progressing further into hypoglycaemia. With recurrent hypoglycaemia, a hypoglycaemic unawareness can develop in which the body's ability to counter-regulate glucose levels is impaired. Therefore, hypoglycaemia can be a cause of anxiety for patients with type-1 diabetes and their families. Furthermore, attempts to avoid hypoglycaemia may lead to an increase in the amount of food eaten and subsequent weight gain. IIT has also been found to increase the risk of hypoglycaemia (DCCT Research Group, 1993).

Nocturnal glycaemic control can be particularly difficult to manage with insulin therapy. Insulin requirements initially fall during the night, but then increase again in the early hours of the morning, just as injected insulin levels would be falling. However, if extra insulin is administered before bed in order to combat the resulting high blood glucose levels, hypoglycaemia can occur. It is therefore important to ensure that a bedtime snack is taken and that the insulin regimen is reviewed.

1.2.7 Chronic Complications in Type-1 Diabetes

1.2.7.1 Macrovascular Complications

The major arteries are affected in diabetes leading to an increase in the risk of atherosclerosis and peripheral vascular disease. People with diabetes therefore have a higher risk of stroke, coronary artery disease and myocardial infarction. This risk is cumulative with other risk factors for atherosclerosis such as smoking. Participation in high-risk behaviours must therefore be carefully considered in diabetes.

1.2.7.2 Microvascular Complications

Microvascular complications, whereby small blood vessels throughout the body become damaged, are specific to diabetes (Gale and Anderson, 2002) and particularly affect the eyes, kidney and nerves.

1.2.7.2a Retinopathy

Diabetes can affect the thickness and permeability of the capillaries of the eyes, leading to diabetic retinopathy (Gale and Anderson, 2002). Almost all patients with type-1 diabetes will develop some degree of retinopathy after 20 years of being diagnosed (Watkins, 2003). In the UK, 5% of people have become blind as a result of diabetic retinopathy (Gale and Anderson, 2002).

1.2.7.2b Nephropathy

As a result of increased blood glucose levels at diabetes onset, glomerular filtration rate is affected leading to changes in kidney function. While these initial changes are reversible (Watkins, 2003), diabetic nephropathy can affect 25-35% of patients after 15-25 years of diagnosis (Gale and Anderson, 2002). Although the progression of nephropathy can lead to end-stage renal failure, this course can be reversed with treatment.

1.2.7.2c Neuropathy

Three main types of neuropathy occur in diabetes as a result of microvascular nerve damage. Mononeuropathies and acute painful neuropathies can occur at any time, are reversible and tend to occur more frequently in type-2 diabetes. In contrast, polyneuropathy, which damages peripheral nerves and the autonomic system, is progressive and often associated with other long-term diabetic complications. These neuropathies can lead to a loss of sensation, especially in the feet, and symptoms such as diarrhoea, postural hypotension and erectile dysfunction. Diabetic foot problems are particularly common and can be caused by the development of ulcers or tissue necrosis as a result of neuropathy. Diabetic foot can also be caused by ischemia and if not treated quickly, may lead to gangrene and possibly amputation.

1.2.8 Metabolic Control in Type-1 Diabetes

1.2.8.1 Glycosylated Haemoglobin (HbA1c)

While day-to-day glycaemic control should be monitored with finger-prick blood glucose testing by the individual, overall metabolic control is measured by glycosylated haemoglobin (HbA1c) at the diabetes clinic. HbA1c is a measure of the rate at which a glucose molecule and haemoglobin molecule bond together and is affected by the level of glucose in the blood (Watkins, 2003). It is expressed as a percentage of the normal haemoglobin level and the normal range is usually 4-8 %, although this varies with the technique used (Gale and Anderson, 2002). HbA1c provides an average of the blood glucose level over approximately, the previous six weeks (the life span of a haemoglobin molecule). It is therefore a more useful estimate of long-term glycaemic control than the finger prick blood test, which only provides information about glucose levels at that particular time.

1.2.8.2 Relationship of Metabolic Control to Diabetic Complications

While knowledge of the long-term macrovascular and microvascular complications in type-1 diabetes is well established, more recent research has focused on how these complications could be prevented or delayed. The Diabetes Control and Complications Trial (DCCT) was a multicentre clinical trial conducted in America between 1983 and 1993, involving 1441 patients with type-1 diabetes (DCCT Research Group, 2000). It investigated the effects of maintaining blood glucose levels and HbA1c as near to the normal range as possible through

Intensive Insulin Therapy. They found that IIT significantly delayed the onset and slowed the progression of the microvascular complications of retinopathy, nephropathy and neuropathy (DCCT Research Group, 1993). Furthermore, a four year follow-up study found that the reduction of risk for retinopathy and nephropathy was maintained (DCCT Research Group, 2000). They concluded that an increased risk of these microvascular complications was associated with chronic hyperglycaemia. Due to the relatively young age of the patients within the group, the original study could not make any conclusions about the effect of IIT on macrovascular complications, although the results showed a non-significant trend that they were once again reduced with tight control (DCCT Research Group, 1993). Therefore it is now accepted that the aim of treatment in type-1 diabetes is to prevent or delay the onset of long-term complications by ensuring that HbA1c levels are kept as near to normal as possible, through tight metabolic control.

1.2.9 Summary

Type-1 diabetes is a chronic illness characterised by insulin deficiency and hyperglycaemia. The aim of treatment is to replicate normal insulin function as closely as possible by maintaining blood glucose levels within a near-normal range and by avoiding hyperglycaemia and hypoglycaemia. However, the treatment regimen is complex and burdensome, involving an individualised insulin therapy regimen, blood glucose monitoring and careful consideration of both dietary intake and involvement in exercise. Good metabolic control is therefore difficult to achieve. More recently, it has been found that the microvascular complications of diabetes can be delayed and prevented by a focus on tight metabolic control through Intensive

Insulin Therapy and as such, treatment is now also aimed at attempting to prevent the onset of such complications, for as long as possible. The disadvantages of IIT include weight gain, an increase in hypoglycaemia and unless an insulin pump is used, an increase in the number of daily injections required.

1.3 ADHERENCE TO TREATMENT REGIMENS

1.3.1 Introduction to Adherence

Adherence is most commonly defined as the extent to which a person's behaviour matches the medical or health advice they are given (Rapoff, 1999). Therefore adherence is not a dichotomous phenomenon but changes with the specific behaviours expected of the patient and the situations concerned. In relation to this, research has moved away from using the term 'compliance', which fails to acknowledge both the co-operative relationship between patient and health-care provider and the patient's active involvement in making decisions about their treatment (Di Matteo & Di Nicola, 1982). As can be seen from the type-1 diabetes treatment regimen, health outcome is at least in part dependent on the self-care behaviours of the patient (Mollem et al, 1996).

It has been consistently found that adherence to medical regimens for both acute and chronic illnesses is poor (Rapoff and Barnard, 1991). This has led to numerous studies which have attempted to determine the factors which may contribute to treatment adherence (La Greca and Schuman, 1995). By gaining a better understanding of these factors, it is hoped that methods

for improving adherence can be developed (Schlundt, Rea, Hodge, Flannery, Kline, Meek, Kinzer and Pichert, 1996; Harris and Mertlich, 2003) with the aim of improving the patients' health status.

1.3.2 Prevalence of Non-Adherence

A number of factors can influence the estimation of non-adherence prevalence rates, such as the measure of adherence used, the behaviour being assessed, the health condition and the patient sample. In general, it is accepted that adherence is particularly poor for chronic conditions, with patients estimated to comply with only half of their recommended treatment (Rapoff and Barnard, 1991). Similarly, the overall adherence rate in paediatric populations has been estimated at about 50% (Litt and Cuskey, 1980).

In type-1 diabetes, adherence rates have been found to vary depending on which component of the treatment regimen is being assessed. Griva, Myers and Newman (2000) suggest that in adults, adherence to insulin administration tends to be better than adherence to the lifestyle factors of diet and exercise. Similarly, Schlenk and Hart (1984) reported that in their group of young to middle aged adults, adherence was better for insulin administration, blood glucose monitoring and management of hypoglycaemia, than it was for exercise and foot care. Overall however, Schlenk and Hart (1984) reported relatively high rates of adherence, with all of their participants adhering to at least 70% of their regimen. In contrast, Morris, Boyle, McMahon, Greene, MacDonald and Newton (1997) compared the medically recommended insulin dose with the cumulative volume of insulin prescriptions supplied, in a group of 89 patients who

were under 30 years old (mean age 16 years) and discovered that at least 28% of their sample did not request enough insulin. They therefore concluded that non-adherence to insulin administration was common in this age group.

1.3.3 Consequences of Non-Adherence

The health outcomes of patients with chronic conditions can be significantly affected by non-adherence and the results of the DCCT trial (DCCT Research Group, 1993) have shown that the microvascular complications of type-1 diabetes can be delayed or prevented by ensuring that tight metabolic control is achieved. The quality of life of patients can also be affected, with failure to adhere to insulin administration being significantly associated with increased acute hospital admissions (Morris et al, 1997). This may also result in decreased school attendance in the paediatric population, thereby impacting on their academic and social functioning (Rapoff, 1999).

In addition to the direct affect on health outcome, non-adherence will also have a financial impact on health care, by decreasing the cost-effectiveness of treatment and increasing clinic and hospital admissions (Rapoff, 1999).

1.3.4 Measures of Adherence

A variety of techniques exist to measure adherence including direct observation, pill counts, health care provider estimates, clinical health outcomes (such as HbA1c measures) and self-

report. However, there are methodological problems with all of these methods and there does not appear to be a consensus within the literature as to an 'ideal' measure of adherence (Rapoff, 1999).

Within type-1 diabetes, measuring adherence to the treatment regimen is particularly difficult due to the variability of treatment recommendations between patients and the lack of an explicitly prescribed treatment regimen (Griva et al, 2000). Instead, patients are expected to take an active role in adapting their self-care to their situation (Toobert and Glasgow, 1994) and consequently are often given non-specific instructions and advice (Glasgow, Wilson and McCaul, 1985). Furthermore, the complexity of the regimen in diabetes adds to the difficulties in assessing adherence. For example, it has been demonstrated that adherence to one part of the regimen is not often correlated with adherence to other parts of the regimen (Glasgow, McCaul and Schafer, 1987; Johnson, Freund, Silverstein, Hansen and Malone, 1990). McNabb (1997) therefore suggests that multiple scores of adherence may be necessary, due to the potentially arbitrary nature of a total adherence score. McNabb (1997) also criticises the use of quantifying adherence in terms of percentages, as this may not adequately reflect the complexity of the individual regimen being considered.

1.3.4.1 Self-report Measures of Adherence

There is a lack of reliable and valid measures of adherence to the type-1 diabetes regimen and it has been acknowledged that no measure has achieved a gold-standard status (Turk and Meichenbaum, 1991). Most research appears to depend on self-report measures of adherence,

although these are often found to be unreliable (Kurtz, 1990). For example, a study which compared self-reported blood glucose monitoring with memory-chip data from blood glucose meters (of which patients were unaware) found that over 70% of patients over-reported blood glucose monitoring and over 30% of entries were fictitious (Mazze, Lucido and Shamoon, 1984). Johnson (1992) has therefore suggested that self-reported low levels of adherence are more likely to be reliable than self-reported high adherence. In addition, Kovacs, Brent, Steinberg, Paulauskas and Reid (1986) found that children's self-ratings did not correspond with information from other sources and concluded that they should not be used in isolation. It is therefore recommended that patient self-reports should not be solely relied upon and that additional reports should be gained from the patients' family or friends (Hayes and DiMatteo, 1989). Furthermore, self-reports tend to be more reliable when recall periods are kept to a minimum and when specific objective questions are asked (La Greca and Schuman, 1995). This has led to the development of a 24-hour recall interview, which has been shown to have good test-retest reliability (Johnson et al, 1986) and has been used successfully with children (Freund, Johnson, Silverstein and Thomas, 1991). However, multiple interviews are required to provide estimates of adherence with this method and so it is often too time consuming and cost-ineffective to use. Instead it has been found that new self-report measures of adherence are often constructed with each new area of research (Toobert and Glasgow, 1994) leaving comparability across studies and reliability and validity calculations, difficult.

1.3.4.2 Clinical Measures of Adherence

As previously discussed, metabolic control in type-1 diabetes is measured by HbA1c assay and this is often cited as a measure of adherence within the medical literature (Clarke, Snyder and Nowacek, 1985). However in reality, many studies have failed to find an association between glycaemic control and adherence (Schafer, McCaul and Glasgow, 1986; Anderson, Auslander, Jung, Miller and Santiago, 1990; Johnson, 1995a). Johnson (1994) studied this relationship in children and adolescents and from a sample of 377, found that the association was not significantly different from chance. It should not therefore be assumed that poor metabolic control is caused by non-adherence and other potentially mediating factors must be considered. Johnson (1995b) suggests that the limitations of standard treatment for diabetes, such as the effectiveness of insulin therapy, must be remembered when assessing the role of adherence in predicting glycaemic control. She therefore recognises that even perfect adherence would not lead to good control if the prescribed treatment regimen is itself not effective. Furthermore, Johnson (1994) discussed that the treatment regimen would have to be communicated properly and any skills or knowledge deficits recognised for patients to be able to adhere appropriately. Johnson (1994) therefore noted the possibility of "inadvertent non-compliance" (p.134), if these factors are overlooked. In addition, it is possible that for adolescents, the hormonal changes which occur during puberty may result in changes in insulin resistance leading to altered metabolic control (Dunger and Edge, 1995). Ratings of adherence by health-care providers should therefore be interpreted with caution, as they may be biased by a patients' level of metabolic control or other clinical history information (La Greca, Follansbee and Skyler, 1990).

While considering the limitations in using HbA1c as a measure of adherence, it must be remembered that reliable and valid self-report adherence measures are also lacking. Therefore this may help to explain the discrepancies found between glycaemic control and adherence. Furthermore, some items on adherence questionnaires may not have a direct impact on glycaemic control (for example items relating to foot care). Overall, it is important to measure both glycaemic control and adherence as they may be differentially affected by any factors being investigated.

1.3.4.3 Other Measures of Adherence

Some other methods of measuring adherence to specific components of the diabetes treatment regimen have been described in the literature. For example, Morris et al (1997) discussed matching the amount of insulin prescribed to the amount of insulin requested and supplied by prescription, to calculate an adherence index. However the limitations of this method included the inability to determine the amount of insulin actually taken and the possibility that patients may have had a supply of insulin before the start of the study which would not have been accounted for. Morris et al (1997) also discussed that they could not control for the adjustments to daily insulin doses that patients are expected to make.

It is now possible to determine the level of adherence to blood glucose monitoring through the recording of blood glucose readings on the memory chips of some meters. However, specially designed computer programs are often needed to download these results (Watkins, 2003). The

assessment of adherence to blood glucose monitoring is therefore dependent on patients remembering, or having the desire, to bring their blood glucose meters to clinic appointments.

1.3.5 Factors Affecting Adherence

Due to the awareness of low adherence rates in chronic conditions generally and in type-1 diabetes specifically, research has focused on determining the factors which may affect adherence and in some cases, on interventions which may help to improve adherence (La Greca and Schuman, 1995). These factors can be broadly defined into three categories: disease and regimen factors, patient factors and family factors. A number of theoretical models have also been applied in the literature in an attempt to better understand medical adherence and self-care behaviour.

1.3.5.1 Disease and Regimen Factors

Conditions of higher severity and longer duration have been associated with a decrease in adherence (La Greca and Schuman, 1995). As type-1 diabetes is a condition for which patients face a life-long treatment regimen, it is not surprising that adherence tends to decrease with time (Jacobsen, Hauser, Lavori, Wolfsdorf, Herskowitz, Milley, Bliss, Gelfand, Wertlieb and Stein, 1990). Furthermore, the treatment regimen for type-1 diabetes is recognised as complex, involving multiple factors which must be considered on a daily basis (McNabb, 1997) and it is a common finding that adherence tends to be lower with more complex regimens (Rapoff, 1999).

The perceived efficacy of the components of treatment is also an important correlate of adherence, with treatment efficacy found to be the strongest predictor of adherence to diet, exercise and blood glucose testing in both type-1 and type-2 diabetes populations (Glasgow, Strycker, Hampson and Ruggiero, 1997). In addition, treatment which has immediate positive effects is more likely to be adhered to than treatment where the effects have more of an impact on future consequences or have negative side-effects (Litt and Cuskey, 1980). Although components of the treatment regimen in type-1 diabetes such as administering insulin or checking blood glucose can have immediate effect in preventing hypoglycaemia or hyperglycaemia, tight metabolic control is more concerned with preventing or delaying the onset of long-term complications. These future consequences may not therefore be sufficient to increase motivation for adherence to daily self-care behaviours. Furthermore, while there may be no obvious negative side-effects of treatment for type-1 diabetes, the social aspects of carrying out treatment have been found to be a significant barrier to adherence for adolescents (La Greca and Hanna, 1983). In addition, Intensive Insulin Therapy has been shown to lead to weight gain (DCCT Research Group, 1993) which may be viewed as a more immediate negative effect of treatment.

1.3.5.2 Patient Factors

Age is perhaps the most important factor in determining adherence, with adolescence known as a particularly problematic time. In type-1 diabetes, adolescents have been found to be less adherent than both younger children (Hanson, Henggeler and Burghen, 1987a; Worrall-Davies, Holland, Berg and Goodyer, 1999; Johnson (1995b) and adults (Morris et al, 1997). Patients

must be knowledgeable and able to understand their condition before they can adhere to it and a lack of diabetes knowledge has been associated with the mismanagement of the condition (Kroll and Shaw, 1994) and hospital admission for DKA (Hurel, Orr, Arthur, Swainston and Kelly, 1997). However, knowledge has been shown to be developmentally related (Harkavy, Johnson, Silverstein, Spillar, McCallum and Rosenbloom, 1983), increasing with age. Although this is a common finding (Johnson, 1994; Johnson, 1995b), it does not appear to be associated with a similar increase in adherence. Adequate knowledge may therefore be necessary for adherence, but it does not appear to be sufficient.

The presence of a chronic illness during adolescence can intensify the difficulties faced at this age due to the changes which occur physically, cognitively and emotionally. Of particular importance during adolescence is the development of autonomy and this may be especially compromised by the presence of a chronic illness (Chassin, Presson, Sherman and McConnell, 1995). For example, in addition to normal developmental challenges, adolescents with type-1 diabetes must also begin to assume more responsibility for their treatment and parental supervision has been shown to decrease with age (Johnson, 1995a). However, it may also be the case that the health concerns associated with such a condition result in parents placing more restrictions on their children during adolescence and limiting the opportunities for them to develop autonomy (Chassin et al, 1995). Adolescents with type-1 diabetes must therefore negotiate the normal demands of development with an increasing level of responsibility for their diabetes care and decreasing parental involvement, potentially explaining the decline in adherence found in this age group.

The desire for social acceptance by peers can also impact on adherence and peer support becomes increasingly important during adolescence (Pendley, 2002). Support from peers has been found to be important in helping adolescents manage and adjust to diabetes (Burroughs, Harris, Pontious and Santiago, 1997) and it has been suggested that adolescents' adherence may increase if treatment behaviours are supported and encouraged by friends, (La Greca, Bearman and Moore, 2002). While peer support can positively reinforce adherence, La Greca and Hanna (1983) found that adolescents did not want to appear different from their friends and thus may not adhere to the dietary and blood glucose monitoring aspects of their regimen. In addition to these social barriers, peers can also affect adolescents' future health status by influencing their health-risk behaviours. For example the uptake of smoking, which adds to the risk of macrovascular complications in type-1 diabetes, may be influenced by peer-pressure and initiated in order to 'fit-in' (La Greca et al 2002).

A number of psychosocial variables have also been shown to impact on adherence. For example, higher self-esteem and social functioning have been found to be associated with increased adherence in children with type-1 diabetes, while behavioural and emotional problems appeared to have an adverse effect on adherence (Jacobsen, Hauser, Wolfsdorf, Houlihan, Milley, Herkowitz, Wertlieb and Watt, 1987; Kovacs, Goldston, Obrosky and Iyengar, 1992). However, psychosocial factors and stress in particular also appear to predict metabolic control, both indirectly through their affect on adherence, but also directly (Johnson, 1995a). For example, Hanson et al (1987a) found that low stress was independently linked to better adherence and better glycaemic control. In a separate study, Hanson, Henggeler and Burghen (1987b) further reported that the link between stress and HbA1c was mediated by

social confidence. Wing, Epstein, Nowalk and Lamparski, (1986a) reviewed the impact that stress may have on metabolic control and discussed the role of the autonomic nervous system in both physiological and psychological stressors.

1.3.5.3 Family Factors

The role of social support is crucial in the management of a complex and chronic condition and the family plays an important role in helping both children and adolescents with their self-care behaviours in type-1 diabetes. As would be expected, family members (usually the mother or primary care-giver) are mainly responsible for the treatment regimen in pre-adolescents, with their involvement decreasing as their child moves into adolescence (Johnson, 1995b). This is a difficult balance to achieve however. While the family's involvement in looking after a child's diabetes should adapt with their child's developing capacity for self-management (Northam, Anderson, Adler, Werther and Warne, 1996), the importance of continued parental support has been highlighted. For example, Hanson et al (1987a) found that positive family relations were significantly associated with good metabolic control in adolescents and Harris and Mertlich (2003) reported an increase in adherence for a small group of adolescents following a behavioural family systems intervention. Unfortunately there are some methodological difficulties with such research. For example, although Harris and Mertlich (2003) found the encouraging results that their intervention increased adherence and reduced both general family conflict and diabetes-related conflict, these results were based on the mother's ratings of family conflict only. Similarly, Schafer et al (1986) reported on the development and validation of the Diabetes Family Behaviour Checklist and found that negative scores on this measure were

predictive of adherence. Once again, this was only in relation to the parents' scores on the measure. In addition, they found that adolescents perceived negative family behaviours to occur more frequently than their parents. Perceptions of family support and conflict may therefore differ between adolescents and their parents.

It would therefore seem that parents must try to balance providing a supportive role, whilst allowing their adolescent child to assume more responsibility for their care and to rely more on their peers for support.

Family lifestyle may also impact on adherence for adolescents. For example, children from families who already engage in exercise and a healthy diet may more easily adapt to these components of the diabetes regimen (Johnson, 1995b). Furthermore, families who appear to cope well with the diagnosis of diabetes are more likely to foster adherence for their child (Hanson, DeGuire, Schinkel and Henggeler, 1992).

1.3.6 Models of Adherence

A number of psychological models have been used in an attempt to provide a framework for considering the multitude of factors which may predict adherence. For example, Brownlee-Duffeck, Peterson, Simonds, Kilo, Goldstein and Hoette, (1987) and Bond, Aiken and Somerville (1992) investigated the usefulness of the health belief model (Becker, 1974) in predicting adherence in adolescents with type-1 diabetes. Both studies found that perceived barriers to adherence in particular were associated with adherence. However, barriers to

adherence have also been found to be a significant predictor of adherence in the investigation of other psychological models. For example, Palardy, Greening, Ott and Atchison (1998) used the protection motivation theory (Rogers, 1975) to examine the health attitudes of adolescents with type-1 diabetes and the relationship of these attitudes to adherence. They concluded that cognitions of adherence (namely response costs of adherence, treatment efficacy and self-efficacy) were more predictive of adherence than cognitions of non-adherence (namely rewards of non-adherence, and personal vulnerability to and severity of the risks of non-adherence). Furthermore, they found barriers of adherence to be the strongest predictor of adherence overall. Self-efficacy has also been shown to have an important relationship with adherence and it describes a person's perceived ability to perform the self-care tasks necessary for adherence. Charron-Prochownik, Becker, Brown, Liang and Bennett, (1993) found that higher self-efficacy in children and their parents was related to better adherence. More recently, Griva et al (2000) used the self-regulation model to show that self-efficacy was significantly associated with adherence, along with beliefs about self-control. However, they also found that self-efficacy was more strongly linked to HbA1c than to adherence. They therefore concluded that self-efficacy could directly affect HbA1c through the physiological affects of stress and that self-efficacy could mediate the association between intentional adherence and glycaemic control. In contrast, Van der Ven, Weinger, Pouwer, Ader, Van der Ploeg and Snoek, (2003) found self-efficacy to be more strongly related to behaviour than glycaemic control. However, they noted that not all the self-care tasks would have a direct impact on HbA1c, potentially explaining this finding.

1.3.7 Summary

The concept of adherence is complex and the prevalence of non-adherence to treatment regimens poses a problem in the management of health problems. In type-1 diabetes, a number of factors must be considered in the formulation of non-adherence. The chronic nature of diabetes and the complexity of the treatment regimen are particular factors which make adherence difficult. Patients must have adequate knowledge of type-1 diabetes if they are to be able to adhere to the regimen and they must also have adequate social support. For adolescents in particular, adherence tends to be poor and obtaining a balance between parental support and development of autonomy appears to be important. The influence and support of peers are also important factors to consider for adherence in adolescence. In addition, personal attributes and psychosocial factors may be important in the prediction of adherence. Adherence is a difficult concept to investigate however, due to the methodological difficulties which exist in its measurement. In type-1 diabetes, estimating adherence is particularly difficult due to the lack of an explicit treatment regimen. Furthermore, the use of HbA1c as a clinical measure of adherence is problematic as despite expectations, HbA1c may not adequately reflect patients' self-care behaviours.

1.4 EATING AND WEIGHT CONCERNS IN TYPE-1 DIABETES

1.4.1 Introduction

Significant weight and shape concerns are common in adolescents in the general population and can develop into disturbances in eating habits as age increases (Cooper and Goodyer, 1997). Such concerns and eating behaviours, along with body image distortions and disturbed attitudes towards food, are the psychological symptoms which characterise eating disorders (American Psychiatric Association, 2000). Clinical eating disorders include anorexia nervosa, bulimia nervosa and Eating Disorders Not Otherwise Specified (ED-NOS). They are characterised by disturbed eating behaviours such as fasting, dieting, vomiting and the use of laxatives, diuretics, diet pills and extreme exercise, to achieve weight loss.

The combination of eating disorder psychopathology with type-1 diabetes has been noted since the 1980s and this has led to specific investigations into the prevalence and clinical presentation of eating disorder symptoms in this group (Hoffman, 2001). While there is some controversy in the research as to whether there is an increased prevalence of eating disorders in type-1 diabetes or not, a number of specific features have been noted. For example, symptoms associated with bulimia (such as binge eating) (Herpertz, Wagener, Albus, Kocnar, Wagner, Best, Schleppinghoff, Filz, Forster, Thomas, Mann, Kohle and Senf, 1998) and a diagnosis of ED-NOS (Williams and Gill, 1997) have been noted to be specifically associated with type-1 diabetes. Furthermore, the use of insulin reduction or omission to achieve weight loss has been found to occur more commonly than the use of laxatives, diuretics or vomiting in type-1

diabetes (Stancin, Link and Reuter, 1989). A number of possible mechanisms have been suggested to explain the co-occurrence of eating and weight concerns in type-1 diabetes and these will be outlined, along with the methodological limitations which occur in research into this phenomenon.

1.4.2 Existing Evidence for the Prevalence of Weight and Shape Concerns in Type-1 Diabetes and Methodological Problems in the Literature

A high prevalence of clinical eating disorders has previously been reported in young females with type-1 diabetes (Steel, Young, Lloyd and Clarke, 1987) and more recently, it has been reported that eating disorders are more than twice as likely to occur in females with type-1 diabetes (Jones, Lawson, Daneman, Olmstead and Rodin, 2000), with diagnoses of bulimia nervosa and ED-NOS particularly common (Jones et al, 2000; Nielsen, 2002). This increased prevalence has been disputed however, with many studies reporting that while disordered eating and weight and shape concerns do exist in this population, clinical eating disorders occur no more commonly than in the general population (Peveler, Fairburn, Boller and Dunger, 1992; Striegel-Moore and Kearney-Cooke, 1992; Marcus, Wing, Jawad and Orchard, 1992; Peveler, Bryden, Neil, Fairburn, Mayou, Dunger and Turner, 2005). Such studies have been criticised for their low sample size (Jones et al, 2000) and some researchers have themselves noted the low power for detecting significant differences between groups in their research (Peveler et al, 1992; Striegel-Moore, Nicholson and Tamborlane, 1992). Indeed, a number of methodological limitations exist in this literature. For example, although Goodwin, Hoven and Spitzer (2003) screened 3000 primary care patients for the co-occurrence of eating disorders

with diabetes, they used a general health survey which was limited in its ability to provide eating disorder diagnoses and they failed to distinguish between type-1 and type-2 diabetes, making their conclusions unhelpful. The diabetes samples chosen for this type of research have been further criticised, with Fairburn, Peveler, Davies, Mann and Mayou, (1991) suggesting that the use of patients from tertiary referral centres may falsely suggest that eating disorders are more prevalent in the type-1 diabetes population as a whole. In support of this, they found that clinical eating disorders were no more prevalent in women with diabetes than in non-diabetic women, when using a sample of patients they believed to be representative of young women with type-1 diabetes in general.

The method used to measure eating disorders is also of particular importance, with self-report measures tending to result in higher eating disorder prevalence rates (Fairburn et al, 1991). In addition, the focus on diet in type-1 diabetes treatment may lead to biased responses on some questionnaire items (such as items relating to the avoidance of sugary foods) whereby participants with type-1 diabetes would respond positively, even in the absence of any eating disturbances or concerns. For example, Wing, Nowalk, Marcus, Koeske and Finegold, (1986b) found that while adolescents with type-1 diabetes scored higher on the Eating Attitudes Test (EAT) when compared to a control group, the differences only occurred on the dieting subscale of the questionnaire, possibly reflecting adherence to dietary recommendations, rather than increased psychopathology. However, Steel, Young, Lloyd and MacIntyre, (1989) suggested that increased prevalence in eating concerns could not be explained by such questionnaire items alone, as they found that significantly higher EAT and Eating Disorder Inventory (EDI) scores in the adolescent type-1 diabetes group remained after the removal of diabetes-related

questions. The questionnaires used to investigate this phenomenon and the removal of any potentially biased items must therefore be carefully considered. Furthermore, Rodin and Daneman (1992) warn against using screening tests inappropriately for diagnostic purposes and suggest that the features of eating disturbances in type-1 diabetes (such as insulin misuse) may be distinct from the diagnostic criteria applied to the general population. Therefore, they recommend the use of interviews for the assessment of eating disorder psychopathology, as these are more likely to have greater reliability, validity and specificity.

The majority of studies to date have focused on the prevalence of eating disturbances in the female adolescent population, as these concerns have been found to be more likely to occur in females with type-1 diabetes (Steel et al, 1989; Daneman and Rodin, 1999). However, some studies have included males in their samples. Neumark-Sztainer, Story, Resnick, Garwick and Blum (1995) reported that a high percentage of boys with type-1 diabetes within their chronic illness group reported similar weight loss behaviours as the girls. Unfortunately their numbers were too small to draw any conclusions about the features of individual chronic conditions. In 2002, Neumark-Sztainer, Patterson, Mellin, Ackard, Utter, Story and Sockalosky, reported that there were no differences in disordered eating behaviours between adolescent and young adult males and females with type-1 diabetes, although more females reported insulin misuse. Similarly, Bryden, Neil, Mayou, Peveler, Fairburn and Dunger (1999) reported that males showed an increase in weight and shape concerns over time, but that their concerns were lower than those of females at both baseline and follow-up. They also found that no males reported insulin misuse, although once again commented that their sample size was relatively small.

More research is therefore required to determine the prevalence and consequence of these concerns in males with type-1 diabetes.

Overall, while some studies have found an increased incidence of clinical eating disorders, others suggest that the incidence is no higher than in the general population and that eating disorder psychopathology is common in adolescents in general. However, a number of methodological limitations must be taken into account when considering these conclusions. Despite these difficulties, there is agreement that sub-clinical eating disturbances and weight and shape concerns are common in adolescents with type-1 diabetes.

1.4.3 Consequences of Weight and Shape Concerns in Type-1 Diabetes

1.4.3.1 Relationship with Diabetic Complications

The effect of disordered eating and weight and shape concerns on the development of microvascular complications has been investigated. Steel et al (1989) concluded that disordered eating attitudes were a risk factor for the early onset of retinopathy, having found that retinopathy was significantly associated with total scores on the EAT. Similarly, Rydall, Rodin, Olmstead, Devenyl and Daneman (1997) found that in their five year follow-up study of female adolescents, retinopathy was three times more likely to occur in those with high disordered eating status than those with no eating disturbances. They also found that disordered eating status accounted for more of the variance in retinopathy, than the duration of diabetes itself. While Williams and Gill (1997) acknowledge the clinical importance of this

finding, they commented that measuring retinopathy by its presence or absence is not as clinically useful as determining the severity of retinopathy, due to the commonality of background retinopathy which is not clinically threatening. However, Peveler et al (2005) also report a significant association between the development of two or more diabetic complications and the presence of a probable clinical eating disorder, a history of disordered eating and a history of insulin misuse. In particular, they reported that as their study had a small sample size, these effects must be large to produce such significant results. They therefore concluded that there are strong associations between disordered eating habits and attitudes, insulin misuse and the development of microvascular complications.

1.4.3.2 Relationship with Glycaemic Control

In addition to being associated with microvascular complications, impaired glycaemic control has also been associated with both disordered eating (Peveler et al, 1992; Wing et al 1986b) and insulin misuse (Polonsky, Anderson, Lohrer, Aponte, Jacobsen and Cole, 1994; Biggs, Basco, Patterson and Raskin, 1994; Bryden et al, 1999). As such, Rodin and Daneman (1992) suggest that the immediate consequences of these behaviours and concerns can be frequent DKA, recurrent hypoglycaemia and therefore increased hospitalisation. Furthermore, Olmstead, Daneman, Rydall, Lawson and Rodin (2002) found that although their psychoeducation intervention led to an improvement in eating attitudes and a decrease in dieting, this was not reflected in an improvement in HbA1c or insulin omission. The effects of disordered eating on glycaemic control may therefore be difficult to alleviate. Of particular importance in the relationship of these concerns with glycaemic control is that the association

is not restricted to clinical eating disorders (e.g. Affenito, Backstrand, Welch, Lammi-Keefe, Rodriguez and Adams, 1997). The prevalence of sub-clinical eating disorders and eating disorder symptoms are therefore of specific clinical importance in adolescents with type-1 diabetes, irrespective of the normality of these concerns within the general adolescent population, due to their negative impact on glycaemic control and the risk of complications (Marcus et al, 1992; Daneman and Rodin, 1999).

1.4.4 Possible Mechanisms to Explain the Co-Occurrence of Eating Disorder Symptoms with Type-1 Diabetes

1.4.4.1 Presence of a Chronic Illness

The medical treatment of many chronic illnesses includes a focus on nutrition or recommended diets which may lead to the development or reinforcement of disordered eating behaviours or attitudes. This was investigated by Schlundt, Rowe, Pichert and Plant (1999) who compared 24 adolescents with a chronic illness which had dietary requirements with 31 adolescents who had a chronic illness that had no special dietary requirements. Contrary to their expectations, the results showed that the adolescents with special dietary requirements had healthier attitudes towards eating and their body weight than the group who did not have to consider their diet. However these results may not be representative of the population due to the use of a small convenience sample, questionnaires which had not been standardised on this population and the lack of a control group with no chronic illness. This latter difficulty had been addressed by Neumark-Sztainer et al (1995) who compared body dissatisfaction and weight loss practices

between adolescents with and without a chronic illness, from a school population. They reported that adolescents with a chronic illness had higher rates of body dissatisfaction and that they were significantly more likely to engage in unhealthy weight control practices. While the numbers within the chronic illness group were too small to make any firm conclusions, the results suggested that adolescents with nutrition-related illnesses had similar concerns and weight loss practices to those with conditions which did not involve a nutritional focus. It would therefore seem that eating and weight concerns are prevalent in adolescents with chronic illnesses in general. Elements common to chronic illnesses, other than a focus on nutrition in treatment, must therefore be considered.

The presence of any chronic illness may increase adolescents' vulnerability to the development of an eating disorder due to feelings of being different to their peers and attempts to fit in. For example, Stein (1996) has suggested that a lack of positive self schemas may result in a focus on the body to provide self worth, thereby precipitating the onset of an eating disorder. Furthermore, family interactions may play an important role in both adaptation to type-1 diabetes and the development of eating disturbances. Maharaj, Rodin, Olmstead, Connolly and Daneman (2003) discuss the difficulties of developing a sense of self, autonomy and maintaining positive family interactions that adolescents may face in the presence of a chronic illness. They investigated this in the type-1 diabetes population, with 88 adolescents between the ages of 11 and 19 years. They found that eating disturbances were associated with self-concept deficits for adolescents and that the extent of their eating disturbances was positively associated with maternal weight and shape concerns. Similarly, Maharaj, Rodin, Olmstead and Daneman (1998) found that the eating disturbances of adolescents with type-1 diabetes were

associated with a perception of poor communication and a lack of trust with their parents, a conflictual family environment and inadequate support. Therefore while a lack of maternal empathy and care (Dare, Le Grange, Eiser and Rutherford, 1994), maternal modelling of weight and shape concerns (Pike and Rodin, 1991), a lack of self-confidence and negative family interactions (Shisslak, Crago, McKnight, Estes, Gray and Parnaby, 1998) are associated with the development of eating disorders in the general population, these factors may be more influential for adolescents with a chronic illness and therefore increase vulnerability to the development of eating disturbances. It must be noted however that there is a lack of research into the impact of these factors on chronic illnesses other than type-1 diabetes.

1.4.4.2 Focus on Diet in the Treatment of Type-1 Diabetes

While the focus on nutritional aspects of treatment does not appear to be a predisposing factor for the development of eating disturbances for chronic illnesses generally, the dietary aspect of type-1 diabetes treatment perhaps deserves separate consideration. It has been suggested that a specific feature of type-1 diabetes is the focus on dietary restraint and regulated eating habits (Colton, Olmstead, Daneman, Rydall and Rodin, 2004; Rodin and Daneman, 1992; Steel et al, 1989). However, with the introduction of Intensive Insulin Therapy which offers more flexibility around both the timing and amount of food eaten, the sense of dietary restraint may be lessened. If a focus on dietary restraint and regulation is instrumental in the development of eating and weight concerns, it may therefore be expected that these concerns would decrease with an increase in IIT. While this remains to be tested empirically, it is notable that in their 8 year follow-up of adolescents with type-1 diabetes, Bryden et al (1999) concluded that eating

and weight concerns had increased with age, even although it was apparent that more participants were on IIT than at baseline. The type of insulin regimen did not appear to be controlled for in the study however and so no conclusions can be made from this observation.

1.4.4.3 Increased Weight/Body Mass Index (BMI) in Type-1 Diabetes

It is a common finding that weight gain is associated with insulin treatment (Rodin and Daneman, 1992). Furthermore, BMI tends to increase over time for adolescents with type-1 diabetes (Peveler et al, 2005; Bryden et al, 1999; Steel, Lloyd, Young and MacIntyre, 1990) and is often found to be higher than when compared to a control group (Scottish Study Group for the Care of the Young Diabetic, 2001; Jones et al, 2000; Steel et al, 1989). This is probably due to the initial correction of weight loss and dehydration following diagnosis, the anabolic effect of insulin, the increased formation of adipose tissue due to systemic insulin circulation and the possible increase in dietary intake in order to avoid hypoglycaemia. BMI has been found to be associated with eating and weight concerns in the normal population (Hausenblas and Fallon, 2002; Shisslak et al, 1998) and it is therefore not surprising that higher BMI is associated with an increase in eating disturbances and concerns (Bryden et al, 1999; Colton et al, 2004) and with poorer glycaemic control (Scottish Study Group for the Care of the Young Diabetic, 2001) in adolescents and young adults with type-1 diabetes. The rapid weight gain following diagnosis has been highlighted as particularly distressing (Steel et al, 1989) and an increase in BMI has also been associated with greater body dissatisfaction (Garfinkel, Goldbloom, Davis, Olmstead, Garner and Halmi, 1992). This increase in weight therefore

constitutes an immediate negative consequence of treatment for type-1 diabetes and may be viewed as a barrier to adherence.

However Steel et al (1989) suggest that higher eating psychopathology scores can not solely be explained by BMI as in their study, differences between the diabetes and control groups remained even after scores were adjusted for BMI. It may therefore be the case that perception of both weight and weight gain are more important than BMI per se. This is supported by evidence from the cystic fibrosis (CF) literature. In CF, patients are more likely to be underweight and their treatment regimen involves a high fat diet, food supplements and usually, pancreatic enzymes, which promote the absorption of fat and proteins (Cystic Fibrosis Trust UK and Solvay Healthcare Ltd, 2000). Walters (2001) reported that in young adults with CF, the perception of being underweight was the strongest predictor of taking food supplements but that females tended to overestimate their weight. Perception of weight, rather than actual weight, therefore directly affected participants' nutritional adherence. Similarly, Truby and Paxton (2001) noted that while children with CF perceived themselves to be thin, they tended to be satisfied with their body size and therefore may not be motivated to adhere to the dietary aspect of their regimen.

Another important consideration in the finding that BMI is higher in type-1 diabetes is the impact of the prescribed insulin regimen. The DCCT research group (1988) reported that while IIT may result in better metabolic control, it also results in increased weight gain. Furthermore, insulin resistance in peripheral glucose metabolism tends to increase during puberty, possibly leading to weight gain as a result of excess peripheral insulin levels (Amiel,

Caprio, Sherwin, Plewe, Haymond and Tamborlane, 1991). In order to achieve good metabolic control, insulin dose may be increased during puberty, but remain at a higher dose even when insulin sensitivity is returning to normal at the end of puberty (Bryden et al, 1999) and high insulin dosages have been associated with adolescence (Rosenbloom and Giordano, 1997). It has therefore been acknowledged that attempts to achieve better glycaemic control may lead to weight gain and a resulting increase in body dissatisfaction and a decrease in self-esteem. Furthermore, with a more flexible IIT regimen, a vicious cycle can develop whereby an increase in insulin leads to an increase in hunger, resulting in increased dietary intake, which then requires an increased insulin dose. Unfortunately, the insulin dose and regimen type are not routinely reported or controlled for in the studies examining eating disorder psychopathology and so it is difficult to make any conclusions on the impact of these factors in the development of eating and weight concerns.

1.4.4.4 Use of Insulin Omission for Weight Loss

Adolescents with type-1 diabetes are likely to quickly learn that the reduction or omission of insulin will lead to weight loss (Rodin and Daneman, 1992) and this population therefore have a very effective method of inducing weight loss. Indeed it has been suggested that lower rates of dieting may be found in patients with type-1 diabetes when compared to the general population, due to insulin misuse being a more effective weight loss method (Jones et al, 2000).

The prevalence of insulin misuse appears to increase with age and has been reported to occur in 2% of pre-teens (Colton et al, 2004), between 11% and 15% of adolescents (Jones et al, 2000; Peveler et al, 1992) and 34% of young adults (Rydall et al, 1997). In an eight year follow-up study, Bryden et al (1999) reported a total prevalence of insulin misuse in 30% of their sample. All of those who misused insulin were female and they reported that insulin misuse occurred for an average duration of two years. However, the range of insulin misuse in this population ranged from reports of insulin omission for two weeks during adolescence, to consistent insulin under-dosing for 7 years. It has been suggested however that it is difficult to obtain accurate estimates of the prevalence of insulin misuse due to it being a covert behaviour and therefore possibly under-reported (Polonsky et al, 1994). In support of this, Biggs et al (1994) found that insulin withholders were more likely to lie to their doctors.

As would be expected, insulin misuse is associated with higher weight and shape concerns (Peveler et al 2005) and eating disorder symptomatology (Biggs et al, 1994; Marcus et al, 1992). However, while the presence of insulin misuse may be higher amongst those with disordered eating (Peveler et al, 2005), insulin omission is not restricted to individuals with clinical eating disorders (Peveler et al, 1992) and has been related to more negative attitudes towards diabetes (Biggs et al, 1994). Polonsky et al (1994) reported a detailed account of the characteristics of those who omitted insulin in a large sample of females between 13 and 60 years old. They reported that 30.5% of their sample admitted to insulin omission and that rates of omission peaked between the ages of 15 and 30 years and were mostly infrequent. Insulin omission was associated with higher levels of general psychological distress, diabetes related distress and lower adherence, but not with BMI or insulin dose. Furthermore, although

omission was significantly related to more disordered eating attitudes and behaviours, only 43.3% of those who omitted insulin, did so for weight related reasons. Weight related omission was however associated with the greatest medical and psychological risk, lower adherence and higher frequency of omission. Polonsky et al (1994) therefore concluded that while some participants omitted insulin as a result of being emotionally overwhelmed by diabetes, weight-related omission was considered more pathological and resulted in greater risk of psychological and medical complications.

1.4.5 Summary

Whether the prevalence of eating disorders is higher amongst adolescents with type-1 diabetes or not, the presence of eating disorder symptoms, sub-clinical psychopathology and eating and weight concerns, is a consistent finding in this cohort. Furthermore, these factors are of clinical importance, due to their association with poor glycaemic control and the increased risk of microvascular complications. However the methodological issues inherent in this type of research have meant that the conclusions which can be made are limited. Furthermore, while a number of mechanisms have been suggested to explain the co-occurrence of eating disorder psychopathology with type-1 diabetes, the extent to which the presence of a chronic illness, the focus on diet, weight gain, insulin dose, insulin regimen and insulin misuse are implicated, remains unclear.

1.5 AIMS AND HYPOTHESES

1.5.1 Aims

The clinical importance of weight and shape concerns in type-1 diabetes is apparent although the extent to which these concerns are more prevalent in type-1 diabetes is unclear. The present study therefore aims to carry out a preliminary investigation into the eating and weight concerns of adolescents with type-1 diabetes, between the ages of 12 and 18 years old, in the Tayside and Fife clinical populations. Low adherence to insulin has already been reported in the Tayside population (Morris et al, 1997) and so it is important to attempt to identify any factors which may act as a barrier to adherence and predict poor glycaemic control. This study therefore aimed to determine whether the prevalence of eating and weight concerns in this population of adolescents with type-1 diabetes was different to a group of adolescents without diabetes. It also aimed to examine whether or not these concerns significantly predicted glycaemic control and adherence in the diabetes group. This study also aimed to examine the relationships of eating and weight concerns with factors specific to type-1 diabetes, by investigating the associations of eating and weight concerns with body mass index, insulin dose and insulin regimen, in both males and females.

1.5.2 Hypotheses

On the basis of previous findings, the following hypotheses have been made.

Hypothesis 1:

Eating and weight concerns will be higher in the type-1 diabetes group than in the control group, with such concerns more prevalent amongst females in both groups.

Hypothesis 2:

Body Mass Index will be significantly higher in the diabetes group than in the control group

Hypothesis 3:

Eating and weight concerns will be positively associated with and predictive of (a) glycaemic control (HbA1c) and (b) adherence, in the diabetes group.

Hypothesis 4:

Body Mass Index will be positively associated with and predictive of, eating and weight concerns in the diabetes group.

Hypothesis 5:

Insulin dose and insulin regimen will be positively associated with and predictive of, eating and weight concerns in the diabetes group.

CHAPTER TWO

METHODS

2.1 DESIGN

A cross-sectional, mixed-design study was carried out. The clinical group consisted of adolescents attending out-patient diabetes clinics in Tayside and Fife, and their parents. The study was introduced to the clinical group at their routine diabetes clinic appointments and participants and their parents were provided with a questionnaire pack to complete and return. A within-subjects design was used to compare participants' questionnaire responses with information from their medical files. A control group was enlisted to provide normative data for eating and weight concerns in a local population. The eating and weight concerns of the two groups could then be directly compared, to prevent any incorrect interpretations of the results from the clinical group. The control group consisted of adolescents who did not have type-1 diabetes, recruited from three schools in North East Fife. Postal-survey and class distribution methods were used to collect questionnaire data from the control group and a between-subjects design allowed the responses of the control group to be compared with the responses from the clinical group.

2.2 PARTICIPANTS

2.2.1 Clinical Group

The participants for the clinical group were adolescents with type-1 diabetes, aged between 12 and 18 years, who attended the outpatient paediatric and young adult diabetes clinics in Tayside and Fife. This age range was chosen for a number of clinical, theoretical and practical reasons. Adolescence has been shown to be a particularly vulnerable time for low adherence to the diabetes regimen (Johnson, 1995b) and it is a time when individuals become increasingly responsible for their own diabetes care (Anderson et al, 1990). Eating and weight concerns have

also been shown to develop and be prevalent in adolescence (Cooper and Goodyer, 1997), making it a critical age range for the investigation of both these factors. A wide age range was chosen to allow any potential developmentally related trends to be identified. Furthermore, the available clinical populations matched this age range, with adolescents in Tayside and Fife tending to transfer to the adult diabetes clinics at a later stage (usually at around age 18 years) than in other area clinics (where transition may begin at age 15 years). Finally, the proposed questionnaires were not believed to be suitable for use with children under 12 years old, due to some items being inappropriate and their lack of validation in this age group.

Both males and females were included in the study. Although much of the previous research into eating concerns in type-1 diabetes has focused on female participants, males with type-1 diabetes have also been found to be at an increased risk for eating disorders (Svensson, Engstrom and Aman, 2003).

Due to the 'honeymoon period', adolescents who had been diagnosed with diabetes for less than one year were excluded from the study. The 'honeymoon period' is where the pancreatic cells continue to produce small amounts of insulin, meaning that a remission occurs and less prescribed insulin is required for blood glucose maintenance. This can last up to one year following initial diagnosis, after which naturally occurring insulin is no longer produced and insulin treatment can be properly regulated. It was not therefore appropriate to include adolescents who had been diagnosed for less than one year, as their prescribed insulin regimens would be an arbitrary variable.

Adolescents with learning difficulties (n =1) or those with concurrent social difficulties (n = 2) for whom members of the diabetes team felt that participation in the study was inappropriate, were also excluded.

In order to ensure that as many potential participants could be recruited as possible, it was decided not to exclude adolescents who had another chronic illness. However, this information was collected and considered in the data analysis (see section 3.3.4).

Seventy-three participants met the inclusion criteria and were invited to take part in the study. The number of participants who agreed to take part in each area, along with the ratio of males to females, can be seen in Table 2.

Table 2: Response Rates for the Diabetes Group

	Number in Tayside	**Number in Fife**	**Total**
Number invited to take part	36	37	73
Number who agreed to take part (%)	32 (88.9)	30 (81.1)	62 (84.9)
Number of females who took part (%)	17 (53.1)	15 (50)	32 (51.6)
Number of males who took part (%)	15 (46.9)	15 (50)	30 (48.4)
Age range	12-18	13-18	12-18
Mean Age	14.84	15.69	15.28

2.2.2 Control Group

The participants for the control group were adolescents without type-1 diabetes, aged between 12 and 18 years, who attended one of three secondary schools in North East Fife. A secondary school population was chosen in order to provide a large potential participant pool, with both the appropriate wide age range and a variety of socio-economic backgrounds. Through availability sampling, five schools in North East Fife were contacted and three agreed to take part in the study.

Adolescents with type-1 diabetes and adolescents with learning difficulties for whom the school expected to have difficulties in understanding the questionnaires were excluded. As the schools were in charge of selecting participants, the number of pupils excluded for these reasons is not available.

Once again, the presence of a chronic illness was assessed, but adolescents were not excluded from the study if they had a chronic illness other than diabetes, although this was considered in the data analysis (see section 3.3.4).

In order to manage data collection, potential participants were restricted to either 20 pupils or one class, from each year at each school (depending on the method of data collection), who met the inclusion criteria. These samples were randomly selected by the school to take part in the study. Three-hundred participants were invited to take part. The number of participants who agreed to take part in each school, along with the ratio of males to females, can be seen in Table 3.

Table 3: Response Rates for the Control Group

	Number in School 1	**Number in School 2**	**Number in School 3: postal survey**	**Total**
Number invited to take part	100	100	100	300
Number who agreed to take part (%)	93 (93)	49 (49)	14 (14)	156 (52)
Number of females who took part (%)	43 (46.2)	22 (44.9)*	8 (57.1)	73 (46.8)
Number of males who took part (%)	50 (53.8)	25 (51.0)*	6 (42.9)	81 (51.9)
Age range	12-17	12-16	13-16	12-17
Mean Age	14.00	13.23	13.83	14.86

* Two participants failed to record their gender.

2.3. MEASURES

The measures used in the study are summarised in Table 4.

Table 4: Table of Measure Used in the Study

Variable	Measure	Reference	Clinical Group	Control Group
Eating and Weight Concerns	Eating Disorders Examination Questionnaire	Fairburn and Beglin (1994)	√	√
Adherence	Self-Report Measure of Adherence	Based on Toobert and Glasgow, 1994	√	X
Glycaemic Control	HbA1c		√	X
Background Information	Self-Report Background Information Questionnaire	Researcher compiled	√	√

2.3.1 The Eating Disorders Examination Questionnaire (EDE-Q).

The EDE-Q (Fairburn and Beglin, 1994) is a self-report version of the Eating Disorders Examination (EDE; Fairburn and Cooper, 1993), an investigator-based semi-structured interview designed to measure the broad range of specific psychopathology of eating disorders. The EDE has been classed as the method of choice for assessing such psychopathology (Wilson, 1993) and has the advantage that the complex features of eating disorders can be defined and addressed in detail, due to its interview format (Cooper and Fairburn, 1987). The EDE is widely used in both community and clinical settings and has established inter-rater reliability (Cooper and Fairburn, 1987; Fairburn and Cooper, 1993), discriminant validity (Cooper, Cooper and Fairburn, 1989) and concurrent validity (Rosen, Vara, Wendt and Leitenberg, 1990). The EDE has also been adapted for use in the type-1 diabetes population, by including questions relating to insulin manipulation and ensuring that a distinction is made between dietary habits relating to diabetes and those relating to eating disorder pathology (Fairburn et al, 1991). It has also been used

extensively for research with adolescents with type-1 diabetes from the age of 11 years (e.g. Striegel- Moore et al, 1992; Peveler et al, 2005).

However, the EDE is not always practical due to the requirement of training for its use, the length of time it takes to administer and its lack of anonymity where sensitive issues are concerned (Wilfley, Schwartz, Spurrell and Fairburn, 1997). The EDE-Q was therefore developed to overcome these difficulties. The items of the EDE-Q are directly based on the corresponding EDE interview questions and the EDE-Q uses the same 7-point rating scale. The EDE-Q is therefore a 38-item instrument and like the EDE, produces four subscale scores (restraint, eating concern, shape concern and weight concern) in addition to a total score.

The EDE-Q has also been shown to have good reliability and validity. Luce and Crowther (1999) examined the internal consistency and test-retest reliability of the EDE-Q in a large sample of female undergraduate students, who were re-tested after a two week interval. They found the Cronbach alpha coefficients to range between 0.78 and 0.93 across all four subscales and the reliability coefficients to range between 0.81 and 0.94 across subscales and 0.57 to 0.70 for items measuring the frequency of key behaviours. Similarly, three studies have investigated the convergent validity of the EDE-Q as compared to the EDE. Fairburn and Beglin (1994) found that in populations of females with and without eating disorders, scores were highly correlated between the two measures across all subscales. However the level of agreement was lower for the shape concern subscale and the EDE-Q generated higher scores for the frequency of binge eating. Black and Wilson (1996) obtained similar results in a clinical sample of female substance abusers and Wilfley et al (1997) found modest to good agreement between the two measures across all subscales in a sample of obese women with binge eating disorder. Wilson, Nonas and Rosenbloom (1993) also showed the EDE-Q to have good discriminant validity in distinguishing between obese binge eaters and non-binge eaters. Fairburn and Beglin (1994)

therefore concluded that the EDE-Q could be used instead of the EDE when assessing features of eating disorders that do not pose problems of definition (such as with binge eating). Similarly, Luce and Crowther (1999) concluded that the EDE-Q appeared to be a psychometrically sound self-report measure for the screening of eating disorders. Black and Wilson (1996) stated more conservatively that the EDE-Q would be useful as an initial screening measure, with the possibility of additional assessment being necessary when scores were elevated.

Wilfley et al (1997) suggest that the decision about which method to use should be based on the purpose of the evaluation, with the EDE being necessary to establish a clinical diagnosis, to measure clinical levels of psychopathology or to obtain a detailed picture of the eating disorder features present. The EDE-Q was therefore chosen in this study due to the reduced administration time, the evidence of reliability and validity and because the aim of this study was not to establish clinical diagnoses or formulations. The EDE-Q was therefore a more economical choice for this study.

Carter, Stewart and Fairburn (2001) adapted the EDE-Q for use in an adolescent population, in order to produce normative data for a British sample of 808 girls between the ages of 12 and 14 years. The EDE-Q was adapted in two ways to make it suitable for this population; the time frame was shortened from 28 days to 14 days to make it more developmentally appropriate and the wording of the questions was simplified. A copy of this adapted questionnaire was obtained from the principle author and permission was granted for its use in this study.

In line with the adaptations made to the EDE for use in the diabetes population and on the advice of one of its authors (Fairburn), the diabetes specialist nurses were consulted and the EDE-Q was adapted in two main ways for use with the diabetes group in this study. Question 33 (How much would it upset you if you had to weigh yourself once a week for the next four weeks?) was

changed to: "How much does it upset you when you get weighed at the diabetes clinic?" In order to address the issue of insulin manipulation, a question was added after question 28, asking: "Have you done anything else to control your shape or weight? If so, what have you done? How many times have you done this over the last two weeks?" This question followed the format of the other questions asking about specific eating disorder behaviours. It was decided to ask an open-ended question rather than specifically ask about insulin manipulation, due to the recommendations made by the Tayside Committee on Medical Research Ethics. A full account of this can be found in the discussion section. As this question was generic rather than specific to diabetes, it was also included in the questionnaire distributed to the control sample. The remaining items in the EDE-Q were reviewed by the diabetes specialist nurses and it was agreed that no other questions had the potential of resulting in biased answers for the diabetes population. The version of the EDE-Q used for the diabetes population can be found in Appendix 1 and the version used for the control group in Appendix 2.

2.3.1.1 Scoring of EDE-Q

The four subscale scores on the EDE-Q are calculated by adding together the scores for the relevant items and dividing by the total number of items rated. A subscale score can be calculated if some of the item scores are missing, as long as more than half of the items have been rated. The EDE-Q total score is calculated by taking the mean of the four subscale scores.

2.3.2 Self-report Measure of Adherence

Due to the lack of widely accepted and reliable measures of adherence in type-1 diabetes, the measure of adherence used in this study was adapted from the Summary of Diabetes Self-Care Activities (SDSCA; Toobert and Glasgow, 1994). The SDSCA is a brief self-report measure of

the frequency of adherence to the regimen over the previous seven days. It assesses level of self-care for the four components of adherence: medication (insulin) taking, blood glucose testing, diet and exercise. The first three components are measured on a 5-point rating scale, while exercise is rated on the number of days for which the regimen was carried out. Toobert and Glasgow (1994) reported the findings of reliability and validity studies of the SDSCA and concluded that they provided some support for the reliability and validity of this measure. However, these studies were carried out in the type-2 diabetes population. Toobert, Hampson and Glasgow (2000) have subsequently investigated the validity and reliability of this measure by reviewing its use across seven separate studies. They concluded that the SDSCA had adequate test-retest reliability, evidence of validity and suggested that it was possibly the most widely used self-report measure of adherence. Due to its brevity, they also concluded that the SDSCA is of practical use both clinically and in research.

Unfortunately, the SDSCA has mainly been used in adults and with those who have type-2 diabetes. It therefore includes questions which would be unsuitable for an adolescent population with type-1 diabetes, such as questions relating to smoking habits and foot care. While these issues are of importance in type-1 diabetes, they are not the focus of treatment for adolescents. The SDSCA has previously been used with adolescents however (e.g. Skinner and Hampson, 1998). The SDSCA was therefore adapted for use in this study. Once again, the diabetes specialist nurses were consulted on the wording of the questions. It was agreed that due to the individualised regimens of the adolescents attending the clinics, the questions would have to be general and cover the four main parts of the diabetes regimen: insulin administration, blood glucose checking, diet and exercise. Each aspect of the regimen was assessed by two questions. In keeping with the SDSCA, the first three components were rated on a five-point scale and exercise was rated as the number of days on which exercise occurred. Additional open-ended questions were also devised to allow potential barriers to adherence to be disclosed.

Due to the wide age range of inclusion, it was also possible that not all participants would be independently responsible for their diabetes regimen. However, it was not considered appropriate to lengthen the questionnaire pack with the inclusion of a measure such as the 17-item Diabetes Family Responsibility Questionnaire (Anderson et al, 1990), as this may have overburdened participants, potentially leading to a reduction in the validity of their responses and a reduced participation rate. One question was therefore added to the adherence questionnaire, enquiring as to the number of daily insulin injections that the adolescent was responsible for. This specific question was chosen on the advice of the diabetes specialist nurses, as responsibility for insulin administration was considered to be most representative of overall responsibility. Furthermore, it was important to ask specifically about responsibility for insulin administration, to allow for the possibility of insulin manipulation to be considered. The adapted self-report measure of adherence can be found in Appendix 3.

It has been suggested that the reliability of self-report measures of adherence would be improved by gaining multiple reports of adherence, for example, by asking a family member or friend to complete the measure (Hayes and DiMatteo, 1989). The adherence measure was therefore administered to both adolescents and their parents, to allow the correlation between the two ratings of adherence to be assessed. Parents were also asked to provide two ratings of responsibility for care. The version of the self-report measure of adherence for parents can be found in Appendix 4.

2.3.2.1 Scoring of Self-Report Adherence Questionnaire

Higher scores on the adherence questionnaire reflected better self-reported adherence and individual item scores were reversed where appropriate. A subscale score was derived for each component of the treatment regimen by adding the scores for each relevant item. The maximum

subscale score was therefore 10. A total adherence score was obtained by adding together the scores for items assessing insulin adherence, blood glucose monitoring and dietary adherence. Adherence to exercise was not included in the total score as it was rated on a different scale to the other components. The maximum total adherence score was therefore 30.

The questions assessing responsibility for injections were scored on a 5-point scale (with a higher score reflecting more personal responsibility) and assessed individually. Responses to the open-ended questions were reviewed for associations between eating and weight concerns with adherence.

2.3.3 HbA1c

The three most recent HbA1c results for each participant were obtained from their medical files, in order to give an estimate of glycaemic control. The most recent HbA1c result was obtained at the clinic in which participants completed their questionnaires. An average estimate of HbA1c was also calculated from the three most recent HbA1c results.

The methods for obtaining HbA1c at both the Tayside and Fife clinics were DCCT aligned, meaning that the results could be directly compared between areas. While there was no locally derived normal HbA1c range, it is recommended that in type-1 diabetes, HbA1c should be below 7.5% (National Institute for Clinical Excellence, 2004).

2.3.4 Background Information

Background demographic information was also collected from all participants. This included sex, age and postcode sector. Postcode sector was obtained in order to examine socio-economic

status using Carstairs scores for Scottish Postcode Sectors (McLoone, 2004). Based on participants' postcodes, deprivation category scores (depcats), ranging from 1 (most affluent) to 7 (most deprived), were assigned.

For the diabetes group, this background information was requested at the beginning of the adherence questionnaire (see Appendices 3 and 4). A parent/guardian was also therefore asked to complete this information. For the control group, a brief background information questionnaire was administered to parents in the postal survey and to adolescents in the school surveys.

2.3.5 Other Information Collected

In addition to the HbA1c results, further information was obtained from the medical files of the diabetes group. This included length of diagnosis and the presence of any other chronic illnesses. The three most recent height and weight measurements were also recorded, to allow BMI to be calculated. Most recent BMI was calculated from the height and weight measurements taken at the clinic at which participants completed their questionnaires. Average BMI was also calculated from the three most recent height and weight measurements.

The insulin regimens of each participant and the units of insulin that they were prescribed to take each day were also recorded. The prescribed units of insulin per kilogram per day for each participant, was subsequently calculated using the daily number of units prescribed and the most recent weight measurement. The calculation of units of insulin per kg per day was therefore used to compare insulin doses between participants.

As medical information was not readily available for the control group, control participants were asked to record whether or not they had any chronic illnesses. They were also asked to record their height and weight measurements if known, on the background information questionnaire. For the control group, BMI was therefore calculated from self-reported height and weight if recorded.

2.4 PROCEDURE

2.4.1 Clinical Group

Prior to commencing the study, the researcher met with the Consultant Paediatricians and Diabetes Specialist Nurses for the Tayside and Fife paediatric and young persons' diabetes clinics, in order to obtain their advice and approval for commencing with the study. Ethical approval was then sought through the Central Office for Research Ethics Committee's (COREC) Central Allocation System (CAS), for multiple site studies. The original study proposal and application were reviewed by the Tayside Committee on Medical Research Ethics and were refused on the basis of "insurmountable" problems (Appendix 5). The study proposal was therefore reviewed and amended to take account of the comments made by the Tayside committee and a new application was submitted through CAS to the Fife and Forth Valley Local Research Ethics Committee. The second proposal was subsequently approved with two minor changes and permission was granted to proceed with the research in both Tayside and Fife regions (see Appendix 6). An account of the changes that had to be made and the time delay incurred due to the original refusal can be found in the discussion section. Following ethical approval being granted, approval from both Tayside and Fife Research and Development committees was obtained before data collection began (see Appendices 7 and 8 respectively). Permission from the Caldicott Guardians for Tayside and Fife was also sought and granted, to

allow information from the participants' medical files to be collected (see Appendices 9 and 10 respectively).

The study was introduced to potential participants and their parents at their routine diabetes clinic appointments. Where practically possible, this was done by the researcher. However due to the rural location of some of the clinics and time limitations, the diabetes specialist nurses, a consultant paediatrician and an assistant psychologist agreed to introduce the study to potential participants at some of the more remote clinics. Collectively, 31% of the data were collected by these staff members.

Potential participants and their parents were each presented with a study pack. Table 5 shows the information included in the parent's pack and Table 6 shows what was included in the adolescent's pack.

Table 5: Contents of the Study Pack for Parents of Participants in the Diabetes Group

Description of Contents	Appendices
1. *Introductory Letter from the Consultant Paediatricians*	11 and 12 (Tayside and Fife)
2. *Introductory Letter from the Researcher*	13
3. *Information Sheet for Parents*	14
4. *Consent Form for Parents*	15
5. *Diabetes (adherence) Questionnaire for Parents*	4

The order of presentation of the EDE-Q and the Diabetes Questionnaire in the packs provided to adolescents was counterbalanced, in order to minimise the potential effects that one questionnaire may have had on the other. However, the order in which the questionnaires were actually completed could not be controlled for.

Table 6: Contents of the Study Pack for Participants in the Diabetes Group

Description of Contents	Appendices
1. *Information Sheet for Adolescents*	16
2. *Consent Form for Adolescents*	17
3. *Diabetes (adherence) Questionnaire for Adolescents*	3
4. *Eating Disorders Examination Questionnaire (EDE-Q)*	1

The study was explained to potential participants and their parents and both parents and adolescents were asked to consent to taking part in the study and to allowing the researcher access to information from their medical file. They were also advised that their GP would be informed of their decision to take part in the study (see Appendix 18).

If they agreed to take part, participants were given the option of either completing the questionnaires while they were waiting at the clinic or taking them home to complete and post back to the researcher in a pre-paid envelope. Only three participants chose to take their questionnaires home and post them back to the researcher. If participants chose to complete their questionnaires at the clinic, they were provided with a quiet space to do so and were assured that their answers would be confidential. Separate envelopes were provided for parents and adolescents to seal their questionnaires in. This was to ensure that participants were confident that their answers would be confidential. Participants were informed that their questionnaires would be coded, to enable the information from their medical file to be matched with their questionnaire responses. The coding included the initials of the person collecting the data, to ensure that this could be controlled for in the data analyses.

If adolescents aged 16 years or over attended the clinic without their parent and were deemed capable of consenting to their own medical treatment, the study was introduced to them at the

clinic in the same way. These participants were therefore allowed to consent to their own participation in the study and were asked to take the parental pack home for their parent/guardian to complete and post back to the researcher in a pre-paid envelope. Twenty participants completed their questionnaires in the absence of a parent and none of these parents subsequently returned their consent form and questionnaire.

If the participants completed their questionnaires at the clinic, the person collecting the data was available to answer any questions they may have had. All participants were encouraged to contact the researcher if their participation in the study raised any issues or questions that they wished to discuss.

Once the completed questionnaires were gathered by the researcher, a Medical Information form (see Appendix 19) was completed by a member of the diabetes team, for each participant who had consented to take part in the study. The Medical Information forms were coded in the same way as the questionnaire responses and the participants' codes and questionnaire responses were kept separately from the medical information.

2.4.2 Control Group

Permission to contact schools was obtained from the Education Authority in Fife (see Appendix 20). The head-teachers of local schools were then contacted and asked if they would agree for their school to take part in the research. Five schools were contacted in total and three agreed to take part. The procedure for distributing the questionnaires and collecting the data was subsequently informed by the schools' own preferences. Two procedures were employed.

In one of the schools, data was collected using a postal survey design. The school was asked to randomly select twenty pupils from each year group. A questionnaire pack was then posted out to the parents of the selected pupils. Table 7 shows the contents of the questionnaire pack.

Table 7: Contents of Postal Survey Questionnaire Pack for Control Group Participants

Description of Contents	Appendices
1. *Introductory Letter for parents*	21
2. *Information Sheet for Parents*	22
3. *Information Sheet for Adolescents*	23
4. *Consent Form for Parents*	24
5. *Consent Form for Adolescents*	25
6. *Background Information Questionnaire for Parents*	26
7. *Eating Disorders Examination Questionnaire (EDE-Q) for Adolescents*	2

Parents were asked to read through the information sheet and give the other one to their child. They were then both asked to consent to taking part in the study. Parents were asked to complete the background information sheet and return it with their consent form in the pre-paid envelope provided. Adolescents were asked to complete the EDE-Q and return it with their signed consent form in the pre-paid envelope provided. One-hundred questionnaire packs were sent out and 14 were returned; a response rate of 14%.

In the remaining two schools, it was agreed that the questionnaires could be distributed to potential participants as part of their social education or registration classes. The schools were therefore asked to randomly select one class from each year group, in which the questionnaires would be handed out. An introductory letter was sent to the parents of each pupil in the selected classes, asking for them to consent to their child taking part in the study (see Appendix 27), along with an information sheet (see Appendix 28). On the advice of the schools, parents were asked to opt-out of consenting rather than opt-in, due to experience of schools receiving a low

response rate from parents to such letters. Two-hundred parents were asked to allow their child to take part in the study and only 1 contacted the schools to say that they were not happy for their child to take part. Table 8 shows the forms distributed to adolescents.

Table 8: Contents of Questionnaire Pack Distributed to Control Group Participants in Schools

Description of Contents	Appendices
1. Information Sheet for Adolescents	29
2. Background Information Questionnaire for Adolescents	30
3. Eating Disorders Examination Questionnaire (EDE-Q) for Adolescents	2

The teachers were asked to advise pupils to read the information sheet before completing the questionnaire and to emphasise that taking part in the study was voluntary. If pupils did not want to take part, they could simply choose not to complete the questionnaire. The teachers were also asked to ensure that the pupils did not discuss their answers with each other and that the adolescents would have adequate privacy to complete the questionnaires. When they had completed the questionnaires, the pupils were asked to seal them in the envelope provided and return them to their teacher. Two hundred questionnaires were distributed and 142 adolescents completed the questionnaires; a response rate of 71%.

2.5 ANALYSIS OF DATA

2.5.1 Data Analysis

The data was analysed using the Statistical Package for Social Sciences (SPSS), Standard Version 10.1, for Windows 2000. When the completed questionnaires were returned, they were scored and the results were entered into a database with no identifying information. Data entry

was checked for accuracy by asking an independent clinician to randomly check 10% of the participants' data.

All variables were checked for assumptions of normality by examining frequency distribution charts and values of skewness and kurtosis. Data which was not normally distributed was transformed. The data were also examined for outliers by using boxplot diagrams and exploratory multiple regression. Where outliers were detected, analyses were conducted both with and without outliers.

2.5.1.1. Between-Subjects Analyses

The clinical and control groups were compared on a number of demographic factors using t-tests, to assess how well matched they were. Where differences were found between the two groups, the relevant variables were controlled for in further data analyses. An ANCOVA was used to compare the two groups on BMI and eating and weight concerns as measured by the EDE-Q.

2.5.1.2. Within-Subjects Analyses

The variables of the clinical group were examined by using parametric bivariate and point-biserial correlations (Pearson's Product-Moment Correlations). Hierarchical regression models were used to predict variance in glycaemic control, adherence and eating and weight concerns. Hierarchical regression was chosen to allow the researcher to enter appropriate variables into the regression analysis in an order which was informed by the findings of previous research (Field, 2000). Variables to be entered into the regression analysis were chosen on the basis of their theoretical importance and the strength of their correlation with the outcome variables.

2.5.2 Statistical Power

Previous research has indicated that eating disturbances are common among adolescents (Cooper and Goodyer, 1997) and that adherence and glycaemic control are often poor in adolescents with type-1 diabetes (Johnson, 1995b). While research into diabetes and eating disturbances has previously been under-powered (e.g. Peveler et al, 1992), this is often due to a specific focus on the prevalence of clinical eating disorders or insulin omission. A larger effect size is anticipated in this study as the prevalence of clinically diagnosable eating disorders is not being examined. However, poor adherence and strategies to control weight may be under reported (Johnson, 1992; Polonsky et al, 1994). A medium effect size is therefore anticipated. In order to carry out correlations and multiple regression with 4 independent variables, Cohen (1992) advises that to obtain a medium effect size at $p=0.05$ and a power level of 0.80, 84 participants would be required.

Following discussions with staff in the diabetes teams at each site, it was expected that approximately 150 patients would meet the inclusion criteria in Tayside and approximately 80 would meet the criteria in Fife. Fewer participants were recruited than was initially anticipated however, due to the changes that had to be made to the study to gain ethical approval and subsequent time limitations. These limitations are explored in the discussion section, along with post-hoc power calculations.

CHAPTER THREE

RESULTS

3.1 PARTICIPANTS

The demographic information for both groups can be found in Table 9.

3.1.1 Diabetes Group

Sixty-two adolescents agreed to take part in the study. However, one adolescent was excluded due to incompletion of their questionnaires, resulting in over half of their data being missing. Questionnaire scores could not therefore be calculated for this participant.

The final sample consisted of 61 participants, with a mean age of 15.28 years and 50.8% females. Eight participants (13.11%) reported the presence of another chronic illness. One participant had cystic fibrosis, 3 had asthma and the remaining four had a variety of conditions including epilepsy and a skin condition. The parental adherence questionnaire was completed for 67.2% of the diabetes sample.

3.1.2 Control Group

A total of 156 pupils completed the questionnaires for inclusion in the study. However two participants were excluded due to incompletion of their questionnaires, meaning that questionnaire scores could not be calculated.

The final sample consisted of 154 participants, with a mean age of 13.84 years and 47.4% females. The presence of a chronic illness was identified by 14 (9.33%) of the control group, although 4 participants failed to respond to this question. Self-reported height and weight measurements were provided by 27 (37%) females and 40 (50%) males.

Table 9: Demographic Information for the Diabetes and Control Groups

	Diabetes Group	**Control Group**
Total Number	61	154
Age Range	12 – 18 years	12 – 17 years
Mean Age (std. dev.)	15.28 years (1.66)	13.84 years (1.38)
No Males (%)	30 (49.2)	80 (52.0)*
No Females (%)	31 (50.8)	73 (47.4)*
Deprivation Category Range	1 – 7	2 – 7
Mean Deprivation Category	4.14	4.01
Presence of Chronic Illness	13.11%	9.33%

***N.B. One participant did not state whether they were male or female**

3.2 EXPLORATORY DATA ANALYSIS

3.2.1 Missing Data

Randomly distributed missing data was accounted for by SPSS, which removed cases with missing values from the analysis on an individual test basis. Variable sample sizes are therefore recorded depending on the variables used.

Due to an error in postcode recording, 33% of the deprivation categories (depcats) were missing for control group. However, enough information was provided to determine that for these participants, the depcat was either 3 or 4. As the mean depcat for the remainder of the sample was 4, missing values were replaced with a depcat of 4 for these participants only.

3.2.2 Normality

The normality of each variable was tested prior to analysis. The Kolmogorov-Smirnov test of normality was considered too powerful and as such, tests of skewness and kurtosis were employed as recommended by Tabachnick and Fidell (1996). For skewness and kurtosis, a z score above 1.96 was considered problematic (Field, 2000)[1].

Variables which were positively skewed were transformed using square-root, logarithm or inverse transformations and variables which were negatively skewed were transformed using reflected square root and logarithm transformations[2] (Tabachnick and Fidell, 1996). These transformations were successful in removing skewness, kurtosis and a number of outliers from the data. It was therefore concluded that there were no extreme departures from normality in the data, following transformation.

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[1] z-score for skewness = skewness/std error of skewness.
z-score for kurtosis = √(kurtosis/std error for kurtosis)

[2] For variables which were reflected in transformation, the direction of the interpretation of results was reversed.

The only variable for which skewness and kurtosis were not removed, was responsibility for injections, as rated by adolescents. This variable was not therefore included in any analyses and was replaced by the parents' rating of overall responsibility.

3.2.3 Data Measurement

For the assumptions of parametric tests to be met, data should be interval. The questionnaire data in this study were measured on 7-point and 5-point Likert scales for the EDE-Q and adherence questionnaires respectively and this would usually be classed as discrete or ordinal data. However, Clark-Carter (2004) reports that statisticians are less concerned with this assumption and Tabachnick and Fidell (1996) argue that the type of measurement is not as crucial as the distribution of the data. If the measurement is ordinal therefore and has a sufficient number of levels (usually considered to be 7 levels or more), then parametric tests can be used (Clark-Carter, 2004). Although the adherence scale was mainly measured on only 5 levels, it was decided that due to the reduced emphasis on this assumption and the common practice of treating such data as continuous (Tabachnick and Fidell, 1996), these measurements could be treated as continuous for the purposes of analysis.

3.2.4 Use of Parametric Statistics

Clark-Carter (2004) states that parametric tests are considered robust even when some of their assumptions are not met. The assumption of normality was met through the

transformation of the variables. Furthermore, data measured on Likert scales are generally considered appropriate for the use of parametric tests (Tabachnick and Fidell, 1996). It was therefore concluded that parametric tests could be used without compromising their robustness.

The particular assumptions which must be met for the use of multiple regression, will be addressed in section 3.5.2.1.

3.2.5 Outliers

Univariate outliers were determined through examination of stem-and-leaf diagrams and boxplots for each variable, following transformation. Outliers were indicated for Body Mass Index (BMI) and units per kg per day in the diabetes group. Analyses involving these variables were therefore carried out before and after the removal of outliers.

The presence of multivariate outliers was examined using an exploratory regression, with group category as a dummy outcome variable. No multivariate outliers were detected for the sample as a whole, using the SPSS default setting of cases being identified as outliers if their standardised residual is more than 3 or less than -3. The presence of outliers in the specific regression models which were carried out was re-examined out however and this process is described in section 3.5.2.2.

3.2.6 Multicollinearity and Singularity

An exploratory correlation analysis was carried out to check for multicollinearity and singularity between the variables (see Table 10).[3] For the diabetes group, most recent BMI and average BMI were highly correlated, as were most recent HbA1c result and the average HbA1c for each participant. For both groups, the EDE-Q total score was highly correlated with each of its subscale scores. It was therefore advisable to omit some of these variables from the following analyses. Most recent BMI was chosen for use in analyses over average BMI, due to the absence of an average BMI for the control group. Furthermore, the most recent weight of participants in the diabetes group was used to calculate units of insulin per kg per day, therefore informing the choice of using most recent BMI. Average HbA1c was chosen due to the presence of a remaining outlier in most recent HbA1c after transformation. The EDE-Q subscales were also omitted from the following analyses due to their high correlation with the EDE-Q total score.

[3] Correlations above 0.80 are generally considered to be problematic (Field, 2000)

Table 10: Exploratory Correlations for Multicollinearity: HbA1c, BMI and EDE-Q

		1	2	3	4	5	6	7	8	9
1. Most Recent BMI	r	1	**0.972****	**-0.281***	**-0.288***	**0.486****	**-0.502****	**-0.468****	**-0.451****	**-0.329***
	p	.	<0.001	0.031	0.028	<0.001	<0.001	<0.001	<0.001	0.011
	N	59	57	59	58	59	59	59	59	59
2. Average BMI	r		1	**-0.276***	**-0.336***	**0.454****	**-0.470****	**-0.433****	**-0.435****	**-0.306***
	p		.	0.038	0.011	<0.001	<0.001	0.001	0.001	0.021
	N		57	57	56	57	57	57	57	57
3. Most Recent HbA1c	r			1	**0.887****	0.028	-0.056	-0.035	-0.123	0.068
	p			.	<0.001	0.832	0.667	0.791	0.343	0.603
	N			61	59	61	61	61	61	61
4. Average HbA1c	r				1	0.038	-0.112	0.010	-0.061	0.015
	p				.	0.776	0.398	0.941	0.646	0.912
	N				59	59	59	59	59	59
5. EDE-Q Total Score	r					1	**-0.799****	**-0.894****	**-0.916****	**-0.807****
	p					.	<0.001	<0.001	<0.001	<0.001
	N					61	61	61	61	61
6. EDE-Q Restraint Subscale	r						1	**0.681****	**0.706****	**0.575****
	p						.	<0.001	<0.001	<0.001
	N						61	61	61	61
7. EDE-Q Weight Concern Subscale	r							1	**0.863****	**0.574****
	p							.	<0.001	<0.001
	N							61	61	61
8. EDE-Q Shape Concern Subscale	r								1	**0.663****
	p								.	<0.001
	N								61	61
9. EDE-Q Eating Concern Subscale	r									1
	p									.
	N									61

- Where r = Pearson co-efficient, p = 2-tailed significance value and N = no. of participants

*** Correlation is significant at the 0.05 level**

**** Correlation is significant at the 0.01 level**

The total adherence scores for both adolescents and their parents were significantly correlated with their respective subscale scores (see Table 11). Furthermore, there were some significant inter-correlations between the subscale scores, which is in contrast to what would be expected from previous research. Although these correlations did not meet the strength suggesting that multicollinearity would be problematic, a decision was made to use only the total adherence scores in the following analyses. This was due to the need to reduce the number of variables used in the regression analyses in order that reliability may be maintained in relation to the sample size (Field, 2000) and due to significant correlations between subscales, suggesting that important information about the differential effect of subscale scores would not be lost.

3.2.7 Reliability of Questionnaires

3.2.7.1 EDE-Q

The internal consistency of the EDE-Q with this sample was tested and the Cronbach's alpha co-efficients for EDE-Q total scores for both the diabetes group and the control group are shown in Table 12. As the alpha co-efficients are both higher than 0.70, it can be concluded that the use of the EDE-Q is reliable with this sample (Clark-Carter, 2004).

Table 11: Exploratory Correlations for Adherence and Parent Rating of Adherence

		1	2	3	4	5	6	7	8	9	10
Adherence Total Score	r	1	**0.664****	**0.837****	**0.544****	**0.318***	**0.627****	**0.368***	**0.568****	**0.401***	0.243
	p	.	<0.001	<0.001	<0.001	0.014	<0.001	0.023	<0.001	0.011	0.136
	N	59	59	59	59	59	38	38	39	39	39
Adherence to Injections	r		1	**0.392****	0.255	0.153	0.188	**0.330***	0.117	0.212	0.050
	p		.	0.002	0.052	0.248	0.258	0.043	0.479	0.195	0.761
	N			59	59	59	38	38	39	39	39
Adherence to Blood Testing	r			1	0.107	**0.258***	**0.660****	0.275	**0.735****	0.214	0.249
	p			.	0.416	0.046	<0.001	0.090	<0.001	0.184	0.122
	N			60	60	60	39	30	40	40	40
Adherence to Diet	r				1	**0.316***	0.211	0.176	-0.096	**0.505****	0.135
	p				.	0.13	0.192	0.277	0.550	0.001	0.399
	N				61	61	40	40	41	41	41
Adherence to Exercise	r					1	0.255	0.221	0.228	0.177	**0.694****
	p					.	0.112	0.170	0.152	0.267	<0.001
	N					61	40	40	41	41	41
Parent Rating of Total Adherence	r						1	**0.697****	**0.808****	**0.617****	0.223
	p						.	<0.001	<0.001	<0.001	0.166
	N						40	40	40	40	40
Parent Rating of Injection Adherence	r							1	**0.357***	**0.425****	0.260
	p							.	0.024	0.006	0.105
	N							40	40	40	40
Parent Rating of Blood Testing Adherence	r								1	0.088	0.195
	p								.	0.584	0.221
	N								41	41	41
Parent Rating of Diet Adherence	r									1	0.099
	p									.	0.538
	N									41	41
0. Parent Rating of Exercise Adherence	r										1
	p										.
	N										41

- Where r = Pearson co-efficient, p = 2-tailed significance value and N = no. of participants

*** Correlation is significant at the 0.05 level**

**** Correlation is significant at the 0.01 level**

Table 12: Alpha Co-Efficients for EDE-Q and Adherence Questionnaires

	Diabetes Group	Control Group
EDE-Q Total Score	0.93	0.95
Adherence Total Score	0.70	
Parent Rating of Adherence	0.70	

3.2.7.2 Adherence Questionnaire

The Cronbach's alpha co-efficients for the total adherence scores for both adolescents and their parents are also shown in Table 12. Once again, both alpha co-efficients are 0.70, suggesting that the use of this measure is reliable (Clark-Carter, 2004). Furthermore, the adolescents' own ratings of adherence and their parents ratings of adherence are significantly and positively correlated (Table 11), showing that parents tended to confirm their children's self-report ratings of adherence.

3.3 DESCRIPTIVE STATISTICS

3.3.1 EDE-Q

Table 13 shows the means and standard deviations of the total EDE-Q scores for the diabetes group, the control group and for males and females. It can be seen that for the overall sample, the mean EDE-Q total score was lower in the diabetes group than in the control group. For both groups, EDE-Q scores were higher amongst females than in males. The overall scores are low however, with a high number of participants recording no symptoms or concerns.

Table 13: Means and Standard Deviations for the EDE-Q Total Scores

	Diabetes Group			**Control Group**		
	N	*Mean*	*SD*	*N*	*Mean*	*SD*
EDE-Q Total Score	**61**	**0.86**	**0.92**	**154**	**1.09**	**1.18**
EDE-Q Total Score for females	**31**	**1.12**	**1.04**	**73**	**1.41**	**1.29**
EDE-Q Total Score for Males	**30**	**0.59**	**0.69**	**80**	**0.77**	**0.98**

The EDE-Q total scores were compared with normative data provided by Carter et al (2001) using z-tests (Clark-Carter, 2004). Their sample consisted of 808 females between the ages of 12-14 years, with a mean age of 13.4 years and a mean EDE-Q total score of 1.6 (SD = 1.4). The mean scores for both the diabetes group and the control group were significantly lower than the normative sample ($z = -4.16$, $p<0.01$ and $z = -$

4.54, $p<0.01$ respectively) and this significance was not removed when males were excluded from the current sample ($z = -3.13$, $p<0.01$ and $z = -2.75$, $p<0.01$ for the diabetes and control groups respectively). However, the mean ages of both the diabetes group and the control group were significantly higher than the normative sample ($z = 31.3$, $p<0.01$ and $z = 11$, $p<0.01$ respectively). The comparison of these two groups must therefore be interpreted with caution.

Table 14 shows the number of participants who scored in the clinically significant range (score ≥ 4) on the EDE-Q subscales and total score. It can be seen that clinically significant scores were more prevalent for the weight and shape concern subscales and that participants in the control group were more likely to report clinically significant concerns. For both groups, females tended to report clinically significant scores more than males.

Table 14: Number of Participants Scoring in the Clinically Significant Range on the EDE-Q Subscales and Total Score

	Diabetes Group			**Control Group**		
	No. Females (%)	*No. Males (%)*	*Total No. (%)*	*No. Females (%)*	*No. Males (%)*	*Total No. (%)*
Restraint Subscale	**0 (0)**	**0 (0)**	**0 (0)**	**2 (2.74)**	**1 (1.25)**	**3 (1.96)**
Eating Concern Subscale	**0 (0)**	**0 (0)**	**0 (0)**	**1 (1.37)**	**0 (0)**	**1 (0.65)**
Weight Concern Subscale	**3 (9.68)**	**0 (0)**	**3(4.92)**	**10 (13.70)**	**3 (3.75)**	**13 (8.50)**
Shape Concern Subscale	**1 (3.23)**	**0 (0)**	**1 (1.61)**	**14 (19.18)**	**4 (5.00)**	**18 (11.76)**
Total Score	**1 (3.23)**	**0 (0)**	**1 (1.61)**	**2 (2.74)**	**1 (1.25)**	**3 (1.96)**

In the control group, 33.3% reported that they had eaten what other people would think was a very large amount of food and this occurred an average of 2.49 times over the previous two weeks. The use of vomiting and laxatives to control weight or shape was reported by 1.9% of participants and this occurred an average of 2.5 and 1.67 times respectively, over the previous two weeks. No participants reported the use of diuretics, but 39.2% reported exercising hard, with an average frequency of 5.21 times over the previous two weeks. Fifty-five participants (35.9%) also reported doing something else to control their weight or shape. Twenty-one participants reported that they undertook a normal amount of exercise, nineteen reported that they ate healthily and 13 reported dieting behaviour. Other responses included using weights, going out with friends and eating more.

In the diabetes group, 42.6% reported that they had eaten what other people would think was a very large amount of food and this occurred an average of 3.08 times over the previous two weeks. No participants reported the use of vomiting, laxatives or diuretics in order to control their shape or weight. However, 26.2% reported that they exercised hard to control their weight or shape and this occurred an average of 7.29 times over the previous two weeks. Furthermore, 26.2% reported that they did something else to control their weight or shape. Ten participants reported that they undertook a normal amount of exercise, four described undertaking healthy eating practices and one participant described dieting. Only one participant admitted that they reduced their amount of insulin in order to control their weight or shape.

3.3.2 Body Mass Index (BMI)

Table 15 shows the means and standard deviations of the BMI scores for the diabetes group, the control group and for males and females. It can be seen that mean BMI is higher in the diabetes group when compared to the control group and this is true for both males and females. In the diabetes group, BMI is higher in females when compared to males, whereas in the control group, mean BMI is higher in males than females. A BMI between 20 and 25 is considered normal and the mean BMI scores for the diabetes group all fall within these normal limits. However, for the control group, the overall mean and the mean for females are below 20, suggesting that the participants in the control group and females in particular, tend to be underweight.

Table 15: Means and Standard Deviations for Body Mass Index Scores

	Diabetes Group			**Control Group**		
	N	*Mean*	*SD*	*N*	*Mean*	*SD*
BMI	59	22.35	3.34	67	19.80	3.72
BMI for females	29	22.94	3.75	27	18.80	2.59
BMI for Males	30	21.78	2.83	40	20.47	4.22

The mean BMI scores for this study were also compared with the sample of 12–14 year old females provided by Carter et al (2001), whose mean BMI was 20 (SD = 3.0). Mean BMI was significantly higher for the diabetes group as a whole ($z = 4.22$, $p<0.01$) and for females in the diabetes group ($z = 5.28$, $p<0.01$) than that in the normative sample.

Conversely, mean BMI for the females in the control group was significantly lower than that found in the normative sample ($z = -2.07$, $p<0.05$) but for the control group as a whole, BMI was not significantly different to the normative sample ($z = -0.35$, $p = 0.73$, ns).

3.3.3 Description of diabetes group

Table 16 shows the means and standard deviations for the additional variables collected for the diabetes group.

Table 16: Means and Standard Deviations for the Variables Specific to the Diabetes Group

	N	Mean	SD
Length of Diagnosis	61	6.77 years	3.87
Units of Insulin per kg per day	61	1.09	0.35
Average HbA1c	59	10.00	1.75
Total Adherence Score (% of total score of 30)	59	22.71 (75.7%)	3.87
Parent Total Adherence Score (%) (% of total score of 30)	40	23.57 (78.57)	3.37

The majority of participants were prescribed an average of 1 unit of insulin per kg per day and the small standard deviation shows that this had low variance across the sample. The average HbA1c of the group was 10%, which was significantly higher than the mean HbA1c reported by the Scottish Study Group for the Care of the Young Diabetic (2001)

using a Scottish sample of young people aged 15 or under ($z = 3.9$, $p<0.01$) and that reported by Morris et al (1997) using an older sample (aged 30 or under) from the Tayside population ($z = 6.4$, $p<0.01$).

A total of 45 (73.8%) participants were on an intensive insulin therapy (IIT) regimen. The means and standard deviations for the BMI scores of participants on IIT and standard insulin therapy are shown in Table 17. A two-tailed independent samples t-test found no significant difference in BMI between the two regimens ($t = 0.958$, $df = 57$, $p = 0.342$, ns) and this result was not changed with the removal of an outlier.

Table 17: Comparison of BMI Scores Between Intensive Insulin Therapy and Standard Insulin Therapy

	Intensive Insulin Therapy	**Standard Insulin Therapy**
Number of Participants (%)	45 (73.8)	16 (26.2)
Mean BMI	22.6	21.67
Standard Deviation of BMI	3.41	3.11
BMI Range	16.61 – 33.37	16.94 – 26.4

The majority of participants and their parents reported very high adherence to their self-care diabetes regimen. Responses to the open-ended adherence questions varied, but of interest were responses relating to weight and shape concerns. Only one participant reported that they would not take their insulin, or take it incorrectly, due to weight gain. One other participant noted weight loss as a consequence of not taking insulin or taking it

incorrectly. Two parents reported that their children would not take their insulin due to not wanting to get fat or gain weight. Weight gain was recorded as a consequence of eating unhealthily and of not exercising by 28 (45.9%) and 36 (59.0%) of the participants respectively. Of the parents, 15 (37.5%) reported weight gain as a consequence of eating unhealthily and 20 (50.0%) reported weight gain as a consequence of not exercising.

3.3.4 Comparisons between groups

As shown in Table 9, the ratio of males to females in both the diabetes and control groups is approximately 50:50. Two-tailed independent samples t-tests were carried out to compare the diabetes and control groups on age and deprivation categories. While the groups did not differ on depcats, the diabetes group was significantly older than the control group ($t = 6.394$, $df = 212$, $p<0.01$). Age was therefore controlled for in subsequent analyses.

The participants with a chronic illness did not differ significantly to those without a chronic illness on any of the variables and this was true for both the whole sample and for the diabetes group alone.

In the diabetes group, the researcher who collected the data made no significant difference to any of the variables.

3.4 COMPARISONS BETWEEN THE DIABETES AND CONTROL GROUPS

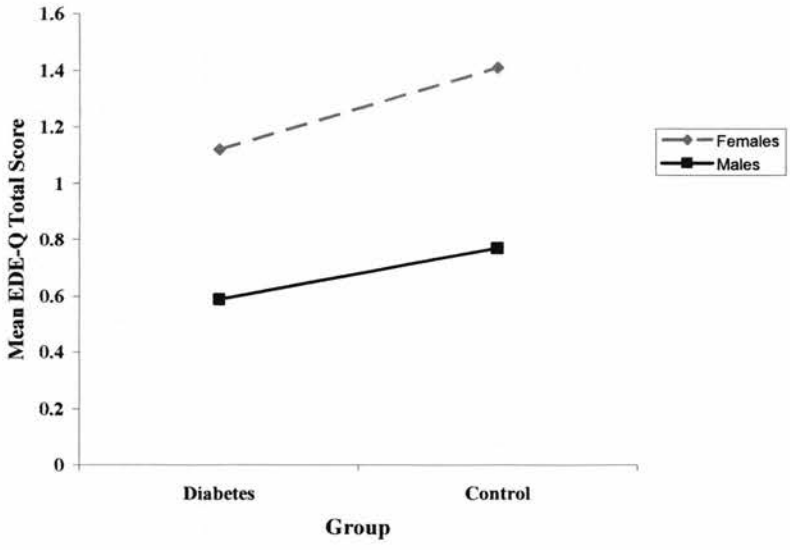
3.4.1. Hypothesis 1

Eating and weight concerns, as measured by the EDE-Q, will be higher in the type-1 diabetes group than in the control group, with such concerns more prevalent amongst females in both groups.

Hypothesis 1 was tested using a 2 x 2 Analysis of Co-Variance (ANCOVA), with age as a co-variant.[4] EDE-Q total scores were compared, with group and gender entered as fixed factors. There was no significant main effect of group ($F(1, 209) = 0.769$, $p = 0.381$, ns) and no significant interaction between group and gender ($F(1, 209) = 0.012$, $p = 0.912$, ns). However, there was a significant main effect of gender ($F(1, 209) = 0.625$, $p<0.01$, effect size = 0.064, power = 0.95). As displayed in Figure 2, the results of the ANCOVA show that females in both groups scored significantly higher on the EDE-Q than males. The results also show that there is no significant difference in eating and weight concerns between the two groups.

[4] Type IV sums of squares was chosen in SPSS to account for the unequal sample sizes and the presence of missing data (Field, 2000).

Figure 2: Mean EDE-Q Total Scores for Males and Females in the Diabetes and Control Groups



3.4.2 Hypothesis 2

Body Mass Index (BMI) will be significantly higher in the diabetes group than in the control group.

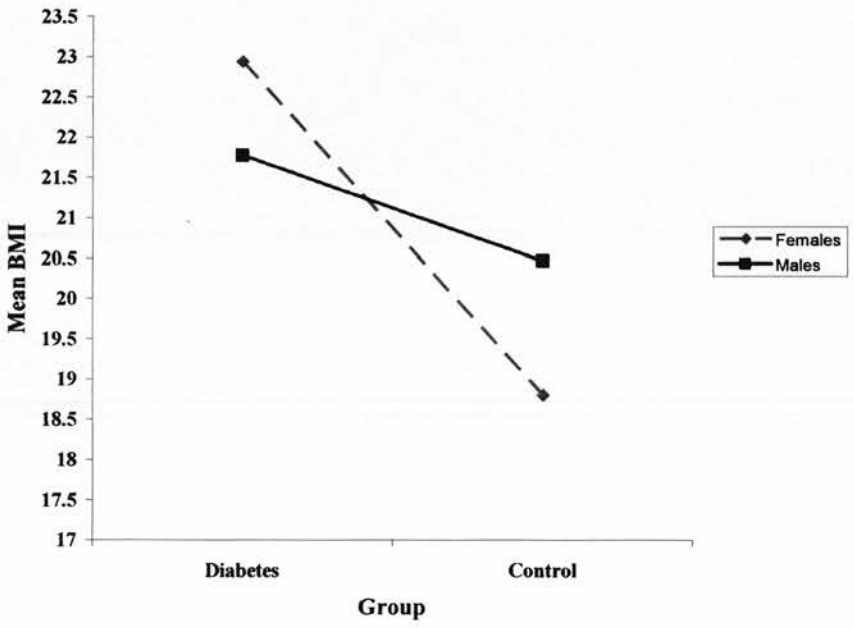
Hypothesis 2 was tested using a 2 x 2 ANCOVA, with age as a co-variant.[5] BMI scores were compared with group and gender entered as fixed factors. There was no significant main effect of gender ($F(1, 121) = 0.036$, $p = 0.601$, ns). However, there was a significant effect of group ($F(1, 121) = 10.145$), $p < 0.01$, effect size = 0.06, power = 0.80) and a significant interaction between group and gender ($F(1, 121) = 0.654$), $p <$

[5] Type IV sums of squares was chosen in SPSS to account for the unequal sample sizes and the presence of missing data (Field, 2000).

0.05, effect size = 0.03, power = 0.19). As displayed in Figure 3, the results of the ANCOVA show that BMI is significantly higher in the diabetes group than in the control group. However, the difference in female BMI between the two groups is larger than the difference in male BMI between the two groups.

The result of this ANCOVA was not changed by the removal an outlier.

Figure 3: Mean BMI Scores for Males and Females in the Diabetes and Control Groups



3.5 COMPARISONS WITHIN THE DIABETES GROUP

3.5.1 Correlational Data

In order to address hypotheses 3, 4 and 5, bivariate and point-biserial two-tailed Pearson product-moment correlations were carried out with the data for the diabetes group, to ensure that any variables included in a multiple regression analysis had a linear relationship. Table 18 shows the correlation matrix.

The correlation results shown in Table 18 demonstrate that BMI was significantly positively associated with age and EDE-Q total score and was significantly negatively correlated with HbA1c. Self-rated adherence was significantly negatively correlated with HbA1c and EDE-Q total score. However, EDE-Q total score was not significantly associated with HbA1c. The pattern and significance of these results remained the same following the removal of outliers.

Table 18 also shows that insulin units per kg per day were significantly positively correlated with HbA1c ($p<0.05$) and therefore, better glycaemic control appears to be achieved with lower insulin doses per kg. However, with the removal of outliers, this result became non-significant. The original significant result is perhaps explained by the relatively high prescribed insulin doses for four of the six outliers, in combination with high HbA1c results.

There were no significant correlations between regimen type and EDE-Q total score, HbA1c, BMI or self-reported adherence. Similarly, units of insulin per kg per day was not correlated with EDE-Q total score, self-reported adherence or BMI and these results were unchanged when outliers were removed from the analysis.

Although as expected, overall responsibility as rated by parents was significantly positively correlated with age ($p<0.01$), this rating was not significantly correlated with EDE-Q total score, HbA1c, BMI or self-reported adherence. This result did not change with the removal of outliers. It was not therefore necessary to include this rating of responsibility in any further analysis.

It should also be noted that none of the variables in Table 18 were significantly correlated with deprivation category. Furthermore, point-biserial correlations with gender showed that gender was significantly correlated with EDE-Q total score ($r = 0.307$, $n = 61$, $p<0.05$) but with no other variables.

Table 18: Correlation Matrix for Within-Subjects Analysis of the Diabetes Group

		1	2	3	4	5	6	7	8	9
1. Age	**r**	1	**0.309***	0.103	0.071	-0.089	0.179	-0.106	**0.511****	0.199
	p	.	0.017	0.436	0.584	0.501	0.167	0.415	0.001	0.124
	N	61	59	59	61	59	61	61	41	61
2. BMI	**r**		1	**-0.288***	**0.486****	0.011	-0.066	-0.127	0.271	0.173
	p		.	0.028	<0.001	0.934	0.621	0.337	0.095	0.189
	N		59	58	59	57	59	59	39	59
3. HbA1c	**r**			1	0.038	**-0.333***	**0.260***	-0.091	-0.022	0.034
	p			.	0.776	0.011	0.046	0.492	0.893	0.798
	N			59	59	57	59	59	39	59
4. EDE-Q Total Score	**r**				1	**-0.312***	-0.181	0.051	0.101	-0.09
	p				.	0.016	0.162	0.694	0.529	0.945
	N				61	59	61	61	41	61
5. Self-reported Total Adherence Score	**r**					1	0.026	0.167	0.163	-0.229
	p					.	0.847	0.206	0.321	0.080
	N					59	59	59	39	59
6. Units of Insulin per kg per day	**r**						1	-0.141	0.068	**0.265***
	p						.	0.277	0.673	0.039
	N						61	61	41	61
7. Insulin Regimen Type (intensive or standard)	**r**							1	-0.097	-0.052
	p							.	0.546	0.692
	N							61	41	61
8. Parent Rating of Overall Responsibility	**r**								1	0.172
	p								.	0.282
	N								41	41
9. Length of Diagnosis	**r**									1
	p									.
	N									61

- Where r = Pearson co-efficient, p = 2-tailed significance value and N = no. of participants

*** Correlation is significant at the 0.05 level**

**** Correlation is significant at the 0.01 level**

3.5.2 Multiple Regression

Hierarchical multiple regression was chosen to allow the order of entry of the predictor variables to be chosen based on the findings of past research and the correlation analyses. Although it is a consistent finding that age is significantly associated with adherence, HbA1c and eating and weight concerns, it was not significantly associated with any of these variables in this study. Age was not therefore entered into the regression models. Where EDE-Q total score is the outcome variable, the variable gender was entered into the model first, due to the significant main effect of gender found in the ANCOVA and the consistent finding in the literature that eating and weight concerns differ between males and females.

3.5.2.1 Testing the Assumptions of Multiple Regression

The following factors were analysed for each multiple regression model to ensure that the assumptions for multiple regression were met. The assumptions of linearity and multicollinearity were tested with the exploratory correlations and the correlations presented in Table 18. Collinearity was also tested with the variance inflation factor (VIF) and tolerance levels produced by SPSS. For the assumption to be met, the average VIF should not be greater than 1 and tolerance should be above 0.2 (Field, 2000).

The assumption of independent errors was tested by the Durbin-Watson statistic, with a value close to 2 showing that the residuals are uncorrelated and the assumption is met

(Field, 2000). The assumptions of homoscedasticity of residuals and linearity were checked with the inspection of plots of standardised residuals against standardised predicted values. The assumption of normally distributed errors was checked by inspection of histograms and normality P-P plots, produced by SPSS.

3.5.2.2 Cross-validation of Multiple Regression Models

The extent to which each multiple regression model could predict the outcome in a different sample was examined in the following ways.

Field (2000) and Dancey and Reidy (1999) suggest that for a multiple regression model to be reliable, at least 15 participants should be obtained for each predictor variable. With a maximum sample size of 61 therefore, a maximum of four predictor variables were used in the following regression models.

The use of adjusted R^2 indicates the amount of variance accounted for in the population, rather than the variance accounted for in the sample R^2. Outliers (and influential cases) were examined using Cook's distance which measures the effect of a single case on the whole model and Mahalanobis distance, which is useful for the identification of multivariate outliers. Field (2000) suggests that a Cook's distance greater than 1 may be problematic. Mahalanobis distance identifies a multivariate outlier if the distance for a case is $p<0.001$ (Tabachnick and Fidell, 1996).[6]

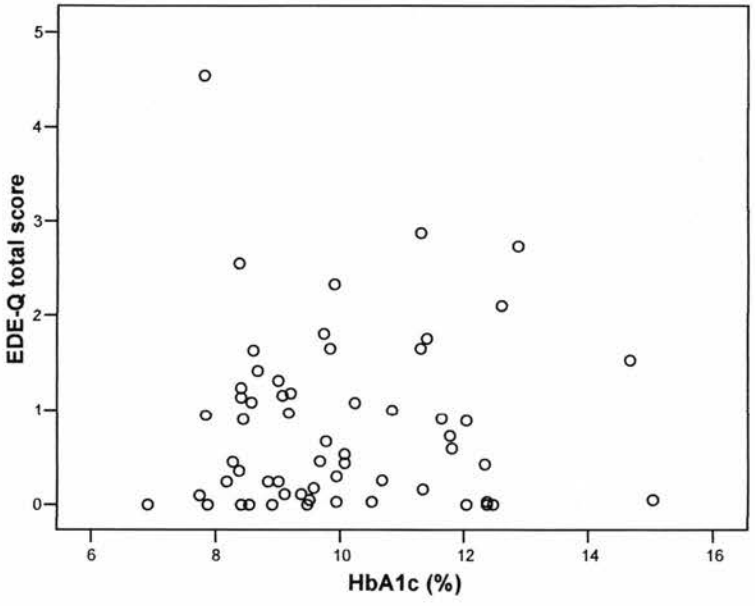
[6] A table of critical values is provided by Tabachnick and Fidell (1996) for comparison.

3.5.3 Hypothesis 3

Eating and weight concerns as measured by the EDE-Q will be positively associated with and predictive of (a) glycaemic control (HbA1c) and (b) adherence, in the diabetes group.

a). EDE-Q total score and HbA1c were not correlated (see Table 18) and therefore no multiple regression was carried out as the assumption of linearity would be violated. Figure 4 shows a scatterplot of EDE-Q total scores with average HbA1c scores. The lack of a significant correlation between these two variables suggests that eating and weight concerns are not associated with glycaemic control in this sample. Figure 4 shows that there is perhaps a trend towards a positive association, such that higher EDE-Q scores are more likely to occur with higher HbA1c scores (and therefore poorer glycaemic control). However, no conclusions can be drawn from this observation as a statistically significant association did not exist.

Figure 4: Scatterplot of EDE-Q Total Scores with Average HbA1c Scores



b). Hierarchical regression was carried out with self-reported adherence as the outcome variable. The variable HbA1c was entered into the model first, due to its significant correlation with self-reported adherence. EDE-Q total score was then entered into the model.[7] The results of the regression are summarised in Table 19.

Table 19: Results of the Regression Model for Predicting Adherence

	Model Summary			ANOVA		Co-Efficients	
Variable	R^2	Adjusted R^2	Significance	F	Significance	Standardised β	Significance
HbA1c	0.111	0.095	0.011	6.856	0.011	0.333	0.011
EDE-Q Total Score	0.201	0.171	0.017	6.787	0.002	0.300	0.017

[7] Cases were excluded on a pairwise basis.

Table 19 therefore shows that HbA1c significantly contributed to the model ($t = 2.618$, $p<0.05$), accounting for 9.5% of the variance in self-reported adherence (adjusted $R^2 = 0.095$, $F_{(1,55)} = 6.856$, $p < 0.05$, effect size = 0.095, power = 0.56). EDE-Q total score also significantly contributed to the model ($t = 2.467$, $p<0.05$) and a total of 17.1% of the variance in self-reported adherence was accounted for (adjusted $R^2 = 0.171$, $F_{(1,54)} = 6.787$), $p<0.01$, effect size = 0.171, power = 0.88).

The assumption of independence of errors was met (Durbin Watson statistic = 1.63), as was the assumption of no multicollinearity (average VIF = 1.001 and no tolerance values below 0.2). Two cases were identified as having a standardised residual less than -2. However, no cases exceeded the limits of Cook's and Mahalanobis distances. There were therefore no multivariate outliers. The plots and histogram were reviewed for the assumptions of homoscedasticity, linearity and normal distribution of residuals and no obvious violations of these assumptions were detected.

3.5.4 Hypothesis 4

Body Mass Index will be positively associated with and predictive of eating and weight concerns in the diabetes group, as measured by the EDE-Q.

Hierarchical regression was carried out with EDE-Q total score as the outcome variable. Due to significant correlations with EDE-Q total score, gender was entered into the

model first, followed by self-reported adherence total score. BMI was then entered into the model.[8] The results of the regression are summarised in Table 20.

Table 20: Results of the Regression Model for Predicting EDE-Q Total Score

	Model Summary			ANOVA		Co-Efficients	
Variable	R^2	Adjusted R^2	Significance	F	Significance	Standardised β	Significance
Gender	0.094	0.078	0.020	5.732	0.020	0.307	0.020
Adherence	0.179	0.149	0.022	5.891	0.005	0.292	0.022
BMI	0.379	0.343	<0.001	10.767	<0.001	0.454	<0.001

Table 20 shows that gender significantly contributed to the model ($t = 2.394$, $p<0.05$), explaining 7.8% of the variance in EDE-Q total score (adjusted $R^2 = 0.078$, $F_{(1,55)} = 5.732$, $p<0.05$, effect size = 0.078, power = 0.46). Adding the variable adherence into the model increased the proportion of variance explained to 14.9% (adjusted $R^2 = 0.149$, $F_{(1,54)} = 5.891$, $p<0.01$, effect size = 0.149, power = 0.46). BMI also significantly contributed to the model ($t = 4.126$, $p<0.01$), with a total of 34.3% of the variance in EDE-Q total score being explained (adjusted $R^2 = 0.343$, $F_{(1,53)} = 10.767$, $p<0.01$, effect size = 0.343, power = 0.97).

The assumption of independence of errors was met (Durbin Watson statistic = 2.314), as was the assumption of no multicollinearity (average VIF = 1.014 and no tolerance values below 0.2). Three cases were identified as having a standardised residual less than -2 or more than 2. However, no cases exceeded the limits of Cook's and Mahalanobis

[8] Cases were excluded on a pairwise basis.

distances. There were therefore no multivariate outliers. The plots and histogram were reviewed for the assumptions of homoscedasticity, linearity and normal distribution of residuals and no obvious violations of these assumptions were detected.

The removal of a univariate outlier did not change the pattern or significance of results.

3.5.5 Hypothesis 5

Insulin dose and insulin regimen will be positively associated with and predictive of eating and weight concerns in the diabetes group, as measured by the EDE-Q.

Both units of insulin per kg per day and insulin regimen were not correlated with EDE-Q total score (see Table 18) and therefore no multiple regression was carried out as the assumption of linearity would be violated. Figure 5 shows a scatterplot of units of insulin per kg per day with EDE-Q total score. The lack of a significant correlation suggests that the amount of insulin taken is not associated with eating and weight concerns and this is confirmed in Figure 5, where no pattern between these two variables is apparent. However, it can also be seen that for the majority of participants, one unit of insulin per kg per day is prescribed and as such, there is perhaps too little variability in the amount of insulin prescribed in this sample, for any potential relationship to be detected.

Figure 5: Scatterplot of Units of Insulin Prescribed with EDE-Q Total Scores

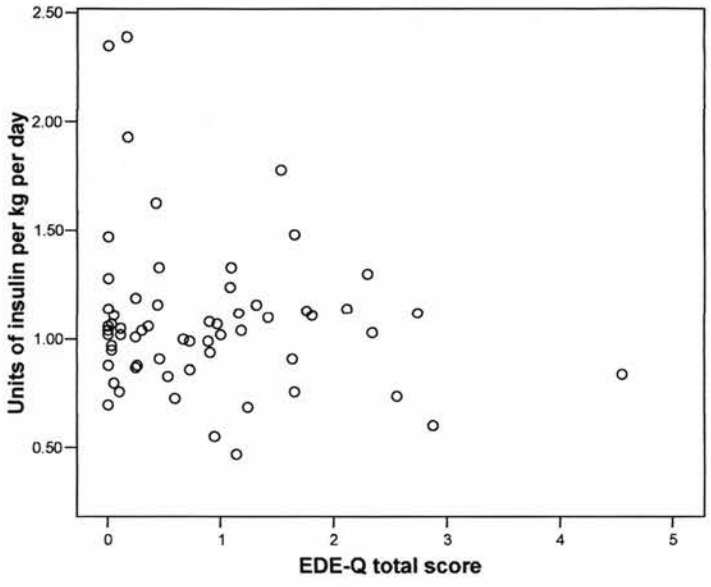
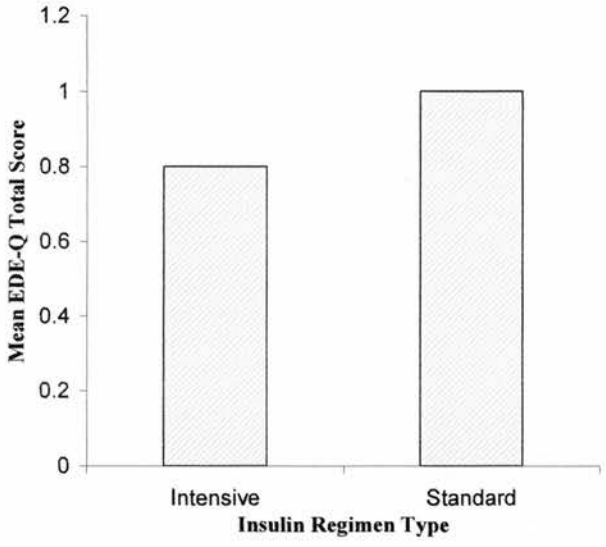


Figure 6 shows the mean EDE-Q Total scores for the participants on an intensive insulin therapy regimen (IIT) and those on a standard regimen. Contrary to expectations, those on an IIT regimen appear to have less eating and weight concerns than those on a standard regimen. However, this difference is not statistically significant ($t = 0.035$, $df = 22$, $p=0.73$, ns). The lack of a significant correlation between these two variables therefore suggests that type of insulin regimen is not associated with eating and weight concerns in this sample.

Figure 6: Mean EDE-Q Total Scores for the Intensive and Standard Insulin Therapy Groups



3.6 SUMMARY OF RESULTS

The diabetes group did not differ from the control group on EDE-Q total score, but there was a significant effect of gender for both groups, with females showing more eating and weight concerns than males. BMI was significantly higher in the diabetes group compared to the control group. However, there was a significant interaction between group and gender, showing that the difference in female BMI scores between groups was greater than that for male BMI scores.

In the diabetes group, glycaemic control, insulin units (per kg per day) and insulin regimen (intensive or standard) were not related to EDE-Q total score. However, poorer

glycaemic control was associated with poorer adherence and lower BMI. Participants with lower adherence showed more eating and weight concerns and EDE-Q total score significantly predicted 17.1% of the variance in self-reported adherence, together with HbA1c. Furthermore, participants with higher BMI scores showed more eating and weight concerns. In total gender, adherence and BMI significantly predicted 34.3% of the variance in EDE-Q total score and BMI significantly contributed to the model after the effect of gender and adherence had been accounted for, predicting a further 19.4% of the variance in EDE-Q total score.

CHAPTER FOUR

DISCUSSION

4.1 SUMMARY OF RESEARCH

The aim of the current study was to investigate the eating and weight concerns of adolescents with type-1 diabetes in a local population. While previous research has concluded that the occurrence of eating disorder psychopathology in type-1 diabetes is of clinical importance, there has been some dispute over whether eating disorders are more prevalent in type-1 diabetes than in the general population. The possible reasons for the hypothesised link between eating disorders and type-1 diabetes have also been discussed. Therefore this study aimed to examine the eating and weight concerns of adolescents with type-1 diabetes and compare them to a control group of adolescents without type-1 diabetes, using a self-report questionnaire. This study also aimed to determine whether eating and weight concerns would predict levels of self-reported adherence and glycaemic control within the diabetes group and the associations between eating and weight concerns with BMI, insulin dose and insulin regimen were also investigated.

4.2 DISCUSSION OF HYPOTHESES

4.2.1 Hypothesis 1: Eating and weight concerns, as measured by the EDE-Q, will be higher in the type-1 diabetes group than in the control group, with such concerns more prevalent amongst females in both groups.

No statistically significant differences in eating and weight concerns were found between the diabetes and control groups. Females reported significantly more concerns than

males and this was the same for both groups, with no significant interaction effect. The finding that females reported more eating and weight concerns than males is a consistent finding in the type-1 diabetes population (Daneman and Rodin, 1999). However, no significant differences in eating and weight concerns were found between the diabetes group and the control group and therefore Hypothesis 1 was not supported. Although it was predicted that eating and weight concerns may have been higher in the diabetes group, the trend of the results was actually in the opposite direction, with more of the control group tending to score in the clinically significant range on the EDE-Q. This finding does not support the studies of Steel et al (1987) and Jones et al (2000), which conclude that the prevalence of eating disorders is more common in type-1 diabetes. Importantly, these studies investigated this effect in females only, potentially explaining the different findings. Therefore it is possible that a significant result may have been achieved if males were excluded from the sample. However if this was the case, a significant interaction between group and gender may have been expected, to show that the difference in female scores between the two groups was of a larger magnitude to that of male scores.

The lack of a significant difference in eating and weight concerns between the diabetes and control groups is not an exclusive finding, with many other studies concluding that eating disorders are no more common in type-1 diabetes than in the general population (Peveler et al, 1992; Striegel-Moore et al, 1992, Marcus et al, 1992; Peveler et al 2005). In common with these studies however, the sample size of the diabetes group may not have been large enough to obtain a significant result. While power at the 0.80 level was

almost achieved for the anticipated medium effect size[1], post-hoc analysis calculated an effect size of only 0.003. The tables provided by Clark-Carter (2004) suggest that with such a small effect size, well over 700 participants would have been required to achieve power. Therefore, it is possible that this effect is not clinically meaningful enough to warrant further investigations. If this is the case, it could be concluded that this finding supports the alternative hypothesis that eating and weight concerns are not more prevalent in the type-1 diabetes population. However, this result must be interpreted with caution. For example, it has been suggested that higher prevalence rates of eating disorders should be expected when self-reports measures like the EDE-Q are used (Rodin and Daneman, 1992). However it is notable in the current study that the EDE-Q scores for males and females in both groups are relatively low. Indeed the female EDE-Q scores for both the diabetes and control groups were significantly lower than the normative EDE-Q data for females provided by Carter et al (2001). Although these two samples can not be directly compared due to the significant age difference between them, the majority of participants in this study tended to report very few symptoms or concerns. This lack of variability in scores may have biased the results, potentially explaining the non-significant finding. It is possible that the effect size of this comparison could be improved by altering the design of the study. The possible limitations of concluding that eating and weight concerns are not more prevalent in type-1 diabetes will be discussed in section 4.5.

[1] For a medium effect size at $p = 0.05$, 64 participants would have been required and 61 were recruited.

4.2.2 Hypothesis 2: Body Mass Index (BMI) will be significantly higher in the diabetes group than in the control group.

Mean BMI was statistically significantly higher in the diabetes group when compared to the control group, providing support for Hypothesis 2. There was no significant difference in BMI between males and females. However, the significant interaction found between group and gender suggests that the difference in BMI between groups was stronger in females. It is notable that on average, the participants in the control group reported that they tended to be underweight and the mean BMI for females in the control group was significantly lower than for the sample reported in Carter et al (2001). It may therefore be the case that it was the low BMI scores reported by the control group in this study that explain the significant difference found between the two groups. However, the BMI scores of the control group as a whole were not significantly different to the mean BMI reported by Carter et al (2001). Furthermore, it is a common finding that BMI is higher amongst adolescents with type-1 diabetes (Scottish Study Group for the Care of the Young Diabetic, 2001; Jones et al, 2000, Steel et al, 1989). Hypothesis 2 can therefore be accepted.

It has previously been reported that weight gain is associated with insulin treatment (Rodin and Daneman, 1992) and the finding in this study would appear to support this. Intensive insulin therapy (IIT) in particular has been shown to result in increased weight gain (DCCT Research Group, 1993). However in this study, no difference in BMI was found between participants on IIT when compared with those on standard insulin therapy.

It must therefore be concluded that in this sample, higher BMI is not specific to the type of insulin regimen, but is related to the presence of type-1 diabetes in general.

4.2.3 Hypothesis 3a: Eating and weight concerns, as measured by the EDE-Q, will be positively associated with and predictive of glycaemic control (HbA1c) in the diabetes group.

There was no significant correlation between eating and weight concerns and glycaemic control. However, the effect size of this comparison was extremely low (0.038), suggesting that well over 800 participants would be needed to obtain a significant correlation at a power level of 0.80 (Clark-Carter, 2004). Therefore, it does not seem likely that EDE-Q total score would have been significantly associated with glycaemic control if the anticipated sample size had been obtained. This is in contrast to previous research which has concluded that even subclinical eating disorder symptoms are associated with impaired glycaemic control (Affenito et al, 1997; Daneman and Rodin, 1999). It is possible that the number of eating and weight concerns reported by this sample was too low for any effect to be detected. Two potential explanations may account for this result. Firstly, it is possible that eating and weight concerns were not a particular problem for this sample of adolescents with type-1 diabetes. This would be a positive finding and may reflect an adequate awareness and the appropriate prevention of these issues by the diabetes teams. Secondly, it is possible that eating and weight concerns were under-reported in this sample. It has previously been suggested that such concerns and subsequent weight loss behaviours may occur privately and therefore be

under-reported (Wilfley et al, 1997; Polonsky et al, 1994; Rosen and Poplawski, 1987). It is also possible that the reporting of these concerns may have been biased by the limitations of the study and this will be discussed in section 4.5.

4.2.4 Hypothesis 3b: Eating and weight concerns, as measured by the EDE-Q, will be positively associated with and predictive of adherence in the diabetes group.

Eating and weight concerns predicted a significant amount of the variance in adherence and this was after the effects of glycaemic control had been accounted for. It has been previously reported that eating and weight concerns are a risk factor for poor glycaemic control (Wing et al, 1986b; Peveler et al 1992) and long term microvascular complications (Steel et al, 1989; Rydall et al (1997). In particular, both diabetic complications (Peveler et al 2005) and glycaemic control (Polonsky et al, 1994; Biggs et al, 1994; Bryden et al, 1999) have been associated with insulin omission as a means of weight loss, suggesting a link between eating and weight concerns with adherence. Although only one participant (and a parent of another participant) in this study admitted to insulin omission, the results do suggest that eating and weight concerns have a direct impact on participants' willingness to adhere to their self-care recommendations. It would therefore seem that adherence to insulin administration may not be the only part of the self-care regimen which is important to consider with eating and weight concerns. For example, diet and exercise may also be manipulated for the purposes of weight loss. However, it is also possible that insulin omission was under-reported. Previous studies have reported the prevalence of insulin omission in adolescents to be between 11-15%,

whereas in the current study, only one participant (1.64%) reported insulin omission. Therefore it is difficult for any definite conclusions to be made about the impact of eating and weight concerns on the individual adherence components. However, Hypothesis 3b is supported.

4.2.5 Overall Discussion of Hypothesis 3

Poorer adherence was found to be associated with poorer glycaemic control. This is in contrast to previous research, which does not often find a link between these two variables (Johnson, 1994). As eating and weight concerns significantly predicted level of adherence, (with more concerns associated with poorer adherence), it would be expected that this association would be reflected in participants' glycaemic control. However, no relationship was found between eating and weight concerns and HbA1c. As suggested by Johnson (1994; 1995) factors other than adherence, such as limitations in insulin therapy or confusion over regimen, may also impact on glycaemic control. In this age group in particular, hormonal changes which occur as a result of puberty, may cause changes in insulin resistance (Dunger and Edge, 1995) and this could explain the relatively high HbA1c results found in this study. It is also likely that other psychological variables, such as self-efficacy and treatment efficacy beliefs (e.g. Palardy et al, 1998; Charron-Prochownik et al, 1993; Glasgow et al, 1997) would significantly predict some of the variance in both adherence and glycaemic control. It is therefore possible that external variables, which were beyond the scope of this study could explain more of the variance in HbA1c than EDE-Q total scores. This is supported by the finding that only 17% of the

overall variance in self-reported adherence was explained by the regression model. Eating and weight concerns do appear to be a significant barrier to adherence however and it is possible that this will have some impact on glycaemic control in the longer term.

4.2.6 Hypothesis 4: Body Mass Index will be positively associated with and predictive of, eating and weight concerns in the diabetes group, as measured by the EDE-Q.

Higher BMI was significantly associated with more eating and weight concerns. Both gender and adherence predicted a significant amount of the variance in these concerns. However, after these variables had been accounted for, BMI further predicted a significant amount of the variance in eating and weight concerns. Participants with a higher BMI were therefore likely to have more eating and weight concerns and this was independent of gender. Hypothesis 4 is therefore supported and this is in accordance with previous research which has found BMI to be related to eating and weight concerns in both the general population (e.g. Hausenblas and Fallon, 2002) and in the diabetes population (Bryden et al, 1999; Colton et al, 2004). Steel et al (1989) suggested that the presence of eating psychopathology could not be explained by BMI alone, as differences between the diabetes and control groups in their study remained after scores were adjusted for BMI. However in this study, BMI appears to be an important variable in explaining the development of eating and weight concerns in adolescents with type-1 diabetes.

Interestingly in this study, higher BMI was also significantly associated with better glycaemic control. This would suggest that adolescents with well managed diabetes control, have a higher BMI. Unfortunately, higher BMI was significantly associated with more eating and weight concerns. Higher BMI may therefore be perceived as a negative consequence of achieving good glycaemic control, leading to a desire to loose weight. However it is notable that although BMI was associated with eating and weight concerns and these concerns were associated with adherence, there was no significant relationship between BMI and adherence. It is therefore possible that another factor mediates the relationship between BMI and adherence. For example, Griva et al (2000) found that both self-efficacy and beliefs about self-control, were significantly associated with adherence in adolescents with type-1 diabetes. As BMI is often higher in type-1 diabetes, it is possible that adolescents may feel they have limited control over the weight gain which can occur. Therefore, beliefs about self-control and self-efficacy for appropriately responding to any eating and weight concerns which develop, may determine whether or not the recommended self-care regimen is adhered to. The potential role of these factors could therefore be examined in future research.

4.2.7 Hypothesis 5: Insulin dose and insulin regimen will be positively associated with and predictive of, eating and weight concerns in the diabetes group, as measured by the EDE-Q.

Insulin dose and insulin regimen were not associated with eating and weight concerns. Hypothesis 5 could not therefore be supported.

4.2.7.1 Insulin Dose

Although a small to medium effect size was achieved in the correlation between insulin dose and eating and weight concerns (effect size = 0.2), the power of this association was only 0.33 and 200 participants would have been required to obtain power at 0.80 (Clark-Carter, 2004). However for the majority of participants insulin was prescribed at around 1 unit per kilogram per day and as such, there was perhaps too little variance for any effect to be detected, rather than too small a sample size per se.

4.2.7.2 Insulin Regimen

As Intensive Insulin Therapy (IIT) has been shown to result in weight gain (DCCT Research Group, 1993) it was expected that participants on IIT would have more eating and weight concerns than those on standard insulin therapy. However, no significant correlation was found between regimen type and eating and weight concerns. The extremely small effect size (0.05) suggests that to achieve power at the 0.80 level, over 800 participants would be required. In fact, the mean number of eating and weight concerns for those on IIT was actually slightly lower than the score for those on standard therapy, although this difference was not significant. However, the variance in eating and weight concerns was perhaps too low for a significant result to be achieved. With more participants (or changes to the design of the study as suggested in section 4.5), this effect may become more substantial. If this is the case, it is possible that IIT actually provides people with more control over their eating habits, due to the increased dietary flexibility

with this regimen. Therefore eating and weight concerns may be lower in participants who feel able to achieve weight loss by manipulating their food and insulin intake. For example, as insulin dose should be matched to food intake, adolescents may reduce the amount of food they eat and therefore take less insulin, without an immediate adverse affect on their HbA1c. However with no significant relationship between insulin regimen and EDE-Q total score and no significant difference in BMI between the two regimen types, it is not possible to support this hypothesis. Furthermore, as the majority of the sample (73.8%) were on IIT, more participants on standard therapy would need to be recruited before any definite conclusions could be made.

4.2.8 Overall Discussion of Hypotheses

In the current study, eating and weight concerns were not found to differ between adolescents with type-1 diabetes and a control group. In general, the sample did not report many eating and weight concerns, although females did report more concerns than males in both groups. In accordance with previous research, adolescents with diabetes were found to have higher BMI scores than those in the control group and this was true for both males and females. Furthermore, within the diabetes group BMI significantly predicted eating and weight concerns, over and above the effect of gender. Two potential conclusions could be made from these results. Firstly, body mass index appears to be an important factor in the occurrence of eating and weight concerns in adolescents with type-1 diabetes. Secondly, as BMI significantly predicted eating and weight concerns

after the effect of gender had been accounted for, BMI appears to be an important factor in the occurrence of such concerns for both males and females.

The expected links between eating and weight concerns, insulin dose and insulin regimen were not apparent. Weight gain is known to be associated with insulin treatment and has specifically been identified as a negative side-effect of intensive insulin therapy (IIT). However, insulin dose and regimen type were not significantly related to BMI, adherence or eating and weight concerns. These non-significant results are possibly a reflection of the low variance in insulin dose throughout the sample and the small sample size within the diabetes group, making comparisons between regimens difficult. Higher insulin doses were significantly associated with poorer glycaemic control however. While this result could be explained by the presence of outliers, it is also possible that adolescents with poor glycaemic control are more likely to have their insulin doses increased, but that this may not result in an improvement in glycaemic control. Therefore, it could be hypothesised that adolescents may manage concerns about their weight and shape by manipulating their diabetes self-care regimen, resulting in poor glycaemic control and a lower BMI. Prescribed insulin dose may then be increased in order to improve glycaemic control. However, an improvement in HbA1c would not occur if the patient wanted to avoid an increase in BMI, by continuing to manipulate their self-care regimen. Furthermore, while it was predicted that IIT would be related to more eating and weight concerns due to its association with weight gain, this relationship may be more complex. For example, the flexibility of this regimen (where insulin dose is balanced with the amount of food eaten) may allow adolescents with eating and weight concerns to more

easily influence their self-care behaviours, without an immediate effect on HbA1c. Figure 7 shows the proposed relationship between these variables, with the correlations which were found to be significant. No conclusion can be made about this proposal however, as while some of the associations between variables were found to be significant, others were not. Furthermore, the causality of these relationships can not be determined. Further research would be therefore needed to test these hypotheses empirically.

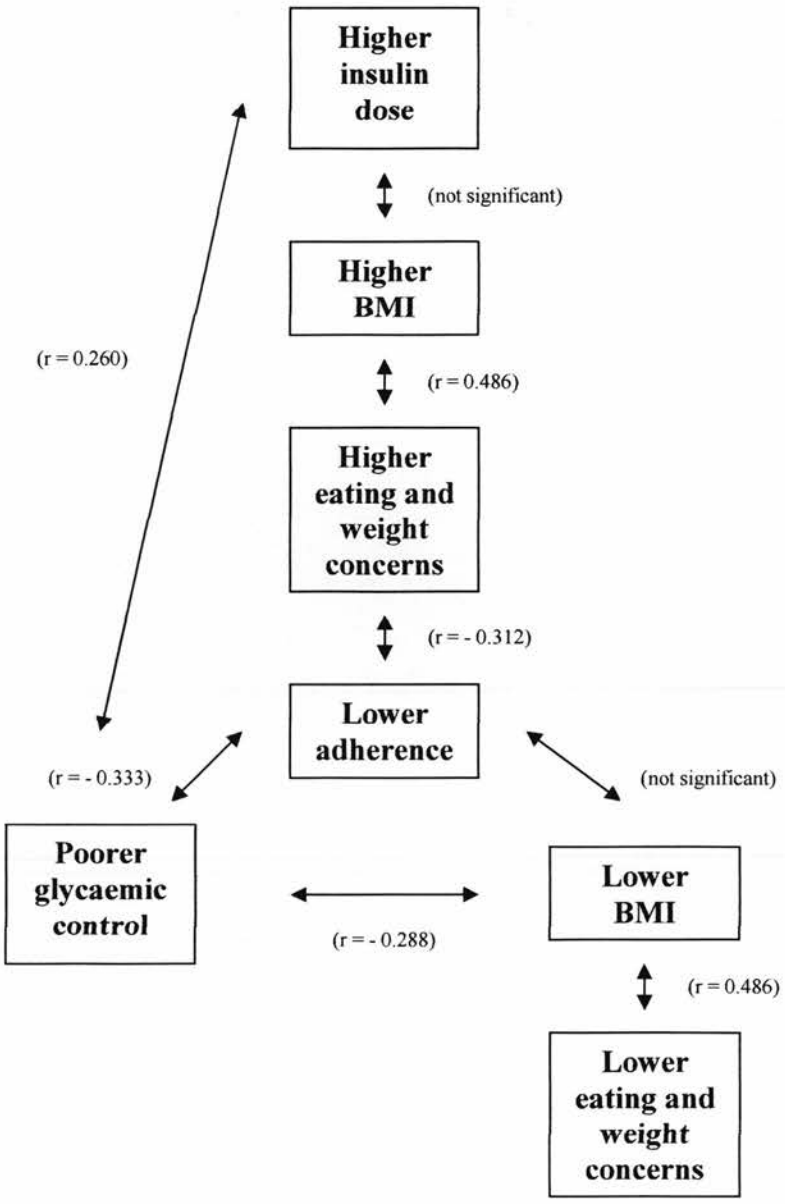
4.2.9 Discussion of Individual Case

As only one participant (Px) reported insulin omission in order to control their shape or weight, it is interesting to examine the data for this case individually.[2] Px was on an intensive insulin therapy regimen and the staff in the diabetes team were aware that she tended to omit her short-acting insulin and would only take her long-acting (basal) dose. Her insulin dose was lower than the mean for the group although not significantly so, but this may reflect the staff's awareness of her insulin omission. Px reported significantly poorer adherence compared to the rest of the sample and significantly more eating and weight concerns. Although her BMI is not significantly different to the mean for the sample, it is higher and was found to have decreased over time, reflecting the weight loss strategies which she engaged in. Similarly, her HbA1c was not significantly different, but reflected poorer glycaemic control and had increased over time. Therefore, it would appear that following diagnosis and the initiation of insulin treatment, Px had a higher

[2] The individual scores obtained for Px are not reported for reasons of confidentiality and no identifying information is provided.

BMI compared to her peers. This may have increased her vulnerability to the development of eating and weight concerns and initiated her use of insulin omission for the purposes of weight loss. As a result, Px now reports poor adherence to her self-care regimen and her BMI has reduced over time. Simultaneously, her HbA1c would appear to be slowly increasing, suggesting that her glycaemic control may indeed be adversely affected over the longer term. This formulation for Px is only a hypothesis however and has been inferred from the data obtained, rather than a direct assessment with Px. The diabetes team were aware of Px's eating and weight concerns and insulin omission and were sensitive to her treatment needs.

Figure 7: Hypothesised Relationships Between Variables



N.B. Arrows in the flow diagram are bi-directional due to the correlational nature of the relationships between variables.

4.3 CLINCAL IMPLICATIONS

4.3.1 Eating and Weight Concerns as a Barrier to Adherence

Although eating and weight concerns were not found to be of particular concern in the diabetes group, they significantly predicted some of the variance in adherence. Eating and weight concerns should therefore be considered as a potential barrier to adherence for some adolescents. Previous research has concluded that even subclinical disordered eating is associated with impaired glycaemic control and a higher prevalence and earlier onset of the long term microvascular complications of diabetes (Affenito et al, 1997; Rydall et al, 1997). While a direct link between eating and weight concerns and glycaemic control was not found in this study, it is possible that the lower adherence associated with these concerns will lead to poorer glycaemic control in the longer term. It has been recommended that teenagers with diabetes should be screened for risk factors of long term complications (Scottish Intercollegiate Guidelines Network, 2001) and more specifically, it has been highlighted that diabetes teams should be aware of the risk of eating disorders in this population (National Institute for Clinical Excellence, 2004). The link between eating and weight concerns and adherence found in this study would therefore support the need for these concerns to be screened for in this population. Furthermore, health professionals working in diabetes teams should be aware of the possibility that these concerns may be impacting on adolescents' motivation to adhere to their self-care regimen. By increasing awareness and implementing a screening protocol,

it may be possible to prevent the development of clinically relevant eating disorders and therefore prevent any potential long-term complications.

4.3.2 Body Mass Index as a Risk Factor

The results of this study suggest that the higher BMI found in the sample of adolescents with type-1 diabetes is an important risk factor for the development of eating and weight concerns. Although higher BMI in adolescents with type-1 diabetes may be common, the presence of eating and weight concerns in association with higher BMI should be considered. From anecdotal evidence and the National Institute for Clinical Excellence (2004) recommendations, it would seem that health professionals often focus on the HbA1c result when assessing how well individuals are managing their diabetes. It may therefore be important for members of the diabetes team to consider HbA1c and BMI in combination, when questioning whether eating and weight concerns and their related behaviours are apparent.

4.3.3 Consideration of Body Mass Index in Males and Females

In this study, BMI was found to be predictive of eating and weight concerns, even after the effect of gender had been accounted for. The investigation of eating and weight concerns is often limited to females however and so it is possible that the presence of these concerns would not be considered in the formulations of males who do not appear to be adhering to their self-care regimen.

A growing number of studies are investigating the presence and aetiology of eating disorders in males and an increase in the prevalence of males presenting with eating disorders has been reported (Braun, Sunday, Huang and Halmi, 1999; Anderson, 2003). Furthermore, Keel, Klump, Leon and Fulkerson (1998) investigated disordered eating in adolescent males and concluded that the pattern of associations with disordered eating in females, could be generalised to males. In the type-1 diabetes population, Svensson et al (2003) reported that although adolescent males reported very low eating disorder concerns overall, they did report higher Drive for Thinness scores on the EDI when compared to a male control group and were also significantly heavier than controls. The results of the current study therefore support this finding and Svensson et al (2003) concluded that males with type-1 diabetes may also be at increased risk for the development of eating and weight concerns. Therefore, BMI should be considered as a risk factor for the development of eating and weight concerns in males with type-1 diabetes as well as females and the presence of these concerns in males should be considered in a formulation of non-adherence.

4.3.4 Prescribed Insulin Doses

No associations were found between insulin dose or insulin regimen with eating and weight concerns in this study. However, it appeared that higher insulin doses were associated with poorer metabolic control. While this result must be interpreted with caution due to the lack of significance when outliers were removed, it may point towards some important implications when considering the prescribing of insulin for adolescents.

Rosenbloom and Giordano (1997) reported that high insulin doses were often associated with adolescence, in an attempt to improve glycaemic control in this age group. However, the effect of increasing insulin may be increased weight gain. Furthermore, it is possible that glycaemic control is poor due to attempts to lose weight. Therefore the possible reasons for poor glycaemic control should be carefully investigated before changes to the insulin regimen are made. Furthermore, if eating and weight concerns are apparent, the impact of increasing insulin dose on BMI should be considered, as an increase in BMI may be perceived as a negative consequence of good glyceamic control. In such cases, it may be important to balance the need to achieve good HbA1c results with ensuring that the patient is willing to co-operate with their prescribed regimen and will not be adversely affected by isolated attempts to improve glycaemic control.

A summary of the clinical implications can be found in Table 21.

Table 21: Summary of Clinical Implications

1. *Eating and weight concerns may be a barrier to adherence and should be routinely screened for.*
2. *Higher BMI may be a risk factor for the development of eating and weight concerns in both males and females.*
3. *BMI and HbA1c should be considered in combination when assessing how well individuals are managing and coping with their diabetes.*
4. *Eating and weight concerns should be considered in the formulation of non-adherence in males as well as females.*
5. *The need for achieving good glycaemic control should be balanced with the patient's willingness to co-operate with a treatment regimen which may lead to increased weight gain.*
6. *The prescribing of insulin doses should be carefully considered where eating and weight concerns may be implicated.*

4.4 THE CO-OCCURRENCE OF EATING DISORDER SYMPTOMS WITH TYPE-1 DIABETES

Although the prevalence of eating and weight concerns in the diabetes group was relatively low in this study, the results may still have some implications for understanding the co-occurrence of eating disorder symptoms with type-1 diabetes. It has been argued that the presence of any chronic illness may increase adolescents' vulnerability to the development of an eating disorder (Maharaj et al, 2003) and Neumark-Sztainer et al (1995) reported that adolescents with a chronic illness were more likely to engage in unhealthy weight loss practices when compared to their peers. This was not supported in the present study however, as the eating and weight concerns of the diabetes group were not significantly different to those of the control group. Furthermore, it would appear that the higher BMI found in the diabetes group was of particular importance in helping to explain the presence of eating and weight concerns in this group. This result is supported by previous research which has also concluded that higher BMI is associated with more eating disturbances and concerns (Bryden et al, 1999; Colton et al, 2004). Therefore eating disorder symptoms may be particularly implicated in type-1 diabetes due to the relationship with BMI, rather than a feature of chronic illnesses in general. Adolescents increasingly look towards their peers for support as they get older (Pendley, 2002) and peer and social influences have been shown to be strong predictors of eating and weight concerns (e.g. Huon, Lim and Gunewardene, 2000). Specifically, Wertheim, Paxton, Schutz and Muir (1997) reported that social comparisons and avoidance of social disapproval were common pressures related to dieting in adolescent females.

Adolescents with type-1 diabetes may therefore compare themselves negatively with their peers due to higher BMI, thereby increasing their vulnerability to the development of eating and weight concerns. Higher BMI may also increase the impact of maternal modelling of weight and shape concerns in adolescents with type-1 diabetes and this has also been shown to be associated with the development of eating disorders (Pike and Rodin, 1991).

It has also been hypothesised that a higher prevalence of eating disorder symptoms in type-1 diabetes could be explained by the opportunity to easily loose weight through insulin omission (Rodin and Daneman, 1992). In this study, eating and weight concerns were not more common in type-1 diabetes when compared to a control group and only one participant admitted to insulin omission. These results would therefore suggest that the availability of this weight-loss method does not increase the likelihood of eating and weight concerns occurring. It is possible that both eating and weight concerns and insulin omission were under-reported in this study however and this will be discussed in section 4.5.

Therefore, the results of this study suggest that eating and weight concerns in type-1 diabetes are associated with the higher BMI found in this population. This relationship implies that the increased prevalence of eating disorder symptoms often found in this population is specific to diabetes, rather than associated with the presence of chronic illnesses in general. However, no firm conclusions can be made about the additional impact of the availability of insulin manipulation as a weight loss strategy.

4.5 METHODOLOGICAL LIMITATIONS

4.5.1 Sample Size

The sample size of the study did not meet Cohen's (1992) criteria that for a medium effect size, 84 participants would be required in each group, to obtain power at the 0.08 level. While the size of the control group exceeded this number, only 61 participants were included in the diabetes group; 73% of the required sample. In particular, this made comparisons between regimen types within the diabetes group difficult. While the sample size of the diabetes group compares favourably with some previous studies (e.g. Striegel-Moore et al, 1992 with n = 46; Biggs et al, 1994 with n = 42; Bryden et al, 1999 with n = 65), Jones et al (2000) has criticised the small sample sizes and subsequent low power of such studies. It is therefore possible that where hypotheses were not supported, this was due to insufficient power in the statistical analyses. As no particular problems were encountered in recruiting subjects to the diabetes group (with a refusal rate of only 15.1%) an extension to the period of data collection would hopefully allow a sufficient sample size to be obtained. An increase in sample size would also allow a more detailed comparison of EDE-Q and adherence subscale scores, as more variables could be reliably entered into a multiple regression model. However, post-hoc analyses demonstrated that the effect sizes obtained for relationships which did not reach statistical significance were very small. This would suggest that even with an increased sample size, the hypothesised relationships would not be found. In addition to increasing the sample size therefore,

other limitations which may have adversely affected the effect size of the relationships examined, must be considered.

4.5.2 Measures Used

4.5.2.1 Measure of Adherence

A self-report, non-standardised measure of adherence was used in this study, due to the lack of reliable and accepted measures of adherence available (Rapoff, 1999). It has been noted that measuring adherence in diabetes is particularly difficult, due to the lack of clearly defined, prescriptive regimen behaviours (McNabb, 1997; Griva et al, 2000). The measure of adherence used in this study was based on the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA; Toobert and Glasgow, 1994). When this was reviewed for suitability by the diabetes specialist nurses, it was agreed that the original questions were too specific and did not reflect the advice given by the diabetes teams in the populations used in this study. While it is suggested that adherence measures should ask specific, objective questions (La Greca and Schuman, 1995), it was felt that this would not reflect the treatment regimens of this population. Adaptations were therefore made to the SDSCA to ensure that the questions were more generally worded and would encompass the different regimens and advice that individuals may have been given. The questionnaire was also simplified for use in an adolescent population and questions more specific to type-2 diabetes or older adults with type-1 diabetes, were removed. The results of this study can not therefore be directly compared to other studies which have

measured adherence. This limitation is not unique however and the need for a standardised and common measure of adherence has been previously highlighted (Toobert and Glasgow, 1994). Further study is therefore required to determine the validity and reliability of the adherence measure used in this study.

A total adherence score was used for statistical analysis in this study rather than the subscale scores for individual regimen components. McNabb (1997) suggested that multiple scores of adherence for the different regimen components may be more meaningful than a total adherence score, due to different levels of adherence often being associated with individual aspects of the regimen. However, the main aim of this study was not to investigate the impact of eating and weight concerns on the individual components of the treatment regimen. Furthermore, the total adherence score was significantly and positively correlated with each of the subscale scores, indicating that as overall adherence increased, adherence to each regimen component also increased. The total score was also found to be reliable, whereas the use of the diet subscale score in isolation would not have been reliable.[3] Even so, the use of the total adherence score meant that exercise adherence was not included in the analysis and with a larger sample size, it would be advisable to examine the differential effects of the individual components of adherence.

[3] Cronbach's alpha co-efficients for the adherence sub-scale scores can be found in Appendix 31.

4.5.2.2 EDE-Q

The Eating Disorders Examination (EDE) has been described as the method of choice for the assessment of eating disorder psychopathology. In particular, the interview format of the EDE has allowed this measure to be easily adapted for use within the type-1 diabetes population, as the interview can ensure that a distinction is made between behaviours relating diabetes care and those related to eating disorder symptoms. However, due to the training requirements and time limitations, the questionnaire version of the EDE was chosen in this study. While the EDE-Q is considered appropriate as an initial screening measure (Black and Wilson, 1996) and has been shown to have good reliability and validity, (e.g. Luce and Crowther, 1999; Fairburn and Beglin, 1994), it has not been used specifically in the type-1 diabetes population. The most recent controlled and follow-up studies into eating disorders in type-1 diabetes have tended to use the EDE and as such, the results of this study can not be directly compared. However, the low EDE-Q scores obtained would suggest that the responses of the participants in the diabetes group were not unduly biased by the presence of ambiguous questions or the use of a self-report questionnaire, rather than an interview. It would still be of interest to administer the EDE in this population however, as more detailed information about the presence of eating and weight concerns and their clinical relevance could be obtained.

4.5.2.3 Insulin Dose

Medically recommended insulin dose was obtained from the medical files of participants and compared with their weight to provide a measure of units of insulin taken, per kilogram per day. However, it was not possible to determine the actual amounts of insulin taken on a daily basis. Patients are required to adapt their insulin doses for a number of reasons such as activity level, amount of food eaten or due to being unwell. In particular, participants on Intensive Insulin Therapy have much more flexibility for adapting the amount of insulin they take. Furthermore, the length of time that participants had been taking their prescribed regimen was not controlled for. As such, the relationship found between insulin dose and glycaemic control must be interpreted with caution. In their study of adherence to insulin administration in Tayside, Morris et al (1997) argued that the medically recommended dose was a true estimate of required insulin, due to the history of clinic information that they had for each patient. In addition, they also used the clinic information to conclude that prescribed insulin doses had not changed during the period of study. Although it is therefore possible that the estimate of daily insulin dose in this study is accurate, clinic data was not reviewed and so this was not tested empirically. Similarly, the length of time that participants had been taking their prescribed insulin doses can not be estimated. In order to overcome this limitation, it would be necessary to investigate daily insulin administration more accurately, thereby allowing the relationships between insulin dose and eating and weight concerns to be more clearly defined. This could be done by asking participants to record the amount of insulin they administer over a small number of randomly selected days, to provide an

estimate of the average insulin dose taken on a daily basis. Alternatively, a 24-hour recall interview (Freund et al, 1991) could be carried out and this has been shown to have good reliability, especially with older children (Freund et al, 1991). In addition, it would be important to review any recent changes of insulin dose.

4.5.2.4 Self-Reported Height and Weight in Control Group

As the control group completed the questionnaires anonymously, no medical or demographic information was available for these participants. Furthermore, the majority of adolescents in the control group were recruited during school-time and so parents were not available to provide any of the background information requested. In order to compare Body Mass Index (BMI) between the two groups, adolescents in the control group were asked to self-report their height and weight, if they knew them. The reliability of this data must therefore be considered. In addition, only 43.5% of the total sample provided their heights and weights and so the generalisability of this data is questionable. However, self-reported weights have previously been shown to be highly correlated with actual weight (Beglin and Fairburn, 1992, Davis and Gergen, 1994). It is also possible that as under half of the sample reported their heights and weights, it was only the participants who accurately knew this information who reported it. Furthermore, the finding that BMI was higher in the diabetes group has been commonly reported, suggesting that the heights and weights reported by the control group were not radically different to those expected. However, in order to increase the validity of these results, it

would be necessary for participants in the control group to be identifiable and direct contact made for height and weight to be measured.

4.5.3 Recruitment Method

4.5.3.1 Diabetes Group

Participants were recruited at their routine diabetes clinic appointments. Participants (and their parents if present) completed the questionnaires while they were waiting to be seen and depending on the clinic, this was either done in the waiting room or in a separate clinic room. In both cases, the researcher was available to answer any questions, as recommended by Wilfley et al (1997). Although it was emphasised to participants that there were no right or wrong answers, that answers would be confidential and that the diabetes team would not have access to their answers, the diabetes clinic setting and the presence of the researcher may have led to questionnaires being completed in a socially desirable way. If this was the case, it may explain the low scores obtained on the EDE-Q and the high adherence scores. Indeed, Johnson (1992) suggests that self-reported adherence may be less reliable when rated as high and the influence of social desirability on self-report measures of adherence has been noted (Israel, Berndt and Barglow, 1986). Participants were all offered private space to complete their questionnaires however and were given the option of taking the questionnaires home to complete and then post back to the researcher. In order to overcome this limitation, it may be necessary to employ an interview method to investigate both eating and weight concerns (using the EDE) and

adherence. Interviews could take place away from the diabetes clinic and perhaps in participants' homes, in order to improve the reliability of information reported. Unfortunately due to time limitations, this was not possible in the present study.

4.5.3.2 Control Group

The majority of participants completed their questionnaires during class time at school. While this method was chosen to maximise possible sample size and to ease administration for the schools involved, it did not allow data collection to be monitored. Therefore participants in the control group may have also provided socially desirable answers if they felt that adequate privacy was not provided. Once again, without the time constrictions of the current study, it may have been possible to interview participants for the control group individually, therefore ensuring that their answers would not be biased in any way.

4.5.4 Generalisation of Results

As previously discussed, the relatively low sample obtained will reduce the extent to which these results can be generalised to the general population of adolescents with type-1 diabetes. The samples obtained must also be considered however. For example, both the diabetes and control groups were obtained through availability sampling. Therefore in the diabetes group, only adolescents who were attending clinics during the period of data collection were recruited. As information about patients could only be obtained if

participants had consented to take part in the study, it was not possible to compare participants with those who refused to take part or did not attend the clinic during data collection. As most adolescents attend the clinic at least once every four months, an extension to the period of data collection may help to overcome this difficulty. However, when considering the high adherence scores obtained, it is also possible that patients who are less likely to adhere are also less likely to attend their clinic appointments. These patients would not therefore be included in the study and so the sample may not be representative of the population as a whole. In order to overcome this limitation, ethical approval could be obtained to contact all eligible participants out with their clinic appointments, to ensure that everyone is given the opportunity to participate in the study.

In the control group, only three schools in one of the geographical areas were involved in the study. As such, the extent to which this sample is representative as a control group is questionable. In terms of demographic data however, the groups did not differ on socio-economic status and males and females were equally represented in both groups. In order to increase the extent to which the diabetes group can be reliably compared with a control group, a wider range of schools throughout the two areas investigated should be recruited into the study.

In terms of the statistical analyses carried out in this study, the extent to which any conclusions can be drawn from the data is limited by the correlational and cross-sectional nature of the design. As such, the causality of any of the relationships found between the variables can only be inferred. Care was taken to ensure that the assumptions of multiple

regression were met during data analyses however, suggesting that the regression models reported are reliable and would predict similar outcomes in different samples within this population.

4.6 PRACTICAL LIMITAIONS

4.6.1 Gaining Ethical Approval

The initial study proposal and ethics application were refused by the Tayside Committee on Medical Research Ethics, due to "insurmountable" problems. The study was initially proposed as a postal survey, in order that all adolescents who met the inclusion criteria could be invited to take part and all parents would be available to complete their version of the adherence questionnaire. In addition to the EDE-Q and the adherence questionnaire, it was also proposed that the Body Shape Questionnaire (BSQ; Cooper, Taylor, Cooper and Fairburn, 1987) would be administered, to overcome the lower accuracy of the EDE-Q shape concern subscale (Fairburn and Beglin, 1994). As shown in Appendix 5, the ethics committee had a number of concerns about the study and in particular, about the use of the BSQ. The original version of the BSQ was submitted to the ethics committee due to the well established reliability and validity of this measure and its common use within the literature (Cooper et al 1987; Anderson et al, 2004). However, shortened versions of the BSQ are available (Evans and Dolan, 1993) and may have been more appropriate for use with this age group. Unfortunately, the researcher was not permitted to attend the ethics meeting to discuss this possibility. Indeed, it is felt

that a number of the concerns raised could have easily been resolved through discussion (rather than being "insurmountable") and this is supported by the fact that amendments to the study were made and approved by a second ethics committee. Furthermore, the second committee encouraged the researcher to attend their meeting and this is believed to have aided the approval of the second application. Inconsistencies between the practices of ethics committees and their responses to applications have been previously reported (Cohen, 1999 and Middle, Jphnson, Petty, Sims and MacFarlane, 1995 respectively). Despite centralisation through COREC, it would appear that these inconsistencies still exist between local ethics committees.

The original ethics committee also commented that the study may be counter-productive and actually encourage eating and weight concerns and poor adherence, as a result of asking participants specifically about these issues. It is notable however that no mental health representative was included in the committee reviewing the application. This may have further obstructed ethical approval being granted, as the need to address these issues openly with adolecents, could have been highlighted. Furthermore, Wilson (1993) commented that the accurate assessment of eating disorder behaviours requires direct questioning. As the comments made by the Tayside committee had to be addressed before a second application could be considered, it was felt that particular care had to be taken in addressing the issue of deliberate insulin manipulation. As a result, it was not felt that a direct question about this behaviour could be included. Instead, a more general question ('have you done anything else to control your shape or weight') was asked, potentially explaining why only one participant reported this behaviour. The need for

members of ethics committees to be adequately trained has also been raised (Garfield, 1995) and it is possible that had the committee members present been more aware of such issues within the areas of mental health and psychology, the proposal may have been more favourably reviewed.

The difficulties encountered with the initial ethical application obviously resulted in a considerable delay to the initiation of the study and a reduction of the time available for data collection. Furthermore, the only options available following refusal were to submit a new application or appeal against the decision with the same application. As it was felt that changes could be made to the study to adequately address some of the concerns raised, it did not seem sensible to appeal against the decision. It was not therefore possible to discuss the potential for change to the application, without having to begin the application process again. Even when ethical approval was granted, similar difficulties were encountered when applying for Research and Development approval, with the departments in the two areas having seemingly different criteria for applications and offering different advice. The initiation of the study was therefore delayed further.

Despite these frustrating events, it must be remembered that the application process for both ethical and Research and Development approval had recently been centralised, with new protocols put in place. Difficulties in the process are therefore to be expected and confusion surrounding the new protocols understandable.

4.6.2 Difficulties within the Local Child Clinical Psychology Department

During the period of the study, three clinical child psychologists, including the lead clinician for the service, left the local department due to differing circumstances. Unfortunately, this left the service extremely under-staffed and led to substantial gaps in service provision. It was therefore difficult to establish necessary links with the diabetes teams, in the absence of appropriate support within the department. Furthermore, a series of unforeseen circumstances led to a lack of consistency in research supervision, with three different supervisors being involved at various stages throughout the study. As the study was being conducted in two geographical areas, these factors served to complicate the initiation and continuation of the study. In addition to the difficulties with obtaining ethical approval, the time limitations for the study were constrained further, reducing the period of data collection and limiting the conclusions that could be made.

4.7 STRENGTHS

4.7.1 Inclusion of a Control Group

While the limitations of the sample obtained for the control group have been discussed, the inclusion of a control group is considered a strength of the study. While some of the previous investigations into eating disorder symptoms in type-1 diabetes have compared adolescents with diabetes to those without, other studies have been more descriptive. Interestingly in this study, no difference was found in the eating and weight concerns

between the two groups, allowing the concerns reported by the diabetes group to be considered in perspective.

4.7.2 The Use of Two Local Clinical Populations

Another strength of this study was that the diabetes sample was obtained from two geographical areas. While the limitations of the diabetes sample must be remembered, the inclusion of two clinic populations helps to improve the generalisability of the results. The study also allowed the preliminary investigation of eating and weight concerns in adolescents with type-1 diabetes locally.

4.7.3 Inclusion of Males

The majority of studies into eating disorder symptoms in both the general population and in type-1 diabetes population have focused on females. The inclusion of males in this sample allowed the investigation of the extent to which males with type-1 diabetes may also be affected by eating and weight concerns. Without the inclusion of males, it would not have been possible to suggest that BMI may be a risk factor in both males and females and that the presence of eating and weight concerns should not be overlooked in males.

4.7.4 Measurement of Adherence

Although the use of a measure that has not been standardised is a limitation of the study, a number of steps were taken to maximise the reliability of self-reported adherence. It has been recommended that patient's self-reported adherence should not be solely relied upon and so in this study, a parent was also asked to complete a copy of the adherence questionnaire. This allowed the comparison of two independent judgements of adherence and provided some evidence towards the accuracy of the accounts given. However, it is possible that parents' reports were also constrained by social desirability and so conclusions about the accuracy of self-reported adherence must be made with caution. In an attempt to improve the accuracy of reports, recall was limited to the previous week (La Greca and Schuman, 1995) and the confidentiality of answers was emphasised.

Due to the number of physiological and psychological factors which can affect both adherence and HbA1c, a further strength of this study was that both adherence and HbA1c were measured. This allowed the differential effects of eating and weight concerns on each measure of diabetes control to be examined.

4.7.5 Statistical Design of the Study

As many of the previous studies in this area have focused on comparing adolescents with and without eating disorder symptoms, the correlational design of this study is believed to be a strength. As some studies have not found an increased prevalence of eating

disorders in type-1 diabetes, it was considered more important to initially investigate the relationships between variables in order to provide clinically relevant information. Had a comparative design been employed, a smaller sample size would have been obtained for each group and it may have been difficult to dichotomise the variables, due to the low reporting of eating and weight concerns. However, while the absence of clinically significant eating and weight concerns in this population must be acknowledged, conclusions surrounding potentially important risk factors could be drawn from the data, due to the design.

4.8 FUTURE RESEARCH

As discussed in the limitations section, it would be useful to increase the sample size of the current study and expand the study to allow a more detailed investigation. This could include investigating the differential relationships between the subscales of both the EDE-Q and the adherence measure and a follow-up study of the relationships between the variables described. The effect size of the relationships between insulin dose, insulin regimen and eating and weight concerns may also be improved by the use of the EDE, a more accurate assessment of insulin dose and an increase in the number of participants on standard insulin therapy. Finally, a more accurate estimate of the prevalence of insulin manipulation may be obtained by asking participants directly about this behaviour.

The results of this study also suggest a number of other hypotheses which could be investigated empirically. For example, it appeared that BMI was an important factor in

the development of eating and weight concerns and as such, the prevalence of these concerns may be more related to type-1 diabetes specifically, rather than due to the presence of a chronic illness. It would therefore be interesting to compare the eating and weight concerns of adolescents with type-1 diabetes with two distinct clinical control groups; one group with a chronic illness, such as cystic fibrosis, which results in a lower BMI and a second chronic illness group for which BMI is not affected (such as epilepsy). The differential impact of BMI on eating and weight concerns could therefore be investigated, while the presence of a chronic illness is controlled for. It would be hypothesised that due to the importance of BMI, (rather than the presence of a chronic illness), the diabetes group would have more eating and weight concerns than the other two groups.

Future studies could also investigate the potential reasons for the impact of BMI on the development of eating and weight concerns. For example, with the higher BMI found in the diabetes group, the extent to which adolescents with type-1 diabetes compare themselves negatively with their peers, could be investigated. In relation to this, the effect of diabetes on self-esteem and the subsequent effect of self-esteem on the development of eating and weight concerns, could also be examined. If BMI is of particular importance for this population, it would be expected that self-esteem would be adversely affected by BMI, rather than diabetes per se. Adolescents with higher BMI could therefore be compared to adolescents with lower BMI, with the hypothesis that within a diabetes group, lower self-esteem would be predicted by higher BMI and that eating and weight concerns would be predicted by lower self-esteem and higher BMI.

Factors such as self-efficacy and beliefs about self-control, which may mediate the relationship between BMI and adherence, could also be investigated.

In addition to these quantitative studies, it would also be useful to carry out a qualitative analysis of the eating and weight concerns in both male and female adolescents with type-1 diabetes. This would allow a detailed analysis of the themes inherent in this association and may direct both further research and clinical practice. For example, it would be interesting to examine the experience of initial weight loss, followed by weight gain, in the development of eating and weight concerns. Furthermore, as the clinical implications of this study suggest, it would be useful for health care professionals working in diabetes teams to be aware of the possibility that eating and weight concerns may be a barrier to adherence and that BMI may be a risk factor for the development of these concerns. A qualitative design could therefore be used to examine the existing awareness of these issues in members of the diabetes team and the way in which these concerns are addressed.

4.9 CONCLUSION

The occurrence of eating disorder symptoms amongst adolescents with type-1 diabetes has been well documented. However, there is some dispute over whether eating disorders are more common in the type-1 diabetes population and the reasons for the co-occurrence of these two factors remains unclear. The results of the present study show that eating and weight concerns in a local population of adolescents with type-1 diabetes

were no more common than in an adolescent control group. Body Mass Index (BMI) was found to be higher in the diabetes group however and this was a significant predictor of eating and weight concerns for both males and females. It is therefore possible that the higher BMI found in type-1 diabetes is of particular importance in explaining the eating and weight concerns which often occur in this population, rather than their development being due to the presence of a chronic illness.

Eating and weight concerns were also identified as a significant barrier to adherence. Therefore these concerns may negatively influence adolescents' motivation to adhere to their self-care regimen. In the longer term, these concerns could adversely affect glycaemic control and lead to an increased risk for the development of the long-term complications of diabetes. The need for the screening of such concerns is therefore apparent, so that early intervention can be implemented and any adverse effects can be prevented. Furthermore, the presence of eating and weight concerns should perhaps be considered when reviewing the insulin regimen prescribed.

The relationship of BMI with eating and weight concerns would also suggest that it is important for members of the diabetes team to consider BMI and HbA1c in combination, when assessing overall diabetes management, as these concerns may be implicated in the absence of poor HbA1c results alone. The impact of BMI on eating and weight concerns in males should also be considered.

Overall, although reports of eating and weight concerns in this sample were low, the results point towards some important clinical implications and suggest some hypotheses for future research to examine the possible mechanisms which explain the presence of eating and weight concerns in type-1 diabetes. However this study should be viewed as a preliminary investigation into these factors in a local population and the conclusions made should be interpreted with caution. Before these conclusions can be confirmed and implemented clinically, further research, which includes a larger sample size and addresses the methodological limitations of this study, is required.

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APPENDICES

Appendix 1: EDE-Q: Version Administered to the Type-1 Diabetes Group

Eating Questionnaire-A

uctions

e questions are about the **PAST TWO WEEKS ONLY (14 DAYS)**. Please read each question carefully and circle umber on the right. Please answer ALL the questions.

MPLES: HOW MANY DAYS OF THE PAST 14 S.....	No days	1-2 days	3-6 days	7 days	8-10 days	12-13 days	Every day
e you tried to eat tables?	0	1	2	3	4	5	6
many times have walked to school?	0	1	2	3	4	5	6

HOW MANY DAYS OUT OF THE T 14 DAYS.....	No days	1-2 days	3-6 days	7 days	8-10 days	12-13 days	Every day
...Have you been trying to cut down on food **to control your weight or shape?**	0	1	2	3	4	5	6
...Have you gone for long periods of time (8 hours or more) without eating anything **to control your shape or weight?**	0	1	2	3	4	5	6
...Have you tried not to eat any foods you like **to control your weight and shape?**	0	1	2	3	4	5	6
...Have you tried to keep to any strict rules about eating **to control your shape or weight?**	0	1	2	3	4	5	6
...Have you wanted your stomach to be empty?	0	1	2	3	4	5	6
...Has thinking about food or calories made it much harder to concentrate on things you are interested in; for example, reading, watching tv, or doing your homework?	0	1	2	3	4	5	6
...Have you been scared of losing control over eating?	0	1	2	3	4	5	6
...Have you had eating binges?	0	1	2	3	4	5	6

N HOW MANY DAYS OUT OF THE AST 14 DAYS.....	No days	1-2 days	3-6 days	7 days	8-10 days	12-13 days	Every day
...Have you eaten in secret? (Do not count binges.)	0	1	2	3	4	5	6
0. ...Have you really wanted your stomach to be flat?	0	1	2	3	4	5	6
1. ...Has thinking about shape or weight made it much harder to concentrate on things you are interested in; for example, reading, watching TV, or doing your homework?	0	1	2	3	4	5	6
2. ...Have you been really scared that you might put on weight and get fat?	0	1	2	3	4	5	6
3. ...Have you felt fat?	0	1	2	3	4	5	6
4. ...Have you had a strong wish to lose weight?	0	1	2	3	4	5	6

VER THE PAST TWO WEEKS (14 DAYS).....

15. ...How often have you felt guilty after eating **because of the effect on your shape and weight?** (Do not count binges.) (Circle the number which applies.)

0. None of the times
1. A few of the times
2. Less than half the times
3. Half the times
4. More than half the times
5. Most of the time
6. Every time

16. ... Over the past two weeks (14 days), have there been any times when you have felt that you ate what other people would think was a very large amount of food given the situation? (Please circle). **0- NO 1- YES**

17. ...How many such times have you done this over the past two weeks? _____

18. ....During how many of these episodes of overeating did you have a sense of having lost control? _____

19. Have there been other times when you felt that you lost control and felt you ate too much, but did NOT eat a very large amount of food given the situation? (Please circle) **0- NO 1- YES**

20. ...How many times has this happened over the past two weeks? _____

21. Over the past two weeks have you made yourself sick (vomit) to control your shape or weight? (Please circle).	0- NO 1- YES
22. ...How many such times have you done this over the past two weeks?	_____
23. ....Have you taken laxatives to control your shape or weight? (Please circle)	0 ----NO 1 ----YES
24. How many times have you done this over the past two weeks?	_____
25. Have you taken diuretics (water tablets) to control your shape or weight? (Please circle)	0 ----NO 1 ----YES
26. How many times have you done this over the past two weeks?	_____
27. Have you exercised <u>hard</u> to control your shape or weight? (Please circle)	0 ----NO 1 ----YES
28. How many times have you done this over the past two weeks?	_____
29. Have you done anything else to control your shape or weight? If so, what have you done? _____	0-----NO 1-----YES
30. How many times have you done this over the past two weeks?	_____

OVER THE PAST 2 WEEKS (14 DAYS).....
(Please circle the number which best describes your behavior)

	NOT AT ALL		SLIGHTLY		MODERATELY		MARKEDLY
31. ....Has your weight affected how you think about (judge) yourself as a person?	0	1	2	3	4	5	6
32. ....Has your shape affected how you think about (judge) yourself as a person?	0	1	2	3	4	5	6
33. ....How much does it upset you when you get weighed at the diabetes clinic?	0	1	2	3	4	5	6
34. ....How unhappy have you felt about your weight?	0	1	2	3	4	5	6
35. ....How unhappy have you felt about your shape?	0	1	2	3	4	5	6
36. How worried have you been about other people seeing you eat?	0	1	2	3	4	5	6

OVER THE PAST 2 WEEKS (14 DAYS).....
(Please circle the number which best describes your behavior)

	NOT AT ALL		SLIGHTLY		MODERATELY		MARKEDLY
37. .... How uncomfortable have you felt seeing your body: for example, in the mirror, in shop windows, when you undress or when you have a bath or shower?	0	1	2	3	4	5	6
38. ....How uncomfortable have you felt about others seeing your body; for example, in shared changing rooms, when swimming or wearing tight clothes?	0	1	2	3	4	5	6

Appendix 2: EDE-Q: Version Administered to the Control Group

Eating Questionnaire-A

Instructions

These questions are about the **PAST TWO WEEKS ONLY (14 DAYS)**. Please read each question carefully and circle the number on the right. Please answer ALL the questions.

EXAMPLES: **ON HOW MANY DAYS OUT OF THE PAST 14 DAYS.....**	No days	1-2 days	3-6 days	7 days	8-10 days	12-13 days	Every day
Have you tried to eat vegetables?	0	1	2	3	4	5	6
How many times have you walked to school?	0	1	2	3	4	5	6

ON HOW MANY DAYS OUT OF THE PAST 14 DAYS.....	No days	1-2 days	3-6 days	7 days	8-10 days	12-13 days	Every day
1. ...Have you been trying to cut down on food **to control your weight or shape?**	0	1	2	3	4	5	6
2. ...Have you gone for long periods of time (8 hours or more) without eating anything **to control your shape or weight?**	0	1	2	3	4	5	6
3. ...Have you tried not to eat any foods you like **to control your weight and shape?**	0	1	2	3	4	5	6
4. ...Have you tried to keep to any strict rules about eating **to control your shape or weight?**	0	1	2	3	4	5	6
5. ...Have you wanted your stomach to be empty?	0	1	2	3	4	5	6
6. ...Has thinking about food or calories made it much harder to concentrate on things you are interested in; for example, reading, watching tv, or doing your homework?	0	1	2	3	4	5	6
7. ...Have you been scared of losing control over eating?	0	1	2	3	4	5	6
8. ...Have you had eating binges?	0	1	2	3	4	5	6

ON HOW MANY DAYS OUT OF THE PAST 14 DAYS.....	No days	1-2 days	3-6 days	7 days	8-10 days	12-13 days	Every day
9. ...Have you eaten in secret? (Do not count binges.)	0	1	2	3	4	5	6
10. ...Have you really wanted your stomach to be flat?	0	1	2	3	4	5	6
11. ...Has thinking about shape or weight made it much harder to concentrate on things you are interested in; for example, reading, watching TV, or doing your homework?	0	1	2	3	4	5	6
12. ...Have you been really scared that you might put on weight and get fat?	0	1	2	3	4	5	6
13. ...Have you felt fat?	0	1	2	3	4	5	6
14. ...Have you had a strong wish to lose weight?	0	1	2	3	4	5	6

OVER THE PAST TWO WEEKS (14 DAYS).....

15. ...How often have you felt guilty after eating **because of the effect on your shape and weight?** (Do not count binges.) (Circle the number which applies.)
    0. None of the times
    1. A few of the times
    2. Less than half the times
    3. Half the times
    4. More than half the times
    5. Most of the time
    6. Every time

16. ... Over the past two weeks (14 days), have there been any times when you have felt that you ate what other people would think was a very large amount of food given the situation? (Please circle). **0- NO 1- YES**

17. ...How many such times have you done this over the past two weeks? _____

18. ....During how many of these episodes of overeating did you have a sense of having lost control? _____

19. Have there been other times when you felt that you lost control and felt you ate too much, but did NOT eat a very large amount of food given the situation? (Please circle) **0- NO 1- YES**

20. ...How many times has this happened over the past two weeks? _____

21. Over the past two weeks have you made yourself sick (vomit) to control your shape or weight? (Please circle).	**0- NO** **1- YES**
22. ...How many such times have you done this over the past two weeks?	_____
23. ....Have you taken laxatives to control your shape or weight? (Please circle)	**0---- NO** **1---- YES**
24. How many times have you done this over the past two weeks?	_____
25. Have you taken diuretics (water tablets) to control your shape or weight? (Please circle)	**0---- NO** **1---- YES**
26. How many times have you done this over the past two weeks?	_____
27. Have you exercised <u>hard</u> to control your shape or weight? (Please circle)	**0---- NO** **1---- YES**
28. How many times have you done this over the past two weeks?	_____
29. Have you done anything else to control your shape or weight?	**0-----NO** **1-----YES**
If so, what have you done? _____	
30. How many times have you done this over the past two weeks?	_____

OVER THE PAST 2 WEEKS (14 DAYS).....
(Please circle the number which best describes your behavior)

	NOT AT ALL		SLIGHTLY		MODERATELY		MARKEDLY
31. ....Has your weight affected how you think about (judge) yourself as a person?	0	1	2	3	4	5	6
32. ....Has your shape affected how you think about (judge) yourself as a person?	0	1	2	3	4	5	6
33. ....How much would it upset you if you had to weigh yourself once a week for the next four weeks?	0	1	2	3	4	5	6
34. ....How unhappy have you felt about your weight?	0	1	2	3	4	5	6
35. ....How unhappy have you felt about your shape?	0	1	2	3	4	5	6
36. How worried have you been about other people seeing you eat?	0	1	2	3	4	5	6

OVER THE PAST 2 WEEKS (14 DAYS).....
(Please circle the number which best describes your behavior)

	NOT AT ALL		SLIGHTLY		MODERATELY		MARKEDLY
37. .... How uncomfortable have you felt seeing your body: for example, in the mirror, in shop windows, when you undress or when you have a bath or shower?	0	1	2	3	4	5	6
38. ....How uncomfortable have you felt about others seeing your body; for example, in shared changing rooms, when swimming or wearing tight clothes?	0	1	2	3	4	5	6

Appendix 3: Self-Report Measure of Adherence for Adolescents

Diabetes Questionnaire

Background Information

Please answer all questions as best as you can.

Age: .....

Sex: Male / Female (please circle)

What are the first four digits of your postcode
(eg if your postcode is DD3 6HH, put DD3 6): ____ ____

How many years have you been diagnosed with Diabetes? .....years

Do you have any other illnesses? .....

How many of your daily insulin injections are you responsible for (i.e. without any help)? *(Please circle the answer which best applies to you).*

All of them	Most of them	Some of them	A few of them	None of them

Adherence Information

We would like to find out how often you follow the advice that is given to you about looking after your diabetes. Remember that your answers will be confidential and you do not have to show your answers to anyone, so please be as honest as you can.

The following questions ask about how you have looked after your diabetes ***over the last 7 days****. If you were ill over the last 7 days, please think back to the last 7 days that you were not ill.*

Please read the following questions and then ***circle the answer which best applies to you****.*

1. How many of their recommended insulin injections did your child take in the last 7 days that they were supposed to?

All of them	Most of them	Some of them	Few of them	None of them

2. How many of their recommended insulin injections did your child have at the time they were supposed to?

None of them	Few of them	Some of them	Most of them	All of them

3. On how many of the last 7 days did your child test their blood sugar level?

All of them	Most of them	Some of them	Few of them	None of them

4. Over the last 7 days, how many of the blood sugar tests recommended by the diabetes team did your child actually do?

None of them	Few of them	Some of them	Most of them	All of them

5. How often do you think your child has eaten healthily over the last seven days?

Always	*Usually*	*Sometimes*	*Rarely*	*Never*

6. How many times over the last week has your child eaten sweet foods (such as, chocolate, cakes, ice cream, sweets)?

Always	*Usually*	*Sometimes*	*Rarely*	*Never*

7. On how many of the last seven days did your child exercise for at least 20 minutes?

0	1	2	3	4	5	6	7

8. On how many of the last seven days did your child exercise on top of what they do at school?

0	1	2	3	4	5	6	7

We would now like to find out a bit more about how you feel about the different parts of your diabetes care. Once again, remember that your answers will be confidential, so please be as honest as you can.
Please read the following questions and answer them as best as you can.

Are there any reasons why you may not take your insulin (or take it incorrectly)?

.....
.....
.....
.....
.....

What are the consequences of not taking your insulin (or taking it incorrectly)?

.....
.....
.....
.....
.....

Are there any reasons why you may not check your blood sugar level?

.....
.....
.....
.....
.....

What are the consequences of not checking your blood glucose?

.....
.....
.....
.....
.....

Are there any reasons why you may not eat healthily?

.....
.....
.....
.....
.....

What are the consequences of not eating healthily?

.....
.....
.....
.....
.....

Are there any reasons why you may not do any/enough exercise?

.....
.....
.....
.....
.....

What are the consequences of not exercising enough?

.....
.....
.....
.....
.....

Thank you very much for taking part in this questionnaire.

Appendix 4: Self-Report Measure of Adherence for Parents

Diabetes Questionnaire For Parents/Guardians

Background Information

Please answer all these questions about your child.

Child's Age: .....

Child's Sex: Male / Female (please circle)

What are the first four digits of your postcode
(eg if your postcode is DD3 6HH, put DD3 6): ___ ___ ___ ___

How many years has your child been diagnosed with Diabetes? .....years

Does your child have any other chronic illnesses?.....

Who is responsible for your child's diabetes care at home? *(please circle the answer which best applies to your child).*

They are	They get a little help	They get some help	They get a lot of help	They are not at all responsible

How many of your child's daily insulin injections are they responsible for themselves?

All of them	Most of them	Some of them	A few of them	None of them

Adherence Information

We would like to find out how often your child follows the advice that is given to them about looking after their diabetes. Remember that your answers will be confidential and you do not have to show your answers to anyone, so please be as honest as you can.

The following questions ask about how your child has looked after their diabetes ***over the last 7 days****. If your child was ill over the last 7 days, please think back to the last 7 days that they were not ill.*

Please read the following questions and then ***circle the answer which best applies to your child****.*

1. How many of your recommended insulin injections did you take in the last 7 days that you were supposed to?

All of them	Most of them	Some of them	Few of them	None of them

2. How many of your recommended insulin injections did you have at the time you were supposed to?

None of them	Few of them	Some of them	Most of them	All of them

3. On how many of the last 7 days did you test your blood sugar level?

All of them	Most of them	Some of them	Few of them	None of them

4. Over the last 7 days, how many of the blood sugar tests recommended by the diabetes team did you actually do?

None of them	Few of them	Some of them	Most of them	All of them

5. How often do you think you have eaten healthily over the last seven days?

Always	*Usually*	*Sometimes*	*Rarely*	*Never*

6. How many times over the last week have you eaten sweet foods (such as, chocolate, cakes, ice cream, sweets)?

Always	*Usually*	*Sometimes*	*Rarely*	*Never*

7. On how many of the last seven days did you exercise for at least 20 minutes?

0	1	2	3	4	5	6	7

8. On how many of the last seven days did you exercise on top of what you do at school?

0	1	2	3	4	5	6	7

We would now like to find out a bit more about how your child feels about the different parts of their diabetes care. Once again, remember that your answers will be confidential, so please be as honest as you can.
Please read the following questions and answer them as best as you can.

Are there any reasons why your child may not take their insulin (or take it incorrectly)?

.....
.....
.....
.....
.....

What are the consequences of not taking insulin (or taking it incorrectly)?

.....
.....
.....
.....
.....

Are there any reasons why your child may not check their blood sugar level?

.....
.....
.....
.....
.....

What are the consequences of not checking blood glucose?

.....
.....
.....
.....
.....

Are there any reasons why your child may not eat healthily?

.....
.....
.....
.....
.....

What are the consequences of not eating healthily?

.....
.....
.....
.....
.....

Are there any reasons why your child may not do any/enough exercise?

.....
.....
.....
.....
.....

What are the consequences of not exercising enough?

.....
.....
.....
.....
.....

Thank you very much for taking part in this questionnaire.

Appendix 5: Response from the Tayside Committee on Medical Research Ethics

Tayside Committee on Medical Research Ethics A
Level 9
Ninewells Hospital & Medical School
DUNDEE
DD1 9SY
Telephone Number: 01382 632701
Fax Number: 01382 496207
www.nhstayside.scot.nhs.uk

NHS Tayside

iss Shona Murphy
ainee Clinical Psychologist
entre for Child Health
) Dudhope Terrace
undee
D3 6HH

Date	11 March 2005
Your Ref	
Our Ref	NFB/FB/05/S1401/15
Enquiries to	Mr Nigel F Brown
Extension	32701
Direct Line	01382 632701
Email	nigel.brown@tuht.scot.nhs.uk or fiona.bain@tuht.scot.nhs.uk

ear Miss Murphy

Full title of study: ***An Investigation of Eating Disturbances and Weight and Shape Concerns, as Predictors of Adherence and Glycaemic Control in Adolescents with Insulin-Dependent Diabetes (IDDM).***

REC reference number: ***05/S1401/15***
Protocol number:

ne Research Ethics Committee reviewed the above application at the meeting held on 25 February 2005.

thical opinion

ne members of the Committee present decided that it was unable to give a favourable ethical opinion of the search, for the following reasons:

Most of the problems the Committee had with the research in its present form are thought to be insurmountable. ne following comments were made:

The Body Shape Questionnaire.

It appears to have been used in people with suspected eating disorders, but it is not known of it has been validated in diabetic and non-diabetic, apparently healthy adolescents. It is considered to be too intrusive and negative and therefore inappropriate in this group.

It appears to target girls, yet both boys and girls will be recruited. The Committee wondered if the issues were really appropriate for boys with diabetes.

Every question is very negative and likely to have a similar effect on the adolescents, especially the diabetics, but also the controls in that some may well have an underlying problem. There are no questions along the lines of 'Are you happy with your body shape, what you eat, etc

Q16 concerning cutting off flesh is somewhat disturbing.

It is likely that some people, eg, those who were previously happy with their shape and body size, might begin to doubt this. It might even be counter-productive and encourage poor compliance with diet and insulin.

The fact that children will complete this at home and return it so that replies are anonymous is disturbing. There was concern as to how a parent might react to their child being asked these questions. Complaints seem almost inevitable.

There is a risk that some children might be 'given ideas' about, for example, taking laxatives and diuretics, vomiting, cutting off flesh, etc.

The Eating Questionnaire also causes concern along the lines of the much of the above, but it is not known if it has been validated for adolescents with diabetes.

regret to inform you that the application is therefore not approved.

ptions for further ethical review

ou may submit a new application for ethical review, taking into account the Committee's concerns. This ould be processed in exactly the same way as any new application. You should enter details of this pplication at Question A55 on the application form.

lternatively, you may appeal against the decision of the Committee by seeking a second opinion on this pplication from another Research Ethics Committee. The appeal would be based on the application form and upporting documentation reviewed by this Committee, without amendment. If you wish to appeal, you should otify the Central Office for Research Ethics Committees (COREC) in writing within 90 days of the date of this etter. If the appeal is allowed, COREC will appoint another REC to give a second opinion within 60 days and ill arrange for the second REC to be provided with a copy of the application, together with this letter and other elevant correspondence on the application. You will be notified of the arrangements for the meeting of the econd REC and will be able to attend and/or make written representations if you wish to do so.

he relevant COREC contact point is:

r. Althea Allison
eputy Director of Operations
entral Office for Research Ethics Committees (COREC)
nd Floor, Block A
0 Eastbourne Terrace
ondon W2 6LX
-Mail: althea.allison@corec.org.uk

n the event that you decide to re-submit to this Committee, you may wish to note these further omments:

- How could the Committee be reassured that no child would be psychologically, if not physically harmed, by taking part in this study? What safeguards could be put in place, eg, referral to an experienced Clinical Psychologist?

- GPs need to be on-board with this research. Would they be able to identify and exclude people with existing eating disorders?

- The Committee would require information of the approval of the Education Authority (being sought).

- If research of this type were to go ahead, it would be necessary to send an introductory letter from Drs Green and Alexander to accompany the Information Sheet and Questionnaires. A copy of the letter template is enclosed.

- At questions A35 and A36 on the Application Form (indemnity and compensation), 'Not applicable' are inappropriate answers. At A59, you would need to give the name of a sponsor and discuss with them indemnity and compensation arrangements.

Documents reviewed

The documents reviewed at the meeting were:

Document Type:	Version:	Dated:	Date Received:
Application		21/01/2005	26/01/2005
Investigator CV			26/01/2005

Document Type:	Version:	Dated:	Date Received:
Investigator CV	Supervisor		26/01/2005
Protocol	1	21/01/2005	26/01/2005
Covering Letter		21/01/2005	26/01/2005
Copy of Questionnaire	Eating Questionnaire		26/01/2005
Copy of Questionnaire	The Body Shape Questionnaire		26/01/2005
Copy of Questionnaire	1	21/01/2005	26/01/2005
Letters of Invitation to Participants	For Control Group - 1	21/01/2005	26/01/2005
Letters of Invitation to Participants	For IDDM Group - 1	21/01/2005	26/01/2005
Participant Information Sheet	For IDDM group - 1	21/01/2005	26/01/2005
Participant Information Sheet	For Control Group - 1	21/01/2005	26/01/2005
Participant Consent Form	For Control Group - 1	21/01/2005	26/01/2005
Participant Consent Form	For IDDM Group - 1	21/01/2005	26/01/2005
Other	Background information - 1	21/01/2005	26/01/2005

lembership of the Committee

ne members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

otification of other bodies

his letter is confidential but we shall notify the research sponsor: and NHS Tayside R & D Department of the itcome of the review.

tatement of compliance

he Committee is constituted in accordance with the Governance Arrangements for Research Ethics ommittees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics ommittees in the UK.

5/S1401/15 ***Please quote this number on all correspondence***

ours sincerely

hair

nclosures List of names and professions of members who were present at the meeting and those who submitted written comments
Introductory Letter Guidance

MEMBERS OF THE TAYSIDE COMMITTEE ON MEDICAL RESEARCH ETHICS (A) WHO WERE PRESENT AT THE MEETING ON FRIDAY 25 FEBRUARY 2005

Dr J Davidson, Chairman, Consultant in Nuclear Medicine

Dr F Daly, Statistician Member

Mr J Angus, Lay Member

Mrs M Crichton, Nurse Member

Mr H Drummond Lay Member

Ms A Duthie, Nurse Member

Mrs L Gray, Lay Member

Dr C Jackson, GP Member

Mr A S Jain, Consultant Orthopaedic Surgeon

Dr R A Lerski, Director, Department of Medical Physics

Mrs S Roff, Deputy for Non-Clinical Scientist Member

Mrs L Van Aalten, Lay Member

Mrs S Walker, Lay Member

Appendix 6: Letter of Ethical Approval

NHS
Fife

Fife and Forth Valley Local Research Ethics Committee
Room 507
Hayfield House
Hayfield Road
KIRKCALDY
Fife
KY2 5AH

Telephone: 01592 643355 ext 8976
Facsimile: 01592 648142
L1295 S0501-51
Email: alison.smit@nhs.net

6 April 2005

Miss Shona Murphy
Trainee Clinical Psychologist
NHS Lothian / University of Edinburgh
Centre for Child Health
19 Dudhope Terrace
Dundee
DD3 6HH

Dear Miss Murphy

Full title of study: ***An Investigation of Eating Disturbances and Weight Concerns as Predictors of Adherence and Glycaemic Control in Adolescents with Type 1 Diabetes***
REC reference number: ***05/S0501/51***
Protocol number:

As you are aware the Research Ethics Committee reviewed the above application at the meeting held on 5 April 2005, and I would like to thank you for your attendance.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

However, the Committee requested that:

- for confidentiality purposes parents and children should be provided with separate return envelopes; and
- the Consent Form should be in a standard format and witnessed by the Researcher.

cont'd/2

"No local investigator" status

The Committee agreed with your declaration that this is a "no local investigator" study. Site-specific assessment is not required for sites involved in the research and no information about the study needs to be submitted to Local Research Ethics Committees. However, you should arrange for the R&D Departments of all relevant NHS care organisations to be notified that the research will be taking place before the research commences.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document Type:	Version:	Dated:	Date Received:
Application		22/03/2005	24/03/2005
Investigator CV		22/03/2005	24/03/2005
Protocol	1	21/03/2005	24/03/2005
Covering Letter		21/03/2005	24/03/2005
Copy of Questionnaire	Eating		24/03/2005
Copy of Questionnaire	Diabetes 1	22/03/2005	24/03/2005
Copy of Questionnaire	Parents/Guardians 1	22/03/2005	24/03/2005
Letters of Invitation to Participants	1	22/03/2005	24/03/2005
GP/Consultant Information Sheets	1	22/03/2005	24/03/2005
Participant Information Sheet	Parents/Guardians 1	22/03/2005	24/03/2005
Participant Information Sheet	Adolescents 1	22/03/2005	24/03/2005
Participant Consent Form	1	22/03/2005	24/03/2005
Supervisor's CV		22/03/2005	24/03/2005
Response from Tayside		11/03/2005	24/03/2005
2 Letters from Specialists to Parents/Guardians		21/03/2005	24/03/2005
Letter of Support		22/03/2005	24/03/2005

Management approval

You should arrange for all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

cont'd/3

All researchers and research collaborators who will be participating in the research at a NHS site must obtain management approval from the relevant care organisation before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/S0501/51	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project,

Yours sincerely,

A J Smit (Mrs)

Mr Robert Buchan
Chair

Enclosures *List of names and professions of members who were present at the meeting*

Standard approval conditions (SL-AC2)

NHS
Fife

Fife and Forth Valley Local Research Ethics Committee
Room 507
Hayfield House
Hayfield Road
KIRKCALDY
Fife
KY2 5AH

Telephone: 01592 643355 Ext 8976
Facsimile: 01592 648142
L1333 S0501-51
Email: alison.smit@nhs.net

9 May 2005

Ms Shona Murphy
Trainee Clinical Psychologist
Child & Adolescent Clinical Psychology Service
Centre for Child Health
19 Dundhope Terrace
Dundee
DD3 6HH

Dear Ms Murphy,

Full title of study: ***An Investigation of Eating Disturbances and Weight Concerns as Predictors of Adherence and Glycaemic Control in Adolescents with Type 1 Diabetes***

REC reference number: ***05/S0501/51***

I refer to letter dated 12 April 2005 in response to concerns raised by the Committee and enclosing amended documentation in relation to the above study and I write to confirm these were **approved** at the Fife and Forth Valley Local Research Ethics meeting held on 3 May 2005.

Yours sincerely,

Mrs Alison Smit
Administrator
Fife and Forth Valley Ethics Committee

Appendix 7: Letter of Approval from the Tayside Research and Development Committee

TAYSIDE R&D CONSORTIUM

LC/AG

23 May 2005

Miss Shona Murphy
Trainee Clinical Psychologist
Centre for Child Health
19 Dudhope Terrace
DUNDEE
DD3 6HH

Dear Miss Murphy

R&D Project: 2005DM09

Title: Eating and Weight Concerns in Adolescents with Diabetes.

MREC Ref: n/a **LREC Ref: 04/S0501/51** **LREC Final Approval Date: 6/4/05**

Funding: Unfunded Study – PhD Studentship

Sponsor: Royal Hospital Edinburgh

NHS Support Required: nil

The above project has been registered on the NHS Tayside R&D database, as required by the Research Governance Framework. Full LREC approval has been obtained and there are no NHS Support costs associated with this research project.

NHS Tayside has no objection to the project proceeding, provided all necessary approvals are in place and all amendments to the protocol, personnel involved and funding be notified to the R&D office and all appropriate personnel.

It is important to note that all research must be carried out in compliance with the Research Governance Framework for Health & Community Care and the new EU Clinical Trials Directive.

Kind Regards,

Elizabeth Coote
Non-Commercial
Research & Development Manager

RECEIVED
25 MAY 2005

c.c. Mr Nigel Brown

Appendix 8: Letter of Approval from the Fife Research and Development Committee

Fife Primary Care Division

Medical Directorate
Cameron House
Cameron Bridge
Windygates
Fife KY8 5RG

Tel 01592 712812

NHS Fife

Date 24th of May 2005
Our Ref SC/MI

Shona Murphy
Centre for Child Health
19 Dudhope Terrace
Dundee
DD3 6HH

Dear Shona

REQUEST FOR MANAGEMENT APPROVAL

Study Title:	***An Investigation of Eating Disturbances and Weight Concerns as Predictors of Adherence and Glycaemic Control in Adolescents with Type 1 Diabetes***
Chief Investigator	Ms Shona Murphy
Sponsor/CRO:	University of Edinburgh
REC reference No:	05/S0501/51

We are pleased to confirm that the study documents for this trial have been reviewed, and this study may now proceed.

Yours sincerely

Stella A Clark

DR STELLA CLARK
Acting Medical Director

RECEIVED
25 MAY 2005

Appendix 9: Letter of Permission to Access Participants' Medical Files in Tayside

Information Security
Ashludie Hospital
Monifieth
Angus
DD5 4HQ
Telephone Number 01382 527920
Fax Number 01382 423082
www.nhstayside.scot.nhs.uk

NHS
Tayside

Shona Murphy
Trainee Clinical Psychologist
Centre for Child Health
19 Dudhope Terrace
Dundee
DD3 6HH

Date	10th May 2005
Your Ref	
Our Ref	Caldicott/access/DG 1005
Enquiries to	Peter McKenzie
Email	information.security@thb.scot.nhs.uk

Study associated with Glycaemic Control in Adolescents

Attached to this letter is copy of the completed Confidentiality Statements giving Caldicott Guardian approval for access to patient records in support of the study as submitted.

Thank you for your co-operation in providing us with the information requested by us in this process.

Should any issues or queries arise during the study, relating to the accessing of patient records, please contact me.

Peter McKenzie, Information Security Officer

Copy:

CONFIDENTIALITY STATEMENT - for users of person identifiable data

NHS Tayside

User Details	
Name:	Shona Murphy
Position:	Trainee Clinical Psychologist
Organisation:	Lothian NHS Trust (Honorary contract with Tayside NHS Trust)
Address:	Centre for Child Health 19 Dudhope Terrace Dundee, DD3 6HH
Tel:	(01382) 346565

Sponsor Details

Name: VICKY ALEXANDER

Position: CONSULTANT

Organisation: TAYSIDE NHS TRUST

Address: Ward 29,
NINEWELLS HOSPITAL +
MEDICAL SCHOOL

Tel: 01382 660111 ext 32716

Data Protection Reg. No. : N/A

Data Requested : Data to be collected from the medical files of consenting adolescents who attend the diabetes clinics in Tayside: measure of glycaemic control (namely HbA1c), body mass index, prescribed insulin dose and number of daily insulin injections. It may also be necessary to collect other data from the files (length of time since diagnosis and diagnosis of any other chronic illnesses) if these have not been completed by the participant. The name and address of the participant's GP will also be collected, to inform GPs of their patient's participation in the study.

Co-Users of the Data : The research is being carried out under the supervision of Dr Becky Samson and Dr Pauline Adair, who will also have access to the data. All data storage will be anonymised however.

Intended use of data (inc. publications) :

The submission of a Doctoral thesis as part of the Edinburgh University Clinical Psychology Training Course, feedback to those involved with the research and the possibility of future publication. No identifying information will be used for these purposes however.

Period for which Data to be Retained : 10 years to allow for publication

User's Declaration

I declare that I understand and undertake to abide by the rules for confidentiality, security and release of data received from NHS Tayside.

Signature S. Murphy

Date 06/05/05

Sponsor's Declaration **(to be signed by a consultant if patient data is requested and the applicant is not of that status or is not medically qualified)**

I declare that the above named user of the data is a bona fide worker engaged in a reputable project and that the data requested can be entrusted to this person in the knowledge that they will conscientiously discharge their obligations in regard to confidentiality of the data.

Signature V. Alexander

Date 6/5/05

On completion, please return this form to:

The Information Security Officer
NHS Tayside
Ashludie Hospital
Monifieth

For NHS Tayside use only

Release authorised by

Date 10/5/05

Appendix 10: Letter of Permission to Access Participants' Medical Files in Fife

e NHS Board
lic Health Department

Cameron House
Cameron Bridge
LEVEN
Fife
KY8 5RG
Tel: 01592 712812
Fax: 01592 712762
www.show.scot.nhs.uk

NHS
Fife

s S Murphy
ld & Adolescent Clinical Psychology
vice Centre for Child Health
Dudhope Terrace
NDEE
3 6HH

Date	20 April 2005
Your Ref	
Our Ref	LM/DS/h:\jeanneb\lm29\lm29013.doc
Enquiries to	Jeanne Brown
Extension	6459
Direct Line/Fax	01592 226459/226925
Email	lesley.macdonald@nhs.net

ar Miss Murphy

ank you for your letter describing the research project which you are undertaking. As dicott Guardian for NHS Fife, I am happy to give my approval to you to collect relevant a from participants' medical files as described in your letter.

urs sincerely

Lesley Macdonald

Lesley Macdonald
ector of Public Health

RECEIVED
28 APR 2005

Appendix 11: Introductory Letter from the Consultant Paediatricians in Tayside

ayside Primary Care

NHS
Tayside

Date 21 March 2005
Enquiries to:
Telephone: 01382-632991

ear Parent/Guardian

E: Eating and Weight Concerns in Adolescents with Type 1 Diabetes

vrite to confirm that Shona Murphy is carrying out a research project as part of her clinical ychology training. I am acting as one of her supervisors and have agreed that she may contact u with an invitation to take part in the research project. I would be grateful if you would take the ne to read the attached Information Sheet and consider taking part and I would be pleased to ovide you with further information or answer any questions you may have concerning the project.

ours sincerely

V. Alexander

S. Greene / Dr V. Alexander
onsultant Paediatricians

Headquarters
Ashludie Hospital, Monifieth, Angus, DD5 4HQ

Chairperson, Mr Murray Petrie
Head of Services, Mr Daniel McLaren
Tayside NHS Board is the common name of Tayside Health Board

Appendix 12: Introductory Letter from the Consultant Paediatrician in Fife

Acute Hospitals
ria Hospital

Hayfield Road
Kirkcaldy
Fife KY2 5AH
Telephone 01592 643355
www.show.scot.nhs.uk/faht

NHS
Fife

Date 21 March 2005
Our Ref
Enquiries to 648001
Extension
Diabetic Department

Parent/Guardian

Eating and Weight Concerns in Adolescents with Type 1 Diabetes

te to confirm that Shona Murphy is carrying out a research project as part of her clinical nology training. I am acting as one of her supervisors and have agreed that she may contact vith an invitation to take part in the research project. I would be grateful if you would take the to read the attached Information Sheet and consider taking part and I would be pleased to de you with further information or answer any questions you may have concerning the project.

s sincerely

Shona Duncan

ncan
ciate Specialist in Diabetes

Appendix 13: Introductory Letter from the Researcher

ide Primary Care

Tayside Area Clinical Psychology Department
Child & Adolescent Clinical Psychology Service
Centre for Child Health
19 Dudhope Terrace
DUNDEE
DD3 6HH
Tel: 01382-346565
Fax: 01382-346555
www.nhstayside.scot.nhs.uk

NHS Tayside

Date:
Our Ref: SM
Your ref:
Enquiries to: Shona Murphy
Telephone: 01382-346565
Date dictated
Date typed

Parent/Guardian,

ould like to invite your child to take part in a research project. You will find attached an nation sheet for you, an information sheet for your child, a consent form and a questionnaire Please read the information sheet and then give the other one to your child to read. If you gree to take part in the study, please sign the consent form and return it with the completed onnaires in the stamped addressed envelope provided. This is a voluntary study and you both he choice whether or not you wish to take part.

child will be asked to complete two questionnaires and there is also one questionnaire for you nplete. If you have any questions before or after completing the questionnaires, please do not te to contact me.

k you for taking the time to read the information about this study.

sincerely,

S. Murphy

a Murphy
ee Clinical Psychologist
rvised by Dr Becky Samson, Clinical Child Psychologist

Appendix 14: Information Sheet for Parents in the Diabetes Group

NHS
Tayside

Information Sheet for Parents/Guardians

Eating and Weight Concerns in Adolescents with Diabetes

ur child is being invited to take part in a research project. Before you decide if you want em to take part, it is important for you to understand why the project is being done and what will involve.

ease take a few moments to read the following information and discuss it with your child. If ere is anything that is not clear or if you have any questions, please do not hesitate to contact e.

hat is the purpose of the project?

carrying out this project we hope to learn more about how young people with diabetes feel out eating habits and how comfortable they are with their weight. We want to know if this fects the willingness of young people to follow the advice they are given to help them to anage their diabetes. By investigating their responses to the questionnaires, we hope to entify specific issues that will help us to provide better support to young people with diabetes, order to improve blood glucose control and reduce long term complications.

hy has my child been chosen?

e are trying to invite as many people in the area with diabetes, between the ages of 12-18 ars, as possible. The paediatricians at the diabetes clinic gave us a list of all the people they e in that age range. All the people on this list have been invited to take part.

oes my child have to take part?

is up to you and your child whether or not to take part. If you both decide to take part, you ould keep this information sheet and both you and your child should sign the attached consent rm. If your child decides to take part and then changes their mind, there is no problem. You d your child can decide to withdraw from the project at any time. If you and your child decide t to take part, your care will not be affected in any way.

Vhat will happen if my child does take part?

our child is being asked to fill in the two questionnaires, attached with this sheet and then post em back in the envelope provided. The questionnaires should only take your child about 15-20 inutes to complete. You are also asked to complete a copy of the Diabetes Information uestionnaire and include it in the envelope provided. This questionnaire should only take you 5-0 minutes to complete. After that, we will collect the information you have provided and match up to some of the routine information collected at the diabetes clinic. You and your child do ot have to do anything else to take part.

Vill the information my child and I provide be confidential?

ll the information you and your child provide will be confidential. Each questionnaire sent out as a number on it. This number will allow me to match up the information your child provides

th information from your child's medical file. If you and your child consent to the study, this ll also allow us to collect the existing information from your child's medical file. We will also form your child's GP and the diabetes team that you have agreed to take part. However, you or our child's names will not be used in the project and no-one else will know about the answers you ve. The only time your child's information *may* be passed on to the diabetes team, is if there e *serious* concerns about your child's health *and* if your child agrees to their information being hared. This is to ensure that your child is getting the best possible care. Otherwise, you and our child's answers will not be shown to anyone else. It is important that your child feels they an fill out the questionnaires in confidence. They therefore do not have to show you their nswers, unless they choose to do so.

What will happen to the results of the project?

he project will be written up as part of my further degree. However, I will provide you with a opy of the overall results once it is completed.

as the project been approved?

he Research Ethics Committee, which is responsible for examining all proposals for research, as examined the proposal for this project and has raised no objections from the point of view f medical ethics. Furthermore, it is a requirement that the conduct of this project is made vailable, to allow the project to be monitored by regulatory authorities.

ontact Details.

f you have any questions or if you wish to talk about the project further, please do not hesitate o contact me or my supervisor, Dr Becky Samson, Clinical Psychologist. If you are worried bout your child filling out the questionnaires or if your answers to any of the questions raise ny issues you would like to discuss, please feel free to contact us. You can also talk to any ember of the diabetes team.

Shona Murphy
Trainee Clinical Psychologist
Centre for Child Health
9 Dudhope Terrace
Dundee
DD3 6HH
Telephone : (01382) 346565

Dr Becky Samson / Dr Pauline Adair
Clinical Psychologist
Diabetes Centre
Victoria Hospital
Kirkcaldy
KY25 5AH
Telephone : (01334) 652611 ext. 336

E-mail: shona.murphy@tpct.scot.nhs.uk (please remember that if you e-mail me, your name will appear on the e-mail. However, your e-mail will remain confidential as explained above).

Thank you for taking the time to read through this information.

If you would like to take part in the study, please sign and return one of the consent forms and sign and keep the other.

Appendix 15: Consent Form for Parents in the Diabetes Group

Tayside Primary Care

Study Number:
Patient Identification Number:

NHS Tayside

Consent Form for Parents

Project Title: Eating and Weight Concerns in Adolescents with Diabetes.

Name of Researcher: Shona Murphy, Trainee Clinical Psychologist.

Please initial box

1. I confirm that I have read and understood the attached information sheet (dated 22/03/05, version 1) for the study and have had the opportunity to ask questions. ☐
2. I understand that my and my child's participation in the project is voluntary and that we are free to withdraw at any time, without giving any reason and without any of our medical care or legal rights being affected. ☐
3. I understand that information from my child's medical file will be collected as part of the project and give permission for Shona Murphy, Trainee Clinical Psychologist to have access to this information. ☐
4. I agree for me and my child to take part in the above project. ☐

Name of parent (Print name here)	(Date)	(Signature)
Name of person taking consent (if different from researcher)	(Date)	(Signature)
(Name of researcher)	(Date)	(Signature)

1 for participant; 1 for researcher; 1 for hospital notes; 1 for GP notes

Appendix 16: Information Sheet for Adolescents in the Diabetes Group

NHS Tayside

Information Sheet for Adolescents

Eating and Weight Concerns in Adolescents with Diabetes

are being invited to take part in a research project. Before you decide, it is important for o understand why the project is being done and what it will involve.
e take a few moments to read the following information and discuss it with your parents if wish. If there is anything that is not clear or if you have any questions, please do not ate to contact me.

is the purpose of the project?

would like to learn more about how young people with diabetes feel about eating habits and comfortable they are with their weight. We want to know if this affects how much young e with diabetes follow the advice they are given about their diabetes. By looking at the nses young people with diabetes give on the questionnaires, we hope to understand these s better. This will help us to provide better support to young people with diabetes.

have I been chosen?

are trying to invite as many people in the area with diabetes, between the ages of 12-18 , as possible. The paediatricians at your diabetes clinic gave us a list of all the people they n that age range. All the people on this list have been invited to take part.

have to take part?

up to you whether or not to take part. If you do decide to take part, you should keep this mation sheet and sign the attached consent form. Your parent/guardian is also being asked gn the consent form. If you decide to take part and then change your mind, there is no lem. You can decide to withdraw from the project at any time. If you decide not to take your care will not be affected in any way.

t will happen if I take part?

ou will have to do, is fill in the questionnaires attached with this sheet and then post them in the envelope provided. The questionnaires should only take about 15-20 minutes to lete. Your parent/guardian will also be asked to complete the Diabetes Information tionnaire. After that, we will collect the information you have provided and match it up to of the routine information collected at the diabetes clinic - you won't have to do anything

the information I provide be confidential?

he information you provide will be confidential. Each questionnaire sent out has a number on This number will allow me to match up the information you provide with information from your cal file. If you consent to the study, this will also allow us to collect the information from medical file. We will also inform your GP and the diabetes team that you have agreed to

ake part. However, your name will not be used in the project and no-one else will know about he answers you give. The only time your information *may* be passed on to the diabetes team, is there are *serious* concerns about your health *and* if you agree to your information being hared. This is to ensure that you are getting the best possible care. Otherwise, your answers ill not be shown to anyone else.

What will happen to the results of the project?

The project will be written up as part of my course. However, I will provide you with a copy of he overall results when I am finished.

Contact Details.

f you have any questions or if you wish to talk about the project further, please do not hesitate o contact me or my supervisor, Dr Becky Samson. If you are worried about filling out the uestionnaires or if your answers to any of the questions raise any issues you would like to iscuss, please feel free to contact us when you need to. You can also talk to any member of the iabetes team.

Shona Murphy
Trainee Clinical Psychologist
Centre for Child Health
9 Dudhope Terrace
Dundee
DD3 6HH
Telephone : (01382) 346565

Dr Becky Samson / Dr Pauline Adair
Clinical Psychologist
Diabetes Centre
Victoria Hospital
Kirkcaldy
KY25 5AH
Telephone: (01334) 652611 ext. 336

E-mail: shona.murphy@tpct.scot.nhs.uk (please remember that if you e-mail me, your name will ppear on the e-mail. However, your e-mail will remain confidential as explained above).

Thank you for taking the time to read through this information.

If you would like to take part in the study, please sign and return one of the consent forms and ign and keep the other.

Appendix 17: Consent Form for Adolescents in the Diabetes Group

Tayside Primary Care

Study Number:
Patient Identification Number:

NHS Tayside

Consent Form for Adolescents

Project Title: Eating and Weight Concerns in Adolescents with Diabetes.

Name of Researcher: Shona Murphy, Trainee Clinical Psychologist.

Please tick the box to show that you agree with each of the statements:

1. I have read and understood the attached information sheet (dated 22/03/05, version 1). ☐
2. I have had the chance to ask questions if I wanted. ☐
3. I understand that taking part in the project is voluntary. ☐
4. I understand that I am free to withdraw at any time, without giving any reason and without any of my care being affected. ☐
5. I understand that information from my medical file will be collected as part of the project and give permission for Shona Murphy, Trainee Clinical Psychologist to have access to this information. ☐
6. I agree to take part in the project. ☐

Name of participant (Print name here)	(Date)	(Signature)
Name of person taking consent (if different from researcher)	(Date)	(Signature)
(Name of researcher)	(Date)	(Signature)

1 for participant; 1 for researcher; 1 for hospital notes; 1 for GP notes

Appendix 18: Letter Sent to GPs

Tayside Primary Care

Tayside Area Clinical Psychology Department
Child & Adolescent Clinical Psychology Service
Centre for Child Health
19 Dudhope Terrace
DUNDEE
DD3 6HH
Tel: 01382-346565
Fax: 01382-346555
www.nhstayside.scot.nhs.uk

Date:	
Our Ref:	SM
Your ref:	
Enquiries to:	Shona Murphy
Telephone:	01382-346565
Date dictated	
Date typed	

Dear Dr [GP's / Consultant's name],

RE: [Patient's name]

The above named individual and their parent/guardian have given their consent to participate in the following research project: **An Investigation of Eating Disturbances and Weight Concerns as Predictors of Adherence and Glycaemic Control in Adolescents with Type 1 Diabetes.**

The study will be undertaken in Ninewells Hospital, Dundee and Victoria Hospital, Kirkcaldy, between April 2005 and July 2005. If you would like any further information or have any questions about the research project, then please do not hesitate to contact me at the Child and Adolescent Clinical Psychology Department on (01382) 346565.

I have enclosed a copy of [patient's name] signed consent form, for your records.

Yours sincerely,

Shona Murphy
Trainee Clinical Psychologist
Supervised by Dr Becky Samson, Clinical Psychologist

Appendix 19: Medical Information Form

Eating and Weight Concerns in Adolescents with Type 1 Diabetes

Required Information from Medical Files

atient code number: .....

ate of Birth .....

atient's GP: Name .....

Address.....

.....

/hen diagnosed with diabetes?: .....(date or number of years ago)

ast three HbA1c results:

) Date..... Result.....

) Date..... Result.....

) Date..... Result.....

ast three height and weight measures:

) Date..... Height..... Weight..... BMI.....

) Date..... Height..... Weight..... BMI.....

) Date..... Height..... Weight..... BMI.....

rescribed insulin doses (and types):

Number of injections per day:.....

Any other chronic illnesses? (if so, what?):.....

Appendix 20: Letter of Permission from Fife Education Authority

Fax: 496325 (5pgs).

RECEIVED
19 MAY 2005

Fife Council

Shona Murphy
Trainee Clinical Psychologist
Tayside Area Clinical Psychology Department
Child & Adolescent Clinical Psychology Service
Centre for Child Health
19 Dudhope Terrace
Dundee
DD3 6HH

EDUCATION SERVICE
Direct Line - Bryan Kirkaldy
01592 413285

Email – bryan.kirkaldy@fife.gov.uk

Our ref: BK/LB

Date: 13th May 2005

Dear Shona

Carolyn Brown has advised me to approve Fife Schools' involvement in your proposed project, and I am happy to do so.

The involvement of schools will be a matter for each headteacher to determine and you should approach these individually.

Depending on your sample size requirements I understand that you may achieve sufficient involvement through 2-3 schools, perhaps those nearest to your base. I attach our contact list of secondary schools.

May I wish you success in your study.

Yours sincerely

Bryan Kirkaldy
Senior Manager

cc Carolyn Brown

enc

Appendix 21: Introductory Letter for Parents in the Control Group (Postal Survey)

vside Area Clinical Psychology Department
ild & Adolescent Clinical Psychology Service
ntre for Child Health
Dudhope Terrace
NDEE
3 6HH
: 01382-346565
x: 01382-346555

Section of Clinical and Health Psychology
SCHOOL OF HEALTH IN SOCIAL SCIENCE
The University of Edinburgh
Kennedy Tower
Royal Edinburgh Hospital
Edinburgh EH10 5HF

Telephone 0131 537 6000
or direct dial 0131 537
Fax 0131 537 6760

ear Parent / Guardian,

e would like to invite your child to take part in a research project. You will find enclosed an formation sheet and consent form for you, an information sheet and consent form for your child d a Background Information sheet and an Eating questionnaire, for your child to complete. ease read the information sheet and then give the other one to your child to read. If you both ree to take part in the study, please sign the consent forms and return them with the completed estionnaires in the stamped addressed envelope provided. This is a voluntary study and you both ve the choice whether or not you wish to take part.

you have any questions before or after taking part in the study, please do not hesitate to contact e.

hank you for taking the time to read the information about this study.

ours sincerely,

S. Murphy

hona Murphy
rainee Clinical Psychologist

Appendix 22: Information Sheet for Parents in the Control Group (Postal Survey)

Information Sheet for Parents/Guardians

Body Image Concerns in Adolescents With and Without Diabetes

Your child is being invited to take part in a research project. Before you decide if you want them to take part, it is important for you to understand why the project is being done and what it will involve.
Please take a few moments to read the following information and discuss it with your child. If there is anything that is not clear or if you have any questions, please do not hesitate to contact me.

What is the purpose of the project?

In carrying out this project we hope to learn more about how young people with and without diabetes feel about body image and how comfortable they are with their weight and shape. We want to know if this affects the willingness of young people with diabetes, to follow the advice they are given to help them to manage their condition. By comparing responses to questionnaires between young people with and without diabetes, we hope to understand these issues better for all adolescents and identify specific issues that will help us to provide better support to young people with diabetes.

Why has my child been chosen?

We are trying to invite as many people in the area without diabetes, between the ages of 12-18 years, as possible. Your child's school has agreed to be involved in the project and has allowed us to contact you.

Does my child have to take part?

It is up to you and your child whether or not they take part. If they do decide to take part, you should keep this information sheet and both you and your child should sign the attached consent forms. If your child decides to take part and then changes their mind, there is no problem. You and your child can decide to withdraw from the project at any time.

What will happen if my child does take part?

Your child is being asked to fill in the enclosed questionnaire along with a Background Information sheet. It should only take about 10 minutes to complete. Your child is then asked to post the two questionnaires, along with the signed consent forms, in the stamped addressed envelope provided. You do not have to do anything else to take part.

Will the information my child provides be confidential?

All the information your child provides will be confidential. They are not asked to give their name on the questionnaires and so all the information they provide will be anonymous. No one else will get to see the answers they give and no identifying information will be used in the project. It is important that your child feels they can fill out the questionnaires in confidence. They therefore do not have to show you their answers, unless they choose to do so.

What will happen to the results of the project?

The project will be written up as part of my further degree. However, I will be able to provide you with a copy of the overall results on request.

Contact Details.

If you have any questions or if you wish to talk about the project further, please do not hesitate to contact me or my supervisor, Dr Becky Samson, Clinical Psychologist. If you are worried about your child filling out the questionnaires or if they raise any issues you would like to discuss, please feel free to contact us when you need to.

Shona Murphy
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E-mail: shona.murphy@tpct.scot.nhs.uk (please remember that if you e-mail me, your name will appear on the e-mail. However, your e-mail will remain confidential as explained above).

Thank you for taking the time to read through this information.

If you would like to take part in the study, please sign and return one of the consent forms and sign and keep the other.

Appendix 23: Information Sheet for Adolescents in the Control Group (Postal Survey)

Information Sheet for Adolescents

Body Image Concerns in Adolescents With and Without Diabetes

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the project is being done and what it will involve.
Please take a few moments to read the following information and discuss it with your parents if you wish. If there is anything that is not clear or if you have any questions, please do not hesitate to contact me.

What is the purpose of the project?

We would like to learn more about how young people with and without diabetes feel about body image and how comfortable they are with their weight and shape. We want to know if this affects how much young people with diabetes follow the advice they are given about their diabetes. By comparing the responses of young people with and without diabetes on the questionnaires, we hope to understand these issues better for all adolescents.

Why have I been chosen?

We are trying to invite as many people in the area without diabetes, between the ages of 12-18 years, as possible. Your school has agreed to be involved in the project and has allowed us to contact you.

Do I have to take part?

It is up to you whether or not to take part. If you do decide to take part, you should keep this information sheet and sign the attached consent form. Your parent/guardian is also being asked to sign a consent form. If you decide to take part and then change your mind, there is no problem. You can decide to withdraw from the project at any time. If you decide not to take part, that is also fine.

What will happen if I take part?

All you will have to do, is fill in the enclosed questionnaire and Background Information sheet and then post it back in the envelope provided, along with the signed consent forms. It should only take about 10 minutes to complete. You don't have to do anything else!

Will the information I provide be confidential?

All the information you provide will be confidential. You are not asked to give your name on the questionnaire and so all the information you provide will be anonymous. No one else will get to see the answers you give and no identifying information will be used in the project.

What will happen to the results of the project?

The project will be written up as part of my course. However, I will be able to provide you with a copy of the overall results if you would like to see them.

Contact Details.

If you have any questions or if you wish to talk about the project further, please do not hesitate to contact me or my supervisor, Dr Becky Samson, Clinical Psychologist. If you are worried about filling out the questionnaires or if your answers to any of the questions raise any issues you would like to discuss, please feel free to contact me when you need to.

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E-mail: shona.murphy@tpct.scot.nhs.uk (please remember that if you e-mail me, your name will appear on the e-mail. However, your e-mail will remain confidential as explained above).

Thank you for taking the time to read through this information.

If you would like to take part in the study, please sign and return one of the consent forms and sign and keep the other.

Appendix 24: Consent Form for Parents in the Control Group (Postal Survey)

Consent Form for Parents/Guardians

Project Title: Body Image Concerns in Adolescents With and Without Diabetes

Name of Researcher: Shona Murphy

Please tick the box to show that you agree with each of the statements:

1. I have read and understood the information sheet. ☐
2. I have had the opportunity to ask questions if I wished. ☐
3. I understand that taking part in the project is voluntary. ☐
4. I understand that my child is free to withdraw at any time, without any of their care being affected. ☐
5. I agree for my child to take part in the project. ☐

----------	----------	----------
(Print name here)	(Date)	(Signature)

Appendix 25: Consent Form for Adolescents in the Control Group (Postal Survey)

Consent Form for Adolescents

Project Title: Body Image Concerns in Adolescents With and Without Diabetes

Name of Researcher: Shona Murphy

Please tick the box to show that you agree with each of the statements:

1. I have read and understood the information sheet. ☐
2. I have had the opportunity to ask questions if I wanted. ☐
3. I understand that taking part in the project is voluntary. ☐
4. I understand that I am free to withdraw at any time, without any of my care being affected. ☐
5. I agree to take part in the project. ☐

| ---------- | ---------- | ---------- |
| (Print name here) | (Date) | (Signature) |

Appendix 26: Background Information Questionnaire for Parents in the Control Group (Postal Survey)

Background Information

Please answer all questions.

Age: .....

Sex: Male / Female (please circle)

What are the first four digits of your postcode
(eg if your postcode is DD3 6HH, put DD3 6): ____ __

Do you have any chronic illnesses? YES / NO (please circle)
(e.g. diabetes, asthma, cystic fibrosis)

If yes, please give details:.....

If you know your height and weight, please write them here:

Height.....

Weight.....

Thank you for taking the time to complete this questionnaire.

Appendix 27: Introductory Letter for Parents in the Control Group (School Survey)

Tayside Primary Care

NHS
Tayside

Tayside Area Clinical Psychology Department
Child & Adolescent Clinical Psychology Service
Centre for Child Health
19 Dudhope Terrace
DUNDEE
DD3 6HH
Tel: 01382-346565
Fax: 01382-346564

June 2005

Dear Parent / Guardian,

Your child's school has agreed to help me with a research project that I am carrying out. I am a trainee clinical psychologist, currently in my final year of the Edinburgh University post-graduate training course. I would like to find out about the eating and weight concerns of adolescents between 12-18 years old, and compare them to the concerns of adolescents with Type-1 diabetes.

To take part in the project, your child will be asked to fill in a background information sheet (which asks for details such as age and gender) and complete a questionnaire about eating and weight concerns. This should only take about 10 - 15 minutes to complete and will be given to your child at school. Please read the attached information sheet to find out more details about the project.

If you do not want your child to take part in the project, please contact Ann Lawson on 01333 592000, by **Tuesday 14th June 2005**. If we do not hear from you, we will assume that you are willing to allow your child to take part.

I am most grateful for your help and thank you for taking the time to read this information.

Yours sincerely,

S Murphy

Shona Murphy
Trainee Clinical Psychologist

Appendix 28: Information Sheet for Parents in the Control Group (School Survey)

Information Sheet for Parents/Guardians

Body Image Concerns in Adolescents With and Without Diabetes

Your child is being invited to take part in a research project. Before you decide if you want them to take part, it is important for you to understand why the project is being done and what it will involve.
Please take a few moments to read the following information and discuss it with your child. If there is anything that is not clear or if you have any questions, please do not hesitate to contact me.

What is the purpose of the project?

In carrying out this project we hope to learn more about how young people with and without diabetes feel about body image and how comfortable they are with their weight and shape. We want to know if this affects the willingness of young people with diabetes, to follow the advice they are given to help them to manage their condition. By comparing responses to questionnaires between young people with and without diabetes, we hope to understand these issues better for all adolescents and identify specific issues that will help us to provide better support to young people with diabetes.

Why has my child been chosen?

We are trying to invite as many people in the area without a chronic illness, between the ages of 12-18 years, as possible. Your child's school has agreed to be involved in the project and has allowed us to contact you.

Does my child have to take part?

This is a voluntary study and so it is up to you and your child whether or not they take part. If you do not want your child to take part, you should contact the school to let them know. If your child decides to take part and then changes their mind, there is no problem.

What will happen if my child does take part?

Your child is being asked to fill in a background information sheet and a questionnaire about eating and weight concerns. These questionnaires should only take about 15 minutes to complete and will be given to your child at school. You and your child do not have to do anything else to take part.

Will the information my child provides be confidential?

All the information your child provides will be confidential. They are not asked to give their name on the questionnaires and so all the information they provide will be anonymous. No one else will get to see the answers they give and no identifying information will be used in the project.

What will happen to the results of the project?

The project will be written up as part of my further degree. However, I will be able to provide you with a copy of the overall results on request.

Contact Details.

If you have any questions or if you wish to talk about the project further, please do not hesitate to contact me or my supervisor, Dr Becky Samson, Clinical Psychologist. If you are worried about your child filling out the questionnaires or if they raise any issues you would like to discuss, please feel free to contact us when you need to.

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E-mail: shona.murphy@tpct.scot.nhs.uk (please remember that if you e-mail me, your name will appear on the e-mail. However, your e-mail will remain confidential as explained above).

Thank you for taking the time to read through this information.

Appendix 29: Information Sheet for Adolescents in the Control Group (School Survey)

Information Sheet for Adolescents

Body Image Concerns in Adolescents With and Without Diabetes

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the project is being done and what it will involve. Please take a few moments to read the following information.

What is the purpose of the project?

We would like to learn more about how young people with and without diabetes feel about body image and how comfortable they are with their weight and shape. We want to know if this affects how much young people with diabetes follow the advice they are given about their diabetes. By comparing the responses of young people with and without diabetes on the questionnaires, we hope to understand these issues better for all adolescents.

Why have I been chosen?

We are trying to invite as many people in the area without a chronic illness, between the ages of 12-18 years, as possible. Your school has agreed to be involved in the project and has allowed us to invite you to take part.

Do I have to take part?

It is up to you whether or not to take part. If you do decide to take part, you should keep this information sheet and complete the attached questionnaires. If you decide to take part and then change your mind, there is no problem. You can decide to withdraw from the project at any time.

What will happen if I take part?

All you will have to do, is fill in the two questionnaires attached to this sheet. The questionnaires should only take about 15 minutes to complete. You don't have to do anything else!

Will the information I provide be confidential?

All the information you provide will be confidential. **You are not asked to give your name on the questionnaire and so all the information you provide will be anonymous.** No one else will get to see the answers you give and no identifying information will be used in the project.

What will happen to the results of the project?

The project will be written up as part of my course. However, I will be able to provide you with a copy of the overall results if you would like to see them.

Contact Details.

If you have any questions or if you wish to talk about the project further, please do not hesitate to contact me or my supervisor, Dr Becky Samson, Clinical Psychologist. If you are worried about filling out the questionnaires or if your answers to any of the questions raise any issues you would like to discuss, please feel free to contact me when you need to.

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E-mail: shona.murphy@tpct.scot.nhs.uk (please remember that if you e-mail me, your name will appear on the e-mail. However, your e-mail will remain confidential as explained above).

Thank you for taking the time to read through this information.

Appendix 30: Background Information Questionnaire for Adolescents in the Control Group (School Survey)

Background Information

Please answer all questions.

Age: .....

Sex: Male / Female (please circle)

What are the first four digits of your postcode
(eg if your postcode is DD3 6HH, put DD3 6): ___ ___ ___ ___

Do you have any chronic illnesses? YES / NO (please circle)
(e.g. diabetes, asthma, cystic fibrosis)

If yes, please give details:.....

If you know your height and weight, please write them here:

Height.....

Weight.....

Thank you for taking the time to complete this questionnaire.

Appendix 31: Cronbach's Alpha Co-Efficients for Adherence Sub-Scale Scores

Table 22: Alpha Co-Efficients for the Adherence Questionnaire Sub-Scale Scores

	Alpha Co-Efficients for Participants	Alpha Co-Efficients for Parents' Ratings
Insulin Injection Adherence	0.74	0.46
Blood Glucose Testing Adherence	0.94	0.88
Dietary Adherence	0.33	0.54
Exercise Adherence	0.83	0.89
Adherence Total Score	0.70	0.70