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CHANGING ILLNESS PERCEPTIONS IN POORLY CONTROLLED TYPE 2 DIABETES: A RANDOMISED CONTROLLED TRIAL OF A PSYCHOLOGICAL, FAMILY-BASED INTERVENTION

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DECLARATION

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SUMMARY

Poor glycaemic (blood sugar) control in type 2 diabetes is associated with the development of microvascular and macrovascular complications, which have serious health and quality of life implications for patients themselves, as well as significant cost implications for healthcare providers. Patients with poorly controlled type 2 diabetes have been found to have significantly more inaccurate and negative beliefs or 'perceptions' about their illness, and report higher levels of emotional distress, when compared to those with good glycaemic control (White, Smith, & O'Dowd, 2001-2004). These individual illness perceptions are a central component of an important theoretical framework in health psychology; Leventhal's Self-Regulatory Model. A psychological intervention was developed to change the illness perceptions of patients with poorly controlled type 2 diabetes, with a view to improving their glycaemic control and psychological well-being. Family members were included in the intervention, as most diabetes management occurs in the home, and as such, may be influenced by, and impact upon, family relationships.

The study presented in this thesis is a randomised controlled trial (RCT) of this psychological, family based intervention. The primary outcome measures were: (1) glycaemic control as assessed by the haemoglobin A1c essay (HbA1c); (2) illness perceptions and (3) psychological well-being. The secondary outcome measures were: (1) blood pressure and body mass index; (2) diabetes self-care behaviours; (3) diabetes self-efficacy; (4) family support and; (5) family members' own illness perceptions. A process evaluation was also conducted, which collected quantitative and qualitative data relating to aspects of the delivery and receipt of the intervention, and facilitated an assessment of treatment fidelity. An economic evaluation was also conducted.

Patients (n=121) with persistently poorly controlled type 2 diabetes (defined as two out of their last three HbA1c readings $\geq$ 8.0%) were recruited from a diabetes outpatient clinic. Participants were randomised to the intervention group (n=60) or the control group (n=61). The intervention was delivered by a health psychologist trained in motivational interviewing techniques. Two weekly intervention sessions were delivered in patients' homes, with their nominated family member present. These home visit sessions lasted approximately 45 minutes each, and were followed-up a week later with

a 10-15minute telephone call with the patient only. Of the 60 participants randomised to the intervention group: 36 received the intervention, 10 withdrew from the trial, 5 were uncontactable, and 9 participants continually cancelled/missed scheduled sessions and were assumed to have withdrawn from the trial. Patients returned to the diabetes clinic for follow-up assessment at approximately six months post intervention. The rate of follow-up for HbA1c was 87% (53/61) for the control group and 82% (49/60) for the intervention group. The rate of follow-up for the psychological data was 75% (45/61) for the control group and 68% (41/60) for the intervention group.

The analysis of the outcome data was intention-to-treat, controlling for prespecified confounding variables (e.g. baseline levels of HbA1c, duration of diabetes, medication change). At six months follow-up there was a modest, but statistically significant improvement of -0.4% in HbA1c in the intervention group compared to the control group, when controlling for a significant interaction between baseline levels of HbA1c and group allocation. Further investigation of this interaction indicated that there was a statistically and clinically significant improvement of -1.2% in HbA1c in those in the intervention group with the poorest control at baseline (HbA1c > 9.5%). Compared to the control group, the intervention group also reported statistically significant improvements in: all illness perception dimensions, except consequences and timeline, psychological well-being, adherence to general diet and exercise behaviours, diabetes self-efficacy, family support and, family members' own illness perceptions. However, there were no significant differences between intervention and control groups in Body Mass Index (BMI), blood pressure, blood glucose testing, foot-care, and non-supportive family behaviour. Qualitative data indicated that the intervention was delivered as intended, and was acceptable to participants. The incremental cost of the intervention per 1% decrease in HbA1c was €548.47 for all participants, or €182.90 for those with the poorest control (HbA1c > 9.5%).

Thus, the results from the trial indicate that changing the inaccurate and negative illness perceptions of patients with poorly controlled type 2 diabetes can improve patients diabetes self-management, psychological well-being and glycaemic control. This particularly seems to be the case in those with the poorest glycaemic control (HbA1c > 9.5%). Including family members in this process, and delivering the intervention in participants homes appears to greatly contribute to these improvements.

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GLOSSARY OF TERMS

ADA	American Diabetes Association
BCT	Behaviour Change Technique
BMI	Body Mass Index
BRIEF-IPQ	Brief Illness Perception Questionnaire
CBT	Cognitive Behavioural Therapy
CODE-2	Cost of Diabetes in Europe
CODE-EIRE	Cost of Diabetes in Ireland
CONSORT	Consolidated Standards of Reporting Trials
DCCT	Diabetes Control and Complications Trail
DFBC	Diabetes Family Behaviour Checklist
DFI	Diabetes Federation of Ireland
DMSES	Diabetes Management Self-Efficacy Scale
DNA	'Did not attend'
DNS	Diabetes Nurse Specialist
DPP	Diabetes Prevention Programme
DSDG	Diabetes Service Development Group
HbA1c	Haemoglobin A1c assay
HSE	Health Service Executive
IDF	International Diabetes Federation
IPHI	Institute of Public Health in Ireland
IIT	Intention-to-treat
LOCF	Last Observation Carried Forward
NDWG	National Diabetes Working Group
MI	Motivational Interviewing
MRC	Medical Research Council
OHA	Oral Hypoglycaemic Agent
PPA	Per-protocol analysis
RCT	Randomised Controlled Trial
SDSCA	Summary of Diabetes Self-Care Activities Questionnaire
SMBG	Self-Monitoring/Management of Blood Glucose
UKPDS	UK Prospective Diabetes Study
WBQ-12	Well-Being Questionnaire 12-item

1 INTRODUCTION

This study is a randomised controlled trial (RCT) of a psychological family-based intervention, designed to improve a range of biophysical, behavioural, and psychosocial outcomes in people with poorly controlled type 2 diabetes.

Diabetes is a chronic metabolic disorder, resulting from a deficit in insulin action, insulin secretion, or both. Insulin is the hormone responsible for blood glucose (sugar) regulation in the body. There are two main types of diabetes: type 1 and type 2. The more common type is type two diabetes, which accounts for 85%-90% of cases (Wass, 2002). A key goal of diabetes treatment is to maintain blood sugar levels as close to normal as possible (good glycaemic control), as poor glycaemic control has been found to be associated with the development of microvascular and macrovascular complications, in both type 1 diabetes (Diabetes Control and Complications Trial (DCCT), 2002) and type 2 diabetes (UK Prospective Diabetes Study (UKPDS) 38, 1998). According to several recent studies, approximately one-third of patients with type 2 diabetes are poorly controlled, as defined by a HbA1c greater than 8.0% (Hartz et al., 2006; Massi-Benedetti, 2006; Saydah, Fradkin, & Cowie, 2004; Singh & Press, 2008). Poor glycaemic control has serious health and quality of life implications for patients themselves, as well as significant cost implications for healthcare providers. Many of the complications associated with diabetes are preventable, in that achieving tight glycaemic control can prevent or delay their onset. However, achieving tight glycaemic control requires patients to adhere to a treatment regime that many can find complex and demanding. This treatment regime requires behavioural self-regulation through, for example, the monitoring of symptoms, adapting to medication and testing blood glucose levels, as well as in many cases, significant lifestyle changes in relation to diet and exercise. The emphasis on the need to change behaviour in order to achieve positive health outcomes in diabetes management, and an appreciation of the difficulties patients experience in accomplishing such behaviour change, has led to a growing recognition of the potentially important contribution of health psychology to diabetes care and outcomes.

The literature on the psychosocial management of chronic illness consistently highlights the importance of understanding the illness from the patient's perspective. This approach uses the term 'illness perceptions' to refer to how patients' own individual thoughts or beliefs about their illness influence their illness-management behaviours. Research undertaken in Ireland has shown that those in poor control of their type 2 diabetes have significantly more inaccurate and negative beliefs about diabetes, and report higher levels of emotional distress related to their illness, when compared to those with good glycaemic control (White et al., 2001-2004). The results of this research by White and colleagues was used to develop a psychological intervention designed to change negative and inaccurate beliefs in patients with poorly controlled type 2 diabetes, with a view to improving their glycaemic control and enhancing their psychological well-being. A unique aspect of the intervention was the inclusion of the family members of patients with poorly controlled type 2 diabetes. Family members were included in the intervention in recognition of the fact that most diabetes management occurs in the home, and as such, may be influenced by, and in turn impact upon, family relationships. Furthermore, whilst family-based approaches to improving the management and outcomes of diabetes have become the norm for children and adolescents with type 1 diabetes, adults with type 2 diabetes are often considered in isolation from their social context. This study reported here is a randomised controlled trial (RCT) of this psychological, family-based intervention.

1.1 AIMS

To examine the effects on biophysical, behavioural, and psychosocial outcomes, of an intervention designed to change the illness perceptions of patients with poorly controlled type 2 diabetes and their family members.

1.2 HYPOTHESES

Two main hypotheses formed the framework to the study.

Null hypothesis

- Changing the illness perceptions of patients and family members has no effect on biophysical, psychosocial and behavioural outcomes in patients with poorly controlled type 2 diabetes

Alternative hypothesis

- Changing the illness perceptions of patients and family members does have effect on biophysical, psychosocial and behavioural outcomes in patients with poorly controlled type 2 diabetes

1.3 THESIS OVERVIEW

The final section of this brief introductory chapter provides an overview of the content of the remainder of the thesis

The following chapter, Chapter Two, presents a critical review of the existing literature that forms the backdrop to the study. Following a short summary of the methodology adopted in undertaking this review, the chapter begins by briefly outlining the epidemiology of diabetes mellitus, and the social and economic implications of the condition. Studies illustrating the critical role of tight glycaemic control in preventing complications are then summarised, alongside a discussion of the difficulties often experienced by patients in achieving such control. Studies investigating the prevalence of poor control of type 2 diabetes are also examined. In addition, sociodemographic and psychosocial factors that have been found to be predictive of poor control are also presented. One well-know psychological theory, Leventhal's Self-Regulatory Model (Leventhal, Brissette, Leventhal, Cameron, & Leventhal, 2003) is then described, together with its application in diabetes research. This model has been widely applied to a range of other chronic illness, and the findings from intervention studies with these other chronic illness populations are reviewed. An argument is put forward that Leventhal's model offers considerable scope as a theoretical framework upon which to base interventions in diabetes. The psychological techniques that may be used in such interventions are then briefly outlined, after which family interventions with adults with chronic illnesses, and in particular diabetes, are briefly described. The paucity of such family interventions with adults with chronic illnesses, and in particular with diabetes, is highlighted.

Chapter Three begins by discussing some basic methodological issues pertinent to RCTs, including procedures to reduce bias (e.g. randomisation, allocation of concealment, blinding, and data analysis), the assessment of treatment fidelity and process evaluation, the role of qualitative methods in RCTs and the quality and reporting of RCTs. The limited use of the RCT trial design in health psychology research is examined, and the growing recognition within the discipline of the need for designing and testing of theory-based interventions is highlighted. The chapter concludes by considering methodological issues principally relating to the design and evaluation of complex interventions. Here, the Medical Research Council (MRC) guidelines (Campbell et al., 2007) for developing such complex interventions are examined, as is the "causal modelling" approach (Hardeman et al., 2005), an approach specifically used by health psychologists to develop behaviour change interventions.

Chapter Four presents the methodology used in this study. This chapter begins by describing the steps taken in developing the intervention, based on the MRC framework and the causal modelling approach. The intervention itself is then described, together with a description of the 'usual care' the control group received. Details regarding the study settings and participants are reported next, followed by a description of the primary and secondary outcome measures. Primary outcomes measures include glycaemic control as assessed by HbA1c, illness perceptions, and psychological well-being. Secondary outcome measures include BMI, blood pressure, diabetes self-management activities (e.g. diet, exercise, blood glucose testing etc), diabetes self-efficacy, family support for diabetes management, and the degree of similarity between patient and family member perceptions of diabetes. The RCT procedures are then described, including participant recruitment, randomisation, intervention delivery, and outcome assessment. Process evaluation and treatment fidelity assessment procedures are also described, including the role of qualitative methods such as focus groups, field notes, and participant diaries. Lastly, the planned analyses of both quantitative and qualitative data, along with the planned economic analysis, are outlined.

Chapter Five presents the results of the study. The chapter begins by outlining recruitment and participation rates, and then presents the baseline socio-demographic characteristics, and the baseline scores on primary and secondary outcomes, of participants in the intervention and control groups. The baseline data from family members are also examined. Next, information regarding the progress of participants through the trial, together with information on overall attrition rates, is provided. The six month follow-up data of participants in the intervention and control groups are then presented. Differences in primary and secondary outcomes between intervention and control groups were investigated by an intention-to-treat analysis, which was implemented using multiple regression modelling, controlling for baseline covariates. Results from this analysis are presented. Primary outcomes were assessed at the $p < 0.05$ level, and secondary outcomes at the $p < 0.01$ level. Result are then presented from a number of additional analyses which were also employed, including: a 'Last Observation Carried Forward' (LOCF) analysis to examine the effects of missing data on study outcomes; a 'per-protocol' analysis (PPA) to examine the effects of the intervention when participants who did not receive the intervention were excluded from the analysis; and a mediational analysis to test the proposed theoretical pathways. Following an examination of results from these additional analyses, results from the process evaluation components of the trial are discussed, with particular reference to the role of the qualitative data analysis in assessing treatment fidelity. The chapter concludes by presenting results from the economic analysis, which was a cost-effectiveness analysis. The direct cost per-patient of delivering the intervention was examined, and the Incremental Cost Effectiveness Ratio (ICER) for the intervention was calculated.

The final chapter, Chapter Six, briefly summarises the results of the trial, and provides a synthesis and critique of the key findings, which are located within the broader empirical and policy context. The different strengths and limitations of the study are then examined, after which the chapter concludes by highlighting the policy and practice implications of the results of the trial, and recommendations for future research.

2 REVIEW OF THE LITERATURE

2.1 LITERATURE SEARCH

A literature search of the following electronic databases was conducted: CINAHL; PubMED; PsycINFO; and the Cochrane Library. The literature on illness perceptions and diabetes was sourced using the search terms (or corresponding MESH terms) "type 2 diabetes" and "illness perceptions" "illness representations" "illness cognitions" "illness beliefs" "self-regulation" "common sense model". The literature on relevant interventions was sourced using the above terms, in combination with "intervention*" "random* controlled trials" and "controlled clinical trials". A search strategy to identify family interventions in type 2 diabetes was developed in collaboration with the Cochrane Metabolic and Endocrine Disorders Review Group (see Appendix A). A search of the grey literature was also performed in order to identify any studies published in non-indexed journals and conference reports.

2.2 EPIDEMIOLOGY OF DIABETES MELLITUS

2.2.1 Definition of diabetes mellitus

Diabetes mellitus is a condition characterized by hyperglycaemia (increased glucose/sugar in the blood), which results from a deficit in insulin secretion and/or insulin action. Insulin is a hormone produced by the pancreas, and is responsible for blood glucose regulation. There are two main type of diabetes; type 1 and type 2. Type 1 diabetes accounts for approximately 10-15% of cases in Europe (Wass, 2002), whilst the more common form, type two diabetes, accounts for 85%-90% of cases (Wass, 2002). In type 1 diabetes, the body is unable to produce any insulin. The beta-cells in the pancreas are destroyed, leading to insulin deficiency and the sudden onset of severe hyperglycaemia (increased glucose/sugar in the blood). In type 2 diabetes the body may still be able to produce some insulin, but not in sufficient amounts, and/or the body can not properly use the insulin that is produced (insulin resistance) (Harris, 1997; Watkins, 2003). The specific aetiology of type 2 diabetes is not known, but there are a number of risk factors for developing the illness. These include: increased age (40+ years);

overweight/obesity; lack of physical activity; family history of diabetes; history of gestational diabetes; history of having a large baby; and Asian or Afro-Caribbean ethnicity (Harris, 1997; Watkins, 2003).

2.2.2 Prevalence and incidence of diabetes

There is much evidence showing a dramatic increase in the global prevalence and incidence of diabetes (International Diabetes Federation, (IDF) 2000; King, 1998; Wild, Roglic, Green, Sicree, & King, 2004). This increase has largely been attributed to changes in population size, age composition, and urbanisation (IDF, 2000). In developing countries the increase is mostly related to rapid cultural and social changes ('urbanisation'), which are impacting on people's lifestyles (e.g. diet/physical activity) and contributing to the growing obesity epidemic. In more affluent or developed societies, such as Ireland, a growing ageing population is viewed as the main contributory factor. While there is a consensus overall that the prevalence of diabetes will continue to increase in coming decades, there are some differences in projections regarding the magnitude of this increase (see Table 2.1, p.8).

These prevalence estimates were based on available survey data from a number of countries, which were collated to produce an overall global estimate. Some of the variation in prevalence estimates may be explained by, differences in the inclusion criteria of eligible studies (e.g. the IDF report had less stringent inclusion criteria), differences in available study data (e.g. later studies include more up-to date information, and data from previously unavailable populations), and differences in the statistical models used to predict future prevalence (e.g. more conservative techniques lead to more optimistic or lower estimates). It must also be noted that some of the underlying assumptions used to generate these prevalence estimates are a source of concern, and may have resulted in inaccurate estimates. For example, the majority of these surveys were generally carried out with middle-aged populations, and as such data for older and younger groups is limited. Also many surveys did not distinguish between type 1 and type 2, thus prevalence estimates are based on a combination of the prevalence of both

types of diabetes. Furthermore, due to the lack of suitable survey data in many countries, results from neighbouring countries were extrapolated to countries where these data were not available. In addition, current and future changes in incidence and mortality were not accounted for, as all reports consider prevalence data only. Finally, the expected increase in global rates of over-weight and obesity were not directly investigated, rather, urbanisation was conceptualized as a proxy measures for other risk factors (e.g. altered diet, obesity, decreased physical activity etc). The underlying assumption is that these other risk factors remain constant in developed countries, which is unlikely given evidence that the prevalence of obesity in developed countries is already increasing dramatically in these populations. Thus, it is probable that the currently available projections provide *underestimates* of the future prevalence of diabetes, even in developed countries. However, what is clear is that prevalence of diabetes is increasing, and that type 2 diabetes constitutes the vast majority (85%-95%) of predicted new cases (King, 1998).

Table 2.1.

Estimates for prevalence of diabetes

Study	Current estimate	Future estimate
Amos, McCarty, & Zimmet (1997)	124 million in 1997	211 million in 2010
King (1998)	171 million in 2000	300 million in 2025
IDF Atlas 2000 estimates	151 million in 2000	380 million in 2025
Green, Christian Hirsch, & Pramming (2003)	141.9 million in 2000	285.5 million in 2025
IDF Atlas 2003 estimates	194 million in 2003	344 million in 2025
Wild, Roglic, Green, Sicree, & King (2004)	171 million in 2000	366 million in 2030

Two recent reports from the Institute of Public Health in Ireland (IPHI) (2006; 2007) focused on estimating the current prevalence of diabetes in Ireland, and predicting future rates. The reports estimated that in 2005, 129,052 persons, or 4.7% of the adult population in the Republic of Ireland, and 5.4% of adults (n=67,000) in Northern Ireland, had diabetes. Assuming that rates of obesity remain at 2005 levels the report predicts that by 2015 5% of adults (n=173,917) in the Republic of Ireland, and 5.6% of adults (n=75,466) in Northern Ireland will have diabetes. However, realistically obesity is forecast to increase in a linear fashion. If this is the case, then by 2015, the population prevalence of diabetes is predicted to increase to 5.6% of adults (n=194,000) in the Republic of Ireland, and 6.3% (n=84,336) in Northern Ireland. The worst case scenario is an exponential increase in the rates of obesity. If this occurs, the report predicts that the prevalence of diabetes in 2015 will be 5.8% (n=200,047) in the Republic of Ireland, and 6.5% (n=86,769) in Northern Ireland. Again, these figures apply to both type 1 and type 2 diabetes, although, the vast majority of the increase is predicted to be due to an increased incidence of type 2 diabetes. However, it is important to note that the figures indicated in the IPH report may not be completely accurate due to some limitations, such as: the lack of consideration of any socio-economic variations in diabetes risk; the use of overweight/obesity estimates based on UK data; and the absence of available data for ethnic minorities. Despite this, the findings are indicative of growing levels of type 2 diabetes.

Differences in Irish prevalence rates are also evident across different study populations. Thus, studies in primary care have reported type 2 diabetes prevalence rates ranging from 3.9% (Creagh et al., 2002) in those aged between 50 and 69, to 9.2% in those aged 40 and over (Smith, Holohan, McAuliffe, & Firth, 2003). However, the study by Smith et al. was attempting to assess the prevalence of both diagnosed and undiagnosed diabetes in this population. Of the 9.2% identified, 23.5% (n=83) were previously undiagnosed. This is in line with findings from other studies, which suggest that the prevalence of undiagnosed diabetes in Ireland is approximately 25-30% of total cases (Creagh et al., 2002; IPHI, 2006).

2.2.3 Economic Costs

The continuing increase in the prevalence of type 2 diabetes has serious economic implications for health care systems and individual patients. This is due, in large part, to the high costs associated with hospital in-patient treatment for those who develop diabetes related complications. For example, The CODE-2 study (Cost of Diabetes in Europe, Jonsson, 2002), which assessed the total health care cost of type 2 diabetes in eight European countries, found that the total direct medical costs of treating 10 million people with type 2 diabetes was €29 billion a year (1999 values). The treatment of diabetes-related complications was the single largest factor impacting on overall costs. Similarly, the CODEIRE study (Cost of Diabetes in Eire, Nolan, O'Halloran, McKenna, Firth, & Redmond, 2006) estimated that the treatment of type 2 diabetes in Ireland costs €377.2 million for diagnosed diabetes, corresponding to 4.1% of total health care expenditure. Again, the main cost contributor was the high numbers of hospital inpatient admissions for the treatment of diabetes-related complications. However, many of the complications of diabetes, and therefore their costs, are potentially preventable. For example, tight control of blood glucose and blood pressure have been shown to delay or prevent complications, thereby decreasing longer term costs (see section 2.2.4. below). The IDF Task Force on Diabetes Health Economics (IDF, 2005) reviewed the cost effectiveness of lifestyle interventions relevant to diabetes, and concluded that evidence is accumulating to show that in the long-term, many of these interventions may offer cost-effective ways of preventing or delaying complications.

2.2.4 Complications & how to prevent them

As type 2 diabetes progresses, patients with the disease are at risk of developing complications related to the *small* blood vessels (microvascular) in the eyes (retinopathy), the kidneys (neuropathy) and/or the nerves (neuropathy). Diabetic retinopathy is the most common complication of diabetes, and is a major cause of blindness (IDF, 2005). Damage to the nerves (neuropathy) is a common late stage complication of type 2 diabetes, which is associated with a range of symptoms (e.g. pain, erectile dysfunction, and foot problems), with limb amputations being one of the key factors contributing towards increased health care costs. Renal failure, as a result of diabetic nephropathy, is

also a significant cause of mortality and morbidity in type 2 diabetes (Watkins, 2003). People with type 2 diabetes also have a greatly increased risk of complications associated with the *larger* blood vessels (macrovascular), such as cardiovascular disease, cerebrovascular disease, and peripheral vascular disease. In fact, arterial damage is the most significant cause of mortality and morbidity in people with type 2 diabetes (IDF, 1999; 2005).

There is considerable evidence to indicate that improved glycaemic control delays the onset and/or progression of complications in type 2 diabetes (Ohkubo et al., 1995; Shichiri, Kishikawa, Ohkubo, & Wake, 2000; Stratton et al., 2000; UKPDS 33, 1998; UKPDS 38, 1998). Findings from UKPDS show that for each 1% reduction in mean HbA1c there is a relative risk reduction of 21% for any diabetes-related endpoint (Stratton et al., 2000), which persists at 10-year follow-up despite a loss of between-group differences in glycaemic control at 1 year (Holman, Paul, Bethel, Matthews, & Neil, 2008). Two separate meta-analyses (Coutinho, Gerstein, Wang, & Yusuf, 1999; Selvin et al., 2004) and a large scale observational study (Khaw et al., 2004)have shown that increases in HbA1c are also associated with an increased risk for developing cardiovascular disease. Findings from the UKPDS (UKPDS 38, 1998) showed that hypertension is a key risk factor for developing macrovascular complications in type 2 diabetes, while achieving tight blood pressure control (<144/82 mm/Hg) was associated with a significant decrease in the risk of developing both macrovascular and microvascular complications. Thus, the critical message emerging from this work is that the tight control of both blood pressure and blood glucose (as assessed by HbA1c) are associated with a delay in the onset and/or progression of complications. Thus, early intervention, which focuses on improving blood glucose control and blood pressure control, is essential for helping to prevent or delay the onset of these complications.

2.3 TREATMENT AND MANAGEMENT OF TYPE 2 DIABETES

The aims of contemporary diabetes treatment are to (ADA, 2007; IDF, 1999, 2005; Watkins, 2003)

- Save life

- Alleviate symptoms and enhance quality of life
- Maintain health by reducing risk factors (e.g. smoking, hypertension, obesity)
- Prevent long-term diabetes-related complications (by achieving tight glycaemic & BP control)
- Detect and manage existing complications as early as possible
- Manage other medical problems
- Educate patients and encourage self-management through providing skills to allow patients to adapt their lifestyle to ensure optimum health

2.3.1 Blood glucose and blood pressure control targets

In essence, the treatment of type 2 diabetes aims to keep blood glucose levels as close to normal as possible, without significant hypoglycaemia (American Diabetes Association (ADA), 2007). For patients with type 2 diabetes, the target HbA1c is 6.5% or less (Harkins, 2008; IDF, 2005). The reduction of cardiovascular risk factors (e.g. hypertension, obesity) has also become a key part of diabetes treatment (IDF, 1999; Zimmet, 2004). The IDF (2005) and ADA (ADA, 2007) recommend a target of less than 130/80 mm Hg for those with diabetes uncomplicated by retinopathy.

While achieving good glycaemic control is key in preventing complications, recent evidence suggests that *intensive* glucose lowering (HbA1c < 6.0%) in high-risk patients with type 2 diabetes (e.g. those with high HbA1c levels and increased cardiovascular risk) is associated with previously unrecognized harm. The Action to Control Cardiovascular Risk in Diabetes (ACCORD, Gerstein et al., 2008) was a randomised controlled trial investigating whether intensive insulin therapy to achieve normal haemoglobin levels (< 6.0%) reduced cardiovascular events in patients with type 2 diabetes, who had established cardiovascular disease or cardiovascular risk factors. Intensive therapy did achieve a reduction in median HbA1c in the intense therapy group (6.4%, compared to 7.5% in the standard therapy group). However, the intensive therapy was discontinued after a mean of 3.5 years follow-up, as it did not significantly reduced major cardiovascular events (stroke, myocardial infarction, etc), and worryingly, was associated with increased mortality. Hypoglycaemia requiring medical assistance and

weight gain of more than 10Kg were also significantly more frequent in the intensive therapy group. No clear explanation for this increased harm was identified by the study. It may be due to a number of factors, including the approaches used for rapidly lowering HbA1c (e.g. changes in drug regimes, undetected adverse drug interactions); the magnitude and the speed of the decrease in HbA1c; the high rates of hypoglycaemia; the clinical characteristics of study patients; a combination of any of these, or many other possibilities. Thus, while it is clearly important for those with poorly controlled type 2 diabetes to improve their glycaemic control, it is still not clear what rate of glucose lowering is optimal.

2.3.2 Self-management and 'empowerment'

The treatment of type 2 diabetes requires the patient to self-manage the illness: that is, patients themselves attend to most of their own health-care needs. Much of this self-care encompasses day-to-day decisions involving activities of daily living (e.g. diet, exercise) and diabetes management (e.g. checking blood sugars, taking medication). Dietary guidelines encourage those with type 2 diabetes to follow a normal, healthy diet, which includes: eliminating sugar; restricting their total energy intake; reducing their fat and sodium intake; increasing their consumption of fibre, fruit and vegetables; and consuming alcohol in moderation (Harkins, 2008). As many people with type 2 diabetes often have weight problems, weight loss is also often a key aim of dietary change, as this has been shown to reduce insulin resistance and enhance insulin sensitivity (ADA, 2007). Regular exercise is also recommended, as it is associated with improved blood glucose and reduced cardiovascular risk factors, whilst also contributing to weight loss (Sigal, Kenny, Wasserman, & Castaneda-Sceppa, 2004). Patients may also be required to engage in other self-care behaviours, such as taking medication. Due to the progressive nature of the disease, the vast majority of patients with type 2 diabetes will at some point also need oral hypoglycaemia agents (OHA's) to control their condition, and if control deteriorates, some patients (approximately 30%) will require further treatment with insulin. Self-monitoring of blood glucose (SMBG) is also widely used in many diabetes care plans. The goal is generally to achieve a fasting blood glucose level of 4.5-7.7 mmol/l (Watkins,

2003). However, it remains unclear if SMBG is related to improved glycaemic control in patients with non-insulin treated type 2 diabetes (Towfigh et al., 2008).

Thus, it is clear that the primary responsibility for managing diabetes lies with patients themselves. It has been argued that the predominant paradigm guiding health care and medicine is derived from the treatment of acute illness, within which health care providers, not patients, are conceptualised as being primarily responsible for treating an illness (Anderson & Funnell, 2005). However, in direct response to the recognition that the management of chronic conditions is fundamentally different from the treatment for acute illnesses, the last decade or so has seen a move away from this traditional medical model for the treatment of *chronic* conditions (Funnel, 2005). By its very nature, diabetes self-care precludes health care professionals from being principally accountable for managing the illness. Instead, the primary responsibility of care shifts to the patient. Thus, the relationship between the health care provider and the patient with a chronic condition becomes more patient-centred and collaborative in nature: the clinical expertise of the health care professional is integrated with the concerns, priorities and resources of the patients in order to develop effective self-management plans (Anderson & Funnell, 2005). Patients are seen not as consumers of health care services, but rather, active partners in the provision of their own care (Funnell et al., 1991).

A key concept guiding this patient-centred, collaborative approach to diabetes care is patient empowerment. Patient empowerment is defined as *"helping people to discover and use their own innate ability to gain mastery over their diabetes*" (Funnell et al., 1991, p.37). Within this paradigm, the role of the health-care professional is seen as assisting patients in the process of empowerment by providing patients with the knowledge and skills necessary for effectively managing their diabetes. Essentially, empowerment is conceptualised as an outcome of diabetes education (Funnell & Anderson, 2003). Patients are said to be empowered when they have (1) sufficient *knowledge* to make and evaluate rational decisions and (2) sufficient *skills* to implement those decisions (Funnell & Anderson, 2003). Healthcare professionals may facilitate this process using a variety of methods, including: providing knowledge and education for informed decision making;

assisting patients to weigh-up the costs and benefits of treatment options; following patient-selected treatment goals; and using reflective listening techniques to understand the patient's own experiences and support self-management (Funnell, 2004). These strategies and techniques would be familiar to many health care professionals working within a patient-centred approach, and this highlights the key point that patient empowerment is not seen as a set of tools that health care professionals apply to patients in order to encourage them to adhere to a treatment regime. Rather it is a philosophy based on the fundamental differences between the treatment of a self-managed chronic condition and an acute illness. Thus, many interventions, or consultations, or interactions, with patients that are not explicitly labelled as *'patient empowerment'*, may still be empowering patients, if they follow the fundamental spirit of patient-centred, collaborative diabetes care.

A number of self-management interventions have been conducted with people with type 2 diabetes. The main aim of such interventions is to enhance the self-management skills of patients with a long-term illness, by enhancing their individual beliefs in their ability to manage their illness, thereby increasing autonomy and improving their overall self-management (Plews, 2005). There is some evidence to suggest that self-management interventions may improve glycaemic control (Ellis et al., 2004; Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003; Norris, Engelgau, & Narayan, 2001; Steed, Cooke, & Newman, 2003; Warsi, Wang, LaValley, Avorn, & Solomon, 2004), diabetes-related knowledge (Piette, 2000), self-care behaviours (Norris et al., 2001), and quality of life (Steed, Cooke, & Newman, 2003). However, there is much less evidence regarding the longer-term benefits of these interventions, and the generally poor quality of reporting, and methodological weaknesses of existing work, have led to a call for further research in the area (IDF, 2005). Despite inconsistent evidence for their longer-term benefits, a number of key findings have emerged to show that self-management interventions appear to be more effective when they: include a longer follow-up period (e.g. > 6months) (Norriset al., 2001); address psychological issues (Ellis et al., 2004; Norris et al., 2001; Piette, 2000); and are tailored to the individual needs and perspectives of the person with diabetes (Piette, 2000).

Perhaps the best known self-management interventions in chronic illness are the Chronic Disease Self-Management Programme (CDSMP) in the US (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001; Lorig et al., 1999), and the corresponding UK version, the Expert Patient Programme ((EPP), Plews, 2005). These programmes consist of six-weekly sessions, delivered by trained lay instructors to mixed groups of chronic illness patients (e.g. some of whom may have diabetes, arthritis, asthma or cardiac problems etc). The focus is on improving self-care skills, through techniques such as modelling and action planning. Considerable resources have been allocated to running these programmes, with the expectation being that 'expert patients' will consume fewer healthcare resources, and lead to long-term savings (Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007). Results from early small-scale studies with arthritis patients appeared promising (e.g. a 40% reduction in physician visits seen in patients in the self-management group (Lorig & Holman, 1989)), and this led to the development of the generic programmes, which also included patients with type 2 diabetes. However, trials of the programme in the US show inconsistent effects on the use of health care, and all four trials in the UK have found no change in the health care utilisation (Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007). It may be that programmes led by lay people do as much to encourage patients to consult with their clinicians, as they do to reduce it, for example, by promoting improved communication with healthcare providers.

2.3.3 Diabetes care delivery and structures

2.3.3.1 The international policy context

The IDF (2005) has recommended that, at a minimum, patients with type 2 diabetes should be offered an annual review of control and complications. Patient-centred care plans should be developed and continuously updated in collaboration with the person with diabetes, and delivered and supported by an appropriately trained multi-disciplinary team. The management of diabetes by a multi-disciplinary team is a central component of this recommendation, recognising that successful diabetes care requires input from a range of healthcare professionals, including doctors, diabetes nurse specialists, dieticians, podiatrists and psychologists. In Europe a key policy document is The St. Vincent's declaration (Keen, 1997), which sets out a number of goals for the future planning of

diabetes care, as well as recommendations for the implementation of measures to reduce diabetes-related complications over a five year framework (see Box 2.1). One of the main aims outlined in the St. Vincent's declaration is to "*provide training and teaching in diabetes management and self-care for the patients, their family, friends, and colleagues*". This acknowledges that diabetes management does not occur in a social vacuum, and that significant members of the patient's social environment (e.g. family members) can also influence disease management and as such may themselves need appropriate education and support.

Box 2.1

Key recommendations of the St. Vincent's' Declaration

General Goals

- Sustained improvement in health and life, approaching normal expectation in quality and quantity
- Intensified research efforts to prevent and cure diabetes and related complications

Five Year Targets

1. Implement programmes to improve the detection and control of diabetes and its complications. Key components should be self-care and community support
2. Raise awareness about the need to prevention diabetes, among the general population and health-care professionals.
3. Provide training and teaching in diabetes management and self-care for the patients, their family, friends, colleagues, and health-care professionals.
4. Specialised teams to provide care for children with diabetes.
5. Support and create centres of excellence in diabetes care, research and education.
6. Remove discrimination against people with diabetes, to allow their full integration into society.
7. Reduce complications
8. Develop IT systems to monitor and control the quality of care provision, and technical procedures (e.g. lab results)
9. International collaboration

2.3.3.2 Care delivery and policy in Ireland

With regard to Irish policy, an early report of a working group conducted by the Diabetes Federation of Ireland (DFI) entitled *"Diabetes Care: Securing the Future"* (Diabetes Service Development Group (DSDG), 2002) paved the way for a later, more influential report. This later report *"Diabetes: Prevention & Model for Patient Care"* (National Diabetes Working Group, 2006), was produced by the National Diabetes Working Group (NDWG), and included a number of recommendations relating both to the model of care provision for diabetes and the prevention and management of the illness (see Box 2.2).

Box 2.2

Recommendations for key services for diabetes (NDWG)

1. Persons with diabetes should have a say in the planning and delivery of services
2. Effective treatment in accordance with guidelines
3. Appropriate care delivered by trained health-care professionals, and subject to audit
4. Access to appropriate treatment for high-risk/vulnerable groups
5. Agreed care plan for each patient
6. Access to local services; primary care and regional specialist services
7. Integrated generalist care which can provide care for multiple chronic conditions
8. Comprehensive review at least once a year
9. Modification of cardiovascular risk factors
10. Screening for diabetic retinopathy every 1-2 years
11. Access to a podiatry service, full foot assessment at least once a year
12. Consultation with a dietician following diagnosis, and further reviews if necessary
13. Access to smoking cessation services and exercise referral as required
14. Access to psychological support as required
15. Inclusion on a diabetes register (unless chose to opt out)
16. Education

Ireland has a mixed public and private health care system (see Figure 2.1). Groups with the lowest income and those over 70 years of age (~30% population), are eligible for a

medical card which entitles them to all health services free at the point of delivery. Non medical card-holders have to pay out-of-pocket for primary care services (approximately €50- €60 for a GP visit) and for pharmaceuticals (up to a maximum of €85 per month), although diabetes and related medications are provided free of charge on a long-term illness card. However, inpatient and specialist outpatient care is accessible for all people through the public system. In a nutshell, this means patients without a medical card are entitled to free specialist diabetes outpatient care and medication, but must pay for visiting their GP. Thus, for patients without a medical card, (approximately two thirds of the population) there may be a financial disincentive to managing their condition in the primary care setting. Finally, patients also have the option to privately access and pay for specialist care. However, very little information is available on the exact numbers that do so, though they represent a significant minority.

Traditionally, diabetes care delivery in Ireland has been provided in hospital outpatient clinics by specialist multi-disciplinary teams (O'Sullivan, 2006; Smith, White, Whitford, Handy, O'Dowd, 2007). However, the increasing prevalence of diabetes means that hospital-based diabetes care for all is no longer sustainable, or desirable. Consequently, there has been a move towards managing diabetes predominantly in the primary care setting (DSDG, 2002). A recent Health Service Executive (HSE) report *"A Practical Guide to Integrated Type 2 Diabetes Care"* (Harkins, 2008) recommends "integrated care" as the most effective way of achieving optimal diabetes management. Integrated care (also known as 'shared care') refers to care which is delivered jointly by primary care and secondary care services, with both services assuming joint responsibility for patients. The recent HSE report recommends that the regular/ongoing review of patients with diabetes occurs in the general practice setting (visits with the GP/ practice nurse approximately every three months), with an annual review taking place in the Diabetes Centre, at a frequency agreed locally between the hospital centres and primary care centres, but at least at 1-2 yearly intervals. However, this remains controversial, and differs from practice in other European countries (e.g. the UK), where the majority of type 2 diabetes is managed at the primary care level.

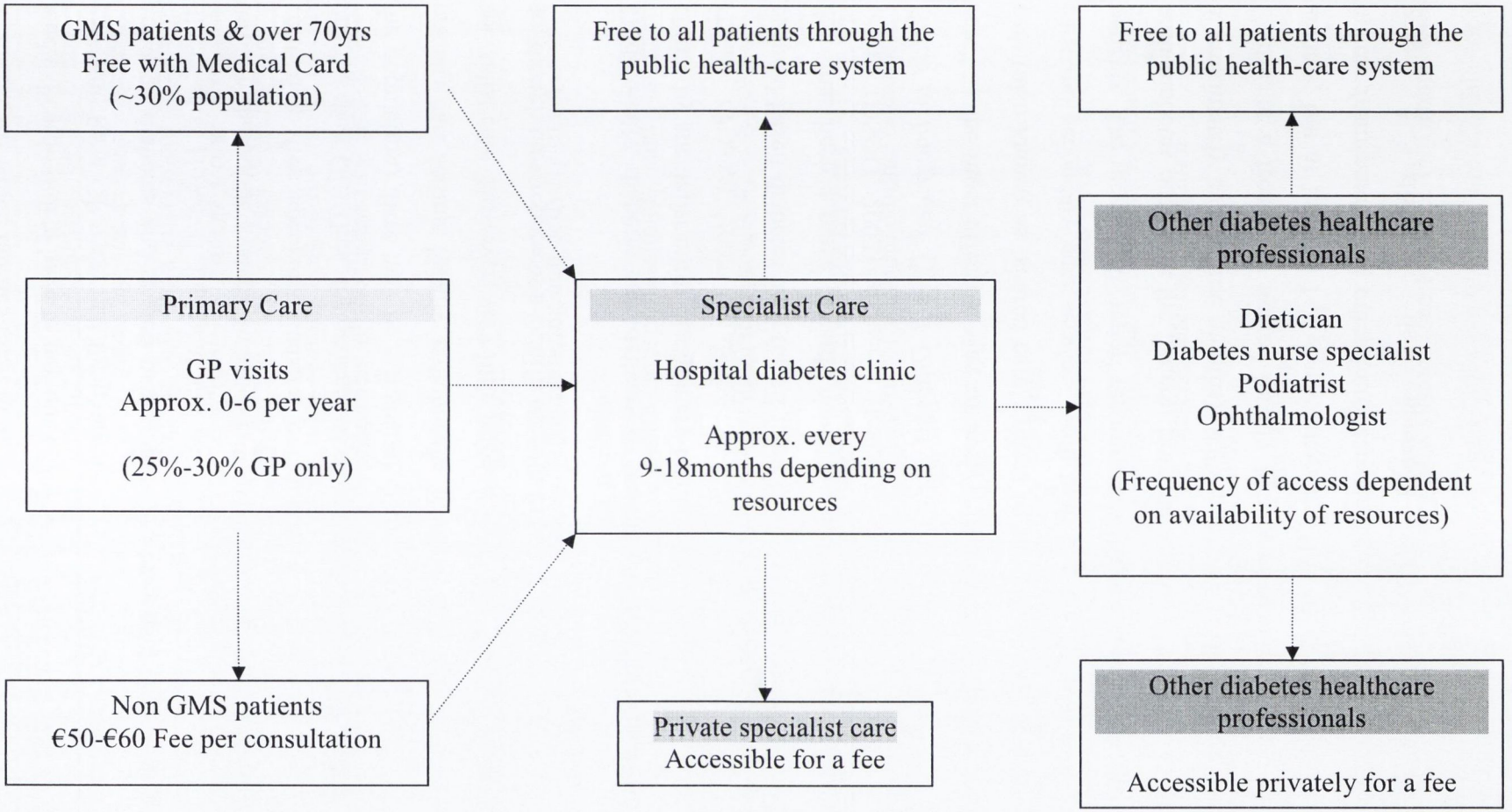

Figure 2.1: *Diabetes care in the Republic of Ireland*

2.3.4 The role of the psychologist

A central recommendation of all of the above diabetes policy reports is that people with diabetes should have access to a range of key services, including those provided by a psychologist. The IDF and the ADA also recommend incorporating psychological support as part of routine diabetes care in order to address situations where patients are: experiencing psychological barriers to effective care (e.g. ineffective coping); going through transition periods (e.g. from OHA's to insulin); coping with other life stressors (e.g. job loss, bereavement, co-morbid illnesses); and cases of poor control of diabetes in the absence of other causes. Psychological support may be necessary not only for the individual with the disease, but also for their family members. This may be particularly important when there is a high degree of family conflict that may impact upon disease management. Perhaps unsurprisingly people with diabetes are also at greater risk of developing mental health problems. For example, depression has been found to be twice as prevalent in persons with diabetes, as those in the general population (Anderson, Freedland, Clouse, & Lustman, 2001). Poorer psychological functioning not only causes increased suffering for the patient, but has also been found to impact on patients' self-management of their diabetes, which in turn is associated with poorer outcomes and higher costs (Anderson et al., 2002; de Groot, Anderson et al., 2001; Egede, Zheng, & Simpson, 2002; Lin et al., 2004).

A diagnosis of diabetes places a lifelong responsibility on the person with the illness, requiring them to engage in multiple self-care behaviours on a daily basis. Indeed, Gonder-Fredrick and colleagues write that: *"...from a psychobehavioural perspective, it is difficult to imagine any other illness that places the same level of demand on patients to self-monitor and self-regulate their own health status"* (Gonder-Frederick, Cox, & Ritterband, 2002, p.613). Emotional and mental well-being may be seriously compromised in the drive to achieve good metabolic control, or alternatively metabolic control may be sacrificed in the pursuit of enjoying ones-self. However, despite the clear need for psychological support for individuals with diabetes and their families, and the recommendation that every diabetes centre should have a psychologist (DSDG, 2002), at

present in the Republic of Ireland there are still no psychologists employed full time to work with adults with diabetes.

2.4 POOR GLYCAEMIC CONTROL IN TYPE 2 DIABETES

2.4.1 Prevalence of poorly controlled type 2 diabetes

The 'gold standard' method of assessing glycaemic control in patients with diabetes mellitus is the haemoglobin A1c assay (HbA1c) (Jeffcoate, 2003). Measuring the levels of HbA1c in the blood gives a reliable indication of how high blood glucose has been over the last 8-12 weeks. The accepted normal non-diabetic HbA1c range is approximately 4.0-6.0% (ADA, 2007; IDF Clinical Guidelines Task Force, 2005). As discussed earlier in section 2.3.1, recommended glycaemic targets for those with type 2 diabetes have been reduced in recent years: from less than 8.0%; to less than 6.5% according to European guidelines and to <7.0% in the US (Massi-Benedetti, 2006). This lowering of HbA1c targets has resulted in comparable changes in how 'poor' or 'inadequate' control is defined. However, these changes in glycaemic targets across studies, contexts and time-periods preclude any meaningful attempts to accurately estimate the true extent of poor control in type 2 diabetes. For example, Table 2.2 (p.23) presents results from studies in the US, Europe and the UK which attempted to assess the prevalence of poor control in type 2 diabetes. It can be seen from this table, that poor control prevalence estimates vary depending on the 'cut-off' HbA1c level employed in the study. Nevertheless, these studies do indicate that poor glycaemic control in type 2 diabetes is a widespread problem, and that a HbA1c of 8.0% is a clear and definite indicator of poor glycaemic control

While less large scale data is available for Ireland, the available findings from primary care research provide a useful indication of the prevalence of poor control. An RCT of a peer-support intervention conducted in general practice (Paul et al., 2007) reported that out of 20 GP surgeries, 41% (169/412) of type 2 diabetes patients had a HbA1c of >7%, while 18% (77/412) had a HbA1c of >8.0%. Similarly, the DiSC study (Smith et al., 2001) reported that out of 30 GP surgeries 21% of patients (38/181) had a HbA1c of

8.0% or greater. Irrespective of how exactly poor or inadequate control is defined, it is clear that large proportions of patients are having difficulty in adequately controlling their diabetes. This has serious resource implications for service providers, as well as serious implications for the quality of life of the poorly controlled individual, who is at a significantly increased risk of developing related complications.

Table 2.2

Differing prevalence estimates of poor glycaemic control

Study	**Setting**	**Good control** Definition & %	**Intermediate Control** Definition & %	**Poor control** Definition & %
Saydah, Fradkin, & Cowie (2004)	United States National Health and Nutrition Examination Survey	*HbA1c<7.0%;* 43% (1988-1994) 37.0% (1999-2000)	*HbA1c 7.0-8.0%;* 19.3% (1988-1994) 25.8% (1999-2000)	*HbA1c>8.0%.* 36.5% (1988-1994) 37.2% (1999-2000)
Liebl, Mata, & Eschwege (2002)	Europe CODE-II Study	*HbA1c<6.5%* 31%	*HbA1c 6.5-7.5%* 27%	*HbA1c>7.5%* 42%
Fox, Gerber Pharmd, Bolinder, Chen, & Kumar (2006)	UK General Practice Databases	*HbA1c < 6.5%* 12% (1998 & 2002) *HbA1c < 7.0%* 21% (1998) 24% (2002) *HbA1c < 7.5%* 31% (1998) 38% (2002)	/	*HbA1c > 6.5%* 88% (1998 & 2002) *HbA1c > 7.0%* 79% (1998) 76% (2002) *HbA1c > 7.5%* 69% (1998) 62% (2002)

2.4.2 Management of poor glycaemic control

One of the key indicators for referring patient with type 2 diabetes from primary care to specialist hospital-based care is continued poor control of the condition (DSDG, 2002; NDWG 2006; Watkins, 2003). It has been suggested that *"...the re-stabilisation of* [type 2] *diabetes that has drifted out of control is a very interactive and labour-intensive process...*[which] *may best be conducted by an endocrinologist"* (DSDG, 2002). However, when compared to clinicians in primary care, the endocrinologist often has better access to the skills of other members of the multi-disciplinary team. If these services were more readily available in community settings, it is likely that poorly controlled patients could be more effectively managed within structured primary care settings. Furthermore, as shared care pathways are recommended as a central feature of diabetes care (NDWG, 2006), there would appear to be a clear role for interventions targeting those in poor control that can be based within structured care schemes, and delivered across the primary-speciality interface. This may be especially relevant for those service providers, such as psychologists, who are extremely difficult for patients to access in the community. In addition, the high proportion of patients with type 2 diabetes failing to achieve adequate glycaemic control highlights a pressing need for interventions aimed at this high risk group.

2.4.3 Predictors of poor control

Developing an understanding of the factors associated with poor glycaemic control represents the first step towards specifying pathways through which glycaemic control may be improved. A number of studies have identified several patient and treatment characteristics that consistently emerge as correlates of poorer glycaemic control. These include:

- *Younger age* (Bebb et al., 2005; Benoit, Fleming, Philis-Tsimikas, & Ji, 2005; Dalewitz, Khan, & Hershey, 2000; Goudswaard, Stolk, Zuithoff, & Rutten, 2004; Nichols, Hillier, Javor, & Brown, 2000)
- *Longer duration of illness* (Bebb et al., 2005; Benoit, et al.,, 2005; Goudswaard, et al., , 2004; Pringle et al., 1993)

- *Treatment with OHA's or insulin* (Bebb et al., 2005; Benoit et al., , 2005; Goudswaard et a;., 2004);
- *Increased BMI* (Bebb et al., 2005; Goudswaard et al., 2004; Nichols et al., 2000);
- *Increased cholesterol level* (Benoit et al., 2005; Goudswaardet al., 2004)

In addition, various aspects of the organisation and delivery of care have been found to be associated with poor glycaemic control in patients with type 2 diabetes. These include;

- GP practices located in deprived areas (Bebb et al., 2005; Benoitet al., 2005; Dalewitz, Khan, & Hershey, 2000)
- Practices smaller and not well equipped, or with no diabetes mini-clinic (Pringle et al., 1993)
- Practices where reviews are carried out by practice nurses only (Bebb et al., 2005)
- Increased GP visits (Goudswaard et al. 2004)
- Attending a hospital clinic (Pringle et al., 1993)

Many of these factors would intuitively seem to be linked with poor control. For example, patients who are having difficulties adequately controlling their diabetes with diet are more likely to be transitioned on to management by OHA's or insulin, and as such require more visits with their GP, or referral to a hospital clinic. This highlights the difficulty of disentangling the complex relationship between poor glycaemic control and the range of predictive factors, and subsequently the problem of identifying the direction of any association. Indeed, it is likely that it is a self-perpetuating or cyclical process. For example, patients from more deprived areas have less access to services, thus, have more difficulties controlling their illness and require increased care. However, these patients continue to have difficulties accessing required care, hence, glycaemic control remains poor. In addition, many of these predictive factors are not amenable to modification, (e.g. duration of diabetes, age), and as such are not viable targets for intervention. Or, in the case of factors relating to delivery of care, interventions can be extremely costly and difficult to implement, and existing studies attempting to modify such aspects of diabetes care have had mixed success in improving outcomes e.g. (Nielsen, de Fine Olivarius, Gannik, Hindsberger, & Hollnagel, 2006; Smith et al., 2004).

It may also be useful to identify factors that are associated with *improvements* in glycaemic control. Two recent studies, one in the UK (Singh & Press, 2008) and one in the US (Hartz et al., 2006), have used prospective cohort designs to investigate such factors. In the UK, Singh and colleagues (Singh & Press, 2008) followed up 130 patients with poorly controlled type 2 diabetes (HbA1c>10.0%) who were attending a hospital diabetes clinic. Poor control at baseline was attributed to one of 15 causes, including for example: inadequate treatment; non-compliance with recommended treatment; comorbid conditions; alcohol excess; and low mood. At one year follow-up, half of the sample (n=64) showed improved glycaemic control. Initial causes of poor control that significantly predicted improvement in HbA1c included: recent diagnosis; inadequate treatment (e.g. needs insulin adjusted); exacerbation of comorbidities (e.g. 'flare-up' of heart condition); and recent stressful life events (e.g. bereavement). Factors predictive of continuing poor control include: low mood; alcohol excess; inadequate blood glucose monitoring; sedentary/poor exercise; refusal/under-dosing of tablets; refusal to take insulin or to increase dose.

In the US, Hartz and colleagues (Hartz et al., 2006) identified 69 patients from 7 primary care practices with poorly controlled type 2 diabetes (defined as HbA1c>8.0%). At one year follow-up 26 patients had become well-controlled (HbA1c<7.0%), 14 had achieved intermediate control (HbA1c 7.0-8.0%), and 26 remained poorly controlled (HbA1c>8.0%). Becoming well-controlled was not significantly associated with gender, age, BMI, duration of diabetes or HBA1c at baseline. However, it was significantly associated with: being prescribed fewer medications; increased understanding in diabetes; increased adherence to dietary and blood glucose monitoring recommendations; and changes in life circumstances (e.g. retirement). There was additional evidence to suggest that changes in medication contributed to improvements in glycaemic control for some (15/26) patients, although patients who gained control generally used lower medication doses than those who did not, whilst 13 patients (50%) became well controlled in advance of medication change. The authors concluded that while medical management was clearly important for some poorly controlled patients, patient factors such as understanding and adherence to treatment recommendations were the primary

determinants of achieving good control. These findings are comparable to a similar study conducted in the US (Dalewitz, Khan, & Hershey, 2000), which reported that patients' understanding of diabetes, and adherence to diet and medication regimes were associated with improved glycaemic control among patients with type 2 diabetes (n=96). Results from these studies should be interpreted with caution, given the limited number of applicable studies, and the small sample sizes and poor methodological quality of available evidence. However, the findings are suggestive of the fact that there may be certain specific factors associated with improvements in glycaemic control.

Overall the evidence suggests a range of patient and treatment factors that are associated with glycaemic control. However, it would appear that a large number of patients with poorly controlled type 2 diabetes are having difficulty achieving tight control due to treatment-related factors, such as difficulty adhering to recommendations relating to diet and exercise (McIntosh, 2001). This is perhaps not surprising, given that achieving good glycaemic control requires patients to follow a treatment regime that many can find difficult to understand and demanding to follow. Furthermore, it is becoming increasingly clear that the ideas and feelings individuals have about their diabetes influence their management of the illness, and this in turn impacts on illness-related outcomes. Consequently, there has been an increasing awareness and recognition of the need to incorporate psychological perspectives into diabetes treatment efforts. An understanding of the psychological factors that are influencing patients' ability to follow their treatment regime, may assist health care professionals to provide patients with the necessary skills and resources required to appropriately manage and control their diabetes.

2.4.4 Depression and glycaemic control

Psychological factors have generally been conceptualised as impacting on glycaemic control in two ways: *directly* through the physiological stress response (McEwen, 1998); or *indirectly* through the influence of a mediating variable (e.g. self-management behaviours). For example, in patients with a comorbid psychopathology (e.g. needle phobia, depression, anxiety) glycaemic control may be affected directly by the physiological changes associated with the comorbid condition (e.g. increased

corticosteroid levels), or indirectly through the behaviours associated with it (e.g. inactivity/poor diet or refusal to use insulin).

The psychological association that has been most frequently investigated in relation to type 2 diabetes is the relationship between depression and glycaemic control. A number of recent systematic reviews and meta-analyses have examined the considerable amount of literature in this area. Evidence from these reviews suggest that the prevalence rate of depression is almost doubled in patients with type 2 diabetes, when compared to those without diabetes (OR=1.6, 95%CI1/5-1.7) (Ali, Stone, Peters, Davies, & Khunti, 2006) (OR=2.0, 95% CI 1.8-2.2) (Anderson et al., 2001). In addition, depression is associated with poorer glycaemic control (Lustman et al., 2000; Lustman & Clouse, 2005), poorer adherence to medication and diet recommendations, reduced quality of life, and increased healthcare costs (Lustman & Clouse, 2005) and increased risk for diabetes complications(de Groot, Anderson et al., 2001). However, the temporal or causal relationship between depression and type 2 diabetes remains unclear. Depression is often regarded as a comorbid condition, occurring secondary to the burden of living with diabetes and/or related complications (Ali et al., 2006; Knol et al., 2006). However, recent evidence from two meta-analyses (Cosgrove, Sargeant, & Griffin, 2008; Knol et al., 2006) suggests that depression may precede, and even act as a causal factor, for development of type 2 diabetes. Both meta-analyses found that the presence of depression or depressive symptoms was associated with a substantially increased risk of developing type 2 diabetes (OR=1.25, 95% CI1.02-1.48) (Cosgrove et al., 2008) (OR=1.26 95%CI 1.13-1.39) (Knol et al., 2006)). However, irrespective of the direction of the association, the effective treatment of depression in type 2 diabetes is of critical importance. While data from controlled studies are limited, a review of the available literature (Lustman & Clouse, 2002) concludes that pharmacological interventions (e.g. treatment with anti-depressants) and psychotherapeutic approaches (e.g. Cognitive Behaviour Therapy (CBT)) have both been successful in improving glycaemic control and relieving depression in patients with type 2 diabetes.

Thus, the negative impact of clinical depression in type 2 diabetes is well-established. However, results from recent studies (Fisher et al., 2007; Gonzalez et al., 2007; Hermanns, Kulzer, Krichbaum, Kubiak, & Haak, 2006) indicate that there are a substantial number of patients (30%-70% depending on study population) who do not meet the diagnostic criteria for clinical depression, but who display high levels of general emotional distress and depressive symptoms. What is perhaps most striking is that the negative impact of depression in diabetes is not limited to those with a clinical diagnosis of depression. Higher levels of general emotional distress and depressive symptoms (i.e. those which do not meet clinical diagnostic levels for depression) are also associated with poorer glycaemic control and poorer self-management in patients with type 2 diabetes (Fisher et al., 2007; Gonzalez et al., 2007). Indeed, one study of primary care patients (n=909) (Gonzalez et al., 2007) reported that even relatively low levels of depressive symptoms can have a significant negative impact on diabetes self-care behaviours. Perhaps the most compelling evidence for the relationship between emotional distress and diabetes outcomes is reported in a recent study (Vedhara et al., 2008) by Vedhara and colleagues, who investigated the effects of emotional distress on the healing rates of patients (n=116) with active diabetes foot ulcers at 6, 12 and 24 weeks follow-up. Patients who exhibited the highest levels of emotional distress at baseline showed the slowest ulcers healing at 24 weeks follow-up. A significant amount of this emotional distress appears to be related to diabetes and its management (Fisher et al., 2007) such as worries concerning complications, hypoglycaemic, and burden of treatment. While there is some overlap between patients with depression and diabetes-related distress, evidence shows that the two groups are not identical: diabetes-specific distress appears to adversely affect glycaemic control and self-care independently of depression (Hermanns et al. 2006). It has also been argued that this group of patients who are significantly distressed may benefit more from interventions which address *"the personal, health-related, and social causes of their distress, including diabetes-specific distress with problem-solving or coping interventions"* (Fisher et al., 2007, p. 547). Such interventions may be more effective at reducing distress and improving glycaemic control, than implementing treatments that have been developed from studies of patients with clinical depression.

A final point worthy of note here is that depression and/or distress are only one part of an individual's emotional landscape. Recent interest in 'positive psychology' has focused attention on the potential health benefits of positive affect or positive feelings. Positive affect has been defined as *"...the feelings that reflect a level of pleasurable engagement with the environment such as happiness, joy, excitement, enthusiasm and contentment"* (Pressman & Cohen, 2005 p.925). Until very recently there has been little critical discussion of the evidence linking positive affect to physical health. However, a recent review (Pressman & Cohen, 2005) found some evidence that positive affect was associated with lower morbidity and increased mortality across a range of illness populations, although, serious conceptual and methodological weaknesses suggest that the results from these studies should be interpreted with caution. While the role of positive affect in diabetes has not been widely investigated, a recent study by Moskowitz and colleagues (Moskowitz, Epel, & Acree, 2008) has reported some very interesting results. The authors conducted a longitudinal cohort study, investigating whether positive affect predicts mortality among people with diabetes (n=715), when compared to people with no chronic health conditions (n=2673). In those with diabetes, positive affect was significantly associated with lower risk of all-cause mortality, but this was not the case in the comparison sample without chronic illness.

Interestingly in the above study, the term *'enjoyed life'* was significantly associated with lower risk of mortality, over and above the effects of negative affect or other significant predictors of mortality. This is an important finding, in view of an ongoing debate in the emotion literature as to whether positive and negative affect are simply extremes of the same scale, or mutually exclusive factors (Pressman & Cohen, 2005). However, the evidence to date seems to suggest that positive affect is not simply the absence of negative affect, and may uniquely contribute to physical health independently of negative affect (Pressman & Cohen, 2005), as was the case in the study by Moskowitz and colleagues. Thus, it may be particularly useful in intervention studies seeking to improve glycaemic control by targeting depression or distress, to also include a measure of positive affect.

2.4.5 Psychological predictors of glycaemic control

In addition to distress and depression, a number of other psychological factors have been found to be correlated with glycaemic control. Research in this area has been guided predominantly by the health belief models and social cognitive theories of health psychology, with self-efficacy and personal health beliefs emerging as consistent predictors of self-management behaviours and clinical outcomes (Robiner & Keel, 1997).

2.4.5.1 Self-efficacy

Self-efficacy is a central element in the social-cognitive theory of behaviour, which was first developed by Albert Bandura (Bandura, 1977, 1986b). According to this theory, the key predictors of behaviour change are confidence in the ability to carry out an action (self-efficacy) and an expectation that a particular goal will be achieved (outcome expectancy). Within this framework, improving self-efficacy is seen as the first step towards successful behaviour change. Self-efficacy can be further defined as *"...people's judgement of their capacity to organise and execute courses of action required to attain designated types of performances"* (Bandura, 1986a, p.395). Self-efficacy is both task-related and situation specific, which is not the case with other more global, stable characteristics or constructs such as self-esteem, self-confidence and locus of control. For example, a person may have a very high level of self-efficacy for walking 2 miles, but a very low level of self-efficacy for running or jogging the same distances. Self-efficacy has been found to be an important predictor of self-care behaviours in type 2 diabetes, and there is some evidence to indicate that interventions to increase self-efficacy for dietary behaviours in patients with type 2 diabetes lead to improvements in dietary self-care (Glasgow et al., 1997; Glasgow, Toobert, Hampson, & Noell, 1995). It has been argued that a history of successful self-care builds patients' confidence in their self-care abilities, and this may account for the relationship between self-efficacy and self-care behaviours (Griva, Myers, & Newman, 2000). However, higher levels of self-efficacy have still been found to be associated with better self-care, even after controlling for past history of self-care and glycaemic control (Kavanagh, Gooley, & Wilson, 1993).

The CDSMP in the US and the EPP in the UK (discussed in section 2.3.2.) are also based on social cognitive theory. Both interventions were found to be successful in increasing self-efficacy and improving psychological health (Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007), but as previously discussed, this did not reduce health care use. While the improvements in self-efficacy and psychological health are welcome, it is disappointing that they did not translate into reduced health care utilization. However, as discussed previously, health care utilization is a complex issue. It is possible that increases in self-efficacy led to improved self-care and improved illness outcomes, in the absence of a reduction in health care utilization. Thus, it may be more useful to assess the impact of improved self-efficacy on key disease-specific outcome measures, such as glycaemic control, blood pressure and weight. There may also be more benefit in delivering interventions to disease-specific groups (e.g. type 2 diabetes, arthritis or asthma), rather than mixed disease groups. Lastly, it may be the case that high risk individuals who experience greater morbidity gain more from professionally led self-management programmes. Indeed, such interventions appear to have had more impact on chronic disease management and outcomes than lay programmes (Griffiths et al., 2007). This is possibly due to the fact that a number of key features distinguish professional-led programmes from lay-led programmes, including: providing disease specific self-management advice, teaching disease-specific, clinical management skills and correcting any inaccurate or negative beliefs about an illness (Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007). However, no studies were identified that addressed these issues specifically in diabetes.

2.4.5.2 Individual health beliefs

Patients' own individual beliefs about their diabetes have also been found to be key predictors of self-management and glycaemic control. Various health belief theories have been proposed, the three main ones being: The Theory of Reasoned Action/The Theory of Planned Behaviour (Ajzen, 1985); the Health Belief Model (Janz & Becker, 1984; Rosenstock & Kazdin, 2000); and Leventhal's Self-Regulatory Model (Leventhal, Meyer, & Nerenz, 1980). According to the Theory of Reasoned Action (TRA) and its extension,

the Theory of Planned Behaviour (TPB), health behaviour results from an intention to perform the behaviour, which in turn is a function of attitudes towards the behaviour, social pressure to perform the behaviour (subjective norm), and perceived behavioural control. The TRA/TPB has only had variable success in explaining diabetes self-care (Harvey & Lawson, 2009), and a key criticism of the model is that intention does not always result in action, which is often influenced by other factors. The Health Belief Model (HBM) was the guiding framework for much of the early work that examined the relationship between health beliefs and self care behaviours in patients with diabetes. It identified five dimensions (or beliefs) as the basis for behaviour: perceived severity of the illness, perceived susceptibility or vulnerability, perceived benefits (belief in efficacy), perceived barriers/costs, and internal/external cues to action. However, two major meta-analyses (Janz & Becker, 1984; Harrison, Mullen, & Green, 1992) indicate that while the principal dimensions of the model do appear to significantly influence behaviour, the HBM has generally only been successful in explaining a small amount of variance in health behaviours, and when applied to behaviours in diabetes, results have been inconsistent (Harvey & Lawson, 2009). This is most likely due to serious theoretical and empirical limitations, for which the HBM has been criticised, including: the narrow focus of the beliefs outlined by the model (e.g. exclusive focus on health consequences); the failure of the HBM to specify how the different dimensions interact; and the exclusion of the emotional responses to health threats (Armitage & Conner, 2000).

Despite the problems with the HBM and the TRA/TPB, over the last decade, evidence is emerging indicating that there is a much stronger relationship than originally thought between patients' highly individualised beliefs about their diabetes and self-management behaviours and glycaemic control. This work is largely based on a theoretical model of self-regulation, developed by Howard Leventhal and his colleagues (detailed in section 2.5 below). This model provides the theoretical framework for the current study. The model and reasons why it was chosen as the theoretical framework for this study are described in more detail below.

2.5 ILLNESS PERCEPTIONS

2.5.1 Leventhal's Self-Regulatory Model

The current theoretical framework guiding much of the research on individual health beliefs within the field of psychology is Leventhal's Self-Regulatory Model (see Figure 2.2, Leventhal et al., 2003; 1992), which is sometimes also referred to as the Common Sense Model (Leventhal et al., 1980) or the Parallel Processing Model (Leventhal, 1970). It is regarded as self-regulatory, because its different elements combine in an iterative manner to maintain the status quo: that is they regulate the self by motivating the individual to maintain (or return to) a state of health. Self-regulation has been defined as *"a systematic process involving conscious efforts to modulate thoughts, emotions, and behaviours in order to achieve goals within a changing environment"* (Cameron, Leventhal, Cameron, & Leventhal, 2003 p.1). Within this self-regulatory process health threat stimuli (e.g. symptoms, diagnoses) activate two motivational systems: one involving cognitive processes for regulating the health threat; the other involving emotional processes for regulating emotions such as anxiety, fear, worry or distress.

In the first stage of the cognitive processing arm of the model, illness information from external stimuli (e.g. social communication, pre-existing cultural knowledge, external social environment) and internal stimuli (e.g. somatic symptoms) are integrated with existing cognitions to create mental representations of an illness. These mental illness representations are called illness perceptions (or sometimes illness cognitions/beliefs) and can be defined as people's own implicit theories or 'common sense beliefs' about their illness. These beliefs (referred to as illness perceptions in this thesis) are used to 'make sense of' and give meaning to the illness experience. In the second stage this meaning directs the types of behaviours or 'action plans' which people engage in to help them cope with the illness, which in turn, may impact on illness outcomes. Appraisal is the third stage of the cognitive processing arm, in which the degree of success of coping procedures in achieving desired goals or outcomes is assessed. A central feature of self-regulation and Leventhal's model is the 'feedback loop': it is through such a feedback loop that the fourth and final stage of the self-regulatory process occurs. Here,

information from the appraisal process is 'fed back' into the self-regulatory system, which in turn leads to modification of cognitions about the illness, and a revision of goals and strategies related to its management.

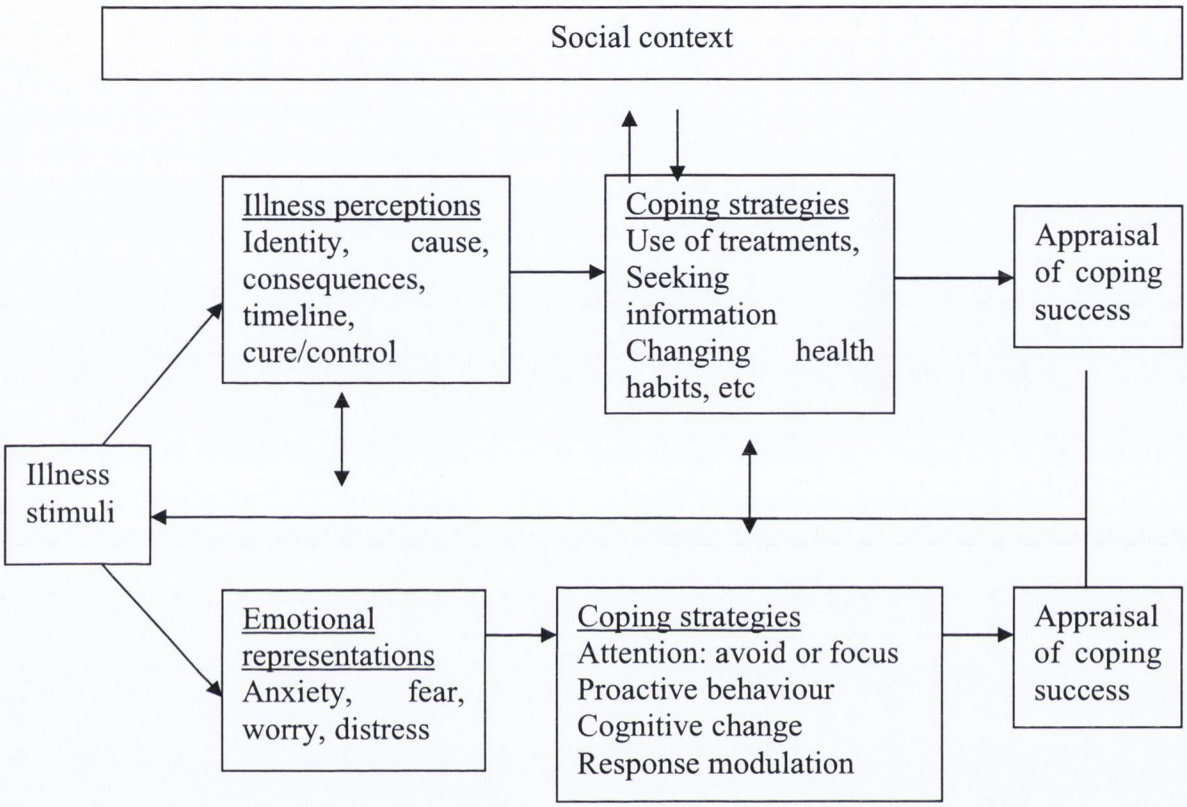

Figure 2.2 *Leventhal's Self-Regulatory Model* (Cameron & Jago, 2008; Leventhal et al., 2003)

A second, self-regulatory process concerned with the *emotional* (i.e. as opposed to the cognitive) representations of the illness, runs in parallel to the above cognitive processes. Early work on illness perceptions (Leventhal, 1970) found that illnesses simultaneously evoke related emotional representations (e.g. fear, distress etc) related to the illness, alongside the cognitive representations. This results in a need for procedures to process these emotional states, in a manner corresponding to the processing of cognitive representations. Thus, the emotional arm involves the elicitation of anxiety and fear, which motivate behaviours specifically targeted at controlling illness-related anxiety and distress (Cameron & Jago, 2008).

2.5.2 Structure of illness perceptions

Acquiring an understanding of how illness perceptions are organised and formed is critically important, as it gives an indication of how they can be influenced and changed. Early research (Leventhal et al., 1980) within health psychology into the nature of representations/perceptions relating to illness found that they could be categorised into the following four basic dimensions: cause; consequences; identity; and timeline (see Box 2.3, p. 33). A fifth dimension, cure/control, was identified at a later stage (Lau & Hartman, 1983). These five dimensions of illness representations have been confirmed in much research, using a variety of research methods, including open-ended interviews, multi-dimensional scaling and factor analysis (Bishop, 1991). In addition, a recent meta-analysis of 45 studies which had used the self-regulatory model (Hagger & Orbell, 2003) found strong evidence for these five theoretically-derived illness perception dimensions, each of which is described below.

Box 2.3

Five dimensions of illness perceptions

1. Identity	• What is this?
2. Cause	• What caused this?
3. Timeline	• How long will it last?
4. Consequence	• What will happen as a result?
5. Cure/Control	• What will make it better?

Identity refers to beliefs about the illness label, and is particularly relevant to symptom perception and identification (e.g. *"I'm tired because of my diabetes" "I'm thirsty all the time because of my diabetes").* The *causal* dimension of illness representations refers to beliefs about factors causing the disease. Causal beliefs may be grouped into a number of potentially over-lapping categories including biological (e.g. germs, virus etc (Heijmans & de Ridder, 1998)), emotional (e.g. stress or depression (Moss-Morris, Petrie, &

Weinman, 1996)), environmental (e.g. pollution or chemical (Heijmans & de Ridder, 1998)) or psychosocial (e.g. personality (Moss-Morris et al., 2002)). The *timeline* dimension refers to beliefs about the course/duration of the illness (e.g. *"My diabetes will never go away"*) and the timescale of symptoms. The *consequence* dimension relates to patients beliefs about the impact of the illness on their lives, such as quality of life, functional capacity, or future complications. The cure/control dimension is related to the effectiveness of treatment in controlling/curing the illness (*treatment control),* and also to beliefs about the person's own ability to cope with the illness (*personal control*, a similar construct to self-efficacy).

Each illness has its own distinctive schema, or pattern of beliefs, depending on for example, symptoms and chronicity (Leventhal et al., 1980) (and indeed, each individual will have their own distinctive pattern of beliefs also). However, a key characteristic of illness perceptions is their bi-directional nature; each illness perceptions dimension contains specific types of semantic (abstract) and perceptual (concrete/experiential) information (Bishop, 1991). For example, in a person with diabetes who believes their illness to be caused by genetic factors, the causal concept of 'genetics' may contain the *concept* of 'a faulty gene', and the *perception* (or memory) of their parents who also had diabetes. The bi-directional nature of illness perceptions is most evident though, with regard to their identity. Illnesses are identified by an abstract label (e.g. 'high blood sugars'), and by concrete-sensory symptoms (e.g. fatigue, polyuria, increased thirst). Thus, illnesses are represented on two interactive levels; semantically as abstract knowledge, and perceptually as concrete experiences.

Over time, the model has been updated and revised to include several changes (Moss-Morris et al., 2002). While the five key dimensions remain, two additional dimensions have been added more recently. The first new dimension assesses *illness coherence*, or how well an individual understands their illness. The second assesses variations in the *timeline* scale: subscales were added to this dimension to take into account beliefs about the cyclical nature of an illness (as opposed to acute/chronic beliefs).

2.5.3 Dynamics of illness perceptions

The semantic and abstract nature of illness perceptions is most evident when examining the dynamics of their formation. Illness schemas are formed (or modified) when people are presented with new illness information. This information is integrated with illness schemas in such a way that the mental representations of the illness, or the 'perceptions' develop breadth, that is their content can expand from one or two domains, to include all five. New illness information can be generated by: experiencing disease-related biological changes that create new symptoms and/or behavioural dysfunctions; by witnessing these changes in others and; by input from other external sources. People process this new illness information, and integrate it with illness schemas, using a number of what have been called 'mental tools' for evaluating the implications of the illness (McAndrew et al., 2008). Essentially, these 'mental tools' are the methods by which internal and external stimuli are converted into perceptions. Five such heuristics or rules have been identified (Leventhal et al., 2003) including: (1) *the symmetry rule* (2) *the stress-illness rule* (3) *the age-illness rule* (4) *the prevalence rule* and (5) *the duration rule.*

The *symmetry rule* (Leventhal et al., 1992) posits that illness information is used to construct perceptions of illness in a symmetrical and bi-directional process, linking concrete and abstract sources of information. The experience of *concrete* symptoms/somatic information leads to a search in semantic memory for *abstract* information linking symptoms to a stored diagnostic label. Similarly, the assignment of an illness label leads to a search for concrete somatic symptoms relating to that label. For example, a patient with undiagnosed diabetes may be experiencing extreme tiredness and polyuria. However, their stored 'label' of diabetes may not include such symptoms, thus, the patient attributes their symptoms down to old age. Equally, upon being diagnosed with diabetes patients will search for symptoms relating to that label (e.g. *"I know diabetes is concerned with blood sugars. That day I felt like I was going to faint must've been because my blood sugar went low.")* The *stress-illness* rule, and the *age-illness rule*, both question whether symptoms or functional changes are the results of a disease or a non-disease. For example, a patient with diabetes who is experiencing extreme

tiredness may question whether this is due to increasing age, work-related stress, or high blood sugars. The conclusion reached by the patient will then influence his/her perceptions about the causes and symptoms of diabetes. The *prevalence* and d*uration rules* assess the potential seriousness of a symptom or a risk factor. For example, if blood sugars remain high over a number of weeks (duration), a patient may perceive this to be particularly serious in the long-term (perceptions of consequence and timeline) and consider speaking to the GP about it. However, if the patient knows other people with persistently high blood sugars who have no ill effects (prevalence), he/she may consider it not to be a problem, and may therefore not attend their GP.

2.5.4 Changing illness perceptions

The dynamic, self-regulative control feature (feedback loop) and the system structure of Leventhal's Self-Regulatory Model make it an ideal theoretical framework for patient-centred interventions in chronic illness (McAndrew et al., 2008; Petrie, Broadbent, Meechan, Cameron, & Leventhal, 2003) Chronic illnesses (such as diabetes) and their effects are rarely static, and the successful management of the illness requires patients to constantly integrate feedback from symptoms and effects in order to adapt their coping behaviours. In other words, the management of a chronic illness is a dynamic system requiring self-regulation. In the case of diabetes in particular, the effects of the illness may change rapidly if symptoms and treatment are not actively managed through appropriate changes in patients' self-care behaviours (e.g. diet, exercise, medication). Another key strength of Leventhal's model is that people are conceptualised as problem solvers, who take an active role in the management of their own health (Wearden & Peters, 2008). The model implies that patients can be helped to achieve better illness outcomes when they have a more adaptive understanding of their illness, and are able to evaluate the affects of acting on this understanding (Wearden & Peters, 2008).According to Leventhal's Self-Regulatory Model, there are two possible ways in which patients may be helped to achieve a more adaptive understanding of their illness (McAndrew et al., 2008): (1) from the *top-down* using abstract/cognitive strategies or (2) from the *bottom up* using concrete/behavioural strategies.

McAndrew and colleagues (McAndrew et al., 2008) describe two such interventions which are currently being investigated in RCTs: a bottom-up approach with patients with diabetes, and a top-down approach with patients with poorly controlled asthma. The diabetes intervention focuses on behaviours, and in particular how specific behaviours (e.g. diet, exercise) impact on blood glucose. The process requires teaching skills for the self-monitoring of blood-glucose (SMBG), selecting actions and time-frames for SMBG, and developing an action plan to conduct daily SMBG. The asthma intervention focuses on patients' perceptions of asthma and its treatment. It is based on evidence showing that patients with poorly controlled asthma have inaccurate beliefs about the condition (Halm, Mora, & Leventhal, 2006), and the aim is to help patients view asthma as chronic and controllable, rather than as acute and uncontrollable.

'Top-down' and 'bottom-up' strategies are not perceived to be mutually exclusive. Rather, successful interventions will integrate the two (McAndrew et al., 2008). Indeed, focusing on behaviours to the exclusion of perceptions may positively change behaviour while negatively influencing illness perceptions (or vice-versa). For example, an RCT (Theunissen, 2003) of a practitioner-focused intervention based on Leventhal's model, was undertaken with the aim of changing the perceptions and behaviours of patients (n=108) with hypertension. Ten GP-trainees performed care-as-usual consultations, and were than randomly assigned to one of two groups: (1) discussing patients' ideas or 'perceptions' about hypertension or (2) discussing patients' action plans for managing hypertension. At one month follow-up, patients in the 'perceptions' group showed significant improvements in their understanding of hypertension, and reduced concern regarding the side affects of the medication, but patients in this group also showed decreased confidence in their ability to take the medication. Patients in the 'action plan' group made positive changes in managing their blood pressure, but also showed increased concern regarding the harmful effects of medication, and a decrease in their confidence in talking to the GP.

Thus, illness perceptions and actions plans are important elements that both need to be incorporated in interventions. However, patients may benefit from *beginning* with one

strategy or the other: in other words, the key decision is whether an intervention should flow from experience to concept (bottom-up) or from concept to experience (top-down). For instance, it has been argued that when a patient with a specific condition attributes symptoms and functional changes to an inappropriate set of perceptions/schema (e.g. as is the case in poorly controlled asthma or diabetes), then it is more appropriate to begin with a top-down or cognitive approach (McAndrew et al., 2008). For example, it may be particularly important to attempt to first change patients' perceptions about diabetes when negative or incorrect beliefs about their illness are either affecting the management of the illness, and/or causing significant emotional distress.

Thus, to summarise, according to Leventhal et al., it is the perception and interpretation of different sources of information (external & internal stimuli) that lead to the construction of illness perceptions, by means of a symmetrical conceptual (abstract) and schematic (concrete) process. Any changes in the schema in which physical symptoms are perceived, (e.g. by providing new information about the illness or new ways of interpreting symptoms) can modify the related illness perceptions. As indicated earlier the model is *self-regulating*, which means that illness perceptions are shaped and reshaped by the success or failure of procedures for preventing, modifying or curing/controlling a disease, and also the distress caused by it. Through the appraisal process, information is fed back into the self-regulatory system as new illness information. This, in turn, is integrated into existing illness schemas, modifying perceptions of the illness, which influences behaviours, which in turn are appraised, and fed back as new information, and so on. The key strength of Leventhal's model, and its application to chronic disease interventions, is that it allows for an investigation of how highly individualised patient beliefs impact on patients' coping behaviours and illness outcomes. The model also provides a pathway by which interventions targeting these highly individualised beliefs may work. Interventions based on this premise are discussed later in section 2.6.1).

2.5.5 Illness perceptions, coping, and illness outcomes

Leventhal's model also proposes that the health behaviours and coping strategies adopted in response to an illness are influenced by thoughts about that illness. This relationship is causal, that is, illness perceptions affect coping behaviours in direct proportion to the perceived severity of the illness which, in turn, is based on the perceptions derived from internal and external stimuli. This represents a mediational model, in which coping mediates the effect of illness perceptions on health outcomes. In their meta-analysis, Hagger and Orbell (Hagger & Orbell, 2003) report that perceived controllability was related to more active coping strategies, while a strong illness identity was related to avoidance and denial coping behaviours. Thus, lower perceived consequences, weaker illness identity and greater perceived control, were associated with adaptive outcomes (e.g. better social, psychological and physical functioning) (Hagger & Orbell, 2003).

2.5.6 Illness perceptions & diabetes

For the most part, the illness perceptions of people with diabetes have been investigated using a modified version of Leventhal's self-regulatory model. Within the field of diabetes, the illness perceptions conceptualised in Leventhal's framework are widely referred to as *'personal models'* of diabetes, a term originally borrowed from medical anthropology (Hampson, Glasgow, & Toobert, 1990). Two early studies (Hampson, Glasgow, & Foster, 1995; Hampson et al., 1990) investigated the illness beliefs of people with type 2 diabetes using a comprehensive interview schedule that included the five components of Leventhal's model. Responses to interview questions were combined to form a set of composite variables assessing symptoms, cause, timeline, consequences and treatment effectiveness. The composites for consequences and timeline were highly correlated, and were combined to form a 'seriousness' construct. Due to the low internal reliability of the 'symptom' construct, it was omitted from the second study prior to analyses. The findings from both studies indicated that the personal model constructs of treatment effectiveness, seriousness and cause contributed significantly to the prediction of dietary self management and exercise, with the treatment effectiveness construct emerging as the most important predictor. Treatment effectiveness and cause were also

found to be significant predictions of HbA1c levels in the second study (Hampson, et al., 1995). However, the results from the first study (Hampson et al., 1990) were based on interviews from a small women only sample (n=46). The second study (Hampson, et al., 1995), though based on a mixed sex sample, was also small (n=78) and only included older adults with type 2 diabetes. Therefore, the generalisability of these findings is limited. Further research using the personal models framework has found that seriousness and treatment effectiveness constructs are significant predictors of self-management behaviours and glycaemic control (Glasgow, Hampson, Strycker, & Ruggiero, 1997; Glasgow et al., 1997a; Glasgow, Toobert, Hampson, & Noell, 1995; Hampson, Glasgow, & Strycker, 2000; Lange & Piette, 2006) although the majority of these studies did not assess the other constructs of symptoms and causes.

A key difficulty with the personal models approach lies in assessing the extent to which the constructs have remained true to Leventhal's original five illness perceptions components; a further question relates to the extent to whether the personal model of diabetes constructs do indeed capture all the various aspects of patients' beliefs about diabetes. It has been argued that personal models of treatment effectiveness are comparable to the cure/control component of Leventhal's model (Hampson, Glasgow, & Strycker, 2000). However, by focusing on beliefs about *treatment* effectiveness, this construct does not take into account a key aspect of control beliefs relating to perceptions of *personal* control. Furthermore, by combining the timeline and consequence perceptions into one seriousness construct, much information is lost about how people may perceive the course of their diabetes (e.g. as cyclical or acute or chronic). The low reliability of the symptom construct, (corresponding to the identity component of Leventhal's model) in early personal models of diabetes studies led to the exclusion of this construct from predictive analysis. As a result symptom perceptions and illness identity are not included in measures assessing personal models of diabetes, such as the Personal Models of Diabetes Interview and Personal Models of Diabetes Questionnaire (Glasgow, et al. 1997; Hampson et al., 1995); these construct have also been virtually ignored in subsequent research using the personal models framework. A final difficulty

with the personal models approach relates to the apparent neglect of a central component of Leventhal's model; emotional representations and emotional processing.

Perhaps due to the predominance of the personal models of diabetes approach, few studies have investigated all of the five original illness perceptions components, and their relationship to illness outcomes in type 2 diabetes. The few studies that have been conducted have not focused explicitly on exploring the relationship between illness perceptions, self-management behaviours and glycaemic control. Rather, these studies have examined the associations between illness perceptions and quality of life (QoL) outcomes (Watkins et al., 2000) psychological well-being (Eiser, Riazi, Eiser, Hammersley, & Tooke, 2001) and anxiety and depression (Paschalides et al., 2004). It is worth noting, though, that the quality of life study (Watkins et al., 2000) did find that increased perceptions of control were predictive of more positive QoL, as well as improved dietary self-management behaviours among a sample of patients with type 1 and type 2 diabetes (n=296). However, the authors assessed illness perceptions using a number of non-standardised questions and they did not assess identity or timeline components, nor did they relate their findings to glycaemic control. In another study involving a mixed sample of type 1 and type 2 patients (Eiser et al., 2001) no relationship was found between illness perceptions and glycaemic control among people with type 2 diabetes, although well-being was found to be associated with control beliefs and perceived consequences. Again, this study only assessed perceptions of control and consequences, using non-standardised questionnaires, and excluded any consideration of self-management behaviours.

The use of author-developed, or non-standardised questionnaires, to assess illness perceptions is problematic because it makes comparisons across studies difficult, and often the reliability of such measures is not reported. A number of standardised measures exist to assess illness perceptions, but one of the most widely used and psychometrically robust is the Illness Perception Questionnaire (IPQ) (Weinman, Petrie, Moss-Morris, & Horne, 1996) and its revised versions - the IPQ-Revised, and the Brief-IPQ. However, few studies have used this measure in research with diabetes, again, perhaps due to the

predominance of the personal model approach. One study using the IPQ (Paschalides et al., 2004) found that perceived symptoms, consequences and control were significantly associated with physical and mental functioning, but there was no significant association between illness perceptions and HbA1c. However, again, this study did not assess self-management behaviours. A failure to assess disease-specific self-care behaviours in this type of research is problematic, as it is through such health behaviours that illness perceptions are conceptualised as impacting upon biological outcomes such as HbA1c.

A recent study (Paddison, Alpass, & Stephens, 2008) used the IPQ-R to assess the relationship between illness perceptions and glycaemic control and QoL among people with type 2 diabetes in New Zealand (n=615). This study found that a belief that diabetes is an acute rather than a life-long condition, and a perception that diabetes has serious consequences, were both significantly predictive of poorer metabolic control. The perception that diabetes has serious consequences was also associated with lower quality of life, as was a perception that diabetes is difficult to control, and emotional distress related to diabetes. The findings from the study by Paddison and colleagues suggest that there may be a pattern of beliefs about type 2 diabetes that are associated with poor metabolic control. Indeed, patients in poor control of their diabetes have been shown to have distinctly different perceptions of their illness than those in good control. In a study of patients with type 2 diabetes (n=153), White and colleagues (White et al., 2001-2004) investigated variations in illness perceptions between those in good control (HbA1c < 7%) and those in poor control (HbA1c > 8.5%). This study incorporated an exploratory qualitative substudy initially (n=19) (White, Smith, & O'Dowd, 2007), followed by a quantitative assessment involving the IPQ (n=153). The findings from the latter indicated that patients in poor control had significantly different perceptions about their diabetes than those in good control. Patients in poor control: had a stronger perception that their illness was caused by hereditary factors; had a stronger illness identity (reported suffering from more diabetes-related symptoms); perceived their diabetes as having significantly more consequences on their lives; and reported more negative emotions in relation to their diabetes. This would suggest that those in poor control of their diabetes may think about their illness in fundamentally different ways to those in good control. If this is

indeed the case, interventions focusing on changing the illness perceptions of those in poor control may lead to improved illness outcomes, including better self-management and glycaemic control. Improving glycaemic control may result in a decrease in diabetes-related symptoms, which through the self-regulatory system (feedback loop) proposed by Leventhal et al, may then in itself act as a reinforcing factor to maintain good glycaemic control.

2.6 PSYCHOLOGICAL INTERVENTIONS

Numerous non-pharmacological interventions have been developed and implemented to improve outcomes in type 2 diabetes (e.g. lifestyle interventions, self-management interventions, educational interventions, discussed in section 2.3.2.). These interventions have been systematically reviewed by a number of different authors, (Hampson et al., 2001; Norris et al., 2001; Steed et al., 2003). However, none of these systematic reviews adequately distinguished between educational and/or self-management type interventions, and psychological interventions. The difference is recognised to be a clinically important one (Ismail, Winkley, & Rabe-Hesketh, 2004), because educational and psychological interventions (while not mutually exclusive) do differ in terms of their theoretical underpinnings, required training, clinical skills, and resource implications. While psychological interventions may often incorporate elements of diabetes education, it is in essence the dynamic between the patient and the trained therapist that is used to change emotions, cognitions and behaviours, and not only the provision of knowledge.

One systematic review has been undertaken which specifically examined randomized controlled trials (n=25) of psychological interventions for type 2 diabetes (Ismail et al., , 2004). Interventions were delivered in either individual or group settings, and were implemented using CBT or other counselling methods, either on a stand alone basis, or in combination with education. Results from the meta-analysis indicated a pooled mean decrease in HbA1c of -0.32 (0.-57 to -0.07) in people assigned to a psychological intervention when compared to the control group, which equates to an absolute reduction of 0.76%. The review also reported significantly lower levels of psychological distress in

the intervention group (-0.58, [-0.95 to-0.20]). None of the interventions were explicitly based on Leventhal's self-regulatory model and none measured changes in illness perceptions. In addition, none of the interventions specifically targeted those in poor control, indeed, no psychosocial interventions were identified that specifically targeted patients with poorly controlled type 2 diabetes. This is surprising, and highlights a pressing need for further research, particularly in view of the evidence to suggest that psychosocial interventions specifically targeting those with poorly controlled type 1 diabetes have been successful in improving glycaemic control (Conget et al., 1995; Fosbury, Bosley, Ryle, Sonksen, & Judd, 1997; Snoek et al., 2001; Zoffmann & Lauritzen, 2006). These psychological interventions were also implemented using a variety of different therapeutic techniques and modes of delivery. For example, one study was CBT-based (Snoek et al., 2001); one was an individual intensive psycho-educational programme (Conget et al., 1995); one was based on guided-self determination in a group setting (Zoffmann & Lauritzen, 2006); and one used cognitive analytic therapy, a form of psychotherapy (Fosbury et al., 1997).

2.6.1 Illness perception interventions

As indicated earlier, few interventions have explicitly utilized Leventhal's self-regulatory model as a theoretical basis for improving illness management and outcomes (McAndrew et al., 2008). Indeed, one of the central criticisms of illness perceptions research is that is has been predominantly cross-sectional in nature, and lacks a theoretical testing of all elements of the model (Wearden & Peters, 2008). However, the few such interventions that have been conducted in this respect, have been successful in restructuring illness perceptions in several different chronic conditions, and some have resulted in improved illness outcomes (Fortune, Richards, Griffiths, & Main, 2004; Goodman, Morrissey, Graham, & Bossingham, 2005; Karamanidou, Weinman, & Horne, 2008; Theunissen, 2003). Perhaps the key such intervention (Petrie, Cameron, Ellis, Buick, & Weinman, 2002) was a RCT investigating the effects of a brief three-session intervention designed specifically to alter patients' perceptions relating to their recent myocardial infarction (n=65). The intervention was of a broadly equivalent structure for all patients, but the

exact content of each session was tailored to individuals based on their responses on the IPQ. The intervention employed behaviour change techniques common in health psychology (see section 2.6.2) such as challenging negative/incorrect perceptions; agreeing goals for behaviour change; and developing a personalized written action plan. At three-month follow up, patients in the intervention group showed significant positive changes in perceptions of their illness as well as a significantly earlier return to work and lower rates of angina symptoms.

Two other interventions, one with patients with psoriasis (Fortune et al., 2004) and one with patients with systematic lupus erythematosus (a connective tissue disorder) (Goodman et al., 2005) have used CBT techniques to change illness perceptions as part of illness management interventions. The first of these, an RCT of CBT-based psoriasis management programme (Fortune et al., 2004) found that at the six month follow-up, patients in the intervention group showed significant reductions in: perceived severity and frequency of symptoms; perceived consequences of their condition; and perceived attributions for emotional causes of the illness. A pilot study of a group CBT intervention for patients with lupus (n=11) (Goodman et al., 2005), reported significant increases in perceptions about treatment control, and illness coherence. However, when compared to a control group (n=22), these changes were not statistically significantly different at four months follow-up, although, the lack of a significance may have been due to a number of methodological issues including the lack of adequate power, the presence of bias due to lack of randomization, and possible contamination of the control group. Patients in the intervention group did report significantly lower levels of stress and distress following the intervention when compared to the control group, but there were no significant changes in any other physical or psychological health measures. A more recent RCT (Karamanidou et al. 2008) was also undertaken to examine the effectiveness of a self-regulatory psycho-educational intervention aimed at improving illness coherence perceptions in haemodialysis patients, by focusing on the need for phosphate control. When compared to the control group (n=20) at the four month follow-up, the intervention group (n=19) showed improved knowledge, treatment coherence, medication outcomes, efficacy beliefs and general understanding of treatment. However, there were no

significant changes in treatment adherence as assessed by self-report questionnaire and serum levels. Again this may be due to methodological issues such as small sample size, and the high attrition rate in the control group at follow-up.

To date, interventions based on Leventhal's model have tended to target the cognitive processing arm of the model, focusing mainly on changing illness cognitions and promoting problem-focused coping. While the effects of such interventions on anxiety, concern, disease-specific distress and well-being, may be assessed, emotional regulation is rarely targeted directly. It has also been argued (Cameron & Jago, 2008) that interventions may be less effective if they divert attention away from patients' efforts to regulate their emotional reactions to their illness. For example, in the RCT of patients recovering from myocardial infarction (Petrie et al., 2002) high levels of negative affectivity were found to moderate the effectiveness of the intervention (Cameron, Petrie, Ellis, Buick, & Weinman, 2005). The intervention group showed significantly increased attendance at cardiac rehabilitation and reduced disability when compared to a standard care control group, but this was only the case for patients with low negative affectivity. In fact, patients with high levels of negative affectivity in the intervention group showed poorer outcomes when compared to the control group, including decreased exercise rates and higher fat intake. The authors (Cameron et al., 2005) hypothesized that the programme may have interfered with the emotional regulation of this group of patients, by inadvertently downplaying the importance of managing distress and anxiety, and redirecting their focus toward cognitive and problems-focused regulation. One of the key advantages of using Leventhal's model as a theoretical framework for intervention research is precisely its parallel processing components: in other words, the reciprocal influences of emotions and cognitions, and problem-focused and emotional-focused coping, are clearly delineated. Thus, for self-regulatory-based interventions to be maximally effective, it has been argued that emotional processing and coping must be addressed in parallel with cognitive regulation (Cameron & Jago, 2008; Cameron et al., 2005).

2.6.2 Intervention techniques in health psychology

The main theories in health psychology have focused predominantly on predicting and explaining behaviour by identifying the determinants of behaviour and behaviour change. These theories provide useful foundations for designing interventions, by highlighting explicit causal pathways through which such interventions may work: that is, if the determinants of behaviour are changed, then the behaviour itself should change correspondingly. However, the majority of theories provide little practical guidance on the actual *techniques* required to successfully achieve such behaviour change (Michie, Johnston, Francis, Hardeman, & Eccles, 2008) and there does not appear to be a simple link between theory and the choice of behaviour change technique (BCT). Indeed, Azjen writes that it is at this point *"where investigators experience and creativity comes into play"* (Azjen, 2006 p.2). Consequently, researchers have developed a wide range of different techniques for health behaviour change, and indeed, often a wide variety of techniques for changing the same behaviour or behavioural determinant. For example, an individual's beliefs about their capabilities to perform a certain health behaviour (i.e. the personal control dimension in Leventhal's model, or the corresponding concept of self-efficacy in social cognitive theory) have been identified as a key determinant of behaviour change. Interventions have successfully used a range of BCT's to these kinds of control beliefs, including: self-monitoring; graded task setting (starting with easier tasks); increasing skills (problem-solving, decision-making, goal-setting); rehearsing skills; social processes of encouragement including pressure and support; feedback; self-talk; and motivational interviewing (see section 2.6.3).

Recently attempts have been made to identify and categorise the considerable array of techniques that health psychologists use in interventions, to map these techniques to theoretical constructs, and to assess their effectiveness (Abraham & Michie, 2008; Michie et al., 2008). The main impetus for this work has been the desire to develop a comprehensive, reliable taxonomy of theoretically-based behaviour change techniques, with standardized definitions. The lack of such a standardized, common vocabulary has meant that descriptions of the content of behaviour change interventions are variable and subjective (Abraham & Michie, 2008). This makes it difficult to identify the effective

components of an intervention, whilst limiting their generalisability and replication. The first study attempting to categorise these BCTs (Abraham & Michie, 2008) identified a total of 26 different techniques, from 195 published descriptions. However, the authors indicate that this was not an exhaustive list. Indeed, a later second study by Michie and colleagues (Michie et al., 2008) identified and defined 137 such BCTs, from a combination of literature reviews, expert 'brainstorming' and textbooks searches. They reviewed the literature and used expert judgment to reach a consensus of which techniques are most effective in changing 11 key theoretical constructs associated with behaviour change (see Table 2.3, p.52). Despite this more comprehensive approach, the resulting taxonomy may still not be considered an exhaustive list, because as the authors point out, developing such taxonomy is a cumulative process. New techniques will be developed and old ones re-developed, combined, and redefined. Nonetheless, such a taxonomy represents a useful starting point for the development of any interventions within health psychology.

2.6.3 Motivational interviewing

In the taxonomy developed by Michie and colleagues, motivational interviewing (MI) emerged consistently as a successful BCT. However, MI is more than a set of behaviour change techniques: it has developed into a coherent theory in its own right, accompanied by detailed clinical procedures for achieving behaviour change (Rubak, Sandbaek, Lauritzen, & Christensen, 2005). MI is a specialist counselling style, which was originally developed in the area of addiction treatment (i.e. alcohol and substance misuse) as a method for helping people who had extreme difficulty changing their behaviours (Miller & Rollnick, 2002). In the definitive book on the subject, Miller and Rollnick define motivational interviewing (MI) as: *"A client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence"* (Miller & Rollnick, 2002 p.25). The same authors describe MI as an evolution of the client-centred, non-directive counselling approach initially developed by Carl Rogers (Rogers, 1951). However, it differs from Rogerian methods, in that is it *consciously directive*: it is intentionally addressed to the resolution of *ambivalence* about change,

Table 2.3

Behaviour change techniques linked with determinants of behaviour (Michie et al. 2008)

Determinants of behaviour	**Techniques judged to be effective in changing each construct domain**
Social/professional roles and identity	• Social processes of encouragement, pressure, support
Knowledge	• Information regarding behaviour outcome
Skills	• Goal/target specified: behaviour or outcome • Monitoring and self-monitoring • Rewards/incentives (inc. self-evaluation) • Graded task (starting with easiest task) • Increasing skills (problem-solving, decision-making, goal-setting) • Rehearsal of relevant skills • Modelling/demonstration of behaviour by others • Homework • Performing behaviour in different settings
Beliefs about capabilities	• Self-monitoring • Graded task (starting with easiest task) • Increasing skills (problem-solving, decision-making, goal-setting) • Coping skills • Rehearsal of relevant skills • Social processes of encouragement, pressure, support • Modelling/demonstration of behaviour by others • Self-talk • Motivational-interviewing
Beliefs about consequences	• Self-monitoring • Persuasive communication • Information regarding behaviour outcome • Feedback
Motivation and goals	• Goal/target specified: behaviour or outcome • Contract • Rewards/incentives (inc. self-evaluation) • Graded task (starting with easiest task) • Increasing skills (problem-solving, decision-making, goal-setting) • Social processes of encouragement, pressure, support • Persuasive communication • Information regarding behaviour outcome • Motivational interviewing
Memory, attention and decision processes	• Self-monitoring • Planning, implementation • Prompts, triggers, cues
Environmental context and resources	• Environmental changes (e.g. objects to facilitate behaviour)
Social influences	• Social processes of encouragement, pressure, support • Modelling/demonstration by others
Emotion	• Stress-management &coping skills
Action planning	• Goal/target specified behaviour: behaviour or outcome • Contract • Planning/implementation • Prompts, triggers, cues • Use of imagery

usually in a particular direction. The focus is on eliciting the person's own *intrinsic* motivation for change. Four broad guiding principles underlie motivational interviewing: (1) expressing empathy; (2) rolling with resistance; (3) developing discrepancy; (4) building self-efficacy. Techniques of MI used to implement these four guiding principles include: reflective listening; eliciting motivation statements from clients (known as 'change talk'); examining and resolving ambivalence; reducing resistance and monitoring clients' readiness for change.

A number of systematic reviews and meta-analyses have found substantial evidence that MI is a particularly effective intervention for substance abuse (Burke, Arkowitz, & Menchola, 2003; Burke, Arkowitz, & Dunn, 2002; Dunn, Deroo, & Rivara, 2001; Knight, McGowan, Dickens, & Bundy, 2006; Rubak et al., 2005). However, MI techniques are increasingly being used in medical settings to address other health behaviours and conditions, including in particular, lifestyle changes and regime adherence in chronic conditions. However, MI may function differently in theory, and in practice, when applied to non-addictive behaviour and chronic disease management (Resnicow, 2002). For example, on a conceptual level the nature and magnitude of ambivalence about change and resistance to change for non-addictive behaviours may be less marked than for those behaviours that are addictive. Reasons for change, and the actual pattern of behaviour change, may also differ. For example, when an individual is attempting to improve their dietary behaviours the process of behaviour change may be more gradual than for the changes in behaviours that are physically addictive: there may be no discrete 'quit day' (as there often is with substance abuse) where individuals suddenly 'quit' engaging in unhealthy eating behaviours. From a more pragmatic point of view, time may be limited when using MI for changing non-addictive behaviours. For instance, MI for addiction counselling may typically involve multiple sessions of considerable duration. However, when using MI in medical settings (particularly primary care), practitioners may only have a 10-15 minute consultation available in which to effect behaviour change with patients. Moreover, in hospital settings (e.g. diabetes clinic), practitioners not only have limited time, but may also have only infrequent contact (or indeed a single contact) with patients. Thus, when using MI to effect non-addictive behaviour change, it may not be appropriate or feasible to implement the full range of MI techniques. In recognition of

this fact, MI has been adapted into a briefer format, referred to as Adapted Motivational Interviewing (AMI) (Rollnick, 1999) for use in behaviour change consultations and/or interventions, when client contact is limited. Figure 2.3 outlines the key tasks when using such AMI.

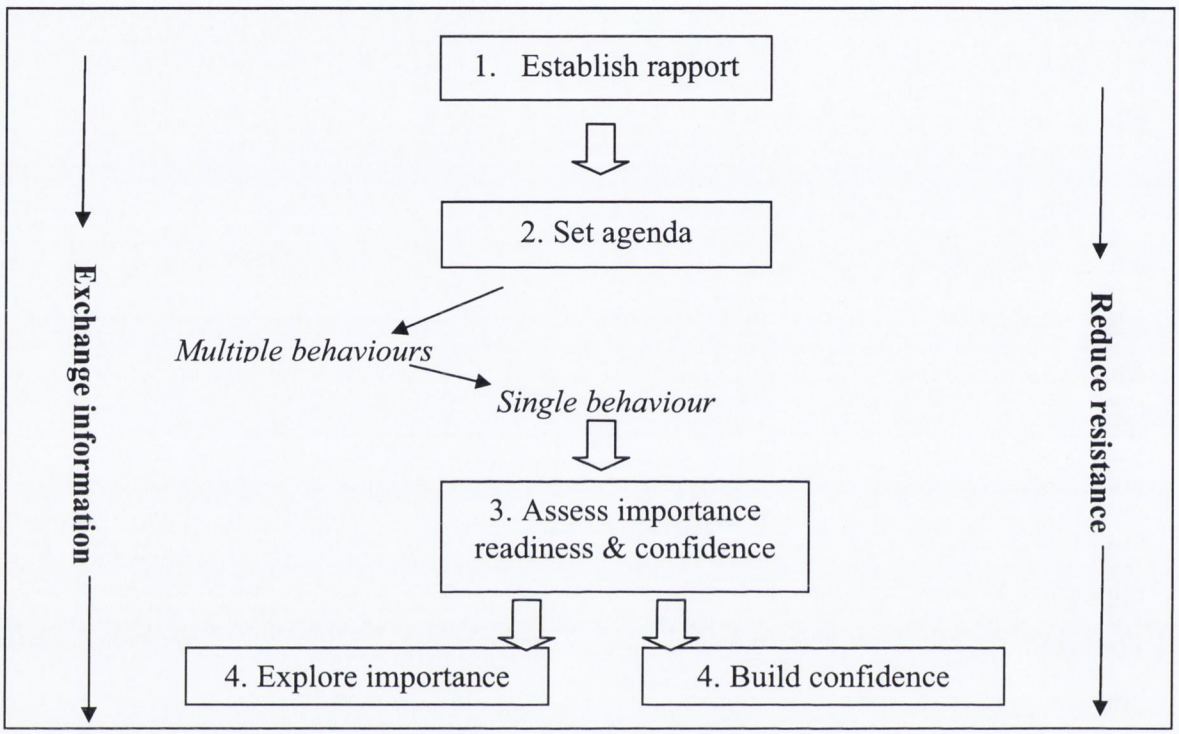

Figure 2.3: *Key tasks in consultations about behaviour change using adapted motivational interviewing (Rollnick, 1999)*

Unfortunately, the precise definition of MI appears to be a source of some confusion perhaps due, in large part, to the complexity of the motivational interviewing approach, and its adaptation for use in fields beyond addiction counselling. As a result, a growing number of researchers and clinicians who claim to use MI fail to adhere to its core principles and techniques. Thus, Miller & Rollnick report that *"we have found ourselves placing less emphasis on techniques of motivational interviewing and an ever greater emphasis on the fundamental spirit that underlies it"* (Miller & Rollnick, 2002 p.33). This underlying 'spirit' or style of motivational interviewing is a way of being with clients that incorporates the four guiding principles of MI described above. Miller and

Rollnick have attempted to specify as clearly as possible what this spirit of motivational interviewing encompasses, and what it does not (see Table 2.4).

Table 2.4

The spirit of motivational interviewing (Miller & Rollnick, 2002)

Fundamental approach of motivational interviewing	**Mirror-image opposite approach to counselling**
• *Collaboration.* Counselling involves a partnership that honours the clients experience and perspectives. The counsellor provides an atmosphere that is conductive to change	• *Confrontation.* Counselling involves overriding the client's impaired perspective by imposing awareness and acceptance of 'reality' that the client cannot see, or will not admit.
• *Evocation.* The resources and motivation for change are presumed to reside within the client. Intrinsic motivation for change is enhanced by drawing on the clients own perceptions, goals and values.	• *Education.* The client is presumed to lack key knowledge, insight, and/or skills that are necessary for change to occur. The counsellor seeks to address these deficits by providing the requisite enlightenment.
• *Autonomy.* The counsellor affirms the client's right and capacity for self-direction and facilitates informed choice.	• *Authority.* The counsellor tells the client what he or she must do.

Knight and colleagues (Knight, McGowan, Dickens, & Bundy, 2006) reviewed the evidence for the efficacy of MI specifically in physical health care settings (i.e. excluding substance abuse intervention). They identified eight trials that met the inclusion criteria, in the areas of diabetes, asthma, hyperlidemia and heart disease. The majority of trials found positive results for the effects of MI on psychological, physiological and lifestyle change outcomes. However, the low quality and content validity of the trials prevented the authors from conducting a meta-analysis, or from drawing any firm conclusions. Two RCTs using MI in interventions for patients with type 2 diabetes were identified: (Clark, Hampson, Avery, & Simpson, 2004; Smith, Heckemeyer, Kratt, & Mason, 1997) Smith

and colleagues (1997) conducted a RCT with overweight women (BMI>27) with type 2 diabetes (n=217). All patients participated in a group-based behavioural obesity intervention, and were then randomly assigned to individual sessions of MI (n=109) or an attention control placebo group (n=108). Women in the MI group lost significantly more weight at 6-months and 18-months follow-up, and showed significant improvements in glycaemic control at six-months, but not at 18-months. Similarly, Clark et al. (2004) assessed the effects of a brief, tailored life-style intervention for patients with type 2 diabetes (n=100). Again, patients in the intervention group (n=50) showed significant improvements in dietary behaviour (e.g. reduced fat intake) at 3 and 12 month follow-up when compared to the usual care control group (n=50). These self-reported changes in lifestyle behaviours were confirmed by objective measures of waist circumference and BMI, both of which showed significant reductions at 3 months follow-up that was maintained at 12 months. Unfortunately, this study did not assess the effects of the intervention on glycaemic control, although weight loss is a key factor contributing to improved glycaemic control in type 2 diabetes.

Thus, initial evidence for the efficacy of MI in physical healthcare settings is promising, particularly as a technique for effecting behaviour change in chronic conditions such as type 2 diabetes. The client-centred focus of MI also makes it an intuitively appealing technique for diabetes interventions, and is consistent with the increasing focus on patient empowerment in diabetes care (discussed in section 2.3.2). In addition, evidence from systematic reviews suggests that MI is as effective in eliciting behaviour change when used in combination with other techniques and treatments, such as those used by health psychology techniques for changing cognitions/determinants of behaviour (described in section 2.6.2).

2.7 TYPE 2 DIABETES AND THE FAMILY

The effective management of diabetes depends to a large extent on the consistent use of appropriate disease management behaviours. These often involve major lifestyle changes, many of which need to be made in the home environment (e.g. changing diet), thereby potentially impacting on family relationships (Weihs, Fisher, & Baird, 2002). Thus,

strategies for coping with diabetes require the patient not only to manage symptoms and treatment, but also to interact with and acquire additional support from significant others (Petrie, 2002). Matire (2005 p. 313) provides a succinct summary of the potential role of family members in illness management, who: *"through their communications and attitudes...often have a significant impact on a patient's psychological well-being, decision to follow recommendations for medical treatment, and ability to initiate and maintain changes in diet and exercise."* However, the family context has been somewhat neglected in adults type 2 diabetes research. Little is known about the influence of the family on disease outcomes in adults with diabetes, especially when compared to children. Therefore, there may be a widely held assumption that perhaps adult patients manage their chronic illnesses independently, and are not influenced to any great extent by the social context of disease management or the interpersonal relationships of the family (Fisher, 2006). Alternatively, it may be that to date, researchers have simply overlooked the role of the family in adult type 2 diabetes management. The importance of the family context in adult type 2 diabetes is however recognized to some degree within the clinical context. For example, spouses are often invited to attend education sessions in many diabetes centres.

2.7.1 Family characteristics and pathways of influence

A review of the available evidence on the influence of family relationships on chronic disease management and outcomes (Weihs et al., 2002) identified a number of key family and couple characteristics that have been consistently linked with chronic disease processes and outcomes (see Table 2.5, p.58). A more recent review in this area, (Fisher, 2006) concluded that of those family characteristics with the most consistent and powerful effects on disease management include: poor conflict resolution skills; high inter-spouse conflict; hostility and criticism/critical behaviour; and a lack of congruence or similarity in disease beliefs and expectations. The last of these is particularly relevant in the context of the earlier discussion around health beliefs and illness representations/cognitions.

Table 2.5

Characteristics of family relationships linked to chronic disease outcomes (Weihs, Fisher, & Baird, 2002)

Protective Factors	**Risk Factors**
• Family closeness, mutuality, connectedness	• Intrafamilial conflict, criticism, blar with poor conflict resolution
• Caregiver coping skills e.g. problem solving	• Psychological trauma related diagnosis & treatment of disease
• Mutually supportive family relationships	• External stress
• Clear family organization	• Lack of an extra-family support system
• Direct communication about the illness and its management	• Disease interrupts family membe developmental tasks
• ***Congruence of beliefs within the family about health and disease***	• Perfectionism and rigidity
	• Low relationship satisfaction

Current research suggests that there are three pathways, or mechanisms, by which families may influence physical health outcomes (Campbell, 2003; Fisher & Weihs, 2000): a direct biological pathway; a psychophysiological pathway; and a health behaviour pathway. The *biological pathway,* simply refers to the direct influence of biological factors such as the spread of infectious illnesses, shared toxic environment and shared genes. The *psychophysiological pathway* refers to ways in which characteristics of family relationships (e.g. secure attachments, hostility, criticism) can impact on cognitions and emotions, which in turn, through the physiological stress response (McEwen, 1998), influences biological systems and illness outcomes. The *health behaviour pathway* refers to the ways in which the responses of family members to the disease and its management can impact on the self-management behaviour of the person with the condition (e.g. providing appropriate support in relation to diet and exercise).

There is no evidence to suggest that any one of these pathways is more influential than another: indeed, both pathways are likely to have an interactive effect, so that changing one may affect the other. However, from the perspective of intervention research, the second and third of the pathways described above are most relevant, as they are more amenable to change. Campbell (2003) provides a useful example of a hypothetical family intervention for diabetes, which aims to improve glycaemic control and emotional well-being, by mobilizing the family to help the patient comply with treatment (health behaviour pathway), and/or by addressing family conflict (psychophysiological pathway) related to the patient's diabetes. Such an intervention may actually involve an interaction of both pathways. Thus, mobilizing family support for treatment compliance may require, or may result from, a change in family dynamics thereby leading to an improvement in glycaemic control either because compliance has improved (health behaviour), or because family conflict has decreased and emotional well-being has improved (deactivation physiological stress response), or perhaps due to a combination of both

2.7.2 Family-based interventions in chronic illness

Family-based interventions designed to improve outcomes in adult patients with chronic illness, such as the example provided above, have been grouped into the following three categories (Campbell, 2003; Weihs et al. 2002): (1) *family education and support interventions*, which are designed to educate family members about the target disease and how to manage it; (2) *family psycho-education interventions,* which are focused on helping families to cope more effectively with an illness by providing specific problem solving skills, whilst also possibly addressing family relationships, and (3) *family therapy interventions*, which focus on family dysfunction rather than on the illness itself. However, it is important to note that the vast majority of family interventions in chronic illness have been conducted either with children and/or adolescents, or the elderly (Weihs, Fisher, & Baird, 2002). A number of recent reviews (Campbell, 2003; Martire, 2005; Martire, Lustig, Schulz, Miller, & Helgeson, 2004) undertaken to investigate the effectiveness of family interventions in chronic disease, have all highlighted the paucity of such interventions for adults. Results from these reviews show that family-based psychosocial interventions are generally more beneficial than one-to-one interventions

(Martire, 2005) and that interventions with mixed groups of family members (i.e. not only the spouse) were effective in improving patient mortality, with the exception of dementia-related diseases (Martire et al. 2004). Importantly, these reviews also indicate that family-based interventions are not associated with negative outcomes (e.g. increased distress, anxiety), for either the patient or the family members (Matire et al., 2004).

The authors of the above systematic reviews concluded that, unfortunately, the majority of family interventions reviewed failed to specify how existing theories have influenced either the development of the intervention or the decision to include family members in the first place. In addition, few are conceptually driven to test specific constructs, or to clearly specify targets for change, whilst even fewer administered clear behavioural interventions in order to achieve targets. Thus, it has been recommended (Fisher, 2006; Martire, 2005; Martire et al., 2004) that future family interventions in chronic illness should be theory-based, highly specific, clinically relevant, and assess structured outcomes that correspond directly to targets. It has also been argued (Campbell, 2003) that there is a need to include family level outcomes, such as family behaviour or types of support. Arguably, without assessing such outcomes, it is impossible to ascertain whether or not the intervention changed targeted family factors (e.g. support, criticism), and if so, to what extent this might have led to changes in health outcomes.

2.7.3 Family interventions in type 2 diabetes

Over the last decade a number of authors have noted that the role of family factors in adult type 2 diabetes intervention research has been particularly neglected (Fisher et al., 1998; Gonder-Frederick et al., 2002; Hixenbaugh, 1998; White, Smith, & O'Dowd, 2005). A family intervention in diabetes may fall under one of the three broad categories discussed above, and can be defined as *"as any intervention designed to improve outcomes in adults with type 2 diabetes, which are delivered to the individual with type 2 diabetes, and/or at least one other family member"* (Keogh, White, Hevey, McGilloway & Smith, 2007). However, to date, very few such interventions have been implemented. In one, albeit dated study, (Gilden, Hendryx, Casia, & Singh, 1989) elderly patients with type 2 diabetes who took part in a 6-week diabetes education programme with their

spouses, showed improved glycaemic control, improved diabetes-related knowledge, and increased family involvement, when compared to a younger male cohort who received the same educational programme but with no spousal participation. However, this study was not a randomized controlled trial, and the two groups were not similar enough to truly facilitate appropriate comparisons. A more recent systematic review (Armour, Norris, Jack, Zhang, & Fisher, 2005 Zhang & Fisher, 2005 #516) identified only one published RCT that could be defined as involving a family intervention for people with type 2 diabetes (Wing, Marcus, Epstein, & Jawad, 1991). However, this systematic review included family-based interventions for both type 1 and type 2 diabetes. It also only included published studies, studies involving an RCT design, and studies where family members were resident together.

Given the limitations of the Armour et al. systematic review, the research team for the current RCT conducted a Cochrane Systematic Review (Keogh et al., 2007), which included studies with non-randomised designs (e.g. controlled clinical trials, controlled before and after studies), and studies where patients and family members were not residing together. This Cochrane review also involved searching the grey literature to identify any eligible unpublished studies. In addition to the Wing et al. RCT (1991), our Cochrane review identified three eligible completed studies; (Brown & Hanis, 1995; Gilliland, 2002; Pearce et al., 2008) and one on-going study (Trief, Brittain, R, Duncan, 2006). (The RCT presented in this thesis is also eligible for inclusion in the review). The Cochrane review is completed, but is currently under-going the peer review process, thus, no results from the review are presented here. However, the eligible studies and their findings are summarized below.

The RCT by Wing et al. (1991) tested a behavioural weight loss intervention for patients with type 2 diabetes who also had obesity. The trial compared a 'treated alone' group (n=25) with a family group (n=24), which included patients' spouses. At 6-month follow-up there were no significant differences between groups in terms of glycaemic control, weight or eating behaviours. However, there was a significant interaction of treatment and gender, with women doing better than men when treated with their spouses than

when treated alone. Brown and colleagues (Brown & Hanis, 1995) conducted a RCT of a culturally competent educational intervention for Mexican Americans with type 2 diabetes, in which family members (or friends) accompanied patients to intervention sessions. At six and 12-months follow-up, patients in the intervention group (n=112) showed significantly lower levels of HbA1c compared to a usual care control group (n=112). The study by Gilliland et al. (2002) was also a culturally appropriate intervention, for Native Americans with type 2 diabetes. The intervention was a cluster trial, which allocated patients to either a family/friends group (n=32), a 'one-on-one' group (n=39), or a usual care control group (n=33), based on their community of residence. At 1-year follow-up, the usual care group showed a statistically significant increase in HbA1c compared to the two intervention groups. However, differences between the family group and the one-on-one group were not statistically tested. Thus, it is not clear if it was the intervention itself that was effective, or the inclusion of the family member, or a combination of the two. The final RCT identified by our Cochrane review was a family-based educational intervention designed to foster the involvement of a relative (or friend) for the reduction of cardiovascular risk in patients with type 2 diabetes (Pearce et al., 2008). It compared a group who received the intervention 'alone' (n=91), with a group whose relative/friend participated with them in the intervention (n=108). At 12-month follow-up there was no significant difference between groups in terms of HbA1c or other outcomes (blood pressure, quality of life etc). However, the study was underpowered to detect any significant changes in these outcomes.

The fact that our Cochrane review identified very few family interventions would seem to confirm that family factors have indeed been neglected in research with adults with type 2 diabetes. The few studies that have been conducted have suffered from methodological issues (e.g. underpowered, small sample size, lack of appropriate analysis) or have only focused on certain sub-populations of those with diabetes. Thus, there would appear to be a clear need for good quality, theory-based interventions for adults with type 2 diabetes and their families.

2.7.4 Social support in type 2 diabetes

One way in which family interventions in diabetes may influence illness-outcomes, is by mobilising social support. Studies have shown that social support from family and friends for adults with diabetes has a positive impact on disease management (Fisher, Greco, Arfken, & Schneiderman, 1997; Schafer, McCaul, & Glasgow, 1986). The burgeoning psychological literature on social support outlines four main types of social support (van Dam et al., 2005) including: *emotional* support (e.g. providing warmth, nurturance, reassurance and approval); *appraisal* support (e.g. helping a patient understand a stressful event even better, and what strategies can be used to cope with it); *information* support (i.e. giving advice and information); and *tangible* or *practical-instrumental* support (material or other practical help, such as services, financial assistance, and goods).. It is hypothesised that social support may impact on self-management and glycaemic control, either *directly* (e.g. through the provision of relevant support), or indirectly through a *buffering effect* (e.g. protecting the patient from the negative effects of stress). Generally social support is conceptualized as a mediator or moderator variable influencing health outcomes through its impact on coping behaviours (van Dam et al., 2005). A recent systematic review (van Dam et al., 2005) identified six controlled trials of social support interventions in type 2 diabetes. However, only two of these studies were concerned with social support provided by the family (i.e. as opposed to peers). The first of these was the study by Wing et al. (1991), and the second was the study by Gilliland et al. (2002), both of which were discussed above.

Research has shown that social support may not always have positive effects (Kaplan & Hartwell, 1987; Wortman, Conway, Cohen, & Syme, 1985), particularly if it is perceived as unhelpful or unwanted by the patient. While there is little research with adults with diabetes, studies of adolescents with diabetes have found significant associations between perceived non-supportive family behaviours (e.g. criticism, nagging) and poor self-management and metabolic control (Lewin et al., 2006; Trief, Grant, Elbert, & Weinstock, 1998). The dynamics of adult relationships obviously differ from those of adolescents, although it is possible that similar perceptions of non-support may also impact on adults' management of their diabetes. Thus, in interventions with adult patients

with diabetes and their families, it would be prudent to focus on and measure the influence of perceptions of both supportive and non-supportive family behaviours, from the perspective of both the patient and the family member, as each may have very different views about the nature and extent of support that is required or desired.

2.8 THE ROLE OF THE FAMILY IN ILLNESS PERCEPTIONS

Leventhal et al. (1986) argue convincingly that a comprehensive understanding of how people think about, and thus manage their illness can only be reached by taking into account the social and family context in which these thoughts are developed. However, until relatively recently the family context has been largely neglected in illness perceptions research. Indeed, one of the main criticisms of Leventhal's Self-Regulatory Model is that it *"stays in the head of the individual and ignores the social context"* (Ogden, 1995 p.20). However, Leventhal and colleagues recognised the importance of social factors in shaping illness perceptions early in the development of the conceptual structure of their model (Leventhal et al., 1986), and stressed that self-regulatory systems operate within a social context, which impacts on the construction of illness perceptions. Thus, illness perceptions are a product of cultural/social information: the social context provides linguistic labels for categorising events that define an illness, thereby ensuring culturally-shared views, whilst also providing personal contacts which strengthen the development of illness schemas.

Despite this, we still know comparatively little about how the illness perceptions of family members differ from those of patients, and how such difference may influence patients' perceptions of their illness, and strategies for coping with it. Recent evidence is emerging from a small number of studies that have explored the illness perceptions of family members across a range of conditions including: heart disease (Benyamini, 2007; Figueiras & Weinman, 2003; Fox, 2001; Weinman, Petrie, Sharpe, & Walker, 2000); systemic lupus erythmatosus (Seawell, 2008); alcohol misuse (Bamford, Barrowclough, & Booth, 2007); schizophrenia (Barrowclough, Lobban, Hatton, & Quinn, 2001); psoriasis (Richards et al., 2004); Alzheimers disease (Roberts & Connell, 2000); Addisons disease (Heijmans, de Ridder, & Bensing, 1999); Hungtingtons's disease

(Kaptein et al., 2007); arthritis (Sterba et al., 2008); and type 1 diabetes (Law, 2002; Olsen, Berg, & Wiebe, 2008). In particular, the degree of similarity, or congruence, between the illness perceptions of the patient and the family member is emerging as a factor that is significantly related to illness outcomes.

For example, a study undertaken in the late 1990's (Heijmans et al., 1999) found that the spouses of patients with Addisons disease, when compared to the patients themselves, were more likely to believe the illness had more negative consequences, were less optimistic about a cure or that the patient could control the illness, and perceived the illness to be more chronic in course. The perceptions of both groups were compared by computing a *dissimilarity score* (i.e. by subtracting the score of spouses from those of the patients). This dissimilarity score was found to have a weak impact on coping behaviours, but a strong impact on physical, psychological and social functioning. Other studies have also used the dissimilarity score method to investigate the degree of similarity between the perceptions of patients and family members. For example, highly congruent patient and spouse perceptions about the cause of a myocardial infarction have been found to be predictive of subsequent changes in diet, exercise and other health behaviours (Weinman, et al., 2000). The congruency between perceptions of control of heart failure between patients and their spouses has also been found to be associated with improved regimen adherence (Fox, 2001). In addition, congruence between the illness perceptions of women with rheumatoid arthritis and their husbands' perceptions of the illness, in relation to personal control and the illnesses cyclical nature, was found to be predictive of better psychological adjustment at four month follow-up (Sterba et al., 2008). In another study of patients with alcohol problems and their significant others, dissimilar beliefs about the consequences of alcohol misuse were associated with poorer relationship quality and poorer treatment attendance (Bamford et al. 2007).

One problem with the use of the dissimilarity score method used in the above studies is that it does not differentiate between scores that are similar or congruent in a negative direction, and those that are similar in a positive direction. This problem was addressed in a study investigating the degree of similarity between patient and spousal perceptions of

recovery from MI (Figueiras & Weinman, 2003). Spouse and patient scores were classified as positive or negative, using a classification system based on the median score on each illness perception subscale. This allowed the authors to compare spouse and patient perceptions with regard to the following three broad categories; similar positive perceptions, similar negative perceptions, or conflicting perceptions. The most prevalent similar positive perceptions were seen in the identity, timeline and consequence dimensions, while the most prevalent negative and conflicting perceptions were seen in the cure/control dimension (causal perceptions were not assessed in this study). Similar positive perceptions of myocardial infarction were also found to be associated with better recovery in terms of physical, psychological, social and sexual functioning, when compared to those with similar negative perceptions. The study of women with rheumatoid arthritis, found similar results, in that, psychological adjustment was better when couples had similar optimistic views about personal control, illness coherence and consequences, when compared to couples with similar pessimistic views (Sterba et al., 2008). Surprisingly, the study by Figuerias & Weinman found that patients in the conflicting perceptions category had a comparable recovery to the similar positive perceptions group. The authors suggest that what may be important for illness outcomes is that one person (patient or spouse) has a positive perception. However, they also highlight the need for more research to establish whether or not any differences arise depending on which person has the positive perception, and how this is related to outcomes. Another important finding from this study showed that the quality of marital functioning (as assessed by a standardized self-report questionnaire) was not associated with similar positive perceptions or outcomes. This is important, as it could be argued that similar positive perceptions and outcomes are simply a reflection of a better quality of marital relationship (e.g. improved communication between couples).

The potential impact of family factors on illness perceptions is particularly relevant for diabetes, as most of the self-regulatory behaviours involved in the self-management of diabetes occur at home. Thus, it has been argued (Weinman et al., 2003) that in diseases such as diabetes where good self-management is essential, the degree of similarity between patient and family member perceptions may be particularly important for

outcomes. A recent study by Searle and colleagues (2007) investigated the illness perceptions of patients with type 2 diabetes (n=164) and their partners, and examined whether these perceptions were related to self-management behaviours. Partners' perceptions were found to partially mediate the relationship between patients' perceptions and diet and exercise. Significant differences between patient and family member perceptions were found for the two illness perception dimensions of coherence and control. Thus, patients had a poorer understanding of the illness than their partners, and patients perceived greater personal control over their illness than their partners believed. White and colleagues (White et al., 2001-2004) also investigated the illness perceptions of family members of patients (n=74) with type 2 diabetes, and found significant differences between family members and patients with respect to their perceptions of diabetes. Family members perceived diabetes as a more serious illness, as having more consequences and as being more controllable by treatment (i.e. medication) as opposed to personal factors (e.g. lifestyle change). Discrepancies were also found between both groups with respect to their understanding of diabetes, whereby family members overestimated the extent to which they felt the patient understood their illness. In other words, while patients felt they did not understand their diabetes, their family members believed that they did. Family members also believed that patients with diabetes experienced more emotional distress in relation to their illness, than reported by the patients themselves.

One hypothesised model by which family members' illness perceptions may influence patient health outcomes in diabetes is presented in Figure 2.4. This model has been developed by the author, and is based on Leventhal's self-regulatory model, whereby patients' perceptions of their illness influence coping behaviours, which in turn impacts upon illness outcomes. However, the model also incorporates the effect of the illness perceptions of family members. The critical feature of this model is the interaction between the perceptions of the patient and family members, in particular, the degree of similarity or congruence between perceptions. The model highlights a possible

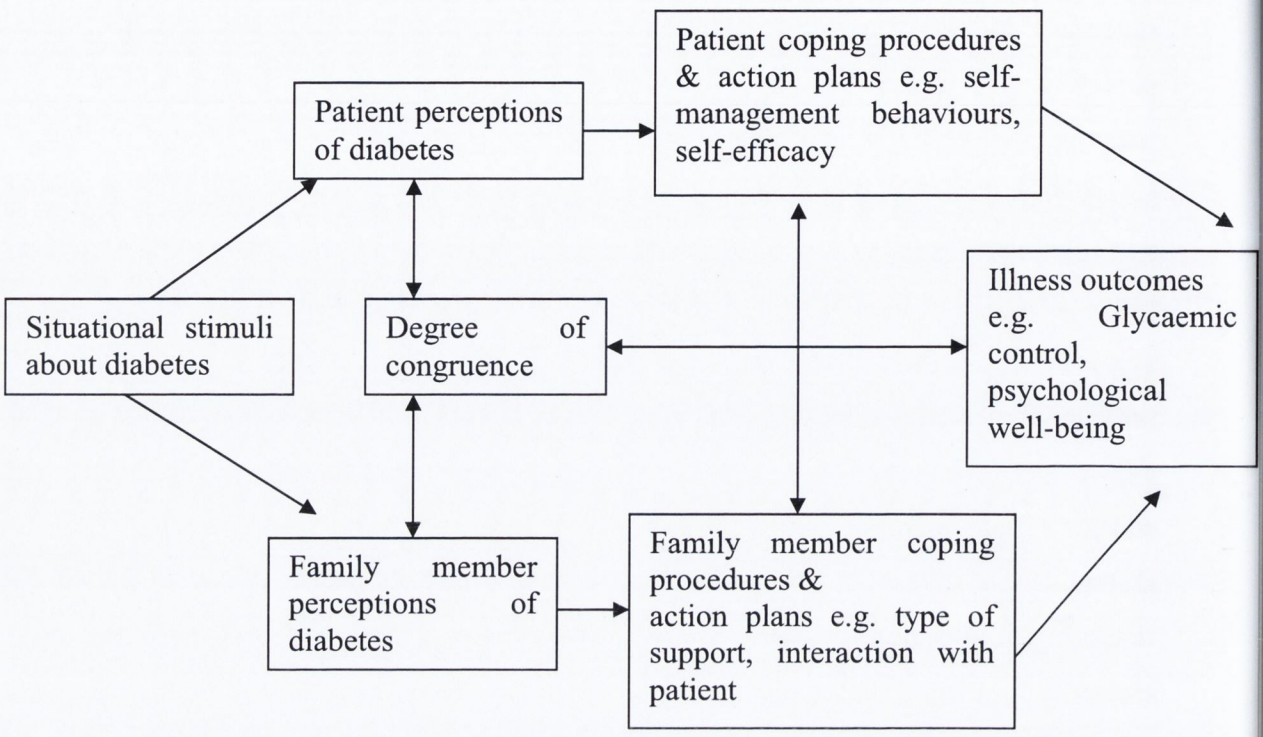

Figure 2.4*: Hypothesised model of how the illness perceptions of family members may influence outcomes in diabetes*

causal pathway by which family-based interventions to change illness perceptions may operate to improve the management of an illness, and illness outcomes. Changing the inaccurate or negative illness perceptions of patients and family members, and improving the degree of congruence between perceptions in a positive direction, may help both patients and family members to cope more effectively with an illness, which may in turn improve outcomes (e.g. glycaemic control in diabetes). The following chapter details the development of such a family-based intervention for patients with poorly controlled type 2 diabetes and their family members.

3 METHODOLOGICAL ISSUES

"Health psychology needs to be more than a catalogue of interventions that investigators have claimed will work. Rather, advancing the science of behaviour change depends on the accumulation of evidence for theory-based interventions targeting specific health-related behaviours" (Dombrowski, Sniehotta, Avenell, & Coyne, 2007 p. 249).

The current study is an RCT; therefore, this chapter provides an overview of some of the key methodological issues that need to be taken into account when undertaking an RCT.

3.1 STUDY DESIGN

The randomised controlled trial (RCT) is the 'gold standard' method for evaluating the effectiveness of health care interventions (Jadad, 1998). Provided that an RCT is adequately designed and effectively implemented, it can be inferred with some confidence that any observed differences in outcomes been intervention and control groups were caused by the treatment.

3.1.1 Randomisation

Randomisation is a method which uses the play of chance to assigned trial participants to treatment groups. Randomising participants to a study 'balances' or 'averages out' the effects of potential confounding variables, in an effort to produce comparable groups at baseline. Randomisation is the only process which allows investigators to balance known and *unknown* confounding variables across groups. It is this fact that permits causal inferences to be made with some confidence. However, while randomisation generates comparable groups, it does not generate identical groups; thus, there is always a small probability of differences due to chance. However, provided that a sufficiently large number of participants are randomised, these differences will be due only to chance and can be controlled for using statistical methods during analysis. The assumption of random sampling which underlies statistical theory, for example the computation of sampling error (Altman & Bland, 1999b), provides another convincing

argument for randomly assigning participants to groups. In a study with randomised groups, the differences between treatment groups are similar to the differences between random samples from a single population. As it is known how random samples are expected to behave (according to statistical theory) observations in an RCT can be compared with what would be expected if there were no differences between treatments. A Recent Cochrane Systematic Review (Kunz, 2007) which assessed the effects of randomisation on the results of healthcare trials, found large differences in effect sizes for non-randomised when compared with randomised trials. These differences in effect sizes ranged from a 76% smaller effect, to a 400% larger effect. On average, estimates of effect were larger in non-randomised trials, but in some instances non-randomised trials found similar treatment effects, smaller treatment effects, or even in one study, a reversal of treatment effects

3.1.2 Block randomisation

The most basic form of randomisation (e.g. in the case of two treatments) each patient's treatment is determined at random independently with no constraints. It is equivalent to allocating treatment by tossing a coin (Altman & Bland, 1999a; Roberts & Torgerson, 1998), although in practice coins are rarely used, instead computer generated random numbers tables are the preferred method. However, such 'simple' randomisation can result in groups of different sizes, even in large trial samples. In small trial samples there may be substantial differences in group sizes that will reduce the precision of estimates of the difference in treatment effects, and hence, the efficiency of the intervention (Roberts & Torgerson, 1998). To keep the numbers in each group very close, a method called 'block' randomization (or restricted randomization) (Altman & Bland, 1999a; Roberts & Torgerson, 1998) can be used. Block randomisation is a method of randomisation which ensures balanced sample sizes in each arm of the trial. A 'block' containing equal number of treatment and control group allocation is set up, and then each participant is assigned an allocation that is randomly selected from the block. This procedure generates balanced sample size, provided that the trial runs its full course. If the trial terminates early, the sample sizes may be unbalanced. To protect against this contingency researchers can randomise multiple blocks, for example, in a trial of 120 participants there could be 3 consecutive blocks of 40, each containing 20 assignments to the control group, and 20 to the treatment group. If the trial is stopped early it may be possible to stop at the end of a block, in which case the sample sizes in

the two groups will be balanced. Even if it is not possible to stop at the end of a block, the maximum imbalance of sample size will be just half the block size (Shaughnessy, 2003).

3.1.3 Concealment of allocation

Successful randomisation involves two key factors:

1. the generation of an unpredictable allocation sequence, with each individual having an equal chance of allocation to either the treatment or control group, and;
2. the concealment of this sequence from investigators recruiting participants (and participants themselves) until group assignment occurs (Kunz, 2007).

This concealment of allocation helps prevent selection bias, which has been defined as "*systematic differences in the way in which individuals are accepted or rejected for a trial, or in the way in which the interventions are assigned to individuals once they have been accepted*" (Jadad, 1998 p.31). Prevention of selection bias is one of the main justifications for the use of RCT's: if a trial is truly randomised, group allocation can not be influenced by the investigators or participants. Empirical evidence has shown that trial results can be influenced if the randomisation sequence is not concealed from the investigators (Chalmers, Celano, Sacks, & Smith, 1983; Moher et al., 1998; Schulz, Chalmers, Hayes, & Altman, 1995). The Cochrane Systematic Review discussed above, (Kunz, 2007) examined over 500 trials comparing adequately and inadequately concealed allocation in RCT's, and found strong evidence that those trials with inadequate concealment tended to over-estimate treatment effects. Thus, concealment of allocation can be essential in achieving similar treatment groups, and by extension, unbiased estimates of treatment effects.

Adequately concealing the allocation sequence can be achieved by ensuring that the person who generates the allocation sequence is not the person who determines eligibility and recruits participants. Furthermore, the mechanism for treatment allocation should use people not involved in the trial (e.g. central telephone randomisation system) (Altman & Schulz, 2001). Another method of concealing the treatment allocation is avoid using a pre-specified allocation sequence when recruiting participants, so that participants are entered into the trial before their treatment allocation is determined. It

has been suggested that such '*last moment*' randomisation (Clark, 2001) is more secure than trying to hide a pre-existing allocation sequence. It may also help to overcome problems with participant refusal due to patient preference for a group allocation. For example, patients may refuse to participate in the trial if they are aware that they have been allocated to the control group, but would prefer to be in the treatment group. Randomising participants after they agree to participate, and after baseline data has been collected, may help to overcome any problems with refusal to participate due to patient preference for a treatment arm.

3.1.4 Blinding

Observation (or ascertainment) bias *"occurs when the results or conclusions of a trial are systematically distorted by knowledge of which intervention each participant is receiving"* (Jadad, 1998 p32). Such a bias can be introduced by the person administering the intervention, the person receiving the intervention, the investigator assessing outcomes, or the people writing trial reports. The best way to protect against this bias is to keep all of the different people involved in the trial (e.g. participants, healthcare providers, outcome assessors) unaware of the identity of treatment group allocation; this is called blinding or masking. Ideally, observation bias should be reduced by blinding the participants who received the intervention, the individuals who administer the intervention, and the individuals who assess outcomes. Randomised trials that have not used appropriate levels of blinding show larger treatment effects than blinded studies (Schulz et al., 1995).

In some cases, however, it is impossible, unfeasible or even unethical to use blinding or masking of all individuals involved in a trial, for instance in surgical trials or psychological interventions (Day & Altman, 2000). Nonetheless, even in cases where participants or the person delivering the intervention can not be blind to group allocation, the investigators in charge of assessing outcomes can be unaware of group allocation. Indeed, it has been argued (Day & Altman, 2000; Lewis & Warlow, 2004) that probably the most important consideration is that the person who assesses the trial outcomes is blinded to treatment allocation, particularly when the outcomes measures involve subjectivity (e.g. well-being, pain alleviation etc). However, this is less important for objective measures, such as automated laboratory tests (e.g. HbA1c).

3.1.5 Data analysis

Ideally all participants in an RCT will complete the study and provide data on all outcome measures. However, in reality there is almost always some degree of attrition in the great majority of trials, which results in missing data. Attrition in an RCT can introduce bias if there are systematic differences in the characteristics of people whose data are missing, or if participants' reasons for withdrawing from the trial are related to some aspect of the intervention. There is no specific level at which attrition related bias becomes acknowledged as a problem. However, a loss to follow-up of 5% or lower is usually considered to be of little concern, but if there is a loss of 20-25% or greater, the possibility of bias must be taken into account (Dumville, Torgerson, & Hewitt, 2006). There are some acceptable circumstances for post-randomisation exclusion of participants (Fergusson, Aaron, Guyatt, & Hebert, 2002) but such exclusions are generally ill advised (Dumville et al., 2006).

One of the only strategies that can confidently eliminate attrition bias is an 'intention-to-treat' analysis (Fergusson et al., 2002). For RCT's that test the effectiveness of an intervention, it is widely agreed that the primary analysis of data should compare patients according to the group to which they were initially randomised, regardless what happens later (e.g. whether they complete the study or not or do not comply with the treatment (Fergusson et al., 2002)). Such an analysis can be achieved by an intent-to-treat design, wherein all patients are followed until death, or the end of the trial, irrespective of whether the patient is still receiving or complying with the assigned treatment (Lachin, 2000). This represents the most cautious approach to analysis, and as such, minimises Type 1 errors (i.e. the risk of concluding that the treatment has a significant effect, when in fact it does not). Indeed, the main criticisms of the intent-to-treat principle is that the analysis is too cautious (Rubin, 1998), and for this reason many trials also conduct a 'per protocol' analysis (PPA), in which patients are analysed according to the treatment they actually received. This analysis essentially examines whether or not the intervention worked in the people who actually received it (Lachin, 2000), For example, if a patient switched from the control group to the treatment group, they are analysed as part of the treatment group. Patients who do not receive the intervention are excluded from the analysis.

3.1.6 Process evaluation and treatment fidelity

Conventionally, RCTs are concerned with evaluating the effects of an intervention on outcomes, and the key question therefore is: *"Does the intervention work?"* However, a number of authors (Audrey, Holliday, Parry-Langdon, & Campbell, 2006; Helitzer et al., 1999; Oakley, Strange, Bonell, Allen, & Stephenson, 2006) have argued that RCTs which examine complex health intervention programmes should also include an evaluation of intervention *processes*. In other words, RCT's should also ask the question: *"How does the intervention work?"* To this end, a process evaluation is often conducted in parallel to the outcome evaluation in RCTs, in order to provide detailed information on how an intervention is delivered and received (Starkey, Moore, Campbell, Sidaway, & Bloor, 2005). The main aim of process evaluation is to use information collected from process measures to establish *why* a given intervention has been a success or failure. This is particularly important in complex behaviour change interventions, (and particularly useful if the trial appears to have had no effect on outcomes) as process evaluation data can help to give a fuller understanding of the *mechanisms* of behaviour change. A process evaluation may have a broad scope of inquiry, but generally authors have particularly focused on exploring the following three aspects of process evaluation data when interpreting outcome results: implementation of the intervention; receipt of the intervention; and the setting/context for the intervention (Audrey et al., 2006; Helitzer et al., 1999; Oakley et al. 2006).

The assessment of treatment fidelity, or the extent to which an intervention was delivered or implemented in exactly the way it was intended, is a key element of process evaluation. When an intervention appears to have no impact on outcomes, fidelity checks and process evaluation data can be particularly useful in avoiding a 'Type 3 error' (Tones, 2000), that is, concluding an intervention is not effective, when the lack of effect is due to a failure of the underlying concept/theory, or because the intervention has not being delivered correctly (implementation failure). Assessing treatment fidelity in complex interventions has inherent challenges, and this is particularly the case for those that target behaviour change or psychological processes. For example, it is not always easy in such interventions to determine if interventions have been accurately delivered by providers, and received and implemented as intended by participants. In response to such challenges, the Treatment Fidelity Workgroup of the National Institutes of Health Behaviour Change Consortium, led by Albert Bellg and

colleagues (Bellg et al., 2004) developed a list of 'best practices' in treatment fidelity for behavioural change studies. These 'best practices' outline a variety of treatment fidelity strategies or methodologies that can be used when monitoring and enhancing the reliability and validity of complex behavioural interventions. Bellg et al. recommend assessing treatment fidelity across five broad areas including; treatment design; training; treatment delivery; receipt of treatment; and enactment of treatment skills (see Table 3.1, p.76). It can be seen from Table 3.1, that there is a wide variety of strategies available for assessing treatment fidelity. Bellg et al. stress that the treatment fidelity needs for each individual study may be very different, and as such, the selection of the components of the treatment fidelity plan should be 'tailored' to each intervention, based of its underlying theoretical and clinical framework. The treatment fidelity strategies selected for use in this study are detailed in the next chapter.

3.1.7 The role of qualitative methods

It has been noted that there are inherent methodological difficulties in implementing process evaluation in RCTs, particularly in maintaining a distinction between activities that are part of the intervention, and activities that are part of the process evaluation (Audrey et al. 2006). However, the general consensus among authors seems to be that a 'triangulation' of information from both qualitative and quantitative sources provides the strongest evidence for process evaluation (Helitzer et al., 1999; Oakley et al. 2006). Triangulation refers to the method whereby results from two data sources are compared and examined to develop, or corroborate, an overall interpretation of study findings (Mays & Pope, 2000). Qualitative methods are increasingly being "mixed" with quantitative methods in all areas of research , and there has been a particularly marked increased in the use of qualitative methods in RCTs (Bryman, 2006). Qualitative methods can be used at all stages of an RCT: from pre-trial (e.g. to inform the design of the trial and development of the intervention); to the trial itself (e.g. by collecting data to assess treatment fidelity); to post-trial (e.g. by using process evaluation data to aid in the interpretation of results). Qualitative methodologies are especially useful as strategies for assessing process evaluation and treatment fidelity in RCTs. As is evident from Table 3.1, a variety of qualitative methods can be used (and have been used) to collect process evaluation data and to assess treatment fidelity, including; focus groups, open-ended individual interviews, participant diaries and evaluations, field notes, and researcher observations (Audrey et al. 2006; Helitzer et al, 1999; Oakley et al., 2006).

Table 3.1

Treatment fidelity strategies

Area	Goal	Suggested Strategies
Treatment design	Ensure equivalent doses within & across conditions	Sessions of fixed length, number & frequency; record protocol deviations; intervention manual; externally monitor sessions; have provider keep session log/notes; specialised training
Training procedures	Standardised training	Standardised training manuals; intervention with pilot participants.
	Ensure skill acquisition & minimise 'drift' in skills	Assess adherence to manual; booster' training sessions; in vivo observations; supervision sessions; interventionist complete field note reports; patient interviews.
Delivery of treatment	Reduce within-treatment differences	Intervention manual; supervisors rate audio/videotapes
	Ensure adherence to treatment protocol	Assess participants' perceptions of intervention e.g. qualitative exit interview; monitor participant complaints; audio/video tape encounters; have interventionist complete log after sessions.
	Minimise contamination between treatment groups	Randomise sites; patient exit interviews; specific training
Receipt of treatment	Ensure participant comprehension	Pre & post-test questionnaires; interviews with participants; interventionist monitors sessions
	Ensure participant ability to use cognitive & behavioural skills	Interviews with participants; assess cognitive skills; observe participants; use behavioural outcomes measures; monitor behavioural adherence (e.g. diary); follow-up telephone contacts.
Enactment of treatment skills in real life settings	Ensure participant use of cognitive & behavioural skills	Use of process measures; assess with questionnaires; exit interviews with participants; use goal sheets/action plans; record telephone contacts; assess mediating process; measure objective or biological markers; maintain contact e.g. follow-up telephone calls; exit interviews

Thus, the increased popularity of including qualitative components in RCTs is not surprising, as qualitative methods may be beneficial to RCTs in a number of ways, including: improving the quality of the RCT by enhancing and assessing treatment fidelity; enhancing the explanatory power of the RCT by providing information on the processes of the trial; and finally, by helping researchers to understand participants' own experience of taking part in the RCT. The qualitative methods implemented as part of the process evaluation in this trial are detailed in the next chapter.

3.1.8 Quality and reporting of randomised controlled trials

It is desirable when conducting RCTs to be able to accurately assess whether any observed treatment effects are attributable to interventions. Therefore, trials must be adequately powered, piloted, checked for fidelity (i.e. that the intervention was delivered properly), and evaluated with regard to pre-specified primary and secondary outcomes, using intention to treat analysis (Davidson et al., 2003). The CONSORT guidelines (Consolidated Standards of Reporting Trials, were developed to facilitate the uniform reporting of RCT results, and allow readers to determine efficiently whether sources of bias threaten internal and external validity. The statement specifies a checklist of 22 items critical for detailed reporting of RCTs (see Appendix B for the CONSORT checklist for this study). Given that RCTs of complex interventions have several unique design characteristics, there are a number of proposed additions to the CONSORT guidelines when applying them to behavioural interventions (Davidson et al., 2003). These include details of the training and supervision of treatment providers, details of patient/provider treatment preference, and details of treatment delivery and treatment adherence. A precise description of the intervention provided to each group is also highlighted as essential. This includes detailing the treatment provided to the control group which, if it is 'usual care' includes specifying the therapeutic elements of such care. At a minimum, descriptions of the intervention treatment should provide details of: content; provider; format; setting; recipient; intensity; duration and fidelity. Treatments or interventions that meet the highest standards of evidence will offer access to written manuals detailing the intervention (Davidson et al., 2003), so that it may be effectively replicated by others (see Appendix C for the intervention manual for this trial).

3.2 RCTS IN HEALTH PSYCHOLOGY

The RCT has not been readily adopted in the field of health psychology (Michie & Abraham, 2004; Stephenson & Imrie, 1998; Yardley & Moss-Morris, 2007). For example, a brief literature search of the three main health psychology journals identified only 20 RCT's published within the 10 period from 1997-2007 (White, Keogh, Smith, 2007). Despite this, there is a growing recognition of the pressing need for more experimental research in health psychology, and in particular, high-quality RCTs that assess behavioural interventions (Michie & Abraham, 2004; Yardley & Moss-Morris, 2007). The impetus behind this move is the recognition that RCTs are essential in order to establish if interventions in health psychology actually work, and if they do work, who do they work for, how do they work, and why do they work? Establishing an evidence base of effective behaviour change interventions is critical for the advancement of health psychologists as practitioners, and also for the future credibility of the discipline.

However, it has been argued that progress in the science of behaviour change is impeded because many health psychology interventions fall short of best practice in research (Dombrowski et al., 2007). These interventions are often characterised by non-randomised interventions, a lack of comparison groups, poor methodological quality, and poor standard of reporting. Consequently it has been suggested (Dombrowski et al., 2007; Michie & Abraham, 2004) that in order to address these limitations the methodological principles and guidelines used in medical trials should be applied to health psychology interventions. Hence, it is important that trials should have adequate statistical power; are piloted and checked for fidelity; are based on interventions that are described in detail; include groups that are randomly allocated and assessed pre and post intervention; and evaluate data with regard to pre-specified primary and secondary outcomes using intention-to-treat analysis.. Framing interventions studies around existing publication guidelines for medical trials has also been recommended (Yardley & Moss-Morris, 2007), as this may help increase credibility. Thus, when developing, designing and writing-up intervention studies it is recommended (Yardley & Moss-Morris, 2007) that the CONSORT guidelines for RCT publications are followed, (discussed in section 3.18 above), as well as the Medical Research Council guidelines (Campbell et al., 2007) for developing complex interventions (discussed in section 3.3. below).

The drive to establish a credible evidence base in health psychology should be based not only on high quality RCTs, but also on developing interventions that are based on empirically-supported theories (Michie et al., 2008). This is key, because as Moss-Morris and colleagues write: "*In order to enhance our credibility within the field of health and medicine we need to show that our theories can be translated into practice and that theory based practice has the potential to both prevent health problems and improves the lives of those who are ill*" (Moss-Morris & Yardley, 2008, p. 3-4). There are three main reasons for advocating the use of theory in designing interventions (Michie et al., 2008). Firstly, interventions are likely to be more effective if they target causal determinants of behaviour and behaviour change; this requires an understanding of these causal determinants (i.e. the mechanisms of change provided by theories). When behaviour change interventions are theory-based, the RCT design facilitates an experimental investigation of how the active components of an intervention (e.g. behaviour change techniques, forms of delivery and target populations) affect outcomes. Secondly, theories can be developed and tested only if interventions are theoretically informed. Thus, ensuring that interventions are theory-based also provides an important means of testing the relationships predicted by theoretical models, thereby permitting an investigation of the validity of the models themselves (Yardley & Moss-Morris, 2007). Finally, atheoretical interventions do not build on the existing knowledge base, they have limited generalisiabitiy, and their effectiveness may be minimised, as they are designed and developed from implicit theories which often fail to include psychological processes critical to successful behaviour change (Michie & Abraham, 2004).

3.3 DESIGNING AND EVALUATING COMPLEX INTERVENTIONS

RCTs have long been established as the most reliable method of evaluating the effectiveness of single component interventions (e.g. drug trials). However, the RCT is increasingly being applied to the rigorous evaluation of more complex interventions (Stephenson & Imrie, 1998). Complex interventions are defined as those that are "*built from a number of components, which may act both independently and interdependently*" (Campbell et al., 2007 p. 455). Campbell and colleagues (2000) provide a useful example of a trial to assess the effects of a specialist stroke unit. Such a trial would need to consider the influence of a large number of factors including; drugs; treatment guidelines; the expertise of the various healthcare professionals; arrangements for

discharge and follow-up; and differences between stroke units (e.g. organisation etc). The trial may also have a large number of outcomes measures including: mortality; levels of morbidity; quality of life; patient satisfaction; and patient well-being. Examples of other complex interventions include community based programmes to prevent heart disease, school-based educational programmes to reduce teenage pregnancy, peer support interventions for those with diabetes, and so on. Behavioural and psychosocial interventions (e.g. group psychotherapies, cognitive behavioural therapy for depression, health promotion interventions to support dietary change) are usually regarded as complex interventions, due to the multiple elements they often contain.

Particular difficulties arise when developing, documenting, and evaluating interventions with such multiple elements. Each component needs to be identified, measured and evaluated to determine its effectiveness, both independently, and in combination with the other elements of the intervention. In response to such difficulties The Medical Research Council (MRC) (Campbell et al., 2000) developed a framework detailing a stepwise approach to the development and evaluation of RCT for complex interventions (see Figure 3.1). Initially, the MRC conceptualised this approach as consisting of four distinct phases, which may be seen as sequential, or more iterative in nature. Phase 0, the 'preclinical phase', involves identifying the existing evidence and reviewing the theoretical basis. Phase I is 'modelling', which refers to defining the active components of the intervention, specifying how the intervention works, and identifying potential barriers. This phase often involves the use of qualitative testing, focus groups, preliminary surveys and descriptive studies. In essence, modelling involves hypothesising and testing both *what* to target (e.g. behavioural determinants) and *how* to do this (e.g. behaviour change techniques). Phase II involves an 'exploratory trial', (essentially a pilot study) in which the trial and intervention design can be defined, optimum interventions and study design can be developed, and the feasibility and acceptability of the study can be tested. Phase III is the 'definitive RCT', while phase IV involves examining the 'long-term implementation' of the results of the trial into practice.

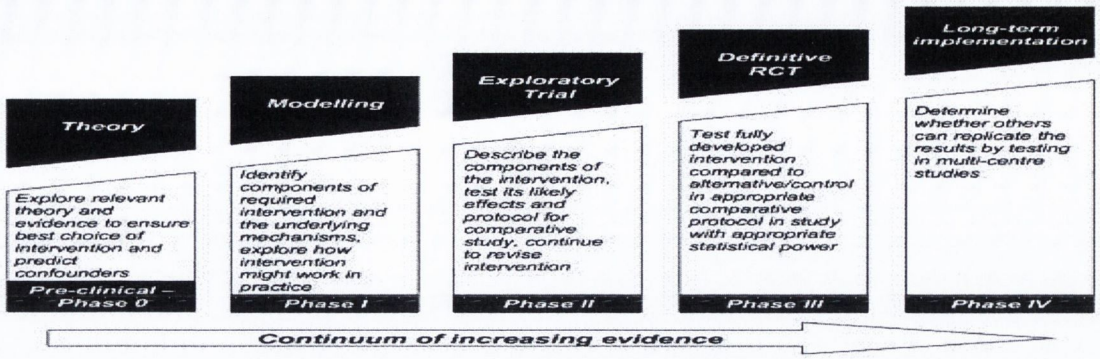

Figure 3.1: *MRC Framework for developing RCTs of complex interventions*

While this framework has been hugely influential since its initial development, the MRC have acknowledged that there are differences in how the approach works in theory and in practice. As a result the MRC have recently redeveloped the framework (Campbell et al., 2007), by drawing on *'lessons learnt'* in trials that have implemented their approach. In practice, when developing complex interventions, it has been found to be more helpful to combine the preliminary phases (0-II) of the framework. According to this updated MRC approach, the three crucial starting points for developing credible complex interventions involve: defining and understanding the problem and its context; developing and understanding the intervention; and developing and optimising the evaluation (see Figure 3.2). However, these three processes can occur in parallel, unlike the stepwise approach proposed in the initial framework.

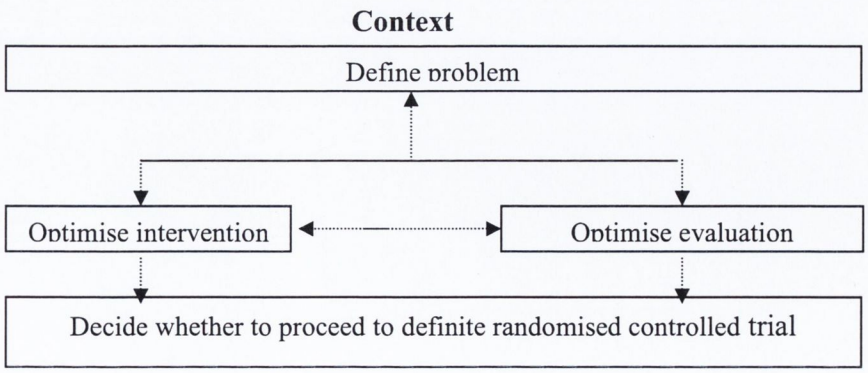

Figure 3.2: *Relation between context, problem definition, intervention, and evaluation for complex interventions (Campbell et al., 2007)*

While the MRC guidelines provide useful strategies for the development of complex interventions, it has been argued that the framework provides little guidance on how to progress through the early stages of intervention development (Hardeman et al., 2005) (Michie et al., 2008). Specifically, little reference is made to how the theory-base is used to select appropriate intervention techniques. This is a particular problem for health psychology interventions that target behaviour change, given the wide variety of behaviour change techniques (BCT) that are currently available (see section 2.6.2). In response to these difficulties, Hardeman and colleagues (Hardeman et al., 2005) developed a 'causal modelling' approach (see Figure 3.3) for mapping theoretical constructs to BCTs.

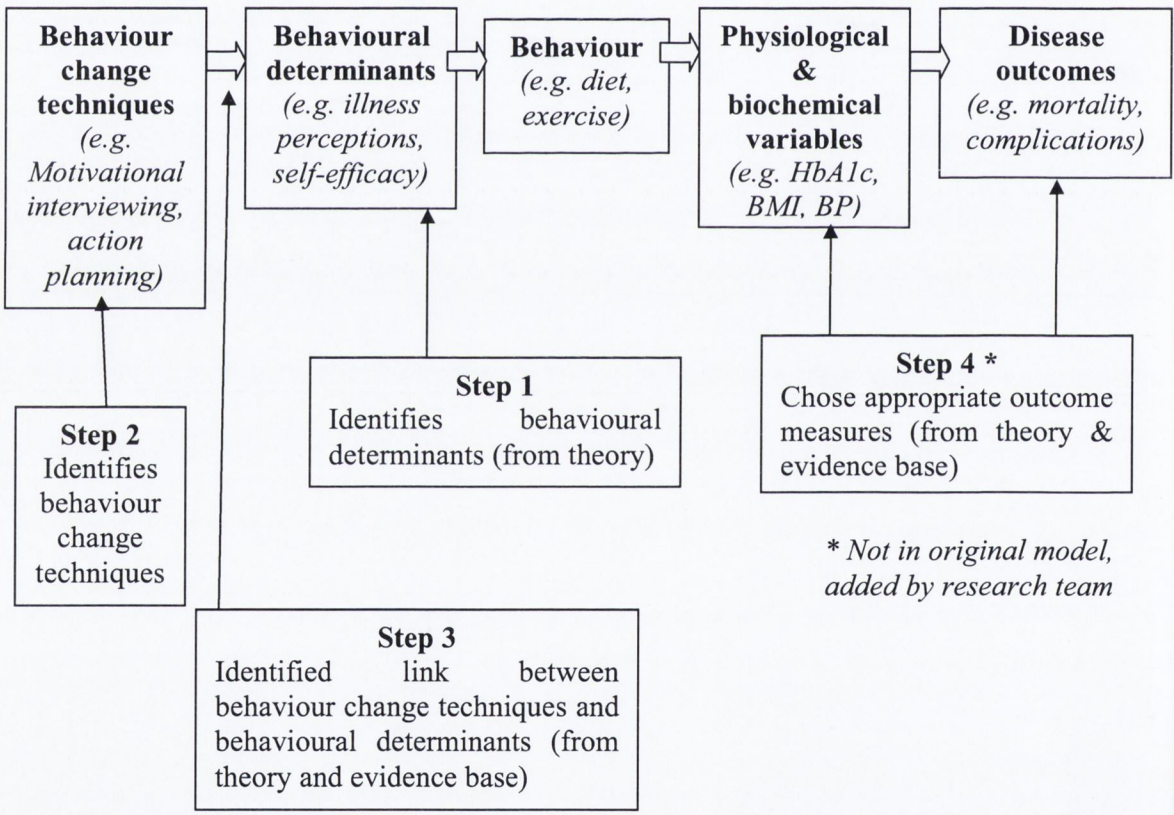

Figure 3.3: *Framework for causal modelling approach to develop psycho-behavioural interventions: with behaviour change techniques* (Hardeman et al., 2005; Miche et al, 2008)

The causal modelling approach proposed by Hardeman and colleagues may be used in conjunction with the MRC framework for developing complex interventions. It highlights, in particular, how theory and evidence can be used to guide the selection of appropriate behavioural determinants, intervention points, and BCTs. Effective mapping requires intervention developers to: (1) address the range of theoretical frameworks available; (2) specify the range of techniques available to change the determinants of behaviour; and (3) select relevant techniques to map on to differing determinants (Michie et al., 2008). It could also be argued that a fourth step should be included in this model; specifying appropriate outcome measures, and how relevant behaviours impact on these.

The next chapter presents the methods for this trial, which highlights how the methodological issues discussed above (e.g. complex intervention development, RCT design issues, process evaluation etc) are applicable for this trial.

4 METHOD

This chapter outlines the methods used in this RCT. It begins with a discussion of the development of the intervention under consideration, followed by a description of the intervention itself. The various other elements of the RCT are then considered. These include; participants and settings; primary and secondary outcomes measures; and procedures of implementing the RCT. The methods and procedures involved in the process evaluation component of the RCT are also discussed. The chapter concludes by outlining the methods of analysis for both quantitative and qualitative data.

4.1 INTERVENTION DEVELOPMENT FOR THE CURRENT TRIAL

4.1.1 Phase 0 -I: Theory and modelling

The MRC Framework and the causal modelling approach referred to in the previous chapter were used as the basis for developing the intervention that was used in the present study. The methods used in developing the intervention are summarized in Table 4.1 (p.85). Evidence from epidemiological studies was used to inform the selection of appropriate health outcomes, participants and target behaviours. Evidence from health psychology was also used to inform the selection of participants, as well as the theory-based determinants of behaviour, appropriate intervention points and behaviour change techniques.

4.1.2 Phase II: Exploratory Trial

The intervention was piloted prior to commencement of the RCT, in order to test the feasibility of the measures and overall approach as well as to provide the interventionist with training and experience in intervention delivery. No changes were made to the intervention itself as a result of the pilot study, although it was decided that participants would be recruited from an additional weekly diabetes clinic to ensure a sufficient sample size would be achieved in the definitive RCT. Participants for the pilot study were recruited over a five-week period in the summer of 2006. Recruitment for the pilot study

Table 4.1

Methods used in the development of the intervention in this study

MRC Phase	General method	Area selected	Methods used
Phase 0: Pre-clinical Theory *Explore relevant theory and evidence to ensure best choice of intervention and to predict confounders*	• Defining the health outcome and its importance	• Type 2 diabetes	• Review of the evidence of type 2 diabetes: burden of disease, clinical and psychological consequences
	• Defining the target population	• Patients with poorly controlled type 2 diabetes & their families	• Review of epidemiological evidence of complications associated with poor control. Focus groups with patients (good & poor control) & families
	• Specifying theory-based determinants of behaviours	• Illness perceptions	• Review of the literature on illness perceptions
		• Diabetes self-care and family support	• Review of epidemiological evidence of self-care in type 2 diabetes & family support
	• Specifying physiological and biochemical variables	• HbA1c, BMI, blood pressure	• Review of epidemiological evidence. Expert meeting with clinicians
Phase 1: Modelling *Identify components of required intervention and the underlying mechanisms, explore how intervention might work in practice.*	• Specifying intervention points	• Patient and family members' own perceptions of diabetes. Degree of similarity of models.	• Informed by selected theory. Expert meetings with health psychologists and clinicians. Focus groups and quantitative study with people with diabetes (good and poor control) and family members
	• Specifying behaviour change techniques	• Motivational interviewing	• Underlying theory. Techniques used in similar interventions. Systematic reviews

was from six clinics in the Diabetes Centre in the Adelaide and Meath Hospitals, incorporating the National Childrens' Hospital (AMNCH), a large suburban teaching hospital in Dublin (this setting is described in further detail in section 4.3) Eligible patients (n=45) were identified from 159 patients attending the clinics. Fourteen patients did not attend the clinic, whilst two eligible patients were missed by the researcher, who was completing questionnaires with other participants. The remaining 29 eligible patients were asked to participate in the study. Seventeen patients declined, and 12 agreed to take part. It was decided by the research team that a sample size of 12 would be sufficient for the pilot study, as it represented 10% of the total sample size (n=122) for the definitive RCT (based on an apriori power calculation, see section 4.3). Pilot participants were divided into intervention and control conditions; six in the intervention and six in the control. Pilot participants were not recalled for follow-up, as due to the small numbers participating, no analysis would be performed on the data.

4.2 INTERVENTION

4.2.1 Phase 3: Definitive RCT

The intervention was designed to identify and change any inaccurate and/or negative illness perceptions which the patient or family member may have, and examine how they influenced self-management behaviours. The next step was to improve the degree of congruence of patient and family member perceptions, in a positive direction, and following on from this, to develop a personalised action plan for improving diabetes management and control. The intervention consisted of three sessions delivered on a weekly basis. The first two took place in the patient's home with their family member, whilst the last was a follow-up telephone call with the person with diabetes only. It was planned that each home visit would last approximately 40 minutes. A detailed description of the content of each intervention session and the techniques used can be found in the intervention manual which was developed for the study (See Appendix C). However, a brief overview of the content for each session is presented below.

4.2.1.1 Session 1

This session was delivered in participants' home, with the patient and their family member. During session one, a brief explanation of the terminology and pathophysiology of diabetes was provided. This was based on both the patient and family member's own level of understanding of diabetes, which was identified from scores on the Brief Illness Perception Questionnaire (BRIEF-IPQ, see section 4.4.1.2 for further details). Common symptoms associated with poor control were discussed, often as a result of talking about how and when patients were initially diagnosed with diabetes. For example, symptoms at initial diagnosis due to high blood sugars (extreme tiredness, thirst, polyuria etc) were linked to present similar symptoms of poor control. This session also began to examine the causes, consequences and timeline that the patient and family members attributed to diabetes, whilst also aiming to broaden causal models to include risk factors not previously considered (e.g. lifestyle factors). Both patients and family members often reported being aware of, and being concerned about, the complications associated with diabetes such as blindness, amputations, and kidney problems. This gave the therapist an opportunity to discuss the importance of good control in reducing the risk of future complications.

4.2.1.2 Session 2

This second session was also delivered in participants' home, with the patient and their family member. This session continued with a discussion of the causes, consequences and timeline factors that had been previously identified (e.g. dispelling myths of the causes of diabetes). Initial efforts were made to improve the patient's sense of personal control and self-efficacy (confidence), and to find future ways of improving their management of their diabetes. Patients beliefs about the controllability of their diabetes were used to develop a written personalized action plan (see Appendix D). This plan was developed by identifying areas of diabetes management that *could* be controlled and improved.

4.2.1.3 Session 3

This session was a follow-up telephone call, with the patient only. The third and final

session involved a review of the action plan developed in the previous session, and a discussion of potential barriers to the proposed changes. The plan was then amended if necessary, in order to address for example, whether or not certain aspects were/were not working, or to amend goals had been overly ambitious. Any further concerns about symptoms, consequences and lifestyle changes were also explored.

4.2.2 Intervention techniques

The intervention was delivered by a health psychologist (i.e. the author/researcher), using techniques from the taxonomy of health psychology intervention techniques (S. Michie, Johnston, M., Francis, J., Hardeman, W., Eccles, M, 2008), in combination with Adapted Motivational Interviewing techniques (Miller & Rollnick, 2002; Rollnick, 1999). Precise details of techniques used are provided in the intervention manual in Appendix 4. Prior to the commencement of the intervention, the interventionist completed 16 hours of MI training with a certified trainer from the *"The International Network Of Motivational Interviewing Trainers"*. A systematic review of MI studies found that 15 hours (range 2 - 31 hours) is the average number of training hours provided to MI interventionists (Dunn, Deroo, & Rivara, 2001).

4.2.3 Components of the intervention

The intervention was complex, with a number of interacting active components. These included:

1. Changing the cognitions/perceptions of patients
2. Changing the cognitions/perceptions of family members
3. Improving the degree of similarity between patient and family member perceptions
4. Facilitating change in self-management behaviours (e.g. diet, exercise etc)
5. Improving family-support for diabetes management
6. Employing motivational interviewing techniques to change behavioural determinants (perceptions) and behaviours
7. Delivering the intervention in the home environment

4.2.4 Usual Care for the control group

As indicated in the following section 4.3, participants for this study were recruited from the type 2 diabetes clinic at the Diabetes Centre of the Adelaide & Meath incorporating the National Children's Hospital (AMNCH). The 'usual' care for patients attending these clinics varied depending on their individual patient needs and circumstances. However, in the traditional hospital-led approach to diabetes management it is standard practice for all patients attending the diabetes clinics to consult with a diabetologist at least once a year, if not more often. The CODEIRE study (Nolan et al., 2006), which examined resource utilisation data from four hospital diabetes centres in Ireland in 1999/200, showed that on average patients had 2.3 visits to the diabetes clinic per year, with the authors noting that typically patients attended at regular six-month intervals. However, data for the CODEIRE study was collected in 1999/2000, and currently in the diabetes clinic in AMNCH patients (even those in poor control of their diabetes) are usually scheduled to return to the clinic at either 12-18 month intervals, depending on when the next free appointment is available. In discussion with clinic staff, it emerged that this increase in appointment intervals is believed to be due to the increasing number of patients attending the clinic, and is occurring in all Irish diabetes centres due to the rising prevalence of type 2 diabetes. In some cases patients were given appointments at earlier intervals (e.g. three or six months). This usually happened, for example, if a doctor was particularly concerned about a certain patient, or if a patient's diabetes was very poorly controlled, or in cases where patients were transitioning from oral medication to insulin, or if patients were newly diagnosed.

Many poorly controlled patients also often meet with the diabetes nurse specialist (DNS) at their appointment, although this may not always occur as it depends on the workload of the DNS. The DNS may also review diabetes management with the patient, and discuss any practical concerns or problems that patients may be experiencing with the treatment, (e.g. using the blood glucose meter, injecting insulin, specific questions about diet and so on) Patients may also telephone the diabetes nurse specialist in the diabetes day centre between outpatient appointments, if they have particular concerns. Some patients may attend nurse-led clinics in the diabetes day centre, whilst some may have appointments

with the dietician, podiatrist or ophthalmologist. Patients may also still attend their GP between hospital appointments, although there is some debate as to how often patients access their GP in relation to their diabetes (Smith & O'Dowd, 2007). The CODEIRE study (Nolan et al. 2006) suggested that patients attending hospital diabetes centres had on average 0.23 GP visits per year. However, research from studies based in general practice settings (e.g. DiSC, Smith et al., 2004; SIC, Jennings, 2007) indicate much higher rates of GP attendance than those documented in the CODEIRE study; at between 4.5 to six GP visits per year on average. However, the CODEIRE study was based on patient self-report of GP visits, as opposed to examining general practice records.

4.3 PARTICIPANTS AND SETTINGS

As discussed in a previous chapter (section 2.3.3.2.) there is a tradition in Ireland of referring all patients with diabetes to specialist hospital based care. The last decade has seen a move towards increased primary care management of type 2 diabetes, however a large proportion of patients still attend hospital clinics for specialist out-patient care. This is particularly the case in urban and suburban areas, and particularly if patients' diabetes is persistently poorly controlled (DSDG, 2002; NDWG, 2006; Watkins, 2003). After consulting with local GPs in the area, it emerged that in would not be possible to recruit a sufficient number of eligible patients from primary care within the time scale of the trial. This was due to the high number of general practice surgeries that would need to have been accessed. For example, data from a large scale RCT of a peer support intervention currently being delivered in primary care centres in Leinster (Paul et al., 2007), indicates that out of 20 GP surgeries, only 18% of type 2 diabetes patients (77/412) would have met the eligibility criteria for this RCT (HbA1c >8.0%).

The possibility of including patients from both GP surgeries and the hospital clinic, (i.e. having two arms to the RCT) was also considered. However, discussions with a biostatistician indicated that control conditions in the primary and specialist care arms would not be comparable, and again, there was the problem of recruiting a sufficient number of poorly controlled patients to the primary care arm. While it must be kept in mind that the sample is not representative of other patient groups (e.g. those attending

private clinics, those whose diabetes is managed solely in primary care, or those who receive no care, or have defaulted from care) there is a large degree of overlap between the patient base in primary and specialist care. For example, the DiSC study in North Dublin (Smith et al., 2001) found that only about one quarter of patients with type 2 diabetes receive diabetes care solely in the general practice setting, and the majority of these patients were patients who defaulted from specialist care. As mentioned above, this is due to the fact that in Ireland, particularly in urban areas, GPs still refer the majority of patients with persistently poorly controlled type 2 diabetes to specialist hospital clinics, and it is in this setting where patients' diabetes care is then predominantly managed.

Thus, in order to recruit a sufficiently large sample of patients with poorly controlled diabetes, participants were recruited from specialist outpatient type 2 diabetes clinics. These clinics are run at the diabetes centre of AMNCH, a large suburban teaching hospital in Dublin. The diabetes centre provides outpatient care to adults with diabetes in west Dublin and surrounding areas. The total population of the patients with type 2 diabetes attending the centre is approximately 4000. Through the centre patients have access to medical and nursing support, as well as services provided by dieticians, ophthalmologists and podiatrists. Outpatient clinics for patients with type 2 diabetes run one to three days a week, with eight to ten clinics being run a month. On average, between 30 and 50 patients attend each clinic. As discussed in the section (4.2.4) on usual care, patients return to the clinic at six, nine, twelve or eighteen month intervals, depending on their individual needs.

Participants were recruited from 80 type 2 diabetes hospital outpatient clinics, between the 17 October 2006 and the 10 January 2008. Clinics were held twice weekly, and on average between 30 and 50 patients were scheduled to attend each clinic. The number of eligible patients varied by clinic; from a minimum of 0, to a maximum of 14. The average number of eligible patients per clinic was 4. Prior to each clinic, eligible patients scheduled to attend for appointments were identified from DIAMOND, the hospital computer database. Participants returned to the clinic for follow-up data collection at

approximately 6 months post-intervention. As indicated earlier, the intervention itself was delivered in the community, in participants homes.

4.3.1 Patient selection criteria

In order to identify potentially eligible participants, it was first necessary to examine the medical records of all patients on the outpatient list for each diabetes clinic. This was carried out, prior to each clinic, by using the auditing facility of DIAMOND. DIAMOND is the diabetes hospital database which holds relevant demographic and medical details for diabetes outpatients (n≈7000). Patients were included in the study if:

- They had type 2 diabetes for more than 1 year
- Were over 18 years of age
- At least two out of their last three HbA1c readings were 8.0% or over
- Had fluency in spoken English
- Were physically well enough to take part
- Were able to give informed consent
- Were residing in their home environment
- Had a family member available to take part (see 2.4.3)

The last three HbA1c readings were examined in order to identify patients who had continuing difficulty in controlling their diabetes, as opposed to those with a 'once-off' high HbA1c result, due to, for example, problems with medication or illness. Persistent poor control was defined as occurring when two out of three of the last three HbA1c readings were 8.0% or over. A HbA1C reading of ≥8% is a recognised value for poor metabolic control (Stratton et al., 2000).

Patients were excluded from the study if:

- They were not physically able to participate (e.g. those with a life-threatening physical illness such as cancer or renal failure, or those with auditory or speech impairments.)
- They had a severe and enduring mental disorder which would impact upon their capacity to participate in the intervention, (e.g. dementia, schizophrenia) as

determined by the patient's clinician.

- They were not responsible for their own care, or did not reside in their home environment, (e.g. those in care homes, prison, in-patient wards).
- They had taken part in the pilot study, or a previous related-study (White et al., 2001-2004) conducted in the same diabetes clinic.

The number of patients eligible for inclusion in the study varied from 0-10 across individual clinics. Previous experience of conducting research in the diabetes clinic (White et al., 2001-2004) indicated that recruitment is maximised when attempts are made to include as many eligible patients as possible. However, within the context of the current study, there was only a single researcher and inevitably, this meant that a number of eligible patients were missed by the researcher and not recruited. This happened, for example, when the patient had come and gone while the researcher was with another participant, or when the patient was unavailable to speak to the researcher because he/she was with one of the other healthcare professionals at the clinic (e.g. the diabetes nurse specialist, the dietician, podiatrist etc). A record of 'missed' patients was maintained throughout the recruitment period, in order that later comparisons could be made between this group and their participating counterparts

4.3.2 Family member recruitment

Patients were only eligible to take part in the trial if they had a family member who was also available and willing to participate. Participants were asked to nominate the most appropriate family member. However, participants were advised that it would likely be more beneficial to nominate the family member who was most involved in helping them manage their diabetes. For the purposes of this study a family member was defined as any relative in regular contact with the person with diabetes (but who was not required to be living with them), and who was most involved in supporting that person in the management of their illness. As most people with diabetes manage their illness themselves, the family member for this study was *not* a carer per se, but someone with whom the person with diabetes had a close relationship, including a spouse/partner; parent; grandparent; child; grandchild; siblings; or other family members.

Family members were included if they were:

- Over 18 years of age
- Had no medical history of type 1 or type 2 diabetes
- Were able to participate in the study (as judged by their participating family member with type 2 diabetes).

4.3.3 Sample Size

The patient measures that were used in this study are described in the next section (4.4). For purposes of identifying the ideal sample size, a power analysis based on HbA1c and Diabetes Well-being as the primary outcomes (section 4.4.1), identified a total sample size of 76 and 86 respectively. This employed 80% power to detect a significant *absolute* change of 0.9% in glycaemic control (this absolute change has been related to clinical outcomes in the UK prospective diabetes study, (UKPDS 38, 1998) and of 3 points in the Diabetes Well-being Scale-12. These calculations allowed for an anticipated 'Hawthorn effect' (Landsberger, 1985) relating to an improvement of 20% for those in the control group, by virtue of the fact that they are participating in the research. Thus, it was calculated on the basis of the larger number of 86 participants (43 in intervention and 43 in control group), that a final total number of 122 participants (61 in each group) would be required to ensure at least a 70% final response rate was met.

4.4 PATIENT MEASURES

4.4.1 Primary Outcomes for person with type 2 diabetes

4.4.1.1 HbA1c

Glycaemic control at baseline and six months follow up was assessed using the HbA1c test, or haemoglobin A1c test. HbA1c has become the gold standard by which to judge the effectiveness of glycaemic control in patients with diabetes mellitus (Jeffcoate, 2003). Measuring the levels of HbA1c in the blood gives an indication on how high blood glucose has been over the last 8-12 weeks. The accepted normal non-diabetic HbA1c range is approximately 4.0-6.0% (ADA, 2007; IDF, 2005). As discussed in chapter two

(see section 2.3.1.), the recommended optimal HbA1c target for patients with type 2 diabetes varies slightly from between 6.5% or less (IDF, 2005) to 7% or less (ADA, 2007). HbA1c levels exceeding 8% are generally recognised as indicating poor glycaemic control, requiring more active management.

There is no valid international standard for HbA1c for all types of assays, as there is for insulin for example (Jeffcoate, 2003). However, the HbA1c assay method used in both the DCCT (DCCT, 1987) and the UKPDS (UKPDS 38, 1998) has become the most widely used reference method, with the vast majority of laboratories now reporting HbA1c results that are 'DCCT/UKPDS' aligned. For this study, all HbA1c assays were assessed by the single hospital laboratory in AMNCH, which is DCCT/UKPDS compliant. HbA1c was assayed using reversed-phase cation exchange liquid chromatography, using an ADAMS A1c HA-8160 Automatic Glyco-Haemoglobin Analyser.

4.4.1.2 Brief Illness Perceptions Questionnaire (BRIEF-IPQ)

Participants' perceptions about their diabetes were assessed using the *Brief-Illness Perception Questionnaire* (BRIEF-IPQ) (Broadbent, Petrie, Main, & Weinman, 2006) (see Appendix E). The BRIEF-IPQ was specifically developed to measure illness perceptions across the five broad dimensions outlined in Leventhal's Self-Regulatory Model. As described earlier in Chapter Two these include: *consequences, timeline, identity, cure/control,* and *causes*. The measure also assesses *emotional representations* connected to the illness, as outlined in the emotional processing component of the model, along with *illness comprehension*. The most general version of the BRIEF-IPQ uses the word "illness", but this can be replaced with the name of a particular illness e.g. diabetes, asthma, etc. The BRIEF-IPQ was developed from the much longer 80-item *Illness Perception Questionnaire-Revised* (IPQ-R) (Moss-Morris et al., 2002). However, it has been argued (Broadbent, Petrie, Main, & Weinman, 2006) that the shorter and simpler BRIEF-IPQ may be beneficial in situations where time is limited, particularly when illness perceptions are measured as part of a larger set of psychological constructs, as was

the case in the current study. A much shorter measure is particularly useful when dealing with very ill or elderly patients who may find the longer IPQ-R burdensome.

The BRIEF-IPQ has nine items. Items one to eight are rated using a 0-to-10 response scale to assess the eight illness dimensions of: consequences; timeline; personal control; treatment control; symptoms (identity); concern; understanding (coherence); and emotional distress. The last item assesses beliefs about the causes of diabetes using an open-ended response format, which asks respondents to list the three most important factors that they believed caused their illness. The Brief-IPQ has been found to be a valid and reliable measure of illness perceptions, and offers the advantages of brevity, speed of completion, and easy interpretation. These were key deciding factors in its selection as a measure of beliefs about diabetes. Other similar measures include the *Personal Models of Diabetes Interview* and *Personal Models of Diabetes Questionnaire* (Glasgow et al., 1997; Hampson et al., 1995). However, as previously discussed (section 2.5.6.), there are some problems with the Personal Models of Diabetes approach so these tools were not used in the present study.

The psychometric properties of the BRIEF-IPQ have been evaluated using data from a sample of six illness groups, including patients with type 2 diabetes (n=119). Pearson's correlations showed that items had adequate test-retest reliability, ranging from 0.42 to 0.75. The BRIEF-IPQ showed good concurrent validity with relevant measures, with moderate to strong correlations between items on the BRIEF-IPQ and equivalent scales on the IPQ-R. The measure also shows good predictive validity in patients recovering from myocardial infarction, with items being related to mental and physical functioning at three month's follow-up. Thus, evidence shows that the BRIEF-IPQ has good validity and reliability across a variety of illness groups. Intervention research has also shown the measure to be sensitive to changes over time (Petrie et al., 2002.). One possible disadvantage of the BRIEF-IPQ is that cyclical timeline beliefs are not assessed, nor does it provide a detailed insight into the specific symptoms which a person may associate with their illness.

4.4.1.3 Well-being

Psychological well-being was assessed for all participants using the 12 item Well-Being Questionnaire (W-BQ 12) (Bradley, 2000). The W-BQ12 (see Appendix F) consists of 12 items assessing cognitive symptoms of mood states. This measure was chosen in preference to other similar measures (e.g. the Hospital Anxiety and Depression Scale, or the General Health Questionnaire) as it has been widely used in the diabetes literature, and the research team also had previous experience of using the measure, thereby facilitating comparisons with previous work. In addition, the WBQ was initially developed in a sample of patients with diabetes and in the development of the questionnaire, items concerning somatic states (e.g. fatigue, loss of appetite, decreased libido) were explicitly excluded. This is important to consider when measuring psychological well-being in a population with chronic illness. While somatic symptoms may often be physical indicators of psychological distress, there is the risk that somatic symptoms, such as fatigue and loss of appetite, in populations with chronic illnesses, may be due to the underlying physical condition, rather than any psychological dysfunction.

Items on the W-BQ12 are scored from 0-3 on a likert scoring scale. The measure comprises three separate four-item subscales, which assess positive well-being, negative well-being and energy. Higher scores on each scale indicate higher levels of the corresponding construct. The three scales are then combined (after reversing the negative well-being scale) to produce an overall general well-being score, with higher scores indicating a greater sense of well-being.

A large multinational clinical trial with patients with diabetes (n=2282) showed that the W-BQ12 has excellent reliability and validity, both in English and a number of other languages (Plowright, 1999). The measure has also proved to be sensitive to changes in psychological well-being across time, for example, in situations where patients are transitioning from tablets to insulin (Witthaus et al., 2000), as well as to more subtler changes in treatment e.g. from short acting to more longer acting insulin (Witthaus et al., 2001). Furthermore, the W-BQ12 has also shown greater sensitivity to change than another measure of well-being, the General Well-being Index (McMillian et al., 2006).

The WBQ-12 is also preferable to this measure as it is considerably shorter, and has three clinically relevant and psychometrically validated subscales.

4.4.2 Secondary Outcomes for person with type 2 diabetes

4.4.2.1 Biomedical Outcomes

Measures of blood pressure and Body Mass Index (BMI) were taken in the clinic on the day participants were recruited, and again at six month follow-up. Blood pressure was measured with the *Criticare 504X digital* sphygmomanometer. Weight and height were measured with the *Seca 941* digital scales and the *Seca 222* stadometer respectively. BMI was calculated according to the standard formula (i.e. weight in Kilograms / (height in Meters)^2). BMI and BP were included as key secondary outcome measures, given that the treatment for diabetes is increasingly emphasising good weight management and tight blood pressure control, in addition to tight glycaemic control.

4.4.2.2 Diabetes Self-efficacy

The 15-item UK English version of the Diabetes Management Self-Efficacy Scale (DMSES UK15 (Sturt & Wakelin, unpubl., See Appendix G) was used to assess improvements in confidence levels for performing diabetes related tasks and lifestyle changes. The *DMSES* was chosen for use in this study, as it has been specifically developed and psychometrically tested for use with adults with type 2 diabetes, unlike other measures (e.g. *Grossman Self-Efficacy for Diabetes Scale*, Grossman, Brink, & Hauser, 1987) and the *Diabetes Empowerment Scale* (Anderson, Fitzgerald, Gruppen, Funnell, & Oh, 2003)), which have been developed for use with adolescents with type 1 diabetes, and later adapted for use with type 2 diabetes populations. In addition, the DMSES is currently being developed as part of a large multinational programme of research based on self-efficacy theory, particularly for assessing changes in self-efficacy in response to intervention. Thus, the use of the *DMSES* in this study facilitates comparisons with current large scale, international research.

The DMSES UK15 has 15 items assessing the extent to which respondents are confident that they can manage their blood glucose levels, foot care, medication, diet and physical

activity. Responses are rated on an 11 point scale (0 to 10), anchored with 'Certain can do' (0), 'Maybe yes/Maybe no' (5) 'Cannot do at all' (10). Responses are summed to produce a single score for self-efficacy, and ranging from 0 to 165. Scores of 0-55 indicate high levels of self-efficacy, 56-110 moderate levels of self-efficacy, and 111-165 low levels of self-efficacy.

To date, versions of the DMSES have demonstrated acceptable reliability and validity in the Netherlands (Bijl, Poelgeest-Eeltink, & Shortridge-Baggett, 1999), the USA (Shortridge-Baggett, 2002), Australia (McDowell, Courtney, Edwards, & Shortridge-Baggett, 2005) and the UK (Sturt & Hearnshaw, unpubl. Data 2004). Validity and reliability testing for the 15-item UK/English version of the DMSES is currently being undertaken, however, data is not yet available.

4.4.2.3 Diabetes Self-management

Diabetes self-management was assessed using the revised version of the Summary of Diabetes Self-care Daily Activities SDSCA (See Appendix H). This was chosen for use in this study for a number of reasons. Firstly, it has been argued that due to the multidimensional nature of diabetes self-management, compliance with the diabetes regimen should be assessed by measuring compliance with each self-management activity separately (Toobert, Hampson, & Glasgow, 2000), as is the case with the SDSCA. Secondly, the SDSCA is the most widely used self-report measure for assessing diabetes self-management in adults, and its use in this study allows for comparison of the results with those from findings from the international literature. Thirdly, it is a brief measure (11 items), with good reliability and validity. Lastly, the measure was previously used in research conducted in the local diabetes clinic (White et al., 2001-2004) by members of the wider research team, thereby also facilitating a comparison of the results from both studies.

The 11 items of the SDSCA assess various aspects of diabetes self-care in which patients have engaged during the last week. Subscales assess: overall general diet; fat intake; fruit and vegetable intake; exercise behaviour; blood glucose monitoring; foot care and

smoking. All items (except that related to smoking) are scored using number of days per week, ranging from 0 to 7. The smoking item is scored using a 'yes/no' response format.

The revised measure of the SDSCA (Toobert et al. 2000) was developed and adapted following a review of the reliability, validity and normative data from seven different studies of people with diabetes (n=1988) using the original SDSCA (Toobert & Glasgow, 1994). Items from the original version were retained if they had shown consistency in mean values across studies, sufficient variability and lack of floor/ceiling effects, as well as temporal stability, internal consistency and sensitivity to change. Medication adherence items, which were assessed in the original measure, were omitted from the revised version, as strong ceiling-effects and a lack of variability among respondents lowered the test-retest reliability. For the revised measure, new items assessing foot care and smoking were added. Significant correlations with appropriate criterion measures were reported for diet and exercise subscales, supporting the validity of the measure for these aspects of diabetes self-care.

4.4.2.4 Family Support

The 16-item *Diabetes Family Behaviour Checklist* (DFBC) (Schafer, McCaul, & Glasgow, 1986) was used to assess supportive and non-supportive family behaviour, specific to diabetes management (see Appendix I). It has been argued (Glasgow & Toobert, 1988; Schafer et al., 1986) that measures which assess family support specifically related to diabetes self-care, are more likely to relate to regime adherence and glycaemic control, when compared with support measures which are more global in nature. Whilst there are a large number of such global measures of social support available, only a few assess diabetes specific support (Annette, La Greca & Bearman, 2002; La Greca et al., 1995; McKelvey et al., 1993; Schafer, McCaul, & Glasgow, 1986). The *DFBC* was selected here in preference to these other instruments, as it has been used in previous research with adults with type 2 diabetes (Glasgow & Toobert, 1988; Karlsen, Idsoe, Hanestad, Murberg, & Bru, 2004; Wen, Parchman, & Shepherd, 2004), whilst the other diabetes-specific measures have been used primarily with adolescents with type 1 diabetes. The DFBC is also one of the only measures to assess diabetes-specific non-

supportive family behaviours, as well as supportive forms of behaviour. One other measure was identified that also assessed non-supportive behaviour - the Perceived Diabetes-Related Social Support subscale of the Multidimensional Diabetes Questionnaire (Talbot, Nouwen, Gingras, & Gosselin, 1997). However, this sub-scale was not as informative as the DFBC, as only two items assess non-supportive family behaviour, neither of which detailed specific support behaviours. Another key advantage of the *DFBC* relates to the fact that it has been adapted and psychometrically tested for use with family members of people with diabetes (Schafer et al., 1986).

The 16 items of the DFBC includes two scales, the first of which comprises nine items designed to assess *supportive or positive* family behaviours specific to diabetes management. The second 7-item scale measures family behaviours related to diabetes management which patients perceive to be *non-supportive or negative.* Respondents are asked to rate how often a particular family member engages in the various types of supportive/non-supportive behaviours. Higher scores on the positive items indicate more supportive or positive behaviour, while higher scores on the negative items indicate more non-supportive or negative family behaviours. The original *DFBC* has five response alternatives scored on a five-point Likert scale from 0-5 ('never', 'twice a month,' 'once a week' 'several times a week' and 'a least once a day'). However, respondents in the pilot study reported difficulties with this response format, as a result of which more general terms were used instead; these ranged from 'never', 'seldom', 'sometimes', 'often' and 'very often'. This response format has also been used in other studies (Karlsen, et al., 2004).

With regard to its psychometric status, the DFBC has shown good internal consistency (α = 0.74 -0.76 for the positive subscale and α = 0.79-0.80 for the negative subscale) whilst good test-retest values (0.95-0.77) have also been reported (Schafer et al., 1986). A recent psychometric evaluation of the *DFBC* (Lewin et al., 2005) confirmed the two factor structure of the positive and negative support subscales, using exploratory and confirmatory factor analytic techniques. Correlations between the DFBC and other measures of diabetes-specific family support, measures of regime adherence, and HbA1c

are moderate to strong, supporting the validity of the measure (Lewin et al., 2005). No studies were identified that used the DFBC prospectively (e.g. in an intervention or longitudinal study); thus, no information is available on the sensitivity of the DFBC to detecting change.

4.5 FAMILY MEMBER MEASURES

4.5.1 Illness perceptions

An adapted version of the BRIEF-IPQ (Broadbent et al., 2006) was used to examine family members' perceptions of diabetes. The modified family version of the BRIEF-IPQ (see Appendix J) assesses the same core constructs as the patient version described earlier. This allowed for a direct comparison of patient and family scores, thereby allowing an assessment of the degree of congruence between the patient and family member perceptions of diabetes. The BRIEF-IPQ can also be modified to assess not only the family member's own illness perceptions, but also how they think the patient perceives their diabetes. Thus, the first item designed to assess consequences in the patient version of the BRIEF-IPQ (*'How much does diabetes affect your life?'*) is assessed in two ways in the family version: (1) *' How much does your family member's diabetes affect YOUR life'* and (2) *'How much does your family member's diabetes affect THEIR life?'* Hence, the modified family version has 14 items, rather than the 11 contained within the patient version. The response formats for both measures are identical.

A review of the literature showed that no study had previously used an adapted version of the BRIEF-IPQ with family members, although adapted versions of the original and revised Illness Perception Questionnaire have been used in previous work with families (Barrowclough et al., 2001; Benyamini, 2007; Figueiras & Weinman, 2003; Heijmans, et al., 1999; Law, 2002; Richards et al., 2004; White et al., 2001-2004).This study is the first to adapt the much shorter, BRIEF-IPQ to assess the illness perceptions of family members. Consequently, no psychometric data are available for this adapted version. However, evaluations have demonstrated that other modified family versions of the (longer) IPQ have acceptable reliability and validity, although they are slightly less robust

than the original patient versions (Weinman, Heijmans, Figueiras, Cameron, & Leventhal, 2003). The adapted family versions of the IPQ and the IPQ-R are also long questionnaires and therefore, very time consuming to complete.

4.5.2 Family support

The *Diabetes Family Behaviour Checklist (DFBC)* was also used to assess the levels of support that family members believed they provide to the person with diabetes (see Appendix K). This measure was originally developed (Schafer et al., 1986) to be completed in parallel by the person with diabetes and their family member, in order to facilitate comparisons between the family member's perception of support provision, and the perceptions of the person with diabetes. The family version of the DFBC has the same structure and response format as the patient version described earlier; in other words, it comprises 16-items, with positive and negative subscales on which respondents report the frequency of various behaviours, scored on a five-point Likert scale. While the reliability and validity of the adapted version of the DFBC has been demonstrated with parents of children with type 1 diabetes (Lewin et al., 2005), the adapted measure has yet to be psychometrically tested with the family members of adults with diabetes. However, the DFBC is one of the only diabetes-specific family support measures that have been used with adults with type 2 diabetes which also assess negative and positive aspects of family support.

4.5.3 Comparing patient and family member perceptions

Evidence has shown that a mismatch between patients' and family members' perceptions of an illness has negative implications for disease outcomes (Weinman et al., 2003). Arguably, therefore, it is important to have some measure of the degree of congruence or similarity between the illness perceptions of patients and family members. Previous studies have assessed similarity in a number of ways. The most straightforward method uses simple significance testing (e.g. t-tests) to investigate if any statistically significant differences exist between patient and family members' mean scores on each relevant illness perception dimension (e.g. patient timeline score vs. family member timeline score). The advantage of this method is its ease of implementation, and also the fact that

it can be used when participant numbers are small. The majority of studies comparing patient and family member perceptions of illness include this type of analysis as an initial assessment of the degree of similarity between perceptions. This was the method used in this study to assess the degree of similarity between patient and family members' perceptions of diabetes.

Some studies conduct further comparison of patient and family member perceptions using either of two additional analytical methods. The first method calculates a *minimisation/maximisation score*, while the second method uses a *positive/negative classification system.* In studies using the minimisation/maximisation approach (e.g. Heijmans et al., 1999; Law, 2002; Richards et al., 2004)), a dissimilarity score for each family dyad was calculated by subtracting the family member's scores on the various subscales of the Illness Perception Questionnaire, from the patient's scores. This creates a continuous variable describing the direction of difference from the family member's framework relative to the patients. Studies have used this to measure the extent to which a family member *maximises* or *minimises* various aspects of the illness, relative to the patient's own rating. However, there are a number of problems with using this method. A calculation of the similarity score relative to the patients' score, seems to imply that the patient has an accurate or positive perception of the illness (which is not the case with patients with poorly controlled type 2 diabetes), and any disparity is a result of the family member exaggerating or underestimating various aspects of the illness. This maximization/minmisation approach does not take into account the relative levels of scores (e.g. high/low or positive/negative). Thus, those situations where dissimilarity arises due to the family member holding accurate or positive perceptions of the illness, and the patient having inaccurate or negative perceptions, are not identified. Nor indeed, are situations identified where both patient and family members have negative perception of an illness.

An alternative approach was taken by Figuerias & Weinman (Figueiras & Weinman, 2003), who assessed the degree of similarity between patients' and spouses' perceptions of myocardial infarction, by calculating a comparative patient-family member score. The

authors developed a classification system based on median score for each group (spouse/patient) for each IPQ subscale (identity, consequences, timeline, cure/control). This identified the extent to which individuals' illness perceptions were broadly positive (e.g. above the median group score) or broadly negative (below the median). The scores of patients and spouses were then recoded according to the median split on each variable; scores below were coded as 0, scores above were recoded as 1. This gave rise to four groups of patient-spouse dyads including: (1) similar positive perceptions, (2) similar negative perceptions (3a) conflicting perceptions (patient positive, family member negative) and (3b) conflicting perceptions (patient negative, family member positive). This scoring method takes into account not only the degree of similarity of perceptions, but also the relative levels of scores (e.g. high/low) on each illness perception component. Such a method of assessing similarity is particularly useful for intervention work, as it differentiates different types of patient-family member dyads based on individual illness perceptions, thereby allowing interventions to be tailored to the individual needs and circumstances of the patient and their family member. It was planned to use this approach as an additional method of assessing similarity between patient and family member perceptions (in addition to comparison of mean scores), if there were sufficient numbers of family member questionnaires returned at follow-up.

4.6 PROCEDURE

4.6.1 Patient recruitment & baseline assessment clinics

Before the start of each clinic, eligible patients were marked on the 'master' clinic list used by the diabetes nurse specialists (DNS). During clinics, eligible patients were approached either directly by the researcher, or by a DNS. Patients were approached after they had checked into the clinic and while they were waiting to see the doctor, at which time the researcher provided them with given written information about the study (see Appendix L), and invited them to participate. On agreement, they were asked to provide their written informed consent (see Appendix M) and to complete the baseline questionnaires with the researcher. On average this took approximately 20 minutes. Questionnaires were presented in a random order to avoid any potential ordering affects. The patients HbA1c, blood pressure, and body-mass index were also taken at this time.

4.6.2 Family member recruitment

Patients were asked to nominate a family member to participate in the study with them and they were then given a questionnaire pack containing the family member measures, which included an explanatory letter about the study (see Appendix N). Patients were invited to ask their nominated family member to complete the questionnaires and return them by post to the researcher, prior to commencement of the intervention.

4.6.3 Randomisation

Following baseline data collection, participants were allocated to control or intervention groups using a computer generated random number sequence (uniform random number distribution in JMP 5.0.1a) by an independent statistician. A block randomisation procedure was used. After the first 40 patients were recruited, they were then randomly allocated to either the intervention or control group, and intervention delivery began with this group, while recruitment of the second group continued. When the second group of 40 patients were recruited, they were then also randomly allocated to intervention or control group, and so on for the third group, until 122 patients were recruited. This meant the intervention could be delivered in a staggered manner, with some participants beginning the intervention while further recruitment continued.

4.6.4 Concealment of allocation

The allocation sequence was concealed in two ways. Firstly participants were not randomized until after they had been recruited and baseline data had been collected. Secondly, randomisation was done remotely, by computer, by an independent expert.

4.6.5 Blinding

Due to the psychological nature of the intervention, it was not possible for the investigator delivering the intervention (KK) or the participants themselves to be blinded to treatment allocation group. Researchers collecting follow-up data (GP & PW) were blinded to participants' group allocation.

4.6.6 Intervention delivery: Participants home

After randomisation participants in both groups were sent a letter to inform them of the

group to which they had been allocated (see Appendices O & P), and to provide them information about when to return for the follow-up appointment. This letter also contained a family member questionnaire pack for any participants who had yet to return family member data, with a reminder requesting participants to ask their family member to complete and return the questionnaire to the researcher. Participants in the intervention group were then contacted by telephone to arrange a suitable time to visit both them and their family member in their home. At the first session, a suitable time for a second session was arranged. A week after the last home visit, the researcher contacted the participants by telephone, as a final follow-up. A number of participants (n=11) received 'two in one sessions', where both sessions were delivered together, in one longer session. This was generally due to the accessibility issues, where participants living a large distance from the hospital (>100km), had requested that the interventionist conduct both sessions at one visit (i.e. spending 90-minutess one week, as opposed to two 45-minute sessions over two weeks).

4.6.7 Outcome assessment clinic

At six months post-intervention (i.e. approximately 24 weeks from completion of the intervention), control and intervention participants were invited to return to the diabetes clinic in the same staggered manner as they were recruited. A month before the follow-up appointment, participants were sent a reminder letter about the appointment. A phone call was also made to participants in the week before the appointment to confirm their attendance. At the follow-up appointment, HbA1c, blood pressure, and body-mass index were taken again and recorded. The baseline questionnaires were also re-administered, by researchers blinded to the participants' group allocation (PW & GP). At this time, patients were asked to return the research diary. In addition, patients were also given a debriefing letter (see Appendix Q), and also an anonymous *Participant Evaluation Form* (as part of the process evaluation component, see section 4.7. below), in order to assess their own experience of participating in the research. Patients were asked to complete this at home in their own time, and to return it to the researcher in the stamped addressed envelope provided. Patients were again given a questionnaire pack for their nominated family members, and requested to ask the family members to complete the questionnaires

and return them to the researcher in the stamped addressed envelope provided. For family members of the intervention group, this pack also contained a *Family Member Evaluation Form* (see section 4.7., process evaluation) assessing their own experience of participating.

4.7 PROCESS EVALUATION

As indicated earlier, a process evaluation component for this RCT was conducted in parallel to the data collection and intervention delivery. The process evaluation component of this RCT was based on the treatment fidelity framework proposed by Bellg et al. (Bellg et al., 2004; discussed in section 3.1.6.), which outlines treatment fidelity strategies across five broad areas: treatment design; training procedures; delivery of treatment; receipt of treatment; and enactment of treatment skills. Both quantitative and qualitative process evaluation data were collected in order to assess various aspects of treatment fidelity (see Table 4.2, p.109,. for process evaluation measures). The use of both quantitative and qualitative data provides the strongest evidence for the process evaluation, as it allows for the triangulation of data for both sources.

4.7.1 Audio-taped sessions

It was anticipated that intervention sessions with 10% of randomly selected participants (n=6) would be audio-taped and examined for treatment fidelity. However, of the six randomly selected participants, three withdrew from the study, and the remaining three did not give permission for their sessions to be audio-taped due to concerns about privacy. It may have been possible to randomly select an additional 10% of participants and audio-tape these intervention sessions. However, it appeared that participants were not comfortable with audio-taping, and therefore the research team felt therefore that audio-taping may actually have a detrimental effect on patient-therapist interactions (e.g. by upsetting the development of rapport etc). Consequently, it was decided by the research team that treatment fidelity should be assessed using a combination of data from structured field note questionnaires (see Appendix R) and focus groups with participants.

Table 4.2

Process evaluation components

Area	Goal	Strategy
Treatment design	Ensure equivalent doses within & across conditions e.g. number & duration of sessions	Recorded in field notes questionnaires
Training procedures	Standardised training	16 hours of training in motivational interviewing with certified trainer
Delivery of treatment	Ensure adherence to treatment protocol	Assess field notes with reference to intervention manual
		Focus groups with participants
Receipt of treatment	Ensure participant comprehension	Focus groups with participants
	Ensure participant ability to use cognitive & behavioural skills	Record of attendance at sessions from field notes
		Participant diaries & evaluation forms
Enactment of treatment skills in real life settings	Ensure participant use of cognitive & behavioural skills	Participant diaries
		Focus groups with participants
		Outcome measures; cognitive, behavioural and objective biological.

4.7.2 Structured field notes

A structured field notes questionnaire (see Appendix R) was developed to assess a number of factors. The interventionist completed the field notes questionnaire immediately after each intervention session (e.g. in the car outside participants homes).

Thus, the impact of any difficulties with recalling the content of interventions sessions was minimised. The questionnaire recorded data relating to the content of intervention sessions, and how the sessions were delivered. Thus, the questionnaire collected information related to: the main focus of discussion in each intervention session; the tailoring of intervention sessions to individuals; the running time of each session; details on the degree of participation in sessions of the interventionist, the patient and the family member; the interventionist's observations relating to participants' mood state, and the patient-family member dynamic; details regarding the development and use of the action plan; and any other relevant observations. Field notes questionnaires were analysed for treatment fidelity by an independent health psychologist (PW) using a thematic and content analysis (see section 4.9.4. *"Qualitative analysis'* for more details).

4.7.3 Participant diaries

All patients who participated in the intervention were asked to complete an intervention diary (see Appendix S). The diaries were designed to assess participants' experience of taking part in the intervention over time, and also to identify points in time where changes resulting from the intervention (e.g. behaviour, mood) may have occurred. Participants were invited to complete the diary on a weekly basis for the first six-weeks, and then on a fortnightly basis for the remaining 18-weeks, until they returned for the six-month follow-up. The diaries had both quantitative elements (e.g. scales assessing diabetes self-management behaviours and psychological well-being) and qualitative elements (e.g. space for recording thoughts, feelings, experiences).

4.7.4 Focus groups

4.7.4.1 Participants

A total sampling approach was used: all participants who participated in the intervention were invited by letter (see Appendix T) to attend a follow-up focus group to discuss their experiences of the trial. Three focus groups were conducted; one for each randomised block of participants. Thus, when follow-up data collection was completed for each of the RCT block, all participants in that block who had participated in the intervention were invited to attend the focus group for that block. Further details of those who participated

in the focus group are provided in the results chapter.

4.7.4.2 Topic guide

In essence the focus groups attempted to investigate participants' own views about partaking in the trial, the appropriateness of the intervention and intervention techniques, and the fidelity of intervention delivery. As such, the topic guide or interview schedule for the focus groups (see Box 4.1) was developed with these aims in mind. The interview schedule was developed using the 6-step process proposed by Kruger and Casey (Kreuger & Casey, 2000). This process involves: (1) brainstorming; (2) phrasing the questions; (3) sequencing the questions; (4) estimating time for questions; (5) getting feedback from others; (6) testing the questions. Kruger and Casey also recommend organising or grouping questions in the interview schedule according to five broad categories: opening; introductory; transition; key and ending. Thus, the interview schedule began with an opening question, followed by a brief introductory question. These were followed by two general transition questions relating to the trial. The schedule then moved on to ask seven more specific key questions, which attempted to address all elements of the intervention, including: the information given; the location and frequency of the sessions; the use of participant diaries; and effectiveness of the intervention in improving diabetes management. A number of probes or prompts were contained within each of the specific key questions, in order to promote discussion if necessary. The interview guide finished with a final concluding question.

Box 4.1

Topic guide for focus groups

Opening Question

- What is your name and what would normally be doing now?

Introductory Question

- Think back to when you first heard about this diabetes study, what were the first things that came into your mind?

Transition Questions

- What was it like taking part in the study?
- Did you feel you got enough information about it all?

Key Questions

- Which parts of the study helped?
    - Location of visits?
    - Number of visits?
    - Phone-calls, should there have been more/less?
- What role did family members play in managing your diabetes?
    - Was it helpful?
- How did the diary work out?
    - Easy to fill out?
    - Reminder texts work?
- Did it help you to change how you manage your diabetes?
- Do you feel you manage your diabetes better now, same or worse?
- What about the long-term management of your diabetes?
- If we were to run this study again what are the things that should be changed?
    - What should stay as it is?

Ending Question

- That's all my questions, is there anything else that anyone would like to add?

4.7.4.3 Procedures

The focus groups took place in a quiet meeting room in the hospital, away from the diabetes day centre. Each focus group consisted of the participants, the facilitator (PW) and an assistant facilitator/observer (CD or GP). The interventionist (KK) was not involved in the focus groups in any way, to ensure participants felt comfortable talking about all aspects of the intervention. Participants were provided with light refreshments when they arrived at the meeting room. The focus group began with an explanation of the focus group and the necessity for the tape recorder, the confidential nature of the discussion, and how results from the focus group would be disseminated. At the end of each focus group the facilitator summarised the main points and looked for clarification

of these points from the group. Each focus group lasted approximately 45-60minutes. Travel expenses of €10.00 were then circulated in a sealed envelope and participants departed. Immediately after the focus group the facilitator and assistant facilitator wrote up an initial report to capture their immediate thoughts and reactions to the process. All three focus groups were audio-taped (with participant consent) using a recorder, and transcribed in full. The process of analysing the focus group data is detailed in section 4.9.4. below. In the weeks following the focus groups, a preliminary analysis of themes was sent out to each focus group participant to check for accuracy.

4.7.5 Evaluation questionnaires

All participants were invited to complete a *Participant Evaluation Questionnaire* to assess their views of the intervention (see Appendix U). The first question asked participants to indicate if they had been allocated to the intervention or the control group. The remaining four open-ended questions asked participants to: describe their experience of taking parting in the study; to discuss if the study had helped them to improve their diabetes self-management; to make any recommendations for improving the study; and to make any other relevant comments. Family members who participated in the intervention were also invited to complete a *Family Member Evaluation Form* (see Appendix V) containing five open-ended questions relating to their own experience of the intervention. These questions asked family members to: describe their own experience of taking part in the study; to discuss if the study had helped the patient to improve their diabetes self-management; to discuss if taking part in the study had helped them in any way; to make any recommendations for improving the study; and to make any other relevant comments.

4.8 ETHICAL APPROVAL

Ethical approval was sought and granted, from the Joint Research Ethics Committee of St. James's Hospital and the Federated Dublin Voluntary Hospitals on the 15 February 2006 (REF 06/01/04). The ethics committee made no amendments or alterations to the trial protocol. The study was conducted in accordance with the code of conduct and the ethical guidelines of the British Psychological Society (BPS) and the Psychological Society of Ireland (PSI) (PSI, 2003), which consist of four overall ethical principles, including: respect for the rights and dignity of the person; competence; responsibility;

and integrity. These overall principles subsume a larger number of ethical standards, such as: privacy and confidentiality; freedom of consent and informed consent; avoidance of harm; recognition of professional limitations; and continuing professional development

4.9 DATA ANALYSIS

4.9.1 Quantitative analysis

Stata10 S.E. was used in the analysis of quantitative data. The quantitative data were analysed using an 'intention-to-treat' approach. Regression models and Analysis of CoVariance (ANCOVA) were used to compare primary and secondary outcomes in the control group and intervention group. Adjustments were made for pre-specified prognostic and confounding factors and covariates which were known apriori to influence the outcomes of interest. These included baseline measures of the dependent variables (e.g. HbA1c or well-being) and other corresponding covariates (e.g. medication change and duration of diabetes). Regression and ANCOVA are a set of statistical techniques commonly implemented in the analysis of RCTs, precisely because they can be adjusted for the effects of covariates that may otherwise obscure the intervention effect (Van Breukelen, 2006) (i.e. values of these variables are included as covariates in regression analysis). Statistical significance was set at the 5% level for primary outcomes. For secondary outcomes statistical significance was set at the 1% level, given the increased risk of Type 1 errors (or false-positive findings) associated with multiple analyses of the same data (Tukey, 1977). A secondary 'per-protocol' analysis was also conducted, in addition to the 'intention-to-treat' analysis, as pre-specified in the trial protocol (Keogh, 2007, see Appendix X).

Significance testing was not conducted to examine baseline differences between groups, as there is an argument in the analysis of RCTs that such baseline significance testing is not appropriate (Altman, 1998; Altman & Dore, 1990; Senn, 1995). If randomisation is conducted correctly, any systematic differences between groups will be the result of chance rather than bias, and as such are accounted for at the follow-up analysis, when inferences are made using P-values and confidence intervals. In addition, adjustment for

variables because they differ significantly at baseline is likely to bias the estimated treatment effects (Altman, 1998). It is still appropriate, however, to adjust the effects of the treatment or intervention for *pre-specified* prognostic factors which are known apriori to influence the outcomes of interest.) Thus, the CONSORT guidelines for the reporting of RCTs (CONSORT, 2007) recommend not testing study groups for significant differences at baseline. However, CONSORT does advocate describing study groups according to their baseline socio-demographic and clinical characteristics, and primary and secondary outcome measures, as this allows readers to themselves assess how comparable groups were. CONSORT recommends that such baseline data for study groups should be summarised in tables by presenting the appropriate descriptive statistics, for example, means and standard deviations for continuous variable, and proportions for categorical variables. This was the method used in the current study.

Missing data were dealt with using the 'last observation carried forward' method. In a LOCF analysis, if follow-up data is missing, participants last available score is substituted in the analysis. Thus, for this trial, if patients were missing six-month follow-up data, their baseline scores were substituted for the analysis. The LOCF analysis is less biased than analysing only data from those who complete the trial: if the treatment has no effect the LOCF analysis will not increase the probability of concluding that it is effective (i.e. Type 1 error). However, it must be noted that when there is a significant treatment effect, the LOCF approach suffers from a loss of power to detect this (Shao & Zhong, 2003). In other words, there is an increased risk of a false-negative finding or making a Type 2 error. Despite this limitation, it was decided to use the LOCF analysis as it is the most simple and straightforward method of dealing with missing data, in addition to being the approach recommended by the CONSORT guidelines (CONSORT, 2007).

4.9.2 Mediational analysis

A formal mediational analysis weas conducted using the *joint significant test*, which is a form of *causal step analysis.* This mediational analysis was performed to establish whether any between-group differences over time in HbA1c were mediated by hypothesized changes in behaviour (e.g. diet, exercise, family support), which in turn,

were mediated by hypothesized changes in illness perceptions. In essence, this meditational analysis involves significance testing of the theoretical pathways proposed by Leventhal's Self-Regulatory Model. The joint significance test approach was initially proposed for the single mediator situation (e.g. X→ M→ Y), it can easily be generalized (Taylor, MacKinnon, & Tein, 2008) to the three-path context hypothesized to occur in the current trial (e.g. X→M1→M2→Y, or "group→ illness perceptions→ behaviour → glycaemic control"). A Monte Carlo study (Taylor, MacKinnon, & Tein, 2008) comparing six different methods of testing mediation in three-path mediation models, concluded that the joint significance test is preferred when hypothesis testing is the main goal. Its main advantages are its simplicity (straightforward null hypothesis testing of three regression coefficients), and the fact that it is the most conservative test; as it has good power and controls for Type 1 errors. The joint significance test finds evidence for mediation if each of the three paths in the mediated effect is significantly non-zero. These paths are shown as ß1, ß2 and ß3 in Figure 8. Estimating these ß values requires that the three following regression equations be estimated:

(1) $M1 = ß01 + ß1X\ I + \varepsilon 1$

(2) $M2 = ß02 + ß2M1 + ß5X + \varepsilon 2$

(3) $Y = ß03 + ß4X + ß3M2 + ß6M1 + \varepsilon 3$

In these equations Y is the dependent variable (e.g. HbA1c/psychological well-being), X is the independent variable (e.g. group allocation), M1 and M2 are the two mediators (e.g. illness perceptions and diet/exercise behaviours). In the first equation, ß1 is the regression of M1 (e.g. illness perceptions) on X (e.g. group allocation). In the second equation, ß2 is the regression of M2 on M1 (e.g. diet/exercise on illness perceptions), and ß5 is the regression of M2 on X (diet/exercise on group allocation). In the third equation, ß3 is the regression of Y on M2 (HbA1c on diet/exercise), ß4 is the regression of Y on X (e.g. HbA1c on group allocation), and ß6 is the regression of Y on M1 (HbA1c on illness perceptions). The interceptions are ß01, ß02 and ß03 and the residuals are ε1, ε2 and ε3.

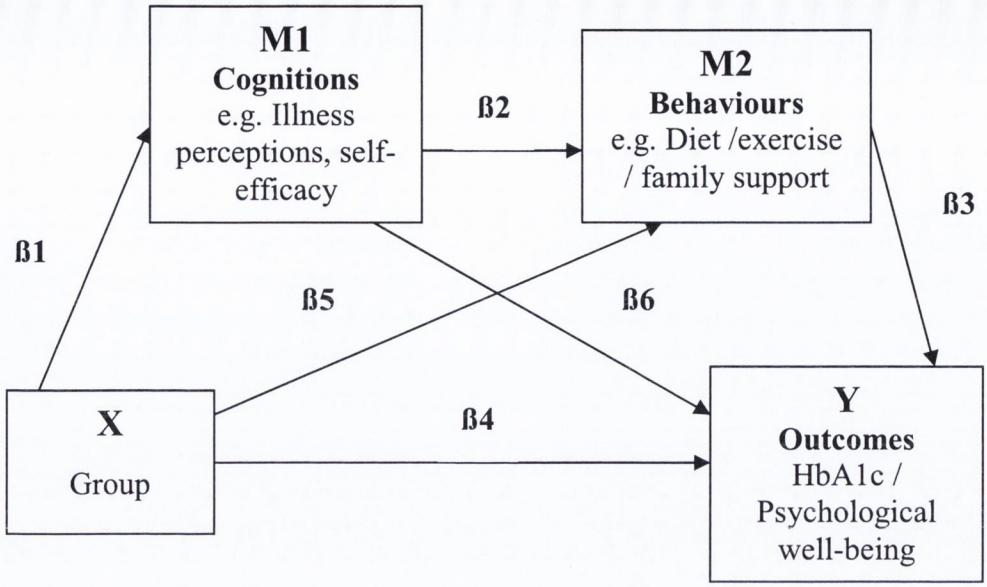

Figure 4.1: Path diagram of the three-path mediated effect model

4.9.3 Economic analysis

The economic analysis method chosen for this trial was a cost-effective analysis (CEA). A CEA is a form of economic analysis which compares the relative costs and outcomes (or effects) of two or more alternative courses of action (Jefferson, 1996). For example, CEA can compare the costs and effects of implementing an intervention with the costs and effects of not implementing the intervention. In essence, a CEA calculates a ratio, in which the cost of an intervention is compared to a relevant measure of its effect. The effect of the intervention is generally based on clinical judgement (e.g. changes in HbA1c in a diabetes treatment intervention). Within this framework, cost effectiveness is expressed as an *Incremental Cost Effectiveness Ratio* (ICER). The ICER represents the additional cost of one unit of outcome gained (e.g. a 1% decrease in HbA1c) by a healthcare strategy or intervention when compared to the alternative strategy. The ICER is calculated by the following formula:

$$ICER = \frac{C1-C2}{E1-E2}$$

Within this formula, CI and E1 correspond respectively to the cost and effect of the first course of action, while C2 and E2 correspond to the second course of action.

As the intervention discussed in this RCT was conceptualised as an adjunct to usual care, not an alternative, the appropriate comparison for the economic evaluation is not usual care, but rather 'no intervention'. Thus, for this trial the first course of action is the cost and effect of the intervention, while the cost and effect of the second course of action is no intervention (i.e. zero effects and zero additional costs to the healthcare providers). For the purposes of the CEA for this RCT, the objective measure of the effectiveness of the intervention was the change in HbA1c, and the perspective of the economic analysis was the direct cost to healthcare providers. The direct costs of the intervention to healthcare providers were calculated by assigning a unit cost to each type of resource used in the intervention. From this perspective, the costs of the intervention correspond directly to staff costs (i.e. the expenditure involved in employing a psychologist to deliver the intervention), as costs relating to consultations with other healthcare professionals, overheads, laboratory tests etc., are covered by the usual care model. Travel costs (e.g. mileage reimbursement) were also included. Although there may have been some direct costs to patient (e.g. travel costs to clinic for follow-up), these were not considered, as the perspective of the evaluation was from that of the healthcare provider. Indirect costs (e.g. the effects on productivity in the wider economy) and intangible costs (e.g. impact on health-related quality of life) were beyond the scope of this study, thus were not included in the analysis.

4.9.4 Qualitative analysis

Qualitative data (focus groups and field notes) was analysed using a straightforward thematic analysis (Braun & Clarke, 2006; Hayes, 1997). Thematic analysis is a method for identifying, analysing and reporting patterns (themes) within data, by minimally organising and describing a data set in rich detail. Within the thematic analysis method, a theme *"...captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set"* (Braun & Clarke, 2006 p.82). Unlike other methods of qualitative analysis such as

Grounded Theory (Glaser & Strauss, 1967) or Interpretative Phenomenological Analysis (Smith, 1996) thematic analysis is not tied to any pre-existing theoretical framework. This theoretical freedom means that thematic analysis is a flexible and useful research tool, which can be used within a variety of different theoretical frameworks. Thematic analysis is also seen as a more accessible form of qualitative analysis, as its use does not necessitate the detailed theoretical and technical knowledge required by other qualitative approaches (Braun & Clarke, 2006).

Thematic analysis produces a relatively systematic and comprehensive summary or overview of the data set as a whole. In essence, it involves examining the data for recurring or common instances (e.g. patient utterances). These are the fundamental units of analysis, which provide the basis for developing a coding system. Codes are grouped together to form common, over-arching themes. Braun et al. outline a six-phase step-by-step guide to performing a thematic analysis (see Table 4.3, p.120).

For this trial all focus groups were audio-taped, transcribed verbatim (phase 1), and entered into QRS NUD*IST version 1.3. Two researchers (PW & KK) read and re-read the transcripts independently (phase 1) and then jointly developed a coding system, which was systematically applied across transcripts from the three focus groups (phase 2). Both researchers were then involved in grouping the codes together into themes (phase 3), which were named, defined and reviewed with reference to the overall data set (phases 4-5). The final phase (phase 6) of producing a report relating back to the original research question (assessing treatment fidelity) was conducted by PW only. It was decided by the research team that it would not be appropriate for the author/interventionist (KK) to be involved in the final stage of evaluating and reporting whether or not the intervention was delivered per-protocol. Similarly, only PW was involved in assessing the field notes questionnaires for treatment fidelity. PW again followed the above phases 1-6 when assessing the field notes: field notes were read in reference to the intervention manual; a coding system was developed and applied across the data set; codes were then grouped into over-arching themes, which were then reviewed, defined and named; and a final report evaluating treatment fidelity was produced

Table 4.3

Phases of thematic analysis (Braun & Clarke, 2006)

Phase	Description of the process
1. Familiarising yourself with the data	• Transcribing data if necessary, reading and re-reading the data, noting down initial ideas
2. Generating initial codes	• Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes	• Collating codes into relevant themes, gathering all data relevant to each potential theme.
4. Reviewing themes	• Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes	• Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report	• The final opportunity for analysis. Selection of vivid, compelling, extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

5 RESULTS

This chapter presents the results from the RCT. Issues relating to recruitment and participation are discussed initially, followed by a presentation of the baseline data (in terms of socio-demographic data and primary and secondary outcomes) for the intervention and control groups. The baseline data from family members is also described. The trial profile (i.e. progress of participants through the RCT, withdrawal and follow-up rates) is then presented. Results from a series of multiple regression models are then examined, in order to investigate the effects of the intervention on primary and secondary outcomes at six months follow-up. This initial 'intention-to-treat' analysis is followed by results from a number of additional analyses, including: a Last Observation Carried Forward (LOCF) analysis to examine the effect of missing data; a per-protocol analysis; and a mediational analysis testing the proposed theoretical pathways. The process evaluation data are then considered, and results from the qualitative analysis of structured field notes and focus groups are presented, along with the findings from participant diaries and evaluation questionnaires. A description of the results from the economic analysis are then presented. The chapter concludes with a summary of the results.

5.1 RECRUITMENT

The numbers (and percentages) of patients at each stage of recruitment are illustrated in Figure 5.1. From the 80 recruitment clinics, 501 patients were initially identified as having poorly controlled type 2 diabetes. Of these, 135 (27%) did not attend the clinic. Patients who attended their appointments (n=365) met with the researcher at this time for an initial assessment. Further to this, 126 patients (26%) were excluded, as they did not meet additional inclusion criteria. Reasons for exclusion are detailed in Figure 5.1.

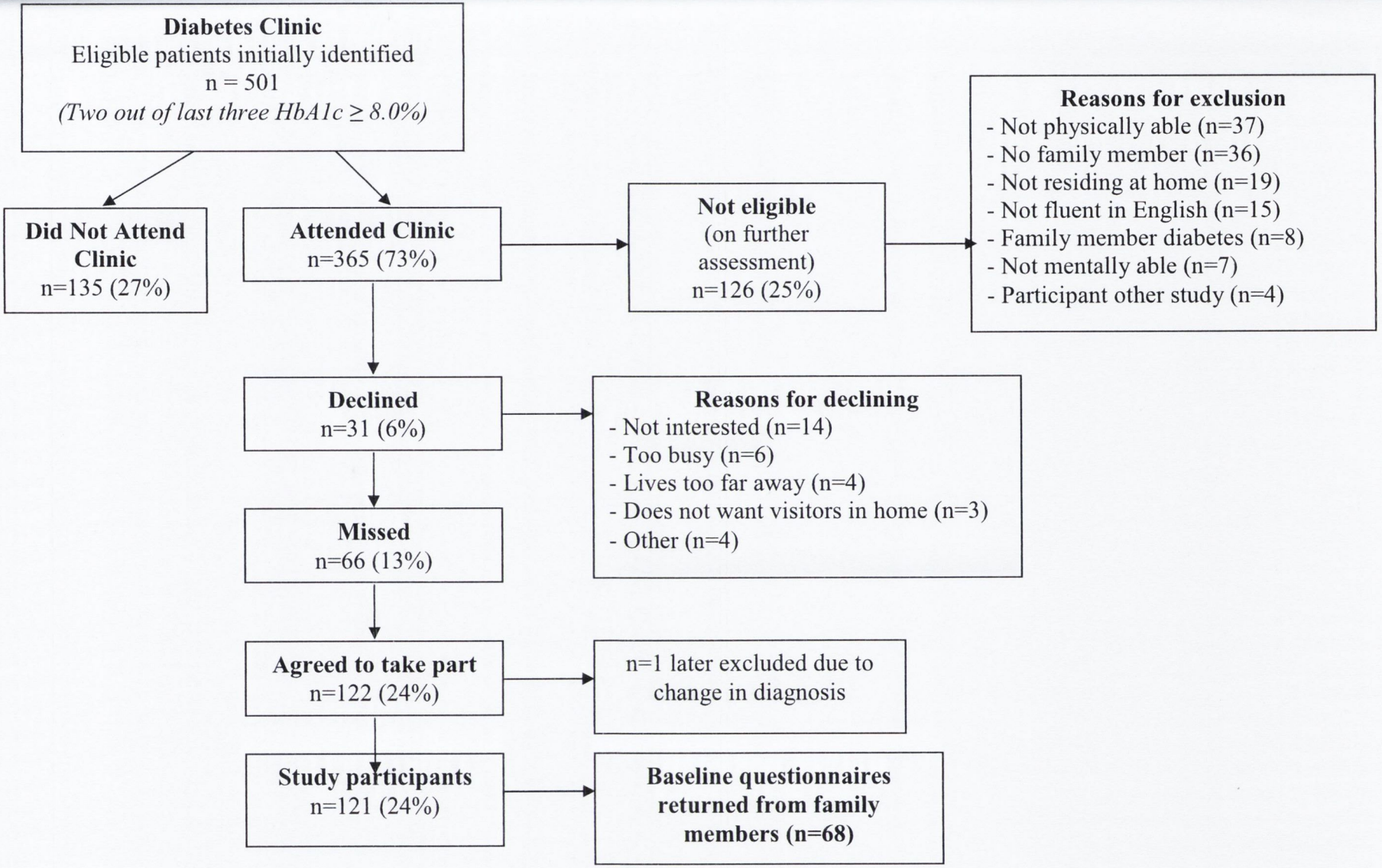

Figure 5.1:*Recruitment and participation rate*

5.1.1 Non-participants

The remaining 239 patients were all invited to take part, 31 (6%) of whom declined to do so. Patients' reasons for declining are outlined in Figure 5.1. There were no significant differences between those who did, or did not agree, to participate (see Table 5.1, p.124). A small proportion of patients (13%, N=66/239) who were eligible for inclusion were not asked to participate, because for example, they had left the clinic while the researcher was with another participant. There were no significant differences between these 'missed' patients, and those who participated in the study, with regards to sex, HbA1c, BMI, blood pressure, treatment type and type complications, (see Table 5.1). This group of patients, however, were slightly older (M=62.6, SD=12.6 vs. M=58.6, SD=11.5, t (185) = 2.21, p=0.03) than those who participated in the study. A total of 122 patients (28%) out of the original 501 patients identified initially as eligible for inclusion, were enrolled in the study. One of these participants was later excluded, when their diagnosis was changed from type 2 diabetes to type 1 diabetes.

Table 5.1

Comparison of participants and non-participants (patients who were 'missed' or declined to participate)

	Participants (n=121)	**Missed** (n=66)	test	df	P	**Declined** (n=31)	test	df	P
% Male	64% (n=77)	55% (n=36)	χ^2=1.47	1	0.27	48% (n=15)	χ^2=1.50	1	0.22
Age (M, SD)	58.6 (11.5)	62.6 (12.6)	t=-2.21	185	**0.03**	62.9 (10.9)	t=-1.46	148	0.14
HbA1c (M, SD)	9.1 (1.0)	9.3 (1.1)	t=-0.99	185	0.32	8.8 (0.80)	t=0.71	148	0.41
BMI (M, SD)	32.3 (4.9)	32.0 (5.3)	t=-0.36	166	0.76	33.1 (6.8)	t=-0.61	135	0.54
BP Systolic (M, SD)	138.7 (18.4)	141.3 (22.9)	t=--0.82	184	0.41	136.6 (19.2)	t=0.54	147	0.58
BP Diastolic (M, SD)	76.8 (10.1)	76.1 (11.7)	t=-0.43	185	0.63	72. 6 (10.8)	t=1.93	147	0.055
Treatment									
% OHA	47 % (n=55)	44% (n=29)	χ^2=1.89	2	0.38	58% (16)	χ^2=0.85	1	0.35
% Insulin	53% (n=61)	56% (n=36)				42% (12)			
% Retinopathy	7.4% (n=9)	2% (n=1)	χ^2=2.96	1	0.10	4% (n=1)	χ^2=0.53	1	0.46
% Neuropathy	6% (n=7)	6% (n=4)	χ^2=0.00	1	0.93	0% (n=0)	χ^2=1.7	1	0.19
% Nephropathy	12 % (n=2)	0% (n=0)	χ^2=1.10	1	0.29	4%% (n=1)	χ^2=0.43	1	0.51
%Hypertension	41% (n=49)	37% (n=24)	χ^2=0.22	1	0.63	36% (n=10)	χ^2=0.21	1	0.64

5.1.1 Non-participants

The remaining 239 patients were all invited to take part, 31 (6%) of whom declined to do so. Patients' reasons for declining are outlined in Figure 5.1. There were no significant differences between those who did, or did not agree, to participate (see Table 5.1, p.124). A small proportion of patients (13%, N=66/239) who were eligible for inclusion were not asked to participate, because for example, they had left the clinic while the researcher was with another participant. There were no significant differences between these 'missed' patients, and those who participated in the study, with regards to sex, HbA1c, BMI, blood pressure, treatment type and type complications, (see Table 5.1). This group of patients, however, were slightly older (M=62.6, SD=12.6 vs. M=58.6, SD=11.5, t (185) = 2.21, p=0.03) than those who participated in the study. A total of 122 patients (28%) out of the original 501 patients identified initially as eligible for inclusion, were enrolled in the study. One of these participants was later excluded, when their diagnosis was changed from type 2 diabetes to type 1 diabetes.

Table 5.1

Comparison of participants and non-participants (patients who were 'missed' or declined to participate)

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% Male	64% (n=77)	55% (n=36)	χ^2=1.47	1	0.27	48% (n=15)	χ^2=1.50	1	0.22
Age (M, SD)	58.6 (11.5)	62.6 (12.6)	t=-2.21	185	**0.03**	62.9 (10.9)	t=-1.46	148	0.14
HbA1c (M, SD)	9.1 (1.0)	9.3 (1.1)	t=-0.99	185	0.32	8.8 (0.80)	t=0.71	148	0.41
BMI (M, SD)	32.3 (4.9)	32.0 (5.3)	t=-0.36	166	0.76	33.1 (6.8)	t=-0.61	135	0.54
BP Systolic (M, SD)	138.7 (18.4)	141.3 (22.9)	t=--0.82	184	0.41	136.6 (19.2)	t=0.54	147	0.58
BP Diastolic (M, SD)	76.8 (10.1)	76.1 (11.7)	t=-0.43	185	0.63	72. 6 (10.8)	t=1.93	147	0.055
Treatment									
% OHA	47 % (n=55)	44% (n=29)	χ^2=1.89	2	0.38	58% (16)	χ^2=0.85	1	0.35
% Insulin	53% (n=61)	56% (n=36)				42% (12)			
% Retinopathy	7.4% (n=9)	2% (n=1)	χ^2=2.96	1	0.10	4% (n=1)	χ^2=0.53	1	0.46
% Neuropathy	6% (n=7)	6% (n=4)	χ^2=0.00	1	0.93	0% (n=0)	χ^2=1.7	1	0.19
% Nephropathy	12 % (n=2)	0% (n=0)	χ^2=1.10	1	0.29	4%% (n=1)	χ^2=0.43	1	0.51
%Hypertension	41% (n=49)	37% (n=24)	χ^2=0.22	1	0.63	36% (n=10)	χ^2=0.21	1	0.64

5.2 BASELINE PATIENT DATA

Baseline data were obtained from 121 patients in total (60 in the intervention group, and 61 in the control group). The baseline results for the intervention and control group are summarised and compared with respect to socio-demographic and clinical characteristics (see Table 5.2, p.126), primary outcomes (see Table 5.3, p.128, & Table 5.4, p.129) and secondary outcomes (see Table 5.5, p.120). The distribution of scores on some of the continuous variables was slightly skewed. However, this is to be expected given that the sample consists only of patients from one end of the glycaemic control spectrum who were specifically sampled in order to target their poorer glycaemic control, which is associated with poorer outcomes in other physical and psychosocial domains (e.g. BMI, blood pressure, illness perceptions, psychological well-being).

5.2.1 Socio-demographic and clinical characteristics

Table 5.2 (p.126) summarises the baseline socio-demographic and clinical characteristics of both groups. There appeared to be no obvious differences between groups across any of these variables, except for employment status. In the intervention group, there were a lower proportion of people in employment (35% vs. 62%), and a higher proportion of participants who were retired (37% vs. 23%), when compared to the control group. Approximately two thirds of participants in both groups were male, and both groups had a similar mean age of around 58 years. The average duration of diabetes in both groups was also comparable, at approximately 9 years since diagnosis. Three quarters of participants in both groups were married, and approximately half of participants in both groups reported leaving school before completely their Leaving Certificate. Both groups had comparable levels of diabetes-related complications, and about half of participants in both groups were treated with OHA's only, and the remaining half were on insulin.

Table 5.2

Socio-demographic & clinical characteristics: intervention & control groups

	Control (n=61)	**Intervention** (n=60)
% Male	63% (n=38)	65% (n=39)
Age (Mean, SD)	57.29 (11.34)	59.96 (11.67)
Marital status		
% single	2% (n=1)	2% (n=1)
% living with partner	3% (n=2)	5% (n=3)
% married	75% (n=46)	75% (n=46)
% divorced/separate	10% (n=6)	8% (n=5)
% widowed	10% (n=6)	10% (n=6)
Employment status		
% work in the home	12% (n=7)	25% (n=15)
% employed	62% (n=38)	35% (n=21)
% unemployed	3% (n=2)	3% (n=2)
% retired	23% (n=14)	37% (n=22)
Level of education		
%Pre-Leaving Cert.	54% (n=35)	53% (n=32)
% With Leaving Cert.	26% (n=16)	25% (n=15)
% 3rd Level	12% (n=7)	18% (n=11)
% Missing	5% (n=3)	3 % (n=2)
% GMS	33% (n=20)	33% (n=20)
Years diagnosed Mean (SD)	9.65 (6.45)	9.17 (7.10)
Complications		
% retinopathy	8% (n=5)	7% (n=4)
% neuropathy	3% (n=2)	8% (n=5)
% nephropathy	2% (n=1)	2% (n=1)
% hypertension	41% (n=25)	40% (n=24)
Treatment type		
% insulin-treated	49% (n=30)	55% (n=33)
% OHA's only	51% (n=31)	43% (n=26)
% Missing	-	2% (n=1)

5.2.2 Primary outcomes

Table 5.3 (p. 128) presents a summary of the primary outcomes for each group at baseline. There were no obvious differences between the groups on any of these

outcomes, indicating that the intervention and control groups were comparable across these outcomes at baseline.

Glycaemic control was assessed by the HBA1c test. The median score is presented here because participants last three HbA1c readings were recorded, in order to establish persistent poor glycaemic control. Both groups had similar HbA1cs (Intervention=9.06, SD=0.96 vs. Control=9.29, SD=1.13, $p \geq 0.05$). The range of values was 7.1-12.0 in the intervention group, and 6.8-13.4 in the control group.

Scores on the BRIEF-IPQ subscales (e.g. Consequences, Timeline, and Personal Control) ranged from 0 to 10 and there appeared to be no obvious differences between intervention and control groups on any of these subscales. Beliefs about the *causes* of diabetes were assessed by asking participants to list the three main factors that they believed caused their illness. Here, 20 different causal beliefs were indicated (see table 5.4, p.130). All participants in the control group (n=60) listed at least one cause for their diabetes, 56.5% (n=34) listed two causes, whilst 30% (n=18) listed three causes. In the control group, all participants (n=61) listed one cause, 67% listed two causes (n=41), and 37.5% listed three causes (n=23). For the purpose of analysis the 20 original beliefs were grouped into eight broad categories, including: "*Don't know*"; *over-weight/obesity*; *genetics/family history*; *diet factors* (e.g. too much sugar, fizzy drinks, irregular eating habits/snacking; caffeine); *lack exercise*; *other lifestyle factors* (e.g. smoking, alcohol misuse); *other physical factors* (e.g. pregnancy, age, other illness, accident/injury); and *psychological factors* (e.g. general stress, work stress, lack of knowledge, bad luck). The proportion of participants attributing the cause of their diabetes to each of these eight factors appeared comparable across groups.

With regard to overall psychological well being, scores on the negative well-being, positive well-being and energy subscales of the W-BQ ranged from 0 to 12. Scores on these scales were summed to obtain an overall mean score of general well-being, which ranged from 0 to 36. Both groups had similar levels of well being.

Table 5.3

Primary Outcomes: baseline comparison intervention and control groups

	Control (n=61) Mean (SD)	**Intervention (n=60)** Mean (SD)
HbA1c (Median)	9.29 (1.13)	.06 (0.96)
Illness perceptions		
Consequences	5.45 (3.2)	5.01 (3.36)
Timeline	8.55 (2.42)	8.63 (2.31)
Personal control	4.55 (2.77)	5.21 (3.01)
Treatment control	6.80 (2.80)	7.01 (2.65)
Symptoms	4.37 (3.57)	4.20 (3.34)
Concern	4.95 (3.51)	4.21 (3.58)
Understanding	5.91 (2.99)	5.91 (2.78)
Emotional representations	5.09 (3.71)	4.25 (3.92)
Causes		
1. "Don't know"	12%	17%
2. Over-weight	45%	33%
3. Genetics	46%	39%
4. Diet factors	30%	40%
5. Lack of exercise	12%	7%
6. Other lifestyle factors	10%	9%
7. Other physical factors	22%	17%
8. Psychological factors	20%	17 %
Well-being		
Negative	4.24 (3.96)	4.06 (4.10)
Energy	4.40 (3.82)	4.23 (3.56)
Positive	8.26 (3.33)	8.28 (3.06)
General well-being	20.29 (8.52)	20.45 (8.28)

Table 5.4

Percentage reporting causal perceptions at baseline: intervention and control groups

Cause	% Cause A		% Cause B		% Cause C	
	Intervention	Control	Intervention	Control	Intervention	Control
1. "Don't know"	17%	12%	-	-	-	-
2. Over-weight	22%	17%	9%	20%	3%	8%
3. Genetics	24%	33%	10%	12%	5%	5%
4. Diet Factors						
Poor diet	10%	5%	5%	10%	5%	5%
Too much sugar	12%	5%	5%	4%	2%	-
Fizzy drinks	-	2%	-	-	-	-
Irregular eating/ snacking	-	-	7%	-	2%	2%
Caffeine	-	-	-	-	2%	-
5. Lack of exercise	-	3%	5%	4%	2%	-
6. Other lifestyle factors						
Smoking	-	-	-	2%	-	2%
Alcohol misuse	-	5%	5%	-	2%	-
7. Other physical factors						
Pregnancy	2%	4%	2%	4%	2%	2%
Age	2%	4%	-	-	2%	-
Accident/injury	2%	-	-	4%	-	-
Other illness	2%	4%	5%	2%	2%	2%
8. Psychological factors						
Stress-general	4%	7%	-	7%	-	5%
Work-stress	2%	2%	5%	2%	2%	-
Lack knowledge	-	-	-	-	-	-
Bad luck	2%	-	-	-	-	-

5.2.3 Secondary outcomes

The baseline scores for the secondary outcomes are provided in Table 5.5. There appeared to be no major differences between groups in terms of BMI or blood pressure. Low mean scores indicate both groups are having difficulty adhering to diabetes self-care recommendations, however, there were no obvious differences between groups on these scales. Thus, it appeared that the intervention and control groups were comparable across these secondary outcomes at baseline. A higher proportion of the control groups reported being smokers (24.5% vs. 13.3%), and for diabetes self-efficacy, the intervention group had a slightly lower mean score (Intervention M=86.83, SD=19.06vs. Control M=78.75, SD=19.06). Both groups reported similar levels of supportive family behaviour and non-supportive behaviour.

Table 5.5

Secondary Outcomes: baseline comparison of mean scores (SD) and percentages in the intervention and control groups

	Control (n=61) Mean (SD)	**Intervention** (n=60) Mean (SD)
BMI	32.60 (4.78) (n=55)	32.01 (5.15) (n=56)
Systolic BP	138.00 (17.93)	139.51 (19.17)
Diastolic BP	77.65 (10.64)	75.96 (9.71)
Self-efficacy	78.75 (19.06)	86.83 (20.85)
Diabetes self-care		
Diet (general)	8.19 (4.36)	8.51 (4.01)
5 Fruit/veg	4.27 (2.32)	4.35 (2.36)
Fat intake	3.26 (2.12)	3.63 (2.13)
Exercise	3.36 (3.26)	3.46 (3.81)
BG testing	8.40 (5.29)	9.88 (4.64)
Foot care	5.57 (4.77)	4.56 (5.13)
% smokers	24.5% (n=15)	13.3% (n=8)
Family support		
Supportive	26.46 (6.89)	24.65 (7.51)
Non-supportive	16.22 (6.45)	15.45 (5.92)

5.3 BASELINE FAMILY DATA

Sixty-eight participants (56%) had family members who completed and returned the baseline measures (32 in the control group, 36 in the intervention group). The socio-demographic characteristics of family members returning questionnaires are presented in Table 5.6. At baseline, the intervention and control groups appear to be comparable across these socio-demographic variables, although, when compared to the control group, a slightly higher proportion of family members in the intervention group were the wives/partners of participants (69% intervention vs. 47% control).

Table 5.6: Sociodemographic characteristics family members

	Control (n=32)	Intervention (n=36)
Age Mean (SD)	47.93 (15.81)	54.09 (12.53)
% Male	38 % (n=12)	25% (n=9)
Relationship		
%Husband/partner	21% (n=7)	14% (n=5)
%Wife/partner	47% (n=15)	69% (n=25)
%Daughter	19% (n=6)	17% (n=6)
%Other	13% (n=4)	0% (n=0)

5.3.1 Comparison of intervention and control groups

There were no obvious differences between the illness perceptions and reports of family support of family members in the intervention and control groups at baseline (see Table 5.7, p.158), indicating that at baseline family members in both the intervention and control had comparable perceptions of diabetes and provided approximately similar levels of support for diabetes management.

Table 5.7

Family members' illness perceptions and family support behaviour at baseline

	Control (n=32)	**Intervention** (n=36)
Illness perceptions		
Consequences (patient's life)	5.86 (3.58)	5.11 (3.24)
Consequences (own life)	3.90 (3.18)	3.48 (3.02)
Timeline	9.90 (0.39)	9.82 (1.01)
Personal control (patient)	5.09 (3.60)	6.00 (2.96)
Personal control (own)	3.58 (3.22)	2.38 (2.91)
Treatment control	7.80 (2.7)	8.88 (2.36)
Symptoms	5.23 (2.83)	4.91 (3.22)
Concern (patient's)	5.12 (3.18)	5.91 (3.49)
Concern (own)	8.19 (2.66)	7.77 (2.75)
Understanding (patient's)	7.58 (2.70)	7.50 (2.77)
Understanding (own)	6.51 (3.41)	7.14 (3.36)
Emotional Representations (patient's)	5.19 (3.28)	4.79 (3.32)
Emotional Representations (own)	5.51 (2.63)	5.48 (3.18)
Causes		
1.Don't know	9.8% (n=6)	6.7% (n=4)
2.Overweight	21.3% (n=13)	16.7% (n=10)
3.Genetics	21.3% (n=13)	20.0% (n=12)
4.Diet factors	27.9% (n=17)	36.7% (n=22)
5.Lack exercise	16.4% (n=10)	10.0% (n=6)
6.Other lifestyle factors	6.6% (n=4)	6.7% (n=4)
7.Other physical factors	3.3% (n=2)	10.0% (n=6)
8.Psychological factors	3.3% (n=2)	10.0% (n=6)
Family support		
Support	24.20 (7.44)	24.06 (7.02)
Non-support	18.00 (5.84)	17.32 (5.33)

5.3.2 Comparison of patient and family member perceptions of diabetes

In both groups, family members had a more accurate perception of diabetes as a chronic condition, and also perceived patients to have a more accurate understanding of diabetes than patients themselves reported Table 5.8 (p.134). A smaller proportion of family members attributed the cause of diabetes to genetic factors. In the intervention group, the family members differed significantly from the patients with respect to their perceptions of treatment control and diabetes-specific concerns. Thus, family members perceived diabetes treatment to be more effective than patients, and also believed that the patient was more concerned about their diabetes than the patients themselves reported.

Table 5.8

Comparison of patients' and family members' illness perceptions and family support behaviour at baseline

	Control					**Intervention**				
	Family (n=32)	Patient (n=32)	t	df	p	Family (n=36)	Patient (n=36)	t	df	p
Illness perceptions										
Consequences	5.86 (3.58)	5.00 (3.24)	-1.607	28	0.11	5.11 (3.24)	4.58 (3.21)	-0.610	34	0.54
Timeline	9.90 (0.39)	8.06 (2.77)	-3.838	30	**0.001***	9.82 (1.01)	8.91 (2.06)	-2.324	34	**0.02***
Personal control	5.09 (3.60)	4.87 (2.70)	-0.373	30	0.71	6.00 (2.96)	5.05 (2.91)	-1.325	35	0.19
Treatment control	7.80 (2.7)	6.81 (2.90)	-1.685	30	0.10	8.88 (2.36)	6.83 (2.54)	-4.163	34	**0.000***
Symptoms	5.23 (2.83)	4.25 (3.69)	-1.410	30	0.16	4.91 (3.22)	4.33 (3.37)	-0.993	34	0.328
Concern	5.12 (3.18)	4.61 (3.55)	-0.533	29	0.59	5.91 (3.49)	3.19 (3.26)	-3.628	35	**0.001***
Understanding	7.58 (2.70)	5.34 (2.94)	-3.843	30	**0.001***	7.50 (2.77)	5.50 (2.73)	-3.558	33	**0.001***
Emotional Rep.	5.19 (3.28)	4.75 (3.94)	-0.402	30	0.691	4.79 (3.32)	3.69 (3.99)	-1.327	33	0.194
Causes			χ^2	df	p			χ^2	df	p
1.Don't know	19%	15.5%	0.334	1	0.56	11%	22%	0.793	1	0.37
2.Overweight	40.5%	37.5%	1.203	1	0.27	29%	27.5%	2.499	1	0.11
3.Genetics	40.5%	44%	5.056	1	**0.025***	33.5%	41.5%	14.157	1	**0.000***
4.Diet factors	53%	31.%	0.615	1	0.43	61%	33.5%	0.305	1	0.58
5.Lack exercise	31.5%	15.5%	0.859	1	0.35	16.5%	5.5%	0.000	1	0.90
6.Other lifestyle factors	12.5%	9.5%	0.042	1	0.83	11%	11%	2.898	1	0.089
7.Other physical factors	6.5%	9.5%	0.000	1	1.00	16.5%	14%	6.275	1	**0.012***
8.Psychological factors	3%	15.5%	0.124	1	0.72	16.5%	19.5%	2.892	1	0.089
Family support								t	df	p
Support	24.20 (7.44)	27.00 (6.87)	1.75	28	0.08	24.06 (7.02)	25.00 (7.32)	0.62	31	0.65
Non-support	16.60 (6.62)	16.36 (6.79)	-1.00	58	0.33	17.32 (5.33)	15.80 (6.15)	-1.32	60	0.22

5.4 FOLLOW-UP PATIENT DATA

5.4.1 Follow-up of patients

The progress of patients through the study is illustrated in the flowchart in Figure 5.2. Of the 121 patients initially recruited, 60 were randomized to the control group, and 61 to the intervention group. However, only 36 participants in the intervention group received the intervention. Of the remaining 24, five participants were unable to be contacted, two withdrew from the study due to ill health (both diagnosed with cancer), whilst eight participants were unable to receive the intervention because their family member was unwilling to participate. The remaining nine participants initially made appointments with the therapist to receive the intervention, but this group of participants continually missed their appointments and were unavailable at the pre-agreed appointment times (i.e. the interventionist arrived at the house, to find that nobody was home). It was decided that if this happened on three occasions, it would be considered that the participant did not want to partake in the intervention (i.e. had withdrawan) and no more attempts would be made to organise appointments (see section 5.9, *"Process Evaluation"* for more information).

Participants were recalled for follow-up data collection in the same staggered manner as they were recruited. Follow-up HbA1c results were available for 84% (102/121) of participants in total, whilst 71% (86/121) completed the psychological measures. In the intervention group, 82% (49/60) were analysed for HbA1c and 68% (41/60) were analysed for psychological outcomes. In the control group, 87% (53/61) were analysed for HbA1c and 74% (45/61) were analysed for psychological outcomes.

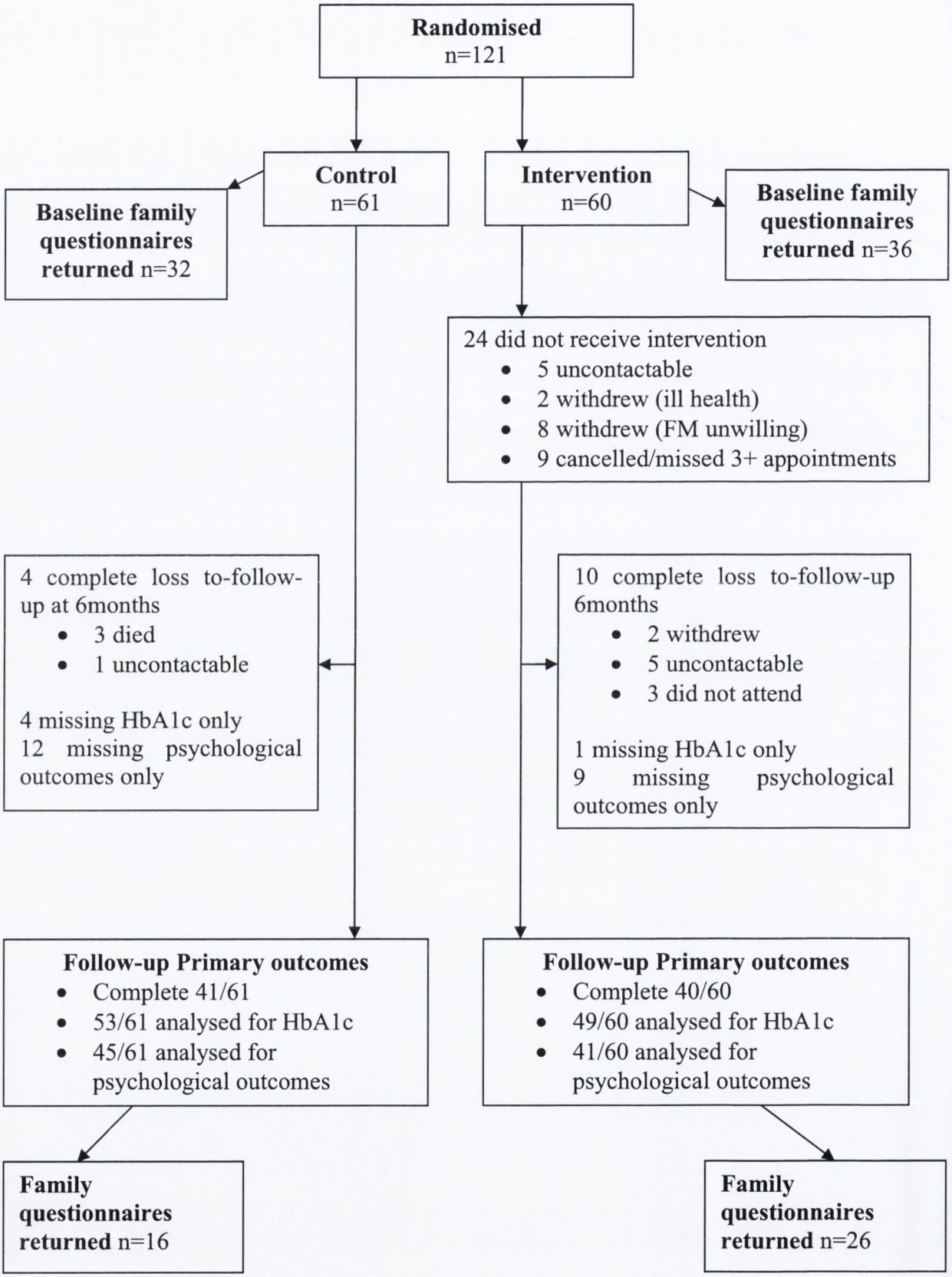

Figure 5.2: *Trial Profile*

5.4.2 Assumptions of Multiple Regression

The data was checked for the assumptions underlying the use of Multiple Regression: multi-collinearity; singularity; outliers; normality; homoscedasity; independence of residuals; homogeneity of variance; homogeneity of regression; and reliability of covariates. All primary outcomes, (except HbA1c), satisfied these assumptions. With regards to HbA1c, the assumption of homogeneity of regression was violated. In essence, the assumption of homogeneity of regression refers to a null hypothesis of *equality of slopes*. That is, that the slopes of the regression of the dependent variable (DV: follow-up HbA1c) on the covariate (CV: baseline HbA1c) are the same for all cells of a design (the intervention and control groups in an RCT). Adjustment of DV scores in MLR is made on the basis of an average within-cell regression coefficient (i.e. the average of the slopes for all cells). Thus, it is assumed that the slopes of the regression between the DV and the CV within each cell do not differ significantly from each other, or from a single estimate of the population regression coefficient (i.e. that the slopes are equal for all cells, or show 'homogeneity of regression').

Heterogeneity of regression implies that there is a different DV-CV slope in some cells, indicating an interaction between the independent variable (IV: group allocation in this case) and the covariate (baseline HbA1c). If IV's and CV's interact, the relationship between the IV and the DV is different at different levels of the IV, thus the CV adjustment that is needed for various cells is different. In this analysis, the slopes of the regression lines for the dependent variable (RCT group) on the covariate (baseline HbA1c) were significantly different (see Figure 5.3), indicating a significant interaction between these variables (B=0.67, SE=0.13, p=0.000), which need to be taken account of in the analysis. Grouping or "blocking" participants according to their pre-intervention scores on the covariate (e.g. low, medium, high), is a well-established method of dealing with heterogeneity of regression (Tabachnick, 2007). The groups or "blocks" become another full-scale IV; interpretation of the main effect of the IV of interest is straightforward, and variation due to the potential CV is removed from the estimate of error variance and assessed as a separate main effect.

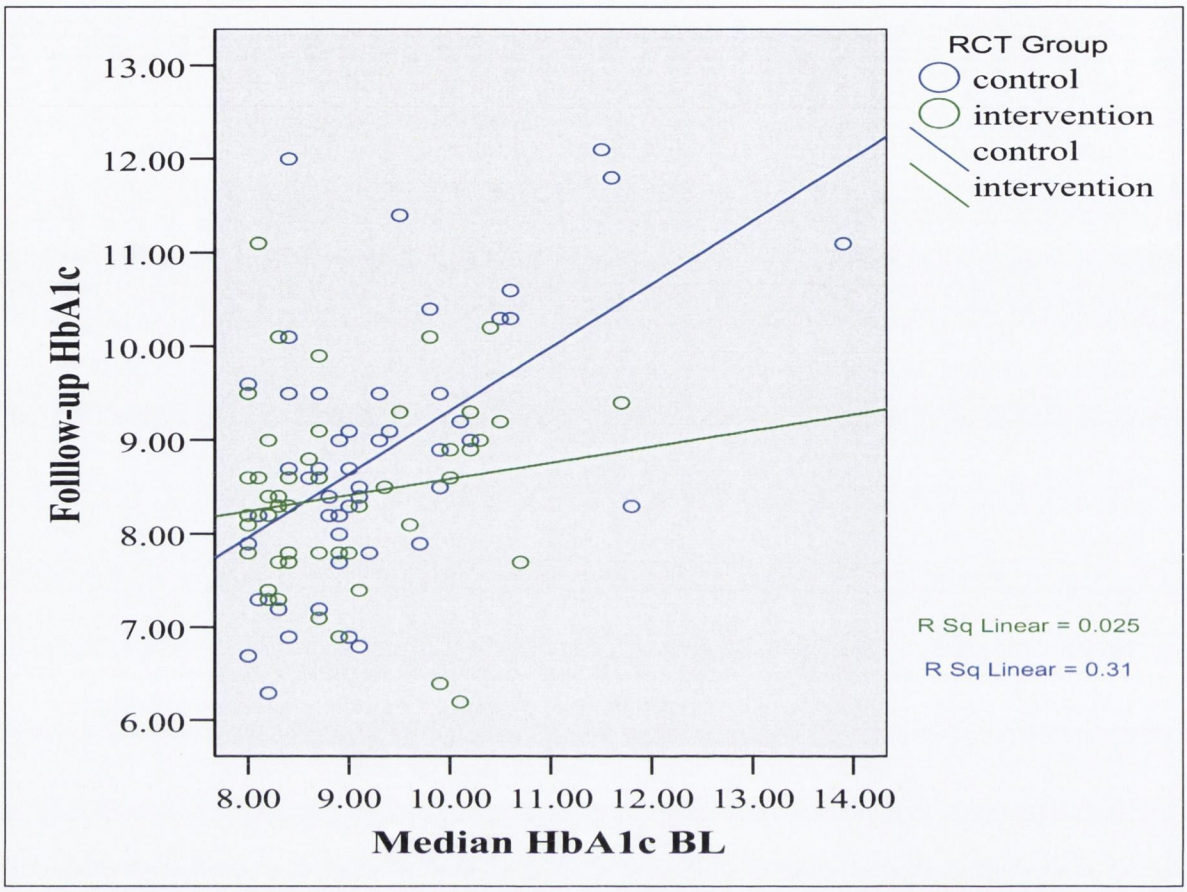

Figure 5.3: *Scatter-plot illustrating heterogeneity of regression of HbA1c covariate*

5.5 PRIMARY OUTCOMES

Table 5.9 (p.139) presents a comparison of intervention and control groups at 6-months follow-up across the primary outcome measures. All analysis was intention-to-treat, adjusting for covariates (corresponding baseline measure, duration of diabetes and medication change).

The findings are described below.

Table 5.9

Adjusted mean intervention effect on primary outcomes

	Control		Intervention								
	Baseline Mean (SD)	6months Mean (SD)	Baseline Mean (SD)	6months Mean (SD)	n	B	SE of B	ß	95% CI	P	
HbA1c ¶	9.29 (1.13)	8.80 (1.36)	9.06 (0.96)	8.41 (0.99)	102	4.01	1.99	1.65	**0.05 to 7.98**	**0.04***	√
Illness perceptions											
Consequences	5.45 (3.21)	5.31 (3.21)	5.01 (3.36)	3.68 (3.13)	86	-0.66	0.51	-0.10	-1.68 to 0.35	0.19	-
Timeline	8.55 (2.42)	9.28 (2.27)	8.63 (2.31)	9.80 (1.24)	86	0.51	0.37	0.13	-0.23 to 1.25	0.17	-
Personal control	4.45 (2.77)	4.75 (3.19)	5.25 (3.01)	7.02 (2.39)	86	1.51	0.58	0.25	**0.35 to 2.67**	**0.00***	√
Treatment control	6.80 (2.80)	6.64 (3.63)	7.01 (2.65)	8.41 (2.22)	86	1.49	0.61	0.23	**0.26 to 2.71**	**0.01***	√
Symptoms	4.37 (3.54)	5.33 (3.64)	4.20 (3.34)	3.48 (3.09)	86	-1.62	0.66	-0.23	**-2.94 to -0.29**	**0.01***	√
Concern	4.95 (3.61)	6.20 (3.55)	4.21 (3.68)	3.85 (3.56)	86	-1.98	0.76	-0.26	**-3.49 to -0.46**	**0.01***	√
Understanding	5.91 (2.99)	6.28 (2.80)	5.91 (2.78)	8.39 (1.89)	86	2.27	0.47	0.43	**1.31 to 3.21**	**0.00***	√
Emotional rep.	5.09 (3.72)	5.60 (3.89)	4.25 (3.92)	3.39 (3.23)	86	-1.79	0.74	-0.24	**-3.28 to -0.30**	**0.01***	√
Causes											
Don't know	11.5% (n=7)	6.6% (n=4)	16.7% (n=10)	6.7% (n=4)	85	-0.049	0.05	-0.08	-1.59 to 0.04	0.37	-
Over-weight	44.3% (n=27)	34.4% (n=21)	33.3% (n=20)	23.3% (n=14)	85	-0.003	0.09	0.01	-0.18 to 0.17	0.97	-
Genetics	45.9% (n=28)	39.3% (n=24)	38.3% (n=23)	21.7% (n=13)	85	-0.196	0.07	-0.21	**-0.34 to -0.05**	**0.00***	√
Diet Factors	29.5% (n=18)	32.8% (n=20)	40% (n=24)	35% (n=21)	85	0.082	0.006	0.24	-0.05 to 0.21	0.21	-
Lack Exercise	11.5% (n=7)	6.6% (n=4)	6.7% (n=4)	13.3% (n=8)	85	0.091	0.10	0.08	-0.11 to 0.03	0.38	-
Other lifestyle	9.8% (n=6)	1.6% (n=1)	8.3% (n=5)	6.7% (n=4)	85	0.158	0.01	0.00	**0.027 to 0.29**	**0.01***	√
Other physical	21.3% (n=13)	9.8% (n=6)	16.7% (n=10)	13.3% (n=8)	85	0.066	0.04	0.00	-0.02 to -0.16	0.16	-
Psychological	19.7% (n=12)	16.4% (n=10)	16.7% (n=10)	8.3% (n=5)	85	-0.083	0.06	0.00	-0.22 to 0.05	0.22	-
Well-being											
Negative	4.24 (3.96)	4.08 (4.02)	4.06 (4.10)	2.48 (2.72)	86	-1.38	0.58	-0.19	**-2.54 to -0.23**	**0.01***	√
Energy	4.40 (3.82)	3.48 (3.30)	4.23 (3.56)	7.31 (3.37)	86	3.57	0.64	0.32	**2.29 to 4.86**	**0.00***	√
Positive	8.26 (3.33)	6.60 (3.68)	8.28 (3.06)	9.53 (3.00)	86	2.33	0.57	0.46	**1.20 to 3.47**	**0.00***	√
General well-being	20.29 (8.52)	18.15 (9.03)	20.45 (8.28)	26.36 (7.01)	86	6.98	1.30	0.38	**4.39 to 9.58**	**0.00***	√

Note: Baseline covariates = corresponding baseline measure, duration of diabetes, and medication change √ Indicates improvement

¶Controlling for interaction between HbA1cBL and Group: HbA1cBL*Group B=-0.47, SE=0.21, 95% CI=-0.90 to -0.03, p =0.03 - Indicates no improvement

B= un-standardised coefficient, SE of B = Standard Error of B, ß = standardised coefficient

5.5.1 HbA1c

At six-months follow-up, the mean HbA1c was 8.80 (SD=1.36) in the control group and 8.40 (SD=0.99) in the intervention group, a difference of 0.4%. This corresponds to a drop in HbA1c of 0.5% in the control group, and 0.7% in the intervention group (see Figure 5.4). As a significant interaction was found between baseline levels of HbA1c and intervention group, this interaction term was controlled for in HbA1c comparison After adjusting for baseline covariates and the interaction HbA1c baseline and RCT allocation group, the difference between intervention and control groups at 6-months follow-up was statistically significant (p=0.047), although marginally so.

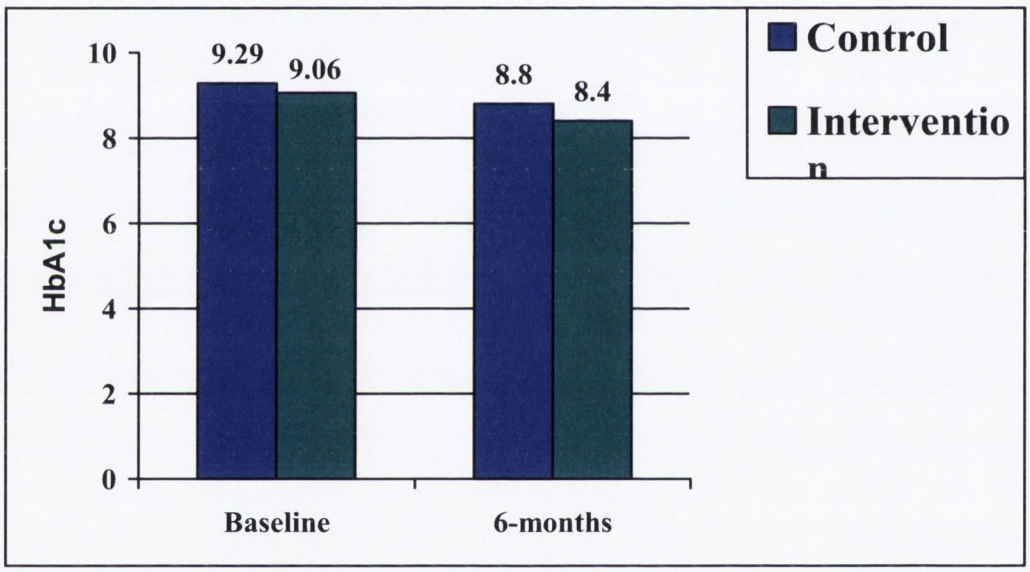

Figure 5.4: *The effect of the intervention on HbA1c*

The influence of the interaction between the covariate (i.e. baseline levels of HbA1c) and treatment group on follow-up HbA1c was investigated further by use of a "blocking" procedure. For this trial, tertile splits were used to group participants into three equal blocks according to their baseline HbA1c scores. This gave rise to three groupings: baseline HbA1c < 8.4; baseline HbA1c 8.5-9.4; and baseline HbA1c>9.5. Figure 5.5 presents the follow-up HbA1c levels in each of these blocks, by treatment group.

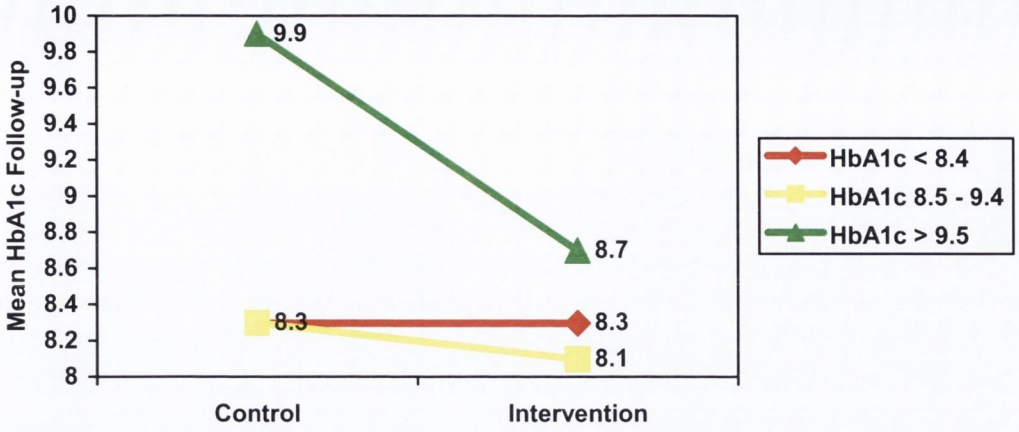

Figure 5.5: *Follow-up HbA1c by grouped baseline HbA1c*

As shown in Figure 5.5, at 6months follow-up there were no differences between treatment and control groups in the block where baseline HbA1c < 8.4 (Intervention M=8.35 SD=0.93, n=22, vs. Control M=8.30, SD=1.56, n=14), or in the block where baseline HbA1c 8.5-9.4 (Intervention M=8.16 SD=0.87, n=12, vs. Control M=8.37, SD=0.73, n=24). However in the block where baseline levels were highest at baseline (HbA1c >9.5), follow-up HbA1c levels in the intervention group were 1.2% lower compared to the control group (see Figure 5.6.) (Intervention M=8.70 SD=1.16, n=15, vs. Control M=9.95, SD=1.31, n=15). This difference was statistically significant (B=-1.28, SE (B)=0.49, p=0.01, 95%CI -2.29 to -0.26).

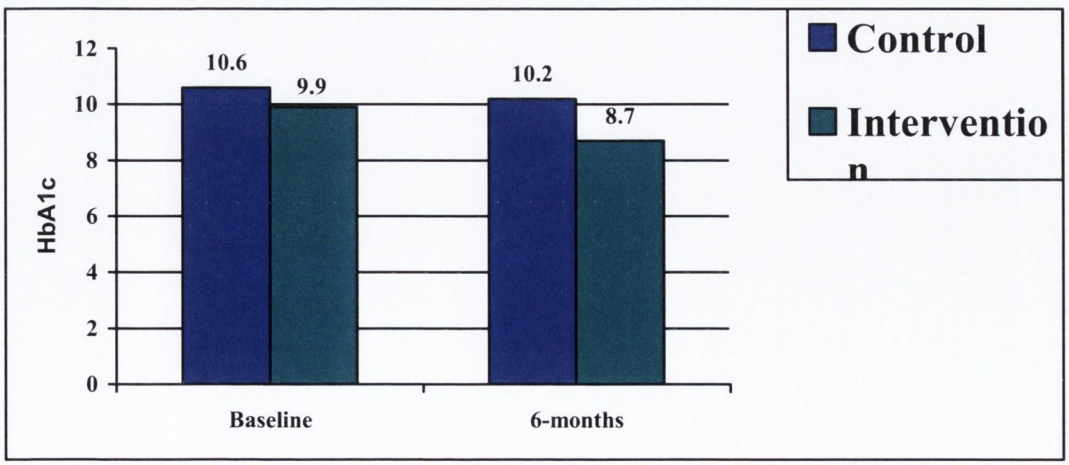

Figure 5.6: *The effect of the intervention on HbA1c in the HbA1c > 9.5% block*

5.5.2 *Illness perceptions*

There were no statistically significant differences at six-month follow-up between groups on the 'consequences' and 'timeline' scales (see Table 5.9). However, there were statistically significant differences on all other scales. At-follow-up, compared to the control group, the intervention group reported significantly higher levels of personal control, significant increases in their beliefs about the effectiveness of diabetes treatment, and also a greater understanding of diabetes. Participants in the intervention group also reported experiencing significantly less diabetes-related symptoms compared to control group participants, along with a significantly less diabetes specific concern and psychological distress related to diabetes. In terms of causal perceptions, significantly fewer participants in the intervention group attributed their diabetes to genetic factors, and significantly more perceived their diabetes to be caused by other lifestyle factors.

5.5.3 *Psychological well-being*

At 6-months follow-up there were statistically significant differences between intervention and control groups on all well-being scales. Compared to the control group, the intervention group reported significantly lower levels of negative well-being, and significantly higher levels of positive well-being, energy and general well-being.

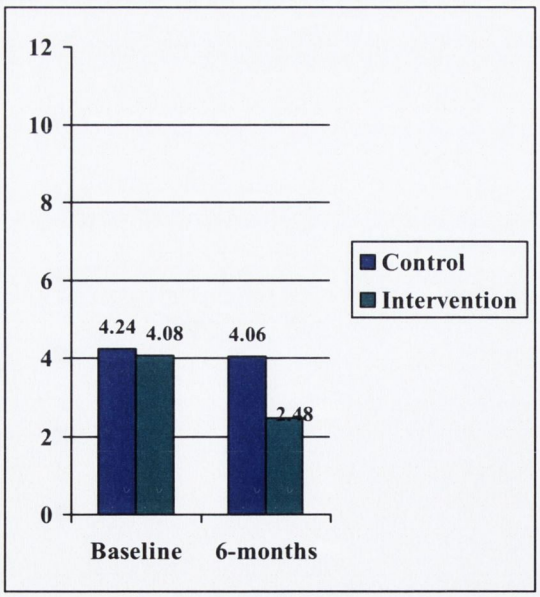

Figure 5.7: *Negative well-being*

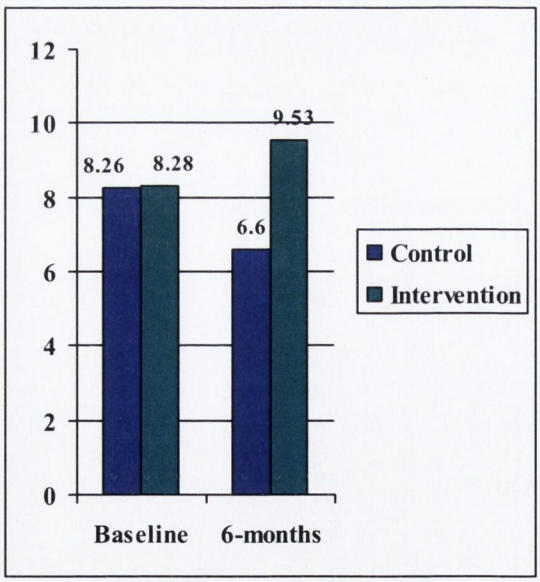

Figure 5.8 *Positive well-being*

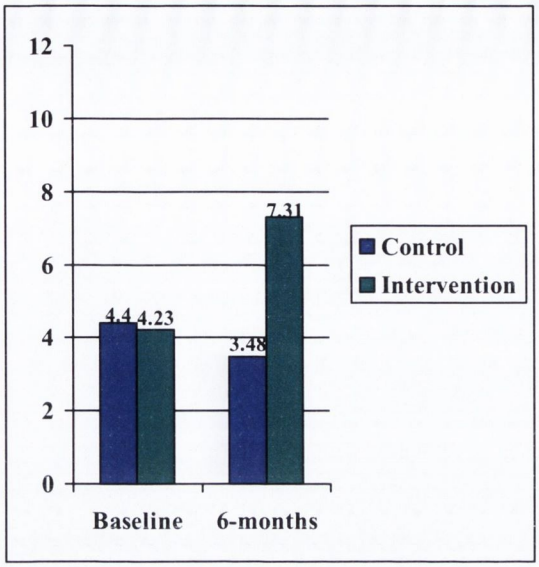

Figure 5.9 *Energy*

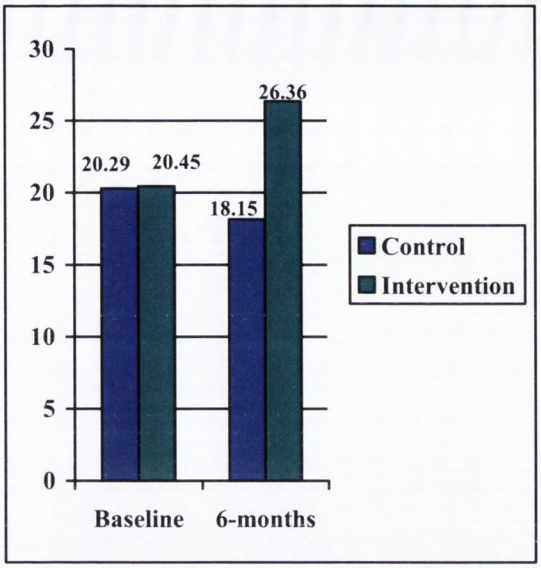

Figure 5.10 *Total well-being*

5.6 SECONDARY OUTCOMES

The analysis for the secondary outcomes was as per primary outcomes. However, the significance level was set at $p \leq 0.01$, given the increased risk of Type 1 errors (or false-positive findings) associated with multiple analyses of the same data (Tukey, 1977). Thus, as for the primary outcomes, all analysis was intention-to-treat, adjusting for covariates (corresponding baseline measure, duration of diabetes and medication change). The secondary data was also checked for the assumptions underlying the use of Multiple Linear Regression: multi-collinearity; singularity; outliers, normality; homoscedasity; independence of residuals; homogeneity of variance; homogeneity of regression; and reliability of covariates. All secondary outcomes satisfied these assumptions. Results from the analysis of secondary outcomes are presented in Table 5.10 and discussed in the subsequent subsections.

Table 5.10

Adjusted mean intervention effect on secondary outcomes

	Control		Intervention		n	Beta	SE of B	ß	95% CI	p	
	Baseline	6-months	Baseline	6 months							
BMI	32.60 (4.78)	33.88 (5.32)	32.01 (5.15)	31.57 (5.16)	87	-0.77	0.55	-0.06	-1.82 to 0.39	0.20	-
Systolic BP	138.00 (17.93)	135.85 (16.48)	139.51 (19.17)	139.72 (20.79)	95	3.47	3.61	0.09	-3.86 to 10.80	0.34	-
Diastolic BP	77.65 (10.64)	77.00 (9.91)	75.96 (9.71)	75.43 (10.32)	95	-0.34	2.01	-0.01	-4.43 to 3.66	0.86	-
Self-care activities											
General diet	8.19 (4.36)	8.42 (4.19)	8.51 (4.01)	10.63 (2.84)	86	1.93	0.67	0.25	**0.58 to 3.28**	**0.005***	√
5 fruit/veg	4.27 (2.32)	3.46 (2.62)	4.35 (2.36)	4.70 (2.46)	86	0.92	0.52	0.17	-0.12 to 1.97	0.09	-
Fat intake	3.26 (2.12)	3.51 (2.26)	3.63 (2.12)	3.36 (2.16)	86	-0.26	0.42	-0.06	-112.to 0.60	0.54	-
Exercise	3.36 (3.26)	3.11 (3.29)	3.46 (3.81)	5.39 (4.02)	86	1.93	0.69	0.25	**0.56 to 3.31**	**0.006***	√
BG testing	8.40 (5.29)	8.82 (5.45)	9.88 (4.46)	10.70 (4.72)	86	1.31	0.91	0.12	-1.20 to 0.70	0.60	-
Foot care	5.57 (4.77)	5.68 (5.35)	4.56 (5.13)	6.34 (5.08)	86	1.06	1.10	0.10	-1.13 to 3.26	0.96	-
No. smokers	13/46 (28.2%)	12/45 (26%)	5/41 (8.3%)	3/41 (7%)	86	-0.28	0.21	-0.08	-0.71 to 0.21	0.19	-
Self-efficacy	78.75 (19.06)	91.26 (28.51)	86.63 (20.85)	116.97 (18.51)	86	22.17	5.34	0.40	**11.53 to 32.82**	**0.000***	√
Family support											
Support	26.46 (6.89)	20.75 (7.32)	24.65 (7.51)	24.951 (8.4)	86	4.45	1.62	0.27	**1.21 to 7.69**	**0.008***	√
Non-support	16.22 (6.45)	17.56 (7.16)	15.45 (5.92)	14.68 (5.96)	86	-2.42	1.34	-0.18	-5.11 to 0.05	0.07	-

B = un-standardised coefficient, SE of B = Standard Error or B, ß = standardised coefficient

√ Indicates improvement
-Indicates no change

5.6.1 BMI & Blood Pressure

At 6 months follow-up there were no significant differences between groups in terms of BMI (see Figure 5.11) or blood pressure (see Figure 5.12)

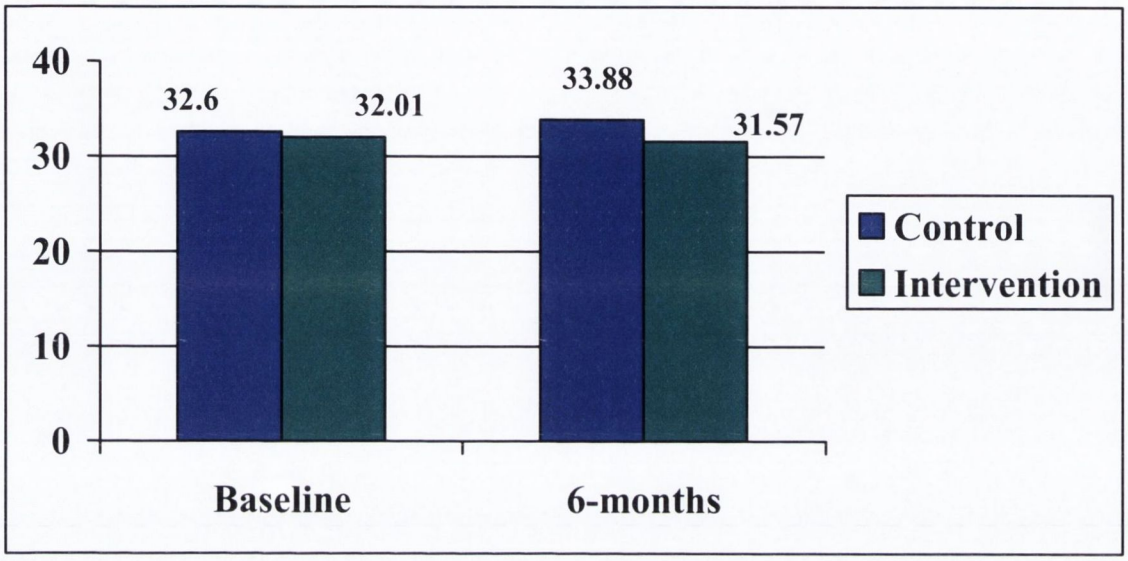

Figure 5.11: *BMI*

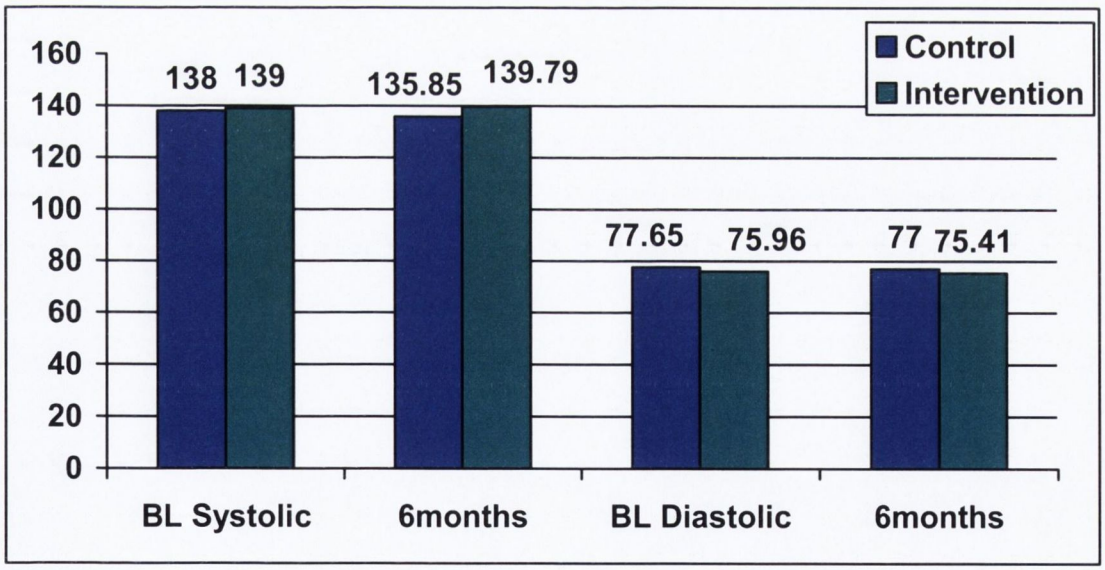

Figure 5.12: *Blood pressure*

5.6.2 Diabetes self-efficacy

The intervention group reported statistically significantly higher levels of diabetes self-efficacy at follow-up, when compared to the control group (see Figure 5.13).

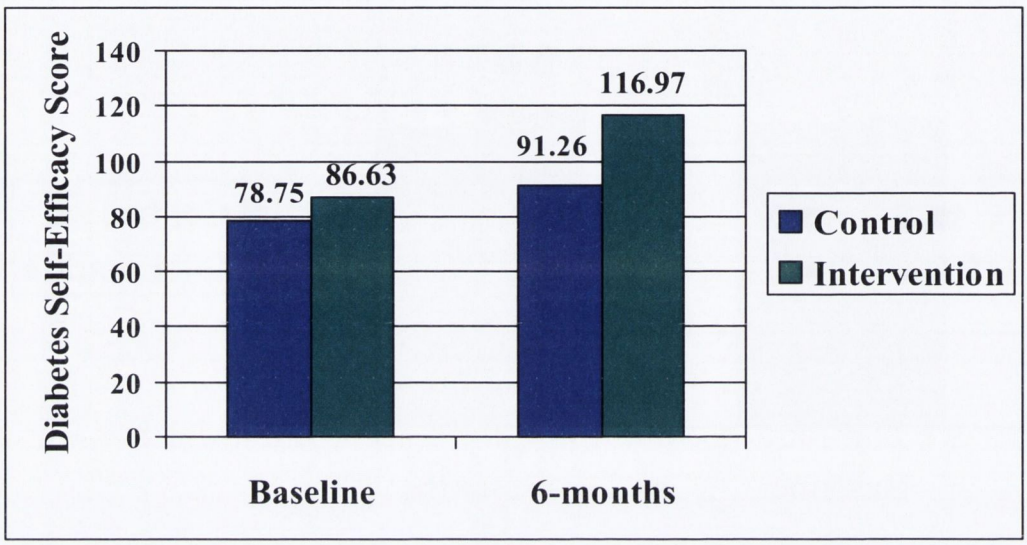

Figure 5.13*: Diabetes self-efficacy*

5.6.3 Diabetes self-care behaviours

At 6-months follow-up, there were no significant differences between groups on the "Five fruit and vegetable a day" scale, fat intake scale, blood glucose testing scale and foot care scale. However, compared to control group, intervention group participants reported statistically significant higher levels of adherence to general dietary recommendations and exercise recommendations, when compared to their control group counterparts (see Figures 5.14 – 5.19).

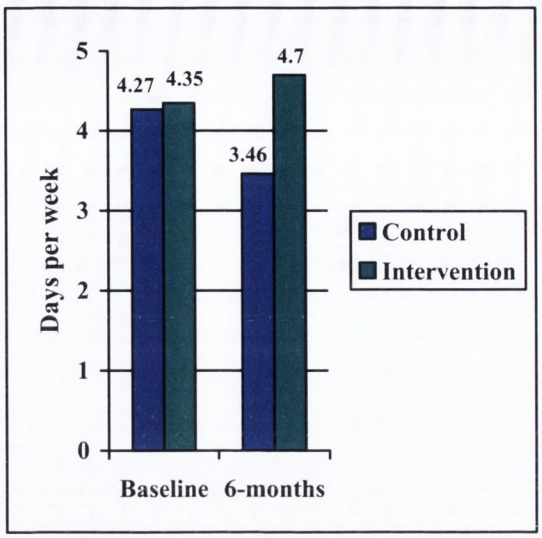

Figure 5.14: *Five fruit and vegetables a day*

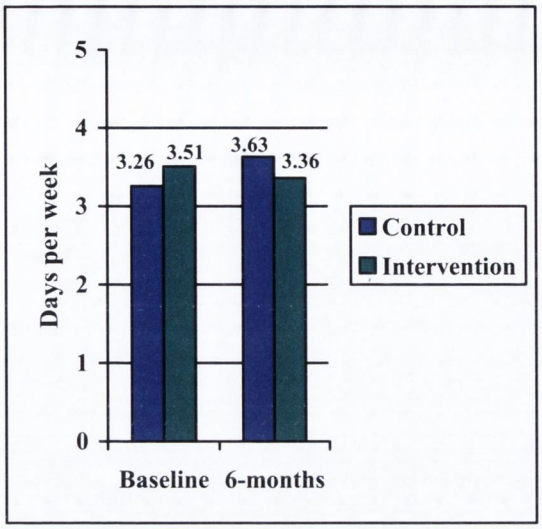

Figure 5.15: *Fat intake*

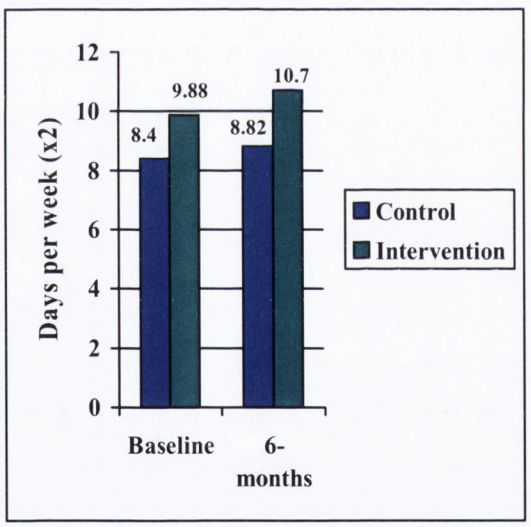

Figure 5.16*: Blood sugar testing*

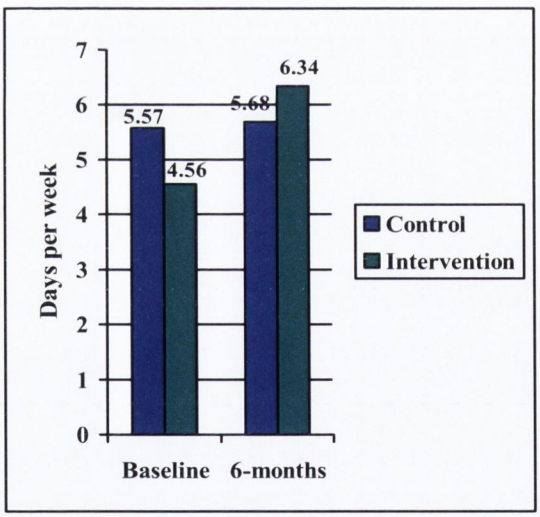

Figure 5.17: *Foot care*

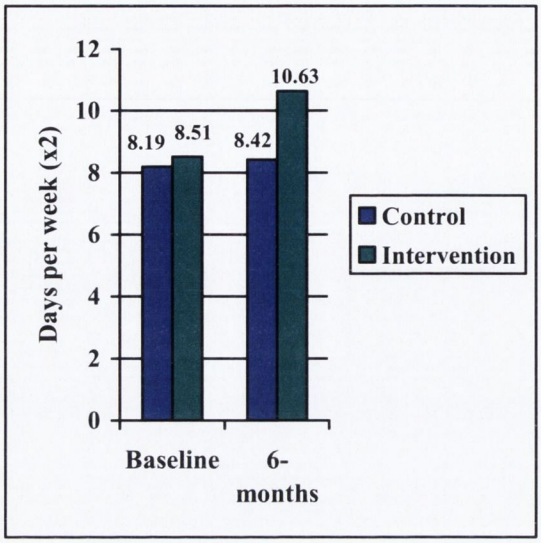

Figure 5.18: *General diet*

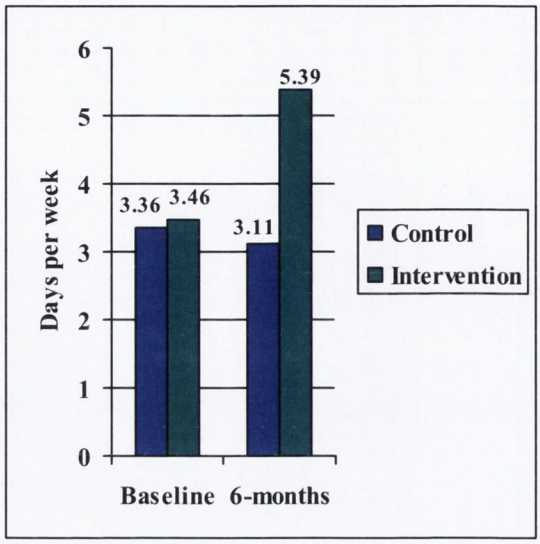

Figure 5.19: *Exercise*

5.6.4 Family support

Compared to the control group, the intervention group reported statistically significant higher levels of supportive family behaviours at 6-month follow-up. There was a trend towards decreased reports of non-supportive family behaviour in the intervention group, however, this did not reach statistical significance (see Figures 5.20-5.21).

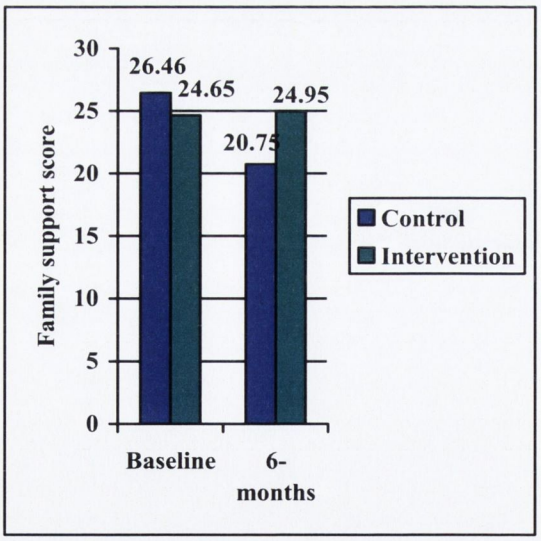

Figure 5.20: *Family support*

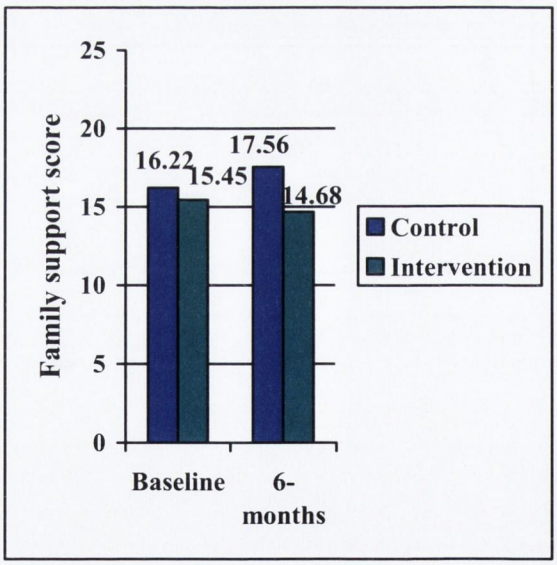

Figure 5.21: *Family non-support*

5.7 FOLLOW-UP FAMILY DATA

Follow-up family questionnaires were returned from 26.2% (n=16) of the control group and 43% (n=26) of participants in the intervention group. These findings are presented below. The analysis comparing the family member outcomes in the intervention and control groups was a per the primary and secondary outcomes analysis. Thus, all analysis was intention-to-treat, adjusting for covariates (corresponding baseline measure, duration of diabetes and medication change). The degree of similarity between patient and family member illness perceptions, and reports of family support, were then assessed using paired t-tests. Given the small number of family member questionnaires returned at follow-up (n = 16 in the control group, n=26 in the intervention group), it was not possible to compare the degree of similarity using the planned *positive/negative classification* approach (see section 4.5.3.).

5.7.1 Family members' illness perceptions and family support

Table 5.11 (p.150) compares the illness perceptions of family members in the intervention and control groups at the six-month follow-up. The former reported statistically significantly lower levels of patient symptoms when compared to their control group counterparts. Their own levels of diabetes-related concern and their perception of the patients' levels of diabetes related-concern were also significantly lower at follow-up when compared to the controls. In addition, family members in the intervention group reported significantly higher levels of diabetes understanding (i.e. illness coherence). There were no other statistically significant differences between the illness perceptions of family members in either group. There were also no significant differences in family members' own reports of the levels of supportive and non-supportive family behaviours for diabetes management.

Table 5.11: Illness perceptions of family members and family support at 6-months follow-up

Illness perceptions	Control (n=16) Baseline	Control (n=16) 6-months	Intervention (n=26) Baseline	Intervention (n=26) 6-months	n	Beta	SE of B	ß	95% CI	p	
Consequences (patients life)	5.86 (3.58)	5.68 (3.62)	5.11 (3.24)	4.65 (3.17)	32	-1.58	0.94	-0.22	-3.51 to 0.33	0.10	-
Consequences (own life)	3.90 (3.18)	2.43 (2.50)	3.48 (3.02)	3.37 (1.38)	32	0.83	0.90	0.14	-1.01 to 2.68	0.36	-
Timeline	9.90 (0.39)	9.75 (0.68)	9.82 (1.01)	9.39 (2.21)	32	-0.16	0.72	-0.04	-1.61 to 1.31	0.823	-
Personal control (patient)	5.09 (3.60)	6.0 (2.50)	6.00 (2.96)	6.37 (3.28)	32	-0.13	0.99	-0.02	-2.16 to 1.69	0.89	-
Personal control (own)	3.58 (3.22)	2.81 (2.88)	2.38 (2.91)	4.04 (3.29)	32	0.66	0.97	0.000	-1/31 to 2.65	0.49	-
Treatment control	7.80 (2.7)	8.25 (2.38)	8.88 (2.36)	8.37 (2.48)	32	-0.43	1.05	0.00	-2.58 to 1.72	0.68	-
Symptoms	5.23 (2.83)	6.37 (3.48)	4.91 (3.22)	4.00 (3.53)	32	-3.12	1.02	-0.44	**-5.21 to -1.04**	**0.005***	√
Concern (patients)	5.12 (3.18)	6.50 (2.96)	5.91 (3.49)	4.20 (3.58)	32	-3.01	1.35	-0.40	**-5.87 to -0.30**	**0.03***	√
Concern (own)	8.19 (2.66)	8.92 (1.28)	7.77 (2.75)	5.29 (3.68)	32	-2.97	1.03	-0.40	**-5.09 to -0.84**	**0.008***	√
Understanding (patients)	7.58 (2.70)	8.37 (1.82)	7.50 (2.77)	8.12 (2.95)	32	0.16	1.05	0.02	-1.99 to 2.32	0.877	-
Understanding (own)	6.51 (3.41)	6.06 (2.81)	7.14 (3.36)	8.29 (2.69)	32	1.98	0.74	0.40	**0.46 to 3.49**	**0.01***	√
Emotional Rep. (patients)	5.19 (3.28)	5.00 (3.61)	4.79 (3.32)	3.63 (3.37)	32	-1.38	1.28	-0.18	-4.01 to 1.24	0.28	-
Emotional Rep. (own)	5.51 (2.63)	5.51 (3.62)	5.48 (3.18)	3.62 (3.56)	32	-2.05	1.32	-0.26	-4.75 to 0.65	0.13	-
Causes											
Don't know	9.8% (n=6)	6.6% (n=4)	6.7% (n=4)	3.3% (n=2)	29	-0.08	0.13	-0.10	-0.35 to -.19	0.54	-
Overweight	21.3% (n=13)	8.2% (n=5)	16.7% (n=10)	13.3% (n=8)	29	0.06	0.17	0.06	-0.29 to 0.42	0.79	-
Genetics	21.3% (n=13)	4.9% (n=3)	20.0% (n=12)	13.3% (n=8)	29	0.22	0.14	0.23	-0.06 to 0.51	0.12	-
Diet factors	27.9% (n=17)	9.8% (n=6)	36.7% (n=22)	18.3% (n=11)	29	0.004	0.18	0.00	-0.37 to 0.38	0.98	-
Lack exercise	16.4% (n=10)	8.2% (n=5)	10.0% (n=6)	8.3% (n=5)	29	0.025	0.14	0.02	-0.27 to 0.32	0.86	-
Other lifestyle factors	6.6% (n=4)	6.6% (n=4)	6.7% (n=4)	11.7% (n=7)	29	0.005	0.15	0.00	-0.31 to 0.32	0.97	-
Other physical factors	3.3% (n=2)	4.9% (n=3)	10.0% (n=6)	6.7% (n=4)	29	0.006	0.09	0.00	-0.13 to 0.26	0.50	-
Psychological factors	3.3% (n=2)	1.6% (n=1)	10.0% (n=6)	8.3% (n=5)	29	-0.02	0.13	0.00	-0.31 to 0.25	0.83	-
Family support											
Support	24.20	23.30	24.06	26.20	30	0.56	2.36	0.05	-4.36 to 5.48	0.81	-
Non-Support	18.00	17.6	17.32	14.79	29	-3.23	2.07	-0.31	-7.60 to 1.13	0.13	-

B = un-standardised coefficient, SE of B = Standard Error of B, ß = standardised coefficient √ Indicates improvement

5.7.2 Degree of similarity between patient & family member perceptions

A comparison of the illness perceptions of both patients and their family members was then undertaken using a series of paired t-tests, and results of this analysis are presented in Table 5.12 (p.152). With regards to the intervention group, there were no statistically significant differences between patients' and family members' illness perceptions of diabetes at 6-months follow-up. This represents a change from baseline (see Table 5.8, p.134), where statistically significant differences were found between patients and family members perceptions of: the timeline of diabetes; the effectiveness of treatment; diabetes-specific concern; levels of understanding about diabetes; and causal perceptions. Turning to the control group, there were still statistically significant differences at follow-up between patient and family members with respect to their perceptions of: the consequences of diabetes; the effectiveness of treatment; and perceptions of understanding. In the control group, family members also continued to perceive diabetes as having a greater impact on patients' life, than patients themselves reported. Furthermore, family members perceived diabetes treatment to be more effective than the patient did, whilst also perceiving patients to have a greater understanding of diabetes than reported by patients themselves. With regards to perceptions of family support for diabetes management, there were no statistically significant differences between patients and family members in either the intervention or control group. However, all these results must be interpreted with caution, due to the small numbers involved in the analysis.

Table 5.12

Comparison of the illness perceptions of patients and family members and the perceptions of family support at 6-months follow-up

	Control					**Intervention**				
	Family (n=32)	Patient (n=32)	t	df	P	Family (n=36)	Patient (n=36)	t	df	p
Illness perceptions										
Consequences	5.68 (3.62)	5.31 (3.21)	-2.96	15	**0.01***	4.65 (3.17)	3.68 (3.13)	-0.79	23	0.43
Timeline	9.75 (0.68)	9.28 (2.27)	-0.839	15	0.41	9.39 (2.21)	9.80 (1.24)	1.32	22	0.20
Personal control	6.0 (2.50)	4.75 (3.19)	-1.51	15	0.15	6.37 (3.28)	7.02 (2.39)	0.95	23	0.35
Treatment control	8.25 (2.38)	6.64 (3.63)	-2.70	15	**0.01***	8.37 (2.48)	8.41 (2.22)	0.25	23	0.80
Symptoms	6.37 (3.48)	5.33 (3.64)	-1.00	15	0.33	4.00 (3.53)	3.48 (3.09)	-1.53	23	0.13
Concern	6.50 (2.96)	6.20 (3.55)	-0.46	15	0.65	4.20 (3.58)	3.85 (3.56)	-0.25	23	0.13
Understanding	8.37 (1.82)	6.28 (2.80)	-4.09	15	**0.001***	8.12 (2.95)	8.39 (1.89)	0.74	23	0.46
Emotional Rep.	5.00 (3.61)	5.60 (3.89)	0.05	15	0.95	3.63 (3.37)	3.39 (3.23)	-0.59	23	0.55
Causes			χ^2	df	P			χ^2	df	p
Don't know	6.6% (n=4)	4.9% (n=3)	0.12	1	0.72	3.3% (n=2)	6.7% (n=4)	9.45	1	0.20
Overweight	8.2% (n=5)	14.7% (n=9)	0.39	1	0.84	13.3% (n=8)	13.3% (n=8)	0.96	1	0.32
Genetics	4.9% (n=3)	14.7% (n=9)	2.69	1	0.10	13.3% (n=8)	11.6% (n=7)	7.15	1	0.10
Diet factors	9.8% (n=6)	4.9% (n=3)	0.02	1	0.87	18.3% (n=11)	15% (n=9)	0.75	1	0.38
Lack exercise	8.2% (n=5)	0% (n=0)	-	-	-	8.3% (n=5)	8.3% (n=5)	0.26	1	0.87
Other lifestyle factors	6.6% (n=4)	0% (n=0)	-	-	-	11.7% (n=7)	5% (n=2)	0.32	1	0.57
Other physical factors	4.9% (n=3)	6.6% (n=4)	0.12	1	0.72	6.7% (n=4)	8.3% (n=5)	3.17	1	0.07
Psychological factors	1.6% (n=1)	3.3% (n=2)	0.07	1	0.78	8.3% (n=5)	3.3% (n=3)	3.64	1	0.11
Family support										
Support	23.30 (8.12)	22.50 (8.14)	-0.26	9	0.79	26.20 (5.85)	25.10 (7.77)	-0.58	19	0.79
Non-Support	17.60 (5.66)	14.60 (5.71)	-1.10	9	0.29	14.94 (4.30)	14.26 (5.86)	-0.52	19	0.60

5.8 ADDITIONAL ANALYSIS

5.8.1 Missing data: Last Observation Carried Forward analysis

Follow-up HbA1c results were missing for 16% (n=19/121) of the total participants, or 13% (n=8) of the control group and 18% (n=11) of the intervention group. Responses on psychological measures were missing for 29% (n=35) of total participants, or 26% (n=16) of the control group and 31% (n=19) of the intervention group. Thus, there was a similar proportion of missing follow-up data in both groups. Table 5.13 (p.154) compares the socio-demographic and baseline clinical characteristics of participants with complete HbA1c at follow-up, with those where follow-up HbA1c levels were missing. The only statistically significant differences between participants with missing and complete HbA1c results, was terms of treatment at baseline: at higher proportion of participants with missing HbA1c levels at follow-up were treated with OHAs only (70% vs.43% in complete HbA1c group). Table 5.14 (p.155) compares the socio-demographic and baseline clinical characteristics of participants with complete psychological measures at follow-up, with participants who did not complete the psychological measures at follow-up. There were no significant differences between these groups.

A sensitivity analysis was conducted to examine the effect of missing data on primary and secondary outcomes. This analysis was undertaken using the "Last Observation Carried Forward" (LOCF) method (see section 4.9.1). Table 5.15 (p.156) presents the results of this analysis for primary outcomes, while Table 5.16 (p.157) presents the results for the secondary outcomes. There were some variations in results when using the LOCF, indicating that missing data may, at least to some extent, be having an effect on outcomes. For instance, when baseline data was substituted in the analysis there were no longer any significant differences between groups in terms of HbA1c, and perceptions of personal control and treatment control. In terms of secondary outcomes, there were no longer any significant differences between groups in terms of diet. However, as discussed in the preceding chapter, when there is a significant treatment effect, the LOCF approach suffers from a loss of power to detect this (Shao & Zhong, 2003).

Table 5.13

Comparison of socio-demographic and baseline clinical characteristics of participants with complete and missing HbA1c values at follow-up

	Available Follow-up HbA1c (n=101)	**Missing Follow-up HbA1c** (n=20)	test	df	p
Sex	Male = 61% (n=62) Female =39% (n=39)	Male = 75% (n=15) Female = 25% (n=5)	χ^2=1.33	1	0.24
Age (Mean, SD)	58.64 (10.75)	58.50 (15.22)	t=0.05	119	0.96
Medical Card	Yes = 34% (n=34) No = 66% (n=67)	Yes = 30% (n=6) No=70% (n=14)	χ^2=0.10	1	0.75
Marital Status	Single = 2% (n=2) Married/partner = 82% (n=83) Separated/Divorced = 8% (n=8) Widowed = 8% (n=8)	Single = 0 Married/partner = 65%(n=13) Separated/Divorced = 15% (n=3) Widowed = 20% (n=4)	χ^2=5.09	3	0.27
Level of Education	Pre-Leaving Cert = 55% (n=56) Leaving Cert. = 27% (n=27) 3rd Level = 13% (n=13)	Pre-Leaving Cert = 55% (n=11) Leaving Cert. = 20% (n=4) 3rd Level = 25% (n=5)	χ^2=1.84	2	0.39
Employment Status	Work in home= 18% (n=18) Employed= 49% (n=49) Unemployed=4% (n=4) Retired=30% (n=30)	Work in home = 20% (n=4) Employed= 50% (n=10) Unemployed=0 Retired=30%(n=6)	χ^2=0.84	3	0.93
Type of treatment	OHA's only=43% (n=43) Insulin=57% (n=57)	OHA's only=70% (n=14) Insulin=30% (n=6)	χ^2=4.87	1	**0.02***
Duration of Diabetes (Mean, SD)	9.71 (7.04)	7.89 (5.08)	t=1.07	117	0.28
HbA1c (Mean, SD)	9.11 (1.03)	9.52 (1.09)	t=-1.61	119	0.11
BMI (Mean, SD)	32.35 (4.99)	32.07 (4.87)	t=0.22	109	0.82
Systolic BP (Mean, SD)	139.15 (17.90)	136.70 (21.62)	t=0.54	119	0.58
Diastolic BP (Mean, SD)	76.40 (10.52)	78.90 (8.19)	t=-1.00	119	0.31

Table 5.14

Comparison of socio-demographic and baseline clinical characteristics of participants with complete and missing psychological measures at follow-up

	Psychological outcomes available at follow-up (n=86)	**Psychological outcomes missing at follow-up** (n=56)	test	df	p
Sex	Male = 62% (n=53) Female =38% (n=33)	Male = 67% (n=24) Female = 33% (n=11)	χ^2=0.51	1	0.42
Age (Mean, SD)	58.22 (11.27)	59.60 (12.26)	t=-0.59	119	0.55
Medical Card	Yes = 36% (n=29) No = 64% (n=57)	Yes = 31% (n=11) No=69% (n=24)	χ^2=0.05	1	0.80
Marital Status	Single = 3% (n=2) Married/partner = 83% (n=71) Separated/Divorced = 8% (n=7) Widowed = 7% (n=6)	Single = 0 Married/partner =71% (n=25) Separated/Divorced =20% (n=7) Widowed = 17% (n=6)	χ^2=5.66	3	0.21
Level of Education	Pre-Leaving Cert = 64% (n=55) Leaving Cert. = 21% (n=18) 3rd Level = 15% (n=13)	Pre-Leaving Cert = 50% (n=17) Leaving Cert. = 37% (n=13) 3rd Level = 20% (n=5)	χ^2=2.17	2	0.24
Employment Status	Work in home= 15% (n=13) Employed= 49% (n=42) Unemployed=5% (n=4) Retired=31% (n=27)	Work in home = 25% (n=9) Employed= 50% (n=17) Unemployed=0 Retired=25%(n=9)	χ^2=4.84	3	0.29
Type of treatment	OHA's only=45% (n=39) Insulin=55% (n=46)	OHA's only=50% (n=18) Insulin=50% (n=17)	χ^2=0.30	1	0.58
Duration of Diabetes (Mean, SD)	8.82 (6.09)	10.96 (8.20)	t=-1.55	117	0.12
HbA1c (Mean, SD)	9.11 (1.06)	9.35 (1.02)	t=-1.61	119	0.24
BMI (Mean, SD)	32.60 (5.08)	31.59 (4.61)	t=0.96	109	0.33
Systolic BP (Mean, SD)	138.36 (17.68)	139.71 (20.60)	t=-0.36	119	0.71
Diastolic BP (Mean, SD)	76.10 (10.09)	78.57 (10.35)	t=-1.12	119	0.22

Table 5.15

Sensitivity analysis of primary outcomes using LOCF method to examine the effects of missing data

	Control		Intervention				SE				
	6-months	6month LOCF	6-months	6months LOCF	n	Beta	of B	ß	95% CI	p	
HbA1c ¶	8.80 (1.36)	8.91 (1.36)	8.41 (0.99)	8.60 (1.80)	118	2.34	1.76	0.93	-1.14 to 5.83	0.18	-
Illness perceptions											
Consequences	5.31 (3.21)	5.21 (3.07)	3.68 (3.13)	4.60 (3.50)	120	-0.27	0.36	-0.04	-1.00 to 0.45	0.46	-
Timeline	9.28 (2.27)	9.11 (2.28)	9.80 (1.24)	9.25 (1.17)	121	0.09	0.31	0.04	-0.53 to 0.72	0.76	-
Personal control	4.75 (3.19)	4.86 (3.05)	7.02 (2.39)	6.01 (3.07)	121	0.59	0.42	0.11	-0.24 to 1.44	0.09	-
Treatment control	6.64 (3.63)	7.04 (3.32)	8.41 (2.22)	7.95 (2.49)	121	0.77	0.44	0.15	-0.11 to 1.66	0.08	-
Symptoms	5.33 (3.64)	4.95 (3.66)	3.48 (3.09)	3.80 (3.10)	121	-1.13	0.51	-0.16	-2.05 to -0.04	**0.02***	✓
Concern	6.20 (3.55)	5.93 (3.96)	3.85 (3.56)	4.31 (3.61)	120	-1.27	0.58	-0.18	-2.44 to -0.11	**0.03***	✓
Understanding	6.28 (2.80)	5.88 (3.18)	8.39 (1.89)	7.55 (2.73)	121	1.66	0.38	0.28	0.90 to 2.42	**0.00***	✓
Emotional rep.	5.60 (3.89)	5.42 (3.83)	3.39 (3.23)	3.78 (3.47)	121	-1.19	0.59	-0.17	-2.30 to -0.08	**0.03***	✓
Causes											
Don't know	6.6% (n=4)	11.4% (n=7)	6.7% (n=4)	8.3% (n=5)	121	-0.61	0.04	-0.10	-0.12 to 0.01	0.13	-
Over-weight	34.4% (n=21)	44.2% (n=27)	23.3% (n=14)	38.3% (n=23)	121	0.01	0.06	0.02	-0.10 to 0.14	0.76	-
Genetics	39.3% (n=24)	50.8% (n=31)	21.7% (n=13)	30% (n=18)	121	-0.14	0.05	-0.16	-0.25 to -0.04	**0.00***	✓
Diet Factors	32.8% (n=20)	37.7% (n=22)	35% (n=21)	55% (n=33)	121	0.11	0.07	0.12	-0.03 to 0.27	0.13	-
Lack Exercise	6.6% (n=4)	11.4% (n=7)	13.3% (n=8)	18.3% (n=11)	121	0.10	0.04	0.16	0.01 to 0.20	**0.02***	✓
Other lifestyle	1.6% (n=1)	4.9% (n=3)	6.7% (n=4)	6.6% (n=4)	121	0.02	0.03	0.00	-0.04 to 0.09	0.50	-
Other physical	9.8% (n=6)	18.0% (n=11)	13.3% (n=8)	20.0% (n=12)	121	0.05	0.04	0.00	-0.04 to 0.15	0.27	-
Psychological	16.4% (n=10)	21.3% (n=18)	8.3% (n=5)	13.3% (n=8)	121	-0.05	0.05	0.00	-0.12 to 0.04	0.23	-
Well-being											
Negative	4.08 (4.02)	4.32 (3.95)	2.48 (2.72)	3.21 (3.53)	121	-0.98	0.44	-0.14	-1.85 to -0.10	**0.03***	✓
Energy	3.48 (3.30)	3.90 (3.48)	7.31 (3.37)	6.11 (3.74)	121	2.32	0.52	0.31	1.28 to 3.55	**0.00***	✓
Positive	6.60 (3.68)	6.91 (3.60)	9.53 (3.00)	8.55 (3.31)	121	1.61	0.41	0.24	0.78 to 2.44	**0.00***	✓
General well-being	18.15 (9.03)	18.60 (8.49)	26.36 (7.01)	23.45 (8.50)	121	4.72	1.00	0.28	0.16 to 5.76	**0.00***	✓

B = un-standardised coefficient, SE of B = Standard Error of B, ß = standardised coefficient

✓ Indicates improvement
- Indicates no change

Table 5.16

Sensitivity analysis of secondary outcomes using LOCF method to examine the effects of missing data

	Control		Intervention								
	6-months	6-months LOCF	6 months	6-months LOCF	n	Beta	SE of B	ß	95% CI	P	
BMI	33.88 (5.32)	32.98 (5.14)	31.57 (5.16)	31.86 (5.23)	110	-0.45	0.41	-0.04	-1.28 to 0.37	0.27	-
Systolic BP	135.85 (16.48)	135.81 (15.78)	139.72 (20.79)	139.06 (21.21)	120	2.38	2.98	0.06	-3.52 to 8.90	0.42	-
Diastolic BP	77.00 (9.91)	77.16 (9.39)	75.43 (10.32)	76.83 (10.14)	120	-0.13	1.64	0.01	-3.39 to 3.13	0.93	-
Self-care											
General diet	8.42 (4.19)	8.67 (4.09)	10.63 (2.84)	9.86 (3.38)	120	0.97	0.54	0.14	-0.10 to 2.05	0.07	-
5 fruit/veg	3.46 (2.62)	3.93 (2.58)	4.70 (2.46)	4.35 (2.48)	120	0.37	0.38	0.07	-0.38 to 1.14	0.32	-
Fat intake	3.51 (2.26)	3.45 (2.10)	3.36 (2.16)	3.51 (2.07)	120	-0.16	0.32	-0.03	-0.80 to 0.47	0.61	-
Exercise	3.11 (3.29)	3.32 (3.40)	5.39 (4.02)	4.51 (4.11)	120	0.69	0.07	0.15	0.12 to 2.19	**0.02***	✓
BG testing	8.82 (5.45)	8.81 (5.50)	10.70 (4.72)	10.53 (4.55)	120	0.70	0.68	0.08	-0.64 to 2.05	0.30	-
Foot care	5.68 (5.35)	5.73 (5.24)	6.34 (5.08)	5.96 (4.93)	120	0.56	0.83	0.06	-1.09 to 2.21	0.50	-
No. smokers	12/45 (26%)	15/61 (24%0	3/41 (7%)	5/60 (8%)	120	-0.07	0.04	-0.09	-0.15 to 0.00	0.07	-
Self-efficacy	91.26 (28.51)	87.75 (26.99)	116.97 (18.51)	105.26 (26.94)	120	11.46	4.23	0.24	3.08 to19.84	**0.008***	✓
Family support											
Support	20.75 (7.32)	22.21 (7.69)	24.951 (8.4)	24.45 (8.36)	120	3.11	1.24	0.20	0.63 to 5.58	**0.01***	✓
Non-support	17.56 (7.16)	17.16 (6.98)	14.68 (5.96)	15.03 (6.01)	120	-1.58	0.58	-0.11	-3.53 to 0.36	0.10	-

B = un-standardised coefficient, SE of B = Standard Error of B, ß = standardised coefficient

✓ Indicates improvement
- Indicates no change

5.8.2 Per-protocol analysis

The intention-to-treat analysis used to compare the effects of the intervention on primary and secondary outcomes analyses participants in the groups to which they were assigned, regardless of whether or not they received the intervention. However, 40% (n=24) of participants in the intervention group received the intervention. Therefore, an additional sensitivity analysis or 'per-protocol' analysis was conducted to examine the efficacy of the intervention on primary outcomes (see Table 5.17, p.159) and secondary outcomes (Table 5.18, p.160) when this group of non-completers was excluded. It is important to note that this type of analysis was pre-specified in the trial protocol (K. M. Keogh et al., 2007). Identical techniques to those described above were used in these analyses

The pattern of significant results from the per-protocol analysis, by and large, mirrors that found in the intention-to treat analysis, although with a stronger effect of the intervention evident. For example, there was an additional decrease of 0.2% in follow-up HbA1c in the per-protocol group (Intervention=8.24, SD=0.87 vs. Control =8.80, SD=1.36), and this remains statistically significant (B=-0.57, SE(B)= 0.26, 95% CI -1.10 to -0.03, p=0.036). Some additional differences between treatment groups also became evident in the per-protocol analysis, which had not been identified in the intention-to-treat analysis. For example, when compared to the control group, the per-protocol intervention group shows a statistically significant reduction in perceptions about the consequences of diabetes (Intervention M=3.02 SD=2.74 vs. Control M=5.31, SD=3.21, p=0.04). There was also a statistically significant decrease in the proportion of participants in the per-protocol intervention group attributing the cause of their diabetes to psychological factors (Intervention = 5% (n=2) vs. Control= 16.4% (n=10), p=0.04).

Table 5.17

Results of the per-protocol analysis of primary outcomes

	Control	Intervention								
		ITT analysis	Per-protocol	n	Beta	SE of B	ß	95% CI	p	
HbA1c	8.80 (1.36)	8.41 (0.99)	8.24 (0.87)	87	-0.57	0.26	1.05	-1.10 to -0.03	**0.036***	✓
Illness perceptions										
Consequences	5.31 (3.21)	3.68 (3.13)	3.02 (2.74)	80	-1.09	0.53	-0.17	-2.17 to -0.02	**0.04***	✓
Timeline	9.28 (2.27)	9.80 (1.24)	9.77 (1.35)	80	0.47	0.40	0.12	-0.32 to 1.28	0.24	-
Personal control	4.75 (3.19)	7.02 (2.39)	7.00 (2.55)	80	1.28	0.69	0.20	0.03 to 2.53	**0.04***	✓
Treatment control	6.64 (3.63)	8.41 (2.22)	8.25 (3.24)	80	1.23	0.65	0.19	-0.07 to 2.55	**0.05***	✓
Symptoms	5.33 (3.64)	3.48 (3.09)	3.11 (2.77)	80	-1.90	0.06	-0.27	-3.24 to -0.55	**0.006***	✓
Concern	6.20 (3.55)	3.85 (3.56)	3.28 (3.40)	80	-2.50	0.78	-0.33	-4.07 to -0.93	**0.01***	✓
Understanding	6.28 (2.80)	8.39 (1.89)	8.54 (1.85)	80	2.53	0.48	0.46	1.56 to 3.50	**0.000***	✓
Emotional rep.	5.60 (3.89)	3.39 (3.23)	2.97 (3.03)	80	-2.05	0.79	-0.27	-3.64 to -0.47	**0.01***	
Causes										-
Don't know	6.6% (n=4)	6.7% (n=4)	11.1% (n=4)	80	-0.04	0.05	-0.08	-0.16 to 0.06	0.40	-
Over-weight	34.4% (n=21)	23.3% (n=14)	36.1% (n=13)	80	0.03	0.09	0.03	-0.15 to 0.21	0.73	✓
Genetics	39.3% (n=24)	21.7% (n=13)	33.3% (n=12)	80	-0.18	0.07	-0.19	-0.33 to -0.03	**0.01***	-
Diet Factors	32.8% (n=20)	35% (n=21)	52.7% (n=19)	80	0.11	0.10	0.10	-0.10 to 0.33	0.29	✓
Lack Exercise	6.6% (n=4)	13.3% (n=8)	22.2% (n=8)	80	0.18	0.06	0.26	0.04 to 0.32	**0.01***	-
Other lifestyle	1.6% (n=1)	6.7% (n=4)	11.1% (n=4)	80	0.08	0.04	0.00	-0.01 to 0.18	0.09	-
Other physical	9.8% (n=6)	13.3% (n=8)	16.6% (n=6)	80	0.04	0.06	0.00	-0.08 to 0.16	0.50	✓
Psychological	16.4% (n=10)	8.3% (n=5)	5.0% (n=2)	80	-0.13	0.06	0.00	-0.27 to -0.00	**0.04***	
Well-being										✓
Negative	4.08 (4.02)	2.48 (2.72)	2.08 (2.11)	80	-1.46	0.58	-0.21	-2.64 t0 -0.29	**0.01***	✓
Energy	3.48 (3.30)	7.31 (3.37)	7.80 (2.80)	80	3.83	0.64	0.37	2.55 to 5.10	**0.000***	✓
Positive	6.60 (3.68)	9.53 (3.00)	10.08 (2.30)	80	2.70	0.53	0.50	1.64 to 3.75	**0.000***	✓
General well-being	18.15 (9.03)	26.36 (7.01)	27.80 (5.38)	80	7.52	1.31	0.41	3.62 to 15.02	**0.000***	

B = un-standardised coefficient, SE of B = Standard Error of B, ß = standardised coefficient

✓ Indicates improvement
- Indicates no change

Table 5.18

Results of the per-protocol analysis of secondary outcomes

	Control	**Intervention**							
		ITT analysis	Per-Protocol	n	Beta	SE of B	ß	95% CI	p	
BMI	33.88 (5.32)	31.57 (5.16)	31.50 (5.16)	75	-0.35	0.58	-0.03	-1.52 to 0.80	0.54	-
Systolic BP	135.85 (16.48)	139.72 (20.79)	140.22 (19.10)	82	3.19	3.58	0.09	-3.95 to 10.33	0.37	-
Diastolic BP	77.00 (9.91)	75.43 (10.32)	76.20 (9.68)	82	0.37	2.04	0.02	-3.69 to 4.43	0.85	-
Self-care										
General diet	8.42 (4.19)	10.63 (2.84)	10.77 (2.99)	80	1.77	0.74	0.25	0.30 to 3.23	**0.01***	✓
5 fruit/veg	3.46 (2.62)	4.70 (2.46)	4.45 (2.54)	80	0.67	0.54	0.13	-0.41 to 1.77	0.22	-
Fat intake	3.51 (2.26)	3.36 (2.16)	3.36 (2.11)	80	-0.35	0.45	-0.07	-1.26 to 0.55	0.44	-
Exercise	3.11 (3.29)	5.39 (4.02)	5.51 (4.18)	80	1.96	0.72	0.24	0.51 to 3.40	**0.008***	✓
BG testing	8.82 (5.45)	10.70 (4.72)	10.77 (4.80)	80	1.26	0.99	0.13	-0.70 to 3.24	0.20	-
Foot care	5.68 (5.35)	6.34 (5.08)	5.88 (5.24)	80	0.46	1.16	0.05	-1.85 to 2.78	0.69	-
No. smokers	12/45 (26%)	3/41 (7%)	3/41 (7%)	80	-0.06	0.05	-0.07	-0.18 to 0.05	0.28	-
Self-efficacy	91.26 (28.51)	116.97 (18.51)	117.88 (19.17)	80	21.00	5.94	0.38	9.15 to 32.85	**0.001***	✓
Family behaviour										
Support	20.75 (7.32)	24.951 (8.4)	24.88 (8.63)	80	4.18	1.69	0.25	0.79 to 7.57	**0.01***	✓
Non-support	17.56 (7.16)	14.68 (5.96)	13.97 (5.53)	80	-3.01	1.35	-0.23	-5.72 to -0.30	**0.03***	✓

B = un-standardised coefficient, SE of B = Standard Error of B, ß = standardised coefficient ✓

Indicates improvement

5.8.3 Mediational Analysis

A set of formal mediational analyses were performed (see Table 5.19, p.162 and Table 5.20, p.164) to investigate whether any between-group differences over time in HbA1c were mediated by hypothesized changes in behaviour (e.g. diet, exercise, family support), which in turn, were mediated by hypothesized changes in illness perceptions. In essence, this meditational analysis involves significance testing of the theoretical pathways proposed by Leventhal's Self-Regulatory Model. These hypothesized relationships, or pathways, were tested using the joint significance test approach, which finds evidence for mediation if each of the three paths in the mediated effect is significantly non-zero. There were statistically significant differences between groups in glycaemic control and psychological well-being, which were hypothesized to result from the statistically significant changes seen in, general diet and exercise behaviour, and family support, which in turn were hypothesized to results from statistically significant changes seen in illness perceptions (all dimensions except consequences and time-line).

5.8.3.1 HbA1c

In terms of the model *"group allocation → illness perceptions→ general diet → HbA1c"*, the only illness perceptions dimensions to emerge as mediating the effect of the intervention on general diet were personal control, understanding, and concern, thus, full mediational models were only conducted with these three dimensions (see Table 5.19, p.162). With regards to the model *"group allocation → illness perceptions→ exercise→ HbA1c"* beliefs about the effectiveness of treatment in controlling diabetes was the only illness perception to emerge as mediating the effect of the intervention on exercise. Finally, personal control was the only illness perception dimension to appear to mediate the effect of the intervention on family support in the hypothesized model *"group allocation → illness perceptions→ family support→ HbA1c."* Beliefs about diabetes self-efficacy also emerged as mediating the effect of the intervention on diet, but not exercise. Thus only results from the model *"group allocation self-efficacy→ diet→ HbA1c"* are reported. The effect of self-efficacy on family support was not assessed, as such a relationship is not hypothesised in the theoretical model. Surprisingly, in each of these mediational analyses, the final causal step in each model (*general diet/exercise/family*

support → HbA1c) is not found to be statistically significant. This indicates that while changes in illness perceptions and self-efficacy do mediate the effect of the intervention on self-care behaviours and family support, changes in diet, exercise and family support do not appear to mediate the effect of the intervention on HbA1c.

Table 5.19

Mediational analysis: effects of intervention on HbA1c mediated by illness perception, self-efficacy, diet, exercise and family support

Model	Effect (B)	SE (B)	95% CI	t	p
Diet as M2					
Personal control & diet	b1= 1.46 (group → per control)	0.57	0.31 to 2.69	2.54	**0.01**
	b2 = 0.43 (per control → diet)	0.13	0.16 to 0.69	3.28	**0.00**
	b3 = 0.01 (diet → HbA1c)	0.03	0.05 to 0.08	0.36	0.73
Understanding & diet	b1=2.20 (group → understanding)	0.52	1.04 to 3.10	3.97	**0.00**
	b2 = 0.43 (understanding → diet)	0.15	0.03 to 0.65	2.20	**0.03**
	b3 = -0.02 (diet → HbA1c)	0.03	-0.09 to 0.05	-0.59	0.55
Concern & diet	b1= -2.30 (group → concern)	0.76	-3.8 to -0.8	-3.05	**0.00**
	b2 = 0.43 (concern→ diet)	0.10	-0.46 to- 0.03	-2.23	**0.02**
	b3 = -0.02 (diet → HbA1c)	0.03	-0.09 to 0.04	-0.66	0.51
Self-efficacy & diet	b1=21.06 (group → self-efficacy)	5.35	10.5 to 31.8	3.95	**0.00**
	b2=0.35 (self-efficacy → diet)	0.01	0.02 to 0.08	4.00	**0.00**
	b3=-0.01 (diet → HbA1c)	0.03	-0.08 to 0.05	-0.35	0.72
Exercise as M2					
Treatment control & diet	b1= 1.77 (group → treat control)	0.65	0.45 to 3.08	2.69	**0.00**
	b2=0.34 (treat control → exercise)	0.12	0.09 to 0.59	2.74	**0.00**
	b3 = -0.01 (exercise → HbA1c)	0.03	-0.08 to 0.04	-0.57	0.57
Family support M2					
Personal control & support	b1= 1.46 (group → person control)	0.57	0.31 to 2.69	2.54	**0.01**
	b2 = 0.67 (per control → support)	0.29	0.08 to 1.26	2.28	**0.02**
	b3 = -0.02 (support → HbA1c)	0.01	-0.05 to -0.00	-1.65	0.10

The finding that diet, exercise and family support behaviours do not appear to be mediated by the effect of the intervention on glycaemic control is unexpected. As such, it raises the question of identifying which mediating variables the intervention *is* working through, since there was a significant improvement in glycaemic control in the intervention group. It is possible that changes in illness perceptions are directly impacting on glycaemic control (path ß6), and this was investigated using a similar mediational analysis as above, except with two paths (X→M→Y or "group →illness perceptions→HbA1c"). Results from this analysis (where group allocation and the various illness perception dimensions were used to predict change in HbA1c) found that beliefs about *personal control* (ß=-0.16, SE(ß)= 0.04, 95%CI=-0.25 to -0.08, p=0.000) *treatment control* (ß=-0.16, SE(ß)= 0.03, 95%CI=-0.24 to -0.08, p=0.000) and *diabetes-specific emotional distress* (ß=0.09, SE(ß)= 0.03, 95%CI=0.02 to 0.16, p=0.001) were statistically significant. This indicates that the effects of the intervention on glycaemic control were mediated by changes in these three illness perception dimensions *directly* i.e. not mediated through diet/exercise behaviours as hypothesized.

Given the significant interaction between baseline HbA1c levels and treatment group, it is possible that the effects of the intervention are mediated through diet and exercise behaviours only in the very poorly controlled group (baseline HbA1c > 9.5%). However, when the above mediational analyses were repeated including only this group, the same pattern of results emerged; the effects of the intervention on diet, exercise and family behaviour are mediated by changes in illness perceptions. However, changes in HbA1c were not mediated by these changes in behaviour; rather, improvements in glycaemic control appear to be directly mediated by changes in illness perceptions.

5.8.3.2 Psychological well-being

A similar set of mediational analyses were conducted to examine whether improvements in psychological well-being were mediated by the significant changes in diet, exercise and family support behaviours, (It has already been established in the HbA1c mediational analyses, that changes in illness perceptions mediated the effect of the intervention on behaviour).Results from this analysis (see Table 5.20, p.164) indicated that changes in

beliefs about *personal control*, *understanding* and *diabetes specific concern*, mediate the effects of the intervention on diet, which in turn mediated the effects of the intervention on psychological well-being. Similarly, beliefs about *treatment control* mediated the effect of the intervention on exercise, which significantly impacts on psychological well-being. Interestingly, however, family support does not emerge as statistically significant in the mediational model, indicating that changes in family support did not appear to mediate the effects of the intervention on psychological well-being.

Table 5.20

Mediational analysis; effects of the intervention on psychological well-being mediated by illness perceptions and diet, exercise and family support

Model	Effect (B)	SE (B)	95% CI	t	p
Diet as M2					
Personal control & diet	b1= 1.46 (group → per control)	0.57	0.31 to 2.69	2.54	**0.01**
	b2 = 0.43 (per control → diet)	0.13	0.16 to 0.69	3.28	**0.00**
	b3 = 0.51 (diet → well-being)	0.23	0.05 to 0.97	2.21	**0.03**
Understanding & diet	b1=2.20 (group → understanding)	0.52	1.04 to 3.10	3.97	**0.00**
	b2 = 0.43 (understanding → diet)	0.15	0.03 to 0.65	2.20	**0.03**
	b3 = 0.63 (diet → well-being)	0.23	-.17 to 1.09	2.76	**0.00**
Concern & diet	b1= -2.30 (group → concern)	0.76	-3.8 to -0.8	-3.05	**0.00**
	b2 = 0.43 (concern→ diet)	0.10	-0.46 to- 0.03	-2.23	**0.02**
	b3 = 0.57 (diet → well-being)	0.12	0.12 to 1.01	2.56	**0.01**
Exercise as M2					
Treatment control & diet	b1= 1.77 (group → treat control)	0.65	0.45 to 3.08	2.69	**0.00**
	b2=0.34 (treat control → exercise)	0.12	0.09 to 0.59	2.74	**0.00**
	b3 = 0.50 (exercise → well-being)	0.24	0.01 to 0.98	2.05	**0.04**
Family support M2					
Personal control & support	b1= 1.46 (group → person control)	0.57	0.31 to 2.69	2.54	**0.01**
	b2 = 0.67 (per control → support)	0.29	0.08 to 1.26	2.28	**0.02**
	b3 = 0.03 (support → well-being)	0.10	-0.18 to 0.04	0.32	0.75

5.9 PROCESS EVALUATION

As discussed in preceding chapters, process evaluation data for this RCT was collected in parallel to the data collection and intervention delivery. Quantitative and qualitative process evaluation data were collected in order to assess various aspects of treatment fidelity. The subsequent sections outline the results from this process evaluation.

5.9.1 Summary of process evaluation

Overall, results from the process evaluation indicate that the intervention was delivered per-protocol, in line with procedures specified in the intervention manual. The trial was found to be acceptable to the participating patients, who reported that home visits and the inclusion of family members were the most beneficial elements. Participants reported changes in the way they thought about diabetes, particularly an increased acceptance of diabetes as a lifelong condition, and an improvement in their levels of perceived personal control/self-efficacy. These cognitive changes appeared to be connected to improvements in diabetes self-management behaviours. Thus, overall the findings from the process evaluation appear to be in line with the results from the trial analysis of primary and secondary outcomes. Elements of the trial that were not found to be effective were in fact, some of the process evaluation components; diaries and text reminders, and evaluation questionnaires. In addition, there were a substantial proportion of intervention group participants who did not receive the intervention (24/60). Data from the "intervention delivery" component of the process evaluation, which collected information regarding the number of withdrawals, and missed and cancelled session appointments, indicated this was partly due to particular difficulties with contacting and accessing participants in order to deliver the intervention. In addition, there were a proportion of participants who had to withdraw from the intervention when their nominated family member declined to participate when the researcher telephoned to organise an appointment time. Thus, given that over one third of intervention group participants did not receive the intervention data, combined with the results from the process evaluation data, there is a suggestion that there were a proportion of patients for whom the intervention was not suitable. In addition, there were also a high number of missed and cancelled sessions amongst participants who did receive the intervention, which resulted in the intervention delivery

being particularly time-consuming, which in turn, contributed to increased running costs (see *"Economic Analysis"* Section 5.10). The following sections present the results of the process evaluation in more detail.

5.9.2 Intervention delivery

As indicated earlier, 36 out of the 60 participants that were randomised to the intervention group received the intervention. All but two of this group received the intervention in full (i.e. two home visits and one follow-up telephone call). Two participants (6%) did not receive a second intervention session as they cancelled three or more of the appointments they made with the interventionist. Eleven participants (31%) received the two sessions in one longer home visit session, because they lived more than 100km away from the research centre and making two visits would have been very time-consuming. There were no statistically significant between group differences on any outcomes with regards to participants who received: (a) only session one; (b) both sessions one week apart; or (c) both sessions in one visit. Notably however, there was a high rate of cancellations and of sessions being 'missed' (i.e. not being home when the researcher called at the pre-arranged time) amongst the 36 participants who did receive the intervention. In total, 39 sessions were cancelled by participants, whilst 30 sessions were missed (see Table 5.21, p.167). As also discussed previously, 24 participants did not receive the intervention. Five were uncontactable, 10 withdrew (two due to health reasons, 8 due to their nominated family member declining to participate) and 9 participants were assumed to have withdrawn after they continually cancelled or missed three or more appointments.

5.9.3 Intervention exposure

The mean durations of the first and second intervention sessions were 43.40 minutes (*SD*=9.80, range 30- 60minutes) and 43.75minutes (*SD*=11.03, range 30- 80minutes) respectively. The mean duration of the 'two-in-one' sessions was 82.72minutes (*SD*= 8.76, range 65- 95minutes). Overall, the average intervention exposure per participant was 86.85minutes (*SD*=13.09), ranging from a minimum of 65minutes to a maximum of 130minutes. Intervention exposure (total number of minutes) was not significantly predictive of follow-up HbA1c (B=0.03, SE (B)=0.01, $p \geq 0.05$), when controlled for in the analysis of primary and secondary outcomes.

Table 5.21

The number of participants cancelling or missing sessions

	N	Total no. cancelled/missed sessions
Cancelled sessions		
No. times cancelled Session One		
0	27	0
1	5	5
2	4	8
3¶	3	9
No. times cancelled Session Two		
0	24	0
1	9	9
2	1	2
3	2	6
Total no. of sessions cancelled overall	-	39
Missed sessions		
No. times missed Session One		
0	27	0
1	6	6
2	3	6
3¶	3	9
No. times missed Session Two		
0	30	0
1	3	3
2	3	6
Total no. missed sessions	-	30

¶ = those who cancelled/missed 3+ appointments were assumed to have withdrawn from intervention

5.9.4 Structured field notes (Treatment Fidelity)

The structured field notes questionnaires (n=59) were examined by an independent expert (PW) in order to assess treatment fidelity. The report and conclusions regarding treatment fidelity were made by the independent expert (PW), as it would not have been appropriate for the author/interventionist (KK) to comment on these aspects of the trial. Four main over-arching themes emerged from the analysis of the field notes analysis including:

1. Changing illness perceptions (see Table 5.22, p.169)
2. The role of the family member (see Table 5.23, p.170)
3. Changing behaviours (see Table 5.24, p.172)
4. The motivational interviewing techniques used (see Table 5.25, p.172).

Each of these main over-arching themes incorporated a number of lesser themes and sub-themes. Thus, the first main theme of 'changing illness perceptions' includes several minor themes related to perceptions of illness coherence, consequences and so on, whilst the minor theme of 'illness coherence' subsumes a number of subthemes (e.g. patient and family member understanding) Results from the field notes analysis were taken to confirm that the intervention was delivered per protocol, adhering to the methods specified in the intervention manual (i.e. changing beliefs about diabetes, in order to change behaviours, and involving the family member in the process). In addition, the results indicated that the most suitable motivational interviewing strategy was implemented when appropriate (e.g. the 'exchanging information' technique was used to provide information; 'negotiating a change plan' techniques were used when developing written action plans).

From Table 5.22 (p.169), it is clear that a large part of the intervention focused on improving patient and family members' understanding of diabetes. This was achieved by using the motivational interviewing strategy of 'exchanging information'. In particular, intervention sessions especially focused on clarifying negative or inaccurate beliefs related to the causes and timeline of the illness and helping participants to identify symptoms associated with poor glucose control. Furthermore, the intervention sessions targeted participants' illness coherence beliefs specifically in

Table 5.22

Main over-arching theme 1: Changing illness perceptions of patients & family members

Theme (number of sessions it occurred in)	**Sub-theme** (number of sessions it occurred in)
• **Illness coherence/ understanding (89)**	• Patient understanding (9) • Family member understanding (8) • Type 1 vs. Type 2 (15) • Interpreting blood sugars & HbA1c (11) • High blood sugars and their role in preventing complications (17) • Role of lifestyle factors in blood sugar control (28) • Blood pressure control (1)
• **Timeline (3)**	• Chronic and progressive nature of diabetes (3)
• **Symptoms (22)**	• Differences in symptoms of high and low blood sugars (22)
• **Medication (10)**	• Importance of medication (6) • Role of insulin (4)
• **Causes (25)**	• General/all causes (10) • Diet, exercise & weight as causes (12) • Family history (2) • Not infectious (1)
• **Consequences (10)**	• Complications (10)
• **Concern/worry related to coping with diabetes (24)**	• Distress connected to current impact of diabetes (10) • Worry related to future impact (e.g. due to complications) (5) • Family member concern and worry (9)

relation to *high* blood sugars or hyperglycaemia. Many patients and family members expressed worry about the complications associated with diabetes, but seemed unaware of the role played by hyperglycaemia in developing these complications. Perhaps the most critical element of the intervention focused on the role of lifestyle factors in blood sugar control: this occurred in discussions with 28/36 patients. While many patients were aware that their own lifestyle behaviours were somehow involved in controlling their high blood sugars, there was much confusion about how exactly this took place. Many patients also spoke of the difficulties they experienced in coping with the daily impact of diabetes, in terms of changing their behaviours and controlling their blood sugars. This, coupled with worry and concern relating to complications, contributed to levels of emotional distress, for both patients and family members.

Table 5.23 outlines the role of the family member. This varied by patient: some family members were very supportive; some were very worried about the diabetes; whilst in other relationships the illness was a source of conflict. Thus, according to data from the field notes, intervention sessions also had to be individually tailored to help patients and family members cope with the emotional impact of diabetes, and also its impact on family relationships. A central aim of many intervention sessions, therefore, was to focus on decreasing family conflict related to diabetes, and mobilising family support for diabetes management. This was achieved using the motivational interviewing techniques of: 'expressing empathy'; 'rolling with resistance'; and 'developing discrepancy'.

Table 5.23

Main over-arching theme 2: The role of the family member

Theme (number of sessions it occurred in)	**Sub-theme** (number of sessions it occurred in)
• **Family support (8)**	-
• **Family conflict (10)**	• Not interested in patients diabetes (2) • Different views re: diabetes & management (5) • Patient resentful of FM role (3)

The third over-arching theme to emerge from the field notes analysis was 'behaviour change' (see table 5.24). This included the subthemes of: 'improving personal control and self-efficacy': 'developing personalised action plans'; and 'the role of the family member in achieving goals'. At baseline, there was an apparent lack of confidence (or low self-efficacy/personal control) amongst a number of patients regarding their own ability to implement any necessary behaviour change. Thus, another key aspect of the intervention was to use the motivational interviewing strategies for building self-efficacy to increase confidence/personal control for diabetes self-care. Following on from this, motivational interviewing techniques for facilitating behaviour change (e.g. rolling with resistance; developing discrepancy; eliciting change talk; and negotiating a change plan) were employed to help patients and family members developed written personalised action plans to improve diabetes management. These plans were individually tailored to the needs and circumstances of each participant and their family.

Table 5.24

Main over-arching theme 3: Behaviour change

Theme (number of sessions it occurred in)	**Sub-theme** (number of sessions it occurred in)
• **Improving personal control & self-efficacy (15)**	–
• **Written action plans/ goal setting (25)**	• Dietary change (10) • Increase exercise (7) • Increased blood sugar testing (5) • Quit smoking (2) • Managing diabetes in social settings (1)
• **Role of FM in helping achieve goals (25)**	-

Table 5.25 (p.172) presents the final over-arching theme: motivational interviewing techniques. This table outlines how and when motivational interviewing strategies were implemented in intervention sessions.

Table 5.25

Main over-arching theme 4: Motivational interviewing techniques and when implemented

Technique (number of sessions it occurred in)	**When MI technique was implemented in sessions**
• **Exchanging information (89)**	• This was used when providing information to change illness perceptions (e.g. when discussing: patient and family member understanding; timeline; symptoms; medication causes; consequences)
• **Expressing empathy (44)**	• This was used when patients and family members expressed concern/worry/distress (e.g. when discussing: the difficulties of coping with diabetes; the current and future impact of living with diabetes; or in situations of family conflict)
• **Rolling with resistance (35)** **and** • **Developing discrepancy (35)**	• Both techniques were used in situations when there were difficulties in the dynamics between the interventionist, the patient, and/or family members (e.g. if participants expressed reluctance to engage in behaviour change; if there was conflict between the patient and the family member).
• **Building self-efficacy (15)**	• This technique was used when patients had low levels of personal control or self-efficacy for achieving behaviour change.
• **Eliciting change talk (25)** **and** • **Negotiating a change plan (25)**	• Both of these techniques were used when discussing behaviour change with participants. In particular, when goal-setting with patients and family members, and developing the written personalised action plans.

Two illustrative case studies are presented below (see Box 6), in order to illustrate how the intervention may have worked for individual participants.

Box 5.1 Case studies

Case study A: MS

MS, male, aged 65. Diagnosed with diabetes for 14 years. On insulin for two years. Last three HbA1c readings: 9.3, 8.6, and 8.7 (Median = 8.8).

At baseline MS reported high levels of consequences, symptoms, concern, and emotional distress, along with low levels of personal control and understanding, and the perception that his diabetes was caused by faulty genes. MS's wife also reported correspondingly high levels of consequences, symptoms, concern and emotional distress. However, his wife believed that MS had a good understanding of diabetes and high levels of personal control. MS's wife also believed that her husband's diabetes was caused not by faulty genes, but was rather due to a combination of overweight, poor diet and increasing age

In intervention sessions it emerged that MS was very worried about *"getting a hypo and going into a coma"*, and he was terrified of going outside his house because of this. MS was purposefully maintaining his blood sugars at a high level to avoid hypoglycaemia e.g. by eating a lot of high sugar/high fat foods and avoiding physical activity. This was having a negative impact on his relationship with his wife, and both partners reported a high degree of conflict regarding diabetes management. Despite keeping his blood sugar levels artificially high, MS reported that he still experienced many episodes of hypoglycaemia. However, upon examination of his blood sugar recordings, it emerged that the symptoms MS had interpreted as being connected to low blood sugars (sweating, tiredness, frequent urination) were in fact connected to episodes of hyperglycaemia.

Sessions with MS and his wife focused on increasing MS's understanding of diabetes, in particular by clarifying his beliefs about symptoms related to high and low blood sugars. For example, MS was asked to check his blood sugars when he believed he was experiencing a hypo to confirm if levels were high or low. Sessions also focused on lessening the anxiety, emotional distress and conflict both himself and his wife experienced in relation to diabetes. This was achieved by improving MS's sense of personal control in relation to managing his diabetes and blood sugar levels, and helping him develop more adaptive coping mechanisms for dealing with his anxiety related to diabetes. For example, it was highlighted for MS that he was already controlling his diabetes by eating high fat/high sugar foods and avoiding exercise to keep his sugar levels high. Thus, if he altered his behaviours and engaged in a healthier diet and increased exercise he would be able to maintain a more *balanced* blood sugar level, in order to avoid hyper- and hypoglycaemia. MS's wife agreed to support her husband in following this healthier lifestyle, by engaging in it with her husband. In developing an action plan, both partners agreed they would go walking together three times a week.

At six months follow-up, MS's HbA1c level had dropped to 7.1 He reported increased levels of personal control and an increased understanding of diabetes. He now believed that his diabetes was caused mainly by lifestyle factors (poor diet, overweight). He reported experiencing less diabetes-related symptoms, and less concern and emotional distress related to diabetes. MS also reported improvements in diet and exercise, and increased family support for diabetes management.

Case study B: KB

Male, aged 73. Diagnosed with diabetes for 13 years. On insulin for 7 years. Last three HbA1c readings; 8.1, 8.3, 8.2 (Median 8.2).

At baseline KB reported low levels of consequences and symptoms in relation to his diabetes. He reported a good understanding of his illness, but did not believe that the treatment (insulin) was effective and also reported low levels of personal control. While KB reported being concerned about diabetes, he was not emotionally distressed by it. KB's wife was also concerned about, but not distressed by, the diabetes. In keeping with her husband's perceptions, she reported similarly low levels of consequences and symptoms. However, in contrast with her husband, KB's wife had high treatment control beliefs regarding insulin, and she reported having no understanding of diabetes.

Intervention sessions began by focusing on KB's belief that insulin was not effective in controlling his diabetes. It became apparent that KB had become disillusioned with insulin as a treatment, because after 7 years his blood sugars were still high. However, in discussion with KB and his wife, it transpired that KB had completely stopped checking his blood sugars, and as such, was not aware of the impact insulin was having on his readings. KB also revealed that he believed alcohol was an effective means of lowering blood sugars, and he reported sometimes having two to three alcoholic drinks to lower his blood sugars. This was something KB's wife was very concerned about, and a source of conflict between the partners. In further discussion, it also emerged that KB and his wife were not fully aware of the importance of other lifestyle factors (e.g. diet and physical activity) either in controlling diabetes.

Sessions with KB and his wife focused on highlighting recommendations regarding the importance of self-monitoring of blood glucose in those treated with insulin. It was stressed that in patients with type 2 diabetes on insulin, self-monitoring of blood glucose can assist in giving a more accurate picture of how lifestyle factors and medication interact to influence blood sugar control. KB was encouraged to contact the diabetes nurse specialist (DNS) in the clinic for further information regarding this (which KB reported, and the DNS confirmed, that he did). Recommendations regarding alcohol use in people with diabetes were also emphasised. Sessions also attempted to increase KB's sense of personal control of diabetes, by encouraging him to engage in more adaptive methods of controlling blood sugars, such as following a health diet and increasing physical activity levels. For an action plan KB decided he would begin checking his blood sugars again, and he agreed to do this twice a day initially. His wife would remind and encourage him to do this. KB also decided to reduce his alcohol consumption, although, he did not wish to formally include this on the written action plan.

At six months follow-up KB's HbA1c had dropped to 7.4. He reported an increased belief in the effectiveness of treatment for controlling diabetes, along with an increased sense of personal control. Both KB and his wife reported feeling less concerned about diabetes, and both reported increased levels of understanding. KB also reported increased self-monitoring of blood glucose.

5.9.5 Focus groups (Treatment Fidelity)

Focus groups were also conducted with intervention participants, in order to amplify the information obtained from the field notes questionnaires, and to further assess treatment fidelity. The focus groups were conducted by an independent expert (PW), who then evaluated the focus group transcripts in order to report on treatment fidelity. As was the case with the structured field notes, the focus groups report and conclusions regarding treatment fidelity, were made by the independent expert (PW), as it would not have been appropriate for the author/interventionist (KK) to comment on these aspects of the trial. All participants who took part in the intervention (n=36) were invited to attend a follow-up focus group; 11 participants attended. The main reason given by participants for declining to take part related to the timing of the focus group, which clashed with other, mainly employment-related, commitments. A profile of the participants who took part in the focus group is presented in Table 5.26 (p.176). The only difference between focus group participants and the total participants in the RCT sample was in terms of gender. In the total RCT sample, 63% were male, and 36% were female, whereas in the focus groups 91% were male. However, this is perhaps reflective of the number of women who did not complete the intervention arm of the trial. Three focus groups were conducted; one for each randomised block. Five participants attended the first focus group; four participants attended the second focus group, and two participants attended the third and final focus group. Each focus group lasted approximately 45 minutes.

A number of themes emerged during the analysis. However, for the purposes of the process evaluation and treatment fidelity, these are subsumed and discussed under three major headings: (1) elements of the intervention that worked according to participant reports; (2) elements of the intervention that did not work; and (3) other themes. To ensure anonymity, participants are identified only by a number (e.g. P3) and the focus group of which they were a part (e.g. FG1). The interventionist is identified as K when mentioned by name.

Table 5.26

Profile of focus group participants

Characteristic	**Participants** (n=11)
Sex	Male = 10 Female = 1
Age (Mean, SD)	60.27 (10.44)
Martial status	Single = 0 Partner/Married = 11 Separated/divorced=0 Widowed = 0
Employment status	Work in home = 1 Employed =2 Unemployed =1 Retired = 7
Level education	Pre-leaving cert = 8 Leaving cert =2 3rd Level=0
Medical card holder	Yes= 3, No= 8
Duration diabetes	8.09 (4.36)
Treatment Baseline Follow-up	 OHA's= 5, Insulin =6 No change
HbA1c Baseline Follow-up	 8.58 (0.627) 8.29 (0.76)
BMI Baseline Follow-up	 30.14 (4.52) 30.83 (3.76)
Blood Pressure Baseline Follow-up	146/76 (22.96/8.79) 144/78 (18.77/8.01)

5.9.5.1 Elements of the intervention that worked

Here, a number of key themes were identified, each of which is illustrated using selected quotes. Overall, the focus groups findings indicate that the intervention was delivered per-protocol. The study was also well-received by participants, who found it acceptable. There were no major changes recommended, and participants were keen to see it continue.

1. Location of sessions

The home-based nature of this intervention proved to be the most successful element. Having someone associated with the diabetes clinic call to the house and sit down to talk with patients and their families was perceived by all focus groups participants as extremely valuable. It seemed to give them a sense of continuity of care with the clinic, and in particular, provided patients with a sense of additional support. This greater sense of support operated on both a micro and macro level. At a micro level, participants felt that taking part in the intervention supported them on a very personal level; they were being listened to, and their questions were being answered:

> *"Well you are listening to someone and they are there to help you" (P1, FG2)*

> *"...and K came out and she explained more about the ways that would help you and everything that you would like to know. So it was a big help and as I say it clarified everything – it's sort of a back up. (P2, FG3)*

The advantages of intervention sessions being delivered in participants' homes appeared to go beyond the simple convenience for them. Thus, delivery of the session in a familiar setting away from the busy service-led diabetes clinic was highlighted by a number of participants. They also felt that they were being given dedicated time, were being listened to, and had the opportunity to ask questions without the time pressures that a full waiting room can bring. Participants' responses also indicated that the sessions provided them with a sense of being valued and of *their* needs being important. The unrushed, individual nature of the home-based sessions was in stark contrast to the busy diabetes clinic.

> *"...you find [out] more knowledge...than you would down in the clinic, because*

the clinic people, it's not their fault...they're so busy...they don't have time to talk to you." (P3, FG1)

"It was really intimate and you could ask questions you wouldn't think about at the clinic. It really was, and even though I have lived for years with the situation, there were questions I did ask K." (P3, FG2)

"When you went in [to the diabetes clinic]...you were trying to take it all in, and yet they were rushing you and rushing you out the door for the next person" (P1, FG1)

"...it was great just to talk to someone and get it out in the open..." (P2, FG3)

Interestingly, one participant observed how physically there were no barriers (i.e. desks, computers) between the patient and the health care professional in the home setting.

"When you go to the diabetic doctor, you're talking to that person and that person's looking at a monitor, it's not on a one-to-one. Like K was on a one-to-one basis and there was nothing in between, that's why it was good" (P4, FG2)

There was just one participant who said that the hospital clinic would be a better location, but he clarified this by adding that he felt it would represent a better use of time for the staff member delivering the intervention, as opposed to conferring any benefits to patients. Thus, the overwhelming response from the group of focus group interviewees was that the home environment was a critical element of the intervention, and should be included in any future similar interventions.

"I think that sending K to our house was a help and I think that should be kept [in future], someone to go to the person's house." (P2, FG1)

"As [P2, FG1] says, just keep sending K out as often as you can" (P4, FG1)

"...just keep going and do what you are doing, 'cos I think you are very good myself...talking to them all in the house...I thought it was very good" (P1, FG2)

"...the hospital...should be able to get in touch with K, or whoever it is that is doing the job, and they can come out [to the home] and tell us what we should be doing." (P4, FG2)

Participants also felt supported on a more "macro" or general level, in the sense that they felt someone was interested in conducting research in the area of diabetes, and genuinely wanted to help those with the illness. For example, several participants reported that they felt supported on a wider or more general level, knowing that there were scientists and health professionals researching different aspects of diabetes:

> *"It gave you the understanding that there was someone behind the diabetes...that there's somebody studying it besides you and these are the people who haven't got diabetes but study it." (P4, FG1)*

> *"As [P4] said...at least there's someone out there who hasn't got diabetes but is following up with it." (P6, FG1).*

2. Involvement of the family member

According to participants, an additional benefit of the home setting was the ease in which a family member could be involved in the intervention, and diabetes management. There was a clear consensus that having a family member present and involved in the intervention was advantageous and beneficial, for both the patient and the family member.

> *PW (focus group facilitator): "Do you think it was more helpful because K saw both of you [patient and family member], as opposed to just seeing [one]?"*
> *"Oh yes, yes." (simultaneously P1 & P2, FG1)*
> *"Yes." (P4, FG1)*
> *"Oh yeah, I'd fully agree (P3, FG1)*

> *"Oh it was a great help...when K came down to us she was a great help to both of us...because she was a great help in what she was telling us." (P2, FG2)*

Participants reported that one of the main advantages of the intervention was that it facilitated or 'opened-up' family discussion around diabetes:

> *"With K coming out to the house and that, you know ...it involved the family more so than usual." (P4, FG1)*

> *"K called out to the house and interviewed the two of us to see what was going on in the family...I found that very helpful." (P2, F3).*

This increased openness and discussion regarding diabetes appeared to be helpful in increasing family members' involvement in, and support for, the management of diabetes. For example, some participants spoke about the role their family members played in providing both emotional and practical support related to diabetes:

> *"[My wife] says to me if I have a pain or and ache...don't worry you will be alright." (P1, FG3)*
>
> *"She [wife] might say...did you take your tablets?" (P1, FG3)*
>
> *"Herself [wife] is a great help now ... cause there are mornings that I get up and I could be running off somewhere, and she'd say to me 'did you take those tablets?' She always puts them in the bag when I'm going away." (P2, FG3)*
>
> *"[My wife] made a dessert, and she said 'you can have this, there's no sugar in it'" (P1, FG1).*
>
> *"[My wife] does her best food-wise." (P2, FG2).*

In addition, some participants mentioned that their family member themselves had benefited from participating in the intervention, because, for example, their understanding of diabetes had increased, and they were less concerned about the illness.

> *"It sorted out a good few things home wise,...you know with herself [wife], she understood it a bit more you know...because she does worry a little bit and [to have] someone else there if she has something to ask she will ask it, and it was grand to have K out so that she could [ask it]" (P2, FG3)*
>
> *"She [wife] was never in here with me at the clinics because I always came on my own because she worries a good bit...but for K to come out now, she was great because she had a good chat with her." (P2, FG2)*

3. Number and duration of sessions

Provision was made in the RCT protocol for two home visits to each participant, lasting on average, 45 minutes each. However, the intervention was designed in the first instance to be individually tailored to participants' specific circumstances. Thus, the two 45-minute sessions were dependent upon participants' own needs and wishes, and if necessary this was extended or reduced depending on the individuals involved (e.g. some people had one longer visit, or a 'two-in-one' visit). Results from the focus groups

indicate that this tailoring was a successful element of the intervention, as in general it appeared that participants felt they had the right amount of contact with the interventionist.

> *PW: (Focus group facilitator) "Do you think there were enough visits? Should there have been more or less?"*
> *"No, I personally think that was enough." (FG1, P4)*
> *"Yeah" (FG1, P1)*

> *PW: (Focus group facilitator) "...and would you have like to had more visits, would it have benefited more?"*
> *"No, I feel I'm doing the best I can." (P4, FG2)*

> *"It was great to talk to K...the twice...when she came out [to the house]." (P2, FG3).*

Two participants mentioned that they would have been happy to have more visits.

> *"Oh no, she [the health psychologist] could come more. I reckon she could come four or five times a year to see what has happened with the time before." (P1, FG2)*

> *"I think myself that K should come see us about four times in the year" (P2, FG2)*

4. **Improving personal control and self-efficacy: *"It brings it home to you"***

Respondents indicated that as much of the management of diabetes takes place in the home and involves the family, the delivery of the intervention in this setting helped patients come to terms with the reality of living with diabetes. For some, it was as if they had come face-to-face with the reality of living with diabetes in their own every-day environment. This added more weight to the information about diabetes that the interventionist was providing, because the implications of behaviour change were immediately apparent. The illness, its implications and its self-management no longer remained within the more distant domain of the diabetes clinic, but was now happening in their own home. Thus, participants reported an increased peoples' awareness of their diabetes, and a greater acceptance of diabetes as a life-long chronic condition. This, in particular, seemed to be a key factor in helping people to change their attitudes towards diabetes (i.e. their illness perceptions):

"Well, with K coming out to the house...it made you more aware of it" (P6, FG1)

"It helped us accept that diabetes was for life, that was one of the things with K coming out to the house...that diabetes is for life, its not just, its not going to go away" (P3, FG1)

"Well now I think you're going to have it for life what ever..." (P1, FG3)

"...it was great talking to K...and [to] just say well this is it I have it, and like, I'm probably never going to get rid of it..." (P2, FG3)

Thus, as a result of taking part in the intervention, participants spoke of a growing acceptance of the fact that diabetes was a life-long condition, and that they themselves, through their own behaviour, were personally responsible for its management. This was closely linked to participants' increased belief in their own ability to manage diabetes themselves: for instance, they spoke about their diabetes with a greater sense of self-efficacy and personal control, as shown by the following comments:

"I go at it from a different angle now." (P1, FG2)

"...they [health behaviours] have to be changed not because K is coming... Whether she's [health psychologist] coming out or not, you have to make the changes yourself" (P4, FG1)

"Exercise is a big important thing, exercise and diet, simple as that... [I] have it [blood sugars] down to 6.5, 6.7...I don't take sugar or anything now, no problem, bit of exercise." (P1, FG1)

"...I do an extra bit of walking or something like that, and it [blood sugars] will be down." (P5, FG1)

"They say its not life threatening but at the back of it, it is. If you are not taking your medication you are doing the wrong thing...you could end up on the floor." (P2, FG3).

"If you don't look after it [diabetes] you are going to go quicker" (P1, FG2)

PW: (focus group facilitator): "Do you feel confident you can manage your blood

sugars now?"
"Yeah will power" (P1, FG1)
"Will power...that's what it's down to (P6, FG1, nods agreement)

5. The interventionist

From the participants' comments it was obvious that the interventionist had the necessary skills and qualities to engage with participants, to put them at their ease, and adhere to the protocol specified in the intervention manual. This is illustrated by the following comments:

"...it was great to talk to K. Anything she said came across well...and been honest... and it was a great help just to talk to her." (P2, FG3)

"She gave me great information." (P2, FG2)

"... plus the fact that K put us at ease." (P2, FG1)

"...just to talk about it with K, and I think it actually eases the problem." (P1, FG3)

"[K visiting] is the very same as...a postman out in the country and he visits an old person up a laneway. That [the visit] is as good as anything to that person. It's better than the letter. So K is the same to a diabetic as [that] postman..." (P1, FG1)

5.9.5.2 Elements of the intervention participants reported did not work

1. Diaries

All of the participants were asked to complete a diary during the course of the intervention (see section 5.9.6 below). The purpose of the diaries was to assess participants' experience of taking part in the intervention over time, and also to identify points in time where changes resulting from the intervention (e.g. behaviour, mood etc) may have occurred. However, this did not prove to be a successful element of the intervention. Some participants complained that the diaries were too structured and repetitive, and too boring and/or unpleasant a task to complete on a weekly basis.

"It was too much. It was always the same... Different types of questions and that might make it better." (P1, FG2)

"Each page was actually the same. Each question was the same. Each thing you turned to was the same." (P3, FG2)

"...to be honest with you, I thought it was a bit of a chores. It was like doing your homework and I wouldn't mind that, but it was quite simple." (P2, FG1)

In contrast, this simplicity was seen as a positive aspect of the diaries by a few people.

"The other thing in the diary is...you go to the next page and you see it was the same as before, it made it very easy." (P1, FG2)

2. Reminder texts

In order to maximise completion of the diaries, a web-based system of mobile phone text messages was set up to send participants a reminder to complete the diary. Unfortunately, this did not work as effectively as anticipated due to technological difficulties and as a result, few participants received the texts. Participants were asked if they felt the texts would have helped, and views were mixed based on their experience of sending and receiving text messages. Thus, some participants (particularly those who were older) did not have a mobile phone or did not know how to send text messages, whilst others indicated that they never reply to texts. One participant suggested a weekly text feedback system:

"Maybe you could give us a number and we could text you and say I'm feeling great and that's it. (P1, FG2)

5.9.5.3 Other themes

1. Participating in the research process: expectations and motivations

During recruitment for the RCT, all potential participants were given detailed written and verbal information about the trial and what participation would entail, along with the opportunity to ask any questions. However, when asked to remember what they initially thought the research would involve when first approached in the clinic, many participants spoke about how they had automatically assumed or expected that it would be medical research or a type of drug trial, involving numerous tests and procedures. This perhaps highlights a lack of awareness among many patients of the role of other forms of research within the health arena involving psychosocial-based interventions.

"Well, I thought you would have to come in for tests and that you know, and go through procedure after procedure." (P4, FG1)

"I thought the same as [P4]" (P6, FG1)

"I thought the same because I have brothers with diabetes as well and one of them went on a thing similar to this but he had to go in and do tests. (P2, FG1)

"I assumed the same." (P5, FG1)

However, when asked directly if they felt they had received sufficient information to decide whether or not to take part, all participants replied in the affirmative.

PW (focus group facilitator): "And when you first heard about the study...did you feel you had enough information to be in it or not?"
"Yeah." from all participants (FG1)

PW (focus group facilitator): "Do you feel you had enough information about what was going to happen and you understood what kind of study it was going to be?"
"Yeah, she [K] gave me great information" (P2, FG2)
"Yeah, I'm glad I came on it" (P1, FG2)

"...when I arrived into the clinic and I met with K...she was talking about the study and she asked me would I be agreeable to take part...so I said...no problem...it was interesting..." (P2, FG3)

Some participants had high expectations about the research, and these appeared, at least in part, to be an important motivating factor for taking part. For example, some felt that it would give them the answers they had been looking for in relation to their diabetes; others believed it would help them to improve their diabetes management or even cure it; whilst still other members of the group alluded to altruistic motivations:

"I though there might be some answers to get rid of it [diabetes], you know...eventually come off the medication...some other substitute for it other than having to inject all the time." (P6, FG1)

"I felt that to come [to] the studies because of my tiredness and things, that it may be of some help to somebody else but not to myself." (P1, FG3)

"...there could be a cure for it. And I actually volunteered to...be a guinea pig in any type of test that would get rid of it." (P4, FG1).

"...you are always looking for new information, [to] find out can you do that better...that's really why I [took part], to see can I learn a little bit more about it [diabetes]." (P5, FG2)

"...maybe they might in a couple of years time... have something better. When I get to 50...they might have some sort of tablet to slow it down or maybe help me more, [so] that I can get to the age of 80." (P2, FG3)

2. Using focus group for process evaluation

One of the most difficult tasks for the focus group facilitator was to keep participants' attention focused on reflecting on their experience of participating in the study. During the focus groups, participants appeared very keen to 'tell their own stories', that is, to share with other participants their *total* experience of living with diabetes (e.g. blood sugar readings, diet, number of hospital visits, medication concerns, etc), and not just their experience of participating in the RCT. Focus group questions relating to the RCT often had to be rephrased several times to bring people back to a relevant discussion. Indeed, two of the most frequently used codes in the analysis of the focus groups were "rephrase question" (facilitator had to rephrase the question) and "off-topic discussion." These 'off-topic' discussion were perhaps not surprising, as it is an 'occupational hazard' of all qualitative interviewing. The focus group format lends itself to a discussion of related factors, and it is the facilitator's role to try to help respondents focus on the specific areas under discussion. While at times this was frustrating for the research team, it proved intriguing, whilst also raising questions about the nature and appropriateness of incorporating a focus group methodology into a process evaluation. After much thought and consultation, the research team concluded that a number of factors may have contributed to these difficulties:

(i) Lapse of time since the intervention;

For all focus group participants, at least six-months had passed since their last intervention session. In addition, due to the staggered nature of recruitment for some participants 12 months or more may have passed for some participant since they first met with the researcher at the clinic and were recruited to the trial. Thus, this time lapse may

have coloured participants' recall of various aspects of participation in the trial.

(ii) Embedded experience and abstract nature of the subject

Participants appeared to have great difficulty separating the research experience from their everyday life with diabetes (e.g. study recruitment and follow-up in the clinic vs. usual clinic visits). Thus, the experience of taking part in the RCT was not a stand-alone separate experience from managing diabetes on a daily basis. Most participants already see numerous health care professionals for their diabetes and other co-morbid conditions, many already fill out diaries for their blood sugar readings, and some have previously taken part in other research projects. Separating out the specific elements relating to this study was difficult for patients, as it was seen simply as another part of their life with diabetes. Thus, any questions that were posed in relation to changes in diabetes management as a result of the trial, could not be considered in isolation. Instead, they were answered in the context of previous changes, or problems with medication, or queries about food, or in relation to that morning's blood sugar readings. This can partly be explained by examining the purpose of the focus group: to reflect upon participants' experience of participating in the RCT. However, the concept of "research" and "RCT" was an abstract one for focus group participants. Participants had no prior professional experience of research, yet they were being asked to comment on various elements of an RCT.

(iii) Opportunity for interaction with others with type 2 diabetes

In addition, much of the difficulties in attempting to keep focus groups 'on topic' was likely related to the fact that the focus groups also provided participants with an opportunity to interact with other people with type 2 diabetes. Hence, much of the off-topic discussions related to participants looking for or offering advice or 'tips' with regards to diabetes management. For example:

> *P2 (FG3): "I always have a good dinner because I enjoy my dinner..."*
> (Speaking about dietary changes since participating in the intervention)
>
> *P1 (FG3): [interrupting] "Sorry, do you have dinner during the day or in the*

evening?"

Or

P2 (FG1): "But like you were saying the meals... about two hours later I zapped my finger and it read 17.2...from the sweet, what do you call them now? Nectarines. And..."

P1 (FG1): [interrupting] ...all that stuff [fruit] is full of sugar...

P6 (FG1): [nodding] "It is. They're all full of sugar"

5.9.5.4 Summary of focus groups

Eleven intervention participants (out of a possible 36) took part in the three focus groups. Two major over-arching themes emerged; elements of the intervention that work, and elements that did not work. Elements of the intervention that worked included: the delivery of the intervention in the home environment; the inclusion of the family member; number and duration of sessions; and improving personal control and self-efficacy. Diaries and reminder texts were the elements of the intervention that were not successful. A number of additional themes emerged, including participants' motivations and expectations of research; and the difficulties involved in using focus groups for process evaluation. From the treatment fidelity aspect, findings from the focus group confirm result from the field notes questionnaire: that for those who received the intervention, it was delivered per protocol in line with procedures pre-specified in the trial protocol and the intervention manual.

5.9.6 Participant diaries

Research diaries were given to all 36 participants who received the intervention. Fifteen participants returned the diaries, however, of these, five were returned blank. Only five of the remaining 10 diaries were completed for the full 24 week period. The other five were partially completed: one up to week 2; one up to week 4; one up to week 8; one up to week 12; and one up to week 18. Given the very small number of participants returning completed diaries, and the large number of blank responses, no conclusions can be drawn from the diary data. Thus, the available data from the diaries are not presented here, but are in included in a series of graphs in Appendix W, which illustrate participants'

responses to the diary questions over the 24-week period, and also the large number of blank responses.

5.9.7 Evaluation questionnaires

All participants in the intervention and control group were invited to complete an anonymous Evaluation Questionnaire at the six-months follow-up, and return it to the research team by post. Family members who had taken part in the intervention (n=36) were also requested to complete a similar evaluation form. Only four participants in the control group and only one participant in the intervention group returned this questionnaire, whilst only three family members who had taken part in the intervention returned the forms. The very low return rate of evaluation questionnaires is indicative of the fact that these questionnaires were an element of the process evaluation which was not successful. Despite the low return rate, results from the questionnaires are still included here, as they represent the only process evaluation data available for family members and control group participants. However, due to the very small numbers, it must be stressed that no definite conclusions can be drawn from these evaluation questionnaires.

Of the four control group participants who returned forms, three described their experience of taking part in the study: one described their experience as *"interesting";* one as *"very good"*; and or as having *"no lasting effect"*. Two of these control group participants reported that taking part in the study had helped them manage their diabetes better, while the remaining two control group participants reported that it had not helped them. None of the four participants had any recommendations on how to improve the study, and or any further comments. The one intervention participant who returned an evaluation form described their experience of taking part in the study as follows:

"It helped me to be able to talk to someone about my diabetes".

However, the above participant reported feeling unsure as to whether or not taking part in the intervention had helped them to manage their diabetes better, whilst no

recommendations for improvement were indicated either.

Of the three family members who returned an evaluation form, one described their experience of taking part in the study as *"very interesting"*, while a second did not respond to the question. The third family member wrote:

"I knew very little about diabetes before. It was a learning experience and now I can help [patient's name] *come to terms with diabetes by being interested and giving him advice. i.e. cut down on salt and sugar and do more exercise."*

Two of the family members reported that taking part in the study helped the patients with diabetes to better manage their condition. They also indicated respectively that they had found the "*entire study*" helpful and that *"listening to and learning from K was very informative."* Both of these family members also reported that they had found it beneficial from their own perspective, to take part in the study. When asked to stipulate which aspects, in particular, were helpful, one respondent mentioned *"all of the questions"*, while the second reported:

"(1) Learning about how to manage [patient's name] *diet (2) the importance of regular meals and (3) doing regular exercise and (4) weight loss – keeping the weight down!"*

The third family respondent was unclear as to whether or not the intervention had helped the patient with diabetes to manage their condition better, and reported that taking part in the study had not helped them in any way. One respondent had no recommendations as to how the study could be improved, while a second commented that they would have *"...benefitted more with help from a dietician."* The third family member wrote the following:

"Sorry – I don't know enough to make any recommendations. But I suggest K coming to visit [patients name] *and I was a great help, and* [patient's name] *is taking more interest in managing his diabetes."*

5.10 ECONOMIC ANALYSIS

The final part of this study involved a brief economic evaluation. The method of analysis was a Cost-Effective Analysis (CEA), where the costs and effects of the intervention were compared with the costs and effects of not implementing the intervention. The first step of the analysis involved estimating the costs of delivering the intervention. The final step involved calculating an Incremental Cost Effectiveness Ratio (ICER), which estimated the cost effectiveness of the intervention by comparing it to its appropriate alternative (no intervention; i.e. zero costs, zero effect). As discussed in Chapter 4 (section 4.9.3), the intervention was conceptualised as an adjunct to usual care, not an alternative, thus 'usual care' was not an appropriate comparison for the CEA.

5.10.1 Calculating per-patient costs

Three main factors were identified as contributing to intervention costs: staff input time; mileage/travel costs; and additional staff training. As expected, staff input time was the main driver for costs. Costs for time were calculated according to the salary scales for a basic grade psychologist (clinical/counselling/health). At 2006/2007 prices, the annual salary of a basic grade psychologist was £54,776, corresponding to an hourly rate of £28.46. The total number of hours dedicated to travelling, collecting data and delivering the intervention were calculated, and this figure was summed by the hourly rate. The interventionist's time was divided into a number of different activities (see Table 5.27, p.192, for a break down of each activity), including: time taken to conduct assessments at baseline and follow-up; time allocated to intervention sessions (including missed/cancelled sessions); travel times to participants' home (including missed sessions); and time involved in administrative tasks. Although the time spent collecting baseline and follow-up data could be conceptualised as a research cost, it was included as an intervention cost in the economic evaluation as it corresponds to the basis pre-treatment assessment and post-treatment evaluation that would occur as part of a psychological treatment in any healthcare setting. Similarly the costs of assessing the control group participants were also included, in recognition of the fact that in a healthcare setting more patients would be initially assessed for eligibility, than would subsequently participate in the intervention.

Table 5.27

Breakdown of staff time costs

Activity	**n=**	**Average time**	**Total time**	**Cost** Time x hourly rate (€28.46)
Data collection				
Baseline assessment	121 patients	30 minutes	60 hours (3600 mins)	€1707.60
Follow-up assessment	86 patients	30 minutes	43 hours (2580 mins)	€1223.78
Intervention				
Intervention sessions	36 patients	87 minutes (mean intervention time)	52.2 hours (3132 mins)	€1485.61
Cancelled/missed sessions	69 sessions	45 minutes	51.75hours (3105 mins)	€1472.80
Follow-up telephone call	36 patients	15 minutes	9hours (540 mins)	€256.14
Travel times				
"2 in 1" sessions (100 + KM travel distance)	11 patients	180 minutes (average travel time 90mins each way)	33 hours (1980 mins)	€939.18
All other sessions (0-60 Km to travel)	48 sessions	60 minutes (average travel time 30 mins each way)	48 hours (2880 mins)	€1366.08
Missed sessions	30 sessions	60 minutes (average travel time 30 mins each way)	30 hours (1800 mins)	€853.80
Total			**327 hours** (19617 mins)	**€9306.43**

As can be seen from Table 5.27, the total staff input time was 327 hours (19,617 minutes) over a 21 month period (October 2006-June2008), at a cost of €9306.43. Other costs relating to mileage and staff training were also included in the overall economic analysis. Travel costs were based on the health care providers 2006/2007 rate for mileage reimbursement (€0.524 per kilometre). The total mileage amounted to 6880km, which was costed at a total of €3605.12. Additional training in motivational interviewing was also costed at €257.28 for the 16 hours of certified training the interventionist received for this intervention (2006 prices). The total estimated costs of delivering the intervention is presented in Table 5.28 (p.194). The cost per patient who received the intervention was calculated by dividing this total cost figure by 60 for the intention-to-treat analysis (the planned number of intervention participants), or by 36 for the per-protocol analysis (the number of participants who received the intervention). Thus, the final cost of the intervention per patient was €219.48 based on an intention-to-treat analysis, and €365.80 based on a per-protocol analysis.

It may also be of interest to health care providers to examine the cost of employing a psychologist to deliver the intervention sessions in the diabetes hospital clinic, as opposed to in participants homes'. While there may be benefits to delivering the intervention in participants' home environment (e.g. convenience and comfort to participants; improved access to vulnerable groups such as clinic non-attenders), there may also be benefits to delivering the intervention in the clinic settings (e.g. cost savings on travel expenses, increased safety for the interventionist). The cost to health care providers of delivering the intervention in the diabetes hospital clinic was calculated by subtracting costs related to travel (travel times and mileage) from the overall intervention cost, and repeating the steps taken in the above analysis. These results are also presented in Table 32. It can be seen from this Table that the costs associated with the intervention drop dramatically when expenses relating to travel are removed. Thus, the cost per-patient of delivering the intervention in the hospital settings is €51.38 based on the intention-to-treat analysis, and €85.64 based on the per-protocol analysis.

Table 5.28

Total estimated costs of intervention

Home-based intervention		**Hospital-based intervention**	
Element of the intervention	Cost	Elements of the intervention	Cost
Staff costs	£9306.43	Staff costs (Home intervention staff costs minus total travel time costs)	£9306.43- €2874.46 €6431.79
Mileage	€3605.12	Mileage (excluded for hospital intervention)	- €3605.12
Training	€257.28	Training	€257.28
Total cost of intervention	£9306.43 +€3605.12 +€257.28 **=€13,168.82**	Total cost of diabetes clinics hospital intervention	€6431.79 – €3605.12 +€257.28 **€3083.85**
Total cost per patient intention-to-treat (Total cost / 60patients)	**€219.48**	**Total cost per patient intention-to-treat** (Total cost / 60patients)	**€51.38**
Total cost per patient per-protocol (Total cost / 36 patients)	**€365.80**	**Total cost per patient per-protocol** (Total cost / 36 patients)	**€85.64**

5.10.2 Calculating the Incremental Cost Effectiveness Ratio

The ICER represents the additional cost of one unit of outcome gained (e.g. a 1% decrease in HbA1c) by a healthcare strategy or intervention when compared to the alternative strategy. The ICER for this intervention was calculated according to the standard formula:

$$ICER = \frac{C1-C2}{E1-E2}$$

For this trial, the costs and effects of the alternative or comparison treatment (i.e. no intervention) was zero. Thus, based on an intention-to-treat analysis (in which the cost of the intervention was €219.48, corresponding to a drop of 0.4% in HbA1c) the ICER = €219.48 / 0.4 = €548.47. Based on a per-protocol analysis (in which the cost of the intervention was €365.80, corresponding to a drop of 0.6% in HbA1c) the ICER = €365.80 / 0.6 = €609.66. Examining the cost-effectiveness of the intervention in the group with the poorest glycaemic control (i.e. those who benefited most from the intervention), the corresponding ICER is the cost of the intervention (€219.48 for the ITT analysis or €365.80 for the PP analysis) divided by the effect on HbA1c in this group (a drop of 1.2%), which equals €182.90 for the ITT analysis, or €304.83 for the PP analysis. In other words, to achieve a 1% decrease in HbA1c for all poorly controlled participants (HbA1c > 8.0%) the intervention would cost €548.47 based on an ITT analysis, or €609.66 based on a PP analysis. While, to achieve a 1% drop in HbA1c for those participants whose HbA1c is great than 9.5%, the intervention would cost €182.90 for the ITT analysis, or €304.83 for the PP analysis.

5.11 SUMMARY OF RESULTS

The main findings of the trial are summarised below.

Recruitment

- One-hundred and twenty-one adults with poorly controlled type 2 diabetes were recruited, and were randomised to intervention (n=60) and control groups (n=61).

- Thirty-six participants completed the intervention.

- Follow-up for HbA1c was 87% (53/61) for the control group and 82% (49/60) for the intervention group.

- Follow-up for psychological data was 75% (45/61) for the control group and 68% (41/60) for the intervention group.

- Follow-up for family member data was 26% (n=16) for the control group and 43% (n=26) for the intervention group.

Primary outcomes at six-month follow-up

- There was a statistically significant improvement of -0.4% in HbA1c (-0.6% based on a per-protocol analysis) in the intervention group compared to the control group, when controlling for a significant interaction between baseline levels of HbA1c and group allocation.

- There was a statistically and clinically significant improvement of -1.2% in HbA1c in those in the intervention group with the poorest control at baseline (HbA1c > 9.5%), compared to the corresponding poorest controlled participants in the control group.

- Compared to the control group, the intervention group reported statistically significant improvements in all illness perception dimensions, except consequences and timeline.

- The intervention group reported statistically significant higher levels of psychological well-being when compared to the control group.

Secondary outcomes at six-month follow-up

- The intervention group reported statistically significantly higher levels of diabetes self-efficacy and family support, and significantly better adherence to general diet and exercise behaviours, when compared to participants in the control group.

- There were no significant differences between intervention and control groups in BMI, blood pressure, blood glucose testing, foot-care, and non-supportive family behaviour.

- The illness perceptions of family members in the intervention group, and the degree of similarity between patient and family members in this group, also significantly improved, when compared to family members in the control group. However, these results must be interpreted with caution due to the low rate of return of family member questionnaires.

Mediational analysis

- Mediational analyses indicated that changes in illness perceptions resulted in changes in diet, exercise and family support, and these changes in diet and exercise (but not family support) resulted in changes in psychological well-being.

- Surprisingly, changes in diet, exercise and family support did not appear to result in changes in HbA1c, rather, improvements in glycaemic control were directly mediated by changes in illness perceptions (i.e. not indirectly through diet and exercise).

Process evaluation

- Results from the process evaluation correspond to findings from the statistical analysis of outcome data: improvements in illness perceptions, particularly in personal control/self-efficacy, and in an increased acceptance of diabetes as a life-long condition, resulted in improved diabetes self-care and a decrease in worry/concern related to diabetes.

- Findings from the qualitative data also show that participants felt the intervention was beneficial to their family members, and resulted in increased family support for diabetes management.

- Fidelity checks based on the qualitative analysis of structured field notes and focus group transcripts indicated that the intervention was delivered per protocol, and was acceptable to participants who received it.

- Participants reported that inclusion of a family member, and the home visits were the most beneficial elements of the intervention.

- The substantial number of participants (n=24) who did not receive the intervention indicated that there may be a proportion of patients with poorly controlled type 2 diabetes for whom the intervention is not suitable.

- The considerable number of participants missing and/or cancelling scheduled session appointments highlighted the practical difficulties of delivering the intervention to this group of patients.

Economic analysis

- The total cost of the intervention to health care providers was €13,168.82, corresponding to a per patient cost of €219.48 based on an intention-to-treat analysis (n=60), or €365.80 based on a per-protocol analysis (n=36).

- Based on a CEA, the incremental cost of the intervention per 1% decrease in HbA1c was €548.47 (or €609.66 based on a per-protocol analysis). However, the intervention was more cost-effective in participants with the poorest glycaemic control (baseline HbA1c > 9.5%), with a 1% decrease in HbA1c amounting to a cost of €182.90 for the ITT analysis, or €304.83 for the PP analysis.

6 DISCUSSION

6.1 INTRODUCTION

The main findings from the randomised controlled trial were summarised at the end of the preceding chapter. Thus, this chapter begins by discussing the results of the trial in the context of the current international literature, with particular reference to the findings of other studies that may be considered broadly similar. The strengths and limitations of each element of the trial are then discussed. This addresses issues related to designing and running the RCT, as well as other methodological considerations. The chapter concludes by outlining a number of recommendations for clinical practice and future research.

6.2 COMPARISON WITH THE INTERNATIONAL CONTEXT

This section will address the findings relating to primary and secondary outcomes respectively, with reference to comparable studies in the international literature.

6.2.1 HbA1c

The overall difference in HbA1c between the intervention and control groups at follow-up in this RCT (-0.4% ITT, -0.6% PPA), is comparable to improvements in glycaemic control found in other psychological and family interventions. For example, a meta-analysis (Armour et al., 2005) of family interventions for patients with diabetes (both type 1 and type 2) reported a pooled mean difference of -0.6% (95% CI -1.2 to -0.1). Our Cochrane review (Keogh et al., 2007) of family interventions for patients with type 2 diabetes is ongoing. However, an examination of the individual eligible studies in the review shows a decrease in HbA1c ranging from 0.5% (Gilliland et al., 2002) to 1.4% (Brown & Hanis, 1995). Similarly, in their meta-analysis of psychological interventions to improve glycaemic control in patients with type 2 diabetes, Ismail and colleagues (Ismail et al., 2004) reported a mean difference of -0.32% (95% CI -0.57 to -0.07) between intervention and control groups. However, none of the above psychological or family interventions specifically targeted those with poorly controlled type 2 diabetes. A number of psychological interventions have been conducted with patients with poorly

controlled type 1 diabetes, and results from these studies indicate similar improvements in HbA1c, ranging from -0.8% (Snoek et al., 2001) to -0.4% (Zoffmann & Lauritzen, 2006). The effects on glycaemic control of the current intervention are also comparable to the effects of other behavioural/lifestyle interventions that have been conducted with adults with type 2 diabetes. For example, a meta-analysis of self-management interventions (Norris, Lau, Smith, Schmid, & Engelgau, 2002) reported a mean difference in HbA1c of -0.76% (95% CI -.34-1.18) between the intervention and control groups at immediate follow-up. However, the effects of these self-management interventions faded over time (-0.26% at 1-3months follow-up). In addition, these interventions were very time-consuming. The duration of contact between those delivering the intervention and the patients was the only significant predictor of effect, with 23.6 hours of contact time necessary to achieve each 1% absolute decrease in HbA1c.

While the difference in HbA1c between groups in this trial was statistically significant (-0.4% ITT, -0.6% PPA), it is modest, given that a decrease of 0.9% to 1% represents what is generally considered to be a clinically significant improvement in glycaemic control. This is based on the fact that the UK Prospective Diabetes Study (UKPDS) (Stratton et al., 2000) found that an absolute reduction in HbA1c of 0.9% was associated with a reduction in risk factors for diabetes complications. However, a decrease in HbA1c of 0.5% is now beginning to be recognised in many clinical trials as a clinically significant difference e.g. (Farmer et al., 2005; Nimri et al., 2006). Indeed, the UKPDS group concludes that *"any improvement in glycaemic control across the diabetic range is likely to reduce the risk of diabetic complications"* (Stratton et al., 2000). In addition, when results from the per-protocol analysis in this study are taken into account, participants in the intervention group showed a clinically and statistically significant decrease of 0.9% in HbA1c from baseline (from 9.0 to 8.2). However, a significant decrease in HbA1c of 0.4% (from 9.2 to 8.8) was also seen in the control group although, this is not unexpected. Such improvements in outcomes are often observed in control groups who take part in RCTs, simply because they are enrolled in a research study e.g. (McCarney et al., 2007). This 'Hawthorne' effect (Landsberger, 1958) was anticipated in the trial design, and an

improvement of 20% in HbA1c in the control group was factored into the original power calculation.

Perhaps the most important finding in relation to glycaemic control in the current study was that those with the poorest control at baseline (i.e. HbA1c >9.5%), showed the greatest improvement in HbA1c after participating in the intervention. At 6-months follow-up, intervention participants with a baseline HbA1c >9.5% show a 1.2% greater decrease in HbA1c, compared to their control group counterparts. Importantly, this difference of 1.2% represents a clinically significant change. For example, findings from the UKPDS show that for each 1% reduction in mean HbA1c there is a relative risk reduction of 21% for any diabetes-related endpoint (Stratton et al., 2000), which persists at 10-year follow-up despite a loss of between-group differences in glycaemic control at 1 year (Holman, Paul, Bethel, Matthews, & Neil, 2008). It could be argued that the intervention was most effective in those with the poorest control initially, simply because they had the greatest scope for improvement. On the other hand, patients with poorly controlled type 2 diabetes are often the most difficult group to manage in the clinical setting, and therefore, pose particular challenges with regard to effecting any positive change.

6.2.2 Psychological well-being

The intervention group also showed statistically significantly higher levels of psychological well-being. Thus, at six months follow-up, they reported lower levels of negative well-being, higher levels of positive well-being, and more energy, when compared to the control group. Overall, this resulted in a statistically significant improvement in general well-being in the intervention group, who scored 8 points higher on the total Well-Being Scale than the control group (or 9.5 points based on a per-protocol analysis). These improvements in psychological well-being are in line with findings from other psychological interventions that have targeted patients with type 2 diabetes. For example, in their meta-analysis, Ismail and colleagues (Ismail et al., 2004) found that psychological distress was significantly lower in the intervention groups (B=-

0.58, 95% CI -0.95 to -0.20). Importantly, however, no family-intervention studies were identified that assessed psychological well-being as an outcome in patients with type 2 diabetes.

The improvements in psychological well-being are important for a number of reasons. Firstly, because low levels of psychological well-being (e.g. distress, anxiety, and low mood), have been found to be consistently associated with poor glycaemic control even when these levels do not meet the criteria for a clinical diagnosis of depression. (Anderson et al., 2002; de Groot et al., 2001; Egede et al., 2002; Lin et al., 2004). Hence, by improving psychological well-being, it is plausible there will be corresponding improvements in glycaemic control (as evidenced in this study.) However, it is important to note that improvements in psychological well-being do not always result in corresponding improvements in biophysical outcomes in diabetes. For example, an RCT of patient-centred care in general practice (Kinmonth, Woodcock, Griffin, Spiegal, & Campbell, 1998) found that while such care was associated with improved psychological well-being in patients with type 2 diabetes, there were no improvements in glycaemic control. In fact, at one year follow-up patients in the intervention group showed a significant increase in cardiovascular risk factors (e.g. increased BMI and triglyceride levels), when compared to the control group. Kinmonth et al. concluded that this may have been the result of practitioners (GPs/practice nurses) focusing on improving well-being, to the detriment of disease management. Thus, the challenge for healthcare professionals working with patients with type 2 diabetes is to achieve a balance in improving both physical health and psychological wellbeing. It is noteworthy that the intervention presented in this thesis was effective in improving glycaemic control, without negatively impacting on psychological well-being, and equally, that psychological well-being was also improved without any detrimental effects on biophysical outcomes.

Aside from its association with glycaemic control and other biophysical outcomes, improving psychological well-being is a worthwhile outcome in its own right and should be a central component of diabetes treatment. It is clear from the findings reported here

that patients with poorly controlled type 2 diabetes experience high levels of emotional distress and anxiety, which appear to be directly related to the perceived burden of managing their illness and concern about its future consequences. Thus, it would appear that targeting patients' inaccurate and/or negative perceptions regarding their diabetes is one way of improving psychological well-being amongst those with poor control. The alleviation of emotional distress, and the active provision of support to cope with the daily burden of diabetes self-management, may also impact on health care utilisation (e.g. through decreased frequency of consultations with health care providers).

6.2.3 Illness perceptions

There have been very few interventions which have specifically targeted illness perceptions, in any disease population. The small numbers of such interventions that have been conducted have had some success in restructuring patients' beliefs about their illness e.g. (Fortune et al., 2004; Goodman et al., 2005; Karamanidou et al., 2008). However, these studies have found inconsistent effects on behavioural and clinical outcomes, due, at least in part, to their poor methodological quality. An intervention (McAndrew et al., 2008) based on Leventhal's Self-Regulatory model, which targets blood glucose self-monitoring in adults with diabetes, is currently underway in the United States, although, results are not yet available. No intervention studies were identified that targeted the illness perceptions of patients with poorly controlled type 2 diabetes. Thus, results from this trial provide the first indication that interventions targeting illness perceptions in those with poorly controlled type 2 diabetes can be effective in altering negative or inaccurate perceptions about diabetes, which in turn can result in improved self-management and glycaemic control. The intervention was effective in changing patients' beliefs about diabetes, on all but two of the illness perceptions dimensions (consequences and timeline). Subsequent sections discuss the effect of the trial on each illness perception dimension, with reference to the current literature and comparable studies.

6.2.3.1 Timeline

Firstly, with respect to the timeline dimension, there was little scope for the intervention to achieve any improvements given that the mean scores here for both groups were almost 10 (the maximum score), at both baseline and follow-up. These high scores on the timeline scale indicate that patients in both groups already had an accurate view of diabetes as a chronic condition that would last indefinitely. This finding is consistent with previous research by White and colleagues (White et al., 2001-2004). However, these authors reported that as well as accurately perceiving their illness to be a chronic condition, patients with poorly controlled type 2 diabetes also believed diabetes to be cyclical (e.g. comes and goes in episodes or 'cycles'), while those in good control did not share this belief and perceived diabetes to be more stable or consistent. These differences are possibly due to the fact those with poorly controlled diabetes are more likely to experience greater fluctuations in blood glucose levels, and as such, increased symptoms at certain times. Unfortunately, the cyclical aspect of the timeline of diabetes was not assessed in this study because The Brief Illness Perception Questionnaire (BRIEF-IPQ), unlike its longer version (the IPQ) only measures the acute/chronic timeline dimension, as opposed to both the acute/chronic and cyclical dimensions. This could be examined in future studies, although researchers may wish to carefully consider the benefits and limitations of using shorter measures to assess illness perceptions (e.g. ease and speed of administration in clinical settings vs. amount of information gathered).

6.2.3.2 Symptoms

The intervention group reported a statistically significant decrease in diabetes related symptoms at follow-up, when compared to the control group participants. Therefore, it is likely that the intervention did help patients perceive diabetes as a more stable condition. However, again it was not possible to assess what specific symptoms, as the BRIEF-IPQ has only one general item measuring overall symptom perception. Thus, the decrease in symptom perceptions may be due to patients experiencing an actual decrease in the symptoms of hyperglycaemia, due to improved glycaemic control (e.g. decrease in sweating, tiredness, thirst, frequent urination, high or low blood sugars etc). It is also

possible that due to an increased understanding of their illness, patients were more able to identify accurately the symptoms of poor glycaemic control, and were less likely to attribute unrelated or unexplained physical sensations or symptoms to their diabetes. For example, in some intervention sessions it emerged that there were a small number of patients who attributed *all* unexplained symptoms to their diabetes: these ranged from breathlessness and a 'racing heart' to a ringing in the ears and hair loss. Unfortunately, however, it was again not possible to examine any individual changes in symptom perceptions.

Despite the fact that the intervention group reported a significant decrease in symptoms, patients in both groups reported experiencing quite low levels of diabetes-related symptoms, at both baseline and follow-up. This is surprising, as it would be expected that patients with poor glycaemic control would experience more of the side-effects of hyperglycaemia, such as tiredness, thirst, sweating and frequent urination. There is some evidence to suggest that patients who have had hyperglycaemia for a prolonged period of time may actually become somewhat habituated to the symptoms, and indeed may initially feel worse as blood glucose levels return to normal (Hampson, Petrie, & Weinman, 1997). This may explain the low levels of symptoms reported by patients overall. It is also possible that a lack of understanding of the symptoms associated with hyperglycaemia accounted for the low levels of symptom perceptions. Indeed, an examination of the field notes questionnaires from the intervention sessions provides some support for this suggestion. These showed that sessions with *all* 36 patients who participated in the intervention, contained explanations and discussions of hyperglycaemia, clarification of its associated symptoms, and its connection to the development of long-term complications.

6.2.3.3 Consequences

The fact that patients reported experiencing low levels of diabetes-related symptoms at baseline, may also explain the findings that the intervention did not seem to impact on patients' perceptions about the *consequences* of their diabetes. It appeared from the intention-to-treat analysis that the intervention was not effective in improving patients'

perceptions about the impact of diabetes on their lives. However, when participants who did not receive the intervention were excluded from the analysis (per-protocol analysis), there was a significant positive improvement in the intervention group with regards to their perceptions about the consequences of diabetes. Though, as is the case with all per-protocol analyses, these findings need to be interpreted with caution, as per protocol analyses are at risk of overestimating any treatment effects. Nonetheless, irrespective of the analysis methods used, baseline and follow-up mean scores on the consequences item were moderate (~5) in both groups. This indicates that patients with poorly controlled type 2 diabetes perceive their illness to have a modest, but not serious, impact on their lives, which is unexpected. In their study White and colleagues (2001-2004) reported that those with poorly controlled type 2 diabetes (n=74) perceived diabetes to have more consequences than those in good control (n=152), because for example, they were more likely to be on insulin, or to have an increased risk of complications. However, in the White et al. study, patients with poor glycaemic control also reported experiencing significantly more symptoms that those in good control. Thus, it could be that the low levels of diabetes-related symptoms experienced by patients in this study accounts for the difference between both studies.

It is also possible that the low levels of perceptions of consequences in the current study (and indeed perhaps symptoms) are reflective of more maladaptive styles of coping such as avoidance or denial. Two main types of coping strategies are generally identified in the literature (Harvey & Lawson, 2009): *problem-focused coping* which uses cognitions and behaviours to proactively address the problem; and *emotional-focused coping* which focuses more on regulating emotions provoked by the stressor. Research has shown that in general, emotion-focused coping leads to poorer clinical outcomes in those with diabetes (Harvey & Lawson, 2009). This is because those with poorly controlled diabetes engage more distraction type coping strategies, such as avoidance or denial, rather than engaging in problem-focused coping strategies, such as changing their diet and exercise behaviours (Lawson, Lyne, Harvey, & Bundy, 2005; White et al., 2001-2004). In other words, in order to reduce emotional distress evoked by their diabetes, patients direct their attention away from the illness (avoidance), or even restructure or change their

perceptions of the illness to such an extent that they believe there is no actual threat from the illness (denial).

Thus, at baseline assessment, the patients in this study may have been somewhat 'in denial' about the affects diabetes could have, hence the low level of consequences perceptions. Patients may have been reporting that diabetes does not have a big effect on their lives, because they are emotionally distressed and worried about it, but feel there is little they can do to control it, which is consistent with the low levels of personal control reported by patients at baseline. Thus, rather than making recommended lifestyle changes and attempting to regulate their blood sugars (*problem-focused coping)*, patients avoided thinking about their diabetes, or denied that it is a problem (*emotion-focused coping),* and as such, their glycaemic control remained poor. This same pattern may account for the low levels of consequences perceptions reported by the control group at follow-up. However, it is likely that there is a different explanation for the low levels of perceptions of consequences reported by the intervention group at follow-up, given the fact that self-care behaviours (i.e. problem-focused coping) and glycaemic control both improved in this group. It is possible that by reducing patients' emotional distress related to the illness, and increasing family support and levels of personal control, the intervention was effective in reducing patients' perceived consequences of diabetes. Thus, the low levels of perceived consequences of diabetes at follow-up in the intervention group may reflect the fact that patients have better adapted to their illness, and developed more appropriate mechanisms for dealing with it (e.g. engaging in more problem-focused coping and less emotion-focused coping).

On a final note with regards to perceived consequences, the 'consequences' item on the BRIEF-IPQ is worded in such a way that it only takes into account the *current* impact that diabetes may be having on patients' lives. It does not measure patients' beliefs or worries about the *future* impact of diabetes, for example, as a result of complications. Beliefs about the future or 'anticipated consequences' of diabetes relate to the concept of the 'seriousness' or perceived severity of diabetes, which is assessed to some degree in the Personal Models of Diabetes (PMD) approach (discussed in section 2.5.6.). However,

neither the PMD approach, nor the various versions of the Illness Perceptions Questionnaire adequately distinguish between perceptions of the current impact of diabetes on patients' lives, and beliefs about its future consequences. The distinction is increasingly recognised as an important one (Harvey & Lawson, 2009). For example, studies have shown that perceptions of high perceived *threat* (i.e. perceptions about the perceived severity of diabetes and vulnerability to the future development of complications) are associated with non-attendance at diabetes clinics (Lawson, Bundy, Lyne, & Harvey, 2004), and poorer metabolic control (Skinner, John, & Hampson, 2000). Thus, it may be the case that the group of poorly controlled patients in this study did not report diabetes as having a serious impact on their current lives (due to denial, avoidance, or for whatever reason), but felt particularly vulnerable to the future impact of the illness. It has been suggested (Harvey & Lawson, 2009) that future studies divide perceptions of consequences into perceptions regarding *Perceived Threat* and *Impact on Life*, so that these two constructs can be measured separately.

6.2.3.4 Emotional distress and concern

The relatively moderate levels of diabetes-specific emotional distress and concern reported by both groups at baseline (mean score approximately 4-5) may initially appear to contradict the proposition that patients were engaging in emotional-focused coping strategies, such as avoidance and denial, as a method of reducing diabetes-related distress. However, this may reflect the success of the emotion-focused coping strategies. Thus, patients have succeeded in convincing themselves that *diabetes* does not affect their lives, and they are no longer worried or distressed about it. The fact that patients still report low levels of *general* psychological well-being (low energy, high negative well-being, low positive well-being) indicates that they are still emotionally distressed, but perhaps do not connect it to their diabetes. It is very probable that the cohort of poorly controlled patients in this study were using more emotion-focused coping strategies. This may particularly be the case, given that previous research in the same clinic (White et al., 2001-2004) found that when compared with patients with good glycaemic control, those with poor control did engage in more distraction-type coping and less in problem focused coping, as assessed by the Coping with Health Problems questionnaires (CHIP) (Endler,

Parker, & Summerfeldt, 1998)) . However, it is not possible to know with any certainty if this was the case in this RCT, as the various types of emotion-focused coping behaviours were not assessed. This is an area that may merit investigation in future studies (e.g. using well known measures such as the CHIP) particularly in view of the growing recognition of the importance of the emotional processing arm of Leventhal's Self-Regulatory Model in intervention research (Cameron & Jago, 2008).

6.2.3.5 Understanding

Aside from emotion-focused coping, patients may also report that diabetes does not have a serious impact on their lives, simply because they do not understand, or do not want to know about, the serious implications of poorly controlled diabetes. Indeed, one of the ethical concerns regarding the current study was that helping patients to develop a more accurate or realistic view of their illness, may have resulted in an increase in patients' perceptions about the negative impact of diabetes on their daily lives, whilst also increasing their levels of worry and concern. For example, the provision of information highlighting the need to change diet and exercise behaviours may have resulted in patients perceiving diabetes as more burdensome than previously, whilst their increased awareness of the link between hyperglycaemia and the risk of developing complications may have impacted negatively on their psychological well-being. However, results from the trial indicate that while patients do report increased levels of understanding, this was not associated with decreased psychological well-being.

6.2.3.6 Treatment control and personal control

It would seem counter-intuitive that the patients who perceive diabetes as most threatening, have the poorest compliance with treatment regimens, and in turn, have the poorest glycaemic control. Arguably the belief that diabetes is a serious condition should be a positive motivating influence. However, it is widely recognised in health promotion (Witte & Allen, 2000) that distress and fear does not act as a motivator for behaviour change for everyone, but rather, can lead to some people focusing on managing the emotions connected to a health threat, rather than the health threat itself (e.g. by avoiding the situation that provokes the fear/distress). Studies have shown that in the case of diabetes, perceptions about the consequences of diabetes act as a positive motivator for

behaviour change only if patients believe that the *treatment regime* is effective (e.g. (Skinner et al., 2000; Witte & Allen, 2000). Thus, for patients' to successfully change their self-management behaviours, they must believe that by doing so they will improve their diabetes (i.e. treatment control). Essentially, however, they must also believe that they are capable of actually implementing the behaviour change. This refers to the concept of personal control/self efficacy.

Results from the mediational analyses, reported in the previous chapter, indicated that it is through this personal control/self-efficacy pathway that the intervention under consideration may work. An improved sense of personal control, an increased understanding of diabetes, and a decrease in diabetes-specific concern, resulted in improvements in diet, whilst a greater belief in the effectiveness of diabetes treatment resulted in increased exercise behaviour. These findings are consistent with results from other (non-intervention) studies with patients with diabetes. For example, Watkins and colleagues (Watkins et al., 2000) also found that increased perceptions of control and understanding were associated with better dietary self-management, while perceptions about treatment control/effectiveness have consistently been found to predict levels of physical activity (Hampson et al., 1990; 1995; Glasgow et al., 1997). However, while other studies have found evidence for an association or correlation between illness perceptions and diet and exercise, the trial reported here is the first to show experimentally that improving patients' beliefs about personal control, treatment control, and understanding, and decreasing disease-specific emotional distress, results in improvements in diet and exercise.

6.2.3.7 Causes

The only statistically significant difference between groups in terms of causal perceptions emerged with regards to patients beliefs that genetics/family history caused their diabetes. Following the intervention, a significantly lower proportion of patients in the intervention group attributed the cause of their diabetes solely to genetic factors. This is an important finding. Research on causal attributions has shown that when individuals attribute their illness to an uncontrollable cause, such as faulty genes, it can have negative health

outcomes e.g. (Reed, Kemeny, Taylor, & Visscher, 1999; Segerstrom, Taylor, Kemeny, Reed, & Visscher, 1996). Existing evidence suggests that this is due to patients' beliefs that there is little they can do to alter the course of the illness (i.e. the concept of personal control). As such, they are more likely to experience negative psychological adjustment, and engage in maladaptive and ineffective coping strategies, which in turn impacts negatively on health outcomes (Riggs & Giuliano, 2007).

6.2.4 Illness perceptions of family members

A key part of the intervention reported here was the targeting of family members' perceptions about diabetes, and improving in a positive direction, the degree of similarity between the perceptions of both patient and family members. At this point, it must be stressed that the low rate of return of family member questionnaires at both baseline (56% n=68) and follow-up (35% n=42) means that this data must be interpreted with caution. Furthermore, as the numbers were so small, it was not possible to assess the degree of similarity using the *positive/negative classification* approach, as originally anticipated and reported within the study protocol (see Appendix X). Rather, similarity was assessed using paired t-tests. However, some interesting trends still emerged from the analysis of available family data.

For example, family members in the intervention group, when compared to their control group counterparts, reported that patients were experiencing fewer diabetes-related symptoms, which mirrored patients' own reports. Following the intervention, family members in the intervention group also reported statistically significant decreases in their own levels of diabetes-related concern, and also the patients' levels of concern, when compared to those in the control group. Family members who participated in the intervention also reported statistically significant higher levels of diabetes understanding compared to family members in the control group. Finally, at the six-month follow-up, there were no statistically significant differences between the illness perceptions of patients and family members in the intervention group, and both family members and patients report significant positive change in diabetes perceptions. Conversely, significant differences remained between the patient and family members in the control group.

Although the numbers are small, this is perhaps the key finding in relation to family members' perceptions of diabetes. Conflicting illness perceptions, and/or similar negative perceptions, have been shown to be associated with poorer health outcomes and increased psychological distress in patients with chronic illness (Figueiras & Weinman, 2003; Heijmans et al., 1999; Olsen et al., 2008; Richards et al., 2004). Thus, one of the central goals of the intervention reported here was to improve the degree of similarity between patient and family members' perceptions, in a positive direction, with a view to improving patient outcomes. Based on the available data, it would appear that the intervention was successful in achieving this goal. No other studies were identified which experimentally tested if in fact it is possible to improve the degree of similarity between patients and family member illness perceptions. However, it must be stressed again that these results should be interpreted with caution, given the small number of family questionnaires that were returned at follow-up.

6.2.5 Blood pressure and BMI

There were no significant differences in blood pressure control between intervention and control groups at the six months follow-up. However, at baseline and follow-up both groups had good blood pressure control, with readings within the recommended range for those with type 2 diabetes (less than 140/80 in the absence of retinopathy (ADA, 2007)). Thus, there was little scope for improvement. The intervention group showed a slight decrease in body mass index (BMI) when compared to the control group (31.5 vs. 33.8), although this was not a statistically significant difference. While BMI may be hypothesised to improve as a result of lifestyle changes associated with improved glycaemic control (e.g. changes in diet and exercise), the key focus of the intervention sessions was achieving good glycaemic control, not weight loss. In other words, diet and exercise behaviours were explored for their impact on glycaemic control, not weight. In addition, successful weight loss generally requires a combination of dietary change and increased exercise. However, the action plans developed during intervention sessions generally addressed a single behaviour only, not a combination. For example: one person quit smoking; another checked blood sugars more regularly; another exercised more.

Although, it is possible that successfully changing one health behaviour, may have a 'knock on' effect, and as such may encourage people to change other health behaviours. Other family intervention studies e.g. (Brown & Hanis, 1995; Gilliland et al.,, 2002; Pearce et al., 2008; Wing et al., 1991), have also found that family-based interventions did not have a statistically significant impact on blood pressure or BMI in patients with type 2 diabetes. This was also the case when the intervention was specifically targeted at weight loss (Wing et al., 1991) or blood pressure control (e.g. Pearce et al., 2008). In their meta-analysis Ismail and colleagues (Ismail et al., 2004) also reported that psychological intervention for patients with type 2 diabetes had no impact on weight control, although blood pressure control was not included as an outcome in that meta-analysis. Nonetheless, these results do not necessarily indicate that psychological and family intervention do not have a role to play in weight management and blood pressure control in people with type 2 diabetes. Rather, it highlights the difficult task faced by patients and healthcare providers in attempting to manage and control three biological outcomes in combination: that is, blood glucose control, blood pressure control and weight control. Interventions have tended to target only one of these measures as a primary outcome in trials (although the other measures are often included as secondary outcomes), rather than explicitly focusing on all three and how they interact. This may be an area on which future interventions might focus, although it is likely that such interventions would require a significant longitudinal element in order to allow sufficient time for medication and behaviour changes to be initiated and to take effect.

6.2.6 Diabetes self-care

Participants in the intervention group reported increased adherence to general diet recommendations and increased participation in exercise at follow-up, when compared to the control group. However, there were no significant differences between the two groups on more specific dietary behaviours (fruit and vegetable intake, and fat consumption). This may be due to the fact that the intervention did not focus explicitly on these specific eating behaviours. Although, the intervention group reported increases in both foot care and self-monitoring of blood glucose, these differences were not statistically significant compared to the control group. Again, the absence of any significant changes in foot care

is likely due to the fact that this behaviour did not form a large part of the intervention. While the importance of good foot care in preventing complications was highlighted, it did not appear to be a major concern for most participants. This raises questions, perhaps, about interventions that emphasise patients' own agenda for behaviour change. For instance, it may be problematic if certain issues, such as foot care, tend to be undervalued by patients, and as such, are not targeted for behaviour change. However, it is in such circumstances that illness perceptions interventions are particularly salient, as they can facilitate an understanding of the importance of such undervalued behaviours amongst patients.

The results regarding self-monitoring of blood-glucose (SMBG) are more difficult to interpret. The role of SMBG in improving glycaemic control in non-insulin treated type 2 diabetes remains questionable (Towfigh et al., 2008). For example, the DiGEM study (Farmer et al., 2009), a recent RCT comparing less-intensive and more-intensive SMBG for patients with non-insulin treated type 2 diabetes, found no improvement in glycaemic control in either group of patients, when compared to a usual care group. The relationship between illness perceptions and SMBG is also controversial. For example, some studies have found that illness perceptions predict SMBG (Glasgow et al., 1997; Hampson et al., 1990), while others have found no association (Hampson et al., 1995; Skinner et al., 2000). Thus, it may be that illness perceptions are only related to SMBG in particular groups of patients with type 2 diabetes, such as those on insulin (French et al., 2008). Equally, it may simply be that illness perceptions are not predictive of SMBG. According to Leventhal's Self-Regulatory Model, if patients are given sufficient information about blood glucose levels (i.e. perceptions are changed), they should be able to make necessary lifestyle changes, if for example, SMBG is used to provide feedback about the impact of a meal high in sugar or a brisk walk. However, results from the DiGEM trial (which also assessed the effect of SMBG on illness perceptions) found that while the intervention changed patients' beliefs about diabetes (as assessed by the Illness Perception Questionnaire Revised), this did not result in changes in. diet and exercise behaviours (French et al., 2008). French et al. concluded that the day to day variability of self-monitored blood glucose levels can be frustrating for some patients (particularly if

the readings do not make sense), and that this variability may mask the benefits derived from any small change in health behaviours over the corresponding time period. This may particularly be the case for those patient not treated with insulin, for whom changes in SMBG do not result in obvious changes in medication. Thus, changing beliefs/perceptions about diabetes may not necessarily result in improvements in SMBG, because patients have learned from experience (perhaps correctly) that behaviours and blood sugar levels are not always correlated on a daily basis. Less variable and longer-term measures of glycaemic control, such as HbA1c, may provide more positive feedback, thereby leading to changes in other lifestyle behaviours. However, this is also difficult in the long-term, as due to the progressive nature of diabetes glycaemic control can often deteriorate regardless of the best self-management efforts, which may be discouraging for patients.

In contrast to the results described above, the findings reported in the current study, indicate that changing perceptions about diabetes can lead to changes in both diet and exercise behaviours. It is possible that French et al. found no association in their trial, because it was not explicitly an illness perceptions intervention. Rather, it assessed the effects of different types of SMBG interventions on illness perceptions, as opposed to the effects of an illness perceptions intervention on SMBG (i.e. the direction of the causal pathway differed). The findings presented here are in line with the self-regulatory pathways predicted by Leventhal's Model, as well as previous cross-sectional and longitudinal research showing an association between perceptions of diabetes and diet and exercise behaviours (Glasgow et al.,. 1997; Griva et al., 2000; Hampson et al., 1995; 1990; Harvey & Lawson, 2009; Skinner et al., 2000). However, this study is the first to experimentally test the proposed pathways. The mediational analyses indicated that as expected, these changes in diet and exercise, resulting from changes in perceptions of personal control, treatment control, understanding and concern, accounted for improvements in psychological well-being, but unexpectedly, not in glycaemic control. Rather, the effects of the intervention on HbA1c appeared to be directly mediated by changes in cognitions.

That changes in lifestyle behaviours *did not* appear to account for corresponding improvements in glycaemic control is surprising. The relationship between diet, exercise and glycaemic control is well-established e.g. (Thomas & Elliott, 2009; Thomas, Elliott, & Naughton, 2006)). Thus, the lack of a mediational relationship in the current study may simply be the result of some statistical anomaly (e.g. a lack of power to test the mediation) or some measurement issue (e.g. the lack of sensitivity of the self-report questionnaire). It may also be that the relationships between illness perceptions, diet and exercise, and glycaemic control are mediated by some fourth problem-focused coping behaviour that was not been assessed. Nonetheless, the possibility of illness perceptions directly impacting on glycaemic control should not be discounted. Leventhal's model does not explicitly specify a 'perceptions → physiology' pathway, and indeed this may be a weakness in the model. However, there is research to suggest that cognitions/beliefs/perceptions may have a direct influence on biological and health outcomes, without a mediating behavioural variable e.g. (Christian, Graham, Padgett, Glaser, & Kiecolt-Glaser, 2006; Gouin et al., 2008; Gouin, Hantsoo, & Kiecolt-Glaser, 2008; Gouin, Kiecolt-Glaser, Malarkey, & Glaser, 2008; Kiecolt-Glaser et al., 2007; Kiecolt-Glaser et al., 2009; Waldman et al., 2008)).

As discussed in Chapter Two (section 2.7.1.) this '*psycho-physiological'* pathway is one of the mechanisms through which family interventions are conceptualised as being effective. For example, improvements in illness perceptions in the patients in this study resulted in patients feeling less stressed or anxious or upset, as evidenced by improvements in psychological well-being. Through the physiological stress response, (McEwen, 1998), this may have directly led to corresponding changes in related physiological systems which are known to influence blood sugar regulation (e.g. reduced cortisol, adrenaline secretion, increased endorphins etc (Kinsley & Simonson, 1996; Levy, Kinsley, Bajaj, & Simonson, 1998)). It is essential to stress again, however, that the results from the meditational analysis presented here must be interpreted with caution, due to the methodological limitations discussed above. However, it could be tentatively suggested that the hypothesised direct relationship between the illness perceptions

components of Leventhal's Model, and physiological systems, may offer some promise as an area for future research.

6.2.7 Diabetes self-efficacy

At six months follow-up, the intervention group reported statistically significant higher levels of diabetes self-efficacy when compared to the control group, and increases in self-efficacy also mediated the effects of the intervention on diet. These findings support those from other intervention studies, which have found that increasing self-efficacy leads to improvements in diabetes self-care behaviours and glycaemic control e.g. (Glasgow et al., 1995; 1997; Klug, Toobert, & Fogerty, 2008; Trief, Teresi, Eimicke, Shea, & Weinstock, 2009;Wangberg, 2008)). It is not surprising in view of such positive findings, that self-efficacy is becoming increasingly popular as a target for intervention in patients with chronic illnesses, including type 2 diabetes. Thus, the construct of self-efficacy has been included in high profile lifestyle intervention programmes, such as : the Expert Patient Programme (Plews, 2005); the Chronic Disease Self-Management Programme (Lorig et al., 2001); and the Diabetes Prevention Programme ((DPP):, 2002). However, despite its growing popularity as a target in such interventions, there is still confusion regarding what *exactly* the construct of self-efficacy refers to. For example, in the intervention under investigation here, improvements in both diabetes self-efficacy, and the illness perception dimension of personal control, were both associated with improvements in diabetes self-care and glycaemic control. On a practical level this raises questions as to whether future similar interventions should target both constructs or focus on only one, whilst on a theoretical level, the question arises as to whether self-efficacy and personal control are in fact two wholly separate constructs.

The second of these questions is one that has, to some extent, been addressed in the literature. Self-efficacy is a central component of the social cognitive theory proposed by Bandura (Bandura, 1977), whilst *personal control* is an illness perception dimension in Leventhal's self-regulatory model (Leventhal et al., 2003). According to Bandura, self-efficacy and personal control *are* distinct (although related) concepts. According to Bandura (Bandura, 1977), self-efficacy focuses on beliefs in one's own *ability* to

effectively perform a specific behaviour or task. For example, a patient with high self-efficacy for blood glucose testing is *confident* that he/she can perform the behaviours necessary for checking their blood sugars correctly. Personal control beliefs, on the other hand, are more related to the *'outcome expectancies'* construct of Bandura's theory; that is, the belief that performing specific behaviours or tasks will ultimately result in desired goals or outcomes. In other words, the concept of personal control relates to beliefs or judgements about whether one's specific actions can produce a given outcome (i.e. the extent to which a given outcome is controllable by the individual themselves). For example, a patient with high personal control for blood glucose testing believes that by testing their blood sugars (performing a behaviour) they can control their blood sugars (the desired outcome). Simplistically, personal control beliefs focus on the question of whether a person can control an outcome by their own behaviour, whilst self-efficacy beliefs focus on the evaluation of one's ability to effectively perform the behaviours necessary to achieve that outcome.

Recent research with patients with type 2 diabetes (O'Hea et al., 2009) has shown a positive, but moderate correlation between the two constructs, indicating that each construct taps into different aspects of beliefs regarding behavioural control. However, this study also showed that there is an interactive relationship between the two constructs. The authors reported that individuals with higher levels of personal control were more likely to believe that self-care behaviours will result in better diabetes control (i.e. high personal control), and they were *also* more likely to have greater confidence in their ability to engage in these self-care behaviours (i.e. high self-efficacy). This interaction between self-efficacy and personal control had a significant effect on glycaemic control; in that patients with high self-efficacy for diabetes management, coupled with high levels of personal control, showed lower levels of HbA1c. Thus, in order to improve diabetes self-management and glycaemic control, it may be necessary to increase not only self-efficacy beliefs, but also personal control beliefs, as was achieved in the current study. The increasing focus on improving self-efficacy in chronic disease intervention is important. However, in addition to improving patients' confidence for performing health behaviours, such interventions may also wish to incorporate attempts to improve patients'

beliefs that changing their own behaviour will achieve desired outcomes (i.e. personal control). In fact, it has been argued that personal control may be the more important of the two constructs, as it may be at the root of self-efficacy (Ross, 2003). For example, even if a person believes that they can effectively check their blood sugars (i.e. high self-efficacy), they may not do so if they believe that blood glucose testing, their own behaviour, is not related to glycaemic control (i.e. personal control is low).

6.2.8 Family Support

Patients in the intervention group reported a statistically significant higher level of family support for diabetes management at six months follow-up, compared to the control group. Findings from the intention-to-treat analysis indicated that there were no statistically significant changes in non-supportive family behaviours (e.g. nagging, criticising, arguing, etc). However, based on the per-protocol analysis, patients who actually participated in the intervention did report statistically significant lower levels of these non-support behaviours. As previously highlighted, there are a surprisingly small number of family interventions for patients with type 2 diabetes; our Cochrane review identified only four, in addition to this RCT. What is perhaps most surprising, is that while all of these interventions aimed to foster family support for diabetes management, only one (Brown & Hanis, 1995) reported formally assessing the effects of the intervention on family support. Brown et al. reported that there were no significant differences between groups in terms of support, however, it was not clear what methods or measures were used to assess family support in, which restricts the conclusions that can be drawn from that study. Given that mobilising family support is a key goal in family interventions for type 2 diabetes, it would seem prudent that any future interventions in this area explicitly assess family support using reliable and validated measures, as was the case in the current study.

In addition, it may be beneficial for any future family interventions to assess both patient and family member reports of family support. Interestingly in this trial, family members themselves did not report any significant changes in their supportive and non-supportive behaviour, as a result of participating in the intervention. However, this lack of a

significant effect is most likely due to low statistical power, resulting from the very low response rate in this group. This is particularly likely to be the case, given the results from the focus groups, in which participants reported that the intervention was effective in mobilising family support for diabetes management. However, it remains difficult to conclusively establish whether the intervention was effective in changing actual family behaviour, or simply patients' perceptions of the type of support they were receiving. In any case, the distinction may not be an important one, as the mediational analyses indicated that family support did not influence either glycaemic control or psychological well-being. This is a surprising finding, but as indicated earlier (with regard to the lack of mediating relationship between diet and exercise and glycaemic control), it may be due to methodological limitations.

6.2.9 Motivational interviewing

The intervention under consideration in this RCT was delivered using techniques from motivational interviewing (MI). The results from the process evaluation components of the trial (see section 5.9) indicate that MI was implemented as intended during intervention sessions. Whilst originally developed as a set of therapeutic techniques in the field of addiction counselling, MI is increasingly being applied as a behaviour change technique in physical healthcare settings. The results from the present study indicate that the intervention was effective in improving diet and exercise behaviours. This supports the findings from systematic reviews and meta-analysis which have reported that MI is consistently effective in improving these lifestyle behaviours across a range of patients with physical health problems (Burke et al., 2003; Dunn et al., 2001; Knight et al., 2006; Rubak et al., 2005). Only two RCTs of motivational interviewing interventions for patients with type 2 diabetes were identified from the literature review undertaken as part of this study (Clark et al., 2004; Smith et al., 2007). The findings from these two trials indicate that motivational interviewing interventions are effective in improving adherence to diet and exercise recommendation, weight management and glycaemic control. The results in relation to lifestyle behaviours and glycaemic control are consistent with those reported here. Despite the fact that the current intervention had no statistically significant effect on BMI, there was a small reduction in BMI in the intervention group, and an

increase in weight in the control group. This is similar to results from the Clark et al. study, in which the authors reported that a tailored lifestyle intervention delivered using motivational interviewing, did not result in significant weight loss in the intervention group, but was effective in maintaining participants' weight when compared to the control group (who showed an increase in weight).

It could be argued that perhaps it was solely the MI components of the intervention that were effective in achieving improvements in self-care behaviours and glycaemic control, rather than changes in illness perceptions. However, as with other psychological therapies, MI is a set of a therapeutic techniques or tools or procedures (e.g. reflective listening, goal-setting, improving self-efficacy), which facilitate the delivery of an intervention, and assist in the achievement of intervention goals. Thus, based on Leventhal's Self Regulatory Model, the intervention was hypothesised to improve glycaemic control in those with poorly controlled type 2 diabetes, by changing their negative or inaccurate illness perceptions, and improving their diabetes self-care and their family's supportive behaviour. MI was conceptualised as the set of therapeutic techniques or procedures by which these changes in perceptions and behaviours were facilitated. The successful delivery of the intervention, therefore, was dependent on the theory-based intervention being implemented using the corresponding therapeutic techniques. It is possible that a different psychological therapy (e.g. CBT) could have effectively been used to implement this intervention. Equally, MI as a psychological therapy can be, and has been, used to deliver interventions based on other psychological theories and in other patient populations. There were, however, a number of key benefits of MI which guided the decision to select it as a therapeutic technique for this intervention, over and above other techniques, for example: its client-centred focus; the fact that it achieves similar effects to CBT but in a shorter time; and its adaptations for physical healthcare settings (these are discussed in more detail in Chapter Two, section 2.6.3).

6.2.10 Economic evaluation

The economic evaluation indicated that the direct per-patient cost of the intervention was €219.48 (based on an ITT analysis, or €365.80 based on a PP analysis). Based on the Cost Effectiveness Analysis (CEA), the incremental cost of the intervention per 1% decrease in HbA1c in all poorly controlled patients was €548.47 (or €609.66 based on a PP analysis). For those with the poorest glycaemic control (baseline HbA1c > 9.5%) the incremental cost of the intervention per 1% decrease in HbA1c was €182.90 (for the ITT analysis, or €304.83 for the PP analysis). The intervention was not conceptualised as an alternative to usual care. Rather, it was conceptualised as a supplement to conventional treatment, for patients having particular difficulties controlling their diabetes. Thus, as is the case with implementing any supplementary service or treatment, it was to be expected that there would be additional costs to healthcare providers.

It is difficult to compare the costs associated with implementing the current intervention with other psychosocial interventions, as the majority of comparable interventions have not included an economic analysis. For example, the majority of studies included in recent reviews examining the cost-effectiveness of interventions for treating diabetes (Bottomley & Raymond, 2007; Klonoff & Schwartz, 2000), were comparisons of anti-diabetic pharmaceuticals. There has been some consideration of the costs of non-pharmaceutical interventions (e.g. lifestyle or educational interventions) for *preventing* type 2 diabetes in individuals at high risk of developing the illness (e.g. Diabetes Prevention Programme((DPP):, 2003)). However, there appears to be little available literature on the cost of similar interventions for *treating* type 2 diabetes. One recent RCT (Handley, Shumway, & Schillinger, 2008) estimated that the cost of an automated telephone self-management support intervention, combined with one-on-one nurse counselling, for people with type 2 diabetes, was $782 per-patient. However, the intervention was not found to improve glycaemic control. Only one RCT of a family intervention was identified that calculated intervention costs: Brown et al. (Brown & Hanis, 1995) estimated that a culturally competent self-management intervention for Mexican Americans with type 2 diabetes, which achieved a decrease of 1.4% in HbA1c at six months follow-up, cost $384 per patient (1995 prices). Thus, it is difficult to judge

the cost of the current intervention relative to other non-pharmacological interventions, given the paucity of comparable economic evaluations.

Despite this, the economic analyses from the UKPDS trial have clearly shown that improving glycaemic control in people with type 2 diabetes is cost effective (although improving glycaemic control was achieved with intensive insulin management in UKPDS). Within the UKPDS, intensive glucose control resulted in an absolute decrease in HbA1c of 0.9% and cost an additional £695 per-patient (1997 prices), when compared to conventional treatment (Gray et al., 2000; Gray & Clarke, 2008). However, while intensive glucose control did increase treatment costs initially, in the longer-term it substantially reduced the cost of complications by £957 per patient. Thus, while there may be initial increased costs associated with interventions to improve glycaemic control in patients with type 2 diabetes, in the long-term these are counter-balanced by significant reductions in the costs of treating diabetes complications. Clearly, the UKPDS and the intervention under consideration here are not comparable, as the UKPDS was a much larger and much longer-running trial of intensive insulin therapy. It also remains to be seen whether the improvements in glycaemic control resulting from this psychological, family-based intervention are maintained. However, if such long-term effects become apparent, it could be hypothesised that as was the case with UKPDS, the initial increased costs of implementing this intervention would be off-set by a reduction in the costs of complications. It must also be noted that the measure of cost effectiveness in the UKPDS analyses was the incremental cost per event-free year gained ('event' = myocardial infarction, stroke, amputation, blindness, death), not the incremental cost per unit decrease in HbA1c. Given the follow-up time period of the intervention presented here (6-months) and the small number of participants, it was not possible to collect similar data on these 'events'. However, as previously discussed, the UKPDS found that decreases in HbA1c are associated with significant reductions in the risk of any of these 'events' or complications.

One of the limiting factors of the economic analysis for this RCT was the fact that health-related quality of life (HRQoL) was not assessed. Whilst the WBQ-12 used in this study

could be conceptualised as measuring aspects of HRQoL (e.g. well-being), it does not assess aspects such as physical functioning, which are assessed by other QoL measures (e.g. the SF-36, Ware et al., 2002) Thus, no analysis could be conducted in relation to 'quality-adjusted-life-years' (QALYs). QALYs are a measure of health outcome that integrate quantity and quality of life into a common measure. Cost-utility analyses use QALYs as a measure of health benefits, and allow for the calculation of the cost of an intervention per QALY gained. For example, the economic analyses of the UKPDS reported that intensive blood glucose control costs £6028 per QALY gained (1997 prices; (Clarke et al., 2005). The QALY is a favoured measure amongst many health economists, as it facilitates a comparison of cost-effectiveness across the widest possible range of different interventions and disease outcomes (Torrance, 1986). In addition, while there is no universally accepted threshold to determine cost-effectiveness based on the 'cost per QALY gained', healthcare providers still often use this method when deciding if an intervention represents an acceptable use of health-care resources (i.e. if it represents value for money). For instance, in the UK interventions appear to have a high chance of acceptance by the National Institute of Clinical Excellence (NICE) if their cost effectiveness is more favourable than the £20,000-£30,000 range per QALY (Gray, 2008). Thus, future psychosocial interventions which plan to conduct an economic analysis may wish to consider including a HRQoL measure, in order to facilitate the calculation of QALYs. This may enable the intervention to be compared more accurately with other alternative treatments, and may assist health care providers in their decisions regarding the cost-effectiveness of the intervention.

6.3 EVALUATION OF THE STUDY

In the following sub-sections, the study is evaluated with respect to its main strengths and limitations. These are considered with regards to a number of key areas of the study, including: recruitment; data collection; participants; settings and intervention delivery; measures; process evaluation; and general RCT methodology.

6.3.1 Recruitment issues

During the recruitment period, 501 patients were identified from the hospital computer database as having persistently poorly controlled type 2 diabetes, and thus, were

potentially eligible for inclusion in the study. However, more than one-quarter (27%, n=135/501) of these patients did not attend for their scheduled clinic appointments during the timeframe of the study. Whilst little work has been undertaken to examine non-attendance rates at diabetes outpatient clinics in the Irish public health care system, previous research (White et al., 2001-2004) in the same diabetes clinic reported a DNA (i.e. 'did not attend') rate of 57%. These levels of non-attendance appear to be high when compared with studies conducted elsewhere. For example, a review of the international literature (Griffin, 1998) reported that, while estimates of the prevalence of DNA rates at diabetes outpatient clinics vary by country and region, it is about 10% on average. Another interesting study (Hogan, McCormack, Traynor, & Winter, 2008) of missed appointments at Irish out-patient clinics, reported a non-attendance rate of 17% across a range of specialties. Thus, Irish non-attendance rates, in general, appear to be higher than the international average but the reasons underpinning this are unclear.

With regard to the present study, the high non-attendance rate is perhaps not surprising given the sub-population of those with diabetes under investigation. It is often suspected in clinical settings that those who default from professional diabetes care are amongst the patients with the poorest glycaemic control. Indeed, in his review of the literature, Griffin (Griffin, 1998) reports a consistently strong association across studies between infrequent clinic attendance, and adverse clinical outcomes and risk factors (e.g. poor glycaemic control). In addition, the patient characteristics (Griffin, 1998) found to be associated with non-attendance such as low-socio economic status, unemployment, low levels of education, and poor psychological well-being, are also those found to be commonly associated with poor glycaemic control. Thus, while the intervention examined here was targeted specifically at a particularly vulnerable population, it is possible given the high DNA rates, that the most vulnerable of that group - those patients with the poorest of poor control overall - were not recruited to the trial. Although it is notoriously difficult to conduct research with those who default from care, it may be that future studies would benefit by making concerted efforts to recruit to trials, and target intervention to, this particular group of patients. This could perhaps be achieved by accessing patients through primary care settings, rather than through hospital clinics.

A further one quarter (n=126) of the 501 patients initially identified as having persistently poorly controlled type 2 diabetes, did not meet additional study inclusion criteria upon further assessment. This was due either to the fact that no family member was available to participate (n=36), or that patients were not physically able to take part in the trial (n=37). For the most part, patients were not physically able to take part in the trial due to the presence of co-morbid life-threatening or severely debilitating conditions, such as cancer or stroke. Arguably, all poorly controlled patients should be recruited in a pragmatic RCT, regardless of the severity of co-morbid conditions. However, it is likely those with serious life-threatening illnesses have poorly controlled diabetes as the result of factors other than those hypothesised by the theory underlying this trial, such as negative or inaccurate illness perceptions; these other external factors might include medication side-effects or an underlying co-morbid disease pathology. In addition, on a purely pragmatic level, such patients were likely to be physically unable to participate in the intervention. As such, it was prudent to exclude this group from the intervention. Participants with co-morbid conditions that were not life-threatening, such as various types of cardiovascular disease or arthritis, were not excluded from the trial. This is perhaps a key strength of the study, as it is more representative of the 'real world' clinical context where patients with diabetes often have multiple chronic conditions or *multimorbidity* (Mercer, Smith, Wyke, O'Dowd, & Watt, 2009; Smith, Ferede, & O'Dowd, 2008).

Of more concern, perhaps, is the proportion of patients (7%, n=36) initially eligible for inclusion in the trial, but who reported that they had no family member available to take part in the study. This may reflect the absence of a family member in patients' lives, or it may reflect patients' perceptions that family members are unsupportive of their diabetes management and would not be willing to participate in the study. Indeed, the hypothesised perception regarding a lack of support may be corroborated by the number of intervention group participants who were required to withdraw from the trial when their family member declined to participate in the intervention sessions. Also, previous research in the same diabetes clinic (White et al., 2001-2004) found that the family members of those in poor control were significantly less likely to return questionnaires,

when compared to the family members of patients' in good control. This suggests that this particular group of patients require most help with regard to mobilising family support for diabetes management Alternatively, it may be the case that patients do have family members available and willing to participate. However, patients do not wish to place additional 'burden' on their family member by asking them to take part. Regardless of the underlying reasons, the proportion of patients excluded from the trial due to the absence of a family member, suggests there may be a need to conduct the intervention on an individual basis with patients.

6.3.2 Data collection: baseline and follow-up

A total of 121 eligible patients were recruited to the trial and randomised to an intervention (n=60) or control (n=61) group. A key strength of the study was that the baseline data for both groups were collected through interview-administered questionnaires, thereby ensuring a standardised approach to data collection, and resulting in a 100% response-rate. The interview nature of the data collection also helped to overcome any difficulties that patients may have had in completing questionnaires, such as literacy or sight problems. In addition, baseline assessments were conducted after randomisation to control and intervention groups had occurred, thereby helping to minimise any recruitment bias.

Baseline questionnaires were returned by only 68 family members (56%); that is, 32 in the control group, and 36 in the intervention group. This represents a relatively low response rate from family members, despite two reminder letters, and means family data must be interpreted with caution. However, such a relatively low response rate is not entirely unexpected with a postal questionnaire survey, where a response rate of about 50% is the average (Pedrana, Hellard, & Giles, 2008). A better response rate may have been achieved if perhaps family members themselves had been interviewed, either in person, or over the telephone. As it happened, the slightly higher response rate in the intervention group reflects the fact that a number of baseline family member questionnaires were completed with family members in the home, when the interventionist delivered the intervention. The reasons for non-completion were not

examined. Thus, it may be that some patients did not give the questionnaire to their family member, either because they forgot to, or they did not see the relevance of doing so. It may also be the case that family members *themselves* forgot to return the questionnaire, or they also did not see the relevance of it. Alternatively, the high non-response rate may be reflective of a more general lack of family support for the patients' management of their diabetes. Therefore, it may be worthwhile in future studies, if possible, to elucidate family members' reasons for not responding, for example, at follow-up data collection or as part of the process evaluation.

Despite the relatively low response rate, there appeared to be no obvious differences between the socio-demographic characteristics or baseline illness perception of family members in the intervention and control group. However, as expected, and as shown in previous research (Law, 2002; Olsen et al., 2008; Searle, Norman, Thompson, & Vedhara, 2007; White et al., 2001-2004), there were significant differences between patient and family members' perceptions about diabetes. Differences between patient and family member perceptions were investigated at baseline using significance testing, as this was the means by which the degree of similarity of patients' and family members' perceptions was assessed at follow-up. While there were some small discrepancies between the intervention and control groups, on the whole, the pattern of these differences between patients and family member illness perceptions was similar across intervention and control groups.

The rate of follow-up for HbA1c and psychological data were 84% (n=102/121) and 71% (n=86/121) respectively. Unfortunately, follow-up data collection at 6-months could not be coordinated with participants' return appointments to the diabetes clinics, as the average interval between diabetes outpatient appointments in the Irish hospital system is 12-18 months. Thus, participants were recalled to the clinic specifically for the purposes of completing the follow-up questionnaire, rather than for a diabetes review appointment. This may have had some impact on participants' decision to attend. Follow-up rates in future studies may be improved, where possible, by coordinating data collection with outpatient clinic appointments. However, the non-attendance rate of 28% (n=35/121) for

follow-up is almost identical to the DNA rate of 27% at the clinic recruitment stage. HbA1c levels at six months follow-up were available for 16 of the 35 patients who did not return for follow-up (e.g. as a result of blood tests requested by other outpatient clinics, or GPs), thereby accounting for the discrepancy between the follow-up rates for HbA1c and psychological measures.

Furthermore, the response rate for follow-up family member questionnaires was very low, at 35% (n=42), although the majority of family members who returned follow-up questionnaires had also returned completed baseline questionnaires. Thus, again, results for the family data must be interpreted with caution due to the risk of bias from the high non-response rate. Finally, while the follow-up period of six-months was an adequate length of time to demonstrate changes in glycaemic control, it was not sufficiently long enough to demonstrate if the improvements in glycaemic control and other outcomes are maintained. It is planned to follow-up participants in the future (e.g. at 12 or 24 months, or longer) to examine if the intervention has longer-lasting effects.

6.3.3 Participants

A central strength of this study was its focus on a high risk population - those with persistently poorly controlled type 2 diabetes. This population has been shown to be the group of patients who are: at most risk of developing complications; the most emotionally-distressed; and have the most inaccurate and negative beliefs about their illness. Thus, it is perhaps this group who might benefit most from some form of intervention. Indeed, results from the current study show that the intervention worked best in the most vulnerable subgroup of this high risk population: that is, those with the poorest of poor control (HbA1c >9.5%).

However, there may have been scope to increase the effectiveness of the intervention by targeting it to even more specific groups. For example, increasing age is an independent risk factor for poorer glycaemic control; thus it could be argued that there should have been an upper age limit for inclusion to the trial. However, while assessing the eligibility of patients for inclusion in the trial, many older people (75 years plus) were identified in the clinic who had good glycaemic control. Thus, age in and of itself may not be the

central factor contributing to poor glycaemic control; rather, it may be that the relationship between age and cognitive functioning is more relevant. There is evidence to suggest that there is a significant association between hyperglycaemia and impaired cognitive functioning in older patients with diabetes (Abbatecola et al., 2006; Ebady, Arami, & Shafigh, 2008; Cukierman-Yaffe et al., 2009; van Harten et al., 2007) although the direction of the relationship is not clear. In addition, the relationship between poorer glycaemic control and reduced cognitive function is also evident even amongst younger populations with diabetes (Cox et al., 2005). Thus, excluding older patients (or even younger patients) from the trial because of suspected cognitive impairment does not seem appropriate. In any case, the assessment of the relationship between cognitive functioning and glucose control is complex, and was beyond the scope of this trial.

It was noted by the researcher when meeting with patients in the clinic, and when delivering the intervention, that there appeared to be two broadly differing groups of poorly controlled patients: comprising older and younger patients respectively. In the former, generally retired, group, poor glycaemic control appeared to be mainly due to a combination of ageing, difficulties managing comorbid conditions, and a lack of understanding about diabetes. However, a different pattern appeared to be evident in the younger group. This group of patients were generally still working, often in jobs involving shift-work, and were trying to manage diabetes around their jobs and family life. This appeared to be very challenging for them. For example, patients spoke of the difficulties of trying to eat healthily while working at night, or when their teenage children were unsupportive of dietary change, or the difficulties of getting enough exercise when driving a taxi/truck/bus for a large part of the day. Most patients were also very emotionally distressed about their diabetes, and the impact it was having on their lives, particularly their relationships with their spouses. These younger poorly controlled patients often reported engaging in maladaptive coping behaviours, such as over-eating or alcohol use, in an attempt to deal with this emotional distress, which possibly contributed to their poor glycaemic control. Clearly the intervention sessions with these two groups of older and younger patients were quite different. However, it is likely that the intervention was effective in improving glycaemic control across all patients, precisely because it could be specifically tailored to the unique needs of individual patients and

their families. This flexibility is another significant strength of the intervention, and it highlights the necessity of taking into account, and working with, the personal circumstances of patients and their families when treating diabetes.

As mentioned earlier, the inclusion of family members in the intervention was perhaps one of the most essential active ingredients. Of particular importance was the fact that patients themselves were able to nominate the family member whom they felt would be the best person to participate in the study. Thus, it was not specified in the inclusion criteria that it must be patients' spouses/partners that participated, as is often the case in other family studies e.g. (Petrie et al., 2002). While the majority of the sample (75%) nominated their spouses, the remaining proportion proposed a variety of other family members, such as their sons or daughters. The study was not adequately powered to detect if there were any differences in intervention effects depending on the relationship of the family member to the patient, and this may be an area for future studies to investigate. What may also be of particular interest for future research is the small number of patients, all married females, who nominated a family member other than their spouses. It is conceivable that this group of female patients perceived their spouses to be particularly unsupportive of their diabetes management, and uninterested in participating in the intervention. This may also account for the higher proportion of males recruited to the trial: many of the participants who declined to participate because they had no available family member were female. In addition, the eight intervention group participants who withdrew from the trial because their family member was unwilling to take part, were also all female. Thus, there may be some differences between male and female patients in the levels of spousal support for diabetes management, which could be a possible target for future interventions. However, further research is needed to establish whether these differences reflect actual spousal behaviour, or simply patients' perceptions of a lack of spousal support, or finally, patients' lack of preparedness to seek social support (e.g. not wishing to 'burden' the family members) .

6.3.4 Setting and intervention delivery

Thirty-six participants received the intervention. Eight participants had to withdraw from the trial when their family member was not willing to take part. Again, this may be reflective of a more generalised lack of family support for diabetes management, and may indicate there is scope for the intervention to be delivered to patients on an individual basis. However, it is also possible that this is the group of patients in whom it is most important to attempt to intervene and mobilise family support. The other main reason participants did not receive the intervention was due to continual cancelling or missing appointments with the therapist. Nine participants cancelled/missed three or more sessions, and after consultation with the research team, these people were excluded from the trial. Even amongst patients who did receive the intervention there was a high rate of patients continually missing or cancelling appointments (see Process Evaluation, section 5.9.), requiring the therapist to persevere in attempting to schedule and deliver sessions. While persistent attempts to deliver the intervention to patients may be possible within a research setting, realistically it has practical implications within the clinical settings, the main issue relating to increased costs.

Despite these issues, the delivery of the intervention in patients' homes appeared to be one of the crucial active ingredients of the study. This was a recurring finding from the focus groups, during which patients alluded to how the home-based nature of the delivery was the most helpful aspect of the intervention. Working with patients in their home environment is not a new concept, particularly for some healthcare professionals such as public health nurses and general practitioners, and home-based interventions have been found to be effective in other illness populations. For example, a systematic review (Jolly, Taylor, Lip, & Stevens, 2006) comparing home-based cardiac rehabilitation to hospital-based rehabilitation for patients post-myocardial infarction, reported that home-based interventions were associated with improvements in blood pressure control, cholesterol, exercise behaviour, smoking status, and levels of depression and anxiety. Similarly, studies of home-based rehabilitation for patients who have experience a stroke, have also reported the benefits of such intervention, These include: a reduced risk of readmission to hospital (Crotty, Giles, Halbert, Harding, & Miller, 2008) or nursing home

(Ricauda et al., 2004); improvements in independent activities of daily living (Thorsen, Holmqvist, de Pedro-Cuesta, & von Koch, 2005), and quality of life (Fjaertoft, Indredavik, Johnsen, & Lydersen, 2004); reduced levels of depression (Ricauda et al., 2004); and higher levels of patient and care-giver satisfaction (Donnelly, Power, Russell, & Fullerton, 2004).

However, the effect of delivering healthcare interventions within patients' homes has been somewhat neglected within research on type 2 diabetes, and no other home-based interventions for patients with poorly controlled type 2 diabetes were identified in the literature. This is surprising, as there are a number of key advantages of home-based interventions. Firstly, home-based interventions may be more acceptable and convenient to patients. There is some evidence to suggest that patients, particularly those who work, prefer a home-based intervention to attending a hospital clinic (Grace, McDonald, Fishman, & Caruso, 2005). Secondly, delivering interventions in the patients' home environment may help to encourage family involvement in disease management. Thirdly, home based interventions may be more effective at accessing populations where attendance at hospital-based care is poor, or even those populations who have defaulted from care. Finally, on a related point, home-based intervention may be especially appropriate for particularly vulnerable populations, for example, the elderly, ethnic minorities, patients from socially deprived areas, or those having difficulties managing their illness. The increased cost associated with home-based interventions is perhaps the one disadvantage of the approach. For example, the economic evaluation of this RCT indicated that the intervention costs would be substantially decreased by delivering the intervention in the hospital-setting, which may also increase the number of participants to whom the intervention could be delivered. On balance, however, the long-term benefits of improving illness outcomes may outweigh any initial increased expenditure.

6.3.5 Measures

One of the strengths of the current study was the use of a combination of standardised biological outcomes (e.g. HbA1c, BMI, blood pressure) and validated, widely-used behavioural and psychological self-report questionnaires. Arguably, the self-report

measures (e.g. those measuring diabetes self-care and family support) may be subject to a certain amount of bias, and therefore, some form of additional behavioural assessment may have been appropriate, such as a pedometer to assess exercise activity, or observations of family interactions. However, such methods are very costly and/or very time-consuming, and in fact such observation may itself act as an intervention and actually alter the observed behaviour. For instance, observing family disputes may in itself alter the family dynamic by preventing such disputes. In addition, the self-report behavioural measures used in this study have been found to correlate with actual behaviour (Toobert et al., 2000). The SDSCA in particular has been widely applied in large scale RCTs to measure diabetes self-care behaviours. However, it does not measure medication adherence because earlier versions included a number of items in this regard, which were found to be redundant, as almost 100% of patients reported being compliant in taking their medication.

Some of the problems with using the Brief Illness Perceptions Questionnaire to measure beliefs about diabetes have already been highlighted. The alternative measure, the Illness Perception Questionnaire Revised (IPQ-R), provides a more comprehensive assessment of illness perceptions. However, the IPQ-R is a much longer measure containing over 80-items. Thus, its use was considered too impractical in the current study because the patient had only a limited amount of time with the researcher in the diabetes clinic. Furthermore, despite its limitations, the BRIEF-IPQ has been found to be as valid and reliable as the longer version of the questionnaire (Broadbent et al., 2006).

While the BRIEF-IPQ measures patients' own perceptions about their levels of understanding regarding diabetes, it does not measure knowledge of diabetes. The intervention may have been effective in improving outcomes simply because it provided patients with more information about their illness. However, the research team decided to consciously exclude an assessment of diabetes knowledge from the study, as the previous study by White et al. conducted in the same diabetes clinic (White et al., 2001-2004) showed that when diabetes knowledge was assessed, those in poor control of their diabetes scored as highly as those in good control. This indicates that poor glycaemic

control of type 2 diabetes is not merely due to a lack of information about the illness. Indeed, it is well-established in the literature that while knowledge about diabetes may be necessary, providing knowledge on its own (e.g. as in educational intervention) is often not sufficient to change behaviour or improve clinical outcomes (Newman et al., 2004; Norris et al., 2001). For example, systematic reviews of RCTs of educational interventions for type 2 diabetes (Loveman, Frampton, & Clegg, 2008; Wens et al., 2008) have reported that, at best, such interventions have inconsistent effects on diabetes outcomes The results from the present study found that patients' perceptions about their own understanding of diabetes did increase as a result of the intervention. This finding, coupled with the results from the White et al. study, suggests that it is not only the levels of knowledge patients have about their diabetes that is influencing their diabetes management. Rather, it is having an adequate and accurate knowledge of the condition, coupled with patients *own* belief that they have adequate and accurate knowledge to successfully manage their illness.

It has been recommended that any family-based intervention should include measures that assess the effects of the intervention on family members (Campbell, 2003). The current study, in line with this recommendation, incorporated an assessment of the illness perceptions of family members, and their own reports of supportive and non-supportive behaviour. However, it may also have been worthwhile, time permitting, to assess family members' own psychological well-being, or indeed, health outcomes. It is well-established that family members caring for those with a chronic or serious illness can often experience care-giver burden, which may have a negative impact on family members' own physical and mental health (Awad & Voruganti, 2008; Rombough, Howse, Bagg, & Bartfay, 2007; Van Der Voort, Goossens, & Van Der Bijl, 2007; Vitaliano et al., 2005). For example, patients in this trial reported a significant increase in family support for diabetes management, which is a positive outcome for patients. However, providing this additional support may potentially have increased carer burden and psychological distress in family members. Equally, however, the intervention may have had a positive effect on the overall well-being of family members, because as well as changing patients' illness perceptions, the intervention was also effective in changing

family members' negative and inaccurate beliefs about diabetes, whilst also improving in a positive direction, the degree of congruence between patients and family members. Dissimilarity in patient and family member illness perceptions has previously been found to be predictive of increased psychological distress in family members (Olsen et al., 2008; Richards et al., 2004). Thus, it is likely that by improving the degree of similarity between patient and family member perceptions, the intervention may have had corresponding positive effects on family members' well-being. Indeed, at six months follow-up, compared to the control group, family members in the intervention group reported statistically significant lower levels of diabetes-specific concern. In the focus groups, patients also report that their family members seemed to understand diabetes better and were less worried about the illness following their participation in the intervention.

6.3.6 Process Evaluation

Increasingly, RCTs of complex interventions include an evaluation of intervention processes as well as outcomes (e.g. *"How did the intervention work?" vs. "Did the intervention work?")*. A key element of such a process evaluation involves assessing treatment fidelity (i.e. was the intervention delivered and received as intended). The process evaluation component of this RCT was one of the key assets of the trial methodology. It involved the collection and analysis of both quantitative and qualitative data, which allowed for an assessment of treatment fidelity, and examination of how the intervention worked in practice. Overall, fidelity checks based on the available process evaluation data (e.g. analysis of structured field notes and focus groups) indicated that the intervention was delivered and received as intended: by implementing MI techniques to assist in changing patients' and family members' illness perceptions and behaviour. Additionally, results indicated that the intervention was acceptable to the participants who received it, with focus group participants reporting that the most beneficial elements of the intervention were the home visits and the inclusion of a family member, although participant diaries were not found to be valuable. Importantly, however, the process evaluation data also highlighted two key difficulties with implementing the intervention. Firstly, the process evaluation data highlighted the fact that the intervention was not

suitable for a significant number of participants (n=24) who did not receive the intervention sessions, as well as highlighting the corresponding reasons for this. Secondly, the results emphasised the very substantial number of missed and/or cancelled appointments, and highlighted the very practical difficulties involved in delivering such a home-based intervention to this at risk-group of patients.

There were some limitations to the process evaluation methodologies. Firstly, participants report that the most beneficial aspects of the intervention were the inclusion of their family member and the home visits. However, it must be noted that it is unlikely that participants would be able to identify or recognise the other theoretical elements of the intervention which were shown to be effective (e.g. changing illness perceptions). Secondly, while all participants who received the intervention (n=36) were invited to attend the focus groups, only 11 did so. Thus, the focus group conclusions regarding treatment fidelity and intervention acceptability may not be reflective of the views of those intervention participants (n=25) who were not present at the focus groups. It is possible that the participants who attended the focus groups were those who found the intervention most beneficial, and wished to express their satisfaction with the study. Equally, it could be argued that if there were participants who were particularly unsatisfied or unhappy about any aspect of the study, they could have taken the focus groups as an opportunity to express these concerns. However, such concerns did not emerge in any focus groups. In addition, some of the difficulties with conducting the focus groups (e.g. such as the large amount of 'off-topic' discussions and the problems participants had with separating aspects of the RCT from conventional diabetes management) may indicate that other qualitative methodologies could have a role to play when assessing treatment fidelity in RCTs (e.g. semi-structured one-on-one interviews).

A third, and perhaps more significant, limitation of the process evaluation approach, relates to the very low return rate of completed participant diaries. While 15/36 diaries were returned (41%), only five were fully completed (13%) and five were partially completed. These small numbers precluded any examination or analysis of the diary data. This was disappointing, although perhaps not surprising. Compliance in diary research is

known to be particularly low (Bolger, Davis, & Rafaeli, 2003; Piasecki, Hufford, Solhan, & Trull, 2007), with situational constraints, lapses in motivation and simple forgetfulness all contributing to the problem. These difficulties were anticipated when designing the intervention, and a system was set up to send text message prompts to participants' mobile phones each week, to remind them to fill in their diaries. Unfortunately, due to technological difficulties, many participants reported not receiving these text messages. It is possible that successful text reminders may have improved the diary completion rates. However, research suggests that while with such prompting or 'signalling' somewhat improves completion rates in diary studies, overall completion rates remain unsatisfactory (Broderick, Schwartz, Shiffman, Hufford, & Stone, 2003). In addition, the repeated queries and responses involved in completing diaries can place substantial demands and burdens on participants, which may impact on their motivation and commitment to fill in the diary (Bolger et al., 2003). In an attempt to address this issue of participant burden, the diaries in this RCT were designed to be short and take only several minutes to complete, and participants were asked to make only 16 diary entries in total over the six-month trial period. However, results from the focus groups indicated that participants still found the diaries boring and repetitive, and therefore, had difficulties filling them in. Furthermore, it is possible that a proportion of the participants may have had literacy difficulties, perhaps accounting for some of the non-completed or non-returned diaries.

Given that the diaries were an unsuccessful element of the process evaluation, future studies may wish to examine alternative ways of reminding and encouraging participants to complete research diaries. For example: by using different or more engaging questions in the diary; by telephoning participants to remind them to complete the diary; or by using electronic or web-based diaries. However, these alternative methods are not without their own limitations, as they may be more costly and time-consuming than paper and pencil diaries, and indeed such methods may not suitable for all participants, for example, those with low computer literacy or problems with manual dexterity. The possibility of using electronic diaries in this trial was investigated. However, the affordable electronic diaries were found to be undesirable for a number of reasons. The font size was small and could not be increased, and the visual contrast was poor, which may have been a limiting

factor for those with sight difficulties. The battery power was not sufficient for the duration of the trial, and questions could only be presented one at a time, thereby increasing the total time needed to complete the diary and possibly increasing participant burden. Thus, the challenge for future RCTs is to weight up any benefits associated with a high proportion of completed diaries, with the increased costs and time associated with the methods necessary to achieve that high level of completion.

The fourth, and final, limitation of the process evaluation approach used in this RCT relates to the low return rate of participant evaluation questionnaires. Only one participant in the intervention group, four in the control group, and three family members in the intervention group returned the questionnaires. Thus, these very small numbers again meant that no conclusions could be drawn from the evaluation questionnaires. The low return rate of evaluation questionnaires may be indicative of the fact that there were few participants who were unsatisfied or unhappy with the research, as they did not take the opportunity provided to express these concerns. However, participants' reasons for not returning the questionnaires may also be similar to the hypothesised reasons underlying the low diary response rate: participants simply forgot (or did not have time) to complete and post back the questionnaires, or they found completing the questionnaires burdensome, and were therefore not motivated to do so. Equally, literacy difficulties again may have accounted for some proportion of the low response rate. Whatever the underlying reason, the low response rate again suggests that there may be other more appropriate methodologies by which participants can evaluate their experience of the RCT (e.g. semi-structured one-on-one interviews).

6.3.7 RCT methodology

One of the difficulties in designing an RCT is determining how many arms are required to accurately establish the effect of the intervention. The trial reported here had two arms; usual care vs. intervention. Arguably, however, a third, or even fourth arm, could have been included, such as, (1) usual care control group vs. (2) family intervention group vs. (3) one-on-one intervention group (intervention minus family member) vs. (4) attention control group. The effects of the trial on glycaemic control and psychological well-being

could simply be due to the increased contact with a healthcare professional, rather than any of the hypothesised active ingredients of the intervention. An additional attention-control arm could also have been included in the trial, where patients and family members still received two 45-minute home visits, but participated in some attention diverting task, rather than receiving the actual intervention. On a related point, it could also be argued that the effect of the intervention may also be connected to some aspect or characteristic of the interventionist, as only one interventionist delivered all sessions. Thus, it is possible that another interventionist may have achieved different results, although, the only way to examine this supposition would have been to have had two (or more) people delivering the intervention, and compared outcomes by interventionist. This possibility was investigated when designing the trial; however, there were not the resources in place to allow for a second interventionist. Interestingly, while the focus group findings with patients indicated that the interventionist was key to the success of the intervention, patients did not mention any individual personal characteristics as being beneficial. Rather, they spoke of characteristics that were in fact motivational interviewing techniques, that any interventionist, psychologist, or healthcare professional trained in motivational interviewing would use (e.g. developing rapport, reflective listening, improving self-efficacy)

In addition, it is difficult to establish the extent to which the inclusion of a family member had an effect on the trial outcomes, although, results from the process evaluation do indicate that it was a key active ingredient of this intervention. There may have been scope to include an additional arm of the trial, involving delivery of the intervention to patients only. This may have been useful in view of those patients who had to be excluded at recruitment because they had no available family member, as well as those patients who withdrew from the intervention because their family member was unwilling to participate. However, it may also be necessary in RCTs with such a 'one-on-one' intervention arm, to control for the availability of family members, for example, by including two such one-on-one intervention groups: one group where patients do not have a family member available; and a second group where patients do have an available family member, but are randomised to receive the intervention alone. However, it

remains difficult to establish the precise effect on an intervention of including a family member. Our Cochrane review of family interventions for type 2 diabetes (Keogh et al., 2007) identified only one RCT (Gilliland et al., 2002)which had three arms comparing usual care, with a family intervention, with the same intervention delivered on a one-to-one basis. Two other studies compared a family versus one-to-one intervention (Pearce et al., 2008; Wing et al., 1991), whilst a further two studies, that by Brown & Hanis (1995) and the current RCT, compared usual care with a family intervention. Although this it still under peer review, results from the meta-analysis suggest that interventions which include a family member, may be more effective at improving glycaemic control than the corresponding intervention delivered to participants alone.

In theory, the inclusion of additional arms in an RCT is intuitively appealing. However, in practice it increases the complexity of running and analysing the trial; for example, a greatly increased sample size is necessary in order for the trial to have adequate power to detect differences between three or more groups. Many of the arguments for including additional arms in an RCT centre around the need to identify the active components of an intervention, which can be difficult in complex interventions such as the one described here. In practice it would be difficult, as well as extremely costly, to have a separate arm comparing every hypothesised component of a complex intervention. This highlights again the importance of having a robust theoretical framework, coupled with appropriate process and outcome measures, underlying complex interventions. It is these elements that illustrate the pathways through which the intervention is effective, or indeed not effective. The role of qualitative research is also of central importance in this regard. A key strength of the current trial was the inclusion of a qualitative sub-study that was implemented in parallel. For example, it could be argued that an additional one-to-one intervention arm may have been necessary to elucidate the effect of including a family member. Importantly however, an examination of the themes emerging from the focus groups with intervention participants indicated that along with the home environment, including a family member was perhaps *the* crucial active ingredient of the intervention.

6.3.8 Summary

The main strengths and weaknesses of this study are summarised in Table 6.1.

Table 6.1

Key strengths and limitations of the study

Area of study	Strengths	Limitations
Recruitment	• Occurred prior to randomisation: reduced the risk of recruitment bias and patient refusal due to group preference.	• High levels of DNA rates at clinic; possible that the most poorly controlled patients weren't recruited
Data collection	• Interview administered: 100% completion at baseline.	• Family member questionnaires were postal questionnaire: relatively low response rate
Measures	• Objective biological outcomes • Standardised and validated psychological and behavioural questionnaires	• Not measured: o Family member well-being and health outcomes o Problem-focused and emotion focused coping o Health-related quality of life, therefore, no assessment of QALY's
Process evaluation & qualitative components	• The assessment of treatment fidelity. • The examination of participants experience • The explanation of the outcome assessment • The identification of the active ingredients of the intervention	• Low response rate of diaries and evaluation questionnaires. • No audio-taping of intervention sessions
Intervention	• RCT design • Theory-based intervention developed using MRC Guidelines • Delivered using MI techniques • Delivered in the home with family members • Relatively brief and low cost • Improved glycaemic control & psychological well-being	• Number of withdrawals: not suitable for all patients • High level of cancelled/missed appointments

The six-month duration of the follow-up period is perhaps one of the key drawbacks of the trial. Six months is a sufficient amount of time within which to demonstrate clinically significant changes in glycaemic control. Ideally, however, the current study would have included a longer follow-up period with additional HbA1c assessments (e.g. at 12 months plus) in order to demonstrate if these changes are maintained. It is planned to follow-up participants in the longer-term, however, these results were not available for inclusion in the present thesis. The other main limitations of the study relate to the general difficulties associated with conducting community-based research with high risk, vulnerable populations. That is, problems with non-attendance at recruitment clinics and follow-up assessment; the low response rates of self-administered study measures, which in this trial these included family member questionnaires, research diaries, and evaluation questionnaires; and finally, the high levels of withdrawals or non-attendance at intervention sessions. Many of the above issues were anticipated when designing the trial, and attempts were made to minimise their effects, for instance, by scheduling all appointments at the patients' convenience. However, these persistent difficulties mean that some of the study results must be interpreted with caution, for example, due to the relatively low response rate for family member questionnaires or the proportion of participants who did not receive the intervention.

There are, however, also a number of key strengths of the study. The first is the RCT design, as this methodology allowed the effects of the intervention to be experimentally tested. The second strong point of the study relates to the fact that the intervention under investigation was: based on a robust theoretical framework (Leventhal's Self-Regulatory Model); designed according to the MRC guidelines for developing complex interventions; and delivered using a set of standardised therapeutic techniques (MI); all of which facilitates the replication of the intervention. A third strength of the study was the inclusion of a process evaluation component, in particular the addition of the qualitative methodologies, which allowed for an assessment of treatment fidelity and enriched the interpretation of the quantitative findings. Fourthly, the current intervention included a number of elements that have been somewhat overlooked in previous research. For example, no other psychosocial or home-based interventions for patients with poorly

controlled type 2 diabetes were identified in the literature search, and only very few (n=4) family-based interventions were identified. Finally, the intervention presented here was found to be effective in improving glycaemic control in those with poorly controlled type 2 diabetes, and was relatively brief (80-90mins average duration) and cost-effective (1% decrease in HbA1c cost €548.47 for all participants, and €182.90 for those with HbA1c > 9.5%).

6.4 PROTOCOL DEVIATIONS

A protocol for this RCT was published prior to the commencement of the trial (Keogh et al., 2007, see Appendix X). There were a small number of deviations from this protocol, which are described briefly below.

1. As part of the process evaluation it was planned that intervention sessions with 10% of participants (n=6) would be randomly selected to be audio-taped. These sessions would then be assessed for treatment fidelity by an independent expert. However, no sessions were audio-taped, after the first six selected participants did not give consent to the audio-taping, due to concerns regarding privacy. Given these concerns, the research team decided not to attempt to record any further sessions.

2. A web-based computer system was set up to send participants text message reminders to fill in their research diaries each week. However, due to technological difficulties with the system, many participants did not receive these reminders.

3. It was initially intended to compare the degree of similarity between patient and family member illness perceptions using the positive/negative classification system proposed by Figueiras and Weinman (Figueiras & Weinman, 2003). However, this was not possible, due to the small number of family questionnaires returned at follow-up.

4. Finally, the significant interaction between baseline levels of HbA1c and group allocation was an unexpected finding. It was not planned in the protocol to analyse the effects of the intervention in different 'blocks' or subgroups of participants, based on their baseline levels of HbA1c. However, it was planned to assess the data for the assumptions underlying the use of multiple regression models, and this assessment indicated that the assumption of 'homogeneity of regression' had been violated. Consultation with a biostatistician indicated that the appropriate way to proceed with the analysis was to 'block' participants according to their baseline levels of HbA1c, and investigate differences in the intervention effect in these blocks. Thus, this method of analysis was implemented in the trial, although it was initially unplanned.

6.5 CONCLUSIONS AND RECOMMENDATIONS

The trial reported here examined the effects of a complex psycho-social-behavioural intervention for patients with poorly controlled type 2 diabetes. The intervention had multiple interacting components. These included: the impact of patients' perceptions of their diabetes on self-management behaviours and physical and psychological outcomes; the influence of the family member on this process, including family members' own illness perceptions and interactions with the patient; the effects of the home environment; and the use of motivational interviewing techniques. While it may be difficult to separately assess the impact of all these elements, in essence, what the results from the trial indicate is that changing patients' inaccurate and negative beliefs about their diabetes improves self-management, psychological well-being and glycaemic control. This particularly seems to be the case in those with the poorest glycaemic control. The inclusion of family members in this process appears to greatly contribute to the improvements seen in psychological behavioural and biological outcomes. This was achieved by targeting the illness perceptions of both patients and family members, whilst also mobilising family support for diabetes self-management in the home environment. Table 6.2 summarises the key active ingredients of the intervention, and indicates what aspect of the study provided the evidence for their effectiveness.

Table 6.2

Key active ingredients of the intervention and evidence for their effectiveness

Active ingredient	Evidence for effectiveness
1. Changing the cognitions/perceptions of patients	• Improvements in BRIEF-IPQ scores at follow-u • Results from focus groups and field notes
2. Changing the cognitions/perceptions of family members	• Improvements in BRIEF-IPQ scores at follow-u
3. Improving the degree of similarity between patient and family member perceptions	• Improvement patient and family member BRIEF IPQ scores at follow-up
4. Changing self-management behaviours (e.g. diet, exercise etc)	• Improvements in glycaemic control • Improvement in SDSCA scores at follow-up: die and exercise scales • Results from focus groups and field notes
5. Improving family-support for diabetes management	• Improvements in glycaemic control • Improvements in DFBC scores at follow-up • Improvement in SDSCA scores at follow-up: die and exercise scales • Results from focus groups and field notes
6. Employing motivational interviewing techniques to change behavioural determinants (perceptions) and behaviours	• Improvements in glycaemic control, illness perceptions, diet and exercise, and family suppo • Results from focus groups and field notes
7. Delivering the intervention in the home environment	• Results from focus groups and field notes

Based on these results, there follow a number of key recommendations for clinical practice and future research.

6.5.1 Clinical practice

- Healthcare professionals working with those with poorly controlled type 2 diabetes may find it worthwhile to ask patients about their own individual and idiosyncratic beliefs regarding diabetes. For example, by asking patients *"What do you think caused your diabetes?"* or *"What do you think you can do to control your diabetes?"* Where possible, healthcare professionals may wish to work with patients on changing these patients' negative and/or inaccurate perceptions. This may be achieved, for example, by using MI techniques to provide more accurate information, or by examining with patients' how their beliefs are influencing their self-management behaviours. Changing patients' inaccurate and/or negative perceptions about their diabetes can help improve adherence to diet and exercise recommendations, psychological well-being, and glycaemic control.

- Patients with type 2 diabetes often experience high levels of psychological distress and anxiety, which appears to be particularly related to concern about their illness. Relieving this distress, and improving psychological well-being, should be a key aim of diabetes treatment, even in the absence of improvements in glycaemic control. However, improvements in glycaemic control may well occur as a result of improving psychological well-being.

- The family and home environment is of critical importance for successful diabetes management. Attempts to incorporate these aspects into the treatment of poorly controlled type 2 diabetes, for example, by inviting family members to participate in consultations or diabetes education, or making house calls to patients' homes, may help to mobilise family support for diabetes management. This, in turn, can help to improve glycaemic control and reduce psychological distress.

- The psychologist is a key member of the multidisciplinary diabetes team, and has a central role to play in diabetes treatment. Support from a psychologist may be especially beneficial for those who are having difficulties managing their diabetes, who are extremely emotionally distressed by the illness, and/or who are experiencing

difficulties in their family and social relationships as a result of their diabetes. Health psychologists are ideally placed to provide such psychological support to patients and their families, as well as to assist the multidisciplinary team in achieving other treatment goals (e.g. improving glycaemic control). However, to date, there are very few health psychologists in Ireland working within this capacity.

6.5.2 Future Research

Throughout this chapter, recommendations were made highlighting a number of possible avenues for future research. These are briefly summarised below.

Firstly, with regards to illness perceptions, it would appear that Leventhal's Self-Regulatory model provides an excellent theoretical framework for intervention in chronic disease. However, it has been suggested that future studies consider dividing perceptions of consequences into perceptions regarding 'perceived threat' and 'impact on life', and measuring these two constructs separately. Such interventions may wish to include a formal assessment of problem-focused and emotion-focused coping, using the available validated questionnaires. It may also be beneficial for future studies to explicitly test the causal pathways proposed by Leventhal's model, by employing a formal mediational analyses. The possible direct relationship between illness perceptions and physiology might also represent an interesting avenue for future research.

With regards to psychosocial, behavioural and family-based interventions for people with type 2 diabetes, it has been suggested here that self-efficacy-based interventions might benefit from also targeting personal control; it may be necessary to achieve improvements in both constructs in order to improve disease self-management. In addition, diabetes treatment often involves the combined management of three biological outcomes: that is, blood glucose control, blood pressure control and weight control. Future psychosocial and behavioural interventions could consider explicitly focusing on all three and how they interact, as to date, there has been little research in this area. Future family-based interventions for patients with type 2 diabetes may also benefit from including three study arms: that is (1) usual care vs. (2) family intervention vs. (3) one-

on-one intervention. Such a study design could possibly allow for a more accurate assessment of the benefits of including family members in interventions. Moreover, it may be worthwhile, if possible, for such interventions to assess any benefits to family members by, for example, assessing family members' own psychological well-being or health outcomes. Differences in the effects of such interventions in males and females, and older and younger patients, may also represent an interesting avenue for future studies.

In addition, in order for health psychology to continue to advance as a discipline, it is essential to have a range of evidence-based interventions from which to draw upon. Thus, future psychosocial and behavioural interventions in health psychology should be theory-based, developed in accordance with the MRC Guidelines for complex interventions (or other appropriate frameworks), tested for effectiveness using high quality RCTs where possible, and reported according to the CONSORT guidelines. Qualitative methods have a central role to play in this process. Results from the current study suggest that qualitative methods are particularly valuable in RCTs, both from a process evaluation point of view, and also in elucidating patients' own experiences of participating in the trial. However, more work remains to be done in examining which methodologies are most appropriate for assessing which aspects of trials. For example, semi-structured interviews may be a more appropriate method for eliciting participants' evaluation of the trial, or for assessing treatment fidelity, rather than written questionnaires or focus groups.

On a final note, this study has highlighted the fact that community-based research, and indeed clinical work, with vulnerable and high-risk populations is especially difficult. In particular, the high level of non-attendance at recruitment clinics, intervention sessions, and follow-up appointments, poses exceptional difficulties for the implementation and evaluation of trials. These high levels of non-attendance pose similar problems for healthcare professionals working in community settings. There is likely no simple solution to these problems. Rather, these difficulties need to be factored as accurately as possible into the timetabling and running costs of trials, and also of services offered by

healthcare providers. Although initially more costly and time-consuming, persistence and flexibility, through repeated attempts at contact and working around patients unique situations, may be the solution to successfully accessing these vulnerable populations, in both research and clinical settings. In the long-term, this may hold the key to improving illness outcomes, and thereby reducing costs, and perhaps most importantly, it may improve the general well-being of these vulnerable patients and their families.

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APPENDICES

APPENDIX A – LITERATURE REVIEW SEARCH STRATEGY

Search Strategy:
Database: Ovid MEDLINE(R) In-Process , Other Non-Indexed Citations , Ovid MEDLINE(R)
Title: Family-based interventions to improve outcomes in patients with type 2 diabetes mellitus.
Author: Keogh K
Date: 2006-05-29 updated 2009-01-10

1 exp Behavior Therapy/
2 exp Problem Solving/
3 exp Family Therapy/
4 exp Counseling/
5 exp Health Behavior/
6 exp Patient Education/
7 exp Self care/
8 exp Patient Compliance/
9 exp Psychotherapy/ed, tu [Education, Therapeutic Use]
10 exp Caregivers/
11 exp spouded/
12 (family adj6 (therap$ or treatment$ or intervention$)).tw.
13 health education$.tw.
14 (group-based or family based).tw.
15 behavio?r therap$.tw.
16 (health behavio?r adj3 change$).tw.
17 (caregiv$ adj6 spous$).tw.
18 self care.tw.
19 home based intervention$.tw.
20 (problem solving or problemsolving).tw.
21 (interpersonal adj6 (therap$ or treatment$ or intervention$)).tw.
22 motivational interview$.tw.
23 BFST.tw.
24 systematic therap$.tw.
25 lifestyle intervention$.tw.
26 or/1-25
27 exp diabetes mellitus, type 2/
28 exp obesity in diabetes/
29 exp insulin resistance/
30 impaired glucose toleranc$.tw.
31 glucose intoleranc$.tw.
32 insulin$ resistanc$.tw.
33 (obes$ adj diabet$).tw.
34 (MODY or NIDDM).tw.
35 (non insulin$ depend$ or noninsulin$ depend$ or noninsulin?depend$ or non insulin?depend$).tw.

36 ((typ$ 2 or typ$ II) adj diabet$).tw.
37 ((keto?resist$ or non?keto$) adj diabet$).tw.
38 ((adult$ or matur$ or late or slow or stabl$) adj diabet$).tw.
39 (insulin$ defic$ adj relativ$).tw.
40 pluri?metabolic$ syndrom$.tw.
41 or/27-40
42 exp diabetes insipidus/
43 diabet$ insipidus.tw.
44 42 or 43
45 41 not 44
46 randomized controlled trial.pt.
47 controlled clinical trial.pt.
48 randomized controlled trials.sh.
49 random allocation.sh.
50 double-blind method.sh.
51 single-blind method.sh.
52 or/46-51
53 limit 52 to animal
54 limit 52 to human [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed
Citations; records were retained]
55 53 not 54
56 52 not 55
57 clinical trial.pt.
58 exp clinical trials/
59 (clinic$ adj25 trial$).tw.
60 ((singl$ or doubl$ or trebl$ or tripl$) adj (mask$ or blind$)).tw.
61 placebos.sh.
62 placebo$.tw.
63 random$.tw.
64 research design.sh.
65 (latin adj square).tw.
66 or/57-65
67 limit 66 to animal
68 limit 66 to human [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed
Citations; records were retained]
69 67 not 68
70 66 not 69
71 comparative study.sh.
72 exp evaluation studies/
73 follow-up studies.sh.
74 prospective studies.sh.
75 (control$ or prospectiv$ or volunteer$).tw.
76 cross-over studies.sh.
77 or/71-76

78 limit 77 to animal
79 limit 77 to human [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed
Citations; records were retained]
80 78 not 79
81 77 not 80
82 56 or 70 or 81
83 26 and 45 and 82
84 limit 83 to "all adult (19 plus years)"

APPENDIX B – CONSORT GUIDELINES CHECKLIST

PAPER SECTION	Item	Descriptor	Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	Scientific background and explanation of rationale.	6-68
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	90
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	86-89
Objectives	5	Specific objectives and hypotheses.	1-3
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	94-99
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	94
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)	106
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	106
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	106
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	n/a
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	114
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	124
Recruitment	14	Dates defining the periods of recruitment and follow-up.	105
Baseline data	15	Baseline demographic and clinical characteristics of each group.	125-129
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	138
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	138-148
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	114
Adverse events	19	All important adverse events or side effects in each intervention group.	n/a
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	224-244
Generalizability	21	Generalizability (external validity) of the trial findings.	224-244
Overall evidence	22	General interpretation of the results in the context of current evidence.	199-222

www.consort-statement.org

"CHANGING ILLNESS PERCEPTIONS IN POORLY CONTROLLED TYPE 2 DIABETES"

A PSYCHOLOGICAL, FAMILY-BASED INTERVENTION

INTERVENTION MANUAL

OUTLINE OF SESSIONS

Session One: Includes person with type 2 diabetes and his/her family member. Delivered in the participant's home.

Opening

Use MI strategies re: opening

- **Illness coherence**

Identify levels of understanding from BRIEF-IPQ
Explanations of pathophysiology and terminology

- **Identity**

Identify how often experience symptoms from BRIEF-IPQ
Explain/discuss symptoms of poorly controlled diabetes

- **Casual beliefs**

Identify causal beliefs from IPQ
Challenge misconceptions and broaden causal beliefs

- **Emotional representations**
- Identify how much diabetes affects emotions

Use MI Strategies re: exchanging information

Session Two: Includes person with type 2 diabetes and his/her family member. Delivered in the participant's home.

- **Consequences**

Identify consequences from BRIEF-IPQ
Challenge misconceptions and link with current behaviour

- **Timeline**

Identify acute/chronic and cyclical/stable illness perceptions
Link with consequences and challenge myths/misconceptions

- **Control**

Identify personal and treatment control beliefs from BRIEF-IPQ
Use control beliefs to develop personal plan by identifying areas of diabetes management that *can* be controlled and that need improvement
Use MI Strategies re: exchanging information

⇓

- Develop **Written Personalised Action Plan**; improving control and minimise complications through agreed goals

Use MI strategies: Negotiating a change plan

Session Three: Phone call with person with type 2 diabetes only.

Review action plan and discuss potential barriers to proposed changes. Amend plan as necessary .Discuss any further concerns

Use motivational interviewing strategies discussed previously, through-out the session where appropriate.

MOTIVATIONAL INTERVIEWING GENERAL PRINCIPLES

Through out the sessions it may be helpful to keep in mind the four general principles of motivational interviewing;

1. Expressing empathy
2. Rolling with resistance
3. Developing discrepancy
4. Building self-efficacy.

These principles, and their corresponding techniques, have not be given a fixed point for being conducted in sessions, rather they may be useful with different participants at different times, as the interventionist feels it is appropriate.

SESSION ONE

OPENING

Use MI strategy re: Opening Structure

It can be useful from the outset to provide participants with a simple and brief structuring statement. This can help participants feel relaxed and comfortable with the session, and allay any fears or concerns. Some elements to incorporate into an opening statement include;

- The amount of time and number of sessions
- An explanation of the interventionists goals and role
- A description of the clients role in the sessions
- Any details that must be attended to
- Finish with an open ended question

EXAMPLE OPENING STATEMENT TO PERSON WITH DIABETES;

> *"We have about 45 minutes together now, and another session of 45 minutes next week and I'll also be contacting you twice by telephone. I'll spend most of the time listening so I can get a better understanding of how you see your diabetes management, and your issues and concerns. You'll probably have some hopes about what will and won't happen here, and I'd like to here about those. I'll probably ask you some more specific information towards the end of the session, but for now why don't you start by telling me what's on your mind?"*

OPENING STATEMENT TO FAMILY MEMBER

It is important from the start to be clear about the role of the family member. The focus of the session is on the person with diabetes. The significant other will be included as a *participant* in session, the goal is not to target couple interactions or conduct motivational interviewing with the family member. Thus, the family members role will be in sharing information collaborate in the planning and development of goals and how to achieve them, and in general, to help promote the client's commitment to change. Participation of the family member may also be useful in revealing "hidden" information, and enhance the truthfulness of the clients talk. An example of an opening statement to a family member might be;

> *"It's great that you're able to be here with us. I hope that you will feel comfortable in playing an active role in the session, and discuss your own*

concerns about your family member's diabetes, and your own hopes about what will happen here."

MOTIVATIONAL INTERVIEWING STRATEGY: EXCHANGING INFORMATION

For the remainder of session one, and part of session two, the predominant MI strategy used will be related to the exchange of information. There are a number of steps relating to the exchange of information using motivation interviewing techniques:

1. Elicit from the participant what s/he already knows; e.g.
   "Could you tell me what you know about your illness?"
   "What is your own understanding of Type 2 diabetes?"

2. Find out what else the participant would like to know? e.g.
   "Is there anything else about your illness you would like to know more about?"
   "Is there any aspects of your illness you feel a bit unsure about?"

3. Ask permission to give information e.g.
   "I have some information you might find useful, if you would like to hear it?"
   "I could give you some more information on that if you would like me to?"

4. Provide the facts neutrally e.g.
   "There are some scientific studies that show...what do you make of that?"
   "It's a medical fact that...but what is important to me what you think about this?"

5. Elicit from the participant how they might apply the facts to their own situation
   "How might that apply to you?"
   "Would any of that be relevant to you and your situation?"

6. Include the family member – may help uncover "hidden" information and develop discrepancy
   "What is your understanding of your family member's diabetes?
   "Are there aspects of your family member's diabetes that you are unsure about or would like to know more about?"
   "What are some of your concerns about your family members' diabetes?"
   "How do you see the situation?"

This strategy can be adapted and applied to following discussions of illness perceptions on in session one, and consequences, timeline and control beliefs in session two.

ILLNESS COHERENCE

Use MI strategy re: exchanging information

Participants' levels of understanding of their type 2 diabetes will be identified from the question on the BRIEF-IPQ *"How well do you feel you understand your type 2 diabetes?"* Answers to the question are scored on a scale from 0 (don't understand at all) to 10 (understand very clearly). An explanation of the pathophysiology and terminology

of type 2 diabetes will be individually tailored to each participant, based on their score, e.g. a score of 0 would require a more in-depth discussion than a score of 10. The exact content of the discussion will vary by individual, but may include a discussion on:

- **What is diabetes?** (using diagrams to provide a concrete image of the illness)
- **Continuum of diabetes and Treatment** (Brief explanation of differing types of treatment for type 2 diabetes and its progressive nature)
- **Controlling/self-managing diabetes**
    - **Lifestyle Factors**
        - **Diet & Exercise**
    - **Medication**
        - **OHAs & Insulin in Type 2 diabetes**
    - **Blood glucose monitoring**

IDENTITY

Use MI strategy re: exchanging information

How often participants experience symptoms of their type 2 diabetes will be identified from the question on the BRIEF-IPQ *"How much do you experience symptoms from your type 2 diabetes?"* Answers to the question are scored on a scale from 0 (no symptoms at all) to 10 (many severe symptoms). A discussion of the symptoms of poorly controlled diabetes will be based on each individuals score, and how these symptoms can be reduced by improved metabolic control. Symptoms of poorly controlled diabetes that may be discussed include; **Hypoglycaemia and hyperglycaemia**

CAUSAL BELIEFS

Use MI strategy re: exchanging information

The causes people attribute to their diabetes will be identified from the last question on the BRIEF-IPQ, which asks people to *"Please list in rank order the three most important factors that you believe caused your illness. The most important causes for me:-"* The discussion will be focused on the answers participants give to this question, and depending on these answers may challenge any misconceptions (e.g. participant believes only cause is hereditary so there is no point in doing anything, or diabetes is caused by eating too much sugar). Where relevant, the discussion will try and broaden the participants' causal model to include the importance of lifestyle factors (e.g. diet and exercise), which could be used as a source of behaviour change.

EMOTIONAL REPRESENTATIONS

The question on the BRIEF-IPQ *"How much does your illness affect you emotionally? E.g. does it make you angry, scared, upset or depressed?"* will be used to assess how much type 2 diabetes affects participants' emotions. This question is scored on a scale of 0 (not at all affected emotionally) to 10 (extremely affected emotionally). The discussion regarding emotions will not focus on changing these emotions per se, but rather the main

focus will be on how participants' feelings about their diabetes impact on their self-care behaviour and diabetes management. (e.g. someone is so angry about their illness they won't take their medication or someone feels that their diabetes is taking over their life and they can do nothing to control it).

THE ROLE OF THE FAMILY MEMBER IN ILLNESS PERCEPTIONS

During the discussion on the person with diabetes illness perceptions (session 1and 2), it may be useful to also refer back to the family members' scores on the BRIEF-IPQ, and bring in their perceptions of their family members diabetes. This includes the family member in the discussion, and may also be useful in highlighting areas of discrepancy between their perceptions of diabetes, and the person with diabetes own illness perceptions. For example, the family member may believe the person with diabetes is very knowledgeable about their illness, whereas the person with diabetes may feel they know very little. After area's of dissimilarity have been identified, the session may focus on improving the degree of congruence, in a positive direction, between patient and family members perceptions of diabetes.

SESSION TWO

CONSEQUENCES

Use MI Strategies re: exchanging information

Participants perceptions of the consequences of their type 2 diabetes will be identified from the question on the BRIEF-IPQ *"How much does your illness affect your life?"* This question is scored on a scale of 0 (no affect at all) to 10 (severely affects my life). A discussion on the consequences of type 2 diabetes on the participants' life will be based on individual participants' answers to the above question. In general, the discussion will focus on challenging any misconceptions participants have about the consequences of their illness, and linking these beliefs with current behaviour, e.g. how participants' beliefs about diabetes consequences impact on their daily adherence to self-care behaviours.

TIMELINE

Use MI strategies re: exchanging information

The BRIEF-IPQ assesses participants' timeline beliefs about their type 2 diabetes by asking the question *"How long do you think your illness will continue?"* This question is scored on a scale of 0 (a very short time) to 10 (forever). Acute/chronic and cyclical/stable illness perceptions will be identified through discussion with the participants. Again, any misconceptions will be challenge (e.g. diabetes comes and goes in cycles). The discussion will link the timeline aspects back to the discussion on consequences and the influence of current behaviour. (e.g. type 2 diabetes may "come and go" because at times diabetes symptoms may be better due to improved metabolic control).

CONTROL

Use MI strategies re: exchanging information

Personal control beliefs about type 2 diabetes will be identified from the BRIEF-IPQ from the question *"How much control do you feel you have over your illness"* This

question is scored on a scale from 0 (absolutely no control) to 10 (extreme amount of control). Beliefs about treatment control will be identified from the question on the BRIEF-IPQ *"How much do you think your treatment can help your illness?"* This question is also scored on a scale of 0 (not at all) to 10 (extremely helpful). Participants' beliefs about personal and treatment control will be discussed, and used to identify areas of diabetes self-management that participants can control, and areas that may need improvement (e.g. feel very confident about taking medication, but less so about exercising).

DEVELOPING PERSONALISED WRITTED ACTION PLAN

Use MI Strategies re: negotiating a change plan

Areas of diabetes self-management that need to be improved should arise from the discussion on control beliefs. Stemming from this will be the development of a written personalised action plan. This plan will be negotiated with participants' using a process of shared decision making and MI strategies. It involves a series of steps.

MOTIVATIONAL INTERVIEWING STRATEGY: NEGOTIATING A CHANGE PLAN

1. Setting goals

The first step in instigating change is to have clear goals to work towards. Ask the participants what these goals are (direct questions to both person with type 2 diabetes and their family member);

"What is it that you want to change?"

"Lets take things one step at time. What do you think is the first step?"

The participants' goals may not correspond to the interventionist's, it is far better to start with the goals that the client is eager to make progress towards. Let the participant chose what area they feel they can, and want to, start to work on. Letting the participant chose which area they feel they can work on and succeed at improves self-efficacy and a sense of personal control. There may also be multiple goal also with multiple and interrelated areas of concern. It may be necessary to prioritise which are most urgent or important.

2. Considering change options

The next step is to consider possible methods for achieving chosen goals.

Use MI strategies re: brain storming and "menu" options

BRAIN STORMING

Involve the person with diabetes and the family member directly in the process of brainstorming and evaluating possible change strategies. There are almost always multiple ways to achieve a behaviour change goal. It can be useful to use a creative brain-storming session, in which evaluation is temporarily blocked, to generate a range of options, even far-fetched ones. This can be a pooling of the person with type 2 diabetes ideas, the family members ideas, and the interventionists. This can help develop personal control and self-efficacy, as the participant can suggest ideas without being blocked by any shortcomings and the interventionist can suggest ideas with out meeting resistance.

"MENU" OPTIONS
It is also often useful to provide a "menu" of strategies, rather than one at a time. The participants' task then becomes one of choosing, rather than refuting.

3. Arriving at a plan
This discussion leads directly to negotiation of a change plan. Elicit this plan by having the participant voice it in person, by asking;

"So what is it specifically that you plan to do?"

"How will you go about it?"

At this stage introduce the *Change Plan Worksheet* (see Appendix 1 p.14) that the person with diabetes can fill out, this is their written personalised action plan. On the basis of this discussion, summarise the plan that has been developed, using "you" language. For example;

"Let me see if I can accurately summarise where you are then. What you want to do is work on controlling your diabetes better, through diet and exercise. You plan to go walking for at least 30minutes most days. And you and your family member have agreed to make healthy meals together, based on the guidelines for healthy eating that I've given you."

4. Eliciting commitment
The plan summary brings you to the point of commitment. The simplest way is to ask;

"Is this what you want to do?"

Getting a "yes" may require a few more steps, by exploring reluctance and ambivalence using previously discussed strategies for resolving ambivalence.
Making the change plan public can enhance commitment, this can be done by making the family member a "witness", and acknowledging that the commitment to change is made with the family member's consent and knowledge and support.

THE ROLE OF THE FAMILY MEMBER IN NEGOTIATING A CHANGE PLAN
The family member can be very actively included in the negotiating of the change plan. They can participate in the *setting of goals*, by indicating what goals they would like to see the person with diabetes work towards. The can contribute to the *considering change options* discussion by taking part in the brain-storming session and coming up with ideas that can help the person with diabetes achieve their goals, and contributing these to the *change plan*. They also act as a "witness" to the person with diabetes *commitment* to change. Most importantly, throughout this process the family member can contribute ways in which they themselves can support the person with diabetes in managing their illness and achieving better metabolic control.

SESSION 3

Outline – with person with type 2 diabetes only, over the phone

1. Review action plan and discuss potential barriers to proposed changes. Amend plan as necessary
2. Discuss any further concerns

3. Use motivational interviewing strategies discussed previously, through-out the session where appropriate.

MOTIVATIONAL INTERVIEWING TECHNIQUES

Millner and Rollinick (2002) write that *"...we have found ourselves placing less emphasis on techniques of motivational interviewing and ever greater emphasis on the fundamental spirit that underlies it"* (Millner & Rollnick, 2002, p. 33). Through the sessions it may be useful and appropriate to follow the four general principles of motivational interviewing; expressing empathy, developing discrepancy, rolling with resistance and supporting and building self-efficacy. These principles are not formally included at a set point during sessions, because as Millner and Rollick point out, they are more a "spirit" than formal techniques. They may be useful at various different time-points, with various participants, as the interventionist feels it is appropriate.

EXPRESSING EMPATHY

ROLLING WITH RESISTANCE

Resistance responses to change are normal. The key point is how the interventionist responds to resistance. In motivational interviewing the goal is to diminish resistance by "rolling" with it, and avoiding arguing for change. General methods for "rolling with resistance" include;

1. **Reflections** – respond to resistance with non-resistance
    - Simple reflections
    - Amplified reflections
    - Double-sided reflections
2. **Shifting focus** (shift attention away from problem area)
3. **Reframing** (recast participants information in a new light)
4. **Agreeing with a twist** (offer initial agreement with change of direction)
5. **Emphasising personal choice and control** (avoids "psychological resistance")

DEVELOPING DISCREPANCY AND ELICITNG CHANGE TALK

When the participants' perceived importance of change is low, the client's motivation to change and their perception of the importance of change may be enhanced by developing discrepancy. Discrepancy can be considered as an awareness of a difference between where one is and where one wants to be. It is discrepancy that underlies the perceived importance of change; without discrepancy there is no motivation, and the larger the perceived difference, the greater the importance of change.

The first step is to develop ambivalence by developing discrepancy between the actual present and the desired future. Change is facilitated by communicating in a way that elicits the person's own reasons for and advantages of change. The interventionist can evoke change talk using some of the following methods;

1. **Asking open-ended evocative questions e.g.**
    - *"What worries you about your current situation?"*
    - *"I can see you're feeling stuck at the moment. What's going to have to change?"*
2. **Using the importance ruler e.g.**

- *"How important would you say it is for you to manage your diabetes well? On a scale from 0 to 10, where 0 is not important at all and 10 is extremely important, where would you say you are?*

3. **Exploring the pro's and con's of change e.g.**
   - *"Why don't you tell me what you like about the way things are at the moment?"*
   - *"What are the advantages of your current situation?"*
4. **Querying extremes e.g.**
   - *"Suppose you continue on as you have been, without changing, What do you imagine are the worst things that could happen?"*
   - *"What might be the best results you could imagine if you make a change?"*
5. **Looking back or looking forward e.g.**
   - *Do you remember a time when you managed your diabetes well? What has changed?"*
   - *"How would you like things to turn out for you 10 years from now?"*

BUILDING PERSONAL CONTROL AND SELF-EFFICACY

Generally, people cannot be ready to change until they perceive both that they want to (importance, discussed above) and that they are able to (confidence/self-efficacy). When a participant wants to change (importance is high) but there confidence in doing so successfully is low, there are a number of motivation interviewing techniques that can be used to improve low-self efficacy;

1. **Scale questions** (about confidence for change) **e.g.**
   - *"How confident would you say you are that if you decided to improve the control of your diabetes, you could do it? On the same scale fro 0 to 10, where 0 is not at all confident, and 10 is extremely confident, where would you say you are?*
   - *"Why are you at____ not ____?"*
   - *"What would it take for you to go from ___ to____ (a higher number)?"*
2. **Reframing** (Discuss previous less successful attempts to change in a positive light).
   - *"What have you learned from previous attempts to control your diabetes, about what works, or doesn't work for you?"*
   - *"It sounds to me like you're an expert in what doesn't work for you"*
3. **Past successes**
   - *"When in your life have you made up your mind to do something, and did it?"*
   - *"What obstacles were there and how did you overcome them?"*
4. **Personal strengths and support**
   - *"What is there about you, what strong points do you have that would help you to succeed in controlling your diabetes better?"*
   - *"Is there anything you know of that has worked for other people*

Diabetes Family Study

Diabetes Family Study

The most important reasons why I want to make these changes are:

The steps I plan to take in changing are:

The ways my family member _____ can help me are:

I will know what my plan is working if:

Some things that could interfere with my plan are:

SIGNED:

APPENDIX D – SOCIODEMOGRAPHIC QUESTIONNAIRE

RCT No._____

For Office Use only

1. Sex (please tick appropriate box): Male Female

2. Age: _____

3. Duration of diabetes:_____

4. Medical card holder: Yes No

5. Name of family member taking part:_____ **Relationship** _____

6. Does your family member have diabetes (Type 1 or Type 2?) Yes No

7. Marital Status (please tick appropriate box):

1. Single
2. Steady relationship
3. Living with partner
4. Married
5. Separated
6. Divorced
7. Widowed
8. Other (please specify)_____

8. Highest level of education completed (please tick appropriate box):

1. Primary School
2. Junior Certificate (or equivalent e.g. GCSEs)
3. Leaving Certificate (or equivalent e.g. A Levels)
4. Third Level Non-Degree qualification (e.g. Cert, Diploma)
5. Third Level Degree or higher qualification

9. Employment (please tick appropriate box):

1. Work in the home
2. Part-time employment
3. Full time employment Please state occupation_____
4. Unemployed
5. Retired
6. Other (Please specify)_____

HbA1c_____ **Date**_____

BMI_____ **Date**_____

BP_____ **Date**_____

For Office Use only

Treatment: **Diet only**_____ Diet &Med_____ Insulin_____

Other: Retinopathy___ Neuropathy___ Nephropathy___ Hypertension___
Other_____

APPENDIX E – BRIEF ILLNESS PERCEPTIONS QUESTIONNAIRE

For the following questions, please circle the number that best corresponds to your views:

How much does your diabetes affect your life?										
0	1	2	3	4	5	6	7	8	9	10
no affect at all										severely affects my life
How long do you think your diabetes will continue?										
0	1	2	3	4	5	6	7	8	9	10
a very short tmie										forever
How much control do you feel you have over your diabetes?										
0	1	2	3	4	5	6	7	8	9	10
absolutely no control										extreme amount of control
How much do you think your treatment can help your diabetes?										
0	1	2	3	4	5	6	7	8	9	10
not at all										extremely helpful
How much do you experience symptoms from your diabetes?										
0	1	2	3	4	5	6	7	8	9	10
no symptoms at all										many severe symptoms
How concerned are you about your diabetes?										
0	1	2	3	4	5	6	7	8	9	10
not at all concerned									extremely concerned	
How well do you feel you understand your diabetes?										
0	1	2	3	4	5	6	7	8	9	10
don't understand at all										understand very clearly
How much does your diabetes affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)										
0	1	2	3	4	5	6	7	8	9	10
not at all										extremely
Please list in rank-order the three most important factors that you believe caused your diabetes. ***The most important causes for me:-***										
1. _____										
2. _____										
3. _____										

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APPENDIX F – WELL-BEING QUESTIONNAIRE 12-ITEM

Please circle one number on each scale, from 3 (all the time) to 0 (not at all), to indicate how often you feel each statement has applied to you in the past few weeks

	all the time			not at all
1. I have crying spells or feel like it.....	3	2	1	0
2. I feel downhearted and blue.....	3	2	1	0
3. I feel afraid for no reason at all.....	3	2	1	0
4. I get upset easily or feel panicky.....	3	2	1	0
5. I feel energetic, active or vigorous	3	2	1	0
6. I fell dull or sluggish.....	3	2	1	0
7. I feel tired, worn out, used up or exhausted.....	3	2	1	0
8. I have been waking up feeling fresh and rested.....	3	2	1	0
9. I have been happy, satisfied, or pleased..... with my personal life.	3	2	1	0
10. I have lived the kind of life I wanted to.....	3	2	1	0
11. I have felt eager to tackle my daily tasks or..... make new decisions.	3	2	1	0
12. I have felt I could easily handle or cope with any serious problem or major change in my life.....	3	2	1	0

Please make sure that you have considered each of the 12 statements and have circles one number in response to each statement.

APPENDIX G – DIABETES MANAGEMENT SELF-EFFICACY SCALE UK 15

By means of the following questionnaire we would like to get an idea about how you manage your diabetes. Take for example the statement:

"I am able to check my blood sugar if necessary"

If you think this is entirely true, place an X in the extreme left box like this:

0**X** 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

The more you disagree with the statement move the X in the direction of "Cannot do at all"

PLEASE PLACE AN "X" IN A BOX BELOW EACH STATMENT

1. I am able to check my blood sugar if necessary

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

2. I am able to correct my blood sugar when the sugar level is too high

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

3. I am able to correct my blood sugar when the sugar level is too low

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

4. I am able to choose the correct food

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

5. I am able to keep my weight under control

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

6. I am able to examine my feet for cuts

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

7. I am able to adjust my eating plan when ill

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

8. I am able to follow a healthy eating plan most of the time

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

9. I am able to take more exercise if the doctor advises me to

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

10. When taking more exercise I am able to adjust my eating plan

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

11. I am able to follow a healthy eating pattern when I am away from home

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

12. I am able to follow a healthy eating pattern when I am eating out or at a party

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

13. I am able to adjust my eating plan when I am feeling stressed or anxious

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

14. I am able to take my medication as prescribed

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

15. I am able to adjust my medication when I am ill

0 1 2 3 4 5 6 7 8 9 10

Certain can do — Maybe yes/ Maybe no — Cannot do at all

APPENDIX H – SUMMARY OF DIABETES SELF-CARE ACTIVITIES

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

How many of the last SEVEN DAYS have you followed a healthy eating plan?

0 1 2 3 4 5 6 7

On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat five or more servings of fruit and vegetables?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat high fat food such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7

Exercise

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

Blood Sugar Testing

On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

Foot Care

On how many of the last SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0 1 2 3 4 5 6 7

Smoking

Have you smoked a cigarette – even one puff - during the past SEVEN DAYS?
No / Yes. If *yes,* how many cigarettes did you smoke on average a day_____

APPENDIX I – DIABETES FAMILY BEHAVIOUR CHECKLIST

How often does your family member; (Please circle the appropriate answer)

1. Nag you about testing your blood

Never Seldom Sometimes Often Very often

2. Help you decide if changes should be made based on blood testing results

Never Seldom Sometimes Often Very often

3. Criticise you for not recording the results of blood tests

Never Seldom Sometimes Often Very often

4. Praise you for following your diet

Never Seldom Sometimes Often Very often

5. Nag you for about not following your diet

Never Seldom Sometimes Often Very often

6. Eat at the same time as you

Never Seldom Sometimes Often Very often

7. Eat foods that are not part of your diabetic diet

Never Seldom Sometimes Often Very often

8. Encourage you to participate in sports activities

Never Seldom Sometimes Often Very often

9. Criticise you for not exercising regularly

Never Seldom Sometimes Often Very often

10. Exercise with you

Never Seldom Sometimes Often Very often

11. Plan family activities so that they will fit in with your diabetes self-care schedule

Never Seldom Sometimes Often Very often

12. Argue with you about your diabetes self-care activities

Never Seldom Sometimes Often Very often

13. Congratulate you for sticking to your diabetes self-care schedule

Never Seldom Sometimes Often Very often

14. Suggest things that might help you take your medication on time

Never Seldom Sometimes Often Very often

15. Buy you things containing sugar to carry with you in case of an insulin reaction

Never Seldom Sometimes Often Very often

16. Let you sleep late rather than getting up to take your medication

Never Seldom Sometimes Often Very often

APPENDIX J– BRIEF ILLNESS PERCEPTION QUESTIONNAIRE (ADAPTED)

We are interested in your own personal views of how you see your family member's diabetes.For the following questions, please circle the number that best corresponds to your views:

How much does your family member's diabetes affect <u>YOUR</u> life?										
0 no affect at all	1	2	3	4	5	6	7	8	9 affects my life	10 severely
How much does your family member's diabetes affect <u>THEIR</u> life?										
0 no affect at all	1	2	3	4	5	6	7	8	9 affects their life	10 severely
How long do you think your family member's diabetes will continue?										
0 a very	1	2	3	4	5	6	7	8	9	10 forever
How much control do you feel <u>YOU</u> have over your family member's diabetes?										
0 absolutely no amount of control	1	2	3	4	5	6	7	8	9	10 extreme amount of control
How much control do you feel <u>YOUR FAMILY MEMBER</u> has over their diabetes?										
0 absolutely no amount of control	1	2	3	4	5	6	7	8	9	10 extreme amount of control
How much do you think treatment can help your family member's diabetes?										
0 not at all	1	2	3	4	5	6	7	8	9	10 all
How much does your family member experience symptoms from their diabetes?										
0 no symptoms at all	1	2	3	4	5	6	7	8	9	10 many severe symptoms
How concerned are <u>YOU</u> about your family member's diabetes?										
0 not at all concerned	1	2	3	4	5	6	7	8	9 extremely concerned	10
How concerned is <u>YOUR FAMILY MEMBER</u> about their diabetes?										
0 not at all concerned	1	2	3	4	5	6	7	8	9 extremely concerned	10

How well do you feel <u>YOU</u> understand your family member's diabetes?

0 1 2 3 4 5 6 7 8 9 10
don't understand at all — understand very clearly

How well do you feel <u>YOUR FAMILY MEMBER</u> understands their diabetes?

0 1 2 3 4 5 6 7 8 9 10
don't understand at all — understand very clearly

How much does your family member's diabetes affect <u>YOU</u> emotionally?
(e.g. does it make you angry, scared, upset or depressed?)

0 1 2 3 4 5 6 7 8 9 10
not atall affected — extremey affected

How much does your family members diabetes affect <u>THEM</u> emotionally?
(e.g. does it make them angry, scared, upset or depressed?)

0 1 2 3 4 5 6 7 8 9 10
not at all affected — emotionally — extremely affected emotionally

Please list in rank-order the three most important factors that <u>YOU</u> believe caused <u>YOUR FAMILY MEMBER'S</u> diabetes.
The most important causes for me:-

1. _____
2. _____
3. _____

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APPENDIX K – DIABETES FAMILY BEHAVIOUR CHECKLIST (FM)

How often do you; (Please circle the appropriate answer)

1. Nag your family member about testing their blood

Never Seldom Sometimes Often Very often

2. Help your family member decide if changes should be made based on blood testing results

Never Seldom Sometimes Often Very often

3. Criticise your family member for not recording the results of blood tests

Never Seldom Sometimes Often Very often

4. Praise your family member for following your diet

Never Seldom Sometimes Often Very often

5. Nag your family member about not following your diet

Never Seldom Sometimes Often Very often

6. Eat at the same time as your family member

Never Seldom Sometimes Often Very often

7. Eat foods that are not part of your family members diabetic diet

Never Seldom Sometimes Often Very often

8. Encourage your family member to participate in sports activities

Never Seldom Sometimes Often Very often

9. Criticise your family member for not exercising regularly

Never Seldom Sometimes Often Very often

10. Exercise with your family member

Never Seldom Sometimes Often Very often

11. Plan family activities to fit in with your family members diabetes self-care schedule

Never Seldom Sometimes Often Very often

12. Argue with your family member about their diabetes self-care activities

Never Seldom Sometimes Often Very often

13. Congratulate your family member for sticking to their diabetes self-care schedule

Never Seldom Sometimes Often Very often

14. Suggest things that might help your family member take their medication on time

Never Seldom Sometimes Often Very often

15. Buy your family member things containing sugar to carry with in case of an insulin reaction

Never Seldom Sometimes Often Very often

16. Let your family member sleep late rather than getting up to take their medication

Never Seldom Sometimes Often Very often

APPENDIX L – PARTICIPANT INFORMATION SHEET

Title of Study: Improving outcomes in Type 2 diabetes: randomised controlled trial of a brief family intervention.

Introduction: The purpose of this study is to examine the effect of a brief family intervention on outcomes in people with type 2 diabetes.

Taking part in the study: Our researcher will attend the diabetes outpatient clinic in Tallaght Hospital. If you are suitable for inclusion in our study, you will be asked to take part. If you agree, you will then be asked to name a family member, who would also like to take part. You will be asked to fill in a number of questionnaires with our researcher. This should take no more than 25 minutes. Our researcher will then contact you in a few weeks to let you know if you have been assigned to the **"test"** or **"control"** group. People will be randomly assigned to either group by a computer, and all participants have an equal chance of being allocated to the test or control group.

Control group: If you are assigned to the control group you will receive the normal diabetes care and treatment you always have, with no changes. Our researcher will contact you in six months to ask you to return to the clinic and re-fill in the original questionnaires, and have your HbA1c, BMI and blood pressure re-checked.

Test group: If you are assigned to the test group you will receive the normal diabetes care and treatment you always have, but in addition you will also take part in a family intervention. This consists of three sessions over three weeks; the first week's session will be in your home with your family member, the second week's session will be in your home with your family member, and the third week will be on the phone, with just yourself. Our researcher will also contact you by phone two weeks after this, to see how you are getting on. Our researcher will then contact you again in six months to ask you to return to the clinic and re-fill in the original questionnaires, and have your HbA1c, BMI and blood pressure re-checked.

Benefits: It is hoped this study will help people control and manage their diabetes more effectively, and therefore improve their health outcomes.

Confidentiality: Your identity will remain completely confidential. Your name will not be published, and will not be disclosed to anyone outside the hospital.

Voluntary Participation: You have volunteered to participate in this study, but you may chose to quit at any time.

Further information: You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the researchers Karen Keogh and Patricia White, who can be contacted on 6081510 or through the diabetes day centre on 4143223.
Thank you for your time and participation.

APPENDIX M – CONSENT FORM

CONSENT FORM

Improving outcomes in Type 2 diabetes: a randomised controlled trial of a brief family intervention.

This study and the consent form have been explained to me. The investigator has answered all my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study.

I have read, or had read to me, this consent form. I have had to opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I will receive a copy of this agreement.

PARTICIPANTS NAME_____

PARTICIPANTS SIGNATURE_____

Date_____

Date on which participant was first furnished with this form:_____

Statement of investigators responsibility: I have explained the nature, purpose, procedures, benefits, risk of, or alternatives to, this research study. I have offered to answer any questions and fully answered any such questions. I believe that the participant understands my explanation and has freely give consent.

Investigators signature:_____

Date:_____

APPENDIX N – INTRODUCTORY LETTER TO FAMILY MEMBERS

Diabetes Family Study

Ms. Karen Keogh
Dept. of Public Health & Primary Care
Trinity Centre for Health Sciences
AMiNCH, Tallaght, Dublin 24
Telephone: (01) 8961510

Dear family member,

Thank you for taking the time to take part in this study. Your family member who is attending the diabetes clinic at Tallaght hospital kindly put your name forward.
This is a study examining the effects of a brief family intervention on outcomes in people with type 2 diabetes. It is hoped this study will help people control and manage their diabetes more effectively, and therefore improve their health outcomes.

Your participation is of course entirely voluntary and your identity will remain confidential. When you have completed the questionnaires, please return them in the stamped addressed envelope provided.

You will then be contacted in a few weeks to let you know if you and your family member have been assigned to the **"test"** or **"control"** group. People will be randomly assigned to either group by a computer, and all participants have an equal chance of being allocated to the test or control group. If you are assigned to the **control group** you will be contacted in six months and asked to re-fill in the original questionnaires. If you are assigned to the **test group** you will be asked to take part in a family intervention. This consists of two sessions over two weeks, and I will come and visit you and your family member in your home. You will then be contacted again in six months and asked to re-fill in the original questionnaires

By taking part in this study you will be providing valuable information that may help to improve the care for those with diabetes and their families. If you have any questions about the study, you can get more information from myself, Karen Keogh, at 01-6081510 or through the diabetes day centre at Tallaght hospital (01-4143223)

Thank you for your time,
Yours sincerely,
Karen Keogh, Researcher

Trinity College

HRB

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING THE NATIONAL CHILDREN'S HOSPITAL

APPENDIX O – CONTROL GROUP ALLOCATION TO TREATMENT LETTER

Diabetes Family Study

Ms. Karen Keogh
Dept. of Public Health & Primary Care
Trinity Centre for Health Sciences
AMiNCH, Tallaght, Dublin 24
Telephone: (01) 8961510

Dear
You may remember meeting with me at your appointment in the diabetes outpatient clinic, where you agreed to take part in a research study about the family and diabetes.

I wanted to thank you again for agreeing to take part in this study, and to let you know that you have been randomly assigned by a computer to the **control** group of the study. All this means is that you should come back to the diabetes clinic in Tallaght on the_____, to fill in a number of questionnaires with me again. I would also ask you to have your bloods tested prior to this appointment, as you normally do before you attended the diabetes clinic.

I have also enclosed a questionnaire for your family member to fill in and post back to me, a stamped addressed envelope is provided. The person in your family who is most involved in helping you manage your diabetes should fill in the form.

If the appointment time I have given you does not suit, please contact me on **(01) 8961510,** and I can rearrange the appointment for a more time convenient. Please feel free to contact me if you have any other queries. I look forward to meeting you again.

Yours sincerely,

Karen Keogh, researcher

Trinity College

HRB

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING THE NATIONAL CHILDREN'S HOSPITAL

APPENDIX P – INTERVENTION GROUP TREATMENT ALLOCATION

Diabetes Family Study

Ms. Karen Keogh
Dept. of Public Health & Primary Care
Trinity Centre for Health Sciences
AMiNCH, Tallaght, Dublin 24
Telephone: (01) 8961510

Dear
You may remember meeting with me at your appointment in the diabetes outpatient clinic, where you agreed to take part in a research study about the family and diabetes.

I wanted to thank you again for agreeing to take part in this study, and to let you know that you have been randomly assigned by a computer to the **test** group of the study. This means I will be contacting you by telephone in the next few weeks to arrange a time that suits you, to visit with you and a family member in your home.

I would also ask that you come back to the diabetes clinic in Tallaght on the _____, to fill in a number of questionnaires with me again. Please have your bloods tested prior to this appointment, as you normally do before you attended the diabetes clinic.

I have also enclosed a questionnaire for your family member to fill in and post back to me, a stamped addressed envelope is provided. The person in your family who is most involved in helping you manage your diabetes should fill in the form.

If the appointment time I have given you does not suit, please contact me on **(01) 8961510,** and I can rearrange the appointment for a more time convenient. Please feel free to contact me if you have any other queries. I look forward to meeting you again.

Yours sincerely,

_____
Karen Keogh, researcher

Trinity College

HRB

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING THE NATIONAL CHILDREN'S HOSPITAL

APPENDIX Q – DEBRIEFING LETTER

Diabetes Family Study

Ms. Karen Keogh
Dept. of Public Health & Primary Care
Trinity Centre for Health Sciences
AMiNCH, Tallaght, Dublin 24
Telephone: (01) 8961510

Dear participant
We would like to take this opportunity to thank you for taking part in this research. We appreciate you have given up much of your time to participate, and we are very grateful.

In order to give us an idea of your own experience of participating in the study, we would ask you to complete the enclosed participant evaluation form and return it to us in the stamped address envelope. This will allow you to give us your own feedback and comments about taking part in the research, which will help us improve how future studies are run. The form is completely anonymous and confidential, and your comments will not be identifiable to us in anyway e.g. there is no research number on the form.

To complete the study, we have also enclosed a questionnaire for your family member to fill in and post back to us, a stamped addressed envelope is again provided. Your family member who filled in the first set of questionnaires should fill in this final set.

If at any stage in the future you have any questions or you want any information about the study, your participation in study or your rights, you can contact Patricia White or Karen Keogh on (01) 8961510. Thank you again for agreeing to take part in the study.

Yours sincerely
Patricia White & Karen Keogh, Researchers

Trinity College

HRB

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING THE NATIONAL CHILDREN'S HOSPITAL

APPENDIX R – STRUCTURED FIELD NOTES QUESTIONNAIRE

1.What is the relationship of the participating family member to the patient?

2.What was the main focus of this session?

3.How long did the session last?

4. Where in the home was it delivered?

5. Were there any interruptions? If so please detail.

6. How much do you feel;

- You participated in the session
- The patient participated in the session
- The family member participated in the session

7. How did you perceived the patient-family member dynamic?

8. During the session, how much did you perceive:

- Your own mood;
- The patient's mood

9. What helped the session to run smoothly?

10. What didn't help the session to run smoothly?

11. Please detail below any other observations you feel may be relevant;

APPENDIX S – DIARY QUESTIONS

Week :_____ Date:_____

1. This week has gone well in relation to my diabetes

yes / no (please circle one)

2. I have made changes to how I manage my diabetes

yes / no (please circle one)

(a)The type of food I am eating this week is

more healthy / less healthy / same as usual (please circle one)

(b) Over the last week I have exercised

more than usual / less than usual / same as usual (please circle one)

(c) Over the last week, I have tested my blood sugar the recommended number of times

more than usual / less than usual / same as usual (please circle one)

3. I feel I have had support with my diabetes this week

yes / no (please circle one)

4. I feel I needed support with my diabetes this week

yes / no (please circle one)

5. On a scale of 1-10, how much has your diabetes affected you emotionally over the last week? (please circle a number)

0	1	2	3	4	5	6	7	8	9	10
not at all										**extremely affected me**

6. At the moment, how happy are you with how you're managing your diabetes (please circle a number)

0	1	2	3	4	5	6	7	8	9	10
not at all happy										**extremely happy**

7. Have you any other comments about your diabetes and how things have been this week?

_____

_____

_____

_____

_____

_____

APPENDIX T – FOCUS GROUP INVITATION LETTER

Diabetes Family Study

Ms. Karen Keogh
Dept. of Public Health & Primary Care
Trinity Centre for Health Sciences
AMiNCH, Tallaght, Dublin 24
Telephone: (01) 8961510

Dear

I hope you're keeping well. I wanted to thank you again for taking part in the research, and ask you one final favour. This is the last thing we will ask you to do as part of the research, I promise!

We are running a meeting for people with diabetes who took part in the study, and we would like to invite you to attend. It will be an informal meeting, with about five to six people. The idea of the meeting is just to meet with other people with diabetes who took part in the study, and have a short discussion about your own experience and thoughts about taking part in the study.

The meeting will be held in the Trinity Centre in Tallaght Hospital next _____. I've enclosed a map showing how to get to the Trinity Centre from the main hospital. Should you decided to attend, €10.00 will be give to cover you're travel costs.

I will be in touch over the next week to see if you can attend or not. Or equally, please feel free to ring me on **8961510** if you have any questions.

Hopefully I will see you there, and thank you again for your time.

Best wishes

_____
Karen Keogh
Researcher

Diabetes Family Study

Participant evaluation form

1. Which group were you assigned to in the study? (Please circle)

   Intervention **Control**

2. Can you briefly describe your experience of taking part in the study?

3. Did taking part in the study help you manage your diabetes better? (Please circle)

   Yes **No** **Don't know**

   - If you answered **"yes"** can you briefly describe what aspects of the study in particular you found most helpful?

4. Have you any recommendations on how the study could be improved?

5. Please feel free to make any other comments here;

Diabetes Family Study

Family Member evaluation form

1. Can you briefly describe your own experience of taking part in the study?

2. Do you think taking part in the study helped your family member to manage their diabetes better? (Please circle)

Yes **No** **Don't know**

- If you answered **"yes"** can you briefly describe what aspects of the study in particular you found most helpful?

3. Did taking part in the study help you in anyway? (Please circle)

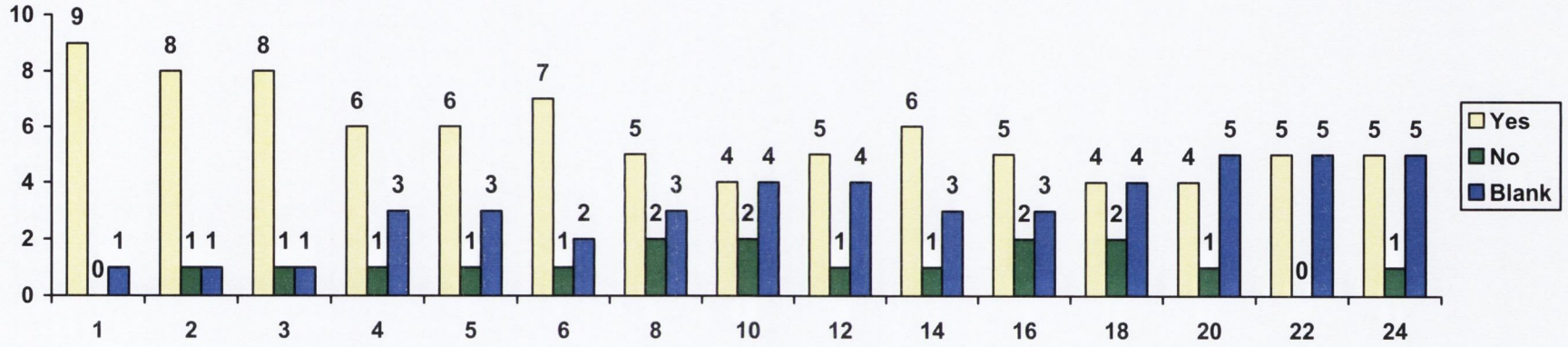
Yes **No** **Don't know**

- If you answered **"yes"** can you briefly describe what aspects of the study in particular you found most helpful?

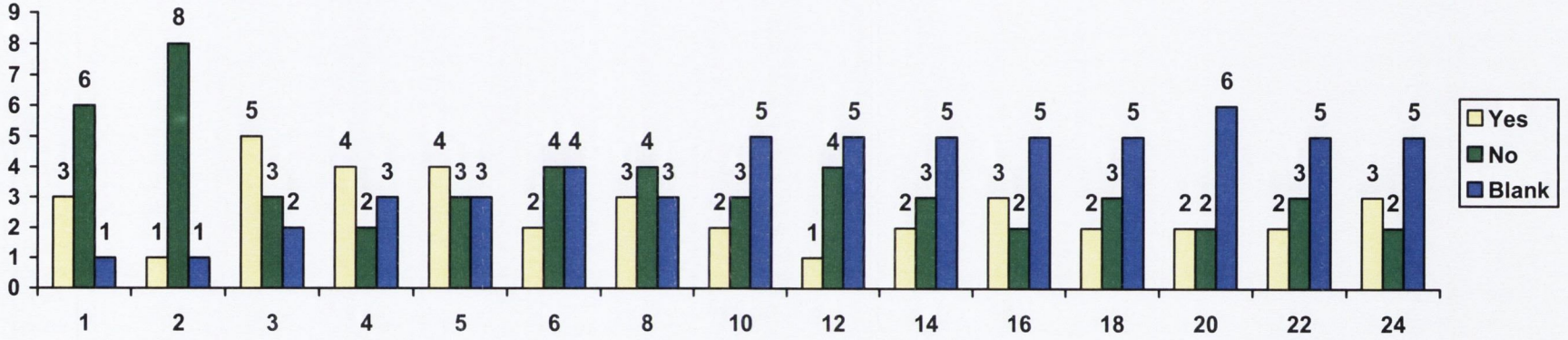
4. Have you any recommendations on how the study could be improved?

5. Please feel free to make any other comments here;

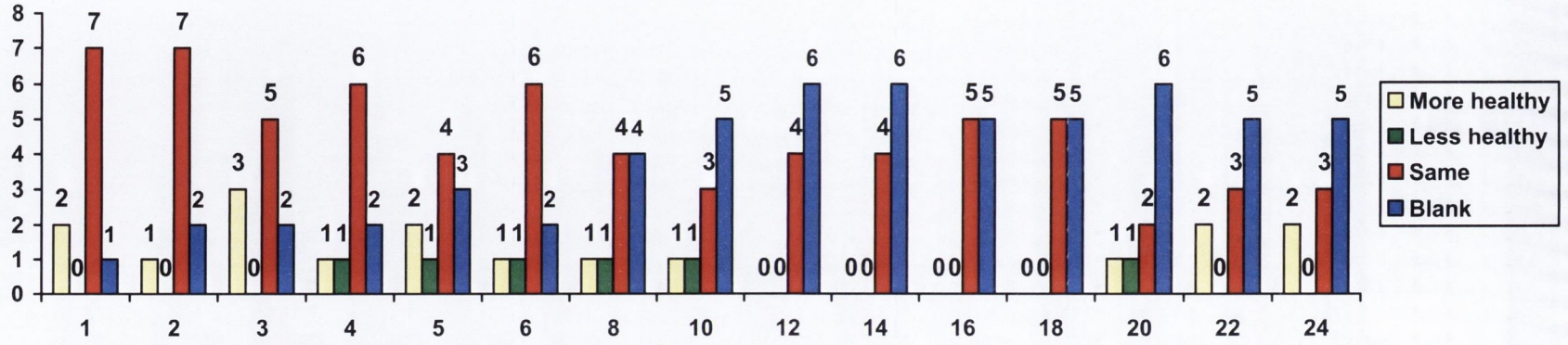
APPENDIX W: DATA FROM DIARIES



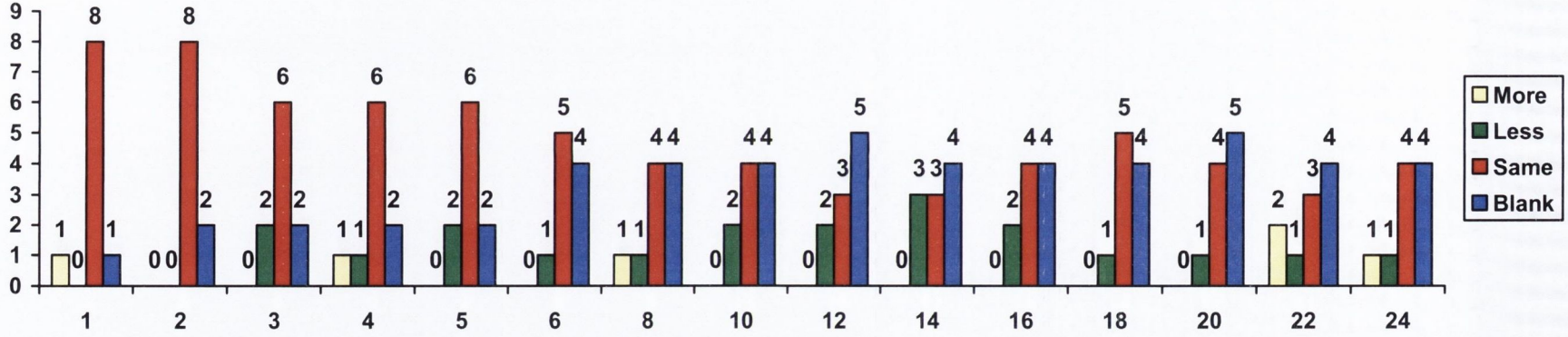
Q1: "This week has gone well in relation to my diabetes"



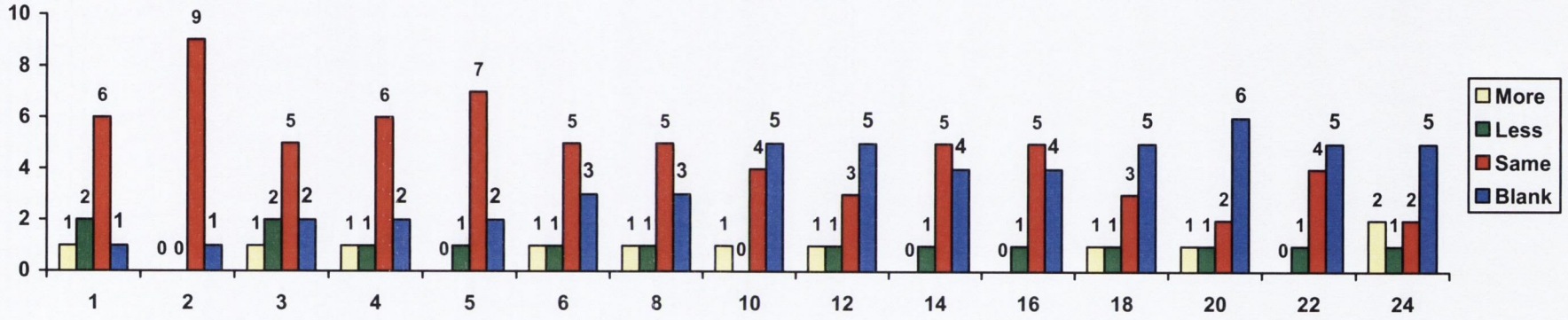
Q2: "I have made changes to how I mange my diabetes"



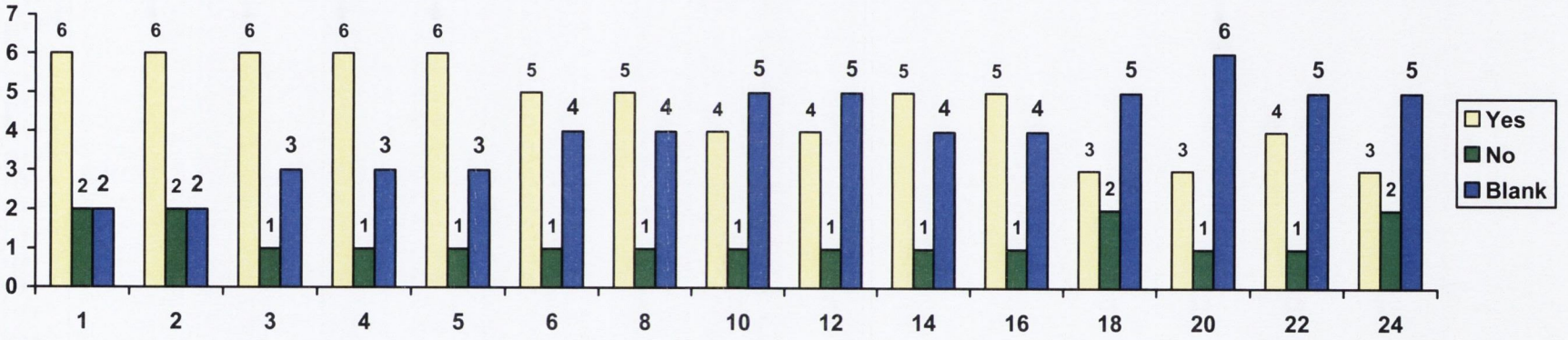
Q2a: "The type of food I am eating this week is….



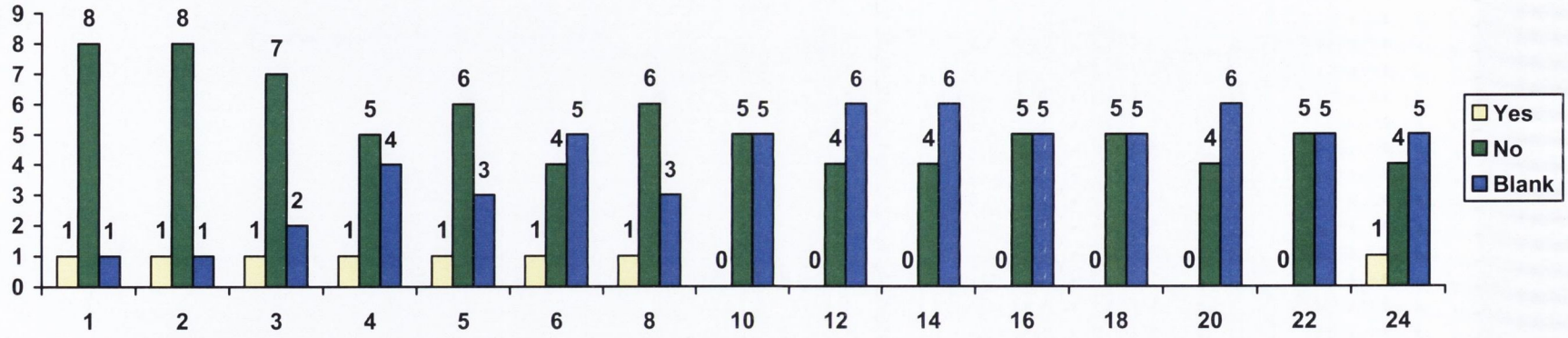
Q2b: "Over the last week I have exercised…"



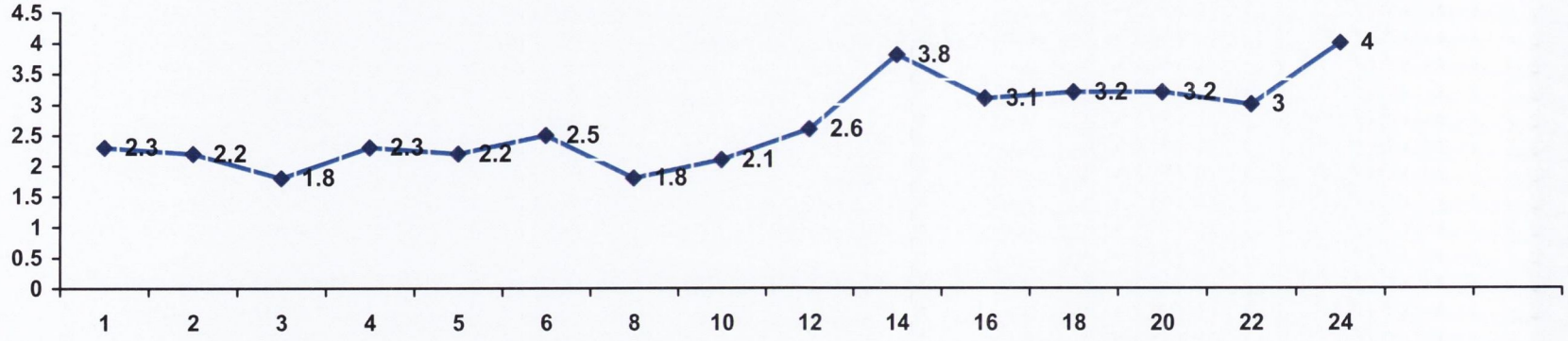
Q2c: "Over the last week I have test my blood sugar the recommended number of times…"



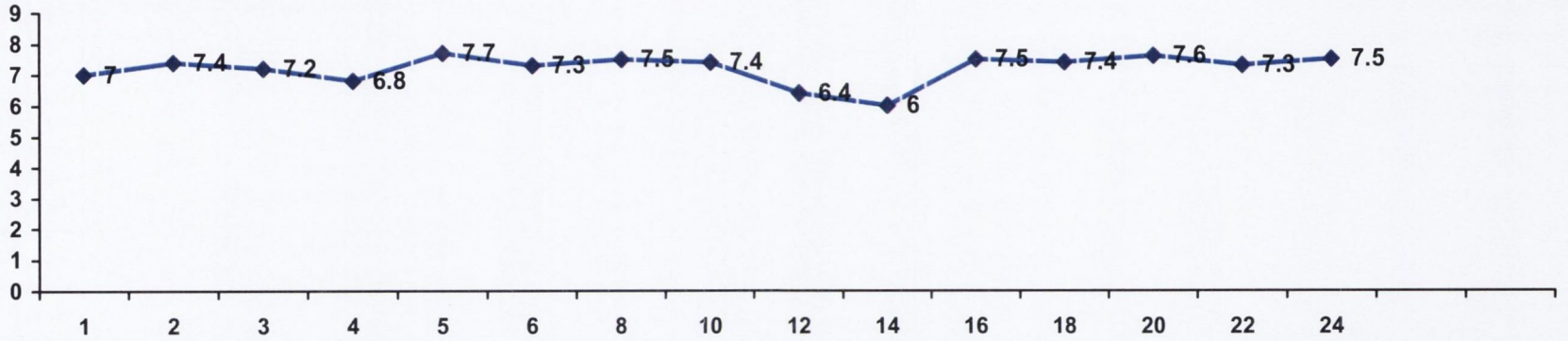
Q3: "I feel I have had support with my diabetes this week"



Q4: "I feel needed support with my diabetes this week…"



Q5: On a scale of 0-10, how much has your diabetes affected you emotionally over the last week?"



Q6: "At the moment how happy are you with how you're managing your diabetes?"

APPENDIX X: PUBLISHED TRIAL PROTOCOL

BMC Family Practice

BioMed Central

Study protocol

Open Access

Changing illness perceptions in patients with poorly controlled type 2 diabetes, a randomised controlled trial of a family-based intervention: protocol and pilot study

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Abstract

Background: This paper presents the pilot study and protocol for a randomised controlled trial to test the effectiveness of a psychological, family-based intervention to improve outcomes in those with poorly controlled type 2 diabetes. The intervention has been designed to change the illness perceptions of patients with poorly controlled type 2 diabetes, and their family members. It is a complex psychological intervention, developed from the Self-Regulatory Model of Illness Behaviour. The important influence the family context can have in psychological interventions and diabetes management is also recognised, by the inclusion of patients' family members.

Methods/design: We aim to recruit 122 patients with persistently poorly controlled diabetes. Patients are deemed to have persistent poor control when at least two out of their last three HbA1c readings are 8.0% or over. Patients nominate a family member to participate with them, and this patient/family member dyad is randomly allocated to either the intervention or control group. Participants in the control group receive their usual care. Participants in the intervention group participate, with their family members, in three intervention sessions. Sessions one and two are delivered in the participant's home by a health psychologist. Session one takes place approximately one week after session two, with the third session, a follow-up telephone call, one week later. The intervention is based upon clarifying the illness perceptions of both the patient and the family member, examining how they influence self-management behaviours, improving the degree of similarity of patient and family member perceptions in a positive direction and developing personalized action plans to improve diabetes management.

Discussion: This study is the first of its kind to incorporate the evidence from illness perceptions research into developing and applying an intervention for people with poorly controlled diabetes and their families. This study also acknowledges the important role of family members in effective diabetes care.

Trial registration: ISRCTN62219234

Background

The importance of glycaemic control

A large body of evidence is now available showing that good glycaemic control in diabetes (as assessed by HbA1c) is associated with improved outcomes [1-6]. Current international guidelines recommend a HbA1c target level of approximately 6.0%–7.5% [7-9]. However, achieving good glycaemic control requires patients to follow a treatment regime which involves lifelong behavioural self-regulation through lifestyle changes (e.g. diet, exercise) and self-management skills (monitoring symptoms, testing blood glucose, taking medication). Many patients can have difficulties following this treatment regime[10,11] and evidence suggests only about one-third of patients with type 2 diabetes achieve glycaemic targets [12]. This has led to a call for concerted efforts to increase the proportion of patients achieving good glycaemic control [12]. It would seem prudent then, for interventions aiming to improve outcomes in diabetes, to be particularly aimed at patients having difficulties controlling their illness.

Psychological interventions

There is growing awareness of the important role of psychosocial and behavioural factors in diabetes management [10], as highlighted by recommendations to integrate psychosocial support into routine diabetes care [8,13]. Psychological interventions to improve outcomes in diabetes have been systematically reviewed by a number of different authors, [14-16], with pooled trial results suggesting psychological interventions in diabetes reduce HbA1c by a clinically significant 1% [17]. Psychosocial interventions targeting those in poor control of their diabetes have been successful in improving glycaemic control in patients with type 1 diabetes [18-20], however there appear to be few interventions targeting those with poorly controlled type 2 diabetes.

Illness perceptions

One psychological approach that has been widely used in diabetes research is based on the Self-Regulatory Model of Illness Behaviour [21,22]. This approach proposes that in response to an illness, or health threat, people form their own common sense beliefs or *illness perceptions* about their illness and treatment. (The terms 'illness perceptions', 'illness representations', 'illness cognitions', and 'illness beliefs' are often used interchangeably in the literature; here the term illness perceptions is used.) These illness perceptions influence the types of health-related behaviours and coping behaviours which a patient uses for managing their illness and which may impact on disease outcomes. Research into illness perceptions [23,24] suggests they encompass five broad dimensions: identity, timeline, causes, consequences, and curability/controllability (see Figure 1: the five domains of illness perceptions). Patients' perceptions of their diabetes have been found to influence self-management behaviours [25-30] which may, in turn, impact on glycaemic control [31,32].

Patients in poor control of their diabetes have been found to have distinctly different perceptions of their illness than those in good control. A study of patients with type 2 diabetes [33] found that compared to patients in good control (HbA1c < 7), those in poor control (HbA1c > 8.5) had a stronger perception that their illness was caused by hereditary factors, reported suffering from more diabetes-related symptoms, perceived diabetes as having significantly greater impact on their lives, and reported more negative emotions in relation to their illness. Interventions focusing on changing these illness perceptions amongst patients in poor control may lead to improved illness outcomes, including better glycaemic control. A brief intervention (3 sessions)[34] designed to alter patients' perceptions about their recent MI was associated with significant positive changes in patients perceptions of their illness, as well as a significantly earlier return to work and lower rates of angina symptoms. However, there would appear to be few interventions which attempt to improve outcomes by explicitly targeting and measuring changes in illness perceptions in of type 2 diabetes.

The role of the family

A comprehensive understanding of how people think about, and thus manage, their illness can only be reached by taking into account the social and family context in which the thoughts were developed [35]. The possible impact of the family context on illness perceptions is particularly relevant for diabetes, as most of the self-regulatory behaviours involved in the self-management of diabetes occur at home. Evidence from a small number of studies suggests that the illness perceptions of family members may influence disease outcomes. Differences between the illness perceptions of patients with chronic

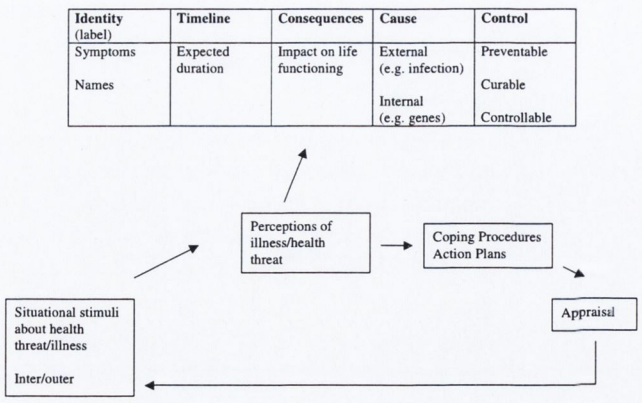

Figure 1
The five domains of illness perceptions [21].

illness and their spouses have been found to have a strong impact on patients' adaptive outcomes [36], while similar positive patient and spouse perceptions about the identity and consequences of MI have been found to be associated with better physical, psychological, social and sexual functioning [37]. Substantial differences have been found between family members' and patients' perceptions of type 2 diabetes [38]. Family members perceived diabetes as a more serious illness, and as having a greater impact on daily life, than those with the illness. Those with diabetes were unaware of their family member's heighten concerns and had a more relaxed approach to living with diabetes. Interventions targeting the illness perceptions of patients and families would seem a promising area for future research in view of the evidence suggesting that the degree of congruence between patient and spouse illness perceptions is related to illness outcomes. A hypothesised model by which family members illness perceptions may influence patient health outcomes in diabetes is presented in figure 2. (Figure 2: how family members may influence outcomes in diabetes.)

Family interventions in type 2 diabetes

A number of authors have noted that the role of family factors in adult diabetes intervention research has been neglected, particularly in type 2 diabetes. [10,39-41] This is despite recent evidence suggesting that the inclusion of a family member in psychosocial interventions for chronic illness may improve illness outcomes [42-45] A recent systematic review [46 Zhang & Fisher, 2005 #516] identified only one published RCTs that included a patient's family member in an intervention for patients with type 2 diabetes [47]. This study [47] was based on a behavioural weight loss intervention, which included patients' spouses. The study found a significant weight loss in both control and family group. However, there was a significant interaction of treatment and gender, with women doing better than men when treated with their spouses as opposed to being treated alone.

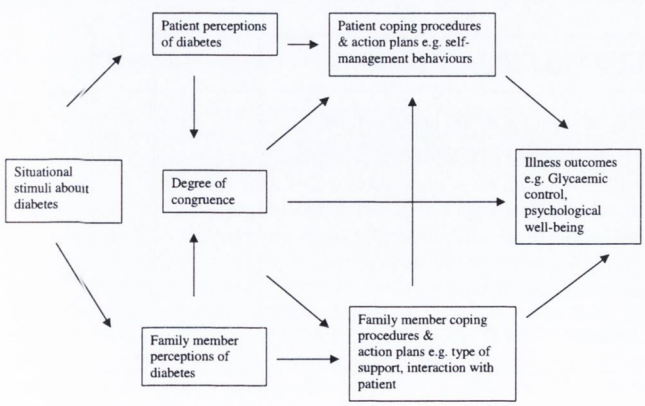

Figure 2
How family members may influence outcomes in diabetes.

This paper presents the pilot study and the protocol for a RCT that is currently underway to test the effectiveness of a family-based intervention, designed to change the illness perceptions of patients with poorly controlled type 2 diabetes and their family members.

Trial objectives

- To examine the effects of a psychological, family-based intervention to improve biophysical, psychosocial and behavioural outcomes for patients with poorly controlled type 2 diabetes.

- To evaluate the experience of participating in the intervention.

Methods/design

This study is a randomised controlled trial. In order to recruit a sufficiently large sample of patients with poorly controlled diabetes, participants are being recruited from diabetes specialist clinics, rather than from a primary care setting. In Ireland, the majority of patient's with type 2 diabetes in poor control of their illness are referred by their GP to a specialist clinic, and are mainly managed there. Thus, it would not have been possible to recruit the required number of participants in poor control of their diabetes from a primary care setting.

Participants

There will be two groups of participants in the study; patients with poorly controlled type 2 diabetes and their family members. A record will be kept of all clinic attendees who do not wish to participate and their reasons for non-participation. Participants and non-participants will be compared across a number of variables (e.g. age, gender etc) to investigate any sub-group differences.

Inclusion and exclusion criteria

People with poorly controlled type 2 diabetes

People with type 2 diabetes are included in the trial if they are over 18 years of age, have fluency in English, have type 2 diabetes for more than one year, and at least two out of their last three HbA1c readings haven been 8.0% or over, in order to identify patients' with persistent poor control. (A HbA1C reading of 8% or over is a recognised value for poor metabolic control of diabetes [48].) Patients with a life-threatening physical illness (e.g. cancer, renal failure) will be excluded. Patients with a severe and enduring mental disorder (e.g. dementia, schizophrenia) as determined by the patients' clinician, will also be excluded. Patients not responsible for their own care, or those not residing in their home environment will be excluded (e.g. those in care homes, prison, in-patient hospital wards).

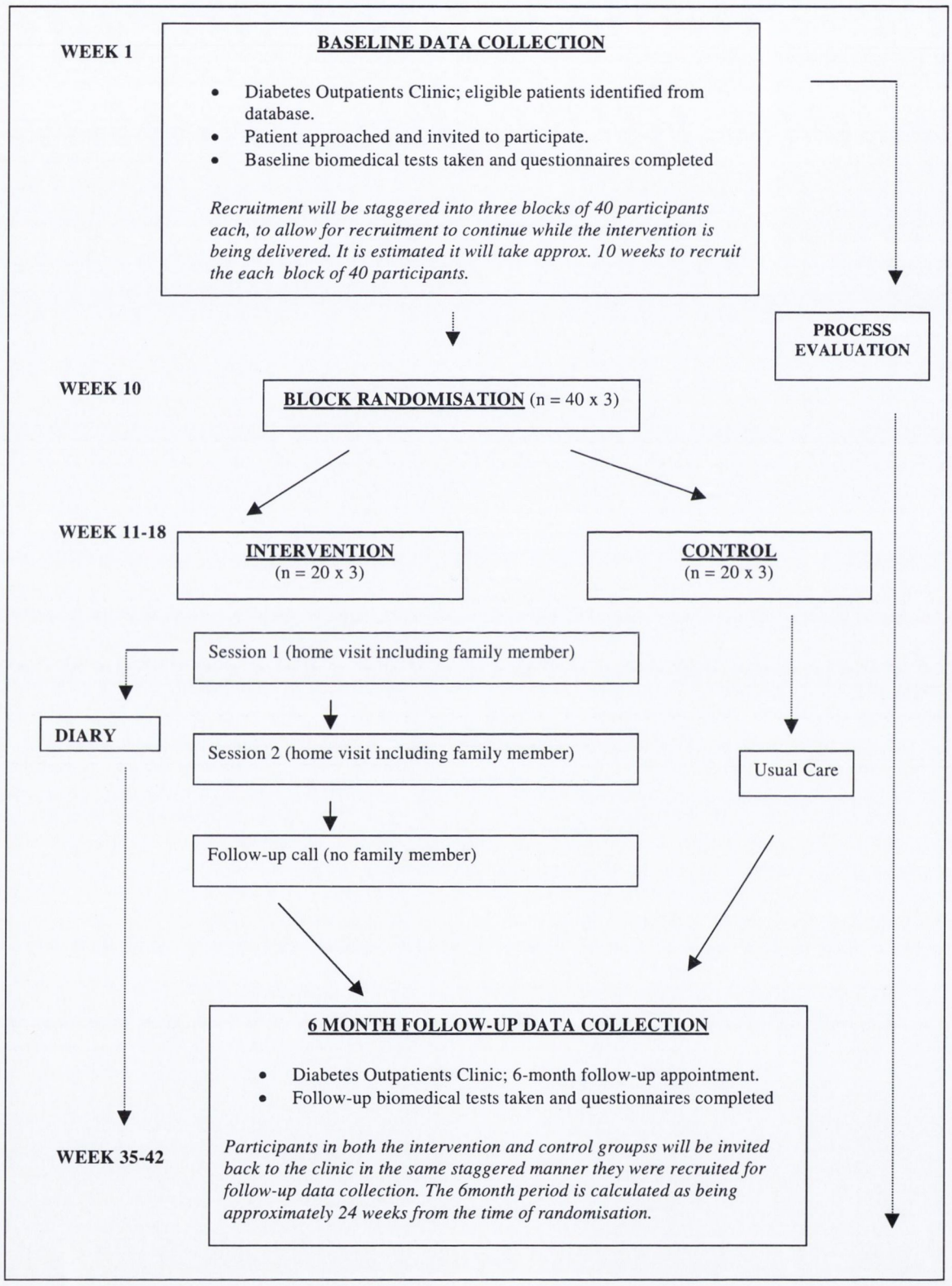

Figure 3
Flow Chart of RCT.

Patients with hearing impairments will also be excluded. Patients who took part in the pilot study, and those who took part in a previous study conducted in the same diabetes clinic [33]will be excluded.

Family members of participants with type 2 diabetes

Participants with poorly controlled type 2 diabetes recruited to the study will be asked to nominate a family member to participate in the research with them. For the purposes of this study family members will be defined as any relative in regular contact with the person with diabetes, and who is most involved in supporting that person in the management of their illness. As most people with diabetes manage their illness themselves, the family member for this study is not a *carer*, but someone with whom the person with diabetes has a close relationship. This may include a spouse/partner, parent, grandparent, child, grandchild, siblings, or other family members. The inclusion criteria for a family member are that they must be over 18 years of age and have no medical history of type 1 or type 2 diabetes.

Screening eligibility

Potential participants will be recruited from two diabetes specialist clinics at the AMNCH Hospital in Tallaght in Dublin. All type 2 patients over 18 years, with at least two of their last three HbA1c readings of 8.0% or greater (eligible participants), will be identified through the auditing facility of the "Diamond" computer database (n~ 3560 type 2). Prior to each clinic a list of eligible patients attending the clinic will be generated by the Diamond database, who will subsequently be asked to participate in the study (see Figure 3: Flowchart of RCT).

Baseline assessment

During the twice-weekly out-patients clinics eligible patients will be approached by the researcher, given information about the study and invited to participate. On agreement, they will be asked provide their written informed consent, and to complete the baseline questionnaires with the researcher (this will take on average fifteen minutes). These questionnaires consist of demographic questions, the brief-illness perceptions questionnaire [49], the well-being 12 scale [50], the diabetes management self-efficacy scale [51], the diabetes family behaviour checklist [52]and the summary of diabetes self-care daily activities [53]). At this appointment time their HbA1c, blood pressure, and body-mass index will also be taken. The person with diabetes will also be given a questionnaire pack containing the family member measures, and asked to ensure their nominated family member completes the questionnaires and returns them by post to the researcher, prior to commencement of the intervention. The family member questionnaire include demographic questions, and adapted versions of the brief illness perceptions questionnaire [49]and the diabetes family behaviour checklist [52].

Outcome assessment

At six months post-intervention (approximately 24 weeks from the time of randomisation), control and intervention participants will be invited back to the diabetes clinic in the same staggered manner as they were recruited. At this time point, HbA1c, blood pressure, cholesterol and body-mass index will be taken again and recorded. The baseline questionnaires will also be re-administered. In addition, a record will be kept of participation rates throughout the intervention and reasons for non-participation where possible. Participants will again be given a questionnaire pack containing the family member measures, and asked to ensure that their nominated family member completes the questionnaires and returns them to the researcher by post.

Randomisation

After consent and baseline data have been collected from the first 40 patients, they will be randomized into intervention and control groups by using computer generated

Table 1: Sample case study for intervention

FC, male mid 50's, with poorly controlled type 2 diabetes. He says he understands very little about his diabetes (illness coherence), but that he feels it has a huge impact on his life e.g. he hates taking the medication, he is tired all the time etc (consequences). FC doesn't believe lifestyle factors are important in controlling his illness (control), because he believes the causes of the illness are purely genetic (he believes he inherited the illness from his mother – causal). His wife, MC, believes that while she does not understand the diabetes, her husband understands his diabetes very well (coherence), but that it has very little impact or effect on his life (consequences); She also thinks that he is over-reacting when he complains about it. She believes his diabetes was caused by stress (cause), and if he stopped working so much and took more time to relax, his condition would improve (control). She also does not recognise the importance of lifestyle factors such as diet and exercise for controlling diabetes (control), because she thinks the illness is stress-related and continues to prepare high-fat, high-sugar meals for her husband.

The intervention sessions with this couple could be tailored to focus on clarifying the causal dimension of illness perceptions of both participants, by focusing on the risk factors associated with developing type 2 diabetes. In particular, the importance of lifestyle factors in controlling the illness could be emphasised, and attempts to improve the patient's level of personal control over the illness. The intervention could also focus on highlighting and resolving differences between the patient's and family member's illness perceptions, such as the discrepancy between the perceived consequences and levels of understanding between the patient and his wife. A written, personalised action plan to improve control of the patient's diabetes could then be developed in collaboration with the patient and his wife. This could include, for example, an agreement for the patient and his wife to take time to go out walking together three times a week, to reduce the levels of fatty and sugary foods consumed etc.

random number tables. The main investigators will not be involved in the randomisation procedure, which will be carried out by an independent expert. The use of block randomisation means that the intervention can be delivered in a staggered manner, with some participants beginning the intervention while further recruitment continues. When the next 40 patients are recruited, they will then be randomly allocated to intervention or control groups, and so on, until 122 patients are included in the trial. Due to the psychological nature of the intervention, it is not possible for the investigator delivering the intervention to be blind to participants' treatment allocation group.

Intervention

The intervention is a complex psychological intervention designed to change the illness perceptions of patients with type 2 diabetes and their family members. The starting point for the intervention is the illness perceptions models of diabetes held by the patient and the family member and the degree of similarity between these models. The intervention is based upon clarifying the five illness perception dimensions of both the patient and the family member in relation to diabetes, examining how they influence self-management behaviours, and developing personalized action plans. The intervention will be tailored to each individual patient and family member; thus, the exact content of each session will depend upon the individual illness perceptions of the patient and family member, and the degree of congruency between these perceptions. In essence, the intervention is designed to change any inaccurate and/or negative illness perceptions which the patient or family member may have, and improve the degree of congruence of patient and family member perceptions, in a positive direction. A sample case study is presented in Table 1 to illustrate how the intervention might work (Table 1: sample case study for intervention). A more detailed description of the intervention can be found in the intervention manual (see additional file 1)

The intervention that is the focus of this study is relatively brief, in view of recent research suggesting that briefer psychosocial interventions can be more easily integrated into routine care. Due to the brief nature of the intervention and its emphasis on behaviour change, techniques from brief motivational interviewing [54] will be used to deliver the intervention. These techniques have been successfully used in other brief interventions of this type [55,56]. The intervention will consist of three sessions delivered on a weekly basis, the first two of which will take place in the patient's home with their family member, and the last one of which consists of a phone call to the person with diabetes. Sessions will be delivered by a health psychologist who is trained in motivational interviewing techniques. Each session will last approximately 40 minutes.

Sample size and rate of recruitment

Taking HbA1c and Diabetes Well-being as primary outcomes, a total sample size of 76 and 86 respectively, were calculated. This was using 80% power to detect a significant *absolute* change of 0.9% in glycaemic control (this

Table 2: Process evaluation components

Process Evaluation Questions	Data Collection Tool	Source	Trial Stage
Implementation			
Was the intervention properly delivered?	1.10% of sessions randomly selected to be taped and analysed by independent expert in illness perceptions and motivational interviewing.	Randomly selected sub-sample of intervention participant's.	Collecting during intervention delivery.
Treatment fidelity to different components.			Analysed post-intervention
Monitor dose/participant exposure to intervention components	Tapes analysed qualitatively and quantitatively using MI & IP checklists.		
Receipt			
1.Participants views of the intervention and partaking in the RCT.	1.Open-ended questionnaires for all participants in control and intervention groups	1. All participants	1. Collected at follow-up data collection
2.Appropriateness of use of intervention and techniques for type 2 diabetes	2. Focus groups with sub-sample of intervention participants	2. Sub-sample of intervention participant's.	2. Collection post-follow-up
Contextual factors			
What was the effect of various setting/contextual factors. e.g. interruptions during session, family dynamic, mood, etc.	Structured field notes questionnaire (e.g. how long each session, where in home delivered, interruptions, dynamic, etc)	Interventionist	Collecting during intervention delivery.
Sub-groups variations (e.g. family member involved)	Interventionist observations – field diary		Analysed post-intervention

absolute change has been related to clinical outcomes in the UK prospective diabetes study, [3] and of 3 points in the Diabetes Well-being Scale-12. These calculations also allow for an anticipated "Hawthorn effect" relating to an improvement of 20% for those in the control group, by virtue of the fact that they are participating in the research. Taking the larger number of86 participants (43 in intervention and 43 in control group), a final total number of 122 participants (61 in each group) is needed to ensure at least a 70% final response rate is met. Previous research in the diabetes clinic [33] has shown that it is possible for one researcher to see approximately two to three eligible patients per clinic. Thus, it is estimated that it will take approximately 8–10 weeks to recruit the required 40 participants for the first block for randomisation.

Qualitative component

Participants with type 2 diabetes (in the intervention group only) will be asked to complete a brief diary on a weekly basis for the first six weeks and every second week for the remaining eighteen weeks. Diaries will be structured to allow for the examination of the intervention and the process of change over time. In order to maximize compliance to filling in the diary, weekly/fornightly text messages will be sent to remind participants to fill in their diary. A computer program will be used to send text messages to a large number of mobile phones at regular intervals.

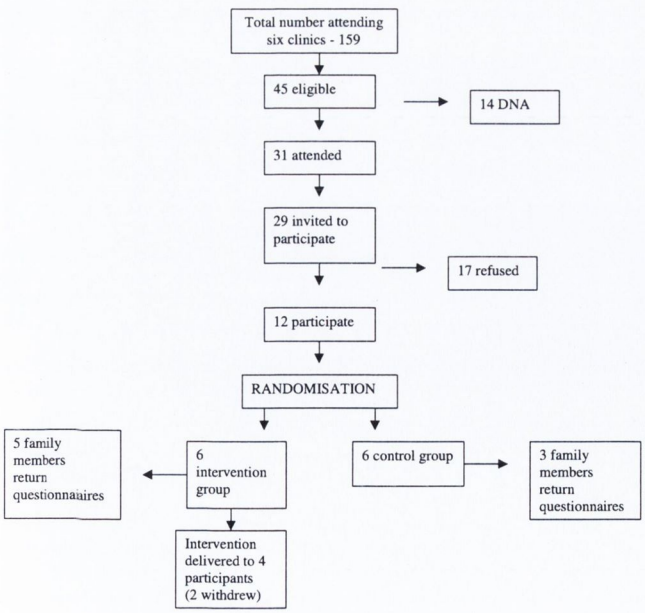

Figure 4
Flowchart of recruitment of pilot participants.

Quality assurance

The process evaluation component of this RCT will run alongside data collection and intervention delivery. The use of both qualitative and quantitative data provides the strongest evidence for process evaluation [57,58]. Therefore, qualitative and quantitative process evaluation data will be collected in this study, focusing on aspects of intervention implementation, participant experience of receipt of the intervention, and the influence of contextual/setting factors. See Table 2 for an outline of the process evaluation questions and data collection tools (Table 2: process evaluation components).

Analysis

Quantitative analysis

SPSS Version 13.01 for Windows will be used in the analysis. Differences in biomedical, psychosocial and illness-specific outcomes between the intervention and control group will be analyzed for the two time-points (baseline and 6 months post- intervention). Further statistical analysis will be based on repeated measures analysis of variance. Statistical significance will be taken at the 5% level for primary outcomes, and at 1% level for secondary outcomes.

Qualitative analysis

Qualitative data will be analysed using phenomenological techniques. Both content analysis and thematic analysis will be applied to the data

Trial organisation and management

The trial is being managed by the Department of Public Health and Primary Care, Trinity College Dublin, and the Diabetes Centre, Adelaide and Meath incorporating the National Children's Hospital, Tallaght, Dublin. Ethical approval was obtained from the Joint Research Ethics Committee of St. James's Hospital and the Federated Dublin Voluntary Hospitals

Pilot study

Participants for the pilot study were recruited from six weekly clinics in the Diabetes Centre, during the summer of 2006. Twelve eligible patients agreed to participate in the pilot and completed baseline assessment. Participants were divided into intervention and control groupss; six in the intervention and six in the control. Two participants in the intervention group, and one from the control group, withdrew from the study, leaving nine participants in the pilot study, four of which completed the intervention sessions. Pilot participants were not recalled for outcome assessment, since the small sample size would not allow for statistical analysis. A flow-chart of the recruitment process for the pilot study is shown in figure. 4 (Figure 4: Flowchart of recruitment of pilot participants).

The pilot study showed that the procedures, measures, and delivery of the intervention worked well and recruitment began for the main study in October 2006. However, following the pilot study, it was considered necessary to change one of the measures to be used in the RCT. Following feedback from some of the participants showing that the original self-efficacy measure was quite difficult for them to understand; this measure was replaced by the Diabetes Management Self-Efficacy Scale[51]. The rate of recruitment for the pilot was also slower than anticipated. To ensure sufficient numbers of participants were recruited for the main trial, it was decided it would be necessary to recruit participants for the main trial from an additional weekly clinic.

Discussion

This trial aims to assess the effectiveness of a family-based, psychological intervention to improve outcomes in those with poorly-controlled type 2 diabetes. The intervention recognises the important role of family members in effective diabetes care, and it is the first of its kind to adapt evidence from the illness perceptions research to an intervention for people with poorly-controlled diabetes and their families.

The intervention is based on a clearly specified theoretical framework; Leventhal's Self-Regulatory Model of Illness Behaviour [21,22]. There is much empirical evidence showing that the concepts of this model are related to illness outcomes in diabetes, and illness perception interventions in various disease populations have also been successful in changing illness perceptions and improving illness outcomes [34].

The study is further located within three main theoretical frameworks outlined by Matire and colleagues [44], including the bio-psychosocial model e.g. [59], martial and family system framework e.g[60], and family care-giving and receiving model e.g. [61], with some evidence to suggest family members own illness perceptions of the patients illness can influence outcomes. It has been proposed that family members may influence outcomes in physical health by means of a psychophysiological and/or health behaviour pathway, [42,43]. This intervention targets both of these pathways insofar as it attempts to change negative illness perceptions and increase the degree of similarity of patient and family member perceptions. These may in turn directly impact upon self-management behaviours (e.g. through increased self-efficacy, support for diabetes-specific activities), and indirectly improve the nature and quality of family functioning and interactions (e.g. through increased understanding, more general support).

This trial includes a combination of both process indicators and outcome measures as recommended by a number of authors [57,58,62], The process evaluation component will provide detailed information on how the intervention was delivered and received, which will allow for increased generalisability of results, whilst also ensuring quality through the assessment of treatment fidelity. A primary aim of the process evaluation is to establish *why* the intervention achieved its results. Thus, if the intervention has little or no impact on outcomes, the process evaluation data should uncover whether this was due to inadequate design (a failure of concept/theory), poor delivery (implementation failure) and/or or other factors.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

PW & SS conceived the development of the intervention. PW, SS and KK developed the intervention. All authors developed the trial protocol and contributed to drafting the manuscript. SS is the principal investigator. KK manages the running of the trial.

Additional material

Additional File 1
Intervention Manual
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