AN EXAMINATION OF THE HEALTH BELIEF MODEL WHEN APPLIED TO DIABETES MELLITUS

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SUMMARY

Previous research studies which have used Health Belief Model (HBM) dimensions in order to understand health outcomes have many problems which prevent clear and reliable conclusions about their results. Studies about diabetes-related health beliefs have proved to be no exception to this rule. The research presented here is an attempt to address some of these problems which include the lack of satisfactory scales to measure diabetes-related health beliefs, the use of heterogeneous samples of patients with different disease and regimen types, and the lack of prospective studies in which health beliefs are used to predict outcomes in the future. Another major problem which applies to all HBM research is that the relationships between the various dimensions of the model have not been determined. As such, the HBM is not a model at all but a catalogue of variables. The present research aimed to specify the relationships between the components of the HBM and attempted to integrate self-efficacy and locus of control beliefs in order to extend the model and improve the amount of outcome variance explained.

Scales to measure diabetes-specific health beliefs were developed from the responses of 187 tablet-treated outpatients with Type II diabetes. Health beliefs were examined, on the one hand, in relation to other psychological and behavioural variables, and on the other, for their sensitivity to change after educational and treatment interventions. Both cross-sectional and longitudinal study designs were employed. The relationships between the HBM components themselves were explored in a linear and non-linear fashion.

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CHAPTER ONE

THE HEALTH BELIEF MODEL

Introduction

There has been a gradual shift of emphasis in medical science this century from fighting infectious disease to dealing with chronic conditions and dangers associated with lifestyle behaviours (Michael, 1982). Modifiable antecedents of disease and death are to be found in the environment and in patterns of behaviour. Changing patterns of morbidity and mortality and the political drive to reduce the cost of medical care have therefore provided impetus for encouraging widespread preventive health behaviours amongst both chronically ill and healthy individuals (Clymer, Baum & Krantz, 1984). Accordingly, there has been a movement towards emphasizing individual responsibility for one's health.

The idea of prevention rather than cure is an excellent one but in practice many people do not follow recommendations for health maintenence or enhancement (Antonovsky & Kats, 1970). In the case of presenting illness, the realization that patients do not always follow doctors' orders spawned a multitude of early studies about patient non-compliance (Sackett & Snow, 1979). Much of this work was based on the biomedical model of disease and therefore ignored the psychological processes underlying decisions to follow treatment recommendations. In practice, this model sees the patient as a passive recipient and performer of regimens and fosters the idea of physician authority. Research on compliance was therefore characterized by a fruitless search for dispositional characteristics of patients which might be corrected (Leventhal & Cameron, 1987). In reality, the decision not to follow health care advice is the result of many motivations. These may involve dissatisfaction with clinical advice, competing social realities (e.g. financial constraints, familial opposition, demands of work, leisure activities, peer group pressures to conform), or even a conscious preference of illness to health (Trostle 1988). Furthermore, in chronic conditions such as diabetes mellitus a patient may come to believe that even if s/he follows the treatment regimen precisely this will not guarantee absence of health problems. Conversely, it is also possible that a person may learn that risky health behaviour does not lead to any harm. Compliance research has therefore evolved into a focus on the beliefs and attributions which influence the health behaviour of individuals. Moreover, implicit in this approach is the acknowledgement that choosing not to follow treatment recommendations or advice may be the result of rational decision-making and not a form of deviant personality or other characteristic as implied by the biomedical model (Christensen, 1978). The notion of compliance is therefore an outmoded one.

Cognitive models of health behaviour

During the past 25 years there has been a gradual development of several models to explain behaviour related and unrelated to health. These models are derived from social psychological learning theories developed from "Stimulus Response" (SR) theory and "Cognitive Theory" (Rosenstock, Strecher & Becker, 1988). The SR theorists argued that reinforcements are sufficient to explain learning and behaviour. Cognitive theorists, however, emphasized the role of expectations held by the individual. In this view, behaviour is influenced by the subjective value of an outcome and the expectation that a particular action will achieve that outcome. Individuals are therefore motivated to maximize gains and minimize losses. Tolman (1932) and Lewin (1935) were prominent in developing this formulation which has come to be known as "value-expectancy" theory.

Examples of prominent value-expectancy theories used to explain health behaviour are the Health Belief Model (Hochbaum, 1958; Rosenstock, 1966) which is the focus of this thesis, the theory of reasoned action (Fishbein & Ajzen, 1975), and social learning theory (Rotter, 1954).

Description of the Health Belief Model

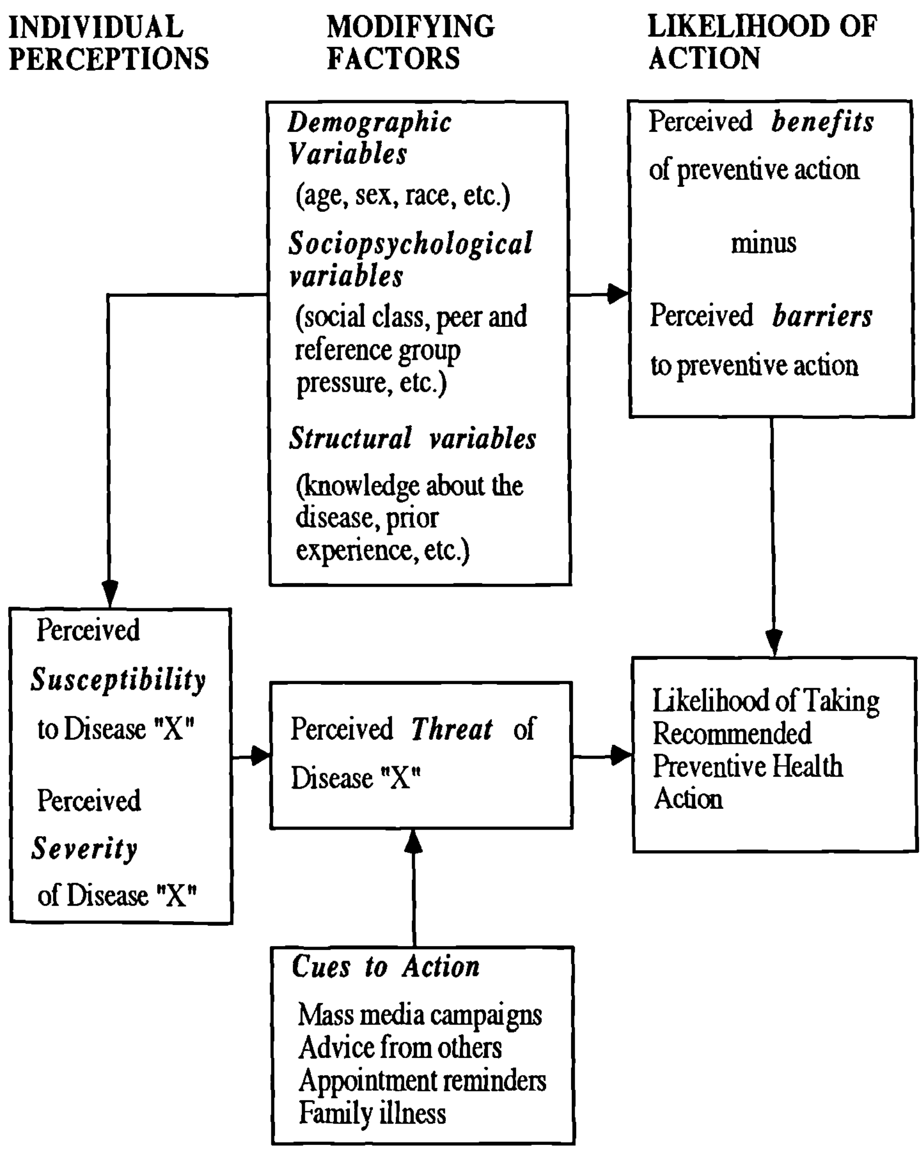
The Health Belief Model (HBM) is the only model which has been developed specifically to explain health behaviour and has generated the most research in this area (Wallston & Wallston, 1984). It was developed by four social psychologists: Hochbaum, Kegeles, Leventhal, and Rosenstock (Hochbaum, 1958; Rosenstock, 1966) and is relevant to behaviours that are under an individual's control. The model was originally conceived in order to predict preventive health behaviours but with later adaptations (Becker, 1974; Becker & Maiman, 1975) has also been used to predict the behaviour of people with acute and chronic illnesses. The value-expectancy approach in the context of health-related matters was translated as: (a) the desire to avoid illness, or if ill, to get well; and (b) the belief that a health behaviour will prevent or ameliorate illness. The likelihood of someone taking a health action is seen to be determined by the individual's perceptions about his/her susceptibility to an illness and the perceived severity of its consequences. Taken together these are said to constitute the perceived threat or risk of the illness which provides the energy or force to act. The behavioural outcome, on the other hand, is influenced by an evaluation of the required action in terms of its efficacy in reducing the threat (perceived benefits) weighed against the perceived costs of or barriers to undertaking the behaviour.

The model assumes that health is a highly valued concern. Furthermore, it proposes that behaviour is triggered by 'cues to action' which make the individual aware of the health threat. Such stimuli might be the individual's internal symptoms or prompts from external sources such as health care providers, family members or the media. Antonovsky and Kats (1970) have argued, however, that including the concept of cues in the theoretical model is unnecessary because individuals effectively create their own cues. In other words, the manifestation of symptoms, the sudden awareness of information or reminders about health threats will affect beliefs about susceptibility and severity. Thus it is not the cue which directly prompts one to take health action but the belief. Similarly, diverse demographic (age, sex, race, etc.), sociopsychological (social class, peer and reference group, personality, etc.) and structural factors (knowledge about the disorder, prior experience, etc.) are likely to play a part in shaping health behaviour but these influence behaviour only indirectly by modifying the other components of the model.

The key components of the model are thus: perceived susceptibility, perceived severity, perceived benefits and perceived barriers. The remaining "health value", "cues to action" and "modifying factors" act as explanatory antecedents to the key components (although "health value" has been conspicuous by its absence from most descriptions of the traditional HBM). It is surprising that these explanatory aspects of the model have not been logically extended to embrace the influence of the various political policies of governments and other institutions such as state financing and educational philosophy. Janz and Becker (1984) have argued that the HBM is a psychosocial model and as such "is limited to accounting for as much of the variance in individuals' health-related behaviour as can be explained by their attitudes and beliefs". However, there is a danger that research which focuses on the individual's responsibility for health outcomes will divert attention away from macro perspectives of how public health can be improved. Indeed, because the HBM has been very influential and has stimulated a large volume of research it has been singled out for criticism because it fails to provide a societal view of health behaviour (Research Unit in Health &

Behavioural Change, 1989). A summary of the HBM is provided in Figure 1.

Figure 1: The Health Belief Model (based on Becker, Drachman and Kirscht, 1974)



Research utilizing the Health Belief Model

The studies which have used the HBM to explain and predict health-related behaviour are too numerous to describe in detail here. In any case, comprehensive reviews of this research are already available. An entire issue of *Health Education Monographs* summarized the findings from research up to 1974 (Becker, 1974) and a further review appeared 10 years later which charted the progress of later findings (Janz & Becker, 1984). Studies using the HBM have been published since the last major review but are not described as they have not made any significant contribution to the body of knowledge already amassed about the model. The aim of this section is to provide a global view of the literature relating to the HBM.

Versions of the HBM have been applied to participation in screening for tuberculosis (Hochbaum, 1958), polio vaccination (Rosenstock, Derryberry & Carriger, 1959), influenza immunization (Leventhal, Hochbaum & Rosenstock, 1960; Aho, 1979; Cummings, 1979; Rundall & Wheeler, 1979), preventive dental and physician visits (Kegeles, 1963; Rundall & Wheeler,1979), osteoporosis prevention (Wurtele, 1988), practice of breast self-examination (Hallal, 1982; Champion, 1987), smoking behaviour (Aho, 1979; Weinberger, Green & Mamlin, 1981; Kaufert, Rabkin, Syrotuik, Boyko & Shane, 1986), and dieting for obesity (Becker, Maiman, Kirscht, Haefner & Drachman, 1977). Beliefs relating to chronic illness treatments have also been studied including antihypertensive regimens (Inui, Yourtee & Williamson, 1976; Kirscht & Rosenstock, 1977; Nelson, 1978; Taylor, 1979; Sackett, Haynes & Gibson, 1975), diabetes regimens (Alogna, 1980; Cerkoney & Hart, 1980; Harris, Skyler, Linn, Pollack & Tewksbury, 1982; Given, Given, Gallin & Condon, 1983; Bradley, Gamsu, Knight, Boulton & Ward, 1986; Bradley, Gamsu, Moses, et al, 1987; Brownlee-Duffeck, Peterson, Simonds, et al, 1987; Lewis, Jennings, Ward & Bradley, 1990), end-stage renal disease regimens (Hartman & Becker, 1978; Cummings, 1982) and psychiatric medication for outpatients (Kelly, Mamon & Scott, 1987).

From the review by Janz and Becker (1984) and a general survey of the subsequent literature it is apparent that all of the studies published to date have limitations related to sampling, design, or measurement. Some research was carried out on small or atypical samples of subjects whilst other studies reported large sample attrition through non-response or drop-out. Another major problem was that a large proportion of the research was retrospective in design. In this case, beliefs were correlated with measures of preventive health behaviour or treatment adherence collected previously or at the same point in time. In retrospective studies it is difficult to determine whether beliefs determine behaviour or whether people rationalize their beliefs to be consistent with their behaviour (McKinlay, 1972). There have also been few attempts to modify beliefs to determine the causal nature of correlations between HBM components and behavioural outcomes (Marteau, 1989). A further major criticism of many of the studies is that Health Belief dimensions were operationalized in questionable ways. Many of the studies, for example, did not evaluate all of the dimensions of the model. Furthermore, the measures in some studies (e.g. Berkanovic, Telesky & Reeder, 1981; Harris, Skyler, Linn, Pollack & Tewksbury, 1982) either overlap with one another creating problems of multicollinearity or lack face validity and are therefore misleadingly labelled. There has also been a problem with inconsistent levels of measurement of the model dimensions. For example, in one study (Tirrell & Hart, 1980) susceptibility to illness in general was evaluated whilst barriers were operationalized on a specific level (i.e. barriers to exercise). Probably the most serious and widespread problem related to the measurement of HBM dimensions, however, is the paucity of scales with reported reliability and validity. Many of the measures were put together on the basis of face validity only, thus raising doubts about the concepts actually measured. In one study (Rundall & Wheeler, 1979) only one question was used to measure each dimension of the model. Another major criticism is that idiosyncratic interpretation of the model has resulted in various styles and types of measurement instrument. Lack of measurement consistency makes comparisons across studies problematic although some variation in measurement is inevitable if researchers are to accommodate the specific characteristics of the illness or health behaviour studied. Nevertheless, it is desirable that ultimately, research within a particular field of study should be comparable.

In order to test the HBM many studies have related its dimensions to measures of treatment adherence provided by the subjects themselves, observations of behaviour, or from physiological indices such as blood glucose levels. However, these measures are often unreliable or invalid. The problem with self-reports of health behaviour is that they may be influenced by a subject's reluctance to report non-adherence to treatment recommendations. Objective measures of health behaviour may be reliable if they involve a single observable action such as attending a health screening programme but this type of measure becomes more difficult, when long-term behaviours are of interest as in a treatment regimen for chronic illness. Studies facing this type of problem have often employed questionable measures of "compliance" such as missing even a single dose of medication within a relatively long time period (Nelson, Stason & Neutra, 1978). The indirect measures of treatment adherence are also problematic in that measures of, for example, metabolic control are also influenced by factors such as incidence of intercurrent illness, and the adequacy of the treatment recommendations for the particular person or illness. Given the shortcomings of sampling, design and measurement related to the HBM already described above, these additional problems of measuring behavioural outcome serve only to compound the difficulty in assessing the utility and validity of the model. Moreover, even if it is possible to obtain a reliable measure of health behaviour, researchers testing the HBM still have to contend with the fact that some behaviours (e.g. dieting and exercise) are performed for reasons other than to improve or maintain health. Furthermore, for some preventive health actions (e.g. dental hygiene) there may be a substantial habitual component involved. As Cleary (1987) has pointed out, "when trying to explain health-relevant behaviour, one confronts the awesome task of explaining human behaviour in general",

Despite all the problems with studies involving the HBM just described, Janz and Becker (1984) concluded that the research provides substantial evidence for the importance of HBM dimensions in explaining and predicting individuals' health-related behaviour. This conclusion was based on a survey of the number of positive and statistically significant findings for each individual HBM dimension. A "significance ratio" was created by dividing each of these totals by the number of studies which reported a statistical outcome for the particular dimension in question. For the studies conducted between 1974 and 1984 the most consistent predictor of health-related behaviour was the "barriers" dimension whilst "severity" produced the least consistent results. When sick role studies were analysed separately, however, the "severity" dimension proved to be the next most consistent predictor of outcomes after "barriers" whilst "susceptibility" was the least consistent. Janz and Becker comment that "susceptibility" was probably the least efficient dimension in this type of research because it is difficult to operationalize where a diagnosis of illness has already been made. Overall, the significance ratios produced from the prospective studies were higher than those from retrospective studies for all of the individual dimensions. For studies prior to 1974 the ordering of the significance-ratios indicated that "susceptibility" was the most consistent predictor of outcomes. However, most of these studies examined preventive health behaviour and the majority did not include the"barriers" dimension.

Three of the studies yielded significant results in a direction opposite to that which the original HBM might have predicted. Janz and Becker argued, however, that in two cases the design of the study was retrospective whilst the third outcome was likely to be a logical result of feeling less susceptible because the patients had followed treatment recommendations. Since the review by Janz and Becker more studies have yielded results contrary to the model's predictions (e.g. Brownlee-Duffeck, Peterson, Simonds, Goldstein, Kilo & Hoette, 1987; Lewis, Jennings, Ward & Bradley, 1990) suggesting the possibility that the relationships between health beliefs and outcomes are not static but dynamic. Not only may health beliefs affect outcomes but these outcomes, in turn, may affect health beliefs. As originally proposed, the HBM makes no explicit provisions for such dynamic relationships. The value of correlational studies in teasing out such relationships is therefore questionable and warrants further research.

Although the review by Janz and Becker is thorough in its coverage of studies published up to that date, surprisingly, it fails to acknowledge a major flaw in HBM research. This flaw concerns the lack of studies which aim to determine how the dimensions of the model *combine* to predict behaviour. Stone (1979) has noted that the HBM makes relative rather than quantitative predictions and Wallston and Wallston (1984) have argued that the original theory implicitly suggests a multiplicative model. However, researchers have either failed to consider more than one variable at a time or the individual variables have been additively combined with no thought as to their relationship. Indeed, Wallston and Wallston have pointed out that the HBM is more a catalogue of variables than a model at present. In the final paragraph of their 1984 review, Janz and Becker comment that "Given the numerous survey-research findings on the HBM now available, it is unlikely that additional work of this type will yield important new information." They then go on to recommend that future research should be concerned with the evaluation of the effects of interventions on the individual HBM dimensions. The number of studies which have continued to evaluate HBM dimensions individually since this review suggest that this view has been accepted uncritically. The main aim of this thesis is to discover, therefore, whether the various elements of the HBM may be interactively combined to *predict* health-related outcomes more efficiently.

Explanations of health-related behaviour not included in the Health Belief Model

The proportion of variance in health outcomes explained by HBM components is not usually high (Rosenstock, 1985). One reason why the model's components account for such small amounts of variance has just been described. However, a further explanation is that key elements are missing from the HBM. These elements have been included in value-expectancy theories of behaviour which were not conceived specifically to predict health-related outcomes. Nonetheless, they have been successful in explaining substantial amounts of variance in health behaviour.

1. Social learning theory

Rotter's (1954) and Bandura's (1977) social learning theories have emphasized the role of subjective expectations regarding self-efficacy, and value of outcome in the prediction of behaviour, although most research attention has been directed towards the expectancy component of the equation.

Rotter focused on generalized expectancy a version of which he operationalized in a measure of locus of control. Locus of control is the generalized expectancy that one's own behaviour or forces external to oneself control reinforcements or behaviour outcomes. The measure began as a unidimensional (internal-external) scale (Rotter, 1966) but research by others, notably Levenson (1973) expanded the measure to include three orthogonal dimensions. These represent beliefs in internality, powerful others, and chance locus of control. It is predicted that a person is most likely to engage in a particular behaviour if s/he has a belief in internal locus of control and low belief in chance locus of control. The Wallstons (1982) have also speculated that particular combinations of locus of control beliefs are more beneficial in health self-care. In particular, they suggested that the most beneficial pattern is a combination of high scores for internality and powerful others and a low score for chance. People with this pattern of beliefs were labelled "Believers in Control" and were expected to make the best use of the resources provided by health professionals giving care and advice as well as their own personal resources. It has been suggested by Strickland (1978) that generalized expectancies will predict behaviour in novel or ambiguous settings but with experience in a given situation, situation-specific expectancies become more important. Indeed, research experience has shown that the more general measures of locus of control were not particularly sensitive when related to specific behaviours. There are now several situation-specific locus of control scales available including a health locus of control scale (MHLC) (Wallston, Wallston, & DeVellis, 1978), and at a greater level of specificity, dental behaviour (Beck, 1980), weight (Saltzer, 1982), fetal health (Labs & Wurtele, 1986), and smoking (Georgiou & Bradley, 1992). Bradley, Brewin, Gamsu and Moses (1984) and Bradley, Lewis, Jennings and Ward (1990) have also developed diabetes-specific perceived control scales based on Peterson's (1982) Attributional Style Questionnaire which allows the examination of attributions for positive and negative outcomes separately. In general, situation-specific scales have been more successful than the scales measuring generalized expectancies. Indeed they have accounted for very respectable proportions of the variance in behavioural outcomes (e.g. Beck 1980; Saltzer, 1982; Labs & Wurtele, 1986; Bradley & colleagues, 1986; 1987; 1990).

Bandura (1977) has pointed out that locus of control is not the same as self-efficacy since locus of control relates more to outcome expectations and disregards whether or not one feels capable of performing that behaviour. In this respect, locus of control belongs to the same HBM dimension of "perceived benefits" which is also an outcome expectation. It is argued by Bandura that a person could perceive outcomes as personally determined but may still lack the necessary skills to carry out recommended behaviours. The utility of self-efficacy expectations in predicting outcomes has been well documented (Maddux & Stanley, 1986; Bandura, 1986). Changes in self-efficacy expectancy and changes in behaviour are highly correlated and self-efficacy has been shown to be an excellent predictor of behaviour. In practice, however, most measures of self-efficacy are confounded to some extent with elements of outcome expectancy and vice-versa (Maddux, Norton & Stoltenberg, 1986). The diabetes-specific measures of perceived control by Bradley and colleagues (1984, 1990) effectively evaluate a combination of perceived self-efficacy in achieving a state of health and expectations regarding locus of control over behavioural outcomes. Respondents are required to rate the extent to which they themselves, medical staff, treatments, other people, and chance, control and determine various hypothetical outcomes related to diabetes. Because the outcomes are hypothetical, the respondent is not restricted to accounting for real-life scenarios.

Rosenstock, Strecher and Becker (1988) have posited a revised explanatory model of health behaviour which incorporates the previously absent concept of self-efficacy into the HBM. They argue that self-efficacy is particularly relevant to coping with a chronic illness which often requires the modification of lifelong habits such as eating, drinking, exercising and smoking. A belief in one's ability to alter such lifestyles is necessary before an intervention can become a success. One aim of the present research is to examine the effects of incorporating an overlapped measure of control and efficacy expectation into the HBM and to test the overall model as a predictor of health outcomes. Rosenstock and colleagues do not specify how a measure of self-efficacy should be incorporated into the HBM so it is assumed that they see it as a simple addition to the catalogue of variables to be tested. In the present research, however, an attempt will be made to investigate any interactive or multiplicative relationships with other components of the HBM in an overall aim to specify the relationships between the components of the model. In particular, it is predicted that self-efficacy beliefs and expectancies about control will interact with perceived benefits of, and barriers to, adopting health-care practices.

2. *The theory of reasoned action:*

The theory of reasoned action was developed as a general model of behaviour but has been used successfully to explain and predict a variety of health behaviours (Grube, Morgan & McGree, 1986). Like the HBM, this theory is applicable only to behaviours that are under voluntary control and thus deals with rational thought processes based on available information. The attitudes included in the theory of reasoned action are similar to the beliefs in the HBM; as Kirscht (1983) has pointed out, dimensions of the HBM can be mapped onto the theory of reasoned action. The theory asserts that behaviour is a function of an individual's intention to perform the behaviour. Behavioural intention, in turn, is hypothesized to be a function of two basic factors: the individual's *attitude towards performing the behaviour* and *subjective norms.* Attitudes are the product of beliefs about the outcome of performing specific behaviours. Subjective norms, on the other hand, reflect one's perception of the degree to which individuals or groups think performing the behaviour is important. The main difference between the HBM and the theory of reasoned action is that the latter emphasizes the importance of normative beliefs. Furthermore, the relations among the constructs of the theory are specified, unlike the HBM. Wallston and Wallston (1984) have suggested that components of the HBM should be combined with the additional elements from the theory of reasoned action [and a similar, though extended model by Triandis (1980)]. Janz and Becker have argued, however, that the normative component of the theory of reasoned action could be considered as a logical refinement of the "benefits" and "barriers" dimension of the HBM. A socially-approved behaviour would be seen as a benefit, while a socially disapproved action might be viewed as a barrier. Whether the operationalization of normative beliefs within the "benefits" and "barriers" dimensions of the HBM would be adequate remains to be seen. Probably the greatest obstacle to the efficient measurement of normative beliefs within the HBM, however, is the correspondence of measurement required by the Fishbein model. Unlike the more generalized components of the HBM, the attitudes and normative beliefs of the theory of reasoned action are measured at a very specific level. For this reason, no attempt will be made to incorporate the concept of normative beliefs in the exploration of the HBM reported in this thesis.

Health Beliefs related to diabetes mellitus

In order to carry out the task of assessing the relationships between the various dimensions of the HBM, measures of diabetes-specific health beliefs have been developed from the responses of individuals with tablet-treated, Type II diabetes. (The psychometric development of these measures is described in Chapter 2). The following sections of this chapter are therefore about the nature, management, and outcomes of diabetes mellitus. This is followed by a review of studies which have utilized versions of the HBM in order to understand and predict diabetes-related health outcomes.

The nature and management of diabetes

In general, diabetes can be classified into two main types. Type I diabetes has previously been labelled as "juvenile-onset" or "insulin-dependent" diabetes and Type II used to be called "maturity-onset" and "non-insulin dependent" diabetes. The new labels of Type I and Type II (based on certain immunological critera and genetic markers) were adopted because the earlier classifications overlap and cause confusion; all juvenile-onset patients are dependent on insulin but individuals with maturity onset diabetes form a heterogeneous group treated by diet alone, diet and tablets, or diet and insulin.

In a report by the World Health Organization (1985) estimates of the prevalence of diabetes ranged from 2% to 5% of the UK population and 5%

to 10% in the USA. Of the total number with diabetes, approximatley 75% will have the Type II disorder (Jarrett, 1986). There is evidence to suggest that Type I diabetes is an autoimmune disease whereby the insulin-producing cells of the pancreas are gradually destroyed in individuals exposed to as yet unidentified environmental triggers. Genetic factors are thought to play an indirect role in both types of diabetes through the inheritance of characteristics which make an individual more susceptible. However, there is a stronger genetic link in Type II diabetes with the concordance rate for identical twins approaching 100%. Very little is known about the aetiology and pathogenesis of Type II diabetes but there are certain well-known predisposing risk factors. A sedentary lifestyle and the consumption of energy-dense foods have been particularly important in contributing to the rise in prevalence of this type of diabetes in all populations (Taylor and Zimmet, 1983). Indeed, most people with Type II diabetes are overweight.

Diabetes is characterized by abnormal metabolism of carbohydrates, proteins, fats, and electrolytes resulting from a deficiency of insulin function. This deficiency may be due to the beta cells of the pancreas producing insufficient insulin or the insulin produced may not be utilized effectively. Under normal circumstances, glucose will enter the liver, muscle, or fat cells for storage or energy when sufficient insulin is bound to the cell wall. When insulin is deficient, however, glucose builds up in excessive quantities in the blood (hyperglycaemia) and spills over into the urine causing dehydration and the classic symptoms of thirst and excessive urination. Defective glucose metabolism also results in incomplete fat combustion which leads to an accumulation of toxic ketone bodies in the blood. If diabetes is not treated by administration of exogenous insulin, sufficient amounts of these ketone bodies will cause acidosis and eventually coma which may be fatal. There is another type of coma which is associated with insulin-treated diabetes which is due to very low blood glucose levels (hypoglycaemia). Hypoglycaemia occurs when insulin is not balanced with sufficient carbohydrate intake, or unusual amounts of exercise are not compensated for by reduced insulin dosage or an increase in carbohydrate consumption. Most people with diabetes, however, with the help of oral agents and/or diet, do not need exogenous insulin to manage their disorder because they still have the benefit of some glucose homeostasis due to endogenous insulin. In this case, therefore, there is only a small risk of ketoacidosis and hyperglycaemic coma.

Treatment for diabetes depends on the amount of endogenous insulin produced by the pancreas and the efficiency of its uptake. In overweight people with Type II diabetes, diet alone may be sufficient to manage the disorder. This diet will involve a reduction of carbohydrate consumption to the point where endogenous insulin can cope. High fibre foods are recommended because their sugar is absorbed more slowly into the bloodstream. Fat content is kept to a minimum in order to limit the number of calories consumed and reduce the risk of atherosclerosis. The caloric content is generally quite low to provoke weight loss which in turn will increase insulin sensitivity and reduce the risk of macrovascular disease. These patients are also encouraged to increase their physical activity although this is not always possible if there is limited mobility. Type II patients with endogenous insulin secretion but insufficient carbohydrate utilization may require, in addition to diet, hypoglycaemic agents in tablet form. These agents may stimulate insulin secretion in the pancreas (sulphonylureas) or increase glucose uptake by the peripheral tissues (biguanides) (Lebovitz, 1985). For individuals with highly deficient or absent insulin secretion regular doses of exogenous insulin are required in order to manage their diabetes. This insulin has to be delivered subcutaneously by injection or via an insulin infusion pump. In this case, the patient's diet is designed so that caloric intake is balanced with the action of injected insulin, otherwise the types of food recommended are similar to those for diet and tablet treated individuals. The main problems of using exogenous insulin are that injections have to be administered 30 minutes before each meal and then that person must eat otherwise hypoglycaemia will occur. Snacks also have to be eaten in order to avoid hypoglycaemia even though the patient may not be hungry. People with diabetes which requires insulin which is administered by injection therefore have to learn to regiment their lives in accordance with insulin injections and mealtimes and have to learn to adapt to unforeseen circumstances such as a delayed meal or unplanned exertion.

It is not only desirable for patients to keep themselves symptom-free but also to maintain blood glucose levels as close as possible to the normoglycaemic range of approximately 3.5 to 8.0 mmol/l. The rationale for such strict control is to avoid or delay the long-term microvascular complications associated with chronic hyperglycaemia (Pirart, 1978; Tchobroutsky, 1978). The tissue damage which results from chronic hyperglycaemia can be found in the nerves (neuropathy), small blood vessels, the kidneys (nephropathy), and the retina and may lead to outcomes such as amputations, blindness, renal failure, and sexual dysfunction. People with diabetes have to be extra vigilant regarding care of the feet as the common occurence of numbness in the lower extremities can render them more vulnerable to undetected wounds which, together with impaired circulation can result in amputations due to gangrene. In addition to the microvascular complications, diabetes also affects the large blood vessels, mainly through abnormal fat metabolism and hypertension. Hypertension and hyperlipidaemia are more common among diabetic than among non-diabetic individuals and may therefore increase the risk of coronary heart disease and cerebral vascular accidents (strokes). In Type II diabetes, 60 to 70 percent of deaths are caused by myocardial infarction and strokes (Burden, 1982) which represents a two- to three-fold increase in mortality rate when compared to the non-diabetic population . Adherence to dietary recommendations therefore plays an important part in the treatment of diabetes, particularly for those who are overweight. Unfortunately, diabetes is not always diagnosed at onset in older people with Type II diabetes as it is possible to be asymptomatic. These patients may therefore present with complications prior to diagnosis and thus the aim of treatment is to arrest further degeneration of the tissues involved. In general, however, it is unusual for people to be free of complications after 20 years of diabetes.

Ideally, in order to monitor blood glucose levels, individuals with diabetes need to test their urine or blood. Urine testing usually involves dipping a glucose-sensitive strip into the urine and observing the strip for colour change. An alternative test involves the addition of a tablet to some diluted urine and observation of the colour change. Urine testing, however, is not as informative as blood testing because the appearance of glucose in the urine is delayed. Moreover, urine glucose levels may not be an accurate reflection of blood glucose levels because the threshold at which glucose spills over into the urine varies between individuals, particularly those who are older (Butterfield, Keen & Whichelow, 1967). For people who test their blood at home, a blood sample is obtained by finger pricking. The sample is then placed on a glucose-sensitive reagent strip which is then read by eye or by a reflectance meter developed for this purpose. Blood glucose testing has now largely replaced urine glucose testing for people with Type I diabetes. However, most people with Type II diabetes use urine tests and some, particularly the elderly, are not encouraged to monitor glucose levels at all. Although attitudes are now changing (Alberti & Gries, 1988), Type II diabetes used to be seen as a mild form of diabetes because it does not have the immediate life-threatening consequences associated with the Type I disorder so patients have not always received optimal care. However, the long-term consequences of Type II diabetes are just as devastating as those for Type I diabetes and represent a major cause of premature death (Fuller, 1985)

It can be seen from the foregoing description of diabetes and its management that the typical regimen is "complex, of life-long duration, and requires many behaviour changes on the part of the patient" (Cerkoney & Hart, 1980). Furthermore, effective control of the disorder depends in large measure upon the participation of the patient in disease management. Research studies have shown, however, that 80% of insulin-requiring patients administered their insulin in an unacceptable manner, 65% to 73% did not follow their diets, and only 30% to 57% regularly tested their urine (Watkins, Williams, Martin, Hogan & Anderson, 1967; Korhonen, Huttunen, Aro et al., 1983). Non-adherence to treatment recommendations may be due to some extent to lack of knowledge. However, research in this area has shown that even if individuals have a very good level of knowledge about the management of their disorder, they may choose not to follow treatment recommendations. Correlations between knowledge scores and level of diabetes control are rarely significant and sometimes even negative (Shillitoe, 1988) As discussed earlier, it seems that non-adherence to treatment recommendations is the result of a decision-making process based on beliefs about such factors as costs, benefits, risks, controllability, and self-efficacy. Thus, patients will differ in the extent to which they believe that a treatment regimen is worthwhile. An increase in research knowledge about these perceptions is therefore desirable in order to design interventions which attempt to change inaccurate or destructive but modifiable beliefs. The next section is a critical review of studies which have employed dimensions of the HBM in order to understand health outcomes in adults with diabetes. A review of the research relating to locus of control and self-efficacy in relation to diabetes is provided in a further section.

The Health Belief Model and diabetes

In a study examining adherence to diet recommendations in 50 obese subjects with non-insulin-dependent diabetes, Alogna (1980) focused on a single HBM dimension: perceived severity. She also administered a measure of locus of control, the results of which will be discussed in the following section. The majority of the subjects were women and 46 of the total were black, thus the sample was atypical. Alogna classified the participants as "compliant" or "non-compliant" on the basis of prior weight loss and blood glucose control resulting from a weight control treatment programme. Perceived severity of diabetes was assessed using a "perception of severity of disease index" derived from the Standardized Compliance Questionnaire developed by Sackett and Haynes (Sackett, Becker, MacPherson, Luterbach & Haynes, 1974). The results indicated that the "compliant" group viewed their disorder as significantly more serious than did the "non-compliant" group. Furthermore, perceived severity did not vary with the incidence of diabetes-related complications in each group. However, because of the retrospective nature of the study, it is not possible to determine whether high levels of perceived severity facilitated weight-reducing behaviour or whether it was a consequence of success in the weight reduction programme. Also, because the study measured only one dimension of the HBM it provides an incomplete picture of how beliefs are related to health outcome in this particular sample.

The Standardized Compliance Questionnaire was also used as a basis to measure dimensions of the HBM in a study by Cerkoney and Hart (1980). In this case, 15 statements from the questionnaire were adapted in order to measure the various dimensions of the HBM including cues to action. One-week test-retest reliability was evaluated but no attempt was made to establish internal reliability. Face validity of the items selected is also impossible to assess because these are not fully described. Thirty insulin-treated patients responded to the questionnaire, 73% of whom were women. Eighty percent of the sample were aged over 50 years and almost half of the subjects had been taking insulin for less than a year. Once again, therefore, the sample studied was atypical. Adherence to treatment was assessed using patient self-reports and direct observation in five areas of management: diet, insulin administration, hypoglycaemia management, urine testing, and foot care. Only self-report was used to measure adherence to diet. On the basis of a study by Gordis, Markowitz and Lilienfeld (1969) which reported that rates of adherence measured by self-report are double those measured by any other method, Cerkoney and Hart allotted double point values to the items measured by direct observation. Given that diet was measured by self-report alone and the "doubling-up" method was based on a single report, this seems to have been a somewhat arbitrary method of obtaining a measure of adherence to treatment. The individual HBM scores were correlated with each of the adherence measures and the total adherence score. The total adherence score was also correlated with a total HBM score which seems to have been calculated on the basis that the various dimensions of the model combine additively. The results of these correlations are summarized in Table 1.1. The strongest correlation was between the total HBM score and the total compliance score. However, as can be seen, this correlation was attenuated by the fact that none of the HBM measures were significantly associated with urine testing or diet scores. Moreover, there was a non-significant trend for greater diet adherence to be negatively associated with perceived severity and greater adherence regarding hypoglycaemia and foot care was negatively associated with perceived benefits. It is also surprising that perceived benefits and perceived barriers did not correlate significantly with any of the adherence measures. With the benefit of knowledge from more recent research concerning the HBM (which has shown these dimensions to be relatively strong predictors of adherence to treatment), the reliability and validity of these measures is highly suspect. The measures of adherence also included items which measured knowledge

Table 1.1: Correlation matrix reproduced from the study by Cerkoney & Hart (1980)

	Health belief motivators					
Compliance	**Total HBM**	**Perceived suscep-tibility**	**Perceived benefits**	**Cues**	**Perceived barriers**	**Perceived severity**
Total compliance score	0.50**	0.23	0.01	0.40*	0.12	0.42*
Insulin and its administration	0.40*	0.20	0.33	0.54**	0.10	0.17
Diet	0.20	-0.20	-0.01	0.33	-0.03	0.25
Hypoglycaemia or insulin reactions	0.08	0.48**	-0.27	-0.19	0.21	0.09
Foot care	0.30	0.21	-0.11	0.14	0.01	0.47**
Urine testing	0.34	0.18	0.20	0.21	0.23	0.07

** $p<0.01$ * $p<0.05$

about the various aspects of the regimen which makes the interpretation of the results problematic.

In the absence of psychometrically developed scales designed to measure HBM dimensions in individuals with diabetes, Given, Given, Gallin and Condon (1983) published the first attempt to develop such measures. The questionnaire items were derived from three sources: (a) previous instruments measuring HBM concepts; (b) diabetes education materials which included descriptions of aspects of the therapeutic regimen and patients' beliefs and reactions related to diabetes; and (c) in-depth interviews with a convenience sample of 25 diabetic patients using open-ended questions. From these sources 76 statements measuring 12 groups of beliefs were constructed. The statement groups measured dimensions of the HBM dimensions but did not distinguish perceived vulnerability. In addition, one group of statements measured beliefs about the degree of perceived personal responsibility for treatment, another two statement groups effectively measured a combination of social support and cues to action (Social Support for Diet and Social Support for Taking Medications), and a further two groups evaluated the impact of work on diet and on taking medications. The groups relating to impact of work could have been conceptualized as perceived barriers but because several items of this nature were constructed and these groups of statements were applicable only to those who were employed, it is not surprising that a separate scale was produced by the factor analysis. Psychometric evaluation was carried out on the responses of 156 Type I and Type II diabetic patients. Factor analyses and inter-scale correlations produced six final scales. These were labelled: (1) *Control of effects of diabetes* (representing a combination of items from the original Personal Responsibility and Severity statement groups); (2) *Barriers to diet ;* (3) *Social support for diet* ; (4) *Barriers to taking medications;* (5) *Impact of job on therapy* (representing items from the original Impact of Job on Taking Medications and Impact of Job on Diet statement groups); and (6) *Commitment to benefits of therapy* (consisting of items from the original Benefits of Diet and Benefits of Taking Medications statement groups). Three of the original 12 hypothesized groups of beliefs did not survive psychometric evaluation. The final scales produced by Given and colleagues do not distinctly represent the dimensions of the HBM as there is a measurement overlap between perceived severity and perceived personal responsibility for treatment. Moreover, although Becker and Janz (1985) have suggested that some of the items measure perceived susceptibility, these are included in scales measuring concepts such as perceived severity. Perhaps because of this lack of distinction between the scales, there have been no published reports of studies utilizing them to measure the health beliefs of individuals with diabetes. Indeed, it would not be possible to determine the relationships between the variables if researchers are to test the HBM as originally conceived. Furthermore, Davis, Hess, Harrison and Hiss (1987) have noted that the psychological responses of patients to their disorder will differ according to disease type and treatment mode, indicating that scale development from the responses of a mixed sample may have produced unrepresentative dimensions of beliefs.

Harris, Skyler, Linn, Pollack and Tewksbury (1982) reported the use of a diabetes-specific measure based on the HBM, although a report regarding the reliability and validity of a modified version of the scale was not published until much later (Harris, Linn, Skyler & Sandifer, 1987). In the 1982 study, Harris and colleagues described the use of a 71-item health beliefs questionnaire adapted from an instrument used to evaluate the beliefs of patients requiring haemodialysis (Hartman and Becker, 1978). The sample studied consisted of 50 men with Type II diabetes (including some who were insulin-treated). Categories of measurement included motivations, perceived threats, perceived benefits, and perceived barriers. Behavioural and physiological indices of adherence were used in this study. Behavioural measures consisted of a nurse's scored assessment of the patients' reported adherence to medication use, diet, urine testing, exercise and foot care. Physiological measures included glycosylated haemoglobin (effectively an average measure of blood glucose control over the previous 6-8 weeks), fasting plasma glucose, fasting triglycerides, and urine glucose; all rated on a scale of 1 (good control) to 4 (poor control). When reporting the results of correlations between the health belief measures and indices of adherence to treatment, it is apparent that only six of the original 71 items are used to demonstrate relationships with the behavioural adherence measures, and five items are used to demonstrate relationships with physiological indices. In the former case, no associations are reported for items representing the perceived severity dimension and in the latter case, no relationships are reported for items concerning perceived barriers. Results from correlations with the remaining health belief items or possible representative scales are not mentioned at all. Attempts to correlate such a large number of single items with the outcome variables also raises the doubt that the significant results reported may have occured by chance. Table 1.2 and Table 1.3 summarize the results of the reported correlations between health belief items and indices of treatment adherence. It can be seen that while there are significant correlations between individual items and the outcome measures, it is not

Table 1.2: Correlations between health belief items and and behavioural measures of adherence. (reproduced from Harris and colleagues, 1982)

Health belief items	Medication use	Dietary compliance	Exercise	Composite scale (weighted average)
Benefits of Treatment				
Believe physician can help with eye disease			0.41**	
Believe physician can help with nerve disease		0.33*		
Cues to action				
More extreme sweating to seek medical help	0.45**			0.31*
Frequency of low blood sugar symptoms		-0.32*		
Perceived susceptibility				
Feel susceptible to having a shorter life		-0.34*		
Psychological barriers				
Feel or imagine painful injections	-0.33*			

* $p<0.05$ ** $p<0.01$

Table 1.3: Correlations between health beliefs and physiological indices of adherence. (reproduced from Harris and colleagues, 1982)

Health belief items	glycosylated haemoglobin	fasting plasma glucose	urine glucose	composite score
Benefits of treatment				
Believe physician can help with reduced life expectancy				-0.35*
Believe physician can help with kidney disease				-0.34*
Perceived susceptibility				
Feel susceptible to amputation	0.36*		0.30*	
Feel susceptible to disease of nerves	0.31*			
Perceived severity				
Disease of nerves would interfere with daily life		-0.31*		

* $p<0.05$

obvious why there should be a relationship between one outcome variable and not another. An example is the item "Believe physician can help with eye damage"; this item is significantly related to greater exercise adherence but not to medication use or adherence to diet. Moreover, believing that a physician can help with eye damage does not seem to correspond with decisions about whether or not to exercise regularly. The face validity of some of the items is also questionable. Harris and colleagues deliberate at length about the reasons for various results, some of which are contrary to expectations. However, this is largely a waste of effort given that individual items were evaluated. This study was commended by Janz and Becker (1984) as "Perhaps the most comprehensive exploration of the role of HBM variables in diabetes-regimen compliance ..." Given the problems described above, however, it is questionable whether this study makes any valuable contribution to health belief research.

A further study reported by Harris, Linn and Pollack (1984) described the use of the Diabetes Health Belief Scale (DHBS) but this was not fully described and no data were presented concerning the instrument's reliability and validity. Elements of the DHBS included general health motivation, "treatment beneficial", perceived severity, perceived susceptibility, psychological barriers, cues to action, and "structural elements" relating to the patient's understanding and family support for the treatment regimen. In this study, the DHBS is correlated with Rotter's (1966) Locus of Control scale, the Health Locus of Control Scale (Wallston, Wallston, Kaplan & Maides, 1976), Hopkins Symptom Checklist (HSCL) (Derogatis, Lipman, Rickels, Uhlenhuth & Covi, 1974), Rosenberg's (1965) Self-Esteem Scale, and the evaluative factor of the Semantic Differential scale (Osgood, Suci & Tannenbaum, 1957) which was used to assess attitudes towards diabetes, doctor and medical care. The rationale for this study was "to understand more precisely the origins of such beliefs and the conditions under which they are acquired". However, because of the correlational nature of this study the direction of cause and effect is impossible to determine. Once again the sample studied consisted of men only with Type II diabetes treated with diet only or additionally with tablets or insulin. Results of the correlations are summarized in Table 1.4. Harris and colleagues found several significant associations with the obsessive-compulsive factor from the HSCL which indicated that more obsessive-compulsive individuals perceived greater benefits of treatment, felt that there were more barriers to treatment, and perceived greater severity and vulnerability to complications. However, Harris and colleagues did not consider that responses to the obsessive-compulsive scale are not necessarily an indication of these characteristics but a reflection of the vigilance and regulation of lifestyle which is often required to adhere to a treatment regimen for diabetes. Similarly, the items in many scales to measure affect such as the Hopkins Symptom Checklist, include somatic symptoms which are confounded with diabetic

Table 1.4: Correlations of health belief and psychological variables. (based on Harris and colleagues, 1984)

	General health motivn	Treatment beneficial	Severity	Suscep-tibility	Psychol. barriers	Cues to action	Struc-tural elements
Health locus of control			-0.21*	-0.26*			-0.26*
Hopkins Symptom Checklist:							
Depression	0.22*			0.25*			
Somatization				0.45**			0.26*
Internal sensitivity					0.23*		
Obsessive-compulsive		0.28**	0.27*	0.39**	0.36**		
Anxiety				0.35**	0.26*		
Self-esteem		-0.27*		-0.25*			
Semantic Differentials							
Diabetes			0.24*	0.35*	0.26*		
Doctor		-0.32**					
Medical care		-0.33**					

* $p<0.05$ ** $p<0.01$

Health Locus of Control scored so higher number indicates a more internal orientation.
HSCL scored so higher number means more of a factor.
Self-esteem and Semantic Differential scored so higher number is less positive.

symptomatology (Bradley & Lewis, 1990). For this reason, the correlations between these variables and health beliefs may be misleading. Indeed, it can be argued that the HSCL is not a valid instrument when used with a diabetic population. Given the atypical sample studied, the mixed nature of the treatment regimens involved, and the unsubstantiated reliability and validity of the DHBS, further research is necessary to determine the reproducibility of the findings.

Harris, Linn, Skyler and Sandifer (1987) eventually published a paper reporting the psychometric development of a 38-item DHBS which is a modified version of the 40-item DHBS used in the earlier study (Harris and colleagues, 1984) with a different scoring system. The nature of the previous scoring system was never described. The scale was developed from the responses of 280 men with Type I (23%) and Type II diabetes (77%). Over half (68%) of the Type II patients were treated with insulin. Again, therefore, the sample is atypical and responses are related to more than one disease type and treatment regimen. The final items produced from the factor analysis accounted for a total of 44.4% of the variance and consisted of seven factors with the same labels described earlier (see Table 1.5). Validity of the scale was assessed from the responses of a sub-set of 120 subjects by relating the DHBS to both behavioural and physiological indices in separate stepwise multiple regression analyses. A total of 18% of the variance in treatment adherence, as measured by behavioural indices, was explained by the seven sub-scales. In this analysis, the majority of the variance was explained by psychological barriers (6%), structural elements (5%) and perceived susceptibility (3%). The second analysis showed that a total of 23% of the variance in physiological control was accounted for, with the majority of this variance explained by perceived severity (6%), "treatment beneficial" (6%) and perceived susceptibility (5%). [Contrary to predictions, better metabolic control was associated with lower perceived susceptibility.] Thus the behavioural and physiological indices of adherence had different patterns of health belief predictors; probably due to the behavioural measure of adherence being obtained from less reliable self-reports. This is one of the first diabetes-related studies which has used health belief variables to predict physiological control, so it is interesting to note that a comparatively greater percentage of the variance in this measure was explained. Although Harris and colleagues set out to test the model as a whole, the use of multiple regression to analyse the data assumes that the various components of the

HBM combine additively and are related in a linear fashion to outcome variables. Furthermore, although it is argued that cues to action and structural variables influence health outcomes through an individual's beliefs Harris and colleagues have included these in the analyses as direct predictors of health outcomes. This approach is typical of the lack of consideration given by research groups to the relationships between HBM dimensions when analyzing the data. In addition to the limitations of the atypical and heterogeneous sample used to develop the DHBS, another criticism concerns the face validity of some of the individual items. For example, the question "How much do you feel your doctor can help if you develop/have kidney disease?" is classed as a "treatment beneficial" item; however, it seems to be measuring patient perceptions about the doctor's control over complications rather than perceived benefits of following a treatment regimen. Interpretation of the findings in this study are therefore hampered by misleading scale labels.

An earlier response to the lack of adequately developed scales to measure HBM dimensions in a diabetic population was published by Bradley, Brewin, Gamsu and Moses (1984). Measures of perceived control specific to diabetes were also designed and developed. These scales were developed from the responses of 286 Type I patients (146 men and 140 women) aged between 16 and 59. The health belief scales measured perceived benefits of, and barriers to treatment, and perceived severity of, and vulnerability to (a) complications of diabetes and (b) disorders not specifically related to diabetes. The usefulness of the scales in understanding individual differences in treatment choice and perceived efficacy of treatment were examined in a feasibility study of CSII (Bradley and colleagues, 1987). Patients choosing conventional insulin therapy (CT), an intensified conventional therapy (ICT) and continuous subcutaneous insulin infusion (CSII) pumps were compared on all of the measures. The Perceived Severity and Perceived Vulnerability scores were not significantly different for any of the comparisons. However, it was found that patients choosing CSII for future treatment believed their current treatment was less "cost-effective" (benefits less barriers) than patients choosing CT. Although the HBM would predict that feelings of vulnerability to severe complications would intensify preventive health care behaviour, and higher Vulnerability and Severity scores would be associated with choosing one of the intensified treatments these relationships were not found. They did find, however, that patients who chose CSII treatment and felt more vulnerable to hyperglycaemic coma were significantly more likely to develop diabetic ketoacidosis when using this form of therapy (Bradley and colleagues, 1986). Nevertheless, Bradley and colleagues (1987) expressed dissatisfaction with the Severity and Vulnerability measures because of problems in interpretation. A low vulnerability score, for example, may indicate that a person may be ignorant of, underestimating, or denying the risks of complications, but it may also be that, while aware of the *general* risks, *personally* they may feel less vulnerable because of their efforts to reduce the risk by improving their diabetes control. The Severity and Vulnerability measures were also criticised because they did not take into account that some respondents already had one or more of the complications. The study in Chapter 2 describes the development of scales to measure health beliefs in tablet-treated Type II patients. These scales were adapted from the measures designed by Bradley and colleagues but the design of the new perceived severity and vulnerability questionnaires was radically altered in response to the problems just described. Although this research team combined the perceived benefits and barriers scales to produce a measure of perceived "cost-effectiveness" of treatment, it is disappointing that they did not attempt to combine the perceived vulnerability and severity scales in this study. This is likely to have reduced the chances of revealing meaningful relationships between these measures and other variables.

Sjoberg, Carlson, Rosenqvist and Ostman (1988) used the scales designed by Bradley and colleagues (1984) to study Type I patients with and without endogenous insulin secretion. They reasoned that because patients with some endogenous insulin secretion should find it easier to control their blood glucose levels, they would perceive fewer treatment barriers, greater treatment benefits, and feel that complications are less severe and less likely to occur to them, when compared to non-excretors. The results indicated that there were no significant differences between the two groups in perceived benefits and barriers. However, in comparisons of scores for individual complications, it was found that insulin-secretors perceived themselves to be significantly less vulnerable to kidney problems than non-secretors. No attempt was made to compare overall vulnerability and severity beliefs. Correlations between measures of glycosylated haemoglobin (HbA_{1c}) and the health belief measures indicated that for insulin-secretors, better metabolic control was significantly related to greater perceived vulnerability to complications. For non-secretors, however, better metabolic control was associated with greater perceived barriers to treatment. Although this latter result is contrary to HBM predictions, Sjoberg and colleagues reasoned that these patients perceived more barriers in their efforts to obtain lower blood glucose levels because they had to impose greater restrictions on their lifestyle. This study indicates, therefore, how the health belief patterns of different groups of patients may vary as a result of their physiological status.

Brownlee-Duffeck, Peterson, Simonds, and colleagues (1987) reported the use of yet another diabetes-specific health beliefs instrument in order to predict behavioural and physiological indices of treatment adherence. The behavioural and physiological outcome data were, however, collected retrospectively. The subjects were insulin-dependent patients drawn from two centres producing predominantly younger and predominently older samples respectively. Data obtained from these sample groups were therefore analyzed separately as well as in combination. Multiple regression analyses indicated that the amount of variance in glycosylated haemoglobin accounted for by the HBM measures was 20% for the younger sample, 19% for the older sample, and 16% for the samples combined. For indices of behavioural adherence (self-reports), the health belief measures accounted for much larger percentages of the variance (52% in the younger sample, 41% in the older sample, and 40% in the combined sample), indicating that the health beliefs were probably a reflection of the respondents' perceived adequacy of their adherence behaviours. These findings also suggest that health beliefs vary according to age, indicating the need to study more specific populations of subjects in health beliefs research. As in the study by Harris and colleagues (1987), the pattern of health beliefs predicting behavioural outcomes differed from the pattern of health beliefs predicting physiological outcomes although they were more similar for the older sample than the younger sample. Support for the specific HBM predictions was mixed with, on the one hand, greater perceived severity, fewer perceived barriers and greater perceived benefits being associated with better metabolic control and reports of greater adherence, while on the other hand, greater perceived susceptibility to complications was associated with poorer metabolic control. The subscales of the Diabetes Health Belief Questionnaire (DHBQ) were conceptually rather than empirically derived. Internal reliability coefficients reported were moderate to high with the exception of "cues to action" (Cronbach's alpha = 0.10). The items in the measure were not described in this paper but assessment of face validity was possible on inspection of the questionnaire obtained from the authors. Face validity of the items appeared to be good but the method of measuring perceived vulnerability to complications of diabetes was unusual. In this case, perceived susceptibility was assessed by asking patients to estimate their chances of having a particular problem in percentage terms. Percentage estimates were assessed on a five-point scale from 1-19% chance to 80-99% chance. In addition, respondents were asked to rate (i) how much of their estimate was based on how well they adhered to treatment recommendations, and (ii) how much of their estimate was based on the disease regardless of how much they adhered to their treatment, on a scale from 1 (none of my estimate) to 5 (almost all of my estimate). Asking patients to rate their susceptibility in percentage terms may have produced inaccurate responses from individuals who had difficulty conceptualizing the risks in this manner. Moreover, some patients may have experienced difficulty in differentiating between the different bases for their estimate due to lack of knowledge about the disease and the actual risks involved. Brownlee-Duffeck and colleagues did not report how the responses from the vulnerability scales were combined nor did they comment on the information gained from measuring perceived vulnerability in this manner. An indication of this research group's dissatisfaction with the DHBQ is that they have designed a revised questionnaire (not yet published) which does not ask for information about the bases for risk appraisal and has a new scoring system.

With a view to producing a needs assessment instrument specifically for people with diabetes, Davis, Hess, Harrison and Hiss (1987) designed the Diabetes Educational Profile (DEP). The theoretical basis for the DEP is largely that of the HBM but the instrument also measures variables external to the model. Sub-scales of the DEP were labelled Control Problems, Social Problems, Barriers to Adherence, Benefits of Adherence, Regimen Complexity, and Risk of Complications. The Social Problems sub-scale consisted of items which could also be classed as perceived barriers to treatment. The instrument was developed initially from the responses of 201 patients whose disease and regimen types were not described (Hess, Davis & Van Harrison, 1986). Later validation of the scales (Davis and colleagues, 1987) was conducted on the responses of 56 Type I patients, 191 Type II patients treated with diet or additionally with tablets, and 181 Type II patients treated with diet and insulin. The DEP scores were correlated with measures of glycosylated haemoglobin and percentage ideal weight collected retrospectively for each patient group separately. Focussing on the HBM variables, the results indicated that for Type I patients, more Social Problems (largely perceived barriers to treatment) were significantly associated with poorer blood glucose control (HbA_1). For non-insulin treated Type II patients, however, more Social Problems and greater perceived Barriers to Adherence were significantly associated with percentage ideal body weight. These results therefore indicate once again the eminence of perceived barriers in predicting (or reflecting) health outcomes. The particular health outcomes associated with perceived barriers in this study are largely a reflection of their importance for individuals with different types of treatment regimen.

An interesting study which focused on perceived barriers to treatment was reported by Glasgow, McCaul & Schafer (1986). A 15-item questionnaire was constructed from a pool of items contributed by six Type I patients and two nurse educators. No attempt was made, however, to assess psychometrically the structure or internal reliability of the responses of the 65 Type I patients studied. Adherence measures collected were based on the one hand on retrospective self-reports, and on the other hand on prospective patient self-reported records of insulin injections, blood glucose testing and frequency of exercise; plus 24-hour dietary recall. Correlations between the Barriers scores and adherence measures were computed concurrently at both the initial and 6-month follow-up stages, and also prospectively using initial scores to predict adherence at the 6-month follow-up. Although more perceived barriers were associated with poorer adherence to treatment both concurrently and prospectively, this association was much stronger for the concurrent correlations at the 6-month assessment. The prospective correlations were not greatly different from the concurrent correlations at the initial assessment. Although Glasgow and colleagues do not attempt to explain these findings it seems likely that the stronger concurrent correlations at 6 months may be due to subjects' perceptions about barriers to treatment changing as a result of taking part in the study. These people had just completed a 6-month period of self-monitoring in all aspects of the treatment regimen so will have been greatly sensitized to how they felt in relation to their degree of success in managing their diabetes. This study therefore highlights the need for more prospective data collection in research concerning diabetes in order to explore the dynamics of health beliefs in relation to outcomes.

Locus of Control, Perceived Control, Self-efficacy and diabetes

Most of the studies which have measured locus of control (LOC) expectations in a diabetic sample have employed Rotter's general internal-external scale, the Health Locus of Control (HLC) Scale (Wallston, Wallston, Kaplan & Maides, 1976) or the Multidimensional Health Locus of Control (MHLC) Scale (Wallston, Wallston & DeVellis, 1978). However, the results of these studies provide a confusing picture of LOC beliefs in relation to diabetes. It has been argued by Bradley and colleagues (1990) that the inconsistent or non-significant results produced by these studies may be attributable to the non-specific nature of the LOC scales employed. The use of scales designed specifically for diabetes has undoubtedly produced consistent results which are also in accordance with predictions of the underlying theory.

One of the first studies to examine locus of control expectations in diabetic patients was carried out by Lowery and DuCette (1976). They used Rotter's scale to measure LOC orientation in 90 black diabetic patients. The results from the LOC measure were assessed in relation to scores from a Diabetes and Health Information Test on the one hand, and the number of episodes of physiological problems (hyper/hypoglycaemia and infections), weight gain, and missed appointments on the other. In accordance with predictions, Lowery and DuCette found that internal subjects were more active seekers of information and were more knowledgeable than external subjects. However, this superiority diminished with duration of diabetes to a point where no significant differences between internals and externals were apparent. They also found that although internals initially had fewer problems than externals, contrary to predictions, this position was reversed in a group who had experienced diabetes for longer. Another study which produced results contrary to the predictions of LOC theory was that carried out by Edelstein and Linn (1987). Once again, Rotter's internal-external scale was employed. Subjects consisted of 120 men with insulin-requiring diabetes and an average age of 51 years. LOC was assessed in relation to fasting blood glucose levels, HbA_1, triglyceride and cholesterol levels which were combined in a single measure of diabetes control. Multiple regression analyses indicated that externally-oriented men had significantly better control than internally-oriented men, however the amount of variance predicted amounted to only 12% despite the inclusion of two covariates.

As mentioned earlier, Alogna (1980) used the HLC scale to assess whether her "compliant" and "non-compliant" subjects differed in their control expectations. She found that although there was no significant difference between the groups in locus of control, there was a trend towards internality in the "compliant" group. Schlenk and Hart (1984) used the MHLC scale to predict adherence to treatment along with measures of social support and health value in Type I patients. Although no measure of physiological control was obtained, they found that greater scores on the internality and powerful others scales predicted the performance of self-management behaviours. In another study by Peyrot and McMurry (1985) use of the MHLC revealed that greater internality was significantly associated with better blood glucose control (represented by glycosylated haemoglobin). Use of the more health-specific LOC scales have therefore provided results more in line with the predictions of the underlying theory but research in other health areas using these scales has also produced inconsistent and confusing results (Wallston, Wallston, Smith & Dobbin, 1987).

The need for more specific LOC scales was acknowledged by Bradley and colleagues who designed and developed the diabetes specific perceived control scales referred to earlier (Bradley, Brewin, Gamsu & Moses, 1984; Bradley, Lewis, Jennings & Ward, 1990). The scales published in 1984 were developed for use with insulin-requiring patients, while the scales published in 1990 were for tablet-treated patients. Both sets of scales have produced comparable results which are in accordance with predictions of the underlying theory when related to outcome variables. In particular, the scales for insulin-users were successful in predicting treatment choice and efficacy in a feasibility study of continuous subcutaneous insulin infusion (CSII) pumps (Bradley, Gamsu, Moses, Knight, Boulton, Drury & Ward, 1987) and the incidence of ketoacidosis in CSII pump users (Bradley, Gamsu, Knight, Boulton & Ward, 1986) while the scales for tablet-treated individuals were successful in predicting HbA_1, percent ideal body weight, psychological well-being, and treatment satisfaction. The Wallstons' speculated LOC typology (see p.12) was also successfully tested and confirmed using the scales for tablet-treated patients.

Ferraro, Price, Desmond and Roberts (1987) have also designed and developed a LOC scale specific to diabetes but it is not clear whether responses to the instrument were obtained from Type I or Type II patients. Furthermore, discriminant validity was not assessed in this study and no subsequent validity data has been published so the utility of the scales has not yet been established. However, the individual items of the instrument (which is modelled on the MHLC) seem to have good face validity. The instrument seems to have been designed for use with both Type I and Type II patients as none of the items refer to specific treatments. It remains to be seen whether this more general instrument is as efficient as the scales developed for specific diabetic populations.

One of the explanations for the success of the scales developed by Bradley and colleagues may be that these instruments also elicit beliefs about self-efficacy expectations when positive outcomes are considered (see p.14). The value of self-efficacy measurement in predicting outcomes related to diabetes has only recently been recognised and this is reflected in the small number of studies which have been published. One of the first studies to include a diabetes-specific measure of self-efficacy was carried out by Grossman, Brink & Hauser (1987). Their Self-efficacy for Diabetes Scale was devised for use with adolescents and consisted of items which assessed subjects' confidence in their abilities to perform various regimen behaviours. It was successful in predicting metabolic control but the correlation was not particularly strong and reliability and validity data on the scale were not reported. In the same year another study was published by McCaul, Glasgow and Schafer (1987) which reported the use of a 24-item diabetes self-efficacy measure. Once again, the instrument assessed respondents' confidence in their ability to perform diabetes regimen behaviours. No indication was given that the measure had been psychometrically developed but the authors found that it was the most consistent, and one of the most powerful predictors of adherence to treatment in both adults and adolescents treated with insulin. Apart from the perceived control scales by Bradley and colleagues, therefore, there have been no psychometrically developed diabetes-specific measures of self-efficacy published to date.

Conclusions

The research studies which have used HBM dimensions in order to understand health outcomes have many problems which prevent clear and reliable conclusions about their results. Studies about diabetes-related health beliefs have proved to be no exception to this rule. Although interesting insights have been gained about the nature of particular beliefs and their relationships with health outcomes, much needs to be done to improve this research to obtain a clearer picture of the efficacy of the HBM.

Major obstacles to reliable research findings have been:

1. The lack of satisfactory scales to measure diabetes-related health beliefs. Although attempts have been made to produce different research instruments, all of them have deficiencies of some kind which affect interpretation of their results.

2. Heterogeneous samples of patients with different disease and regimen types have often been studied together. It is now recognized that the nature of the different types of diabetes will differentially affect patterns of health beliefs and different patient samples should therefore be studied separately.

3. With few exceptions, most of the studies attempting to predict adherence to treatment regimens from health belief measures have collected the outcome data retrospectively. In order to determine the direction of the relationship between health beliefs and health outcomes, prospective studies are required. Studies of interventions would also help to determine the direction of these relationships.

4. A problem which applies to all HBM research is that the relationships between the various dimensions have not been determined. The original formulation suggested a multiplicative relationship between certain components but this hypothesis remains to be tested.

5. The various dimensions of the HBM have been successful in accounting for only a moderate amount of variance in health behaviours. Although this may be due to the various problems described earlier, certain key elements may be missing from the model. The relationship between the HBM and concepts such as locus of control and self-efficacy need to be explored further in order to establish whether these may usefully extend the model.

The aim of the research described in the following chapters is to address the above problems. Scales to measure diabetes-specific health beliefs in a specific population of individuals with diabetes have been developed. These scales are used to explore the relationships between the HBM dimensions in retrospective and prospective studies. An attempt is also made to understand the effects of various interventions on these beliefs. Finally, a measure of perceived control of diabetes, which incorporates elements of locus of control and self-efficacy, is studied in relation to the HBM.

CHAPTER TWO

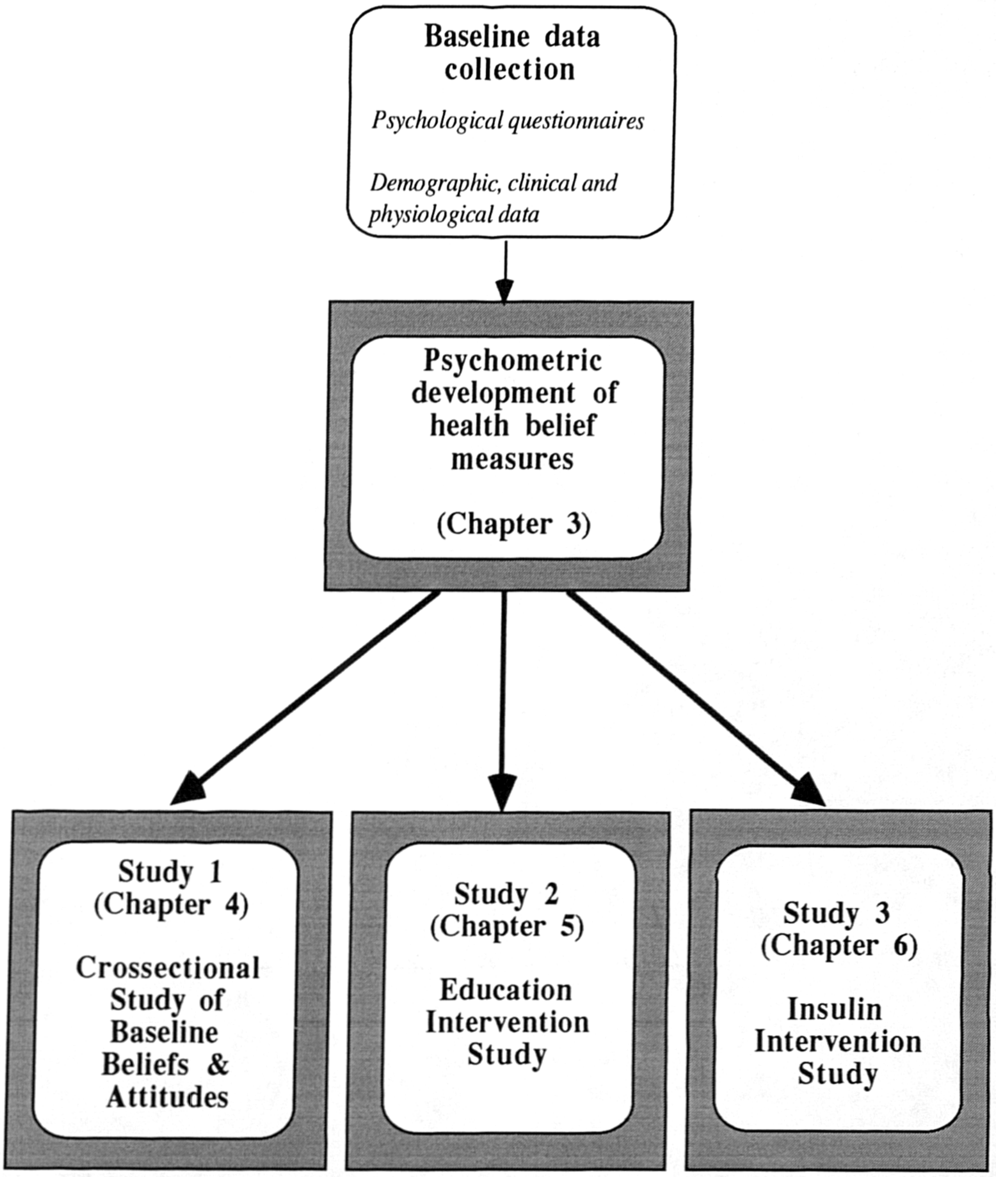
BASELINE STUDY DESIGN AND METHODOLOGY

Psychological, clinical, physiological, and demographic data were collected at baseline, in a study of people with tablet-treated Type II diabetes, for the purposes of developing diabetes-specific health belief and perceived control scales and assessing beliefs and attitudes before educational and treatment interventions. Patients from this sample were approached for inclusion in subsequent intervention studies which involved the use of several of the baseline clinical and demographic measures and the previously developed psychological scales. Because the studies have subjects and variables drawn from the same baseline, therefore, the whole of this chapter is devoted to a description of the design and methodology in order to avoid repetition in later chapters. Figure 2.1 provides an overview of the research studies reported in the present thesis.

Overall Research Strategy

In collaboration with Clare Bradley, health psychologist, John Ward, consultant physician, and Adrian Jennings, research fellow, research studies were planned with two main aims:

1. The diabetologists aimed to study the efficacy of a limited period of insulin treatment in patients whose diabetes could not be optimally controlled by diet and oral hypoglycaemic agents but for whom insulin would not have normally been indicated. Details of the rationale and main hypotheses for this



A questionnaire booklet was administered in the baseline and intervention studies and included measures of Health Beliefs, Perceived Control of Diabetes, Well-being, and Treatment Satisfaction. A general information questionnaire was also included and additional demographic, clinical and metabolic data were provided by the physicians.

Figure 2.1: An Overview of the Research Studies

study are presented in Chapter 6. In order to select subjects, an initial screening of the overall population of tablet-treated patients attending the hospital was necessary. Health status and degree of diabetes control were to be assessed and suitable patients could then be approached for the insulin intervention study. Patients whose diabetes was satisfactorily controlled or potentially controllable with diet and tablets were to be offered the opportunity to attend one of a series of diabetes education days.

2. The clinical research presented the opportunity for psychological studies of the beliefs and attitudes of a specific population of diabetic patients before and after the planned interventions. At the time of initial screening, psychological data could be collected for the purposes of developing diabetes-specific scales and to assess beliefs and attitudes in a crossectional manner. Longitudinal research was also possible with the subsequent collection of similar data at the various stages of the intervention studies.

Methods

Subjects

During an 18 month period, patients aged between 40 and 65 years with tablet-treated Type II diabetes and attending routine appointments in two clinics at the Royal Hallamshire Hospital, Sheffield, were approached for inclusion in the baseline screening study. Invitation to join the study was by letter (see Appendix 1) which was distributed to 239 patients (141 men and 98 women). Those who were blind or partially-sighted were not included. Two hundred and nineteen (92%) patients (130 men and 89 women) agreed to take part and attended an individual screening consultation with one of the physicians (AJ). There were no significant differences between participants and those who refused to take part for any of the available measures, including sex, age, duration of diabetes, and glycosylated haemoglobin levels. At the end of the consultation, the diabetologist gave each participant a booklet of questionnaires (see Appendix 2) to complete at home. Patients were asked to return the completed booklet, in confidence, direct to the present author. Anyone who did not respond within 1 month of their appointment received a reminder and invitation to contact the author if they had any difficulty in completing the questionnaires. (A total of 41 reminders were sent out.) One hundred and eighty-seven (85%) patients (110 men, 77 women) returned completed booklets of questionnaires. This final sample provided data for the baseline study. There were no significant differences between responders and non-responders to the questionnaires in sex, age, duration of diabetes, glycosylated haemoglobin levels, or percent ideal body weight.

Procedure

All patients who agreed to take part in the study attended the hospital for an individual consultation with one of the physicians (AJ). At this consultation, the physiological health status of participants was assessed in relation to their diabetes and its control through physical examination, laboratory investigations, and interview. Some of these data were used in subsequent statistical analyses with psychological measures, and included

Percent ideal body weight:

This is the ratio of actual weight to ideal body weight for height as given in the Metropolitan Life Insurance Tables (1959). The mean percentage of ideal body weight for the general population between the ages of 25 and 65 is 112% for men and 116% for women (Multi-centre Study, 1988). In the Sheffield study, obesity was defined as greater than 120% ideal body weight (Jennings, Spencer, Dean, Wilson, Bottazzo & Ward, 1989)

Glycosylated haemoglobin (HbA_1):

This gives an indication of the amount of glucose circulating in the bloodstream in the 6-8 weeks prior to assay. The most usual fraction of haemoglobin to be measured is A_1 leading to the abbreviation by which the test is generally recognised: HbA_1 (Shillitoe, 1988). The normal range of the Royal Hallamshire Hospital assay was 29.0 to 39.0 mmol HMF. Poor glycaemic control was defined by the physicians who collaborated in the Sheffield study to be greater than 55 mmol HMF.

Presence of diabetic complications:

All patients attending the consultation were screened for the recognized complications of diabetes. These were heart disease, history of stroke, kidney disease (nephropathy), hypertension, peripheral neuropathy, impotence, eye disease (cataract, retinopathy, maculopathy), present and past foot ulcers and amputations.

The booklet of psychological questionnaires contained the following:

1 .General Information Questionnaire:

Information was requested about age, sex, weight, height, age at leaving full-time education, average daily intake of carbohydrate, duration of diabetes, type of glucose testing (i.e. blood or urine tests), if and how the treatment regimen was adjusted by the patient on the basis of blood or urine testing, the patient's general impression of how well the respondent's diabetes had been controlled over the past few weeks [rated on a seven-point scale from 1 (very well controlled) to 7 (very poorly controlled)], duration of present treatment, and dose frequency of oral hypoglycaemic agents.

2 .Psychological Well-being:

Investigations of psychological well-being of people with general medical disorders have typically used assessment instruments developed for use with psychiatric or general populations (Friis & Nanjundappa, 1986; Derogatis, 1986; Wilkinson, Borsey, Leslie, Newton, Lind & Ballinger, 1988). The problem with using such instruments is that somatic symptoms of depression and anxiety are usually included in these measures and are often similar to the somatic symptoms of illnesses such as diabetes and cancer (Plumb & Holland, 1977; Lustman, Amado H & Wetzel RD, 1983; Lustman & Harper, 1987). The commonly used Beck Depression Inventory, for example, includes items concerning tiredness, loss of appetite, loss of libido, and weight loss. However these symptoms are also typical of hyperglycaemia, hypoglycaemia, chronic complications of diabetes, and the advanced stages of acute illnesses such as cancer. Psychological well-being measures designed for patients with a physical disorder therefore need to be particularly sensitive to the more cognitive symptoms and to minimize as far as possible the inclusion of somatic symptoms. The choice of items in the psychological well-being measure included in the present research was therefore guided by these considerations.

The original version of the well-being measure was put together for a WHO multi-centre European study of continuous subcutaneous insulin infusion (CSII) pumps and was constructed in order to measure depression, anxiety, and positive well-being. The depression and anxiety scales were taken from a measure already developed by Warr and colleagues on another population (Warr, Banks & Ullah, 1985) while the positive well-being items were newly put together by Clare Bradley (now at University of London). In the present study, respondents rated a four-point scale from 3 (all the time) to 0 (not at all) to indicate how often they felt each statement applied to them in the past few weeks. Psychometric analyses were necessary in order to ensure that the final instrument met criteria for reliability and validity for the population studied and to select final positive well-being items from the initial pool of sixteen. Internal reliability of the scales was found to be satisfactory (Cronbach Alpha = 0.70 for Depression scale; 0.80 for Anxiety scale; 0.88 for Positive Well-being scale) and construct validity was demonstrated by predicted correlations with metabolic outcome variables and the other psychological measures. A full description of the psychometric development of the Well-being scales is reported elsewhere (Bradley & Lewis, 1990). The developed scales (Figure 2.2) provided the data reported in the present thesis.

Figure 2.2: The Well-being Scales

Depression

I feel that I am useful and needed

I have crying spells or feel like it

I find I can think quite clearly

My life is pretty full

I feel downhearted and blue

I enjoy the things I do

Anxiety

I feel nervous and anxious

I feel afraid for no reason at all

I get upset easily or feel panicky

I feel like I'm falling apart and going to pieces

I feel calm and can sit still easily

I fall asleep easily and get a good night's rest

Positive Well-being

I have been happy, satisfied or pleased with my personal life

I have felt well adjusted to my life situation

I have lived the kind of life I wanted to

I have felt eager to tackle my daily tasks or make new decisions

I have felt I could easily handle or cope with any serious problem or major change in my life

My daily life has been full of things that were interesting to me

---

Respondents rated a four-point scale from 3 (all the time) to 0 (not at all) to indicate how often they felt each statement applied to them in the past few weeks. (See Appendix 2)

3. *Treatment Satisfaction*

The treatment satisfaction questionnaire was an adapted and extended version of a satisfaction measure designed for insulin-requiring patients (Lewis, Bradley, Knight, Boulton & Ward, 1988). Psychometric analyses of the responses to this questionnaire were necessary in order to select items for inclusion in the final scale and to assess reliability and validity. The final measure consisted of six items which provided a scale with satisfactory internal reliability (Cronbach Alpha = 0.79) and construct validity was indicated by predicted relationships with both psychological and metabolic outcome variables. In addition to the final scale, two items concerning hypo- and hyperglycaemia did not load in principal components analyses with the six scale items or with each other. However, because the incidence of hypo- and hyperglycaemia is likely to be important in the assessment of treatment satisfaction in certain contexts, they were included in the overall Treatment Satisfaction measure as separately scored items. A detailed description of the design and development of the measure is given by Bradley & Lewis, 1990. Responses relating to the final Treatment Satisfaction measure (Figure 2.3) provided the data reported in the present thesis.

Psychological well-being and treatment satisfaction were measured in order to obtain a baseline assessment before interventions, and were particularly relevant to the evaluation of treatment efficacy in the insulin intervention study which is reported elsewhere (Jennings, Lewis, Murdoch, Talbot, Bradley & Ward, 1991). In the present research, the well-being and treatment satisfaction measures were used in the assessment of construct validity of the health belief scales (see Chapter 3).

Figure 2.3:

The Treatment Satisfaction Scale and Individual Items

Items from the scale:

How satisfied are you with your current treatment?

How well controlled do you feel your diabetes has been recently?

How convenient have you been finding your treatment to be recently?

How flexible have you been finding your treatment to be recently?

How satisfied are you with your understanding of your diabetes?

How satisfied would you be to continue with your present form of treatment?

Individual items:

How often have you felt that your blood sugars have been unacceptably high recently?

How often have you felt that your blood sugars have been unacceptably low recently?

Respondents rated degree of Treatment Satisfaction on a seven-point scale. (See Appendix 2)

4. Perceived Control of Diabetes

The perceived control scales were adapted from a measure previously developed for use with insulin-requiring patients (Bradley, Brewin, Gamsu & Moses, 1984). Perceived control is a construct derived from attribution theory which is concerned with the way people attribute or explain their own and other's behaviour. In the context of health self-care, people's motivation to carry out a particular preventive health behaviour is likely to be influenced by past experience of a similar nature and their attributions for previous successful and unsuccessful outcomes. As discussed in Chapter 1, attributions about locus of control and self-efficacy have been shown to be important in understanding people's motivation to manage their diabetes. The Perceived Control of Diabetes measure used in the present research not only incorporates the notion of locus of control by eliciting respondents' attributions for outcome responsibility, but also assesses perceived self-efficacy because the instrument has been designed so that it measures responses to specific hypothesized outcomes.

The design of the perceived control of diabetes questionnaire was influenced by work on locus of control measurement (Rotter, 1966; Wallston, Wallston & DeVellis, 1978) and attributional style measurement (Peterson, Semel, Von Baeyer, Abramson, Metalsky & Seligman, 1982). The instrument measures Perceived Control for both positive and negative outcomes associated with diabetes management, since individuals may perceive more control over positive outcomes than negative outcomes, or vice-versa (Brewin & Shapiro, 1984; Gamsu & Bradley, 1987; Gillespie & Bradley, 1988). Furthermore, attribution about responsibility for positive outcomes also provides information about perceived self-efficacy (i.e. whether the respondent feels they can actually make the outcome happen in the first place). The instrument consists of descriptions of hypothetical events relevant to, or experienced by, people with tablet-treated diabetes (Figure 2.4) For each scenario, respondents were asked to imagine that they had recently experienced the outcome described and write down its most likely cause. This was then rated by the respondent on seven separate 7-point scales designed to measure attributions of causality labelled Internality, Treatment, Externality, Chance, Personal Control, Medical Control, and Foreseeability. Figure 2.5 illustrates an example of a page in the questionnaire which describes one of the hypothetical events and shows the format of the

Figure 2.4 Descriptions of hypothetical events

Positive outcomes

'Imagine that you have been able to keep your weight at an acceptable level for a period of several weeks and you have felt fit and well.'

'Imagine that you have successfully avoided the complications of diabetes such as problems with your feet.'

'Imagine that you have reduced your weight to a satisfactory level after a period when you gained too much weight.'

Negative outcomes

'Imagine that you have recently become unacceptably overweight.'

'Imagine that for several days you have found high levels of sugar when you tested your urine.'

N.B. The original questionnaire included an extra negative outcome ('Imagine that you are very thirsty and have passed unusually large amounts of urine recently'). This item elicited a significant number of responses unrelated to diabetes so it was removed from the final measure. (See Bradley, Lewis, Jennings & Ward (1990) for details.)

Figure 2.5: Illustrative item from the Perceived Control Scales

Imagine that for several days you have found high levels of sugar when you tested your urine.

Write down the single most likely cause of the high sugar levels in the space below.

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of the high sugar levels?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

attribution scales used for each item.

Psychometric analyses of the responses to the questionnaire produced three composite scales: Personal Control (consisting of the Internality, Personal Control, and Foreseeability scales), Medical Control (consisting of the Treatment and Medical Control scales), and Situational Control (consisting of the Externality and Chance scales). Internal reliability was found to be satisfactory for all three of these scales (Cronbach's Alpha = 0.70 to 0.91) and construct validity was indicated by predicted relationships with the metabolic outcomes and the other psychological measures. A full description of the development of the Perceived Control of Diabetes scales is given in Bradley, Lewis, Jennings & Ward (1990).

As mentioned in Chapter 1, Wallston and Wallston (1982) have offered a speculative typology (based on the MHLC scales) in an attempt to clarify the relationships between Locus of Control and health behaviour by looking at patterns of beliefs and their effects on outcomes. The various types identified by Wallston and Wallston are described in Table 2.1. It can be seen from this table that the MHLC instrument provides scores on three scales: Internality, Powerful Others, and Chance. The developed Perceived Control of Diabetes scales therefore mirror the MHLC scales quite well so it is feasible to apply the Wallstons' typology to them. Indeed, when this typology was tested during the psychometric evaluation of the Perceived Control of Diabetes scales, the pattern of scores provided support for the initial hypotheses (Bradley, Lewis, Jennings & Ward, 1990).

Table 2.1: Summary of Wallston and Wallston's typology and predicted consequences for diabetes management
(reproduced from Bradley, Lewis, Jennings & Ward, 1990)

Label	Scale scores			Predicted consequences for diabetes management
	Internality	Powerful Others	Chance	
Believers in Control	High	High	Low	Good use of personal resources and health service
'Pure' Internals	High	Low	Low	Good use of personal resources but may not recognize when these are inadequate
'Pure' Powerful Others Externals	Low	High	Low	Poor use of personal resources and unrealistic expectations of health service resources
'Pure' Chance Externals	Low	Low	High	Fatalistic: poor use of all resources
Double Externals	Low	High	High	Poor use of personal resources, unrealistic expectations of health service resources, and element of fatalism
Type VI	High	Low	High	The Wallstons suggested that this type would be non-existent or rare
Yea-sayers	High	High	High	Response bias? No clear predictions
Nay-sayers	Low	Low	Low	Response bias? No clear predictions

5. Diabetes-specific Health Beliefs

In accordance with the HBM, the scales were constructed to measure perceived benefits of, and barriers to treatment, and perceived severity of, and vulnerability to complications of diabetes. The design of the scales was an attempt to represent unambiguously the dimensions of the HBM in relation to a specific type of diabetes based on the experience of developing and interpreting findings from similar measures for insulin-users (Bradley, Brewin, Gamsu & Moses, 1984) .

The benefits of, and barriers to, treatment questionnaire initially consisted of 24 statements with which respondents agreed or disagreed on a seven-point scale from 0 (strongly disagree) to 6 (strongly agree). The original questionnaire is included in Appendix 2 and an example of the questionnaire format is provided in Figure 2.6. Because the HBM makes the prior assumption that health is important to the individual, two of the items were constructed in order to measure health value:

> Good diabetes control has to take second place to some other more important things in my life

> The benefits of good weight control and a healthy diet are much more important to me than the regular enjoyment of sugary and fatty foods.

The benefits and barriers statements were constructed or adapted from items used with insulin-requiring patients to make them relevant to respondents' views about themselves and tablet-treated diabetes.

Figure 2.6: Format of the Perceived Benefits and Barriers Questionnaire

HEALTH BELIEFS SCALE

In this section would you please circle one of the numbers on each of the scales to indicate how strongly you agree or disagree with each of the following statements.

On these scales 0 would indicate that you strongly disagree
1 = moderately disagree
2 = mildly disagree
3 = neither agree nor disagree
4 = mildly agree
5 = moderately agree
6 = strongly agree

	strongly disagree						strongly agree
1. Regular, controlled exercise helps in the management of my diabetes	0	1	2	3	4	5	6
2. By careful planning of diet and exercise, I can control my diabetes at least as well as most other people with diabetes	0	1	2	3	4	5	6
3. Controlling my diabetes well imposes restrictions on my whole lifestyle	0	1	2	3	4	5	6
4. Sticking to my diet makes eating out difficult	0	1	2	3	4	5	6
5. High blood sugars can be prevented if I plan ahead	0	1	2	3	4	5	6
6. I find it difficult to remember to take all my tablets at the times recommended by the doctor	0	1	2	3	4	5	6
7. It is important for me to visit the diabetic clinic regularly even in the absence of symptoms	0	1	2	3	4	5	6
8. The better my diabetes is controlled, the healthier I feel	0	1	2	3	4	5	6
9. It is just not possible to control my diabetes properly and live in a way that is acceptable to me	0	1	2	3	4	5	6
10. Testing urine is an unpleasant task to have to undertake	0	1	2	3	4	5	6
11. A well-balanced, healthy diet can be just as enjoyable as a diet which is rich in fat or sugar	0	1	2	3	4	5	6

/continued over

Perceived severity was measured by asking respondents to rate on a five-point scale from 0 (not serious at all) to 4 (extremely serious) the severity of various disorders if they were to develop them. Based on the experience of the perceived severity questionnaire designed for insulin-users, the items were made more specific than previously in order to avoid patients construing certain disorders in different ways Cancer, for eample, covers a multitude of different types and stages with differing prognoses whereas leukaemia is more specific in type and prognosis. Eight of the disorders were complications of diabetes (high blood pressure, blindness, kidney disease, aching legs, numbness in the feet, heart disease, failing eyesight, gangrene) and eight were not specifically related to diabetes (stomach ulcer, ear infection, leukaemia, gum disease, bronchitis, deafness, asthma, loss of hearing). In addition, two further items were included ('Your diabetes now' and 'Your diabetes in 10 years' time') which focused respondents' attention on the disorder of diabetes as a whole. The questionnaire was constructed so that if patients were unable to rate the seriousness of a problem because they did not know what the problem was, they could indicate this by ticking a box next to the disorder concerned. An example of the questionnaire format is given in Figure 2.7.

The list of disorders included in the perceived vulnerability questionnaire was the same as that used for the measurement of perceived severity. However, it was not sensible to include the two specific diabetes items in this questionnaire so they were substituted with a single item: 'Complications arising from diabetes'. Patients were asked to rate 'how likely you feel it is that you will develop the following problems' on a five-point scale from 0 (extremely unlikely) to 4 (extremely likely). If respondents thought they already had any of the problems listed, however, they could indicate this next to the disorder concerned. The measure of perceived vulnerability designed

Figure 2.7: Format of the Perceived Severity Questionnaire

BELIEFS ABOUT SEVERITY

On these scales 0 would indicate that the problem is not serious at all
1 = not serious enough to be worrying
2 = moderately serious
3 = very serious
4 = extremely serious

If you are unable to rate the seriousness of a problem because you are not sure what the problem is, please tick the box on the right-hand side.

	not serious at all				extremely serious	not sure what the problem is
1. High blood pressure	0	1	2	3	4	☐
2. Stomach ulcer	0	1	2	3	4	☐
3. Blindness	0	1	2	3	4	☐
4. Ear infection	0	1	2	3	4	☐
5. Kidney disease	0	1	2	3	4	☐
6. Aching legs	0	1	2	3	4	☐
7. Leukaemia (cancer of the blood)	0	1	2	3	4	☐
8. Your diabetes now	0	1	2	3	4	☐
9. Your diabetes in 10 years time	0	1	2	3	4	☐
10. Gum disease	0	1	2	3	4	☐
11. Bronchitis	0	1	2	3	4	☐
12. Deafness	0	1	2	3	4	☐
13. Numbness in the feet	0	1	2	3	4	☐
14. Heart disease	0	1	2	3	4	☐
15. Asthma	0	1	2	3	4	☐
16. Failing eyesight	0	1	2	3	4	☐
17. Loss of hearing	0	1	2	3	4	☐
18. Gangrene	0	1	2	3	4	☐

PLEASE MAKE SURE THAT YOU HAVE CIRCLED ONE NUMBER ON EACH OF THE 18 SCALES.

for insulin-users did not elicit this type of information which may explain why it was, on occasion, unsuccessful in predicting outcomes (Bradley, Gamsu, Moses, Knight, Boulton, Drury & Ward, 1987). Another problem with the previous measure, which the present measure took steps to deal with, was that while patients may be aware of the general risks of complications, these perceptions of vulnerability are mediated by what patients see as personal risk-reducing strategies. Such strategies might be the patient's efforts to improve blood glucose or weight control, or they may feel that because they have regular checks at the hospital this renders them less vulnerable. It is also possible that factors such as family history may make an individual feel more vulnerable to a particular disorder but s/he may be unaware that it is a complication of diabetes and so behaviour related to diabetes management may be unaffected. Factors such as this are likely to cause 'noise' in the data which will cloud any association between perceived risks of diabetes and behaviour relating to diabetes management and between perceived risks and clinical outcomes. The present measure was therefore designed so that respondents were also asked to rate the vulnerability of an 'average person with your kind of diabetes who is the same age, sex, follows the same kind of treatment, and has 'average control over his/her diabetes'. It was reasoned that ratings of an 'average person' would provide an estimate of vulnerability which is less influenced by mediating influences and 'noise' from other factors. The format of the questionnaire is illustrated in Figure 2.8.

The measures of perceived severity and vulnerability designed for insulin-requiring patients employed six-point scales. The present measures of perceived severity and vulnerability were redesigned to include five-point scales because of the similarity of two of the points on the previous scale and to create a mid-point. A full description of the development of all the health belief scales will be reported in Chapter 3.

BELIEFS ABOUT VULNERABILITY

In this section we are asking you to make two ratings for each of the problems listed.

First: Indicate how likely you feel it is that you will develop the following problems.

Second: Consider an average person with your kind of diabetes who is

- your age
- your sex
- follows the same kind of treatment as yourself
- has average control over his or her diabetes

On these scales 0 would indicate that you feel that you are extremely unlikely to develop the problem
1 = neither likely nor unlikely
2 = quite unlikely
3 = quite likely
4 = extremely likely

If you already have or think you may have any of these problems, please tick the box on the right-hand side.

	extremely unlikely				extremely likely	I already have this problem
1. **High blood pressure**						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
2. **Stomach ulcer**						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
3. **Blindness**						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
4. **Ear infection**						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	

/continued over

Statistical Analyses

A significance test for skewness was used to assess score distributions which compared the standard error for skewness with zero using the z distribution (Tabachnick & Fidell, 1989). The distributions of scores for the Well-being, Treatment Satisfaction, Perceived Control, and Perceived Benefits of Treatment scales were skewed, indicating the need for non-parametric statistical tests or data transformation when analysing these measures. Score distributions relating to Perceived Vulnerability satisfied the assumptions of parametric statistical tests. Details of the tests used in analyses of the various psychological measures will be given in the following chapters where appropriate.

CHAPTER THREE

PSYCHOMETRIC DEVELOPMENT OF THE HEALTH BELIEF SCALES

In order to explore the possible combinations of HBM variables in the baseline and intervention studies, it was necessary to develop first a HBM instrument that was reliable in terms of internal consistency and had evidence of validity. This chapter will describe the psychometric procedures used to select and test the diabetes-specific health belief scales for internal reliability and construct validity. Chapter 2 has already presented a description and rationale for the design of the scales together with details of the sample of patients who provided responses to the questionnaires.

Statistical Analyses

The structure of the perceived benefits of, and barriers to treatment measure was explored using a principal components factor analysis with varimax rotation (Harman, 1967). Reliability of all the scales was assessed using Cronbach's alpha coefficient of internal consistency (Cronbach, 1951). As mentioned in Chapter 2, the distributions of scores for the perceived benefits of treatment and perceived severity scales were skewed, indicating the need for non-parametric statistical tests in subsequent analyses of these measures. Between-scale comparisons were therefore explored using the Wilcoxon matched pairs signed ranks test and their relationships to other variables were examined using Spearman rank correlations. The distributions of the perceived vulnerability scores satisfied the assumptions of parametric tests, so between-scale comparisons were explored using Student's t -tests (paired scores), and relationships to other variables were examined using Pearson's correlation coefficient.

Structure of the Health Belief Measures

Perceived Benefits of, and Barriers to Treatment

Scores for all 24 of the benefits and barriers statements were submitted for factor analyses in order to determine the structure of patient responses to the questionnaire. It was predicted that three factors would emerge relating to perceived benefits, perceived barriers, and health value. However, an initial analysis produced six factors which could not be labelled in this way.

Although the benefits and barriers items loaded together in sensible patterns relating to diet, complications, etc., the two items constructed to measure health value did not load together. Forced three-factor and two factor solutions were sought, therefore, in order to determine whether health value would emerge as a separate factor in the three-factor solution and if not, whether the items would load with the predicted benefits and barriers factors in the two-factor solution. The results of these analyses indicated that one of the health value items ('The benefits of good weight control and a healthy diet are much more important to me than the regular enjoyment of sugary and fatty foods') was responded to as a perceived benefits item in both the three- and two-factor solutions. However, the remaining health value item ('Good diabetes control has to take second place to some other more important things in my life') did not load with any of the benefits or barriers items in either of the forced solutions. On the basis of these findings, the former health value item was not used in the final scales because it was not intended to measure perceived benefits. However, although future research should aim to produce a measure consisting of more than one item, it was considered possible that the remaining health value item may be usefully employed as a single measure when exploring the relationships between the HBM variables.

The forced two-factor solution provided distinct factors characterized by items with loadings >0.4 relating to perceived benefits and barriers, respectively. Eleven of the items loaded on the perceived barriers factor and nine loaded on the perceived benefits factor. Each of the items in the scales was examined for item-total correlations and items were dropped if they:

(a) inflated the reliability coefficient because of their similarity to other items,

(b) had the lowest item-total correlations,

(c) reduced internal reliability, or

(d) qualitatively, restricted the measure to a subgroup of patients such as those testing for urinary glucose rather than blood glucose.

An equal number of items in each scale was sought and thus the final perceived benefits and barriers scales comprised five items each. A confirmatory, unforced factor analysis was carried out on the responses to the final items which produced two factors comprising the benefits and barriers items separately (Table 3.1) and accounted for a total of 52% of the variance (30% and 22%, respectively). Data relating to the five perceived benefits and five perceived barriers items were summed to form scales labelled *Perceived Benefits of Treatment* and *Perceived Barriers to Treatment.* Following the example of Bradley and colleagues (1987) a measure of *Treatment 'Cost-effectiveness'* was also calculated by subtracting the Perceived Barriers score from the Perceived Benefits score for each individual.

Perceived Severity and Vulnerability

Scores relating to the eight complications items and eight disorders unrelated to diabetes (Table 3.2) were summed separately to form the following measures:

(a) Perceived Severity of Complications
(b) Perceived Severity of General Disorders
(c) Perceived Vulnerability to Complications
(d) Perceived Vulnerability to General Disorders
(e) Perceived Vulnerability of the Average Person to Complications
(f) Perceived Vulnerability of the Average Person to General Disorders

The scores relating to perceived severity of the patient's diabetes now and in 10 years' time were summed to form a measure labelled *Perceived Severity of Diabetes.* The single perceived vulnerability item *Complications arising from diabetes* was treated separately in analyses.

Table 3.1: Factor loadings for Perceived Benefits of, and Barriers to Treatment items (N = 178)

	Factor loadings	
	Factor 1	Factor 2
Perceived Benefits		
By careful planning of diet and exercise, I can control my diabetes at least as well as most other people with diabetes.	-0.04	**0.80**
High blood sugars can be prevented if I plan ahead.	-0.05	**0.60**
Good control of my diabetes reduces the possibility of developing complications.	0.09	**0.54**
It is important to take all my tablets at the times recommended by the doctor if I am to achieve good control of my diabetes.	-0.09	**0.52**
I find that keeping to a diet is helpful in controlling my diabetes.	-0.07	**0.81**
Perceived Barriers		
Sticking to my diet makes eating out difficult.	**0.73**	0.07
It is just not possible to control my diabetes properly and live in a way that is acceptable to me.	**0.72**	-0.08
Sticking to my diet causes inconvenience to other people.	**0.79**	0.07
Controlling my diabetes well interferes with my social life.	**0.84**	-0.05
The diet I am supposed to follow is rather dull and uninteresting.	**0.65**	-0.29

The magnitude of the factor loading indicates degree of relationship to each factor

Respondents who ticked the box "not sure what the problem is" on the Beliefs about Severity questionnaire were coded as missing for the particular disorder(s) concerned. The only diabetes-related item which produced a significant number of these responses (32) was "Your diabetes in 10 years". A likely explanation is that these patients were not aware that diabetes is a progressive disease. In view of the number of missing cases for this item, responses to "Your diabetes now" and "Your diabetes in 10 years" were treated separately in some exploratory analyses of HBM variables (in addition to the composite measure of Perceived Severity of Diabetes).

Frequency counts of the "I already have this problem" responses from the Beliefs about Vulnerability questionnaire revealed that a substantial proportion of patients (50%) believed they already had one or more of the complications. The frequency counts for each individual disorder are shown in Table 3.2. As the method of listwise deletion of cases was to be employed when analysing total perceived vulnerability scores, this would have created a large amount of missing data. In order to utilize data from the maximum number of respondents, therefore, the mean of the available perceived vulnerability scores for the individual complications was calculated for each respondent. This measure of meaned scores was labelled: *Mean Perceived Vulnerability to Complications.*

The design of the perceived severity and vulnerability questionnaires predetermined the content of each scale so it was not necessary to conduct factor analyses for the purpose of scale construction. However, factor analyses were carried out in order to examine the pattern of responses to these questionnaires. The results indicated that perceived severity ratings depended upon whether the items related to:

Table 3.2: Frequencies of "I already have this disorder" from the Beliefs about Vulnerability questionnaire.

Disorders unrelated to diabetes	
Stomach ulcer	**10**
Ear infection	**10**
Leukaemia	**0**
Gum disase	**4**
Bronchitis	**8**
Deafness	**13**
Asthma	**2**
Loss of hearing	**15**
Complications	
High blood pressure	**47**
Blindness	**4**
Kidney disease	**1**
Aching legs	**59**
Numbness in the feet	**37**
Heart disease	**25**
Failing eyesight	**28**
Gangrene	**2**
Single item:	
"Complications arising from diabetes"	**10**

(a) Life-threatening/end-stage disorders
(b) Not immediately life-threatening/early stage disorders
(c) Eyesight
(d) Diabetes as a whole ("your diabetes now/in 10 years")

A total of 68% of the variance was accounted for by these four factors. Factor analysis of the perceived vulnerability data indicated that ratings were influenced by whether the disorders were perceived to be

(a) Life-threatening
(b) Not immediately life threatening and related to diabetes (complications)
(c) Not immediately life threatening and unrelated to diabetes

The three factors accounted for a total of 67% of the variance. The perceived vulnerability data relating to the "average person" was also factor-analysed and produced three factors relating to:

(a) Disorders unrelated to diabetes
(b) Life-threatening complications of diabetes
(c) Not immediately life-threatening complications of diabetes

These three factors accounted for a total of 63% of the variance. The differing factor patterns relating to the personal and "average person" ratings provide evidence for the separate utility of these measures. Tables 3.3 and 3.4 show the means, standard deviations and other statistics relating to the perceived severity and vulnerability scores for the individual items in the questionnaires.

Table 3.3: Mean (SD), range, median and mode of the Perceived Severity scores for each item in the questionnaire

	Mean	(SD)	Range	Median	Mode	N
Complications						
High blood pressure	3.3	(1.0)	0-4	4	4	178
Blindness	3.9	(0.4)	0-4	4	4	177
Kidney disease	3.8	(0.5)	0-4	4	4	178
Aching legs	2.7	(1.1)	0-4	3	3	176
Numbness in the feet	3.2	(1.0)	0-4	4	4	179
Heart disease	3.9	(0.5)	0-4	4	4	180
Failing eyesight	3.5	(0.7)	0-4	4	4	180
Gangrene	3.9	(0.4)	0-4	4	4	179
Diabetes						
Your diabetes now	2.3	(1.1)	0-4	2	2	178
Your diabetes in 10 yrs	2.6	(1.1)	0-4	3	2	152
General Disorders						
Stomach ulcer	3.1	(1.0)	0-4	3	4	167
Ear infection	2.7	(1.1)	0-4	3	2	174
Leukaemia	3.9	(0.4)	0-4	4	4	176
Gum disease	2.1	(1.2)	0-4	2	2	161
Bronchitis	2.6	(1.1)	0-4	3	3	177
Deafness	2.9	(1.1)	0-4	3	4	178
Asthma	3.2	(1.0)	0-4	3	4	174
Loss of hearing	3.1	(1.0)	0-4	3	4	178

Table 3.4: Mean (SD), range, median and mode Perceived Vulnerability scores for each item in the questionnaire

	Mean	(SD)	Range	Median	Mode	N
Personal Vulnerability						
Complications						
High blood pressure	1.9	(1.2)	0-4	2	2	136
Blindness	1.9	(1.3)	0-4	2	2	178
Kidney disease	1.5	(1.3)	0-4	2	0	178
Aching legs	2.2	(1.2)	0-4	2	3	123
Numbness in the feet	2.1	(1.2)	0-4	2	2	145
Heart disease	1.6	(1.3)	0-4	2	2	158
Failing eyesight	2.3	(1.2)	0-4	3	3	154
Gangrene	1.6	(0.1)	0-4	2	0	177
Single item:						
Complications arising from diabetes	2.2	(1.2)	0-4	2	2	169
General Disorders						
Stomach ulcer	1.3	(1.2)	0-4	1	0	171
Ear infection	1.4	(1.2)	0-4	1	2	171
Leukaemia	1.0	(1.2)	0-4	1	0	181
Gum disease	1.1	(1.1)	0-4	1	0	175
Bronchitis	1.5	(1.3)	0-4	1	0	173
Deafness	1.3	(1.2)	0-4	1	0	166
Asthma	1.0	(1.1)	0-4	1	0	177
Loss of hearing	1.4	(1.2)	0-4	2	0	165
"Average Person" Vulnerability						
Complications						
High blood pressure	2.2	(1.2)	0-4	2	2	170
Blindness	2.0	(1.2)	0-4	2	2	176
Kidney disease	1.7	(1.2)	0-4	2	2	176
Aching legs	2.4	(1.1)	0-4	2	2	171
Numbness in the feet	2.3	(1.1)	0-4	2	2	171
Heart disease	1.8	(1.2)	0-4	2	2	174
Failing eyesight	2.4	(1.1)	0-4	3	3	173
Gangrene	1.7	(1.3)	0-4	2	2	175
Single item:						
Complications arising from diabetes	2.3	(1.2)	0-4	2	2	171
General Disorders						
Stomach ulcer	1.5	(1.2)	0-4	2	2	174
Ear infection	1.5	(1.1)	0-4	2	2	175
Leukaemia	1.1	(1.2)	0-4	1	0	175
Gum disease	1.3	(1.1)	0-4	1	2	174
Bronchitis	1.5	(1.2)	0-4	2	2	174
Deafness	1.4	(1.1)	0-4	2	2	171
Asthma	1.1	(1.2)	0-4	1	0	175
Loss of hearing	1.5	(1.2)	0-4	2	2	173

Distribution of Baseline Health Belief Scores

Perceived Benefits of, and Barriers to Treatment

The range of scores possible for each of the scales is 0 to 30, higher scores indicating greater Perceived Benefits or Barriers. Scale mean, standard deviation, and minimum and maximum scores obtained are shown in Table 3.5. The distribution of the Perceived Benefits of Treatment scores was highly negatively skewed, indicating that most respondents scored towards the top end of the range on this scale, perceiving more benefits of treatment. Scores for the Perceived Barriers scale and measure of treatment 'Cost-effectiveness' were more normally distributed, however. A Wilcoxon test indicated that respondents gave higher ratings to Perceived Benefits of Treatment than to Perceived Barriers to Treatment ($z = -10.9$; $p<0.001$).

Perceived Severity of, and Vulnerability to Complications

The range of scores possible for each of the eight-item Perceived Severity and Vulnerability scores is 0 to 32. Scores possible for the two-item Perceived Severity of Diabetes measure range from 0 to 8. Mean, standard deviation, minimum and maximum scores for the scales are shown in Table 3.5. Respondents felt that Complications were significantly more severe than General Disorders ($z = -9.5$; $p<0.001$) and perceived themselves to be significantly more vulnerable to Complications than General Disorders ($z = -6.5$; $p<0.001$). Compared with the 'average person', however, patients saw themselves as less vulnerable to both Complications ($z = -4.0$; $p<0.001$) and General Disorders ($z = -2.9$; $p<0.01$).

Table 3.5: **Mean (SD), minimum and maximum scores, reliability (alpha) coefficient, and range of item-total correlations for each scale**

	N	Mean	(SD)	Minimum score obtained	Maximum score obtained	Possible range	Reliability coefficient	Range of item-total correlations
Perceived								
Benefits	178	27.2	(3.4)	9	30	0-30	0.67	0.32 - 0.59
Barriers	179	13.5	(8.2)	0	30	0-30	0.80	0.51 - 0.69
Perceived Severity								
Complications	164	28.3	(3.5)	8	32	0-32	0.77	0.30 - 0.64
General Disorders	149	23.8	(5.8)	0	32	0-32	0.88	0.40 - 0.72
Diabetes (2 items)	152	4.9	(1.9)	0	8	0-8	--	---
Perceived Vulnerability								
Complications	83	13.5	(7.6)	0	31	0-32	0.84	0.46 - 0.68
Complications (averaged)	182	1.9	(1.0)	0	4	0-4	--	---
General Disorders	140	9.3	(6.6)	0	32	0-32	0.89	0.53 - 0.70
'Complications arising from diabetes' (single item)	169	2.3	(1.2)	0	4	0-4	--	---
Perceived Vulnerability of the 'Average Person"								
Complications	162	16.6	(6.8)	0	32	0-32	0.87	0.49 - 0.75
General Disorders	165	10.8	(6.9)	0	32	0-32	0.89	0.61 - 0.78
'Complications arising from diabetes' (single item)	171	2.3	(1.2)	0	4	0-4	--	---

Higher scores indicate more perceived Benefits and Barriers, and greater perceived Severity and Vulnerability

When inspecting the Perceived Vulnerability data, it was noted that frequency counts for 'I already have this problem' were much lower for the single complications item ('Complications arising from diabetes') than for most of the individual complications. For example, 10 respondents indicated that they already had 'complications arising from diabetes' whereas 47 said they had high blood pressure, 59 had aching legs, 37 had numbness in the feet, and 25 had heart disease. This suggests that respondents in this sample were not aware of all the complications, or perceived 'complications arising from diabetes' as something other than the disorders listed in the questionnaire. It was predicted, therefore that the single complications item would be more strongly related to metabolic outcome variables than a composite score from the individual complications data.

Reliability

The internal reliability of each of the health belief scales was calculated and produced a satisfactory alpha coefficient in each case. The reliability coefficients and item-total correlations for each scale are presented in Table 3.5. Once again, because listwise deletion methods would have reduced the number of cases to be analysed, calculation of the reliability of the Perceived Vulnerability to Complications scale was carried out including available data from missing cases. This increased the number of cases analysed to a satisfactory level for internal reliability analysis (Kline, 1986). An alpha coefficient is not reported for Perceived Severity of Diabetes as it comprises only two items. All item-total correlations exceeded the minimum required coefficient of 0.20 (Kline, 1986).

Validity

Content Validity

In order to establish content validity, an initial pool of items was constructed for each measure which were relevant to, and typical of the experience of having diabetes treated with oral hypoglycaemic agents. The final items included in the questionnaire were chosen after detailed consideration and discussions with a health psychologist specialising in diabetes research (Dr. Clare Bradley) and a physician specialising in diabetes (Dr. Adrian Jennings) about breadth of inclusion and the suitability and representativeness of the items for the population studied.

Construct Validity

In order to assess construct validity the scales were correlated with other variables collected in the baseline study. Construct validity was established if associations between appropriate variables and scales were significant and consistent. A correlation matrix is presented in Table 3.6. The following significant results were obtained:

Glycosylated haemoglobin (HbA_1)

The higher the patients' HbA_1 levels, the more vulnerable they perceived themselves ($r = 0.16$; $p<0.05$) and the 'average person' ($r = 0.15$; $p<0.05$) to Complications.

Table 3.6: Correlation of the health belief measures with other variables
(Lower N value for each pair of variables determines N for correlation coefficient)

N		HbA1	% Ideal body weight	Subjective estimates of diabetic control	Depression	Anxiety	Positive well-being	Satisfaction
N		186	187	183	171	172	174	172
	Perceived							
178	Benefits	0.11	0.14*	0.22**	0.27***	-0.34***	-0.34***	-0.27***
179	Barriers	-0.02	-0.19**	-0.18*	-0.10	-0.14*	0.19**	0.31***
178	Treatment 'cost-effectiveness'	-0.11	-0.20**	-0.29***	-0.27***	-0.33***	0.36***	0.35***
	Perceived Severity							
164	Complications	0.06	0.16*	0.08	-0.01	0.01	0.05	-0.01
149	General Disorders	-0.01	0.15*	0.00	-0.09	0.00	0.08	-0.04
152	Diabetes	0.10	0.24***	0.19**	0.20**	0.14*	-0.13	-0.22**
	Perceived Vulnerability							
83	Complications (n = 83)	0.15	-0.08	0.27**	0.39***	0.25*	-0.27	-0.34***
182	Complications (averaged)	0.16*	0.09	0.24***	0.34***	0.26***	-0.29***	-0.29***
140	General Disorders	0.13	-0.06	0.21**	0.28***	0.20**	-0.37***	-0.27***
169	'Complications arising from diabetes' (single item)	0.24***	0.07	0.33***	0.25***	0.14*	-0.23**	-0.27***
	Perceived Vulnerability of 'Average Person'							
162	Complications	0.15*	0.15*	0.22**	0.37***	0.33***	-0.32***	-0.31***
165	General Disorders	0.16*	-0.03	0.16*	0.27***	0.19**	-0.26***	-0.23**
171	'Complications arising from diabetes' (single item)	0.23***	0.11	0.31***	0.27***	0.17*	-0.24***	-0.24***

*** p<0.001; ** p<0.01; * p<0.05

Higher scores indicate subjective estimates of poorer control, more perceived Benefits, Barriers, and Treatment 'cost-effectiveness and greater perceived Severity, Vulnerability, Depression, Anxiety, and Positive Well-being.

Percent Ideal Body Weight

Greater obesity was significantly associated with more perceived Barriers to ($r = 0.14$; $p < 0.05$) and fewer Benefits of treatment ($r = -0.19$; $p<0.01$). Overall, the more overweight an individual was, the less treatment was felt to be 'Cost-effective' ($r = -0.20$; $p<0.01$). More obese individuals also perceived their Diabetes ($r = 0.24$; $p<0.001$) and Complications ($r = 0.16$; $p<0.05$) to be more severe and they felt that the 'average person' was more vulnerable to Complications than did less overweight respondents ($r = 0.15$; $p<0.05$). The expected association between perceived personal Vulnerability to Complications and percent ideal body weight was not significant ($r = 0.09$; $p>0.05$).

Subjective Estimates of Control

Subjective estimates of poorer diabetes control over the previous few weeks were significantly associated with more perceived Barriers to treatment ($r = 0.22$; $p<0.01$), fewer perceived Benefits of treatment ($r = -0.18$; $p<0.05$), and lower perceived treatment 'Cost-effectiveness' ($r = -0.29$; $p<0.001$). More pessimistic estimates of diabetes control were also associated with greater perceived severity of the individuals' Diabetes ($r = 0.19$; $p<0.01$) and greater Vulnerability to Complications for the patients themselves ($r = 0.24$; $p<0.001$) and the 'average person' ($r = 0.22$; $p<0.01$).

Well-being and Treatment Satisfaction

Greater Depression scores were associated with more perceivedBarriers to treatment ($r = 0.27$; $p<0.001$), lower treatment 'Cost-effectiveness' ($r = -0.27$; $p<0.001$), greater Severity of Diabetes ($r = 0.20$; $p<0.01$), and greater Vulnerability to Complications for themselves ($r = 0.34$; $p<0.001$) and the 'average person' ($r = 0.37$; $p<0.001$).

Higher Anxiety scores were associated with more perceived Barriers to treatment ($r = 0.34$; $p<0.001$), fewer perceived Benefits of treatment ($r = -0.14$; $p<0.05$), lower perceived treatment 'Cost-effectiveness' ($r = -0.33$; $p<0.001$), greater perceived Severity of Diabetes ($r = 0.14$; $p<0.05$) and greater perceived Vulnerability to Complications for the patients themselves ($r = 0.26$; $p<0.001$) and the 'average person' ($r = 0.33$; $p<0.001$).

Greater Positive Well-being was related to fewer perceived Barriers ($r = -0.34$; $p<0.001$), more Benefits ($r = 0.19$; $p<0.01$), greater treatment 'Cost-effectiveness' ($r = 0.36$; $p<0.001$), and less Vulnerability to Complications for themselves ($r = -0.29$; $p<0.001$) and the 'average person' ($r = -0.32$; $p<0.001$).

Greater Treatment Satisfaction was associated with fewer perceived Barriers ($r = -0.27$; $p<0.001$), more perceived Benefits ($r = 0.31$; $p<0.001$), greater perceived 'Cost-effectiveness' of treatment ($r = 0.35$; $p<0.001$), lower perceived Severity of Diabetes ($r = -0.22$; $p<0.01$), and less perceived Vulnerability for the patients themselves ($r = -0.29$; $p<0.001$) and the 'average person' ($r = -0.31$; $p<0.001$).

Discussion

The Health Belief scales reported in this chapter have been shown to have satisfactory alpha coefficients of reliability. Cronbach's alpha ranged from 0.67 to 0.89 and item-total correlation coefficients were within the required range for each scale.

Patterns of correlations with other variables also provide preliminary evidence for the construct validity of the scales. Respondents in the present study tended to perceive more Barriers to treatment and fewer Benefits of treatment if they were more overweight and/or if they estimated control of their diabetes to be poorer. Perceptions of more Barriers to treatment and fewer Benefits of treatment were also assocated with greater Depression and Anxiety scores and lower Positive well-being and Treatment Satisfaction. Greater Perceived Vulnerability to Complications was similarly associated with being overweight, subjective estimates of poorer diabetes control, higher Depression and Anxiety scores, and lower Positive well-being and Treatment Satisfaction. In addition, those who reported greater Vulnerability to Complications for themselves and/or for the "average person" were also more likely to have higher HbA_1 levels. Perceived Severity of Complications was associated with being overweight but not with higher HbA_1 levels.

Because of the retrospective design of the present study, it is not possible to conclude whether patients' beliefs are the cause, or the consequence of the metabolic and psychological outcomes measured here. However, these associations reflect realistic subjective estimates of diabetes control. Awareness of the consequences of poor control may have been raised with these patients when they were informed about their need to take oral hypoglycaemic agents in the first place. Furthermore, many of the patients attending the clinic are there because of doctors' concerns about complications they have or because of problems in attaining adequate diabetes control. The direction of association between diabetes health beliefs and these outcomes is likely to be different if patients have unrealistic perceptions about their diabetes control and its consequences. This highlights the need, therefore, to assess beliefs about diabetes in the context of the treatment involved and policies about information given to patients. It is interesting to note here that associations between the health belief variables and estimated diabetes control were much stronger than correlations with either percentage of ideal body weight or HbA_1. The difference in strength of associations is likely to be explained by the kind of information given to these patients about their diabetes control. If beliefs are to have maximum constructive impact on health care behaviour, therefore, it is important that patients should have accurate feedback about their control and information about scope for improvement (as well as appropriate advice about methods for improving diabetes control).

Although associations between the perceived Benefits and Barriers scales and clinical outcomes were as expected, the direction of associations between the perceived severity and vulnerablility scales and these outcome variables was contrary to that which the original Health Belief model might have predicted. However, other researchers who have correlated diabetes control with measures of perceived susceptibility to complications have reported a similar direction of relationship between these variables (Harris, Linn & Skyler, 1987; Brownlee-Duffeck, Peterson, Simonds, Goldstein, Kilo & Hoette, 1987). As already mentioned in Chapter 1, a likely explanation for these findings is that relationships between health beliefs and outcomes are dynamic. Not only may health beliefs affect outcomes but these outcomes, in turn, may affect health beliefs. It is likely, therefore, that if individuals believe their diabetes is so poorly controlled it makes them feel vulnerable to complications, they are more likely to take steps to improve their control or reduce their weight. In order to achieve this goal the patient may comply with the recommendations of the diabetes health care team. This process probably explains why some researchers have reported behavioural measures of compliance to be associated with *greater* perceived vulnerability (Bloom Cerkoney & Hart, 1980; Harris, Linn & Skyler, 1987) whilst better metabolic control has been associated with *lower* perceived vulnerability (Harris, Linn & Skyler, 1987; Brownlee-Duffeck, Peterson, Simonds, Goldstein, Kilo & Hoette, 1987).

Patients beliefs about severity and vulnerability are likely to be influenced by their knowledge of diabetes and its complications which is determined largely by the type of education received. At the start of the study only a small proportion of respondents had attended an education session, although all patients were offered education subsequently. It can be seen from Table 3 that the single perceived vulnerability item "Complications arising from diabetes" is more strongly associated with HbA_1 levels and subjective estimates of diabetes control than the composite Perceived Vulnerability to Complications scale. It is evident, however, that scores for the single item are artificially reduced by lack of knowledge about which health problems are complications of diabetes; frequency counts of "I already have this problem" for "Complications arising from diabetes" fell far short of frequencies relating to the individual complications. The single item therefore measures perceived vulnerability to what are understood to be complications of diabetes. This distinction should be borne in mind particularly when inspecting relationships between health beliefs and behaviour. If, for example, a patient is unaware that heart disease is a complication of diabetes, then he or she may make less effort to reduce fat intake, consume fewer calories or take more exercise than if the risks were known. Perceived vulnerability to "Complications arising from diabetes" may be high, therefore, but perceived vulnerability to heart disease may be relatively low. This distinction between the scores for the scale and scores for the single item allows researchers to identify discrepancies in beliefs about vulnerability to complications which may benefit from intervention. It is interesting to note here that many of the items in scales designed by other research groups to measure perceived vulnerability to complications of diabetes (Harris, Linn & Skyler, 1987; Brownlee-Duffeck, Peterson, Simonds, Goldstein, Kilo & Hoette, 1987) effectively inform the respondent that a particular complication is related to diabetes. It is possible therefore that if the respondent was previously unaware of this relationship, ratings of susceptibility to the particular disorder may be affected by perceptions about current metabolic control rather than metabolic control being affected by feelings about susceptibility.

The improvements to the format of the Perceived Severity and Vulnerability questionnaires since the design of the scales for insulin-dependent patients (Bradley, Brewin, Gamsu & Moses, 1984) allow the researcher to gain more information about the perceptions of respondents. Patients now report which complications they already have and these reports can be compared with information from their medical records. Discrepancies between actual and perceived occurrence of complications are likely to be reflected in the patients' health beliefs. Perceived Vulnerability to Complications may also be examined in relation to both the patient personally, and his or her estimate for the "average person". It is interesting to note that patients in this study perceived the "average person" to be significantly more vulnerable than themselves to both Complications and General Disorders. Weinstein (1982, 1984, 1987) found a similar optimistic bias when assessing the perceived susceptibility of individuals to a variety of environmental and health hazards. Inspection of the correlation matrix in Table 3.6 also indicates that whilst perceived vulnerability scores for both the patients themselves and the "average person" are similarly correlated with most of the metabolic and psychological variables in this study, percentage of ideal body weight is associated with perceived vulnerability of the "average person" to

Complications but not with personal perceived vulnerability. The reason for measuring perceived vulnerability of the "average person" to Complications was to remove the mediating effects of what patients see as personal risk reducing strategies and "noise" from factors such as a family history of disorders which patients do not realise are complications of diabetes. The optimistic bias mentioned earlier and the greater sensitivity of the "average person" ratings in the correlation with percentage of ideal body weight provide good grounds for the inclusion of the measure. Indeed, the next chapter describes an attempt to integrate this measure into a model which specifies the relationship between the HBM variables.

In conclusion, the scales reported here are internally reliable and relationships with other psychological and metabolic variables demonstrate their sensitivity and construct validity. The scales are likely to be particularly useful in research which aims to assess the efficacy of interventions such as education in modifying Health Belief model dimensions to achieve desired health behaviours. They may also be useful as an instrument of audit if indicators about the suitability of possible interventions are sought. Chapters 5 and 6 describe the use of the developed scales in such studies. It should be noted that the scales were designed and developed for people with tablet-treated Type II diabetes, not for diabetic individuals treated with diet alone. Modification of certain items and psychometric development would be required if the scales were to be used with diet-alone-treated patients.

CHAPTER FOUR

EXPLORATION OF RELATIONSHIPS BETWEEN HBM COMPONENTS USING BASELINE DATA

After establishing the reliability and validity of the diabetes-specific HBM scales, the next aim was to investigate the relationships between components of the HBM using the same baseline data. As discussed in Chapter 1., there has been no published account of such an investigation despite discussion of the possible relationships in earlier publications (e.g. Becker, Drachman & Kirscht, 1972; Leventhal, Safer & Panagis, 1983; Wallston & Wallston, 1984). Indeed, with the exception of one study (Haefner & Kirscht, 1970) it appears that the research using the HBM to date has assumed implicitly that the HBM components combine additively and that they are linearly related to health outcomes. However, value-expectancy theories imply that the theoretical components of perceived severity and vulnerability combine in a multiplicative fashion (Feather, 1982).

It may be that researchers using the HBM have tested for a multiplicative relationship between perceived severity and vulnerability and found no evidence for a multiplicative combinatorial rule. However, no-one has published the results of such a study. Another possibility is that they have noted other researchers' lack of success in demonstrating the advantage of multiplicative terms when testing other theories involving similar or alternative components to the HBM. There has been some notable research involving hypothesized multiplicative relationships between variables by Rogers and colleagues (Rogers, 1985; Rogers, 1983; Maddux & Rogers, 1983; Rogers & Mewborn, 1976) in the context of fear appeals and attitude change using Rogers' own theoretical approach termed *protection motivation theory*. Protection motivation theory incorporates the main components of the HBM when applied to fear communications and in the latest formulation states that the three most important variables in a fear appeal are (a) the noxiousness of a depicted event, (b) the probability that the event will occur provided no adaptive activity is performed, and (c) the effectiveness of a coping response that might avert the noxious event. The fear appeal is said to initiate two appraisal processes: threat appraisal and coping appraisal which produce both adaptive and maladaptive responses. The probability of maladaptive responses are increased by intrinsic and extrinsic rewards and decreased by beliefs about severity of, and vulnerability to the noxious event. On the other hand, the probability of adaptive responses are increased by perceptions about self-efficacy and response efficacy (perceived benefits), and decreased by the perceived costs (barriers). The original formulation of protection motivation theory specifically postulated that attitude change is a multiplicative function of the mediating beliefs and attitudes produced by the fear appeal (Rogers & Mewborn, 1976). When put to the test, however, the research failed to produce evidence for a two-way interaction between severity and vulnerability (and the predicted three-way interaction between perceived severity, vulnerability and efficacy) and Rogers has therefore concluded that these variables are independent. Although Rogers and colleagues may be justified in reaching this conclusion, the design of the studies used to test interactions between the variables may have affected the results. For example, in three separate experiments by Rogers and Mewborn (1976) subjects were allocated to one of two groups who were shown a film about a noxious outcome. (Each experiment was performed on a different health topic: smoking, road safety and venereal diseases.) One group was randomly allocated to see a film portraying the outcome (e.g. lung cancer) as being highly noxious, and the other group saw a film portraying the same outcome as being low in noxiousness. Within these conditions each subject was randomly assigned to either a high or low probability of occurrence condition and either a high or low efficacy of response condition. The probability of occurrence and efficacy of response conditions were determined by written communications. After seeing the film and reading the communications, in order to check the effect of the experimental manipulations, each subject rated the noxiousness and probability of exposure to the outcome and the efficacy of the coping responses. They were also asked to rate their intentions to adopt the coping responses recommended. Although the experimental manipulations produced equivalent ratings for perceived vulnerability and response efficacy, it is significant that the films did not have a significant effect on the measure of appraised severity (noxiousness). Rogers and Mewborn argued that the films did not affect perceived severity in the expected way because emotional arousal is likely to drop rapidly after exposure to a fear appeal. However, it could also be argued that the subjects in the low noxiousness condition perceived the portrayed outcome to be highly noxious, probably as a result of prior knowledge or experience. It is also conceivable that those in the high noxiousness condition may have perceived the outcome to be low in noxiousness, especially if they were allocated to the low probability of occurrence condition. In summary, the experimenters did not appreciate that the effects of the experimental manipulations were probably confounded with the enduring perceptions of the subjects. Given that Rogers and Mewborn used the experimental classification variables to test predictions about behavioural outcome and not the manipulation check ratings of the subjects themselves, it was not surprising that an interaction between perceived severity and vulnerability was not found. Sutton (1982) also points out that protection motivation theory suffers from a number of other logical-theoretical problems. In particular, he draws attention to the low probability of occurrence/high efficacy of response condition where subjects are given inconsistent information about the effects of a particular health threat. They may be told, for example, that on the one hand, if they continue to smoke, the likelihood of getting lung cancer is low whilst on the other, that giving up smoking would greatly reduce their chances of getting lung cancer.

It is worthy of note here that the design of studies by Rogers and colleagues was probably influenced by the perceived need to use analyses of variance (ANOVA) to test predictions about interactions between the theoretical constructs of protection motivation theory. This is evident in the study reported above where data relating to the experimental manipulations themselves were used in the ANOVA rather than the subjects' own perceptions of severity, vulnerability and efficacy which were not so neatly categorized. As argued earlier, however, the experimental manipulations may be contaminated if subjects bring their own experience and knowledge to the laboratory. Ironically, this flaw in the study design is likely to have produced misleading categories of data for the ANOVA which influenced the design of the study in the first place. It seems, therefore, that while the data from this type of experimental manipulation research is ideally suited to ANOVA, if the perceptions of the subjects themselves are to be analysed, this requires statistical techniques which can handle continuous rather than categorical data. An alternative strategy is to ask respondents to rate their beliefs and attitudes according to simple categories; however, several categories might be needed in order to produce a reasonably sensitive measure of the construct. The use of ANOVA to test for interactions becomes more unwieldly as the number of variables and categories within them increases. It is not surprising, therefore, that most of the research concerning health care behaviour has been of a correlational nature.

Unfortunately, as Evans (1991) has pointed out:

> "Those undertaking studies using a correlational perspective seem to have come late to the problem of dealing with interactions."

Evans showed that there is considerable confusion about the correct method of testing theoretical models which contain multiplicative terms. In particular, he pointed out that many researchers have inappropriately used simple correlational analysis for assessing the relationship between a simple variable and a multiplicative composite. The misuse of correlational analyses occurred because researchers failed to notice, on the one hand, that correlation coefficients are dependent on the scales used to measure the components of the composite variable, and on the other, that the variance explained by the individual components needs to be partialled out when accounting for the unique variance explained by the composite variable. In the first instance, changes in the scale such as the interval level or zero point can have marked effects on the size of the correlation coefficient. Schmidt (1973) demonstrated this by altering the means and standard deviations of components of a composite variable to produce markedly different correlation coefficients. This occurs because the standard deviation of the composite is a function of the means and standard deviations of its components. However, if the correlations between the components of a multiplicative composite and the dependent variable are partialled out, not only does this provide an index of the unique contribution of the interaction effect but it also takes care of the scaling issue just raised. Despite warnings by Schmidt (1973; Schmidt & Wilson, 1975) many researchers continue to report the use of inappropriate methods to analyze multiplicative models. This is particularly notable in the extensive research literature concerning Fishbein and Ajzen's (1975) theory of reasoned action in which the attitude and norm measures are multiplicative composites. Evans commented that the reason for the recent decline of interest in value-expectancy theory may have been the failure to show an advantage to the multiplicative models but this failure could be due to the use of inappropriate correlational analyses. The apparent reluctance to test for possible multiplicative relationships within the HBM may, conversely, be due to an awareness of the problems involved, but uncertainty as to how they could be solved. Evans (1991) recommended the use of hierarchical multiple regression as the most appropriate method for the analysis of variables constructed by multiplying two or more variables together. When using this method, the multiplicative composite is entered into an equation that already contains the components of the composite. The overall squared multiple correlation (R^2) for the two stages represents the amount of variance explained by the model being tested, while the increase in R^2 from the first stage (when the separate components are entered) to the second stage (when the composites are entered) indicates the value of the multiplicative model over and above the additive model. This is a conservative technique for testing multiplicative models because a certain amount of the overall variance which might be more efficiently explained by a multiplicative composite will be removed at the first stage of the hierarchical analysis by its individual components. However, until better methods are developed, hierarchical multiple regression is the only technique available which can take care of the scaling issue in correlational analyses and provide an index of the unique variance accounted for by the multiplicative composite. All possible interactions between the components of the HBM are examined using this technique in the present study.

The use of regression analyses relies on the assumption that the independent variables are related in a linear fashion to the dependent variable. However, it is possible that some or all of the HBM variables may be related to outcomes in a non-linear fashion. Janz and Becker (1984) reported, for example, that perceived severity was not correlated with indices of preventive health behaviours in a large number of studies. This may be because perceived severity must reach a certain level to be of concern, but above that level the decision to act is a function of other variables in the model such as perceived vulnerability. Weinstein (1988) suggested a more complex version of this decision rule in order to explain the lack of evidence for multiplicative models of behaviour generally. He postulated that people may not respond to a threat if *either* vulnerability *or* severity is below a minimum level. Once both variables exceed the cutoffs, however, severity and vulnerability become independent and function according to an additive rather than a multiplicative rule. In order to test such decision rules, it is clear that variables need to be combined in a non-linear fashion. The notion of cutoffs provides the rationale for categorizing variables and crosstabulating them with others using appropriate techniques such as ANOVA or its non-parametric equivalent. One can then predict that if the multiplicative rule is valid, more favourable health outcomes are associated with a particular combination (or combinations) of belief magnitude. The study described in this chapter employs this method of data combination and analysis in order to test the non-linearity hypothesis. The Wallstons' hypothesized locus of control typology (see Chapter 1) has been tested in a similar manner (Bradley, Lewis, Jennings & Ward, 1990).

Details of the subjects and methods of this study have already been provided in Chapter 2. The description of this study therefore begins with the variables selected followed by the analyses undertaken and their results.

Variables selected for analyses

Perceived Severity and Vulnerability

Given that the newly-developed diabetes-specific questionnaires provided composite and individual item measures of perceived severity and vulnerability, an initial task was to select a representative and sensitive measure for each of these constructs for the present study. It has been reported in Chapter 3 that the frequency analyses relating to 'I already have this problem' (Perceived Vulnerability questionnaire) indicated that a large number of the respondents were not aware of all the complications, or perceived the complications of diabetes to be something other than the disorders listed individually. Furthermore, the correlations involving the composite measures of perceived vulnerability and severity indicated that little more than 2 per cent of the variance in percent ideal body weight or HbA_1 was explained whereas the single-item measures of perceived vulnerability and severity accounted for nearly 6 percent of the variance in these outcomes. It seems that the single-item measures of perceived vulnerability and severity are more relevant to health outcomes in diabetes because the composite measures depended upon respondents' knowledge about the complications of this disorder. Because of the greater sensitivity of the single item measures of perceived severity and vulnerability, therefore, these were selected for inclusion in the analyses for this study. A further advantage of selecting the single-item measures was that they were both normally distributed; the composite measure of perceived Severity was positively skewed and would have required transformation. The single-item measure of perceived vulnerability was obtained from respondents' response to the item: "Complications arising from diabetes". Perceived severity was assessed from the summed responses to two items regarding the seriousness of the respondents' own diabetes: "Your diabetes now" and "Your diabetes in 10 years' time". (See Chapter 2 for details of the rating scales.)

With a view to incorporating perceptions of vulnerability for the 'average person' in the HBM, the single-item measure was selected for consistency with the personal vulnerability measure. Ratings for personal vulnerability were also subtracted from ratings for the 'average' person for each subject to produce a measure of Optimistic Bias. Results of the analyses described in Chapter 3 indicated that there was a significant tendency for the respondents to rate themselves as less vulnerable to complications than the 'average' person. A similar optimistic bias has been found in studies concerning susceptibility to a variety of hazards (Weinstein, 1987). If this optimism is unrealistic, it is likely to constitute a barrier to preventive action and therefore an attempt to measure this attitude may provide additional explanation of the variance in health outcomes.

'Cost-effectiveness' of treatment

Because responses to the perceived Benefits scale were skewed (positive) and regression analyses assume that the individual variables are normally distributed, the Benefits and Barriers measures were combined by subtracting the Barriers score from the Benefits score for each individual. This provided a measure of perceived 'Cost-effectiveness' of treatment which satisfied the assumptions of normality.

Personal Control/Self-efficacy

As discussed in Chapter 2, the Perceived Control of Diabetes sub-scale labelled Personal Control, is not only a measure of personal control but is also a measure of self-efficacy. This is because the respondent's attributions about personal responsibility for positive outcomes are combined synergistically with beliefs about the ability to make outcomes happen in the first place. As described in Chapter 1, recent studies relating to diabetes have indicated the value of measuring self-efficacy and locus of control in order to explain the variance in health outcomes. Rosenstock and colleagues (1988) have also suggested that the concept of self-efficacy should be incorporated into the HBM. The Personal Control measure was therefore selected for this study with a view to incorporating the combined self-efficacy and personal control constructs into the HBM and to specify their relationship to the original components of the model.

Because the distribution of the Personal Control measure was moderately and negatively skewed, the data were reflected and a square root transformation was applied (Tabachnick & Fidell, 1989). The transformed variable was included in all analyses where the statistical technique required a normal distribution.

Results

Intercorrelation of the HBM components

In order to check for multicollinearity between the original and newly-introduced HBM components and their relationship to the baseline outcome measures, all the variables were intercorrelated. Table 4.1 shows the correlation matrix obtained. Multicollinearity is indicated by correlations of .90 and above (Tabachnick & Fidell, 1989).

It can be seen from the correlation matrix that the measures of personal Vulnerability and 'average person' Vulnerability are multicollinear and they would therefore render one another redundant in a regression equation. Subsequent analyses therefore examined the separate utility of these measures in explaining outcome variance in concert with the other HBM components.

Table 4.1: Intercorrelations between the original and newly-introduced HBM variables and their relationship to health outcomes (Lower N determines N for correlation coefficient for each pair of variables)

		N	1	2	3	4	5	6	7	8	9
1.	Treatment 'Cost-effectiveness'	178	1.0								
2.	Severity of Diabetes	152	-0.14	1.0							
3.	Vulnerability to Complications	169	-0.16*	0.48***	1.0						
4.	Vulnerability to Complications ('average person')	171	-0.07	0.50***	0.93***	1.0					
5.	Optimistic Bias	169	0.16*	0.02	-0.26***	0.11	1.0				
6.	Personal Control/ Self-efficacy	153	-0.18*	0.17*	0.07	0.05	-0.09	1.0			
7.	Baseline HbA1	186	-0.11	0.10	0.24***	0.23***	-0.13	0.09	1.0		
8.	Percent ideal body weight (baseline)	187	-0.20**	0.24***	0.07	0.11	0.00	0.24***	0.12	1.0	
9.	Subjective estimates of diabetic control	183	-0.29***	0.19**	0.33***	0.31***	-0.12	0.30***	0.47***	0.13	1.0

*** $p < 0.001$; ** $p<0.01$; * $p<0.05$

Higher scores indicate subjective estimates of poorer control, greater Optimistic Bias and greater perceived treatment 'Cost-effectiveness', Severity, and Vulnerability. The measure of Personal Control/Self-efficacy was reflected during transformation and thus higher scores indicate lower perceived Personal Control/Self-efficacy.

These results (described later) determined the selection of the most efficient measure of perceived Vulnerability to Complications.

The measure of optimistic bias did not correlate significantly with any of the outcome measures and the direction of the correlations indicated that any bias was associated with a realistic appraisal of diabetes control. Inspection of a frequency analysis indicated that an overwhelming majority (89%) of the respondents had rated their own Vulnerability to Complications to be the same as that for the 'average person'. Of the respondents who deviated from this trend, 5 per cent felt that they were more vulnerable, while 6 per cent felt they were less vulnerable. Given the small percentage of respondents who had rated themselves differently to the 'average person' and the realistic nature of these responses, Optimistic Bias was not included in subsequent analyses as it was unlikely to add significantly to the overall explanation of variance in health outcomes. It was noted previously (see Chapter 3) that 'average person' Vulnerability scores were significantly greater than scores for personal Vulnerability. However, this difference was in relation to perceived vulnerability to the individual complications.

Test of the multiplicative model: Hierarchical multiple regression analyses.

Multiplicative combinations of several of the HBM components were tested using hierarchical multiple regression analyses on the assumption that the independent and dependent variables were related in a linear fashion. The interactions predicted were as follows:

(a) SEVERITY x VULNERABILITY: Perceived Severity of Diabetes and perceived Vulnerability to Complications will tend to increase in relation to one another.

(b) TREATMENT 'COST-EFFECTIVENESS' x SEVERITY x VULNERABILITY: Perceived Treatment 'Cost-effectiveness' will tend to increase in relation to decreases in Perceived Severity and Vulnerability.

(c) PERSONAL CONTROL/SELF-EFFICACY x TREATMENT 'COST-EFFECTIVENESS' x SEVERITY x VULNERABILITY: Decreases in perceived Severity and Vulnerability and increases in perceived Treatment 'Cost-effectiveness" will occur in relation to increases in perceived Personal Control/Self-efficacy.

The choice of interaction effects in the multiplicative regression models was based on predictions made by the present author based on the observation of relationships between the individual measures and outcome variables. It is appreciated, however, that other interactive models could have been tested but in the absence of prior predictions these were not attempted. The model was tested by entering the interactions and their individual components in order to predict baseline HbA_1, percent ideal body weight, and subjective estimates of diabetes control. The individual variables were entered on the first step of the analyses and the interactions were entered in a hierarchical fashion on the second and subsequent steps. The interactions were calculated by converting the component variables to z scores and obtaining their product. The reason for initial standardization of the variables before multiplication was to avoid high correlations between the multiplicative composite and its components. The results of correlations between the component and composite variables and their relationship to health outcomes are provided in Table 4.2.

Table 4.2: Intercorrelations between the individual and composite HBM variables and their relationship to health outcomes. (Lower N determines N for correlation coefficient for each pair of variables.)

	N	1	2	3	4	5	6	7	8	9	10
1. Treatment 'Cost-effectiveness	178	1.0									
2. Severity of Diabetes	152	-0.14	1.0								
3. Vulnerability to Complications	169	-0.16*	0.48***	1.0							
4. Personal Control/Self-efficacy	153	-0.18*	0.17	0.07	1.0						
5. Severity x Vulnerability	147	-0.14	-0.11	-0.23**	-0.02	1.0					
6. Severity x Vulnerability x Treatment 'Cost-effectiveness'	138	0.40	-0.08	-0.14	-0.15	0.19*	1.0				
7. Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	119	-0.15	0.09	0.13	0.03	-0.38***	-0.50***	1.0			
8. Baseline HbA1	186	-0.11	0.10	0.24***	0.09	0.01	-0.06	-0.08	1.0		
9. Percent ideal body weight (baseline)	187	-0.20**	0.24***	0.07	0.24***	0.06	-0.18*	-0.04	0.12	1.0	
10. Subjective estimates of diabetes control	183	-0.29***	0.19**	0.33***	0.30***	-0.08	-0.06	0.12	0.47***	0.13	1.0

*** $p < 0.001$; ** $p<0.01$; * $p<0.05$

Higher scores indicate subjective estimates of poorer control and greater perceived treatment 'Cost-effectiveness', Severity, and Vulnerability. The measure of Personal Control/Self-efficacy was reflected during transformation and thus higher scores indicate lower perceived Personal Control/Self-efficacy.

1. Prediction of outcomes from the original HBM components and their interactions:

The first aim was to establish how much of the variance in the outcome measures could be explained by the original components of the HBM, individually and interactively. On the first step, perceived Severity of Diabetes, perceived Vulnerability to Complications and perceived Treatment 'Cost-effectiveness' were entered. This stage of the analyses corresponded to the usual formulation of the HBM in which all components are assumed to be related in an additive fashion. On the second step, the first multiplicative composite of Severity x Vulnerability was entered. Finally, on the third step the multiplicative composite of Severity x Vulnerability x Treatment 'Cost-effectiveness' was entered.

Two sets of analyses were conducted initially in order to determine the most efficient measure of perceived Vulnerability to Complications. In the first set of analyses, scores relating to perceived personal vulnerability were entered into the regression equation both independently and multiplicatively. The results of these analyses are summarised in Table 4.3. The scores relating to perceived vulnerability of the 'average person' replaced the personal vulnerability scores in the second set of analyses. The corresponding results are summarised in Table 4.4. These results indicated that the measure of personal vulnerability was slightly more efficient than the measure relating to the 'average person' in accounting for the variance in outcomes. All subsequent regression analyses therefore included the measure of personal vulnerability only.

Table 4.3 also indicates that, overall, the diabetes-specific HBM measures were very poor predictors of baseline HbA_1 and percent ideal body weight, whilst only moderate amounts of the variance in subjective estimates of

Table 4.3: Prediction of health outcomes from original HBM components and their interactions. (Includes measure of *personal vulnerability*)

	B	ß	$sr^{2\,a}$
Baseline HbA1 (n = 138)			
Treatment 'Cost-effectiveness'	-0.029	-0.02	.00
Severity of Diabetes	0.260	0.04	.00
Vulnerability to Complications	1.914	0.18	.02
Severity x Vulnerability	0.688	0.07	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-0.249	0.03	.00
R^2 = .05; Adjusted R^2 = .01 (F = 1.30; df = 5,132 p>0.05)			
Percent ideal body weight (n = 139)			
Treatment 'Cost-effectiveness'	-0.312	-0.12	.01
Severity of Diabetes	2.245	0.19	.03*
Vulnerability to Complications	0.884	0.04	.00
Severity x Vulnerability	2.002	0.10	.01
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-1.903	-0.12	.01
R^2 = .11 Adjusted R^2 = .07 (F = 3.13 df = 5,133; p<0.01)			
Subjective estimates of diabetes control (n = 135)			
Treatment 'Cost-effectiveness'	-0.044	-0.25	.05**
Severity of Diabetes	0.005	0.01	.00
Vulnerability to Complications	0.403	0.29	.06**
Severity x Vulnerability	-0.077	-0.06	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	0.099	0.10	.01
R^2 = .16 Adjusted R^2 = .12 (F = 4.82; df = 5,129 p<0.001)			

** p<0.01 * p<0.05

[a] sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable

Table 4.4:

Prediction of health outcomes from original HBM components and their interactions. (Includes measure of *'average person'* *vulnerability*)

Baseline HbA1 (n = 138)

	B	β	sr^2 a
Treatment 'Cost-effectiveness'	-0.123	-0.09	.01
Severity of Diabetes	0.142	0.02	.00
Vulnerability to Complications	1.578	0.15	.01
Severity x Vulnerability	0.086	0.01	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	0.124	-0.02	.00

R^2 = .04; Adjusted R^2 = .00 (F = 1.01; df = 5,132; $p>0.05$)

Percent ideal body weight (n = 138)

	B	β	sr^2 a
Treatment 'Cost-effectiveness'	-0.383	-0.15	.02
Severity of Diabetes	2.399	0.21	.03*
Vulnerability to Complications	0.364	0.02	.00
Severity x Vulnerability	1.539	0.08	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-1.043	-0.07	.00

R^2 = .07 Adjusted R^2 = .03 (F = 1.77 df = 5,132; $p<0.05$)

Subjective estimates of diabetes control (n = 137)

	B	β	sr^2 a
Treatment 'Cost-effectiveness'	-0.051	-0.30	.07***
Severity of Diabetes	-0.007	0.01	.00
Vulnerability to Complications	0.344	0.24	.04*
Severity x Vulnerability	-0.135	-0.10	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	0.122	0.12	.01

R^2 = .16; Adjusted R^2 = .12 (F = 4.86; df = 5,131 $p<0.001$)

*** $p<0.001$ ** $p<0.01$ * $p<0.05$

a sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable diabetes control were explained. A total of 5% (1% adjusted) of the variance in baseline HbA_1, 11% (7% adjusted) of the variance in percent ideal body weight, and 16% (12% adjusted) of the variance in subjective estimates of control were accounted for by the HBM variables. None of the variables contributed significantly to the overall prediction of HbA_1 values, although perceived Vulnerability to Complications accounted for 2% of unique variance in this outcome. Perceived Severity of Diabetes contributed significantly ($p<0.05$) to the overall prediction of percent ideal body weight values, and accounted for 3% of unique variance. Perceived Vulnerability to Complications and perceived Treatment 'Cost-effectiveness' both contributed significantly ($p<.01$) to the explanation of variance in subjective estimates of diabetes control and accounted for 6% and 5% of unique variance respectively. None of the interactions produced a significant increase in the R^2, indicating that the components of the HBM may operate independently. The multiplicative hypothesis was not completely rejected at this stage, however, as it was hypothesized that if perceived Personal Control/Self-efficacy is added to the regression equation, it may not only explain variance in its own right, but on the one hand, may also act as a suppressor variable, and on the other, may have a multiplicative relationship with the original HBM components. A suppressor variable "suppresses" variance that is irrelevant to prediction of the dependent variable and may be useful in increasing the multiple R^2 by virtue of its correlations with other independent variables (Tabachnick & Fidell, 1989).

2. *Introduction of Perceived Control/Self-efficacy into the regression equation.*

In order to investigate the role of Personal Control/Self-efficacy as a predictor of outcomes in concert with the original HBM variables, this

Table 4.5:
Personal Control/Self-efficacy added to the regression equation.

	B	β	sr^2 a
Baseline HbA1 (n = 120)			
Treatment 'Cost-effectiveness'	-0.045	-0.03	.00
Severity of Diabetes	0.053	0.10	.01
Vulnerability to Complications	1.430	0.14	.01
Personal Control/Self-efficacy	0.823	0.11	.01
Severity x Vulnerability	1.105	0.11	.01
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-0.247	-0.03	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	0.597	0.09	.00
R^2 = .08; Adjusted R^2 = .02 (F = 1.38; df = 7,112 p>0.05)			
Percent ideal body weight (n = 121)			
Treatment 'Cost-effectiveness'	-0.297	-0.11	.01
Severity of Diabetes	1.193	0.10	.01
Vulnerability to Complications	0.856	0.04	.00
Personal Control/Self-efficacy	2.659	0.18	.03*
Severity x Vulnerability	-0.641	-0.03	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-2.461	-0.17	.01
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	-2.135	0.18	.02
R^2 = .13; Adjusted R^2 = .08 (F = 2.44 df = 7,113 p<0.05)			
Subjective estimates of diabetes control (n = 117)			
Treatment 'Cost-effectiveness'	-0.035	-0.20	.03*
Severity of Diabetes	0.041	0.05	.00
Vulnerability to Complications	0.447	0.33	.07**
Personal Control/Self-efficacy	0.241	0.24	.05**
Severity x Vulnerability	0.086	0.06	.00
Severity x Vulnerability x Treatment 'Cost-effectiveness'	0.205	0.20	.02
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	0.136	0.17	.02
R^2 = .25; Adjusted R^2 = .20 (F = 5.18; df = 7,109; p<0.001)			

** p<0.01 * p<0.05
a sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable

variable was introduced to the regression equation on the first step in order to ascertain its independent value as a predictor. Personal Control/Self-efficacy was then assessed in an interaction with the original HBM variables on the last step. The results of these analyses are summarized in Table 4.5. It can be seen that, once again, only a small amount of the variance in HbA_1 and percent ideal body weight could be explained by all the variables. Adding perceived Personal Control/Self-efficacy to the equation increased the R^2 only marginally. Indeed, this variable had claimed some of the variance previously explained by the health belief variables. A total of 8% (2% adjusted) of the variance in HbA_1 and 13% (8% adjusted) of the variance in percent ideal body weight was accounted for by the variables. None of the variables contributed significantly to the prediction of HbA_1 values but perceived Control/Self-efficacy significantly explained 3% of unique variance in percent ideal body weight ($p<0.05$). The prediction of subjective estimates of diabetes control improved when perceived Personal Control/Self-efficacy was added to the equation with a total of 25% (20% adjusted) of the variance in this outcome being explained. Once again, perceived Treatment 'Cost-effectiveness' and perceived Vulnerability to Complications accounted for significant amounts of unique variance [3% ($p<0.05$) and 7% ($p<0.01$) respectively] and perceived Personal Control/Self-efficacy added a further 5% ($p<0.01$) to the prediction. For all three outcome variables, none of the multiplicative composites added significantly to the variance explained when entered on separate steps into the regression equation.

3. Inclusion of Health Value in the regression equation.

As mentioned in Chapter 3, one of two items constructed to measure health value in the benefits of, and barriers to treatment questionnaire loaded separately when factor analyzed. Health value is posited by the HBM to be a necessary prerequisite if beliefs are to have an effect on health behaviour. This item ('Good diabetes control has to take second place to some other more important things in my life') was therefore added to the regression equation on the first step in order to see if predictions in outcomes could be improved. The HBM variables and perceived Personal Control/Self-efficacy were added on the second step, and the multiplicative composites were entered on the third and subsequent steps. The results of these analyses indicated that the measure of health value did not contribute a significant amount of unique variance in the prediction of HbA_1 ($sr^2 = .00$; $p>0.05$), percent ideal body weight ($sr^2 = .02$; $p>0.05$), or subjective estimates of diabetes control ($sr^2 = .00$; $p>0.05$). Furthermore, this measure did not appear to act as a suppressor variable because the amount of variance explained overall for the three outcomes did not change significantly [HbA_1: 8% (1% adjusted); percent ideal body weight: 16% (10% adjusted); subjective estimates of diabetes control: 26% (20% adjusted)].

Categorizing and combining the HBM variables. (The non-linear hypothesis).

Given that none of the predicted interactions contributed significantly to predictions, it is possible that the variables do not combine to predict outcomes in a linear fashion. The non-linear hypothesis was therefore tested by combining categories of each variable in a similar manner to the Wallstons' locus of control typology (Wallston & Wallston, 1982). Data relating to each variable were split at the median to produce high and low categories and these categories were combined to form groups of subjects. The group types were explored in relation to baseline HbA_1, percent ideal body weight, and

Table 4.5: Prediction of outcomes from interactions between categories of perceived Severity and Vulnerability

	N	Mean Rank	Mean (SD)	Median
Baseline HbA1				
High Severity/High Vulnerability	35	89.3	60.0 (12.8)	61.0
High Severity/Low Vulnerability	21	57.5	50.9 (11.3)	48.0
Low Severity/High Vulnerability	29	82.0	57.7 (11.6)	57.0
Low Severity/Low Vulnerability	57	60.4	51.2 (12.3)	50.0
Chi-square = 15.1; p<0.01				
Percent ideal body weight				
High Severity/High Vulnerability	36	82.4	134.5 (30.8)	122.5
High Severity/Low Vulnerability	21	71.1	122.9 (21.8)	122.0
Low Severity/High Vulnerability	29	76.6	126.4 (21.2)	122.0
Low Severity/Low Vulnerability	57	63.4	119.3 (21.8)	116.0
Chi-square = 5.1; p>0.05				
Subjective estimates of diabetes control				
High Severity/High Vulnerability	32	84.7	3.5 (1.7)	3.0
High Severity/Low Vulnerability	21	55.5	2.2 (1.1)	2.0
Low Severity/High Vulnerability	28	86.8	3.6 (1.7)	3.5
Low Severity/Low Vulnerability	57	57.6	2.4 (1.5)	2.0
Chi-square = 17.5; p<0.001				

subjective estimates of diabetes control using Kruskal-Wallis H tests. Initially, the perceived Severity and Vulnerability data were categorized and combined in order to assess a two-way interaction between these variables.

(1) Two-way interaction: Perceived Severity of Diabetes and Vulnerability to Complications

The HBM predicts that patients with high perceived Severity and Vulnerability scores would have the best diabetes control and those with low perceived Severity and low Vulnerability scores would have the worst diabetes control. The Kruskal-Wallis tests (Table 4.5) indicated that if diabetes control was poor as determined by objective criteria (baseline HbA_1 and percent ideal body weight) or perceived (subjective estimates of diabetes control), perceived vulnerability was always greater but scores for perceived Severity could be either high or low (see vertical patterns for each outcome variable in Table 4.6). Conversely, if diabetes control was actually or perceived to be good, perceived vulnerability was always lower but, once again, perceived Severity could be either high or low. Although, contrary to the predictions of the HBM, these relationships are in accordance with the results of correlations reported earlier in this chapter. The general pattern of results was statistically significant for baseline HbA_1 (chi-square = 15.1; $p<0.01$) and subjective estimates of control (chi-square = 17.5; $p<0.001$) but did not reach significance for percent ideal body weight (chi-square = 5.1). Table 4.5 indicates that a combination of high perceived Severity and low perceived Vulnerability was associated with the lowest levels of baseline HbA_1 and the most optimistic subjective estimates of diabetes control while a combination of high perceived Severity and high perceived Vulnerability was associated with the highest levels of baseline HbA_1. The most pessimistic subjective estimates of diabetes control were related to a belief pattern of low perceived Severity and high perceived Vulnerability. For percent ideal body weight, a combination of low perceived Severity and low perceived Vulnerability was associated with the best weight control while a combination of high perceived Severity and high perceived Vulnerability was associated with the greatest obesity.

Table 4.6: Patterns of perceived Severity and Vulnerability in relation to behavioural outcomes.

	Baseline HbA1		Percent ideal body weight		Subjective estimates of diabetes control	
	Severity	Vulner-ability	Severity	Vulner-ability	Severity	Vulner-ability
Best control	High	Low	Low	Low	High	Low
	Low	Low	High	Low	Low	Low
Poorest control	Low	High	Low	High	High	High
	High	High	High	High	Low	High

In conclusion, although the combinations of perceived Severity and Vulnerability were statistically significant in relation to baseline HbA_1 and subjective estimates of diabetes control, inspection of the belief patterns across all three outcomes indicated that levels of perceived Vulnerability were critical in determining diabetes control (or vice-versa), whilst levels of perceived Severity seemed to vary *randomly*. In order to understand the three-way interactions described below, it is important to note at this point, that perceived Severity and Vulnerability appear to function independently in relation to health outcomes.

(3) *Three-way interaction: Perceived Severity, Vulnerability and Treatment 'Cost-effectiveness'*

Because the combination of high and low categories of perceived Severity and Vulnerability did not provide evidence for a consistent two-way interaction in relation to the health outcomes, the next step was to examine the results of three-way interactions between perceived Severity, Vulnerability and treatment 'Cost-effectiveness'. Once again, the data relating to these variables were split at the median but this time they were combined to form 8 groups of subjects as the increase in the number of variables increased the number of possible combinations. The results of the Kruskal-Wallis tests used on these data are presented in Table 4.7 and summarized in Table 4.8. It was predicted that those patients with the best diabetes control would have high or low perceived Severity scores, low Perceived Vulnerability scores, and high treatment 'Cost-effectiveness' scores (in the table: Low/Low/High or High/Low/High patterns). Conversely, it was predicted that those with very poor diabetes control would have high or low perceived Severity scores, high perceived Vulnerability scores and low treatment 'Cost-effectiveness' scores (in the table: Low/High/Low or High/High/Low patterns).

When related to baseline HbA_1 and percent ideal body weight, the pattern of ranks was not totally in line with predictions. Although the pattern of beliefs predicted to be related to the poorest diabetes control was as expected, the best diabetes control was assocated with a pattern of high perceived Severity scores, low perceived vulnerability scores, and low treatment 'Cost-effectiveness' scores (in the table: High/Low/Low). Furthermore, the pattern of beliefs ranked second in relation to good control comprised of low perceived Severity, low perceived Vulnerability, and low treatment 'Cost-effectiveness' (in the table: Low/Low/Low). Thus, contrary to predictions, low perceived treatment 'Cost-effectiveness' scores were

Table 4.7: Prediction of outcomes from interactions between categories of perceived Severity, Vulnerability, and Treatment 'Cost-effectiveness

	Score Categories			N	Mean Rank	Mean	(SD)	Median
	Severity	Vulner-ability	'Cost-effectiveness'					
Baseline HbA1	High	High	High	7	66.4	54.8	(14.1)	52.5
	High	High	Low	26	91.2	62.1	(12.5)	62.0
	High	Low	High	13	63.1	53.5	(12.8)	51.0
	Low	High	High	16	73.3	52.2	(9.6)	51.0
	Low	Low	High	30	61.3	48.5	(12.4)	49.0
	Low	High	Low	12	86.9	50.6	(13.9)	52.0
	High	Low	Low	8	45.1	47.0	(7.3)	46.0
	Low	Low	Low	26	58.5	57.7	(12.3)	60.0
				Chi-square = 16.7; p<0.05				
Percent ideal body weight	High	High	High	7	62.6	122.8	(23.3)	121.0
	High	High	Low	27	87.2	149.1	(31.8)	145.0
	High	Low	High	13	76.0	120.6	(22.6)	115.0
	Low	High	High	16	65.9	119.2	(19.5)	125.0
	Low	Low	High	30	61.3	110.9	(19.0)	108.0
	Low	High	Low	12	85.2	127.7	(22.5)	115.0
	High	Low	Low	8	54.9	127.6	(18.8)	129.0
	Low	Low	Low	26	61.3	120.6	(25.0)	114.0
				Chi-square = 11.1; p>0.05				
Subjective estimates of diabetes control	High	High	High	6	64.4	3.0	(2.5)	2.0
	High	High	Low	25	86.8	3.6	(1.5)	3.0
	High	Low	High	13	53.8	2.1	(1.1)	2.0
	Low	High	High	16	78.3	3.2	(1.6)	3.0
	Low	Low	High	30	45.7	1.9	(1.1)	2.0
	Low	High	Low	11	93.3	4.1	(2.0)	2.0
	High	Low	Low	8	55.6	2.2	(1.3)	2.0
	Low	Low	Low	26	70.4	3.0	(1.8)	2.5
				Chi-square = 23.9; p<0.001				

associated with good diabetes control. The patterns of scores predicted to be related to the best diabetes control were ranked next in line. These results were statistically significant for baseline HbA_1 (chi-square = 16.7; $p<0.05$) but did not reach significance for percent ideal body weight (chi-square = 11.1).

The combinations of beliefs in relation to subjective estimates of diabetes control were totally in line with predictions. A belief pattern of low perceived Severity, low perceived Vulnerability, and high perceived treatment 'Cost-effectiveness' was associated with the most optimistic estimates of control (in the table: Low/Low/High), followed by a pattern of high perceived Severity, low perceived Vulnerability, and high perceived treatment 'Cost-effectiveness' (in the table: High/Low/High). At the other extreme, a pattern of low perceived Severity, high perceived Vulnerability, and low perceived treatment 'Cost-effectiveness' was associated with the most pessimistic estimates of control (in the table: Low/High/Low), followed by a pattern of high perceived Severity, low perceived Vulnerability, and low perceived treatment 'Cost-effectiveness' (in the table: High/High/Low). The Kruskal-Wallis test indicated that the overall pattern of results was highly significant (chi-square = 23.9; $p<0.001$).

In summary, the patterns of perceived Severity, Vulnerability, and treatment 'Cost-effectiveness' were statistically significant in relation to baseline HbA_1 and subjective estimates of control but not for percent ideal body weight. In the latter case, however, the pattern of weight control rankings was comparable to those for glycaemic control and subjective estimates of control. Inspection of Table 4.8 indicates that perceived Vulnerability and treatment 'Cost-effectiveness' varied in relation to one another but, once again, perceived Severity appeared to function

Table 4.8: Patterns of perceived Severity, Vulnerability and treatment 'Cost-effectiveness' in relation to behavioural outcomes.

	Baseline HbA1			Percent ideal body weight			Subjective estimates of diabetes control		
	Sev-erity	Vulner-ability	'Cost-effectiveness	Sev-erity	Vulner-ability	'Cost-effectiveness	Sev-erity	Vulner-ability	'Cost-effectiveness
Best Control	High	Low	Low	High	Low	Low	Low	Low	High
	Low	Low	Low	Low	Low	Low	High	Low	High
	Low	Low	High	Low	Low	High	High	Low	Low
	High	Low	High	High	High	High	High	High	High
Poorest Control	High	High	High	Low	High	High	Low	Low	Low
	Low	High	High	High	Low	High	Low	High	High
	Low	High	Low	Low	High	Low	High	High	Low
	High	High	Low	High	High	Low	Low	High	Low

Light shading: Patterns of beliefs predicted to b e associated with the best diabetes control

Dark shading: Patterns of beliefs predicted to b e associated with the poorest diabe tes control

independently and inconsistently across the three outcomes. A pattern of low perceived Vulnerability and low perceived treatment 'Cost-effectiveness' was associated with the two highest rankings of control for all three outcomes whereas a pattern of high perceived Vulnerability and low perceived Treatment 'Cost-effectiveness' was associated with the two lowest rankings of control for all three outcomes. It can also be seen from Table 4.8 that in relation to baseline HbA_1 and percent ideal body weight, the combination of these beliefs produced a boomerang pattern of relationships for perceived treatment 'Cost-effectiveness'. This pattern of associations provides evidence, therefore, for a two-way interaction between perceived Vulnerability and treatment 'Cost-effectiveness'.

(4) Categories of Personal Control/Self-efficacy combined with the HBM variables

If categories of Personal Control/Self-efficacy were combined with those for perceived Vulnerability, Severity, and treatment 'Cost-effectiveness', the number of possible combinations would become unwieldly and more difficult to interpret and the likelihood of very small numbers in each category or even empty cells would increase. It was therefore decided that perceived Severity and Vulnerability would be combined multiplicatively and then split at the median into categories of high and low values; this new variable was labelled 'perceived Threat'. Personal Control/Self-efficacy scores were split at the median after first selecting out subjects who had also scored highly on the Situational Control scale. This method provided a 'purer' measure of the construct but reduced the number of subjects. The categories of perceived Threat and perceived Personal Control/Self-efficacy were then combined with those for perceived treatment 'Cost-effectiveness' to produce 8 combinations of beliefs. The results of the Kruskal-Wallis tests on these data are presented in Table 4.9 and summarized in Table 4.10. It was predicted that patients with the best diabetes control would have a belief pattern of high perceived treatment 'Cost-effectiveness, low perceived Threat, and high perceived Personal Control/Self-efficacy (in the table: High/Low/High), whilst those with the poorest diabetes control would have a belief pattern of low perceived treatment 'Cost-effectiveness, high perceived Threat, and low perceived Personal Control/Self-efficacy (in the table: Low/High/Low).

When related to all three outcomes, the patterns of beliefs were not exactly as predicted. Patients with the lowest levels of HbA_1 had a belief

Table 4.9: Prediction of outcomes from interactions between categories of perceived Treatment 'Cost-effectiveness', Threat, and Personal Control/Self-efficacy

Outcome	Cost-effectiveness	Threat	Personal Control/ Self-efficacy	N	Mean Rank	Mean	(SD)	Median
Baseline HbA1	High	High	High	10	39.2	49.1	(7.3)	48.0
	High	Low	High	20	35.8	48.4	(13.0)	45.0
	High	High	Low	12	58.4	57.3	(11.8)	58.3
	High	Low	Low	12	53.4	54.7	(9.0)	51.5
	Low	High	High	9	65.1	60.7	(11.9)	61.0
	Low	Low	High	5	16.5	41.2	(4.3)	41.0
	Low	High	Low	21	59.8	58.3	(13.7)	57.0
	Low	Low	Low	9	53.1	54.0	(11.4)	57.0
				Chi-square = 19.7; $p<0.01$				
Percent ideal body weight	High	High	High	10	34.1	112.6	(12.2)	115.0
	High	Low	High	20	44.2	122.4	(20.2)	115.5
	High	High	Low	13	43.9	123.4	(27.0)	113.0
	High	Low	Low	12	46.5	121.3	(22.5)	123.0
	Low	High	High	9	49.1	125.3	(22.7)	119.0
	Low	Low	High	5	32.8	111.6	(33.7)	100.0
	Low	High	Low	21	70.3	144.9	(25.4)	150.0
	Low	Low	Low	9	57.3	129.8	(19.9)	129.0
				Chi-square = 17.5; $p<0.05$				
Subjective estimates of diabetes control	High	High	High	10	50.5	2.8	(1.4)	2.5
	High	Low	High	20	23.9	1.4	(0.5)	1.0
	High	High	Low	12	62.5	3.8	(2.1)	3.5
	High	Low	Low	12	47.5	2.6	(1.2)	2.0
	Low	High	High	9	60.8	3.4	(1.6)	3.0
	Low	Low	High	5	29.1	1.6	(0.5)	2.0
	Low	High	Low	19	61.3	3.5	(1.6)	3.0
	Low	Low	Low	9	55.1	3.6	(2.5)	4.0
				Chi-square = 27.4; $p<0.001$				

pattern of low perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy (in the table: Low/Low/High). However, this group consisted of only five subjects. The next best HbA_1 ranks were associated with the predicted belief pattern of high perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy (in the table: High/Low/High). At the other extreme, the poorest glycaemic control was associated with a belief pattern of low perceived Cost-effectiveness, high perceived Threat and, contrary to prediction, high perceived Personal Control/Self-efficacy (in the table: Low/High/High). This combination of beliefs was followed, however, by the predicted pattern of low perceived treatment 'Cost-effectiveness', high perceived Threat, and low perceived Personal Control/Self-efficacy (in the table: Low/High/Low). The Kruskal-Wallis test indicated that the overall pattern of results was statistically significant (chi-square = 19.7; $p<0.01$)

The pattern of beliefs associated with the lowest values of percent ideal body weight was the same as that associated with the lowest levels of HbA_1 (in the table: Low/Low/High). Once again, only 5 subjects reported this belief pattern. This was followed, however, by a belief pattern of high perceived treatment 'Cost-effectiveness', high perceived Threat, and high perceived Personal Control (in the table: High/High/High). This latter combination of beliefs is in line with HBM predictions but was not predicted in this study. At the other extreme, the greatest obesity was associated with the predicted pattern of low perceived treatment 'Cost-effectiveness', high perceived Threat, and low perceived Personal Control/Self-efficacy (in the table: Low/High/Low). The overall pattern of results was statistically significant (chi-square = 17.5; $p<0.05$).

Table 4.10: Patterns of perceived treatment 'Cost-effectiveness', Threat, and Personal Control/Self-efficacy in relation to behavioural outcomes.

	Baseline HbA1			Percent ideal body weight			Subjective estimates of diabetes control		
	'Cost-effectiveness'	Threat	Pers. Ctrl/ Self-efficacy	'Cost-effectiveness'	Threat	Pers. Ctrl/ Self-efficacy	'Cost-effectiveness'	Threat	Pers. Ctrl/ Self-efficacy
Best Control	Low	Low	High	Low	Low	High	High	Low	High
	High	Low	High	High	High	High	Low	Low	High
	High	High	High	High	High	Low	High	Low	Low
	Low	Low	Low	High	Low	High	High	High	High
Poorest Control	High	Low	Low	High	Low	Low	Low	Low	Low
	High	High	Low	Low	High	High	Low	High	High
	Low	High	Low	Low	Low	Low	Low	High	Low
	Low	High	High	Low	High	Low	High	High	Low

Patterns of beliefs predicted to b e associated with the best diabetes control

Patterns of beliefs predicted to b e associated with the poorest diabet es control

The most optimistic subjective estimates of diabetes control were associated, as predicted, with a belief pattern of high perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy (in the table High/Low/High). Contrary to prediction, the most pessimistic estimates of diabetes control were related to high perceived treatment 'Cost-effectiveness' scores, high perceived Threat scores, and low perceived Personal Control/Self-efficacy scores (in the table: High/High/Low). This combination of beliefs was followed in rank by the pattern predicted to be associated with estimates of the poorest diabetes control (in the table: Low/High/Low). The Kruskal-Wallis test indicated that the overall pattern of results was highly significant (chi-square = 27.4; $p<0.001$).

In summary, the patterns of beliefs were statistically significant in relation to all three outcome variables. Although the combinations of variables were not always associated with outcomes as predicted, the overall results were roughly in accordance with expectations. Furthermore, inspection of Table 4.10 indicates that, in general, all three belief variables varied in relation to one another, although the patterns associated with good weight control and obesity were different to those for percent ideal body weight and subjective estimates of diabetes control.

(5) Categories of Personal Control/Self-efficacy and HBM variables related to Well-being and Treatment Satisfaction.

In general, the patterns of perceived treatment 'Cost-effectiveness, perceived Threat, and perceived Personal Control/Self-efficacy were associated with health outcomes as predicted but there were some notable exceptions. For example, the lowest levels of baseline HbA_1 were associated with the predicted categories of low *perceived Threat and high perceived* Personal Control/Self-efficacy, but contrary to HBM predictions, were also related to low perceived treatment 'Cost-effectiveness'. It was considered possible that the unpredicted combinations of beliefs may have been a result of the respondents' psychological Well-Being and Treatment Satisfaction at the time of completing the questionnaires and thus all the patterns of HBM and Personal Control/Self-efficacy beliefs were examined in relation to these psychological outcomes. The results of these analyses are summarized in Table 4.11.

The results indicate that those with the best diabetes control (indicated by HbA_1 and percent ideal body weight) and the associated belief pattern of low perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy (in the table: Low/Low/High), were also the most depressed, and were among the most anxious and least satisfied. The group of patients with the belief pattern predicted to be associated with the best diabetes control (in the table: High/Low/High) had the next best HbA_1 levels and the most optimistic subjective estimates of diabetes control. These patients also reported the greatest Positive Well-being, General Well-being, and Treatment Satisfaction. It seems likely, therefore, that the low perceived treatment 'Cost-effectiveness' scores associated with the best blood glucose and weight control were a result of feeling more depressed and anxious, and less satisfied with treatment. The most pessimistic subjective estimates of diabetes control were associated with high perceived treatment 'Cost-effectiveness', high perceived Threat, and low perceived Personal Control/Self-efficacy (in the table: High/High/Low). However, the group of patients with this belief pattern were among the least obese and had high Treatment Satisfaction scores. It is likely, therefore, that high perceived treatment 'Cost-effectiveness' was related to these patients having relatively good weight control and, as a result, being very satisfied with their treatment.

Table 4.11: Numbers of subjects, mean (SD) and range of Well being, Treatment Satisfaction, HbA1, percent ideal body weight, and subjective estimates of diabetes control by patterns of HBM and Personal Control/ Self-efficacy beliefs.

'Cost-effectiveness'	High	High	High	High	Low	Low	Low	Low
Threat	High	Low	High	Low	High	Low	High	Low
Pers.Control/ Self-efficacy	High	High	Low	Low	High	High	Low	Low
Number of subjects	10	20	13	12	9	5	21	9
Depression								
Mean(SD)	15.5(2.5)	15.9(2.9)	14.8(2.8)	16.0(2.5)	13.9(2.4)	13.6(2.7)	13.7(3.2)	16.1(1.8)
Range	11-18	8-18	9-18	9-18	9-17	11-18	6-18	13-18
Anxiety								
Mean(SD)	13.9(4.0)	14.8(4.5)	13.3(4.4)	13.9(4.4)	12.6(2.6)	12.0(3.9)	11.3(4.0)	14.9(2.3)
Range	6-18	5-18	5-18	3-18	8-15	8-18	5-17	11-18
Positive Well being								
Mean(SD)	13.6(3.7)	15.3(4.3)	12.9(4.3)	14.0(3.1)	11.4(3.2)	12.4(3.6)	11.2(4.5)	14.1(2.6)
Range	7-18	3-18	6-18	6-18	5-16	8-18	4-18	11-18
General Well being								
Mean(SD)	42.0(9.3)	45.9(10.2)	41.1(9.8)	43.9(9.6)	37.9(7.4)	38.0(9.0)	36.1(9.8)	45.1(5.7)
Range	26-53	17-54	24-54	18-52	25-45	32-54	20-51	36-54
Treatment Satisfaction								
Mean(SD)	30.8(4.1)	33.8(2.8)	26.8(6.5)	31.5(4.0)	30.0(4.9)	31.0(6.2)	27.5(5.3)	26.8(5.7)
Range	23-36	27-36	13-36	22-36	22-35	20-35	19-36	19-34
Baseline HbA1								
Mean(SD)	49.1(7.3)	48.4(13.0)	57.3(11.8)	54.7(9.0)	60.7(11.9)	41.2(4.3)	58.3(13.7)	54.0(11.4)
Range	40 62	29-79	40-80	45-72	43-75	35-47	34-83	32-70
Percent ideal body weight								
Mean(SD)	112.6(12.2)	122.4(20.2)	123.4(27.0)	121.3(22.5)	125.3(22.7)	111.6(33.7)	144.9(25.4)	129.8(19.9)
Range	90-129	100-178	92-173	79-157	96-173	83-164	101-210	94-161
Subjective estimates of diabetes control								
Mean(SD)	2.8(1.4)	1.4(0.5)	3.8(2.1)	2.6(1.2)	3.4(1.6)	1.6(0.5)	3.5(1.6)	3.6(2.5)
Range	1-5	1-2	1-7	1-5	2-6	1-2	1-7	1-7

Higher Scores indicate less Depression and Anxiety, and greater Positive Well being, General Well being, and Treatment Satisfaction.

Normal reference range for HbA1 is 29.0 to 39.0 mmol HMF.

Discussion

In the present study, ratings of an 'average person's' Vulnerability to Complications were not significantly different to those for personal Vulnerability. Furthermore, when ratings did differ, both pessimistic and optimistic biases were associated with a realistic appraisal of the respondents' own diabetes control. It was also found subsequently that scores relating to personal Vulnerability were slightly superior to those for the 'average person' when these variables were entered into two separate regression equations. Personal Vulnerability was therefore selected for inclusion in all subsequent analyses and 'average person' Vulnerability was dropped completely.
In Chapter 3, it was noted that, for the individual complications, Vulnerability scores relating to the 'average person' were significantly greater than those for personal Vulnerability. The contrast between these findings and those in the present study is probably explained, on the one hand, by lack of knowledge regarding which disorders are complications, and on the other, by a restricted or idiosyncratic interpretation of the single item, "Complications arising from diabetes". If this is the case, then it seems that optimistic biases *will only* prevail if the disorder in question is perceived to be irrelevant to current health status. Thus, the general tendency to assume that "it won't happen to me" (Weinstein, 1987), will diminish when a risk becomes more salient. In the present study, it was anticipated that Optimistic Bias could be usefully incorporated in the HBM in the course of specifying the relationships between its components. However, because no significant Optimistic Bias was found, it was excluded from subsequent analyses. As previously noted (Chapter 3), the optimistic bias found in relation to Vulnerability to the individual complications, provides useful information for the targeting of educational interventions.

The main aim of this study was to establish whether the individual components of the HBM combine in a purely additive fashion, or whether multiplicative composites of the various components would add significantly to the overall amount of outcome variance explained. On the assumption that the components of the HBM are linearly related to health outcomes, the initial sets of analyses were carried out using hierarchical multiple regression. The amount of variance explained by the individual components of the original HBM was only small to moderate [4% to 16% (0% to 12% adjusted] and, in all cases, none of the multiplicative composites added significantly to the overall explanation. As found previously in individual correlations, the HBM variables were more strongly related to subjective estimates of diabetes control than to actual control (HbA_1 and percent ideal body weight). None of the variables contributed significant amounts of unique variance in the prediction of baseline HbA_1 and perceived Severity of Diabetes was the only variable which significantly predicted percent ideal body weight. Subjective estimates of diabetes control were predicted by perceived treatment 'Cost-effectiveness' and perceived Vulnerability to Complications. These results indicated that the HBM components combine in an additive rather than a multiplicative manner. Furthermore, certain beliefs were not salient in the prediction of outcomes; for example, perceived Severity of Diabetes and treatment 'Cost-effectiveness' made extremely weak contributions to the prediction of baseline HbA_1, and perceived Vulnerability to Complications barely contributed to the prediction of percent ideal body weight.

When perceived Personal Control/Self-efficacy was added to the regression equation, both individually and as part of a multiplicative composite, the amount of overall variance explained increased significantly [8% to 25% (2% to 20% adjusted)]. Furthermore, although this variable did not contribute a significant amount of unique variance in the prediction of

HbA_1, it did account for significant amounts of unique variance in the prediction of percent ideal body weight and subjective estimates of diabetes control. (In relation to percent ideal body weight, perceived Personal Control/Self-efficacy claimed some of the variance explained by perceived Severity and thus became the most important predictor of this outcome.) When considered as part of a multiplicative composite, however, it did not significantly increase the overall amount of variance explained in any of the outcome variables. Furthermore, inclusion of this variable did not significantly improve the efficiency of the previous multiplicative composites in the prediction of outcomes. These results indicate, therefore, that perceived Personal Control/Self-efficacy adds significant explanatory power to the HBM but is related in an additive rather than a multiplicative fashion. Once again, the amounts of variance explained overall by these variables was only small to moderate. Moreover, subsequent inclusion of the single-item health value measure in the regression equation did not improve these predictions. It is possible, however, that the single item was a poor or unrepresentative measure of health value.

As none of the multiplicative composites contributed significantly to predictions of baseline HbA_1, percent ideal body weight, and subjective estimates of diabetes control, it was considered possible that these variables do not combine to predict outcomes in a linear fashion. Indeed, non-linear combinations of the belief variables revealed patterns which were not predicted to be associated with particular outcomes. When all possible combinations of perceived Severity and perceived Vulnerability were combined after being categorized into high and low scores, a consistent pattern of associations between perceived Vulnerability and diabetes control became apparent. On the one hand, low perceived Vulnerability scores were associated with the best diabetes control (as indicated by baseline HbA_1, percent ideal body weight, and subjective estimates of diabetes control), and on the other, high perceived Vulnerability scores were associated with the poorest diabetes control. However, levels of perceived Severity seemed to vary randomly in relation to all three outcome variables. This result is consistent with findings from several other HBM studies which have shown that perceived Severity was not a useful predictor of preventive health behaviour (Janz & Becker, 1984). Furthermore, the random variation of perceived Severity in relation to outcomes suggests that a minimum level of this belief had been exceeded to be of concern, and thus preventive health behaviour was largely a function of perceived Vulnerability only. An alternative explanation for these findings is that perceived Severity of Diabetes may be a particularly dynamic belief. Thus, if a person has reached a point where their diabetes control is perceived to be unsatisfactory, perceived Severity may increase and preventive health behaviour is likely to be initiated. When control is perceived to have returned to a satisfactory level, however, perceived Severity of Diabetes is likely to reduce to its original low level. The magnitude of perceived Severity will therefore depend on whether glycaemic and/or weight control is deteriorating or improving. If this latter explanation is correct, an intervention which has been designed to increase perceived Severity should produce non-random patterns of this belief in relation to health outcomes. Although the pattern of beliefs was consistent across all three outcome variables, the combinations of high and low perceived Severity and Vulnerability were not significantly associated with percent ideal body weight. However, as shown by the previous regression analyses, this was probably due to beliefs about Vulnerability to Complications being less salient to behaviour concerning weight control.

When combinations of perceived Severity, Vulnerability, and treatment 'Cost-effectiveness' were examined, the same apparently random pattern of perceived Severity scores was noted in relation to the outcome variables. However, perceived Vulnerability and treatment 'Cost-effectiveness' appeared to vary in relation to one another indicating that these variables interacted in a non-linear fashion. It is particularly interesting to note that combinations of these variables produced an unexpected boomerang pattern of relationships between perceived treatment 'Cost-effectiveness' on the one hand, and HbA_1 and weight control on the other. Low perceived treatment 'Cost-effectiveness' was associated with both extremes of control whilst high perceived treatment 'Cost-effectiveness' was associated with intermediate levels of control. However, the associated beliefs about Vulnerability varied as predicted with lower scores for this variable being related to better control whilst higher scores were associated with poorer control. The most optimistic and pessimistic subjective estimates of diabetes control were associated with the predicted patterns of Vulnerability and treatment 'Cost-effectiveness' beliefs as predicted. Again, the patterns of beliefs were more strongly associated with subjective estimates of control than actual measures of HbA_1 and percent ideal body weight. Indeed, percent ideal body weight was not associated significantly with these belief patterns, indicating once again that this was probably due to weight control being only weakly associated with beliefs about Vulnerability to Complications.

The final combinations of perceived treatment 'Cost-effectiveness', perceived Threat (Severity x Vulnerability), and perceived Personal Control/Self-efficacy were significantly associated with all three outcome variables. However, some of the outcomes were associated with patterns of beliefs which were not predicted. In particular, low perceived treatment 'Cost-effectiveness' was associated with the lowest HbA_1 levels and the best weight control when combined with low perceived Threat and high perceived Personal Control/Self-efficacy. When examined in relation to Well-being and

Treatment Satisfaction scores, however, the respondents with this belief pattern were also the most depressed, and were among the most anxious and least satisfied. Furthermore, the group of patients with the belief pattern predicted to be associated with the best diabetes control (high perceived treatment 'Cost-effectiveness'/low perceived Threat/high perceived Personal Control/Self-efficacy) had the next best HbA_1 levels and the most optimistic subjective estimates of diabetes control. They also reported the greatest Positive Well-being, General Well-being and Treatment Satisfaction. In view of these findings, it seems likely that the unexpected patterns of beliefs associated with the best blood glucose and weight control were a result of feeling more depressed, anxious and less satisfied with treatment. A pattern of high perceived treatment 'Cost-effectiveness' in combination with high perceived Threat, and low perceived Personal Control/Self-efficacy was associated with the most pessimistic estimates of control. However, the group of patients with this belief pattern were among the least obese and were very satisfied with their treatment. The high treatment 'Cost-effectiveness' scores were likely, therefore, to be the result of having relatively good weight control and, consequently, being very satisfied with the treatment. Thus, when Well-being and Treatment Satisfaction were taken into account, the patterns of beliefs predicted to be associated with the best and poorest control were generally as expected. A slight variation was apparent for percent ideal body weight, however, in that a pattern of high rather than low perceived Threat in association with high perceived treatment 'Cost-effectiveness' and high perceived Personal Control/Self-efficacy predicted better weight control. This pattern of beliefs was not predicted in this study but is in accordance with the predictions of the HBM.

One of the shortcomings of this set of analyses was that single item measures of perceived severity and vulnerability were used. These measures were selected because of their greater sensitivity in correlations with the outcome measures but single items are limited in the breadth of their measurement and thus variability in responses is reduced when compared with multi-item measures. Accordingly, spurious agreement between subjects may be obtained and idiosyncratic responding is more likely because the elements of the construct measured are not made explicit. Furthermore, the measure of perceived Severity of *Diabetes* was not the same as the composite measure of perceived Severity of *Complications.* The multiplicative combination of perceived Severity of Diabetes x perceived Vulnerability to Complications may have been compromised, therefore, because of the different levels of measurement. Nevertheless, given that the composite measures were affected by knowledge, it appeared that the single item measures were more representative.

A problem with using the measure of perceived Treatment "Cost-effectiveness" was that this eliminated the possibility of examining the impact of absolute level of perceived Barriers to, and Benefits of treatment. However, since the responses to the perceived Benefits scale were skewed and regression analysis assumes that variables are normally distributed, the difference score was employed because it satisfied assumptions of normality.

In summary, the results of the regression analyses indicated that the components of the HBM (including perceived Personal Control/Self-efficacy) are related in an additive fashion because none of the multiplicative composites provided a significant contribution to the variance explained. However, the Kruskall-Wallis ANOVAs indicated a significant three-way interaction between perceived treatment 'Cost-effectiveness', perceived Threat, and perceived Personal Control/Self-efficacy for all three outcome variables. The results of categorizing and combining the health beliefs in a non-linear fashion provided a clearer picture as to why the composite variables did not add significantly to the variance explained in regression analyses. In particular, it was noted that Well-being and Treatment Satisfaction seemed to influence perceived 'Cost-effectiveness' of treatment and, as a result produced combinations of beliefs which were not predicted to be associated with the best and poorest diabetes control. When these factors were taken into account, however, the predicted interactions between perceived treatment 'Cost-effectiveness', perceived Threat, and perceived Personal Control/Self-efficacy were largely as expected in relation to the three outcome variables. Moreover, when the patterns of beliefs were ordered in relation to the outcome variables, it was clear that the relationships were not linear. The expected interaction between perceived Severity and Vulnerability was not demonstrated in either the regression analyses or the Kruskal-Wallis one-way ANOVAs indicating that either a critical cut-off point for perceived Severity had been exceeded or that this belief is particularly dynamic and therefore difficult to assess in cross-sectional analyses. The results of the analyses including perceived Threat should be interpreted, therefore, with some caution. It should be remembered that these variables were combined multiplicatively when testing the non-linear hypothesis because the number of combinations in the analyses would have become unwieldly and difficult to interpret. Furthermore, the numbers in each category would have been small, increasing the likelihood of empty cells.

It is appreciated that the outcome variables used in this study were collected at the same time as the psychological variables and thus conclusions about cause and effect are problematic. Furthermore, the respondents' beliefs about their diabetes and its managment were affected by knowledge about this disorder and the quality of feedback about blood glucose control. Most of the patients in this study had not been to an organized education session at all and many were receiving inadequate feedback about the effects of their blood glucose control. In view of these factors, it is not surprising that, compared with subjective estimates of diabetes control, only small amounts of variance in blood glucose control and percent ideal body weight were explained. The next study attempted to tackle these problems in that it examines the effects of an education session on the health beliefs and psychological well-being of a sub-set of the patients from the present study. The effects of the beliefs on health behaviour were then assessed using measures of HbA_1 recorded approximately six months later. This study provided the opportunity, therefore, to re-examine the relationships between the HBM components in the light of better patient knowledge, and with the benefit of outcome data which had been collected prospectively.

CHAPTER FIVE

THE EFFECTS OF AN EDUCATIONAL INTERVENTION ON HEALTH BELIEFS, OTHER PSYCHOLOGICAL VARIABLES, AND GLYCOSYLATED HÆMOGLOBIN.

In Chapter 4 it was noted that health beliefs and psychological well-being were affected by patients' knowledge about the complications of diabetes and the quality of feedback they had received regarding their diabetes control. As a consequence, the psychological variables explained more of the variance in subjective estimates of diabetes control than the laboratory and clinical measures. The results were also difficult to interpret because the health outcome measures were collected at the same time as the psychological measures so it was impossible to determine whether beliefs caused the outcomes or whether they were merely a reflection of current health status. It is likely that a combination of these explanations was true which may explain why the hypothesized interactions between the health beliefs did not emerge as significant predictors of health outcome.

Given that patients have a large part to play in the control of their diabetes, education about the disorder and its management is very important. Furthermore, because the treatment regimen is pervasive and often intrusive, it is helpful if patients are given a rationale for taking exercise, following the recommended diet, and taking oral hypoglycaemic agents as prescribed. In the traditional diabetes clinic, virtually no time is allowed for education and instruction, although many hospitals now offer separate education sessions of varying kinds and quality. Since Type II diabetes has been, until recently, considered to be a mild form of the disease, perhaps because it does not have the immediate life-threatening consequences of the Type I disorder (Bloom, 1982; Burden, 1982), the needs of this patient group have often been neglected (Moor & Gadsby, 1984; Alberti & Gries, 1988). Indeed, Type II patients are generally found to have poorer knowledge about their disorder than Type I patients (Shillitoe, 1987). Prior to the research reported in this thesis, Clare Bradley and her colleagues found that when education was offered to some diet-only and tablet-treated patients in Sheffield, many of them were unclear about the treatment goals to be aimed for, and there was considerable ignorance about methods of attaining these goals. The major block to appropriate health care, however, appeared to be due to lack of understanding as to the reasons why their physicians had recommended these goals in the first place. Many patients appeared to be disturbingly ill-informed about the relationship between glycaemic control and microvascular complications, on the one hand, and diet and macrovascular complications on the other, yet this is the major source of motivation behind physicians' attempts to improve the glycaemic and weight control of their patients. Without such motivation it is easy to see why it is often the case that patients do not achieve the treatment goals set. Very few of the patients from the baseline study had previously received any formal education about diabetes and its management, thus, in recognition of their needs, they were invited to attend one of a series of specially designed education sessions at the hospital. The present study examines the effects of this education on the beliefs, knowledge, psychological well-being, and treatment satisfaction of those who attended. These variables were then examined in relation to HbA_1 approximately six months later. A particular aim was to re-examine the relationships between the HBM variables (including the newly-introduced measure of perceived Personal Control/Self-efficacy) when used to predict a prospective measure of blood glucose control.

Methods

Measures

Diabetes-specific Health Beliefs, Perceived Control, Well-being, and Treatment Satisfaction.

The psychological measures used in the present study were the same as those administered at baseline (See Chapter 2). As before, the questionnaires were given to the participants in the form of a booklet but a different front sheet was attached giving information about the nature of the research at this stage. The general information questionnaire included questions about current weight, how well respondents felt their diabetes had been controlled over the past few weeks, whether they had attended an education session before, and whether they had ever read any books about diabetes before. Copies of the front sheet and General Information questionnaire are included in Appendix 3.

Knowledge about Diabetes and its Management

The knowledge questionnaire used in the present study was adapted from the Charing Cross questionnaire (CCQ2) developed for tablet and/or diet treated patients (Meadows and colleagues, 1988), the diabetes knowledge (DKN) scales developed by Dunn and colleagues (1984), an unpublished questionnaire constructed by Clare Bradley for non-insulin-requiring patients which had been used to evaluate previous education sessions in Sheffield, and new items constructed by the present author. The process of choosing and generating suitable questions for the patient group studied was carried out in consultation with another psychologist and a dietitian. A pilot version of the questionnaire was filled in by a group of 6 doctors (1 consultant and 5 Registrars), 4 dietitians, and 2 diabetes nurse specialists in order to eliminate questions for which there was no consensus of opinion about the correct answers and to seek comments about the suitability and clarity of the suggested questions. The final questionnaire (Appendix 4) was designed according to a multiple-choice format (including "I do not know" options) with questions concerning diet (8 questions), complications (10 questions), and diabetes and its management generally (8 questions). Because of the multiple-choice format, responses were assessed using the Middlesex scoring procedure (Buckley-Sharp & Harris, 1971). This method takes into account guessed responses by calculating the difference between the total percentage of correctly identified options and the total percentage of incorrectly identified distractors (the adjusted percentage score or APSCORE). "I do not know" responses were ignored in this calculation. In order to assess the difficulty of the individual items in the questionnaire, facility indices were calculated for all the options (percentage of patients responding correctly to each option). Eighty-seven per cent of the options had facility indices within the acceptable range of thirty to ninety per cent. The relationship of the items to overall knowledge scores was assessed using discrimination coefficients (phi-coefficients) computed for options and distractors using upper and lower criteria groups. (These groups were defined according to whether APSCORES were above or below the median.) Coefficients ranged from 0.01 to 0.57 for options and from 0 to 0.27 for distractors. Eighty per cent of the options exceeded the minimum standard coefficient of 0.2. Questions with options having facility indices greater than 0.90 (90%) and/or discrimination coefficients less than 0.2 should be rejected or revised (Windsor, Roseman, Gartseff & Kirk, 1974). Furthermore, in relation to the group with APSCORES below the median, the questions with very attractive distractors (discrimination coefficients >0.2) should also be rejected. The questions which survived the psychometric selection procedure just described are presented in Figure 5.1 Responses to these items were used to assess knowledge in the present

Figure 5.1: Knowledge of Diabetes: The final measure after psychometric analysis

General

Glucose is detected in the urine when

- A person who hasn't got diabetes eats too many sweet things
- The kidney threshold is passed and glucose spills into the urine
- The dose of tablets is too large
- Blood sugar levels are very low
- I do not know

If you experience symptoms of hypoglycaemia (low blood sugar) you should

- Take extra tablets for your diabetes
- Continue what you are doing
- Take two sugar cubes or a sweetened drink
- Drive yourself to hospital
- I do not know

Which of the following is true?

- It does not matter if your diabetes is not fully controlled, as long as you do not have a coma
- Poor control of diabetes may result in complications later
- Blood or urine testing is only necessary when symptoms occur
- It is best to have some sugar in the urine
- I do not know

Diet

Which of the following so-called "diabetic food items are approved by the hospital clinic?

- Diabetic jam
- Diabetic jellies
- Sorbitol sweetened, sugar-free canned fruit
- "Low-caloric" soft drinks
- I do not know

Which of the following should be avoided or restricted if you are overweight?

- Cream
- Tomatoes
- Margarine/butter
- Alcohol
- I do not know

Which 3 of the following contain added sugar?

- Rice pudding
- Chocolate mousse
- Marmalade
- Pasta
- I do not know

Which of the following are high in fibre?

- Jacket potato
- Cornflour
- Cream crackers
- Peas
- I do not know

Complications

After washing your feet you should:

- Remove any dry skin from the feet
- Remove any hard skin from the feet
- Blot dry between the toes with a soft towel
- Avoid rubbing the feet with a towel
- I do not know

To check for any long term complications to your diabetes, yearly examinations should be carried out at the hospital clinic...

- On your hearing
- On your blood pressure
- For nerve damage to your feet
- On your eyes
- I do not know

Wounds on a diabetic person's feet may become infected because....

- Diabetes can cause resistance to antiseptics
- Of poor blood supply
- Of loss of feeling
- Of the increased insulin in the blood
- I do not know

Minor injuries to the feet are more likely to get infected when blood sugar levels....

- Occasionally get too low
- Are low all the time
- Are high much of the time
- Occasionally get too high
- I do not know

study. Reliability analysis was performed on the final measure using the Kudor-Richardson KR20 formula which was modified to incorporate the Middlesex scoring procedure (Buckley-Sharp &Harris, 1972) The reliability coefficient of 0.68 indicated that the internal consistency of the responses was satisfactory for the purposes of the present study. Validity data will be presented in the results section of this chapter.

Format of the Education Sessions

The education sessions were designed to meet the specific needs of tablet-treated patients. Each session lasted from 9.30 am to about 3.30 pm and included a midday meal where foods recommended in the diet regimen were provided and informal discussions took place between patients, partners and educators. The style of the education sessions was a mixture of formal lectures, patient-led discussion, and practical demonstrations. Each session began with a slide presentation and talk by the doctor who had seen all the patients for a screening appointment at baseline. This talk was about the nature of diabetes, its complications and the medical treatments available, and was followed by a question and answer session. One of the reasons for this talk was to ensure that patients and their partners understood the rationale behind the recommended treatment regimen. The remainder of the education session was spent talking to patients and their partners about the value of the different aspects of treatment for avoiding or arresting complications and improving the quality of life generally. Following the initial talk there was a discussion led by a diabetes nurse specialist about oral hypoglycaemic agents, the symptoms of hypo- and hyperglycaemia, when they occur, and what to do about them. This was followed by a demonstration of, and discussion about the different urine tests, how and why they should be used, and how to interpret their results. Prior to the break for lunch, a talk and slide presentation was given by a senior dietitian about the foods recommended together with information and tips about food purchase and preparation. Once again, time was allowed for discussion after the talk. Recommended foods were also displayed in the room where the education session took place so that those attending could inspect sample food packages. After lunch, a second diabetes nurse specialist gave a talk about footcare which was followed by another discussion period. The patients were then asked if they had any questions or worries about their diabetes which had not been resolved by the education session. When these queries and worries had been addressed, the education session was brought to a close.

Subjects and Procedure

Some of the participants from the baseline study were selected according to certain criteria and approached to take part in an insulin treatment study. These patients were classified as 'borderline poorly-controlled' because their blood glucose levels were chronically high, not very well controlled by diet and oral hypoglycaemic agents, and close to a threshold where insulin would be routinely prescribed. A description of this study and the rationale for the insulin intervention will be described in Chapter 6. The patients who did not meet the selection criteria for the insulin study were invited to attend an education session when they went to their screening appointment with the doctor. All were encouraged to bring a spouse, partner or friend if they desired. Altogether, 81 (47%) of the 173 patients who were invited attended one of the 13 sessions. The demographic and clinical characteristics of those attending and not attending for education are presented in Table 5.1 which shows that there was a significant difference in duration of diabetes. Those who attended an education session had experienced their diabetes for significantly fewer years ($p<0.01$) when compared to non-attenders. Differences in baseline psychological characteristics between attenders and non-attenders were also investigated and it was found that attenders had significantly greater Severity of Complications scores than non-attenders (z = -2.0; p<0.05). Eight of the education attenders (4 men and 4 women) were subsequently approached for inclusion in the insulin study because one of the selection criterion (percent ideal body weight) was widened in order to increase the number of people eligible for study.

Table 5.1: Demographic and clinical characteristics of education session attenders and non-attenders

	Attenders	Non-attenders	p
	Mean (SD)	Mean (SD)	
Baseline HbA1 (mmol/HMF)	52.4 (11.3)	55.6 (12.9)	0.111
Baseline percent ideal body weight	123.3 (24.8)	126.0 (24.1)	0.476
Baseline subjective estimates of diabetes control	2.7 (1.7)	2.7 (1.6)	0.766
Age	57.2 (5.2)	57.8 (6.2)	0.257
Duration of diabetes	5.7 (5.5)	7.9 (5.1)	0.002
Sex	48 Men 33 Women 81 Total	55 Men 37 Women 92 Total	0.944
Clinic	51 - Clinic 1 30 - Clinic 2	59 - Clinic 1 33 - Clinic 2	0.874

Prior to the start of each education session the patients were asked by the present author to complete the Knowledge of Diabetes questionnaire. Questionnaires were also given to any spouses, partners and friends who attended in order to ensure that they were occupied and the measure of knowledge obtained from each patient was not the result of collaboration. At this stage everyone was informed that they would be asked to complete the same questionnaire after the education session. When the questionnaires were completed at the end of the session, everyone was provided with a correctly completed version to take home with them. In addition, after explaining the nature of the research being undertaken, all of the patients were given the booklet of psychological questionnaires to complete at home. They were asked to complete the questionnaires within the following two days and return them to the present author in the stamped addressed envelope provided. Those who did not return a booklet within two weeks were sent a reminder. Seventy-nine (97.5%)

patients returned a completed booklet of questionnaires.

Approximately six months after each education session, 57 of the 81 people who had attended were followed up in relation to their HbA_1. The selection of those who were followed up was determined by routine attendance at the clinics at this time. The majority of these patients came from one clinic source: 45 (88%) of 51 attenders were followed up from the first clinic and 12 (40%) of 30 attenders were followed up from the second clinic. Mann-Whitney tests indicated that those who were followed up had experienced their diabetes for significantly fewer years [mean(sd) 5.0(5.5) years) when compared with those who were not followed up (mean(sd) 7.3(5.2) years] ($z = -2.34$; $p<0.02$). No other significant differences were found between these groups of patients for any of the demographic and clinical measures. Furthermore, no significant differences were noted between the clinic groups who attended for education (although there was a tendency for patients from the first clinic to have experienced their diabetes for fewer years than patients from the second clinic ($z = -1.72$; $p = 0.08$).

Statistical Analyses

The distributions of scores for the post-education perceived Benefits of, and Barriers to treatment measures, the measure of perceived Severity of Complications, and the knowledge measures were skewed, indicating the need for non-parametric statistical tests in subsequent analyses. All the other post-education psychological measures satisfied the assumptions of parametric statistical tests. Between-scale comparisons were made using the Wilcoxon matched pairs signed ranks test or the Student's *t* -test (paired scores), as appropriate, and relationships to other variables were examined using either Spearman rank correlations or Pearson's correlations. In order to determine the relationships between the original and newly-introduced

HBM components and their combined effectiveness in the prediction of prospectively measured HbA_1, hierarchical multiple regression analyses and Kruskal-Wallis tests were employed.

Results

Comparison of Baseline and Follow-up HbA_1

HbA_1 at baseline and approximately six months later were compared in order to assess the impact of education on blood glucose control. The results indicated that after education, HbA_1 was not significantly different to that at baseline ($z = -0.82$; $p<0.41$). However, because some of the education attenders already had fairly good blood glucose control, another analysis was conducted after selecting only those with a baseline HbA_1 greater than 55 mmol/HMF ($n = 18$). The results of this analysis indicated that for these patients, there was a significant improvement in HbA_1 approximately six months later ($z = -2.1$; $p<0.05$). The baseline and post-education HbA_1 statistics are presented in Table 5.2.

Table 5.2: Mean (SD), median, mimimum and maximum baseline and follow-up HbA1(mmol HMF)

	Mean(SD)	Median	Minimum	Maximum	p (2-tailed)	N
All patients who attended for education						
Baseline HbA1	52.4 (11.3)	51.0	29.0	80.0	0.41	57
Follow-up HbA1	52.6 (10.6)	51.0	36.0	77.0		
Education attenders with baseline HbA1 >55 mmol HMF						
Baseline HbA1	64.5 (7.3)	62.0	56.0	80.0	0.03	18
Follow-up HbA1	59.7 (11.9)	59.0	37.0	77.0		

Normal reference range for HbA1 is 29.0 to 39.0 mmol HMF.

Comparison of Pre- and Post-Education Health Beliefs, Perceived Control, Psychological Well-being and Treatment Satisfaction

When the scores for the pre- and post-education psychological measures were compared, it was noted that after education, patients perceived significantly more Benefits of treatment ($z = -2.52$; $p<0.05$), fewer Barriers to treatment ($z = -2.85$; $p<0.01$), and overall, perceived their treatment to be significantly more 'Cost-effective' ($t = -3.88$; $p<0.001$). These patients also perceived significantly greater Personal Control/Self-efficacy ($z = -2.48$; $p<0.05$) and Treatment Satisfaction ($z = -2.94$; $p<0.01$) after education. No other significant differences were found between the pre-and post-education measures. The means and standard deviations for all the measures are presented in Table 5.3.

Table 5.3: Pre- and Post-education Health Beliefs, Personal Control/ Self-efficacy, psychological Well being,and Treatment Satisfaction scores for patients who attended for education

	N	Baseline Mean (SD)		Post Education Mean (SD)		p (2-tailed)
Perceived						
Benefits	77	27.4	(3.2)	28.5	(2.1)	0.012
Barriers	77	13.1	(8.3)	10.8	(6.4)	0.004
'Cost-effectiveness'	76	14.3	(9.5)	17.7	(7.0)	0.000
Perceived Severity						
Complications	68	28.8	(3.1)	29.1	(2.8)	0.930
General Disorders	58	24.7	(4.6)	24.5	(5.0)	0.810
Diabetes (2 items)	59	4.8	(1.9)	5.1	(1.9)	0.202
Perceived Vulnerability						
Complications	21	13.9	(6.1)	16.8	(4.8)	0.384
Complications (averaged)	77	2.0	(0.9)	2.1	(0.8)	0.262
General Disorders	59	9.8	(6.3)	10.4	(6.0)	0.687
'Complications arising from diabetes' (single item)	67	2.3	(1.1)	2.4	(1.1)	0.384
Perceived Vulnerability of the 'Average Person'						
Complications	62	17.0	(5.9)	17.3	(5.1)	0.702
General Disorders	64	10.9	(6.7)	11.1	(6.0)	0.783
'Complications arising from diabetes' (single item)	72	2.3	(1.1)	2.3	(1.0)	1.000
Perceived						
Personal Control/Self-efficacy	67	70.1	(14.5)	74.5	(11.6)	0.013
Medical Control	69	25.5	(12.1)	26.0	(13.6)	0.947
Situational Control	69	12.2	(11.1)	13.6	(10.2)	0.411
Psychological Well being						
Depression	74	4.2	(2.7)	4.6	(3.0)	0.052
Anxiety	74	6.0	(3.9)	6.3	(4.2)	0.178
Positive Well being	72	12.8	(3.9)	12.5	(3.9)	0.219
General Well being	72	40.6	(9.1)	39.6	(10.0)	0.062
Satisfaction with Treatment	76	29.1	(5.1)	30.8	(4.9)	0.003

Higher scores indicate more perceived Benefits and Barriers, and greater perceived treatment 'Cost-effectiveness', Severity, Vulnerability, Personal, Medical and Situational Control, Depression, Anxiety, Positive Well being, General Well being, and Treatment Satisfaction.

Pre- and Post-Education Knowledge Scores

When compared to pre-education scores, significant improvements in diabetes knowledge scores (Table 5.4) for each of the sections and overall were noted after education (General: z = -6.2, p<0.001; Diet: z = -7.1, p<0.001; Complications: z = -6.3, p<0.001; Total Knowledge: z = -6.2; p<0.001). Given that some of the patients who attended an education session already had a good knowledge of diabetes with relatively little scope for improvement, a measure of knowledge improvement was calculated which took into account pre-education scores. This measure was computed by expressing the difference scores as a percentage of the pre-education score. Scores for this variable (labelled percent Knowledge Improvement) ranged from 0% to 231.6% with a mean (SD) of 39.4 % (43.5) and a median of 25.4%. It was predicted that greater percent Knowledge Improvement would be associated with favourable changes in the psychological variables and better blood glucose control at follow-up. The pre- and post-education APSCORES, the difference scores, and the percent Knowledge Improvement scores were correlated with all the other psychological variables and the baseline and follow-up demographic, clinical and biochemical variables. The results of these analyses are presented in Table 5.5 and Table 5.6.

Table 5.4: Pre- and Post-Education Diabetes Knowledge Scores (Adjusted percentage scores)

		Pre-Education				Post-Education				p
	N	Mean	(SD)	Min	Max	Mean	(SD)	Min	Max	(2-tailed)
General	68	38.7	(23.6)	-16.8	93.3	56.8	(20.8)	-2.7	93.3	0.000
Diet	71	61.6	(21.1)	7.0	100.0	75.7	(18.2)	37.9	100.0	0.000
Complications	69	52.2	(19.1)	-2.7	89.3	63.6	(19.8)	18.7	96.0	0.000
Total Knowledge	68	60.6	(21.5)	-6.3	100.0	72.8	(19.4)	5.0	100.0	0.000

Table 5.5: Spearman Correlations (N) between Knowledge Scores and the demographic, clinical, and biochemical variables

	Pre-Education APSCORE	Post-Education APSCORE	APSCORE Difference	Percent Knowledge Improvement
Baseline HbA1	0.16 (70)	0.07 (76)	-0.21* (68)	-0.30** (67)
Baseline percent ideal body weight	-0.05 (70)	0.13 (76)	0.13 (68)	0.07 (67)
Baseline subjective estimates of diabetes control	-0.02 (70)	0.14 (76)	0.06 (68)	-0.03 (67)
Follow-up HbA1 (approx 6 months after education)	0.07 (50)	-0.01 (53)	-0.15 (48)	-0.27* (47)
Post-education subjective estimates of diabetes control	0.02 (67)	0.18 (73)	0.15 (65)	0.08 (64)
Age	0.10 (70)	-0.10 (76)	-0.11 (68)	-0.02 (67)
Sex (1=Men, 2=Women)	-0.05 (70)	-0.01 (76)	-0.10 (68)	0.05 (67)
Duration of diabetes	-0.02 (70)	0.05 (76)	-0.03 (68)	-0.08 (67)

** $p<0.01$ * $p<0.05$

Higher scores indicate subjective estimates of poorer control

The results of correlations between the demographic, clinical, and biochemical variables, and knowledge scores indicated that greater percent Knowledge Improvement was associated with lower levels of HbA_1 approximately six months later ($r = -0.27$; $p<0.05$). However, there was an even stronger association between percent Knowledge Improvement and baseline HbA_1 ($r = -0.30$; $p<0.01$) suggesting that education attenders with better blood glucose control were able to take greater advantage of the education sessions than those with relatively poor blood glucose control. Lower baseline HbA_1 was also associated with greater difference APSCORES ($r = -0.21$; $p<0.05$).

The correlations between the knowledge scores and post-education health beliefs, Perceived Control, Well-being, and Treatment Satisfaction measures indicated that

Table 5.6: Correlations (Spearman) between Knowledge Scores and Post-Education Health Beliefs, Perceived Control, Well Being and Treatment Satisfaction.
(Lower N determines N for correlation coefficient for each pair of variables)

		Pre-Education APSCORE	Post-Education APSCORE	APSCORE *Difference*	Percent Knowledge *Improvement*
Perceived	N	70	76	68	67
Barriers	77	-0.11	0.01	0.21*	0.18
Benefits	77	0.15	-0.04	-0.13	-0.22*
'Cost-effectiveness'	76	0.15	0.00	-0.22*	-0.24*
Perceived Severity					
Complications	68	0.20	-0.01	0.02	0.06
General Disorders	58	0.21*	-0.05	-0.14	-0.11
Diabetes (2 items)	59	0.08	-0.05	-0.10	-0.06
Perceived Vulnerability					
Complications	21	-0.19	-0.08	-0.20	-0.11
Complications (averaged)	77	0.05	0.09	-0.04	-0.03
General Disorders	59	-0.12	-0.10	-0.01	0.01
'Complications arising from diabetes' (single item)	67	0.03	-0.02	-0.15	-0.05
Perceived Vulnerability of the 'Average Person'					
Complications	62	0.14	0.21*	0.01	0.06
General Disorders	64	-0.03	-0.01	0.02	0.06
'Complications arising from diabetes' (single item)	72	-0.03	-0.02	-0.06	0.04
Perceived					
Personal Control/Self-efficacy	67	0.30**	0.13	-0.19	-0.15
Medical Control	69	-0.32**	-0.32**	0.07	0.08
Situational Control	69	-0.25*	-0.33**	0.05	0.03
Psychological Well being					
Depression	74	-0.08	0.22*	0.19	0.13
Anxiety	74	-0.13	0.07	0.17	0.13
Positive Well being	72	0.03	-0.26*	-0.24*	-0.18
General Well being	72	0.10	-0.18	-0.24*	-0.17
Satisfaction with Treatment	76	0.04	-0.19*	-0.21*	-0.17

Higher scores indicate more perceived Benefits and Barriers, and greater perceived Treatment 'Cost-effectiveness', Severity, Vulnerability, Personal, Medical and Situational Control, Depression, Anxiety, Positive Well-being, General Well-being, and Treatment Satisfaction.

** $p<0.01$ * $p<0.05$

greater pre-education APSCORES were associated with greater perceived Severity of General Disorders ($r = 0.21$; $p<0.05$), greater perceived Personal Control/Self-efficacy ($r = 0.30$; $p<0.01$), lower perceived Medical Control ($r = -0.32$; $p<0.01$), and lower perceived Situational Control ($r = -0.25$; $p<0.05$). Greater post-education APSCORES were associated with lower perceived Medical Control ($r = -0.32$; $p<0.01$), lower perceived Situational Control ($r = -0.33$; $p<0.01$), greater Depression scores ($r = 0.22$; $p<0.05$), lower Positive Well-being ($r = -0.26$; $p<0.05$), and lower Treatment Satisfaction ($r = -0.19$; $p<0.05$). The correlations with the difference APSCORES indicated that greater increases were associated with more perceived Barriers ($r = 0.21$; $p<0.05$), lower perceived treatment 'Cost-effectiveness' ($r = -0.22$; $p<0.05$), lower Positive Well-being ($r = -0.24$; $p<0.05$), lower General Well-being ($r = -0.24$; $p<0.05$), and lower Treatment Satisfaction ($r = -0.21$; $p<0.05$). Greater percent Knowledge Improvement was associated with fewer perceived Benefits ($r = -0.22$; $p<0.05$) and lower perceived treatment 'Cost-effectiveness' ($r = -0.24$; $p<0.05$). Contrary to predictions, the overall pattern of correlations between the psychological measures and knowledge scores indicated that those who increased their knowledge about diabetes the most were more negative about themselves and their diabetes management after education. However, inspection of the results of correlations between knowledge scores and baseline health beliefs, Perceived Control, Well- being, and Treatment Satisfaction revealed a fairly similar, albeit weaker, pattern of associations (Table 5.7) indicating that these patients' were predisposed to negative perceptions about themselves and their diabetes management.

Table 5.7: Correlations (Spearman) between Knowledge Scores and Pre-Education Health Beliefs, Perceived Control, Well Being and Treatment Satisfaction.
(Lower N determines N for correlation coefficient for each pair of variables)

		Pre-Education APSCORE	Post-Education APSCORE	APSCORE Difference	Percent Knowledge Improvement
Perceived	N	70	76	68	67
Barriers	77	-0.03	-0.02	0.00	-0.02
Benefits	77	0.19	0.07	-0.24*	-0.28*
'Cost-effectiveness'	77	0.10	0.01	-0.11	-0.09
Perceived Severity					
Complications	68	0.12	-0.01	0.02	0.00
General Disorders	58	0.23	-0.05	-0.07	-0.04
Diabetes (2 items)	59	0.12	0.01	-0.15	-0.13
Perceived Vulnerability					
Complications	21	-0.07	-0.12	0.02	-0.19
Complications (averaged)	77	0.08	0.00	-0.05	-0.12
General Disorders	59	-0.07	-0.03	-0.12	0.02
'Complications arising from diabetes' (single item)	67	0.12	0.08	-0.09	-0.18
Perceived Vulnerability of the 'Average Person'					
Complications	62	0.09	-0.02	-0.11	-0.12
General Disorders	64	-0.02	-0.09	-0.12	0.06
'Complications arising from diabetes' (single item)	72	0.09	-0.02	-0.11	0.02
Perceived					
Personal Control/Self-efficacy	67	0.04	-0.01	-0.13	-0.11
Medical Control	69	-0.23	-0.07	0.13	0.12
Situational Control	69	0.10	-0.00	-0.13	-0.21
Psychological Well being					
Depression	74	-0.06	0.03	0.13	0.11
Anxiety	74	-0.04	0.18	0.20	0.18
Positive Well being	72	0.05	-0.23*	-0.23*	-0.18
General Well being	72	0.08	-0.16	-0.22	-0.18
Satisfaction with Treatment	76	-0.04	-0.09	-0.01	-0.09

Higher scores indicate more perceived Benefits and Barriers, and greater perceived Treatment 'Cost-effectiveness', Severity, Vulnerability, Personal, Medical and Situational Control, Depression, Anxiety, Positive Well-being, General Well-being, and Treatment Satisfaction.

** $p<0.01$ * $p<0.05$

Relationships between the Post-education Psychological Measures and the Demographic, Clinical, Biochemical, and Psychological Variables.

The post-education psychological variables were correlated with the demographic, clinical, biochemical, and psychological outcome variables (Table 5.8) in order to assess further the construct validity of the scales in the light of the educational intervention.

HbA_1 approximately six months after education:

Lower HbA_1 levels were significantly associated with more perceived Benefits of treatment following education ($r = -0.30$; $p<0.01$) and greater perceived Personal Control/Self-efficacy ($r = -0.38$; $p<0.01$). The correlation between perceived Vulnerability to Complications (single item) and follow-up HbA_1 did not reach significance ($r = 0.22$; $p=0.07$) but the direction of the relationship was the same as that found with the baseline data.

Post-education subjective estimates of diabetes control:

More optimistic subjective estimates of control were significantly associated with lower perceived Vulnerability to Complications ($r = 0.19$; $p<0.05$), and greater perceived Personal Control/Self-efficacy ($r = -0.30$; $p<0.01$).

Baseline percent ideal body weight :

Better weight control was significantly associated with fewer perceived Barriers to treatment ($r = 0.22$; $p<0.05$), greater perceived treatment 'Cost-effectiveness' ($r = -0.22$; $p<0.05$), greater perceived Severity of Diabetes ($r = 0.23$; $p<0.05$) and greater perceived Personal Control/Self-efficacy ($r = -0.29$; $p<0.01$).

Table 5.8 Correlations between the post-education psychological measures and the demographic, clinical, biochemical, and psychological outcome variables. (Lower N determines N for correlation coefficient for each pair of variables)

		Follow-up HbA1	Subjective estimate of diabetes (post-educ)	Percent ideal body weight (baseline)	Depression	Anxiety	Positive Well-being	Satisfaction with Treatment
	N	57	79	81	75	75	74	*80*
Perceived								
Barriers	77	0.15	0.15	0.22*	0.17	0.34**	-0.20*	-0.23
Benefits	77	-0.30*	-0.12	-0.09	-0.29**	-0.35**	0.28**	0.31**
'Cost-effectiveness'	77	-0.21	-0.17	-0.22*	-0.23*	-0.40***	0.25*	0.29**
Perceived Severity								
Complications	68	0.03	0.09	0.08	-0.05	0.03	-0.01	0.00
General Disorders	58	0.05	0.07	0.19	-0.08	0.04	0.13	-0.06
Diabetes (2 items)	59	-0.03	0.16	0.23	-0.05	-0.02	0.16	-0.01
Perceived Vulnerability								
Complications	21	0.08	0.01	0.25	0.39*	0.35*	-0.03	-0.04
Complications (averaged)	77	0.07	0.19*	0.17	0.30**	0.26*	-0.23*	-0.05
General Disorders	59	-0.04	0.01	0.15	0.28*	0.36**	-0.18	-0.18
'Complications arising from diabetes' (single item)	67	0.22	0.19*	0.12	0.26*	0.20	-0.19	-0.22*
Perceived Vulnerability of the 'Average Person'								
Complications	62	-0.03	0.16	0.19	0.30**	0.17	-0.26*	-0.24*
General Disorders	64	-0.03	-0.04	0.05	0.26*	0.33**	-0.19	-0.19
'Complications arising from diabetes' (single item)	72	0.08	0.17	0.07	0.30**	0.18	-0.23*	-0.23*
Perceived								
Personal Control/Self-efficacy	67	-0.38**	-0.30**	-0.29**	-0.26*	-0.41***	0.25*	0.33**
Medical Control	69	0.03	-0.03	0.04	-0.21*	-0.05	0.26*	0.13
Situational Control	69	0.18	0.05	0.17	0.12	0.37**	0.10	-0.10

*** p<0.001 ** p<0.01 *** p<0.05
Sex: 1 = men 2 = women

Higher scores indicate more of the construct measured.
Subjective estimate of diabetes control: 1 = very well controlled 7 = very poorly controlled

Well-being and Treatment Satisfaction:

Lower Depression scores were significantly associated with more perceived Benefits of treatment (r = -0.29; p<0.01), greater perceived treatment 'Cost-effectiveness' (r = -0.23; p<0.05), lower perceived personal Vulnerability to Complications [r = 0.30, p<0.01; r = 0.26; p<0.05 (single item)], lower perceived personal Vulnerability to General Disorders (r = 0.28; p<0.05), lower perceived Vulnerability of the 'average person' to Complications (r = 0.30, p<0.01) and General Disorders (r = 0.27, p<0.05), and greater perceived medical control (r = -0.21; p<0.05).

Lower Anxiety scores were significantly associated with fewer perceived Barriers to treatment (r = 0.32; p<0.01), more perceived Benefits of treatment (r = -0.35; p<0.01), greater perceived treatment 'Cost-effectiveness' (r = -0.40; p<0.001), lower perceived personal Vulnerability to Complications [r = 0.26, p<0.05; r = 0.20, p<0.05 (single item)], lower perceived Vulnerability to General Disorders (r = 0.36; p<0.01), lower perceived Vulnerability of the 'average person' to General Disorders (r = 0.33; p<0.01), greater perceived Personal Control/Self-efficacy (r = -0.41; p<0.001), and lower perceived Situational Control (r = 0.37; p<0.01).

Greater Positive Well-being scores were significantly associated with fewer perceived Barriers to treatment (r = -0.20; p<0.05), more perceived Benefits of Treatment (r = 0.28; p<0.01), greater perceived treatment 'Cost-effectiveness' (r = 0.25; p<0.05), lower perceived personal Vulnerability to Complications (r = -0.23; p<0.05), lower perceived Vulnerability of the 'average person' to Complications [r = -0.26, p<0.05; r = -0.23, p<0.05 (single item)], greater perceived Personal Control/Self-efficacy (r = 0.25; p<0.05), and again, contrary to expectations, greater perceived Medical Control (r = 0.26; p<0.05).

Greater Treatment Satisfaction was significantly related to fewer perceived Barriers (r = -0.23; p<0.05), more perceived Benefits (r = 0.31; p<0.01), greater perceived treatment 'Cost-effectiveness' ($r = 0.29$; $p<0.01$), lower perceived personal Vulnerability to Complications ($r = -0.22$; $p<0.05$), lower perceived Vulnerability of the 'average person' to Complications [$r = -0.24$, $p<0.05$; $r = -0.23$, $p<0.05$ (single item)], and greater perceived Personal Control/Self-efficacy ($r = 0.33$; $p<0.01$).

Patients whose blood glucose control improved compared with those whose blood glucose control deteriorated.

In order to assess the impact of the education on beliefs, attitudes, and knowledge in relation to changes in blood glucose control at follow-up, the patients were divided according to whether HbA_1 approximately six months later was better (N=20) or worse (N=25) than at baseline. (Twelve of the subjects for whom follow-up HbA_1 data were obtained did not show improvement or deterioration in glycaemic control.) These groups were then assessed for differences in post-education beliefs, attitudes, knowledge and demographic and clinical characteristics. The results indicated that those who improved their blood glucose control later felt significantly less Vulnerable to Complications (single item) after education ($z = -1.9$; $p<0.05$), but estimated their diabetes control after education to be worse ($z = -1.9$; $p<0.05$) when compared to those whose blood glucose control did not improve or deteriorated. There was also a significant tendency for women rather than men to improve their blood glucose control after education ($z = -2.2$; $p<0.05$). No other significant differences were found between the groups. In view of the sex difference reported above, further similar analyses were conducted in order to assess whether there were differences in beliefs, attitudes, or demographic and clinical characteristics for men and women separately. These analyses revealed that the women who improved their blood glucose control after education perceived their treatment to be significantly more 'Cost-effective' (post education) than their counterparts ($z = -3.2$; $p<0.01$). On the other hand, the men who improved their blood glucose control estimated their diabetes control after education to be significantly worse than their counterparts ($z = -2.0$; $p<0.05$). No other within-sex differences were noted.

Reassessment of the multiplicative HBM model: Post-education beliefs

The procedure used with the baseline data (Chapter 4) was repeated. The individual variables were entered on the first step of the regression analyses and the interactions were entered in a hierarchical fashion on the second and subsequent steps. As before, the interactions were calculated from the z scores of the component variables. The HBM variables included in the regression analyses were the same as those used for the baseline analyses because, once again, these variables proved to be the most sensitive in correlations with the health outcome measure (see Table 5.8). No attempt was made to include a measure of Optimistic Bias as the respondents' ratings for the single item Vulnerability to Complications measures (personal Vulnerability versus the 'average person's' Vulnerability) were not significantly different. However, they did rate themselves to be signficantly less vulnerable than the 'average person' to the individual complications ($z = -2.16$; $p<0.05$). The results of correlations between the component and composite variables and their relationship to the follow-up measure of HbA_1 are provided in Table 5.9. The pattern of correlations indicated that none of the variables were multicollinear. Interestingly, the direction of correlations between the variables indicated that on the one hand, perceived treatment 'Cost-effectiveness' was associated with greater perceived Threat (Severity x Vulnerability), but on the other hand, it was associated with lower perceived Severity and Vulnerability. (Similar correlations at baseline indicated that greater perceived treatment 'Cost-effectiveness' was associated with

Table 5.9: Intercorrelations between the individual and composite post-education HBM variables and their relationship to HbA1 approximately six months later. (N = 44)

	1	2	3	4	5	6	7	8
1. Treatment 'Cost-effectiveness'	1.0							
2. Vulnerability to Complications	-0.21	1.0						
3. Severity of Diabetes	-0.16	0.14	1.0					
4. Personal Control/Self-efficacy	0.34	0.07	0.08	1.0				
5. Severity x Vulnerability	0.20	-0.09	0.10	0.23	1.0			
6. Severity x Vulnerability x Treatment 'Cost-effectiveness'	0.05	-0.10	-0.20	0.02	-0.05	1.0		
7. Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	0.39	0.23	-0.09	0.19	0.29	0.53	1.0	
8. Follow-up HbA1	-0.28	0.23	0.10	-0.33	0.11	-0.11	0.08	1.0

Higher scores indicate greater perceived treatment 'Cost-effectiveness', Severity, Vulnerability, and Personal Control/ Self-efficacy.

lower scores for all three of these variables.) Given that the number of subjects who attended for education and provided data for the present study was small, the regression analyses reported in the present chapter should be interpreted with caution.

1. Prediction of follow-up HbA_1 from the original and newly-introduced HBM components and their interactions:

On the first step, perceived Severity of Diabetes, perceived Vulnerability to Complications, perceived treatment 'Cost-effectiveness', and perceived Personal Control/Self-efficacy were entered. The first multiplicative composite of Severity x Vulnerability was entered on the second step, the multiplicative composite of Severity x Vulnerability x treatment 'Cost-effectiveness' was entered on the third step, and the multiplicative composite of Severity x Vulnerability x treatment 'Cost-effectiveness' x Personal Control/Self-efficacy was entered on the final step. The results of this regression analysis are summarised in Table 5.10. It can be seen that when all the individidual and composite variables were entered, a total of 35% (22% adjusted) of the variance in follow-up HbA_1 was explained. Perceived Personal Control/Self-efficacy and the multiplicative composite of Severity x Vulnerability x treatment 'Cost-effectiveness' x Personal Control/Self-efficacy accounted for significant amounts of unique variance [11% ($p<0.05$) and 10% ($p<0.05$) respectively]. On the final step of the analysis, the R^2 increased by 0.10 ($p<0.05$) indicating that an interaction between perceived Severity of Diabetes, perceived Vulnerability to Complications, perceived treatment 'Cost-effectiveness', and perceived Personal Control/Self-efficacy significantly improved the prediction of follow-up HbA_1.

2. Inclusion of post-education General Well-being in the regression equation.

As indicated earlier (Table 5.8), post-education Well-being was significantly associated with perceptions about Vulnerability, perceived treatment 'Cost-effectiveness' and perceived Control yet the association between General Well -being and follow-up HbA_1 was relatively weak and not statistically significant ($r = 0.07$). In view of the pattern of these associations which suggested that General Well-being might act as a suppressor variable, a second regression analysis was conducted in which General Well-being entered the equation on the first step, the individual HBM variables were entered on the second step, and the multiplicative composites were entered on the third and subsequent steps. The results of this analysis are summarized in Table 5.11. It can be seen that when the variance

Table 5.10:

Prediction of follow-up HbA_1 from the original and newly-introduced HBM components and their interactions (N=44).

	B	ß	sr^2 [a]
Treatment 'Cost-effectiveness'	-0.513	-0.28	0.06
Severity of Diabetes	0.075	0.01	0.00
Vulnerability to Complications	2.778	0.28	0.07
Personal Control/Self-efficacy	-0.367	-0.36	0.11*
Severity x Vulnerability	1.510	0.13	0.01
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-3.844	-0.29	0.05
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	5.895	0.45	0.10*

Statistics for each step in the Regression Analysis:

	Step	R	R^2	Adj R^2	ΔR^2	F
Personal Control/Self-efficacy Vulnerability to Complications Severity of Diabetes Treatment 'Cost-effectiveness'	1	0.44	0.19	0.11	0.19	2.30
Severity x Vulnerability	2	0.49	0.24	0.14	0.05	2.42
Severity x Vulnerability x Treatment 'Cost-effectiveness'	3	0.49	0.24	0.12	0.00	2.00
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	4	0.59	0.35	0.22	0.10*	2.72*

[a] sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable.

* $p<0.05$

Table 5.11:

General Well-being added to the regression equation. (N = 44)

	B	ß	*sr*[2] [a]
General Well-being	0.391	0.35	0.06
Treatment 'Cost-effectiveness'	-0.481	-0.26	0.05
Severity of Diabetes	0.747	0.12	0.01
Vulnerability to Complications	4.584	0.45	0.16**
Personal Control/Self-efficacy	-0.602	-0.55	0.16**
Severity x Vulnerability	6.295	0.47	0.12*
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-3.482	-0.20	0.03
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	-0.049	-0.00	0.00

Statistics for each step in the Regression Analysis:

	Step	R	R^2	Adj R^2	ΔR^2	F
General Well-being	1	0.10	0.01	-0.02	0.01	0.43
Personal Control/Self-efficacy Vulnerability to Complications Severity of Diabetes Treatment 'Cost-effectiveness'	2	0.49	0.24	0.12	0.23	2.04
Severity x Vulnerability	3	0.66	0.43	0.33	0.19**	4.07**
Severity x Vulnerability x Treatment 'Cost-effectiveness'	4	0.69	0.47	0.35	0.03	3.94**
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	5	0.69	0.47	0.33	0.00	3.33**

[a] sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable.

* p<0.05 ** p<0.01

associated with General Well-being was partialled out on the first step, the prediction of follow-up HbA_1 from the HBM variables substantially improved. When all the variables had been entered into the equation a total of 47% (33% adjusted) of the variance in HbA_1 was explained. Perceived Vulnerability to Complications, perceived Personal Control/Self-efficacy, and the multiplicative composite of Severity x Vulnerability all contributed unique amounts of explained variance [16% ($p<0.01$); 16% ($p<0.01$); and 12% ($p<0.02$) respectively]. When the multiplicative composite of Severity x Vulnerability was entered on the third step, the R^2 increased by 0.19 ($p<0.01$) indicating that there is a significant multiplicative relationship between perceived Severity of Diabetes and perceived Vulnerability to Complications. None of the other multiplicative composites significantly increased the overall amount of variance explained.

3. Inclusion of Health Value in the regression equation.

Although the single-item measure of health value did not contribute to the prediction of baseline HbA_1, this may have been due to the fact that the outcome measure was not recorded prospectively. Given that the measure of HbA_1 in the present study was collected approximately six months after the psychological measures, a further regression analysis was conducted in which post-education Health Value was entered on the first step together with General Well-being. As before, the individual HBM variables were entered on the second step, and the multiplicative composites were entered on the third and subsequent steps. The results of this analysis indicated that, once again, the post-education measure of Health Value did not contribute a significant amount of unique variance in the prediction of follow-up HbA_1 ($sr^2 = .00$; $p>0.05$). Furthermore, this measure did not appear to act as a suppressor variable because the amount of variance explained by the individual and composite HBM variables did not increase; on the final step 48% (31%) of the variance in follow-up HbA_1 was explained. The multiplicative composite of Severity x Vulnerability remained a significant contributor to the overall explanation ($\Delta R^2 = 0.20$; $sr^2 = 0.13$, $p<0.05$). As in the previous analysis, perceived Vulnerability to Complications and perceived Personal Control/Self-efficacy also contributed significant amounts of unique variance ($sr^2 = 0.17$, $p<0.01$; $sr^2 = 0.16$, $p<0.01$ respectively).

4. *Introduction of 'Percent Knowledge Improvement' into the regression equation.*

As mentioned earlier (Table 5.5), Percent Knowledge Improvement was significantly associated with follow-up HbA_1. A further regression analysis was conducted, therefore, in which the variance associated with Percent Knowledge Improvement was partialled out prior to entering the individual and HBM variables. General Well-being was entered on the first step, Percent Knowledge Improvement was entered on the second step, the individual HBM variables were introduced on the third step, and the multiplicative composites were introduced on the fourth and subsequent steps. The results of this analysis are summarized in Table 5.12. A total of 57% (41% adjusted) of the variance in follow-up HbA_1 was explained when all of the variables had been entered. Percent Knowledge Improvement, perceived Vulnerability to Complications, perceived Personal Control/Self-efficacy, and the multiplicative composite of Severity x Vulnerability all contributed significant amounts of unique variance [9% ($p<0.05$); 16% ($p<0.01$); 18% ($p<0.01$); and 8% ($p<0.05$) respectively]. As before, the multiplicative composite of Severity x Vulnerability significantly increased the R^2, although the increase was slightly less than previously when Percent Knowledge Improvement was not included in the

Table 5.12:

Inclusion of Percent Knowledge Improvement in the regression equation. (N = 44)

	B	ß	sr^2 [a]
General Well-being	0.442	0.39	0.07
Percent Knowledge Improvement	-0.019	-0.33	0.09*
Treatment 'Cost-effectiveness'	-0.436	-0.22	0.03
Severity of Diabetes	1.386	0.21	0.04
Vulnerability to Complications	4.780	0.45	0.16**
Personal Control/Self-efficacy	-0.645	-0.58	0.18**
Severity x Vulnerability	5.122	0.38	0.08*
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-3.861	-0.23	0.04
Severity x Vulnerbility x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	-0.082	-0.00	0.00

Statistics for each step in the Regression Analysis:

	Step	R	R^2	Adj R^2	ΔR^2	F
General Well-being	1	0.13	0.02	-0.01	0.02	0.53
Percent Knowledge Improvement	2	0.29	0.08	0.03	0.07	1.45
Personal Control/Self-efficacy Vulnerability to Complications Severity of Diabetes Treatment 'Cost-effectiveness'	3	0.63	0.40	0.26	0.31*	2.96*
Severity x Vulnerability	4	0.72	0.52	0.39	0.12*	4.05**
Severity x Vulnerability x Treatment 'Cost-effectiveness'	5	0.75	0.57	0.43	0.05	4.13**
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	6	0.75	0.57	0.41	0.00	3.53**

[a] sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable.

* $p<0.05$ ** $p<0.01$

equation. When compared to the previous analysis, the proportions of variance explained by the HBM variables and General Well-being did not change very much so it appears that the increase in total variance explained for this analysis was due to the inclusion of Percent Knowledge Improvement in the regression equation.

5. Exclusion of respondents who took part in the insulin study.

As discussed earlier (see Methods section), eight of the participants in the present study were approached for inclusion in the insulin study (Chapter 6) after they had taken part in the education intervention study. Given that these patients were subsequently classed as 'borderline poorly-controlled' because their tablet and diet treatment was inadequate, it could be argued that they were members of a different diabetic population. Indeed, when the insulin study participants were compared with the remainder of the education attenders, they had significantly greater HbA_1 both at baseline ($z = -2.1$; $p<0.05$) and follow-up ($z = -2.2$; $p<0.05$), they tended to perceived themselves as more Vulnerable to Complications ($z = -1.9$; $p<0.06$), they were significantly less Satisfied with Treatment ($z = -2.2$; $p<0.05$), and their subjective estimates of diabetes control tended to be more pessimistic ($z = -1.9$; $p<0.06$). A further regression analysis was conducted, therefore, which excluded the data from these patients. As before, General Well-being was entered on the first step, Percent Knowledge Improvement was entered on the second step, the individual HBM variables were entered on the third step, and the multiplicative composites were entered on the fourth and subsequent steps. The results from this analysis are summarized in Table 5.13. It can be seen that much of the variance in follow-up HbA_1 previously accounted for by perceived Vulnerability to Complications and the multiplicative composite of Severity x Vulnerability disappeared when the data from the insulin study participants were excluded. An increased amount of unique variance was accounted for by Percent Knowledge

Table 5.13:
Exclusion of the eight insulin study participants (N=36)

	B	ß	sr^2 [a]
General Well-being	0.356	0.29	0.04
Percent Knowledge Improvement	-0.018	-0.39	0.13*
Treatment 'Cost-effectiveness'	-0.353	-0.20	0.02
Severity of Diabetes	1.026	0.17	0.02
Vulnerability to Complications	2.722	0.28	0.05
Personal Control/Self-efficacy	-0.565	-0.56	0.18*
Severity x Vulnerability	2.257	0.18	0.01
Severity x Vulnerability x Treatment 'Cost-effectiveness'	-5.379	-0.32	0.03
Severity x Vulnerbility x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	5.097	0.28	0.02

Statistics for each step in the Regression Analysis:

	Step	R	R^2	Adj R^2	ΔR^2	F
General Well-being	1	0.15	0.02	-0.02	0.02	0.58
Percent Knowledge Improvement	2	0.37	0.13	0.06	0.11	1.93
Personal Control/Self-efficacy Vulnerability to Complications Severity of Diabetes Treatment 'Cost-effectiveness'	3	0.63	0.39	0.22	0.26	2.25
Severity x Vulnerability	4	0.67	0.45	0.26	0.06	2.33
Severity x Vulnerability x Treatment 'Cost-effectiveness'	5	0.68	0.46	0.23	0.01	2.03
Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy	6	0.69	0.48	0.21	0.01	1.82

[a] sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable.

* $p<0.05$

NB When Percent Knowledge Improvement was omitted from the analysis, Severity x Vulnerability became a significant predictor of outcome and increased R^2 significantly on entry to the equation.

Improvement ($sr^2 = 0.13$; $p<0.05$), and as before, perceived Personal Control/Self-efficacy ($sr^2 = 0.18$; $p<0.05$) accounted for a further significant amount of unique variance. A total of 48% (21% adjusted) of the variance in follow-up HbA_1 was explained when all the variables had been entered into the regression equation. Perceived Vulnerability and the multiplicative composite of Severity x Vulnerability no longer contributed significant amounts of variance to the overall explanation. In a separate analysis, Percent Knowledge Improvement was not included in the regression equation which resulted in a total of 34% (12% adjusted) of explained variance in follow-up HbA_1. Furthermore, R^2 was increased significantly when the multiplicative composite of Severity x Vulnerability was entered into the equation ($p<0.05$). Only perceived Personal Control/Self-efficacy contributed a significant amount of unique variance when all the variables had been entered ($sr^2 = 0.14$; $p<0.05$). However, prior to entering the multiplicative composite of Severity x Vulnerability x treatment 'Cost-effectiveness' x Personal Control/Self-efficacy, the composite of Severity x Vulnerability also contributed a unique amount of variance to the explanation ($sr^2 = 0.14$; $p<0.05$). The unique variance contributed by Perceived Vulnerability to Complications did not quite reach significance ($sr^2 = 0.11$; $p<0.06$).

Education attenders' baseline beliefs used to predict baseline health outcome measures.

It was noted earlier (see Subjects and Procedure) that those attending for education had experienced their diabetes for significantly fewer years than non-attenders. It could be argued, therefore, that the relatively large amount of variance in follow-up HbA_1 explained by the HBM variables was due to a differential pattern of beliefs associated with duration of diabetes. The baseline beliefs of the education attenders alone were therefore re-assessed in regression analyses in order to ascertain whether predictions of baseline HbA_1, percent ideal body weight, and subjective estimates of control were improved. The results of these analyses indicated that when only the data from education attenders were assessed outcome predictions were generally improved relative to the whole sample [Baseline HbA_1: $R^2 = 0.16$ (-0.006 adjusted); Percent ideal body weight: $R^2 = 0.28$ (0.14 adjusted); Subjective estimates of diabetes control: $R^2 = 0.31$ (0.18 adjusted)]. However, the amounts of variance explained in baseline outcomes were still substantially less than the amount of variance explained in follow-up HbA_1. Furthermore, none of the multiplicative composites added significantly to the explained variance when entered into the regression equation.

Further regression analyses were carried out in which General Well-being was entered on the first step, and Pre-education APSCORES (Knowledge scores)were entered on the second step. Given that knowledge about complications was poor at baseline and certain unpredicted patterns of baseline beliefs were associated with Well-being, it was hypothesized that these variables might act as suppressor variables and improve the prediction of the baseline health outcomes from health beliefs. As before, the individual HBM variables were entered on the third step, and the multiplicative composites were entered on the fourth and subsequent steps. The results of these analyses indicated some improvement in the prediction of percent ideal body weight, but little or no improvement in the prediction of baseline HbA_1 and subjective estimates of diabetes control [Baseline HbA_1: $R^2 = 0.18$ (-0.06 adjusted); Percent ideal body weight: $R^2 = 0.36$ (0.17 adjusted); Subjective estimates of diabetes control: $R^2 = 0.38$ (0.19 adjusted)]. Once again, the amounts of variance explained in baseline outcomes were still substantially less than the amount of variance explained in follow-up HbA_1. Furthermore, the multiplicative composites did not add significantly to the overall amounts of variance explained when introduced to the regression equations.

Prediction of improvements in follow-up HbA_1 from the HBM variables.

In order to investigate which HBM variables were associated with improvements in blood glucose control after education, General Well-being, all the individual HBM variables and the multiplicative composite of Severity x Vulnerability were entered into a hierarchical multiple regression analysis. Because some of the patients already had relatively good control and were unlikely to improve HbA_1 only those patients with an HbA_1 greater than 45 mmol HMF were included in the analysis. The multiplicative composites of Severity x Vulnerability x Treatment 'Cost-effectiveness', and Severity x Vulnerability x Treatment 'Cost-effectiveness' x Personal Control/Self-efficacy were not included because there were only 28 cases (20 women, 8 men) analysed. Tabachnick and Fidell (1989) state that a bare minimum of 5 times more cases than independent variables should be used. Given that the present analysis included 6 independent variables (including the multiplicative composite of Severity x Vulnerability) the number of cases analysed was 2 less than the bare minimum recommended. The results should therefore be interpreted with extreme caution. Improvements in blood glucose control were calculated by subtracting baseline HbA_1 from follow-up HbA_1. Higher scores were therefore equivalent to greater improvements at follow-up. General Well-being was entered on the first step, the individual HBM variables were entered on the second step, and the multiplicative composite of Severity x Vulnerability was entered on the final step. It was predicted that improvements in HbA_1 would be associated with greater perceived treatment 'Cost-effectiveness', greater perceived Severity of

Diabetes, greater perceived Vulnerability to Complications, and greater perceived Personal Control/Self-efficacy. The results of this analysis are summarized in Table 5.14 which shows that a total of 42% (26% adjusted) of the variance in HbA_1

Table 5.14:

Prediction of HbA_1 improvement from the HBM variables (N = 28)

	B	ß	sr^2 [a]
General Well-being	-0.340	-0.34	0.06
Treatment 'Cost-effectiveness'	0.309	0.17	0.02
Severity of Diabetes	-0.091	-0.02	0.00
Vulnerability to Complications	-4.477	-0.49	0.22**
Personal Control/Self-efficacy	0.502	0.46	0.08
Severity x Vulnerability	-5.932	-0.51	0.21*

Statistics for each step in the Regression Analysis:

	Step	R	R^2	Adj R^2	ΔR^2	F
General Well-being	1	0.05	0.00	-0.04	0.00	0.06
Personal Control/Self-efficacy Vulnerability to Complications Severity of Diabetes Treatment 'Cost-effectiveness'	2	0.46	0.22	0.04	0.21	1.22
Severity x Vulnerability	3	0.65	0.43	0.26	0.21*	2.61*

[a] sr^2 = squared semipartial correlation using Type III sums of squares to indicate the unique variance accounted for by the variable.

* p<0.05 ** p<0.01

improvement was explained when all the variables had been entered. Only perceived Vulnerability to Complications and the multiplicative composite of Severity x Vulnerability contributed significant amounts of unique variance to the overall explanation [$sr^2 = 0.22$ ($p<0.01$); $sr^2 = 0.21$ ($p<0.02$) respectively]. When the multiplicative composite of Severity x Vulnerability was entered on the final step, the R^2 increased significantly ($\Delta R^2 = 0.21$; $p<0.02$). Contrary to predictions the unstandardized regression coefficients (B) indicated that greater improvements in blood glucose control were associated with lower perceived Vulnerability to Complications and lower perceived Threat (Severity x Vulnerability).

Categorizing and combining the HBM variables. (The non-linear hypothesis re-examined.)

Although fairly large amounts of variance in follow-up HbA_1 were explained by the individual and composite post-education HBM variables, non-linear combinations of the variables were assessed for comparison with the baseline results. As in the previous study, data relating to each HBM variable were split at the median to produce high and low categories which were then combined to form belief patterns.

(1) Two-way interaction: Perceived Severity of Diabetes and Vulnerability to Complications.

The Kruskal-Wallis test indicated that follow-up HbA_1 was not significantly different for any of the four belief patterns (chi-square = 7.6; p=0.06). Moreover, when the data from the insulin study participants were excluded, the results were also non-significant (chi-square = 5.6; p = 0.13).

(2) Three-way interaction: Perceived Severity, Vulnerability and Treatment 'Cost-effectiveness'.

The Kruskal-Wallis test indicated that there was no significant difference in follow-up HbA_1 for any of the eight belief patterns (chi-square = 12.3; p = 0.09). Furthermore, when the data for the insulin study participants were excluded, a non-significant result was also obtained (chi-square = 9.9; p = 0.19).

(3) Three-way interaction: Perceived treatment 'Cost-effectiveness', Threat (Severity x Vulnerability), and Personal Control /Self-efficacy.

This analysis indicated that follow-up HbA_1 did not differ significantly for any of the eight belief patterns (chi-square = 11.2; p = 0.08). Furthermore, when the insulin study participants were excluded, the result did not quite reach significance (chi-square = 12.4; p = 0.052). None of the subjects had a belief pattern of low perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy. (At baseline, this group had the best mean HbA_1.) It was predicted that when the patterns of beliefs were ranked in relation to mean follow-up HbA_1 (Table 5.15), the belief pattern associated with the best blood glucose control approximately six months after education would be high perceived treatment 'Cost-effectiveness', high or low perceived Threat (depending upon whether blood glucose control was improving or deteriorating), and high perceived Personal Control/Self-efficacy (in the table: High/Low/High or High/High/High). On the other hand, the belief pattern predicted to be associated with the poorest blood glucose control was low perceived treatment 'Cost-effectiveness', low or high

Table 5.15: Patterns of perceived treatment 'Cost-effectiveness', Threat, and Personal Control/Self-efficacy in relation to follow-up HbA1

Including insulin study participants					Excluding insulin study participants				
N	'Cost-effectiveness'	Threat	Personal Control/ Self-efficacy	Mean follow-up HbA1	N	'Cost-effectiveness	Threat	Personal Control/ Self-efficacy	Mean follow-up HbA1
2	Low	High	High	44.5	2	Low	High	High	44.5
10	High	Low	High	46.5	9	High	Low	High	45.2
3	Low	High	Low	51.3	2	Low	High	Low	51.5
7	High	High	High	53.7	5	High	High	High	52.6
6	High	Low	Low	57.3	6	High	Low	Low	57.3
5	High	High	Low	60.2	4	High	High	Low	60.3
2	Low	Low	Low	63.0	2	Low	Low	Low	63.0

Light shading: Patterns of beliefs predicted to b e associated with the best diabetes control after education

Dark shading: Patterns of beliefs predicted to b e associated with the poorest diabet es control after education

perceived Threat, and low perceived Personal Control/Self-efficacy (in the table: Low/Low/Low or Low/High/Low). It can be seen from Table 5.15 that the predictions were largely correct in that those with a belief pattern of high perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy were among the best controlled patients approximately six months after education while those with a belief pattern of low perceived treatment 'Cost-effectiveness', low perceived Threat, and low perceived Personal Control/Self-efficacy had the poorest blood glucose control six months later. Contrary to predictions, those with a belief pattern of low perceived treatment 'Cost-effectiveness', high perceived Threat, and low perceived Personal Control/Self-efficacy (in the table: Low/High/Low) had better blood glucose control than many of the other patients. However, there were only 3 subjects (2 when the insulin study participants were excluded) with this belief pattern and thus the mean follow-up HbA_1 for this group may be unrepresentative.

Discussion

When the patients from the baseline study were invited for an education session, only 47% of them attended. Those who did attend were found to have experienced their diabetes for significantly fewer years, and perceived Complications to be significantly more severe than those who did not attend. Clearly, because the patients constituting the sample in the present study were self-selected, and as a result, had different characteristics from the remaining sample, the results of this study cannot be generalized to the population as a whole. Those patients whose HbA_1 was followed up approximately six months after education were also found to have experienced their diabetes for significantly fewer years than those who were not followed up. However, this was largely due to the patients coming from one clinic source which consisted of people who had experienced their diabetes for fewer years when compared to the people from the second clinic. Nevertheless, the relationships found between follow-up HbA_1 and the health beliefs, perceived control, and well-being cannot be generalized to the tablet-treated population as a whole. The self-selection of patients in the present study indicates that education attendance is more likely when diabetes has been diagnosed more recently. It seems that those who had diabetes of longer duration felt they had nothing to gain from the education sessions, possibly because they thought they knew enough about their diabetes or, given their lower perceived Severity of Complications scores, they were less motivated to improve their knowledge about diabetes.

For those patients whose HbA_1 was followed-up approximately six months after education, no significant improvement in blood glucose control was observed when compared to the baseline measure despite significant improvements in post education APSCORES. However, for a sub-group of patients with baseline HbA_1 levels greater than 55 mmol HMF there was a significant improvement at follow-up. The education sessions therefore seem to have had the greatest impact on those whose diabetes control needed to be improved the most. Several studies which have assessed the impact of education on blood glucose control (eg Bloomgarden and colleagues) have found that metabolic status did not improve significantly after education even though knowledge has improved. Several researchers (eg Germer and colleagues) have also attempted to correlate knowledge scores with diabetes control and found no association. Indeed in the present study, no association was found between pre- and post-education knowledge scores (APSCORES) and the baseline and follow-up outcome measures. However, as Meadows, Lockington and Wise (1987) have pointed out, it is naive to expect a linear relationship between knowledge and diabetes control. Indeed, although a minimum level of diabetes knowledge is probably required for maintaining good blood glucose and weight control, above this threshold social and psychological factors are likely to play a prominent important part in determining metabolic control. Thus, even if patients have a very good knowledge about diabetes they may choose not to use it if they lack the motivation, support, or means to bring their diabetes under control. In the present study, a significant association was found between Percent Knowledge Improvement and baseline as well as follow-up HbA_1 levels, indicating that those patients whose diabetes was relatively well controlled in the first place were able to take greater advantage of the education sessions than their counterparts. The reason for this finding is probably due to the well-controlled patients having a superior knowledge framework on which they could readily add new knowledge. This points to the need for several education sessions when knowledge is particularly poor, rather than just the single session offered, to allow time for a knowledge framework to be built up and new information to be assimilated.

After education, the respondents perceived significantly more Benefits, fewer Barriers, and overall, perceived their treatment to be more 'Cost-effective'. They also perceived significantly greater Personal Control/Self-efficacy and greater

Treatment Satisfaction. The post-education measures of perceived Severity, Vulnerability, Medical Control and Situational Control were not significantly different when compared to baseline. There was, however, a tendency for Well-being to deteriorate although this did not quite reach significance. Furthermore, the correlations between the psychological measures and the knowledge scores indicated that greater impact of the education (Percent Knowledge Improvement and/or APSCORE difference), was associated with more perceived Barriers, fewer perceived Benefits, lower perceived treatment 'Cost-effectiveness', lower Positive Well-being, lower General Well-being, and lower Treatment Satisfaction. Greater post-education APSCORES were also associated with greater Depression, lower Positive Well-being, and lower Treatment Satisfaction scores. Although these negative effects of education were not predicted, these findings indicate that prior lack of knowledge may have been associated with an unrealistic view of diabetes and thus large increases in knowledge would have been very disconcerting. In accordance with predictions greater post education APSCORES were associated with lower perceived Medical Control and lower perceived Situational Control. Although greater perceived Personal Control/Self-efficacy was associated with greater pre-education APSCORES, the association with post-education APSCORES was not significant. This finding indicates that higher post-education knowledge scores may have had a deleterious effect on perceived Personal Control/Self-efficacy for some of the patients in the study or that, in certain cases, the education sessions had the effect of increasing perceived Personal Control/Self-efficacy without concomitant increases in knowledge.

The pattern of correlations between the HBM and perceived control variables and the demographic, clinical, and psychological outcomes in the present study provided further evidence for the validity of these measures, although in many cases the strength of the associations was much weaker. Similar to baseline, lower HbA_1 levels were significantly associated with more perceived Benefits and greater perceived Personal Control/Self-efficacy. More optimistic subjective estimates of diabetes control were associated with lower perceived Vulnerability to Complications, whilst better weight control was related to fewer perceived Barriers, greater perceived Severity of Diabetes, and greater perceived treatment 'Cost-effectiveness'. The pattern of correlations between the Well-being and Treatment Satisfaction measures and the HBM and perceived control measures was also similar to that found at baseline. In general, greater Well-being and Treatment Satisfaction were associated with fewer perceived Barriers, more perceived Benefits, and greater perceived treatment 'Cost-effectiveness'. Greater Well-being and Treatment Satisfaction were also associated with lower perceived Vulnerability to Complications, greater perceived Personal Control/Self-efficacy, lower perceived Situational Control, and greater perceived Medical Control.

In order to assess whether particular characteristics were associated with improved glycaemic control, the patients whose blood glucose control improved were compared with those whose blood glucose deteriorated. It was found that those who improved their control felt less Vulnerable to Complications but were more pessimistic when estimating their diabetes control. Furthermore, women rather than men tended improve their blood glucose control after education. The women who improved their blood glucose control tended to perceive their treatment as more 'Cost-effective' compared to their counterparts, whereas the men who improved their blood glucose control were more pessimistic than their counterparts when estimating their diabetes control. These findings also provide further support for the HBM. The sex difference noted when comparing those whose glycaemic control improved with those whose control deteriorated may be due to women generally valuing their health more highly than men because of the socialization process. Verbrugge & Wingard (1987) suggested that males may be actively encouraged to be tough and expected to minimize symptoms of illness, whereas females are socialized to attend to their health in preparation for their caretaker role in the family. Indeed, Kristiansen (1990) found sex differences in values (Rokeach Terminal Value Survey) consistent with sex role norms and in particular, noted that women valued their health to a greater extent than did men. An alternative explanation, is that men with tablet-treated Type II diabetes are more prone to progressive ß-cell dysfunction requiring eventual insulin treatment than women with tablet-treated Type II diabetes (Kobayashi and colleagues; 1989). If this explanation is correct, then women would have found it easier to improve their glycaemic control.

A major aim of the present study was to re-examine the relationships between the original and newly-introduced HBM variables, when used to predict a prospective measure of blood glucose control, and with the benefit of increased patient knowledge about diabetes. However, the number of cases analysed in the regression analyses was very small and therefore the amount of variance in health outcome explained may have been inflated, despite adjustments to R^2. The results of the analyses must therefore be interpreted with some caution. The first regression analysis indicated that a moderate amount of total variance [35% (22% adjusted)] in follow-up HbA_1 was explained by the individual and composite HBM variables. Interestingly, the multiplicative composite of Severity x Vulnerability x treatment 'Cost-effectiveness' x Personal Control/Self-efficacy contributed a significant amount of unique variance to the explanation and, when entered into the regression equation, significantly increased the R^2. In this analysis, Perceived Personal Control/Self-efficacy was the only individual variable to contribute a significant amount of unique variance to the overall explanation. Inspection of the correlations between Well-being and the HBM variables indicated fairly strong associations between these variables yet the association between Well-being and follow-up HbA_1 was relatively weak. This pattern of associations and the generally decreased Well-being found after education suggested that introduction of General Well-being on the first step of the analysis would suppress irrelevant variance and improve the prediction of health outcome from the HBM variables. As a result, the multiplicative composite of Severity x Vulnerability contributed a significant amount of unique variance to the overall explanation and significantly increased the R^2. Furthermore, the overall amount of variance explained increased substantially to 47% (33% adjusted). In addition to Severity x Vulnerability, perceived Vulnerability to Complications and perceived Personal Control/Self-efficacy also contributed significant amounts of unique variance. The single-item Health Value measure was introduced in another regression analysis, but prediction of follow-up HbA_1 did not improve at all, probably because health value was an important determinant of education attendance. When Percent Knowledge Improvement was introduced in a further analysis, the overall amount of variance explained increased to 57% (41%). However, there were no further improvements in the prediction of follow-up HbA_1 from the HBM variables. These results therefore suggested that when General Well-being was partialled out, a large proportion of the variance in follow-up HbA_1 was explained by the individual and composite HBM variables. Moreover, because the composite variable of Severity x Vulnerability significantly increased the amount of variance explained, a multiplicative relationship between perceived Severity of Diabetes and perceived Vulnerability to Complications was indicated. Although a much smaller amount of outcome variance was explained when the eight participants in the insulin study were excluded from the analyses and Percent Knowledge Improvement was excluded from the equation, the interaction between perceived Severity and Vulnerability remained a significant contributor to the prediction of health outcome. (Percent Knowledge Improvement shared some of the same variance as perceived Vulnerability and the multiplicative composite of Severity x Vulnerability.) In the light of the results just described the relationships between the components of the HBM when predicting health outcome should be specified as

$$HO \approx S^r + V^r + (S \times V)^r + (Ben - Barr) + PCSE$$

where HO represents health outcome, S^r represents reversed perceived Severity, V^r represents reversed perceived Vulnerability, $(S \times V)^r$ represents the interaction between perceived Severity and Vulnerability (Threat) reversed, Ben - Bar represents perceived Benefits less perceived Barriers (treatment 'Cost-effectiveness'), and PCSE represents perceived Personal Control/Self-efficacy. Obviously, the relationship between perceived Personal Control and perceived Self-efficacy could not be investigated in this study because these constructs were measured in unison. Further research is therefore desirable in which separate measures of these beliefs are utilized in order to facilitate the investigation of their relationship. It could be argued that because perceived Severity was a consistently poor predictor of health outcome on its own that it should be omitted from the previous equation to give the following equation:

$$HO \approx V^r + (S \times V)^r + (Ben - Bar) + PCSE$$

Given that greater perceived Vulnerability to Complications and greater perceived Threat were associated with higher HbA_1 levels approximately six months later (when the insulin study participants were included or excluded from the regression analyses), it would appear that increased vulnerability and Threat not only reflect current health status but also predict continuing poor control. Indeed, when the post-education HBM variables were used to predict changes in HbA_1 approximately six months later, contrary to the predictions of the HBM, greater improvements were associated with lower perceived Vulnerability to Complications. A possible explanation for these findings is that the diabetes control of a significant proportion of the sample studied was slowly deteriorating due to progressive ß-cell dysfunction and therefore attempts to improve control would have been increasingly difficult. An additional explanation might be that very poor control and the concomitant feelings of Vulnerability to Complications may have been due to poor management skills or knowledge which were not improved significantly by the education sessions and therefore frustrated any attempt to improve diabetes control. Either of these explanations would tie in with the finding that lower perceived Personal Control/Self-efficacy was associated with poorer control six months later. Furthermore, lower post-education APSCORES were associated with greater Situational Control. As mentioned earlier in relation to knowledge improvement, the patients whose glycaemic control was already relatively good seem to have benefitted more from the education sessions than their less well controlled counterparts. An extension to this reasoning would be that those who were already managing their diabetes fairly competently felt more able to improve their control if so motivated and were therefore predisposed to feeling less vulnerable to complications. If this reasoning is correct, it might be argued that perceived Severity and Vulnerability are not preventive health motivators in themselves, but a reflection of the degree of perceived treatment 'Cost-effectiveness', Personal Control/Self-efficacy and the ability (knowledge, skills, or resources) to manage the disorder generally. Indeed, in the analysis where the eight insulin study participants were excluded, perceived Vulnerability and perceived Threat became insignificant contributors to the prediction of health outcome when Percent Knowledge Improvement was added to the equation.

It is interesting to note from the intercorrelations between the HBM variables that greater perceived treatment 'Cost-effectiveness' was associated on the one hand, with greater perceived Threat (Severity x Vulnerability) whilst on the other, it was associated with lower perceived Vulnerability and lower perceived Severity. Indeed, although the multiplicative composite of Severity x Vulnerability x treatment 'Cost-effectiveness' did not explain a significant amount of unique variance in follow-up HbA_1 in any of the regression analyses, in accordance with HBM predictions, greater scores for this variable were associated with predictions of lower follow-up HbA_1. This would suggest that for some people at least, increased Vulnerability and Severity acted as motivators to improve control provided that treatment was also perceived to be 'Cost-effective'. Clearly, the relationships between the HBM variables and health outcome are fairly complex because health beliefs appear to be context dependent, i.e. vary according to physiological status, knowledge, skills, resources, feedback, and so on. Interrelationships found between the HBM variables and their association with health outcome, therefore need to be discussed in the context of the characteristics and source of the sample studied. Furthermore, a larger sample would allow more definitive interpretations.

Because the amounts of variance in outcomes explained by the baseline data were very low, particularly for HbA_1, it could be argued that the more successful prediction of follow-up HbA_1 from the post-education beliefs was due to the characteristics of the sample who attended for education or the small number of cases used in the analyses of the post-education data. The baseline data of the education attenders were re-analysed, therefore, in order to see if the prediction of baseline HbA_1 was comparable. The results indicated that relative to the whole of the sample, predictions generally improved. However, in relation to HbA_1, when the R^2 was adjusted for the size of the sample, none of the variance in this outcome was explained. A similar result was found even after the variance relating to General Well-being was partialled out. Moreover, the amounts of variance explained in baseline outcomes were still substantially less than the amount of variance explained in follow-up HbA_1. These findings suggest, therefore, that the improved prediction in follow-up HbA_1 was due to improved knowledge of the respondents and the prospective nature of the health outcome measure.

When the HBM data were categorized and combined, none of the belief patterns were significanly different from one another when related to follow-up HbA_1, indicating that the post-education beliefs combined to predict health outcome in a linear rather than a non-linear fashion. Furthermore, when the patterns were ranked according to follow-up HbA_1, some of the belief combinations were associated with levels of control which were not predicted. Moreover, the rankings were different from those found when analysing the baseline data. In some cases the number of subjects with a particular belief pattern was small. Indeed, in one of the analyses, none of the respondents had the belief pattern of low perceived treatment 'Cost-effectiveness', low perceived Threat, and high perceived Personal Control/Self-efficacy. A larger sample, therefore, may have produced different results. However, given the superior prediction of follow-up HbA_1 from the same sample in the regression analyses, this seems unlikely. It is interesting to contrast these findings with the baseline results, which indicated significant differences in health outcome when associated with non-linear combinations of beliefs.

In summary, the results from this study have shown that the education sessions had a significant effect on knowledge, beliefs, Well-being, Treatment Satisfaction, and, for those whose HbA_1 was relatively poor at baseline, glycaemic control. In the latter case, sex differences were noted. The prospective nature of the health outcome measure, and the greater knowledge of many of the patients in this study appear to have improved the ability of the HBM variables to predict HbA_1 when combined in a linear fashion. The relationships between the HBM variables were found to be additive with the exception of perceived Severity and Vulnerability which contributed a significant amount of unique variance to the overall prediction when combined multiplicatively. Contrary to expectations, greater perceived Vulnerability and greater perceived Threat were associated with poorer control six months later which indicates that these variables probably do not act as predictors of preventive health behaviour but merely reflect other beliefs and continuing health status. It was also interesting to note that the relationships between the HBM variables seemed to vary according to the characteristics of the sample included in the analyses. It appears that the interrelationships between the HBM variables and their association with health outcome are mediated by many contextual factors, thus making it difficult to specify the relationships between the components of the model.

Although, the present study investigated belief changes after education, it was not possible to assess the dynamics of health beliefs in the longer term. The next study reports the effects on beliefs of the various stages of an insulin intervention. In addition to the baseline data, beliefs were measured after the participants were first informed of their poor glycaemic control and its implications, after a period of optimizing control on current treatment, and several months later when they had become used to using one of two different insulin delivery methods. The main aim was to investigate the reactivity of health beliefs to new information and treatments and to examine the nature and extent of any change in relation to health outcome.

CHAPTER SIX

EFFECTS OF AN INSULIN INTERVENTION STUDY ON HEALTH BELIEFS

Janz and Becker (1984) pointed out in their review of HBM studies that there has been a paucity of research which attempts to evaluate the effects of interventions on health beliefs. Instead, most studies have focussed on the relationship of beliefs to health outcomes. Although several years have passed since this major review, the position is still the same. Indeed, publications concerning the HBM have generally diminished in recent years. Janz and Becker were referring specifically to the need for research which assesses the impact of interventions designed to alter beliefs in order to achieve desired health behaviours. It could be argued, however, that studies of this type are premature from a theoretical standpoint because past research has not been able to establish fully which HBM dimensions would benefit from change and what the levels of these beliefs should be in order to warrant intervention. Not only would inappropriate interventions be less effective in terms of time and money, they could also produce changes in beliefs which may lead to negative health outcomes. It has been noted in Chapter 5 that the relationship between health outcomes and two of the HBM dimensions (perceived Severity and Vulnerability) appears to be particularly dynamic making it unclear when an intervention might be appropriate. Indeed it is not certain whether these beliefs are the cause or simply a reflection of health status. Clearly, more research is needed concerning the dynamics of health beliefs in order to understand better how, why and if they can be changed. This could be achieved through longitudinal studies which assess the impact of different interventions on HBM dimensions rather than designing interventions which aim to change beliefs in a particular direction. It is predicted that studies of this kind would produce a better understanding of the origins and context of health beliefs.

This chapter describes the impact of the various stages of an insulin intervention study on health beliefs. The aim of this research was to gain an insight into the reactivity of health beliefs to information, education, feedback about control, and the introduction of two types of insulin delivery. The subjects of this study had Type II diabetes which was progressively inadequately controlled with oral hypoglycaemic agents and diet. Insulin treatment would have been routinely prescribed at a particular threshold of hyperglycaemia but these patients were approached before they reached this threshold in order to ascertain whether they would volunteer to take part in the insulin study, whether they could improve their diabetes control prior to insulin therapy after an educational imput and improved feedback about control, and to assess the efficacy of insulin injections and CSII pump therapy. Health beliefs, Well-being and Treatment Satisfaction were assessed prior to, and after each intervention of the study. The rationale for the clinical part of the research was to assess the effects of insulin therapy on the physiological status of patients with poorly-controlled Type II diabetes. It was hypothesized that glycaemic control would be improved and this would be associated with improvement in lipid status and in some aspects of the abnormalities of coagulation and platelet function. In particular, the efficacy of two methods of insulin delivery: conventional injection therapy (CIT) and continuous subcutaneous insulin infusion (CSII) pump therapy were compared. CIT is the regimen routinely prescribed when oral hypoglycaemic agents are not successful whereas CSII has rarely been used for this type of patient. Moreover, prior to the present study, CSII had not been evaluated when used by Type II patients on an outpatient basis. On the basis of experience with insulin-dependent patients (Lewis, Bradley, Knight, Boulton

& Ward, 1988), it was predicted that CSII would be the more acceptable form of insulin treatment. The most worrying and severe complication of CSII use by insulin-dependent patients is the rapid development of diabetic ketoacidosis but the very nature of Type II diabetes means that this dangerous complication cannot arise. The results of the clinical part of the study are reported elsewhere (Jennings, Lewis, Murdoch, Talbot, Bradley & Ward, 1991). This chapter focusses on the impact of the interventions on health beliefs and the accompanying psychological outcomes.

Methods

Subjects and Procedure

The subjects of the present study were selected from an initial pool of patients attending for a full clinical assessment described in Chapter 2. Those who were approached to take part in the insulin study were Caucasian, aged 40 to 65 years, treated with maximum doses of sulphonylureas, had HbA_1 concentrations above 55 mmol HMF/mol Hb, were free from severe diabetic complications, and had been satisfactorily treated with sulphonylureas for at least 1 year. Initially only patients with an ideal body weight < 130% were included but in order to recruit a sufficient number of people for the study this criterion was modified to < 160%. Furthermore, because more people were required for the insulin study after the baseline sample had been exhausted, 6 of the subjects were drawn directly from the outpatient clinics. Due to time limitations at this late stage of the study, these patients were not asked to complete a baseline questionnaire before being approached. Figure 6.1 illustrates the design of the insulin study.

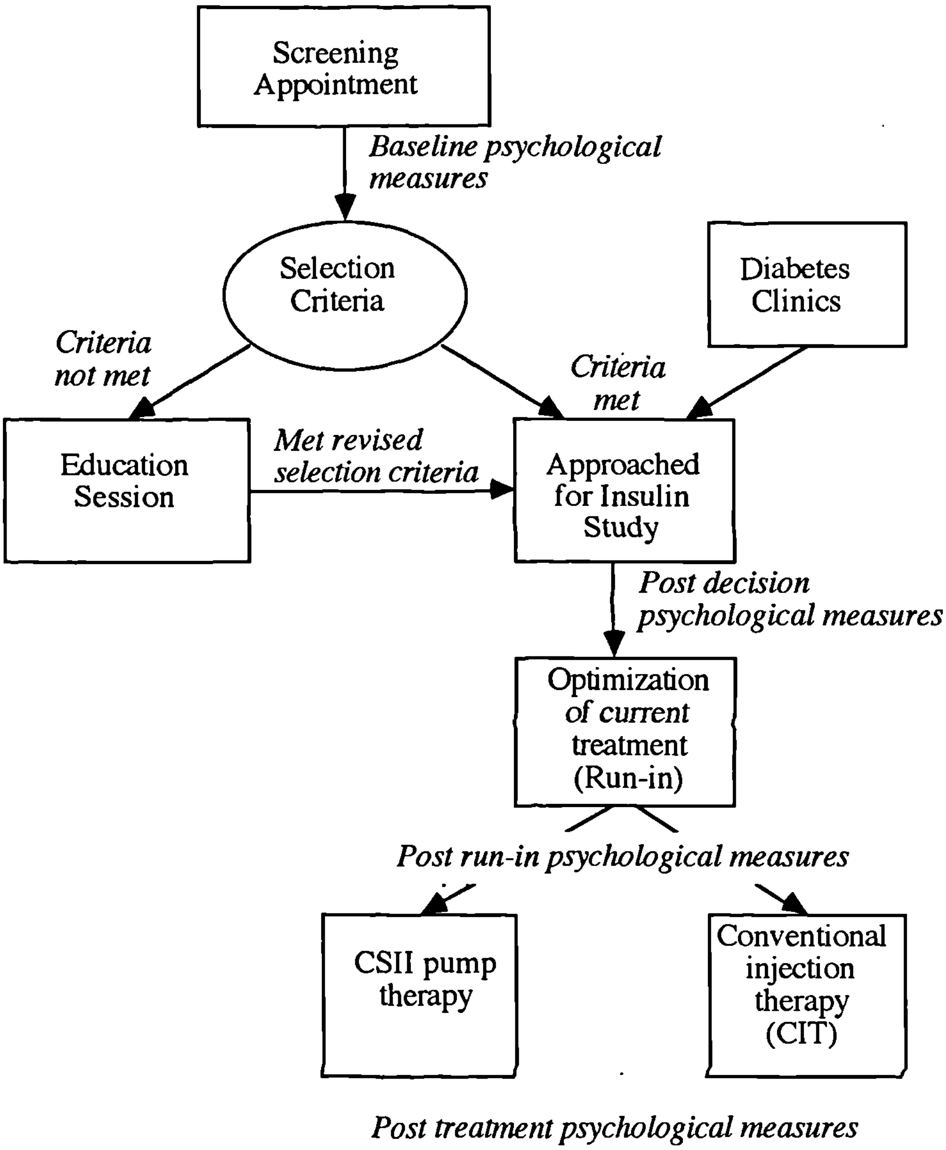


Figure 6.1: Design of the study

Intervention 1: Feedback about patients' poor diabetes control and the increased risk of complications.

Thirty two consecutive patients who fulfilled the selection criteria were informed by the doctor who carried out the clinical assesment about the unsatisfactory control of their diabetes on current treatment and their increased risk of developing complications should hyperglycaemia continue. These patients were then told about the likelihood of needing insulin treatment in the near future. After giving this information, the patients were informed about the insulin study and were asked to consider whether they would take part. They were given written information about the complications of diabetes and details of the insulin study to take home with them for consideration and for educational purposes (see Appendix 5). The patients were also asked to complete a booklet of psychological questionnaires at home, similar to the one distributed at baseline. Included in the booklet was a questionnaire (see Appendix 6) which asked respondents to estimate how well their diabetes had been controlled over the past few weeks, to give their decision regarding whether or not they had decided to take part in the insulin study, and to rate their apprehensiveness about the thought of insulin injections, insulin pump treatment, and blood test finger pricking, on three respective 7-point scales. They were asked to return the completed booklet of questionnaires within the next 2 or 3 days. Those who did not return a booklet within 2 weeks were sent a reminder. Prior to being informed about the unsatisfactory control of their diabetes, and during the time of the consultation with the doctor, all the patients were asked to complete the diabetes knowledge questionnaire described in Chapter 5. A correctly completed copy of this questionnaire was provided for them to peruse at home. Twenty-five (78%) of those approached agreed to participate in the insulin study. Of those who declined to take part, 3 subsequently achieved improved glycaemic control ($HbA_1 < 55$ mmol HMF/ mol Hb), 2 failed to attend the clinic as necessary, 1 died following a myocardial infarction, and 1 received insulin therapy according to the usual clinic regime. The patients who decided not to take part in the insulin study gave significantly more optimistic estimates of their diabetes control when compared with those who agreed to participate ($z = -0.50$; $p<0.01$). No other significant psychological, demographic, or clinical differences were noted between these groups.

Intervention 2: Dietary advice, intensified dietary therapy, and home blood glucose monitoring for a period of 3 months.

The 25 patients who agreed to take part were entered into a preliminary run-in phase of the study. This entailed a period of 3 months in which treatment with diet and tablets was optimised. They attended the hospital every 2 weeks for the first month and thereafter on a monthly basis. At each visit progress was reviewed by a dietitian and the doctor who carried out the initial clinical assessment. At the beginning, each patient was taught the technique of home blood glucose monitoring (HMBG) which meant that feedback about the control of their diabetes was improved. They were also advised to increase the fibre and carbohydrate content of their diet and to reduce fat intake. Obese individuals were advised to reduce their total energy intake. At the end of the 3 months, 5 of the participants achieved good glycaemic control (defined as $HbA_1 < 50$ mmol HMF/ mol Hb), and therefore continued with sulphonylurea therapy. The 20 patients who were unable to achieve $HbA_1 < 50$ mmol HMF/ mol Hb were entered into the insulin treatment phase of the study. Prior to commencing insulin treatment, the patients were asked to complete another copy of the diabetes knowledge questionnaire in order to assess whether knowledge had improved after the run-in phase. They were also asked to complete another copy of the booklet of psychological questionnaires at home. Included in the booklet was a questionnaire in which they were asked to indicate on 7-point scales how well they thought their diabetes had been controlled during the previous few weeks, to what extent they felt that HBGM had helped them to manage their diabetes, and to what extent they felt that their diabetes control had improved as a result of HBGM (See Appendix 7). A further questionnaire was included in which they were asked to rate on 7-point scales their expectations about the treatment to which they had been allocated. The questions from the Expectations of Treatment questionnaire are presented in Figure 6.2. A full copy of this questionnaire is provided in Appendix 9. As before, the participants were asked to return the completed booklets within the next 2 or 3 days. Those who did not respond within a week were sent a reminder. However, no attempt was made to obtain a completed booklet once the insulin treatment phase of the study began. Sixteen of the 20 participants who went on to use insulin returned completed questionnaires. Psychological measures were not obtained from those who continued with tablet and diet treatment.

Figure 6.2: Questions from the Expectations of Treatment questionnaire.

1. I will feel able to control my own diabetes with little need for other people's help.
2. I will feel handicapped.
3. It will be easy to regulate my blood sugar.
4. I believe that I may develop infections with the treatment.
5. I believe that the treatment will reduce the risk of my developing complications of diabetes (such as deteriorating eyesight).
6. It will be obvious to other people that I have diabetes. .
7. I will have freedom to choose when I want to eat.
8. I expect my blood sugar levels to become similar to those of non-diabetic people.
9. I will need to adapt my lifestyle.
10. Insulin reactions (hypos) will be frequent.
11. I believe there might be technical problems with the treatment.
12. I will feel dependent on professional help for managing my diabetes.
13. It will be difficult to deal with the treatment.
14. People around me will accept my using this form of treatment.
15. I think the study will produce valuable scientific information.
16. I will be able to forget that I have diabetes for most of the time.
17. I believe that I might put on too much weight.
18. It will be inconvenient to do the number of blood tests required.
19. I will be able to be flexible with what I eat and still maintain control of my diabetes.
20. I will be able to take part fully in social activities.
21. I believe that a short period of using insulin will lead to good blood sugar control in the long term.

Table 6.1: Demographic and clinical characteristics of the insulin study participants.

	All patients (n=20)		CSII (n=10)		CIT (n=10)	
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**
Age	56.5	(6.4)	56.7	(7.4)	56.3	(5.6)
Duration of diabetes	6.4	(4.5)	6.9	(5.8)	5.9	(3.1)
Percent ideal body weight (pre-treatment)	125.3	(23.9)	125.6	(24.4)	124.9	(24.8)
Sex	8 12	Men Women	4 6	Men Women	4 6	Men Women

Intervention 3 : Insulin treatment using injections or CSII pumps

The demographic and clinical characteristics of the insulin study participants are presented in Table 6.1. It is interesting to note that this final sample consisted of more women than men, whereas the baseline and education study samples consisted of more men than women. This may indicate that the insulin study sample is not representative, especially given that there is some evidence (Kobayashi and colleagues, 1989) that maleness is a risk factor for progressive ß-cell dysfunction. The patients who provided baseline data from this sample were compared with the remainder of the baseline sample in order to ascertain whether there were any differences in the psychological measures at this stage. Mann-Whitney tests indicated that there were no significant differences between the samples with the exception of perceived Severity of Diabetes which was significantly greater in the insulin study patients ($z = -2.6$; $p<0.01$) The insulin study sample were therefore characterized by higher perceived Severity of Diabetes scores prior to any of the interventions.

The patients were randomised to either CSII or CIT (twice daily injections) for 4 months. The randomisation was stratified so that equal proportions of patients above and below 120% ideal body weight were included in each group. The progress of the participants was reviewed by the doctor weekly for 2 weeks, then fortnightly for 6 weeks, then monthly. They were also reviewed at least once a month by the dietitian. CSII or CIT was commenced on an outpatient basis. Initially patients attended the diabetes ward on three consecutive mornings to receive instruction and advice about insulin therapy. The dietitian advised patients about carbohydrate exchanges and recommended a diet designed to minimise weight gain because insulin therapy is known to increase weight in patients with Type II diabetes (Peacock & Tattersall, 1984; Scott and colleagues, 1988). Those who were randomised to CSII also received instruction about insulin injections in case these became necessary, in the event of the pump malfunctioning. Injection technique was taught by a diabetes nurse specialist. At the end of the insulin treatment phase of the study, the patients were asked to complete the knowledge questionnaire in the hospital. They were also given a further copy of the booklet of psychological questionnaires to complete at home. Included in the booklet there was an additional questionnaire which asked respondents to rate the experience of their treatment (Fig 6.3). This was similar to the Expectations of Treatment questionnaire for the purpose of comparison. The patients were also asked to rate how well they felt their diabetes had been controlled over the previous few weeks. As before, they were asked to return the completed booklet within the next 2 or 3 days. Reminders were sent if responses were not received within about a week. Eighteen of the participants returned a completed booklet at the end of the study.

Figure 6.3: Questions from the Experience of Treatment questionnaire.

1. I have felt able to control my own diabetes with little need for other people's help.
2. I have felt handicapped.
3. It has been easy to regulate my blood sugar.
4. I have developed infections with the treatment.
5. I believe that the treatment has reduced the risk of my developing complications of diabetes (such as deteriorating eyesight).
6. It has been obvious to other people that I have diabetes.
7. I have had freedom to choose when I want to eat.
8. My blood sugar levels have become similar to those of non-diabetic people.
9. I needed to adapt my lifestyle.
10. There have been frequent insulin reactions (hypos).
11. I have experienced technical problems with the treatment.
12. I have felt dependent on professional help for managing my diabetes.
13. It has been difficult to deal with the treatment.
14. People around me have accepted my using this form of treatment.
15. I think the study is producing valuable scientific information.
16. I have been able to forget that I have diabetes for most of the time.
17. I have put on too much weight.
18. It has been inconvenient to do the number of blood tests required.
19. I have been flexible with what I eat and still maintain control of my diabetes.
20. I have been able to take part fully in social activities.

Statistical Analyses

The distributions of scores for the psychological variables at all stages of the study met the assumptions of parametric statistical tests. Exceptions were Treatment Satisfaction after insulin treatment, perceived Severity of General Disorders at baseline, and perceived Severity of Complications after deciding whether or not to take part in the study, which were all negatively skewed. Between stage comparisons were made using the Wilcoxon matched pairs signed ranks test, the Student's t -test (paired scores), analyses of variance, or Friedman's chi-square test, as appropriate.

Predictions

The following predictions were made in relation to the impact of the study interventions on health beliefs, perceived control, Well-being, and Treatment Satisfaction:

1. After being given feedback and information about the poor state of their diabetes control and the increased risk of complications, the patients would report reduced Personal Control/Self-efficacy, fewer perceived Benefits of Treatment, more perceived Barriers to treatment, lower perceived treatment 'Cost-effectiveness', greater perceived Severity of Diabetes and its Complications, and greater perceived Vulnerability to Complications. It was also predicted that psychological Well-being and Treatment Satisfaction would deteriorate.

2. After the opportunity to optimize their current treatment using improved feedback about control from HBGM, it was predicted that the patients who managed to improve their blood glucose control would report small but favourable changes in health beliefs, perceived control, psychological Well being, and Treatment Satisfaction when compared to the previous phase of the study. Conversely, those who were unable to improve their control would report negative or non-significant changes in these psychological variables.

3. The insulin treatment phase of the study was predicted to have the greatest effect on health beliefs and the other psychological variables because of its marked impact on blood glucose control overall. It was predicted that the improvements would produce very favourable changes in health beliefs, perceived control, psychological Well-being and Treatment

Satisfaction. Higher levels of HbA_1 and percent ideal body weight after insulin treatment were predicted to be associated with greater perceived Severity of Diabetes and greater perceived Vulnerability to Complications.

Results

Clinical and physiological outcomes

Details of all the clinical and physiological outcomes of the present study are reported elsewhere (Jennings, Lewis, Murdoch, Talbot, Bradley & Ward, 1991). Only outcomes which may have affected the psychological parameters measured are summarized here. All 20 patients completed the insulin treatment phase of the study, none of them requested a change in treatment, and none of the CSII-treated patients experienced difficulty in operating the pump device.

There were no significant differences between the treatment groups in HbA_1 or ideal body weight prior to insulin treatment. After 4 months of insulin treatment, however, HbA_1 significantly improved for both groups of patients (CSII: $z = -2.74$, $p<0.01$; CIT: $z = -2.67$; $p<0.01$). Eight of the 10 patients treated with CSII were able to achieve HbA_1 below 50 mmol HMF/mol Hb whereas only 3 of 10 patients treated with CIT were able to do so ($z = -2.1$; $p<0.05$). Body weight increased significantly in both groups after treatment with insulin (CSII: $z = -2.2$; $p<0.05$; CIT: $z = - 2.1$; $p<0.05$) but there were no significant between-group differences. Statistical information relatingto HbA_1 and percent ideal body weight at each stage of the study are presented in Table 6.2.

Table 6.2: Statistics relating to HbA1 and percent ideal body weight at each stage of the study.

	CSII (N = 10)					CIT (N = 10)					Difference between groups (p value)
	Min	Max	Mean	(SD)	Median	Min	Max	Mean	(SD)	Median	
HbA1											
Baseline	52.0	77.0	63.6	(9.3)	60.0	42.0	82.0	66.4	(13.6)	71.0	NS
Post decision	55.0	80.0	64.1	(7.6)	61.5	55.0	83.0	70.6	(9.3)	71.0	NS
Post run-in	51.0	78.0	64.7	(8.6)	64.5	51.0	83.0	65.6	(10.8)	62.5	NS
Post-treatment	41.0	60.0	47.5	(6.2)	45.5 **	44.0	60.0	52.0	(5.4)	52.0 **	<0.05
Percent ideal body weight											
Baseline	98.0	160.0	126.0	(24.0)	119.0	83.0	173.0	128.3	(26.4)	123.0	NS
Post decision	98.0	158.0	125.6	(24.4)	117.5	82.0	164.0	124.9	(24.8)	122.0	NS
Post run-in	97.0	157.0	122.9	(24.4)	115.0	83.0	164.0	122.8	(25.4)	117.5	NS
Post-treatment	108.0	174.0	129.8	(22.9)	120.5 *	95.0	167.0	126.6	(20.7)	127.5 *	NS

** $p<0.01$ vs end of Run-in phase   * $p<0.05$ vs end of Run-in phase

Reference range for HbA1: 29-39 mmol HMF/ mol Hb

One patient in each group experienced frequent mild hypoglycaemia during insulin treatment (>2 attacks per month) and a total of 3 patients, 2 of whom were treated with CIT, experienced infrequent mild hypoglycaemia (<3 attacks during the 4 month insulin treatment period). None of the patients developed infections at the needle site or uncontrolled hyperglycaemia. Eye assessments indicated retinal deterioration in one of the CSII-treated patients and 4 of the CIT-treated patients after insulin treatment.

Subjective estimates of control at each stage of the study

A two factor mixed measures ANOVA indicated that there were no significant differences in subjective estimates of diabetes control between the treatment groups ($F=0.11$; df 1,9; $p=0.7$). However, subjective estimates of diabetes control did vary significantly during the study ($F=6.72$; df 3,27; $p<0.01$). A multiple comparison test (Tukey HSD method) indicated that subjective estimates of control became significantly more optimistic after insulin treatment when compared with the post run-in measure ($p<0.05$). However, correlations between the objective and subjective indices of diabetes control were non-significant at all stages of the study.

Impact of the insulin study interventions on health beliefs and psychological outcomes

Statistics relating to the psychological measures at baseline and after each intervention are presented in Tables 6.3 and 6.4.

Table 6.3: Mean (SD) health belief and perceived control scores at each stage of the study

	All patients			CSII-treated patients			CIT-treated patients		
	Mean	(SD)	N	Mean	(SD)	N	Mean	(SD)	N
Perceived Benefits									
Baseline	26.8	(2.8)	14	26.7	(2.9)	8	26.8	(2.9)	6
Post decision	25.5	(3.8)	20	25.0	(2.9)	10	26.0	(4.7)	10
Post run-in phase	26.4	(3.5)	17	25.6	(4.0)	9	27.4	(2.7)	7
Post insulin treatment	27.6	(2.5)	18	27.0	(3.0)	9	28.2	(1.9)	9
Perceived Barriers									
Baseline	14.6	(7.4)	14	13.0	(7.4)	8	16.8	(7.4)	6
Post decision	15.0	(6.5)	20	13.7	(6.1)	10	17.4	(7.6)	10
Post run-in phase	11.4	(6.5)*	16	11.8	(6.5)	9	11.6	(7.3)	7
Post insulin treatment	10.2	(6.7)	18	8.0	(5.0)**	9	11.6	(7.9)	9
Perceived Treatment 'Cost-effectiveness'									
Baseline	12.1	(8.2)	14	13.8	(7.7)	8	10.0	(8.9)	6
Post decision	10.8	(4.4)	20	11.7	(4.2)	10	9.7	(4.8)	10
Post run-in phase	14.9	(6.7)*	16	14.2	(7.0)	9	15.9	(6.7)*	7
Post insulin treatment	19.1	(7.5)*	18	19.0	(6.8)*	9	16.7	(9.1)	9
Perceived Severity of Complications									
Baseline	28.7	(3.0)	15	28.4	(2.9)	8	29.0	(3.4)	7
Post decision	29.1	(3.0)	20	29.1	(2.2)	10	29.0	(3.7)	10
Post run-in phase	29.1	(3.0)	16	28.3	(3.6)	9	30.0	(1.6)	7
Post insulin treatment	28.3	(3.1)	17	28.8	(3.1)	8	27.9	(3.2)	9
Perceived Severity of Diabetes									
Baseline	6.6	(1.4)	14	6.7	(1.4)	8	6.4	(1.7)	6
Post decision	5.9	(1.6)	18	5.3	(1.7)*	9	6.8	(1.1)	9
Post run-in phase	5.8	(2.0)	16	6.0	(2.2)	9	5.4	(1.8)	7
Post insulin treatment	4.9	(4.6)	18	5.0	(2.1)**	9	4.9	(1.1)	9

** $p<0.01$ versus prior study phase
* $p<0.05$ versus prior study phase

/continued ....

Table 6.3 continued ....

	All patients		CSII-treated patients		CIT-treated patients	
	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N
Perceived Severity of General Disorders						
Baseline	23.2 (7.2)	13	24.5 (4.8)	8	21.2 (10.5)	5
Post decision	24.8 (4.0)	19	25.0 (3.5)*	10	24.6 (4.7)	9
Post run-in phase	23.9 (4.7)	15	22.6 (5.6)**	8	25.3 (3.4)	7
Post insulin treatment	23.2 (4.6)	17	25.1 (4.5)	8	21.6 (4.2)	9
Perceived Vulnerability to Complications (averaged)						
Baseline	2.2 (1.0)	15	2.0 (1.0)	8	2.5 (1.1)	7
Post decision	2.5 (0.8)	19	2.4 (0.8)	10	2.7 (0.8)	9
Post run-in phase	2.5 (0.9)	16	2.3 (1.1)	9	2.7 (0.9)	7
Post treatment	2.6 (0.7)	18	2.6 (0.8)	9	2.6 (0.6)	9
Perceived Vulnerability to Complications (single item)						
Baseline	2.6 (1.3)	14	2.6 (1.4)	8	2.5 (1.1)	6
Post decision	2.9 (0.9)	19	2.9 (0.7)	10	2.7 (0.8)	9
Post run-in	3.1 (0.9)	16	3.1 (1.1)	9	2.7 (0.9)	7
Post treatment	2.7 (0.7)	17	2.9 (1.5)	8	2.6 (0.6)	9
Perceived Vulnerability to General Disorders						
Baseline	11.4 (6.8)	14	11.6 (7.2)	7	11.3 (7.1)	7
Post decision	14.0 (7.2)	16	15.1 (6.9)	8	12.9 (7.8)	8
Post run-in	13.1 (6.6)	15	14.5 (7.8)	8	11.6 (4.9)	7
Post treatment	16.4 (3.6)	16	17.8 (3.9)	8	15.1 (2.9)	8

** $p<0.01$ versus prior study phase
* $p<0.05$ versus prior study phase

/continued ....

Table 6.3 continued ....

	All patients			CSII-treated patients			CIT-treated patients		
	Mean	(SD)	N	Mean	(SD)	N	Mean	(SD)	N
Perceived Vulnerability of 'Average Person' to Complications									
Baseline	19.1	(8.4)	13	17.0	(9.2)	7	21.5	(7.4)	6
Post decision	21.4	(5.5)	17	20.8	(3.8)	9	22.0	(7.2)	8
Post run-in phase	21.0	(4.7)	13	19.1	(4.6)	7	23.2	(4.1)	6
Post insulin treatment	21.4	(5.2)	18	20.2	(6.0)	9	22.6	(4.2)	9
Perceived Vulnerability of 'Average Person' to Complications (single item)									
Baseline	2.6	(1.3)	14	2.8	(1.5)	8	2.5	(1.2)	6
Post decision	2.8	(0.8)	19	2.5	(0.5)	10	3.1	(0.9)	9
Post run-in phase	2.9	(0.9)	15	2.8	(1.0)	8	3.1	(0.7)	7
Post treatment	2.7	(0.7)	18	2.7	(0.7)	9	2.7	(0.7)	9
Perceived Vulnerability of 'Average Person' to General Disorders									
Baseline	13.0	(7.2)	14	13.8	(8.0)	8	12.0	(6.6)	6
Post decision	15.3	(7.0)	18	16.2	(6.2)	10	14.1	(8.2)	8
Post run-in	15.7	(4.2)	14	16.1	(3.7)	7	15.3	(4.9)	7
Post treatment	16.9	(4.4)	18	17.1	(4.4)	9	16.8	(4.6)	9

/continued ....

Table 6.3 continued ....

	All patients			CSII-treated patients			CIT-treated patients		
	Mean	(SD)	N	Mean	(SD)	N	Mean	(SD)	N
Perceived Personal Control/Self-efficacy									
Baseline	67.8	(14.3)	13	62.0	(15.5)	7	74.5	(10.0)	6
Post decision	64.5	(16.3)	20	61.7	(17.0)	10	67.4	(16.0)	10
Post run-in phase	69.5	(15.7)	16	65.1	(19.1)	9	75.1	(8.2)	7
Post insulin treatment	71.7	(8.4)	18	71.0	(7.9)	9	72.4	(9.3)	9
Perceived Medical Control									
Baseline	30.8	(13.7)	13	34.9	(9.6)	7	26.0	(16.9)	6
Post decision	30.5	(11.8)	20	28.1	(10.4)	10	32.9	(13.2)	10
Post run-in phase	29.5	(11.7)	16	29.4	(11.0)	9	29.6	(13.5)	7
Post treatment	32.3	(10.1)	18	34.6	(7.3)	9	30.0	(12.4)	9
Perceived Situational Control									
Baseline	18.4	(13.6)	13	25.5	(13.9)	7	11.3	(9.7)	6
Post decision	18.5	(11.1)	20	20.1	(11.5)	10	16.9	(11.1)	10
Post run-in	15.4	(12.1)	16	16.0	(12.1)	9	14.6	(13.1)	7
Post treatment	16.2	(13.6)	18	17.7	(12.7)	9	14.7	(15.0)	9

Table 6.4: Mean (SD) Well being and Treatment Satisfaction scores at each stage of the study

	All patients			CSII-treated patients			CIT-treated patients		
	Mean	(SD)	N	Mean	(SD)	N	Mean	(SD)	N
Depression									
Baseline	4.5	(2.4)	14	4.3	(2.8)	8	4.8	(1.9)	6
Post decision	5.6	(2.7)	20	6.2	(3.2)	10	5.0	(2.1)	10
Post run-in phase	3.8	(2.6)	16	4.2	(2.8)	9	3.3	(2.4)	7
Post insulin treatment	4.9	(2.8)	18	5.0	(2.9)	9	4.9	(2.8)	9
Anxiety									
Baseline	6.3	(3.8)	15	6.8	(3.8)	8	5.7	(4.1)	7
Post decision	6.7	(3.8)	20	6.3	(4.1)	10	7.1	(3.5)	10
Post run-in phase	6.3	(4.3)	15	7.2	(4.8)	9	5.1	(3.4)	6
Post insulin treatment	5.5	(3.7)	18	6.1	(2.9)	9	4.9	(4.4)	9
Positive Well being									
Baseline	12.5	(3.5)	15	12.9	(3.4)	8	12.1	(3.8)	7
Post decision	12.3	(3.6)	20	12.1	(4.0)	10	12.5	(3.3)	10
Post run-in phase	13.4	(3.1)	15	13.4	(3.5)	9	13.3	(2.6)	6
Post insulin treatment	12.5	(3.3)	18	12.3	(4.6)	9	12.7	(3.7)	9
General Well being									
Baseline	39.4	(7.7)	14	39.9	(7.5)	8	38.7	(8.7)	6
Post decision	38.0	(8.2)	20	37.6	(9.9)	10	38.4	(6.7)	10
Post run-in phase	40.3	(8.4)	15	39.0	(10.1)	9	42.2	(5.2)	6
Post insulin treatment	40.1	(8.3)	18	39.2	(8.3)	9	40.9	(8.7)	9
Treatment Satisfaction									
Baseline	26.3	(5.9)	15	29.0	(3.9)	8	23.3	(6.6)	7
Post decision	22.8	(7.6)	20	23.9	(7.9)	10	21.6	(7.6)	10
Post run-in phase	25.6	(5.9)	16	24.6	(6.2)	9	27.0	(5.7)*	7
Post insulin treatment	30.2	(5.1)**	17	29.0	(6.3)	9	31.6	(3.1)*	8

** $p<0.01$ versus prior phase of study

* $p<0.05$ versus prior phase of study

1. Baseline versus Intervention 1 (feedback and information about diabetes and its control/approached for insulin study).

<u>All patients</u>

There were no significant changes in Well-being, Treatment Satisfaction, perceived control, perceived Benefits of, and perceived Barriers to treatment, perceived treatment 'Cost-effectiveness', perceived Vulnerability, or perceived Severity (of Complications or Diabetes). Although not statistically significant, there appeared to be a tendency to view current treatment as less 'Cost-effective' (t = 1.9; p=0.08), to report greater Severity of Complications (z = -1.8; p<0.09), and to perceive greater Vulnerability to Complications (meaned measure) (t = -2.1; p<0.06).

<u>CSII-treated patients</u>

No significant changes were observed in Well-being, Treatment Satisfaction, perceived control, perceived Benefits of, and Barriers to treatment, perceived treatment 'Cost-effectiveness', and perceived Vulnerability. However, this group did report significantly decreased perceived Severity of Diabetes (t = 2.7; p<0.05). There was also an apparent tendency to perceive greater Vulnerability to Complications (t = -1.99; p<0.09)

<u>CIT-treated patients</u>

There were no significant differences in any of the psychological variables measured after Intervention 1 when compared with baseline.

2. *Intervention 1 vs Intervention 2 (HBGM and optimization of diet).*

All patients

There were no significant changes in Well-being, Treatment Satisfaction, perceived control, perceived Severity or perceived Vulnerability after the run-in phase of the study. Patients did report significantly fewer Barriers to treatment ($t = 2.2$; $p<0.05$), and overall, perceived their current treatment to be significantly more 'Cost-effective' ($t = -2.6$; $p<0.05$). As stated earlier, one of the predictions made was that favourable changes in health beliefs and the other psychological variables would be reported by those who managed to improve their glycaemic control, whereas negative or non-significant changes would be reported by those who were unable to improve their glycaemic control. The 9 patients who improved their blood glucose control after this phase of the study (and provided psychological data) reported their treatment to be significantly more 'Cost-effective' ($z = -2.3$; $p<0.05$). However, no other significant changes in the psychological variables were reported by this sub-group. As predicted, no significant changes were observed in health beliefs, perceived control, Well-being, or Treatment Satisfaction by the 7 patients whose blood glucose control did not improve during the run-in phase

CSII patients

No significant changes were observed in Well-being, Treatment Satisfaction, perceived control, perceived Benefits of, and Barriers to treatment, perceived treatment 'Cost-effectiveness', or perceived Vulnerability. These patients did report greater perceived Severity of General Disorders ($t = 2.8$; $p<0.05$).

CIT-treated patients

There were no significant changes in Well-being, perceived control, perceived

Severity or perceived Vulnerability. These patients did report significantly greater Treatment Satisfaction (t = -2.5; p<0.05), and perceived their treatment to be significantly more 'Cost-effective' (t = -3.0; p<0.05).

3. Intervention 2 vs Intervention 3 (insulin treatment)

All patients

No significant changes in Well-being, perceived control, perceived Severity or perceived Vulnerability were noted after the insulin treatment phase of the study. Patients did report significantly greater Treatment Satisfaction (z = -2.4; p<0.02), fewer Barriers to treatment (t = 2.2; p<0.05) and overall viewed the treatment as significantly more 'Cost-effective' (t = -2.6; p<0.02). Although not statistically significant, there was an apparent tendency for the patients to report reduced perceived Severity of Diabetes (t = 1.9; p<0.08).

CSII-treated patients

There were no significant changes in Well-being, Treatment Satisfaction, perceived control, or perceived Vulnerability after pump therapy. This group did report significantly fewer perceived Barriers to treatment (t = 3.9; p<0.01), significantly greater perceived treatment 'Cost-effectiveness' (t = -3.0; p<0.05) significantly decreased perceived Severity of General Disorders (t = -3.5; p<0.02) and significantly decreased perceived Severity of Diabetes (t = 4.6; p<0.01).

CIT-treated patients

No significant changes were observed in Well-being, Treatment Satisfaction, perceived Benefits of, or Barriers to treatment, perceived treatment

'Cost-effectiveness', or perceived Vulnerability after injection therapy. However, this group did report significantly greater Treatment Satisfaction (z = -2.2; $p<0.05$. There was also an apparent tendency for perceived Severity of Complications (t = 2.12; $p<0.08$) and perceived Vulnerability to General Disorders (t = -2.1; $p<0.09$) to decrease.

4. Baseline vs Intervention 3

<u>All patients</u>

In order to assess the overall impact of all the interventions on the psychological variables, the baseline measures were compared with the post-treatment measures. These comparisons indicated that there were no significant changes in Well-being, perceived control, or perceived Vulnerability by the end of the study. There were, however, significant increases in Treatment Satisfaction scores (z = -3.3; $p<0.05$), and perceived treatment 'Cost-effectiveness' scores (t = -3.4; $p<0.01$). In addition, significant decreases were noted in perceived Barriers to treatment scores (t = 3.4; $p<0.01$), and perceived Severity of Diabetes scores (t = 3.5; $p<0.01$).

<u>CSII-treated patients</u>

There were no significant changes in Well-being, Treatment Satisfaction, perceived control, perceived Benefits of, or Barriers to treatment, perceived treatment 'Cost-effectiveness', or perceived Vulnerability. This group did report significantly decreased perceived Severity of Diabetes (t = 2.6; $p<0.05$) at the end of the study when compared to baseline.

CIT-treated patients

No significant changes in Well-being, perceived control, perceived Severity or perceived Vulnerability were observed. However, these patients did report significantly greater Treatment Satisfaction (t = -4.3; $p<0.01$), fewer perceived Barriers to treatment (t = 3.0; $p<0.05$), and overall, perceived their treatment to be significantly more 'Cost-effective' (t = -3.6; $p<0.05$) when compared with baseline.

Comparisons between the treatment groups.

When scores from all the psychological measures were compared no significant treatment group differences were observed at any stage of the study. There was, however, a tendency for patients treated with CSII to report greater Treatment Satisfaction at baseline ($t = 2.0$; $p = 0.07$) and to perceived greater Situational Control at baseline ($t = 2.05$; $p = 0.07$).

Impact of the interventions on those who responded to questionnaires at all stages of the study

Given that some patients did not return completed booklets of questionnaires and some did not progress to insulin treatment, repeated measures ANOVAs and Friedman's tests were computed as appropriate in order to assess the impact of the interventions on those who provided psychological data at all stages of the study (N=10: 5 treated with CSII, 5 treated with CIT). The results indicated that Well-being, perceived control, and perceived Vulnerability did not vary significantly. However, there were significant changes in Treatment Satisfaction (chi-square = 8.4; $p<0.05$), perceived Barriers to treatment ($F = 5.7$; df 3,27; $p<0.01$), perceived treatment 'Cost-effectiveness' ($F = 8.5$; df 3,27; $p<0.001$), and perceived Severity of Diabetes ($F = 6.6$; df 3,27; $p<0.01$) during the study. Multiple comparison tests indicated that

Treatment Satisfaction increased significantly between the decision to take part (Intervention 1) and insulin treatment (Intervention 3) ($p<0.05$);

perceived Barriers to treatment decreased significantly between baseline and insulin treatment (Intervention 3) ($p<0.05$) and between the decision to take part (Intervention 1) and insulin treatment (Intervention 3) ($p<0.01$);

perceived treatment 'Cost-effectiveness' increased signficantly between baseline and insulin treatment (Intervention 3) ($p<0.01$), between the decision to take part (Intervention 1) and the run-in phase (Intervention 2) ($p<0.05$), and between the decision to take part (Intervention 1) and insulin treatment (Intervention 3) ($p<0.01$);

perceived Severity of Diabetes decreased significantly between baseline and insulin treatment (Intervention 3) ($p<0.01$)

Knowledge of Diabetes scores

When knowledge scores (Table 6.5) were compared, the results of a two factor mixed measures ANOVA indicated that there were no significant differences between the knowledge scores of the treatment groups ($F=0.00$; df 1,16; $p=0.9$), knowledge did not improve significantly at any stage of the study ($F = 1.08$; df 2,32; $p=0.4$), and there was no interaction between treatment group and knowledge scores ($F=0.24$; df 2,32; $p=0.8$).

Table 6.5: Mean (SD), median, and range of Diabetes Knowledge scores* at each stage of the study

	Mean (SD)		Median	Range	N
Approached for study	67.6	(19.1)	66.3	12.5 - 100.0	19
Post run-in	70.9	(16.9)	76.3	27.5 - 95.0	19
Post insulin treatment	70.8	(22.4)	83.1	23.8 - 100.0	18

* APSCORE (adjusted percentage score)

Expectations and Experience of Treatment compared

Scores relating to the individual items from the Expectations of Treatment and Experience of Treatment questionnaires were compared for the CSII-treated and CIT-treated patients separately. These analyses indicated that for both treatment groups, hypos were significantly less frequent than expected (CSII: $z = -2.2$, $p<0.05$; CIT: $z = -2.0$; $p<0.05$), and the treatment was significantly less difficult to deal with than expected (CSII: $z = -2.1$, $p<0.05$; CIT: $z = -2.2$; $p<0.05$). In addition, the CSII-treated patients reported that they were able to forget their diabetes significantly more than expected ($z = -2.1$; $p<0.05$). No other significant differences were noted in relation to either treatment group.

Apprehension regarding insulin injections, pump therapy, and finger pricking for HBGM

There were no significant differences between the treatment groups in the degree of their apprehension about the use of insulin injections, CSII pump therapy, or finger pricking in order to blood test at home. There was, however, an apparent tendency for patients subsequently randomised to CSII pump therapy to be more apprehensive about finger pricking than those subsequently randomised to CIT (z = -1.9; p<0.07). Statistics relating to the apprehension scales are provided in Table 6.6.

Table 6.6: Mean (SD), median, and range apprehension scores.

	Apprehension re insulin injections	Apprehension re CSII pump therapy	Apprehension re finger pricking for HBGM
All patients (N = 20)			
Mean (SD)	3.4 (2.3)	3.0 (2.0)	1.7 (1.9)
Median	4.0	3.0	1.0
Range	0-6	0-6	0-6
CSII-treated patients (N = 10)			
Mean (SD)	4.2 (2.0)	3.4 (2.0)	2.4 (2.0)
Median	4.5	3.5	2.5
Range	0-6	0-6	0-6
CIT-treated patients (N = 10)			
Mean (SD)	2.5 (2.4)	2.6 (2.1)	0.9 (1.5)
Median	2.0	3.0	0
Range	0-6	0-6	0-4

0 = not at all apprehensive or worried
6 = very apprehensive or worried

Patient perceptions regarding the efficacy of HBGM after the run-in phase of the study

When the two treatment groups were compared, HBGM efficacy ratings in relation to the management and control of their diabetes were not significanly different. Mean (SD) scores relating to the efficacy of HBGM in aiding management of their diabetes and in improving control were 3.5 (1.7) and 4.2 (1.5) respectively (lower scores = greater efficacy).

Prediction of improvements in control after Intervention 2 (post run-in phase) from the HBM variables measured after Intervention 1 (feedback about control).

It was predicted that the impact of the first intervention on health beliefs and the opportunity to optimize current treatment during the run-in phase of the study, would generally increase the patients' motivation to improve their diabetes control as far as possible. In order to assess whether health beliefs would predict improvements in weight and blood glucose control, the post-decision HBM variables were correlated with changes in percent ideal body weight and HbA_1 after the run-in phase of the study. However, none of the correlations were significant. Similar correlations were computed using the post decision HBM variables and the absolute measures of weight and blood glucose control collected after the run-in phase. Once again, however, no significant associations were observed.

It was not possible to use pre-treatment health beliefs to predict health outcomes after the insulin intervention because of the potency of the intervention itself on control. Indeed, no significant associations were observed between these variables.

Relationship of diabetes control to health beliefs at each stage of the study

HbA_1 and percent ideal body weight measured at the various stages of the study were correlated with concurrent health beliefs (Tables 6.7 to 6.10) in order to assess the impact of the interventions from a cross-sectional perspective.

At baseline, greater obesity was associated with fewer perceived Benefits of treatment ($r = -0.54$; $p<0.05$) and greater perceived Severity of Complications ($r = 0.52$, $p<0.05$). More pessimistic subjective estimates of diabetes control were significantly associated with greater perceived Vulnerability to Complications [$r = 0.59$; $p<0.05$ (meaned measure); $r = 0.55$; $p<0.05$ (single item)]. There were no significant correlations between HbA_1 and the HBM variables at baseline.

Table 6.7: Relationship between the baseline HBM variables and diabetes control (baseline)

	Ideal body weight	HbA1	Subjective estimate of control	N
Perceived				
Benefits	-0.54 *	0.14	-0.13	14
Barriers	0.09	0.30	0.12	14
Treatment 'Cost-effectiveness'	-0.27	-0.23	-0.15	14
Severity of Diabetes	0.24	0.06	-0.23	14
Severity of Complications	0.52 *	0.15	-0.21	15
Vulnerability to Complications (averaged)	0.09	-0.00	0.59 *	15
Vulnerability to Complications (single item)	0.10	0.38	0.55 *	14
Personal Control/Self-efficacy	-0.04	0.21	0.07	13

* $p<0.05$

Lower health outcome scores = better control

After being approached to take part in the insulin study, more pessimistic estimates of diabetes control were significantly associated with fewer perceived Benefits of treatment ($r = -0.45$; $p<0.05$). No significant correlations were observed between percent ideal body weight or HbA_1 and the health belief variables.

Table 6.8: Relationship between the post decision HBM variables and diabetes control (post decision)

	Ideal body weight	HbA1	Subjective estimate of control	N
Perceived				
Benefits	-0.32	0.15	-0.45 *	20
Barriers	-0.18	0.21	-0.31	20
Treatment 'Cost-effectiveness'	-0.00	-0.16	0.08	20
Severity of Diabetes	0.10	0.27	0.18	18
Severity of Complications	0.35	-0.12	-0.01	20
Vulnerability to Complications (averaged)	-0.07	-0.16	-0.33	19
Vulnerability to Complications (single item)	-0.17	-0.28	0.05	19
Personal Control/Self-efficacy	-0.10	-0.06	-0.23	20

* $p<0.05$

Lower health outcome scores = better control

After the run-in phase of the study, greater obesity was associated with greater perceived Severity of Diabetes ($r = 0.55$; $p<0.05$). No other significant associations were observed between the outcome variables and health beliefs (Table 6.9).

After 4 months of insulin treatment, greater obesity was significantly associated with greater perceived Severity of Diabetes ($r = 0.52$; $p<0.05$), greater perceived Severity of Complications ($r = 0.59$; $p<0.05$), and greater perceived Vulnerability to Complications (meaned measure) ($r = 0.48$; $p<0.05$). Higher HbA_1 levels after the insulin treatment were significantly associated with greater Vulnerability to Complications (single item) ($r = 0.55$; $p<0.05$). It is interesting to note that no significant associations were found

Table 6.9: Relationship between the post run-in HBM variables and diabetes control (post run-in)

	Ideal body weight	HbA1	Subjective estimate of control	N
Perceived				
Benefits	-0.18	0.01	-0.33	17
Barriers	0.04	-0.06	0.04	16
Treatment 'Cost-effectiveness'	-0.13	-0.06	-0.22	16
Severity of Diabetes	0.55 *	-0.02	0.22	16
Severity of Complications	0.47	-0.08	0.07	16
Vulnerability to Complications (averaged)	-0.01	0.01	0.46	16
Vulnerability to Complications (single item)	0.23	0.17	0.41	16
Personal Control/Self-efficacy	-0.10	-0.16	-0.23	16

* $p<0.05$

Lower health outcome scores = better control

Table 6.10: Relationship between the post treatment HBM variables and diabetes control (post treatment)

	Ideal body weight	HbA1	Subjective estimate of control	N
Perceived				
Benefits	0.28	0.22	-0.18	18
Barriers	-0.28	-0.02	0.32	18
Treatment 'Cost-effectiveness'	0.33	0.09	-0.33	18
Severity of Diabetes	0.52 *	0.21	0.22	18
Severity of Complications	0.59 *	0.27	0.13	17
Vulnerability to Complications (averaged)	0.48 *	0.34	0.28	18
Vulnerability to Complications (single item)	0.34	0.55 *	-0.20	17
Personal Control/Self-efficacy	0.23	-0.12	-0.31	18

* $p<0.05$

Lower health outcome scores = better control between subjective estimates of control and health beliefs after the insulin treatment. Moreover, although not significant, the direction of the correlations between subjective estimates of control and the health beliefs were, in some cases, opposite to that found between the objective measures of control and the health beliefs. In particular, it was noted that on the one hand, greater perceived Vulnerability to Complications (single item) was associated with higher levels of HbA_1 whilst on the other, greater perceived Vulnerability tended to be associated with more optimistic subjective estimates of diabetes control. A similar pattern of contrary associations was found for perceived Benefits and Barriers to treatment, perceived treatment 'Cost-effectiveness', and perceived Personal Control/Self-efficacy (see Table 6.10).

Discussion

The clinical and physiological results indicated that, after the doctor provided patients with feedback about their diabetes control (Intervention 1) and after being given the opportunity to optimize current treatment (Intervention 2), percent ideal body weight and HbA_1 did not change significantly . However, as predicted, HbA_1 reduced significantly and percent ideal body weight increased significantly after the insulin treatments (Intervention 3). The incidence of hypoglycaemia in each treatment group was generally equivalent after the insulin intervention. However, eye assessments indicated that slight retinal deterioration occurred in more of the CIT-treated patients. Given that 8 of the 10 patients treated with CSII were able to achieve HbA_1 below 50 mmol HMF/mol Hb whereas only 3 of the 10 CIT-treated patients were able to do so, from a medical viewpoint, CSII was regarded as the most successful method of insulin delivery in the present study. From the patients' point of view, subjective estimates of diabetes control did not change significantly until after the insulin interventions. There were no significant differences between the treatment groups in ratings of control at any stage and both groups estimated their post-treatment diabetes control to be significantly improved when compared with pre-treatment estimates.

The impact of Intervention 1 on the health beliefs, perceived control, Well-being, and Treatment Satisfaction of the patients was not significant although there was a tendency to perceive treatment to be less 'Cost-effective', and to perceive greater Severity of, and Vulnerability to Complications. The impact of this intervention on the psychological variables was much less than expected because it may have been mediated by reassurances from the doctor or the patients' own expectations regarding insulin therapy. Indeed, it is interesting to note that the patients who were subsequently randomised to the CSII treatment group reported significantly decreased perceived Severity of Diabetes after the intervention.

After the run-in phase of the study, which involved improved feedback from blood glucose monitoring, intensive dietary advice and therapy, and more frequent visits to the hospital, the patients reported significantly fewer Barriers to treatment, and, overall perceived their treatment to be more 'Cost-effective'. In addition, the patients who were subsequently randomised to CIT therapy, reported significantly increased Treatment Satisfaction. It was predicted that those who managed to improve their blood glucose control during this phase of the study would report increased treatment

'Cost-effectiveness' (more perceived Benefits and/or fewer perceived Barriers), reduced perceived Severity of Diabetes, reduced perceived Vulnerability to Complications, and improved psychological Well-being and Treatment Satisfaction. What actually happened was that these patients perceived their treatment to be significantly more 'Cost-effective' after the run-in phase, but there were no other positive changes in any of the psychological variables. As predicted, no significant changes were observed in any of the psychological variables for those who did not manage to improve their diabetes control. The most likely explanation for the lack of impact on perceived Severity, Vulnerability, and Personal Control/Self-efficacy in particular, was that the doctor had told the patients that improvements in their glycaemic control were not sufficient to postpone the insulin intervention. As mentioned earlier, psychological data were not collected from those who improved their control sufficiently to continue with the tablet treatment after the run-in phase. It is likely that positive changes in more of the psychological variables would have been reported by these patients.

The insulin interventions were predicted to have the greatest effect on the psychological variables because of the marked impact of both types of insulin delivery on the glycaemic control of the majority of the patients in the study. Overall, the patients reported significantly greater Treatment Satisfaction, fewer perceived Barriers to treatment, and greater treatment 'Cost-effectiveness'. In addition, the CSII-treated patients reported significantly reduced perceived Severity of Diabetes and General Disorders, while the CIT-treated patients reported significantly less Situational Control. It is interesting to note that despite the greater success of CSII therapy in reducing blood glucose levels, Treatment Satisfaction increased significantly in the CIT-treated patients only. Although Treatment Satisfaction increased in five of the eight CSII-treated patients who responded to the psychological questionnaires, because two patients reported no significant change and one patient was markedly less satisfied with CSII than with tablet treatment, overall Treatment Satisfaction did not improve significantly for this group. Given that a significant proportion of the patients reported reduced perceived Severity of Diabetes, it is surprising that equivalent reductions in perceived Vulnerability were not observed. Moreover, there were no improvements in perceived Personal Control/Self-efficacy overall or within either of the treatment groups after the insulin treatment. It is possible, however, that beliefs about Personal Control/Self-efficacy did not change because the intervention itself was largely responsible for improving glycaemic control. Although psychological Well-being did not improve significantly after insulin therapy, no significant changes were observed after the earlier interventions either, which from a positive point of view, indicates that Well-being was not damaged by the study.

It might be argued that significant changes in some of the psychological variables were not evident because each intervention produced only small incremental changes. The impact of the whole study was therefore assessed by comparing the psychological measures at baseline with those measured after the insulin intervention. It was found that by the end of the study, perceived Barriers and perceived Severity of Diabetes had reduced significantly, and perceived treatment 'Cost-effectiveness' and Treatment Satisfaction had increased significantly. There were no changes, however, in the HBM measures of perceived Vulnerability or perceived Personal Control/Self-efficacy. Furthermore, no significant changes were observed in psychological Well-being, perceived Medical Control or perceived Situational Control.

When the psychological data from the patients who responded to questionnaires at all stages of the study were assessed in repeated measures ANOVAs and Friedman's tests, the pattern of results was similar to that reported above. Significant changes were observed in Perceived Barriers to treatment, perceived treatment 'Cost-effectiveness', perceived Severity of Diabetes, and Treatment Satisfaction. As found previously, however, perceived Vulnerability, perceived control, and psychological Well-being did not vary significantly at any stage of the study.

Given that CSII therapy was more successful than CIT therapy in reducing blood glucose levels, the psychological measures.relating to each group were compared. The results of these analyses indicated that there were no significant differences between the treatment groups for any of the psychological measures (including Treatment Satisfaction) at any stage of the study. Perhaps this is not surprising given that there were also no significant differences between the groups in subjective estimates of diabetes control, ratings of apprehension regarding insulin injections and CSII pumps, and efficacy of HBGM ratings. Furthermore expectations about the insulin treatments were generally in accordance with subsequent experience for both of the treatment groups. In addition, not only were Diabetes Knowledge scores comparable for each group, longitudinally the scores overall did not improve significantly at any stage of the study.

From a cross-sectional perspective, it was notable that the correlations between some of the baseline health beliefs and concurrent health outcomes were much weaker than was found for the whole of the baseline sample (see Chapter 3). In particular, no significant associations were found between the health outcomes and perceived Barriers to treatment, perceived treatment 'Cost-effectiveness', perceived Severity of Diabetes, and perceived Personal

Control/Self-efficacy. These results may be explained by the small number of subjects who provided psychological data at this stage of the study: only 14 of the 20 insulin study participants were asked to complete psychological questionnaires. However, as noted earlier, the sex ratio of the insulin study participants was reversed when compared to the overall baseline and education study samples, so it is also possible that these patients were not representative of Type II patients with progressive ß-cell dysfunction. Another possible, and more likely explanation may be that patients of this type who are not particularly overweight, do not receive adequate feedback about their diabetes control until an intervention becomes necessary and thus their health beliefs are only weakly related to health outcomes. It is interesting to note that after the first and second interventions, any correspondence between health beliefs and the objective and subjective indices of diabetes control virtually disappeared whereas one might have expected a greater correlation because of improved feedback. However, since on the one hand, the patients were told that their diabetes control was unsatisfactory, irrespective of actual levels of glycaemic control, and on the other, that their tablet treatment was not satisfactory, the patients' health beliefs and subjective estimates of diabetes control were probably distorted. After four months of using CSII or CIT, it was predicted that the patients would be able to assess accurately the efficacy of the insulin treatments in improving their diabetes control because of continuous feedback from HBGM during the insulin treatment phase and feedback from the doctor at the end of the study. As a result, the correspondence between health beliefs and the health outcomes at this stage was expected to increase significantly. In practice, however, although several of the predicted correlations re-emerged at this point, most of the significant associations observed were between the health beliefs and ideal body weight rather than HbA_1. Moreover, none of the health beliefs were significantly associated with subjective estimates of diabetes control. This pattern of results indicates that the patients beliefs about Severity and Vulnerability were affected by feedback about their weight control rather than their blood glucose levels. Furthermore, the direction of some of the correlation coefficients relating to subjective estimates of control were sometimes opposite to those for ideal body weight and HbA_1 indicating that some of the patients with relatively poor blood glucose and weight control were more optimistic when giving their subjective estimates of control or vice-versa. Indeed, when the objective and subjective post treatment measures of diabetes control were correlated, the results were non-significant. It seems that several of the patients were unable to use the continuous feedback from HBGM in order to self assess their diabetes control, possibly because the feedback from the doctor at the beginning of the study had undermined their confidence to make such judgements. (It is also worth noting that knowledge scores for some of the patients were very poor.) Alternatively, these patients may have been unable to translate their blood glucose readings into meaningful information such as good, adequate, or poor control. The results also suggest that the doctor may have given some of the patients the impression that their diabetes was better controlled than it was, possibly because patients with poorer control were more likely to seek reassurance. The unclear relationships found in the cross-sectional data may explain why perceived Vulnerability and perceived Personal Control/Self-efficacy did not change as predicted during the study.

When the results of the present study are assessed overall, the impression given is that only beliefs about Barriers to treatment, treatment 'Cost-effectiveness', Severity of Diabetes, and Treatment Satisfaction were reactive to the different kinds of intervention used here. The clinical and educational implications may be that attempts to change perceived

Vulnerability and perceived Personal Control/Self-efficacy using similar interventions will be unsuccessful. However, given that significant improvements in perceived Personal Control were reported in the educational intervention study (Chapter 5), it is possible that the interventions in this study did not make a sufficient impact or were of the wrong kind in order to change these beliefs. It is also likely that these beliefs were mediated by other variables such as expectations about the insulin treatment, personal coping strategies, reassurance by the medical staff, and subjective self-assessments of control. Given the number of variables and interventions examined and the complicated picture which emerged, the greatest limitation of this study was that the number of subjects was too small. As such, it was not possible to generalize the results to the population as a whole. A series of single case studies might have been a more fruitful approach for this sample size, or, given a much larger sample, sub-group effects could have been examined. As far as the present author is aware, there have been no published studies concerning diabetes which have assessed the effects of any type of intervention on all of the HBM variables. Further research involving a variety of interventions and greater numbers of patients are needed, therefore, in order to confirm the present findings and to assess the effect of any health belief mediators. When a greater pool of information about the dynamics of health beliefs, their origins, and relationships with mediating variables has been collected, researchers will be in a better position to tailor future interventions accordingly and target beliefs appropriately.

CHAPTER SEVEN

OVERVIEW AND CONCLUSIONS

Rationale for the research

The studies described in the preceding chapters have attempted to address some of the major problems of previous HBM research which were discussed in Chapter 1. Shortcomings of this research include the paucity of health belief scales with reported reliability and validity, the use of data drawn from heterogeneous samples of subjects, and outcome measures which were measured retrospectively making it impossible to determine the direction of associations with HBM components. The health beliefs research reported in the present thesis involved the development and validation of health belief scales designed specifically for people with tablet-treated diabetes. The scales were also validated using prospectively measured outcome data. A particular problem with past health beliefs research, has been that previous researchers either failed to consider more than one variable at a time or made the implicit assumption that the dimensions of the HBM combine additively. The original formulation of the HBM suggested a multiplicative relationship between certain components. However, there have been no attempts to specify the precise way in which the variables combine to predict behaviour or health outcomes. One of the main aims of the present thesis, therefore, was to attempt to specify the relationships between the components of the HBM (Chapters 4 & 5). Furthermore, since the various dimensions of the HBM have previously been successful in accounting for only a moderate amount of variance in health behaviours, it was considered possible that certain key elements may be missing from the model. The research described in Chapter 4 and Chapter 5 therefore additionally explored the possibility of extending the model to include the concepts of locus of control and self-efficacy. Finally, since previous research has failed to acknowledge that the associations between health beliefs and outcomes are likely to involve a dynamic process; outcomes will affect health beliefs as well as health beliefs affecting outcomes; a considerable amount of longitudinal research is warranted in order to understand and specify the nature of the process involved. The longitudinal study described in Chapter 6 is an attempt to explore the dynamics of health beliefs before and after the various interventions of an insulin treatment study.

Development and validation of the HBM measures

An attempt was made to represent unambiguously all the dimensions of the HBM in relation to tablet-treated diabetes. The design of the measures was based on previous experience of developing and interpreting findings from scales developed for insulin-requiring patients and ultimately consisted of five separate scales to measure perceived Benefits of treatment, perceived Barriers to Treatment, perceived Severity of Complications, perceived Vulnerability to Complications, and perceived Vulnerability of the "average person" to Complications. For the purpose of comparison, scales to measure perceived Severity of General Disorders, perceived Vulnerability to General Disorders, and perceived Vulnerability of the "average person" to General Disorders were also constructed. Furthermore, a two item measure of perceived Severity of Diabetes and a single item measure of "Complications arising from Diabetes" were employed in the studies.

The objective outcome variables used in order to assess the efficiency of the HBM measures were HbA_1 and percent ideal body weight. The HBM predicts behaviour, however, and while the outcome measures employed were intended to be the result of relevant behaviour, they are vulnerable to other factors such as incidence of intercurrent illness and the adequacy of the treatment recommendations for the individual concerned. (Indeed, given these mediating influences, it could be argued that the HBM measures used were extremely effective in explaining the outcome variance.) On the other hand, it was not possible to obtain reliable behavioural measures from the samples studied because the treatment regimen involves daily lifestyle behaviours. This is in contrast to other types of health behaviours which might involve a single observable action such as attending a health screening programme. It may have been possible to obtain self-report measures of diet and exercise as indices of behaviour but self-report measures are often influenced by a subject's reluctance to report non-adherence to treatment recommendations. On balance, therefore, it was considered that HbA_1 and percent ideal body weight were more appropriate outcome measures in diabetes management.

The health belief scales were shown to have satisfactory internal reliability, and patterns of correlations with other variables in the baseline and education studies provided evidence for the construct validity of all the measures. Since the participants were able to indicate on the perceived Vulnerability questionnaire whether or not they already had a particular health problem, it was noticed that responses to the single item measure of perceived Vulnerability were different from the composite measure, probably as a result of inadequate knowledge regarding which disorders are complications of diabetes. As predicted, therefore, the two item measure of perceived Severity of Diabetes, and the single item measure of perceived Vulnerability to Complications were more strongly associated than the composite measures with health outcomes. It was also noted that the baseline health belief measures were more strongly associated with subjective estimates of diabetes control than with percent ideal body weight or HbA_1, indicating that prior to the interventions, these patients had received inadequate or misleading feedback about their diabetes management.

Contrary to the predictions of the original HBM, greater perceived Vulnerability and Severity were found to be associated with poorer diabetes control. Although the health outcomes were measured retrospectively, the findings were in accordance with other published studies in this field (Harris, Linn & Skyler, 1987; Brownlee-Duffeck, Peterson, Simonds, Goldstein, Kilo & Hoette, 1987) and seemed to indicate that not only may health beliefs affect outcomes but these outcomes, in turn, may affect health beliefs. The education intervention study should have helped to clarify these associations because the outcome variable was measured prospectively. However, unexpectedly, greater perceived Vulnerability and Severity were significantly associated with *poorer* blood glucose control six months later indicating that Vulnerability and Severity not only reflected current health status but also seemed to predict continuing poor control. Given that lower perceived Personal Control/Self-efficacy was associated with poor control six months later, the results suggest that very poor control and the concomitant feelings of high perceived Vulnerability to Complications and low perceived Personal Control/Self-efficacy may have been due to poor management skills or knowledge which were not improved significantly by the education sessions and therefore frustrated any attempt to improve diabetes control. It was interesting to note, however, that greater perceived treatment "Cost-effectiveness" was associated on the one hand, with greater perceived Threat (Severity x Vulnerability) whilst on the other, it was associated with lower perceived Vulnerability and lower perceived Severity. Moreover, subsequent regression analyses indicated that greater scores for the composite of Severity x Vulnerability x treatment "Cost-effectiveness" were associated with lower follow-up HbA_1. This suggests that for some people at least, increased Vulnerability and Severity acted as motivators to improve control provided that treatment was also perceived to be "Cost-effective". The results suggest that the interrelationships between the HBM variables and their association with health outcomes are complex and mediated by many contextual factors such as physiological status, knowledge, skills, resources, and feedback. Consideration of the characteristics and source of any sample studied would therefore appear to be crucial when assessing the explanatory power of the HBM.

The perceived Vulnerability questionnaire was designed so that respondents were not only asked to rate their own susceptibility to complications and other disorders but they were also asked to rate the susceptibility of an "average person". In accordance with the findings reported by Weinstein (1982, 1984, 1987) the patients rated themselves to be less vulnerable to the individual complications and other disorders when compared to the "average person". However, when the single-item measures of personal and "average person" Vulnerability to Complications were compared, the optimistic bias disappeared. When patients responded to the individual items from the composite measures of perceived Vulnerability, the ratings depended upon their knowledge about which disorders are complications of diabetes. It seems that the general tendency to assume that "it won't happen to me" was present when disorders were thought to be unrelated to diabetes. With the single item measures, however, patients were in no doubt about what they were being asked to rate and thus the optimistic bias diminished because the risk seemed more salient. The measures of "average person" Vulnerability were therefore discarded when exploring the relationships between the components of the HBM. However, it would still be worthwhile comparing perceived Vulnerability of the "average person" with beliefs about personal Vulnerability if knowledge about the individual complications is poor. This would provide useful information for the targeting of educational interventions.

Relationships found between the HBM components

Exploration of the relationships between the HBM components was first carried out using the baseline data (Chapter 4). The aim was to establish whether the individual dimensions of the HBM combine in a purely additive fashion, or whether multiplicative relationships between the various components would explain significant additional amounts of variance in health outcomes. An additional aim was to assess whether the measure of perceived Personal Control/Self-efficacy (developed from the responses of the same sample) could be integrated within the HBM and if so, specify its relationship to the other components. In order to investigate the relationships between the HBM variables and the outcome variables, multiple regression analyses were employed. It is possible, however, to use other types of analyses in causal inference such as path analysis or structural equation modelling. However, at the time of the studies, the resources enabling use of these techniques were not available to the present author. As recommended by Evans (1991), hierarchical multiple regression was used to test for the hypothesized multiplicative relationships between the variables because simple correlational analyses would have been inappropriate (Schmidt, 1973). The amount of variance explained in all three outcome variables (baseline percent ideal body weight, HbA_1, and the patients' subjective estimates of diabetes control) was, however, only small to moderate, and in all cases none of the multiplicative composites added significantly to the overall explanation. When perceived Personal Control/Self-efficacy was included in the regression equation both as an individual variable and as part of a multiplicative composite, the amount of variance explained increased significantly, particularly in relation to percent ideal body weight and subjective estimates of diabetes control, which indicated that this construct could be usefully integrated into the HBM. However, once again, none of the multiplicative composites contributed significantly to the overall explanation. These results seemed to indicate, therefore, that the original and newly-introduced components of the HBM combine in an additive rather than a multiplicative manner.

Since regression analyses assume that the independent variables in the equation are linearly related to the dependent variable, it was considered possible that non-linear combinations of the health beliefs might provide a better explanation of health outcomes. The baseline health belief variables were therefore dichotomized and combined in various ways and then related to the outcome variables in non-parametric ANOVAs. Kruskal-Wallis H tests were used in order to explore the non-linear hypothesis because the outcome variables were continuous. It has been pointed out to the present author, however, that if the outcome variables were categorized as well as the process variables, loglinear modelling could have been employed. The results indicated that when the original and newly-introduced health belief variables were all combined, they were very significantly related to all three outcomes. In relation to HbA_1 and percent ideal body weight, however, the best diabetes control was found to be associated with a pattern of beliefs predicted to be associated with poorer control [low perceived treatment "Cost-effectiveness"/ low perceived Threat (Severity x Vulnerability)/high perceived Personal Control/Self-efficacy]. However, the respondents with this belief pattern were also the most depressed, and were among the most anxious and least satisfied. Non-linear combinations of the health beliefs were therefore particularly successful in predicting health outcomes and when viewed in relation to Well-being and Treatment Satisfaction, helped to explain why linear combinations of the baseline health beliefs were successful in explaining, at best, only moderate amounts of outcome variance.

Although combining the variables in a non-linear fashion was successful in the prediction of health outcomes, surprisingly, the predicted interaction between perceived Severity and Vulnerability was not observed. However, it was possible that these results were due to the retrospective nature of the baseline outcome variables, and because the respondents' beliefs about their diabetes and its management were mediated by lack of knowledge and inadequate feedback. The relationships between the HBM components were therefore reassessed using data from the educational intervention study (Chapter 5) which involved a measure of outcome collected approximateley six months later. Unfortunately, the number of cases analysed was relatively small and therefore the amount of variance in health outcome explained may have been inflated. Nevertheless, the results of the regression analyses indicated that when all the education attenders were considered, and General Well-being was partialled out on the first step, a substantial amount of variance in HbA_1 six months later was explained by all the health belief variables, including perceived Personal Control/Self-efficacy. Moreover, a significantly unique contribution to the overall explanation was provided by an interaction between perceived Severity of Diabetes and perceived Vulnerability to Complications (single item). As found at baseline, however, perceived Severity contributed insignificant amounts of unique variance to the overall explanation when considered individually. These results suggested, therefore, that the relationships between the components of the HBM when predicting health outcome should be specified as

$$HO \approx V^r + (S \times V)^r + (Ben - Barr) + PCSE$$

where HO represents health outcome, V^r represents reversed perceived Vulnerability, $(S \times V)^r$ represents the interaction between perceived Severity and Vulnerability (Threat) reversed, (Ben - Barr) represents perceived

Benefits less perceived Barriers (treatment "Cost-effectiveness"). and PCSE represents perceived Personal Control/Self-efficacy. Unfortunately, the relationship between perceived Personal Control/Self-efficacy could not be investigated because these constructs were measured in unison. Future research involving the separate measurement of these beliefs is therefore desirable in order to clarify their relationship. As suggested earlier, when discussing the direction of the association between health outcome and perceived Severity and Vulnerability, the relationships between the HBM components might need to be redefined depending on the characteristics of the sample studied. Indeed, the education study data were collected from patients who were self-selected and not representative of the population as a whole. Moreover, because greater perceived Vulnerability and perceived Threat were associated with poorer control six months later, these variables probably did not act as true predictors of health outcome in this study but merely reflected other beliefs and continuing health status. In general, the findings indicate that the improved prediction of HbA_1 was due to the improved knowledge of the patients and the prospective nature of the health outcome measure in this study. An additional explanation may be that the educational intervention was instrumental in health beliefs becoming more salient to health outcomes. It is possible that beliefs may remain dormant and become increasingly less influential in the determination of behaviour until a change demands that beliefs should be reappraised in order to decide how to respond. Indeed, in the context of the HBM, the educational intervention could be viewed as a "cue to action".

The assessment of health beliefs in relation to baseline and post education health outcomes has highlighted that Well-being is a powerful mediator which affects the explanatory power of the HBM. Dunn (1986) found that the people who left an education programme feeling more emotional about diabetes showed a bigger improvement in glycosylated haemoglobin than those who went away feeling less emotional distress and argued that it is necessary to reappraise the assumption that feeling better is a satisfactory criterion for educational success. Indeed, this would be consistent with the predictions of the original HBM. The results from the baseline study suggest, however, that some people with very good diabetes control also reported poor psychological Well-being. Clearly, the achievement of excellent blood glucose levels is far from satisfactory if this results in the patient feeling miserable. The implication of this finding is that studies assessing the efficacy of treatment interventions need to consider psychological as well as the usual physiological, clinical, and behavioural outcomes. Future research in diabetes might benefit, therefore, from using a multivariate measure of health outcome so that, for example, the best outcome would be *low* HbA_1/***high*** psychological Well-being/***high*** treatment satisfaction and the worst outcome would be ***high*** HbA_1/*low* psychological Well-being/*low* treatment satisfaction.

The effects of the intervention studies on health beliefs and related outcomes

The education sessions resulted in significantly increased knowledge and Treatment Satisfaction, and for those whose HbA_1 was relatively poor at baseline, improved glycaemic control. Furthermore, there was a tendency for Well-being to deteriorate but this did not quite reach significance. After education the participants also perceived significantly more Benefits, fewer Barriers, greater treatment "Cost-effectiveness", and increased Personal Control/Self-efficacy. However, beliefs about Severity and Vulnerability were not significantly different from those at baseline. Interestingly, greater improvements in knowledge were associated with more perceived Barriers, fewer perceived Benefits, lower perceived treatment "Cost-effectiveness", lower psychological Well-being and lower Treatment Satisfaction. Although these negative effects of education were not predicted, it is likely that prior lack of knowledge was associated with an unrealistic view of diabetes and thus large increases in knowledge would have been very disconcerting in the short term.

In the insulin study, the effects of a series of interventions on health beliefs and related outcomes were assessed over a longer period. In addition to the baseline data, beliefs were measured after the participants were first informed of their poor glycaemic control and its implications, after a period of optimizing control on current treatment with the aid of home blood glucose monitoring, and several months later when they had become used to using CIT or CSII pump therapy. The idea behind this research was to gain a better understanding of the dynamics and reactivity of components of the HBM. The first intervention did not produce significant changes in health beliefs but the second intervention resulted in reduced perceived Barriers and greater treatment "Cost-effectiveness". Although it was predicted that the insulin intervention would have the greatest impact on the psychological variables, it was surprising that more changes in beliefs were not observed after the first two interventions. Post hoc assessment of these results suggested, however, that the beliefs and attitudes of the study participants were probably mediated by reassurances and feedback from the doctor. After the insulin intervention, the patients overall reported significantly fewer perceived Barriers, greater treatment "Cost-effectiveness", and greater Treatment Satisfaction. In addition, the CSII-treated patients reported significantly reduced perceived Severity of Diabetes. However, no changes in perceived Vulnerability or perceived Personal Control/Self-efficacy were observed. It is likely that beliefs about Personal Control/Self-efficacy did not alter because the intervention itself was largely responsible for improving glycaemic control. It was surprising, however, that despite reductions in perceived Severity of Diabetes, there were no equivalent changes in perceived Vulnerability to Complications. Given that, in the education study, greater perceived Vulnerability was associated with poorer glycaemic control six months later it may be that this belief is not as dynamic as first thought. However, it is also possible that, beliefs about Vulnerability were mediated throughout the study by reassurances and feedback from the doctor. Indeed, cross-sectional analyses of the post-treatment data indicated that some of the patients were under the impression that their diabetes was better controlled than it was. A considerable amount of further research involving a variety of interventions and greater numbers of patients are needed in order to clarify the sources and nature of changes in the HBM components. When a greater pool of information about the dynamics of health beliefs and their mediators have been assessed, however, it is likely that researchers will be better placed to tailor future interventions accordingly and target beliefs appropriately.

Critique

The studies described earlier have provided interesting information about the nature of the relationships among HBM components and the value of including efficacy and control beliefs in the model. However, some limitations of the research should be acknowledged.

In Study 1 (Chapter 4), health outcomes were collected at the same time as the psychological variables and thus conclusions about cause and effect are problematic. Moreover, most of the sample studied had relatively poor knowledge about diabetes and its management and received limited or inaccurate feedback about their control which confounded the belief-behaviour link. It is not surprising, therefore, that relatively small amounts of the variance in health outcomes were explained. Study 2 (Chapter 5) aimed to tackle these problems by examining the effects of an education session on the health beliefs and psychological well-being of the participants, and collecting a measure of health outcome six months later. However, the sample studied was self-selected and proved to have some characteristics which differed significantly from those of the baseline sample. The results from the study cannot be generalized, therefore, to the population as a whole. A further problem with Study 2 was that the number of subjects was quite small and, in some cases, barely sufficient for the number of variables included in the regression analyses. The results from these analyses should be interpreted, therefore, with some caution.

Study 3 (Chapter 6) examined a large number of variables before and after several interventions over a relatively short period of time. Given the small number of subjects in the study and the complex picture which emerged, it was not possible to make broad generalizations about the results. A series of single-case studies might have been more appropriate with such a small sample, enabling inspection of individual variations in beliefs in conjunction with outcomes. A larger sample would have enabled the inspection of sub-group variations.

Certain belief measures selected for analysis in the studies (perceived Severity of Diabetes and perceived Vulnerability to Complications) were composed of one or two items only and, as such, may be unrepresentative measures of these belief constructs. These measures were selected, however, because the composite measures were affected by knowledge and would have provided a less reliable indicator of these beliefs. It is also acknowledged that use of the treatment "Cost-effectiveness" variable (Benefits minus Barriers) prevented the possibility of examining the impact of absolute levels of perceived Benefits and Barriers in the additive and interactive models. Since responses to the perceived Benefits measure were skewed, however, the treatment "Cost-effectiveness" measure was employed in regression analyses because it normalised the distribution.

Multiple regression analyses and Kruskall-Wallis H tests were used to examine the relationships between the HBM components and the outcome variables. However, it is recognised that other types of analyses could have been employed such as path analysis, structural equation modelling, and loglinear modelling. Consideration of these statistical techniques is recommended for future HBM research.

Implications of the studies for future HBM research

In accordance with the revised explanatory model of Rosenstock, Strecher and Becker (1988) which includes self-efficacy in the HBM, the present research examined the effects of incorporating an overlapped measure of control and efficacy expectation into the model. This measure of perceived Personal Control/Self-efficacy was successful in predicting small amounts of variance in outcome in the baseline study and significant amounts of variance in outcome after education. It would seem, therefore, that control and efficacy expectations are important in the prediction of health behaviour and that these should be incorporated into the HBM.

A major aim of the research was to assess whether additional proportions of variance could be explained by multiplicative or categorical combinations of the HBM variables. Previous HBM research has focused on the predictive power of the individual components of the model and virtually ignored the possibility of looking at interactions between its components. Results from the present studies indicated that the relationships between health beliefs and outcome variables are complicated because there are several mediating factors. Indeed, researchers need to consider the characteristics and source of any sample when assessing the explanatory power of the HBM. In Study 1 (Chapter 4) it appeared that the relationships with outcome variables were best predicted by non-linear combinations of variables but only when viewed in relation to Well-being and Treatment Satisfaction. On the other hand, when outcome was measured prospectively after an education intervention (Chapter 5), individual and multiplicative combinations of variables were successful in accounting for significant proportions of the variance in outcome but, once again, only after General Well-being had been partialled out. It appears, therefore, that health beliefs are mediated by the well-being of the patient and thus future HBM research should take account of this variable.

Overall, it seems that health outcomes were best predicted from HBM variables in a linear model but only after an intervention which significantly improved knowledge about diabetes management (removing another mediating factor) and which also provided a cue to action. Indeed, when variance from mediating factors was removed, the multiplicative combination of perceived Severity of Diabetes x perceived Vulnerability to Complications accounted for an extra 12% of the variance in HbA_1 six months later. One of the unexpected findings of the research studies, however, was that greater perceived Vulnerability and Threat (Severity x Vulnerability) not only reflect current health status but also predict continuing poor control. As such these variables do not appear to be predictors of outcome but merely reflect other beliefs (e.g. perceived control/self-efficacy) and abilities (knowledge, skills, or resources). This raises doubts, therefore, about the necessity of including these variables in the HBM in the first place but more research is needed in order to clarify the efficacy of these components in the model. It should also be remembered that only a limited number of possible interaction effects were tested in the analyses. Other combinations of variables in the HBM (including perceived Severity or Vulnerability) could have been examined given suitable predictions.

In conclusion, the present research has indicated that beliefs about efficacy and control are important in the prediction of health behaviour and as such should be included in the HBM. In addition, it appears that interactive components of the model can explain extra variance not accounted for in the purely additive model after controlling for mediating variables such as well-being and knowledge. However, the efficacy of the severity and vulnerability components as *predictors* of health outcomes needs to be examined in further research. Moreover, other multiplicative relationships not assessed in the present research could be explored.

Suggestions for future research

Measurement of health value

Since health value is posited by the HBM to be a necessary prerequisite if beliefs are to have an effect on behaviour, adequate measurement of this construct appears to be particularly important when predicting health outcome from the HBM components. In the baseline and education intervention studies, health value was measured using a single item which proved to have poor explanatory value. It is possible, however, that the item was an unrepresentative measure of health value and thus further research involving the development of a multi-item instrument is required.

Health professionals as a source of variance in health outcomes

The present research has suggested that health professionals can be potent mediators of patients' health beliefs through the quality of feedback and advice they provide. In order to tease out such mediating influences, it is desirable that future studies should also measure the beliefs and behaviours of relevant health care staff. Indeed, Marteau and Johnson (1990) have argued that there is a case for using the HBM on a different level to explain and predict the behaviour of health professionals. They have also suggested that more of the variance in health outcomes of patients might be explained by the behaviour of health professionals than the behaviour of the patients themselves.

The dynamic perspective

The HBM and other theories of health behaviour treat beliefs as continuous dimensions. The underlying assumption is that progress from ignorance to action in relation to a particular belief is determined by the individual's position along a continuum. However, a number of researchers have suggested that a single prediction rule is inadequate to explain reactions to health threats. The alternative suggestion is that beliefs should be described in terms of a series of stages (Janis & Mann, 1977; Weinstein, 1988; DiClemente, Prochaska, Fairhurst, Velicer, Velasquez & Rossi, 1990).

Weinstein's (1988) model of the Precaution Adoption Process suggests that there are distinct stages in the development of each type of belief. First of all, individuals must learn that a hazard exists. Failure to adopt a particular health protective behaviour may reflect ignorance of the threat. Indeed, in the present research, a large number of the patients were not aware that heart disease is a complication of diabetes so it is likely that they did not appreciate fully why a low fat diet is particularly recommended for this population. After this first stage, Weinstein suggests that individuals must be convinced that the risk is significant to the population as a whole. Patients with Type II diabetes, for example, need to know that 60 to 70 per cent of deaths in this population are caused by myocardial infarction and strokes, which represents a two- to three-fold increase in mortality rate when compared to the non-diabetic population. Once the size of the risk has been established, however, some people may be over optimistic regarding their own risk ("it won't happen to me"). Individuals therefore need to move on to a further stage of belief development where they acknowledge their own personal risk before they are likely to consider taking action. Weinstein suggests that development stages in other beliefs such as perceived severity and beliefs about precaution effectiveness can also be differentiated in a similar manner. He points out, however, that although beliefs about vulnerability, severity, benefits and barriers may develop simultaneously, it is unlikely that interest in precautions would precede the perception that a hazard is a significant personal threat. A further stage in the precaution adoption process involves the degree of priority attached to the intended action in the context of an individual's general lifestyle. As illustration, Weinstein uses a messy desk analogy where proposals for new initiatives arrive every day but there are also routine responsibilities to be carried out. A good idea may get approved but constraints on time and resources may make it impossible to carry out immediately. Over time, the good idea may become buried and forgotten, or may be passed over in favour of a low priority task that can be accomplished quickly. Weinstein suggests therefore that action depends on the complexity of the precaution, on events which make the information about action more salient, and on reminders.

The stage perspective of preventive health behaviour seems to dismiss the idea that individuals perform a cost-benefit analysis of precautions recommended or that the force behind the decision to act is an algebraic function of vulnerability and severity. However, it could be argued that when (or if) people reach the final stage of belief development that such mathematical formulations are still valid. Indeed, a significant finding of the research presented in the present thesis is that beliefs vary according to different contexts such as knowledge, feedback, physiological status, and resources. Outcome prediction in the education intervention study was probably improved, not only because the intervention itself was a cue to action (recall the messy desk analogy) but also because most participants had been able to develop their health beliefs further through the education process. The strength of Weinstein's precaution adoption theory is that it is a dynamic perspective and as such may account for large amounts of variance in health outcome previously unexplained. The implication for the HBM is that a more complex formulation of its basic components needs to be tested. This would involve the development of scales which measure the stage of belief development as well as the strength of the particular belief. Furthermore, because a stage theory suggests that variables important in producing movement towards action at one point in the precaution adoption process may not be relevant at another, intervention studies would need to be tailored accordingly. Finally, since the inclusion of a combined measure of self-efficacy and personal control in the model increased the amount of variance explained in the baseline and education intervention studies, it is likely that these constructs could also be integrated in any new formulation of the HBM.

Final Conclusions

The research presented in this thesis has shown that the relationships between the HBM variables are complex because beliefs are mediated by many factors such as inadequate feedback and knowledge. As a result, it is feasible to specify the relationships between the HBM components for a specific group of people, but not for the population in general. Indeed, the improved outcome prediction after the education intervention was probably the result of reducing the effects of particular mediating factors. Since the patients studied had experienced their diabetes for varying periods of time, had different educational experiences, and differed in health status, their individual beliefs were likely to differ in a qualitative as well as a quantitative manner. Given these conclusions, it would appear that current formulations of the HBM do not adequately account for the dynamics of beliefs in real life. Adoption of the stage perspective of preventive health behaviour would therefore seem to be the best way forward in this field of research. The results of the insulin intervention study also suggest that measurement of medical staff's beliefs would provide further explanations of patients' health behaviour. It is even possible that the two frameworks of beliefs could be integrated.

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APPENDICES

APPENDIX 1

Letter inviting outpatients to join the baseline study

We would like to review the type of health care that we recommend to patients with diabetes who are treated with diet and tablets. Our impression is that there is room for considerable improvement to the treatment that is offered to people like yourself but in the first instance we need to obtain more information about diabetes and the way it affects our patients. This will be done partly by questionnaire and partly by consultation with a doctor (Dr. Adrian Jennings) who is taking a special interest in patients with your kind of diabetes.

In order to obtain accurate and representative information for the purposes of introducing improvements in the near future, we are asking as many patients as possible to attend for an appointment within the next few months. The appointment would take approximately one hour and will not be held at the time of the diabetes clinic to ensure that no-one is kept waiting.

Please complete all of the section below even if you cannot help us:

NAME ....

MALE/FEMALE*

HOSPITAL NO. (From appointment card) ....

ADDRESS ....

....

TEL. NO. ....

DATE OF BIRTH .... COUNTRY OF BIRTH ....

IS ENGLISH YOUR FIRST LANGUAGE? ....

HOW LONG HAVE YOU HAD DIABETES? ....

AGE AT LEAVING FULL-TIME EDUCATION ....

1. I am able to attend for a consultation with Dr. Jennings YES/NO*

2. If any day is difficult for you to come please enter here:

....

3. Do you require transport? (please answer yes if transport is absolutely necessary) YES/NO*

4. Please tick box if you have filled in this form for someone who is blind/partially sighted. ☐

* delete as applicable

Please hand in to the doctor in the clinic

Dr Adrian Jennings
Mrs Kathryn Lewis
Dr Clare Bradley
Dr J D Ward

APPENDIX 2

BOOKLET OF QUESTIONNAIRES

A Introduction to booklet

B General Information Questionnaire

C Well-being Questionnaire

D Satisfation with Treatment Questionnaire

E Perceived Control of tablet-treated Diabetes Scales

F Health Beliefs about tablet-treated Diabetes Questionnaire (perceived Benefits of, and Barriers to treatment)

G Beliefs about Severity Questionnaire

H Beliefs about Vulnerability Questionnaire

TYPE II DIABETES STUDY BOOKLET

We are interested in gaining a better understanding of the difficulties which arise for people with your kind of diabetes.

On the following pages of this booklet you will find a general information sheet and a series of questionnaires dealing with beliefs and opinions about diabetes.

We would like you to complete the booklet today if possible (or within the next 2 or 3 days) and post it in the stamped addressed envelope provided.

In this research, we will be asking about 150 people to complete these questionnaires. All answers will be treated in strict confidence.

If you have any problems in completing the questionnaires, please do not hesitate to get in touch with us.

Mrs K S Lewis
Dr C Bradley
Department of Psychology
University of Sheffield
Sheffield S10 2TN

Telephone: 768555 ext. 6550

GENERAL INFORMATION

Name ....

Age .... Sex ....

Weight .... Height ....

Age at leaving full-time education ....

How many grams of carbohydrate, on average, do you take each day? .... gms

How long have you had diabetes? .... years .... months

Do you test your urine for sugar? yes .... no ....

If "yes", how often do you test your urine? (please tick)

Occasionally ....

Every day ....

Do you test your blood for sugar? yes .... no ....

If "yes", how often do you test your blood? .... times per week

Do you regularly adjust your treatment regime on the basis of blood or urine test results? yes .... no ....

If "yes", what adjustments do you make if your blood or urine sugar tests show too much sugar? (please tick appropriate items)

tablet dose .... food intake .... exercise ....

other (please describe) ....

Please indicate your general impression of your diabetes control during the past few weeks by circling a number on the scale below

Very well controlled	1	2	3	4	5	6	7	Very poorly controlled

For how long have you been following your present type of treatment (diet and tablets)?

.... years .... months

How many tablets do you take at any one time? ....

How many times a day do you take the tablets ....

WELL BEING QUESTIONNAIRE

Please circle a number on each of the following scales to indicate how often you feel each phrase has applied to you in the past few weeks:

		all the time			not at all
1.	I feel that I am useful and needed	3	2	1	0
2.	I have crying spells or feel like it	3	2	1	0
3.	I find I can think quite clearly	3	2	1	0
4.	My life is pretty full	3	2	1	0
5.	I feel downhearted and blue	3	2	1	0
6.	I enjoy the things I do	3	2	1	0
7.	I feel nervous and anxious	3	2	1	0
8.	I feel afraid for no reason at all	3	2	1	0
9.	I get upset easily or feel panicky	3	2	1	0
10.	I feel like I'm falling apart and going to pieces	3	2	1	0
11.	I feel calm and can sit still easily	3	2	1	0
12.	I fall asleep easily and get a good night's rest	3	2	1	0
13.	I feel energetic, active or vigorous	3	2	1	0
14.	I feel dull or sluggish	3	2	1	0
15.	I feel tired, worn out, used up, or exhausted	3	2	1	0
16.	I have been waking up feeling fresh and rested	3	2	1	0
17.	I have felt lonely	3	2	1	0
18.	My love/sex life is full and complete	3	2	1	0
19.	I have felt loved and wanted	3	2	1	0

/continued over

		all the time			not at all
20.	I have been happy, satisfied, or pleased with my personal life	3	2	1	0
21.	I have felt cheerful, lighthearted	3	2	1	0
22.	I have felt well adjusted to my life situation	3	2	1	0
23.	I have enjoyed life	3	2	1	0
24.	I have lived the kind of life I wanted to	3	2	1	0
25.	I have felt eager to tackle my daily tasks or make new decisions	3	2	1	0
26.	I have felt proud or good about some things I did	3	2	1	0
27.	I have felt I could easily handle or cope with any serious problem or major change in my life	3	2	1	0
28.	My daily life has been full of things that were interesting to me	3	2	1	0

PLEASE MAKE SURE THAT YOU HAVE CONSIDERED EACH OF THE 28 STATEMENTS AND HAVE CIRCLED A NUMBER ON EACH OF THE 28 SCALES.

SATISFACTION WITH TREATMENT

The following questions are concerned with *the form of treatment you are using now and your* experience over the past few weeks. Please answer each question by circling a number on each of the scales.

How satisfied are you with your current treatment?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

How well controlled do you feel your diabetes has been recently?

very well controlled	6	5	4	3	2	1	0	very poorly controlled

How often have you felt that your blood sugars have been unacceptably high recently?

most of the time	6	5	4	3	2	1	0	none of the time

How often have you felt that your blood sugars have been unacceptably low recently?

most of the time	6	5	4	3	2	1	0	none of the time

How convenient have you been finding your treatment to be recently?

very convenient	6	5	4	3	2	1	0	very inconvenient

How flexible have you been finding your treatment to be recently?

very flexible	6	5	4	3	2	1	0	very inflexible

How satisfied are you with your understanding of your diabetes?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

/continued over

How demanding is your present method of treatment?
(in terms of time, effort, thought, etc.)

very demanding 6 5 4 3 2 1 0 very undemanding

How satisfied have you been with life in general?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

How satisfied would you be to continue with your present form of treatment?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

How worthwhile do you consider your present treatment to be?

very worthwhile 6 5 4 3 2 1 0 not at all worthwhile

PLEASE MAKE SURE THAT YOU HAVE CIRCLED ONE NUMBER ON EACH OF THE SCALES.

The following questions are about the causes of situations which you may have experienced recently.

While events may have causes, we want you to pick only one (the major cause) of the situation as you see it.

Please write this cause in the space provided after each event.

Next, we want you to answer some questions about the cause by circling the most appropriate number on a sliding scale from 0 to 6.

Imagine that your eyesight has become noticeably blurred for more than a few hours.

Write down the most likely cause of your blurred eyesight in the space below.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of the blurred eyesight?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have been able to keep your weight at an acceptable level for a period of several weeks and you have felt fit and well.

Write down, in the space below, the single most likely cause of this period of good weight control and sense of general well-being.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of the period of good weight control?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that for several days you have found high levels of sugar when you tested your urine.

Write down the single most likely cause of the high sugar levels in the space below.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of the high sugar levels?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have reduced your weight to a satisfactory level after a period when you gained too much weight.

Write down the single most likely cause of this weight reduction in the space below.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of the weight reduction?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have successfully avoided the complications of diabetes such as problems with your feet.

Write down, in the space below, the single most likely cause of the successful avoidance of diabetic complications such as problems with your feet.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of successfully avoiding complications?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have recently become unacceptably overweight.

Write down, in the space below, the single most likely cause of becoming overweight.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of becoming overweight?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you are very thirsty and have passed unusually large amounts of urine recently.

Write down, in the space below, the single most likely cause of being very thirsty and passing a lot of urine.

____

____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7. To what extent do you think you could have foreseen the cause of being thirsty and/or passing a lot of urine?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

HEALTH BELIEFS SCALE

In this section would you please circle one of the numbers on each of the scales to indicate how strongly you agree or disagree with each of the following statements.

On these scales 0 would indicate that you strongly disagree
1 = moderately disagree
2 = mildly disagree
3 = neither agree nor disagree
4 = mildly agree
5 = moderately agree
6 = strongly agree

		strongly disagree						strongly agree
1.	Regular, controlled exercise helps in the management of my diabetes	0	1	2	3	4	5	6
2.	By careful planning of diet and exercise, I can control my diabetes at least as well as most other people with diabetes	0	1	2	3	4	5	6
3.	Controlling my diabetes well imposes restrictions on my whole lifestyle	0	1	2	3	4	5	6
4.	Sticking to my diet makes eating out difficult	0	1	2	3	4	5	6
5.	High blood sugars can be prevented if I plan ahead	0	1	2	3	4	5	6
6.	I find it difficult to remember to take all my tablets at the times recommended by the doctor	0	1	2	3	4	5	6
7.	It is important for me to visit the diabetic clinic regularly even in the absence of symptoms	0	1	2	3	4	5	6
8.	The better my diabetes is controlled, the healthier I feel	0	1	2	3	4	5	6
9.	It is just not possible to control my diabetes properly and live in a way that is acceptable to me	0	1	2	3	4	5	6
10.	Testing urine is an unpleasant task to have to undertake	0	1	2	3	4	5	6
11.	A well-balanced, healthy diet can be just as enjoyable as a diet which is rich in fat or sugar	0	1	2	3	4	5	6

/continued over

	strongly disagree						strongly agree
12. Sticking to my diet causes inconvenience to other people	0	1	2	3	4	5	6
13. Controlling my diabetes well interferes with my social life	0	1	2	3	4	5	6
14. Good control of my diabetes reduces the possibility of developing complications	0	1	2	3	4	5	6
15. It is important to take all my tablets at the times recommended by the doctor if I am to achieve good control of my diabetes	0	1	2	3	4	5	6
16. I often wonder whether it is worth all the trouble involved to get to see a doctor at the diabetes clinic	0	1	2	3	4	5	6
17. I find it hard to cut down on sugary and fatty foods	0	1	2	3	4	5	6
18. Regular urine checks enable me to control my diabetes well	0	1	2	3	4	5	6
19. Good diabetes control has to take second place to some other more important things in my life	0	1	2	3	4	5	6
20. The diet I am supposed to follow is rather dull and uninteresting	0	1	2	3	4	5	6
21. I find that keeping to a diet is helpful in controlling my diabetes	0	1	2	3	4	5	6
22. Controlling my diabetes well interferes with my family and social relations	0	1	2	3	4	5	6
23. Serious problems with my feet can be prevented if minor problems are recognised and dealt with immediately	0	1	2	3	4	5	6
24. The benefits of good weight control and a healthy diet are much more important to me than the regular enjoyment of sugary and fatty foods	0	1	2	3	4	5	6

PLEASE MAKE SURE THAT YOU HAVE CONSIDERED EACH OF THE 24 STATEMENTS AND HAVE CIRCLED A NUMBER OF EACH OF THE SCALES.

BELIEFS ABOUT SEVERITY

In this section would you please circle a number on each of the scales to indicate how serious you think the following problems would be if you were to develop them.

On these scales 0 would indicate that the problem is not serious at all
1 = not serious enough to be worrying
2 = moderately serious
3 = very serious
4 = extremely serious

If you are unable to rate the seriousness of a problem because you are not sure what the problem is, please tick the box on the right-hand side.

		not serious at all				extremely serious	not sure what the problem is
1.	High blood pressure	0	1	2	3	4	☐
2.	Stomach ulcer	0	1	2	3	4	☐
3.	Blindness	0	1	2	3	4	☐
4.	Ear infection	0	1	2	3	4	☐
5.	Kidney disease	0	1	2	3	4	☐
6.	Aching legs	0	1	2	3	4	☐
7.	Leukaemia (cancer of the blood)	0	1	2	3	4	☐
8.	Your diabetes now	0	1	2	3	4	☐
9.	Your diabetes in 10 years time	0	1	2	3	4	☐
10.	Gum disease	0	1	2	3	4	☐
11.	Bronchitis	0	1	2	3	4	☐
12.	Deafness	0	1	2	3	4	☐
13.	Numbness in the feet	0	1	2	3	4	☐
14.	Heart disease	0	1	2	3	4	☐
15.	Asthma	0	1	2	3	4	☐
16.	Failing eyesight	0	1	2	3	4	☐
17.	Loss of hearing	0	1	2	3	4	☐
18.	Gangrene	0	1	2	3	4	☐

PLEASE MAKE SURE THAT YOU HAVE CIRCLED ONE NUMBER ON EACH OF THE 18 SCALES.

BELIEFS ABOUT VULNERABILITY

In this section we are asking you to make two ratings for each of the problems listed.

First: Indicate how likely you feel it is that **you** will develop the following problems.

Second: Consider an **average person** with your kind of diabetes who is

- your age
- your sex
- follows the same kind of treatment as yourself
- has average control over his or her diabetes.

On these scales 0 would indicate that you feel that you are extremely unlikely to develop the problem
1 = quite unlikely
2 = neither likely nor unlikely
3 = quite likely
4 = extremely likely

If you already have or think you may have any of these problems, please tick the box on the right-hand side.

	extremely unlikely				extremely likely	I already have this problem
1. High blood pressure						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
2. Stomach ulcer						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
3. Blindness						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
4. Ear infection						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	

/continued over

	extremely unlikely				extremely likely	I already have this problem
5. Kidney disease						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
6. Aching legs						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
7. Leukaemia (cancer of blood)						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
8. Complications arising from diabetes						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
9. Gum disease						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
10. Bronchitis						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	

/continued over

	extremely unlikely				extremely likely	I already have this problem
11. Deafness						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
12. Numbness in the feet						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
13. Heart disease						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
14. Asthma						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
15. Failing eyesight						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
16. Loss of hearing						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	
17. Gangrene						
Yourself	0	1	2	3	4	☐
Average person with your kind of diabetes	0	1	2	3	4	

PLEASE MAKE SURE THAT YOU HAVE CIRCLED A NUMBER ON EACH OF THE SCALES.

APPENDIX 3

Introduction to booklet of questionnaires
and
General Information Questionnaire

(Post-Education)

TYPE II DIABETES STUDY BOOKLET
(POST EDUCATION)

When you recently came to the hospital for a consultation with Dr Jennings, you were given a booklet of questionnaires dealing with beliefs and opinions about diabetes.

The information that you gave to us in this booklet will be very useful in gaining a better understanding of the difficulties which arise for people with your kind of diabetes.

Now that you have attended an education session, we are interested to know whether your beliefs and opinions about your diabetes have changed. For this reason, you will find attached another copy of the booklet of questionnaires similar to the one given to you before.

We would like you to complete the booklet today, if possible (or within the next 2 or 3 days) and post it in the stamped addressed envelope provided.

Once again, all answers will be treated in strict confidence.

If you have any problems in completing the questionnaires, please do not hesitate to get in touch with us.

Mrs K S Lewis
Dr C Bradley
Department of Psychology
University of Sheffield
Sheffield S10 2TN

Telephone: 768555 ext. 6550

GENERAL INFORMATION

Name ....

Age .... Sex ....

Weight .... Height ....

Please indicate your general impression of your diabetes control during the past few weeks by circling a number on the scale below

Very well controlled	1	2	3	4	5	6	7	Very poorly controlled

Have you ever been to an education session before?

(Please tick) Yes .... No ....

Have you ever read any books about diabetes?

(Please tick) Yes .... No ....

APPENDIX 4

Knowledge Questionnaire

D I A B E T E S K N O W L E D G E Q U E S T I O N N A I R E

Name...

PLEASE READ THE FOLLOWING INSTRUCTIONS BEFORE ANSWERING THE QUESTIONS IN THIS BOOKLET.

1. On the following pages you will find some questions and statements on diabetes.

2. Each question or statement is followed by a number of choices.

3. You should choose from these choices **one or more** which you think correctly answers the question or completes the statement. Please put a tick by your choice(s).

For example:

Q. Which of the following foods are vegetables?

☐ Banana

☐ Carrot

☐ Cabbage

☐ Turnip

☐ I do not know

4. If you cannot answer a question or complete a statement please put a tick next to "I do not know".

5. Please attempt to answer all the questions.

Thank you.

**Please make sure that you consider <u>all</u> the choices for a particular statement
or question.**

GENERAL

1. **Glucose is detected in the urine when:**

- [ ] A person who hasn't got diabetes eats too many sweet things
- [ ] The kidney threshold is passed and glucose spills over into the urine
- [ ] The dose of tablets is too large
- [ ] Blood sugar levels are very low
- [ ] I do not know

2. **High blood sugar levels can be caused by:**

- [ ] Missing a meal
- [ ] Being less active than usual
- [ ] Getting an infection
- [ ] Emotional stress
- [ ] I do not know

3. **Common symptoms of low blood sugars are...**

- [ ] Feeling hungry and sweating
- [ ] Blurred vision
- [ ] Slurred speech
- [ ] Passing a lot of urine
- [ ] I do not know

4. **Some common symptoms of very high blood sugar levels are:**

- [ ] Feeling faint
- [ ] Blurring of vision
- [ ] Passing more urine
- [ ] Feeling thirsty
- [ ] I do not know

5. If you experience symptoms of hypoglycaemia (low blood sugar) you should:

- [ ] Take extra tablets for your diabetes
- [ ] Continue what you are doing
- [ ] Take two sugar cubes or a sweetened drink
- [ ] Drive yourself to hospital
- [ ] I do not know

6. If a urine test shows 2% (++++) sugar this suggests that you have

- [ ] A slightly high blood sugar level
- [ ] A low blood sugar level
- [ ] A high blood sugar level
- [ ] A normal blood sugar level
- [ ] I do not know

7. Which of the following is true:

- [ ] It does not matter if your diabetes is not fully controlled, as long as you do not have a coma
- [ ] Poor control of diabetes may result in complications later
- [ ] Blood or urine testing is only necessary when symptoms occur
- [ ] It is best to have some sugar in the urine
- [ ] I do not know

8. A person who has diabetes should try to:

- [ ] Avoid high blood sugar levels
- [ ] Keep blood sugar levels high
- [ ] Avoid becoming overweight
- [ ] Avoid taking exercise of any kind
- [ ] I do not know

DIET

1. **Foods containing refined sugar:**

- [ ] Always cause blood sugar levels to go too low
- [ ] Raise blood sugar levels quicker than starchy foods
- [ ] Will have no effect on blood sugar levels
- [ ] Are slower than starchy foods in raising blood sugar levels
- [ ] I do not know

2. **Which of the following are high in fat?**

- [ ] Cottage cheese
- [ ] Skimmed milk
- [ ] Pastry
- [ ] Cheddar cheese
- [ ] I do not know

3. **Which of the following are high in fibre?**

- [ ] Jacket potato
- [ ] Cornflour
- [ ] Baked beans
- [ ] Cream crackers
- [ ] Peas
- [ ] I do not know

4. **Which of the following so-called "DIABETIC" food items are approved by the hospital clinic?**

- [ ] Diabetic jam
- [ ] Diabetic jellies
- [ ] Sorbitol-sweetened, sugar-free canned fruit
- [ ] "Low Calorie" soft drinks
- [ ] I do not know

5. **Which of the following should be avoided or restricted if you are overweight?**

- ☐ Cream
- ☐ Tomatoes
- ☐ Margarine/butter
- ☐ Alcohol
- ☐ I do not know

6. **Which 3 of the following contain added sugar?**

- ☐ Rice pudding
- ☐ Chocolate mousse
- ☐ Marmalade
- ☐ Pasta
- ☐ I do not know

7. **On a diabetic person's diet, which of the following can be eaten freely?**

- ☐ Cauliflower
- ☐ Lettuce
- ☐ Digestive biscuits
- ☐ Honey
- ☐ I do not know

8. **Rice is mainly:**

- ☐ Protein
- ☐ Carbohydrate
- ☐ Fat
- ☐ Mineral and vitamin
- ☐ I do not know

COMPLICATIONS

1. Which of the following *does* help in the care of your feet?

- ☐ Changing your socks/tights frequently
- ☐ Wearing the same shoes every day
- ☐ Checking your feet regularly for sores
- ☐ Rinsing socks/tights carefully after washing to remove soap
- ☐ I do not know

2. After washing your feet you should:

- ☐ Remove any dry skin from the feet
- ☐ Remove any hard skin from the feet
- ☐ Blot dry between the toes with a soft towel
- ☐ Avoid rubbing the feet with a towel
- ☐ I do not know

3. When a person with diabetes smokes the effect it has is.....

- ☐ To increase the risk of damage to blood vessels
- ☐ To increase the risk of poor blood circulation in the legs
- ☐ To increase the risk of heart disease
- ☐ To cause problems with weight control
- ☐ I do not know

4. Keeping diabetes well controlled over the years can lower the risk of damage to:

- ☐ Nerves in the feet
- ☐ The kidneys
- ☐ The lungs
- ☐ The eyes
- ☐ I do not know

5. **To check for any long term complications due to your diabetes yearly examinations should be carried out at the hospital clinic...**

- [ ] On your hearing
- [ ] On your blood pressure
- [ ] For nerve damage to your feet
- [ ] On your eyes
- [ ] I do not know

6. **For people with diabetes, good weight and good blood sugar control lower the risk of having...**

- [ ] A stroke
- [ ] A heart attack
- [ ] Kidney failure
- [ ] Cancer
- [ ] I do not know

7. **Wounds on a diabetic person's feet may become infected because.....**

- [ ] Diabetes can cause resistance to antiseptics
- [ ] Of poor blood supply
- [ ] Of loss of feeling
- [ ] Of the increased insulin in the blood
- [ ] I do not know

8. **Minor injuries to the feet are more likely to get infected when blood sugar levels...**

- [ ] Occasionally get too low
- [ ] Are low all the time
- [ ] Are high much of the time
- [ ] Occasionally get too high
- [ ] I do not know

9. **Control of diabetes is affected by...**

- [ ] The kind of food eaten
- [ ] The amount of food eaten during the day
- [ ] The amount of water drunk during the day
- [ ] The amount of exercise done
- [ ] I do not know

10. **Your urine or blood tests have started to show increased sugar, you...**

- [ ] Should rest for 4-5 hours
- [ ] Should check your diet is correct
- [ ] Should check for any infections
- [ ] May need to eat less at meal times
- [ ] I do not know

APPENDIX 5

Written information supplied to patients regarding diabetes and its complications

(Insulin Study)

INFORMATION FOR PEOPLE WITH DIABETES WHO ARE TREATED WTH DIET AND TABLETS

In diabetes the level of sugar in the blood becomes higher than normal and it spills into the urine. People who develop diabetes in middle life often do not feel unwell with their diabetes and frequently it is only found by chance. They are recommended to follow a diet and many take tablets to help control their diabetes.

Why control diabetes?

Diabetes that starts in middle life may seem "mild", but like the diabetes that occurs in younger people there are long-term effects. These effects, commonly called "the complications of diabetes", occur much less frequently in people whose diabetes is "well controlled".

How do we measure control?

Often there are no obvious symptoms of poor control and we therefore rely largely on "tests" to measure diabetes control. Urine tests are used by many people and they should, ideally, show no sugar. A few patients with tablet-treated diabetes measure blood sugar by pricking their fingers. This can be more accurate than urine testing. Control is also assessed by the blood sugar test done in the diabetic clinic and from time to time by a blood test to measure "glycosylated haemoglobin". Glycosylated haemoglobin is a measure of a person's diabetes control over a two month period.

What are the complications of diabetes?

Diabetes can damage a number of parts of the body and these will be outlined in turn.

(a) *Blood vessels.* Hardening of the arteries is more pronounced in diabetes and tends to come on at an earlier age. This results in an increased risk of heart attacks and poor circulation to the legs.

(b) *Eyes.* Changes occur at the back of the eye that, left untreated, can lead to loss of vision. Fortunately, if these changes are detected early, the risk of losing vision is greatly reduced by laser treatment.

(c) *Nerves.* Diabetes affects nerves, particularly those that carry sensation from the feet. Some people with damage to these nerves may notice "pins and needles",

pain or numbness in their feet most of the time. Others have severely damaged nerves but do not have any symptoms.

(d) *Feet.* These deserve special mention. They may be affected by a number of the complications of diabetes and need to be carefully looked after. As a result of nerve damage, people may not notice their shoes rubbing or may not feel anything when a pin has pierced the sole of their shoe. The blood supply may be poor and healing may be slow. It is therefore important to inspect your feet daily, keep them clean and dry, and keep the toe nails trimmed.

(e) *Kidneys.* The kidneys can be damaged by poorly controlled diabetes leading to kidney failure in a small proportion.

How can complications be prevented or arrested?

The risk of complications can be greatly reduced by good control of your diabetes. Good control can be achieved in most people who develop diabetes in middle life by following a diet and taking tablets. It is very important that people with diabetes are not overweight as extra weight has the effect of making their diabetes worse. The diet recommended by the dietician not only helps with weight loss but also reduces the risk of certain complications. Smoking increases the risk of hardening of the arteries and we therefore strongly recommend that you do not smoke.

How can diabetes be treated if diet and tablet treatment does not achieve good control?

The tablets prescribed for diabetes generally work by stimulating the body's own insulin. However, despite treatment with diet and tablets, some people cannot make enough insulin. In this case insulin injections are usually necessary in order to improve control and reduce the risk of complications. Usually, once started, insulin is continued indefinitely.

Are there any new alternatives?

There are no new alternatives to insulin, but recently a short course of insulin has been found to improve control, not only during the period of treatment with insulin, but also after stopping the insulin and restarting tablets.

Here in Sheffield, we are assessing the effect of a four month period of insulin treatment on people with poorly controlled tablet-treated diabetes. We hope this will help determine who is likely to do better on insulin. It is also possible that, as a result of the insulin therapy, some people will be better controlled on tablets after using insulin.

Insulin treatment

Insulin is normally made by the pancreas gland and it helps the body to use sugar. However, in diabetes, the pancreas does not make enough insulin. As a result of this, some of the sugar collects in the blood instead of being used by the body. Insulin treatment helps the body to make use of this sugar. Unfortunately, insulin cannot be taken by mouth and must be injected under the skin (not into a vein).

Insulin injections

Injections are usually done twice a day, before breakfast and before the evening meal. Disposable plastic syringes are normally used nowadays and they have a very fine needle. After a short period of time most people barely notice the injections. Insulin can be injected into the upper arm, the upper leg, or under the skin of the abdomen. People starting insulin receive a lot of help and instruction from the doctors and nurses based at the hospital and most learn to give their own insulin within a few days.

The insulin pump

In this hospital, we have considerable experience with another method of giving insulin, namely the insulin infusion pump. This is a small device that slowly injects insulin throughout the day through a small needle placed under the skin. The pump is about the size of a pack of playing cards and is usually carried in a pocket or attached to a belt. Before each meal the patient sets the pump to give a small "boost" of insulin. As with injection treatment people starting treatment with the insulin pump receive a lot of help and instruction from the hospital staff.

Is any change in the diet necessary?

Yes, people treated with insulin have to spread the foods that have any form of carbohydrate in them (eg potatoes, bread, rice) regularly throughout the day to counterbalance the insulin as, if this is not done, the blood sugar may become lower than normal (hypoglycaemic, "hypo") or higher than usual. People treated with insulin prevent hypoglycaemia (hypo) by eating regular meals and taking some sugar if they are going to be late for a meal.

Blood testing

People who use insulin usually check their blood glucose by pricking their finger using an automatic device called an "autolet". This also has a fine needle and people rapidly get used to this form of testing. The drop of blood formed by pricking the finger is dropped onto a test stick which changes colour according to the level of sugar in the blood. Controlling diabetes is made easier by knowing the level of sugar in the blood.

Insulin treatment evaluation

We are trying to determine the best way to treat people with your type of diabetes where blood sugars are not well controlled. As stated previously the risk of complications is reduced by improving the control of your diabetes. We are therefore asking people like yourself to take part in a study to look closely at the effect of changing from tablets to insulin. If you agree to take part you will initially continue your tablets, receive further advice about diet and learn how to measure your own blood glucose at home. These measures may help to improve the control of your diabetes and will continue for three months. At the end of this period your diabetes control will be assessed again and if there has been a significant improvement you will stay on this treatment.

If your diabetes control has not significantly improved after this period of blood testing, you will be treated in *one* of two ways for a further period of four months. The two forms of treatment are:-

(i) *insulin injections*

(ii) insulin pump treatment.

The form of treatment you receive will be determined randomly as this is the best way to compare the two forms of treatment.

At the end of this four month assessment you will stop your injections or pump treatment and will continue with diet only. During this time blood glucose control will be assessed regularly and tablets will be reintroduced as soon as they are necessary. When the assessment has been completed, there will be an opportunity to try the other form(s) of treatment.

If you take part in this assessment, you will be seen by the same doctor on each occasion, in his room (P floor) rather than in the diabetic clinic. As usual when starting insulin, appointments will need to be more frequent than previously, while your treatment is adjusted. There will, however, be very little waiting and your appointments will be more flexible. During the assessment our nursing staff will also help you adjust to your new form of treatment and advise you about various aspects of insulin treatment.

As mentioned previously, some people may find that a period of insulin treatment will have improved their diabetes control compared with their previous control when using tablets and diet. We do not know how long this will last. Some people may find that the blood testing alone helps them control their diabetes. Other people will find that in order to maintain good diabetes control, they need to continue insulin treatment indefinitely.

APPENDIX 6

Introduction to booklet of questionnaires

and

General Information Questionnaire

(Insulin Study - Post Decision)

TYPE II DIABETES STUDY BOOKLET
(POST DECISION)

When you recently came to the hospital for a consultation with Dr Jennings, you were given a booklet of questionnaires dealing with beliefs and opinions about diabetes.

The information that you gave to us in this booklet will be very useful in gaining a better understanding of the difficulties which arise for people with your kind of diabetes.

Now that you have more information about your diabetes control and have made a decision as to whether or not to take part in the insulin study, we are interested to know whether your views about your diabetes have changed. For this reason, you will find attached another copy of the booklet of questionnaires similar to the one given to you before.

We would like you to complete the booklet today, if possible (or within the next 2 or 3 days) and post it in the stamped addressed envelope provided.

Once again, all answers will be treated in strict confidence.

If you have any problems in completing the questionnaires, please do not hesitate to get in touch with us.

Mrs K S Lewis
Dr C Bradley
Department of Psychology
University of Sheffield
Sheffield S10 2TN

Telephone: 768555 ext 6550

GENERAL INFORMATION

Name ....

Age .... Sex ....

Weight .... Height ....

Please indicate your general impression of your diabetes control during the past few weeks by circling a number on the scale below

Very well controlled	1	2	3	4	5	6	7	Very poorly controlled

What have you decided to do? (please tick where applicable)

Take part in the insulin study ....

Continue with present treatment ....

Other (please state) ....

....

Please describe in the space below your reasons for the above decision:

/continued over......

Please answer the questions below to indicate how you feel about the treatments you have been offered **(whether or not you have decided to take part in the insulin study)**:

1. Does the thought of injecting yourself with insulin make you feel apprehensive or worried? Please circle a number on the scale below:

Very apprehensive or worried	6	5	4	3	2	1	0	Not at all apprehensive or worried

2. Does the thought of using an insulin pump make you feel apprehensive or worried? Please circle a number on the scale below:

Very apprehensive or worried	6	5	4	3	2	1	0	Not at all apprehensive or worried

3. Does the thought of pricking your finger to sample your blood sugar make you feel apprehensive or worried? Please circle a number on the scale below.

Very apprehensive or worried	6	5	4	3	2	1	0	Not at all apprehensive or worried

APPENDIX 7

Introduction to booklet of questionnaires

and

General Information Questionnaire

(Insulin Study - Pre-Treatment)

TYPE II DIABETES STUDY BOOKLET
(PRE-TREATMENT)

Over the past 3 months, you have been monitoring your blood sugar levels at home and have been finding out more about your diabetes control. You have also been given advice and instruction about the management of your diabetes by Dr Jennings and the dietician, Susan Murdoch. We are interested to learn whether these experiences have changed your views about your diabetes and its management.

We would therefore like you to complete another copy of the booklet of questionnaires similar to the ones given to you before. Please do this today, if possible (or within the next 2 or 3 days) and post it in the envelope provided.

Once again, all answers will be treated as confidential.

Please do not hesitate to contact us if you have any problems in completing the questionnaires.

Mrs K S Lewis
Dr C Bradley
Department of Psychology
University of Sheffield
Sheffield S10 2TN

Telephone: 768555 ext. 6550

GENERAL INFORMATION

Name ....

Weight ....

Please indicate your general impression of your diabetes control during the past few weeks by circling a number on the scale below

Very well controlled	1	2	3	4	5	6	7	Very poorly controlled

To what extent do you feel that monitoring your blood sugar levels over the past few weeks has helped you to manage your diabetes.

Please circle a number on the scale below:

Has greatly helped me to manage my diabetes	1	2	3	4	5	6	7	Has not helped me to manage my diabetes

To what extent do you feel that your diabetes control has improved as a result of blood glucose monitoring?

Has greatly improved as a result of blood glucose monitoring	1	2	3	4	5	6	7	Has not improved as a result of blood glucose monitoring

APPENDIX 8

Introduction to booklet of questionnaires

and

General Information Questionnaire

(Insulin Study - Post-Treatment)

TYPE II DIABETES STUDY BOOKLET
(POST-TREATMENT)

Now that you have been using insulin for 4 months, we are interested to know whether your views about your diabetes and its management have changed. We also want to know what your experience of using this form of treatment has been like.

We would therefore like you to complete another booklet of questionnaires similar to those given to you before.

Please complete the booklet today, if possible (or within the next 2 or 3 days) and post it in the stamped addressed envelope provided.

Once again, your answers will be treated as confidential.

Please feel free to add comments or information to the questionnaires where you feel this might help.

If you have any problems in completing the questionnaires, please do not hesitate to get in touch with us.

Mrs K S Lewis
Dr C Bradley
Department of Psychology
University of Sheffield
Sheffield S10 2TN

Telephone: 768555 ext. 6550

GENERAL INFORMATION

Name ....

Weight ....

Please indicate your general impression of your diabetes control during the past few weeks by circling a number on the scale below

Very well controlled	1	2	3	4	5	6	7	Very poorly controlled

APPENDIX 9

A Expectations of Treatment Questionnaire

B Experience of Treatment Questionnaire

EXPECTATIONS OF THE TREATMENT

Please consider your expectations about the form of diabetes treatment which you are about to use. Circle one of the numbers on each of the scales to indicate how strongly you agree or disagree with each of the following statements.

On these scales 0 = strongly disagree
1 = moderately disagree
2 = mildly disagree
3 = neither agree nor disagree
4 = mildly agree
5 = moderately agree
6 = strongly agree

	strongly disagree						strongly agree
1. I will feel able to control my own diabetes with little need for other people's help	0	1	2	3	4	5	6
2. I will feel handicapped	0	1	2	3	4	5	6
3. It will be easy to regulate my blood sugar	0	1	2	3	4	5	6
4. I believe that I may develop infections with the treatment	0	1	2	3	4	5	6
5. I believe that the treatment will reduce the risk of my developing complications of diabetes (such as deteriorating eyesight)	0	1	2	3	4	5	6
6. It will be obvious to other people that I have diabetes	0	1	2	3	4	5	6
7. I will have freedom to choose when I want to eat	0	1	2	3	4	5	6
8. I expect my blood sugar levels to become similar to those of non-diabetic people	0	1	2	3	4	5	6
9. I will need to adapt my life-style	0	1	2	3	4	5	6
10. Insulin reactions (hypos) will be frequent	0	1	2	3	4	5	6
11. I believe there might be technical problems with the treatment	0	1	2	3	4	5	6

	strongly disagree						strongly agree
12. I will feel dependent on professional help for managing my diabetes	0	1	2	3	4	5	6
13. It will be difficult to deal with the treatment	0	1	2	3	4	5	6
14. People around me will accept my using this form of treatment	0	1	2	3	4	5	6
15. I think the study will produce valuable scientific information	0	1	2	3	4	5	6
16. I will be able to forget that I have diabetes for most of the time	0	1	2	3	4	5	6
17. I believe that I might put on too much weight	0	1	2	3	4	5	6
18. It will be inconvenient to do the number of blood glucose tests required	0	1	2	3	4	5	6
19. I will be able to be flexible with what I eat and still maintain control of my diabetes	0	1	2	3	4	5	6
20. I will be able to take part fully in social activities	0	1	2	3	4	5	6
21. I believe that a short period of using insulin will lead to good blood sugar control in the long term.	0	1	2	3	4	5	6

PLEASE MAKE SURE THAT YOU HAVE CONSIDERED EACH OF THE 21 STATEMENTS AND HAVE CIRCLED A NUMBER ON EACH OF THE 21 SCALES.

TREATMENT EXPERIENCE

Please think back over the **past few weeks** and consider your experience about the form of diabetes treatment which you have been using recently.
Circle one of the numbers on each of the scales to indicate how strongly you agree or disagree with each of the following statements.

On these scales 0 = strongly disagree
1 = moderately disagree
2 = mildly disagree
3 = neither agree nor disagree
4 = mildly agree
5 = moderately agree
6 = strongly agree

	strongly disagree						strongly agree
1. I have felt able to control my own diabetes with little need for other people's help	0	1	2	3	4	5	6
2. I have felt handicapped	0	1	2	3	4	5	6
3. It has been easy to regulate my blood sugar	0	1	2	3	4	5	6
4. I have developed infections with the treatment	0	1	2	3	4	5	6
5. I believe that the treatment has reduced the risk of my developing complications of diabetes (such as deteriorating eyesight)	0	1	2	3	4	5	6
6. It has been obvious to other people that I have diabetes	0	1	2	3	4	5	6
7. I have had freedom to choose when I want to eat	0	1	2	3	4	5	6
8. My blood sugar levels have become similar to those of non-diabetic people	0	1	2	3	4	5	6
9. I needed to adapt my life-style	0	1	2	3	4	5	6
10. There have been frequent insulin reactions (hypos)	0	1	2	3	4	5	6
11. I have experienced technical problems with the treatment	0	1	2	3	4	5	6

	strongly disagree						strongly agree
12. I have felt dependent on professional help for managing my diabetes	0	1	2	3	4	5	6
13. It has been difficult to deal with the treatment	0	1	2	3	4	5	6
14. People around me have accepted my using this form of treatment	0	1	2	3	4	5	6
15. I think the study is producing valuable scientific information	0	1	2	3	4	5	6
16. I have been able to forget that I have diabetes for most of the time	0	1	2	3	4	5	6
17. I have put on too much weight	0	1	2	3	4	5	6
18. It has been inconvenient to do the number of blood glucose tests required	0	1	2	3	4	5	6
19. I have been flexible with what I eat and still maintained control of my diabetes	0	1	2	3	4	5	6
20. I have been able to take part fully in social activities	0	1	2	3	4	5	6

PLEASE MAKE SURE THAT YOU HAVE CONSIDERED EACH OF THE 20 STATEMENTS AND HAVE CIRCLED A NUMBER ON EACH OF THE 20 SCALES.