THE EFFECT OF BLOOD GLUCOSE SELF-MONITORING IN PATIENTS WITH NON-INSULIN TREATED TYPE 2 DIABETES

Alisha N. Wade

Trinity College

Division of Public Health and Primary Care

University of Oxford

Submitted in fulfillment of the requirements of the degree of Doctor of Philosophy, University of Oxford

Trinity Term 2005

RADCLIFFE SCIENCE LIBRARY OXFORD
DEPOSITED
- 6 APR 2006
THESIS

Acknowledgements

There are so many people to whom I owe a special debt of gratitude for their support and guidance through this project. I would particularly like to thank my supervisors, Andrew Neil and Andrew Farmer for the opportunity to work with them on this project and for their support over the last four years.

I would also like to thank the DiGEM team, Mary Selwood, Anthea Craven, Sarah Turner, Heather Kirwood, Margaret Chapman and Alice Fuller for their professionalism and dedication to this project.

The support and advice of Irene Stratton, Pat Yudkin, David French and Sue Ziebland has been invaluable. Their willingness to go above and beyond the call of duty was very much appreciated.

My family and friends have through this, as always, been pillars of support and encouragement. I would like to thank my parents and my sister Lisa, who answered statistical queries, day or night, as well as my extended family. My office mates, Lucy Wright and Janine Hartweg, have been wellsprings of good advice and inspiration. Heartfelt thanks as well to Dumi, Idara, Sharon, Dawn, Chantal and of course the Caribbean crew at Oxford for the camaraderie and for keeping me grounded.

Last, but not least, thank you to the Trinity College family for making my time at Oxford so memorable.

THE EFFECT OF BLOOD GLUCOSE SELF-MONITORING IN PATIENTS WITH NON-INSULIN TREATED TYPE 2 DIABETES

Alisha N Wade
Trinity College
University of Oxford

Submitted for the degree of Doctor of Philosophy
Trinity 2005

ABSTRACT

Significant debate exists about the utility of blood glucose self-monitoring (BGSM) in patients with non-insulin treated type 2 diabetes. Previous studies lacked any theoretically based intervention and produced conflicting results. The novel randomized controlled trial reported in this thesis used a theoretically based intervention to evaluate the effectiveness of BGSM as a strategy of glycaemic feedback to promote self management.

Psychological theory was used to develop an intervention to support use of glycaemic feedback to promote self-management. Measures based on similar psychological theory were also developed to assess the effectiveness of the intervention in targeting the hypothesized mediators of behaviour. Participants were randomized to one of three intervention arms: regular HbA_{1c}, BGSM with facilitator interpretation and BGSM with patient interpretation and application.

There was no significant difference in HbA_{1c} between the three groups after one year ($p=0.653$), although significant reductions were noted in all groups in patients with HbA_{1c} over 8%. There were no significant differences in secondary clinical outcomes of change in weight ($p=0.649$) or systolic or diastolic blood pressure ($p=0.890$ and $p=0.860$ respectively). Significant changes in beliefs and behaviour were limited to change in illness coherence ($p=0.041$) and in eating high fat diets ($p=0.009$) and five portions of fruit and vegetables daily ($p=0.017$).

Semi-structured qualitative interviews were used to explore patients' experiences and perceptions of BGSM. Participants who had difficulty in adhering to self-management recommendations found BGSM helpful, whereas those who had previously followed recommendations were discouraged by BGSM results if they did not reflect their efforts.

BGSM with patient interpretation and application did not significantly improve HbA_{1c} or other clinical parameters when compared to BGSM with facilitator feedback or regular HbA_{1c} measurement. It also had little effect on illness beliefs and self-reported behaviour. It did, however, appear to be beneficial in patients who had difficulty in following self-management recommendations.

Statement of authorship

This thesis describes an evaluation of blood glucose self-monitoring in patients with non-insulin treated type 2 diabetes. I carried out the review of the existing literature and was the primary author of the study intervention protocols and quality assurance checklist, which were developed in consultation with my supervisors and reviewed by external collaborators with experience in behavioural interventions. I also acted as the internal assessor of the quality of intervention delivery.

I conducted the interviews from which the item pool for the measure development was generated and was one of three independent data coders. I collated and analysed the contributions of the three coders and developed the preliminary questionnaire. I carried out the statistical analysis of the data from the questionnaire evaluation study and decided, in conjunction with the other two independent coders, which items should be included in the final study questionnaire. Existing measures of beliefs and behaviour for inclusion in the final study questionnaire were selected in consultation with my supervisors.

I contributed to the trial protocol, which was developed in conjunction with my supervisors and the other trial investigators and acted as the study co-ordinator for the trial. The trial intervention was delivered by four facilitators who identified and contacted patients and carried out all study visits. I supervised these four trial facilitators and was one of two persons who conducted monthly sessions to address administrative and intervention delivery issues; I was also one of the persons who coded adverse events during the trial and served on the management committee which oversaw smooth running of the trial. A study administrator was responsible for ensuring completeness of data and accurate data entry.

I carried out all of the statistical analysis of the trial data using an analysis plan that I had developed and which had been revised in conjunction with my supervisors, the trial statistician and an external statistician.

The qualitative study was conducted using a topic guide which I developed and revised in collaboration with my supervisors and a trained qualitative researcher. I conducted all of the qualitative interviews and analysed the resulting data. The final analysis was also discussed with a qualitative researcher.

Table of contents

Acknowledgements ii

Statement of authorship iv

Chapter 1
Introduction 1

Chapter 2
Background 5
2.1 Evidence for BGSM in non-insulin treated type 2 diabetes 5
2.1.1 Review methods 5
2.1.2 Observational studies 6
2.1.3 Intervention studies 16
2.1.4 Systematic Reviews 29
2.1.5 Summary of epidemiological evidence 35
2.2 Psychological models of behaviour change 37
2.2.1 Role of blood glucose self-monitoring in behaviour change 37
2.2.2 Blood glucose self-monitoring- a possible framework 38
2.3 Conclusion 41

Chapter 3
Development of the study intervention 42
3.1 Introduction 42
3.2 Intervention development 43
3.2.1 Theoretical and modelling phases 43
3.2.2 Operationalization of the intervention 56
3.2.3 Quality assurance of the intervention 58
3.3 Conclusion 61

Chapter 4
Development of study questionnaire 63
4.1 Introduction 63
4.2 Selection of measures 64
4.2.1 Measures of belief 64
4.2.2 Measures of behaviour 66
4.2.3 Measures of well being 68
4.3 Development of new measures and evaluation of existing measures 70
4.3.1 Study 1- Development of the preliminary questionnaire 70
4.3.2 Study 2- Evaluation of preliminary questionnaire 84
4.4 Discussion 136

Chapter 5
The randomized controlled trial- design and methods 144
5.1 Aims of the randomized controlled trial 144
5.2 Trial design 145
5.2.1 Outcome measures and sample size 145
5.3. Assessment of eligibility 147
5.3.1 Identification from practice lists 147
5.3.2 Telephone contact 148
5.3.3 Assessment of glycaemic control 148
5.4 Randomization procedures 149
5.5 Study visits 150
5.5.1 Initial assessment visit 150
5.5.2 Post randomization study visit 152
5.5.3 Follow-up visits 155
5.5.4 Final study visit 158
5.6 Data management 159
5.6.1 Maintenance of confidentiality 159
5.6.2 Data collection and entry 160
5.7 Adverse events 160
5.8 Trial monitoring 161
5.8.1 Delivery of the intervention 161
5.8.2 Adherence to BGSM protocol 161
5.8.3 Accuracy of monitors 161
5.8.4 Patients lost to follow-up 161
5.9 Biochemical analyses 162
5.9.1 Handling and storage of samples 162
5.9.2 Analysis of samples 162
5.10 Statistical analysis 163
5.11 General organization of trial 164

Chapter 6
The randomized controlled trial- results 165
6.1 Response to trial 165
6.2 Characteristics of participants 166
6.2.1 Baseline demographic characteristics 166
6.2.2 Baseline clinical characteristics 169
6.2.3 Baseline belief and behaviour scores 169
6.2.4 Baseline well-being, health status and treatment satisfaction scores. 173
6.3 Trial outcomes 174
6.3.1 Primary outcome 174
6.3.2 Secondary outcomes 175
6.3.3 Adherence to protocol 182
6.3.4 Loss to follow-up 188
6.4 Summary of results 192

Chapter 7
The randomized controlled trial- discussion 193
7.1 Introduction 193
7.2 Summary of main findings and comparison with other trials 193
7.2.1 Change in HbA_{1c} 193
7.2.2 Changes in weight, blood pressure and cholesterol 196
7.2.3 Changes in beliefs and behaviour 198
7.2.4 Changes in well-being and treatment satisfaction 200
7.2.5 Episodes of hypoglycaemia 201
7.2.6 Occurrence of diabetes related complications 201
7.2.7 Adherence to protocol 202
7.2.8 Loss to follow-up 203
7.3 Strengths of this study 203
7.4 Limitations of this study 205
7.5 Implication of analysis 207
7.5.1 Implications for causal model 207
7.5.2 Implications for on-going trial 209
7.5.3 Clinical implications 209
7.6 Summary 209

Chapter 8
The qualitative study 211
8.1 Introduction 211
8.2 The qualitative study: literature review 212
8.3 The qualitative study: methods 215
8.3.1 Patient recruitment and data collection 215
8.3.2 Data analysis 220
8.4 Results and discussion 221
8.4.1 Participant characteristics 221
8.4.2 Perspectives of blood glucose self-monitoring 222
8.5 Conclusions 239

Chapter 9
Conclusion 243

References 246

Glossary of abbreviations 265

List of appendices 266

Chapter 1

Introduction

Diabetes mellitus presents a significant international public health problem. The disease, characterized by abnormalities in glucose metabolism, affected an estimated 171 million people over the age of twenty years in 2000, with a projected increase of 114% by 2030(1). Hyperglycaemia results in significant morbidity and mortality(2,3), with one study reporting a standardized mortality ratio of 1.24 in patients with diabetes when compared to non-diabetic individuals, primarily due to excess cardiovascular mortality(4).

This global trend is mirrored in the United Kingdom(5,6). The prevalence of diabetes results in significant National Health Service (NHS) utilization, both in primary and secondary care. Patients with diabetes are more likely to be followed up in general practice and to be referred to community services than those without diabetes(7). Patients with diabetes also have a higher age-adjusted relative risk for hospital admissions for cerebrovascular events(8), coronary heart disease events(9) and peripheral vascular disease, neuropathy, infection and ulceration(10). Treatment of diabetes complications is costly(11,12), with one study estimating that the cost of treating type 2 diabetes and its complications will continue to rise over the next forty years, peaking at £2.2 billion(5).

Type 2 diabetes accounts for over 90% of cases worldwide(13) and is therefore responsible for a significant proportion of expenditure. There are, however, several modifiable risk factors which present potential areas for intervention. The United Kingdom Prospective Diabetes Study (UKPDS) found that strict glycaemic control (HbA_{1c} of 7.0%) resulted in a significant reduction in microvascular complications(14). There was also a reduction in macrovascular complications, although this was not statistically significant. Modification of other risk factors such as dyslipidaemia(15,16) and blood pressure(17) have, however, been shown to reduce the risk of macrovascular

disease. Appropriate strategies targeting these risk factors should result in a reduction in complications and associated cost.

Pharmacological therapy is the *sine qua non* of diabetes therapy. Risk factor modification in clinical trials has largely been effected by drug therapy, but the efficacy of lifestyle modification should not be ignored. The Diabetes Prevention Program demonstrated that an intensive lifestyle intervention, in which participants were encouraged to target a minimum weight loss of 7% of initial weight through improved diet and increased physical activity and supported with education and frequent individualized and group sessions, reduced the incidence of diabetes in people with impaired glucose tolerance and did so more effectively than metformin (18). Participants in the intensive lifestyle intervention group also had more significant decreases in blood pressure and triglycerides and increases in high density lipoprotein (HDL) cholesterol and had lower levels of pharmacotherapy for hypertension and dyslipidaemia at three year follow-up(19). Other clinical trials in which the primary intervention was pharmacological have included lifestyle counselling(20) or lifestyle modification as one element of intensified treatment(21). The role of diet and physical activity in the treatment of diabetes is also recognized in national guidelines. The American Diabetes Association acknowledges that medical nutrition therapy (MNT) is an integral aspect of diabetes management and recommends physical activity and individualized MNT to assist in attaining metabolic outcomes and preventing and treating complications of diabetes(22).

Achieving tight glycaemic control remains difficult, even in health care systems where medication is widely available and lifestyle modification is actively encouraged. Patient adherence to therapy recommendations is often limited(23,24) which may provide one explanation for the failure to observe improved outcomes. We hypothesized that the use of blood glucose self-monitoring (BGSM), a technique in which patients can obtain an instantaneous evaluation of their blood glucose might improve adherence to diet, physical activity and medication taking, resulting in improved glycaemic control.

The role of BGSM in improving glycaemic control patients with type 1 diabetes and insulin-treated type 2 diabetes is supported by existing research(25,26). Use of BGSM in clinical practice suggests that health care professionals have assumed that this benefit extends to patients with non-insulin treated type 2 diabetes as well. A significant proportion of the 29% increase in prescriptions for BGSM in the UK between 2001 and 2003 (and the associated annual increase in cost of seventeen million pounds) is likely to be attributable to an increase in prescriptions for non-insulin treated patients(27). There is, however, no conclusive evidence to support the use of BGSM in non-insulin treated patients, either to improve glycaemic control or behavioural and psychosocial outcomes.

The failure of BGSM to improve glycaemic control may be due to a genuine lack of efficacy or a failure to optimally incorporate the technology into management strategies. Wysocki(28) suggests that the failure to derive the maximum effect from BGSM is due to a combination of compliance factors and inappropriate utilization of the resulting data. Issues such as accuracy and reliability of results have been addressed by the development of modern meters which can be regularly calibrated and have extensive memories to record results. Utilization factors, such as knowledge and data usage, both by patient and health care professional, are potentially modifiable and use of psychological theory may provide a basis for developing an intervention which systematically addresses these factors and promotes more effective use of this technology.

This thesis combines epidemiological and qualitative methods to provide a novel, comprehensive analysis of the biochemical, behavioural and psychosocial effects of blood glucose self-monitoring in non-insulin treated type 2 diabetes. The existing evidence for the technology is reviewed and the development of a theoretically-based intervention which incorporates BGSM in an intervention to promote self-management is described. The theoretically-guided development of measures to assess possible mediators of improved self-care activities and glycaemic control and psychosocial

aspects of BGSM is also reported. A randomized controlled trial, utilizing the intervention and measures, is reported and a qualitative study, conducted in a sub-sample of trial participants explores in depth patient perceptions of blood glucose self-monitoring. The results of these studies are used to underpin recommendations for use of blood glucose self-monitoring in non-insulin treated type 2 diabetes.

Chapter 2

Background

Since its introduction in 1978(29,30), BGSM has been advocated as an important tool in achieving tight glycaemic control in patients with diabetes. Its role in patients who are treated with insulin is well-supported by clinical studies(25,26,31) and several mechanisms for this have been postulated, including that the instant biofeedback provided by BGSM allows for contemporaneous modifications in insulin dosage. The use of BGSM in patients with non-insulin treated diabetes is, however, less well established. Several studies have produced conflicting results and this lack of consensus is reflected in current clinical guidelines(32,33). This chapter reviews the epidemiological evidence for blood glucose self-monitoring in non-insulin treated type 2 diabetes. Psychological models for health behaviour change are also reviewed and a theoretical framework for utilization of BGSM in improving glycaemic control in patients with non-insulin treated type 2 diabetes is suggested.

2.1 Evidence for BGSM in non-insulin treated type 2 diabetes

2.1.1 Review methods

An electronic literature search was carried out in the MEDLINE (1951-March 2005), EMBASE (1974-March 2005), Allied and Complementary Medicine (1985-March 2005), CINAHL and British Nursing Index databases. In the MEDLINE database, the MeSH headings "blood glucose self-monitoring", "self-care" and "type 2 diabetes mellitus" were combined. In the EMBASE and CINAHL databases, the terms "blood glucose self-monitoring", "self-care" and "non-insulin dependent diabetes" were specified as descriptors and combined while in the remaining databases, searches were done using a combination of the descriptors "self-care" and "diabetes" as blood glucose self-monitoring was not a recognized term in the thesauri of these databases and the term "self-care" was the closest approximation. All search terms were exploded. Citations in retrieved publications were also searched for relevant studies. No

other attempt was made to locate publications which were not electronically indexed or unpublished literature.

Nineteen hundred and ninety publications were located, 92 of which were potentially relevant and reviewed further. Fifteen of these were published in non-English language journals(34-48) and were excluded from further review as were six publications exploring technical aspects of BGSM(49-54) and twenty-two articles which provided commentaries, audits, case histories, non-systematic reviews or practice recommendations(55-76). Of the 50 publications describing clinical studies and systematic reviews, seven were excluded because they examined BGSM only in insulin-treated type 2 diabetes(25,26,77-81). A further five studies were excluded, three of which described patterns of BGSM use(82-84), one which described the relationship between insurance coverage of BGSM supplies and glycaemic control(85) and one which evaluated glycaemic control in patients with BGSM targets(86). Studies were not excluded on the basis of type of therapy unless all participants were expressly stated to be using insulin. The remaining 38 publications described four distinct systematic reviews and thirty two distinct clinical studies evaluating glycaemic control as a primary or secondary outcome in patients with non-insulin treated type 2 diabetes and these, along with seven further studies(87-93) identified by a reference search of the identified publications, are discussed below.

2.1.2 Observational studies

Observational studies can be defined as those in which the investigator observes associations between exposures and outcomes without actively controlling which subjects are exposed(94). Case-control, cohort and cross-sectional studies are considered here and summarized in Table 2.1.

(i) Case-control studies

In case-control studies, persons with the outcome of interest (cases) and persons without the outcome (controls) are selected and history to the exposure under investigation compared(94). In this context, patients with poor

glycaemic control or pre-defined complications of diabetes would be compared with those with good control or absence of these complications and history of use of BGSM compared. This study design has not been frequently used to examine blood glucose self-monitoring, which may be a reflection of the increasing use of the technology(95) which might make finding controls difficult. One such study, conducted in health clinics in the United States, has, however, been described(96). Retrospective data for more than 3000 clinic visits of 228 patients with type 2 diabetes were analysed; type of therapy was not specified. Patients were divided into those with good diabetes control (defined as HbA_{1c} of less than 8% for more than 95% of the readings done during the preceding 3 years) and those with poor control (HbA_{1c} of 8% or more in more than 95% of readings done over the same period). Patients were then classified as regular BGSM users, irregular BGSM users or not monitoring depending on how often clinic notes documented use of BGSM. 70% of those classified as regular users had an HbA_{1c} of less than 8%, while only 18% of the irregular users and 22% of those not monitoring had an HbA_{1c} less than or equal to 8% ($p<0.0001$).

(ii) Cohort studies

Cohort studies are another type of observational study. In these studies, individuals are defined by the presence or absence of an exposure(94). In prospective cohort studies, the exposure of interest may or may not have occurred, whereas in retrospective studies both the exposure and outcome of interest have occurred.

Studies on blood glucose self-monitoring have commonly used a retrospective cohort design with seven published studies identified. The design has the advantage of being relatively inexpensive, but recording of exposures may be inadequate and information regarding confounding factors may also not be available(97).

The retrospective study by Newman et al(87) compared 21 patients who practised BGSM and 17 participants who did not over a three year period in a

Veterans Administration (VA) hospital in the United States. The study included both insulin and non-insulin treated patients with type 1 and type 2 diabetes, but the proportions of patients with each type of diabetes and using insulin were not specified. Patients who monitored used either visual strips or a reflectance meter and while BGSM values were considered in therapy adjustment, it was not the sole factor. Patients who monitored had a mean glycohaemoglobin of 8.7% over the three year period, while mean glycohaemoglobin in the unmonitored group was 8.8%.

Gilden(98) et al compared quality of life, diabetes knowledge and glycaemic control in elderly patients in the United States using BGSM and urine monitoring. Twenty patients, eleven of whom were on insulin, were divided into two groups, depending on whether they used blood or urine monitoring. There were significantly more insulin treated patients in the BGSM group (80% vs. 30%, $p<0.05$). Glycosylated haemoglobin was measured in clinic, but the method used to determine monitoring technique was not specified. There was no significant difference in glycosylated haemoglobin between the two groups (BGSM 8.6 ± 0.7 vs. urine monitoring 8.8 ± 0.9) and BGSM did not result in a poorer quality of life.

Klein et al(99) compared the use of BGSM and urine monitoring on glycaemic control and lab utilization in a retrospective chart review in a VA medical centre in the United States. Patients who were receiving strips for blood glucose self-monitoring were identified from a pharmacy profile and classified either as insulin dependent diabetes mellitus (IDDM) or non-insulin dependent diabetes mellitus (NIDDM) depending on clinical notes. A random sample of patients receiving urine monitoring supplies was selected for comparison. The records for 228 patients (BGSM 181, urine monitoring 47) for the twelve months preceding the study were obtained from the laboratory and pharmacy databases. Thirty seven percent of these patients were controlled on diet therapy or oral hypoglycaemic medication alone. There was no difference in glycaemic control in those using BGSM when compared to those monitoring their urine (11.37% vs. 11.32%). Comparison of those who used the technology for less than six months, more than six months and not at all also

revealed no significant difference in HbA_{1c}. There was also no evidence that those who monitored more frequently had improved glycaemic control.

Rindone et al(100) evaluated BGSM in a primary care population. One hundred and fifteen records of sulphonylurea-treated patients were randomly selected from a computer-generated patient list. Records were reviewed for HbA_{1c} measurements and BGSM strip use. Data were collected for a two year period and mean HbA_{1c} calculated for this interval. There was no difference in HbA_{1c} in patients utilizing BGSM (8.1 ± 1.3 vs. 8.1 ± 1.6, p=0.65).

Wieland et al(101) examined the relationship between BGSM and HbA_{1c} in 216 patients with glyburide-treated type 2 diabetes in a VA medical centre in the United States. Patients were identified from a hospital database and BGSM use was determined by examining pharmacy profiles. Patients were classified depending on frequency of monitoring and grouped as not monitoring, monitoring once a day or monitoring twice or more often daily. There was no difference in mean HbA_{1c} between the three groups (not monitoring= 7.71 ± 1.41, monitoring once daily= 7.97 ± 1.5, monitoring twice or more= 7.96 ± 1.3, p=0.45). Univariate regression analysis revealed no association between frequency of monitoring and HbA_{1c} (r=0.07, p=0.29); absence of association persisted after adjustment for clinical and demographic factors (r=0.02, p>0.50).

The relationship between BGSM and glycaemic control in an American managed care population was explored by Karter et al(102). Participants were included if they had been continuously registered with the group for the 2 years preceding the study, had full pharmacy benefits and therefore full access to monitoring strips and had an HbA_{1c} value recorded during the follow-up period. Patients were categorized as "adherent" or "non-adherent" depending on the frequency of monitoring. Patients with pharmacologically-treated type 2 diabetes who used an average of at least 0.75 strips daily and those who were monitoring at least occasionally in the diet treated group were classified as adherent. 17 601 patients with non-insulin treated type 2 diabetes were reviewed. HbA_{1c} was lower in patients on oral hypoglycaemic

agents (8.0 ± 1.8 vs. 8.7 ± 2.3, p=0.001) and in those who were diet controlled (7.6 ± 1.8 vs. 8.1 ± 2.3, p=0.001) who monitored their blood sugar. These significant differences between adherent and non-adherent patients persisted when HbA_{1c} was adjusted for demographic, socioeconomic and clinical characteristics[1] with a reduction of 0.6% in HbA_{1c} in tablet-treated patients (p=0.001) and 0.4% in diet treated patients (p=0.001).

Meng et al(103) examined the subject in a convenience sample of 106 patients recruited from polyclinics in Singapore. Fifty one self-monitoring patients, one of whom used insulin, were compared with 55 non-monitoring patients. A retrospective note review was used to establish HbA_{1c} prior to commencement of monitoring and six months after monitoring. Patients who monitored had a reduction of 1.2 % in HbA_{1c} while those who did not had a reduction of 0.1%.

A fourth evaluation of BGSM in an American VA population was carried out by Wen et al(104) who examined the technology in patients with tablet-treated type 2 diabetes who attended a single hospital over a three year period. Use was determined by review of local pharmacy databases. The cohort was divided into four groups depending on use of BGSM-patients in group 1 had not had any strips prescribed over the three year period, group 2 received strips in the final year under study, group 3 in the final two years and group 4 for the duration of the study period. Nine hundred and seventy six patients were included in the study. Regression analysis was used to examine the relationship between BGSM and HbA_{1c} at the end of the three year period. Duration of monitoring was not a significant predictor of HbA_{1c} (Group 2: β=-0.227, p=0.161, group 3: β =0.124, p=0.324, group 4: β =-0.126, p=0.132).

[1] HbA_{1c} was adjusted for age, sex, ethnicity, educational attainment, block group annual income, occupation, duration of diabetes, diabetes therapy refill adherence, clinic attendance adherence, annual eye examination adherence, self reported diet and exercise, smoking status, alcohol consumption, hospitalization and emergency room visits during the baseline year.

(iii) Cross-sectional studies

Cross-sectional studies are useful for determining prevalence of a condition and are therefore more appropriately and often used to establish the frequency of BGSM (82,105), rather than its relationship with glycaemic control. While an association between BGSM and HbA_{1c} can be established using a cross-sectional design, the direction of that association cannot be determined. Five cross-sectional studies on this subject have been published.

Patrick et al(106) reviewed the records of 200 non-insulin treated diabetes in a United Kingdom hospital clinic. 23.7% of patients were performing blood glucose self-monitoring, either in isolation or in combination with urine monitoring. Comparison of the urine and/or blood self-monitoring group with the non-monitoring group revealed no difference in glycaemic control in those who were currently monitoring (HbA1 9.7 ± 2.2 vs. 9.4 ± 2.0, p=NS). There was no difference noted between the 37 patients in the monitoring group who used results to alter behaviour or prompt contact with their health professionals and the remaining monitoring patients (HbA1 9.5 ± 2.0 vs. 9.9 ± 2.3, p=NS).

Oki et al(107) examined the impact of BGSM in a cross-sectional study in 98 patients with NIDDM in the United States, 61 of whom were using BGSM. Some of the patients interviewed were treated with insulin, but the proportion in the sample was not specified; significantly more insulin-using patients were using BGSM (75% vs. 51%, p=0.02).Glycated haemoglobin was not significantly different between monitoring and non-monitoring groups (10.7 ± 2.2 vs. 10.4 ± 2.5, p=0.18); neither was there a significant difference in glycated haemoglobin based on the frequency of monitoring.

Chan (89) conducted a cross-sectional study in 562 Chinese patients with type 2 diabetes newly-referred to a hospital clinic in Hong Kong. All newly referred patients completed a standard assessment including assessment of monitoring and HbA_{1c} determination. Three hundred and ninety six patients were on drug therapy, with 9% of these taking insulin. HbA_{1c} was significantly lower in patients using BGSM (7.9% vs. 8.6%, p=0.001)

In a cross-sectional sectional study by Harris(108), data from 1480 subjects with type 2 diabetes in the United States were examined. Information on BGSM use was obtained from structured questionnaires while HbA_{1c} measurement was done at a separate clinical visit. Although the patient sample included people treated with insulin, data were analysed according to treatment group. An increase in the proportion of patients testing at least once per week or at least once per day was associated with an increasing HbA_{1c}. No association was noted between the proportion who tested at least once a week and HbA_{1c} in the tablet-treated group; test frequency was however, higher in those diet-treated patients who had higher HbA_{1c}. Logistic regression models revealed no relationship between any of the monitoring groups and HbA_{1c}.

Francioisi et al(109) evaluated the technique in 3567 patients with type 2 diabetes in Italy. The study included patients who were insulin treated, but analysis by treatment group was also presented. Information on BGSM was collected with a self-completed questionnaire, while HbA_{1c} was obtained from the last available clinical value with data regarding BGSM available for 80% of the study population. Linear regression analysis showed that in non-insulin treated patients, monitoring at least once a week or at least once a day was associated with higher HbA_{1c} levels (β=0.27, $p<0.001$, β=0.30, $p=0.008$, respectively) when compared to those who never monitored or did so less than once a week.

Author, Location, Year	Type of diabetes Type of therapy	Sample size	Study design	Comparison groups	Primary glycaemic measure	Findings
Blonde et al USA, 2002(96)	Type 2 Therapy not specified	228	Case control	Poor glycaemic control vs. good glycaemic control	HbA_{1c}	Lower HbA_{1c} in frequent BGSM users
Newman et al, USA, 1990(87)	Type 1, Type 2 Diet, oral, insulin[2]	38 No BGSM (45%) BGSM (55%)	Retrospective cohort	BGSM vs. not monitoring	Glycohaemoglobin	No significant difference between groups
Gilden et al, USA 1990(98)	Type of diabetes not specified Oral (45%) Insulin (55%)	20 Urine (50%) BGSM (50%)	Retrospective cohort	BGSM vs. urine	Glycosylated haemoglobin	No significant difference between groups
Klein et al, USA, 1993(99)	Type 2 Diet (4%) Oral (33%) Insulin (63%)	228 Urine monitoring (21%) BGSM (79%) • < 3 months (8%) • 3-6 months (10%) • 6-12months (18%) • >12 months (64%)	Retrospective cohort	BGSM vs. urine monitoring Different durations of monitoring Different frequencies of monitoring	HbA_{1c}	No significant difference between urine monitoring and BGSM No difference associated with duration of monitoring No difference associated with frequency of monitoring
Rindone et al, USA 1997	Type 2 Sulphonylurea therapy	115 No monitoring (50%) BGSM (50%)	Retrospective cohort	BGSM vs. no monitoring	HbA_{1c}	No significant difference between groups
Wieland et al USA, 1997(101)	Type 2 Sulphonylureas	216 No BGSM (32%) BGSM • 1/day (38%) • ≥2/day (30%)	Retrospective cohort	Different frequencies of monitoring	HbA_{1c}	No significant difference between groups No association between monitoring frequency and HbA_{1c}
Karter et al USA, 2001(102)	Type 2 Diet (27%) Oral (73%)	17 601 Non-adherent(74%) Adherent[3] (26%)	Retrospective cohort	Adherence to BGSM vs. non adherence	HbA_{1c}	Significantly lower HbA_{1c} in those adhering to monitoring recommendations

Table 2.1 Observational studies of blood glucose self-monitoring and glycaemic control

[2] Percentages not specified
[3] See text for definition of adherence

Author, Location, Year	*Type of diabetes Type of therapy*	Sample size	Study design	Comparison groups	Primary glycaemic measure	Findings
Meng et al, Singapore, 2003(103)	Type 2 Diet (19.1%) Oral (72.2% Insulin (1%)[4]	106 Not monitoring (52%) BGSM (48%)	Retrospective cohort	BGSM vs. not monitoring	HbA_{1c}	Significantly lower HbA_{1c} in those monitoring
Wen, USA, 2004(104)	Type 2 Oral	976 No BGSM (16%) Duration of BGSM • 1 year (8%) • 2 years (14%) • 3 years (62%)	Retrospective cohort	Different durations of monitoring	HbA_{1c}	Duration of monitoring not a significant predictor of HbA_{1c}
Patrick et al, UK, 1993(106)	Type 2 Diet (46%) Oral (54%)	200 No monitoring (52%) BGSM or urine (48%)	Cross-sectional	BGSM or urine monitoring vs. no monitoring	Glycated haemoglobin	No significant difference between groups
Oki et al, USA 1997(107)	Type 2 Diet[1] Oral Insulin	98 No monitoring (38%) BGSM (62%)	Cross-sectional	BGSM vs. no monitoring	Glycated haemoglobin	No significant difference between groups
Chan et al, Hong Kong 2000	Type 2 No therapy (9%) Diet (20.6%) Drug (70.5%)	562 No monitoring (75%) BGSM (25%)	Cross-sectional	BGSM vs. no monitoring	HbA_{1c}	Significantly lower HbA_{1c} in monitoring group

Table 2.1 Observational studies of blood glucose self-monitoring and glycaemic control

[4] Figures given for therapy in text do not total 100%

Author, Location, Year	**Type of diabetes Type of therapy**	**Sample size**	**Study design**	**Comparison groups**	**Primary glycaemic measure**	**Findings**
Harris, USA 2001(108)	Type 2 Diet (27.2%) Oral (45.5%) Insulin (27.3%)	1480 BGSM use (a) Oral agents • Never or <1/month (65.2%) • 1-3/month (9.2%) • 1-6/week (21.0%) • ≥ 1/day (4.6%) (b) Diet • Never or < 1/month (79.7%) • 1-3/month (4.6%) • 1-6/week (9.2%) ≥ 1/day (6.5%)	Cross-sectional	Different frequencies of BGSM	HbA_{1c}	No association between frequency and HbA_{1c}
Franciosi et al, Italy 2001(109)	Type 2 diabetes Diet[1] Oral Insulin	BGSM[5] • Never (38%) • <1/week (14%) • ≥ 1/week (31%) • ≥ 1/day (17%)	Cross sectional	Different frequencies of monitoring	HbA_{1c}	More frequent monitoring associated with poorer glycaemic control

Table 2.1 Observational studies of blood glucose self-monitoring and glycaemic control

[5] Data by treatment type not available

2.1.3 Intervention studies

Intervention or experimental studies represent the most rigorous form of epidemiological inquiry. In these studies, the investigator determines which patients are exposed to the factor of interest and therefore has greater control over the study conditions(94). In a study with appropriate randomization and sample size, this study design can provide results with a greater deal of validity than is possible in observational studies(97). Seven uncontrolled trials and one non-randomized controlled clinical trial have been performed and are summarized in Table 2.2.The gold standard epidemiological study is however, the randomized controlled trial (RCT) and eleven such trials have been conducted to evaluate BGSM and are summarized in Table 2.3.

(i) Uncontrolled intervention studies

Cohen and Zimmet(110) evaluated the technique in 66 patients consecutively referred to an Australian diabetes centre. Twenty percent of these patients received dietary treatment only, while the remainder were on oral therapy. Patients were instructed in the use of a reflectance meter and asked to record blood glucose before each meal and at bedtime; post prandial monitoring was also included as the study progressed. Patients were reviewed as clinically indicated (usually between one and three months) with advice on diet and exercise given and therapy adjustments made, depending on blood glucose profile and body weight. The authors reported an average weight loss of 5 kilograms (kg) per patient. 56.6% of patients on oral therapy had their therapy withdrawn or dosage reduced, while none of the diet treated patients required addition of oral agents.

Martin et al(88) investigated home blood monitoring in 22 elderly patients on sulphonylurea therapy in the United Kingdom. Subjects were taught to use blood glucose monitoring strips and asked to monitor five times a day (fasting, mid-morning, mid-afternoon, mid-evening and 3.00 a.m.) at two-week intervals. Patients then had to visit the hospital the day after testing so blood glucose levels could be recorded and hypoglycaemic therapy adjusted if necessary. Mean glycosylated haemoglobin fell from 13% to 9.3% ($p<0.0001$) over the sixteen week period.

Malik(111) conducted an uncontrolled intervention study in 16 patients (including insulin-treated patients) with NIDDM in the United States. All participants received instruction in BGSM and individualized instruction on planning low-calorie meals. A two calorie-level meal plan was provided and patients were asked to follow the exchanges for the normal calorie meal plan if their pre-meal blood test was below 180 mg/dl or urine test was negative. If the blood test was above this level or their urine test was positive, they were asked to use the low calorie exchange plan. Glycosylated haemoglobin decreased from a mean of 11.0 ± 2.9% to 9.9 ± 2.4% and weight decreased from a mean of 200.5 ± 26 pounds to 197.2 ± 31 pounds, but neither of these reductions was statistically significant.

Rindone(112) examined the effect of restricting BGSM strips in patients with tablet-treated type 2 diabetes in the United States. Medical records for 68 patients were reviewed over a two year period. In the first year, there were no restrictions on strips, but during the second year, patients were limited to one bottle (50 strips) every three months. No difference in mean haemoglobin was noted between the first and second year (8.3 ± 1.3% vs. 8.0 ± 1.5%, p=0.30).

Meier et al(113) evaluated glycaemic control after reduction in BGSM in an uncontrolled clinical study and compared glycaemic control between monitoring and non-monitoring groups in a retrospective study in an American veteran population. Patients were included if they had records of a BGSM strip prescription filled in both the six month baseline period and the six month follow-up period. Patients with non-insulin treated type 2 diabetes who were already monitoring their blood glucose had their prescriptions limited to 50 strips within a 90 day period. The number of strips issued was determined from an electronic database that recorded prescription refills. HbA_{1c} was recorded before and after the BGSM strip policy was implemented in 471 subjects. There was no significant change in mean HbA_{1c} after strip reduction (data for medication cohort: baseline:7.82 ± 0.22%; post-implementation: 7.83 ± 1.21%, p=NS). Linear regression of HbA_{1c} as a function of changes in strip use frequency did not reveal a significant impact on glycaemic control either. Patients who did (n=1055) and did not use BGSM (n=897) during a one year period were also compared. Patients were classified as using BGSM if they had filled at least one prescription for strips during the study interval, which overlapped with the intervention study. Patients who

monitored had significantly lower HbA_{1c} (7.84 ± 0.04%) than those who did not (8.27 ± 0.05%) ($p<0.0001$).

BGSM was evaluated as part of a diabetes self-management programme in a community clinic in the United States(114). Seventy patients with type 2 diabetes were recruited to the programme which involved group diabetes education, individual dietary counseling and monthly support meetings where behaviour changes, glycaemic control, weight and medication were discussed. Participants were all given blood glucose meters and asked to test daily and keep a record. Mean HbA_{1c} improved significantly from 9.7 ± 2.4% to 8.2 ± 2.0% ($p<0.001$).

The efficacy of BGSM in seven Japanese pilots with diet controlled type 2 diabetes who had been grounded for hyperglycaemia was evaluated(115). Participants were taught to monitor their blood sugar and then had review sessions during the course of the study. Fasting blood glucose measures were done at least three times weekly with occasional post prandial readings. HbA_{1c} and fasting values were assessed at regular medical check ups. Fasting blood glucose significantly improved after six months; a decrease in HbA_{1c} was not, however, significant (5.8 ±0.7% vs. 5.4 ±0.4%).

(ii) Non-randomized controlled clinical trials

Ozmen and Boyvada(116) evaluated the relationship between BGSM and HbA_{1c} in patients in Turkey with both Type 1 and Type 2 diabetes. Three hundred and fifteen patients, 259 of whom used BGSM, took part in a training program. The remaining 56 patients, all of whom had type 2 diabetes, were used as the control group; treatment modality in this group was not specified. Two hundred and thirty eight patients with type 2 diabetes were included in the monitoring group. These patients, who had never monitored before, were included with no restriction on treatment modality and 99 of them were on insulin therapy.

All patients took part in an educational programme that focused on diabetes-related topics, while patients in the monitoring group were taught to measure their blood glucose. Patients were asked to monitor their fasting and post-prandial glucose levels two or three times a week for the first month; during the rest of the trial they monitored

as necessary to maintain normoglycaemia (the frequency was not specified). Fasting and post prandial glucose measurements were done every two to three months in the control group. There was no significant reduction in HbA_{1c} in either the control group or in patients with type 2 diabetes at 12 months. Analysis of patients with type 2 diabetes by treatment group also failed to reveal any significant changes in HbA_{1c} within groups. The same authors did report a significant reduction in HbA_{1c} between baseline and 6 months (9.09 ± 2.61 vs. 7.87 ± 1.78, p=0.001) and baseline and twelve months (9.09 ± 2.61 vs. 7.21 ± 1.3, p=0.001) in those who monitored in a second paper on this study(117). The sample reported in the second paper included 29 more participants which may account for the discrepancy. The second paper also reported a subgroup analysis in patients with and without diabetic retinopathy. There was a significant difference in HbA_{1c} reduction between those with normal fundi and background retinopathy and those with normal fundi and proliferative retinopathy, but not between those with background and proliferative retinopathy.

Author Country Year	*Study design*	*Sample size*	**Inclusion criteria**	**Intervention**	**Groups in study**	**Duration**	**Main glycaemic measures**	**Main findings**
Cohen et al, Australia 1983(110)	Uncontrolled intervention	66	Type 2 DM Diet or oral therapy Consecutive referral for BGSM instruction	BGSM	Single group before and after intervention	Not specified	Blood glucose	Reduction on blood glucose, reduction in hypoglycaemic therapy
Martin et al, UK, 1986(88)	Uncontrolled intervention	22	Type 2 DM Sulphonylurea therapy Age > 65 years	BGSM	Single group before and after intervention	16 weeks	HbA1	Significant improvement in HbA1
Malik et al, USA, 1989(111)	Uncontrolled intervention	16	Type 2 DM Glycosuria or BGSM>180mg/dl twice weekly Not adjusting caloric intake	Dietary education and instruction BGSM or urine monitoring Dietary adjustment based on monitoring result	Single group before and after intervention	12 weeks	Glycated haemoglobin	Non significant decrease in HgA1
Tajima et al, Japan 1989(115)	Uncontrolled intervention	7	Type 2 DM	BGSM	Single group before and after intervention	6 months	HbA_{1c} Fasting blood glucose	No change in HbA_{1c} Significant improvement in fasting blood glucose
Rindone, 1998(112)	Uncontrolled intervention	68	Type 2 DM Oral therapy BGSM strips provided in first year of study period	Restriction in BGSM strips in second year of study	Single group before and after intervention	2 years	HbA_{1c}	No difference in mean HbA_{1c}

Table 2.2 Uncontrolled intervention and non-randomized controlled clinical studies of blood glucose self-monitoring and glycaemic control

Author Country Year	Study design	Sample size	Inclusion criteria	Intervention	Groups in study	Duration	Main glycaemic measures	Main findings
Meier et al USA, 2002(113)	(a) Uncontrolled intervention study (b) Retrospective cohort	(a) 471 (b) 1467	Type 2 DM Diet or oral therapy (a) Received BGSM strips during baseline and post implementation period (b) Filled at least 1 prescription in 1 year interval	(a) Reduction in prescribed BGSM strips (b) N/A	(a) Single group before and after intervention	6 months	HbA_{1c}	(a) No significant change (b) Significantly lower HbA_{1c} with BGSM
Banister et al, USA 2004(114)	Uncontrolled intervention	70 Insulin (17%)	Type 2 DM	Self management training programme with diabetes education, dietary counseling; support meetings; BGSM with daily monitoring	Single group before and after intervention	Variable (2-12 months)	HbA_{1c}	Significantly lower HbA_{1c}
Ozmen et al Turkey 2002, 2003(116,117)	(a) Non-randomized controlled clinical trial (b) Uncontrolled intervention	(a) 315 Type 2=238 (insulin 42%) (b) 267	(a) Type 1 or type 2 DM (b) Type 2 DM	(a) BGSM; DM education (b) BGSM; DM education	(a) Control group: DM education Intervention group: DM education, BGSM (b) Single group before and after intervention	12 months	HbA_{1c}	(a) No significant change in HbA_{1c} (b) Significantly lower HbA_{1c}

Table 2.2 Uncontrolled intervention and non-randomized controlled clinical studies of blood glucose self-monitoring and glycaemic control

(iii) Randomized controlled trials

Wing et al(118) examined whether BGSM improved dietary compliance in obese patients with type 2 diabetes in the United States. Fifty patients, approximately half of whom were using insulin, were randomized to one of two groups. The first group was exposed to a standard behavioural weight reduction program. Participants were given target caloric intake based on their baseline weight and asked to monitor their intake. Specific goals to assist in limiting high calorie foods and increasing fibre were later introduced and exercise was also encouraged. Blood glucose was checked at each meeting to facilitate medication adjustment according to a standard algorithm. Participants in the second group, in addition to the standard program, were taught to monitor blood glucose and were educated about the relationship between blood glucose and weight. They were given monitoring strips and asked to perform five fasting and two pre- and post- prandial measurements weekly. This was reduced to five fasting values after three months. Participants in this group were encouraged to maintain glucose targets by modifying intake and to observe relationships between lifestyle and blood glucose values. Medication was adjusted by health care professionals according to the same algorithm. At the end of the study there was no significant difference in glycosylated haemoglobin between the weight control group (10.44 ± 2.16%) and the self-monitoring group (10.19± 2.29%).

Rutten et al(119) evaluated the effect of a blood glucose self-monitoring protocol in general practice in the Netherlands. One hundred and forty nine patients from four control practices and four experimental practices were recruited. Sixty-six patients were in the experimental group and of these, 33 monitored their blood glucose at home (subgroup 1). The remaining two subgroups in the experimental group comprised 20 patients who were unwilling or unable to self-monitor (subgroup 2) and 13 patients who had been under specialist care (subgroup 3). Patients were instructed to monitor if they were feeling unwell, after abnormal meals or if they were curious about the level of their blood sugar and they contacted the practice nurse monthly to report the fasting glucose level. Patients saw their GP at six monthly intervals or if their BGSM values were outside of pre-determined limits. Patients in the experimental group who were not self-monitoring saw their GP at least four times annually. At these visits, feedback on current blood glucose level was given and the need for good

diabetes control, weight loss and physical activity emphasized and therapeutic goals and strategies to overcome difficulties were agreed. For all patients in the experimental group, a therapeutic algorithm was used with fixed targets for weight and blood sugar regulation. In the control group, there were no fixed follow-up appointments or therapeutic scheme. There was a 0.38% decrease in HbA_1 in the experimental group which was significantly different from the 0.46% increase in the control group ($p<0.01$), after adjustment for baseline HbA_1 which was significantly higher in the experimental group. There was also a reduction within the experimental subgroups, but none of these was significant.

Fontbonne et al(120) carried out a randomized controlled trial in France, comparing regular HbA_{1c} monitoring, urine monitoring and BGSM in 208 non-insulin treated participants. Patients in the first group had an HbA_{1c} every two months and had the result sent to them with the physician's comments on metabolic control. The second group was asked to monitor twice every other day on the first urine voided in the morning and the first voided after the evening meal with an additional test after the evening meal on Sundays. Participants in the third group were asked to test blood sugar twice every other day, fasting and 2 hours after the evening meal with an extra test two hours after lunch on Sundays. No specific algorithm for behaviour change was used although personal dietary recommendations were discussed. Patients were seen at two-monthly intervals for six months and physicians modified dietary or hypoglycaemic therapy at visits depending on metabolic control. Fifty subjects were needed per group in order to ensure a 90% probability of detecting a maximum difference of 0.75% between groups at the 5% significance level. Changes in HbA_{1c} and weight were not significant between groups although there was a positive correlation between the number of strips used and HbA_{1c} in the monitoring group ($r=0.36$, $p<0.02$).

Allen et al(121) compared blood glucose self-monitoring with urine monitoring in 54 patients with non-insulin treated diabetes in the United States who were naïve to BGSM. All participants received dietary counseling with particular emphasis on increasing fibre intake. Patients randomized to the urine group were asked to check their urine before each meal every other day, striving for negative checks. Those in the BGSM group were asked to check their blood glucose before each meal every other

day and aim for fasting levels of less than 7 mmol/l and pre-lunch and pre-dinner levels of 8.8 mmol/l. Alterations to therapy were physician-initiated and guided by a specific algorithm based on self-monitoring results and monthly fasting blood results. Sample size estimates were calculated to detect 25% improvement in any of the major outcome variables at 5% significance level with 95% power. Significant reductions in fasting plasma glucose and HbA_{1c} were noted within both the urine and blood self-monitoring group, but these reductions were not significantly different between groups. There were no significant changes in weight either between or within groups.

Estey et al(122) evaluated the relationship between BGSM frequency and glycaemic control after a follow-up intervention in 60 patients with non-insulin treated type 2 diabetes in Canada. Participants were randomized to either a control or intervention group. All participants received a three day educational program comprising group diabetes education with individual educational and dietary sessions. One month after the initial session, a brief review was held. All subjects were taught to monitor blood glucose and to do so at a mutually agreed frequency and record their results. The intervention group commenced 10 weeks of follow-up two weeks after the education session. Follow-up was intended to reinforce skills and provide support and consisted of a series of telephone contacts and a visit from a nurse. Dietary and blood glucose self-monitoring practices were reinforced at each contact. HbA_{1c} was measured in both the control and intervention groups 12 weeks after the education session. Participants in the intervention group monitored significantly more frequently but there was no significant improvement in HbA_{1c}.

Gallichan(123) compared glycaemic control in 27 patients randomly allocated to either urine or blood testing in the United Kingdom. Randomized patients had previously been monitoring their urine. All participants were educated about their monitoring method and asked to monitor twice a day (before breakfast and after the main meal) on two days of the week and record their results. Participants visited their surgeries monthly for the six months of the trial and had their glycaemic control assessed by venous fructosamine measures. A small increase in fructosamine was noted in the blood monitoring group, and a small decrease in the urine group, but the difference between these was not significant.

Muchmore et al(124) investigated the effect of using BGSM to facilitate carbohydrate counting in 29 obese patients with non-insulin treated type 2 diabetes in the United States. All randomized patients were assigned to one of four groups and took part in an eight week run-in period during which all groups were exposed to a formal weight control program. Patients also participated in individual counseling sessions with a diabetes nurse educator and dietician. After the initial run-in period, three groups were randomly assigned to control or BGSM interventions while the fourth group was used as a control. Patients in the intervention group received individual and group counseling on the concept of carbohydrate counting, while control groups had a similar number of appointments focusing on general principles of nutrition. Patients in the intervention group were also taught to monitor their blood glucose at home and asked to monitor before and two hours after each meal for the initial four weeks. Monitoring frequency was then reduced to before and after a single meal for the next 16 weeks. Education focused on post prandial glucose as a function of carbohydrate intake and encouraged modification of diet and exercise. Compliance was assessed by checking meter memory. There was significant improvement within the BGSM group (1.54%, $p<0.05$), but this was not significantly different from the improvement noted in the control group. Changes in weight were not significant between groups.

Jaber et al evaluated a pharmaceutical care model in patients with type 2 diabetes attending a clinic in the United States(90). Forty-five patients were randomized, but a per protocol approach was used to analyse the data for the 39 patients who completed the study. The twenty-two participants in the control group received standard care from their physician while the 17 in the intervention group received general diabetes education and counselling on diet, exercise, medication and BGSM. Patients in the intervention group were asked to monitor four times a day two days a week and these values were used to guide hypoglycaemic therapy. After four months, there was significant improvement within the intervention group and the difference between final glycated haemoglobin between groups was also significant ($2.2 \pm 2.6\%$ vs. $0.1 \pm 3.0\%$, $p<0.05$), with a correlation between magnitude of glycated haemoglobin change and baseline values.

BGSM was compared in 10 sulphonylurea-treated patients in the United States(93). All patients had $HbA_{1c} \geq 8\%$ and were either randomized to the control group in which they

received a standardized treatment algorithm incorporating diet, exercise and medication adjustments or the intervention group in which they were asked to use BGSM in addition to being treated according to the algorithm. Six months after randomization, there was a significant reduction in HbA_{1c} in the intervention group (10.6% to 9.2%, $p<0.05$), but no change in the control group.

Miles et al(125) compared blood and urine testing in 150 newly diagnosed type 2 diabetics in the United Kingdom. Participants were asked to test their urine once daily, either at bedtime or before or two hours after a meal, aiming for aglycosuria or to test blood glucose daily either before a meal or at bedtime, aiming for values less than 8 mmol/l. After three months, participants were switched to the other monitoring method and after 6 months, patients continued with their preferred method for a further six months. All participants took part in a structured education programme. There was no significant difference in glycosylated haemoglobin at any of the three, six or twelve month time points.

Kibriya et al(126) conducted a randomized controlled trial in Bangladesh in 64 patients with type 2 diabetes[6]. Patients were allocated to two groups- in one group patients attended monthly hospital visits while in the second group patients monitored their blood glucose at home and attended three-monthly hospital visits. All patients were treated to target fasting plasma glucose less than 6 mmol/l and HbA_{1c} less than 7% and both groups received health education including the need for glycaemic control, dietary control, monitoring of urinary sugar, self-adjustment of medication and hypoglycaemia. Patients in the blood glucose self-monitoring group were taught how to use the meters and advised to monitor three times a day (fasting and two hours after each of breakfast and lunch) at two weekly intervals. If BGSM values were above target (fasting 6 mmol/l, 2 hr post-prandial 7.8 mmol/l), the patient was advised to adjust their insulin or oral hypoglycaemic medication accordingly and re-check the reading within 4-5 days. Patients in group 1 visited their physician monthly and had their medication adjusted if necessary. There was a significant decrease in HbA_{1c} in patients not using BGSM through 15 months of follow-up but this was not sustained at the end of the study at 18 months, while significant reduction in HbA_{1c} was noted in

[6] 11 patients discontinued follow up after three months and were replaced by a further 11 patients who were not randomized.

group 2 at 18 months (8.48 ± 1.44 to 7.11 ± 1.08, p=0.022). There was also a significant reduction in fasting blood glucose in group 2. No comparison was done to see whether the differences in HbA_{1c} reduction were significant.

BGSM was evaluated as part of a culturally appropriate intervention in 256 Mexican Americans(127), 25% of whom were taking insulin. Participants in the intervention group received intensive instruction on nutrition, exercise, other self care activities and BGSM and participated in support group sessions where behaviour change was promoted through problem solving, while those in the control group received regular care. After 12 months, the mean HbA_{1c} in the experimental group, adjusted for baseline HbA_{1c} was significantly lower (10.87% vs. 11.66%, p=0.011).

Schwedes et al(128) evaluated meal-related structured BGSM in 250 non-insulin treated diabetics in Germany and Austria. Patients were randomized into one of two groups with the monitoring group checking blood glucose before and one hour after each main meal twice weekly and recording the results and their eating habits in a combined diary. Patients were informed that BGSM would provide day-to-day information to facilitate changes in diet and lifestyle. Patients were seen on a monthly basis with those in the intervention group receiving a defined counseling algorithm which was aimed at promoting self-perception, self-reflection and self-regulation and participants in the control group receiving non-standardized counseling focused on diet and lifestyle. The study had 80% power to detect a mean difference of 0.7% in HbA_{1c} between the two groups. The per-protocol analysis revealed HbA_{1c} had improved in both groups after 24 weeks, with the change between the two groups at the endpoint being statistically significant (0.54 ± 1.41% vs.1.0 ± 1.08%) .

A telephone intervention to improve glycaemic control was evaluated in 50 Korean patients with type 2 diabetes(91). Forty percent of patients were taking insulin. Patients in the control group received standard care, while those in the intervention group received diabetes education and twelve weeks of telephone contacts during which diet, exercise, medication adherence and frequent BGSM were encouraged. Participants were asked to log at least two BGSM results daily and to keep daily records of diet and activity. Diet records were analysed and dietary recommendations were made on the basis of intake and exercise and posted back to patients.

Medication adjustments were made after review of blood glucose logs. There was a significant decrease in HbA_{1c} in the intervention group (1.2%, p=0.002), while those in the control group had a significant increase (0.6%, p=0.005).

The Auto-Surveillance Intervention Active (ASIA) study(129) was a randomized, controlled trial conducted in tablet-controlled patients with type 2 diabetes in France. Recruited patients had HbA_{1c} between 7.5% and 11% and were naïve to BGSM. All patients received dietary advice and guidelines for self-adjustment of diet while walking was encouraged as exercise. Those randomized to the conventional group had HbA_{1c} measured every twelve weeks, while those in the self-monitoring group, in addition to HbA_{1c} measurements, were asked to monitor their blood sugar at least six times a week. Therapy adjustments in both groups were made at the 12 week visit by the general practitioner based on the HbA_{1c} measurements. Nine hundred and eighty eight patients were randomized, but 689 (345 in BGSM group and 344 in conventional group) were included in the final modified intention to treat analysis[7]. Two hundred and thirty four patients were required in each group for 90% power to detect a difference of 0.5% HbA_{1c} between the two groups at 5% significance level. The mean reduction in HbA_{1c} in the BGSM group after 24 weeks was significantly greater than in the control group (0.88 ± 1.54% vs. 0.60 ± 1.54%, p=0.009), with the improvement in HbA_{1c} occurring primarily in the first three months. Multivariate analysis also revealed that BGSM was predictive of improvement in HbA_{1c} of more than 0.5% (odds ratio=0.665, p=0.015). No significant differences were found in fasting blood glucose or change in weight.

Kwon et al evaluated an internet–based glucose monitoring system in 110 Korean patients with type 2 diabetes(130). Participants in the control group were encouraged to monitor one to three times a day and thereafter received usual clinical care where they were provided with lifestyle and medication advice at regular visits. Participants in the intervention group sent fasting and post-prandial BGSM results, diet and exercise information and medication information to researchers via a website. Recommendations for lifestyle of medication alteration were also transmitted to patients via the website, although no standard algorithm was used. Participants were

[7] The remaining patients were excluded from the analysis because of the unavailability of the primary criterion of at least two evaluations of HbA_{1c} at least two months apart.

also prompted to send BGSM results for review if they did not do so spontaneously. The study had 80% power to detect a change of 0.75% in HbA_{1c} at a 5% significant level. Participants in the intervention group monitored significantly more frequently than those in the control group. There was a significant reduction in HbA_{1c} within the intervention group (0.54%, $p<0.05$) with follow-up HbA_{1c} adjusted for baseline significantly lower in the intervention group (7.62 ± 0.13% vs. 6.94 ± 0.13%, $p<0.001$). Analysis of non-insulin treated patients revealed a significant difference in change between the monitoring and non-monitoring groups (0.84%, $p<0.05$)(131).

BGSM was also evaluated in 88 non-insulin treated patients in the United States(92). Patients in the control group saw a dietician at regular intervals and had two monthly HbA_{1c} evaluations and fasting plasma glucose levels measured according to a pre-existing algorithm. Participants in the intervention group followed a similar programme and were asked to assess pre-and post prandial glucose around a single meal on six days a week. Nutritional counseling at dietary visits was based on BGSM results. Treatment decisions were made on the basis of FPG and HbA_{1c} by a nurse who was blinded to randomization. An intention to treat analysis was done and revealed a significant decrease in HbA_{1c} in both groups (control:0.85 ± 1.61%, $p<0.001$; intervention: 0.62 ± 2.11%, $p=0.05$), but not between groups. There was also no correlation between frequency of monitoring and HbA_{1c} in the intervention group.

2.1.4 Systematic Reviews

A criteria based literature review by Faas et al(132) published in 1997 reviewed the subject. Eleven papers were identified, four of which were uncontrolled prospective studies, one a retrospective study and the remaining six, randomized controlled trials. Of the six randomized controlled trials(118-122,133) of BGSM in non-insulin treated type 2 diabetes, only four of these(118-121) met the quality criteria of the review. No meta-analysis of outcome data was performed, but the authors concluded that the efficacy of the method was still questionable, given that five of the randomized trials concluded that there was no evidence of efficacy. A similar conclusion was reached by Griffith et al(134) in her review of the subject.

Coster et al(135,136) published a systematic review and meta-analysis in 2000. Eighteen publications were identified, eight of which were randomized controlled trials. Six randomized controlled trials were included in the meta-analysis with the other two being excluded, one because the outcome measure was fructosamine(123) and the other because it was cluster randomized(119). Meta-analysis of four trials which compared blood or urine monitoring with no monitoring(118,120,122,124) revealed no significant difference while meta-analysis of three trials comparing blood and urine monitoring(120,121,125) revealed no significant difference between these methods.

Sarol et al(131) published a meta-analysis of trials that compared BGSM groups to non- BGSM groups. Trials which compared BGSM to urine monitoring(121,123,125) and those in which only combined data for insulin treated and non-insulin treated were available (91,118,126,127) were excluded from the analysis. One further study was excluded because there were significant baseline differences and therapeutic schemes between groups(119). An additional study was excluded because standard errors for the HbA_{1c} outcomes were not available from the abstract(93).
Meta-analysis of the remaining eight studies(90,92,120,122,124,128-130) resulted in a weighted mean difference in HbA_{1c} of -0.39% (95% confidence intervals:-0.54%, -0.23%) under a fixed effects model and a similarly significant result under a random effects model. Exclusion of Jaber et al(90) which had the largest effect on HbA_{1c} still resulted in a significant difference in treatment groups as did an analysis omitting Guerci et al(129) which had a high attrition rate and one omitting the studies by Kwon et al(130) and Schwedes et al(128) which conducted per protocol analyses, a method which may have produced detection bias and been more likely to produce a positive intervention effect(137). The effect size was reduced, but still significant when the three studies with the lowest quality ratings(90,122,130) were excluded[8]. Stratified analysis revealed the summary measure of effect was greater in studies with confounded interventions which included components other than BGSM(90,122,128,130) than those without(92,120,124,129), although in both instances the summary measure was statistically significant.

[8] Studies had lower quality due to non-comparability of treatment components

Author Country Year	Sample size	Inclusion criteria	Groups in study	Duration	Main glycaemic measures	Main findings
Wing et al, USA, 1986(118)	50	Age 35-65 years ≥ 120% ideal weight DM after age 30 Naïve to BGSM	Weight control group: monitoring of intake; dietary and caloric goals; walking encouraged; behaviour modification techniques presented Intervention group: as with weight control group, BGSM 7 times a week; Caloric intake and expenditure modified to reach BGSM target	12 months	Glycosylated haemoglobin	No significant difference
Fontbonne et al, France, 1989(120)	208	Type 2 DM Poorly controlled Diet or oral therapy Glycosuria DM ≥ 3 years Regular attendance at DM clinic	Control group: Two-monthly HbA_{1c} with physician feedback on control Urine monitoring: seven tests weekly BGSM: 7 tests weekly	6 months	HbA_{1c}	No significant difference
Rutten et al, The Netherlands 1990(119)	149	Type 2 DM≥ 6 months Age 40-75 years Diet or oral therapy	Control group: Usual clinical care Experimental group[9] Sub group 1:BGSM with specified targets; reported results to nurse or GP; therapeutic algorithm Subgroups 2&3:Glucose control feedback from GP, education on DM and weight control; therapeutic algorithm	12 months	HbA_1	Significant improvement in experimental group; non-significant decreases in sub groups

Table 2.3 Randomized controlled trials of blood glucose self-monitoring and glycaemic control

[9] See text for description of subgroups

Author Country Year	*Sample size*	*Inclusion criteria*	**Groups in study**	**Duration**	**Main glycaemic measures**	**Main findings**
Allen et al, USA 1990(121)	61	Type 2 DM Diet and oral therapy Fasting glucose 8.8-22mmol/ l No history of ketoacidosis Naïve to BGSM	Urine monitoring group: dietary advice; urine monitoring at least 36/month; physician initiated treatment alterations based on algorithm BGSM: dietary advice, alternate day pre-meal monitoring; physician initiated treatment alterations based on algorithm	6 months	Glycosylated haemoglobin Fasting glucose	Significant change in glycosylated haemoglobin and fasting glucose within groups; no significant difference between groups
Estey et al, Canada 1990(122)	60	Type 2 DM Diet or oral therapy Willing to use BGSM Accessible by telephone	Control group: education programme, dietary counseling, BGSM Intervention group: education programme, dietary counseling, BGSM, telephone intervention to reinforce BGSM	4 months	HbA_{1c}	No significant difference
Gallichan, UK 1994(123)	27	Type 2 DM Oral therapy Urine monitoring	Urine monitoring: twice daily twice a week BGSM: twice daily twice a week	6 months	Fructosamine	No significant difference
Muchmore et al, USA 1994(124)	29	Type 2 DM≥ 1 year Age 40-75 years Obese Diet or oral therapy HbA_{1c} 9.5-13.5% No BGSM within 3 months No previous CHO counting	Control group: behavioural weight control program; dietary counseling Intervention group: behavioural weight control programme, dietary counseling; instruction in carbohydrate counting, BGSM six times daily[10]	44 weeks	HbA_{1c}	No significant difference
Jaber et al, USA 1996(90)	45	Type 2 DM	Control group: Standard medical care Intervention group: DM education, diet, exercise, medication counseling; BGSM	4 months	Glycated haemoglobin	Significant improvement in intervention group Final glycated haemoglobin significantly lower in intervention group

Table 2.3 Randomized controlled trials of blood glucose self-monitoring and glycaemic control

[10] Reduced to twice daily after 4 weeks

Author Country Year	*Sample size*	*Inclusion criteria*	*Groups in study*	*Duration*	*Main glycaemic measures*	*Main findings*
Seaton, USA, 1996(93)	10	Type 2 DM Sulphonylurea therapy $HbA_{1c} \geq 8\%$	Control group: standardized diet, exercise and drug therapy Intervention group: standardized diet, exercise and drug therapy and BGSM	6 months	HbA_{1c}	Significant improvement in intervention group
Miles et al, UK 1997(125)	150	Newly diagnosed type 2 DM	Urine monitoring group: structured education; daily testing BGSM group: structured education, daily testing	6 months	HbA_{1c}	No significant difference
Kibriya et al Bangladesh, 1999(126)	64	Type 2 DM Oral or insulin therapy	Control: health education Intervention: health education and BGSM two to three times daily at fortnightly intervals with medication adjustment depending on results	18 months	HbA_{1c} Fasting blood glucose 2 hr post prandial glucose	Significant reduction in BGSM group in HbA_{1c} and fasting blood glucose
Brown et al, USA 2002(127)	256	DM after age 35 Age 35-70 Oral or insulin therapy	Control: usual care Intervention: Education on nutrition, exercise, self care, BGSM and support group sessions on behaviour change	12 months	HbA_{1c}	Significantly lower in intervention group
Schwedes et al Germany, Austria 2002(128)	250	Type 2 DM≥ 3months BMI >25 kg/m^2 HbA_{1c}7.5-10% Age 40-75 years Diet or oral therapy DM education within 2 years No regular BGSM	Control: Non standardized diet and lifestyle counseling Intervention: BGSM before an dafter meals twice weekly; counseling algorithm	6 months	HbA_{1c}	Significantly greater decrease in HbA_{1c} in intervention group
Oh et al, Korea 2003(91)	38	Type 2 DM Able to perform BGSM HbA_{1c}>7%	Control: routine group Intervention: diabetes education, BGSM at least twice daily, telephone reinforcement, dietary plans, medication adjustment based on BGSM	12 weeks	HbA_{1c}	Significant decrease in intervention group

Table 2.3 Randomized controlled trials of blood glucose self-monitoring and glycaemic control

Author Country Year	*Sample size*	*Inclusion criteria*	**Groups in study**	**Duration**	**Main glycaemic measures**	**Main findings**
Guerci et al, France, 2003(129)	988	Type 2 DM >1 year Inadequate glycaemic control Aged 40 - 75 years Diet or oral therapy Naïve to BGSM	Control group with dietary and physical activity advice Intervention group with diet and physical activity advice and BGSM at least six times weekly	24 weeks	HbA_{1c} Fasting blood glucose	Significantly greater decrease in HbA_{1c} in intervention group No change in fasting blood glucose
Kwon et al Korea 2004(130)	110	Type 2 DM≥1 year Internet access No previous web-based interventions	Control: BGSM, standard care Intervention: BGSM at least 3/week, web-based submission of results and feedback of recommendations	12 weeks	HbA_{1c}	Significant decrease in intervention group[11] Significantly lower HbA_{1c} in intervention group
Davidson et al, USA 2004(92)	88	Type 2 DM Diet or oral therapy	Control: Dietary counseling, treatment modification based on lab FPG and HbA_{1c} Intervention: BGSM before and after a meal 6/week; dietary counseling based on BGSM results; treatment modification on lab FPG an $dHbA_{1c}$	12 weeks	HbA_{1c}	Significant reduction within intervention group No difference between groups

Table 2.3 Randomized controlled trials of blood glucose self-monitoring and glycaemic control

[11] These significant changes were evident in the entire group and the non-insulin treated patients

2.1.5 Summary of epidemiological evidence

Five of the fifteen observational studies reported lower HbA_{1c} in patients using BGSM (89,96,102,103,113). Conclusions from observational studies must, however, be interpreted in light of the methodological limitations of the studies. While an association between BGSM and glycaemic control can be shown, determination of causality is limited by the study design. Both in studies reporting positive and negative findings, use of BGSM was determined by self-report or from pharmacy databases which may not be a true reflection of whether patients monitored or not and only two studies(101,102) reported analyses adjusted for potential confounders. In the case-control study which reported a positive association, no data on the characteristics of the groups were presented, limiting assessment of comparability.

Three of the eight uncontrolled intervention studies reported an improvement in glycated haemoglobin (88,114,117). Interpretation of these is limited by the absence of a control group which differed from the experimental group only by exposure to the intervention- there is no way of assessing definitively whether these changes would have occurred in the absence of the intervention due to other factors such as therapy modification. The single non-randomized controlled clinical trial reported found no significant change in HbA_{1c}(116) but was limited by the non-random allocation of the control group which had significantly different baseline characteristics from the intervention group and the analyses which did not however take these baseline differences into account.

Ten of sixteen randomized controlled trials reported a significant reduction in HbA_{1c}. These RCTs had several limitations related to study design, including sample size and power, comparability of interventions, methods of monitoring used and analyses of results. Three of the RCTs compared BGSM with urine monitoring (121,123,125) and four of them included both insulin-treated and non-insulin treated participants (91,118,126,127), limiting conclusions about the virtues of BGSM compared with no monitoring and the use of the technology in non-insulin treated patients respectively. Sample size ranged

from 27 to 988, but only four studies had a sample size over 200 and a priori power calculations designed to detect reductions in HbA_{1c} of 0.5% or more.

Interventions used in the RCTs varied widely. Comparability between control groups and intervention groups may have been confounded by the presence of other elements in the intervention that could have contributed to improved control. For example, in one study which reported a significant decrease in HbA_{1c}, the control group received non-standardized dietary counseling, while the intervention group, in addition to performing BGSM, received standardized counselling according to a pre-determined counseling algorithm aimed at supporting diet and lifestyle changes(128).

Monitoring techniques also varied as did methods of ensuring that patients' techniques were accurate and that there was compliance with monitoring regimens. Of the six studies which reported the type of meter used, three(120,121,124) used reflectance meters, which were more cumbersome to use and may have affected patient compliance. Compliance was usually assessed with self-reported measures, with only one study assessing meter memory(124) and another using a "marked-item" technique(118).

The randomized trials reported were also limited by the analyses performed. Of the twelve studies in which type of analysis could be determined, only one reported performing a modified intention to treat analysis(129). Per protocol analyses may result in detection bias as the reasons for non-adherence may be related to outcome(137). The study which reported a modified intention to treat analysis may also have been subject to detection bias as participants had to remain in the study for a minimum of three months to be included in the analysis. Characteristics of patients who left the study prior to this point may have been related to their leaving the study and no data were reported comparing those who completed the study and those who dropped out.

The two meta-analyses comparing self-monitoring in type 2 DM came to contrasting conclusions. The study by Coster et al concluded no benefit exists, but compared blood and/or urine monitoring with no monitoring rather

than interventions including BGSM to those without, which was the comparison in the meta-analysis by Sarol et al. Although the latter concluded that BGSM results in improved glycaemic control, meta-analyses are limited by the quality of the trials included and as previously described, the RCTs conducted to date have design and reporting limitations. The epidemiological evidence supporting use of BGSM in non-insulin treated type 2 diabetes therefore remains inconclusive.

A notable limitation of the study interventions described is the absence of a theoretically-based framework for encouraging behaviour change. The failure of BGSM to effect change may be due either to a lack of efficacy or the absence of a framework clearly delineating how it might work and key components of a successful strategy for its use. The remainder of this chapter reviews psychological models of behaviour change and suggests a potential theoretical framework for BGSM to improve glycaemic control.

2.2 Psychological models of behaviour change

2.2.1 Role of blood glucose self-monitoring in behaviour change

Previous clinical studies have evaluated interventions to increase adherence to blood glucose self-monitoring(138-140). These interventions are based on the assumption that use of the technique should be encouraged as a self care method on its own merits. This is however unsustainable in non-insulin treated patients in view of available evidence. In this group of patients, BGSM may, however, mediate adherence to self care activities such as eating, physical activity and medication taking shown to improve glycaemic control. Cognitive factors, namely knowledge, beliefs and attitudes have been widely explored as determinants of behaviour and possible targets for interventions to mediate behaviour change(141). BGSM used appropriately may affect one or all of these factors.

2.2.2 Blood glucose self-monitoring- a possible framework

Leventhal's common sense model (CSM) of self-regulation of health and illness(142) provides a possible framework for exploration of the role of BGSM in mediating behaviour change. The model suggests that internal and external stimuli result in two parallel processes. In one process, beliefs or representations about the illness are formed. These beliefs are separated into five domains, namely identity (the symptoms the patient associates with the illness), timelines (whether the patient believes the illness is acute or chronic), consequences (possible physical disability resulting from the illness), cause (the factors which the individual believes resulted in their illness) and control (whether or not the treatments are thought to be effective). These beliefs are then thought to influence the development of coping procedures. A dynamic process ensues where appraisal of the effectiveness of these coping procedures feeds back to influence both illness beliefs and continued use of coping behaviour. In the other cognitive process, the individual develops an emotional response to their illness and similarly develops and evaluates emotional coping procedures.

This model can be applied to BGSM and type 2 diabetes (Fig. 1.1). Eating, physical activity and medication adherence can be considered the coping behaviours employed to combat diabetes. BGSM would provide an almost instantaneous (when compared to three monthly visits with health care professionals) method of appraising the effectiveness of these strategies and individuals would be motivated to continue their current behaviour or alter it, depending on whether results were in the desired range. Blood glucose values can also influence beliefs about diabetes. If, for example, blood glucose levels are persistently elevated, perceptions of diabetes as a chronic rather than an acute condition might be altered. Monitoring of blood glucose and association of values with physical symptoms can clarify what symptoms are associated with an abnormal blood sugar and therefore affect illness identity.

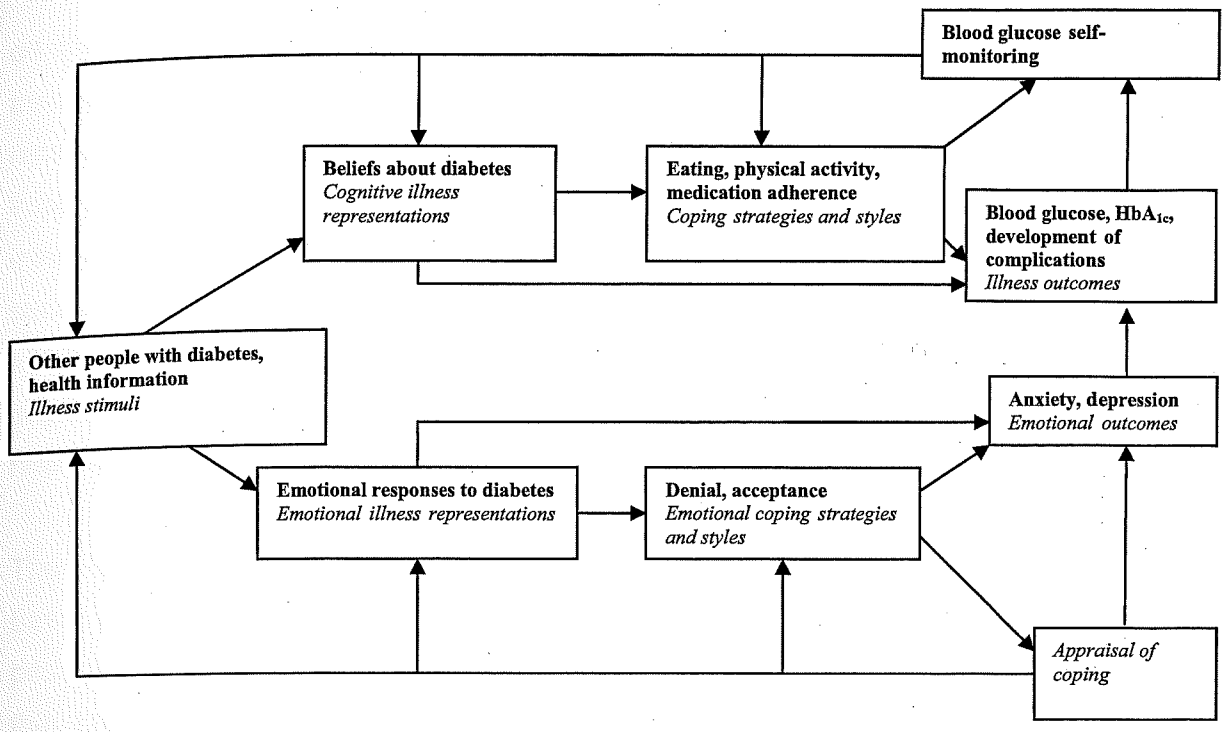


Figure 1.1 Schematic representation of Leventhal's common sense model of self regulation applied to BGSM

There are other models of health behaviour change, but they lack the comprehensive and dynamic nature of the CSM of self-regulation. The Health Belief Model(143) suggests that perceptions of illness threat and evaluation of response behaviours contribute to an individual's beliefs about health behaviour. A patient's beliefs about eating, physical activity and medication adherence would therefore depend on how susceptible the individual felt he or she was to diabetes and how serious they considered diabetes to be as well as to how effective they felt their self care behaviour might be and its possible benefits and disadvantages. The Health Belief Model does not specify the way in which components interact and is therefore often tested as separate variables. Other social cognitive factors which are also thought to be predictive of behaviour such as intentions and perceptions surrounding individual control over actions are not considered in the model.

The Health Locus of Control(144) model is derived from the social learning theory(145) and is based on the principle that the likelihood of a behaviour occurring results from the expectation that the individual will receive particular reinforcement from that behaviour and the value which the individual places

on that reinforcement. In this context, the likelihood of a patient following treatment recommendations might depend on the positive reinforcement received from blood glucose values within a specified range and how important these acceptable values are. This positive reinforcement might be internal i.e. personal satisfaction at satisfactory readings or external, i.e. satisfaction at praise received from health professionals or family for satisfactory results. The model neglects other potentially important social cognitive factors such as beliefs about an illness and its consequences and how the effectiveness of treatment might influence adherence.

The Protection Motivation Theory(146) suggests that coping with a health threat is motivated by how a patient views the threat and how they evaluate possible coping mechanisms. This theory resembles the health belief model in that beliefs about susceptibility and severity of diabetes for example, and evaluation of behavioural strategies influence adherence to treatment. The theory also explores whether an individual is capable of carrying out a health behaviour. BGSM might influence ideas about the effectiveness of treatment, but its influence on ideas of susceptibility and severity would be dependent on what connection individuals make between high blood sugar values and disease severity and would not influence perceptions regarding ability to carry out behaviours.

The Theory of Planned Behaviour(147) suggests that execution of behaviour is determined by intention to perform that behaviour as well as beliefs regarding control over that behaviour. This would not be an ideal theory to explore the role of BGSM in isolation, but abnormal blood glucose readings might serve as motivation and therefore reinforce intentions to carry out specific eating, exercise or medication behaviours.

The self-efficacy model(148) suggests that behaviour is determined by beliefs about consequences if action is not taken, belief that a given behaviour will result in a given outcome and the belief that a behaviour is within one's control. Elevated blood glucose values that result from a failure to follow treatment advice might influence perceptions regarding consequences of

diabetes, but only if a relationship between elevated blood glucose and complications is appreciated. Use of the technique might be more useful in establishing whether self care behaviours result in the desired outcome of lower blood sugar and encouraging patients' beliefs regarding their ability to undertake self care might affect adherence.

Many of the psychological theories of behaviour change incorporate similar elements. Several of them are static however, and provide explanations for initial behaviour change, but not the continuous evaluation and modification necessary for maintaining change. Leventhal's common sense model of self regulation provides a model which considers the dynamic nature of behaviour change which might be encouraged by BGSM and appears the most suitable for designing an intervention to evaluate its use.

2.3 Conclusion

The epidemiological evidence supporting blood glucose self-monitoring in non-insulin treated type 2 diabetes remains inconclusive. Incorporation of this technique in a structured intervention, based on Leventhal's CSM of self-regulation may optimize its benefits and result in improved glycaemic control in this patient group. The following chapter describes the development of such an intervention and its implementation and results are discussed in Chapters 5 to 7.

Chapter 3

Development of the study intervention

3.1 *Introduction*

The review of current psychological theory in the previous chapter suggests that optimal benefit of BGSM may be derived from using it to assess self-care activities and provide feedback to encourage self-management. The way in which feedback is provided may, however, influence the effectiveness of this approach. The effect of physician-mediated feedback in which health care professionals review BGSM values and give patients overall feedback on the effectiveness of their diabetes control strategies may differ from the effect of a more intensive approach, in which the information provided by BGSM is used immediately by patients to evaluate specific behaviours and inform decisions about whether to modify or continue these. The latter approach may support more consistent adherence to self-management behaviours which may then be reflected in improved glycaemic control. To date, no studies have described rigorously-developed interventions which promote both methods of interpretation of BGSM and therefore facilitate their comparison in randomized controlled trials.

Several of the interventions described in the previous chapter which reported a positive effect on glycaemic control had several elements, suggesting that a multi-component approach may be more successful. It is not evident, however, whether it is other elements of the intervention, such as the use of behaviour change strategies, rather than differential BGSM use, that mediate improvement in glycaemic control. Controlling for this factor and standardizing all other aspects of the intervention would help to clarify which components were key and provide a focus for further intervention development and clinical practice.

This chapter describes the development of an intervention that addresses these deficiencies in the literature. The theoretical, modelling and operationalization phases (as described in the Medical Research Council framework(149)), in the development of a theoretically-based, complex intervention promoting three different types of glycaemic feedback (namely regular HbA_{1c} measurements as performed in standard clinical care, BGSM with facilitator feedback and BGSM with patient interpretation and application to behaviour) in supporting improved self-management behaviour are described. Evidence supporting the use of Leventhal's CSM of self-regulation in an intervention to alter behaviour is presented and, in the absence of sufficient information to determine what behavioural theories, tools and modes of delivery are most effective in affecting clinical, behavioural and psychosocial outcomes(150-153), key elements in previously effective behaviour change strategies are also presented. The modelling of the intervention, based on a psychological framework and incorporating educational, cognitive and behavioural aspects, and its operationalization are described and the evaluation of its content and delivery discussed.

3.2 *Intervention development*

3.2.1 Theoretical and modelling phases

These initial phases of intervention development are closely related and are therefore considered together. The theoretical phase of intervention development involves examination of evidence that could potentially inform the intervention by identifying potential targets and what might comprise effective intervention content. Modelling aims to translate theory into practice by identifying the essential components of the intervention and clarifying which elements have to be consistently delivered for the intervention to be effective.

(i) Methods of intervention modelling

There are several methods of intervention modelling, including the modelling phases of logic modelling and intervention mapping and causal modelling. Logic modelling describes an approach to intervention development. In the

modelling phase, the context in which the intervention is to be used, the nature of the problem to be addressed, the objectives of the intervention and processes by which it will achieve outcomes determine the key intervention components(154). One limitation of this approach is that underlying theory and objectives are often based on reasonable assumptions of what might work and how it might do so, rather than on evidence-based models.

Like logic modelling, intervention mapping describes an approach to intervention development with a discernible modelling stage(155). Programme objectives, such as specific behaviour change, are determined and evidence reviewed to establish what determinants affect the desired objectives. Theoretical methods are then used to develop key strategies that might affect determinants. Intervention mapping may be better used when developing group interventions designed to target well-defined behaviours, such as eating five fruit and vegetables daily, rather than individualized interventions that might span several objectives and therefore require some flexibility.

The causal modelling approach proposes use of available theoretical evidence to modify a general causal model which links behavioural determinants to behaviour, intermediate clinical and biochemical outcomes and long term health outcomes (Fig 3.1) (156). Causal modelling, by highlighting behavioural determinants, identifies potential intervention targets which can then also be measured to evaluate whether the intervention worked as hypothesized.

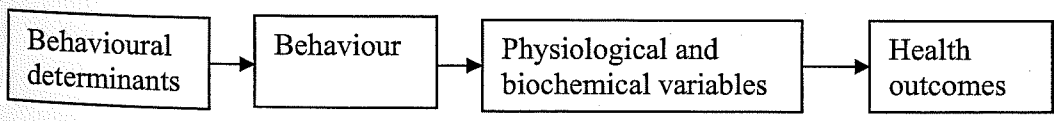


Figure 3.1 Generic causal model(156)

The causal modelling approach was ideal for use in the development of this intervention. As discussed in the preceding chapter, Leventhal's CSM of self regulation which guided the intervention specifies a similar causal pathway, in

which illness beliefs and success of behavioural strategies determine subsequent behaviour and therefore represent potential intervention targets.

Further review of available evidence was aimed at refining behavioural determinants and potential intervention targets, defining techniques to facilitate behaviour change and establishing what factors, if any, could optimize intervention delivery.

(ii) The CSM of self-regulation- beliefs as a determinant of behaviour?

A primary assertion in the psychological framework guiding development of the intervention is that beliefs about diabetes influence self-management behaviour. Changes in beliefs, as might be produced by an intervention, might then be reflected by changes in behaviour. This is supported by existing research examining the relationship between personal models (theoretically similar to illness representations) and self-management behaviour. A cross-sectional study in 46 patients with type 2 diabetes found that personal models significantly improved prediction of dietary intake(157). Beliefs about the importance of treatment and seriousness of diabetes were the two elements of personal models which were significant predictors of dietary intake, while beliefs about the importance of treatment were also predictive of more frequent exercise. This was confirmed in further work where beliefs about treatment effectiveness were found to be predictive of eating behaviour in three other studies(158-160). Beliefs about treatment effectiveness were also found to be concurrently predictive of physical activity, although not predictive of future activity(158) and beliefs about regimen-specific treatment effectiveness i.e. effectiveness of dietary intake or physical activity were more strongly predictive of those self-management behaviours than general beliefs(160).

The relationship between beliefs and medication adherence has also been examined. Cross-sectional studies carried out on patients undergoing haemodialysis and with asthma and diabetes found that illness

representations were correlated with medication adherence, although the dimensions of illness representations that were related to adherence differed across illnesses(161), with patients with diabetes more likely to take their medication if they had stronger beliefs about timelines, consequences and identity. Regimen-specific beliefs about medication were also found to be related to patient adherence(162). Horne has suggested that medication beliefs or representations may be general or medication specific and are an important determinant of medication adherence(161).

Conclusions about causality in these studies is limited by their cross-sectional nature. Nevertheless, this research suggests that a relationship exists between illness beliefs and self-management behaviour with beliefs about treatment strategies and their effectiveness (the cure/control component of illness representations) being the most consistently related to self-management behaviour. These beliefs about diabetes and treatment-specific beliefs provide potential points of intervention to produce behaviour change.

(ii) Facilitating behaviour change

An important aspect of the intervention is use of glycaemic feedback to facilitate self-management behaviour. However, given the current limited adherence to self-management guidelines in patients with type 2 diabetes(23,163), participants recruited to the trial were likely to be non-adherent and would therefore require a well-negotiated behaviour change strategy to help them improve their dietary and physical activity patterns and medication adherence to optimize their use of glycaemic feedback. There are several strategies for encouraging behaviour change(164) and while a review of these is beyond the scope of this thesis, crucial elements of a potentially successful strategy are outlined. Strategies which emphasize the role of the patient in determining the behaviour change to be targeted and which stress the use of transferable skills such as coping and evaluation of situations and outcomes are more likely to produce sustainable change(165). This is because behaviour change requires motivation and cognitive activity such as planning and actual execution and can therefore only be realistically achieved

when the patient is involved. The acquisition of transferable skills enables the patient to deal with ongoing challenges and therefore maintain behaviour change.

As noted previously in this chapter, systematic reviews have failed to identify any one strategy for effectively facilitating behaviour change. The use of a self-regulatory model as a basis for the intervention guided selection of the elements of the behaviour change strategy used in the intervention. All models of self-regulation postulate that behaviour change is the result of a process involving both cognitive and behavioural aspects, in which goals are set, strategies to achieve them are developed and implemented, progress is appraised and subsequent goals and strategies are revised accordingly(166). An intervention incorporating these components might therefore be expected to be effective. Although evidence for strategies unifying these components is limited, several have been examined independently or in conjunction with other techniques and evidence supporting their use is presented below.

Targeting patient beliefs

The most proximal determinants of behaviour, as suggested by the Leventhal's model are illness beliefs. Targeting these beliefs may therefore result in a change in behaviour. Research in this area has been limited, but a randomized, controlled trial in which illness beliefs after myocardial infarction (MI) were targeted has been described(167). The intervention consisted of exploration of patients' illness beliefs with challenging of misconceptions. Participants were also educated about the pathophysiology of myocardial infarction and developed individualized plans for reducing risk based on their personal ideas of causation. Negative beliefs about the consequences of MI and duration of absence from work were also challenged. Illness perceptions were significantly altered in patients in the intervention group, with these patients having lower levels of belief that their condition would have serious consequences or last a long time, lower levels of distress about symptoms and higher levels of belief that their condition could be controlled. Differences

in timeline and control beliefs persisted three months after discharge. This suggests that illness beliefs are indeed modifiable.

Incorporating goals and goal setting

A goal can be defined as the object or aim of an action(168); it is therefore logical that, as the self-regulation theory proposes, goals are important mediators of action or behaviour. Research has suggested they improve performance by focusing efforts, energizing patients and encouraging persistence(168).

There were several factors to be considered when developing the goal setting approach utilized in the intervention. The hierarchical models of goal organization proposed by some self-regulation theories(169) provided a useful framework because broad targets, which are thought to be more important to individuals, could be identified at the outset and used to direct choice of more specific targets, promoting coherent motivation and action(166). These "higher-level" goals such as the desire to get more physical activity determine more concrete or "lower-level" goals such as walking thirty minutes daily. A review of the subject suggests that this approach to goal setting enhances self-efficacy and satisfaction because "lower-level" goals are more tangible and feedback on their attainment is received more frequently(170).

Other factors which were considered in the goal setting approach were patient-determination of goals and self-efficacy. Self-determined goals, because they are in keeping with an individual's interests, are more likely to generate effort and therefore be attained(171). Self-efficacy, which relates to an individual's belief that he or she can undertake a behaviour successfully, was also a consideration. As discussed in the previous chapter, it is a particularly prominent construct in some psychological theories, but is common across all social cognition models(172). Self-efficacy can enhance motivation by influencing effort and outcome expectations(173): a patient who believes he can achieve a goal is more likely to put in sustained effort to do so.

Most of the research on the effects of goals and goal setting in promoting behaviour has been done in organizational settings (168). Cullen et al(174) reviewed the use of a goal setting strategy in dietary interventions in adults and children. The authors specified a four-stage goal setting strategy which included recognizing the need for change, establishing a goal, monitoring goal attainment and reward for goal attainment. Of the studies conducted in adults, only one incorporated all four of these stages and although the group that used this strategy had more success than a control group, the authors suggest that this may have been confounded by the frequency of contacts. Studies that included two of these stages, namely setting goals and monitoring goal attainment were, however, consistently associated with improved outcomes, supporting the use of these two elements in our behaviour change strategy.

Use of action planning

Research suggests that establishing goals is an important, but sometimes insufficient prerequisite for behaviour change(175). Individuals often encounter difficulties in initiating and maintaining goal-directed behaviour and the use of specific plans, known variably as action plans(176) and implementation intentions(177) may help to counter this.

Implementation intentions are specific step-by-step plans which specify when, where and how a goal is to be achieved and are formulated for use when specific situations are encountered and may work by improving recall and focusing attention(177). Use of implementation intentions has been shown to improve goal attainment, particularly the attainment of difficult goals(175,178) and was therefore included in our behaviour change strategy to facilitate the transition from goal formulation to implementation.

Use of goal monitoring

As noted previously, a review has shown that studies incorporating goal monitoring in addition to goal setting in strategies for dietary behaviour change result in improved outcomes(174). Goal monitoring (or self-monitoring of goals) is crucial to the dynamic nature of self-regulation models, providing the feedback which determines future goals. In our intervention, two separate

aspects of goals were monitored: the attainment of goals and the success of goals in achieving the desired outcome.

Monitoring of goal attainment involved assessment of whether goals were achieved and if not, the possible reasons for failure. Participants were taught problem solving skills (the identification of the obstacles, formulation and selection of alternatives, implementation of those alternatives and re-evaluation(179) to help them overcome the obstacles they faced in goal achievement and facilitate further attempts at those goals. This approach is supported by the literature, with problem solving skills having been shown to be prospectively predictive of diet and physical activity in patients with type 2 diabetes(180).

The second aspect which was monitored was the success of goals in improving glycaemic control. We hypothesized that the extent to which goals improved glycaemic control would influence beliefs (as determinants of behaviour and goals), adherence to existing goals as well as future goals, with the method with which goal success was evaluated as the important variable in this feedback process.

As noted earlier in this chapter, one limitation of previous trials evaluating BGSM interventions is the variability between trial arms. We therefore developed two versions of an intervention in which all components were kept constant except the method of assessment of glycaemic control. All participants were therefore equipped to use their glycaemic feedback to modify their self-care activities using a comprehensive, evidence- based strategy for effecting behaviour change.

Use of glycaemic feedback

The causal model guided by the theoretical framework proposes that information on glycaemic control might affect beliefs about how effective treatment for diabetes is and how successful their goals or control strategies have been. The information provided by differing methods of glycaemic

assessments differs in content, timing and frequency and may therefore affect these components differently.

HbA_{1c} indicates glycaemic control over the preceding 80-120 days. The measurement reflects average blood glucose levels during this period, so an HbA_{1c} within range may reflect steadily acceptable blood glucose levels during this period or equally frequent instances of hyperglycaemia and hypoglycaemia(181). HbA_{1c} can therefore only give a general assessment of medium to long term glycaemic control every three months and by extension, the effectiveness of self-management goals during this period and while this may improve adherence to self-management, more specific evaluations may be helpful.

BGSM, by contrast, provides the opportunity for such specific evaluations. The technology provides point assessments of blood glucose and is essentially available for patients to use as frequently as they wish. The difference between pre- and post- prandial readings can indicate the effect of certain foods on glycaemic control and a similar strategy might be used to explore the effect of physical activity or periods without medication. Results may then change patient beliefs about effectiveness of treatment strategies (for example, a realization that exercise can lower blood sugar). Both changes in beliefs and directly observing the effects of behaviour on glycaemic control may motivate participants to set new goals, such as to omit certain foods, or to persist with existing ones, such as to walk for a specified number of minutes daily. Other outcomes, such as patient empowerment, may result which, although not included in the causal model are also important.

This model of BGSM use presupposes the ability of patients to understand what influences blood sugar, relate it to their behaviour and institute measures to correct abnormal values. Physicians may also review BGSM values to provide feedback similar to that provided by HbA_{1c}, that is, general assessment of glycaemic control rather than the more intensive approach outlined above. While the influence of this approach on the components of the model is unlikely to differ from that of HbA_{1c}, other aspects, such as patient

empowerment, which are not part of the causal model but which may be important either in their own right or in influencing behaviour, may be affected. This, coupled with the absence of conclusive epidemiological evidence establishing this as a ineffective method of BGSM use mandated its inclusion in the intervention.

We therefore determined three methods of glycaemic feedback which, because of their different characteristics, might have a differing effect on beliefs about treatment strategies and goals which mediate glycaemic outcomes.

Factors relating to intervention delivery

A taxonomy of diabetes interventions(182) suggests that the following dimensions should be considered in intervention development: setting, delivery, teaching method, content, provider, whether the intervention has been tailored to an initial patient assessment, whether there has been follow-up and modification during the intervention and the number of episodes within the intervention, length of each intervention visit and duration of the intervention. The evidence supporting a teaching method and intervention content involving patient-directed goal setting with action planning and goal monitoring with problem solving strategies and glycaemic feedback has been reviewed; evidence definitively supporting other aspects of intervention delivery is, however, limited. Factors relating to the delivery of our intervention were therefore guided by theoretical and practical considerations.

Group and individual lifestyle interventions appear to be equally effective in producing positive effects on diet and self-care and skills teaching(150), although individual interventions appear to increase adherence based on indirect measures of adherence(183). Our intervention involved setting of specific goals, guided by beliefs about diabetes. Beliefs and therefore goals were likely to be individual, making a tailored, individual intervention most appropriate. Diabetes specialist nurses deliver a significant amount of diabetes care in primary care and clinical nurses were therefore selected as

facilitators. This approach also allowed us to evaluate whether nurses could be trained to consistently deliver the intervention which would have implications for its wider implementation if warranted. Intervention visits were scheduled at three monthly visits in keeping with recommendations for clinical visits in intensively treated patients(32). Length of intervention visits was based on what might be reasonably be expected to be available for consultation in normal clinical practice, while the duration of follow-up was chosen to allow adequate time for implementing and maintaining behaviour change and evaluation of BGSM over a longer duration than in most previous studies.

Based on the theoretical evidence available, we developed a causal model (Fig 3.2) and individualized intervention utilizing glycaemic feedback to promote diabetes self-management. Table 3.1 summarizes the theoretical underpinnings of the intervention and the intervention components associated with each theory. The remainder of this chapter describes the operationalization and evaluation of the delivery of that intervention.

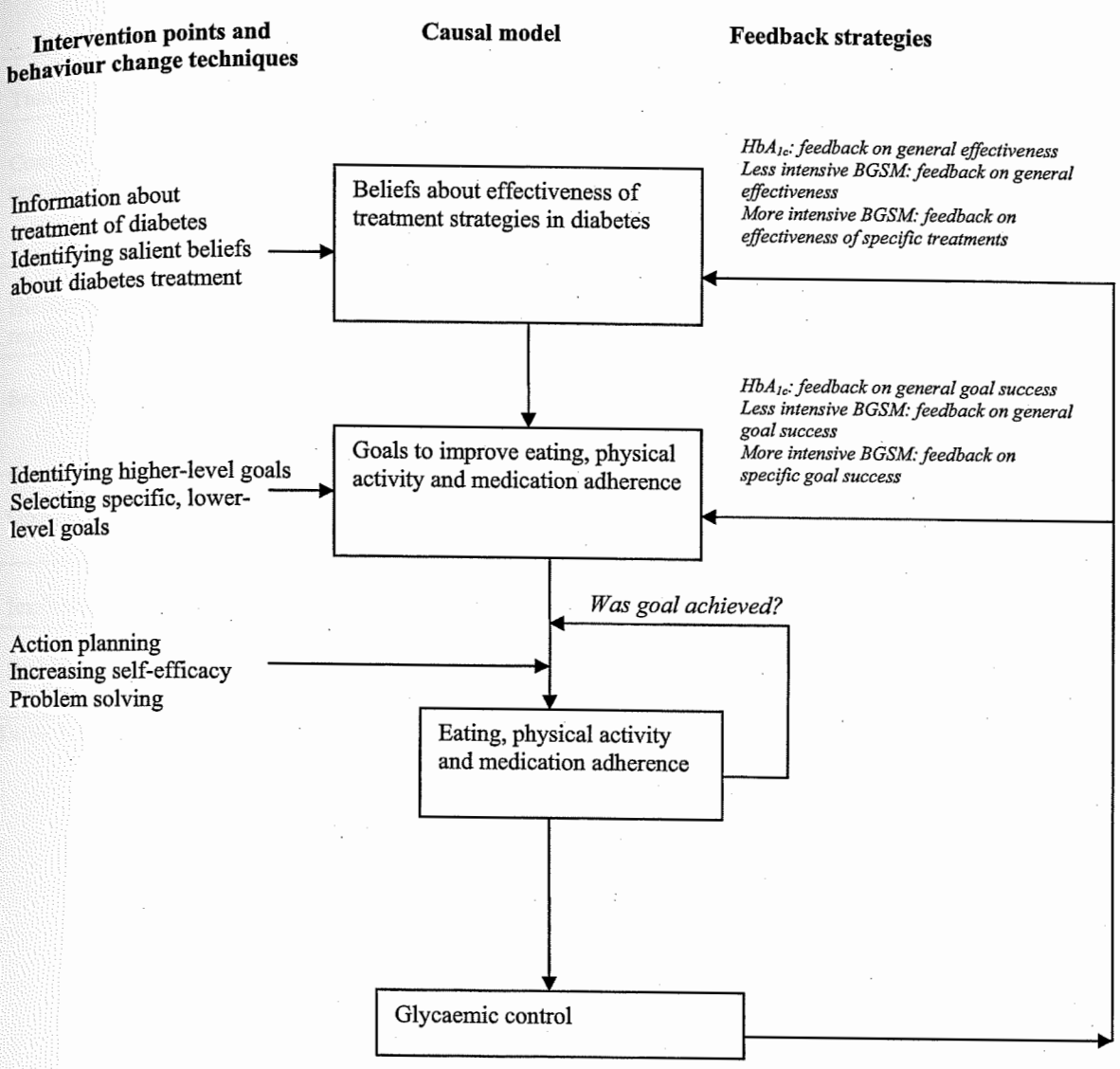


Figure 3.2 Causal model of intervention with intervention points and behaviour change techniques

Theory	Intervention component
Common sense model of self-regulation	Elicitation of beliefs about effectiveness of diabetes treatment; provision of information about effectiveness of treatment; use of feedback on glycaemic control to influence beliefs about treatment effectiveness
Hierarchical models of self-regulation	Initial setting of higher-level goals with subsequent identification of lower-level, specific goals
Self-efficacy model	Elicitation of patient's beliefs in personal ability to carry out behaviours and exploring reasons and possible solutions for low self-efficacy
Goal setting theory	Setting specific goals and monitoring success both in attaining goals and of goals in achieving desired outcomes
Implementation intentions	Establishing specific step-by-step plans to achieve desired goals
Problem solving skills	Identification of obstacles to goal achievement and methods to overcome these

Table 3.1 Summary of psychological theories and associated intervention components

3.2.2 Operationalization of the intervention

The causal model of the intervention highlighted key components that might be affected by glycaemic feedback. Evaluation of the intervention in a clinical trial required operationalization of the model which is described in this section. The delivery of the intervention is described in detail in Chapter 5 and so this section focuses only on how the model was operationalized at each stage.

(i) Development of intervention protocols

The first stage in operationalization of the model was the development of intervention protocols. Protocols were developed for each of the study visits, with behaviour change techniques and feedback strategies incorporated depending on the stage of the intervention.

In the initial assessment visit, prior to randomization, salient beliefs about diabetes treatment strategies were elicited and information about treatment strategies presented, targeting beliefs about effectiveness of treatment strategies, one of the proposed determinants of goals and behaviour. In subsequent intervention visits, the behaviour change strategy of hierarchical goal setting was used to identify areas that the participant felt were important to change to increase motivation. This was coupled with action planning skills and techniques to increase self-efficacy to assist in attainment of goals as discussed previously. Problem solving skills were introduced after participants had had the opportunity to attempt their goals.

Feedback strategies were operationalized with facilitators giving those in the comparison and less intensive monitoring groups general feedback on the success of their control strategies, while encouraging those in the more intensive monitoring group to consider the implications of their monitoring, specifically how it assisted them in achieving their goals, what information it provided about their goals, how it informed future goals and how it affected their beliefs about effectiveness of treatment strategies.

(ii) Facilitator training

All facilitators underwent a programme of training prior to delivering the intervention. Four nurses with varying clinical backgrounds participated in a training program designed to ensure all of them possessed the necessary skills to deliver the intervention and remove allocation of facilitator as a source of confounding. The 90 hour training programme contained both theoretical and practical aspects. An education session, which included an overview of type 2 diabetes, its features, complications, monitoring and treatment methods, was conducted by a trained diabetes educator. The theoretical basis of the intervention was explained to help facilitators understand what elements were important in encouraging behaviour change and the importance of maximizing use of different types of feedback. Clinical psychologists conducted an interactive skills session in which interviewing techniques to facilitate behaviour change discussion were demonstrated and rehearsed. Further opportunities to rehearse interviewing skills were provided in seven three hour role play sessions conducted by the author during which each intervention protocol was reviewed and rehearsed. The aims and structure of the randomized controlled trial were also discussed and facilitators were taught how to use the MediSense Optium blood glucose meter which was to be used in the trial by an agent of the company.

A small pilot study was carried out to ensure the feasibility of delivering the two separate BGSM interventions. The study was restricted to the BGSM interventions because they were quite similar and we anticipated that facilitators would have greater difficulty maintaining separation between these two than between either BGSM group and the comparison group. Two participants[12] with non-insulin treated type 2 diabetes were seen by each of the facilitators at two visits two weeks apart. The post-randomization intervention protocol was delivered at the first visit and the general follow-up intervention protocol at the second visit. All sessions were audio taped and reviewed by the author who then discussed the delivery with the facilitators.

[12] Patients were randomly selected form those who participated in the questionnaire validation study (described in Chapter 4) who agreed to be contacted about further studies

Review of the audio taped sessions showed that while delivery of two distinct interventions was feasible, facilitators did, on occasion, deviate from protocol and discuss the relationship between blood glucose and behaviour in the less intensive monitoring group. An additional review session was held with the facilitators prior to the start of the RCT, to emphasize the need to maintain separation between the two monitoring groups.

Facilitators were also provided with a comprehensive training manual for personal review which detailed all of the information presented in the training sessions.

(iii) Promotion of fidelity

Several strategies were used to promote fidelity in delivery of the intervention. Detailed intervention protocols were written to ensure consistency and completeness in intervention delivery. As the intervention progressed, the layout of protocols was revised to ensure that while the essential content was unchanged, actual text was less proscribed and protocols were easier to follow. Intervention materials were also colour coded according to patient group allocation to serve as an *aide memoire* to facilitators as to which intervention was being delivered. Six months after commencement of the trial, a session reviewing its theoretical basis was held with the facilitators to reinforce the rationale for the key components of the intervention.

3.2.3 Quality assurance of the intervention

The preceding sections of the chapter describe the supporting theory, modelling and operationalization of the study intervention. Assessment of the effectiveness of the intervention required that its delivery be consistent with the theory underlying its development. Intervention protocols had been developed to guide intervention delivery and we developed a checklist to assess fidelity in delivery of the intervention.

The checklist was primarily a training tool which allowed identification of any areas in the intervention delivery that required improvement and clarification.

The presence of the key theoretical components in an intervention session was assessed with a categorical (yes/no) scale. As each of the key components was significant, it would have been inappropriate to define how many or which of these needed to be delivered to define delivery of the intervention. There was therefore no scoring system used in the checklist.

All study visits were taped and 1 in 30 were reviewed on two occasions by an external reviewer, once shortly after the beginning of the trial to evaluate assessment and post-randomization visits and again after six months to review follow-up visits. A six month review of a random sample of tapes was also carried out by trial investigators, while ongoing review during the trial was carried out by the author to identify any further difficulties and to ensure issues raised by the external reviewer were addressed. A narrative summary of the main concerns raised by the external reviewer during each intervention session and the methods used to redress them are reviewed below.

General comments from the external reviewer focused on patient centeredness and striking a balance between non-didactic interventions and focus on the intervention. Facilitators demonstrated a range of ability in this regard and the need to establish rapport with patients without sacrificing adherence to protocol was continually reinforced with facilitators at regular meetings.

Delivery of assessment visit interventions routinely incorporated most of the theoretical aspects. Discussion about diabetes, guided by the illness representations model, was encouraged by facilitators, but failure to elicit emotional concerns was demonstrated by all facilitators. Although every effort was made to compensate for the diverse backgrounds of the facilitators by a comprehensive overview of diabetes and although protocols and study manuals outlined potential situations that patients might raise and possible responses, it was not possible to anticipate all issues. Facilitators may not have felt qualified to discuss some of the issues raised, some of which were unrelated to diabetes. Although we recognized that this eventuality could never be completely addressed, group sessions in which facilitators shared

experiences and queries raised by patients were used to help generate ideas for responses in these situations.

The primary concern at post-randomization visits was the delivery of behaviour change methods and appropriate separation of groups. Participants were guided in setting goals, but while specific goals were discussed, goal setting as a maintainable skill that could be repeatedly applied was not taught by facilitators. The second issue arising was separation between the intervention groups. Separation between the comparison group and the other two was easily maintained; however separation between the less and more intensive groups proved challenging initially, particularly with introducing ideas of monitoring as a prompt to action and possible uses of and experimenting with monitoring. Review of BGSM results by facilitators in the less intensive monitoring group was also not significantly emphasized. These were all seen as deficiencies in the intervention protocols. Protocols were revised to highlight the need for discussion of goal setting skills. Lengthy scripts in the protocol were abbreviated to highlight important points, while leaving specific conversation to the discretion of the facilitator. Reinforcement of these protocol issues was also addressed at regular facilitator meetings.

As with the post-randomization visits, emphasis on the behaviour change strategy and separation between the less and more intensive monitoring groups were the key issues at follow-up visits. Facilitators demonstrated a range of protocol fidelity in reviewing of previous goals and helping patients set new ones. Separation issues at this stage focused on counselling less intensively monitoring patients who drew connections between their BGSM results and self care behaviour. A protocol amendment was made to include a discussion reminding patients about the aims of the trial at the six month visit to encourage continuation of use of behaviour change techniques. Facilitators were encouraged to explain to participants in the less intensive monitoring group the importance to the trial of not experimenting with their BGSM and to ask them to refrain from doing so.

The approach to quality assurance which we used allowed us to identify and correct any issues in intervention delivery as they arose. The issues raised by the external reviewer and continually monitored by internal assessors were not thought to invalidate the intervention or group allocation. The trial, which is described in detail in Chapter 5, was a pragmatic one and therefore aimed to evaluate the effectiveness of the intervention in real world situations, where similar challenges in intervention delivery, particularly maintenance of separation between less and more intensive monitoring groups would be present.

3.3 Conclusion

This chapter describes the development of a novel, rigorously-developed intervention to promote the use of BGSM to facilitate self-management. Unlike other multi-component interventions evaluating BGSM, this intervention facilitated assessment of whether the additional elements of interpreting and applying BGSM results affected glycaemic control in excess of any effect caused by BGSM. Evaluation of the intervention showed that facilitators can be trained to deliver a complex intervention, but continuing review of delivered interventions, coupled with feedback and on-going training is essential for maintaining fidelity to protocols.

The method of intervention development used has several strengths. Firstly, a systematic, well-defined approach(149) was used. The intervention was based on a well-established psychological theory which had previously been associated with behaviour change in patients with diabetes and which guided selection of behaviour change techniques. The intervention might be described as complex, because it comprised several interacting components with potentially unpredictable effects which may have been more than the effects of the component parts(184). The use of a causal modelling approach helped to elucidate these components and how they might interact, demonstrating potential intervention points as well as facilitating assessment of the effect of the intervention on the components of the determinant-behaviour model. Development of comprehensive intervention protocols

encouraged faithful delivery of interventions, and evaluation with the checklist allowed us to identify potential difficulties which were then addressed in training sessions.

There were however, limitations to the development process. A significant one was the omission of the pilot phase recommended by the MRC framework. While we did undertake a small pilot study to assess the feasibility of intervention delivery, we did not explore other issues such as patient opinion of the intervention which could have informed development by identifying other components not considered in our model which were important to patient behaviour.

The final intervention protocols used the trial are appended (Appendix 1). The evaluation of the intervention in the randomized, controlled trial is described in Chapters 5 to 7.

Chapter 4

Development of study questionnaire

4.1 Introduction

As discussed previously in this thesis, Leventhal's CSM of self-regulation(142) provides a model for exploring the relationship between patients' beliefs about diabetes and the self-care activities that they undertake to manage it. It suggests that patient adherence to these self-care activities is influenced both by their illness beliefs and by their evaluation of the success of their management efforts. The previous chapter described the development of the study intervention, which was based on the hypothesis that in patients who used blood glucose self-monitoring (BGSM), the instantaneous method of assessing glycaemic control and by extension, the effectiveness of the behavioural strategies adopted might alter patients' beliefs about diabetes and the usefulness of treatment and therefore the extent to which they undertake self-care activities.

The causal model which guided development of the intervention also identified characteristics which might be expected to differ depending on the intervention arm to which patients were allocated. A questionnaire was designed for use in the randomized controlled trial (RCT) to assess these characteristics. These included beliefs about diabetes and beliefs about self care activities thought to have a direct effect on control of diabetes, namely eating, physical activity and medication taking and adherence to these activities. Patients' sense of well being might also be expected to differ between trial groups as previous work has suggested that those who monitor more intensively experience a decreased quality of life(109). Measures were included in the questionnaire to assess these variables and the questionnaire was administered both at the beginning and end of the RCT to examine whether the intervention had any effect on patient beliefs and whether changes in beliefs were reflected by changes in behaviours.

This chapter justifies the selection of the measures used in the questionnaire and describes, where necessary, evaluation of their psychometric characteristics in a sample drawn from a population similar to the trial population. It also discusses the development of new measures in instances where no appropriate measures existed.

4.2 *Selection of measures*

The questionnaire was designed to evaluate the effect of the intervention on the key elements of our causal model. It included previously validated measures to assess beliefs about diabetes and beliefs about self care activities, which our model suggested were behavioural determinants, and measures of self-reported adherence to self-care activities. Measures of well being were also included. The pre-existing measures selected for inclusion in the study questionnaire are summarized in Table 4.1 and a brief description of each measure is given below.

Measures of belief	
• Beliefs about type 2 diabetes	Revised Illness Perception Questionnaire
• Beliefs about self care activities	Beliefs about Medicines Questionnaire
Measures of behaviour	
• Medication adherence	Medication Adherence Rating Scale
• Eating and physical activity habits	Summary of Diabetes Self Care Activities Scale
Measures of wellbeing	
• General well-being	Well Being Questionnaire (12-item)
• Satisfaction with treatment	Diabetes Treatment and Satisfaction Questionnaire
• Self-evaluated health status	EQ-5D

Table 4. 1 Pre-existing measures selected for use in questionnaire

4.2.1 Measures of belief

(i) Revised Illness perception Questionnaire (IPQ-R)

Weinman et al developed the Illness Perception Questionnaire (IPQ)(185) as a generic measure of illness representations. It was specifically designed to assess the domains of the common sense model and comprised five scales, namely identity, cause, timeline, consequences and cure/control. In 2001, a revised version of the questionnaire was published (revised Illness Perception Questionnaire; IPQ-R)(186) in order to address deficiencies in the original

questionnaire. These included omission of the emotional representations domain originally identified by Leventhal, items which appeared to relate to more than one scale and the poor internal consistency which had been observed when the questionnaire was used to evaluate illness representations in a number of illnesses. These problems were particularly evident in the timeline and cure/control scales and in the latter case, re-analysis of items suggested that two separate scales, one dealing with personal control and the second with treatment control, might be appropriate. The new measure also sought to assess illness coherence which reflects the overall understanding a patient has of his illness. The identity scale was modified and the intensity rating removed with patients being asked to first report whether they had experienced a symptom and then whether they believed the symptom to be related to their illness.

The illness identity subscale score is calculated by summing the number of positive responses. The remaining scales are scored using a five-point Likert rating scale ranging from strongly disagree to strongly agree (scored 1 to 5). Negatively-worded items are reverse scored and scores on the relevant items summed to give the score for the scale.

The IPQ-R was derived from Leventhal's theory and was therefore appropriate for inclusion in the study questionnaire. It is, however, a generic measure which had been developed with patients with a variety of illnesses and was designed to assess the more common thoughts associated with illness, rather than those associated with diabetes specifically. We hypothesized that the addition of diabetes-specific questions might improve the construct validity and ability of the questionnaire to predict self care behaviour in the patient population in which we were interested. This hypothesis was evaluated in a cross-sectional survey described below.

(ii) Beliefs about Medicines Questionnaire

The Beliefs about Medicines Questionnaire(187) (BMQ) was developed to assess the cognitive representations of medication. It was based on the

theory that beliefs about medicines may be divided into general beliefs and specific beliefs with further subdivision into beliefs about the general overuse of medication and general harm that medication can cause and beliefs about the necessity of specific medications and concerns about the effects of specific medications. Responses are scored on a 5 point Likert rating scale again ranging from 1 to 5 (1=strongly disagree, 5=strongly disagree) and scale scores obtained by reverse scoring negatively worded items and summing the scores for each scale.

We sought to test patients' beliefs as they related to diabetes medication, rather than medication in general and therefore selected the specific necessity and specific concern scales of the measure. As with the IPQ-R, the measure was developed using a mixed illness group and reflected beliefs about medicines for multiple diseases, which might not necessarily reflect beliefs about diabetes medications. It was therefore worthwhile assessing whether the structural validity of the questionnaire was maintained in a sample from a population similar to the trial population and whether efforts to improve its predictive validity with diabetes-specific questions were effective.

4.2.2 Measures of behaviour

(i) Medication Adherence Rating Scale (MARS)

The Medication Adherence Rating Scale(162) (MARS) is a self report scale of medication adherence. It was based on adaptations of previously validated questionnaires and item responses are scored on a five point scale ranging from very often to never. Scores for each item are summed with higher scores indicating higher levels of reported adherence and adherence assessed as a continuous rather than categorical (i.e. adherent/non adherent) variable.

The MARS was selected for inclusion as it is a simple, inexpensive method of assessing medication adherence and offered, rather than an absolute assessment of when and how medication was taken, the ability to assess adherence on a relative scale. This was particularly useful as the trial aimed to determine the effect of the intervention on adherence and compare adherence between trial groups. As a measure which required patients to simply record

how they take their medication, it would not be expected to vary depending on the illness in question as so did not require evaluation in the trial population.

(ii) Summary of Diabetes Self care Activities scale (SDSCA)

The Summary of Diabetes Self Care Activities Scale(188) (SDSCA) is a brief self-report measure developed to assess levels of self-management across different components of the diabetes regimen, namely diet, physical activity, medication taking and blood sugar testing. The revised version(189), was produced after examination of seven studies which evaluated the scale and included additional items on foot care and smoking as important elements of self care. Items referring to "inclusion of 'sweets'" in the diet were changed to inquire about carbohydrates and items regarding medication were eliminated from the revised version because of strong ceiling effects and a lack of variability among respondents. The specific diet scale lacked internal consistency and the authors recommend that its constituent items should therefore be considered separately.

The SDSCA scale is scored for each of the five assessed regimen areas. For items which assess the numbers of days per week an activity was carried out, the mean number of days per week is calculated to give the score for the relevant scale.

The scales relating to diet and physical activity were selected for use in our study as these were the self-care activities which, along with medication taking, were being targeted in the study intervention. As with the MARS, it has the advantage of being inexpensive and its development in a population similar to that being tested obviated the need for further testing in the study population.

4.2.3 Measures of well being

(i) Well Being Questionnaire

The 12 item Well Being Questionnaire(190) (WBQ-12) was derived from its parent, the 22 item WBQ(191). The 22 item WBQ was developed to assess depressed mood, anxiety and aspects of positive well being in patients with diabetes. The WBQ-12 version provides a short form while retaining a balance of positively and negatively worded items. The WBQ-12 is scored from 0 to 3 ("not at all" to "all the time") and the score for each scale is calculated by summing the scores of its component items.

This questionnaire was included to allow us to evaluate what effect if any, the intervention had on patients' sense of well-being. Patients who monitored their blood sugar at home might be more distressed, especially if they experienced high values and felt they had no means of reducing them. Conversely, knowing blood glucose values might empower patients and reduce anxiety. This questionnaire was developed in patients with diabetes and required no further evaluation before use in the RCT.

(ii) Diabetes Treatment Satisfaction Questionnaire (DTSQ)

The Diabetes Treatment Satisfaction Questionnaire(192) was designed to measure satisfaction with diabetes treatment regimens in people with type 2 diabetes. In addition to evaluating changes in satisfaction with changes in treatment regimen, it can also be used for comparing satisfaction in patients using different regimens, such as those in the different trial groups.

Each item on the DTSQ is scored on a scale ranging from 0 (very dissatisfied) to 6 (very satisfied). Items relating to treatment satisfaction are scored to give a score of 0 to 36 as a measure of satisfaction with treatment. The remaining two items are treated individually and provide indications, each within a range of 0 to 6, of perceived frequency of hypoglycaemia and perceived frequency of hyperglycaemia.

Patients who monitored their blood sugar might be expected to have a higher frequency of perceived high or low blood sugar because of the ability to actually measure their blood sugar to confirm symptoms. The use of a meter may also affect satisfaction with care, depending on how valuable patients feel the use of the technology is. As with the Well-Being Questionnaire, the development of this questionnaire in patients with type 2 diabetes made it appropriate for inclusion in the study questionnaire without need for further evaluation.

(iii) EQ-5D

The EQ-5D(193) is a self-reported measure of health status. Respondents are asked to rate their health in the categories of mobility, self-care, usual activities, pain/discomfort and anxiety/depression and to give an indication of their health scale on a visual rating scale where 0 is the worst imaginable health state and 100 is the best. This allowed us to obtain an overall assessment of patients' sense of how healthy they were which might vary depending on whether the values obtained from BGSM confirmed their perceptions of their health or not. Although this is a generic measure, we did not anticipate any difference in people with diabetes and so it was not evaluated for use in the RCT.

4.2.4 Summary

There were, therefore, measures available to assess the general representations about diabetes and beliefs about medicines identified in our causal model; these measures of belief were constructed using mixed illness groups however, and therefore required evaluation in a population similar to that in the RCT. Additionally, no measures existed to evaluate beliefs about eating and physical activity, the other two treatment methods which we postulated might affect behaviour, or blood glucose self-monitoring. The remainder of this chapter describes two studies which were carried out to address these issues. The first study aimed to develop a preliminary questionnaire which was then evaluated in the second study, a cross-sectional survey.

4.3 *Development of new measures and evaluation of existing measures*

4.3.1 Study 1- Development of the preliminary questionnaire

The first study was carried out to develop a preliminary questionnaire for evaluation in a population similar to that used in the RCT. Its specific aims were:

- to elicit salient beliefs about type 2 diabetes and its pharmacotherapy to augment the IPQ-R and BMQ
- to elicit salient beliefs about the perceived benefits and disadvantages associated with adhering to dietary and physical activity recommendations to construct scales relating to these beliefs
- to identify key beliefs and behaviours associated with blood glucose self-monitoring to develop scales relating to these beliefs and behaviours

(i) Methods

(i) Generation of items

This section describes the methods used in generating a pool of items for inclusion in the preliminary questionnaire. Items for use in the preliminary questionnaire were generated from a series of in depth interviews conducted in a sample of patients from a population similar to that in the RCT. This is one of several techniques used in generating item pools(194).This method was chosen because interviewing a large enough sample can ensure that all important themes of concern to the population under study are identified. In our study, while items were not generated purely on a theoretical basis, Leventhal's CSM of self-regulation did guide the development of the topic guide used in the interviews. The existing IPQ-R also contributed to the item pool which was evaluated in the second study. Other methods of generating items such as clinical observation would have been inappropriate for assessing patient beliefs as these beliefs are unlikely to be spontaneously expressed by patients with much frequency.

Patient recruitment

Ethics approval was obtained for the study from the Oxfordshire Psychiatric Research Ethics Committee (OPREC) and four general practice surgeries in Oxfordshire were invited to participate. General practitioners identified patients from their lists with type 2 diabetes who met the following criteria:

Inclusion criteria

- type 2 diabetes
- aged 25 or older at diagnosis
- managed with lifestyle or oral hypoglycaemic agents

Exclusion criteria

- aged 80 years or over
- significant co-morbidity which precluded performance of activities of daily living
- unwilling or unable to follow study protocol
- unable to give informed consent
- diagnosis of malignancy within the past two years
- major psychiatric illness.

The criteria were established to ensure that the patients who participated were similar to the patients who would be recruited for the RCT. Patients were required to be 25 or older to try to ensure only patients with type 2 diabetes were recruited. Patients with significant co-morbidities were excluded as physical limitations may have prevented them from undertaking self care activities such as physical activity. Those with major psychiatric illnesses were also excluded as that may have affected their beliefs about their diabetes and its management.

Eligible patients were sent an invitation letter on the general practice letterhead and signed by their doctor. The letter stated that their involvement would be limited to one interview, conducted either in their home or in the surgery, during which they would be asked about their experience of diabetes.

The letter was accompanied by a detailed information sheet and a reply slip which patients were asked to return to the author in the enclosed FREEPOST envelope if they were interested in participating.

Conduct of interviews

A series of 26 in depth interviews was undertaken in a sample of patients from Oxfordshire. Informed consent was obtained from each patient prior to the interview. Interviewing continued until data saturation had been reached and all of the important themes identified. Each interview began with demographic data and questions on current health status. Further inquiry was based on a topic guide developed using Leventhal's CSM of self-regulation with ideas about causes of diabetes, its effects, the timelines over which consequences might be expected and its controllability and consequences being explored. Salient beliefs about the benefits and harms associated with adhering to self management behaviours of eating, physical activity and medication adherence and barriers which might interfere with adherence were also discussed. If a patient was using a blood glucose monitor, additional enquiry about motivation and prompts for using it were made. If patients were not using a monitor, reasons for not doing so were also explored. The topic guide was serially revised as new ideas emerged which provided useful areas of inquiry in subsequent interviews and the final version is included (Appendix 2). Interviews were audio taped and transcribed verbatim for analysis.

Analysis of the interviews

Interviews were analysed using the framework approach(195), with the thematic framework used based on the theory of self-regulation. Transcripts were analysed and coded independently by the author, an academic psychologist and an academic general practitioner. The first five transcripts analysed were used to develop the coding framework and each of these transcripts was analysed twice by each of the coders to ensure no themes were omitted. The common themes identified were each assigned a unique

identifier and then used to construct a coding framework to facilitate analysis of the remaining transcripts.

The three coders read the remaining transcripts and identified each instance of the codes identified in the framework. Any other concepts which emerged when further transcripts were analysed and which were considered theoretically important, but had not been included in the original coding framework, were added to subsequent versions. The author then collated the individual analyses and calculated the frequency with which codes were identified.

(ii) Selection of items

Compilation of draft questionnaire

A draft questionnaire was compiled using the items listed in the coding framework; a section on demographic data was also included. Items from the coding framework were included in the questionnaire if they did not duplicate items or concepts already covered in the IPQ-R or BMQ or if they were not simply negatively-phrased concepts already included in the questionnaire. Items which related to emotional responses on diagnosis rather than at present and questions which addressed the importance of behaviours for overall health, rather than diabetes were also omitted. Items relating to consequences of diabetes were reworded to refer to "my diabetes" rather than "people with diabetes" in order to reflect a more personal relationship to potential consequences. Responses to items were scored on a 5 point rating scale ranging from "strongly agree" to "strongly disagree" to ensure compatibility with the pre-existing measures. For the identity scale, patients were asked to indicate whether they had experienced a symptom and if so whether they believed that symptom was related to their diabetes. If they believed there to be a relationship, they were asked to indicate whether they thought they experienced this symptom when their blood sugar was high or low. The questionnaire was then piloted to evaluate it for comprehensibility, flow and distribution of items.

Piloting of draft questionnaire

The questionnaire was evaluated in a convenience sample of patients drawn from a hospital diabetes clinic and in those patients initially interviewed. Patients in a hospital diabetes clinic who had non-insulin treated type 2 diabetes were approached while waiting for their appointments. The study was explained to them and if willing to participate, they were asked to complete a consent form. They were then asked to complete the questionnaire whilst "thinking aloud" (196) which allowed us to assess whether patient interpretation of items was in keeping with the intended meaning. It also allowed feedback on how well the questionnaire flowed and highlighted items which were difficult to understand which we then reworded. Patients who had participated in the interview stage of the study were also sent copies of the questionnaire and invited to fill them out. The questionnaires obtained were analysed to determine the mean, standard deviation and skew of each item.

Selection of items for questionnaire validation study

Codes which appeared in at least 4 of the 26 interviews were included in the questionnaire to be evaluated in the second study. Items which displayed a skewed distribution were reworded as were items which presented difficulty during the piloting process. Items which were considered theoretically important but which did not meet the frequency criteria were included in the questionnaire, while those thought to be less theoretically relevant were discarded. The items were used to compile the following:

a) additional diabetes-specific illness representation items

b) additional diabetes-specific medication representation items

c) items relating to beliefs about eating and physical activity

d) items relating to beliefs about blood glucose self-monitoring

e) items relating to blood glucose self-monitoring behaviours

Measures of the above items were again created with responses on a five point rating scale with answers ranging from strongly disagree to strongly agree (1=strongly disagree, 5=strongly agree). Scale scores were obtained by

summing the scores of each item, after reverse scoring the appropriate items. The additional identity items were scored as described in the IPQ-R. Additional items eliciting beliefs about the perceived threat of high blood sugar and the accuracy of and confidence in BGSM were included as ideas about the threat could potentially influence illness representations and beliefs about the confidence and accuracy of BGSM could potentially affect its use. These additional items were rated on a 7-point rating scale in order to elicit greater discrimination.

(ii) Results

Respondent characteristics

Table 4.2 presents the characteristics of the 26 patients interviewed. Values are n (%) unless otherwise stated. Approximately half of the patients interviewed were male and the majority of them were on oral therapy for their diabetes and using BGSM

Male	12 (46.2%)
Mean (SD)age/years	62.2 (8.4)
Median (IQR) duration of diabetes/years	2 (5.2)
Oral hypoglycaemic therapy	16 (61.5%)
Use of BGSM	18 (69.2%)

Table 4.2 Demographic characteristics of patients interviewed

Interview analysis

Analysis of the initial five interviews produced a coding framework with 85 codes which were classified as beliefs about causes of diabetes, prevention of diabetes, timelines related to diabetes, consequences of diabetes, controllability of diabetes, and the effects of eating, physical activity and medication adherence on diabetes and blood glucose self-monitoring. The final coding framework is shown below (Table 4.3) with the frequency with which each code appeared in the transcripts indicated.

Construction and piloting of questionnaire

The items from the coding framework which were omitted from the draft questionnaire and the reasons for their omission are shown in Table 4.4. The other item excluded was "Exercise would help me lose weight but would not directly affect my blood sugar" as it was a complex item relating both to beliefs about exercise and weight and exercise and blood sugar and would be likely to evaluate more than one construct.

Other items were reworded to improve their relevance or simplify their meaning. These are shown in Table 4.5.

Piloting of the draft questionnaire revealed that patients had difficulty in understanding the responses to the identity section of the questionnaire. The question asking about the perceived level of blood sugar when a symptom was experienced was therefore removed from the response scale. The means, standard deviations and skews of the draft questionnaire items are shown in Table 4.6.

Beliefs about causes	**Frequency**
Diabetes is caused by being overweight	13
Diabetes is caused by eating too many sweets and puddings	11
Diabetes is caused by eating too many fatty foods	3
Diabetes is caused by aging	6
Diabetes is genetic	11
Diabetes is caused by stress	7
Diabetes is caused by not getting enough exercise	9
Diabetes is caused by a bad diet	12
Diabetes is caused by an unhealthy lifestyle	8
I do not know what causes diabetes	
Emotional responses to diabetes	**Frequency**
I was relieved when I was diagnosed with diabetes	3
I was worried when I was diagnosed with diabetes	10
I was unconcerned when I was diagnosed with diabetes	2
I was surprised when I was diagnosed with diabetes	10
Being diagnosed with diabetes depressed me	1
I am worried about my diabetes getting worse	4
I am concerned if my blood sugar goes up	1
I feel guilty if my blood sugar is high	2
I am now comfortable with the idea of having diabetes	5
I am afraid of the consequences of diabetes	7
Beliefs about timelines	**Frequency**
I think my diabetes will get better if I improve my lifestyle	3
I think my diabetes will get worse if I don't improve my lifestyle	7
I think my diabetes will stay the same if I improve my lifestyle	16
I do not know what will happen to my diabetes	1
Beliefs about symptoms	**Frequency**
When my blood sugar is high, I get recurrent infections	1
When my blood sugar is high, I feel tired	8
When my blood sugar is high, I feel thirsty	5
When my blood sugar is high, I get irritable	3
When my blood sugar is high, I urinate often	7
When my blood sugar is low, I feel faint	5
Diabetes has no significant effect on me physically	8

Beliefs about consequences of diabetes	**Frequency**
High blood sugar over a short period of time would not cause any damage	1
High blood sugar over a long period of time can damage the organs	6
People with diabetes can go into comas	4
People with diabetes can have kidney damage	5
People with diabetes can have problems with their feet	18
People with diabetes can have problems with eyesight	17
People with diabetes are more likely to have heart attacks	6
People with diabetes are more likely to get infections	5
People with diabetes are more likely to be tired	6
People with diabetes are more likely to be thirsty	6
People with diabetes have a reduced quality of life	1
Beliefs about controllability	
I think my diabetes can be cured	
Progression of diabetes is unavoidable	3
Beliefs about eating	
I eat less food because I have diabetes	10
Having an occasional sweet will not affect my diabetes significantly	20
Eating sweet food affects the way I feel	6
Carbohydrates that release sugar slowly are important to include in the diet	3
It is important for my diabetes to reduce sugar in my diet	26
It is important for my overall health to exclude high-fat food from my diet	17
It is important for my diabetes to exclude high fat food from my diet	7
It is important for my overall health to include fruit in my diet	22
It is important for my overall health to include vegetables in my diet	23
It is important for my diabetes to include fruit in my diet	7
It is important for my diabetes to include vegetables in my diet	8
It is important for my diabetes control to include cereals and fibre in my diet	6
Eating too much fruit can harm my diabetes	10
Drinking too much alcohol affects my diabetes	5

Table 4.3 Frequency of items from interviews

Beliefs about eating	**Frequency**
Eating a sensible diet is the most important factor in controlling my diabetes	16
I enjoy eating sweet/fatty food	6
Beliefs about exercise	
Exercise is important for my overall health	3
Exercise is important for my diabetes in particular	16
Exercise has a direct effect on my blood sugar	8
Exercise would help me lose weight, but would not directly affect my blood sugar	2
I could improve my diabetes by losing weight	14
I feel better after I exercise	2
I feel worse after I exercise	5
If my blood sugar were high, I would go for a walk	2
Beliefs about medication	
My medication is important in controlling my diabetes	21
My medication is not important in controlling my diabetes	3
My medication serves as a crutch and allows me to be less strict about my diet	2
I do not notice any physical effects from my diabetes medication	5
I would be unhappy if I had to use insulin	10
If I ate something that I knew would send up my blood sugar, I might increase the dose of my medication	2
If I had to start taking tablets or increase the dose I was on, I would think my diabetes was getting worse	9
If I had to start taking insulin, I would think my diabetes was getting worse	4
I would think my diabetes was getting better if I could stop or reduce my tablets	4
Beliefs about BGSM	
I check my blood sugar at home because my health professional recommended it	12
I check my blood sugar at home because I am curious to see what the results are	11
I check my blood sugar according to a routine	7
Checking my blood sugar helps me to control my eating habits	10
I check my blood sugar after a big meal to see if it has gone up	5

Beliefs about BGSM	**Frequency**
I check my blood sugar if I am not feeling well	9
If my blood sugar were high, I would eat less at my next meal	7
If my blood sugar were high, I would recheck it later	8
If my blood sugar were high I would try to figure out what I had done that caused it to increase	15
If my blood sugar were high, I would do nothing differently	2
If my blood sugar were persistently high, I would see my health professional	23
If my blood sugar were low and I was feeling well, I would not do anything	8
If my blood sugar were low and I was feeling unwell, I would have something to eat	11
If my blood sugar were persistently low, I would see my health professional	11
Checking my blood sugar at home alerts me early if there's a problem with my blood sugar control	7
Checking my blood sugar would cause me to worry	9
I prefer if the health professional checks my blood sugar	2
Other people with diabetes can tell if their blood sugar is abnormal without testing it	13
Other people with diabetes can not tell if their blood sugar is abnormal without testing it	4
I can tell if my blood sugar is abnormal without testing it	16
I can not tell if my blood sugar is abnormal without testing it	13
I do not think that I need to check my blood sugar often (more than once a week)	5
Checking my blood sugar reassures me	9
Checking my blood sugar is not important	6
Checking my blood sugar is painful	5

Table 4.3 Frequency of items from interviews

Reason for omission	**Item omitted**
Duplication of items in existing questionnaire	Aging (causes)
	Genetic (causes)
	Stress (causes)
	Bad diet (causes)
	Tiredness (symptoms)
	Feeling faint (symptoms)
	I do not know what will happen with my diabetes (timelines)
	I think my diabetes can be cured (controllability)
	I do not notice any physical effects from my diabetes medication (specific concerns)
Duplication of other items in the framework	I do not know what causes diabetes
	High blood sugar over a period of times would not cause any damage
	I believe my diabetes will get worse if I don't improve my lifestyle
	Exercise has a direct effect on my blood sugar
	My medication is not important in controlling my diabetes
	If I had to start taking insulin I would think my diabetes was getting worse
	Other people with diabetes cannot tell if their blood sugar is abnormal without testing it
	I cannot tell if my blood sugar is abnormal without testing it
Theoretical irrelevance	I was relieved when I was diagnosed with diabetes
	I was worried when I was diagnosed with diabetes
	I was unconcerned when I was diagnosed with diabetes
	I was surprised when I was diagnosed with diabetes
	Being diagnosed with diabetes depressed me
	I feel guilty if my blood sugar is high
Reference to general health rather than diabetes	Eating sweet food affects the way I feel
	It is important for my overall health to exclude high fat food from my diet
	It is important for m overall health to include fruit in my diet
	It is important for my overall health to include vegetables in my diet
	Exercise is important for my overall health

Table 4.4 Items omitted from the questionnaire

Original wording	**Reworded item**
Reworded to reflect a more personal relationship to consequences	
People with diabetes can go into comas	My diabetes could cause me to go into a coma
People with diabetes can have kidney damage	My diabetes could cause me to have kidney damage
People with diabetes can have problems with their feet	My diabetes could cause me to have problems with my feet
People with diabetes can have problems with eyesight	My diabetes could cause me to have problems with my eyesight
People with diabetes are more likely to have heart attacks	My diabetes makes me more likely to have heart disease
People with diabetes are more likely to get infections	My diabetes makes me more likely to get infections
People with diabetes have a reduced quality of life	My diabetes reduces the quality of my life
Simplification and clarification of item	
I think my diabetes will stay the same if I improve my lifestyle	I think my diabetes will stay the same
Progression of my diabetes is unavoidable	Worsening of my diabetes is unavoidable
My medication serves as a crutch and allows me to be less strict about my diet	My medication would allow me to be less strict about my diet (included as an important theoretical construct although the frequency criteria was not met)
I check my blood sugar at home because my health professional recommended it	My health care professional recommends I check my blood sugar at home
I check my blood sugar at home because I am curious to see what the results are	I am curious about the level of my blood sugar
Checking my blood sugar would cause me to worry	Checking my blood sugar at home would cause me to worry
Checking my blood sugar is not important	Checking my blood sugar at home is not important
I enjoy eating sweet food	I would enjoy eating sweet food
I enjoy eating fatty food	I would enjoy eating fatty food

Table 4.5 Reworded questionnaire items

Item	Mean	S.D.	Skew
Beliefs about causes			
Diabetes is caused by being overweight	3.35	1.355	-.444
Diabetes is caused by eating too many sweets and puddings	2.87	1.408	.014
Diabetes is caused by eating too many fatty foods	2.87	1.279	.054
Diabetes is caused by not getting enough exercise	2.90	1.296	-.006
Diabetes is caused by an unhealthy lifestyle	2.48	1.184	.321
Emotional responses to diabetes			
I am worried about my diabetes getting worse	3.67	1.028	-.891
I am concerned if my blood sugar goes up	3.74	.815	-1.055
I am now comfortable with the idea of having diabetes	3.39	1.022	-.674
I am afraid of the consequences of diabetes	3.62	.979	-.364
Beliefs about timelines			
I think my diabetes will get better if I improve my lifestyle	3.17	1.177	-.073
I think my diabetes will stay the same	3.10	.831	.184
Beliefs about consequences of diabetes			
If my diabetes were high over a short period of time it would damage my body	3.13	1.118	.189
My diabetes could cause me to go into a coma	3.55	1.028	-.139
My diabetes could cause me to have kidney damage	3.84	.898	-1.435
My diabetes could cause me to have problems with my feet	4.23	.669	-1.006
My diabetes could cause me to have problems with my eyesight	4.23	.669	-1.006
My diabetes makes me more likely to have heart disease	4.03	.605	-.010
My diabetes makes me more likely to get infections	3.65	.877	-.476
My diabetes reduces the quality of my life	2.87	1.252	.042
Beliefs about controllability of diabetes			
Worsening of diabetes is unavoidable	2.80	.761	.362
Beliefs about eating			
I should eat less food because I have diabetes	2.93	1.081	.140
It is important for my diabetes to reduce the sugar in my diet	4.35	.551	-.015
Having an occasional sweet will not affect my diabetes significantly	3.74	.631	-2.304
Carbohydrates that release sugar slowly are important to include in the diet	4.14	.516	.235
It is important for my diabetes to exclude high fat food from my diet	3.87	.957	-1.190
It is important for my diabetes to include fruit in my diet	4.10	.651	-.093
Eating too much fruit can harm my diabetes	2.57	1.006	.349
It is important for my diabetes to include vegetables in my diet	4.16	.779	-2.108
It is important for my diabetes control to include cereals and fibre in my diet	4.16	.523	.226
Drinking too much alcohol affects my diabetes	3.93	.944	-1.966
Eating a sensible diet is the most important factor in controlling my diabetes	4.19	.792	-2.088
I would enjoy eating sweet foods	3.07	1.100	.028
I would enjoy eating fatty foods	2.66	1.078	.394

Table 4.6 Statistical distribution of items from draft questionnaire

Item	Mean	S.D.	Skew
Beliefs about exercise			
Exercise is important for my diabetes	4.07	.583	-1.114
If I lost weight, I could improve my diabetes	3.81	1.078	-.955
Exercise makes me feel better	3.77	.560	-1.268
Exercise makes me feel worse	2.21	.620	.816
Beliefs about medication			
Medication is important in controlling my diabetes	3.76	1.057	-1.035
Medication allows me/ would allow me to be less strict about my diet	2.57	.898	.399
I would be unhappy if I had to use insulin to control my diabetes	4.13	.763	-.708
I might increase the dose of my medication if I ate something that I knew would send up my blood sugar	2.55	1.021	.824
I would think my diabetes was getting worse, if I had to start taking tablets or increase the dose I was on	3.47	.860	-.412
I would think my diabetes was getting better if I could stop or reduce my tablets	3.69	.930	-1.317
Beliefs about BGSM			
Checking my blood sugar at home would cause me to worry	1.97	.850	.787
I prefer if my health professional checks my blood sugar	2.40	1.102	.603
Other people with diabetes can tell if their blood sugar is abnormal without testing it	3.13	.973	-.042
I can tell if my blood sugar is abnormal without testing it	2.94	1.093	.462
It is not important for me to check my blood sugar	2.33	1.124	.681
Checking my blood sugar is painful	2.47	1.137	1.522
I do not think that I need to check my blood sugar often (more than once a week)	2.57	1.223	1.047
My health professional suggests I check my blood sugar at home	4.57	.971	.525
I am curious about the level of my blood sugar	4.50	1.075	.089
I check my blood sugar according to a routine	4.32	1.194	.200
Checking my blood sugar helps me to control my eating habits	4.35	1.199	-.005
I check my blood sugar after a big meal to see if it has gone up	3.67	1.647	.329
I check my blood sugar if I am not feeling well	4.42	1.232	-.202
If my blood sugar were high, I would eat less at my next meal	4.13	1.383	-.087
If my blood sugar were high, I would recheck it later	4.53	1.074	-.003
If my blood sugar were high I would try to figure out what I had done that caused it to increase	4.66	.974	.277
I would not do anything differently if my blood sugar were high	3.00	1.964	.790
If my blood sugar were persistently high, I would see my health professional	4.63	1.098	-.867
If my blood sugar were lower than usual and I was feeling well, I would not do anything	3.70	1.725	.025
If my blood sugar were lower than usual and I was feeling unwell, I would have something to eat	4.61	.919	.607
If my blood sugar were persistently lower than usual, I would see my health professional	4.83	.874	.344
Checking my blood sugar at home alerts me early if there's a problem with my blood sugar control	4.71	.902	.340
Checking my blood sugar reassures me	4.60	1.070	-.188
If my blood sugar were high, I would get some exercise	3.93	1.510	.325

Table 4.6 Statistical distribution of items from draft questionnaire

Selection of items for questionnaire evaluation study

Selection of items for the questionnaire evaluation study was based on the frequency with which codes appeared in the transcripts, their theoretical relevance and the distribution of items obtained during the piloting. Items which appeared fewer than 4 times were omitted. Items which were skewed, but thought to be theoretically important were reworded in an effort to reduce skew.

Items which were discarded on the basis of frequency were:

a) Symptoms of recurrent infection and irritability
b) Diabetes is caused by eating too many fatty foods
c) I am concerned if my blood sugar goes up
d) Exercise makes me feel better
e) If my blood sugar were high, I would get some exercise
f) I would not do anything differently if my blood sugar were high

Items which were reworded were

a) "Having an occasional sweet will not affect my diabetes significantly" was reworded "Having an occasional sweet will not affect my diabetes" to reduce skew
b) All items relating to eating behaviours were reworded to begin with the phrase "Because I have diabetes" and include the phrase "every day" in order to emphasize the relationship between diabetes and following that particular advice
c) "Drinking too much alcohol" was reworded to read "Drinking small amounts of alcohol could affect my diabetes" in order to reduce skew.
d) Items were reworded to refer to physical activity rather than exercise in keeping with current recommendations

Items regarding consequences were skewed, but this may have reflected factual knowledge and might be expected to reveal less variation in a well-educated population. These items were therefore not reworded.

The measures constructed from the remaining items were assembled into a questionnaire which was evaluated in a cross-sectional study described below.

4.3.2 Study 2- Evaluation of preliminary questionnaire

A second study was carried out to evaluate the questionnaire developed in study 1. Its specific aims were:

- to evaluate the factor structures of the IPQ-R and BMQ in a population with non-insulin treated type 2 diabetes
- to evaluate the effect of additional diabetes-specific questions on the factor structures of the IPQ-R and BMQ
- to develop scales of beliefs about eating, physical activity and blood glucose self-monitoring and BGSM behaviours
- to evaluate the internal consistency and predictive validity of the above scales

(i) Methods

Study design and recruitment of patients

A cross-sectional survey was carried out to evaluate the performance characteristics of some of measures to be used in the RCT. A questionnaire including measures of belief (IPQ-R, BMQ, additional diabetes-specific items, items relating to beliefs about eating and physical activity and BGSM) and measures of behaviour (SDSCA, MARS and items on BGSM use) was compiled. The WBQ-12 and DTSQ were omitted as these had already been validated in populations with non-insulin treated type 2 diabetes. The EQ-5D was also excluded as it is expected to behave similarly in all illness groups.

Six Buckinghamshire practices were contacted and agreed to participate and approval from the Aylesbury Vale Ethics Committee was obtained. Inclusion and exclusion criteria were the same as for the development of the preliminary questionnaire. Practice doctors reviewed lists of patients with non-insulin treated type 2 diabetes and removed patients who were not eligible to participate. A questionnaire, accompanied

by an information sheet, consent form and pre-paid return envelope, was mailed to all eligible patients who, if they wished to participate, were asked to complete the consent form and return it with the completed questionnaire. If a reply was not received within a month, a second questionnaire, invitation letter and consent form were mailed.

Statistical analysis

Summary of questionnaire analysis techniques

(i) Principal components analysis

Exploratory principal components analysis (PCA) was used extensively in analysis of the questionnaire data to identify coherent scales from the item pool. PCA is a mathematical procedure in which data can be simplified and the major dimensions or constructs underlying a larger number of dimensions identified(197). These dimensions are known as components and represent hidden or latent variables which account for much of the variance in the "observed" variables in the data collected. The relationship between an item and any given component is determined by the loading value, with a higher absolute value indicating a stronger relationship. Items should ideally load on to a single factor to ensure separate scales are assessing separate constructs. In our study, we generally chose a loading value of 0.4, unless otherwise specified, which is widely accepted as the level of which an item is considered to be loading on to a factor(194). There was one exception to this however, which is described below.

Components may be represented in a multi-dimensional space in which they are represented by axes(197). The axes on which they are represented are not fixed however and may be rotated, which alters the loading of an item on to a component, although the amount of variance accounted for by all components does not change. Rotation can significantly alter interpretation of component analyses and in theory, an infinite number of solutions exist for a single analysis. Two main types of rotation are specified in factor analysis. In orthogonal rotation, the axes are fixed at right angles to each other and this method therefore assumes the factors are uncorrelated. Varimax rotation is the most commonly accepted method. The Direct Oblimin method is the most commonly used method of oblique rotation in which the factors are allowed to be correlated and are therefore allowed to take up unrestricted positions in relation to

each other as dictated by their correlation. We generally used Varimax rotation in the factor analysis on the assumption that there was no relationship between the factors produced.

The total amount of variance explained by a component is known as the eigen value or characteristic root of a factor, with the component with the largest eigen value explaining the most variance(197). Eigen values are often used to determine which factors in an analysis are most likely to be significant and should be selected for rotation. We chose an eigen value of 1 as our threshold because a component with an eigen value of one accounts for the variance present in a single observed variable and is therefore likely to be important.

(ii) Assessment of validity and reliability

While there are numerous forms of validity and reliability, not all of these may be applicable to a particular measure. In our study we calculated the internal consistency of each scale using Cronbach's alpha(198) to ensure that all items within a scale were measuring the same construct. We evaluated the structure of the pre-existing measures of belief before and after addition of diabetes-specific items to assess whether their factor structures could be duplicated in our population.

We also assessed the predictive validity of the pre-existing and newly developed measures of belief to see whether beliefs were predictive of self care activities as suggested by our causal model. This was done using multiple linear regression models in which the behaviours of interest were entered as dependent variables and demographic data and belief measures were used as independent variables. This is outlined in greater detail below; in each case, however, demographic data were entered as the first block and scores on belief measures entered as the second and, where applicable, third block. An enter rather than step-up or step-down method was used in the regression as we were evaluating our theory that general illness beliefs would significantly improve the prediction of demographic data and that specific illness beliefs would, in turn, significantly improve the prediction of general illness beliefs. Use of linear regression assumes normality of the dependent variables(199); the

distributions of scores on self care behaviour scales were visually assessed for normality prior to using this method to ensure no changes of scale or transformations were necessary.

Analysis of questionnaires

Questionnaire data were entered into a SPSS database (SPSS for Windows, v 11.0.1) along with demographic information for study respondents. A dummy variable was created for the qualitative variable of gender, with the dummy variable equalling 0 for male respondents and 1 for female respondents.

a) Blood glucose self-monitoring behaviours

Items relating to blood glucose self-monitoring behaviour were analysed first to provide an outcome scale for multiple regression models. These items were subjected to exploratory principal components analysis under the conditions specified above and the internal reliability of the resulting scales was calculated.

b) IPQ-R

The causal and identity items were analysed separately and the methods used for this are outlined below. PCA was used to explore the factor structure of the other dimensions and was carried out on the original IPQ-R items using an eigen value >1 and a loading threshold of 0.4. The PCA was repeated using an eigen value >1.1 and a loading threshold of 0.5 (the criteria used in the original validation study(186)) to facilitate comparison of the published IPQ-R scales and those obtained in this population. After reverse scoring the negatively-worded items, the internal reliability of the original IPQ-R scales and those obtained from the factor analysis of the questionnaire data were calculated using Cronbach's alpha.

The score for each factor obtained was calculated by summing the scores of its constituent items. Multiple regression analyses were used to evaluate the predictive validity of each of the original IPQ-R scales as well as the scales resulting from the PCA using the IPQ-R dimensions as independent variables and the following behaviour measures as dependent variables – general diet, eating five or more fruit or vegetables daily, eating high fat foods, exercise (all derived from the SDSCA),

medication adherence as assessed by the MARS and undertaking of blood glucose self-monitoring. In each case, demographic information was entered as the first regression step and the ability of the IPQ-R dimensions to improve on the prediction of demographic data assessed. The original IPQ-R scales and the scales derived from the study were compared.

c) Additional diabetes-specific items

PCA was performed on a pool of items comprising both the IPQ-R items and the additional diabetes-specific items in order to evaluate the effect of these items on the IPQ-R factor structure. The PCA was initially performed using an eigen value > 1, but the rotation failed to converge and was repeated using an eigen value > 1.1 and a loading threshold of 0.4. The necessary items were reverse scored and the internal reliability of the resulting scales was determined using Cronbach's alpha and the scores for the resulting scales were calculated by summing the scores of its constituent items. The predictive validity of the new scales was evaluated as with the IPQ-R scales. The factor structure, internal reliability and predictive validity of the original IPQ-R scales, the scales derived from the IPQ-R items in the cross sectional study and the scales resulting from addition of diabetes-specific items were compared.

d) IPQ-R Causal items

PCA was performed on the original IPQ-R causal items using an eigen value > 1 and a threshold of 0.4. Analyses were repeated until a structure was obtained in which each item loaded on to a single factor. Where necessary, items were reverse scored and Cronbach's alpha was calculated for both the scales originally identified and those empirically determined in the present study. The score for each factor was calculated by summing the score of the constituent items and the ability of original and new scales to predict the behaviours outlined above was evaluated using multiple hierarchical regression.

e) Additional causal items

PCA was performed on a pool of items comprising the IPQ-R causal items and the additional interview-derived causal items in order to evaluate the effect on the IPQ-R causal factor structure. The PCA was performed using an eigen value > 1, and a

loading threshold of 0.4 with repeat analyses being performed until a structure was obtained in which an item loaded on to a single factor. The necessary items were reverse scored and the internal reliability of the resulting scales was determined using Cronbach's alpha and the scores for the resulting scales were calculated by summing the scores of its constituent items. The predictive validity of the new scales was evaluated as with the original causal scales and the factor structure, internal reliability, and predictive validity of the original causal scales in this population, the scales derived from the cross-sectional study and the scales resulting after the addition of interview derived items were compared.

f) IPQ-R identity scales

The frequency with which each symptom was observed was calculated. The validity of the separation of the symptoms experienced and identity subscales was evaluated with a paired sample t-test. The internal reliability of the identity scale was calculated using Cronbach's alpha and the predictive validity of the identity subscale was evaluated using multiple hierarchical regression with the behaviours noted above as dependent variables.

g) Additional identity items

The frequency of the additional items was calculated. The additional items were added to the scales and the paired sample t-test was repeated to evaluate whether the new identity scale was valid. Internal reliability and predictive validity were recalculated using Cronbach's alpha and multiple hierarchical regression respectively. The reliability and predictive validity of the two scales were compared.

h) Beliefs about medication items

The factor structure of the BMQ in this population was evaluated using PCA with a threshold of 0.4. Direct Oblimin rotation, with specification of two factors was used in this instance since this was the method used in the development of the original measure and we wanted to duplicate the procedures employed. The PCA was repeated after inclusion of the newly developed medication items and in each case the internal reliability of the resulting scales was calculated using Cronbach's alpha and

their ability to improve the predictive validity of the IPQ-R dimensions for medication adherence was investigated using multiple hierarchical regression. The internal reliability and predictive validity of these scales were compared.

i) Items relating to beliefs about eating and physical activity

The factor structure of items relating to beliefs about eating and physical activity was determined by PCA with an eigen value > 1 and a loading threshold of 0.4. Successive analyses were carried out until a structure was obtained in which each item loaded on to a single factor and the reliability of the resulting scales was calculated. Multiple hierarchical regression was carried out to investigate whether these beliefs increased the predictive validity of illness perceptions of diabetes with relation to eating and physical activity.

j) Beliefs about blood glucose self-monitoring

The factor structure of the beliefs about blood glucose self-monitoring was explored using PCA with an eigen value > 1 and a threshold of 0.4. Analyses were repeated until a stable solution was obtained. Cronbach's alpha was used to calculate the internal reliability of each scale and the ability of these beliefs to predict BGSM use was evaluated using multiple hierarchical regression.

(ii) Results

Respondent characteristics

428 questionnaires were sent out, of which 257 (60%) were returned. The demographic characteristics of the respondents are shown below in Table 4.7. and values are n (%) unless otherwise stated.

Male	162 (64.5%)
Mean (SD) age (years)	65.6 (11.9)
Median (IQR) duration of diabetes (years)	4 (IQR 6.5)
Oral hypoglycaemic medication use	191 (74.6%)
BGSM more than once a week	139 (55.2%)

Table 4.7 Demographic characteristics of questionnaire respondents

Questionnaire analysis

a) Analysis of blood glucose self-monitoring behaviour

Factor structure and internal reliability of BGSM use

Two analyses were performed on BGSM behaviour items. One PCA was performed on the two items eliciting information on whether patients had ever used BGSM and how frequently they currently used it. One component was produced and the alpha coefficient for this two-item scale was .90. This scale was used as the BGSM outcome measure in the multiple regression models.

Factor structure and internal reliability

Eleven items were entered into a PCA using an eigen value of more than one and a loading threshold of .4. This produced three factors accounting for 52% of the variance. Three items- "I check my blood sugar according to a routine", "If my blood sugar were lower than usual, I would have something to eat" and "If my blood sugar were persistently lower than usual, I would see my health professional" loaded on to two factors and were omitted from subsequent analysis. A second analysis produced three factors accounting for 61% and is shown below in Table 4.8.

	Component		
	1	2	3
My health professional suggests I check my blood sugar at home	**.714**	.046	.026
If my blood sugar were high, I would try to figure out what I had done to cause it to increase	**.788**	-.081	.017
If my blood sugar were persistently high, I would see my health professional	**.727**	-.046	.172
I check my blood sugar after a big meal to see if it has gone up	-.060	**.790**	.062
If my blood sugar were high, I would eat less at my next meal	-.021	**.804**	.054
I check my blood sugar if I am not feeling well	.311	.282	**.651**
If my blood sugar were high, I would recheck it later	.333	.259	**.609**
If my blood sugar were lower than usual and I was feeling well, I would not do anything	.257	.247	**-.807**

Table 4.8 Factor structure of BGSM behaviours

Internal reliability

The internal reliability of the BGSM behaviour scales is shown in Table 4.9. In each case, the internal reliability was less than optimal.

Scale
(α= .65) My health professional suggests I check my blood sugar at home If my blood sugar were high, I would try to figure out what I had done to cause it to increase If my blood sugar were persistently high, I would see my health professional
(α= .53) I check my blood sugar after a big meal to see if it has gone up If my blood sugar were high, I would eat less at my next meal
(α=. 52) I check my blood sugar if I am not feeling well If my blood sugar were high, I would recheck it later If my blood sugar were lower than usual and I was feeling well, I would not do anything

Table 4.9 Internal reliability of BGSM behaviours scales

The BGSM behaviour items did not form reliable, coherent scales and items should probably be considered separately.

b) Analysis of IPQ-R

Mean and SD of non-causal IPQ-R items

The means and standard deviations of the scores of the non-causal IPQ-R items are attached in Appendix 3.

Structural validity of IPQ-R items

The initial PCA was carried out on the 38 original IPQ-R items using an eigen value >1 and a loading threshold of 0.4. This produced 10 factors which accounted for 67% of the variance. Of the 38 items initially entered into the analysis, five of these ("This diabetes will pass quickly", "I have the power to influence my diabetes", "My treatment can control my diabetes", "There is nothing which can help my diabetes" and "My diabetes does not worry me") loaded on to more than one factor and were omitted from subsequent analysis. The analysis was repeated and nine factors were produced which accounted for 69% of the variance. The results of this PCA are shown in Table 4.10.

The factor structure of the diabetes-specific IPQ-R was not similar to that of the original IPQ-R. Items which had originally loaded on to the timelines (acute/chronic), consequences and personal control scales loaded on to two separate scales in each instance. There was overlap between the timelines (acute/chronic) scale and consequences scale and the timelines (acute/chronic) scale and treatment control scale as well as between the treatment control and personal control scales. The items which originally loaded on to the treatment control scale all redistributed to other scales.

The PCA conducted in the IPQ-R paper, utilized eigen values of greater than 1.1 and a loading threshold of 0.5. In order to facilitate comparison of the factor structure published in this paper and that obtained in this study, the PCA was repeated using these criteria.

Item	Component								
	1	2	3	4	5	6	7	8	9
My diabetes is likely to permanent rather than temporary	-.098	.035	-.040	**.859**	.101	-.091	.004	-.010	-.085
My diabetes will last for a long time	-.127	-.013	-.021	**.865**	.074	-.007	.012	.030	-.046
I expect to have this diabetes for the rest of my life	-.170	.052	.041	**.815**	.065	-.027	.056	.073	-.126
My diabetes is a serious condition	-.221	.015	.073	**.501**	.174	-.067	.095	.353	-.118
My diabetes has major consequences on my life	-.008	.144	.064	.152	.075	-.064	.244	**.809**	-.100
My diabetes does not have much effect on my life	.026	-.148	-.060	-.018	-.041	.175	-.138	**-.835**	.077
My diabetes strongly affects the way others see me	.150	.092	.200	.038	.080	.119	**.755**	.048	.087
My diabetes has serious financial consequences	.004	.148	.097	.032	-.157	-.011	**.701**	.122	-.040
My diabetes causes difficulties for those who are close to me	-.078	.276	.099	.044	-.006	-.051	**.703**	.235	-.005
There is a lot which I can do to control my symptoms	-.189	-.191	-.025	.113	**.703**	-.120	-.070	.125	-.068
What I do can determine whether my diabetes gets better or worse	-.065	.022	-.057	.159	**.786**	-.244	.076	-.007	.025
The course of my diabetes depends on me	-.022	-.047	.046	.073	**.792**	.002	-.096	.013	-.034
Nothing I do will affect my diabetes	.153	.128	.051	-.115	-.251	**.730**	.040	-.063	.132
My actions will have no effect on the outcome of my diabetes	.065	-.002	.038	.059	-.117	**.796**	-.027	-.056	.040
There is very little that can be done to improve my diabetes	.239	.096	-.024	-.181	.014	**.582**	.079	-.275	-.241
My diabetes will last a short time	.064	-.067	.051	-.304	-.168	.375	.056	.063	**.576**
My diabetes will improve in time	.107	-.004	.047	.000	-.057	-.078	-.025	-.125	**.674**
My treatment will be effective in curing my diabetes	.175	-.046	.119	-.194	-.043	.140	.011	-.133	**.713**
The negative effects of my diabetes can be prevented (avoided) by my treatment	-.085	.027	-.132	-.041	.340	-.168	.038	.086	**.473**
The symptoms of my condition are puzzling to me	**.842**	.108	.064	.030	-.049	.006	.086	-.054	.166
My diabetes is a mystery to me	**.849**	.018	.071	-.178	-.079	.123	-.052	-.035	.108
I don't understand my diabetes	**.821**	.104	.097	-.061	-.109	.205	-.002	.004	.093
My diabetes doesn't make any sense to me	**.854**	.050	.106	-.176	-.103	.140	.041	.015	.055
I have a clear picture or understanding of my condition	**-.701**	-.165	-.128	.277	-.007	.042	-.037	.035	.142
The symptoms of my diabetes change a great deal from day to day	.109	.272	**.713**	-.033	-.101	.077	.099	.173	.005
My symptoms come and go in cycles	.015	.101	**.871**	.002	.030	.036	.105	-.065	.075
My diabetes is very unpredictable	.223	.207	**.770**	-.044	-.070	.028	.246	.016	-.013
I go through cycles in which my diabetes gets better and worse	.109	.136	**.856**	.060	.051	-.031	.026	.064	.039
I get depressed when I think about my diabetes	.116	**.800**	.108	-.053	-.027	-.012	.200	.074	-.116
When I think about my diabetes I get upset	.084	**.789**	.158	-.009	-.070	-.040	.281	.025	-.134
My diabetes makes me feel angry	.051	**.739**	.220	.080	-.076	.005	.188	-.050	.092
Having this diabetes make me feel anxious	.030	**.821**	.137	.065	.028	.083	.082	.218	-.011
My diabetes makes me feel afraid	.154	**.797**	.101	.010	-.088	.141	-.120	.070	.072

Table 4.10 Rotated component matrix of IPQ-R items using eigen value > 1 and loading threshold of 0.4

The original IPQ-R items were again entered into a PCA, producing nine factors which accounted for 65% of the variance. Four items which failed to load on to any factors ("This diabetes will pass quickly", "My illness is a serious condition", "The negative effects of my illness can be prevented [avoided] by my treatment" and "My diabetes does not worry me") were omitted and the analysis repeated. This produced nine factors which accounted for 68% of the variance as opposed to the seven factors produced in the published IPQ-R which accounted for 64% of the variance. The items from the timelines (acute/chronic) scale loaded on to two scales which we labeled timelines (acute) and timelines (chronic) respectively. The items from the consequences scale loaded on to two scales which we labeled general consequences and specific consequences; in each case, an item from the original scale was omitted. There was again overlap between the items from the personal control and treatment control scales. The resulting scales related to positive and negative beliefs about control and were labeled efficacy of control strategies and futility of control strategies respectively. There was omission of an item from each of the treatment control and emotional representations scale. The results of the PCA are shown in Table 4.11.

Internal reliability

A comparison of the scales and their alpha coefficients is shown in Table 4.12. Internal reliability for illness coherence and emotional representation scales was satisfactory in the scales produced using eigen values > 1.0 (α coefficient=.90 and .88, respectively) and comparable to that produced in the IPQ-R paper. These scales were reproduced when an eigen value > 1.1 was used and therefore had similar coefficient values. The timelines cyclical scale was also duplicated in both analyses and had an alpha coefficient of .87, which was a slight improvement over that in the published IPQ-R.

	Component								
	1	2	3	4	5	6	7	8	9
My diabetes is likely to be permanent rather than temporary	-.121	.046	-.036	.116	**.867**	-.079	.022	-.120	.017
My diabetes will last for a long time	-.152	-.005	.008	.042	**.877**	-.026	.023	-.121	.052
I expect to have this diabetes for the rest of my life	-.157	.081	.042	.138	**.828**	-.047	.085	-.106	.061
My diabetes has major consequences on my life	-.007	.141	.065	.066	.175	-.087	.283	-.100	**.760**
My diabetes does not have much effect on my life	.030	-.123	-.054	-.072	.039	.173	-.158	.112	**-.830**
My diabetes strongly affects the way others see me	.141	.089	.165	.053	.015	.048	**.783**	.047	.004
My diabetes has serious financial consequences	.002	.173	.097	-.104	.050	.003	**.663**	.034	.165
My diabetes causes difficulties for those who are close to me	-.100	.264	.118	-.007	.068	.009	**.676**	-.017	.286
There is a lot which I can do to control my symptoms	-.190	-.218	-.003	**.655**	.067	-.159	-.068	-.175	.105
What I do can determine whether my diabetes gets better or worse	-.081	-.009	-.046	**.734**	.043	-.249	.109	-.126	-.071
The course of my diabetes depends on me	-.022	-.079	.082	**.737**	.080	-.010	-.060	-.082	-.007
I have the power to influence my diabetes	.054	.041	-.127	**.700**	.050	-.144	.065	.147	-.012
My treatment can control my diabetes	-.246	.003	-.051	**.596**	.095	.056	-.146	.090	.204
Nothing I do will affect my diabetes	.128	.132	.061	-.173	-.076	**.681**	.018	.339	.009
My actions will have no effect on the outcome of my diabetes	.033	-.012	.098	-.198	.110	**.768**	-.062	.110	.002
There is very little that can be done to improve my diabetes	.240	.064	-.030	.026	-.178	**.654**	.078	-.189	-.253
There is nothing which can help my condition	.265	.083	-.044	-.239	-.164	**.516**	.104	-.003	-.248
My diabetes will last a short time	.031	-.037	.076	-.120	-.251	.309	.006	**.667**	.117
My diabetes will improve in time	.102	.002	-.005	.008	-.006	-.111	.049	**.739**	-.168
My treatment will be effective in curing my diabetes	.164	-.061	.106	-.013	-.174	.121	.006	**.714**	-.089
The symptoms of my condition are puzzling to me	**.840**	.112	.080	-.056	.042	.008	.085	.141	-.071
My diabetes is a mystery to me	**.847**	.018	.062	-.056	-.153	.156	-.062	.145	-.018
I don't understand my diabetes	**.813**	.107	.100	-.123	-.042	.207	-.002	.118	.008
My diabetes doesn't make any sense to me	**.843**	.046	.088	-.110	-.159	.174	.037	.112	.035
I have a clear picture or understanding of my condition	**-.702**	-.159	-.113	.063	.254	.038	-.031	.148	.027
The symptoms of my diabetes change a great deal from day to day	.091	.281	**.710**	-.090	-.047	.099	.109	.035	.183
My symptoms come and go in cycles	.020	.109	**.880**	.014	.012	.042	.093	.074	-.056
My diabetes is very unpredictable	.217	.231	**.762**	-.108	-.051	.030	.233	.028	-.001
I go through cycles in which my diabetes gets better and worse	.114	.144	**.861**	.028	.070	-.034	.036	.037	.050
I get depressed when I think about my diabetes	.103	**.796**	.135	-.016	-.019	.049	.172	-.047	.138
When I think about my diabetes I get upset	.079	**.796**	.142	-.074	-.023	-.002	.274	-.141	.039
My diabetes makes me feel angry	.048	**.727**	.211	-.105	.067	-.022	.219	.036	-.091
Having this diabetes make me feel anxious	.051	**.821**	.140	.013	.069	.045	.085	-.061	.146
My diabetes makes me feel afraid	.151	**.803**	.113	-.064	.036	.121	-.121	.117	.045

Table 4.11 Rotated component matrix of IPQ-R items using eigen value > 1.1 and loading threshold of 0.5

Original IPQ-R PCA Scales	IPQ-R PCA scales derived from validation study (eigen > 1.0)	IPQ-R PCA scales derived from validation study (eigen > 1.1)
Timelines(acute/chronic)(α=.89) My illness will last a short time My illness is likely to be permanent rather than temporary My illness will last for a long time This illness will pass quickly I expect to have this illness for the rest of my life My illness will improve in time	*Timelines acute/ treatment control(α=.57)* My diabetes will last a short time My diabetes will improve in time My treatment will be effective in curing my diabetes The negative effects of my diabetes can be prevented (avoided) by my treatment	*Timelines (acute) (α=.65)* My diabetes will last a short time. My diabetes will improve in time My treatment will be effective in curing my diabetes
	Timelines (chronic)(α=.83) My diabetes is likely to be permanent rather than temporary My diabetes will last for a long time I expect to have this diabetes for the rest of my life My diabetes is a serious condition	*Timelines (chronic)(α=.87)* My diabetes is likely to be permanent rather than temporary My diabetes will last for a long time I expect to have this diabetes for the rest of my life
Timelines (cyclical) (α=.79) The symptoms of my illness change a great deal from day to day My symptoms come and go in cycles My illness is very unpredictable I go through cycles in which my illness gets better and worse	*Timelines (cyclical) (α=.87)* The symptoms of my illness change a great deal from day to day My symptoms come and go in cycles My illness is very unpredictable I go through cycles in which my illness gets better and worse	*Timelines (cyclical) (α=.87)* The symptoms of my diabetes change a great deal from day to day My symptoms come and go in cycles My diabetes is very unpredictable I go through cycles in which my diabetes gets better and worse
Consequences (α=.84) My illness is a serious condition My illness has major consequences on my life My illness does not have much effect on my life My illness strongly affects the way others see me My illness has serious financial consequences My illness causes difficulties for those who are close to me	*General consequences (α=.78)* My diabetes has major consequences on my life My diabetes does not have much effect on my life	*General consequences (α=.79)* My diabetes has major consequences on my life My diabetes does not have much effect on my life
	Specific consequences (α=.67) My diabetes strongly affects the way others see me My diabetes has serious financial consequences My diabetes causes difficulties for those who are close to me	*Specific consequences (α=.67)* My diabetes strongly affects the way others see me My diabetes has serious financial consequences My diabetes causes difficulties for those who are close to me

Table 4.12 Comparison of original and study-derived IPQ-R scales

Personal control (α=.81) There is a lot which I can do to control my symptoms What I do can determine whether my illness gets better or worse The course of my illness depends on me Nothing I do will affect my diabetes I have the power to influence my illness My actions will have no affect on the outcome of my illness	*Efficacy of control strategies (α=.76)* There is a lot which I can do to control my symptoms What I do can determine whether my diabetes gets better or worse The course of my diabetes depends on me	*Efficacy of control strategies (α=.75)* There is a lot which I can do to control my symptoms What I do can determine whether my diabetes gets better or worse The course of my diabetes depends on me I have the power to influence my diabetes My treatment can control my diabetes
Treatment control (α=.80) There is very little that can be done to improve my illness My treatment will be effective in curing my illness The negative effects of my illness can be prevented (avoided) by my treatment* My treatment can control my illness There is nothing which can help my condition	*Futility of control strategies (α=.61)* There is very little that can be done to improve my diabetes Nothing I do will affect my diabetes My actions will have no effect on the outcome of my diabetes	*Futility of control strategies (α=.68)* There is very little that can be done to improve my diabetes Nothing I do will affect my diabetes My actions will have no effect on the outcome of my diabetes There is nothing which can help my condition
Illness coherence (α=.87) The symptoms of my condition are puzzling to me My illness is a mystery to me I don't understand my illness My illness doesn't make any sense to me I have a clear picture or understanding of my condition	*Illness coherence (α=.90)* The symptoms of my condition are puzzling to me My illness is a mystery to me I don't understand my illness My illness doesn't make any sense to me I have a clear picture or understanding of my condition	*Illness coherence (α=.89)* The symptoms of my condition are puzzling to me My diabetes is a mystery to me I don't understand my diabetes My diabetes doesn't make any sense to me I have a clear picture or understanding of my condition
Emotional representations (α=.88) I get depressed when I think about my illness When I think about my illness I get upset My illness makes me feel angry My illness does not worry me* Having this illness makes me feel anxious My illness makes me feel afraid	*Emotional representations (α=.88)* I get depressed when I think about my diabetes When I think about my diabetes I get upset My diabetes makes me feel angry Having this diabetes make me feel anxious My diabetes makes me feel afraid	*Emotional representations (α=.88)* I get depressed when I think about my diabetes When I think about my diabetes I get upset My diabetes makes me feel angry Having this diabetes make me feel anxious My diabetes makes me feel afraid

Table 4.12 Comparison of original and study-derived IPQ-R scales

The internal reliability of the acute timelines scale produced using an eigen value > 1.1 was better than that obtained using an eigen value > 1.0 (.57 and .65, respectively). The timelines (chronic) scale had better internal consistency (alpha coefficient of .83 [eigen >1.0] and .87 [eigen > 1.1]) which was comparable to the originally published of alpha coefficient of .89. The general consequences, specific consequences and positive control scales had similar internal consistency under both conditions, while the internal consistency of the negative control scale produced with an eigen > 1.1 was higher with an alpha of .68.

Further analyses done with the study-derived IPQ-R scales were done with the scales derived under the same conditions as those used in the published IPQ-R (eigen value >1.1, loading threshold 0.5) as the scales derived in this method included more items and had better internal consistency.

Predictive validity

The relationships between the dimensions of the original IPQ-R and self care activities and between the study-derived factor structure produced by analysis with eigen >1.1 and loading threshold of 0.5 and self care activities are shown below. In each case, demographic information of age, gender and duration of diabetes was entered as the initial step in the regression analysis.

General diet

Age was the only demographic variable which was significantly related to general dietary behaviours (β=.202; p=.007) with older people being more likely to follow general dietary advice. Illness representations did not account for a significant amount of variance in general dietary behaviours, with the original IPQ-R scales accounting for only 3.1% more variance (p=.415) than that accounted for by demographics and the modified scales accounting for 2.9% (p=.699). The analyses are shown in Table 4.13 and Table 4.14.

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.202**	.007	.022 (.044)	.035 (.044)
	Gender	.058	.391		
	Duration	-.127	.068		
2	Timelines (acute/chronic)	.058	.452	.023 (.127)	.031 (.415)
	Timelines (cyclical)	.044	.554		
	Consequences	.099	.214		
	Personal control	.058	.460		
	Treatment control	-.079	.278		
	Illness coherence	.045	.560		
	Emotional representations	-.126	.115		

Table 4.13 Regression analysis for IPQ-R scales and general diet

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.206**	.007	.018 (.073)	.031 (.073)
	Gender	.045	.521		
	Duration	-.133	.062		
2	Timelines (acute)	-.080	.281	.006 (.350)	.029 (.699)
	Timelines (chronic)	.030	.688		
	Timelines (cyclical)	.040	.609		
	General consequences	.074	.346		
	Specific consequences	.047	.551		
	Positive control	.035	.650		
	Negative control	.005	.952		
	Illness coherence	-.033	.680		
	Emotional representations	-.105	.198		

Table 4.14 Regression analysis for study-derived IPQ-R scales and general diet

Specific diet- eating five or more servings of fruits and vegetables daily

Demographic factors as a block were not predictive of eating five or more servings of fruit and vegetables a day, although older patients were also more likely to follow this advice (β=.222; p=.003). Illness representations accounted for nearly 10% of variance beyond that accounted for by demographics both when calculated using original IPQ-R scales and the study-derived scales (ΔR^2=.099, p=.001 and ΔR^2=.096, p=.009, respectively). In both instances, this was due to ideas about illness coherence and cyclical timelines. Patients who thought there were cyclical variations in their diabetes were more likely to follow this advice (β=.185, p=.011; β=.181, p=0.16) Illness coherence was also a significant predictor (β=.227, p=.002; β=-.232, p=.003).The analyses are shown in Tables 4.15 and 4.16.

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.222**	.003	.016 (.086)	.029 (.086)
	Gender	-.032	.625		
	Duration	.007	.915		
2	Timelines (acute/chronic)	.090	.232	.088 (.001)	.099 (.001)
	Timelines (cyclical)	**.185**	.011		
	Consequences	.124	.110		
	Personal control	-.074	.338		
	Treatment control	-.081	.251		
	Illness coherence	**.227**	.002		
	Emotional representations	-.118	.124		

Table 4.15 Regression analysis of IPQ-R scales and specific diet- eating five portions of fruits and vegetables a day

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.210**	.005	.016 (.086)	.030 (.086)
	Gender	-.041	.546		
	Duration	.009	.898		
2	Timelines (acute)	-.067	.351	.076 (.005)	.096 (.009)
	Timelines (chronic)	.094	.194		
	Timelines (cyclical)	**.181**	.016		
	General consequences	.030	.694		
	Specific consequences	.088	.254		
	Positive control	-.044	.558		
	Negative control	.093	.238		
	Illness coherence	**-.232**	.003		
	Emotional representations	-.109	.163		

Table 4.16 Regression analysis of study derived IPQ-R scales and specific diet- eating five portions of fruits and vegetables a day

Specific diet- eating high fat food

There were no demographic factors that significantly predicted eating high fat foods. Illness representations did not significantly account for the variance observed in this behaviour (Tables 4.17 and 4.18).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.025	.743	-.005 (.622)	.008 (.622)
	Gender	-.021	.765		
	Duration	.100	.158		
2	Timelines (acute/chronic)	-.015	.845	-.012 (.689)	.025 (.586)
	Timelines (cyclical)	.069	.362		
	Consequences	-.154	.057		
	Personal control	.026	.755		
	Treatment control	.053	.474		
	Illness coherence	-.042	.587		
	Emotional representations	.040	.619		

Table 4.17 Regression analysis of IPQ-R scales and specific diet- eating a high fat diet

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.026	.733	-.003 (.522)	.010 (.522)
	Gender	-.043	.546		
	Duration	.121	.095		
2	Timelines (acute)	-.010	.898	-.015 (.730)	.030 (.696)
	Timelines (chronic)	-.060	.439		
	Timelines (cyclical)	.056	.468		
	General consequences	-.116	.148		
	Specific consequences	-.060	.449		
	Positive control	-.021	.793		
	Negative control	-.078	.343		
	Illness coherence	.056	.490		
	Emotional representations	.061	.455		

Table 4.18 Regression analysis of study-derived IPQ-R scales and specific diet- eating a high fat diet

Physical activity

Demographic details accounted for 2.9% of the variance observed in undertaking physical activity in the original IPQ-R model and 2.4% of the variance in the model with the diabetes-specific IPQ-R scales. Duration of diabetes made a significant contribution to this model in both cases (β=.159, p=.022; β=.146, p=.039). None of the dimensions of illness representations made a significant contribution to the regression model in either case and neither of the models explained a significant amount of variance beyond that explained by the demographic information (ΔR^2=.015, p=.822; ΔR^2=.021, p=.852) (Tables 4.19 and 4.20).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.033	.657	.029 (.021)	.042 (.021)
	Gender	-.129	.061		
	Duration	**.159**	.022		
2	Timelines (acute/chronic)	-.021	.787	.014 (.214	.015 (.822)
	Timelines (cyclical)	-.054	.469		
	Consequences	-.004	.959		
	Personal control	.007	.932		
	Treatment control	.043	.553		
	Illness coherence	.069	.369		
	Emotional representations	-.030	.704		

Table 4.19 Regression analysis of IPQ-R scales and physical activity

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.034	.652	.024 (.041)	.037 (.041)
	Gender	-.120	.088		
	Duration	**.146**	.039		
2	Timelines (acute)	.043	.561	.004 (.376)	.021 (.852)
	Timelines (chronic)	-.042	.576		
	Timelines (cyclical)	-.070	.360		
	General consequences	.011	.889		
	Specific consequences	.012	.876		
	Positive control	.073	.338		
	Negative control	.040	.626		
	Illness coherence	-.087	.275		
	Emotional representations	-.021	.798		

Table 4.20 Regression analysis of study-derived IPQ-R scales and physical activity

Medication adherence

Demographic variables were not significant predictors of medication adherence and illness representations did not significantly improve the amount of variance observed (ΔR^2=.061, p=.151; ΔR^2=.057, p=.388). Beliefs about the chronicity of diabetes made significant contributions to the illness representations model in each case with a β coefficient of .214 (p=.016) and .222 (p=.011) respectively, suggesting that patients who believed their diabetes was chronic were more likely to take medication as prescribed. Treatment control was also a significant contributor to the regression model using the original IPQ-R scales with a β coefficient of .178 (p=.038), but neither of the control factors was significantly predictive of medication adherence in the model using the diabetes-specific scales. (Tables 4.21 and 4.22).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.164	.061	.012 (.165)	.029 (.165)
	Gender	.131	.100		
	Duration	-.039	.623		
2	Timelines (acute/chronic)	**.214**	.016	.034 (.105)	.061 (.151)
	Timelines (cyclical)	-.075	.391		
	Consequences	-.062	.477		
	Personal control	-.075	.403		
	Treatment control	**.178**	.038		
	Illness coherence	-.137	.131		
	Emotional representations	.007	.938		

Table 4.21 Regression analysis of IPQ-R scales and medication adherence

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.148	.098	.008 (.237)	.026 (.237)
	Gender	.090	.280		
	Duration	-.003	.968		
2	Timelines (acute)	.002	.984	.011 (.316)	.057 (.388)
	Timelines (chronic)	**.222**	.011		
	Timelines (cyclical)	-.067	.472		
	General consequences	-.062	.482		
	Specific consequences	-.043	.633		
	Positive control	-.022	.800		
	Negative control	-.071	.464		
	Illness coherence	.135	.152		
	Emotional representations	.006	.951		

Table 4.22 Regression analysis of study-derived IPQ-R scales and medication adherence

Blood glucose self-monitoring

Demographic details accounted for a significant amount of the variance observed in the use of BGSM in both cases (adjusted R^2=.076, p=.000; adjusted R^2=.060, p=.001). Age was a significant contributor to this model with a β coefficient of -.198 (p=.005) in the original IPQ-R scales and a β coefficient of -.157 (p=.027) in the diabetes-specific IPQ-R scales, suggesting older patients were less likely to use this technology. Illness representations accounted for significant variance beyond that accounted for by demographics. In both instances, illness coherence was a significant contributor to the model. Beliefs about the cyclical timelines of diabetes also contributed significantly to the model in the original IPQ-R scales (β=.143, p=.041) but was not however a significant predictor in the diabetes-specific IPQ-R scales. (Tables 4.23 and 4.24).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**-.198**	.005	.076 (.000)	.088 (.000)
	Gender	-.020	.755		
	Duration	.024	.707		
2	Timelines (acute/chronic)	.031	.671	.122 (.000)	.071 (.010)
	Timelines (cyclical)	**.143**	.041		
	Consequences	.043	.567		
	Personal control	.127	.086		
	Treatment control	-.044	.520		
	Illness coherence	**.196**	.007		
	Emotional representations	.028	.702		

Table 4.23 Regression analysis of IPQ-R scales and BGSM

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**-.157**	.027	.060 (.001)	.073 (.001)
	Gender	-.012	.858		
	Duration	.032	.627		
2	Timelines (acute)	-.007	.919	.106 (.000)	.080 (.020)
	Timelines (chronic)	.013	.861		
	Timelines (cyclical)	.134	.067		
	General consequences	.048	.514		
	Specific consequences	-.012	.876		
	Positive control	.110	.133		
	Negative control	-.050	.510		
	Illness coherence	**-.200**	.008		
	Emotional representations	.074	.334		

Table 4.24 Regression analysis of study-derived IPQ-R scales and BGSM

c) IPQ with additional diabetes specific items

Mean and SD of diabetes-specific illness representation items

The means and SD of additional diabetes-specific items are appended (Appendix 3).

Factor structure of IPQ with additional items

Principal components analysis was carried out using the 38 original items from the IPQ-R and 15 additional interview derived items. An initial attempt was made to analyse the factor structure using an eigen value > 1, but this failed to converge. The analysis was repeated using an eigen value > 1.1 and a loading threshold of 0.4. Twelve components were obtained (Table 4.25) which accounted for 64% of the variance. Four items loaded on to more than one factor, but were thought to be of enough theoretical significance to be retained.

The items from the timelines (acute/chronic) scale again loaded on two scales. However, one item ("This diabetes will pass quickly") which had failed to load in the analysis of the IPQ-R items loaded on to both of these scales. It should be noted that the loading in one of these instances was just at the threshold of .4. "My treatment will be effective in curing my diabetes" again loaded on to the timelines (acute) scale. An item from the consequences scale – "My diabetes is a serious condition"- loaded on to the timelines (chronic) scale. The remainder of these items however loaded on to a single consequences scale, rather than two scales as was seen previously. Two of the additional items also loaded on to this scale – "If my blood sugar were high over a

period of time, it would damage my body" and "My diabetes reduces the quality of my life". This last item also loaded on to the emotional representations scale along with the items "I am worried about my diabetes getting worse", "I am now comfortable with the idea of having diabetes" and "My diabetes reduces the quality of my life". "My diabetes does not worry me", which had been omitted previously, loaded on to the emotional representation scale.

The overlap between the treatment control and personal control scales seen previously was duplicated here. Three of the diabetes-specific questions- "I think my diabetes will stay the same", "Worsening of my diabetes is unavoidable" and "I try not to think about my diabetes as much as possible" loaded on to the treatment control scale.

The timelines (cyclical) and illness coherence scales were duplicated as previously. Three other scales were formed which we labeled concerns about diabetes, influence of control strategies and specific physical consequences.

The factor structure, obtained using the additional diabetes-specific questions, more closely approximated the published factor structure of the original IPQ-R. The original IPQ-R scales, the study-derived scales (eigen > 1.1, threshold 0.5) and the scales including additional items and their alpha coefficients are summarized in Table 4.26.

Internal reliability

The internal reliability of each scale is shown in Table 4.26. Internal consistency was satisfactory in each scale produced with the exception of the scale on general efficacy of control strategies (α=.42).

Predictive validity

The predictive validity of the augmented illness representations scales produced by addition of the diabetes-specific items to the IPQ-R items is explored below.

	Component											
	1	2	3	4	5	6	7	8	9	10	11	12
My diabetes is likely to be permanent rather than temporary	.008	-.126	.008	**.792**	-.019	-.110	-.007	.182	-.052	.099	-.049	.009
My diabetes will last for a long time	-.069	-.153	.021	**.822**	.036	-.064	.034	.105	-.027	.077	-.113	-.024
I expect to have this diabetes for the rest of my life	.032	-.133	.182	**.803**	-.034	.014	.061	.079	-.131	-.063	.124	-.026
This diabetes will pass quickly	.083	-.006	-.142	**-.540**	.277	-.027	-.023	-.089	**.400**	.192	-.102	-.084
My diabetes is a serious condition	-.009	-.170	.383	**.458**	-.210	.108	.095	.119	-.147	.239	.060	.079
Nothing I do will affect my diabetes	.094	.169	.036	-.177	**.621**	.042	.073	-.234	.122	.040	.013	.084
My actions will have no effect on the outcome of my diabetes	-.079	.051	.063	-.008	**.697**	.035	.036	-.163	.029	.140	-.195	.089
There is very little that can be done to improve my diabetes	.142	.201	-.216	-.062	**.588**	.009	.004	.015	-.096	-.122	.026	-.074
There is nothing which can help my condition	.161	.297	-.151	-.073	**.443**	-.044	-.002	-.171	.154	-.271	-.354	-.015
I think my diabetes will stay the same	-.029	-.002	-.065	.057	**.507**	.114	-.129	-.149	.137	-.268	.028	-.197
Worsening of my diabetes is unavoidable	.024	.197	.039	.165	**.499**	-.030	.080	-.097	-.362	.104	-.001	-.054
I try not to think about my diabetes as much as possible	.054	.125	-.102	-.180	**.440**	.082	-.101	.065	.010	.171	-.261	-.331
My diabetes will last a short time	-.155	.100	-.033	-.371	.288	.051	.117	-.119	**.488**	.312	.058	.029
My diabetes will improve in time	.010	.129	.001	-.027	-.071	.005	-.056	-.013	**.689**	-.204	.019	.166
My treatment will be effective in curing my diabetes	-.078	.214	-.109	-.263	.099	.096	.032	-.060	**.639**	.052	.197	.015
The symptoms of my condition are puzzling to me	.120	**.846**	-.056	.032	.051	.074	.054	-.074	.131	.057	.078	.063
My diabetes is a mystery to me	.001	**.848**	.006	-.198	.197	.084	-.024	-.093	.033	.004	.077	-.046
I don't understand my diabetes	.122	**.779**	-.084	-.046	.219	.110	.025	-.094	.190	-.017	-.072	-.059
My diabetes doesn't make any sense to me	.070	**.831**	-.050	-.182	.156	.109	.058	-.067	.110	.013	-.139	-.033
I have a clear picture or understanding of my condition	-.222	**-.682**	.049	.223	.019	-.155	-.036	.035	.167	-.003	.062	-.172
The symptoms of my diabetes change a great deal from day to day	.283	.125	.103	-.094	.012	**.688**	.142	-.078	.009	.019	-.195	.012
My symptoms come and go in cycles	.109	.027	-.067	-.019	.057	**.865**	.068	.027	.042	.028	.097	.054
My diabetes is very unpredictable	.218	.215	-.063	-.078	.017	**.787**	.189	-.084	-.019	-.008	.019	.063
I go through cycles in which my diabetes gets better and worse	.105	.120	.044	.030	.032	**.845**	.084	.065	.055	-.031	-.062	-.001

Table 4.25 Factor structure of IPQ-R items and additional diabetes-specific items

	Component											
	1	2	3	4	5	6	7	8	9	10	11	12
I am afraid of the consequences of having diabetes	.357	.052	.158	.005	.035	-.020	.024	.007	-.040	**.727**	.057	-.026
I am worried about my diabetes getting worse	**.433**	.043	.198	.093	-.074	.003	.043	.066	-.046	**.619**	.082	.123
I get depressed when I think about my diabetes	**.826**	.101	.007	-.049	.008	.079	.216	-.007	-.053	-.022	-.052	.002
When I think about my diabetes I get upset	**.818**	.037	.039	-.031	.058	.135	.244	-.027	-.068	-.056	-.078	.046
My diabetes makes me feel angry	**.725**	.024	-.071	.101	.053	.262	.112	-.113	.121	.079	.042	.019
Having this diabetes make me feel anxious	**.760**	.026	.151	.042	.096	.151	.129	-.001	.007	.259	.014	.027
My diabetes makes me feel afraid	**.720**	.172	.114	-.034	.176	.112	-.101	-.102	.038	.225	.034	.012
My diabetes does not worry me	**-.461**	-.086	-.174	-.163	.314	-.064	-.070	-.024	.234	-.188	.289	-.012
I am now comfortable with the idea of having diabetes	**-.499**	-.188	-.039	.277	.211	.033	-.041	-.028	.116	-.070	-.060	.041
My diabetes reduces the quality of my life	**.461**	.085	.202	.005	.016	.263	**.431**	-.107	.053	.070	-.151	-.046
If my blood sugar were high over a short period of time, it would damage my body	-.058	.164	.285	-.231	.222	-.131	**.442**	.090	.208	.055	-.273	.090
My diabetes has major consequences on my life	.174	-.049	.236	.268	-.282	.120	**.500**	-.020	.007	.280	-.194	-.228
My diabetes does not have much effect on my life	-.136	.062	-.193	-.077	.386	-.081	**-.450**	.022	.023	-.327	.190	.266
My diabetes strongly affects the way others see me	.140	.165	-.094	.048	.056	.205	**.711**	.077	.037	-.012	.045	.126
My diabetes has serious financial consequences	.175	.005	.172	-.026	.070	.102	**.647**	-.131	-.135	-.085	.145	.138
My diabetes causes difficulties for those who are close to me	.313	-.083	-.075	.073	-.074	.136	**.680**	-.032	-.004	.065	.105	-.156
My treatment can control my diabetes	-.026	-.175	.184	.024	-.012	-.045	-.037	**.537**	-.042	.034	.222	-.374
There is a lot which I can do to control my symptoms	-.188	-.168	.124	.108	-.261	-.015	-.013	**.640**	-.141	.070	.024	-.026
What I do can determine whether my diabetes gets better or worse	.028	-.093	.131	.134	-.228	-.066	.066	**.773**	.002	-.026	-.016	.174
The course of my diabetes depends on me	-.062	-.046	.063	.158	-.022	.082	-.095	**.725**	.025	.039	.044	-.006
I have the power to influence my diabetes	.035	.090	.262	.104	-.115	-.108	.019	**.491**	.046	-.110	**.455**	.063
The negative effects of my diabetes can be prevented (avoided) by my treatment	-.062	-.034	.058	-.081	-.157	-.063	.087	.171	.205	.129	**.665**	-.098
My diabetes could cause me to go into a coma	-.019	.017	**.738**	-.017	.037	.083	.134	.188	-.042	.072	-.138	.113
My diabetes could cause me to have kidney damage	.077	-.009	**.809**	.079	-.102	-.058	.078	.144	-.026	.013	-.023	.044
My diabetes could cause me to have problems with my feet	.148	-.016	**.717**	.064	-.170	-.035	-.071	-.020	.032	-.059	.114	-.310
My diabetes could cause me to have problems with my eyesight	.055	-.035	**.632**	.129	-.065	-.004	-.080	.215	.007	.091	.069	-.385
My diabetes makes me more likely to have heart disease	.117	-.120	**.532**	.093	.078	.043	-.008	.011	-.179	.220	.321	.256
My diabetes makes me more likely to get infections	.143	-.286	**.607**	.144	.026	-.027	.146	.026	-.033	.261	.124	.198
I think my diabetes will get better if I improve my lifestyle	.114	.041	.045	.022	-.142	.182	-.024	.098	.346	.126	-.061	**.672**

Table 4.25 Factor structure of IPQ-R items and additional diabetes-specific items

Original IPQ-R PCA scales	**IPQ-R PCA scales derived from cross sectional study**	**IPQ-R with additional items**
Timelines (acute/chronic) (α=.89) My illness will last a short time My illness is likely to be permanent rather than temporary My illness will last for a long time This illness will pass quickly I expect to have this illness for the rest of my life My illness will improve in time	*Timelines (acute) (α=.65)* My diabetes will last a short time. My diabetes will improve in time My treatment will be effective in curing my diabetes	*Timelines(acute) (α=.70)* My diabetes will last a short time. This diabetes will pass quickly My diabetes will improve in time My treatment will be effective in curing my diabetes
	Timelines(chronic) (α=.87) My diabetes is likely to be permanent rather than temporary My diabetes will last for a long time I expect to have this diabetes for the rest of my life	*Timelines (chronic) (α=.82)* My diabetes is likely to be permanent rather than temporary My diabetes will last for a long time This diabetes will pass quickly I expect to have this diabetes for the rest of my life My diabetes is a serious condition
Timeline (cyclical) (α=.79) The symptoms of my illness change a great deal from day to day My symptoms come and go in cycles My illness is very unpredictable I go through cycles in which my illness gets better and worse	*Timelines(cyclical) (α=.87)* The symptoms of my diabetes change a great deal from day to day My symptoms come and go in cycles My diabetes is very unpredictable I go through cycles in which my diabetes gets better and worse	*Timelines (cyclical) (α=.87)* The symptoms of my diabetes change a great deal from day to day My symptoms come and go in cycles My diabetes is very unpredictable I go through cycles in which my diabetes gets better and worse
Consequences (α=.84) My illness is a serious condition My illness has major consequences on my life My illness does not have much effect on my life My illness strongly affects the way others see me My illness has serious financial consequences My illness causes difficulties for those who are close to me	*General consequences (α=.79)* My diabetes has major consequences on my life My diabetes does not have much effect on my life	*Consequences (α=.74)* My diabetes has major consequences on my life My diabetes does not have much effect on my life My diabetes strongly affects the way others see me My diabetes has serious financial consequences My diabetes causes difficulties for those who are close to me If my blood sugar were high over a short period of time, it would damage my body My diabetes reduces the quality of my life

Table 4.26 Comparison of factor structures of original IPQ-R items, study-derived IPQ-R scales and scales with additional items

	Specific consequences (α=.67) My diabetes strongly affects the way others see me My diabetes has serious financial consequences My diabetes causes difficulties for those who are close to me	
Personal control (α=.81) There is a lot which I can do to control my symptoms What I do can determine whether my illness gets better or worse The course of my illness depends on me Nothing I do will affect my illness I have the power to influence my illness My actions will have no affect on the outcome of my illness	*Efficacy of control strategies (α=.75)* There is a lot which I can do to control my symptoms What I do can determine whether my diabetes gets better or worse The course of my diabetes depends on me I have the power to influence my diabetes My treatment can control my diabetes	*Efficacy of control strategies (α=.75)* There is a lot which I can do to control my symptoms What I do can determine whether my diabetes gets better or worse The course of my diabetes depends on me I have the power to influence my diabetes My treatment can control my diabetes
Treatment control (α=.80) There is very little that can be done to improve my illness My treatment will be effective in curing my illness The negative effects of my illness can be prevented (avoided) by my treatment My treatment can control my illness There is nothing which can help my condition	*Futility of control strategies (α=.68)* My actions will have no effect on the outcome of my diabetes There is very little that can be done to improve my diabetes There is nothing which can help my condition	*Futility of control strategies (α=.69)* Nothing I do will affect my diabetes My actions will have no effect on the outcome of my diabetes There is very little that can be done to improve my diabetes There is nothing which can help my condition I think my diabetes will stay the same Worsening of my diabetes is unavoidable I try not to think about my diabetes as much as possible
Illness coherence (α=.87) The symptoms of my condition are puzzling to me My illness is a mystery to me I don't understand my illness My illness doesn't make any sense to me I have a clear picture or understanding of my condition	*Illness coherence (α=.89)* The symptoms of my condition are puzzling to me My diabetes is a mystery to me I don't understand my diabetes My diabetes doesn't make any sense to me I have a clear picture or understanding of my condition	*Illness coherence (α=.89)* The symptoms of my condition are puzzling to me My diabetes is a mystery to me I don't understand my diabetes My diabetes doesn't make any sense to me I have a clear picture or understanding of my condition

Table 4.26 Comparison of factor structures of original IPQ-R items, study-derived IPQ-R scales and scales with additional items

Emotional representations (α=.88) I get depressed when I think about my illness When I think about my illness I get upset My illness makes me feel angry My illness does not worry me Having this illness makes me feel anxious My illness makes me feel afraid	*Emotional representations (α=.88)* I get depressed when I think about my diabetes When I think about my diabetes I get upset My diabetes makes me feel angry Having this diabetes make me feel anxious My diabetes makes me feel afraid	*Emotional representations (α=.85)* I get depressed when I think about my diabetes When I think about my diabetes I get upset My diabetes makes me feel angry My illness does not worry me Having this diabetes make me feel anxious My diabetes makes me feel afraid I am worried about my diabetes getting worse I am now comfortable with the idea of having diabetes My diabetes reduces the quality of my life
		Influence of control strategies (α=.42) I have the power to influence my diabetes The negative effects of my illness can be prevented (avoided) by my treatment
		Concerns about diabetes (α=.75) I am worried about my diabetes getting worse I am afraid of the consequences of having diabetes
		Specific physical consequences (α=.79) My diabetes could cause me to go into a coma My diabetes could cause me to have kidney damage My diabetes could cause me to have problems with my feet My diabetes could cause me to have problems with my eyesight My diabetes makes me more likely to have heart disease My diabetes makes me more likely to get infections
		I think my diabetes will get better if I improve my lifestyle

Table 4.26 Comparison of factor structures of original IPQ-R items, study-derived IPQ-R scales and scales with additional items

General diet

Illness representations were again not a significant predictor of general dietary behaviours, accounting for 2.4% (p=.923) more variance than demographics (Table 4.27).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.177**	.038	.020 (.066)	.034 (.066)
	Gender	.037	.612		
	Duration	-.087	.240		
2	Timelines (acute)	-.061	.425	-.008 (.590)	.024 (.923)
	Timelines (chronic)	.035	.660		
	Timelines (cyclical)	-.018	.820		
	Consequences	.111	.211		
	Efficacy of control strategies	.047	.634		
	Futility of control strategies	-.056	.495		
	Illness coherence	.014	.869		
	Emotional representations	-.100	.336		
	Influence of control strategies	-.023	.810		
	Concerns about diabetes	-.018	.842		
	Specific physical consequences	-.072	.392		

Table 4.27 Regression analysis of augmented illness representations and general diet

Specific diet- eating five servings of fruit and vegetables a day

Illness perceptions accounted for 10.6% (p=.017) more variance than demographic data alone. Cyclical timelines (β=.157, p=.042), illness coherence (β=-.195, p=.017) and specific physical consequences (β=.171, p=.036) were all significant predictors (Table 4.28).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.241**	.004	.016 (.100)	.030 (.100)
	Gender	-.049	.483		
	Duration	-.029	.682		
2	Timelines (acute)	-.057	.437	.074 (.009)	.106 (.017)
	Timelines (chronic)	.075	.322		
	Timelines (cyclical)	**.157**	.042		
	Consequences	.078	.360		
	Efficacy of control strategies	-.113	.243		
	Futility of control strategies	.041	.601		
	Illness coherence	**-.195**	.017		
	Emotional representations	-.126	.209		
	Influence of control strategies	-.011	.900		
	Concerns about diabetes	-.005	.956		
	Specific physical consequences	**.171**	.036		

Table 4.28 Regression analysis of augmented illness representations and specific diet- eating five portions of fruits and vegetables daily

Eating a high fat diet

Illness representations were not a significant predictor of eating a high fat diet. None of the individual dimensions made a significant contribution to the model (Table 4.29).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.004	.965	-.001 (.435)	.013(.435)
	Gender	.009	.905		
	Duration	.106	.154		
2	Timelines (acute)	-.077	.318	-.017 (.726)	.037 (.733)
	Timelines (chronic)	-.112	.167		
	Timelines (cyclical)	.046	.563		
	Consequences	-.050	.576		
	Efficacy of control strategies	-.059	.560		
	Futility of control strategies	.002	.981		
	Illness coherence	.081	.337		
	Emotional representations	-.073	.492		
	Influence of control strategies	.123	.197		
	Concerns about diabetes	.092	.334		
	Specific physical consequences	.046	.587		

Table 4.29 Regression analysis of augmented illness representations and specific diet- eating high fat foods

Physical activity

Demographic information accounted for a significant amount of variance observed (adjusted R^2=.031, p=.021), with gender (β=-.148, p=.037) and duration of diabetes (β=.158, p=.028) being significant predictors. Illness perceptions did not account for a significant increase in variance and none of the dimensions were significant predictors (Table 4.30).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.025	.764	.031 (.021)	.045 (.021)
	Gender	**-.148**	.037		
	Duration	**.158**	.028		
2	Timelines (acute)	.035	.636	.036 (.089)	.054 (.370)
	Timelines (chronic)	-.059	.442		
	Timelines (cyclical)	-.060	.441		
	Consequences	-.047	.584		
	Efficacy of control strategies	-.014	.880		
	Futility of control strategies	.157	.050		
	Illness coherence	-.109	.189		
	Emotional representations	-.022	.831		
	Influence of control strategies	.131	.158		
	Concerns about diabetes	.056	.535		
	Specific physical consequences	.089	.273		

Table 4.30 Regression analysis of augmented illness representations and physical activity

Medication adherence

Illness representations did not account for a significant amount of variance beyond that accounted for by demographic information (ΔR^2=.065, p=.495). Beliefs about chronicity contributed significantly to the model (β = .182, p=.040) (Table 4.31).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.127	.196	.004 (.314)	.022 (.314)
	Gender	.071	.409		
	Duration	-.061	.477		
2	Timelines (acute)	-.099	.266	.000 (.456)	.065 (.495)
	Timelines (chronic)	**.182**	.040		
	Timelines (cyclical)	-.031	.755		
	Consequences	-.058	.560		
	Efficacy of control strategies	.000	.998		
	Futility of control strategies	.045	.635		
	Illness coherence	.073	.468		
	Emotional representations	-.090	.434		
	Influence of control strategies	.009	.938		
	Concerns about diabetes	.126	.224		
	Specific physical consequences	-.121	.204		

Table 4.31 Regression analysis of augmented illness representations and medication adherence

BGSM

Illness representations significantly improved the prediction of demographics in relation to BGSM. An additional 8.7% of variance (p=.041) was explained by illness perceptions, with illness coherence (β=-.198, p=.013) being a significant predictor (Table 4.32).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.120	.130	.055 (.002)	.068(.002)
	Gender	-.038	.581		
	Duration	-.003	.960		
2	Timelines (acute)	-.004	.953	.096 (.001)	.087 (.041)
	Timelines (chronic)	-.005	.945		
	Timelines (cyclical)	.100	.189		
	Consequences	.034	.682		
	Efficacy of control strategies	.043	.647		
	Futility of control strategies	-.082	.285		
	Illness coherence	**-.198**	.013		
	Emotional representations	.051	.602		
	Influence of control strategies	.041	.640		
	Concerns about diabetes	-.042	.627		
	Specific physical consequences	.108	.180		

Table 4.32 Regression analysis of augmented illness representations and BGSM

Comparison of illness perception models

Table 4.33 compares the predictive validity of three illness perception models- the original published IPQ-R scales, the scales derived from the study and the scales with the additional items. In each instance, illness perceptions were predictive of the specific dietary behaviour of eating five fruits and vegetables and blood glucose self-monitoring. In each of these instances the amount of variance predicted was similar- between 10 and 11% of variance in eating five portions of fruits and vegetables daily was predicted by illness representations and between 7 and 9% of variance in BGSM was predicted by illness perceptions.

Dependent variable	ΔR^2 (p)		
	IPQ-R	Study derived IPQ-R scales	IPQ-R scales with additional items
General diet	.031 (.415)	.029 (.699)	.024 (.923)
Eating five fruits and vegetables	.099 (.001)	.096 (.009)	.106 (.017)
Eating high fat diet	.025 (.586)	.030 (.696)	.037 (.733)
Physical activity	.015 (.822)	.021 (.852)	.054 (.370)
Medication adherence	.061 (.151)	.057 (.388)	.065 (.495)
BGSM	.071(.010)	.080 (.020)	.087 (.041)

Table 4.33 Comparison of predictive validity of illness representations models

d) IPQ-R causal items

Mean and SD

The means and standard deviations of the causal items are appended (Appendix 3).

Factor structure of causal items

PCA was conducted on the original IPQ-R causal items using an eigen value >1 with a loading threshold of 0.4. Five factors explaining 60% of the variance were produced compared to the four factors accounting for 57% produced in the IPQ-R paper. Two factors from the psychological attributes scale- "My mental attitude" and "My personality"- loaded on to two factors and were discarded. Repeat analysis generated five factors explaining 62% of the variance.

The PCA is shown below in Table 4.34. There was considerable overlap between the risk factor, immunity and accident or chance scales.

	Component				
	1	2	3	4	5
Stress or worry	**.822**	.002	-.087	.096	.010
Family problems or worries	**.795**	.190	.075	-.012	-.011
Overwork	**.702**	.019	.156	.231	-.056
My emotional state	**.777**	.171	.078	.025	.130
Hereditary	.010	-.016	.187	-.172	**.713**
Aging	.027	.027	-.153	.374	**.711**
A germ or virus	.080	**.631**	.088	-.297	.079
Chance or bad luck	-.096	**.578**	-.022	.275	-.292
Poor medical care in my past	.055	**.698**	.119	-.019	.129
Pollution in the environment	.184	**.828**	.070	.005	.011
Altered immunity	.275	**.440**	.109	.168	-.133
Diet or eating habits	.109	-.121	.140	**.745**	-.055
My own behaviour	.205	.152	.146	**.787**	.114
Alcohol	-.084	.056	**.818**	.321	.017
Smoking	.040	.087	**.850**	.123	.079
Accident or injury	.290	.199	**.712**	-.117	-.014

Table 4.34 Rotated component matrix of original causal items (eigen value >1, loading threshold of 0.4)

The analysis was repeated using the criteria specified in the paper (eigen >1.1, threshold 0.5) This produced 5 factors accounting for 61% of the variance. Two items- "My mental attitude" and "Altered immunity" did not load on to any factors and were omitted from the subsequent analysis which produced five factors accounting for 64% of the variance (Table 4.35).

	Component				
	1	2	3	4	5
Stress or worry	**.811**	-.098	-.027	.107	.003
Family problems or worries	**.800**	.089	.170	-.005	-.020
Overwork	**.697**	.165	-.034	.220	-.036
My emotional state	**.782**	.102	.186	.029	.107
Hereditary	.001	.187	-.046	-.193	**.738**
Aging	.033	-.148	.055	.360	**.710**
A germ or virus	.100	.107	**.663**	-.275	.027
Chance or bad luck	-.082	.002	**.572**	.279	-.274
Poor medical care in my past	.076	.134	**.711**	.007	.099
Pollution in the environment	.175	.069	**.811**	.035	.003
Diet or eating habits	.103	.125	-.121	**.758**	-.057
My own behaviour	.218	.164	.120	**.786**	.110
Alcohol	-.092	**.815**	.025	.325	.014
Smoking	.020	**.835**	.053	.130	.077
Accident or injury	.272	**.705**	.187	-.112	-.029
My personality	.458	**.528**	.334	.024	.040

Table 4.35 Rotated component matrix of causal items (eigen > 1.1, threshold of .5)

A summary table (Table 4.36) comparing original IPQ-R causal scales and those derived from the survey data is included. The factors produced did not appear to represent identifiable, coherent constructs and further analysis with original causal items was limited to the published scales.

Original IPQ-R Causal PCA Scales	IPQ-R Causal PCA scales derived from validation study (eigen >1)	IPQ-R Causal PCA scales derived from validation study (eigen >1.1)
Psychological attributions (α=.86) Stress or worry My mental attitude Family problems or worries Overwork My emotional state My personality	*(α=.80)* Stress or worry Family problems or worries Overwork My emotional state	*(α=.80)* Stress or worry Family problems or worries Overwork My emotional state
Risk Factors (α=.77) Hereditary – it runs in my family Diet or eating habits Poor medical care in my past My own behaviour Aging Smoking Alcohol	*(α=.24)* Hereditary-it runs in my family Aging	*(α=.24)* Hereditary-it runs in my family Aging
Immunity (α=.67) A germ or virus Pollution in the environment Altered immunity	*(α=.65)* A germ or virus Chance or bad luck Poor medical care in my past Pollution in the environment Altered immunity	*(α=.64)* A germ or virus Chance or bad luck Poor medical care in my past Pollution in the environment
Accident or chance (α=.23) C5 Chance or bad luck C16 Accident or injury	*(α=.70)* Diet or eating habits My own behaviour	*(α=.70)* Diet or eating habits My own behaviour
	(α=.75) Alcohol Smoking Accident or injury	*(α=.76)* Alcohol Smoking Accident or injury My personality

Table 4.36 Comparison of causal item factor structure

Predictive validity of original causal scales

General diet

Causal factors did not account for a significant amount of variance in general diet (ΔR^2=.020, p=.325). Age was predictive (β=.169, .020), but demographic details did not account for a significant amount of variance (adjusted R^2=.020, p=.059) (Table 4.37).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.169**	.020	.020 (.059)	.033 (.059)
	Gender	-.042	.546		
	Duration	-.118	.088		
2	Psychological attributes	.041	.582	.023 (.099)	.020 (.325)
	Risk factors	-.122	.106		
	Immunity	-.056	.467		
	Accident or chance	-.035	.640		

Table 4.37 Regression analysis of causal items and general diet

Specific diet- eating five fruits and vegetables a day

Beliefs about causes accounted for a significant 7.7% of variance (p=.001) more in eating five portions of fruit and vegetables a day than accounted for by demographics. Psychological attributes (β=.149, p=.046) and risk factors (β=-.308, p=.000) were significant predictors (Table 4.38).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.110	.119	.013 (.121)	.026 (.121)
	Gender	-.125	.068		
	Duration	.041	.547		
2	Psychological attributes	**.149**	.046	.074 (.001)	.077 (.001)
	Risk factors	**-.308**	.000		
	Immunity	-.022	.768		
	Accident or chance	.090	.220		

Table 4.38 Regression analysis of causal items and specific diet- eating five portions of fruit or vegetables daily

Specific diet- eating high fat foods

Causal beliefs accounted for 5.4% of the variance observed which was significantly more (p=.016) than that accounted for by demographics alone in eating high fat foods. Risk factors were a significant predictor (β=.188, p=.015) (Table 4.39).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.015	.836	-.006 (.672)	.007 (.672)
	Gender	.078	.260		
	Duration	.070	.310		
2	Psychological attributes	-.135	.078	.031 (.054)	.054 (.016)
	Risk factors	**.188**	.015		
	Immunity	-.072	.354		
	Accident or chance	.139	.064		

Table 4.39 Regression analysis of causal items and specific diet- eating a high fat diet

Physical activity

Causal factors did not significantly increase the variation explained by demographics in undertaking physical activity (ΔR^2=.015, p=.470). Gender and duration of diabetes were significant predictors (β=-.167, p=.017, β=.140, p=.043 respectively) (Table 4.40).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.055	.441	.021 (.053)	.033 (.053)
	Gender	**-.167**	.017		
	Duration	**.140**	.043		
2	Psychological attributes	.125	.100	.019 (.131)	.015 (.470)
	Risk factors	-.100	.190		
	Immunity	-.038	.620		
	Accident or chance	.007	.931		

Table 4.40 Regression analysis of causal items and physical activity

Medication adherence

Causal attributions accounted for a significant 7.5% (p=.010) more variance than demographics alone. Immunity (β=-.301, p=.001) and accident or chance (β=.185, p=.026) were significant predictors of medication adherence (Table 4.41).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.155	.059	.006 (.263)	.023 (.263)
	Gender	.065	.408		
	Duration	-.035	.655		
2	Psychological attributes	.090	.302	.060 (.016)	.075 (.010)
	Risk factors	-.029	.729		
	Immunity	**-.301**	.001		
	Accident or chance	**.185**	.026		

Table 4.41 Regression analysis of causal items and medication adherence

BGSM

Causal attributions accounted for 4.2% more variance (p=.034) than demographic factors, with accident or chance being a significant predictor (β=-.189, p=.007) (Table 4.42).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**-.267**	.000	.062 (.001)	.074 (.001)
	Gender	-.063	.345		
	Duration	.032	.620		
2	Psychological attributes	.034	.638	.088 (.000)	.042 (.034)
	Risk factors	-.078	.284		
	Immunity	.015	.839		
	Accident or chance	**-.189**	.007		

Table 4.42 Regression analysis of causal items and blood glucose self-monitoring

e) Additional diabetes-specific causal items

Mean and SD

The means and standard deviations of the additional causal items are appended. (Appendix 3).

Factor structure of original and additional causal items

PCA was performed on the original IPQ-R causal items and the additional causal items using an eigen value greater than 1 and loading threshold of 0.4. Seven scales were produced which accounted for 67% of the variance. The items "My personality" and "Eating too many sweets and puddings" loaded on to two scales and were omitted from subsequent analysis. Repeat analysis produced six factors accounting for 64% of the variance, with "My mental attitude" loading on to two factors and "Altered immunity" failing to load. A third analysis was done omitting these items and producing six factors again accounting for 67% of the variance. Three further analyses resulted in the omission of "Chance or bad luck" and "Aging" and the resulting analysis produced five factors which accounted for 65% of the variance. The PCA matrix is shown in Table 4.43.

Internal reliability of causal scales with additional items

The internal reliability of the new scales is shown in Table 4.44. Internal consistency was good for each scale with the exception of the personal factors where the alpha coefficient was .33.

Comparison of causal scales factor structure and internal reliability

A comparison of the original factor structure of the causal items, that derived from the survey data and that derived when additional causal items were added is shown below in Table 4.44. The scales produced when additional diabetes-specific causal items were added still lacked coherence with two separate lifestyle scales produced and overlap between biomedical and lifestyle scales. Further analysis on these scales was therefore not done.

	Component				
	1	2	3	4	5
Stress or worry	**.837**	.060	-.082	-.015	.065
Family problems or worries	**.791**	.001	.079	.204	-.040
Overwork	**.722**	-.105	.209	-.065	.222
My emotional state	**.746**	.158	.070	.273	-.046
A germ or virus	.044	-.097	.023	**.753**	-.151
Poor medical care in my past	.076	-.066	.136	**.704**	.080
Pollution in the environment	.176	-.103	.071	**.811**	.130
Diet or eating habits	.100	.319	.218	-.114	**.656**
My own behaviour	.229	.264	.296	.081	**.641**
Hereditary	.080	.082	.306	-.090	**-.558**
Alcohol	-.057	.012	**.851**	.012	.262
Smoking	.054	.054	**.857**	.081	.003
Accident or injury	.269	.017	**.639**	.262	-.151
Being overweight	-.030	**.796**	.039	-.188	.080
Not getting enough exercise	.021	**.881**	-.008	.029	.033
An unhealthy lifestyle	.096	**.811**	.054	-.125	.176

Table 4.43 Rotated component matrix of original and additional causal items

Original IPQ-R Causal PCA Scales	IPQ-R Causal PCA scales derived from validation study	Augmented causal scales
Psychological attributions (α=.86) Stress or worry My mental attitude Family problems or worries Overwork My emotional state My personality	*(α=.80)* Stress or worry Family problems or worries Overwork My emotional state	*Psychological attributions (α=.80)* Stress or worry Family problems or worries Overwork My emotional state
Risk Factors (α=.77) Hereditary – it runs in my family Diet or eating habits Poor medical care in my past My own behaviour Aging Smoking Alcohol	*(α=.24)* Hereditary-it runs in my family Aging	*Lifestyle factors (α=.81)* Being overweight Not getting enough exercise An unhealthy lifestyle
Immunity (α=.67) A germ or virus Pollution in the environment Altered immunity	*(α=.64)* A germ or virus Chance or bad luck Poor medical care in my past Pollution in the environment	*Bio-medical factors (α=.68)* A germ or virus Poor medical care in my past Pollution in the environment
Accident or chance (α=.23) Chance or bad luck Accident or injury	*(α=.70)* Diet or eating habits My own behaviour	*Lifestyle/biomedical factors (α=.33)* Diet or eating habits My own behaviour Hereditary-it runs in my family
	(α=.76) Alcohol Smoking Accident or injury My personality	*External factors (α=.75)* Alcohol Smoking Accident or injury

Table 4.44 Comparison of factor structure and internal reliability of causal scales

f) IPQ-R identity items

Validity and internal reliability

The paired sample t-test revealed a significant difference between the two subscales (t=12.26, p=.000) suggesting that there is a difference between somatization (experience of a symptom) and illness identity (association of that symptom with the illness). Fatigue was the most frequently endorsed symptom and was identified by 56.4% of the respondents. The alpha coefficient for the identity subscale was .79 suggesting high internal reliability despite the variety of symptoms named.

Predictive validity for the identity subscale

Beliefs about the relationship between symptoms and diabetes did not account for significant variance in general dietary behaviour (ΔR^2=.001, p=.646), eating five servings of fruits and vegetables a day (ΔR^2=.000, p=.799) or eating a high fat diet (ΔR^2=.001, p=.600) (Tables 4.45-4.47).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.160**	.020	.018 (.062)	.031 (.062)
	Gender	.004	.945		
	Duration	-.108	.106		
2	Identity	-.031	.646	.015 (.110)	.001 (.646)

Table 4.45 Regression analysis of identity scale and general diet

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.134	.054	.011 (.132)	.024 (.132)
	Gender	-.057	.378		
	Duration	.040	.556		
2	Identity	.017	.799	.007 (.226)	.000 (.799)

Table 4.46 Regression analysis of identity scale and specific diet- eating five portions of fruits and vegetables daily

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.029	.672	-.008 (.757)	.005 (.757)
	Gender	-.010	.879		
	Duration	.073	.276		
2	Identity	-.035	.600	-.011(.834)	.001 (.600)

Table 4.47 Regression analysis of identity scale and eating a high fat diet

Beliefs about identity accounted for 2.9% of variance (p=.007) in undertaking physical activity. It did not account for significant variance in medication adherence (ΔR^2=.001, p=.728) or blood glucose self-monitoring (ΔR^2=.000, p=.759) (Tables 4.48-4.50).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.107	.110	.031 (.014)	.044 (.014)
	Gender	**-.129**	.040		
	Duration	.172	.008		
2	Identity	-.175	.007	.057 (.001)	.029 (.007)

Table 4.48 Regression analysis of identity scales and physical activity

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.084	.288	.005 (.281)	.021 (.281)
	Gender	.113	.127		
	Duration	.018	.811		
2	Identity	.027	.728	.000 (.415)	.001 (.728)

Table 4.49 Regression analysis of identity scales and medication adherence

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**-.278**	.000	.067 (.000)	.079 (.000)
	Gender	-.031	.612		
	Duration	.031	.631		
2	Identity	.020	.759	.064 (.000)	.000 (.759)

Table 4.50 Regression analysis of identity scale and BGSM

g) Additional diabetes-specific identity items

Validity and internal reliability

The additional diabetes specific symptoms were added to the identity subscale and the paired sample t-test repeated. The result again showed a significant difference between somatization and identity (t=13.178, p=.000). Frequent urination was the most frequently identified symptom, being identified by 68.9% of the patients of whom 49.4% felt it was related to their diabetes. The new scale also had high internal reliability of .80.

Predictive validity

Beliefs that symptoms were related to diabetes did not account for significant variance in general diet (ΔR^2=.001, p=.625), eating five portions of fruits or vegetables a day (ΔR^2=.002, p=.506) or eating a high fat diet (ΔR^2=.000, p=.855) (Table 4.51-4.53).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.160**	.021	.018 (.062)	.031 (.062)
	Gender	.005	.937		
	Duration	-.109	.105		
2	Augmented identity	-.033	.625	.015 (.109)	.001 (.625)

Table 4.51 Regression analysis of augmented identity scale and general diet

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.142**	.043	.011 (.132)	.024 (.132)
	Gender	-.058	.370		
	Duration	.039	.559		
2	Augmented identity	.045	.506	.009 (.196)	.002 (.506)

Table 4.52 Regression analysis of augmented identity scale and specific diet- eating five portions of fruit and vegetables daily

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.017	.803	-.008 (.757)	.005 (.757)
	Gender	-.010	.883		
	Duration	.072	.285		
2	Augmented identity	.012	.855	-.012 (.876)	.000 (.855)

Table 4.53 Regression analysis of augmented identity scale and specific diet- eating a high fat diet

Beliefs that symptoms were related accounted for a significant increase in variance in physical activity (ΔR^2=.017, p=.040), but not in medication adherence (ΔR^2=.002, p=.554) or BGSM(ΔR^2=.005, p=.256) (Tables 4.54-4.56).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.098	.145	.031 (.014)	.044 (.014)
	Gender	**-.127**	.046		
	Duration	**.170**	.010		
2	Augmented identity	**-.134**	.040	.045 (.005)	.017 (.040)

Table 4.54 Regression analysis of augmented identity scale and physical activity

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.090	.259	.005 (.281)	.021 (.281)
	Gender	.113	.128		
	Duration	.019	.800		
2	Augmented identity	.046	.554	.001 (.384)	.002 (.554)

Table 4.55 Regression analysis of augmented identity scale and medication adherence

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**-.264**	.000	.067 (.000)	.079 (.000)
	Gender	-.033	.596		
	Duration	.029	.644		
2	Augmented identity	.073	.256	.069 (.000)	.005 (.256)

Table 4.56 Regression analysis of augmented identity scale and BGSM

Comparison of predictive validity of identity scales

A comparison of the predictive validity of the identity scales is shown in Table 4.57. Significant variance was explained only for physical activity where the original identity scale explained 2.9% of variance(p=.007) and the augmented identity scale explained 1.7% (p=.040).

	ΔR^2(p)	
	IPQ-R identity scale	Augmented identity scale
General diet	.001 (.646)	.001 (.625)
Eating more than five fruit and vegetables	..000(.799)	.002 (.506)
Eating a high fat diet	.001 (.600)	.000 (.855)
Physical activity	.029 (.007)	.017 (.040)
Medication adherence	.001(.728)	.002 (.554)
BGSM	.000 (.759)	.005 (.256)

Table 4.57 Comparison of predictive validity of identity scales

h) Beliefs about Medicines Questionnaire (BMQ)

Mean and SD

The means and standard deviations of the original BMQ items are appended (Appendix 3).

Factor structure of BMQ

A PCA was carried out on the 11 BMQ items using direct Oblimin rotation and specifying two factors. In the structure matrix produced, the first factor produced accounted for 24% of the variance produced and the second factor accounted for 21%. The item "My diabetes medicines give me unpleasant side effects" did not load on to either factor and was discarded from the subsequent analysis. Of note, this item was not included in the original paper. Repeat analysis produced a matrix in which the first accounted for 26% of the variance and the second for 23% of the variance. Each item loaded on to the factor which it loaded on to in the original BMQ paper. The structure matrix is shown in Table 4.58.

	Component	
	1	2
My health at present depends on my diabetes medicines	**.745**	-.158
My life would be impossible without my diabetes medicines	**.708**	.172
Without my diabetes medicines I would be very ill	**.812**	.037
My health in the future will depend on my diabetes medicines	**.697**	-.285
My diabetes medicines protect my health from becoming worse	**.531**	-.030
Having to take diabetes medicines worries me	-.004	**.781**
I sometimes worry about the long term effects of my medicines	.067	**.718**
These diabetes medicines are a mystery to me	.024	**.546**
These diabetes medicines disrupt my life	-.190	**.539**
I sometimes worry about becoming too dependent on my diabetes medicines	-.131	**.752**

Table 4.58 Structure matrix of BMQ items

Internal reliability

Both the specific necessity and specific concern scales had satisfactory reliability with alpha coefficient values of .74 and .69 respectively. The scales with their reliability coefficients are shown in Table 4.59.

Scale
Specific necessity (α=.74)
My health at present depends on my diabetes medicines
My life would be impossible without my diabetes medicines
Without my diabetes medicines I would be very ill
My health in the future will depend on my diabetes medicines
My diabetes medicines protect my health from becoming worse
Specific concerns (α=.69)
Having to take diabetes medicines worries me
I sometimes worry about the long term effects of my medicines
These diabetes medicines are a mystery to me
These diabetes medicines disrupt my life
I sometimes worry about becoming too dependent on my diabetes medicines

Table 4.59 BMQ scales and reliability coefficients

Predictive validity

Beliefs about medicines improved the prediction of medication adherence by illness representations by 7.7% (p=.002), with those who were less concerned more likely to take their medication (β=-.330, p=.001). (Table 4.60).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.138	.148	.003 (.320)	.022 (.320)
	Gender	.057	.498		
	Duration	-.112	.183		
2	Timelines (acute)	-.093	.280	-.002 (.480)	.064 (.519)
	Timelines (chronic)	**.185**	.032		
	Timelines (cyclical)	.008	.932		
	Consequences	-.020	.840		
	Efficacy of control strategies	-.012	.919		
	Futility of control strategies	.138	.157		
	Illness coherence	.139	.162		
	Emotional representations	-.034	.763		
	Influence of control strategies	.013	.909		
	Concerns about diabetes	.133	.183		
	Specific physical consequences	-.131	.175		
3	BMQ necessity	.065	.472	.069 (.045)	.077 (.002)
	BMQ concerns	**-.330**	.001		

Table 4.60 Regression analysis of illness perceptions, BMQ scales and medication adherence

(i) Additional beliefs about medicines items

Mean and SD of additional items

The means and standard deviations of the additional beliefs about medication items are appended (Appendix 3).

Factor structure of beliefs about medication with additional items

Principal components analysis was carried out on the original BMQ items and the diabetes-specific items using Direct Oblimin rotation with two factors specified and a loading threshold of 0.4. The two factors produced accounted for 19% and 17% of variance respectively. "My diabetes gives me unpleasant side effects", "My medication allows me/ would allow me to be less strict about my diet" and "I might increase the dose of my medication if I ate something which I knew might send up my blood sugar" did not load and were omitted from the second analysis in which the two factors produced accounted for 22% and 20% of the variance produced. "I would think my diabetes was getting better if I could stop or reduce my tablets" did not load on to any factors and was omitted from the third analysis in which the two factors accounted for 24% and 21% of the total variance. The structure matrix is shown below in Table 4.61.

	Component	
	1	2
My health at present depends on my diabetes medicines	**.764**	-.059
My life would be impossible without my diabetes medicines	**.639**	.304
Without my diabetes medicines I would be very ill	**.762**	.160
My health in the future will depend on my diabetes medicines	**.707**	-.163
My diabetes medicines protect my health from becoming worse	**.508**	-.035
Medication is important in controlling my diabetes	**.710**	-.184
Having to take diabetes medicines worries me	-.105	**.723**
I sometimes worry about the long term effects of my medicines	.002	**.667**
These diabetes medicines are a mystery to me	-.024	**.599**
These diabetes medicines disrupt my life	-.268	**.461**
I sometimes worry about becoming too dependent on my diabetes medicines	-.204	**.716**
I would be distressed if I had to use insulin to control my diabetes	.223	**.567**
I would think my diabetes was getting worse if I had to start taking tablets or change the ones I was on	.144	**.465**

Table 4.61 Structure matrix of BMQ and additional beliefs items

Internal reliability

The internal reliability of the augmented BMQ scales is shown below in Table 4.62 with each scale exhibiting satisfactory internal reliability.

Scale
Specific necessity (α= .77)
My health at present depends on my diabetes medicines
My life would be impossible without my diabetes medicines
Without my diabetes medicines I would be very ill
My health in the future will depend on my diabetes medicines
My diabetes medicines protect my health from becoming worse
Medication is important in controlling my diabetes
Specific concerns (α= .71)
Having to take diabetes medicines worries me
I sometimes worry about the long term effects of my medicines
These diabetes medicines are a mystery to me
These diabetes medicines disrupt my life
I sometimes worry about becoming too dependent on my diabetes medicines
I would be distressed if I had to use insulin to control my diabetes
I would think my diabetes was getting worse if I had to start taking tablets or change the ones I was on

Table 4.62 Internal reliability of augmented beliefs about medicines scales

Comparison of factor structure and internal reliability

The factor structures of the original and study-derived BMQ scales and the augmented scales were similar, with those produced with the additional items having marginally better internal consistency (Table 4.63).

Original and study derived BMQ scales	Augmented beliefs about medicines scales
Specific necessity (α=.74) My health at present depends on my diabetes medicines My life would be impossible without my diabetes medicines Without my diabetes medicines I would be very ill My health in the future will depend on my diabetes medicines My diabetes medicines protect my health from becoming worse	*Specific necessity (α= .77)* My health at present depends on my diabetes medicines My life would be impossible without my diabetes medicines Without my diabetes medicines I would be very ill My health in the future will depend on my diabetes medicines My diabetes medicines protect my health from becoming worse Medication is important in controlling my diabetes
Specific concerns (α=.69) Having to take diabetes medicines worries me I sometimes worry about the long term effects of my medicines These diabetes medicines are a mystery to me These diabetes medicines disrupt my life I sometimes worry about becoming too dependent on my diabetes medicines	*Specific concerns (α= .71)* Having to take diabetes medicines worries me I sometimes worry about the long term effects of my medicines These diabetes medicines are a mystery to me These diabetes medicines disrupt my life I sometimes worry about becoming too dependent on my diabetes medicines I would be distressed if I had to use insulin to control my diabetes I would think my diabetes was getting worse if I had to start taking tablets or change the ones I was on

Table 4.63 Comparison of factor structure and internal reliability of original, study derived and augmented beliefs about medicines scales

Predictive validity

The augmented BMQ scales were predictive of medication adherence, accounting for a further 10% of variance (p=.000). Concerns about diabetes medicines were again a significant predictor (β=-.390, p=.000) (Table 4.64).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.131	.160	.003 (.320)	.022 (.320)
	Gender	.060	.465		
	Duration	-.106	.198		
2	Timelines (acute)	-.122	.152	-.002 (.480)	.064 (.519)
	Timelines (chronic)	**.180**	.034		
	Timelines (cyclical)	-.004	.967		
	Consequences	-.040	.676		
	Efficacy of control strategies	-.006	.959		
	Futility of control strategies	.182	.065		
	Illness coherence	.167	.091		
	Emotional representations	-.018	.871		
	Influence of control strategies	.020	.857		
	Concerns about diabetes	.175	.080		
	Specific physical consequences	-.161	.095		
3	Augmented necessity of diabetes medication	.117	.204	.096 (.013)	.101 (.000)
	Augmented concerns about diabetes medication	**-.390**	.000		

Table 4.64 Regression analysis of illness representations, augmented beliefs about medication and medication adherence

Comparison of predictive ability of BMQ scales

In both regression analyses, beliefs about medication accounted for a significant increase in prediction of medication adherence over that accounted for by illness representations. The original BMQ scales accounted for a 7.7% increase (p=.002) and the augmented scales accounted for a 10.1% increase (p=.000) (Table 4.65).

	ΔR^2(p)	
	BMQ	Augmented BMQ scale
Medication adherence	.077 (.002)	.101 (.000)

Table 4.65 Comparison of predictive ability of BMQ scales

(j) Beliefs about eating and physical activity questionnaire

Mean and SD

The means and standard deviations of the items relating to beliefs about eating and physical activity are appended (Appendix 3).

Factor structure of BEPAQ items

This was conducted using eigen value greater than 1 and a threshold of 0.4. 15 items relating to beliefs about eating and physical activity were included in the analysis which produced five factors accounting for 58% of the variance produced (Table 4.66).

Internal reliability

Internal reliability was generally modest for the scales derived from the eating and physical activity items, with the exception of items regarding the importance of lifestyle modification where the alpha coefficient was .79 (Table 4.67).

	Component				
	1	2	3	4	5
Because I have diabetes, it is very important for me to reduce the sugar in my diet	**.656**	.055	.015	-.095	.140
Because I have diabetes, it is important for me to include carbohydrates that release sugar slowly in my diet	**.582**	.052	.310	.145	-.015
Because I have diabetes, it is important for me to include fruit in my diet every day	**.628**	-.065	.371	-.012	.247
Because I have diabetes, it is important for me to include vegetables in my diet every day	**.804**	-.023	-.147	-.108	-.015
Because I have diabetes, it is important for me to include cereals and fibre in my diet every day	**.718**	-.108	-.173	.004	-.231
Eating a sensible diet is the most important factor in controlling my diabetes	**.554**	-.093	.085	.042	.117
Regular physical activity is important for my diabetes	**.655**	.117	.049	.228	-.173
Having an occasional sweet will not affect my diabetes	.053	.308	**.576**	-.142	-.146
Eating too much fruit can harm my diabetes	.030	.130	**-.749**	.008	-.021
Because I have diabetes, it is important for me to exclude high fat food from my diet	.327	-.115	.343	.118	**.604**
Drinking small amounts of diabetes could affect my diabetes	-.141	.177	-.328	.007	**.746**
I would enjoy eating sweet foods	-.014	**.846**	.071	-.042	.121
I would enjoy eating fatty foods	-.025	**.801**	-.063	.181	-.041
Because I have diabetes, it is important for me to eat less food	-.216	.037	-.070	**.788**	.155
If I lost weight I could improve my diabetes	.346	.097	-.030	**.704**	-.086

Table 4.66 Rotated component matrix of eating and physical activity

Scale
Importance of lifestyle modification (α= .79)
Because I have diabetes, it is very important for me to reduce the sugar in my diet
Because I have diabetes, it is important for me to include carbohydrates that release sugar slowly in my diet
Because I have diabetes, it is important for me to include fruit in my diet every day
Because I have diabetes, it is important for me to include vegetables in my diet every day
Because I have diabetes, it is important for me to include cereals and fibre in my diet every day
Eating a sensible diet is the most important factor in controlling my diabetes
Regular physical activity is important for my diabetes
Lack of impact of straying from diet (α=.24)
Having an occasional sweet will not affect my diabetes
Eating too much fruit can harm my diabetes
Importance of dietary exclusions (α=.13)
Because I have diabetes, it is important for me to exclude high fat food from my diet
Drinking small amounts of alcohol could affect my diabetes
Enjoyment of straying from recommended diet (α=.63)
I would enjoy eating sweet foods
I would enjoy eating fatty foods
Importance of weight loss (α= .37)
Because I have diabetes, it is important for me to eat less food
If I lost weight I could improve my diabetes

Table 4.67 Internal reliability of eating and physical activity items

Predictive validity

The ability of the BEPAQ scales to improve upon the prediction of the IPQ-R was tested. As discussed previously, the illness representation model derived when diabetes specific questions were added was used in the analysis.

Diet

Representations about eating and physical activity improved the ability of illness representations to predict adherence to general dietary recommendations by 7.3% (p=.008) due to the predictive ability of beliefs about straying from recommended eating patterns (β=-.241, p=.001). Illness representations and beliefs about eating and physical activity significantly predicted 8.1% of the variance in following advice about eating five servings of fruit and vegetables a day, but in the model, beliefs about eating and physical activity accounted for only 3.1% (p=.228). Illness representations and beliefs about eating a high fat diet predicted a significant 6.1% of variance (p=.035) with beliefs about eating and physical activity improving upon the prediction of illness representations by 9.6% (p=.001). Beliefs about straying from eating patterns made a significant contribution to this prediction (β=.285, p=.000) (Tables 4.68-4.70).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.177**	.040	.021 (.057)	.035 (.057)
	Gender	-.002	.974		
	Duration	-.076	.299		
2	Timelines (acute)	-.077	.306	-.007 (.562)	.024 (.921)
	Timelines (chronic)	.051	.524		
	Timelines (cyclical)	-.026	.747		
	Consequences	.125	.156		
	Efficacy of control strategies	.040	.685		
	Futility of control strategies	-.072	.376		
	Illness coherence	.022	.796		
	Emotional representations	-.072	.489		
	Influence of control strategies	-.005	.960		
	Concerns about diabetes	-.028	.764		
	Specific physical consequences	-.086	.307		
3	Importance of lifestyle modification	.048	.537	.047 (.071)	.073 (.008)
	Lack of impact of straying from diet	-.018	.811		
	Importance of dietary exclusions	.095	.178		
	Enjoyment of straying from recommended diet	**-.241**	.001		
	Importance of weight loss	-.083	.266		

Table 4.68 Regression analysis of illness representations, beliefs about eating and physical activity and general diet

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	**.242**	.005	.019 (.072)	.033 (.072)
	Gender	-.061	.402		
	Duration	-.024	.744		
2	Timelines (acute)	-.067	.362	.071 (.011)	.100 (.026)
	Timelines (chronic)	.065	.406		
	Timelines (cyclical)	.149	.057		
	Consequences	.101	.245		
	Efficacy of control strategies	-.136	.167		
	Futility of control strategies	.025	.760		
	Illness coherence	**-.179**	.033		
	Emotional representations	-.108	.294		
	Influence of control strategies	-.014	.878		
	Concerns about diabetes	-.035	.701		
	Specific physical consequences	.118	.163		
3	Importance of lifestyle modification	.140	.074	.081 (.012)	.031 (.228)
	Lack of impact of straying from diet	.048	.512		
	Importance of dietary exclusions	.032	.650		
	Enjoyment of straying from recommended diet	-.103	.137		
	Importance of weight loss	-.003	.971		

Table 4.69 Regression analysis of illness representations, beliefs about eating and physical activity and specific diet- eating five portions of fruit and vegetables daily

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.015	.857	-.001 (.444)	.013 (.444)
	Gender	.019	.791		
	Duration	.095	.193		
2	Timelines (acute)	-.032	.671	-.018 (.737)	.037 (.741)
	Timelines (chronic)	-.110	.168		
	Timelines (cyclical)	.047	.547		
	Consequences	-.072	.409		
	Efficacy of control strategies	-.044	.659		
	Futility of control strategies	.026	.752		
	Illness coherence	.035	.678		
	Emotional representations	-.076	.466		
	Influence of control strategies	.119	.198		
	Concerns about diabetes	.098	.293		
	Specific physical consequences	.065	.436		
3	Importance of lifestyle modification	-.089	.252	.061 (.035)	.096 (.001)
	Lack of impact of straying from diet	-.108	.146		
	Importance of dietary exclusions	-.027	.698		
	Enjoyment of straying from recommended diet	**.285**	.000		
	Importance of weight loss	-.050	.504		

Table 4.70 Regression analysis of illness representations, beliefs about eating and physical activity and specific diet- eating a high fat diet

Beliefs about eating and physical activity did not significantly improve the ability of illness perceptions to predict undertaking activity (ΔR^2=.048, p=.056), although when both constructs were considered, they accounted for 6.4% (p=.029) of the variance observed. Beliefs about necessary behaviour modifications (β=.169, p=.030) and

beliefs about straying from eating habits (β=-.143, p=.038) were significant individual predictors of physical activity (Table 4.71).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	.001	.994	.031 (.021)	.045 (.021)
	Gender	**-.163**	.025		
	Duration	**.144**	.048		
2	Timelines (acute)	.028	.706	.036 (.092)	.054 (.375)
	Timelines (chronic)	-.056	.472		
	Timelines (cyclical)	-.050	.526		
	Consequences	-.035	.683		
	Efficacy of control strategies	-.043	.654		
	Futility of control strategies	**.168**	.038		
	Illness coherence	-.104	.218		
	Emotional representations	-.034	.741		
	Influence of control strategies	.137	.138		
	Concerns about diabetes	.053	.559		
	Specific physical consequences	.037	.656		
3	Importance of lifestyle modification	**.169**	.030	.064 (.029)	.048 (.056)
	Lack of impact of straying from diet	-.050	.497		
	Importance of dietary exclusions	-.026	.709		
	Enjoyment of straying from recommended diet	**-.143**	.038		
	Importance of weight loss	.059	.423		

Table 4.71 Regression analysis of illness representations, beliefs about eating and physical activity and physical activity

(k) BGSM beliefs and behaviours

Mean and SD

The means and standard deviations of BGSM beliefs and behaviours are appended (Appendix 3).

BGSM Beliefs

Factor structure and internal reliability of BGSM belief items

Eleven items were entered into the PCA. This produced four factors accounting for 61% of the variance. Two items- "Checking my blood sugar at home alerts me early if there's a problem with my blood sugar control" and "Checking my blood sugar reassures me" loaded on to two separate scales and were omitted from subsequent analysis. The second analysis produced four scales accounting for 66% of the variance. The item "Checking my blood sugar is painful" loaded on to two factors and was discarded prior to the third analysis which produced four factors accounting for 69% of the variance. (Table 4.72).

	Component			
	1	2	3	4
Checking my blood sugar at home would cause me to worry	-.140	**.809**	.250	.015
I prefer if my health professional checks my blood sugar	.179	**.807**	-.092	-.052
Other people with diabetes can tell if their blood sugar is abnormal without testing it	**.782**	-.022	.226	.089
I can tell if my blood sugar is abnormal without testing it	**.797**	.064	.016	-.091
It is not important for me to check my blood sugar	.168	.112	**.806**	.018
I do not think I need to check my blood sugar more than once a week	.043	.007	**.736**	-.104
I am curious about the level of my blood sugar	-.285	-.180	.059	**.787**
Checking my blood sugar helps me to control my eating habits	.268	.134	-.181	**.796**

Table 4.72 Rotated component matrix of beliefs about BGSM

Internal reliability of BGSM beliefs scales

The internal reliability for the BGSM beliefs scale was generally quite modest with the exception of the BGSM deterrents which had an alpha coefficient of .72. (Table 4.73).

Scales
BGSM deterrents (α=.72) Checking my blood sugar at home would cause me to worry I prefer if my health professional checks my blood sugar
Physical symptoms of abnormal blood sugar (α= .60) Other people with diabetes can tell if their blood sugar is abnormal without testing it I can tell if my blood sugar is abnormal without testing it
Unimportance of BGSM (α= .43) It is not important for me to check my blood sugar I do not think I need to check my blood sugar more than once a week
Incentives for checking blood sugar (α= .41) I am curious about the level of my blood sugar Checking my blood sugar helps me to control my eating habits

Table 4.73 Internal reliability of BGSM scales

Predictive validity of BGSM beliefs scales

Beliefs about BGSM predicted 8.1% more variance in BGSM use than demographic data. This was due to the influence of concerns about BGSM with patients who were more concerned about BGSM less likely to use the technology (β=-.264, p=.003) (Table 4.74).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.141	.121	.049 (.026)	.072 (.026)
	Gender	-.153	.076		
	Duration	.128	.148		
2	Deterrents to BGSM	-.264	.003	.104 (.005)	.081 (.026)
	Physical symptoms of abnormal blood sugar	.076	.390		
	Unimportance of BGSM	-.098	.278		
	BGSM incentives	-.055	.519		

Table 4.74 Regression analysis of BGSM beliefs and BGSM use

BGSM beliefs also significantly improved the ability of illness representations to predict BGSM use (ΔR^2= .093, p=.024), due to the contribution of concerns about blood glucose monitoring with persons who were more concerned again being less likely to monitor (β=-.330, p=.003). The overall prediction of illness representations and BGSM beliefs was not, however significant (adj. R^2=.07, p=.102) (Table 4.75).

Step	Independent variable	β coefficient	p	Overall adjusted R^2 (p)	ΔR^2 (p)
1	Age	-.080	.483	.042 (.049)	.066 (.049)
	Gender	-.121	.221		
	Duration	.086	.376		
2	Timelines (acute)	.010	.925	.003 (.437)	.055 (.831)
	Timelines (chronic)	.099	.412		
	Timelines (cyclical)	.080	.466		
	Consequences	-.008	.946		
	Efficacy of control strategies	-.173	.231		
	Futility of control strategies	.097	.394		
	Illness coherence	.004	.975		
	Emotional representations	-.041	.792		
	Influence of control strategies	.292	.019		
	Concerns about diabetes	.035	.779		
	Specific physical consequences	.047	.670		
3	Deterrents to BGSM	-.330	.003	.072 (.102)	.093 (.024)
	Physical symptoms of abnormal blood sugar	.054	.612		
	Unimportance of BGSM	-.107	.310		
	BGSM incentives	-.094	.328		

Table 4.75 Regression analysis of illness representations, BGSM beliefs and BGSM behaviours

4.4 *Discussion*

This study aimed to explore the performance of the IPQ-R and BMQ in a population with non-insulin treated type 2 diabetes and to evaluate effect of the addition of diabetes-specific questions to these scales. It also sought to develop scales to measure beliefs about eating and physical activity and blood glucose self-monitoring and establish scales to assess BGSM behaviours.

Analysis of our study data showed that the factor structure of the IPQ-R was not reproducible in our population. Inconsistencies were evident in three scales, namely ideas about chronicity, control and consequences. Beliefs about the chronicity of diabetes consistently loaded on to two separate factors, one dealing with acuteness and the second with chronicity. The former may indicate that patients tend to dissociate ideas about acuteness- perhaps as relating to exacerbations of illness or blood sugar- and the chronicity of the condition. Beliefs about control, rather than

loading on to scales relating to personal and treatment control, produced factors relating to the efficacy and futility of control strategies. This may be because a significant element of diabetes "treatment" involves self care activities, so patients' beliefs may center around how effective these strategies are rather than whether they are a result of personal efforts. People with diabetes also appeared to think about their diabetes with regard to specific and general consequences rather than overall. The strong internal consistency in the study-derived scales supported their reliability. No published study has evaluated the factor structure of this questionnaire in a population with non-insulin treated type 2 diabetes, however, so we lacked other data with which to compare.

Although the IPQ-R has not been evaluated in a population similar to ours, research has suggested that the five dimensions of illness representations do not apply to patients with type 2 DM with merging of the consequences and timelines constructs(157). Our study shows that these dimensions are indeed relevant in this population.

Analysis of the causal items was unable to reproduce the original causal scales or produce coherent scales. This may be because some of the original factors were formed from weakly related items(186). Additionally the items analysed were quite general and ideas about causes of diabetes appeared quite specific. Hampson et al in their studies of personal models of diabetes(157,158), which are also based on Leventhal's theory, limited their causal items to those related to personal responsibility for diabetes and were able to produce coherent scales that may be more applicable to this population.

In both the model with the original scales and that with the augmented scales, representations predicted significant additional variance in eating five portions of fruit and vegetables a day, due to the contribution of illness coherence and beliefs about cyclical timelines. Previous research has also found that overall understanding of diabetes was a significant predictor of dietary adherence (200). Beliefs were, however, unable to predict other self care activity such as following general dietary advice,

eating a high fat diet and undertaking physical activity. This may be due to limitations in the outcome measure. Questions in the SDSCA scale relating to general diet inquire about healthful eating plans and the frequency with which individual eating plans were followed. This assumes that all patients have the same understanding of healthful eating plans and that all individuals have personal eating plans which may not be the case.

Illness representations also predicted use of BGSM, with those who had a better overall understanding of their illness using this technology, which may reflect those with better understanding being able to incorporate results of BGSM into their routine and therefore finding it helpful or, conversely, that use of BGSM increases understanding by illustrating a relationship between behaviour and blood glucose results. Cyclical timelines also predicted use of BGSM and this may be because those who used BGSM were able to observe variations in their blood sugar which encouraged use of the technology to monitor their levels of blood sugar.

Other studies have supported the ability of personal models to predict self care activities. These have generally demonstrated the ability of personal models to predict dietary adherence and undertaking physical activity (157-159). A fourth study found that personal models were also predictive of BGSM (160). These studies were carried out in patients with both type 1 and type 2 diabetes however and those with type 1 diabetes and those with insulin treated type 2 diabetes might reasonably be expected to have different personal models and consequent behaviour.

The causal scales from the original IPQ-R were predictive of several care activities including eating five portions of fruit and vegetables a day, eating high fat food, adhering to medication and undertaking BGSM. Risk factors contributed significantly to the model, predicting dietary behaviour with those who believed their diabetes was due to risk factors more likely to eat five portions of fruit and vegetables a day and less likely to eat a high fat diet. In the model that predicted medication adherence, belief in immunity as a cause predicted those who were less likely to adhere to medication, while those who did not believe their diabetes was due to accident or chance less

likely to monitor. Interpretation of these models must be limited however, due to our inability to reproduce these factors in our sample. This inability may be a function of a theoretical overlap in the original scales. The risk factors scale included items which related to biomedical risk factors such as "hereditary" and "poor medical care" as well as items which could be associated with lifestyle such as "diet or eating habits" and "my own behaviour". Other biomedical causes such as "a germ or virus" and "altered immunity" were included in the immunity scale.

Addition of the diabetes-specific items resulted in a closer theoretical approximation to the illness representations model in our population. While one consequences scale was produced rather than two, separate timelines (chronic) and timelines (acute) scales persisted. Three additional scales relating to specific consequences of diabetes, influence of control strategies and concerns about diabetes were also produced. These scales are within the theoretical framework, suggesting that augmentation of the measure can include beliefs which are not currently assessed without compromising construct validity.

Addition of diabetes-specific items also generally improved the predictive validity of illness representations. While the self-care activities which were predicted by illness beliefs, namely eating five portions of fruit and vegetables a day and undertaking blood glucose self-monitoring were unchanged, the augmented illness representation scales accounted for more variance. The factor structure of the causal scales still lacked coherence, however, and the augmented identity scale predicted less variance in physical activity prediction.

Research suggests that the dimensions of illness representations are disease-specific(201). The authors of the IPQ-R acknowledge the difficulties in applying a uniform measure to differing disease groups and recommend modification of the questionnaire as necessary(186). Our study shows that utilizing theoretically derived items not only improves the factor structure, but can also improve on the reliability of the original scales.

Analysis of the BMQ reproduced the published scales with good internal reliability, suggesting that people with diabetes have the same concerns about their diabetes medication and think about the necessity of their diabetes medication in the same way as other people on medication. As expected, beliefs about medication improved the ability of illness representations to predict medication adherence, with people who had fewer concerns about their medication being more likely to take it. Beliefs about necessity of medication did not significantly contribute to the model. This is in keeping with previous research that showed that medication beliefs predicted a significant amount of variance in medication adherence and those whose concerns outweighed beliefs about necessity less likely to adhere(162). While all of the interview-derived items could not be accommodated within the two-factor structure, those that were did not compromise the reliability of the scales and actually increased the variance predicted.

Analysis of items relating to eating and physical activity produced scales relating to lifestyle modification, lack of impact of straying from diet, importance of dietary exclusions, enjoyment of straying from diet and importance of weight loss. With the exception of the scale relating to lifestyle modification, the scales produced had modest reliability. While the items were theoretically important, it may be useful to consider them individually. The scales did however, improve the ability of diabetes beliefs to predict adherence to general diet with people who enjoyed straying from their diet less likely to adhere to these recommendations, suggesting the importance of short term affective consequences as well as long term outcomes in these people. Beliefs about eating and physical activity also improved the ability of illness representations to predict eating a high fat diet with those who enjoy straying from diet likely to eat a high fat diet. Previous research has also suggested that regimen-specific models or beliefs are strong predictors of regimen adherence(160).

Analysis of BGSM beliefs produced four factors namely BGSM deterrents, physical symptoms of abnormal blood sugar, unimportance of BGSM and incentives for BGSM. Internal reliability was modest with the exception of the scale relating to BGSM deterrents. As with beliefs about eating and physical activity, it may be useful to consider these beliefs as individual items rather than as scales. Beliefs about BGSM

did predict undertaking of BGSM and also improved on the ability of illness representations to do so. The three BGSM behaviour scales had modest internal reliability and items should probably be analysed separately as outcome measures. Alternatively, more items could be generated and the procedure repeated which might result in more reliable scales.

The systematic development and evaluation of the questionnaire which we planned to use in the RCT had several benefits. The selection of measures which were theoretically compatible with the study intervention made it more likely that we would be able to detect changes in those areas that the intervention targeted, namely beliefs about diabetes and self-care activities, and evaluate whether any changes in beliefs were reflected by change in behaviour. The inclusion of specific beliefs was also likely to increase the sensitivity of the measures. Use of cognitive interviewing in the initial stages also allowed us to ensure that patients' understanding of the questionnaire was clear and allowed us to correct problems that arose with interpretation. Assessment of the predictive ability of various dimensions of the theory of self-regulation facilitated intervention development as those areas in which change in belief might be expected to result in behaviour change could be identified and the intervention developed appropriately. Evaluation in the target population also allowed us to assess performance of the questionnaire and identify potential weaknesses such as modest internal reliability in some belief scales which would direct future analysis. We were also able to confirm that a theoretically-based augmentation of the existing questionnaires produced valid, reliable scales.

There were, however, limitations. We were not able to access data on the non-responders in the questionnaire evaluation study which made it impossible for us to comment on the generalisability of our findings. The use of self-report measures is also a potential weakness. Self-report as a measure of adherence may be affected by recall bias or by the patient's desire to please the researcher(162). The questionnaire was also posted, so a "priming" effect may have occurred where patients altered their behaviour in the days prior to completing the questionnaire. While evaluation of the belief measures was carried out in the target population, the behaviour measures, with the exception of the use of BGSM were adopted from other studies. The SDSCA, for

example, is a simple measure which in six items is not likely to adequately explore all of the issues relating to dietary adherence and physical activity.

We did not evaluate the test-retest reliability of the augmented or newly developed measures which is another potential limitation. This may make it difficult to assess whether differences between baseline questionnaire scores and those completed at one year are due solely to changes in beliefs due to the intervention or to a lack of stability in the measures. Evaluation of this characteristic would have been challenging however; if the test-retest interval was too short, this may have led to patients simply recalling and recording their previous responses, if the interval was too long, patients' beliefs and therefore responses may have changed(194).

It is also difficult to draw conclusions of causality from a cross-sectional survey. Use of these measures in a longitudinal study such as the RCT will enable more robust conclusions to be drawn about the ability of beliefs to predict behaviour. The potential change in beliefs which will be influenced by the intervention can then be evaluated with regard to changes in behaviour.

Implications for trial

The final trial questionnaire included the IPQ-R without causal items, the BMQ, additional diabetes specific questions, the Beliefs about Eating and Physical Activity scale, MARS, SDSCA, WBQ-12, DTSQ and EQ-5D. Two items were omitted from the final beliefs about eating and physical activity questionnaire because they were thought to be less theoretically relevant and more items about physical activity were added to further elicit beliefs about activity and its relationship to diabetes. Additional questions were also added to the beliefs about BGSM scale to elicit the extent to which use caused anxiety or worry. While omission of the causal scales meant that all elements of the illness representations theory were not being tested, we felt this was justified give the poor factor structure of the causal items in our population. This decision is supported by previous studies(202) which suggest that causal beliefs are more important at initial diagnosis, rather than in day-to-day management of chronic disease. Self-care activities are likely to be determined more about ideas about what

causes day-to-day fluctuations in blood sugar and exacerbations in diabetes i.e. timelines and consequences which were assessed in our model.

The final questionnaire used in the RCT is appended (Appendix 4). The questionnaire was administered at baseline and at the end of the trial and the results of this are discussed in chapters 6 and 7.

Chapter 5

The randomized controlled trial- design and methods

5.1 *Aims of the randomized controlled trial*

As discussed in Chapter 2, blood glucose self-monitoring (BGSM) has been advocated as a means of improving glycaemic control in patients with non-insulin treated diabetes(96). The literature review presented earlier in this thesis highlighted some of the deficiencies in the design and analysis of previous studies of this subject that have led to conflicting results and ambiguous clinical recommendations(32) . This chapter describes the design and methods used in a clinical trial to address these deficiencies.

This trial was designed with the primary objective of establishing whether BGSM, either used on its own or to actively encourage use of self-management techniques, is superior to usual care in improving glycaemic control. Secondary objectives included comparison of treatment satisfaction, well-being, health service use and economic cost between groups, comparison of changes in mean HbA_{1c} among subgroups as defined by duration of diabetes, age, self-reported health status and co-morbidity and qualitative analysis to explore how BGSM influences beliefs about diabetes and self care activities .

The trial was conducted in two centres. This chapter describes the conduct of the trial in the Oxfordshire centre. The number of participants recruited here was insufficient for health economic analysis so this is not discussed further in the thesis. The methods and results of the qualitative study are discussed in Chapter 8.

5.2 *Trial design*

An open, randomized, controlled, pragmatic, parallel group trial design was used. All patients received the same baseline educational information to provide a standard framework for discussion of lifestyle modification. They were then randomized into one of three groups, each of which used different methods of glycaemic monitoring as follows:

a) a comparison group which received standardized usual care with an HbA_{1c} every three months

b) a less intensive monitoring group which, in addition to three monthly HbA_{1c} measurements, was asked to monitor their blood sugar at home three times a day on any two days of the week to provide their study nurse with information about their glycaemic control

c) a more intensive monitoring group which was asked to monitor their blood sugar three times a day on any two days of the week and given support in applying the results of their blood sugar to their self-care behaviour

Patients were followed for one year after randomization.

5.2.1 Outcome measures and sample size

The primary outcome measure was change in HbA_{1c} between baseline and 1 year. Changes in the following parameters between baseline and one year were secondary outcomes:

(i) Clinical and laboratory measures

- Systolic and diastolic blood pressure
- Weight
- Total cholesterol, High Density Lipoprotein (HDL) cholesterol and HDL cholesterol/ Total cholesterol ratio

(ii) Self-reported behaviour measures

- Smoking status
- Dietary intake and physical activity (SDSCA)
- Medication adherence (MARS)

(iii) Medical management

- Increases in hypoglycaemic therapy

(iv) Patient psychological outcomes

- Treatment satisfaction (DTSQ)
- Patient well being (WBQ-12)

(v) Patient beliefs

- Beliefs about diabetes (IPQ-R with diabetes-specific items)
- Beliefs about diabetes medicines (BMQ with diabetes-specific items)
- Beliefs about the effect of eating and physical activity (BEPAQ)

The development and evaluation of the measures used to assess patient psychological outcomes and beliefs are described in Chapter 4. Measures were scored as described in Chapter 4 with the scales in the WBQ-12 being summed to give a composite score of well-being.

(vi) Sample size calculation

Sample size was calculated to detect a clinically significant difference of 0.5%(2) in absolute HbA_{1c} at 1 year follow-up between any two groups at a 5% significance level with 90% power. We selected a power of 90% because at the start of the trial, two of the largest studies of BGSM(128,129) had yet to be published and the existing research suggested that any effect was likely to be small. Initial sample size calculation was based on a conservative estimate of a standard deviation in HbA_{1c} of 1.5% which was taken from UKPDS data(14) since we were using the same laboratory. A total of 630 participants with 190 participants per arm, allowing for a 10% loss to follow-up was required[13]. A study limited to the 245 patients recruited by the Oxfordshire centre therefore had reduced power to detect the 0.5% difference in HbA_{1c} between groups with a post hoc calculation revealing a power of 54%.

[13] Revisions to the sample size calculation were later made after there was difficulty meeting recruitment targets. Various sample size were estimated using conservative estimates for the standard deviation of HbA_{1c} (based on recruited patients) for the Oxfordshire data and the original estimation of 1.5 for patients recruited from another centre. A study with 84% power to detect a difference of 0.5% between groups was conducted, requiring 130 patients per group.

5.3. *Assessment of eligibility*

Assessment of patient eligibility took place in three separate stages: identification from practice lists, telephone contact with study staff and then assessment of glycaemic control.

5.3.1 Identification from practice lists

The sampling frame comprised patients with type 2 diabetes from 24 general practices from the five Oxfordshire Primary Care Trusts. Practice staff generated lists of patients with type 2 diabetes who were not being treated with insulin. These lists were reviewed by practice staff and persons whom practice staff thought had co-morbidities or limited life expectancy which would preclude tight glycaemic control were excluded. The use of BGSM was then assessed by the study facilitator attached to that practice, with patients with a prescription for more than 100 BGSM test strips or 100 lancets within the last year assumed to be monitoring their blood sugar more than once a week and excluded from the trial. These patients were excluded as those monitoring more than once a week were likely to already have pre-conceived notions of the technology and may already have been using results to influence their self-care behaviour. This was suggested by the in depth interviews described in Chapter 4, where some interviewees reported adjusting eating habits if blood glucose values were high. It would therefore have been very difficult to randomize patients who were already interpreting and applying their BGSM results to their behaviour into the less intensive monitoring group where patients were expressly discouraged from drawing these conclusions.

Patients who met these criteria were sent a letter on their practice letterhead and signed by one of the surgery general practitioners inviting them to take part in a study to help people with diabetes improve their health (Appendix 5). The letter also stated that participants would be offered the opportunity to discuss their experience of diabetes and methods of controlling it and offered additional help in keeping a check on their diabetes. This help would either be by more frequent blood tests at the surgery or by use of a blood glucose monitor at home. These were presented as equally useful options to avoid

influencing participants' views as to the desirability of either method. Interested patients were invited to complete an enclosed reply slip with their contact details and return it to the study centre in the provided pre-paid envelope. Patients who did not respond to the first mailing were sent a second invitation letter. If no response was received from this, no attempt was made to contact them again.

5.3.2 Telephone contact

Patients who responded to the invitation letter were contacted by telephone by a study facilitator for a further assessment. Questions were asked about the frequency of BGSM to confirm how frequently it was being undertaken. Questions based on the eating, bathing, grooming, dressing, toilet use, transfers and mobility domains of the Barthel Index(203) were used to assess independence in activities of daily living as improvement in self care activities such as physical activity would require a certain degree of mobility. Patients who were randomized into the less and more intensive monitoring groups would also have to be sufficiently agile and sighted to use the blood glucose meter. Patients who were not independent in these areas were excluded from the study.

5.3.3 Assessment of glycaemic control

Patients who were determined eligible after this stage were invited to attend an assessment visit. As part of the protocol for this visit, which is described in further detail below, a 5 millilitre (ml) sample of venous blood was taken in a Vacutainer (Becton Dickinson and Co., U.S.A) tube containing ethylenediaminetetraacetic acid (EDTA) for assessment of HbA_{1c}. Patients with an HbA_{1c} of less than 6.2% were excluded from the study as this was the upper limit of normal for our assay (described below) and patients below the level would be unlikely to experience a discernible decrease during the course of the study.

Patients who met all eligibility criteria were randomized into the trial. A summary of inclusion and exclusion criteria is shown in Table 5.1.

Inclusion criteria	Exclusion criteria
Age 25 or over at diagnosis	Current use of insulin
Type 2 diabetes	Use of blood glucose self-monitoring more than once a week
Controlled with lifestyle modification or oral hypoglycaemic agents	Contra-indications to tight glycaemic control
Independent in activities of daily living	Unable to follow trial protocol or attend trial clinics
	$HbA_{1c} < 6.2\%$
	Pregnancy

Table 5.1 Inclusion and exclusion criteria

5.4 Randomization procedures

A total of 245 patients were randomized into the study at the Oxfordshire centre. A minimization procedure was used during the randomization to ensure prognostic factors of interest were equally distributed between study arms. In minimization, the allocation of each patient depends on the characteristics of the participants already allocated(204). Patients were minimized on the basis of duration of diabetes, since, given the natural history of the disease, the HbA_{1c} would likely be lower in those with a shorter duration and these participants would likely experience a smaller decrease in HbA_{1c} than those with a higher HbA_{1c}. Similarly, baseline HbA_{1c} was used as a minimization criterion. Treatment modality (lifestyle modification, oral monotherapy or oral combination therapy) was also used as a minimization criterion since those on more intensive therapy may have had poorer glycaemic control.

Minimization was carried out by the study administrator at the Department of Primary Care, University of Oxford using the MINIM computer program (Evans, S., Royston, P., Day, S, St. George's Medical School) after receipt of the assessment HbA_{1c} result. Group allocation was entered into the central study database and inserted into study folders for collection by study facilitators prior to the next contact with the patient. Recording of allocation in the study database safeguarded against study facilitators deciding not to allocate a patient to their assigned group.

5.5 *Study visits*

5.5.1 Initial assessment visit

As noted above, patients who expressed interest in the study and who were eligible after the initial telephone contact were invited to attend an assessment visit with the study facilitator. These visits lasted approximately one hour. The trial was explained fully and the opportunity to ask questions provided. Informed consent was obtained from patients who were willing to take part and the remainder of the visit was divided into four parts: data collection and notes review, administration of questionnaire, clinical assessment and baseline discussion of diabetes.

(i) Data collection and notes review

Basic demographic data were collected from each patient. Self-reported smoking status and all medications being used were recorded as was use of health services in the last 12 months. The five class, self-coded version of the National Statistics Socio-Economic Classification (NS-SEC)(205) was used to collected data on employment status. If patients had responded positively during the telephone interview to the presence of diabetes related complications, the general practice notes were reviewed and data regarding these events collected on a notes review form which was then coded independently and verified by the author and principal investigator. Discrepancies in coding were resolved by discussion and final codes were entered into the patient database.

(ii) Clinical assessment

A baseline clinical assessment was performed at the assessment visit. Weight was measured using a digital scale (Boots Group PLC, UK) with the subject in indoor clothing and without shoes. Height was measured with the Seca Leicester Height Measure to the nearest centimetre with the patient standing without shoes (Seca, Hamburg).

The patient's blood pressure was measured using an electronic sphygmanometer (LifeSource UA-779(206), A&D Medical, Japan). The participant was seated with both feet flat on the ground and rested for five minutes prior to the first measurement. Restrictive clothing on the subject's left arm was loosened and the blood pressure cuff was applied 3 cm above the antecubital fossa. Large cuffs were available and were used if necessary to ensure the bladder of the cuff covered two-thirds of the patient's arm. The cuff was inflated and the first blood pressure measurement done. Second and third measurements were then done with a ten minute interval between each reading. The systolic and diastolic blood pressures were recorded for each of the second and third measurements only.

In addition to the venous sample for HbA_{1c} described above, a second 5 ml venous sample was collected in a Vacutainer containing EDTA for assessment of total and HDL cholesterol.

(iii) Administration of questionnaire

The development of the questionnaire used in the study is described in Chapter 4. The questionnaire was given to participants at the assessment visit and they were given the option of completing it at the visit or taking it home for completion and returning it in the provided pre-paid envelope. Patients who had not returned the questionnaire prior to the post-randomization visit were contacted by telephone by their study facilitator and asked to bring the questionnaire to the visit. This was to ensure that questionnaires were completed prior to patients being aware of their randomization so post-randomization events would not affect their beliefs and behaviour.

(iv) Baseline discussion about diabetes

All patients were invited to discuss their knowledge of diabetes with the study facilitator. As discussed previously, this provided a standard framework within which to discuss lifestyle changes. The discussion was modeled around domains of the CSM(142) and beliefs about causes, consequences, timelines, and methods of control were elicited. Discussion then focused on possible areas of lifestyle change which the participant might undertake. Patients had

each been sent copies of Living with Diabetes (ADDITIONS II study team, University of Cambridge, 2001 Version 7: 2 April, 2002) (Appendix 6) prior to their assessment visit and asked to read it and this formed the basis for this part of the discussion, with particular reference to the suggestions that the document makes for modification of lifestyle. Ideas arising during the discussion were recorded by the study facilitators for future discussion. Patients were asked to think about the broad areas in which they could make lifestyle adjustments and to try to think of some specific goals for discussion at their next visit in keeping with the principles of goal setting discussed in Chapter 3.

5.5.2 Post randomization study visit

Randomized patients were invited to attend a post-randomization visit two weeks after their assessment visit. All patients were informed at this visit of their group allocation.

At the beginning of the visit, patients were provided with the opportunity to discuss any concerns arising from the previous visits. They were then informed of their group allocation and the implications of this for their glycaemic monitoring technique.

The development of the intervention used in the study is described in Chapter 3. Discussion here will be limited to a description of the methods used in the intervention delivery.

(i) Common intervention

All patients were introduced to the skill of goal setting. Discussion was initiated by eliciting previous experience of lifestyle change with a focus on barriers and facilitators experienced during previous attempts at change. Participants were then introduced to behaviour change as a sequence of techniques- goal setting, action planning and goal monitoring. They were asked to select one of the broad domains of lifestyle change discussed at the assessment visit and identify a particular goal within that domain that they

would like to achieve. If they were unable to think of a goal, the study facilitator reviewed a typical day in their lives with them to see if any potential changes could be identified. If that was unsuccessful, reference was made to the Living with Diabetes handout and participants were asked if any of the suggestions it contained for changes might be applicable to them. Facilitators were non-directive and suggestions for changes were patient-led. Patients were not restricted with regard to the number of goals they set, but were encouraged to set realistic goals and if necessary, to start with one or two goals and then add other goals as the study progressed.

Concerns about making changes and possible barriers and facilitators were discussed. After having set a goal, patients were then asked to establish an action plan for achieving it. They were asked to identify how they might achieve their goal, when they would do it and any support mechanisms, special preparations and strategies for overcoming any difficulties.

The third stage involved goal- monitoring. Patients were encouraged to keep a check on how successful they were in achieving their goals and overcoming barriers to achieving them. Diaries were provided to each participant to help them keep track of their goals, action plans and success in implementing them (Appendix 7). Diaries were colour-coded according to group allocation.

(ii) Comparison group

Post-randomization visits in this group took between 30 and 45 minutes. In addition to the common intervention, patients in the comparison group were informed that their diabetes control would be monitored by more frequent HbA_{1c} tests. They were asked to attend the surgery to have these done two weeks prior to their study visits so the results would be available to provide feedback on their glycaemic control.

(iii) Less intensive monitoring group

Visits in this group took between 45 minutes and 1 hour. Patients in this group, in addition to the common intervention, were given blood glucose self

monitors (Medisense Optium, Abbott Laboratories, U.K.) for assessment of their glycaemic control. Participants all received similar instructions for use of the meters from their study facilitator and were asked to monitor their blood sugar three times a day on any two days of the week. They were asked to do fasting samples and samples either before a meal or two hours after a meal with target fasting and pre-meal readings between 4 and 6 mmol/l and readings done two hours after meals between 6 and 8 mmol/l. Patients were asked to measure at these times because both fasting and post-prandial plasma glucose are important contributors to HbA_{1c} (207), with two hours after eating generally accepted as the most appropriate timing for post-prandial readings(208). Targets were guided by UKPDS data(14) and post-prandial values in non-diabetic patients(208). Each patient was given an information sheet specifying these levels as desirable and giving advice on behaviour if low readings or excessively high readings were obtained (Appendix 8).

Patients were also taught how to calibrate the monitor and asked to do so each time they opened a new package of test strips. Patients were given a starter pack of ten strips and ten lancets and arrangements were made with their surgeries to provide further prescriptions. They were also provided with sharps disposal bins for disposal of used lancets. These were returned to the surgery for incineration when full.

A blood glucose monitoring diary (Appendix 7) was provided so patients could record their BGSM result and the time it was taken.

(iv) More intensive monitoring group

Visits in this group took between one hour and ninety minutes. The intervention delivered in this group built on that provided in the other two groups. Skills of goal setting were also taught in this group, but participants were asked to consider ways in which they could assess the effect their goals were having on their diabetes control. They were also encouraged to consider particular instances, as they related to their chosen domain, in which

monitoring of blood glucose might be helpful, such as after a large meal or after undertaking physical activity.

Patients were provided with Medisense Optium meters and given the same instructions for use as the less intensive group. They were also asked to use the same monitoring pattern and given the same reference ranges and safety information, but were also encouraged to experiment and monitor at additional times, such as after a behaviour they felt might affect their blood glucose or if they were feeling unwell.

Patients in this group were given a single diary which combined recording of goals and goal monitoring with recording of blood glucose results to reinforce the connection between behaviour and blood glucose results (Appendix 7). The section on blood glucose monitoring, in addition to space for recording the result and the time of taking, provided space to record details of eating and physical activity.

5.5.3 Follow-up visits

(i) Timing of follow-up intervention visits

Patients were seen at one month, three months, six months and nine months following randomization for intervention visits. Visits were considered to be on time if they took place within a period starting two weeks before the target date and ending two weeks after this date. Visits outside this date were classified as late and these data recorded by the study administrator.

Participants within the more intensive monitoring group also had an additional telephone contact two weeks after their post randomization visit in order to address any technical difficulties which may have arisen with monitoring.

(ii) Content of follow up visits

Common intervention

At the follow-up visits, patients were given the chance to express any concerns which had arisen since their previous visit. Goals which had been identified at the previous visit were discussed with particular emphasis on whether they had been achieved and a problem solving approach (described in Chapter 3) was used to identify and address any barriers which may have arisen. The usefulness of goal monitoring was also discussed and any goals set by patients in the interim were elicited. They were encouraged to persist with these changes if successful or attempt them again if they had not been successful. Participants were encouraged to set further goals within their desired behavioural domain or, if they felt that domain had been exhausted, to set goals within another domain.

At each visit, information on adverse events, current medications and health service use in the last three months was collected.

Comparison group

Two weeks prior to the three, six and nine month visits, participants attended the surgery for collection of a venous sample for HbA_{1c}. If this was not feasible, the study facilitator visited the participant's home to obtain the sample. This result was returned to the facilitator prior to the visit and served as a basis for discussion at these visits. The study nurse gave one of two distinct messages depending on whether HbA_{1c} had improved or deteriorated. If HbA_{1c} had improved, patients were encouraged to think about what they had been doing which may have contributed to this and what they could do to maintain it. If it had deteriorated, they were encouraged to again consider their lifestyle and how they might improve, with reference made to the Living with Diabetes hand out to stimulate discussion if necessary. Participants with persistently elevated HbA_{1c} levels were advised to see their general practitioner. General practitioners had been provided with a non binding treatment algorithm for poorly controlled type 2 diabetes(209) prior to the start of the trial (Appendix 9).

These visits lasted between 20 and 30 minutes.

Less intensive monitoring group

Feedback on glycaemic control was based on review of the blood glucose monitoring diaries. Again, one of two messages was given to patients. If 75% or more of readings were within the required ranges, patients were told that their control was satisfactory. If this was not achieved, they were asked what they could do to improve their control and if necessary, prompted to recall their behavioural goals. Discussion about individual results was discouraged and patients were told that the focus was on the overall picture rather than on individual results. If patients initiated discussion about connections between individual results and behaviour, the study facilitator referred to the Living with Diabetes handout which focused on generally improving lifestyle to help diabetes, but any further discussion was discouraged as far as possible to prevent contamination between the less and more intensive monitoring groups. If BGSM results were persistently out of range, participants were advised to see their general practitioners to discuss modification of medication.

A venous sample for HbA_{1c} was taken by the study nurses at these visits, but these were for data analysis rather than for feedback to patients on their glycaemic control.

These visits last approximately 30 minutes.

More intensive monitoring group

In addition to review of goals and setting new goals, study facilitators discussed with patients how their goals were reflected by changes in their blood glucose results and whether monitoring their blood glucose had assisted them in achieving their goals. Study facilitators also initiated discussion about how BGSM influenced beliefs about diabetes such as its consequences, as identified at the assessment visit.

Feedback on glycaemic control was based on review of BGSM values. If at least 75% of results were in range, patients were told that their control was generally good and asked whether BGSM had helped them maintain behaviour conducive to maintaining control. If their results were outside this range, they were prompted to consider ways in which they could improve and asked to consider whether their BGSM might assist with this. Individual results were also reviewed with patients and unusually high or low results highlighted and behaviour which may have contributed to them discussed. If patients were taking appropriate lifestyle adjustments, but their blood glucose results remained out of range, the study facilitator suggested that they see their general practitioner to discuss adjustment of medication.

As with patients in the less intensive monitoring group, a venous sample for HbA_{1c} was taken at this visit, but was not fed back to patients.

These visits lasted between 45 minutes and 1 hour.

5.5.4 Final study visit

The final study visit took place 12 months after the post randomization visit and lasted approximately 30 minutes.

(i) Clinical assessment

Two 5 ml venous samples were taken for HbA_{1c} and total and HDL cholesterol. Patients in the comparison group had the HbA_{1c} phlebotomy done two weeks prior to their final visit with the sample for cholesterol done at the final visit. Weight and blood pressure were measured as noted above. Medication use and self-reported smoking status were recorded as were adverse events and use of health resources over the three months prior to the visit.

(ii) Administration of questionnaire

Patients were asked to complete a follow-up study questionnaire. Participants in the comparison group were given questionnaires at their phlebotomy visit two weeks prior to their final visit, while questionnaires were posted to patients in the other two groups two weeks before the final study visit. They were asked to return them in the provided pre-paid envelope prior to their final study visit. If the questionnaire had not been returned, participants were contacted and asked to bring it with them. If it still was not brought, the patient was asked to return it after this visit.

Patients interested in continuing blood glucose monitoring were referred to their GP for further discussion of the subject. All general practitioners received a letter from the study centre informing them their patients had completed the study.

5.6 Data management

5.6.1 Maintenance of confidentiality

All patients who consented to take part in the study were assigned a unique identifier, comprising a practice identification number and a patient identification number. All case record forms were identified only by use of this identifier and patient initials, while study questionnaires were labeled only with the patient identifier. Patients' identities and identifying numbers were linked on a password-protected Microsoft Access database held by the study administrator.

Each patient was assigned a folder in which case record forms were kept. Folders were labeled with patient's name and identification numbers and kept in locked filing cabinets.

All data were held in protection with the 1998 Data Protection Act.

5.6.2 Data collection and entry

All data were recorded on duplicate case record forms (Appendix 10) and kept in individual patient folders. Data were checked for completeness by the study administrator after receipt from the study facilitators and the original case record form was removed for data entry. The carbon copy of the CRF remained in the patient's folder throughout the study.

All data were double entered by a professional data entry company (Document Technologies Limited, Monument Business Park, Chalgrove) with the exception of data on adverse events and medication and questionnaire data which were double data entered by staff at the study centre. Data were entered according to entry rules pre-determined by the author. Data entered professionally were returned electronically to the study administrator.

Range, consistency and logic checks were performed on the data and any discrepancies in data entry resolved by checking the source data. Missing data were coded as "999".

5.7 Adverse events

Data on adverse events were collected at each visit by the study facilitator. These included new diabetes related complications and episodes of hypoglycaemia, which were graded according to the World Health Organization grading system[14]. As with pre-existing complications identified in the notes review, adverse events were reviewed and coded independently by the author and the principal investigator, using a pre-determined codes (Appendix 11) with any discrepancies resolved through discussion, prior to being entered in the patient database.

[14] Grade 1 was defined as glucose less than 4 mmol/l without symptoms; grade 2 as mild to moderate symptoms requiring minor intervention; grade 3 as moderate symptoms requiring immediate intervention to overcome symptoms and grade 4 as severe symptoms or loss of consciousness requiring extensive external intervention.

5.8 *Trial monitoring*

5.8.1 Delivery of the intervention

Quality assurance of the intervention was discussed in Chapter 3. In summary, all intervention visits were audio-taped and 1 in 30 tapes were reviewed externally using a checklist (Appendix 12) to assess fidelity to protocol. The author also reviewed tapes on an ongoing basis, while members of the Trial Management group also reviewed tapes at the six month stage. Monthly sessions were held with study facilitators to provide feedback on intervention delivery and address any concerns which may have arisen.

5.8.2 Adherence to BGSM protocol

Data on blood glucose test strip use were collected from all groups during the course of the study. Patients in the comparison group were asked if they had used a meter since their last visit and if so, how often, as they may have commenced monitoring of their own volition or been asked to monitor because their physician thought it was clinically indicated. The frequency of monitoring in the other two groups was recorded to assess whether they were monitoring as frequently as requested.

5.8.3 Accuracy of monitors

Blood glucose meters were calibrated prior to distribution to patients. Patients were also taught how to calibrate the monitor and ask to do so each time a new package of strips was opened. At the six month visit, quality comparison solution provided by MediSense was used by facilitators to ensure that the monitors were working correctly.

5.8.4 Patients lost to follow-up

The number of patients lost to follow-up was recorded. Reasons for loss to follow-up were also recorded where possible. The study facilitators asked patients who declined to attend interim visits for permission to contact them for 1 year visits.

5.9 *Biochemical analyses*

5.9.1 Handling and storage of samples

All samples were labeled with bar coded study identification labels generated by the Diabetes Trials Unit laboratory and accompanied by laboratory request forms. Samples for HbA_{1c} assay which were collected by study facilitators were transported to the study centre and stored at 4°C prior to being transported to the laboratory. Samples for HbA_{1c} which were collected by practice staff were posted to the study centre via first class post using SafeBox packaging (Royal Mail, UK). All samples were triple packaged and transported in accordance with Diabetes Trials Unit laboratory standard operating procedures.

Samples for HbA_{1c} assay were stored for a maximum of four days prior to transport to the laboratory for analysis. Samples for cholesterol assay were spun on receipt at the study centre at 2000 g for 10 minutes. Two millilitres of plasma was aliquoted into a 3.5 ml Sarstedt tube and stored at -80°C. Baseline and 1 year cholesterol samples for each participant were analysed in the same batch.

5.9.2 Analysis of samples

Biochemical analyses were carried out at the Diabetes Trials Unit laboratory, University of Oxford. HbA_{1c} was analysed using a Variant II Haemoglobin Testing System (Bio-Rad Laboratories, UK) which utilizes high performance liquid chromatography of whole blood and is aligned to Diabetes Control and Complications Trial (DCCT) standards. The normal range is 3.9-6.1% and the inter-assay coefficient of variation is less than 2%.

Total cholesterol was assayed using the Olympus AU400 analyser which uses an enzymatic colorimetric endpoint method (Olympus System Reagent Cholesterol CHOD-PAP method, Olympus Optical Co (UK) Ltd). Optimal total cholesterol is less than 6.5 mmol/l and the interassay coefficient of variation is approximately 2%.

HDL cholesterol was assayed with the Olympus AU400 analyser using a homogenous method with a two reagent format (Ultra N-Geneous HDL Cholesterol, Biostat Ltd, UK). The reference range is 0.91-1.69 mmol/l and the interassay coefficient of variation is less than 3%.

5.10 Statistical analysis

Data were analysed using SPSS version 12.0 (SPSS, Chicago, IL, USA). A modified intention to treat analysis was carried out with all patients who were randomized included in the final analysis if they had attended the post-randomization visit. Where patients were lost to follow-up and no one year values were available, one year values were imputed from the last available observation.

The distributions of continuous variables were visually assessed for normality. Means and standard deviations were used to describe normally distributed continuous variables and medians and interquartile ranges to describe non-normally distributed continuous variables.

Chi-squared tests were used to compare proportions and the Mann-Whitney U test to compare non-normally distributed variables between two groups. Comparison of normally distributed variables across the three trial groups was carried out using analysis of variance, with post hoc Dunnett's tests to compare each of the less and more intensive monitoring groups to the comparison group if a significant result was obtained. Analysis of covariance was also carried out for the normally distributed primary and secondary outcomes, controlling for baseline values. Non-normally distributed data was compared across the three trial groups using the Kruskal-Wallis test. Chi-squared test for trend was used to compare the frequency of episodes of hypoglycaemia grade 2 and above. Kaplan-Meier plots were used to compare loss to follow-up between the three groups. Significance was tested at a 5% level (two-tailed).

5.11 General organization of trial

Ethical approval was obtained from the Oxfordshire Psychiatric Research Ethics Committee (OPREC Number O2.059). Day to day management of the trial was overseen by a management committee (Appendix 13). The study centre was situated in the Department of Primary Health Care at University of Oxford. Each practice involved in the study was assigned a study facilitator who dealt primarily with the patients in that practice. The author acted as study coordinator, supervising study facilitators and data management and ensuring smooth running of the trial.

The study was funded by the Health Technology Assessment programme.

Chapter 6

The randomized controlled trial- results

6.1 Response to trial

Trial recruitment took place between April 2003 and February 2004. Of the 4134 patients with type 2 diabetes identified from the general practice registers, 40% were eligible for further assessment for inclusion in the study. Thirty three percent of the 1669 persons invited responded positively. Table 6.1 compares the ages and genders of those who agreed to be contacted for further assessment and the non-responders, defined as those who either declined to take part or did not respond at all. There were no significant differences in these two characteristics between responders and non-responders.

	Responders n=550	**Non-responders[15] n=951**	**p**
Median (IQR) age (years)[16]	68.2 (16)	67.5(19)	0.661
Gender[17] n(%)			0.179 (1 d.f)
Male	309 (56.2)	499 (52.5)	
Female	241 (43.8)	451 (47.5)	

Table 6. 1 Comparison of trial responders and non responders

Three hundred and forty two of the positive responders were eligible for assessment visits. The remainder were excluded because of meter use (70%), not being fit enough (19%), insulin use (2%) and other reasons (9%). A further 97 patients were excluded after the assessment visit, with the majority of these (84%) excluded because of meter use.

Of the 245 participants randomized to the trial, 82 (33.5%) were randomized to the comparison group, 81 (33.1%) to the less intensive monitoring group and 82 (33.5%) to the more intensive monitoring group. A modified intention to treat analysis was used, with all randomized patients included in the final

[15] Includes those who declined the invitation and those who did not respond at all
[16] Ages were available for 531 responders and 719 non-responders
[17] Gender was not available for one non- responder

analysis with the exception of nine participants (three in each intervention arm) who withdrew prior to their post randomization visits and therefore never received the intervention. If one year values were unavailable, they were imputed from the last available observation. Twenty four participants had their one year values for the primary outcome of change in HbA_{1c} imputed from their last available values, 23 because they did not attend their one year follow-up visit and one because the one year sample could not be assayed. Flow of participants through the trial is shown in Figure 6.1.

6.2 Characteristics of participants

6.2.1 Baseline demographic characteristics

The demographic characteristics of trial participants included in the analysis are shown in Table 6.2. Values are n (%) unless otherwise stated. There was a smaller proportion of males in the comparison group and a higher proportion of persons in lower supervisory and technical occupations in the less intensive monitoring group, but neither of these differences was significant. Trial participants were predominantly male (58.1%), in managerial and professional occupations (45.8%) and of White ethnicity (92.4%). The median age of participants was 68.3 years with an interquartile range of 16.

	Comparison n=79	Less intensive monitoring n=78	More intensive monitoring n=79	Total N= 236
Gender				
Male	42(53.2)	48 (61.5)	47(59.5)	137 (58.1)
Female	37 (46.8)	30 (38.5)	32 (40.5)	99 (41.9)
Median(IQR) age (years)	70.2 (17)	67.7 (17)	67.9 (16)	68.3 (16)
Socio-economic classification[18]				
Managerial and professional	32 (43.2)	36 (47.4)	36 (46.8)	104 (45.8)
Intermediate	7 (9.5)	5 (6.6)	8 (10.4)	20 (8.8)
Small employers and own account	11 (14.9)	8 (10.5)	9 (11.7)	28 (12.3)
Lower supervisory and technical	10 (13.5)	14 (18.4)	10 (13.0)	34 (15.0)
Semi-routine and routine	14 (18.9)	13 (17.1)	14 (18.2)	41 (18.1)
Ethnic group				
White	72 (91.1)	72 (92.3)	74 (93.7)	218 (92.4)
Asian	3 (3.8)	2 (2.6)	1 (1.3)	6 (2.5)
Black	2 (2.5)	4 (5.1)	2 (2.5)	8 (3.4)
Mixed	1 (1.3)	0 (0)	1 (1.3)	2 (0.8)
Chinese or other	1 (1.3)	0 (0)	1 (1.3)	2 (0.8)

Table 6.2 Baseline demographic characteristics of analysed patients

[18] Data available on 227 participants

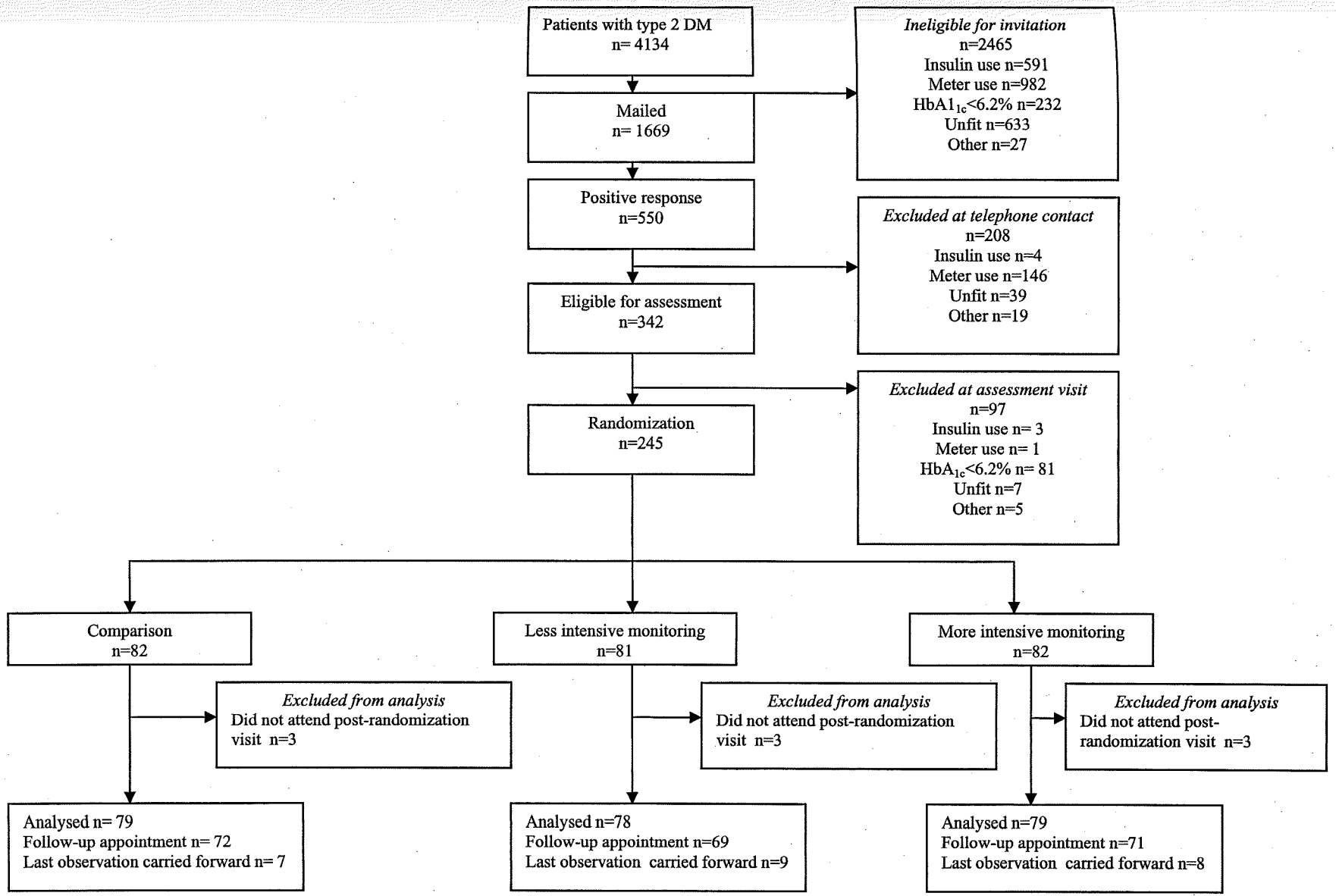


Figure 6.1 Flow of participants through trial

6.2.2 Baseline clinical characteristics

The baseline clinical characteristics of patients included in the analysis are shown in Table 6.3 (values are n [%] unless otherwise stated). All characteristics were comparable across the three groups. Glycaemic control among trial participants was good, with a median HbA_{1c} of 7.0% and interquartile range of 1.1% and 84.3% of participants with an HbA_{1c} of 8% or less. Median duration of diabetes was 3.5 years, (interquartile range 6.0), with just over half of participants having diabetes for four years or less. There was an approximately equal distribution of participants between types of therapy, while the majority of participants (69.9%) had no diabetes related complications at randomization and only 10.2% were current smokers. Mean BMI was in the obese range (31.0 kg/m^2, SD 5.4) and mean systolic blood pressure was elevated (140.5 ± 19.2 mmHg).

6.2.3 Baseline belief and behaviour scores

All of these scores were comparable across the three trial groups. Of the two hundred and thirty six patients included in the analysis, 219 (92.8%) returned the baseline questionnaire. Seventy-six were in the comparison group, 72 were in the less intensive monitoring group and 71 were in the more intensive group. There was no association between group allocation and return of baseline questionnaire (p=0.300, 2 d.f.). There were no significant differences in the gender (p=0.619, 1 d.f), age (p=0.928), baseline HbA_{1c} (p=0.512), duration of diabetes (p=0.559), diabetes therapy (p=0.416, d.f.=3) or presence of diabetes complications (p=0.166, 2 d.f.) between those who did and not return the questionnaire. Questionnaires were returned with varying degrees of completeness. Scores for each scale were calculated if all items in that scale had been answered. The mean baseline scores of the belief and behaviour measures for the analysed patients are shown in Table 6.4. Means and standard deviations are given as the measures of central tendencies where the distribution of scores was approximately normal and as medians with interquartile ranges otherwise. The number of patients for whom each score was calculated and the maximum score for each scale are also indicated.

	Comparison n=79	Less intensive monitoring n=78	More intensive monitoring n=79	Total N= 236
HbA_{1c} (%)				
Median (IQR)	7.0 (1.0)	7.0 (1.2)	7.2 (1.2)	7.0 (1.1)
≤8%	67 (84.8)	65 (83.3)	67 (84.8)	199(84.3)
>8%	12 (15.2)	13 (16.7)	12 (15.2)	37 (15.7)
Duration of diabetes (years)[19]				
Median (IQR)	3.0 (4.0)	4.0 (5.25)	3.5 (7.9)	3.5 (6.0)
Four or less	46 (59.0)	48 (61.5)	42 (53.2)	136 (57.9)
More than four	32 (41.0)	30 (38.5)	37 (46.8)	99 (42.1)
Diabetes therapy				
Lifestyle modification	23 (29.1)	24 (30.8)	23 (29.1)	70 (29.7)
Oral monotherapy	27 (34.2)	28 (35.9)	30 (38.0)	85 (36.0)
Oral combined therapy	29 (36.7)	26 (33.3)	26 (32.9)	81 (34.3)
Diabetes complications				
No complications	57 (72.2)	56 (71.8)	52 (65.8)	165 (69.9)
CHD	7 (8.9)	11 (14.1)	7 (8.9)	25 (10.6)
Non-CHD complications	15 (9.0)	8 (10.3)	15 (19.0)	38 (16.1)
Both CHD and non-CHD complications	0 (0.0)	3 (3.8)	5 (6.3)	8 (3.4)
Smoking status[20]				
Never smoked	34 (43.0)	29 (37.7)	31 (39.2)	94 (40.0)
Former smoker	39 (49.4)	40 (51.9)	38 (48.1)	117 (49.8)
Current smoker	6 (7.6)	8 (10.4)	10 (12.7)	24 (10.2)
Mean (SD) weight (kg)[21]	85.2 (18.6)	88.4 (17.3)	87.8 (17.0)	87.1 (17.6)
Mean (SD) BMI (kg/m^2)	30.5 (5.9)	31.2 (4.9)	31.1 (5.5)	31.0(5.4)
Mean (SD) Blood pressure (mmHg)				
Systolic	139.9 (18.7)	142.4 (18.5)	139.3 (20.4)	140.5 (19.2)
Diastolic	79.7 (10.7)	82.1 (11.1)	78.7 (11.6)	80.2 (11.2)
Mean (SD)Cholesterol mmol/l[22]				
Total	4.7 (1.0)	4.9 (1.1)	4.9 (1.0)	4.8 (1.0)
HDL	1.1 (0.2)	1.1 (0.3)	1.1 (0.3)	1.1 (0.3)
Total/HDL	4.6 (1.1)	4.6 (1.3)	4.7 (1.5)	4.6 (1.3)

Table 6.3.Baseline clinical characteristics of analysed participants

[19] Duration of diabetes was not available for one participant in the comparison group

[20] Baseline smoking status not available for one patient in the less intensive monitoring group

[21] The weight of one participant exceeded the recording threshold of the scale and was recorded as 149.9 kg, the upper limit of the scale

[22] Baseline total and HDL cholesterol values were not available for one participant in the comparison group and two participants in the more intensive monitoring group

		Comparison	Less intensive monitoring	More intensive monitoring	Total
Illness perception scales					
Identity	*n=*	40	41	39	120
(Max 16)	*Median (IQR)*	2 (4)	2 (5)	2 (5)	2 (5)
Timelines (acute)	*n=*	70	63	60	193
(Max 20)	*Mean(SD)*	9.1 (2.8)	9.0 (2.6)	8.6 (2.7)	8.9 (2.7)
Timelines (chronic)	*n=*	64	64	65	193
(Max 25)	*Median (IQR)*	20(5)	20(3)	21(4)	20 (4)
Timelines (cyclical)	*n=*	71	63	64	198
(Max 20)	*Mean(SD)*	9.6 (3.2)	9.8 (2.8)	10.4 (2.8)	9.9 (3.0)
Consequences	*n=*	68	65	64	197
(Max 35)	*Mean (SD)*	19.0 (4.4)	19.3 (4.3)	19.4 (4.1)	19.2 (4.2)
Efficacy of control strategies	*n=*	67	67	66	200
(Max 25)	*Mean (SD)*	20.0 (2.3)	20.1 (1.8)	20.6 (2.5)	20.2 (2.2)
Futility of control strategies	*n=*	65	64	66	195
(Max 35)	*Mean (SD)*	17.8 (3.2)	17.6 (3.0)	17.5 (3.2)	17.6 (3.1)
Illness coherence	*n=*	69	65	63	197
(Max 25)	*Mean (SD)*	13.1 (4.3)	14.0 (4.3)	12.9 (4.0)	13.3 (4.2)
Emotional representations	*n=*	68	66	66	200
(Max 45)	*Mean (SD)*	23.4 (5.6)	24.0 (6.2)	24.2 (6.3)	23.9 (6.0)
Influence of control strategies	*n=*	70	62	65	197
(Max 10)	*Mean (SD)*	7.4 (1.3)	7.6 (1.2)	7.6 (1.2)	7.5 (1.2)
Concerns about diabetes	*n=*	71	65	67	203
(Max 10)	*Mean (SD)*	6.6 (1.5)	6.7 (1.8)	6.9 (1.7)	6.7 (1.7)
Specific physical consequences	*n=*	72	67	66	205
(Max 30)	*Mean (SD)*	22.4 (2.8)	22.9 (2.7)	23.5 (2.8)	22.9 (2.8)
Beliefs about medicines scales					
Specific necessity	*n=*	48	45	49	142
(Max 30)	*Mean(SD)*	22.9 (2.7)	22.6 (3.2)	23.0 (3.3)	22.8 (3.1)
Specific concerns	*n=*	43	42	46	131
(Max 35)	*Mean(SD)*	21.4 (3.4)	21.0 (4.3)	21.2 (4.9)	21.2 (4.2)
BEPAQ					
Importance of lifestyle modification	*n=*	69	62	62	193
(Max 35)	*Median (IQR)*	28 (3)	28 (2)	28 (3)	28 (2)
Enjoyment of straying from diet	*n=*	71	66	66	203
(Max 10)	*Mean (SD)*	5.6 (1.9)	6.0 (2.0)	5.2 (2.0)	5.6 (2.0)
Importance of physical activity	*n=*	69	61	64	194
(Max 25)	*Mean (SD)*	20.2 (2.2)	20.3 (2.4)	20.4 (1.9)	20.3 (2.2)
SDSCA					
General diet	*n=*	71	61	65	197
(Max 7)	*Median (IQR)*	5.0 (2.5)	5.5 (3.0)	6.0 (2.5)	5.5 (3.0)
Eating five fruit and vegetable daily	*n=*	72	65	68	205
(Max 7)	*Median (IQR)*	5.0 (3.0)	6.0 (3.0)	6.0 (2.0)	6.0 (3.0)
Eating a high fat diet	*n=*	73	65	66	204
(Max 7)	*Median (IQR)*	2.0 (3.0)	2.0 (3.0)	2.0 (2.0)	2.0(2.0)
Physical activity	*n=*	73	64	68	205
(Max 7)	*Mean (SD)*	3.3 (2.2)	3.2 (2.3)	3.5 (2.3)	3.3 (2.3)
MARS					
Medication adherence	*n=*	48	46	50	144
(Max 25)	*Median (IQR)*	24.5 (1.0)	24.0 (1.0)	24.0 (2.0)	24.0 (1.0)

Table 6.4 Mean baseline scores for belief and behaviour measures for analysed patients

Trial participants related few symptoms to their diabetes, reporting a median of two of the symptoms listed as being related to their diabetes. Thirst was the symptom most frequently reported as being related to diabetes (84%) and frequency of urination was the second most frequent (80%). Measure scores indicated that participants thought that their diabetes was chronic and persistent with low mean timelines (acute) and timelines (cyclical) scores and a high median timelines (chronic) score. Participants held stronger beliefs about the specific physical consequences of diabetes with a mean (SD) score of 22.9 (2.8) out of a maximum of 30 on this scale, than they did about the general consequences of diabetes, with a mean (SD) score of 19.2 (4.2) out of a maximum of 35. Participants also had strong beliefs about the ability of their strategies to control their diabetes with a high mean score on the efficacy of control strategies and influence of control strategies scales and lower scores on the futility of control strategies scale. Mean illness coherence scores were low, suggesting that patients did not feel they had a good understanding of their diabetes while the low mean emotional representations score indicated that participants were not particularly worried abut their diabetes.

Of the 166 trial participants who were taking medication, 142 completed the scale about the necessity of their diabetes medication and 131 completed the scale about their concerns about their diabetes medication. The mean necessity score was relatively higher than the mean concerns score, suggesting beliefs about the need for medication were more prominent than any concerns.

Participants placed significant emphasis on the need for following lifestyle recommendations with high mean scores on the importance of lifestyle modification scale (median score of 28 out of a maximum of 35) and importance of physical activity (mean score of 20.3 out of 25) and a low mean score on the enjoyment of straying from diet scale (5.6 out of a maximum of 10). These beliefs were reflected in eating behaviour with participants reporting adhering to general dietary recommendations a median of 5.5 days per week, eating five fruit and vegetable portions a median of 6 days a week

and eating a high fat diet a median of 2 days a week. Trial subjects only undertook physical activity a mean of 3.3 days a week, however, although median medication adherence scores were very high (24.0 out of a maximum of 25).

6.2.4 Baseline well-being, health status and treatment satisfaction scores

All characteristics were again comparable between groups. Mean baseline scores for well-being, health status and treatment satisfaction measures are shown in Table 6.5. Participants had a fairly high median well-being score (26 out of a maximum of 36), and a high median treatment satisfaction score (32 out of a maximum of 36). Most participants felt their perceived blood sugar was satisfactory, with low median scores on the perceived hyperglycaemia and perceived hypoglycaemia scales. Patients also felt they were quite healthy, with a median EQ-5D score of 0.8.

		Comparison	Less intensive monitoring	More intensive monitoring	Total
WBQ-12					
Well-being	*n=*	61	60	62	183
(Max 36)	*Median (IQR)*	26.0 (9.5)	26.5 (9.0)	26.0 (10.25)	26.0 (9.0)
DTSQ					
Treatment satisfaction	*n=*	66	63	63	192
(Max 36)	*Median (IQR)*	32.0 (8.25)	31.0 (7.0)	32.0 (6.0)	32 (8.0)
Perceived hyperglycaemia	*n=*	72	62	61	195
(Max 6)	*Median (IQR)*	1 (3)	1 (3)	1.5 (4)	1.0 (3)
Perceived hypoglycaemia	*n=*	70	61	61	192
(Max 6)	*Median (IQR)*	0 (0)	0 (0)	0 (1.0)	0 (0.0)
EQ-5D					
Health status	*n=*	73	66	66	205
(Max 1)	*Median (IQR)*	0.8 (0.3)	0.8 (0.3)	0.8 (0.3)	0.8 (0.3)

Table 6.5 Mean baseline scores for well being, health status and treatment satisfaction measures

6.3 *Trial outcomes*

6.3.1 Primary outcome

The primary outcome, change in HbA_{1c}, is reported in Table 6.6. There was a reduction in HbA_{1c} in all three groups but the difference between these reductions was not significant (p=0.653). The difference did not attain statistical significance after adjustment for baseline HbA_{1c} (p=0.677).

	Comparison n=79	**Less intensive monitoring n=78**	**More intensive monitoring n=79**	**p value for differences in change between groups**	**p value for differences in change between groups after adjustment[23]**
Mean (SD) HbA_{1c} (%)					
Baseline	7.34 (1.2)	7.35 (1.0)	7.45(1.1)	0.653	0.677
Follow-up	7.28 (1.2)	7.18 (0.9)	7.27 (1.0)		
Change	-0.06(1.0)	-0.17 (0.8)	-0.18 (0.8)		

Table 6.6 Change in HbA_{1c} between baseline and 1 year follow-up

The trial was not powered to detect differences in subgroups, but exploratory analyses were done in subgroups defined by median baseline duration of diabetes, median age at randomization, presence of complications at randomization and median baseline self-reported health status. These are reported in Table 6.7.

Patients with poorer glycaemic control (HbA_{1c}>8%) experienced greater mean reductions in HbA_{1c} than those with better control. Paired t-tests were used to compare baseline and follow-up HbA_{1c} in randomization groups in patients with poorer control, and while there was a significant reduction in each group (p=0.000 in each case), there was no significant difference between groups. Patients who had diabetes for 3.5 years or less at randomization all had reductions in HbA_{1c}, regardless of group allocation, but this was not significantly different between randomization groups (p=0.947). Similarly, participants with a duration of diabetes of more than 3.5 years experienced a decrease in HbA_{1c} in all three groups which was not significant between groups (p=0.414).

[23] Adjusted for baseline HbA_{1c}

There was a mean reduction in participants who were younger than the trial median of 68.3 years with the largest mean reduction of 0.42% seen in the more intensive monitoring group. No significant differences were present between the three randomization groups in these patients (p=0.481) or in the trial participants who were older than 68.3 years (p=0.372).

Change in HbA_{1c} was not significantly different between randomization groups in the 71 patients who had diabetes related complications at baseline (p=0.280) or in the 165 patients who did not (p=0.724). There was no significant difference in randomization groups in patients with an EQ-5D score of 0.8 or below (p=0.709) or above 0.8 (p=0.294).

6.3.2 Secondary outcomes

(i) Changes in clinical parameters

Changes in weight, cholesterol and blood pressure are shown in table 6.8. There was a reduction in mean weight in all three groups, but these differences were not significantly different between groups, either before or after adjustment for baseline weight (p=0.649, p=0.748, respectively).

Mean systolic and diastolic blood pressure also decreased in all three randomization groups, but again these decreases were not significantly different between groups, either before (SBP: p=0.890, DBP: p=0.860) or after adjustment for baseline blood pressure: (SBP: p=0.601, DBP: p=0.336).

There were however significant differences between randomization groups for changes in unadjusted total cholesterol (p=0.039) and the total cholesterol/HDL cholesterol ratio (p=0.005). A post hoc Dunnett's test compared the change in mean total cholesterol of each of the monitoring groups to that of the control group while a Dunnett's T3 test was used to compare the change in the mean total cholesterol/HDL ratio as the variances of this variable were not equal.

		Comparison n=79	Less intensive monitoring n=78	More intensive monitoring n=79	p value for differences in change between groups after adjustment for baseline HbA_{1c}
Baseline HbA_{1c}					
≤8%	n=199	67	65	67	
	Baseline	6.92 (0.5)	6.97 (0.5)	7.07 (0.5)	
	Follow-up	7.02 (0.8)	6.93 (0.6)	7.01 (0.7)	0.525
	Change	0.10 (0.7)	-0.04 (0.7)	-0.05 (0.7)	
>8%	n=37	12	13	12	
	Baseline	9.71 (0.9)	9.23 (1.0)	9.58 (1.2)	0.987
	Follow-up	8.70 (1.8)	8.41 (0.9)	8.69 (1.4)	
	Change	-1.00 (1.6)	-0.82 (1.0)	-0.88 (1.2)	
Duration of diabetes					
Below or at 3.5 years	n=119	41	37	41	
	Baseline	7.05 (1.1)	7.33(1.1)	7.16 (0.8)	
	Follow-up	6.97 (1.1)	7.17 (1.0)	7.01 (0.6)	0.947
	Change	-0.08 (0.9)	-0.16 (0.8)	-0.15 (0.8)	
More than 3.5 years	n=116	37	41	38	
	Baseline	7.67 (1.2)	7.36 (1.0)	7.75 (1.3)	
	Follow-up	7.61 (1.2)	7.19 (0.7)	7.55 (1.2)	
	Change	-0.06 (1.1)	-0.18 (0.7)	-0.21 (0.9)	0.414
Age					
Below or at 68.3 years	n =118	33	42	43	
	Baseline	7.82 (1.4)	7.54 (1.2)	7.76 (1.4)	
	Follow-up	7.60 (1.5)	7.35 (1.0)	7.34 (1.2)	0.481
	Change	-0.22 (1.0)	-0.20 (0.9)	-0.42 (0.9)	
Above 68.3 years	n =118	46	36	36	
	Baseline	7.00 (0.8)	7.12 (0.8)	7.08 (0.6)	0.372
	Follow-up	7.05 (0.9)	6.98 (0.6)	7.18 (0.8)	
	Change	0.04 (0.9)	-0.14 (0.6)	0.11 (0.7)	
Diabetes complications					
Presence of complications	n=71	22	22	27	
	Baseline	7.10 (1.0)	6.97 (0.5)	7.06 (0.7)	
	Follow-up	7.29 (1.2)	6.89 (0.6)	7.22 (0.7)	0.280
	Change	0.20 (1.0)	-0.08 (0.6)	0.16 (0.6)	
Absence of complications	n=165	57	56	52	
	Baseline	7.44 (1.2)	7.50 (1.2)	7.65 (1.3)	0.724
	Follow-up	7.27 (1.2)	7.29 (0.9)	7.29 (1.1)	
	Change	-0.16 (1.0)	-0.21 (0.8)	-0.36 (0.9)	
Self-reported health status					
Below or at 0.8	n =97	34	33	30	
	Baseline	7.24 (1.2)	7.51 (1.2)	7.38 (0.9)	
	Follow-up	7.03 (0.9)	7.22 (1.1)	7.25 (0.9)	0.709
	Change	-0.21 (0.9)	-0.29 (0.8)	-0.13 (0.7)	
Above 0.8	n =108	39	33	36	
	Baseline	7.39 (1.2)	7.17 (0.8)	7.24 (0.9)	0.294
	Follow-up	7.43 (1.3)	7.15 (0.7)	7.05 (0.7)	
	Change	0.05 (1.1)	-0.03 (0.7)	-0.19 (0.9)	

Table 6.7 Changes in HbA_{1c} by duration of diabetes, age, presence of diabetes complications and self-reported health status

	Comparison n=79	Less intensive monitoring n=78	More intensive monitoring n=79	p value for difference in change between groups	p value for difference in change between groups after adjustment[24]
Mean (SD) weight (kg)					
Baseline	85.2 (18.6)	88.4 (17.3)	87.8 (17.0)	0.649	0.748
Follow-up	84.7 (18.8)	87.5 (17.1)	87.2 (16.1)		
Change	-0.5 (2.9)	-0.9 (1.8)	-0.6 (3.3)		
Mean (SD) blood pressure (mmHg)					
Systolic					
Baseline	139.9 (18.7)	142.4 (18.5)	139.3 (20.4)		
Follow-up	135.8 (19.5)	138.1 (19.3)	134.1 (18.9)	0.890	0.691
Change	-4.1 (13.8)	-4.3 (16.4)	-5.2 (15.7)		
Diastolic					
Baseline	79.7 (10.7)	82.1 (11.1)	78.7 (11.6)		
Follow-up	77.7 (9.8)	79.8 (10.3)	75.9 (11.0)	0.860	0.336
Change	-2.0 (8.5)	-2.3 (9.9)	-2.8 (8.3)		
Mean (SD) Cholesterol (mmHg)					
n=233	78	76	79		
Total	4.70 (1.0)	4.87 (1.1)	4.93 (1.0)	0.039	0.108
Baseline	4.51 (1.0)	4.44 (0.9)	4.36 (0.9)		
Follow-up	-0.19 (0.9)	-0.43 (0.9)	-0.57 (1.0)		
Change					
HDL	1.06 (0.2)	1.10 (0.3)	1.11 (0.3)		
Baseline	1.06 (0.2)	1.09 (0.2)	1.12 (0.3)	0.450	0.342
Follow-up	-0.01 (0.1)	0.00 (0.1)	0.02 (0.1)		
Change					
Total/HDL	4.57 (1.1)	4.64 (1.3)	4.72 (1.5)	0.005	0.004
Baseline	4.43 (1.1)	4.25 (1.2)	4.10 (1.2)		
Follow-up	-0.14 (0.7)	-0.39 (0.8)	-0.61 (1.1)		
Change					

Table 6.8 Comparison of changes in weight, blood pressure and cholesterol

The reduction in mean total cholesterol in the more intensive monitoring group was significantly greater than the reduction in the control group (difference between change:-0.389, p=0.011) as was the reduction in the total cholesterol/HDL cholesterol ratio (difference between change:-0.47, p=0.001).

Differences in change in mean total cholesterol and total cholesterol/HDL ratio remained significant after adjustment for change in lipid lowering therapy (p=0.007 and p=0.009, respectively)[25].

[24] Adjusted for baseline values.
[25] Values here were adjusted for lipid lowering therapy, but not baseline lipid levels.

(ii) Changes in beliefs and behaviour

One hundred and eighty six (78.8%) of the participants included in the analysis returned both the baseline and follow-up questionnaires. As with baseline questionnaires, there were varying degrees of completeness. If follow-up measure scores could not be calculated from the items completed in the final questionnaire, these were imputed from baseline scores and changes between baseline and final scores calculated.

Changes in mean scores between baseline and one year follow-up on belief and behaviour measures are shown in Table 6.9. When unadjusted means were compared, there was a significant difference in illness coherence scores between groups (p=0.041). Post hoc analyses revealed the change in the less intensive monitoring group was significantly greater than in the comparison group (difference between change:-1.6, p=0.018). Comparison of mean illness coherence scores after adjustment for baseline revealed no significant difference between the three trial groups (p=0.107). Differences between mean changes in consequences were also significant after adjustment for baseline beliefs.

There were no significant differences in changes in beliefs about medication taking, eating or physical activity between groups. No significant differences between groups in general dietary behaviour, undertaking physical activity or medication adherence were found either, but there were significant differences in eating five portions of fruit and vegetables daily (p=0.017) and eating a high fat diet (0.009). Post hoc analyses showed that the reduction in score for eating five portions of fruit and vegetables daily was significantly greater in the more intensive monitoring group when compared to the comparison group (difference in change: -0.672, p=0.004), while those in the more intensive monitoring group significantly increased their high fat food intake when compared to the comparison group (difference in change:0.8, p=0.004).

		Comparison	Less intensive monitoring	More intensive monitoring	p value for difference	p value for difference after adjustment[26]
Illness perception scales						
Identity	*n=*	40	41	39		
	Mean (SD) change	-0.3 (2.3)	0.2 (1.5)	-0.3 (1.3)	0.417	0.675
Timelines (acute)	*n=*	70	63	60		
	Mean (SD) change	-0.49 (2.1)	0.03 (2.1)	-0.17 (2.0)	0.354	0.344
Timelines (chronic)	*n=*	64	64	65		
	Mean (SD) change	0.8 (3.5)	0.19 (2.2)	0.02 (3.2)	0.315	0.402
Timelines (cyclical)	*n=*	71	63	64		
	Mean (SD) change	-0.17 (2.9)	0.4 (2.6)	0.1 (2.9)	0.452	0.246
Consequences	*n=*	68	65	64		
	Mean (SD) change	-0.7 (3.3)	0.0 (3.7)	0.7 (3.7)	0.073	0.035
Efficacy of control strategies	*n=*	67	67	66		
	Mean (SD) change	0.3 (1.8)	0.0 (2.3)	0.2 (2.5)	0.651	0.532
Futility of control strategies	*n=*	65	64	66		
	Mean (SD) change	0.6 (2.4)	-0.3 (2.4)	0.2 (2.9)	0.164	0.100
Illness coherence	*n=*	69	65	63		
	Mean (SD) change	-0.1 (4.0)	-1.7 (3.5)	-0.3 (3.9)	0.041	0.107
Emotional representations	*n=*	68	66	66		
	Mean (SD) change	-0.5 (3.3)	0.1 (3.8)	0.3 (4.3)	0.442	0.304
Influence of control strategies	*n=*	70	62	65		
	Mean (SD) change	0.3 (0.9)	0.0 (1.2)	0.1 (1.3)	0.312	0.358
Concerns about diabetes	*n=*	71	65	67		
	Mean (SD) change	-0.1 (1.3)	-0.3 (1.7)	-0.1 (1.3)	0.630	0.538
Specific physical consequences	*n=*	72	66	67		
	Mean (SD) change	-0.3 (2.6)	0.2 (2.0)	0.1 (2.7)	0.535	0.184
Beliefs about medicines scales						
Specific necessity	*n=*	44	42	46		
	Mean (SD) change	0.0 (2.4)	0.3 (2.0)	0.5 (2.8)	0.627	0.411
Specific concerns	*n=*	41	39	43		
	Mean (SD) change	-0.8 (2.8)	0.0 (2.7)	-0.3 (3.5)	0.462	0.599
BEPAQ						
Importance of lifestyle modification	*n=*	69	62	62		
	Mean (SD) change	0.3 (2.5)	0.7 (3.3)	-0.4 (3.5)	0.131	0.166
Enjoyment of straying from diet	*n=*	71	66	66		
	Mean (SD) change	0.2 (2.0)	0.0 (1.6)	0.0 (1.4)	0.789	0.455
Importance of physical activity	*n=*	69	61	64		
	Mean (SD) change	0.4 (2.1)	0.3 (2.6)	0.4 (2.4)	0.917	0.867
SDSCA						
General diet	*n=*	71	61	65		
	Mean (SD) change	0.37 (1.6)	0.56 (1.7)	-0.1 (1.9)	0.084	0.084
Eating five fruit and vegetables daily	*n=*	72	65	68		
	Mean (SD) change	0.3 (1.2)	0.0 (1.3)	-0.4 (1.6)	0.017	0.040
Eating a high fat diet	*n=*	73	65	66		
	Mean (SD) change	-0.5 (1.4)	-0.4 (1.7)	0.2 (1.7)	0.009	0.011
Physical activity	*n=*	73	64	68		
	Mean (SD) change	0.5 (1.8)	0.6 (1.8)	0.3 (1.7)	0.650	0.818
MARS						
Medication adherence	*n=*	47	45	49	0.830	0.763
	Mean (SD) change	-0.1 (1.6)	-0.1 (1.5)	0.1 (1.7)		

Table 6.9 Comparison of changes in belief and behaviour measures

[26] Adjusted for baseline values

(iii) Changes in well-being, treatment satisfaction and health status

Mean changes in scores in well-being, health status and treatment satisfaction measures are shown in Table 6.10. There were no significant differences in changes in unadjusted mean scores in well-being (p=0.868), treatment satisfaction (p=0.436), perceived hyperglycaemia (p=0.416), perceived hypoglycaemia (p=0.894) or self-reported health status (p=0.093). There no significant differences between groups after adjustment for baseline values either.

	Comparison n=	Less intensive monitoring n=	More intensive monitoring n=	p value for difference between groups	p value for difference between groups after adjustment[27]
WBQ-12					
Well-being *n=*	61	60	62	0.868	0.757
Mean (SD) change	0.4 (3.9)	0.1 (3.8)	0.0 (4.1)		
DTSQ					
Treatment satisfaction *n=*	66	63	63	0.436	0.483
Mean (SD) change	-0.7 (4.4)	0.4 (6.0)	-0.2 (4.5)		
Perceived hyperglycaemia *n=*	72	62	61	0.416	0.213
Mean (SD) change	0.3 (1.9)	0.7 (1.8)	0.4 (1.9)		
Perceived hypoglycaemia *n=*	70	61	61	0.894	0.726
Mean (SD) change	0.1 (1.3)	0.2 (1.1)	0.2 (1.6)		
EQ-5D					
Self-reported health status *n=*	73	66	66	0.093	0.104
Mean (SD) change	0.0 (0.1)	0.0 (0.2)	0.0 (0.1)		

Table 6.10 Comparison of scores in well-being, health status and treatment satisfaction measures

(iv) Increase in medication

Table 6.11 compares the proportion of patients in each group with an increase in medication (defined as an increase in the dosage of an individual hypoglycaemic tablet, addition of another hypoglycaemic tablet or the addition of insulin). Therapy at one year was imputed from the last available observation if the data were not available. The proportion with an increase in medication ranged between 15.2% and 19.2% , but there was no significant association between group allocation and increase in medication (p=0.758, 2 d.f.).

[27] Adjusted for baseline values

	Comparison	Less intensive monitoring	More intensive monitoring	p value for difference between proportions
Increase in medication				
Yes	12 (15.2)	15 (19.2)	15 (19.0)	0.758 (2 d.f.)
No	67 (84.8)	63 (80.8)	64 (81.0)	

Table 6.11 Comparison of proportion of patients with increase in medication

(v) Episodes of hypoglycaemia

Sixty-eight of the trial participants reported hypoglycaemic episodes. In half of these patients the most severe grade of hypoglycaemia experienced was grade 1, while in the other half the most serious grade experienced was grade 2. All of the hypoglycaemic episodes reported in patients in the comparison group were grade 2. Chi-square for trend was used to examine the relationship between randomization group and maximum grade of hypoglycaemia experienced (Table 6.13). There was no association between randomization group and the maximum grade of hypoglycaemic episode experienced (p=0.335, 1 d.f.).

	Comparison	Less intensive monitoring	More intensive monitoring	p
Maximum grade of hypoglycaemic episode n (%)				
Grade 1	0 (0%)	21 (60.0)	13 (48.1)	0.335 (1 d.f.)
Grade 2	6 (100.0)	14 (40.0)	14 (51.9)	

Table 6.12 Association between group allocation and occurrence of hypoglycaemic episodes grade 2 and above

(vi) Other adverse events

The number of adverse events occurring in each group is compared in Table 6.13. Three participants in each of the comparison and more intensive monitoring groups experienced CHD complications during the course of the trial, but there was no significant difference between groups (p=0.219, 2 d.f.). Neither was there an association between randomization group and the occurrence of non-CHD events (p=0.263, 2 d.f).

	Comparison n= 79	Less intensive monitoring n=78	More intensive monitoring n=79	p value for difference between groups
Coronary heart disease n(%)	3 (3.8)	0	3 (3.8)	0.219 (2 d.f.)
Non-coronary heart disease n(%)	9 (11.4)	15 (19.2)	9 (11.4)	0.263 (2 d.f.)

Table 6.13 Comparison of occurrence of adverse events

6.3.3 Adherence to protocol

Table 6.14 shows the number of participants included in the analysis who attended study visits as scheduled and the number of participants in each group who adhered to monitoring protocol. Proportions in each randomization group attending all study visits ranged between 72.2% to 80.8%, but there was no association between randomization group and attendance at study visits.

Data on monitoring according to protocol were available for 209 participants. Participants in the less intensive monitoring group were least adherent with only 1 patient (1.4%) monitoring as requested. There was a significant association between randomization group and monitoring according to protocol (p=0.000, 2 d.f.).

The majority of those not following protocol were monitoring less frequently than requested, with 87.0% of those in the less intensive monitoring group and 76.8% of those in the more intensive group monitoring less frequently. There was no association between monitoring less frequently and randomization group (p=0.184, 1.d.f.). Twenty-six participants in the comparison group were also monitoring more often than requested with a median of 0 and IQR of 9.

	Comparison	Less intensive monitoring	More intensive monitoring	p value for difference between groups
Attendance at all study visits n(%)				
Yes	59 (74.7)	63 (80.8)	57 (72.2)	0.432 (2 d.f.)
No	20 (25.3)	15 (19.2)	22 (27.8)	
Testing according to protocol n(%)				
Yes	45 (63.4)	1 (1.4)	16 (25.8)	0.000 (2 d.f.)
No	26 (36.6)	68 (98.6)	53 (76.8)	

Table 6.14 Comparison of adherence to protocol

Characteristics of patients attending all study visits are compared with those not attending all visits in Tables 6.15 and 6.16. The only significant difference in baseline demographic and clinical characteristics between patients who did and did not attend all study visits was in median baseline HbA_{1c} (p=0.035).

Emotional representations were significantly different between these two groups (p=0.033) as were concerns about diabetes p=0.015), with those not attending being more worried about their diabetes and having more concerns. There was also a significant difference in undertaking physical activity (p=0.020), with those not attending visits undertaking less activity and a significant difference in medication adherence (p=0.002).

	Attended all study visits n=179	Did not attend all study visits n=57	p
Gender n (%)			
Male	103 (57.5)	34 (59.6)	0.878 (1 d.f.)
Female	76 (42.5)	23 (40.4)	
Median (IQR) Age (years)	68.2 (15)	69.0 (18)	0.658
Socio-economic classification			
Managerial and professional	80 (46.5)	24 (43.6)	0.237 (4 d.f.)
Intermediate	12 (7.0)	8 (14.5)	
Small employers and own account	19 (11.0)	9 (16.4)	
Lower supervisory and technical	29 (16.9)	5 (9.1)	
Semi-routine and routine	32 (18.6)	9 (16.4)	
Median (IQR) baseline HbA_{1c} (%)	7.0 (1.0)	7.3 (2.0)	0.035
Median (IQR) Duration of diabetes (years)	3.0 (6.19)	5.0 (7.25)	0.173
Baseline diabetes therapy			
Lifestyle modification	54 (30.2)	16 (28.1)	0.735 (2 d.f.)
Oral monotherapy	66 (36.9)	19 (33.3)	
Oral combined therapy	59 (33.0)	22 (38.6)	
Baseline smoking status			
Never smoked	74 (41.6)	20 (35.1)	0.640 (2 d.f.)
Former smoker	87 (48.9)	30 (52.6)	
Current smoker	17 (9.6)	7 (12.3)	
Mean (SD) baseline weight (kg)	86.9 (17.5)	87.8 (18.2)	0.736
Mean (SD) baseline blood pressure (mmHg)			
Systolic	140.5 (18.0)	140.5 (22.8)	0.998
Diastolic	80.7 (11.3)	78.6 (10.6)	0.228
Mean (SD) baseline cholesterol (mmol/l)			
Total	4.8 (1.0)	4.9 (1.2)	0.595
HDL	1.09 (0.26)	1.09 (0.27)	0.963
Total/HDL	4.6 (1.2)	4.7 (1.6)	0.549

Table 6.15 Baseline demographic and clinical characteristics of patients who did and did not attend all study visits

		Attended all study visits n=179	Did not attend all study visits n=57	p
Illness perception scales				
Identity	*n=*	98	22	
	Median (IQR)	2 (4.0)	3 (6.0)	0.423
Timelines(acute)	*n=*	151	42	
	Mean (SD)	8.8 (2.7)	9.3 (2.8)	0.282
Timelines (chronic)	*n=*	150	43	
	Median (IQR)	21.0 (4.0)	20.0 (4.0)	0.392
Timelines (cyclical)	*n=*	154	44	
	Mean (SD)	9.8 (2.8)	10.3 (3.5)	0.360
Consequences	*n=*	153	44	
	Mean (SD)	19.0 (4.2)	20.0 (4.4)	0.202
Efficacy of control strategies	*n=*	156	44	
	Mean (SD)	20.2 (2.1)	20.1 (2.7)	0.704
Futility of control strategies	*n=*	154	41	
	Mean (SD)	17.6 (3.1)	17.6 (3.3)	0.997
Illness coherence	*n=*	154	43	
	Mean (SD)	13.1 (4.1)	14.1 (4.6)	0.149
Emotional representations	*n=*	156	44	
	Mean (SD)	23.4 (5.8)	25.6 (6.5)	0.033
Influence of control strategies	*n=*	154	43	
	Mean (SD)	7.6 (1.1)	7.4 (1.5)	0.372
Concerns about diabetes	*n=*	158	45	
	Mean (SD)	6.6 (1.7)	7.3 (1.5)	0.015
Specific physical consequences	*n=*	160	45	
	Mean (SD)	22.8 (2.7)	23.4 (3.1)	0.156
Beliefs about medicines scales				
Specific necessity	*n=*	109	33	
	Mean (SD)	22.9 (3.0)	22.5 (3.4)	0.430
Specific concerns	*n=*	102	29	
	Mean (SD)	20.9 (4.1)	22.4 (4.6)	0.091
BEPAQ				
Importance of lifestyle modification	*n=*	152	41	
	Median(IQR)	28 (2.0)	28 (3.5)	0.344
Enjoyment of straying from diet	*n=*	157	46	
	Mean (SD)	5.5 (2.0)	5.9 (1.8)	0.333
Importance of physical activity	*n=*	151	43	
	Mean (SD)	20.4 (2.2)	19.9 (2.2)	0.236
SDSCA				
General diet	*n=*	154	43	
	Median (IQR)	5.5 (2.5)	5 (3.2)	0.200
Eating five fruit and vegetables daily	*n=*	160	45	
	Median (IQR)	6 (3)	5 (2.5)	0.193
Eating a high fat diet	*n=*	160	44	
	Median (IQR)	2 (2.0)	2 (2.5)	0.953
Physical activity	*n=*	161	44	
	Mean (SD)	3.6 (2.2)	2.5 (2.3)	0.020
MARS				
Medication adherence	*n=*	111	33	
	Median (IQR)	24 (1)	24 (4)	0.002

Table 6.16 Mean baseline scores in belief and behaviour measures in patients who did and did not attend all study visits

Characteristics of those participants who did and did not adhere to the monitoring protocol are compared in Tables 6.17 and 6.18. There was a significant association between baseline smoking status and adhering to monitoring protocol (p=0.043). There was also a significant difference in identity scores (p=0.011) and beliefs about enjoyment of straying from recommended diet (p=0.039) between these two groups.

	Adhered to monitoring protocol n= 62	**Did not adhere to monitoring protocol n=147**	**p**
Gender n (%)			
Male	31 (50.0)	93 (63.3)	
Female	31 (50.0)	54 (36.7)	0.090
Median (IQR) Age (years)	70.24 (16.0)	68.0 (16.0)	0.422
Socio-economic classification			
Managerial and professional	25 (41.7)	67 (47.9)	
Intermediate	3 (5.0)	13 (9.3)	
Small employers and own account	10 (16.7)	15 (10.7)	0.532
Lower supervisory and technical	9 (15.0)	22 (15.7)	
Semi-routine and routine	13 (21.7)	23 (16.4)	
Median (IQR) baseline HbA_{1c} (%)	7.0 (0.9)	7.0 (1.3)	0.412
Median (IQR) Duration of diabetes (years)	2.75 (3.5)	4.0 (7.0)	0.031
Baseline diabetes therapy			
Lifestyle modification	17 (27.4)	45 (30.6)	
Oral monotherapy	25 (40.3)	49 (33.3)	0.628
Oral combined therapy	20 (32.3)	53 (36.1)	
Baseline smoking status			
Never smoked	33 (53.2)	51 (34.9)	
Former smoker	25 (40.3)	78 (53.4)	0.043
Current smoker	4 (6.5)	17 (11.6)	
Mean (SD) baseline weight (kg)	85.6 (16.0)	88 (18.5)	0.387
Mean (SD) baseline blood pressure (mmHg)			
Systolic	138.0 (18.5)	141.0 (19.2)	0.286
Diastolic	80.1 (10.7)	80.2 (11.4)	0.956
Mean (SD) baseline cholesterol (mmol/l)			
Total	4.8 (1.0)	4.8 (1.1)	0.997
HDL	1.1 (0.2)	1.1 (0.3)	0.856
Total/HDL	4.6 (1.1)	4.7 (1.4)	0.726

Table 6.17 Baseline demographic and clinical characteristics of patients who did and did not adhere to monitoring protocol

		Adhered to monitoring protocol	Did not adhere to monitoring protocol	p
Illness perception scales				
Identity	*n=*	37	73	
	Median (IQR)	3.0 (5.0)	2.0 (4.0)	0.011
Timelines(acute)	*n=*	57	120	
	Mean (SD)	9.3 (2.6)	8.8 (2.8)	0.283
Timelines (chronic)	*n=*	52	124	
	Median (IQR)	20.0 (4.0)	21.0 (4.0)	0.637
Timelines (cyclical)	*n=*	58	123	
	Mean (SD)	10.1 (3.1)	9.9 (2.8)	0.687
Consequences	*n=*	57	123	
	Mean (SD)	18.9 (4.8)	19.3 (4.0)	0.589
Efficacy of control strategies	*n=*	56	127	
	Mean (SD)	20.2 (2.2)	20.2 (2.2)	0.928
Futility of control strategies	*n=*	55	124	
	Mean (SD)	17.7 (2.9)	17.7 (3.2)	0.924
Illness coherence	*n=*	56	125	
	Mean (SD)	13.1 (4.0)	13.4 (4.4)	0.606
Emotional representations	*n=*	56	127	
	Mean (SD)	24.1 (6.0)	23.6 (5.9)	0.591
Influence of control strategies	*n=*	58	123	
	Mean (SD)	7.4 (1.2)	7.6 (1.1)	0.178
Concerns about diabetes	*n=*	57	129	
	Mean (SD)	6.7 (1.6)	6.6 (1.7)	0.757
Specific physical consequences	*n=*	60	128	
	Mean (SD)	22.6 (2.9)	22.9 (2.6)	0.520
Beliefs about medicines scales				
Specific necessity	*n=*	41	89	
	Mean (SD)	22.4 (2.9)	23.2 (3.0)	0.184
Specific concerns	*n=*	38	84	
	Mean (SD)	21.9 (3.9)	20.8 (4.3)	0.174
BEPAQ				
Importance of lifestyle modification	*n=*	57	122	
	Median(IQR)	28.0 (2.0)	28.0 (2.0)	0.644
Enjoyment of straying from diet	*n=*	58	128	
	Mean (SD)	6.1 (1.9)	5.4 (2.0)	0.039
Importance of physical activity	*n=*	56	122	
	Mean (SD)	20.5 (1.9)	20.2 (2.3)	0.417
SDSCA				
General diet	*n=*	56	123	
	Median (IQR)	6.0 (2.5)	5.0 (3.0)	0.457
Eating five fruit and vegetables daily	*n=*	58	128	
	Median (IQR)	5.0 (3.0)	6.0 (2.75)	0.187
Eating a high fat diet	*n=*	58	128	
	Median (IQR)	2.0 (3.0)	2.0 (2.0)	0.838
Physical activity	*n=*	60	126	
	Mean (SD)	3.7 (2.2)	3.2 (2.2)	0.136
MARS				
Medication adherence	*n=*	42	89	
	Median (IQR)	24.5 (1.0)	24.0 (1.0)	0.564

Table 6.18 Mean baseline scores in belief and behaviour measures in patients who did and did not attend all study visits

6.3.4 Loss to follow-up

Twenty-three of the 236 patients included in the analysis were lost to follow-up. These were defined as patients who did not attend the final study visit. Participants who attended the final study visit but did not attend interim study visits were classified as not following the study protocol and were considered in the preceding analysis. Four of those included in those lost to follow-up died, one from a CHD-related event and the other three from non-diabetes related events.

Time to loss to follow-up was calculated as the time from the post-randomization visit to the first missed scheduled visit and is illustrated in the Kaplan-Meier curve in Fig 6.2. Seven participants in the comparison group and 8 in both of the less intensive and more intensive monitoring groups were lost to follow up. Mean trial participation time in the comparison and less intensive monitoring groups was 50 weeks (95% CI: 48, 52), while it was 49 weeks in the more intensive group. There was no significant difference between groups when the distributions of time until patients were lost to follow-up were compared (p=0.770).

Baseline demographic and clinical scores and scores on belief and behaviour measures of those completing the trial and those lost to follow-up are compared in Tables 6.19 and 6.20. The only baseline clinical characteristic which differed significantly between those lost to follow-up and those who completed the trial was median HbA_{1c}, which was 7.7 in those lost to follow-up and 7.0 in those completing the trial (p=0.030). Baseline beliefs about concerns were also significantly different, with those with lost to follow-up having stronger beliefs (p=0.004).

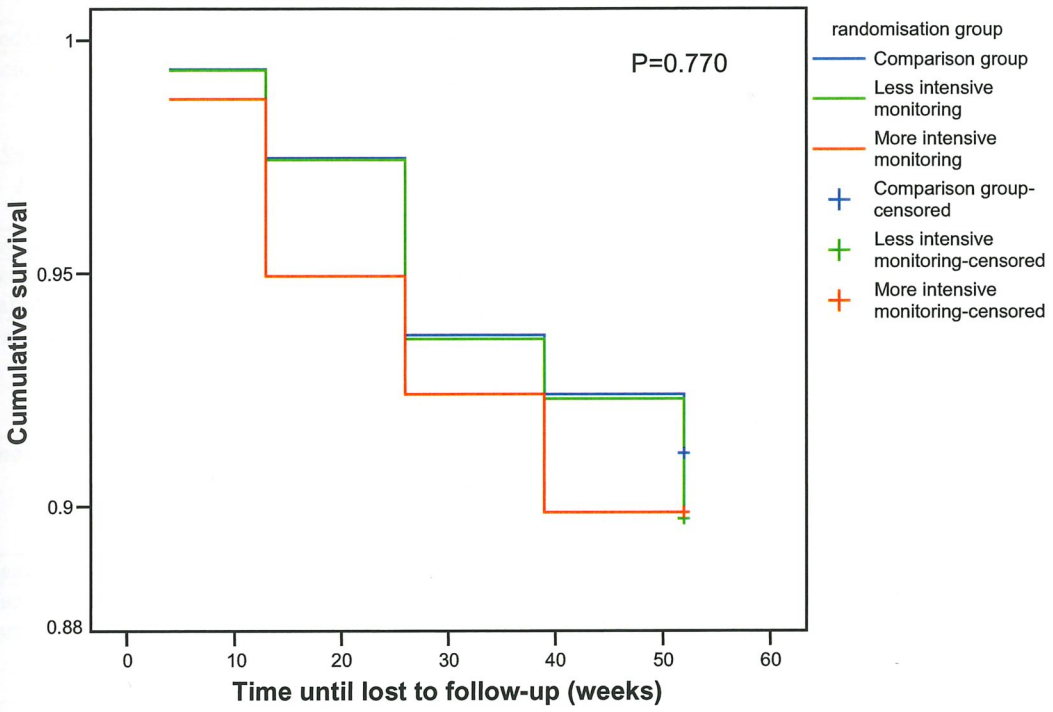


Figure 6.2 Comparison of time until loss to follow up between randomization groups

	Participants lost to follow up n=23	Patients not lost to follow-up n=213	p
Gender n (%)			
Male	11 (47.8)	126 (59.2)	0.374 (1 d.f.)
Female	12 (52.2)	87 (40.8)	
Median (IQR) Age (years)	70.1 (16.0)	68.2 (16.0)	0.575
Socio-economic classification			
Managerial and professional	9 (39.1)	95 (46.6)	
Intermediate	4 (17.4)	16 (7.8)	
Small employers and own account	3 (13.0)	25 (12.3)	0.650 (4 d.f.)
Lower supervisory and technical	3 (13.0)	31 (15.2)	
Semi-routine and routine	4 (17.4)	37 (18.1)	
Median (IQR) HbA_{1c} (%)	7.7 (1.9)	7.0 (1.1)	0.030
Median (IQR) duration of diabetes (years)	5.0 (12.0)	3.0 (5.63)	0.170
Diabetes therapy			
Lifestyle modification	4 (17.4)	66 (31.0)	
Oral monotherapy	10 (43.5)	75 (35.2)	0.395 (2 d.f.)
Oral combined therapy	9 (39.1)	72 (33.8)	
Smoking status			
Never smoked	10 (43.5)	84 (39.6)	
Former smoker	2 (8.7)	22 (10.4)	0.926 (2 d.f.)
Current smoker	11 (47.8)	106 (50.0)	
Mean (SD) weight (kg)	86.3 (15.3)	87.2 (17.9)	0.802
Mean (SD) Blood pressure (mmHg)			
Systolic	145.8 (23.0)	139.9 (18.7)	0.166
Diastolic	81.5 (11.8)	80.0 (11.1)	0.539
Mean (SD)Cholesterol (mmol/l)			
Total	4.7 (0.9)	4.8 (1.0)	0.569
HDL	1.0 (0.2)	1.1 (0.3)	0.443
Total/HDL	4.7 (1.2)	4.6 (1.3)	0.930

Table 6.18 Comparison of baseline demographic and clinical characteristics in those completing trial and those withdrawn or lost to follow up

		Participants lost to follow-up	Patients completing trial	p
Illness perception scales				
Identity	*n=*	9	111	
	Median (IQR)	2.0 (6.0)	2.0 (5.0)	0.968
Timelines(acute)	*n=*	13	180	
	Mean (SD)	8.0 (2.0)	9.0 (2.8)	0.224
Timelines (chronic)	*n=*	15	178	
	Median (IQR)	20.0 (3.0)	20.5 (4.0)	0.961
Timelines (cyclical)	*n=*	14	184	
	Mean (SD)	8.9 (4.0)	10.0 (2.9)	0.190
Consequences	*n=*	15	182	
	Mean (SD)	20.5 (4.7)	19.1 (4.2)	0.243
Efficacy of control strategies	*n=*	14	186	
	Mean (SD)	19.6 (3.0)	20.2 (2.2)	0.332
Futility of control strategies	*n=*	13	182	
	Mean (SD)	17.3 (4.1)	17.7 (3.1)	0.697
Illness coherence	*n=*	13	184	
	Mean (SD)	13.6 (4.4)	13.3 (4.2)	0.794
Emotional representations	*n=*	14	186	
	Mean (SD)	25.8 (7.6)	23.7 (5.9)	0.217
Influence of control strategies	*n=*	13	184	
	Mean (SD)	7.0 (1.9)	7.6 (1.1)	0.322
Concerns about diabetes	*n=*	14	189	
	Mean (SD)	7.8 (1.2)	6.7 (1.7)	0.004
Specific physical consequences	*n=*	14	191	
	Mean (SD)	24.1 (2.6)	22.8 (2.8)	0.103
Beliefs about medicines scales				
Specific necessity	*n=*	12	130	
	Mean (SD)	21.2 (3.7)	23.0 (3.0)	0.062
Specific concerns	*n=*	9	122	
	Mean (SD)	22.6 (5.3)	21.1 (4.2)	0.324
BEPAQ				
Importance of lifestyle modification	*n=*	11	182	
	Median(IQR)	28.0 (5.0)	28.0 (2.0)	0.664
Enjoyment of straying from diet	*n=*	14	189	
	Mean (SD)	5.6 (1.9)	5.6 (2.0)	0.965
Importance of physical activity	*n=*	12	182	
	Mean (SD)	19.5 (2.1)	20.3 (2.2)	0.202
SDSCA				
General diet	*n=*	15	182	
	Median (IQR)	5.0 (3.0)	5.5 (3.0)	0.943
Eating five fruit and vegetables daily	*n=*	15	190	
	Median (IQR)	5.0 (2.0)	6.0 (3.0)	0.335
Eating a high fat diet	*n=*	14	190	
	Median (IQR)	2.0 (2.5)	2.0 (2.0)	0.517
Physical activity	*n=*	15	190	
	Mean (SD)	2.5 (2.3)	3.4 (2.2)	0.147
MARS				
Medication adherence	*n=*	12	132	
	Median (IQR)	24.0 (4.0)	24.0 (1.0)	0.289

Table 6.20 Comparison of baseline scores in belief and behaviour measures in those completing trial and those lost to follow up

6.4 Summary of results

The results of our randomized, controlled trial indicate that BGSM, either with health professional-mediated feedback or with patient interpretation and application to adjust behaviour did not improve glycaemic control. Neither did use of BGSM significantly affect beliefs about the general effectiveness of diabetes treatment or about the effectiveness of specific treatment i.e. diet, physical activity and medication adherence, which we postulated in our causal model would determine behaviour. There were, however, significant differences between groups in the change in the specific dietary behaviours of eating five portions of fruits and vegetables daily and eating a high fat diet.

The results of the randomized controlled trial are discussed in Chapter 7.

Chapter 7

The randomized controlled trial- discussion

7.1 Introduction

The randomized controlled trial evaluated a theoretically-derived intervention to promote self-management in patients with non-insulin treated type 2 diabetes through the use of one of three different methods of glycaemic monitoring, namely regular HbA_{1c} measurements, BGSM with facilitator feedback and BGSM with patient interpretation and consequent behaviour modification. The primary outcome was change in HbA_{1c} between baseline and one year, while changes in clinical parameters, beliefs about diabetes and its treatment, self-management behaviours of eating, physical activity and medication adherence and well-being and patient satisfaction were the main secondary outcomes. This chapter reviews the main findings of the study and compares them with existing literature. The strengths and limitations of the study are also discussed and the theoretical, and clinical implications of the results are examined.

7.2 Summary of main findings and comparison with other trials

7.2.1 Change in HbA_{1c}

The primary outcome of the trial was change in HbA_{1c}, with a comparison revealing that although there was a decrease in HbA_{1c} in all three groups, these decreases were not significantly different between groups. In none of the three groups did the change reach clinical significance (defined as a decrease in HbA_{1c} of 0.5% or more) nor statistical significance.

Exploratory analyses in sub-groups defined by baseline HbA_{1c}, the median duration of diabetes, median age, presence of complications at randomization and self-reported health status also revealed no significant differences between trial groups, although clinically and statistically significant reductions

in HbA_{1c} were noted within groups (p=0.000 in all cases) in participants with baseline HbA_{1c} above 8%.

These findings suggest that BGSM did not improve glycaemic control in these patients and while those with poorer baseline control of diabetes did experience improvement in both monitoring groups, this was not significantly different from the improvement experienced in those who were not monitoring. These findings have two major implications, namely that those with poorer glycaemic control might benefit more from such interventions than those better controlled and that in the multi-component interventions utilizing BGSM which have been evaluated to date, improvement may have been a consequence of other components, such as increased interaction with health care professionals and not use of BGSM.

As discussed in Chapter 2, previous studies of the effect of BGSM on glycaemic control in non-insulin treated type 2 diabetes have produced conflicting results. The analysis presented in this thesis supports those randomized trials which have found no significant effect of BGSM use on glycaemic control in non-insulin treated type 2 diabetes when compared to regular HbA_{1c} monitoring (92,120,122,124).

There may have been several reasons why our results supported some studies and not others. The following discussion compares important aspects of our study, namely patient population and intervention intensity both with negative trials and with those which found a significant effect. The discussion is restricted to trials such as ours in which BGSM was compared to periodic HbA_{1c} monitoring and excludes those which compared BGSM to urine monitoring.

A significant way in which our trial differs from the existing literature is in the selection of patients. Our study selected patients with a wide range of glycaemic control, with a lower HbA_{1c} limit of 6.2 %. Five other studies to date have specified a glycaemic control threshold as an inclusion criterion(93,120,124,128,129), and in all of these, HbA_{1c} threshold was at

least 7.5%[28]; three of these studies have found a significant difference between the BGSM group and the control group. This may be because patients in these trials had poorer glycaemic control than recommended(32) and therefore had scope for improvement and would have been expected to be more likely to show an improvement than those in our trial where median HbA_{1c} was 7% and most patients were already meeting target HbA_{1c}. The role of eating and physical activity not withstanding, improvement in glycaemic control in patients with low HbA_{1c} would likely be mediated primarily by increasing pharmacotherapy. Where patients were already meeting glycaemic goals, there would have been little incentive for health care professionals to further increase pharmacotherapy.

A subgroup analysis based on baseline HbA_{1c} allowed us to explore this issue more thoroughly. Patients with HbA_{1c} above 8% in each randomization group had significant improvement in HbA_{1c}, but there was no difference between those who had periodic HbA_{1c} monitoring and those who used BGSM. This might suggest that these patients benefited from the intensive support provided by such interventions to improve self-management, regardless of the method of monitoring, which has been previously suggested in the literature(124). Our results support two of the existing studies conducted in those with poorly controlled diabetes (120,124), but contrast quite sharply with the other two studies conducted in this population (128,129). One possible explanation for this may be that per protocol rather than intention to treat analyses were conducted in both of the latter trials. In the study by Schwedes(128), only patients who were at least 70% compliant with monitoring were included in the analysis and in the study conducted by Guerci (129), only those participants who remained in the study for at least two months were included. These patients might arguably have been more motivated than those who did not monitor as frequently or who dropped out of the trial and may therefore have been more enthusiastic about altering their self management behaviour.

[28] Fontbonne et al defined poor glycaemic control as fasting blood glucose more than 8.8 mmol/l or post prandial glucose more than 11 mmol/l

Another significant difference between our trial and those described in the literature is the intensity of the intervention, particularly with regard to the length of intervention and techniques used. Our study lasted for one year, whereas the majority of the other studies lasted only for six months. This is important because the data from some studies(118,120,129) suggest that improvement was seen in the initial three to six months with consequent stabilization of HbA_{1c} in the BGSM group which was the case in the two large positive trials described thus far. BGSM may therefore support behavioural change initially, but this effect may not be maintained.

7.2.2 Changes in weight, blood pressure and cholesterol

Three other clinical parameters, namely change in weight, change in systolic and diastolic blood pressure and change in cholesterol were also compared in this analysis. Weight reduction in patients with type 2 diabetes is associated with improved glycaemic control and improvement in other cardiovascular risk factors such as lipids and blood pressure(210). It can also serve as a proxy indicator for decreased caloric intake and/or increased physical activity, both of which were behaviours targeted during the trial. Differential weight reduction in the BGSM group would therefore have been an important finding, supporting the use of the technology. Analysis of data revealed that although there was a reduction in weight in all three groups, these were not significantly different. Although intensively supported self-management weight reduction programmes may be effective, our results show that BGSM does not confer the additional benefit of weight reduction.

There were no weight criteria for entry into our trial and participants had a mean baseline BMI of 31.0 kg/m^2, which is in the obese range. Our data support other controlled trials examining the effect of BGSM on weight in obese patients which have shown no significant difference in weight reduction in patients using BGSM(118,124). Trials conducted in patients who were normal or overweight at baseline(119,120,122,128,129) also showed no evidence of significant weight reduction in this group.

Blood pressure was also compared between trial groups, with no significant differences noted, in keeping with one other trial which has examined this outcome(129). Modification of diet and physical activity have been associated with improved blood pressure control(211,212), but use of BGSM would be more likely to have encouraged adherence with dietary habits that were reflected by blood glucose levels. Pharmacologic agents and compliance with these would have been the most important mediators of blood pressure and, as discussed later, patients in our sample had very high baseline mean adherence which limited the scope for improvement.

There was, however, a greater reduction in total cholesterol (and consequently total cholesterol to HDL ratio) in the more intensive monitoring group than the comparison group when unadjusted values were compared, even after adjustment for changes in lipid lowering therapy. This may be a true finding, but may also be a chance finding given the multiple comparisons done in this analysis.

Multiple comparisons increase the likelihood of type 1 statistical error(213), which in this case would be the likelihood of finding a significant difference between groups where none exists(199). Statistical methods exist to adjust for multiple comparisons; one of the most commonly used is the Bonferroni method in which the level of significance is determined in part by the number of comparisons made(213). Some authors criticize the use of this technique, however, as it increases the likelihood of rejecting a truly significant finding and instead recommend describing the rationale for the tests carried out and discussing possible interpretations of the results(214).

In this instance, the likelihood of the difference between the more intensive monitoring group and comparison group being a chance finding is supported by the contradictory finding, discussed later in this chapter, of increased fat intake in those in the more intensively monitoring group. In the absence of explanatory factors such as a differential change in lipid lowering therapy or an increased awareness of and consequent adherence to a low fat diet, it is likely that chance was responsible for this finding.

7.2.3 Changes in beliefs and behaviour

Comparison of the unadjusted mean scores on the illness coherence scale revealed that those in the less intensive monitoring group had a reduction of greater magnitude than those in the comparison group, indicating a significant decrease in understanding in those in the less intensive monitoring group when compared to those in the comparison group. As with the cholesterol findings, this may have been a true finding or a due to chance. It is possible that this is a true finding and does fit with our initial hypothesis and existing literature(109,215) that those who are given blood glucose monitors without additional education about how to modify behaviour to improve results can experience feelings of confusion and guilt.

There was also a significant difference in change in beliefs about the consequences of diabetes, with post hoc analyses revealing that those in the more intensive monitoring group had stronger beliefs about the consequences of diabetes than those in the comparison group. There was, however, no significant difference between those in the less intensive group and either of the two groups. This is an interesting finding, as all three groups received the same baseline information about the consequences of diabetes and blood sugar levels were illustrated to both monitoring groups. It is possible that those who were attempting to improve their glycaemic control by manipulating their behaviour were more conscious of their diabetes and therefore more concerned about the consequences.

There were no significant differences between groups in scores on the beliefs about medicines scales. Although at baseline all participants had very high medication adherence scores, scores on the corresponding scales of belief were not as high, suggesting that other factors besides beliefs about the necessity of and concerns about diabetes medicines influenced adherence. We initially hypothesized that use of BGSM would have affected beliefs about necessity of medication more than periodic HbA_{1c} by illustrating, in the short term, the effects of not taking medication as prescribed. The very high medication adherence scores at baseline, however, probably resulted in a ceiling effect making it impossible to demonstrate any significant differences in

medication adherence. Additionally, patients who were already highly motivated to take their medication would be unlikely to experiment with their medication to see the effects of not taking it, which would also have made it difficult to test our hypothesis about the effect of BGSM on medication adherence.

It is difficult to compare these results with existing literature because few published studies have prospectively evaluated our primary assumptions, namely that change in beliefs about diabetes, particularly change in beliefs about the effectiveness of treatment would result in change in self care activities and that differential methods of glycaemic feedback would affect these beliefs. Cross-sectional studies have evaluated the first assumption to some extent by establishing a relationship between beliefs and behaviour(157,158), but their nature limits assumptions about causality and it may well be that it was behaviour that predicted beliefs in these patients. Secondly, these studies evaluated the relationship between existing beliefs and behaviour rather than a relationship between change in these parameters. Use of illness beliefs to formulate interventions necessitates that it is change in beliefs that result in behaviour change. There is one ongoing trial which is prospectively targeting illness representations in patients with type 2 diabetes which will inform research(216). None, however, of the trials of BGSM have evaluated it as a mediator of illness beliefs.

Our causal model hypothesized that changes in glycaemic control would be mediated by changes in eating, physical activity and medication adherence. Even though changes in glycaemic control did not differ between groups, significant changes in behaviour may have been evident, though not sufficient to affect HbA_{1c}. We may even have been more likely to see significant changes in these mediating behaviours rather than in HbA_{1c}, given that BGSM more directly assesses these behaviours and might therefore support or discourage them and secondly, because of the overarching role medication changes play in improving HbA_{1c}.

The limitations in assessing medication adherence have been discussed previously; significant differences between groups were only evident in two behaviours; these were eating five portions of fruit and vegetables daily and eating a high fat diet. Post hoc analyses indicated that participants in the more intensive monitoring group had a significant reduction in eating five portions of fruit and vegetables daily when compared to the monitoring group and a significant increase in eating a high fat diet, again when compared to the comparison group. This was an unexpected finding, as we thought that use of BGSM would help participants in this group to improve their self-care activities by reflecting their effect on blood sugar and, as observed previously, may be a chance finding due to multiple comparisons. It may, however, be a true finding as well. This is supported by the consistency of the two findings, as both reflect significantly worse eating habits in the more intensive monitoring group when compared to the comparison group, and by a previous study in obese patients with type 2 diabetes(118). A second trial noted a significantly poorer dietary compliance in a control group when compared to a BGSM group(129), but interpretation of this is limited: a proportion of the trial sample was asked to follow a diet, but the characteristics of those participants and the method of selection is not specified. It may well be that were differential characteristics that resulted in those in the control group less likely to adhere to dietary recommendations.

Our hypothesis assumed that participants with supported use of BGSM would be able to interpret their results and use them to support healthy eating habits. As emerged in the qualitative study discussed in the next chapter, this was not always the case and some participants in the more intensive monitoring group felt frustrated when they obtained counterintuitive results and ceased to adhere to dietary recommendations.

7.2.4 Changes in well-being and treatment satisfaction

We evaluated whether differing methods of glycaemic feedback would result in significantly different changes in well-being, treatment satisfaction and health status. No significant differences between groups were found in any of these parameters. Interestingly, patients in the monitoring groups did not

experience significant differences in perceived hypoglycaemia or perceived hyperglycaemia when compared with the comparison group, despite having blood glucose meters that allowed them to check their levels. This might be because those in the monitoring groups did not use their meters to confirm their physical symptoms, although those in the more intensively monitoring group were expressly encouraged to do so. Other prospective trials have documented either no significant change (124) or improvement(128) in these measures of well-being suggesting that even if there no significant improvement is associated with BGSM, it does not result in significantly decreased well being as suggested by one cross-sectional study(109).

7.2.5 Episodes of hypoglycaemia

One suggested use for BGSM in non-insulin treated patients is detection of hypoglycaemia. Sixty eight trial participants reported experiencing hypoglycaemic episodes, with grade 2 being the most severe grade experienced. Comparison of trial groups revealed no association between the maximum grade of hypoglycaemia experienced and randomization group, although the analysis was somewhat limited by the inability to assess grade 1 hypoglycaemia in the comparison group since it is, by definition, asymptomatic. One trial reports a significantly more hypoglycaemic events in those using BGSM(129), but this was due to reporting of grade 1 hypoglycaemia.

7.2.6 Occurrence of diabetes related complications

The occurrence of diabetes related complications in trial participants was also compared and no difference between randomization groups was found. This was likely a reflection of the good baseline control of trial participants rather than a result of the trial intervention, particularly since glycaemic control changes did not differ between groups. Additionally, the trial lasted only one year, which would have been a relatively short time for complications to develop.

7.2.7 Adherence to protocol

We carried out a modified intention to treat rather than per protocol analysis to evaluate our primary outcome of change in HbA_{1c}. Participants who did not attend study visits to receive the counselling component of the intervention or who did not monitor according to the study protocol were still included in the final analysis. The merits and disadvantages of this approach are discussed later in the chapter, but analysis of adherence to protocol can inform interpretation of trial results as well as indicate how the intervention might work in practice.

Our analysis revealed that there was no significant association between attendance at all study visits and randomization group. There was, however, a significant association between randomization group and monitoring according to protocol, with the most frequent deviation in both monitoring groups being monitoring less frequently than requested. Twenty six participants in the comparison group also monitored their blood sugar. Those not adhering to protocol were more likely to have had diabetes for a longer period of time, to be smokers, less likely to enjoy straying from diet and to associate more symptoms with their diabetes. Patients who did not attend all visits also had a higher median HbA_{1c}, higher scores on their emotional representations and concerns scales, exercised less and even in the context of high medication adherence in participants, had a lower medication adherence. This suggests that those who might benefit most from such an intervention, that is those with poorer control who were more concerned about their condition and whose behaviours were not optimized, were also the ones less likely to maintain involvement in the trial.

Compliance with BGSM varies in the trials reported, with some trials reporting adherence as high as 89%(118). Conclusions about rates of compliance in some trials are limited by the per protocol approach to analysis where participants were only included in the analysis if they reached a minimum threshold for monitoring frequency. We used both self-report and meter checking to ascertain frequency of monitoring. However, we assessed only

the four weeks immediately prior to study visits which may not have been a true reflection of the entire interim period, either because participants were more motivated immediately after visits and monitored more frequently, or they monitored more immediately prior to visits to complete the requested number of tests. Compliance with the monitoring regimen was low, however, and this could have been due to the frequency with which we asked people to monitor. The particularly low rate in the less intensive monitoring group may be a reflection of their not using the results to support self-management and therefore being less engaged.

7.2.8 Loss to follow-up

We also compared time to loss to follow-up between randomization groups. There was no difference in time to loss in different randomization groups, but those who were lost had a higher median baseline HbA_{1c} and higher baseline concern scores. This may be because these patients had poorer behaviours and therefore were more concerned about their diabetes. This contrasts with the one trial which reports a comparison between those completing the study and those lost to follow up (120) in which there was no significant difference in baseline HbA_{1c}. In this trial however, patients in both groups had average HbA_{1c} above target thresholds, whereas in our trial, those lost to follow-up had a median baseline HbA_{1c} of 7.7%, above target thresholds, compared to 7%, the median HbA_{1c} for those completing the study.

7.3 Strengths of this study

Our study is one of the most rigorously conducted trials of BGSM in non-insulin treated patients to date, with several strengths in both its design and analysis. These included its theoretical basis, the three arms used in the intervention and the pragmatic design with modified intention to treat analysis.

The analysis presented here evaluated a theoretically- derived intervention which was based on plausible psychological theory. The selection of theory was guided by existing research which suggested mechanisms by which glycaemic feedback might facilitate behaviour change. The use of measures was guided by the same psychological theory which ensured that the effect of the intervention on the appropriate elements of our causal model was

assessed. The use of this approach also lends credence to our results- by utilizing an approach which, based on existing evidence, would be most likely to facilitate behaviour change, participants were all equipped to implement behaviour changes, regardless of method of glycaemic monitoring.

None of the trials reported in the literature utilized a theoretical, systematic approach to intervention development. Our use of a systematic method assured a rational, reproducible approach to intervention development, which will allow further testing of this model. Modelling of the intervention allowed us to identify the key aspects of the intervention which we expected to determine patient outcomes, namely changes in beliefs and behaviour, and to assess these intervention points to evaluate whether the intervention worked as hypothesized.

Our trial also used a three arm design, with a stepwise approach to intervention development and tight control of the varying elements. The intervention in each arm built on the foundation of the previous arm, such that those in the less intensive monitoring group were exposed to all of the intervention elements that those in the comparison group were exposed to, with use of BGSM being the single additional component. Likewise, those in the more intensive monitoring group were exposed to BGSM with education on interpretation and application. This stepwise approach made it easier to elucidate what components of the intervention, if any, were responsible for improved outcomes.

Randomized controlled trials may be broadly defined as explanatory or pragmatic. In the former, the primary objective is to evaluate how an intervention works in ideal circumstances and through what mechanisms it works, while in the latter, the focus is on establishing how an intervention might work in the real world(217). Our trial incorporated elements from both these approaches. The causal modelling approach to developing the intervention facilitated understanding of what intervention components and targets might mediate behaviour change. In contrast, the trial was conducted in primary care by facilitators with no prior special training in diabetes.

Inclusion criteria were also quite broad in an effort to recruit a sample representative of those in the community. The use of a modified intention to treat analysis is also in keeping with a pragmatic approach. We included all patients who were randomized, provided they attended the post randomization visit and were therefore aware of their group allocation. This allowed us to evaluate how effective the intervention would be in a randomly selected group of people, some of whom would not adhere to monitoring protocol as would be likely to happen if the intervention were implemented in practice. Use of per protocol analyses such as those reported by two large trials of BGSM use(128,129) only inform the effectiveness of BGSM if it is used as requested, which is unlikely to happen with all patients.

7.4 Limitations of this study

Although this thesis presents one of the most rigorously conducted enquiries into this subject thus far, there were limitations. These included the sample size presented in this thesis, the population under study and the absence of a defined treatment algorithm.

A major limitation of the analysis of the sample from the RCT reported in this thesis is the sample size. A sample of 450 would have provided a power of 80% at the 5% level, but the sample size of 245 provided a power of only 54% at this level. The results of the analysis must therefore be interpreted with caution. The analysis, however, can still be informative- particularly for the larger clinical trial from which the sample was taken.

Another limitation in the study design was the selection of the population to be studied. The median HbA_{1c} of trial participants was 7.0 %, which, in addition to being within acceptable range under current guidelines, was the HbA_{1c} achieved in intensively treated patients in the UKPDS study(14). The margin for improvement in these patients would have therefore been minimal. This was borne out by the subgroup analysis by baseline HbA_{1c}, where those with higher HbA_{1c} experienced clinically and statistically significant reductions in HbA_{1c}.

In 2001, the mean HbA_{1c} of patients with type 2 diabetes in the UK was 7.69%, with 52.3% of patients having an HbA_{1c} of less than 7.5%(6), suggesting that our study had a disproportionate number of well controlled participants and was therefore unrepresentative of the population for whom the intervention was designed. The unavailability of HbA_{1c} for those who declined makes it difficult to confirm whether the population in Oxfordshire from which we recruited had HbA_{1c} levels lower than national levels or if it was those patients with better control who agreed to participate. The latter assumption is somewhat supported by the higher median HbA_{1c} in those who were lost to follow-up during the trial.

While diet and physical activity are important in diabetes control, pharmacotherapy may be the most effective means of reducing HbA_{1c}. Increase in pharmacotherapy and/or increased adherence may therefore have been the most likely way to see an improvement in glycaemic control in our trial participants. Participants were asked to see their general practitioners if they persistently had elevated HbA_{1c} (comparison group) or if more than 25% of readings were out of range despite maximizing eating, physical activity and medication adherence (less intensive and more intensive monitoring), but were still free not to do so if they chose. Decisions about increasing pharmacotherapy were also left up to the participant's GP, with a suggested, but non-binding, algorithm for medication adjustment provided. The algorithm provided suggested target HbA_{1c} of between 6.5% and 7.5%, which, given our median baseline value, meant many of them would not have their therapy increased. Increase in medication ranged from 15.2% to 19.2% with no significant differences between trial groups.

In addition to increasing prescribed pharmacotherapy, any improvement in glycaemic control would have been mediated by medication adherence. As noted previously, trial participants reported a high median medication adherence (24 out of a maximum of 25) and therefore appeared to already have been maximizing their medication adherence, resulting in a ceiling effect in this mediator.

As noted in chapter 4, the theoretical basis of the measures used helped to ensure measurement of the appropriate aspects of our causal model. We did however use self-report to garner information about eating, physical activity and medication adherence and, as also discussed in chapter 4, this may not be the most accurate way of assessing behaviour.

7.5 Implication of analysis

The analysis presented in the preceding chapter has several implications. This section discusses the implications for the causal model upon which the trial was based, the implications for the larger on-going trial and clinical and economic implications.

7.5.1 Implications for causal model

Our causal model, described in detail in Chapter 3, hypothesized that beliefs about the effectiveness of treatment for diabetes influence adherence to dietary recommendations, physical activity and medication adherence and consequently glycaemic control and that glycaemic feedback would influence these beliefs by illustrating the effects of adhering or not adhering to recommendations, reinforcing healthy behaviour and discouraging unhealthy behaviour. We further hypothesized that the method of glycaemic feedback would differentially influence behaviour, with BGSM having a more significant effect because it provided an instantaneous method of feedback when compared to the periodic feedback provided by HbA_{1c} measurements. We also hypothesized that the method in which BGSM was used would affect results, with those patients who were given training in understanding the relationship between their blood sugar and their behaviour more likely to use the technology to support behaviour, resulting in improved control.

The results of the analysis suggest that our causal model may have excluded important determinants of behaviour in these patients. No differential changes in beliefs about the effectiveness of eating, physical activity or medication adherence were observed, yet there was a significant difference when change in specific eating behaviours were compared, with those in the more intensive

monitoring group having a significantly greater decrease in the number of days on which they ate five portions of fruit and vegetables daily and a significantly greater increase in the days on which they ate a high fat diet when compared to the comparison group. These changes were seen in the absence of changes in beliefs, suggesting either that there are other beliefs determining these specific behaviours that were not encompassed by our causal model or that there were other determinants other than beliefs which were important.

Although our analysis failed to confirm this, it is reasonable to assume that change in eating, physical adherence and medication adherence would improve glycaemic control, although as noted previously in this chapter, in our sample with such low median baseline HbA_{1c} and excellent baseline medication adherence, increase in medication would have been the factor most likely to significantly improve glycaemic control. Even though those in the more intensively monitoring group reported significantly worsened eating habits when compared to the comparison group, these changes were likely not severe enough for HbA_{1c} to deteriorate. Additionally, the measure used to assess eating was somewhat insensitive as it only inquired specifically about two eating behaviours, namely high fat diet and daily portions of fruit and vegetables, neither of which might be expected to have a very significant effect on HbA_{1c}.

The second element of our causal model was the feedback provided by glycaemic control and the hypothesis that the differential effects of different types of glycaemic control would have an effect on beliefs about treatment effectiveness. Our results do not support a differential effect, with both instantaneous and distant information being equally effective. This is important, as it illustrates the contrast between those treated with insulin and our population. In the former, immediate information is critical for medication adjustment and improved control. In our population, however, it appears that the timing of information is less important than receiving the information and being equipped with the skills to act upon it.

7.5.2 Implications for on-going trial

This thesis presents an interim analysis for an on-going trial for which the negative results have implications. As this was an unplanned analysis, its findings will not influence the selection criteria, described in Chapter 5, under which further participants are being recruited. The larger trial is therefore likely to come to similar conclusions because of the near normal HbA_{1c} of those recruited. If, as alluded to earlier, patients in Oxfordshire have an anomalously low HbA_{1c} when compared to the rest of the UK population, recruitment outside of this area, as is currently being done, may result in a higher median HbA_{1c} in the final sample recruited for the trial. The lower threshold for inclusion makes it likely however that those with HbA_{1c} within target ranges will continue to be recruited and it will be difficult to demonstrate a differential improvement in glycaemic control for the reasons discussed earlier.

7.5.3 Clinical implications

Chapter 1 described the increasing use of BGSM and associated increasing cost in non-insulin treated patients with type 2 diabetes in the United Kingdom. Although underpowered, this analysis evaluates one of the most rigorously designed interventions to compare techniques of glycaemic feedback and the findings augment previous studies that suggest the widening use of BGSM in all patients with non-insulin type 2 DM is not supported by the evidence. Although broad conclusions should be avoided at this stage, the analysis suggests that more intensive support, regardless of the method of feedback might be the most useful way to improve glycaemic control in those patients who are less well controlled.

7.6 Summary

This chapter discusses the results of the RCT presented in Chapter 6. These data do not suggest that use of BGSM is associated with improvement in any of several clinical parameters assessed, including glycaemic control, weight and blood pressure. Neither was it associated with improved eating, physical activity or medication adherence. There may be, however, individuals with particular characteristics who might benefit from its use. Chapter 8 presents a qualitative study conducted in a sub-sample of trial participants which

explores experiences of BGSM and discusses characteristics of individuals who might benefit from it.

Chapter 8

The qualitative study

8.1 Introduction

Denzin and Lincoln(218) define qualitative research as "a situated activity that locates the observer in the world....Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them". Qualitative research has its roots in the social sciences, but is increasingly being used in health research to augment information obtained from quantitative analysis, or in some cases, investigate areas which are not amenable to quantitative assessment(219,220). Its strength lies in its ability to elucidate processes and facilitate understanding of how and why people behave the way they do(219).

A qualitative study was included in this clinical trial to explore the experiences and perspectives of BGSM in a sample of the trial participants. The clinical and biochemical effects of BGSM have been discussed in preceding chapters and some psychosocial outcomes such as illness and treatment beliefs and satisfaction with care have also been assessed quantitatively with validated measures. Other more exploratory aspects of BGSM use, such as how participants actually viewed the technology, use of results on a day-to-day basis, the burden of testing and how use affected their perceptions of diabetes and their self care behaviour do not lend themselves to quantitative techniques. Qualitative methodology, which is primarily concerned with the individual's understandings and interpretations of experiences, was an ideal method to explore these issues which may impact on patient use of the technology and the utility of BGSM, both for the patient and health professional.

This chapter reviews previous qualitative literature on blood glucose self-monitoring and presents the qualitative study conducted in a sample of patients drawn from the DiGEM trial.

8.2 *The qualitative study: literature review*

A literature search was carried out to identify previous qualitative research on blood glucose self-monitoring. Searches were carried out using the search terms qualitative, blood glucose self-monitoring, diabetes, focus groups, discussion groups and interviews in the MEDLINE (1951-2004), CINAHL, PsychInfo, and EMBASE (1974-2004) databases.

Only one paper was found which specifically discussed patient perspectives on BGSM in non-insulin treated type 2 diabetes. Peel et al (221) conducted a qualitative repeat interview study in Scotland in patients with newly-diagnosed non-insulin treated type 2 diabetes to explore the benefits and disadvantages of BGSM from the patients' perspectives. Forty newly-diagnosed patients were recruited from general practices and hospitals and interviewed twice, with an intervening six month interval (only 38 round two interviews were conducted due to patient unavailability). The study identified several benefits of BGSM, including increased awareness of having diabetes, improved understanding of diabetes, reassurance (when results were within range), an emphasis on the personal nature of diabetes control and encouraging modification of diet in response to results. Participants described inconvenience and pain as barriers to monitoring. Some participants also felt that monitoring could become obsessive and others felt that the information they had been given about monitoring was limited and were therefore unsure of what activities might impact on their blood sugars. Results that were not in keeping with their behaviour were also a source of distress, while others felt that results were ignored by their physician, rendering monitoring a waste of time.

Patients in this study obtained their meters either from a hospital or purchased them themselves and there was therefore no way of standardizing how meters were used by participants. Technical aspects of use which can affect comfort and accuracy, as well as education about monitoring and use of results, varied among patients, although the authors assert that this did not appear to

influence patient perceptions. There was no information regarding when patients monitored or prompts to checking blood sugar, whether patients observed an impact on their diabetes by activities other than diet or how confident they felt in their BGSM results or in their ability to control those results. Information on what characterized patients who held particular views was also lacking, limiting the extent to which the study could inform which participants might benefit from BGSM use. Patients in this study were also newly diagnosed and this may well have impacted on understanding of diabetes and awareness of the disease.

Fox et al(222) conducted a study in patients in the United Kingdom who monitored their blood sugar at home. Interviewers administered questionnaires to 33 patients either in person or over the telephone. The sample comprised both patients with type 1 and Type 2 diabetes, with 29 of the participants being on insulin. As with Peel et al, technical difficulties and inconvenience were reported as problems. Patients reported using BGSM in one of three ways- recording of results only, using results to adjust self care behaviour and analysis of results without adjustment of self-care behaviour. Reinforcing the existence of diabetes and feelings of improved control were identified as benefits, although others resented the constant reminder of their illness. This study explored beliefs about BGSM in patients with both type 1 and type 2 diabetes, the majority of whom were using insulin. The utility of BGSM in type 1 diabetes is undisputed as discussed in Chapter 2, and although some participants in this survey were patients with non-insulin treated type 2 diabetes, the study results do not indicate how their beliefs differed from others and it therefore has limited applicability in those with this illness. The study was also conducted using an interviewer-administered questionnaire which may have limited the extent to which participants could have expanded on issues, particularly in those interviews conducted over the telephone. The authors do not explicitly indicate the design of the questionnaire, although some open-ended questions appear to have been included, so it is difficult to ascertain how restricted participants were in their answers. It did not appear, however, that follow-up questions were asked; this method therefore would not have facilitated the pursuing of topics

important to the respondent as efficiently as individual interviews. Opportunities for establishing rapport and encouraging respondents to be forthcoming would also have been limited over the telephone and affected the data acquired.

Tak-Ying Shiu and Yee-Man Wong(223) reported a qualitative study from Hong Kong in which semi-structured interviews were conducted in patients with type 1 and insulin-treated type 2 diabetes. Patients were purposively sampled from a wider survey and were chosen to reflect those with higher anxieties. Pre-monitoring anxiety and sense of failure with poor readings were identified as psychological burdens, while others reported they felt a need to falsify records for their health care professionals. The expense of monitoring strips was also identified as a burden in this study, echoing the findings of a study on barriers to self-care activities in older women with non-insulin treated diabetes(224). These patients in the study from Hong Kong were all using insulin and their beliefs may well differ from those not being treated with insulin. The study on barriers to self-care activities discussed BGSM only briefly, confined itself to older women, and also included some insulin-treated patients.

Hall et al(225) reported on five in-depth interviews in patients with type 2 diabetes. Participants were purposively selected from a previous study of 200 participants if they had self-reported that they had been able to maintain behaviour changes in diet, exercise and BGSM for a minimum of six months. Obstacles to BGSM included scheduling difficulties, alteration of normal routine which resulted in forgetting to monitor, pain from finger pricking and distress from being constantly reminded about diabetes. Equipment was kept in a visible place to overcome the obstacle of forgetting to monitor. Respondents reported that unexpected results from BGSM prompted consideration of possible behavioural causes and affected future behavioural plans. As with previous studies, the population was not well defined. The treatment regimens of participants was not specified and at least one participant was being treated with insulin.

In summary, qualitative studies addressing BGSM have been limited. With one exception, they have been conducted in samples that included insulin-treated participants, which, as noted, may affect their perspectives. No sample has had standardized advice which makes it difficult to explore what characteristics determine who might benefit from education and use BGSM most effectively . Previous work in non-insulin treated patients has also been confined to newly diagnosed patients whose perspectives may well differ from persons who have lived with diabetes for some time. Other important issues such as motivation to monitor, personal control over results and comparisons between standard care and BGSM are not addressed in current literature.

Our study provided the opportunity to explore in depth issues relating to BGSM in a non-insulin treated population using a systematic method of monitoring within the context of a structured education programme. The three group design meant that views could be solicited from (i) those whom we were sure had had education about interpretation and application of BGSM results, (ii) those who were simply using a meter without this feedback and (iii) a control group who were not utilizing the technology at all. We are therefore able to compare views and experiences in these groups. We were also able to explore previously unexamined areas relating to patients' perspectives of self-efficacy and relative advantages of BGSM versus regular HbA_{1c} tests as well as what characteristics might be related to effective use of BGSM.

8.3 The qualitative study: methods

8.3.1 Patient recruitment and data collection

(i) Patient recruitment

Ethical approval for the study was obtained from the Oxfordshire Psychiatric Research Ethics Committee (OPREC Number O2.059). A sample of 40 patients was recruited from participants in the clinical trial. In qualitative research, a sample size is considered appropriate if it adequately answers the research question(226) and may therefore vary from single digit sample sizes to large numbers, depending on the sampling technique. We chose 40 as our

initial sample size with the intention of interviewing until data saturation had been reached. If new themes were still emerging after interviewing the first forty patients, further participants would have been recruited and interviewing continued until no new ideas emerged. This would ensure that all important ideas were included without the unnecessary generation of redundant data.

A subset of trial participants were contacted by post and asked if they would like to take part in a related sub-study, involving a single, semi-structured interview, to discuss their experience of having diabetes and taking part in the trial. Invitations were sent to those who had been in the trial for a minimum of three months to ensure that patients had had at least their three month follow-up visit with the study nurse and so would be able to discuss their views on the feedback they had received about their glycaemic control, enabling a comparison across the three intervention groups.

Convenience sampling was used to recruit the first twenty patients, that is, interviews were conducted with those who replied positively to the invitation. This technique, while inexpensive, can result in a poor quality sample with participants who volunteer being unwilling or unable to discuss the subject matter in detail(227). This can present difficulty in qualitative inquiry as participants who make the most productive respondents are those who are more adept at observation, interpretation and reflection(226). We overcame this difficulty by asking the study facilitators who had interacted with trial participants to review patient lists and indicate which patients they thought would make the most informative respondents prior to sending out invitations for the qualitative study. This increased our chances of selecting participants who would be forthcoming about their experiences and opinions.

After the first group of interviews had been conducted and the characteristics of these participants determined, we adopted a purposive sampling technique to recruit the remaining participants. Further letters of invitation were sent only to those whose characteristics had not been represented in the initial interviews with patients selected to span a range of age groups, socio-economic classifications, both genders and the three intervention groups.

Selection was also balanced to obtain an equal number of participants attending clinics with each study facilitator, as well as a range of baseline medication adherence scores (as assessed by the self-reported MARS questionnaire) and dietary and exercise behaviours (assessed by the self-reported SDSCA questionnaire). All respondents were given the option of being interviewed on a weekday or weekend and in a place of their choosing so employed people and those who were not mobile would not be excluded.

Purposive or judgment sampling allows the researcher to select participants who would most usefully answer the research question and allows participant selection based on specific variables(226). We chose variables that we thought might have a bearing on a patient's experience. Older patients, for example, might have been less comfortable with the technology of BGSM and we therefore attempted to interview patients across a wide age range.

Unlike in quantitative research, random sampling is impractical in qualitative research for several reasons. Random sampling requires the population characteristics of the variable under study to be known and to be normally distributed. Qualitative studies focus on complex psychological and sociological characteristics which may not meet these criteria(226,227). We were attempting to assess patients' beliefs about BGSM and behaviour and it was reasonable to assume that these were a result of individual experience and therefore unlikely to be generalisable. Selection of a purposive sample would, however, allow us to explore a wide range of experiences.

Attempts were made to recruit participants whose characteristics represented a wide range across the variables noted above. Participant selection was, however, necessarily limited by several factors. It was difficult to recruit younger patients due to the preponderance of trial participants from older age groups. It was also difficult to obtain equal numbers of patients in each study group- although letters of invitation were targeted to patients who met selection criteria, selection was necessarily dependent on participants' consent. In any case, emphasis was less on ensuring at least some patients

from each category were interviewed as analysis of qualitative data seeks to reflect the range of data within themes, not the frequency.

(ii) Data collection

Individual interviews were chosen as the method of data collection for this study. We selected this method since health can be considered quite a personal topic and other methods, such as focus groups, may have made patients reluctant to discuss their feelings frankly (228). Focus groups have been used more appropriately to explore a shared perspective, such as cultural attitudes to illness(229), but as we were primarily interested in the individual narrative, we chose to conduct individual interviews. This method also had advantages over other methods such as observational studies which, although they allow collection of data on what participants actually do rather than on what they say they do(230), can result in difficulties such as patients altering their behaviour as a consequence of being observed- the Hawthorne effect(230). Constant observation of participants would have been very inconvenient for both participant and observer since most BGSM takes place in the home and while it would have provided information on when people monitored their blood sugar, it would have provided no data as to why. An ethnographic study would also have involved significantly more observation and interviews and would not have been practical in this instance.

Interview setting may influence the data obtained(231). Interviews were conducted by the author in respondents' homes at a time of their choosing since it was felt that participants would feel more comfortable in familiar surroundings. Three interviews were conducted in general practice surgeries at the request of the respondents; given these requests, respondents were likely to have felt at least as comfortable being interviewed in their surgeries as at home.

Interviews were conducted by the author, who introduced herself as a researcher doing a study related to, but separate from, the clinical trial. We believed it was important to make patients feel more comfortable and less

reluctant to be frank about their opinions of and experiences during the trial. Participants were encouraged to address both the positive and negative aspects of their experiences and were also assured of the anonymity of their comments. No mention was made of the author's medical background and any medical questions were deferred to the end of the interview as perception of the interviewer as a medical professional might result in patients refraining from describing what they may have felt was "inappropriate" behaviour or attempting to answer to please the interviewer rather than answering honestly(231).

Interviews were semi-structured in design to allow both open-ended questioning where respondents would be able to speak in an undirected fashion as well as inquiry about specific topics. The interview began with questions about demographics which were followed by narrative style of interview, where patients were encouraged to talk at length about their experiences since being diagnosed with diabetes. In the second part of the interview, inquiry was made about specific topics which are summarized in Table 8.1. The topic guide is appended (Appendix 14).

Self-care behaviours affecting control of diabetes
Understanding of the RCT process
Usefulness of taking part in the RCT
Comparison of BGSM and clinic monitoring
Usefulness of knowledge of glycaemic control
Use of BGSM – ease, prompts, timing, relationship to behaviour

Table 8.1 Topics for specific inquiry in qualitative interviews

Use of semi-structured interviews allowed pertinent follow-up questions to be asked so themes which emerged during the interview, but which had not been anticipated during design of the topic guide, could be explored.

Interviews lasted between 25 and ninety minutes. All interviews were audio taped and transcribed verbatim. A subset of the interviews was also videotaped, with patient consent, for inclusion in a future DIPEx (Personal Experience of Health and Illness)(232) module on diabetes. While videotaping allows for conveying of non-verbal cues of respondents as well as words, it obviously removes the aspect of anonymity and might make participants more

reluctant to participate. This was illustrated by our recruitment rate which was much lower than expected when we asked patients for permission to videotape their interviews, but which improved when we limited our request to audiotaping, indicating that some persons may have been deterred by videotaping.

8.3.2 Data analysis

(i) Statistical analysis

The characteristics of the patients interviewed were compared with the other participants in the trial. Means and standard deviations were used to describe normally distributed continuous variables and medians and interquartile ranges used to describe non-normally distributed continuous variables. Chi-squared tests were used to compare proportions, with independent sample t-tests used to compare normally distributed variables between the two groups and the Mann-Whitney U tests used to compare non-normally distributed variables. Significance was tested at the 5% level (two-tailed),

(ii) Analysis of interviews

Analysis of the interviews was conducted concurrently with data collection to facilitate exploration of emergent themes in on-going interviews. A modified grounded theory approach was used in which the analytical themes are derived from or "emerge" from the data. The technique does not ignore prior hypothesis, but emphasizes that these prior hypotheses should not limit analysis (233). Use of this technique allowed examination of the issues and themes that were important to our respondents rather than imposing a pre-determined structure.

The transcripts from the semi-structured interviews were imported into the NU*DIST computer programme (QSR International, 2002) which simplifies text coding and allows for development of coding structure and cross-referencing of text. Qualitative data analysis programmes do not, however, replace data analysis but do simplify data sorting and retrieval.

Considerable data were generated by the interviews, but as the focus of this thesis is BGSM, only data relevant to that subject are reported here. Interview transcripts were read and re-read in order to identify general themes, in consultation with a qualitative researcher with a social science background. Any text relating to BGSM was highlighted and assigned a unique code under one of these general themes. These themes were determined as the transcripts were read and added to the coding structure as necessary. Items in general themes were compared to each other and coding was refined to produce sub-themes based on the similarities and differences between items (the constant comparison method)(233). Broader categories were then identified and text units reviewed to ensure all categories emerging from the data had been identified. Results were gathered into broad categories to facilitate discussion.

8.4 Results and discussion

This section presents and discusses patients' experiences of using blood glucose self-monitoring. Each of the emergent themes and relevant sub themes is discussed and illustrated by quotations from patients with each patient identified by a selection of age, gender, group allocation and baseline and change in scores on the MARS and SDSCA measures.

8.4.1 Participant characteristics

The characteristics of the forty patients interviewed are shown in Table 8.2. The patients interviewed were comparable with the remaining trial participants in all characteristics with the exception of socio-economic classification, where there was a higher proportion of managerial and professional occupations and a lower proportion of small employers and own account workers and semi-routine and routine occupations in the qualitative sample.

	Patients interviewed n=40	Patients not interviewed n=196	p
Median (IQR) age (years)	69.5 (13.0)	68.0(17.0)	.289
Gender			
Male n (%)	21 (52.5)	116 (59.2)	.484
Female n (%)	19 (47.5)	80 (40.8)	
Socio-economic classification (SEC)[29] n (%)			
Managerial and professional occupations	26 (66.7)	78 (41.5)	
Intermediate occupations	3 (7.7)	17 (9.0)	
Small employers and own account workers	1 (2.6)	27 (14.4)	.027
Lower supervisory and technical occupations	6 (15.4)	28 (14.9)	
Semi-routine and routine occupations	3 (7.7)	38 (20.2)	
Group allocation n (%)			
Comparison	12(30.0)	67 (34.2)	
Less intensive	12 (30.0)	66 (33.7)	.631
More intensive	16 (40.0)	63 (32.1)	
Median (IQR) baseline MARS score (max. 25)[30]	24.0 (1.0)	24.0 (2.0)	.951
Mean (SD) baseline SDSCA score (max. 28)[31]	18.9 (4.5)	18.0 (5.0)	.347
Mean (SD) change in MARS score	-0.28 (1.9)	0.02 (1.4)	.343
Mean (SD) change in SDSCA score	0.91 (4.2)	0.96 (3.8)	.937

Table 8.2. Comparison of characteristics of patients included in the qualitative sample and other trial participants

8.4.2 Perspectives of blood glucose self-monitoring

Interviewees' perspectives of BGSM focused around three overarching themes, namely awareness, influence on health behaviour and empowerment. Both benefits and disadvantages associated with these themes were expressed and these are presented together to illustrate the range of patient views.

(i) Awareness

Increased awareness of diabetes

Several patients, from each of the intervention arms, raised an increased awareness of having diabetes as a consequence of BGSM. Type 2 DM can be asymptomatic before the occurrence of complications and respondents explained that it was therefore easy to forget or ignore they had an illness that required active management. The presence of an elevated blood sugar on monitoring was viewed by respondents as tangible evidence of an abnormality. Respondents differed regarding whether increased awareness

[29] Data on (SEC) were not available for nine participants, one of whom was a qualitative subject

[30] Eight of the participants interviewed and 62 of those not interviewed were treated with diet and exercise modification only; baseline MARS scores were not available for 22 of patients on medication

[31] Composite SDSCA scores were calculated by reverse scoring the item on high fat food and summing the component scales; these scores not available for three interviewees and 43 of those not interviewed

was a benefit. One interviewee in the more intensive monitoring group, who earlier in her interview had commented that she had thought her diabetes was curable and only temporary when diagnosed, noted that BGSM had help to demonstrate that there was a persistent abnormality:

"Well, it makes it real that you've got it. [um] That there, there is sugar there" (D21, 57 yr old female, more intensive monitoring group, MARS: baseline 24, change -6; SDSCA: baseline 18, change 4).

This participant had a low baseline self-care activity score at the beginning of the trial, but experienced an higher than average increase which may have been attributable in part to her increased awareness of her diabetes. She reported decreased medication adherence, perhaps due to the side effects from her medication which she discussed during her interview.

The increased awareness of diabetes was typically viewed as beneficial. Two respondents, however, considered it a disadvantage. In one instance, this was a perceived disadvantage as the respondent had never monitored. She controlled her illness with lifestyle changes and felt quite strongly that monitoring her blood sugar would distress her:

" I would feel like an ill person. I would walk about feeling 'I am a sick person' and I'd hate that because I know that I'm not, I'm a healthy animal." (D22, 71 yr old female, comparison group, MARS: not applicable; SDSCA: baseline 20, change 4).

This respondent clearly placed significant emphasis on her self-image as a "healthy" person which she felt would be threatened by constant reminders of illness. BGSM may have been particularly significant for her because she did not have the daily reminder of taking medication which might reinforce the presence of disease in other patients. This illustrates a potential barrier to initiating BGSM in non-pharmacologically treated patients who may not consider themselves ill and find close monitoring unnecessary and distressing. This did not seem to be a concern once BGSM had been started.

None of the non-pharmacologically treated patients monitoring during the trial expressed distress about increased awareness of their diabetes.

The second respondent who reported increased awareness of diabetes was a disadvantage was in the less intensive monitoring group and had one of the lowest baseline medication adherence and self-care adherence scores of the respondents in the qualitative study, reflecting her acknowledgement that she had never made concerted efforts to control her illness. She reported that BGSM was:

" ...a sort of reminder of the fact that [um] you know that I've got something wrong with me...I don't like to be reminded particularly." (D15, 67 yr old female, less intensive monitoring group, MARS: baseline 20, change 4; SDSCA: baseline 11, change 7).

It is difficult to distinguish whether she preferred not to be reminded of her diabetes because she was not actively controlling it or whether she did not actively control it because she tended not to be conscious of it. Despite her dislike however, she recorded higher than average increases in both medication adherence and self care scores, suggesting that with appropriate support, such as that provided during the trial, use of BGSM to improve self care and medication adherence might still be promoted and useful in patients who are reluctant to acknowledge the presence of their diabetes.

Increased awareness of diabetes has been identified as a consequence of BGSM in other studies. Patients with newly-diagnosed diabetes as well as those with longer-standing illness found increased awareness beneficial(221,222), although the constant reminder was also reported as a disadvantage by a patient in one of these studies(222).

Increased understanding of the relationship between physical symptoms and blood sugar

Some participants noted that BGSM helped them to establish the relationship between their physical symptoms and their blood sugar. Most of the interviewees who reported this benefit checked their blood sugar to confirm suspected hypoglycaemia, rather than suspected hyperglycaemia. One other study reported use of BGSM to confirm hypoglycaemia, but did not comment on whether respondents used it to confirm high blood sugar(223). The use of BGSM to preferentially detect low blood sugar is not surprising given that mild hyperglycaemia is asymptomatic and likely to go unnoticed, while hypoglycaemia, in addition to triggering symptoms, may need to be distinguished from other conditions which mimic its symptoms. One participant who had a medical condition whose symptoms were similar to hypoglycaemia commented:

"And as I said, whenever I have one of these bad bouts I always, now I've got the equipment, I always [uh] go and check my blood to make sure that, which one or what, which one it is that's doing the problem". (D3, 65 yr old male, more intensive monitoring group, SEC 1, MARS: baseline 24, change not available; SDSCA: baseline 17, change 0[32]).

Only those respondents who had been exposed to monitoring, either as part of the trial or previous occasional users, considered BGSM a tool to detect hypoglycaemia. Those who had never used the technology perceived it solely as a tool for detecting hyperglycaemia, analogous to the blood tests which they had at their GP surgery. As such, several felt that BGSM was an unnecessary further check on glycaemic control and could lead to unnecessary worry:

"I feel I get it done often enough so [um] that quite suits me. I think very often [um] you could get worried if you keep doing it yourself, ... I'd rather just have it done

[32] SDSCA change was calculated using a follow-up score imputed from baseline data

there at the doctor's surgery" (D18, 78 yr old female, comparison group, SEC 1, MARS: not applicable; SDSCA: baseline 22, change -1).

Participants in the monitoring groups were educated about the symptoms of hypoglycaemia and acceptable lower thresholds while those who monitored previously may have been educated by their health care professional or learnt through experimentation, explaining why they used BGSM to detect hypoglycaemia. Respondents who never used BGSM may never have received this information. BGSM-naïve patients could be encouraged to use the technology as a means of detecting low as well as high blood sugar, particularly since low blood sugar can remedied quite easily if detected in its early stages.

Reassurance about health status

Awareness of blood sugar levels also provided reassurance. Some used BGSM to ensure previously detected high readings had returned to normal, while others with readings within normal parameters were comforted their diabetes had not worsened, with BGSM providing reassurance between visits to their health professional. Even within the context of the high mean baseline medication adherence scores in the patients interviewed, with two exceptions, participants who mentioned reassurance between clinic visits as a benefit all had higher baseline medication adherence scores than average. The emphasis on medication adherence may reflect a more biomedical view of health and these patients might therefore place more emphasis on objective evidence of good glycaemic control such as that provided by BGSM. For example:

"So if I woke up one morning and took it on a fasting reading and it was, I don't know, twenty-two or twenty-four, for example, then the alarm bells really would start to ring. [er] But because it's, they've been contained within a, a band which doesn't seem to [um] ever increase as dramatically as what I've indicated, then there is a crumb of comfort there, if you see what I mean." (D8, 62 yr old male, less intensive monitoring group, MARS: baseline 25, change -3; SDSCA: baseline 17, change 4).

Reassurance was clearly associated with normal readings. Readings outside the specified parameters were associated with feelings of failure, particularly in participants who had higher than average baseline SDSCA scores. These participants clearly made efforts to adhere to dietary and physical activity recommendations as part of their diabetes control strategies and abnormally high readings may have been considered a failure of these efforts:

"I think I'm disappointed because I feel, I suppose, in a way that I've failed, even though you know, I sit there afterwards and think, well no, I didn't actually, I haven't done anything I shouldn't have done, so why do I feel it, but I still do. I feel guilty and, and a bit of a failure and I don't know why." (D33, 45 yr old female, more intensive monitoring group, MARS: baseline 25 change -4; SDSCA: baseline 27, change -1).

These participants either experienced no change or a decrease in their medication and self care scores, suggesting that failure of BGSM to confirm the benefits of adherence resulted in decreased adherence. Inexplicable readings have been reported to promote nihilistic attitudes and consequently, decreased adherence to diabetic regimens(221). This provides a possible explanation for the decreased adherence in these respondents, although not explicit from our data. Our other findings regarding the relationship between normal readings and reassurance support previous findings that while normal readings reassured patients, participants often blamed themselves for high readings(221).

Some respondents in the comparison and less intensive monitoring group felt patients might become obsessed with checking blood sugar if they had access to a monitor. This was not a concern in the more intensive monitoring group, perhaps because values were being used to support behaviour change and were therefore thought necessary.

Understanding of diabetes

Two participants volunteered that BGSM helped them to understand their diabetes by illustrating the fluctuations in blood sugar. One commented:

"I would have thought that was a good idea, just to give every, anybody, when they first get it a meter, and to do it for three months, even just for two, two or three months, even if you take it back off them then, at least they can see what, you know, what's happening to the body and [um], and they'd understand it more" (D25, 69 yr old male, less intensive monitoring group, MARS: not applicable; SDSCA: baseline 22, change 1).

The participants who made this observation represented both monitoring groups in the trial. While this may be a reflection of the value of simply seeing what BGSM values were, the interviewee in the less intensive monitoring group discussed how BGSM had helped him to understand his diet, suggesting that he was behaving more like a participant in the more intensive group and relating BGSM to his behaviour. Understanding how his diet influenced those fluctuations, rather than simply seeing that his blood sugar went up and down, was useful. Indeed, respondents in both monitoring groups reported frustration when they were unable to understand why they got the BGSM values they did.

"...it seems to me that [er] the figures, other than the fasting reading, are very high [er] some days, reasonable the next, I cannot see why this should be, because when I think I, [er] I think 'Ooh I've over-indulged a little bit my figures will be really high', [um] they're not necessarily high. And other times when I've had a very lean day in terms of what I've eaten, [um] the figures can be high. And I can't, I cannot see a, a, a balance of why this should be as I've said, and that's the only thing about taking these readings that tends to confuse me a little, because I just cannot make sense of it." (D8, 62 yr old male, less intensive monitoring group, MARS: baseline 25, change -3; SDSCA: baseline 17, change 4).

This suggests that the benefits derived from illustration of fluctuations are related to the ability to understand the relationship between fluctuations and

behaviour, rather than simply observing them. When interpretation of BGSM results is difficult, it can result in frustration and anxiety.

(ii) Health behaviour

Assessing the effect of self-management behaviour

A major benefit of BGSM emerging from the data was the ability to assess the effects of behaviour. In the trial intervention, facilitators encouraged participants in the more intensive monitoring group to experiment with the timing of their monitoring to see, for example, how certain food affected their blood sugar. Interviewees confirmed that this was a useful strategy for BGSM:

"I think you can certainly tell [um] whether you've eaten the wrong things. [um] Or whether you've overdone it and then you obviously need to go [um] and correct that by doing exercise or being extremely good, you know." (D33, 45 yr old female, more intensive monitoring group, MARS: baseline 25, change -4; SDSCA: baseline 27, change -1).

Although participants in the less intensive monitoring group were not encouraged to use BGSM as a check on their behaviour, some reported having done so. One participant noted:

"But, the thing that has, has also been extremely helpful with the exercise is that because you're monitoring your blood sugar levels, you actually see what pushes it up and what, what doesn't. [um] Not only in connection with what you eat, but what you're doing, so that you can stray from straight and, and narrow [um] in terms of diet provided you are active enough. [um] Whereas you can eat the same things and if you're not active you know it shows-immediately" (D15, 67 yr old female, less intensive monitoring group, MARS: baseline 20, change 4; SDSCA: baseline 11, change 7).

Use of BGSM to test theories of effects of behaviour in some participants in the less intensive monitoring group was almost inevitable, although facilitators encouraged people in this group to avoid doing so as far as possible.

Realistically however, particularly motivated participants with access to a monitor were likely to explore the effects of their behaviour. Participants who did this appeared to use BGSM to support change, with all but one of these having low baseline SDSCA scores and a higher than average increase after one year.

Promoting adherence to self-management behaviour

A related theme, promotion of adherence to self-management, also emerged as a benefit of BGSM. As noted previously in this thesis, adherence to these behaviours is often less than optimal in people with diabetes. Interviewees in both the less intensive and more intensive monitoring groups felt that BGSM was a useful tool in providing discipline and helping them to adhere, echoing findings in previous studies, because it demonstrated what happened when they failed to do so:

"Because I've seen exactly what happens if I forget to take those night time pills from monitoring the blood sugar, I can see what happens and [uh], so yes it has had an effect, yeah" (D15, 67 yr old female, less intensive monitoring group, MARS: baseline 20, change 4; SDSCA: baseline 11, change 7)

As with respondents who found BGSM useful in assessing behaviour, those who noted its usefulness in illustrating the consequences of non-adherence, had low baseline SDSCA scores and, with one exception, reported higher than average increases in self-management behaviours. This suggests these particular benefits of BGSM may be more pronounced in patients who otherwise have difficulty in adhering to lifestyle and medication advice.

The previous sub-theme relates to behaviour change which was prompted when specific instances of non-adherence demonstrated elevated blood glucose. Elevated readings also prompted behaviour change even when they were not attributable to a particular behaviour.

"So if I'm very, if I'm high which, by that I mean by over ten [uh] which I know that's probably much too high by everyone else's standards but by my standards I think ten isn't too bad, but if I go over ten then I will take great care with my diet for two or three days till I bring it right down to about five or six." (D4, 67 yr old male, more intensive monitoring group, MARS: baseline 20, change 3; SDSCA: baseline 18, change -8)

Respondents in both monitoring groups with a range of characteristics reported using BGSM to provide information about the general state of their diabetes, suggesting this was a widely derived benefit of BGSM. The trial intervention was based on the hypothesis that BGSM could provide two types of feedback to patients: feedback on their general diabetes control and feedback on specific behaviour which might influence glycaemic control. The data from the qualitative study suggest that both these methods of feedback were employed by some respondents in both monitoring groups.

Those who did not see improvement after they modified their behaviour were discouraged. Several interviewees, all of whom were in the more intensive monitoring group, commented on how little their behaviour seemed to impact on their blood sugar. For example:

"But, but, even if I, even if I do everything they say, for a couple of days, I still don't get good readings, so you know there's nothing there to encourage me, saying oh, you know 'I didn't have a drink for two day, I didn't eat a pork pie, I didn't have a packet of crisps, I didn't have any bacon, I didn't fry any food and look at that, my reading is six, that is wonderful'. Oh no, it's still seven, it's still eight, you know, and so you don't think to yourself that's the way forward, because nothing's happening, I'm just the same, it doesn't seem to matter whether I have ten pint, I mean I don't have ten pints, but you know, it doesn't seem to matter if I have a lot to drink or a little to drink, my readings very, very rarely alter, they're all between 7 and 10, depending which time of day I take them." (D1, 60 yr old male, more intensive monitoring group, MARS: baseline 25, change 0; SDSCA: baseline 22, change -1)

The trial intervention in the more intensive monitoring group may have contributed to this perspective. In this group, the relationship between lifestyle and blood glucose was stressed and participants were encouraged to make lifestyle changes and to keep track of them by BGSM. This may have created unrealistic expectations regarding the extent of change that might be observed and the timelines over which they might be observed. Changes such as those discussed by this interviewee, if maintained, might result in longer term improvements in glycaemic control by contributing to weight loss, but would be unlikely to do so in the shorter term. Other incentives might be needed to encourage maintenance of behaviour change in these patients.

Comments regarding the role of BGSM in assessing and promoting behaviour were generally made by those who had been exposed to the technology either before or during the trial. Only one BGSM-naïve respondent in the comparison group commented on this use of BGSM. Not surprisingly, she placed less emphasis on its role than those who had used the technology:

"And you see you can't, whether you, you check it at home or not it doesn't make any difference, you have to, still have to do the right thing you see." (D20, 73 yr old female, comparison group, MARS: not applicable; SDSCA: baseline 26, change 0).

This respondent had a high baseline SDSCA score, indicating she was motivated to maintain self care activities and perhaps did not require the additional support provided by BGSM that appears to be useful in less motivated respondents.

Two participants volunteered that they timed their BGSM to ensure they only got satisfactory readings. One respondent did this by testing only on days he felt he had adhered to his regimen, while the other strayed from her regimen only when not testing:

"I have to say this now, that [er] I be p- be completely honest here, on the days I check me blood I behave meself, whereas I can come- I come in this morning [er] lunch time, I say when I have me breakfast about, quarter past eight this morning,

then I went into town, I come back, well I might have a, I might have [er] occasionally have a treat, a cup of tea, about half ten I'll read the paper and have a cake, but I won't when I'm about to have the [er] blood check, so that makes me stick to something, now I don't know what the difference to me to have the cake because, I guess there'll be some sugar in it so that would probably send it the wrong way really, you know." (D11, 64 yr old male, less intensive monitoring group, MARS: baseline 25, change 0; SDSCA: baseline 14, change 5)

Strategic timing of BGSM has been reported previously in the literature (223,234), with the authors suggesting that this is done in an effort to create an appearance of normality for health care professionals. In our study, use of BGSM seemed to provide motivation for transient behaviour change on days values were checked, but as the two respondents who described this behaviour did not share any of the characteristics which we measured, it is difficult to say which participants will exhibit this behaviour. Daily BGSM might promote daily adherence to behaviour, but may not be justifiable on clinical grounds and other strategies to promote consistent behaviour change need to be explored.

(iii) Empowerment

The third major theme emerging from the data was empowerment. This related to respondents' access to a convenient method of assessing glycaemic control that allowed them more control over their health care and their ability to contribute to their physician's evaluation of their status.

Convenience

Several participants noted the convenience of BGSM. It allowed them to check on their glycaemic control whenever they wanted, without having to visit their surgery:

"You've only got to press a button and it will show you your averages for the period, so it's no problem, no difference but then you haven't got the inconvenience of making appointments and sitting in doctor's surgery etc. and then going back for the

results" (D30, 53 yr old male, less intensive monitoring group, MARS: not applicable; SDSCA: baseline 19, change 3)

Respondents who commented on the convenience of BGSM all recorded, with one exception an increase in their SDSCA score. These participants might be using BGSM to support their self care activities and therefore desire frequent feedback on their glycaemic control, which would be inconvenient to arrange at a GP surgery.

The convenience of BGSM was tempered by the physical discomfort reported by some respondents. Several previous studies identify physical discomfort as a barrier to or disadvantage of BGSM(221,222,225,235). While interviewees in both monitoring groups reported some physical discomfort associated with use of BGSM, this was noted to be trivial:

"It, it's not particularly pleasant, but [um] it's not that bad" (D12, 68 yr old male, more intensive monitoring group, MARS: baseline 25 change 0; SDSCA: baseline 22, change 2)

Fear of the discomfort associated with BGSM was not a significant deterrent, either in the respondents in the monitoring groups or in the comparison group where only one respondent raised a fear of needles as a potential barrier to use of BGSM. The interruption of routine caused by BGSM and the expense to the NHS were also raised by respondents.

Initiation of physician visits

Some respondents also noted that BGSM prompted them to initiate physician visits if they thought it was warranted, allowing them to take more responsibility for their care. One reported:

"...any trend that comes up with, I don't have to wait for a doctor to [uh] tell me the answer. I mean if I have any problems, if I find my blood sugar low, low, low, I can go straight into the doctor and [er] say 'Look what's happening'. If I have to wait for

somebody else then I could be done by then." (D3, 65 yr old male, more intensive monitoring group, MARS: baseline 24, change not available; SDSCA: baseline 17, change 0)

Being prompted to visit the doctor was reported by patients in both monitoring groups as well as in one patient in the comparison group who had been previously exposed to monitoring, suggesting that this was a widely experienced benefit.

Informing health care decisions

Although respondents appeared to use their BGSM results primarily to inform their own behaviour, some did report that they considered these values an important source of information and as such, showed their values to their health care professionals outside of the setting of the trial. As described previously, trial participants received two different levels of advice and feedback from study facilitators, depending on group allocation, but adjustments to medication were done by the participant's GP if they thought it was warranted. Some participants, all of whom were in the more intensive monitoring group, felt that BGSM values were important in informing treatment. This may reflect their trial group allocation as the potential of BGSM to evaluate and inform treatment decisions was emphasized in this group. The emphasis may also account for the confusion described by these participants when discussing the value placed by health care professionals on their BGSM. Participants felt more emphasis was placed on HbA_{1c} than BGSM, especially if information from these contrasted. One participant who was monitoring intensively felt her physician was ignoring important information, rendering monitoring a waste of time.

"Well, I think 'what a waste of, what a waste of effort, you know, there's a lot of information here that that would give them more [um] feedback than [um] they can obviously do from one reading, once in six months". (D40, 71 yr old female, more intensive monitoring group, MARS: baseline 25, change 0; SDSCA: not available)

Comparison of BGSM and HbA_{1c}

Although use of BGSM enabled participants to assume more control over their diabetes, only two respondents expressed an absolute preference for BGSM over periodic clinic visits and HbA_{1c}. One was concerned that the feedback from her health care professional was deficient and felt her only source of feedback was BGSM. The other participant, in the less intensive monitoring group, felt that clinic assessment was unable to give an accurate assessment as it was a one-off reading:

"I can keep a more up-to-date tab on it. I mean, for example, if it were every three months, on the occasion of that third month, I might go along when it, it could be as low as anything on here. Now, a- a- a- another day before or after it might be high, but I wouldn't know that, so this is by far the better thing, in my view." (D8, 62 yr old male, less intensive monitoring group, MARS: baseline 22, change -3; SDSCA: baseline 17, change 4)

This respondent thought that the blood tests done at his surgery provided the same information (i.e. his blood sugar at that point in time) as those done at home and therefore could not detect variations. Consequently he felt more regular monitoring to detect such variations was necessary. This reflects a misunderstanding of the nature of HbA_{1c} tests, which was not seen in other patients.

Some respondents, all of whom were in the comparison group, expressed a preference for clinic testing. While willing to test if their health care professionals thought it necessary, they were somewhat reluctant to do so, commenting on the appropriateness of that level of health care involvement and their ability to carry it out:

"I don't think it's a good thing for people to mess about like that, unless the doctor suggests that I get something of that nature, then I would. But I would only do it, [um] under his instruction or if he told me or showed me how to do it, or the nurse. I , I don't mess about with those sort of things on my own." (D10, 80 yr old male, comparison group, MARS: baseline 25, change 0; SDSCA: baseline 21, change 5)

"I think I might prefer possibly to, to do, stick to the three months, really. [um] I mean I would do the other way if, if, if they thought it was [um] of benefit to, to them and to me. But [um] I think I, as I say, my, my, my memory is not the best. [laugh] I, I'd forget it now and again and then that would, [um] you know, probably upset the whole system." (D27, 74 yr old female, comparison group, MARS: baseline 24, change 0; SDSCA: baseline 22, change 1)

Most of the respondents in this study reported using their BGSM values independently to guide their behaviour, rather than depending on interpretation by their health care professional or study facilitator. Participants who require continued significant input from health care professionals may therefore not benefit as much from use of the technology. Anxieties about misuse of BGSM might be allayed by reassurance that BGSM was an adjunct rather than a replacement for standard care. The absence of these concerns in those actually monitoring does suggest that these might be overcome with exposure to BGSM and appropriate education.

Most respondents however, described benefits of utilizing both HbA_{1c} and BGSM. The value of HbA_{1c} in giving a longer term assessment of glycaemic control than BGSM was widely raised as were the other services provided at clinic visits:

"The nurse does checks on me feet and she does me urine, urine test and things like that, and weighs me and all that." (D25, 69 yr old male, less intensive monitoring group, MARS: not applicable; SDSCA: baseline 22, change 1)

The wide range of participants who reported this benefit suggests that most people recognize a role for dual monitoring strategies, with distinct objectives for each strategy.

Views of BGSM and urine monitoring

Perceptions about accuracy were relevant to perceptions of empowerment. Participants who felt BGSM was inaccurate were less likely to use it or to feel their results were relevant to their management. Concerns about accuracy were reported in comparison to urine monitoring.

Three participants compared BGSM to their experience with urine monitoring. While urine monitoring was simple, all felt it was not as accurate and did not provide adequate information, supporting previously published findings(236).

"Well I had some little strips which you put in your urine and [er] I think it's, is it red is it? And they go blue, or they go a different colour anyway, and [er] I noticed once when I'd just checked it a-and I had had some chocolate or something and it, woy, it went the wrong colour completely, and I thought 'Well, I know that was wrong for me'. But no, there wasn't, it wasn't the same as with this because it's it's not, it's not very [er] it's not very good method that really. It's like y- y- if i- w- if it goes the wrong colour, you don't know how bad it is really, do you?" (D11, 64 yr old male, less intensive monitoring group, MARS: baseline 25, change 0; SDSCA: baseline 14, change 5)

Although BGSM was thought to be more accurate than urine monitoring, participants expressed reservations about its accuracy when compared to HbA_{1c}. Three participants across both monitoring groups expressed reservations about the accuracy of BGSM. Doubts about accuracy were related to the volume of blood, with one patient suggesting that the blood tests done at the surgery should have been more accurate by virtue of the larger quantity of blood. Another patient obtained a lower reading after washing his hands and felt this was a reflection of the accuracy of the technique:

"I have my doubts sometimes, have my doubts. [um] Like I washed my hands. [um] I came down, where did I come from, I went somewhere. Anyway I came in, took my blood sugar and it was [um] 11 something. And I said to my wife, I said that's got to be wrong. She said wash your hands. So I did and it went down to 10.0. That makes

a difference." (D29, 75 yr old male, more intensive monitoring group, MARS: baseline 25, change 0; SDSCA: baseline 9, change 0).

In this instance, the patient attributed the difference in readings to deficiencies in the meter, rather than his technique. Appropriate technique and informing patients about potential sources of error might reduce this and increase confidence in the accuracy of the meter.

8.5 Conclusions

This qualitative study provided the opportunity to explore perspectives of blood glucose self-monitoring in a sample of patients with non-insulin treated diabetes. This study was unique for several reasons. Unlike most previous studies, it was conducted in a sample of patients with non-insulin treated diabetes and so could inform use of BGSM in these patients. Most of the previous studies have used mixed populations and failed to report whether type of diabetes or treatment modality influenced perspectives. It allowed comparison of perspectives of participants who had been exposed to a standardized programme of BGSM, removing much of the variation that may have influenced perspectives of patients in previous studies. Patient characteristics that could inform who might benefit most from BGSM, and how they might do so, were also explored, expanding on existing literature which identifies benefits and disadvantages of using BGSM without describing the characteristics of the those who might experience them. Interviewing participants in both monitoring and non-monitoring groups allowed examination of whether anticipated disadvantages of BGSM were of concern to those actually monitoring.

Three overarching themes of awareness, influence on health behaviour and empowerment emerged from the data. Positive perspectives were expressed by those with the ability to independently interpret results in light of self-management behaviour and use them to support improved adherence to self-management. This was particularly useful in those who initially had difficulty adhering. Those who demonstrated significant adherence at the start of the

trial were sometimes de-motivated if BGSM results did not reflect their efforts. Negative perspectives were expressed by those who found difficulty in understanding the relationship between their BGSM values and their behaviour or who experienced no improvement after behaviour modification.

Exposure to BGSM also appeared to affect perspectives. Anticipated disadvantages such as physical discomfort, distress from increased awareness of diabetes and undue responsibility for care, which were raised by respondents in the comparison group, were not concerns for those actually monitoring. These represent potential barriers that may need to be addressed when initiating monitoring. The use of BGSM to monitor low as well as high blood sugars was also limited to those who had actually used it and reluctant users or new users should be advised of this potential use.

Our findings had implications for the clinical trial. Using BGSM did influence beliefs about the effectiveness of general and specific treatment strategies (both positively and negatively), resulting in changes in behaviour in some individuals and thus providing support for our causal model. However, efforts to maintain separation between groups were only moderately successful with some respondents in the less intensive monitoring group interpreting BGSM in light of eating, physical activity and medication taking and modifying behaviour accordingly. This does not invalidate the results of the trial since, as a pragmatic trial, it was designed to evaluate what was likely to happen if the intervention was applied in real practice. Rather, it suggests that in a group of participants given meters without additional support or education, some will teach themselves to interpret and apply results, particularly if they have difficulty in following self-management recommendations.

These results could also inform clinical practice. Potential barriers which might be encountered when initiating and continuing monitoring in patients could guide development of educational strategies, with particular emphasis on interpretation of results and managing expectations regarding the extent to which behaviour might be reflected in BGSM values, since difficulties in interpreting results presented the most prominent disadvantage. Providing

information about the difference between BGSM and HbA_{1c} and the usefulness of both types of information to both patient and health care provider might prevent patients becoming discouraged if health care professionals appear not to place much emphasis on BGSM values.

This qualitative study had several strengths. Use of qualitative methodology was in itself a strength. This technique allowed identification of issues that were of importance to the respondents rather than to the researchers(220). We were also able to identify idiosyncratic behaviour such as "strategic monitoring" which may not have been evident on a questionnaire with fixed items. It also allowed us some insight into why people monitored and what motivated them to do so more or less frequently than requested. As the characteristics of the respondents were similar to those in the entire trial, these results could be extrapolated to the trial population.

The study did, however, have limitations, particularly as a study of BGSM perspectives in the wider population of patients with non-insulin treated type 2 diabetes. Although respondents were typical of those in the RCT, it was not possible to assess whether they were more widely representative. Interviewees and trial participants, for example, had high baseline medication adherence scores, which made it impossible to interview participants with very poor adherence who may well be less strict about their health overall and therefore have different views about BGSM. Only one patient interviewed was non-Caucasian. Cultural factors have been shown to affect beliefs about diabetes and self care(237,238) and we would not have been able to adequately evaluate any of these differences in our sample. Patient perspectives were viewed in the context of their self-management behaviours, but there may be other individual characteristics that influence how people think about BGSM.

This qualitative study suggests that the key factors influencing patient perspectives of BGSM are exposure to the technology and ability to understand and use the results to support improved self-management practices. It can provide a route to increasing awareness, empowering

patients and helping them to improve their management which may well be adequate grounds to support its use in select patients who want to use it, regardless of its effect on glycaemic control.

Chapter 9

Conclusion

This thesis presents a uniquely comprehensive examination of the biochemical, behavioural and psychosocial effects of BGSM in patients with non-insulin treated type 2 diabetes. Despite the numerous studies published in the literature and reviewed in Chapter 2, the role, if any, of this technology in this patient population remains unclear. The intervention described in this thesis is one of the most rigorously developed to date to optimize BGSM use in these patients and the results of both the randomized controlled trial and the qualitative study can inform further use of BGSM in this patient population.

Some authors have suggested that BGSM in patients with non-insulin treated type 2 diabetes can serve a purpose similar to that served in patients with insulin treated diabetes, namely reflecting the effects of past behaviour and encouraging self-manipulation of therapy(124,129). While in insulin treated diabetes, this usually entails adjustment of insulin doses, in patients not treated with insulin, this involves manipulation of other therapies such as eating, physical activity and oral medication. Manipulation of oral medication doses in response to BGSM levels is potentially much more complicated than manipulation of insulin and therefore adherence to medication might be a more realistic objective. BGSM in non-insulin treated patients would indeed be useful if it could encourage adherence to these behaviours and that could be reflected in improved glycaemic control.

The results of our randomized controlled trial suggest, however, that BGSM with patient interpretation and feedback offers no improvement in glycaemic control over BGSM with facilitator feedback or regular HbA_{1c} feedback. In addition to having no effect on the primary outcome of HbA_{1c}, methods of glycaemic feedback did not have differential effects on most of our hypothesized outcome mediators of beliefs about diabetes and its treatment and self-management behaviour or on patients' sense of well-being and treatment satisfaction. The only significant differences were evident in illness

coherence beliefs where those in the less intensive monitoring group had significantly decreased understanding about their diabetes and an unexpected worsening in the diets of those who were monitoring their blood sugar more intensively.

Our intervention and its evaluation are unique for several reasons. Firstly, established psychological theory about how a dynamic process of behaviour change might be effected underpinned intervention development. This common intervention was delivered to participants in all groups to ensure no group was preferentially equipped to implement behaviour changes. Secondly, the elements of the causal model which were targeted by the intervention were clearly defined, which facilitated evaluation of the intervention not only with regard to whether it worked, but also how it might have done so. In our study, we observed changes in two behaviours without corresponding changes in beliefs, suggesting that there may have been important beliefs that we did not assess with our measures or that there are other factors besides beliefs that influenced behaviour and therefore should have been included in our causal model. Future work could be directed at identifying other potential mediators of behaviour change that might also serve as areas of intervention.

Our randomized controlled trial revealed little benefit of BGSM in improving either glycaemic control or the self-management behaviours we hypothesized might affect it. This thesis also describes a qualitative study which explored what patients, if any, might benefit from BGSM use. Purposive sampling was used to ensure participants with a range of characteristics were interviewed. Several themes emerged; participants offered both negative and positive perspectives on some of these themes including the increased awareness of diabetes stimulated by BGSM, and the reassurance about health status. The perspectives which participants expressed appeared to be related to the feedback they obtained, with those who received results within recommended ranges more satisfied than those who did not. Participants who previously had difficulty adhering to self management recommendations found BGSM useful support, whereas other participants were discouraged when their efforts were

not reflected by their BGSM results. Perspectives on BGSM also appeared to be influenced by exposure to the technology with those who had never used it viewing it as a tool primarily for detecting hyperglycaemia and expressing more concern about becoming obsessed with monitoring. Those who had been exposed felt it was a convenient method of assessing their glycaemic control, gave them some power over their health and allowed them to play a role in their health care decisions.

The findings from the qualitative study suggest that although BGSM may not provide any benefit over HbA_{1c} with regard to glycaemic control and improved self management behaviour, there may be some people with non-insulin treated type 2 diabetes who may benefit from its use, particularly those who have difficulty following behavioural recommendations. These people appear to benefit from the illustration of the effects of behaviour provided by BGSM. Future work might explore whether long term use of a meter is necessary in these patients or whether a brief period of use with periodic reinforcement is sufficient to establish and maintain behavioural patterns.

Monitoring in chronic disease requires a rational approach which must consider, among other things the method of monitoring(239). While BGSM can fulfill many of the purposes of monitoring, namely assessing response to therapy and detecting deviation from and the regaining of control(239), our study suggests that self-monitoring of these parameters does not offer any advantage over periodic HbA_{1c} in improving self-management behaviours or glycaemic control in most patients with non-insulin treated type 2 diabetes. Its use might therefore be restricted to those patients who require behavioural reinforcement and support.

References

1. Wild S, Roglic G, Green A, Sicree R, King H: Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 27:1047-1053, 2004

2. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR: Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ* 321:405-412, 2000

3. Selvin E, Marinopoulos S, Berkenblit G, Rami T, Brancati FL, Powe NR, Golden SH: Meta-analysis: glycosylated hemoglobin and cardiovascular disease in diabetes mellitus. *Ann Intern Med* 141:421-431, 2004

4. Morgan CL, Currie CJ, Peters JR: Relationship between diabetes and mortality: a population study using record linkage. *Diabetes Care* 23:1103-1107, 2000

5. Bagust A, Hopkinson PK, Maslove L, Currie CJ: The projected health care burden of Type 2 diabetes in the UK from 2000 to 2060. *Diabet Med* 19 Suppl 4:1-5, 2002

6. Lusignan S, Sismanidis C, Carey IM, DeWilde S, Richards N, Cook DG: Trends in the prevalence and management of diagnosed type 2 diabetes 1994-2001 in England and Wales. *BMC Fam Pract* 6:13, 2005

7. Morgan CL, Currie CJ, Hunt J, Evans JD, Rogers C, Stott NC, Peters JR: Relative activity and referral patterns for diabetes and non-diabetes in general practice. *Diabet Med* 17:230-235, 2000

8. Currie CJ, Morgan CL, Gill L, Stott NC, Peters JR: Epidemiology and costs of acute hospital care for cerebrovascular disease in diabetic and nondiabetic populations. *Stroke* 28:1142-1146, 1997

9. Currie CJ, Morgan CL, Peters JR: Patterns and costs of hospital care for coronary heart disease related and not related to diabetes. *Heart* 78:544-549, 1997

10. Currie CJ, Morgan CL, Peters JR: The epidemiology and cost of inpatient care for peripheral vascular disease, infection, neuropathy, and ulceration in diabetes. *Diabetes Care* 21:42-48, 1998

11. Currie CJ, Morgan CL, Dixon S, McEwan P, Marchant N, Bearne A, Sharplin P, Peters JR: The financial costs of hospital care for people with diabetes who have single and multiple macrovascular complications. *Diabetes Res Clin Pract* 67:144-151, 2005

12. Clarke P, Gray A, Legood R, Briggs A, Holman R: The impact of diabetes-related complications on healthcare costs: results from the United Kingdom Prospective Diabetes Study (UKPDS Study No. 65). *Diabet Med* 20:442-450, 2003

13. Zimmet P, Alberti KG, Shaw J: Global and societal implications of the diabetes epidemic. *Nature* 414:782-787, 2001

14. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. *Lancet* 352:837-853, 1998

15. Collins R, Armitage J, Parish S, Sleigh P, Peto R: MRC/BHF Heart Protection Study of cholesterol-lowering with simvastatin in 5963 people with diabetes: a randomised placebo-controlled trial. *Lancet* 361:2005-2016, 2003

16. Colhoun HM, Betteridge DJ, Durrington PN, Hitman GA, Neil HA, Livingstone SJ, Thomason MJ, Mackness MI, Charlton-Menys V, Fuller JH: Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. *Lancet* 364:685-696, 2004

17. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group. *BMJ* 317:703-713, 1998

18. Diabetes Prevention Program Research Group: Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. *N Engl J Med* 346:393-403, 2002

19. The Diabetes Prevention Program Research Group: Impact of Intensive Lifestyle and Metformin Therapy on Cardiovascular Disease Risk Factors in the Diabetes Prevention Program. *Diabetes Care* 28:888-894, 2005

20. UK Prospective Diabetes Study (UKPDS). VIII. Study design, progress and performance. *Diabetologia* 34:877-890, 1991

21. Gaede P, Vedel P, Parving HH, Pedersen O: Intensified multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria: the Steno type 2 randomised study. *Lancet* 353:617-622, 1999

22. American Diabetes Association: Standards of Medical Care in Diabetes. *Diabetes Care* 28:S4-36, 2005

23. Nelson KM, Reiber G, Boyko EJ: Diet and exercise among adults with type 2 diabetes: findings from the third national health and nutrition examination survey (NHANES III). *Diabetes Care* 25:1722-1728, 2002

24. Donnan PT, MacDonald TM, Morris AD: Adherence to prescribed oral hypoglycaemic medication in a population of patients with Type 2 diabetes: a retrospective cohort study. *Diabet Med* 19:279-284, 2002

25. Evans JM, Newton RW, Ruta DA, MacDonald TM, Stevenson RJ, Morris AD: Frequency of blood glucose monitoring in relation to glycaemic control: observational study with diabetes database. *BMJ* 319:83-86, 1999

26. Murata GH, Shah JH, Hoffman RM, Wendel CS, Adam KD, Solvas PA, Bokhari SU, Duckworth WC: Intensified blood glucose monitoring improves glycemic control in stable, insulin-treated veterans with type 2 diabetes: the Diabetes Outcomes in Veterans Study (DOVES). *Diabetes Care* 26:1759-1763, 2003

27. Farmer A, Neil A: In response to 'variations in glucose self-monitoring during oral hypoglycaemic therapy in primary care'. *Diabet Med* 22:511-512, 2005

28. Wysocki T: Impact of blood glucose monitoring on diabetic control: obstacles and interventions. *J Behav Med* 12:183-205, 1989

29. Sonksen PH, Judd SL, Lowy C: Home monitoring of blood-glucose. Method for improving diabetic control. *Lancet* 1:729-732, 1978

30. Walford S, Gale EA, Allison SP, Tattersall RB: Self-monitoring of blood-glucose. Improvement of diabetic control. *Lancet* 1:732-735, 1978

31. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *N Engl J Med* 329:977-986, 1993

32. American Diabetes Association: Clinical Practice Recommendations 2005. Diabetes Care . 2005.

33. A desktop guide to Type 2 diabetes mellitus. European Diabetes Policy Group 1999. *Diabet Med* 16:716-730, 1999

34. Latalski M, Jaworska J, Dziemidok P: [Frequency of self-monitoring in relation to metabolic control in patients with type I and type II diabetes treated at the diabetic clinic of the Institute of Agricultural Medicine in Lublin]. *Wiad Lek* 55 Suppl 1:305-312, 2002

35. Clua EJL, Puig JJ, Ciurana RE, Garcia BG, Monclus BJF, Gonzalez HA, Prims CJM, Rivera GP, Checa SE: Blood glucose self-monitoring (BGSM): an evaluation of its prescription and results in type-2 diabetes. The research group in primary care of Tortosa. *Atencion Primaria* 24:316-325, 1999

36. Cava F, Cantos E, Molina MC, Fernandez MI, Parron T, Carrillo L: [The self-measurement of blood glucose and mean glycemias in patients with diabetes mellitus]. *Aten Primaria* 23:82-86, 1999

37. Tulokas T: [Relationship of self-monitoring of blood glucose and HbA1c in diabetic patients]. *Duodecim* 111:1304-1309, 1995

38. Llamas UC, Ares CC, Hernandez FE: [Self monitoring using a capillary glycemia measurement. Diabetes mellitus, type 2]. *Rev Enferm* 19:17-20, 1996

39. Charbonnel B, Boivineau C, Chopinet P, Daninos JM, Drouin P, Durain D, Guyon F, Passa P: [Blood glucose self-monitoring in diabetes. Recommendations of ALFEDIAM (French Language Association for the Study of Diabetes and Metabolic Diseases)]. *Diabete Metab* 21:285-289, 1995

40. Groh G: [Blood glucose self-monitoring with the Glucosignal test strip in routine practice--experiences of a district diabetes center]. *Z Gesamte Inn Med* 45:12-14, 1990

41. Wagner G: Blood sugar self-monitoring in type 2 non-insulin dependent diabetes- a view of literature. *Zeitschrift fur Allgemeinmedizin* 80:201-203, 2004

42. Grimaldi A, Sachon C: [Self-monitoring blood glucose in type 2 diabetes: for whom? And why? Which proofs?]. *Diabetes Metab* 29:S42-S46, 2003

43. Halimi S, Wion-Barbot N, Lambert S, Benhamou P: [Self-monitoring of blood glucose in type 2 diabetic patients. What could we propose according to their treatment?]. *Diabetes Metab* 29:S26-S30, 2003

44. Affres H: The value of glycemic self-monitoring in type 2 diabetes. *Medecine Therapeutique* 7:305-310, 2001

45. Charbonnel B, Aptel I, Amouyel P, Attali JR, Aulanier S, Balarac N, Bukowski JV, Cathelineau B, De Broucker T, Denis C, Mausset J, Ormieres JJ, Passa P, Paulhan A, Pousset F, Pouteil Noble C, Laversin S: Monitoring of type 2 diabetic patients with exception of follow-up of complications. *Revue du Praticien-Medecine Generale* 13:207-210, 1999

46. Halimi S: [Benefits of blood glucose self-monitoring in the management of insulin- dependent (IDDM) and non-insulin-dependent diabetes (NIDDM). Analysis of the literature: mixed results]. *Diabetes Metab* 24 Suppl 3:35-41, 1998

47. Withold W: Monitoring of metabolic control in diabetic patients with special regard to self-monitoring. *Clinical Laboratory* 43:249-256, 1997

48. Villiger U: Metabolic self-monitoring by diabetics: when to monitor blood and urine. *Schweizerische Medizinische Wochenschrift* 116:82-86, 1986

49. Herndon CM, Dole EJ, Rhyne RL, Fike DS: Validity of home blood glucose reporting by geriatric patients. *Am J Health Syst Pharm* 58:320-322, 2001

50. Bernbaum M, Albert SG, McGinnis J, Brusca S, Mooradian AD: The reliability of self blood glucose monitoring in elderly diabetic patients. *J Am Geriatr Soc* 42:779-781, 1994

51. Higgins C: Blood and urine tests for diagnosis and monitoring of diabetes. *British Journal of Nursing* 3:886-892, 1994

52. Raine CH: Self-monitored blood glucose: a common pitfall. *Endocrine Practice* 9:137-139, 2003

53. Kabadi UK, Kabadi MU: Capillary blood glucose testing in older people: reliable and accurate. *J Am Geriatr Soc* 51:136-137, 2003

54. Tippetts A, Callaway P, Leatherdale B, Rowe D: Assessing glycaemic control in non-insulin dependent diabetes: acceptability of blood sampling at home. *BMJ* 298:497-498, 1989

55. Owens D, Barnett AH, Pickup J, Kerr D, Bushby P, Hicks D, Gadsby R, Frier B: Blood glucose self-monitoring in type 1 and type 2 diabetes: reaching a multidisciplinary consensus. *Diabetes Primary Care* 6:8-16, 2004

56. Persell SD: What is the role of self-monitoring of blood glucose in non-insulin-treated diabetes? *Journal of Clinical Outcomes Management* 10:7-10, 2003

57. Tattersall R: Self monitoring of blood glucose concentrations by non-insulin dependent diabetic patients. *BMJ* 305:1171-1172, 1992

58. Roach P: Better systems, not guidelines, for glucose monitoring. *BMJ* 329:E332, 2004

59. Reynolds RM, Strachan MW: Home blood glucose monitoring in type 2 diabetes. *BMJ* 329:754-755, 2004

60. Heisler M: Glycemic self-monitoring and insurance coverage. *CMAJ* 171:48-49, 2004

61. Rose E, Ketchell D, Markova T: Clinical inquiries. Does daily monitoring of blood glucose predict hemoglobin A1c levels? *J Fam Pract* 52:485-490, 2003

62. Kerr D: Involving patients can work in home blood glucose testing. *BMJ* 326:103, 2003

63. Court M: The value of self-monitoring of blood glucose. *Diabetes Care* 25:1255-1256, 2002

64. Kennedy L: Self-monitoring of blood glucose in type 2 diabetes: time for evidence of efficacy. *Diabetes Care* 24:977-978, 2001

65. Butler RN, Rubenstein AH, Gracia AM, Zweig SC: Type 2 diabetes: patient education and home blood glucose monitoring. 3. *Geriatrics* 53:60, 63-64, 67, 1998

66. Cradock S: Blood glucose monitoring by people with diabetes. *Prof Nurse* 13:S11-S13, 1997

67. Tallis GA, Phillips PJ, Popplewell PY: Monitoring glucose control. *Aust Fam Physician* 26:976-977, 1997

68. Dunning T: How valuable are patients' blood glucose monitoring results? *Aust Fam Physician* 20:997, 1000, 1991

69. Nomura DM: Importance of using and understanding self-monitoring of blood glucose (SMBG) data in assessing ambient and long-term glycaemic control. *J Indian Med Assoc* 100:448, 450-448, 451, 2002

70. Burrill P: Is self-monitoring of glycaemic control of any value? *Pharmaceutical Journal* 268:847-848, 2002

71. Burrill P: Good management does not depend on self-monitoring. *Pharmaceutical Journal* 272:14, 2004

72. Phillips CA, Schaefer BJ, Molitch ME: Recent advances in self-monitoring of blood glucose. *Drug Benefit Trends* 13:41-45, 2001

73. Coster S, Gulliford M, Seed PT: Review: self-monitoring does not improve blood glucose control in type 2 diabetes mellitus. *Evidence Based Medicine* 6:81, 2001

74. Guthrie RA, Karem JH, Langer O: Self-monitoring of blood glucose. *Patient Care* 21:56-62, 1987

75. Patient education. Blood glucose monitoring at home. *Aust Fam Physician* 19:1283-1284, 1990

76. Maschak-Carey BJ: Monitoring blood glucose in the home. *Journal Home Health Care Practice* 4:35-38, 1992

77. Hoffman RM, Shah JH, Wendel CS, Duckworth WC, Adam KD, Bokhari SU, Dalton C, Murata GH: Evaluating once- and twice-daily self-monitored blood glucose testing strategies for stable insulin-treated patients with type 2 diabetes : the diabetes outcomes in veterans study. *Diabetes Care* 25:1744-1748, 2002

78. Murata GH, Hoffman RM, Duckworth WC, Wendel CS, Shah JH: Contributions of weekly mean blood glucose values to hemoglobin A1c in insulin-treated type 2 diabetes: the Diabetes Outcomes in Veterans Study (DOVES). *Am J Med Sci* 327:319-323, 2004

79. Lam KS, Ma JT, Chan EY, Yeung RT: Sustained improvement in diabetic control on long-term self-monitoring of blood glucose. *Diabetes Res Clin Pract* 2:165-171, 1986

80. Nyomba BL, Berard L, Murphy LJ: Facilitating access to glucometer reagents increases blood glucose self-monitoring frequency and improves glycaemic control: a prospective study in insulin-treated diabetic patients. *Diabet Med* 21:129-135, 2004

81. Schiel R, Muller UA, Rauchfub J, Sprott H, Muller R: Blood-glucose self-monitoring in insulin treated type 2 diabetes mellitus a cross-sectional study with an intervention group. *Diabetes Metab* 25:334-340, 1999

82. Harris MI, Cowie CC, Howie LJ: Self-monitoring of blood glucose by adults with diabetes in the United States population. *Diabetes Care* 16:1116-1123, 1993

83. Chwalow AJ, Costagliola D, Mesbah M, Moret L, Eschwege E: SMBG in NIDDM patients treated by general practitioners in France. *Diabetes Care* 13:454, 1990

84. Scorpiglione N, el Shazly M, Abdel-Fattah M, Belfiglio M, Cavaliere D, Carinci F, Labbrozzi D, Mari E, Massi BM, Tognoni G, Nicolucci A: Epidemiology and determinants of blood glucose self-monitoring in clinical practice. *Diabetes Res Clin Pract* 34:115-125, 1996

85. Bowker SL, Mitchell CG, Majumdar SR, Toth EL, Johnson JA: Lack of insurance coverage for testing supplies is associated with poorer glycemic control in patients with type 2 diabetes. *CMAJ* 171:39-43, 2004

86. Bjorsness DK, Krezowski PA, Harwell TS, McDowall JM, Butcher MK, Helgerson SD, Gohdes D: Self-blood glucose monitoring practices: do patients know and act on their target? *Diabetes Care* 26:3353-3354, 2003

87. Newman WP, Laqua D, Engelbrecht D: Impact of glucose self-monitoring on glycohemoglobin values in a veteran population. *Arch Intern Med* 150:107-110, 1990

88. Martin BJ, Young RE, Kesson CM: Home Monitoring of blood glucose in elderly non-insulin-dependent diabetics. *Practical Diabetes* 3:37, 1986

89. Chan WB, Chan JC, Chow CC, Yeung VT, So WY, Li JK, Ko GT, Ma RC, Cockram CS: Glycaemic control in type 2 diabetes: the impact of

body weight, beta-cell function and patient education. *QJM* 93:183-190, 2000

90. Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H: Evaluation of a pharmaceutical care model on diabetes management. *Ann Pharmacother* 30:238-243, 1996

91. Oh JA, Kim HS, Yoon KH, Choi ES: A telephone-delivered intervention to improve glycemic control in type 2 diabetic patients. *Yonsei Med J* 44:1-8, 2003

92. Davidson MB, Castellanos M, Kain D: Self-monitoring of blood glucose (SMBG) linked to nutritional counseling in minority type 2 diabetic patients on diet and oral antidiabetes medication does not improve glycaemic outcomes (Abstract). *Diabetes* 53 Supplement:A73, 2004

93. Seaton T: Benefit of self-monitoring of blood glucose in patients with NIDDM receiving oral sulfonylureas (Abstract). *Pharmacotherapy* 16:498, 1996

94. Lilienfeld DE, Stolley PD: *Foundations of epidemiology*. Oxford, Oxford University Press, 1994

95. Gulliford M, Latinovic R: Variations in glucose self-monitoring during oral hypoglycaemic therapy in primary care. *Diabet Med* 21:685-690, 2004

96. Blonde L, Ginsberg BH, Horn S, Hirsch IB, James B, Mulcahy K, Nettles A, Smout R, Wright H: Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. *Diabetes Care* 25:245-246, 2002

97. Hennekens CH, Buring JE: *Epidemiology in medicine*. Philadelphia, Lippincott, Williams and Wilkins, 1987

98. Gilden JL, Casia C, Hendryx M, Singh SP: Effects of self-monitoring of blood glucose on quality of life in elderly diabetic patients. *J Am Geriatr Soc* 38:511-515, 1990

99. Klein CE, Oboler SK, Prochazka A, Oboler S, Frank M, Glugla M, Winters S: Home blood glucose monitoring: effectiveness in a general population of patients who have non-insulin-dependent diabetes mellitus. *J Gen Intern Med* 8:597-601, 1993

100. Rindone JP, Austin M, Luchesi J: Effect of home blood glucose monitoring on the management of patients with non-insulin dependent diabetes mellitus in the primary care setting. *Am J Manag Care* 3:1335-1338, 1997

101. Wieland LD, Vigil JM, Hoffman RM, Janis LW: Relationship between home glucose testing and hemoglobin Alc in type II diabetes patients. *Am J Health Syst Pharm* 54:1062-1065, 1997

102. Karter AJ, Ackerson LM, Darbinian JA, D'Agostino RB, Jr., Ferrara A, Liu J, Selby JV: Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry. *Am J Med* 111:1-9, 2001

103. Meng TA, Devi PS, Tin AP, Lin AT, Kian TG: Impact of self-monitoring of blood glucose on glycaemic control in patients with type 2 diabetes mellitus. *Singapore Nursing Journal*41-47, 2003

104. Wen L, Parchman ML, Linn WD, Lee S: Association between self-monitoring of blood glucose and glycemic control in patients with type 2 diabetes mellitus. *Am J Health Syst Pharm* 61:2401-2405, 2004

105. Hjelm K, Nyberg P, Apelqvist J: Self-monitoring of blood glucose; frequency, determinants and self adjustment of treatment in an adult Swedish diabetic population. *Practical Diabetes International* 18:157-163, 2001

106. Patrick AW, Gill GV, MacFarlane IA, Cullen A, Power E, Wallymahmed M: Home glucose monitoring in type 2 diabetes: is it a waste of time? *Diabet Med* 11:62-65, 1994

107. Oki JC, Flora DL, Isley WL: Frequency and impact of SMBG on glycemic control in patients with NIDDM in an urban teaching hospital clinic. *Diabetes Educ* 23:419-424, 1997

108. Harris MI: Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. *Diabetes Care* 24:979-982, 2001

109. Franciosi M, Pellegrini F, De Berardis G, Belfiglio M, Cavaliere d, Di Nardo B, Greenfield S, Kaplan SH, Sacco M, Tognoni G, Valentini M, Nicolucci A: The Impact of Blood Glucose Self-Monitoring on Metabolic Control and Quality of Life in Type 2 Diabetic Patients: An urgent need for better educational strategies. *Diabetes Care* 24:1870-1877, 2001

110. Cohen M, Zimmet P: Self-monitoring of blood glucose levels in non-insulin-dependent diabetes mellitus. *Med J Aust* 2:377-380, 1983

111. Malik RL, Horwitz DL, McNabb WL, Takaki ET, Hawkins HA, Keys AG, Unterman TG: Adjustment of caloric intake based on self-monitoring in noninsulin-dependent diabetes mellitus: development and feasibility. *J Am Diet Assoc* 89:960-961, 1989

112. Rindone JP: Restricting home glucose-monitoring strips in patients taking oral antidiabetic agents. *Am J Health Syst Pharm* 55:2509-2511, 1998

113. Meier JL, Swislocki AL, Lopez JR, Noth RH, Bartlebaugh P, Siegel D: Reduction in self-monitoring of blood glucose in persons with type 2 diabetes results in cost savings and no change in glycemic control. *Am J Manag Care* 8:557-565, 2002

114. Banister NA, Jastrow ST, Hodges V, Loop R, Gillham MB: Diabetes self-management training program in a community clinic improves patient outcomes at modest cost. *J Am Diet Assoc* 104:807-810, 2004

115. Tajima N, Yamada C, Asukata I, Yamamoto K, Hokari M, Sakai T: Pilots with non-insulin-dependent diabetes mellitus can self-monitor their blood glucose. *Aviat Space Environ Med* 60:457-459, 1989

116. Ozmen B, Boyvada S: Can self-monitoring of blood glucose control decrease glycated hemoglobin levels in diabetes. *Endocrinologist* 12:349-356, 2002

117. Ozmen B, Boyvada S: The relationship between self-monitoring of blood glucose control and glycosylated haemoglobin in patients with type 2 diabetes with and without diabetic retinopathy. *J Diabetes Complications* 17:128-134, 2003

118. Wing RR, Epstein LH, Nowalk MP, Scott N, Koeske R, Hagg S: Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with type II diabetes? *Am J Med* 81:830-836, 1986

119. Rutten G, van Eijk J, de Nobel E, Beek M, van d, V: Feasibility and effects of a diabetes type II protocol with blood glucose self-monitoring in general practice. *Fam Pract* 7:273-278, 1990

120. Fontbonne A, Billault B, Acosta M, Percheron C, Varenne P, Besse A, Eschwege E, Monnier L, Slama G, Passa P: Is glucose self-monitoring beneficial in non-insulin-treated diabetic patients? Results of a randomized comparative trial. *Diabete Metab* 15:255-260, 1989

121. Allen BT, DeLong ER, Feussner JR: Impact of glucose self-monitoring on non-insulin-treated patients with type II diabetes mellitus. Randomized controlled trial comparing blood and urine testing. *Diabetes Care* 13:1044-1050, 1990

122. Estey AL, Tan MH, Mann K: Follow-up intervention: its effect on compliance behavior to a diabetes regimen. *Diabetes Educ* 16:291-295, 1990

123. Gallichan MJ: Self-monitoring by people receiving oral hypoglycaemic agents: a survey and a comparative trial. *Practical Diabetes* 11:28-30, 1994

124. Muchmore DB, Springer J, Miller M: Self-monitoring of blood glucose in overweight type 2 diabetic patients. *Acta Diabetol* 31:215-219, 1994

125. Miles P, Everett J, Murphy J, Kerr D: Comparison of blood or urine testing by patients with newly diagnosed non-insulin dependent diabetes: patient survey after randomised crossover trial. *BMJ* 315:348-349, 1997

126. Kibriya MG, Ali L, Banik NG, Khan AK: Home monitoring of blood glucose (HMBG) in Type-2 diabetes mellitus in a developing country. *Diabetes Res Clin Pract* 46:253-257, 1999

127. Brown SA, Garcia AA, Kouzekanani K, Hanis CL: Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. *Diabetes Care* 25:259-268, 2002

128. Schwedes U, Siebolds M, Mertes G: Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care* 25:1928-1932, 2002

129. Guerci B, Drouin P, Grange V, Bougneres P, Fontaine P, Kerlan V, Passa P, Thivolet C, Vialettes B, Charbonnel B: Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the Auto-Surveillance Intervention Active (ASIA) study. *Diabetes Metab* 29:587-594, 2003

130. Kwon HS, Cho JH, Kim HS, Song BR, Ko SH, Lee JM, Kim SR, Chang SA, Kim HS, Cha BY, Lee KW, Son HY, Lee JH, Lee WC, Yoon KH: Establishment of blood glucose monitoring system using the internet. *Diabetes Care* 27:478-483, 2004

131. Sarol JN, Jr., Nicodemus NA, Jr., Tan KM, Grava MB: Self-monitoring of blood glucose as part of a multi-component therapy among non-insulin requiring type 2 diabetes patients: a meta-analysis (1966-2004). *Curr Med Res Opin* 21:173-184, 2005

132. Faas A, Schellevis FG, Van Eijk JT: The efficacy of self-monitoring of blood glucose in NIDDM subjects. A criteria-based literature review. *Diabetes Care* 20:1482-1486, 1997

133. Wing RR, Epstein LH, Nowalk MP, Scott N, Koeske R, Hagg S: Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with type II diabetes? *Am J Med* 81:830-836, 1986

134. Holmes V, Griffiths P: Self-monitoring of glucose levels for people with type 2 diabetes. *Br J Community Nurs* 7:41-46, 2002

135. Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R: Monitoring blood glucose control in diabetes mellitus: a systematic review. *Health Technol Assess* 4:i-93, 2000

136. Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R: Self-monitoring in Type 2 diabetes mellitus: a meta-analysis. *Diabet Med* 17:755-761, 2000

137. Montori VM, Guyatt GH: Intention-to-treat principle. *CMAJ* 165:1339-1341, 2001

138. Schreurs KM, Colland VT, Kuijer RG, de Ridder DT, van Elderen T: Development, content, and process evaluation of a short self-

management intervention in patients with chronic diseases requiring self-care behaviours. *Patient Educ Couns* 51:133-141, 2003

139. van den Arend I, Stolk RP, Rutten GE, Schrijvers GJ: Education integrated into structured general practice care for Type 2 diabetic patients results in sustained improvement of disease knowledge and self-care. *Diabet Med* 17:190-197, 2000

140. Jones PM: Use of a course on self-control behavior techniques to increase adherence to prescribed frequency for self-monitoring blood glucose. *Diabetes Educ* 16:296-303, 1990

141. Conner M, Norman P: The role of social cognition in health behaviour. In *Predicting health behaviour.* Conner M, Norman P, Eds. Buckingham, Open University Press, 1996, p. 1-22

142. Leventhal H, Brissette I, Leventhal E: The common-sense model of self-regulation of health and illness. In *The self-regulation of health and illness behaviour.* Cameron L, Leventhal H, Eds. London, Routledge, 2003, p. 42-65

143. Rosenstock IM: The health belief model and preventive health behavior. *Health Education Monographs* 2:354-386, 1974

144. Norman P, Bennett P: Health locus of control. In *Predicting health behaviour.* Conner M, Norman P, Eds. Buckingham, Open University Press, 1996, p. 62-94

145. Rosenstock IM, Strecher VJ, Becker MH: Social learning theory and the Health Belief Model. *Health Educ Q* 15:175-183, 1988

146. Boer H, Seydel ER: Protection motivation theory. In *Predicting health behaviour.* Conner M, Norman P, Eds. Buckingham, Open University Press, 1996, p. 95-121

147. Ajzen I: From intentions to action: a theory of planned behaviour. In *Action control:from cognitions to behaviours.* Kuhl J, Beckman J, Eds. New York, Springer, 1985, p. 11-39

148. Bandura A: *Social foundations of thought and action: a social cognitive theory.* New Jersey, Prentice-Hall, 1986

149. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, Tyrer P: Framework for design and evaluation of complex interventions to improve health. *BMJ* 321:694-696, 2000

150. Norris SL, Engelgau MM, Narayan KM: Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 24:561-587, 2001

151. Loveman E, Cave C, Green C, Royle P, Dunn N, Waugh N: The clinical and cost-effectiveness of patient education models for diabetes: a

systematic review and economic evaluation. *Health Technol Assess* 7:iii, 1-iii190, 2003

152. Gary TL, Genkinger JM, Guallar E, Peyrot M, Brancati FL: Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educ* 29:488-501, 2003

153. Padgett D, Mumford E, Hynes M, Carter R: Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *J Clin Epidemiol* 41:1007-1030, 1988

154. Conrad KJ, Randolph FL, Kirby MWJ, Bebout RR: Creating and using logic models: four perspectives. *Alcoholism Treatment Quarterly* 17:17-31, 1999

155. Kok G, Schaalma H, Ruiter RA, van EP, Brug J: Intervention mapping: protocol for applying health psychology theory to prevention programmes. *J Health Psychol* 9:85-98, 2004

156. Hardeman W, Sutton S, Griffin S, Johnston M, White A, Wareham NJ, Kinmonth AL: A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health Educ Res* 2005

157. Hampson SE, Glasgow RE, Toobert DJ: Personal models of diabetes and their relations to self-care activities. *Health Psychol* 9:632-646, 1990

158. Hampson SE, Glasgow RE, Foster LS: Personal models of diabetes among older adults: relationship to self- management and other variables. *Diabetes Educ* 21:300-307, 1995

159. Hampson SE, Glasgow RE, Strycker LA: Belief versus feelings: A comparison of personal models and depression for predicting multiple outcomes in diabetes. *British Journal of Health Psychology* 5:27-40, 2000

160. Glasgow RE, Hampson SE, Strycker LA, Ruggiero L: Personal-model beliefs and social-environmental barriers related to diabetes self-management. *Diabetes Care* 20:556-561, 1997

161. Horne R: Representations of medication and treatment: advances in theory and measurement. In *Perceptions of health and illness*. Petrie KJ, Weinman J, Eds. Amsterdam, Harwood Academic Publishers, 1997, p. 155-188

162. Horne R, Weinman J: Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *J Psychosom Res* 47:555-567, 2001

163. Ruggiero L, Glasgow R, Dryfoos JM, Rossi JS, Prochaska JO, Orleans CT, Prokhorov AV, Rossi SR, Greene GW, Reed GR, Kelly K,

Chobanian L, Johnson S: Diabetes self-management. Self-reported recommendations and patterns in a large population. *Diabetes Care* 20:568-576, 1997

164. *Helping people change: a textbook of methods*. New York, Pergamon Press, 1986

165. Kanfer FH, Gaelick L: Self-management methods. In *Helping people change: a textbook of methods*. 3 ed. Kanfer FH, Goldstein AP, Eds. New York, Pergamon Press, 1986, p. 283-345

166. Cameron LD, Leventhal H: Self-regulation, health, and illness: an overview. In *The self-regulation of health and illness behaviour*. 1 ed. Cameron LD, Leventhal H, Eds. London, Routledge, 2003, p. 1-13

167. Petrie KJ, Cameron LD, Ellis CJ, Buick D, Weinman J: Changing illness perceptions after myocardial infarction: an early intervention randomized controlled trial. *Psychosom Med* 64:580-586, 2002

168. Locke EA, Latham GP: Building a practically useful theory of goal setting and task motivation. A 35-year odyssey. *Am Psychol* 57:705-717, 2002

169. Scheier MF, Carver CS: Goals and self-confidence as self-regulatory elements underlying health and illness behaviour. In *The self-regulation of health and illness behaviour*. 1 ed. Cameron LD, Leventhal H, Eds. London, Routledge, 2003, p. 17-41

170. Strecher VJ, Seijts GH, Kok GJ, Latham GP, Glasgow R, DeVellis B, Meertens RM, Bulger DW: Goal setting as a strategy for health behavior change. *Health Educ Q* 22:190-200, 1995

171. Sheldon KM, Elliot AJ: Goal striving, need satisfaction, and longitudinal well-being: the self-concordance model. *J Pers Soc Psychol* 76:482-497, 1999

172. Norman P, Conner M: The role of social cognition models in predicting health behaviours: future directions. In *Predicting health behaviour*. Conner M, Norman P, Eds. Buckingham, Open University Press, 1996, p. 197-225

173. Senecal C, Nouwen A, White D: Motivation and dietary self-care in adults with diabetes: are self-efficacy and autonomous self-regulation complementary or competing constructs? *Health Psychol* 19:452-457, 2000

174. Cullen KW, Baranowski T, Smith SP: Using goal setting as a strategy for dietary behavior change. *J Am Diet Assoc* 101:562-566, 2001

175. Gollwitzer PM, Branstaetter V: Implementation intentions and effective goal pursuit. *Journal of Personality and Social Psychology* 73:186-199, 1997

176. Schwarzer R, Fuchs R: Self-efficacy and health behaviours. In *Predicting health behaviour: research and practice with social cognition models*. 1 ed. Conner M, Norman P, Eds. Buckingham, Open University Press, 1996, p. 163-196

177. Gollwitzer PM: Goal Achievement: The role of Intentions. *European Review of Social Psychology* 4:141-185, 1993

178. Gollwitzer PM: Implementation intentions: strong effects of simple plans. *American Psychologist* 54:493-503, 1999

179. Hill-Briggs F: Problem solving in diabetes self-management: a model of chronic illness self-management behavior. *Ann Behav Med* 25:182-193, 2003

180. Toobert DJ, Glasgow RE: Problem solving and diabetes self-care. *J Behav Med* 14:71-86, 1991

181. Kilpatrick ES: Glycated haemoglobin in the year 2000. *J Clin Pathol* 53:335-339, 2000

182. Elasy TA, Ellis SE, Brown A, Pichert JW: A taxonomy for diabetes educational interventions. *Patient Educ Couns* 43:121-127, 2001

183. Roter DL, Hall JA, Merisca R, Nordstrom B, Cretin D, Svarstad B: Effectiveness of interventions to improve patient compliance: a meta-analysis. *Med Care* 36:1138-1161, 1998

184. Plsek PE, Greenhalgh T: Complexity science: The challenge of complexity in health care. *BMJ* 323:625-628, 2001

185. Weinman J, Petrie KJ, Moss-Morris R, Horne R: The Illness Perception Questionnaire: a new method for assessing the cognitive representation of illness. *Psychol Health* 11:431-445, 1996

186. Moss-Morris R, Weinman J, Petrie KJ, Horne R, Cameron LD, Buick D: The Revised Illness Perception Questionnaire. *Psychology and Health* 17:1-16, 2002

187. Horne R, Weinman J, Hankins M: The Beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol Health* 14:1-24, 1999

188. Toobert DJ, Glasgow RE: Assessing diabetes self-management: the summary of diabetes self-care activities questionnaire. In *Handbook of psychology and diabetes*. Bradley C, Ed. Amsterdam, Harwood Academic Publishers, 1994, p. 351-378

189. Toobert DJ, Hampson SE, Glasgow RE: The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* 23:943-950, 2000

190. Bradley C: The 12-Item Well-Being Questionnaire: origins, current stage of development, and availability. *Diabetes Care* 23:875, 2000

191. Bradley C: The Well-Being Questionnaire. In *Handbook of Psychology and Diabetes*. Bradley C, Ed. Amsterdam, Harwood Academic Publishers, 1994, p. 89-110

192. Bradley C: Diabetes Treatment Satisfaction Questionnaire: (DTSQ). In *Handbook of psychology and diabetes*. Bradley C, Ed. Amsterdam, Harwood Academic Publishers, 1994, p. 111-132

193. Rabin R, de Charro F: EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 33:337-343, 2001

194. Todd C, Bradley C: Evaluating the design and development of psychological scales. In *Handbook of psychology and diabetes*. Bradley C, Ed. Amsterdam, Harwood Academic Publishers, 1994, p. 15-42

195. Pope C, Ziebland S, Mays N: Analysing qualitative data. In *Qualitative Research in Health Care*. 2nd ed. Pope C, Mays N, Eds. London, BMJ Publishing Group, 1999, p. 75-88

196. Greenhalgh J: Cognitive Interviewing: What use is it to health psychologists? *?* 2002

197. Kline P: *Handbook of Psychological Testing*. Routledge, 1993

198. Bland JM, Altman DG: Statistics notes: Cronbach's alpha. *BMJ* 314:572, 1997

199. Kirkwood BR: *Essentials of medical statistics*. Oxford, Blackwell Science Ltd., 2001

200. Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B: Effect of adults' self-regulation of diabetes on quality-of-life outcomes. *Diabetes Care* 23:1511-1515, 2000

201. Heijmans M, de Ridder D: Assessing illness representations of chronic illness: explorations of their disease-specific nature. *J Behav Med* 21:485-503, 1998

202. Hampson SE: Illness Representations and the Self-Management of Diabetes. In *Perceptions of Health and Illness*. 2002, p. 323-347

203. Mahoney FI, Barthel DW: Functional evaluation: the Barthel index. *Md State Med J* 14:61-65, 1965

204. Altman DG, Bland JM: Treatment allocation by minimisation. *BMJ* 330:843, 2005

205. The national statistics socio-economic classification. [article online], 2005. Accessed 4 June 2005

206. Daniele L, Olivio B, Gianluca T, Paola F, Palatini P: Validation of the A&D UA-631 (UA-779 Life Source) device for self-measurement of blood pressure and relationship between its performance and large artery compliance. *Blood Pressure Monitoring* 7:1-6, 2002

207. Monnier L, Lapinski H, Colette C: Contributions of Fasting and Postprandial Plasma Glucose Increments to the Overall Diurnal Hyperglycemia of Type 2 Diabetic Patients: Variations with increasing levels of HbA1c. *Diabetes Care* 26:881-885, 2003

208. Postprandial blood glucose. American Diabetes Association. *Diabetes Care* 24:775-778, 2001

209. National Institute of Clinical Excellence. Management of type 2 diabetes. 2002.

210. Anderson JW, Kendall CW, Jenkins DJ: Importance of weight management in type 2 diabetes: review with meta-analysis of clinical studies. *J Am Coll Nutr* 22:331-339, 2003

211. Sacks FM, Svetkey LP, Vollmer WM, Appel LJ, Bray GA, Harsha D, Obarzanek E, Conlin PR, Miller ER, III, Simons-Morton DG, Karanja N, Lin PH: Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group. *N Engl J Med* 344:3-10, 2001

212. Whelton SP, Chin A, Xin X, He J: Effect of aerobic exercise on blood pressure: a meta-analysis of randomized, controlled trials. *Ann Intern Med* 136:493-503, 2002

213. Schulz KF, Grimes DA: Multiplicity in randomised trials I: endpoints and treatments. *Lancet* 365:1591-1595, 2005

214. Perneger TV: What's wrong with Bonferroni adjustments. *BMJ* 316:1236-1238, 1998

215. Gallichan M: Self monitoring of glucose by people with diabetes: evidence based practice. *BMJ* 314:964-967, 1997

216. Carey M, Daly H: Developing and piloting a structured, stepped approach to patient education. *Prof Nurse* 20:37-39, 2004

217. Roland M, Torgerson DJ: What are pragmatic trials? *BMJ* 316:285, 1998

218. Denzin NK, Lincoln YS: Introduction: the discipline and practice of qualitative research. In *Handbook of Qualitative Research*. 2nd ed. Denzin NK, Lincoln YS, Eds. Thousand Oaks, Sage Publications Inc., 2000, p. 1-28

219. Pope C, Mays N: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ* 311:42-45, 1995

220. Black N: Why we need qualitative research. *J Epidemiol Community Health* 48:425-426, 1994

221. Peel E, Parry O, Douglas M, Lawton J: Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. *Br J Gen Pract* 54:183-188, 2004

222. Fox MA, Cassmeyer V, Eaks GA, Hamera E, O'Connell K, Knapp T: Blood glucose self-monitoring usage and its influence on patients' perceptions of diabetes. *Diabetes Educ* 10:27-31, 1984

223. Tak-Ying Shiu A, Yee-Man Wong R: Fears and worries associated with hypoglycaemia and diabetes complications: perceptions and experience of Hong Kong Chinese clients. *Journal of Advanced Nursing* 39:155-163, 2002

224. Schoenberg NE, Drungle SC: Barriers to non-insulin dependent diabetes mellitus (NIDDM) self-care practices among older women. *J Aging Health* 13:443-466, 2001

225. Hall RF, Joseph DH, Schwartz-Barcott D: Overcoming obstacles to behavior change in diabetes self-management. *Diabetes Educ* 29:303-311, 2003

226. Marshall MN: Sampling for qualitative research. *Fam Pract* 13:522-525, 1996

227. Morse J: What's wrong with random selection? *Qual Health Res* 8:733-735, 1998

228. Morgan DL: *Focus groups as qualitative research.* Newbury Park, California, Sage Publications, 1997

229. Hjelm K, Nyberg P, Isacsson A, Apelqvist J: Beliefs about health and illness essential for self-care practice: a comparison of migrant Yugoslavian and Swedish diabetic females. *J Adv Nurs* 30:1147-1159, 1999

230. Kitzinger J: Focus groups with users and providers of health care. In *Qualitative research in health care.* 2nd ed. London, BMJ Books, 2000, p. 20-29

231. Britten N: Qualitative interviews in medical research. *BMJ* 311:251-253, 1995

232. Herxheimer A, McPherson A, Miller R, Shepperd S, Yaphe J, Ziebland S: Database of patients' experiences (DIPEx): a multi-media approach to sharing experiences and information. *Lancet* 355:1540-1543, 2000

233. Ezzy D: *Qualitative analysis: practice and innovation.* London, Routledge, 2002

234. Broom D, Whittaker A: Controlling diabetes, controlling diabetics: moral language in the management of diabetes type 2. *Soc Sci Med* 58:2371-2382, 2004

235. Fox C, Wade G, Fox A: What makes people with diabetes measure their own blood glucose? *Practical Diabetes* 11:244-246, 1994

236. Lawton J, Peel E, Douglas M, Parry O: 'Urine testing is a waste of time': newly diagnosed Type 2 diabetes patients' perceptions of self-monitoring. *Diabet Med* 21:1045-1048, 2004

237. Hjelm K, Bard K, Nyberg P, Apelqvist J: Religious and cultural distance in beliefs about health and illness in women with diabetes mellitus of different origin living in Sweden. *Int J Nurs Stud* 40:627-643, 2003

238. Simmons D, Weblemoe T, Voyle J, Prichard A, Leakehe L, Gatland B: Personal barriers to diabetes care: lessons from a multi-ethnic community in New Zealand. *Diabet Med* 15:958-964, 1998

239. Glasziou P, Irwig L, Mant D: Monitoring in chronic disease: a rational approach. *BMJ* 330:644-648, 2005

Glossary of abbreviations

ASIA	Auto-Surveillance Intervention Active
BEPAQ	Beliefs about Eating and Physical Activity Questionnaire
BGSM	Blood glucose self-monitoring
BMI	Body mass index
BMQ	Beliefs about Medicines Questionnaire
CHD	Coronary heart disease
CI	Confidence intervals
CSM	Common sense model
DCCT	Diabetes Control and Complications Trial
DIPEx	Personal experience of health and illness
DM	Diabetes mellitus
DTSQ	Diabetes Treatment Satisfaction Questionnaire
EDTA	Ethylenediaminetetraacetic acid
FPG	Fasting plasma glucose
GP	General practitioner
HDL	High density lipoprotein
IDDM	Insulin dependent diabetes mellitus
IPQ-R	Revised Illness Perception Questionnaire
MARS	Medication Adherence Rating Scale
MI	Myocardial infarction
MNT	Medical nutrition therapy
MRC	Medical Research Council
NHS	National Health Service
NIDDM	Non-insulin dependent diabetes mellitus
NS-SEC	National Statistics Socioeconomic Classification
OPREC	Oxford Psychiatric Research Ethics Committee
PCA	Principal components analysis
RCT	Randomized controlled trial
SD	Standard deviation
SDSCA	Summary of Diabetes Self-Care Activities scale
SEC	Socioeconomic classification
UKPDS	United Kingdom Prospective Diabetes Study
VA	Veterans Administration
WBQ	Well-Being Questionnaire

List of appendices

1. Intervention protocols[33]
2. Topic guide for development of preliminary questionnaire
3. Statistical distribution of items from evaluation of preliminary questionnaire
4. Final study questionnaire
5. Letter of invitation to potential trial participants
6. Living with Diabetes information pack
7. Action planning and BGSM diaries
8. Information sheet on BGSM
9. Diabetes treatment algorithm
10. Case record forms
11. Coding schedule for notes review/adverse events
12. Intervention fidelity checklist
13. Trial management committee list
14. Topic guide for qualitative study

[33] In the intervention protocols, the comparison group is referred to as Group 1, the less intensive monitoring group as Group 2 and the more intensive monitoring group as Group 3

Appendix 1

Intervention protocols

DiGEM

Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Assessment visit protocol v2.2

Changes since version 2.0

The following changes have been made to increase the focus on eliciting beliefs

- "What consequences might diabetes have for you" has been changed to read" What consequences do you think diabetes might have for you?"
- "What kinds of things do you think you could do to improve the control of your diabetes?" has been replaced with "Is there anything you think you could do to improve the control of your diabetes?"
- "How do you think medication might affect your diabetes?" has been changed to "Do you think medication might affect your diabetes? How?"
- The section regarding the information pack has been reworded to read " How do you feel about these suggestions? Do you think some of them might be feasible for you?"
- Reformatting of sections on discussion of diabetes and review of session

Aims of session:

- Explain the trial process and what will be required of the patient
- Explain role of the research nurse
- Obtain informed consent for participation in the trial
- Completion of self-reported measures and appropriate CRF's
- Obtain required blood samples
- Discussion of material presented in information pack
    - Reinforcing recognition of complications of diabetes and need for control of blood sugar
    - Identification of self-care activities that can influence diabetes
- Arrange randomization appointment in two weeks

Approach to patient

Good morning [patient name]. Thank you very much for agreeing to meet with me.

Ask permission to tape the interview, tape on, date and study number.

How are you feeling at the moment?

I'd like to tell you a bit more about the study to start off with. Is that okay with you?

Please ask me if you have any questions or of there is anything you aren't quite sure about.

We sent you a sheet giving some details about how the study will run. Have you had a chance to read it?

Do you have any questions about it?

Do you feel you have enough information about it to decide whether you would like to take part?

I'd like to check some details with you about the study to make sure there isn't anything you would like me to clarify.

The study will involve finding out ways that we can help people with diabetes manage their condition better. Does that seem like something you'd like to do?

We are asking people to follow one of three different programmes to try and improve their diabetes control. People will be placed in groups at random- one group will be asked to have extra blood tests done at the surgery and the other two groups will be asked to check their blood sugar at home. It is important that people continue with the programme that they start out in. Do you think you would be able to manage this, which ever group you were placed in?

The study would last for a year and I would see you for another six visits during the year. Do you think you would be able to manage that?

Our visits would involve mainly discussion about your views about your diabetes and how best you think you might be able to manage it. We would also review how you were doing with your diabetes control. How does that sound?

A second person who works with me may also be in touch with you during the year to ask if you'd be willing to discuss your experience of diabetes in more detail. You will have a chance to think about this and decide if you want to do it. Would that be okay with you?

Do you have any questions either about the information sheet or what we just discussed?

Proceed with completion of consent form.

If you are still willing to take part in the study, we need to ask you to complete this consent form.

Proceed with completion of CRFs 1-5 and taking of blood samples

Thank you. Now I'd like to get some information from you. Some of this will be things that we discussed over the telephone, so please bear with me.

Discussion around beliefs about diabetes and its seriousness (adapted from ADDITION II)

- Establish what attitudes and beliefs about diabetes are and its potential consequences, both in general and for the patient in particular. Note any unhelpful beliefs, but do not attempt to modify these specifically at this time.

Can you tell me a bit about how you view your diabetes? There are no right or wrong answers- I'm interested in your opinion.

- *possible causes of your diabetes*
- *effects of diabetes (emotional, physical and lifestyle) on your life*
- *Potential health consequences of diabetes for you*
- *what might happen in the future wrt your diabetes*
- *methods of controlling your diabetes*
- *effect of medication on your diabetes*

Did you receive our information pack? We will be using this as a basis for our discussions.

- *What did you think about it?*
- *thoughts about the suggestions for changes*
- *feasibility of the suggestions for you*

[If patient cannot recall suggestions, refer to ADDITION II pack] (Note helpful and unhelpful beliefs for future sessions.)

Thank you for discussing that with me. We'll have a chance to go into some more detail at future visits.

Review of session- checklist

- mention identification of broad areas in which changes might be possible
- ask patient to think about some areas for discussion at next visit
- make appointment for next visit in 2 weeks' time
- overview of next visit i.e what group they are assigned to and discussion of areas for change
- give patient questionnaire for completion- option of completing it in clinic or taking it home and returning it
- provide opportunity to ask questions
- telephone contact for nurse
-Thank patient for his/her time

DiGEM

Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Group 1 Contact 3 Protocol v2.2

Changes since v2.0

- Some questions regarding the motivation for change have been omitted to avoid repetition
- Additional questions regarding previous success/ failure with achieving goals have been included
- An explanation regarding the benefits of achieving goals via planning by stages has been included
- Confirmation of CRF 1 and 4 has been removed

Aims of session:

- Clarify concerns from previous session.
- Elicit previous experience of behaviour change and techniques used
- Identify priority areas for behaviour change
- Teach goal setting skills and identify specific behavioural goals within priority areas.
- Teach action planning skills and facilitate formulation of plans to achieve stated goals.
- Teach skills of monitoring of goals

Ask permission to tape the interview, tape on, date and study number.

Review of previous visit

- *current worries*
- *reaction after last visit*
- *clarification regarding last visit or information pack*
- *feedback on results from assessment visit if requested by patient*

Group allocation

You have been allocated you to group 1. This means that I will be teaching you skills that will help you to identify areas in which you can change your lifestyle in order to improve your diabetes control. We will also be offering you additional blood tests so we can monitor your blood sugar a little more closely. Is that okay with you?

Identification of priority areas for change (adapted from Hobbis and Hardeman)

I'd like to teach you a series of skills that you might find helpful in making changes. Have you ever tried making changes before?

- *type of change*
- *how was it done*
- *things that helped*
- *things that hindered*
- *ability to maintain changes*
- *any lessons learnt from the experience*

This programme suggests three steps in making changes

- *setting goals- helps us focus on what exactly we want to do*
- *action planning- helps us decide how we are going to do it and makes it easier to remember*
- *monitoring goals- helps us to keep an eye on things and see how they're going*

The first step in this process is to identify an area in which you might be able to make some changes. Last time we mentioned a number of ways that you might be able to control your diabetes better.

Of the areas we mentioned, is there one you would most like to make changes in? (if patient is unable to recall areas, refer to ADDITION II sheets as prompt)

Useful probes

"Do you feel more confident about making changes in one area than another?"

"Does one area seem more relevant to work on at this time?"

Do you think it might be important for you to make changes in [this area]? Why?

How confident are you that you can make changes in [this area]?

What might be the consequences of change in [...]?

Do you have any concerns about changing?

[Refer to notes made at assessment visit- reflect beliefs about diabetes and treatment raised there by patients to help with goal setting]

Setting of goal within priority area (adapted from Hobbis and Hardeman)

You've raised [...] as the area which you'd like to work on first. What about your [...] would you most like to work on?

Useful probes

" What about your [...] would you feel most confident about working on?"

How likely is it that you will [make this change]?

Is there anything else in your [...] you would like to work on?

(If patient is unable to select an area, review of a "typical day" may also help to determine where changes might be made in diet or physical activity)

If patient is unable, even after discussion of "typical day" to identify a goal, refer to ADDITION II information and highlight other recommended changes in selected domain as possible goals. Remember goals selected by patient are more likely to be successfully implemented. Goals identified should be specific- the size of the change and the manner of achieving it should be clear.

These are some areas in the information we gave you . Do you think you might make changes in any of these?

1. *Eating:*
    a. *Eating foods with less sugar and fat*
    b. *Filling up on fibre-rich foods including whole grains*
    c. *Taking care with alcohol*

OR

2. *Physical activity*
    a. *Increasing your activity*

OR

3. *Medication*
    a. *Taking your medication regularly*

Do you think you might like to work on this?

How likely is it that you will make [this change]?

Formulation of action plan (adapted from Hobbis and Hardeman)

You have decided to set [...] as a goal.

We have found that even with the best intentions, we may have problems remembering what we plan to do and how best to achieve it. Thinking about our goals in specific stages can help us to stay focussed and writing these things down can remind us what we'd like to do.

We've identified a number of stages which might help you in planning your goals and developed this diary where you can write these down.
The diary has the following headings:
When will you carry out your goal?

Where will you do it?

Are there any special preparations you need to make?

Who could support you?

Might anybody discourage you?

How could you remind yourself to carry out your goal?

How could you get round any difficulties?

What do you think you might put in each of those slots to help you in reaching your goal of [...]?

Self monitoring of goals (adapted from Hobbis and Hardeman)

Another skill I'd like to discuss with you is keeping a check on your goals to see how things are going. Some people have found this helpful when trying to achieve their goals.

What do you think it might be helpful to monitor?
Useful probes
- steps in your action plan
-whether or not you actually achieved your goal
- how you felt about achieving your goal
-what helped you achieve your goal
-what hindered you in achieving your goals

Why do you think might it be helpful to monitor these?

The diary I have given you has space to record how things are going for you- when do you think you might complete it?

How often do you think you might complete it?

Recap of session

- *broad areas*
- *goal selected within specific area*
- *action plan*
- *goal monitoring*
- *opportunity for questions*
- *next appointment in a month (bring diaries)*

DiGEM

Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Group 2 Contact 3 Protocol v2.2

Changes since v2.0

- Some questions regarding the motivation for change have been omitted to avoid repetition
- Additional questions regarding previous success/ failure with achieving goals have been included
- An explanation regarding the benefits of achieving goals via planning by stages has been included
- Confirmation of CRF 1 and 4 has been removed

Aims of session:

- Clarify concerns from previous session.
- Elicit previous experience of behaviour change and techniques used
- Identify priority areas for behaviour change
- Teach goal setting skills and identify specific behavioural goals within priority areas.
- Teach action planning skills and facilitate formulation of plans to achieve stated goals.
- Teach skills of monitoring of goals
- Teach patient techniques of blood glucose self-testing.

Ask permission to tape the interview, tape on, date and study number.

Review of previous visit

- *current worries*
- *reaction after last visit*
- *clarification regarding last visit or information pack*
- *feedback on results from assessment visit if requested by patient*

Group allocation

You have been allocated you to group 2. This means that I will be teaching you skills that will help you to identify areas in which you can change your lifestyle in order to improve your diabetes control. We will also be asking you to check your blood sugar at home so we can see how you're getting on. How does that sound?

Identification of priority areas for change (adapted from Hobbis and Hardeman)

I'd like to teach you a series of skills that you might find helpful when making changes. Have you ever tried making changes before?

- *type of change*
- *how was it done*
- *things that helped*
- *things that hindered*
- *ability to maintain changes*
- *any lessons learnt from the experience*

This programme suggests three steps in making changes

- *setting goals- helps us focus on what exactly we want to do*
- *action planning- helps us decide how we are going to do it and makes it easier to remember*
- *monitoring goals- helps us to keep an eye on things and see how they're going*

The first step in this process is to identify an area in which you might be able to make some changes. Last time we mentioned a number of ways that you might be able to control your diabetes better.

Of the areas we mentioned, is there one you would most like to make changes in? (if patient is unable to recall areas, refer to ADDITION II sheets as prompt)

Useful probes

"Do you feel more confident about making changes in one area than another?"

"Does one area seem more relevant to work on at this time?"

Do you think it might be important for you to make changes in [this area]? Why?

How confident are you that you can make changes in [this area]?

What might be the consequences of change in [...]?

Do you have any concerns about changing?

[Refer to notes made at assessment visit- reflect beliefs about diabetes and treatment raised there by patients to help with goal setting]

.

Setting of goal within priority area (adapted from Hobbis and Hardeman)

You've raised [...] as the area which you'd like to work on first. What about your [...] would you most like to work on?

Useful probes

" What about your [...] would you feel most confident about working on?"

How likely is it that you will [make this change]?

Is there anything else in your [...] you would like to work on?

(If patient is unable to select an area, review of a "typical day" may also help to determine where changes might be made in diet or physical activity)

If patient is unable, even after discussion of "typical day" to identify a goal, refer to ADDITION II information and highlight other recommended changes in selected domain as possible goals. Remember goals selected by patient are more likely to be successfully implemented. Goals identified should be specific- the size of the change and the manner of achieving it should be clear.

These are some areas in the information we gave you . Do you think you might make changes in any of these?

1. *Eating:*
    a. *Eating foods with less sugar and fat*
    b. *Filling up on fibre-rich foods including whole grains*
    c. *Taking care with alcohol*

OR

2. *Physical activity*
    a. *Increasing your activity*

OR

3. *Medication*
    a. *Taking your medication regularly*

Do you think you might like to work on this?

How likely is it that you will make [this change]?

Formulation of action plan (adapted from Hobbis and Hardeman)

You have decided to set [...] as a goal.

We have found that even with the best intentions, we may have problems remembering what we plan to do and how best to achieve it. Thinking about our goals in specific stages can help us to stay focussed and writing these things down can remind us what we'd like to do.

We've identified a number of stages which might help you in planning your goals and developed this diary where you can write these down.
The diary has the following headings:
When will you carry out your goal?

Where will you do it?

Are there any special preparations you need to make?

Who could support you?

Might anybody discourage you?

How could you remind yourself to carry out your goal?

How could you get round any difficulties?

What do you think you might put in each of those slots to help you in reaching your goal of [...]?

Self monitoring of goals (adapted from Hobbis and Hardeman)

Another skill I'd like to discuss with you is keeping a check on your goals to see how things are going. Some people have found this helpful when trying to achieve their goals.

What do you think it might be helpful to monitor?

Useful probes
- steps in your action plan
-whether or not you actually achieved your goal
- how you felt about achieving your goal
-what helped you achieve your goal
-what hindered you in achieving your goals

Why do you think might it be helpful to monitor these?

The diary I have given you has space to record how things are going for you- when do you

think you might complete it?

How often do you think you might complete it?

Teach technique of blood testing

Things to remember

- *preparatory materials- calibrated strips, meter, lancet, tissue/cotton wool, sharps bin*
- *method- clean hands, use of lancet, disposal of sharps, what to do if time elapses*
- *opportunity for questions*
- *CRF 7*
- *Opportunity to test blood*
- *Frequency of monitoring- three times a day on any two days of the week, fasting and either pre-lunch and pre-dinner or 2 hours after lunch and dinner*
- *Arrangements for refills*
- *Blood glucose diary- results, time,*
- *Target readings- 4-6 mmol/l if fasting or pre-meal; 6-8 mmol/l if 2 hours after meals*
- *Information sheet*
- *What to do if blood sugar is higher/lower than suggested*

Recap of session

- *broad areas*
- *goal selected within specific area*
- *action plan*
- *goal monitoring*
- *technique of BGSM*
- *opportunity for questions*
- *next appointment in a month (bring diaries)*

DiGEM

Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Group 3 Contact 3 Protocol v2.2

Changes since v2.0

- Some questions regarding the motivation for change have been omitted to avoid repetition
- Additional questions regarding previous success/ failure with achieving goals have been included
- An explanation regarding the benefits of achieving goals via planning by stages has been included
- Confirmation of CRF 1 and 4 has been removed

Aims of session:

- Clarify concerns from previous session.
- Elicit previous experience of behaviour change and techniques used
- Identify priority areas for behaviour change
- Teach goal setting skills and identify specific behavioural goals within priority areas.
- Teach action planning skills and facilitate formulation of plans to achieve stated goals.
- Teach skills of monitoring of goals
- Teach patient techniques of blood glucose self-testing.
- Explore patient's perceptions of how BGSM might be used to support behaviour change.

Ask permission to tape the interview, tape on, date and study number.

Review of previous visit

- *current worries*
- *reaction after last visit*
- *clarification regarding last visit or information pack*
- *feedback on results from assessment visit if requested by patient*

Group allocation

You have been allocated to group 3. This means that we are going to ask you to monitor your blood sugar at home so you can see how you are getting on. I will also discuss with you how you might be able to use these results to improve control of your blood sugar. Is that okay with you?

Identification of priority areas for change (adapted from Hobbis and Hardeman)

I'd like to teach you a series of skills that you might find helpful when making changes.

Have you ever tried making changes before?

- *type of change*
- *how was it done*
- *things that helped*
- *things that hindered*
- *ability to maintain changes*
- *any lessons learnt from the experience*

This programme suggests three steps in making changes

- *setting goals- helps us focus on what exactly we want to do*
- *action planning- helps us decide how we are going to do it and makes it easier to remember*
- *monitoring goals- helps us to keep an eye on things and see how they're going*

The first step in this process is to identify an area in which you might be able to make some changes. Last time we mentioned a number of ways that you might be able to control your diabetes better.

Of the areas we mentioned, is there one you would most like to make changes in? (if patient is unable to recall areas, refer to ADDITION II sheets as prompt)

Useful probes

"Do you feel more confident about making changes in one area than another?"

"Does one area seem more relevant to work on at this time?"

Do you think it might be important for you to make changes in [this area]? Why?

How confident are you that you can make changes in [this area]?

What might be the consequences of change in [...]?

Do you have any concerns about changing?

[Refer to notes made at assessment visit- reflect beliefs about diabetes and treatment raised there by patients to help with goal setting]

.

Setting of goal within priority area (adapted from Hobbis and Hardeman)

You've raised [...] as the area which you'd like to work on first. What about your [...] would you most like to work on?

Useful probes

" What about your [...] would you feel most confident about working on?"

How likely is it that you will [make this change]?

Is there anything else in your [...] you would like to work on?

(If patient is unable to select an area, review of a "typical day" may also help to determine where changes might be made in diet or physical activity)

If patient is unable, even after discussion of "typical day" to identify a goal, refer to ADDITION II information and highlight other recommended changes in selected domain as possible goals. Remember goals selected by patient are more likely to be successfully implemented. Goals identified should be specific- the size of the change and the manner of achieving it should be clear.

These are some areas in the information we gave you . Do you think you might make changes in any of these?

1. *Eating:*
    a. *Eating foods with less sugar and fat*
    b. *Filling up on fibre-rich foods including whole grains*
    c. *Taking care with alcohol*

OR

2. *Physical activity*
    a. *Increasing your activity*

OR

3. *Medication*
    a. *Taking your medication regularly*

Do you think you might like to work on this?

How likely is it that you will make [this change]?

Formulation of action plan (adapted from Hobbis and Hardeman)

You have decided to set [...] as a goal.

We have found that even with the best intentions, we may have problems remembering what we plan to do and how best to achieve it. Thinking about our goals in specific stages can help us to stay focussed and writing these things down can remind us what we'd like to do.

We've identified a number of stages which might help you in planning your goals and developed this diary where you can write these down.
The diary has the following headings:
When will you carry out your goal?

Where will you do it?

Are there any special preparations you need to make?

Who could support you?

Might anybody discourage you?

How could you remind yourself to carry out your goal?

How could you get round any difficulties?

What do you think you might put in each of those slots to help you in reaching your goal of [...]

Introduce the idea of the process of monitoring as a prompt to action, short term results as a prompt to action in certain circumstances, patterns of results both prompting changes and acting as a reward. Behavioural domain discussed should be the one which the patient has identified as the most important for them. Other domains may be discussed at follow-up visits.

Making changes in eating

How do you think that [your planned change in diet] might affect your blood sugar (short term - at different times of the day, long term)?

How might you see the effect of your diet on your blood sugar?

Are there any times when you think it might be useful to monitor your blood sugar?

Introduce idea of testing blood sugar after following foods if not raised by patient (depending on time - may need to leave to follow up sessions when the impact of these foods is raised):

- Sweets or pudding
- A high-fat meal
- Fruit
- A large meal
- A meal with starchy carbohydrates
- Cereals/fibre
- Alcohol

Beliefs about physical activity

We've mentioned [change in activity] as a useful change in behaviour. How do you think you might check to see the effect of physical activity on your blood sugar?

Introduce idea of BGSM as a check on activity

When might BGSM be useful if you are undertaking activity?

If not mentioned, introduce idea of:

- Before exercise to make sure levels are safe for exercise and reduce likelihood of hypoglycaemic attacks if on sulphonylureas
- Before exercise for a baseline level
- After exercise to see effect of activity on blood glucose
- As a prompt to get exercise to reduce blood sugar if it is too high

Beliefs about medication

Do you think taking your medication (if any) has any effect on your blood sugar? How do you think it affects your sugar?
How might you see what the effect of your medication on your blood sugar is?

How else might checking your blood sugar be useful as it regards your medication?
Introduce idea of pattern of results as a guide for doctor in adjusting medication.

Self monitoring of goals (adapted from Hobbis and Hardeman)

Another skill I'd like to discuss with you is keeping a check on your goals to see how things are going. Some people have found this helpful when trying to achieve their goals.

What do you think it might be helpful to monitor?
Useful probes
- steps in your action plan
-whether or not you actually achieved your goal
- how you felt about achieving your goal
-what helped you achieve your goal
-what hindered you in achieving your goals

Why do you think might it be helpful to monitor these?

The diary I have given you has space to record how things are going for you- when do you think you might complete it?

How often do you think you might complete it?

Teach technique of blood testing

Things to remember

- *preparatory materials- calibrated strips, meter, lancet, tissue/cotton wool, sharps bin*
- *method- clean hands, use of lancet, disposal of sharps, what to do if time elapses*
- *opportunity for questions*
- *CRF 7*
- *Opportunity to test blood*
- *Frequency of monitoring- three times a day on any two days of the week, fasting and either pre-lunch and pre-dinner or 2 hours after lunch and dinner*
- *Arrangements for refills*
- *Blood glucose diary- results, time, details of eating, physical activity and medication*

- *Target readings- 4-6 mmol/l if fasting or pre-meal; 6-8 mmol/l if 2 hours after meals*
- *Information sheet*
- *What to do if blood sugar is higher/lower than suggested*
- *Encourage measurements at other times e.eg not feeling well, after activity, different foods*

Recap of session

- *broad areas*
- *goal selected within specific area*
- *action plan*
- *goal monitoring*
- *technique of BGSM*
- *usefulness of information gained from BGSM*
- *opportunity for questions*
- *next appointment in a month (bring diaries) ; two week call*

DiGEM
Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Group 1 Follow up visit protocol (Three/Six/Nine month) v2.2

Changes from version v2.1

- The phrase "blood sugar control" has been replaced by "diabetes control"
- Reinforcement of the purpose of the trial and the steps involved in making changes has been added (6 month visit only)

Aims of session:

- Clarify concerns from previous session.
- Reinforce purpose of study (6 month visit only)
- Reiterate steps involved in making changes (6 month visit only)
- Review priority area selected at last visit and progress with goals
- Identify other priority areas for behaviour change to achieve improved overall glycaemic control.
- Identify behavioural goals within other priority areas.
- Facilitate formulation of plans to achieve goals.
- Reinforce lifestyle changes
- Review HbA_{1c}

Ask permission to tape the interview, tape on, date and study number.

Review of previous visit and completion of CRF 6 (if necessary); CRF 4, CRF 10

- *current worries*
- *reaction after last visit*
- *clarification regarding last visit or information pack*
- *feedback on results from assessment visit if requested by patient*

Reinforce purpose of study (6 month visit only)

You've been taking part in this study for six months now. How do you feel you've been getting on?

We hope that taking part in the study will help you to identify areas in which you can change your lifestyle in order to improve your diabetes control. How has this been going for you?

Recap of steps involved in making changes (6 month visit only)

I'd like to recap the steps for making changes that we discussed at the start of the trial

- *setting goals- helps us focus on what exactly we want to do*
- *action planning- helps us decide how we are going to do it and makes it easier to remember*
- *monitoring goals- helps us to keep an eye on things and see how they're going*

Do you think using these steps has been of any help to you during the trial?

Goal review

- review of domain and goal selected (review individually using probes)

Useful probes

- success in achieving goal
- usefulness of action plan
- usefulness of prompts and reminders
- was expected support provided
- usefulness of monitoring goal
- things that helped achieve goals
- things that hindered goal achievement
- methods of dealing with difficulties
- lessons learnt
- ability to maintain goal
- desire to attempt goal again (will require review of difficulties and development of strategies to deal, with them)
- addition of any other goals since last visit

Identification of further priority areas for change (adapted from Hobbis and Hardeman)

In our last visit, you chose [.....] as the area you'd like to work on first

Useful probes

Are there any other things in this area you'd like to work on? [see box below before moving on to another domain]

Of the other areas we mentioned, is there one you would most like to make changes in next?

"Do you feel more confident about making changes in one area than another?"

"Does one area seem more relevant to work on at this time?"

Do you think it might be important for you to make changes in [this area]? Why?

How confident are you that you can make changes in [this area]?

What might be the consequences of change in [...]?

Do you have any concerns about changing?

[Refer to notes made at assessment visit- reflect beliefs about diabetes and treatment raised there by patients to help with goal setting]

Setting of goal within priority area (adapted from Hobbis and Hardeman)

You've raised [...] as the area which you'd like to work on next. What about your [...] would you most like to work on?

Useful probes

" What about your [...] would you feel most confident about working on?"

How likely is it that you will [make this change]?

Is there anything else in your [...] you would like to work on?

(If patient is unable to select an area, review of a "typical day" may also help to determine where changes might be made in diet or physical activity)

If patient is unable, even after discussion of "typical day" to identify a goal, refer to ADDITION II information and highlight other recommended changes in selected domain as possible goals. Remember goals selected by patient are more likely to be successfully implemented. Goals identified should be specific- the size of the change and the manner of achieving it should be clear.

These are some areas in the information we gave you . Do you think you might make changes in any of these?

1. *Eating:*
    a. *Eating foods with less sugar and fat*
    b. *Filling up on fibre-rich foods including whole grains*
    c. *Taking care with alcohol*

OR

2. *Physical activity*
    a. *Increasing your activity*

OR

3. *Medication*
    a. *Taking your medication regularly*

Do you think you might like to work on this?

How likely is it that you will make [this change]?

Formulation of action plan (adapted from Hobbis and Hardeman)

You have decided to set [...] as your next goal.

Last time we looked at helpful stages in making plans- how do you think you might go about achieving this goal?

- *When will you carry out your goal?*
- *Where will you do it?*
- *Are there any special preparations you need to make?*
- *Who could support you?*
- *Might anybody discourage you?*
- *How could you remind yourself to carry out your goal?*
- *How could you get round any difficulties?*
- *What do you think you might put in each of those slots to help you in reaching your goal of [...]?*

Self monitoring of goals (adapted from Hobbis and Hardeman)

You've been monitoring your goals at home- how has that gone for you?

What do you think it might be helpful to monitor now?
Useful probes
- steps in your action plan

-whether or not you actually achieved your goal
- how you felt about achieving your goal
-what helped you achieve your goal
-what hindered you in achieving your goals

Why do you think might it be helpful to monitor these?

Do you think you'll complete the diary for these goals as well?

- *When will you do it?*
- *How often will you do it?*

Review of glycaemic control

One of two distinct messages should be provided, depending on the HbA_{1c}.

I've received the test result that tells us how well your diabetes is being controlled. It gives us an idea of how good the control of your blood sugar has been over the last three months.

Your results are excellent. Do you think that there is anything in particular that you have been doing which may have contributed to this? Do you think there is anything else you might do to help you maintain your control of your diabetes?

OR

Your results are higher than ideal. Do you think there is anything that you might have done that may have contributed to this? Is there anything that you might be able to do differently that might improve your diabetes control? [if not mentioned, prompt patient to recall the areas identified in each domain as target behaviours]

Review of session

- *Reviewed initial goals*
- *Selected area and specific goals again*
- *action plan*
- *goal monitoring*
- *reviewed HbA_{1c}*
- *opportunity for questions*
- *next appointment in three months (bring diary)*
- *blood test ten days before next visit, will be reviewed at visit [NOT AT NINE MONTH VISIT]*

DiGEM
Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Group 2 Follow up visit protocol (Three/six/nine month)v2.2

Changes since v2.1

- Emphasis on monitoring as per protocol has been added
- Reinforcement of the purpose of the trial and the steps involved in making changes has been added (6 month visit only)

Aims of session:

- Clarify concerns from previous session.
- Reinforce purpose of study (6 month visit only)
- Reiterate steps involved in making changes (6 month visit only)
- Review priority area selected at last visit and progress with goals
- Identify other priority areas for behaviour change to achieve improved overall glycaemic control.
- Identify behavioural goals within other priority areas.
- Facilitate formulation of plans to achieve goals.
- Reinforce lifestyle changes
- Review blood glucose readings
- Meter quality control (six month visit only)
- Obtain blood samples

Ask permission to tape the interview, tape on, date and study number.

Review of previous visit and completion of CRF 6 (if necessary), CRF 4, CRF 10

- *current worries*
- *reaction after last visit*
- *clarification regarding last visit or information pack*
- *feedback on results from assessment visit if requested by patient*

Reinforce purpose of study (6 month visit only)

You've been taking part in this study for six months now. How do you feel you've been getting on?

We hope that taking part in the study will help you to identify areas in which you can change your lifestyle in order to improve your diabetes control. How has this been going for you?

Recap of steps involved in making changes (6 month visit only)

I'd like to recap the steps for making changes that we discussed at the start of the trial

- *setting goals- helps us focus on what exactly we want to do*
- *action planning- helps us decide how we are going to do it and makes it easier to remember*
- *monitoring goals- helps us to keep an eye on things and see how they're going*

Do you think using these steps has been of any help to you during the trial?

Goal review

- review of domain and goal selected (review individually using probes)

Useful probes

- success in achieving goal
- usefulness of action plan
- usefulness of prompts and reminders
- was expected support provided
- usefulness of monitoring goal
- things that helped achieve goals
- things that hindered goal achievement
- methods of dealing with difficulties
- lessons learnt
- ability to maintain goal
- desire to attempt goal again (will require review of difficulties and development of strategies to deal, with them)
- addition of any other goals since last visit

Identification of further priority areas for change (adapted from Hobbis and Hardeman)

In our last visit, you chose [.....] as the area you'd like to work on first

Useful probes

Are there any other things in this area you'd like to work on? [see box below before moving on to another domain]

Of the other areas we mentioned, is there one you would most like to make changes in next?

"Do you feel more confident about making changes in one area than another?"

"Does one area seem more relevant to work on at this time?"

Do you think it might be important for you to make changes in [this area]? Why?

How confident are you that you can make changes in [this area]?

What might be the consequences of change in [...]?

Do you have any concerns about changing?

[Refer to notes made at assessment visit- reflect beliefs about diabetes and treatment raised there by patients to help with goal setting]

Setting of goal within priority area (adapted from Hobbis and Hardeman)

You've raised [...] as the area which you'd like to work on next. What about your [...] would you most like to work on?

Useful probes

" What about your [...] would you feel most confident about working on?"

How likely is it that you will [make this change]?

Is there anything else in your [...] you would like to work on?

(If patient is unable to select an area, review of a "typical day" may also help to determine where changes might be made in diet or physical activity)

If patient is unable, even after discussion of "typical day" to identify a goal, refer to ADDITION II information and highlight other recommended changes in selected domain as possible goals. Remember goals selected by patient are more likely to be successfully implemented. Goals identified should be specific- the size of the change and the manner of achieving it should be clear.

These are some areas in the information we gave you . Do you think you might make changes in any of these?

1. *Eating:*
    a. *Eating foods with less sugar and fat*
    b. *Filling up on fibre-rich foods including whole grains*

c. *Taking care with alcohol*

OR

2. *Physical activity*
   a. *Increasing your activity*

OR

3. *Medication*
   a. *Taking your medication regularly*

Do you think you might like to work on this?

How likely is it that you will make [this change]?

Formulation of action plan (adapted from Hobbis and Hardeman)

You have decided to set [...] as your next goal.

Last time we looked at helpful stages in making plans- how do you think you might go about achieving this goal?

- *When will you carry out your goal?*
- *Where will you do it?*
- *Are there any special preparations you need to make?*
- *Who could support you?*
- *Might anybody discourage you?*
- *How could you remind yourself to carry out your goal?*
- *How could you get round any difficulties?*
- *What do you think you might put in each of those slots to help you in reaching your goal of [...]?*

Self monitoring of goals (adapted from Hobbis and Hardeman)

You've been monitoring your goals at home- how has that gone for you?

What do you think it might be helpful to monitor now?

Useful probes

- steps in your action plan
-whether or not you actually achieved your goal
- how you felt about achieving your goal
-what helped you achieve your goal
-what hindered you in achieving your goals

Why do you think might it be helpful to monitor these?

Do you think you'll complete the diary for these goals as well?

- *When will you do it?*
- *How often will you do it?*

Review of blood sugar results and completion of CRF 14

You've also been testing your blood sugar at home

-how has that gone for you?
- any problems
-results review
-emphasize monitoring as per protocol

Focus on results over the four weeks immediately preceding the visit, provided there have been no unrepresentative periods e.g. illness.

If 75% or more (i.e. 6 or more assuming 8 results in past 4 weeks) pre-breakfast (fasting) results are within range (4-6 mmol/l) then control is good: *Your results are generally good- this means that the things you've been doing to control your blood sugar are working quite well.*

If more than 25% or more (i.e. 2 readings, assuming 8 results in last 4 weeks) fasting results are out of range (more than 6 mmol/l): *Your results suggest that your diabetes control could be improved. What do you think you might be able to do about that?* [if not mentioned, prompt regarding behavioural goals set out in this and previous visit]

If patients ask about the other results- *We are most are interested in seeing whether the other results are high (>15 mmol/l) low (<4 mmol/l).*

If patients raise questions regarding the direct relationship between their blood sugar and their eating and physical activity- refer to original information pack.
As we discussed at our last few visits, increasing your physical activity and modifying your diet are helpful in controlling your diabetes and reducing the likelihood of your developing complications from diabetes.

Completion of CRF 8 (at 6 month visit only)

I'd like to test your meter to be sure that it's working correctly. Is that okay with you?

Review of session and collection of blood sample

- *Reviewed initial goals*
- *Selected area and specific goals again*
- *action plan*
- *goal monitoring*
- *reviewed BGSM*
- *opportunity for questions*
- *next appointment in three months (bring diary)*
- *blood sample*

DiGEM
Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Group 3 Follow up visit protocol (Three/six/nine month)v2.2

Changes since v2.1

- Emphasis on monitoring as per protocol at each visit has been added
- Reinforcement of the purpose of the trial and the steps involved in making changes has been added (6 month visit only)

Aims of session:

- Clarify concerns from previous session.
- Reinforce purpose of study (6 month visit only)
- Reiterate steps involved in making changes (6 month visit only)
- Review priority area selected at last visit and progress with goals
- Identify other priority areas for behaviour change to achieve improved overall glycaemic control.
- Identify behavioural goals within other priority areas.
- Facilitate formulation of plans to achieve goals.
- Reinforce lifestyle changes
- Review blood glucose diary and encourage recognition of relationship between behaviour and blood glucose results
- Address concerns relating to blood glucose monitoring
- Meter quality control (six month visit only)
- Obtain blood samples

Ask permission to tape the interview, tape on, date and study number.

Review of previous visit and completion of CRF 6 (if necessary)

- *current worries*
- *reaction after last visit*
- *clarification regarding last visit or information pack*
- *feedback on results from assessment visit if requested by patient*

Reinforce purpose of study (6 month visit only)

You've been taking part in this study for six months now. How do you feel you've been getting on?

We hope that taking part in the study will help you to identify areas in which you can change your lifestyle in order to improve your diabetes control and see how using your blood glucose meter might help you with this. How has this been going for you?

Recap of steps involved in making changes (6 month visit only)

I'd like to recap the steps for making changes that we discussed at the start of the trial

- *setting goals- helps us focus on what exactly we want to do*
- *action planning- helps us decide how we are going to do it and makes it easier to remember*
- *monitoring goals- helps us to keep an eye on things and see how they're going*

Do you think using these steps has been of any help to you during the trial?

Goal review

- review of domain and goal selected (review individually using probes)

Useful probes

- success in achieving goal
- usefulness of action plan
- usefulness of prompts and reminders
- was expected support provided
- usefulness of monitoring goal
- things that helped achieve goals
- things that hindered goal achievement
- methods of dealing with difficulties
- lessons learnt
- ability to maintain goal
- desire to attempt goal again (will require review of difficulties and development of strategies to deal, with them)
- addition of any other goals since last visit

Identification of further priority areas for change (adapted from Hobbis and Hardeman)

In our last visit, you chose [.....] as the area you'd like to work on first

Useful probes

Are there any other things in this area you'd like to work on? [see box below before moving on to another domain]

Of the other areas we mentioned, is there one you would most like to make changes in next?

"Do you feel more confident about making changes in one area than another?"

"Does one area seem more relevant to work on at this time?"

Do you think it might be important for you to make changes in [this area]? Why?

How confident are you that you can make changes in [this area]?

What might be the consequences of change in [...]?

Do you have any concerns about changing?

[Refer to notes made at assessment visit- reflect beliefs about diabetes and treatment raised there by patients to help with goal setting]

Setting of goal within priority area (adapted from Hobbis and Hardeman)

You've raised [...] as the area which you'd like to work on next. What about your [...] would you most like to work on?

Useful probes

" What about your [...] would you feel most confident about working on?"

How likely is it that you will [make this change]?

Is there anything else in your [...] you would like to work on?

(If patient is unable to select an area, review of a "typical day" may also help to determine where changes might be made in diet or physical activity)

If patient is unable, even after discussion of "typical day" to identify a goal, refer to ADDITION II information and highlight other recommended changes in selected domain as possible goals. Remember goals selected by patient are more likely to be successfully implemented. Goals identified should be specific- the size of the change and the manner of achieving it should be clear.

These are some areas in the information we gave you . Do you think you might make changes in any of these?

1. *Eating:*

a. *Eating foods with less sugar and fat*
b. *Filling up on fibre-rich foods including whole grains*
c. *Taking care with alcohol*

OR

2. *Physical activity*
   a. *Increasing your activity*

OR

3. *Medication*
   a. *Taking your medication regularly*

Do you think you might like to work on this?

How likely is it that you will make [this change]?

Formulation of action plan (adapted from Hobbis and Hardeman)

You have decided to set [...] as your next goal.

Last time we looked at helpful stages in making plans- how do you think you might go about achieving this goal?

- *When will you carry out your goal?*
- *Where will you do it?*
- *Are there any special preparations you need to make?*
- *Who could support you?*
- *Might anybody discourage you?*
- *How could you remind yourself to carry out your goal?*
- *How could you get round any difficulties?*
- *What do you think you might put in each of those slots to help you in reaching your goal of [...]?*

Self monitoring of goals (adapted from Hobbis and Hardeman)

You've been monitoring your goals at home- how has that gone for you?

What do you think it might be helpful to monitor now?
Useful probes
- steps in your action plan
-whether or not you actually achieved your goal
- how you felt about achieving your goal
-what helped you achieve your goal
-what hindered you in achieving your goals

Why do you think might it be helpful to monitor these?

Do you think you'll complete the diary for these goals as well?

- *When will you do it?*
- *How often will you do it?*

Review of blood sugar results and completion of CRF 14 (adapted from Hobbis and Hardeman

You've also been monitoring your blood sugar at home- how has that gone for you?

Discuss changes individually using following probes

- *Has change affected blood glucose results?*
- *How do you think change has affected results?*
- *Do your results tell you anything about the change?*
- *Did monitoring your blood sugar help you to achieve your goals?*

General probes

- *Do you think there is anything you might be able to learn from these results?*
- *What about from monitoring your blood sugar at home in general?*
- *Has monitoring your blood sugar influenced the way you think about managing your diabetes?*
- *Have the results of your monitoring influenced how you think about diabetes e.g. its complications?*
- *Are there any changes you could make to your goal in light of these results?*
- *Have you had any problems with monitoring? May I see your results?*

Focus on results over the four weeks immediately preceding the visit, provided there have been no unrepresentative periods e.g. illness.

If 75% or more (i.e. 6 or more assuming 8 results in past 4 weeks) pre-breakfast (fasting) results are within range (4-6 mmol/l) then control is good: *Your results are generally good. Do you think there is anything you have been doing to contribute to this? Has monitoring your blood sugar helped you in this process?*

If more than 25% or more (i.e. 2 readings, assuming 8 results in last 4 weeks) fasting results are out of range (more than 6 mmol/l): *Your blood sugar results are higher than ideal. Do you think there is anything that you've been doing that might have contributed to that? What do you think you might do about this now?* [if not mentioned, prompt regarding behavioural goals set out in this and previous visit] *How do you think your blood sugar monitoring might help you do these things?*

If no lifestyle factors can be identified, i.e. pt undertakes regular activity and follows appropriate diet plan, medication adjustment may be warranted- *From our discussion, it seems that even though you are doing everything you should, your blood sugars remain high. It might be worth making an appointment with your GP to discuss this and see whether a change in medication is warranted.*

Highlight individual out of range results and discuss behaviours which might have influenced them: *This result is higher/lower than usual(advisable). Had you done anything unusual? Did you do anything in particular when you got this result? If so, what?*

Possible issues with BGSM which may be raised by patient (be familiar with these; discussion of them should be initiated by the patient):

- *I find it painful-* How do you think you might overcome that? Could you do it a different way? May need to suggest areas in which finger pricking can be less painful
- *I keep getting the same reading and it's normal all the time-* What do you think that might mean? How do you feel about that? Tell me more about exactly when you are testing yourself? Tell me more about your lifestyle. May need to explore whether blood sugar is well controlled or there is a problem in achieving better control (or using the meter). Try and encourage continuing use of the meter.
- *It causes me to worry-*Tell me how it affects you? Why is that? What are the good points of checking for you? May need to investigate underlying beliefs about 'good' and 'bad' control or other fears.
- *I prefer if my doctor checks my blood sugar-*Tell me how you feel when you check your blood sugar. What sort of things does it make you feel or think? What additional benefits might you be able to give to your health care professional with the results of regular checks?
- *I can tell whether my blood sugar is abnormal without testing it-* Tell me more? Give me some examples. Identify extent to which systematic assessment has been undertaken. Emphasis on personal control. 'Some people find that they become less able to tell over time - especially if their control becomes less good

Completion of CRF 8 (at 6 month visit only)

I'd like to test your meter to be sure that it's working correctly. Is that okay with you?

Emphasize at all visits the importance of monitoring as per protocol.

Review of session and collection of blood sample

- *Reviewed initial goals*
- *Selected area and specific goals again*
- *action plan*
- *goal monitoring*
- *reviewed BGSM and relationship of results to monitoring*
- *opportunity for questions*
- *next appointment in three months (bring diary)*
- *collect blood sample*

DiGEM
Diabetes Glycaemic Education and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

One year follow-up visit for all groups v1.3

Changes since v1.2

- Use of quality control solution for groups 2& 3 has been removed

Aims of session:

- Perform clinical assessment
- Obtain blood samples
- Inform patients about arrangements for return to usual care
- Meter quality control
- Recording of blood glucose readings (grp 2 & 3 only)

Review of previous visit and completion of CRF 6 (if necessary), CRF 4, CRF 10, CRF 12

Thank you for coming back to see me. Is there anything from our last session that you would like to talk about? How have you been since our last appointment?

This will be our last appointment. Is there anything you'd like to ask me?

Today, I'll need to ask you a few extra questions, check your weight and blood pressure and take a blood sample. Is that okay with you?

Recording of blood glucose results and meter quality control (completion of CRF 8 & 14, with exception of control solution)

I'd like to see your blood glucose results so I can record how they have been since our last visit.

Collection of blood sample and arrangements for return to GP

I'd like to take that blood sample from you now, if that's okay.

Do you have any questions? I'd like to thank you very much for taking part in this study. Have you found our sessions useful? Now that the trial is over, you'll go back to your GP for all of your care and I won't be seeing you anymore. We will be in touch with your GP to let him/her know that the trial is over now and that we will not be seeing you any more.

Decisions about continuing blood sugar monitoring

If patient asks, explain that the frequency of monitoring was for the purposes of the study and whether or not they continue to monitor should be determined by their clinical needs and should be discussed with their GP.

I'd like to ask you to complete this questionnaire- it's similar to the one you completed at the start of the trial. If you have time, please complete it now. If not, you can post it back to me in the FREEPOST envelope.

Thank you very much for your participation.

Appendix 2

Topic guide for development of preliminary questionnaire

Development and evaluation of an intervention to link the results of blood glucose self monitoring to increased awareness of medication adherence, eating, and physical activity

Topic Guide

Objective

The purpose of this programme of work is

a) To develop a standardized training package to support the use of self monitoring of blood glucose as a method of increasing adherence to medication, concordance with dietary advice and undertaking of moderate levels of physical activity in people with type 2 diabetes mellitus

b) To develop measures of attitudes towards concordance with dietary advice and undertaking moderate levels of physical activity among people with type 2 diabetes, which may be used to explain changes in outcome in a proposed clinical trial.

c) To evaluate a previously developed measure of attitude to medication adherence, and the proposed measure of attitude to diet and physical activity, for internal consistency and external validity in a survey of people with type 2 diabetes

The interviews undertaken using this topic guide will inform all stages of the programme described above. The structure of this interview is based around an initial narrative account in order to identify the range of areas that are relevant. However, the interview will then move to focus on beliefs and attitudes guided by self-regulation.

This topic guide will be serially revised, and then used to develop a brief structured interview schedule that will inform the content of measures of belief and attitude in relation to eating and physical exercise, in addition to further exploration of the mechanisms through which eating, physical activity and medication might affect blood glucose and hence assist in the development of the intervention.

Topic	Mediators of behaviour	Question	Further prompts
Basic demographics		Tell me a little bit about yourself	Age, occupation, family, ethnic origin
Narrative story of diabetes		Tell me about how you came to have diabetes and how things have gone for you? *(Try and cover as many of the subsequent points by open ended questioning leading on from issues raised by the interviewee)*	Why not start at the beginning? What happened next? When was that in relation to..? Perhaps you could go back to…? Could you tell me more about that? How did it make you feel? What were you thinking at the time?
Explore specific beliefs about diabetes	Cause	Tell me how you came to have diabetes?	Is there anything you think causes people to develop diabetes? Is there anything that you think might have caused you to have diabetes? Do you think that something you did may have been responsible? Is there anything anybody can do to prevent himself or herself from developing diabetes? Is there anything you think you could have done to prevent yourself from developing diabetes?
	Illness identity	Tell me how you think diabetes affects you at the moment (physically, emotionally, lifestyle)	How did you feel when you first were found to have diabetes? How does diabetes make you feel now? What is it about diabetes that affects you in this way? *(mechanism/metaphor)* Do you think it's important to control your blood sugar? Why? Do you think that changes in blood sugar lead to any effects on you in the long/short term? How do you think changes in blood sugar cause those effects? Can people tell if their blood sugar is high/low? Can you tell if your blood sugar is high/low?
	Timeline	What do you think will happen as far as <u>your</u> having diabetes is concerned?	Do you think <u>your</u> diabetes will get better or worse over time? Do you think <u>your</u> diabetes comes and goes or is it there all the time? Does your diabetes affect you at the moment? How so? Over what sort of period of time do you think it might lead to problems?

	Controllability	Is there anything that might make your diabetes get worse or better?	Could you tell me more about that..? What do you mean by getting worse? What do you mean by getting better? (*check timeline/? Ideas about cure*) What would signify for you that your diabetes was getting better? What would signify for you that your diabetes was getting worse? What sort of things might <u>you</u> do to help control your diabetes? Is there anything you can do to influence your diabetes? Can I check exactly what behaviour you are describing? How do you think that will make the diabetes get worse or better *(mechanism – look for metaphors)* Do you know anybody with diabetes? How do they control their condition? Have you ever tried any of these things? *Enquire specifically about eating, physical activity and taking medication. Delineate carefully their first thoughts about formulating these behaviours.*
	Consequences	Tell me how you think diabetes might affect you in the future	What sorts of things happen to people with diabetes? Are those things likely to happen to you? Why? How does diabetes lead to those things? What sort of things might make those things happen or not happen?
Explore beliefs about following advice to eat *(using phrasing elicited above)*		If you were to eat ……. , how would this affect you – how would it help, how would it harm you? How necessary is …. to your diabetes? • excluding sugary foods • eating low fat food • eating fruit and vegetables	How do you think this might help with control of diabetes (*blood sugar?*)? How do you think it might affect the way you feel (in general)? How would doing this help you and your diabetes? How would doing this harm you and your diabetes? *Mechanisms/Metaphors*
Explore beliefs about undertaking activity *(using phrasing elicited above*		If you were to do ……. , how would this affect you – how would it help, how would it harm you? How necessary is exercising to your diabetes control? Has your exercise pattern changed since you were diagnosed with diabetes?	How do you think this might help with control of diabetes (*blood sugar?*)? How do you think it might affect the way you feel (in general)? How would doing this help you and your diabetes? How would doing this harm you and your diabetes? Does physical activity have any effect on your diabetes? How so? Does it affect our diabetes in particular or your health in general? *Mechanisms/Metaphors*

Explore beliefs about taking medication *(using phrasing elicited above*		If you were to take you medication regularly, how would this affect you – how would it help, how would it harm you? How necessary is taking your medication in controlling your diabetes? How easy is it for you to control your diabetes?	How do you think this might help with control of diabetes (*blood sugar*?)? How do you think it might affect the way you feel (in general)? How would doing this help you and your diabetes? How would doing this harm you and your diabetes? *Mechanisms/Metaphors*
Explore beliefs about control of blood sugar		Do you test your blood sugar? *(If yes)*How does testing your blood sugar affect you? (*If no*)How do you think testing your blood sugar might affect you?	In relation to [behaviour] what might you do differently if you knew the results of blood sugar tests? (check back – is the mechanisms of how the behaviour might affect the blood sugar clear?) Why do you check your blood sugar? What prompted you to start checking your blood sugar? How long have you been checking your blood sugar for? When do you check your blood sugar (i.e. according to a routine, if feeling ill, after a big meal, before exercise)? What do you do when you get the results of a blood sugar reading? Does knowing the results of your blood sugar affect the way you eat/exercise/take your medication? Have you ever treated your blood sugar results differently than you do now? If you had a single reading that was high/low what would you do? If you had a series of high or low readings – what would you do? What difference would different readings throughout the day make? Check that comments made for eating, physical activity and medication taking

Appendix 3

Statistical distribution of items from evaluation of preliminary questionnaire

Item	Mean	S. D.
My diabetes will last a short time	1.66	.927
My diabetes is likely to be permanent rather than temporary	4.24	.952
My diabetes will last for a long time	4.26	.896
This diabetes will pass quickly	1.50	.700
I expect to have this diabetes for the rest of my life	4.34	.819
My diabetes is a serious condition	3.86	1.015
My diabetes has major consequences on my life	3.34	1.125
My diabetes does not have much effect on my life	2.72	1.126
My diabetes strongly affects the way others see me	2.09	.975
My diabetes has serious financial consequences	2.13	.981
My diabetes causes difficulties for those who are close to me	2.39	1.038
There is a lot which I can do to control my symptoms	4.17	.652
What I do can determine whether my diabetes gets better or worse	4.14	.696
The course of my diabetes depends on me	4.05	.708
Nothing I do will affect my diabetes	1.97	.977
I have the power to influence my diabetes	3.93	.866
My actions will have no effect on the outcome of my diabetes	2.10	.980
My diabetes will improve in time	2.32	1.042
There is very little that can be done to improve my diabetes	2.43	1.089
My treatment will be effective in curing my diabetes	2.46	1.103
The negative effects of my diabetes can be prevented (avoided) by my treatment	3.62	.863
My treatment can control my diabetes	2.15	.526
There is nothing which can help my condition	1.89	.845
The symptoms of my condition are puzzling to me	2.47	1.022
My diabetes is a mystery to me	2.44	1.019
I don't understand my diabetes	2.30	.931
My diabetes doesn't make any sense to me	2.31	.941
I have a clear picture or understanding of my condition	3.73	.834
The symptoms of my diabetes change a great deal from day to day	2.38	.852
My symptoms come and go in cycles	2.54	.940
My diabetes is very unpredictable	2.43	.922
I go through cycles in which my diabetes gets better and worse	2.63	.967
I get depressed when I think about my diabetes	2.39	.983
When I think about my diabetes I get upset	2.18	.891
My diabetes makes me feel angry	2.22	.955
My diabetes does not worry me	2.98	1.015
Having this diabetes make me feel anxious	2.58	.959
My diabetes makes me feel afraid	2.24	.848

Means and standard deviations of non-causal IPQ-R items

Item	Mean	S.D.
I am worried about my diabetes getting worse	3.37	.984
I am now comfortable with the idea of having diabetes	3.42	.852
I am afraid of the consequences of having diabetes	3.17	1.047
If my blood sugar were high over a short period of time, it would damage my body	3.14	.942
My diabetes could cause me to go into a coma	3.43	1.032
My diabetes could cause me to have kidney damage	3.78	.792
My diabetes could cause me to have problems with my feet	4.10	.509
My diabetes could cause me to have problems with my eyesight	4.18	.539
My diabetes makes me more likely to have heart disease	3.78	.758
My diabetes makes me more likely to get infections	3.53	.814
My diabetes reduces the quality of my life	2.81	.975
I think my diabetes will get better if I improve my lifestyle	2.96	1.029
I think my diabetes will stay the same	3.07	.917
Worsening of my diabetes is unavoidable	2.82	.901
I try not to think about my diabetes as much as possible	3.48	.919

Means and standard deviations of additional diabetes-specific illness representation items

Item	Mean	S.D.
Stress or worry	2.99	1.108
Hereditary	3.05	1.358
A germ or virus	1.95	.806
Diet or eating habits	3.64	.955
Chance or bad luck	2.55	1.134
Poor medical care in my past	1.96	.827
Pollution in the environment	2.04	.822
My own behaviour	3.00	1.130
My mental attitude	1.97	.842
Family problems or worries	2.35	1.079
Overwork	2.41	1.049
My emotional state	2.42	1.049
Aging	3.65	.880
Alcohol	2.28	1.034
Smoking	2.06	1.007
Accident or injury	1.94	.773
My personality	2.06	.868
Altered immunity	2.51	.903

Means and standard deviations of IPQ-R causal items

Item	Mean	S.D.
Being overweight	3.81	.939
Eating too many sweets and puddings	3.24	1.059
Not getting enough exercise	3.51	.986
An unhealthy lifestyle	3.31	1.030

Means and standard deviations of additional diabetes-specific causal items

Item	Mean	S.D.
My health at present depends on my diabetes medicines	4.01	.676
Having to take diabetes medicines worries me	2.32	.877
My life would be impossible without my diabetes medicines	3.50	.889
I sometimes worry about the long term effects of my medicines	2.93	.981
Without my diabetes medicines I would be very ill	3.58	.946
These diabetes medicines are a mystery to me	2.62	.943
My health in the future will depend on my diabetes medicines	3.98	.611
These diabetes medicines disrupt my life	2.00	.679
I sometimes worry about becoming too dependent on my diabetes medicines	2.46	.965
My diabetes medicines protect my health from becoming worse	4.03	.621
My diabetes medicines give me unpleasant side effects	2.42	1.011

Means and standard deviations of BMQ items

Item	Mean	S.D.
Medication is important in controlling my diabetes	3.96	.968
Medication would allow/allows me to be less strict about my diet	2.79	.987
I would be distressed if I had to use insulin to control my diabetes	3.92	1.018
I might increase the dose of my medication if I ate something which I knew would send up my blood sugar	2.38	.981
I would think my diabetes was getting worse if I had to start taking tablets or change the ones I was on	3.52	.917
I would think my diabetes was getting better if I could stop or reduce my tablets	3.34	.986
Medication is important in controlling my diabetes	3.96	.968

Means and standard deviations of additional beliefs about medication items

Item	Mean	SD
Because I have diabetes, it is important for me to eat less food	2.84	.971
Because I have diabetes, it is very important for me to reduce the sugar in my diet	4.37	.612
Having an occasional sweet will not affect my diabetes	3.64	.781
Because I have diabetes, it is important for me to include carbohydrates that release sugar slowly in my diet	4.10	.671
Because I have diabetes, it is important for me to exclude high fat food from my diet	3.92	.745
Because I have diabetes, it is important for me to include fruit in my diet every day	4.11	.592
Eating too much fruit can harm my diabetes	2.75	.965
Because I have diabetes, it is important for me to include vegetables in my diet every day	4.12	.593
Because I have diabetes, it is important for me to include cereals and fibre in my diet every day	4.02	.666
Drinking small amounts of diabetes could affect my diabetes	2.58	.883
Eating a sensible diet is the most important factor in controlling my diabetes	4.36	.564
I would enjoy eating sweet foods	3.16	1.064
I would enjoy eating fatty foods	2.78	.997
Regular physical activity is important for my diabetes	4.05	.688
If I lost weight I could improve my diabetes	3.83	.915

Means and standard deviations of eating and physical activity items

Item	Mean	S.D.
Checking my blood sugar at home would cause me to worry	2.17	1.006
I prefer if my health professional checks my blood sugar	2.83	1.139
Other people with diabetes can tell if their blood sugar is abnormal without testing it	2.53	.882
I can tell if my blood sugar is abnormal without testing it	2.49	.949
It is not important for me to check my blood sugar	2.29	1.084
Checking my blood sugar is painful	2.15	.793
I do not think I need to check my blood sugar more than once a week	2.74	1.053
My health professional suggests I check my blood sugar at home	4.11	.575
I am curious about the level of my blood sugar	3.99	.606
I check my blood sugar according to a routine	3.78	.851
Checking my blood sugar helps me to control my eating habits	3.74	.869
I check my blood sugar after a big meal to see if it has gone up	2.74	.931
I check my blood sugar if I am not feeling well	3.65	.993
If my blood sugar were high, I would eat less at my next meal	3.11	.931
If my blood sugar were high, I would recheck it later	3.79	.832
If my blood sugar were high, I would try to figure out what I had done to cause it to increase	4.17	.528
If my blood sugar were persistently high, I would see my health professional	4.39	.550
If my blood sugar were lower than usual and I was feeling well, I would not do anything	3.21	.981
If my blood sugar were lower than usual and I was feeling unwell, I would have something to eat	4.05	.578
If my blood sugar were persistently lower than usual, I would see my heath professional	4.14	.722
Checking my blood sugar at home alerts me early if there's a problem with my blood sugar control	4.21	.525
Checking my blood sugar reassures me	4.14	.523

Means and standard deviations of BGSM items

Appendix 4

Final study questionnaire

OPREC No: O02.059

YOUR VIEWS ABOUT YOUR HEALTH AND DIABETES

Thank you for agreeing to answer these questions about the way that people with diabetes think about their condition and their health in general.

We are interested in your views of diabetes and how you think your eating, physical activity and medication might influence your health.

If you have any questions or would like to speak to one of the research team, please contact the Study Co-ordinator:

Dr Alisha Wade

Telephone (01865) 226 910.

YOUR VIEWS ABOUT YOUR DIABETES

Listed below are a number of symptoms that you may or may not have experienced since your diabetes. Please indicate by circling *Yes* or *No*, whether you have experienced any of these symptoms since your diabetes, and whether you believe that these symptoms are related to your diabetes.

	I have experienced this symptom *since my diabetes*			This symptom is *related to my diabetes*	
Pain	Yes	No	_____	Yes	No
Sore Throat	Yes	No	_____	Yes	No
Nausea	Yes	No	_____	Yes	No
Breathlessness	Yes	No	_____	Yes	No
Weight Loss	Yes	No	_____	Yes	No
Fatigue	Yes	No	_____	Yes	No
Stiff Joints	Yes	No	_____	Yes	No
Sore Eyes	Yes	No	_____	Yes	No
Wheeziness	Yes	No	_____	Yes	No
Headaches	Yes	No	_____	Yes	No
Upset Stomach	Yes	No	_____	Yes	No
Sleep Difficulties	Yes	No	_____	Yes	No
Dizziness	Yes	No	_____	Yes	No
Loss of Strength	Yes	No	_____	Yes	No
Thirst	Yes	No	_____	Yes	No
Frequent urination	Yes	No	_____	Yes	No

YOUR VIEWS ABOUT YOUR DIABETES

/e are interested in your own personal views of how you now see your current diabetes.
lease indicate how much you agree or disagree with the following statements about your diabetes
y ticking the appropriate box.

	VIEWS ABOUT YOUR DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP1	My diabetes will last a short time.					
IP2	My diabetes is likely to be permanent rather than temporary					
IP3	My diabetes will last for a long time					
IP4	This diabetes will pass quickly					
IP5	I expect to have this diabetes for the rest of my life					
IP6	My diabetes is a serious condition					
IP7	My diabetes has major consequences on my life					
IP8	My diabetes does not have much effect on my life					
IP9	My diabetes strongly affects the way others see me					

	VIEWS ABOUT YOUR DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP10	My diabetes has serious financial consequences					
IP11	My diabetes causes difficulties for those who are close to me					
IP12	There is a lot which I can do to control my symptoms					
IP13	What I do can determine whether my diabetes gets better or worse					
IP14	The course of my diabetes depends on me					
IP15	Nothing I do will affect my diabetes					
IP16	I have the power to influence my diabetes					
IP17	My actions will have no effect on the outcome of my diabetes					
IP18	My diabetes will improve in time					
IP19	There is very little that can be done to improve my diabetes					

	VIEWS ABOUT YOUR DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP20	My treatment will be effective in curing my diabetes					
IP21	The negative effects of my diabetes can be prevented (avoided) by my treatment					
IP22	My treatment can control my diabetes					
IP23	There is nothing which can help my condition					
IP24	The symptoms of my condition are puzzling to me					
IP25	My diabetes is a mystery to me					
IP26	I don't understand my diabetes					
IP27	My diabetes doesn't make any sense to me					
IP28	I have a clear picture or understanding of my condition					

	VIEWS ABOUT YOUR DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP29	The symptoms of my diabetes change a great deal from day to day					
IP30	My symptoms come and go in cycles					
IP31	My diabetes is very unpredictable					
IP32	I go through cycles in which my diabetes gets better and worse					
IP33	I get depressed when I think about my diabetes					
IP34	When I think about my diabetes I get upset					
IP35	My diabetes makes me feel angry					
IP36	My diabetes does not worry me					
IP37	Having this diabetes make me feel anxious					
IP38	My diabetes makes me feel afraid					

	VIEWS ABOUT DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
V1	I am worried about my diabetes getting worse					
V2	I am now comfortable with the idea of having diabetes					
V3	I am afraid of the consequences of having diabetes					
V4	If my blood sugar were high over a short period of time, it would damage my body					
V5	My diabetes could cause me to go into a coma					
V6	My diabetes could cause me to have kidney damage					
V7	My diabetes could cause me to have problems with my feet					

	VIEWS ABOUT DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
V8	My diabetes could cause me to have problems with my eyesight					
V9	My diabetes makes me more likely to have heart disease					
V10	My diabetes makes more likely to get infections					
V11	My diabetes reduces the quality of my life					
V12	I think my diabetes will stay the same					
V13	Worsening of my diabetes is unavoidable					
V14	I try not to think about my diabetes as much as possible					

YOUR VIEWS ABOUT MEDICINES FOR DIABETES

- We would like you to tell us your views about diabetes medicines.

- Here is a list of statements that other people have made about their medicines.

- Please show how much you agree or disagree with these statements by ticking the appropriate box.

There are no right or wrong answers.
We are interested in your personal views.

YOUR VIEWS ABOUT YOUR DIABETES MEDICINES PRESCRIBED FOR YOU

Please show how much you agree or disagree with the statements below by ticking the appropriate box.

	VIEWS ABOUT THE DIABETES MEDICINES PRESCRIBED FOR YOU IN GENERAL	STRONGLY DISAGREE	DISAGREE	UNCERTAIN	AGREE	STRONGLY AGREE
BM Q1	My health at present depends on my diabetes medicines					
BM Q2	Having to take diabetes medicines worries me					
BM Q3	My life would be impossible without my diabetes medicines					
BM Q4	I sometimes worry about the long-term effects of my diabetes medicines					
BM Q5	Without my diabetes medicines I would be very ill					
BM Q6	These diabetes medicines are a mystery to me					
BM Q7	My health in the future will depend on my diabetes medicines					
BM Q8	These diabetes medicines disrupt my life					
BM Q9	I sometimes worry about becoming too dependent on my diabetes medicines					
BM Q10	My diabetes medicines protect my health from becoming worse					
BM Q11	My diabetes medicines give me unpleasant side effects					

YOUR VIEWS ABOUT DIABETES

- We would like you to tell us your views about diabetes and things you do that might affect how well your diabetes is controlled.

- Here is a list of statements that other people have made about their diabetes.

- Please show how much you agree or disagree with these statements by ticking the appropriate box.

There are no right or wrong answers.
We are interested in your personal views.

YOUR VIEWS ABOUT DIABETES

We would like you to tell us your views about the things that you do that may affect your diabetes control.

	YOUR VIEWS ABOUT DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
L1	Because I have diabetes, it is important for me to eat less food					
L2	Because I have diabetes, it is very important for me to reduce the sugar in my diet					
L3	Because I have diabetes, it is important for me to include carbohydrates that release sugar slowly e. g. pasta, potatoes and rice in my diet					
L4	Because I have diabetes, it is important to exclude high fat food from my diet					
L5	Because I have diabetes it is important for me to include fruit in my diet every day					
L6	Eating too much fruit can harm my diabetes					
L7	Because I have diabetes it is important for me to include vegetables in my diet every day					
L8	Because I have diabetes it is important for me to include cereals and fibre in my diet every day					
L9	Eating a sensible diet is the most important factor in controlling my diabetes					
L10	I would enjoy eating sweet foods					
L11	I would enjoy eating fatty foods					

	YOUR VIEWS ABOUT DIABETES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
L12	Including fruit in my diet is important for my overall health					
L13	It is important for my overall health to exclude high fat foods from my diet					
L14	Regular physical activity is important for my diabetes					
L15	If I lost weight I could improve my diabetes					
L16	Physical activity is important for my overall health					
L17	Physical activity would have a direct effect on my blood sugar					
L18	Even a small amount of physical activity would be good for my diabetes					
L19	Medication is important in controlling my diabetes					
L20	Medication would allow/allows me to be less strict about my diet					
L21	I would be distressed if I had to use insulin to control my diabetes					
L22	I would think my diabetes was getting worse if I had to start taking tablets or change the ones that I was on					
L23	I would think my diabetes was getting better if I could stop or reduce my tablets					

YOUR VIEWS ABOUT CHECKING YOUR BLOOD SUGAR

- We would like you to tell us your views about checking your blood sugar at home.

- Here is a list of statements that other people have made about checking their blood sugar.

- Please show how much you agree or disagree with these statements by ticking the appropriate box.

There are no right or wrong answers. We are interested in your personal views.

YOUR VIEWS ABOUT CHECKING YOUR BLOOD SUGAR

Some people check their blood sugar at home. We would like your views on this.

	VIEWS ABOUT CHECKING YOUR BLOOD SUGAR	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
B1	Checking my blood sugar at home would cause me to worry					
B2	I prefer if my health professional checks my blood sugar					
B3	Other people with diabetes can tell if their blood sugar is abnormal without testing it					
B4	I can tell if my blood sugar is abnormal without testing it					
B5	It is not important for me to check my blood sugar					
B6	Checking my blood sugar is painful					
B7	I do not think I need to check my blood sugar more than once a week					

How serious a threat to your health is high blood sugar? (please circle the appropriate number)	1 Not at all serious	2	3	4 Moderately serious	5	6	7 Very serious
How common do you think diabetes is? (please circle the appropriate number)	1 Not at all common	2	3	4 Moderately common	5	6	7 Very common

Have you ever carried out blood tests at home to check your blood sugar? (please circle the appropriate number)	1 Never	2 Yes-but not in the past year	3 Yes- but not in the past three months	4 Yes-within the past three months
Currently, how often do you check your blood sugar at home? (please circle the appropriate number)	1 Never	2 Less than once a month	3 At least one or more times a month	4 At least one or more times a week

If you do not check your blood sugar at home **at least once a week**, there is no need to complete any more questions in this section. Please go on to section 6.

If you check your blood sugar at home **at least once a week**, please complete the remaining questions in this section.

	VIEWS ABOUT CHECKING YOUR BLOOD SUGAR	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
B8	My health professional suggests I check my blood sugar at home					
B9	I am curious about the level of my blood sugar					
B10	I check my blood sugar according to a routine					
B11	Checking my blood sugar helps me to control my eating habits					
B12	I check my blood sugar after a big meal to see if it has gone up					
B13	I check my blood sugar if I am not feeling well					
B14	If my blood sugar were high, I would take some action to lower it					
B15	If my blood sugar were high, I would recheck it later					
B16	If my blood sugar were high, I would try to figure out what I had done to cause it to increase					
B17	If my blood sugar were persistently high, I would see my health professional					
B18	If my blood sugar were lower than usual and I was feeling well, I would not do anything					

	VIEWS ABOUT CHECKING YOUR BLOOD SUGAR	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
B19	If my blood sugar were lower than usual and I was feeling unwell, I would not do anything					
B20	If my blood sugar were persistently lower than usual, I would see my health professional					
B21	Checking my blood sugar at home alerts me early if there's a problem with my blood sugar control					
B22	Checking my blood sugar reassures me					
B23	When I test my blood sugar, I worry what the result might be					
B24	I would be concerned if my blood sugar were higher than usual					
B25	Checking my blood sugar at home makes me feel anxious					

How accurate do you think monitoring your blood sugar at home is? (please circle the appropriate number)	1 Not at all accurate	2	3	4 Moderately accurate	5	6	7 Very accurate
How confident are you in the results of your self-monitoring? (please circle the appropriate number)	1 Not at all confident	2	3	4 Moderately confident	5	6	7 Very confident

HOW YOU USE YOUR DIABETES MEDICINES

- Many people find a way of using their medicines or tablets that suits them.

- This may differ from the instructions on the label or what their doctor has said.

- We would like to ask you a few questions about how you use your diabetes medicines.

QUESTIONS ABOUT USING YOUR DIABETES MEDICINE

These statements show some ways in which other people have said they use their diabetes medicines in general.

For each of the statements below, please tick the box that best describes how you have used your diabetes medicines or pills **in general**.

	QUESTIONS ABOUT USING DIABETES MEDICINES PRESCRIBED FOR YOU	ALWAYS TRUE	OFTEN TRUE	SOME-TIMES	RARELY	NEVER
M1	I forget to take my medicines					
M2	I alter the dose of my medicines					
M3	I stop taking my medicines for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					

DIABETES SELF CARE ACTIVITIES SCALE

The questions below ask you about your diabetes self-care activities during the past seven days. If you were sick within the last seven days, please think back to the last seven days when you were not sick.

Diet

- On how many of the last SEVEN DAYS have you followed a healthy eating plan?

  0 1 2 3 4 5 6 7

- On average, over the past month, on how many DAYS PER WEEK have you followed your eating plan?

  0 1 2 3 4 5 6 7

- On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

  0 1 2 3 4 5 6 7

- On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

  0 1 2 3 4 5 6 7

Exercise

- On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)

  0 1 2 3 4 5 6 7

- On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

  0 1 2 3 4 5 6 7

YOUR OWN HEALTH STATE TODAY

The following five questions are about your general health.
Please indicate which answer, **either 1, 2 or 3**, best describes your own health state today **by circling one number in each section**.

Mobility

I have no problems in walking about.	1
I have some problems in walking about.	2
I am confined to bed.	3

Self-Care

I have no problems with self-care.	1
I have some problems washing or dressing myself.	2
I am unable to wash or dress myself.	3

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities.	1
I have some problems with performing my usual activities.	2
I am unable to perform my usual activities.	3

Pain/Discomfort

I have no pain or discomfort.	1
I have moderate pain or discomfort.	2
I have extreme pain or discomfort.	3

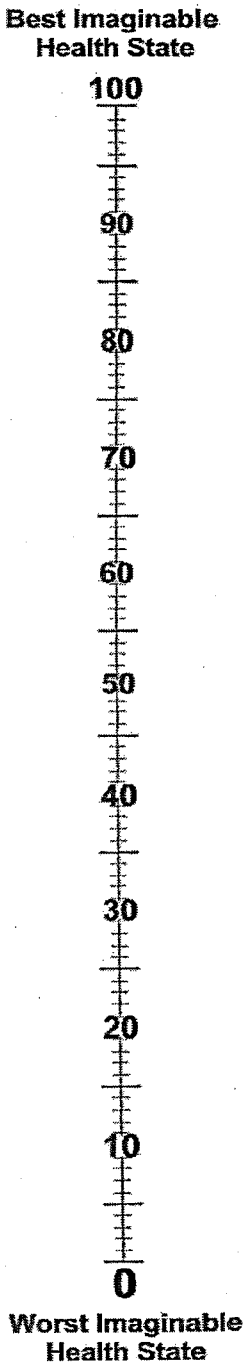
Anxiety/Depression

I am not anxious or depressed.	1
I am moderately anxious or depressed.	2
I am extremely anxious or depressed.	3

HEALTH THERMOMETER

In order to help people say how good or bad their health state is, we have drawn a scale – rather like a thermometer – on which the best state you can imagine is marked by 100 and the worst state is marked by 0. We would like you to indicate on the scale below how good or bad your health is, in your opinion. Please do this by drawing a single line from the box on the left (labelled your own health today) to whichever point on the scale that indicates how your health state is.

Your own health state today



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 have crying spells or feel like it	3	2	1	0
2	I feel downhearted and blue	3	2	1	0
3	I feel afraid for no reason at all	3	2	1	0
4	I get upset easily or feel panicky	3	2	1	0
5	I feel energetic, active or vigorous	3	2	1	0
6	I feel dull and sluggish	3	2	1	0
7	I feel tired, worn out, used up or exhausted	3	2	1	0
8	I have been waking up feeling fresh and rested	3	2	1	0
9	I have been happy, satisfied, or pleased with my personal life	3	2	1	0
10	I have lived the kind of life I wanted to	3	2	1	0
11	I have felt eager to tackle my daily tasks or make new decisions	3	2	1	0
12	I have felt I could easily handle or cope with any serious problem or major change in my life	3	2	1	0

Please make sure that you have considered each of the 12 statements and have circled a number on each of the 12 scales.

© September 1993 Dr Clare Bradley, Diabetes Research Group, Royal Holloway, University of London, Egham, Surrey, TW20 0EX

DIABETES TREATMENT SATISFACTION QUESTIONNAIRE

The following questions are concerned with the treatment of your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks. Please answer each question by circling a number on each of the scales.

1. How satisfied are you with your current treatment?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

2. 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

3. 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

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

very convenient	6	5	4	3	2	1	0	very inconvenient

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

very flexible	6	5	4	3	2	1	0	very inflexible

6. How satisfied are you with your understanding of diabetes?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

7. Would you recommend this form of treatment to someone with your kind of diabetes?

Yes, I would definitely recommend the treatment	6	5	4	3	2	1	0	No, I would definitely not recommend the treatment

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

very satisfied	6	5	4	3	2	1	0	very dissatisfied

Please make sure you have circled one number on each of the scales

DTSQ © Sept 1993 Dr. Clare Bradley, Diabetes Research Group, Royal Holloway, University of London, Egham, Surrey, TW20 0EX

Thank you very much for taking the time to complete these questions. Your views and responses are important to us.

If you have any other comments or points that you would like to share with us, please use the space below.

Dr. Andrew Farmer

Dr. Alisha Wade

Additional comments:

Appendix 5

Letter of invitation to potential trial participants

Practice letterhead

(Date)
OPREC Number: O02.059

Study Co-ordinators
Dr. Andrew Farmer 01865 226768
Dr. Alisha Wade 01865 226896

Dear «Title» «Surname»

Diabetes Glycaemic Education and Monitoring Study

I am writing to invite you to take part in a research project being undertaken by some of my colleagues at Oxford University. This research aims to help people with diabetes improve their health. I am writing to you because I have a record that you have type 2 diabetes (the type that develops in adult life) and are controlling your diabetes by taking tablets or by adjusting your lifestyle.

If you were to agree to take part in this research, my colleagues would arrange for a trained nurse to meet you at the surgery. You would be given a chance to discuss your experience of having diabetes and how you might improve the control of your blood sugar. You would be offered help in checking how well your blood glucose is being controlled, either by additional blood tests or by using a blood glucose monitor at home, depending on which of three groups in which you might be placed. You would also be offered follow-up visits at intervals during the trial to check how you were and offer you further help and support with your plan to improve your diabetes. Follow up visits should last about 20 minutes.

We would be grateful if you would read the enclosed information leaflet. If you are able to help with this study, please fill out and return the attached slip in the envelope provided (no stamp is required). If you do not wish or are unable to take part, you may also let us know by returning the slip. If you have any questions my research colleagues have a direct number and are happy to discuss what might be involved in taking part in the study in more detail. Please contact them on **01865 226910**.

Thank you for thinking about whether or not you would wish to take part in this study. Any information we get from you would be used to improve the information, help and advice we offer to people with diabetes in the future.

Yours sincerely,

(GP)

OPREC No.: O02.059

DIABETES GLYCAEMIC EDUCATION AND MONITORING STUDY (DiGEM)

REPLY SLIP

RETURN TO: (please use the enclosed reply paid envelope)
DiGEM Study, University of Oxford
Division of Public Health and Primary Health Care
Institute of Health Sciences
Old Road, Headington
Oxford OX3 7LF

Please tick one:

☐ Yes, I would like to discuss this with a study nurse

☐ No, I would prefer not to take part in the study

Please complete/amend your contact details below:

Surname: «Surname»

First name: «Fnam1»

«Add1»
«Add2»
«Add3»
«Add4»

Postcode .....

Daytime telephone number .....

Evening telephone number .....

Practice No: **«PracID»**

Thank you for your interest

What do I have to do?

You would be asked to keep a simple record of any changes in your eating habits or patterns or physical activity. The nurse would help you draw up a plan to identify any changes that you could make to help improve your blood sugar control. If you were asked to monitor your blood sugar at home, we would also ask you to keep a record of the results of the blood sugar checks.

What are the possible benefits from taking part?

We hope that taking part would help you understand more about looking after your diabetes and give you more information about ways that it can be controlled.

What are the possible disadvantages of taking part?

You will need to arrange visits with the study nurse at the practice and you will need to have some additional blood tests done during the study. You may also be asked to test your blood sugar at home by pricking your finger. Some people may find that they do not like being reminded about a continuing problem such as diabetes.

Would my taking part in the study be kept confidential?

Any detailed information, which you might give us during the course of the research, would be kept strictly confidential.

What would happen to the results of the research study?

We will use the results to help us decide the best possible educational programme. This may eventually influence how patients with diabetes are best supported in managing their own health.

Who is organizing and funding this research?

This work is being funded by the Health Technology Assessment Board and is being conducted by the Department of Primary Health Care at the University of Oxford in collaboration with the Department of Public Health and Primary Health Care at the University of Cambridge.

D*i*GEM

DIABETES GLYCAEMIC EDUCATION AND MONITORING STUDY

Department of Primary Health Care
Institute of Health Sciences
Old Road, Headington
Oxford OX3 7LF

Information Sheet

For further information please telephone:

01865 226 910

Project Title:

Diabetes Glycaemic Education and Monitoring Study

OPREC Number: O02.059

Study Co-ordinators

Dr. Alisha Wade 01865 226896
Dr. Andrew Farmer 01865 226768

Invitation

You have received a letter from your general practitioner inviting you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with your friends, relatives and GP if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

We are developing a programme to help people with diabetes make positive changes to their lifestyles, through better feedback of information about control of blood sugar. The information gained from this study, which will last a year, would help us make recommendations to patients, specialists and general practitioners about the best methods to use.

Why have I been chosen?

You have been chosen because your general practitioner has a record that you may have type 2 diabetes and are not taking insulin. We hope to recruit 630 people with diabetes to participate in this study.

Do I have to take part?

It is your decision whether or not to take part in the study. If you do decide to be involved, please keep this information sheet. You would be free to withdraw from the study at any time and without giving a reason. This would not affect the care you receive.

What would happen to me if I take part?

A trained nurse would meet with you at your general practitioner's surgery and answer any questions you might have about the study. If you agreed to take part you would be asked to sign a consent form, complete a questionnaire, and have your height, weight and blood pressure checked. You would also be asked for a sample of blood. The nurse would then discuss with you ways in which you could alter your lifestyle in order to improve your blood sugar control and a follow-up visit would be arranged after two weeks.

At the second visit, you would have the opportunity to discuss any problems and you would be offered help in checking how well your blood glucose is being controlled, either by additional blood tests or by using a blood glucose monitor at home. This kind of trial, where people are put into groups and then compared, is known as a randomized trial.

The groups are selected by a computer which has no information about the individual, i.e. by chance. In this trial, one group will have additional blood tests done at the practice to check how well their blood sugar is controlled, while the other two groups will check their blood sugar at home with monitors.

The study will run for one year. Follow-up visits would be arranged by the nurse at one month, three months, six months, nine months and one year after the start of the study. Each follow up visit will last between 15 and 20 minutes. At each visit, your blood sugar control would be reviewed with you and any problems that you might be having would be discussed with you.

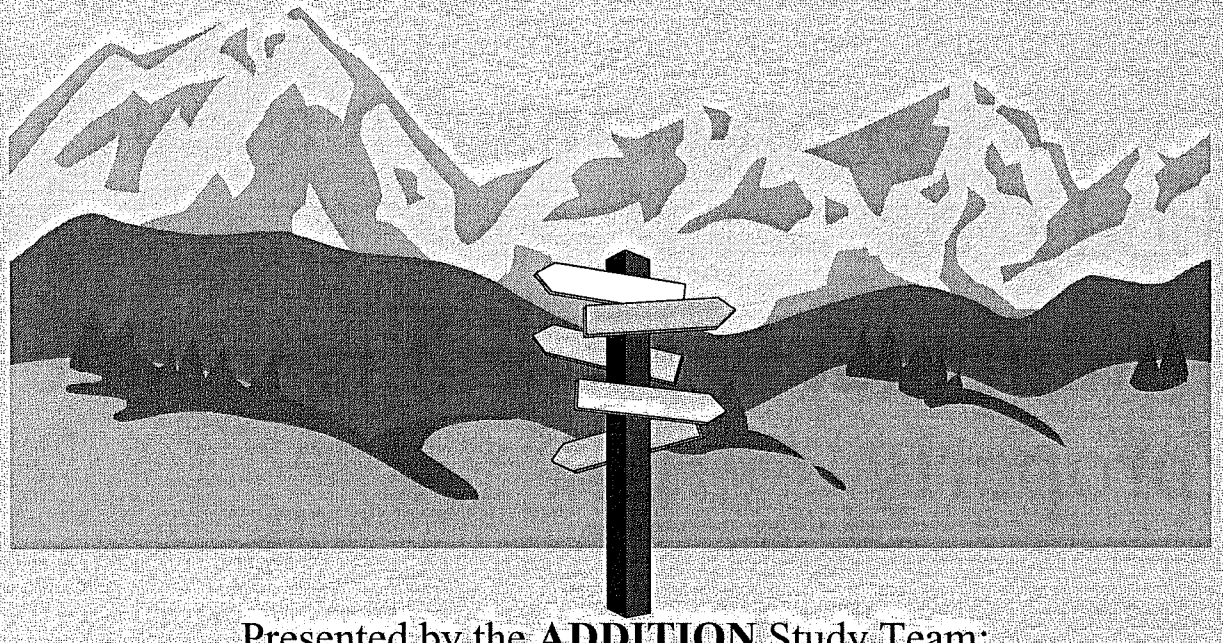
At some point during the study you may be asked if you would be willing to meet an additional researcher to discuss your experiences with diabetes in more detail.

.../cont.

Appendix 6

Living with Diabetes information pack

Looking after yourself with Diabetes



Presented by the **ADDITION** Study Team:

Prof Ann Louise Kinmonth, Prof Stephen Sutton, Dr Sean Dinneen, Dr Rob Horne, Wendy Hardeman, Ros Barling, Dr Imogen Hobbis, Jackie Reynolds, Helen Brown

© University of Cambridge, 2001 Version 7: 2 April, 2002

So you have Type 2 Diabetes …
what has happened?

Either:

- There is not enough insulin available in your body, *or*
- The insulin that is present is unable to work properly

This means:

- Blood glucose levels rise

Diabetes Is Not Good News

- Once you have been properly diagnosed, you have the risks of diabetes for life
- If left uncontrolled diabetes can cause problems for your health
- Even if you feel well now, you still need to take care of your future health

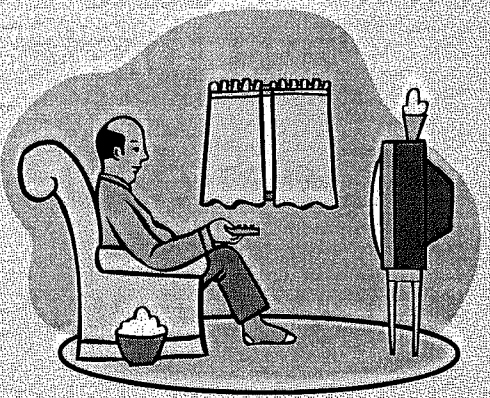
BUT…

... things can be done about it

- Most people live full and healthy lives with diabetes
- You can increase your chances of being one of them
- Here we tell you how

Who is more likely to get Type 2 Diabetes?

- Anyone who is:
  - –overweight
  - –over 40 years old
  - –inactive



Why does it matter?

People with diabetes detected by a routine test usually feel perfectly well. But, as blood glucose rises they can:

- Pass urine full of glucose frequently
- Dehydrate ("*Dry out*") and get thirsty
- Lose energy and weight
- Feel less well

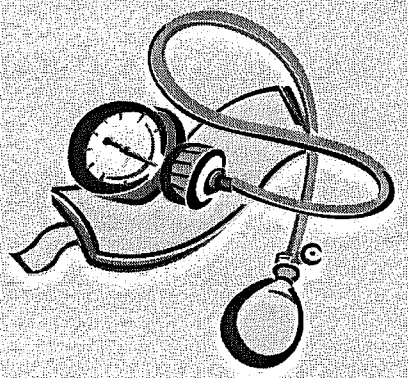
Why does it matter?

If blood glucose is high over many years it can cause problems leading to:

- angina, heart attack, stroke
- amputation
- kidney failure, dialysis
- blindness
- loss of feeling in the hands and feet
- problems with sexual function
- premature death

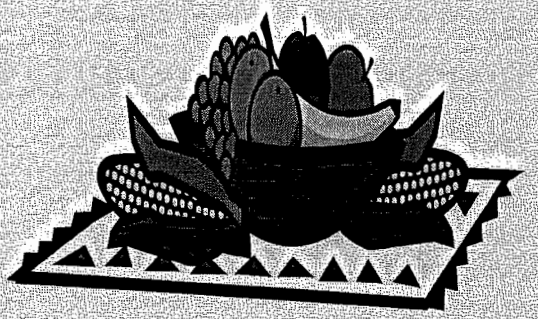
What makes these problems more likely?

- High levels of :
  - –blood glucose
  - –cholesterol
  - –blood pressure
- Smoking
- Weight gain



How to make health problems less likely

- Review your energy balance:
  - –be more active
  - –eat healthy foods lower in energy



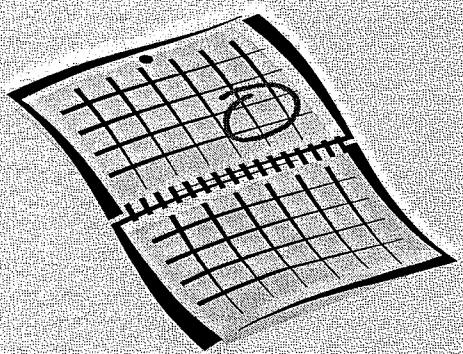
Making health problems less likely 2

- Take the medicines prescribed for:
  - –blood glucose
  - –cholesterol
  - –blood pressure



Making health problems less likely 3

- Picking up problems early:
  - annual checks

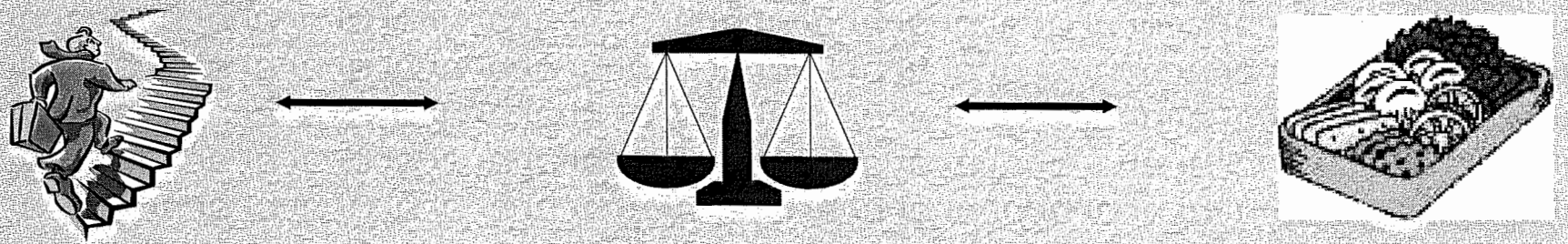


Rebalance Your Energy

Imagine your energy needs as a pair of scales.

To adjust this balance you may need to:

- *Increase your activity*
- *Change what you eat*
- *This will also help weight loss and prevent weight gain*



Rebalance Your Energy

Increase Your Activity

This doesn't mean having to go to the gym 5 times a week. Simply being more active through the day can do it:

- use the stairs not the lift
- get off the bus a stop early
- walk round the block every evening



Rebalance Your Energy

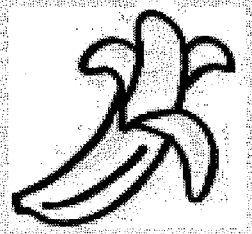
Change What you Eat

You don't have to stop eating everything you like or only eat salad. The following will help to reduce energy intake:

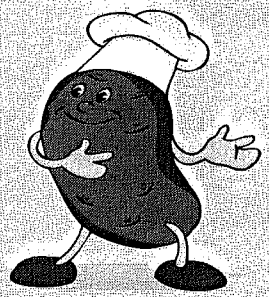
- Eating foods with less sugar and fat
- Filling up on fibre-rich foods including whole grains
- Taking care with alcohol

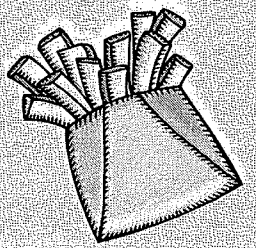


Eating Foods with Less Sugar and Fat



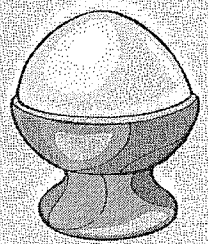


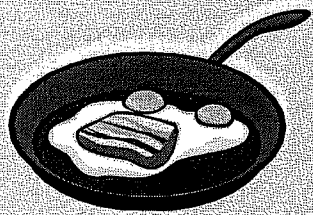


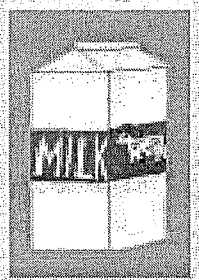


Foods with
LESS Sugar
and Fat

Foods with
MORE Sugar
and Fat





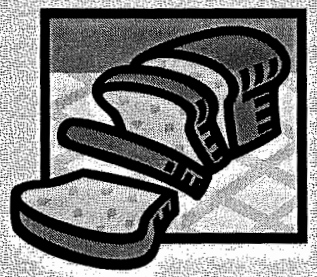


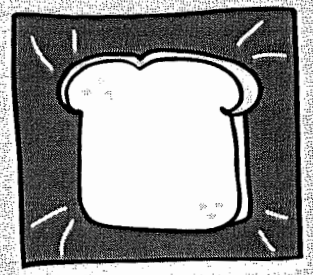


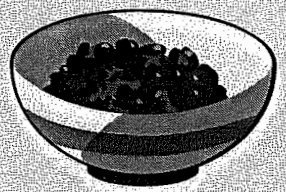
Skim

Full Fat

Filling up on Fibre-rich Foods including Whole Grains



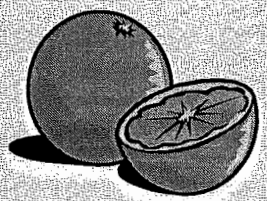


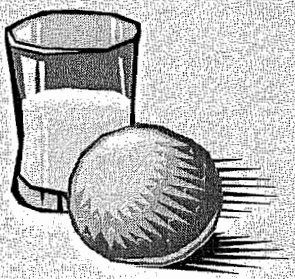


Foods with
MORE Fibre

Foods with
LESS Fibre







Taking Care with Alcohol





Drinks with
LESS Sugar

Drinks with
MORE Sugar

Diet
Drink





Sugary
Drink

Take your Medication Regularly

- You might have several tablets to take each day for:
  - *blood glucose*
  - *cholesterol*
  - *blood pressure*
  - *other health problems*



Take your Medication Regularly

- Ask if you have queries about:
  - Doses
  - Timing
  - Side effects



Where do we go from here?
Remember ...

You are **NOT** alone

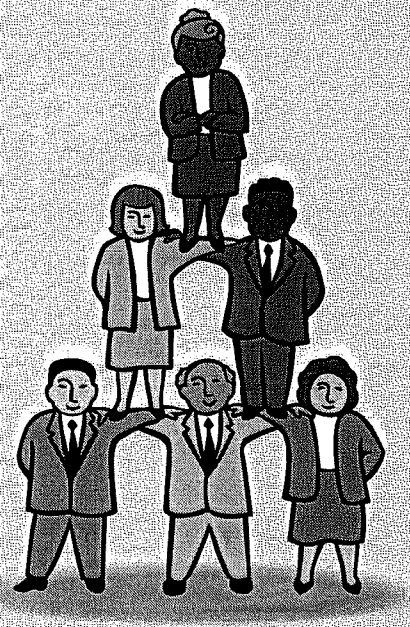
- Type 2 diabetes is very common, and getting more common
- 1 in 10 older people in the UK are diagnosed with Type 2 diabetes

Help is at Hand

There are many sources of support available to you:

- your GP
- the practice nurse
- Diabetes UK

Ask if you have any questions about your diabetes and its treatment



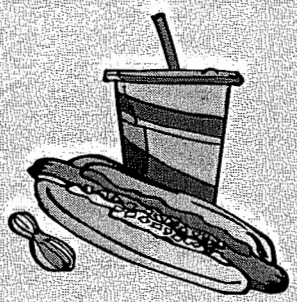
Key Messages - 1

- Diabetes does cause problems **BUT** risks can be reduced

Key Messages - 2

- Rebalance your energy
  - ⬆ activity
  - ⬇ fatty foods and sugar
  - ⬆ fruit, vegetables, and whole grains







Key Messages - 3

- Take your medication regularly
- Stop smoking
- Get yourself checked each year



Appendix 7

Action planning and BGSM diaries

DiGEM

DIABETES GLYCAEMIC EDUCATION AND MONITORING STUDY

Action planning diary

Name: .....

This booklet has been designed to help you make modifications in your lifestyle that will help you improve your health.

When you meet with the study nurse, you will have the chance to discuss your lifestyle and medication. You can then think about ways you might be able to make helpful changes.

When you come across things you might be able to change, you can make a note of them in this booklet on the goal setting sheet. That way you will have a reminder of the things you would like change.

You can use the goal-monitoring forms to write down how things have gone with getting started and sticking with your goals. We recommend that you use one goal-monitoring sheet per week to keep a record of whether or not you were able to achieve your goals and what helped or hindered you in the process.

Goal Setting Sheet

Date	What I would like to do	How I will do it	When I will do it	Where I will do it

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Goal– monitoring form

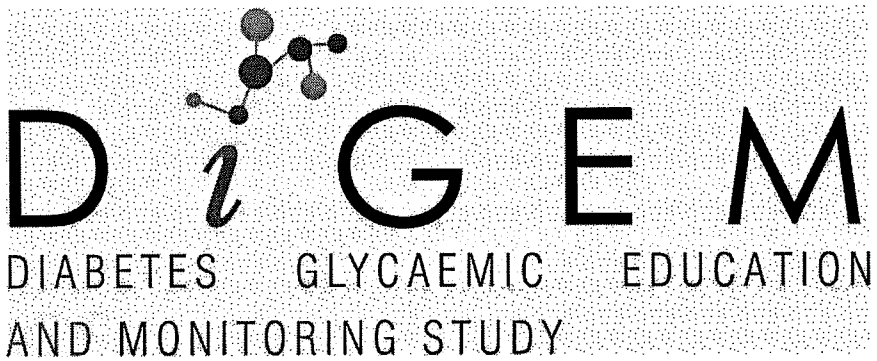
GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?



Blood Glucose Monitoring Diary

Name:.....

This diary has been designed to help you keep a record of your blood sugar.

We recommend that you test your blood sugar three times a day on any two days of the week. At least one of these tests should be first thing in the morning before you've eaten and the other two may be either before or preferably, two hours after a meal. We recommend that you use one results sheet per week.

Please record your blood glucose readings, as well as the time they were taken in this diary. The nurse will review your results at the study visits.

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

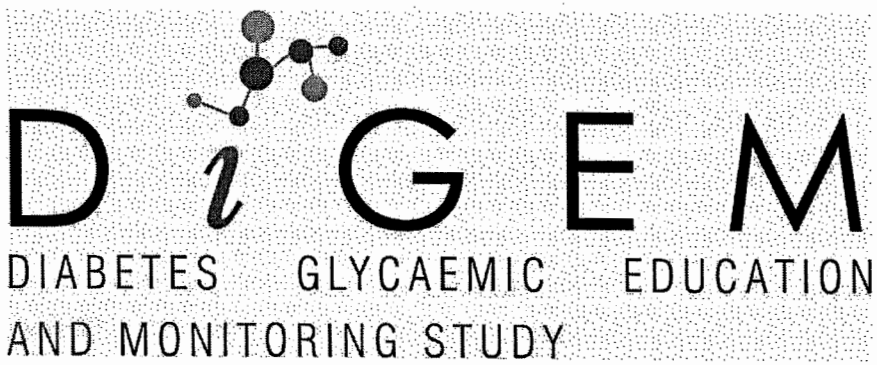
Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal	Result



Action Planning and Blood Glucose Monitoring Diary

Name:.....

This diary has been designed to help you make modifications in your lifestyle that that will help you improve your blood sugar control. When you meet with the study nurse, you will have the chance to discuss your lifestyle and medication. You can then think about ways you might be able to make helpful changes.

When you come across things you might be able to change, you can make a note of them in this booklet on the goal setting sheet. That way you will have a reminder of the things you would like change.

You can use the goal-monitoring forms to write down how things have gone with getting started and sticking with your goals. We recommend that you use one goal-monitoring sheet per week to keep a record of whether or not you were able to achieve your goals and what helped or hindered you in the process.

You can use the blood glucose results sheets to write down the results of your blood glucose self monitoring. We recommend that you use one sheet per week.

We recommend that you test your blood sugar three times a day on any two days of the week. At least one of these tests should be first thing in the morning before you've eaten and the other two may be either before or preferably, two hours after a meal. Feel free to do tests at other times as well– for example if you aren't feeling well or if you're curious about the effects of a meal or exercise.

Please record your blood glucose readings, as well as the time they were taken in this diary. Please also record details of the timing and content of your meals, any physical activity undertaken and when you took your medication (if any).

Goal Setting Sheet

Date	What I would like to do	How I will do it	When I will do it	Where I will do it

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel afterwards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:

Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Goal– monitoring form

GOALS:				
Day and date	Were goals achieved?	What helped ?	What got in the way?	How did you feel after-wards?

Blood glucose results sheet

Date	Was it fasting, pre-meal or 2 hrs after a meal or at another time? (please specify)	Result	Comments about meals, activity, medication

Appendix 8

Information sheet on BGSM

DiGEM

Diabetes Glycaemic Education
and Monitoring Study

Department of Primary Health Care
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

DiGEM Study telephone number 01865 26910

Monitoring your blood sugar at home

We have given you a blood glucose meter and are asking you to monitor your blood sugar at home. Please record the results of your tests and give them to the study nurse at your next appointment. Please read the following information carefully and ask the study nurse if you have any questions.

How often should I test my blood sugar?
We would like you to test your blood sugar three times a day on any two days of the week. The study nurse will show you how to do this- if you have any questions, please ask her. At least one test should be done first thing in the morning before you have anything to eat, while the other two tests may be taken either before a meal or two hours after a meal. We ask you to take it two hours after a meal because, by that time, your body should have started to process the sugar in your meal. Be sure to write down when the test was taken as well as the result in your diary.

What should I do with my test results?
Please keep a record of your results and show them to the study nurse at each of your visits.

What should I expect when I test my blood sugar?
The result you get when you test your blood sugar may be within normal range (between 4 and 6 mmol/l if taken fasting or before a meal or 6-8 mmol/l if taken two hours after a meal), low or high.

What If my blood sugar result is normal?
By continuing to follow the advice given by your health care professional, you should be able to maintain your blood sugar in the recommended ranges.

What if my blood sugar result is high?
High blood sugar results can be worrying. It is important to remember that patterns of results may be more important than a single reading. Consistently high readings may suggest that your blood sugar control could do with some improvement. If your blood sugars in the morning (fasting) start to go above 15 mmol/l and you are not feeling well you should consider contacting your GP.

p.t.o.

What if my blood sugar result is low?

Low blood sugar or hypoglycaemia can happen if you're taking a sulphonylurea tablet (one of the kinds of tablets that is used to control diabetes), especially if you miss a meal or are more active than normal. Symptoms may include sweating, shaking, tingling lips and feeling wobbly or faint.

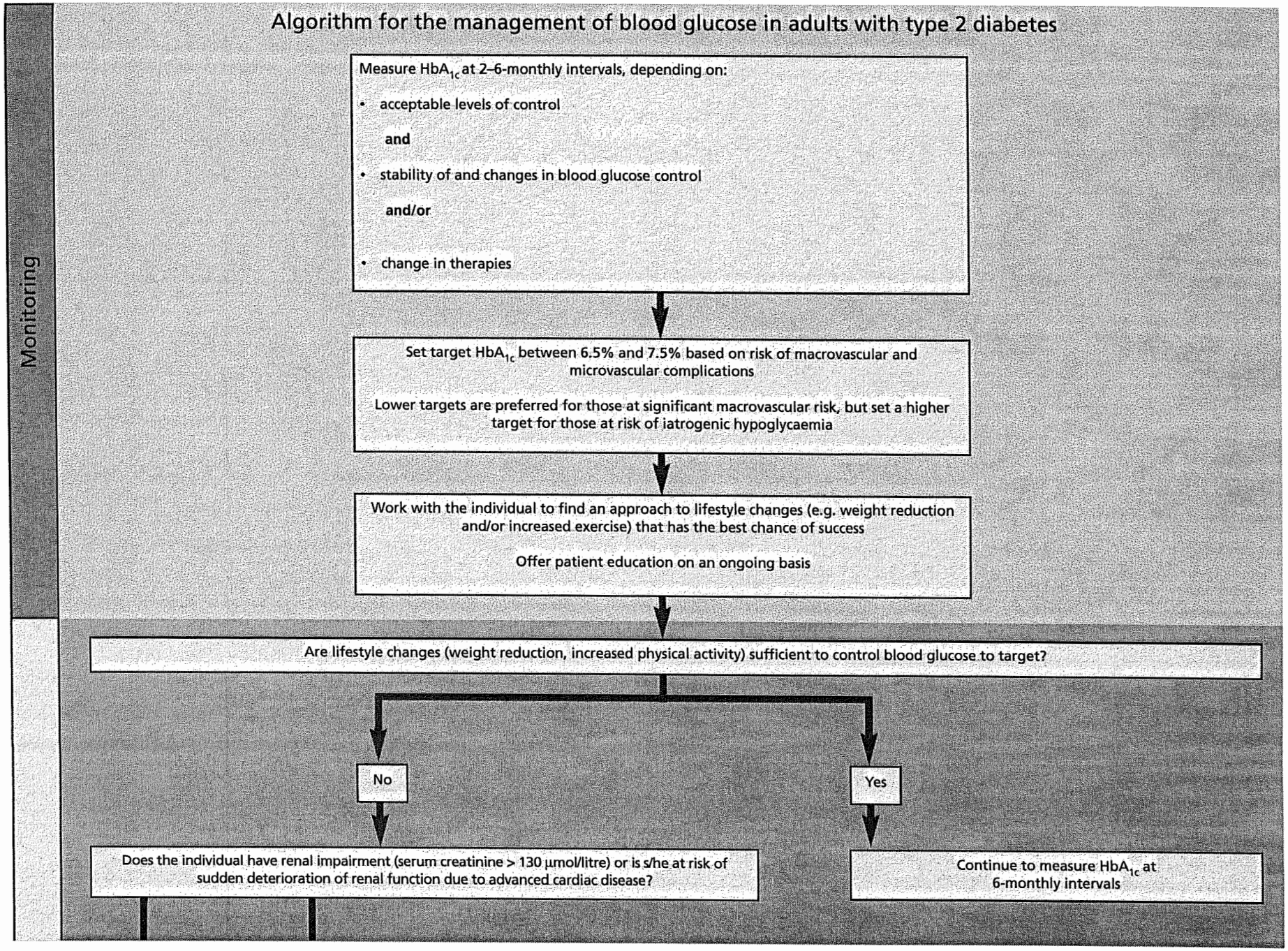
If you begin to experience these symptoms, you need to eat some fast acting carbohydrates such as sweets, a non-diet fizzy drink or glucose tablets and then follow this up with some sort of longer acting carbohydrate like a sandwich.

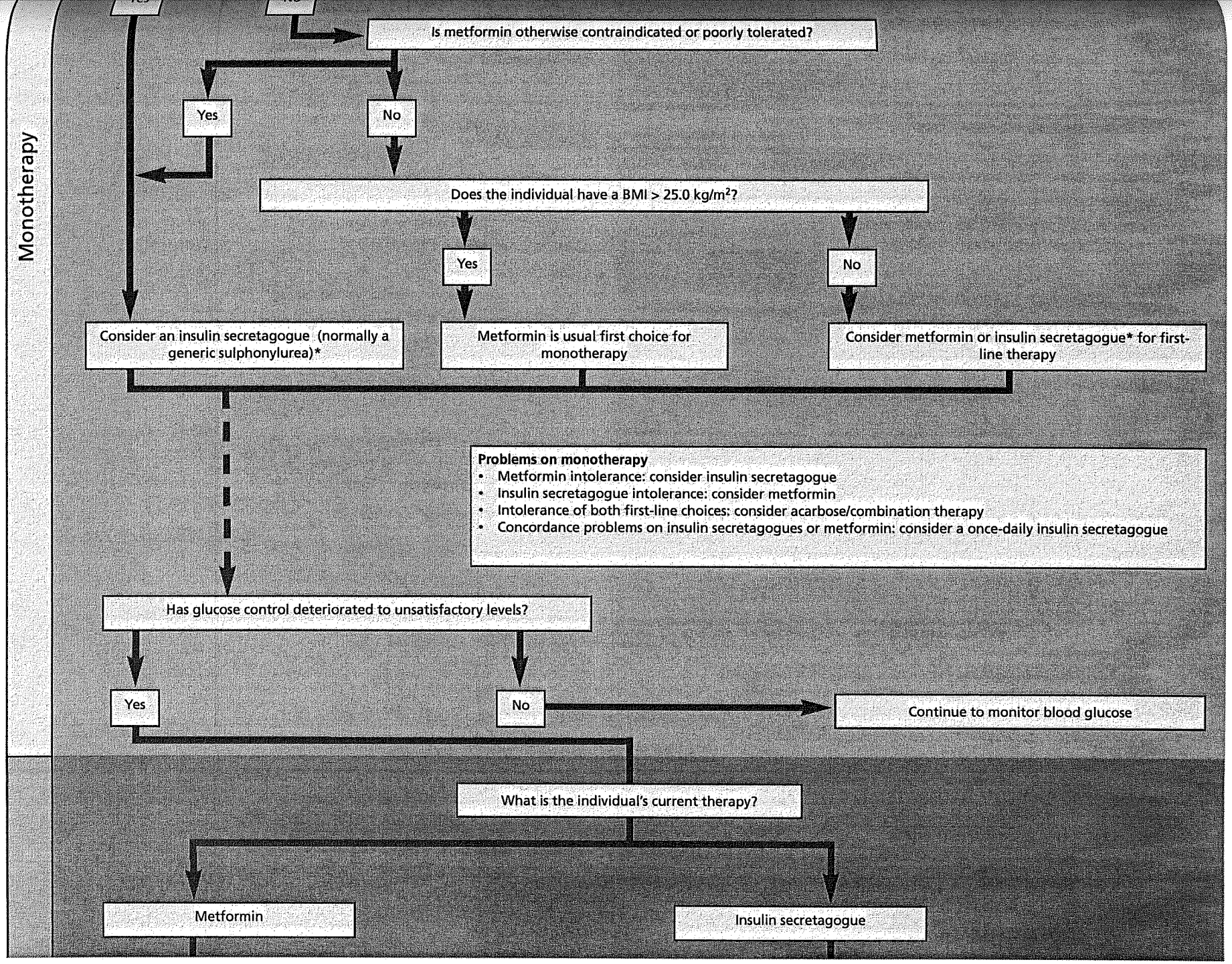
If you are on tablets, you should not have hypoglycaemic attacks often. If you do, contact your GP as it may be necessary to alter your medication.

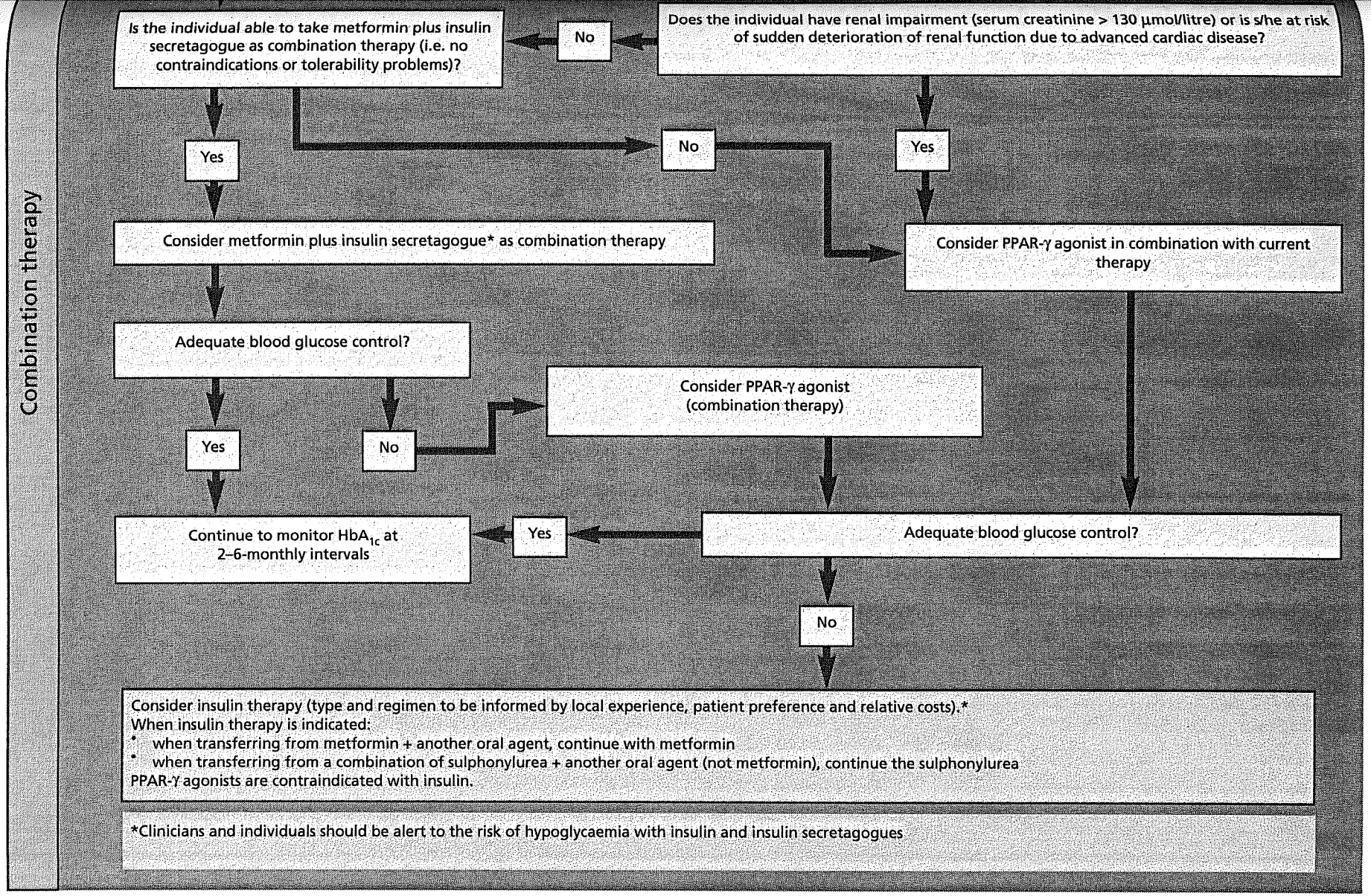
If you have any problems relating to the study then phone the study nurse on 01865 226910. However, in the event of an emergency or if you need urgent advice then please contact your own surgery as usual or, if necessary, follow the surgery's out of hours arrangements.

Appendix 9

Diabetes treatment algorithm


Algorithm for the management of blood glucose in adults with type 2 diabetes
Monitoring
Measure HbA1c at 2–6-monthly intervals, depending on:
• acceptable levels of control
and
• stability of and changes in blood glucose control
and/or
• change in therapies
Set target HbA1c between 6.5% and 7.5% based on risk of macrovascular and microvascular complications
Lower targets are preferred for those at significant macrovascular risk, but set a higher target for those at risk of iatrogenic hypoglycaemia
Work with the individual to find an approach to lifestyle changes (e.g. weight reduction and/or increased exercise) that has the best chance of success
Offer patient education on an ongoing basis
Are lifestyle changes (weight reduction, increased physical activity) sufficient to control blood glucose to target?
No
Yes
Does the individual have renal impairment (serum creatinine > 130 μmol/litre) or is s/he at risk of sudden deterioration of renal function due to advanced cardiac disease?
Continue to measure HbA1c at 6-monthly intervals


Monotherapy
Is metformin otherwise contraindicated or poorly tolerated?
Yes
No
Does the individual have a BMI > 25.0 kg/m²?
Yes
No
Consider an insulin secretagogue (normally a generic sulphonylurea)*
Metformin is usual first choice for monotherapy
Consider metformin or insulin secretagogue* for first-line therapy
Problems on monotherapy
• Metformin intolerance: consider insulin secretagogue
• Insulin secretagogue intolerance: consider metformin
• Intolerance of both first-line choices: consider acarbose/combination therapy
• Concordance problems on insulin secretagogues or metformin: consider a once-daily insulin secretagogue
Has glucose control deteriorated to unsatisfactory levels?
Yes
No
Continue to monitor blood glucose
What is the individual's current therapy?
Metformin
Insulin secretagogue


Combination therapy
Is the individual able to take metformin plus insulin secretagogue as combination therapy (i.e. no contraindications or tolerability problems)?
No
Does the individual have renal impairment (serum creatinine > 130 µmol/litre) or is s/he at risk of sudden deterioration of renal function due to advanced cardiac disease?
Yes
No
Yes
Consider metformin plus insulin secretagogue* as combination therapy
Consider PPAR-γ agonist in combination with current therapy
Adequate blood glucose control?
Consider PPAR-γ agonist (combination therapy)
Yes
No
Continue to monitor HbA1c at 2–6-monthly intervals
Yes
Adequate blood glucose control?
No
Consider insulin therapy (type and regimen to be informed by local experience, patient preference and relative costs).*
When insulin therapy is indicated:
• when transferring from metformin + another oral agent, continue with metformin
• when transferring from a combination of sulphonylurea + another oral agent (not metformin), continue the sulphonylurea
PPAR-γ agonists are contraindicated with insulin.
*Clinicians and individuals should be alert to the risk of hypoglycaemia with insulin and insulin secretagogues

Appendix 10

Case record forms

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF 01 Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact 01 Date d d m m y y y y Nurse Initials ☐☐

INITIAL ASSESSMENT (verified at Contact 2 and Contact 3)

Practice No. ☐☐

Gender *male=1 female=2* ☐

Date of birth ☐☐ ☐☐ ☐☐☐☐

Duration of diabetes ☐☐ years ☐☐ months

How often are you currently checking your blood sugar? ☐

Never = 1 Less than once a month = 2 At least once a month = 3
At least once a week = 4 At least two or more times a week = 5

Is this person independent in activities of daily living? Yes = 1 No = 2 ☐

Assessed by ability to be independent in each of the areas of eating, bathing, grooming dressing, toilet use, transfers and mobility (see Barthel's index)

Person able to follow trial protocol? Yes = 1 No = 2 ☐

See operational manual for criteria

Medical record review required to check previous related diabetes events? ☐

Yes = 1 No = 2 (no symptoms, diseases, investigations or admissions reported)

If yes, *circle relevant items and add dates to assist notes review*:
Chest pain, angina, heart disease, blocked arteries, stroke.
Nerve damage or muscle weakness
Amputations
Kidney problems.
Eye problems (retinopathy, cataracts or laser treatment)

Date form verified ☐☐ ☐☐ ☐☐☐☐ **Nurse initials** ☐☐ ***(Contact 2)***

(Revisions to be made by a single line to cross out and writing correct information in place. Initial all alterations

Date form verified ☐☐ ☐☐ ☐☐☐☐ **Nurse initials** ☐☐ ***(Contact 3)***

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **02** Study ID [ ][ ] [ ][ ][ ][ ] Patient Initials [ ][ ][ ]

Contact **02** Date [d][d][m][m][y][y][y][y] Nurse Initials [ ][ ]

DEMOGRAPHICS

Interview location [ ]

Surgery = 1, Participant's home = 2, Other= 8

At what age did you leave fulltime education? [ ]

(For example school, college or university)
16 years or less = 1, 17 years = 2, 18 years = 3, 19 or over = 4

What type of accommodation are you living in? [ ]

Owned / mortgaged = 1, Rented from the council = 2
Rented from a housing association = 3, Rented from a private landlord = 4

What is your ethnic group? [ ]

White (British, Irish or any other white background) = 1
Mixed (white and black Caribbean, white and black Africa, white and Asian any other mixed background) = 2
Asian or British Asian (Indian, Pakistani, Bangladeshi, any other Asian background) = 3
Black or Black British (Caribbean, African, any other black background) = 4
Chinese or other ethnic group (Chinese, other) = 5

Do (did) you work as an employee or are (were) you self-employed? [ ]

1 = employee 2 = self-employed

How many people worked for your employer or were employed by you? [ ][ ]

1 to 24 = 1, 25 or more = 2, Not known = 99

Do (did) you supervise any other employees? [ ]

Yes = 1 No = 2

Which box best describes the sort of work you do? (show them the list) [ ]

If you are not working now, what you did in your last job.
If you have retired, what did you do before retirement?

Write the job down here with as much information as possible so we can review the coding

Occupations list for use with CRF2

Modern professional occupations
such as: teacher - nurse - physiotherapist - social worker - welfare officer - artist - musician - police officer (sergeant or above) - software designer ☐ 1

Clerical and intermediate occupations
such as: secretary - personal assistant - clerical worker - office clerk - call centre agent - nursing auxiliary - nursery nurse ☐ 2

Senior managers or administrators
(usually responsible for planning, organising and co-ordinating work and for finance)
such as: finance manager - chief executive ☐ 3

Technical and craft occupations
such as: motor mechanic - fitter - inspector - plumber - printer - tool maker - electrician - gardener - train driver ☐ 4

Semi-routine manual and service occupations
such as: postal worker - machine operative - security guard - caretaker - farm worker - catering assistant - receptionist - sales assistant ☐ 5

Routine manual and service occupations
such as: HGV driver - van driver - cleaner - porter - packer - sewing machinist - messenger - labourer - waiter / waitress - bar staff ☐ 6

Middle or junior managers
such as: office manager - retail manager - bank manager - restaurant manager - warehouse manager - publican ☐ 7

Traditional professional occupations
such as: accountant - solicitor - medical practitioner - scientist - civil / mechanical engineer ☐ 8

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **02.1** Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact **2.1** Date d d m m y y y y Nurse Initials ☐☐

INELIGIBILITY AFTER ASSESSMENT VISIT

HbA1c results < 6.2% ☐

Yes = 1 No = 2

HbA1c result? ☐☐.☐

Date of assessment visit ☐☐/☐☐/☐☐☐☐

Other reason for exclusion (please refer to coding below) ☐

Unable to comply = 1 Patient declines to continue in study = 2
Insulin use = 3 Other reason = 4 (please state reason below)

Has participant been notified? ☐

Yes = 1 No = 2

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **03** Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact **02** Date d d m m y y y y Nurse Initials ☐☐

CLINICAL ASSESSMENT

Blood Pressure

Take 3 times, disregard the first and record the second and third.
Readings should be taken at least 10 minutes apart

2nd ☐☐☐ /☐☐☐ mm Hg

3rd ☐☐☐ /☐☐☐ mm Hg

Height ☐☐☐ . ☐ **cm**

Weight ☐☐☐ . ☐ **kg**

Smoking

Cigarettes at least once per day Yes = 1 No = 2 ☐

Other tobacco at least once per day Yes = 1 No = 2 ☐

Past smoker Yes = 1 No = 2 ☐
(has ever smoked cigarettes or other tobacco at least 1/day)

If yes how long ago did you give up?

☐☐ years ☐☐ months

Current medication

Are you taking medication for your diabetes?
(specifically oral hypoglycaemic drugs)

Yes = 1 No = 2 ☐

If so, how many different types of hypoglycaemic drugs are you taking? ☐

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF 04 Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐ Nurse Initials ☐☐

1. Diabetes Medication

PATIENT MEDICATION RECORD

Oral hypoglycaemic agents	Assessment visit		Verified/revised at Randomisation visit	Three month visit		Six month visit		Nine month visit		One year visit	
Name (Generic)	Dose per tablet	No. of tablets/ day	Nurse Initials	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day
a) SU:											
b) 2nd SU:											
c) Metformin:											
d) TZD:											
e) Acarbose:											
f) Short acting secretagogue:											

Insulins		No. of units at 3 month visit	No. of units at 6 month visit	No. of units at 9 month visit	No. of units at 12 month visit
Name	Date started				

CRF 04 (page 2) Study ID | | | | | | | Patient Initials | | Nurse Initials | |

2. Other medications Name (Generic)	Assessment/ Randomisation visits		Three month visit		Six month visit		Nine month visit		One year visit	
	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day	Dose per tablet	No. of tablets/day
1.										
2.										
3.										
4.										
5.										
5.										
6.										
7.										
8.										
9.										
10.										
11.										
12.										
13.										
14.										

	Assess	Verified/revised Randomisation	3 mth	6 mth	9 mth	12 mth
3. How many antihypertensive drugs is the patient taking?						
4. How many lipid lowering drugs is the patient taking?						
5. Is the patient taking aspirin daily? *Yes = 1 No = 2*						

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **05** Study ID [ ][ ] [ ][ ][ ][ ] Patient Initials [ ][ ][ ]

Contact **02** Date [d][d][m][m][y][y][y][y] Nurse Initials [ ][ ]

HEALTH SERVICE USE IN THE LAST 12 MONTHS
(leading up to the assessment visit)

We would like to know how much use has been made of the listed health services over the last 12 months, for any reason. We would rather have a best guess than no information at all. Please answer every question, even if the answer is 0, by filling in both boxes (for example 03 if the answer is three times).

Primary care:

How many times in the last 12 months have you been:

1. Seen by GP a) in surgery [ ][ ] b) at home [ ][ ]

2. Seen by a nurse a) in surgery [ ][ ] b) at home [ ][ ]

Secondary care:

How many times in the last 12 months have you been:

3. Seen in Accident and Emergency (A&E) Department [ ][ ]

4. Seen in any other hospital outpatient clinic [ ][ ]

5. Admitted to day hospital [ ][ ]

6. Admitted to inpatient care (been in hospital overnight) [ ][ ]

Inpatient episode:	Number of nights spent in hospital:	Type of department: *(medical=1, surgical=2, other=3)*
a)	[ ][ ]	[ ]
b)	[ ][ ]	[ ]

(cont)

Q.6 (cont)

Inpatient episode:	Number of nights spent in hospital:	Type of department: *(medical=1, surgical=2, other=3)*
c)		
d)		

Other health services:

How many times in the last 12 months have you been:

7. Seen by a dietician

8. Seen by an optician

9. Seen by a podiatrist a) NHS b) private

10. Seen by any private practitioner (e.g. acupuncturist)

Type of practitioner:	Number of times:
a)	
b)	
c)	
d)	

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **06** Study ID | | | | | | Patient Initials | | |

Contact | | Date | d | d | m | m | y | y | y | y | Nurse Initials | |

ADVERSE EVENTS / NOTES REVIEW FORM
(complete 1 form per incident)

AE = adverse event **NR** = notes review | |

Date of incident | | | | | | | | |
(dd/mm/yyyy)

Please describe the nature of incident and attach any relevant information:-
investigations, blood tests, results and treatments.
(Include photocopies from notes if possible)

Investigator's Verification: **Type of event** | |

Date form verified | | | | | | | | | **Investigator initials** | |

(Revisions to be made by a single line to cross out and writing correct information in place. Initial all alterations)

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **07** Study ID [ ][ ] [ ][ ][ ][ ] Patient Initials [ ][ ][ ]

Contact **03** Date [d][d][m][m][y][y][y][y] Nurse Initials [ ][ ]

METER DETAILS

Meter issue serial number _____

Quality control at issue:

High reading = [ ][ ].[ ]

Low reading = [ ][ ].[ ]

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **08** Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact ☐ Date d d m m y y y y Nurse Initials ☐☐

METER QUALITY CONTROL

Are you still testing your blood sugar? Yes = 1 No = 2 ☐

If no please give reason ☐

Dexterity issue = 1 Unable to obtain blood = 2 Information not helpful= 3 Other = 8 (specify)

Still using meter that was issued? Yes = 1 No = 2 ☐

If no, what kind of meter are you using?

Please give reason for changing meter ☐

New meter easier = 1 New meter more reliable = 2 Other = 8 (specify)

How have you found using the meter? (please circle you answer)

Very easy	easy	neither easy or difficult	difficult	very difficult
1	**2**	**3**	**4**	**5**

AT SIX MONTH VISIT ONLY (Contact 6)

Quality control

High reading = ☐☐.☐

Low reading = ☐☐.☐

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **10** Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact ☐ Date d d m m y y y y Nurse Initials ☐☐

HEALTH SERVICE USE SINCE YOUR LAST FOLLOW-UP VISIT

We would like to know how much use has been made of the listed health services since your last follow-up visit, for any reason. We would rather have a best guess than no information at all. Please answer every question, even if the answer is 0, by filling in both boxes (for example 03 if the answer is three times).

Primary care:

How many times since your last visit have you been:

1. Seen by GP a) in surgery ☐☐ b) at home ☐☐

2. Seen by a nurse a) in surgery ☐☐ b) at home ☐☐

Secondary care:

How many times since your last visit have you been:

3. Seen in Accident and Emergency (A&E) Department ☐☐

4. Seen in any other hospital outpatient clinic ☐☐

5. Admitted to day hospital ☐☐

6. Admitted to inpatient care (been in hospital overnight) ☐☐

Inpatient episode:	Number of nights spent in hospital:	Type of department: *(medical=1, surgical=2, other=3)*
a)	☐☐	☐
b)	☐☐	☐
c)	☐☐	☐

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **10** Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact ☐ Date d d m m y y y y Nurse Initials ☐☐

Other health services:

How many times since your last visit have you been:

7. Seen by a dietician ☐☐

8. Seen by an optician ☐☐

9. Seen by a podiatrist a) NHS ☐☐ b) private ☐☐

10. Seen by any private practitioner (e.g. acupuncturist)

Type of practitioner:	Number of times:
a)	☐☐
b)	☐☐
c)	☐☐

GROUP 1 ONLY

Blood sugar test:

Since your last visit:

11. Have you used a blood sugar meter to check your blood sugar results yourself?

Yes = 1 No = 2 ☐

12. If yes, what is the total number of readings taken (including those not recorded)?

☐☐☐

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **11** Study ID | | | | | | | | Patient Initials | | |

Date | d | d | m | m | y | y | y | y | Nurse Initials | |

CONTACT OUTSIDE OF SCHEDULE

Phone calls, visits, associated problems or queries.

Type of contact Phone =1 Visit =2 ☐

Type of problem or query ☐

Technical problem with meter = 1 Concern about readings = 2
Other concerns about health = 3 Change appointment = 4 Other =8 (specify)

_____

_____

_____

What action / advice was given? ☐

Advice given by study nurse = 1 Referred to study co-ordinator = 2
Advised to contact GP/ Practice Nurse = 3 Other = 8 (specify)

_____

_____

_____

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **12** Study ID ☐☐ ☐☐☐☐ Patient Initials ☐☐☐

Contact **08** Date d d m m y y y y Nurse Initials ☐☐

CLINICAL ASSESSMENT AT THE END OF THE STUDY

Blood Pressure

Take 3 times, disregard the first and record mean of the second and third.
Readings should be taken at least 10 minutes apart.

2nd ☐☐☐ /☐☐☐ mm Hg

3rd ☐☐☐ /☐☐☐ mm Hg

Weight ☐☐☐ .☐ **kg**

Smoking

Have you changed your smoking habits since last year? ☐

Yes = 1 No = 2

If yes how have you changed? ☐

Have cut down = 1 Stopped smoking = 2 Increased = 3 Started = 4

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF 13 Study ID [ ][ ] [ ][ ][ ][ ] Patient Initials [ ][ ][ ]

Date [d][d][m][m][y][y][y][y] Nurse Initials [ ][ ]

LOST TO FOLLOW UP/ WITHDRAWS FROM STUDY

Reason for leaving [ ][ ]

Moved away = 1
Patient refused further contact = 2
Patient too frail to continue = 3
Patient died = 4
Unable to make contact = 5
Other reason = 6

Details

_____

_____

_____

Has the patient agreed to be contacted at 12 months for final assessment?

Yes / No

Complete CRF 6 if any adverse event since last visit

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

CRF **14** Study ID [ ][ ] [ ][ ][ ][ ] Patient Initials [ ][ ][ ]

Contact [ ] Date [d][d][m][m][y][y][y][y] Nurse Initials [ ][ ]

BLOOD SUGAR MONITORING (Groups 2 and 3 only)

Location: Surgery = 1 Home = 2 Other = 8 [ ]

Total number of blood sugar readings recorded in diary since last visit [ ][ ][ ]

Total number of readings taken (including those not recorded) [ ][ ][ ]

this should be equal to or higher than total number of blood sugar readings recorded since last visit (previous data item)

Were any readings below (<) 4.0 mmol/L identified? Yes = 1 No = 2 [ ]

If yes, has CRF6 (adverse event form) been completed? Yes = 1 No = 2 [ ]

The following data ONLY relates to the four weeks immediately prior to the visit date:
(do not include any readings outside specified time periods)

How many fasting blood sugar readings were recorded in the last four weeks? [ ][ ]

How many of these fasting readings were above 6.0 mmol/L? [ ][ ]

How many pre-midday / pre-evening meal readings were recorded? [ ][ ][ ]

How many of pre-midday/pre-evening readings were above 6.0 mmol/L? [ ][ ]

How many readings taken 2 –3 hours after the end of a meal were recorded? [ ][ ][ ]

How many of these post-meal readings were above 8.0 mmol/L? [ ][ ]

Appendix 11

Coding schedule for notes review/ adverse events

DiGEM Diabetes Glycaemic Education and Monitoring Study (OPREC No:O02.059)

MASTER CODING SHEET FOR CRF 6

Grade 1 hypoglycaemia	01	Ischaemic heart disease (except angina/ ACS; not including old MI)	19
Grade 2 hypoglycaemia	02	Angina (not unstable)	20
Grade 3 hypoglycaemia	03	DM neuropathy	21
Grade 4 hypoglycaemia	04	Cataract extraction	22
Myocardial infarction (incl. previous MI)	05	Blindness in one eye	23
Acute coronary syndrome (i.e. unstable angina ONLY)	06	Diabetic retinopathy (not background; incl. maculopathy)	24
Stroke	07	Angioplasty	25
Transient ischaemic attack	08	Fatal CHD event	26
Peripheral vascular event	09	Fatal stroke	27
Coronary artery bypass graft	10	Non-diabetes mortality	28
Peripheral vascular procedure	11		29
Heart failure	12	Not applicable	88
Amputation	13		
Possible drug reaction	14		
New prescription of anti depressant	15		
New prescription of other psychotropic	16		
Other hospital admission	17		
Renal failure	18		

14 is sub-divided into:

Adverse drug reaction to a hypoglycaemic drug	14
Adverse drug reaction to a non-hypoglycaemic drug	29

Appendix 12

Intervention fidelity checklist

DIGEM STUDY

CHECKLISTS TO REVIEW INTERVIEWS FOR FIDELITY TO INTERVENTION PROTOCOL AND THEORETICAL APPROACH

VERSION 1.1

16TH JUNE 2003

DiGEM Study Checklist

Patient ID: **Date of visit:**

Study Nurse Initials:

Assessment visit

	Criterion	Examples	No	Yes
1	Has the nurse facilitated the patient's expression of any emotional concerns that may influence the meeting?	Asked directly about mood/used consulting skills to help expression of emotional concerns		
2	Have beliefs about the cause of diabetes been discussed?			
3	Have beliefs about the symptoms of diabetes been discussed?			
4	Have beliefs about the course of diabetes been discussed?	e.g. Acute/chronic		
5	Have beliefs about the consequences of diabetes been discussed?	e.g. complications		
6	Have beliefs about possibility of medication to control diabetes been discussed?			
7	Have beliefs about possibility of physical activity to control diabetes been discussed?			
8	Have beliefs about possibility of eating patterns to control diabetes been discussed?			
9	Has study nurse referred to "diabetes control" when appropriate and refrained from using "blood sugar control" during discussion?			
10	Has any patient initiated discussion about blood sugar been limited to "sugar leading to damage" and "assessment of long term control", and avoided discussion of measures that might be used to directly control blood sugar from day to day?			

Additional comments:

DiGEM Study Checklist

Patient ID: **Date of visit:**

Study Nurse Initials:

Randomisation visit

All groups

	Criterion	Examples	No	Yes
1	Has the skill of goal setting been discussed with the patient?			
2	Has the skill of goal setting been applied to a behaviour either selected by the patient or suggested by the nurse on the basis of the information gained at the assessment visit?	Specific goal required.		
3	Has the skill of forming a specific plan been discussed with the patient?			
4	Has the skill of forming a specific plan been demonstrated by facilitating the patient in formulating a specific plan?	Specific plan required.		
5	Has the skill of monitoring behaviours and outcomes been discussed with the patient?			
6	Has the patient formulated a specific plan to monitor progress in their specific plan towards a goal?	Specific plan for monitoring required		
7	Has the consultation been conducted with reference to general consulting skills (patient centred approach, avoiding didactic instruction)?			

Group 1 only

	Criterion	Examples	No	Yes
8	Has the randomisation visit been conducted without suggesting regular use of a meter to measure blood sugar?			

Group 2 only

	Criterion	Examples	No	Yes
9	Has patient been told that the nurse, GP or practice nurse will review the blood test results?			
10	Has the randomisation visit been conducted without suggesting that behaviours should be altered as a result of day-to-day information gained by using the meter?			

DiGEM Study Checklist

Patient ID: **Date of visit:**

Study Nurse Initials:

Randomisation visit sheet 2

Group 3 only

	Criterion	Examples	No	Yes
11	Has the blood glucose meter been presented as a means of gaining information about the effects of lifestyle changes and changes in medication?			
12	Has the patient been encouraged to experiment with the timing of testing, in addition to the requested readings?			
13	Has the patient been told about the possibility of using information gained from the blood sugar meter to modify behaviour from day-to-day or week-to-week?	Modify foods after seeing effect		
14	Has the possibility of using blood sugar tests as a prompt or reinforcement to identified goals been discussed?	e.g. test before and after activity to see impact on blood sugar		

Additional comments:

DiGEM Study Checklist

Patient ID: Date of visit:

Study Nurse Initials: Contact No.:

Follow-up visit

All groups

	Criterion	Examples	No	Yes
1.	Has there been discussion about revising or maintaining the previous behavioural goals?			
2.	Has there been discussion about revising or maintaining the previous specific plan to achieve the behavioural goals?			
3.	Has there been discussion about revising or maintaining the previous plans for self-monitoring?			

Group 1

	Criterion	Examples	No	Yes
4.	Has standardised feedback on glycaemic control been given based on HbA_{1c} avoiding reference to day to day changes in blood sugar in relation to behaviours?			
5.	Has the patient had the opportunity to discuss lifestyle and/or medication changes that might be indicated in relation to the HbA_{1c} test result?			
6.	Have previously noted beliefs been discussed in relation to the targeted behaviours?			
7.	Has the visit been conducted without suggesting regular use of a meter to measure blood sugar?			

Group 2

	Criterion	Examples	No	Yes
8.	Has discussion of blood glucose self-monitoring results been limited to generalization of whether results were satisfactory or in need of improvement?			
9.	Has the patient had the opportunity to discuss medication changes that might be indicated in relation to the overall level of control indicated by the test results (as protocol)?			
10.	Have previously noted beliefs been discussed in relation to the targeted behaviours.			
11.	Has the visit been conducted without suggesting that behaviours should be altered as a result of day-to-day information gained by using the meter?			

DiGEM Study Checklist

Patient ID: Date of visit:

Study Nurse Initials: Contact No.:

Follow-up visit sheet 2

Group 3

	Criterion	Examples	No	Yes
12.	Have the results of blood glucose monitoring been discussed in relation to specific behavioural goals and other behaviours?			
13.	Has the patient had the opportunity to discuss medication or lifestyle changes in relation to blood glucose test results?	Open and direct questions, communication skills to facilitate discussion.		
14.	Have previously noted beliefs been discussed in relation to the blood glucose test results and to the targeted behaviours?			

Additional comments:

Appendix 13

Trial management committee list

DiGEM Management Group

Mrs. Anthea Craven

Dr. Andrew Farmer

Ms. Alice Fuller

Prof. Andrew Neil

Ms. Mary Selwood

Dr. Judit Simon

Dr. Alisha Wade

Dr. Pat Yudkin

Ms. Sue Ziebland

Appendix 14

Topic guide for qualitative study

Topic guide for DiGEM qualitative study

Objectives

(i) to obtain an oral history of each individual's diabetes
(ii) to explore patients' perceptions about control of their diabetes
(iii) to explore patients' perceptions of the trial intervention
(iv) to explore perceptions about glycaemic control
   a. use
   b. use of results
   c. burden of testing
   d. role of self-monitoring in perceptions/beliefs and behaviour
   e. Overall evaluation of utility
(v) to explore impact of planned behaviours on perceptions

Topic focus	*Core questions/topics*	*Additional questions and probes*
Preamble and demographic information	Briefing about interview Tell me a bit about yourself	• use of non-technical terms; absence of names etc • Age, occupation, family
Illness narrative	Could you tell me all about what has happened since you first began to suspect that you might have a health problem?	Patients diagnosed due to symptoms • What first made you think there might be a problem? • What did you think when you first started having symptoms? • What did you do when you first thought something was wrong (eg ask advice from friends, family; pharmacist, try to self treat, look for information etc)? • How long were you feeling unwell before you went to your doctor? • What made you decide to see your doctor? Asymptomatic patients diagnosed at screening • How did you happen to go to your doctor? • What method was used to screen for your diabetes? • What did you think of the method used to check for your diabetes? • Had you ever checked for your diabetes before? Both groups on diagnosis • What happened when you went to your doctor? • Were you referred to see someone else? • Did you see anyone else? • Did you know anything at all about diabetes at that point? What did you know? Did you know anyone else with diabetes?

		• How did you feel about being diagnosed with diabetes? • What happened after you were diagnosed? <u>Effect of diagnosis on life</u> • How have things gone for you since you were diagnosed? • What impact has diabetes had on your life? <u>Information on diabetes</u> • Were you given any information about diabetes? Was it enough? • Did you go anywhere else for information? <u>Sharing of diagnosis</u> • Have you told other people about your diabetes? • Is there anyone you have chosen not to tell? • Do you know anyone else with diabetes? <u>Causes of diabetes</u> • Did you have any ideas about what causes diabetes when you were diagnosed? • Do you have any ideas about what caused your diabetes? <u>Illness identity</u> • How does having diabetes make you feel now? (physically, emotionally) • What is it about diabetes that affects you in this way? • Do you think it is important to control your blood sugar? Why? • Do you think your diabetes has any effect on you in the short/long term? <u>Timelines</u> • Do you have any ideas about what will happen to your diabetes in the future? • Do you think your diabetes will get better or

		worse over time? • Do you think your diabetes comes and goes or is it there all the time? <u>Consequences</u> • What effect do you think diabetes might have on your life? • Do you have any fears or concerns about the future? <u>Treatment options</u> • What treatment has been discussed with you? What do you think about the options? • Have you tried any complementary approaches? Tell me about them? <u>Further information</u> • Do you have any questions about diabetes that you would like answered? • Do you have any advice for other people diagnosed with diabetes? • Is there anything you would like to say to doctors and nurses training to treat people with diabetes?
Control of diabetes	Do you think there is anything you can do to control your diabetes? What?	• Do you feel your diet contributes to your diabetes control? • Do you feel physical activity contributes to your diabetes control? • Do you feel medication contributes to your diabetes control? • Is there anything that makes it difficult for you to follow recommendations about eating/exercising/medication taking?
Perceptions of trial intervention	For the past few months, you've been taking part in a trial to help you improve your health. Can you tell me, in your words, what the trial is about and why you think you were invited to take part?	<u>Understanding of trial process</u> • What do you think the trial is trying to discover? • Why do you think you've been chosen to take

	How useful has the trial been for you?	part? • Do you have any ideas how you were chosen for your group? (prompt understanding of random allocation to groups) • Do you think the group you are in is (the most) appropriate for you? <u>Usefulness of trial</u> • What information have you been given as part of this trial? • How helpful has it been? • Has the trial helped you in any way? Anything in particular? • Were the skills you were introduced to (goal setting, action planning, monitoring of goals) useful in any way? • How did you feel about the feedback about your diabetes control? Was that helpful in any way? • Is there anything which you think is not helpful for you? Anything in particular? • Is there anything you think should be done differently in the trial? Anything in particular? <u>Interaction with study nurse</u> • What did you think of the approach of the study nurse? DO you remember anything that was helpful/ not so helpful about her approach? • Did you think you had the chance to discuss your concerns with her?
Perceptions about glycaemic monitoring	People have different ways of keeping a check on their diabetes control. Some people have their control checked by their doctor and some people check it themselves. Tell me about how your keep a check on	<u>Methods of monitoring</u> • If you had the option of A. checking your diabetes control by testing your blood at home or B. having your doctor get an idea of your

	your diabetes control. Tell me a bit about how useful you find it knowing about your diabetes control. Do you check your blood sugar at home? Tell me what testing your blood sugar is like for you.	long term control by checking every three months, which would you prefer? Why? Any other reasons? <u>Usefulness of monitoring</u> • Is knowing your diabetes control of any use to you/ your doctor? • Does monitoring your diabetes control make any difference to you? In what way? • Do you like knowing how your diabetes control is? Why? <u>Ease of use</u> • Is there anything that makes it difficult for you to keep a check on your diabetes control? <u>Use of BGSM</u> • How often do you test? • What do you do with the results? • How has testing your blood sugar affected you? • What prompts you to check your blood sugar at home? • Do you use the result to alter your eating/activity/medication taking in any way? • Do you find the process easy/difficult? Why? • Has testing your blood sugar changed the way you think about your diabetes? In what way? • Does testing your blood sugar change the way you behave? In what way? • Has testing your blood sugar been useful for you? In what ways? • Is there anything you find difficult or unpleasant about monitoring your blood sugar?
Impact of planned behaviour on diabetes	You've set some goals during this trial- have they changed the way you think about diabetes in any way?	• Have your views about the way your eating/physical activity/medication affects your diabetes changed?

		• Has knowing what your diabetes control is like made any difference?