

Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study)

FINAL REPORT

JULY 2006



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Acknowledgements

Australian Government Department of Health and Ageing – For funding this project through the Third Community Pharmacy Agreement.

Pharmacy Guild of Australia – For having the vision to support research into new clinical services for community pharmacy.

WA Data Linkage Unit – The expert assistance of Di Rosman and her staff in the provision of Emergency Department Attendance, Hospital Admission and Mortality data for the pharmacoeconomic evaluation of the project.

Health Insurance Commission – For the provision of Medicare and PBS data for the pharmacoeconomic evaluation of the project.

The Pharmacists – For enthusiastically taking on this program and giving us valuable feedback on its implementation in community pharmacy. The pharmacists who participated were as follows:

Pharmacist Educators: Diana Benino, Shelley Kinsella, Julie Turich

Control Pharmacists: Robina Elliott, Paul Jardine, Jim Koios,
Erica Nardi

Intervention Pharmacists: Peta Bennett, David Henrisson, Paul Ponsford,
Michelle Rocchiccioli

Training Workshops: We are grateful to the following people for their contribution:

Mark Coles, Jeff Hughes, Jenny Wilkinson

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Glossary of Abbreviations

ΔAR	Change in Absolute Risk
ACEI	Angiotensin Converting Enzyme Inhibitor
AR	Absolute risk
ARR	Absolute risk reduction
ATT II	Angiotensin II
AusDiab	Australian Diabetes Study
BGL	Blood Glucose Level
BMI	Body Mass Index
BP	Blood Pressure
BSL	Blood Sugar Level
CHD	Coronary Heart Disease
CI	Confidence Interval
CMMS®	Comprehensive Medication Management Software
CRDQ	Chronic Respiratory Disease Questionnaire
D-BP	Diastolic Blood Pressure
DMEP	Diabetes Mellitus Education Program
DPAQ	Diabetes Patient Assessment Questionnaire
DSC-R	Diabetes Symptoms Checklist-Revised
DSME	Disease State Management Education
FBG	Fasting Blood Glucose
GP	General Practitioner
HbA1c	Haemoglobin A1C
HDL	High Density Lipoprotein
HRQoL	Health Related Quality of Life
IGT	Impaired Glucose Tolerance
LDL	Low Density Lipoprotein
M	Million
MCID	Minimum Clinically Important Difference
N	Total number of patients
NIDDM	Non-Insulin Dependent Diabetes Mellitus
NNT	Number Need-to-Treat
NPS	National Prescribing Service
OR	Odds Ratio
OTC	Over-the-Counter
PBS	Pharmaceutical Benefits Scheme
PC	Pharmaceutical Care
PCPs	Primary Care Providers
PDCP	Pharmacy Diabetes Care Project
QALYs	Quality Adjusted Life Years
QID	Four times daily
QoL	Quality of Life
RAS	Renin Angiotensin System
S-BP	Systolic Blood Pressure
SD	Standard Deviation
SE	Standard Error
SEM	Standard Error of the Mean
SF-36	Short-Form 36 Questionnaire
SMBG	Self-Monitoring of Blood Glucose
SPSS	Statistical Package for Social Sciences
TC	Total Cholesterol
UKPDS	United Kingdom Prospective Diabetes Study
US	United States

1. EXECUTIVE SUMMARY

1.1 Objectives

The specific aims of the Diabetes Mellitus Education Program (DMEP) were to examine the role of the community pharmacist in the disease state management for type 2 diabetes; to implement a specialized service for patients with type 2 diabetes; to evaluate the model in terms of process and outcomes indicators; and to investigate patient and pharmacist satisfaction with the service.

1.2 Null Hypotheses

H_0 : There will be no significant difference between Intervention and Control

Groups pre- and post intervention in:

- Patients' knowledge of diabetes and its management
- Compliance with diabetes treatment and monitoring regimens
- The number of patients achieving desired blood glucose and HbA1c levels
- The incidence of hyper- and hypoglycaemic episodes
- Quality of life and well-being scores
- Consumption of health resources

1.3 Research Design

The DMEP utilised a multi-site clustered, randomised control versus intervention, repeated measures design within four socioeconomic regions within the Perth metropolitan area. The eight community pharmacies recruited for the DMEP program came from a representative sample Diabetes Australia Sub-Agencies. The project pharmacies were divided into two groups – Intervention and Control.

Patients in the Control Group received “standard care”. While patients in the Intervention Group were enrolled into the DMEP program which involved:

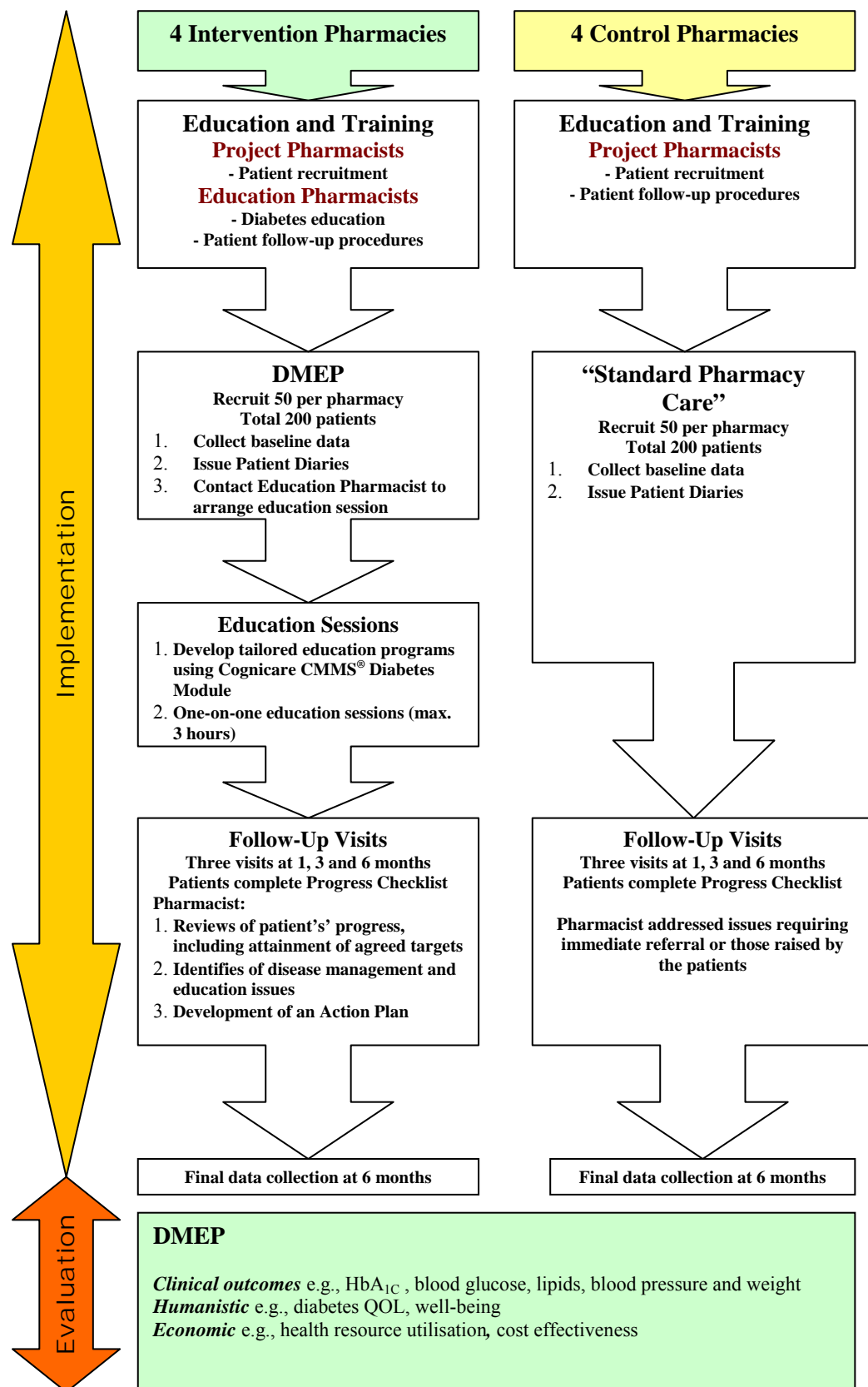
- the administration of a diabetes mellitus specific questionnaire designed to identify individual patient's educational needs

- development and delivery of a tailored education program
- regular monitoring of blood glucose levels (BGLs) and other treatment targets
- progress assessment, and
- Identification of barriers to adherence and interventions to overcome these.

Patients in both groups were provided with diaries in which to record their BGLs and weekly weights, together with episodes of hypo- and hyper-glycaemia, and record other health-related matters. The diaries contained information on diabetes and its management, a current list of the patient's medications and targets for good diabetes care. There was also provision for the patients to record appointments with other health care professionals.

Patients in the Intervention groups were provided with up to 3 hours of one-on-one diabetes education by a trained pharmacist diabetes educator. After the completion of the education sessions patients were followed up at 1, 3 and 6 months. At each of these sessions patients were asked to complete a Patient Checklist, which was used in the monitoring of patient progress and the identification of barriers to adherence. These sessions also involved the provision of further education, goal setting, identification and resolution of drug related problems and where necessary referral of patients to other health care providers. At the completion of these sessions patients were provided with an action plan setting out issues identified and actions required to address these, which were reviewed at subsequent visits. Control patients were assessed also at 1, 3 and 6 months, and were asked to complete a Progress Checklist; however they received no other intervention except for the usual pharmacist's advice/care over the 6 month period.

Figure: DMEP Study Schema



1.4 Key Findings

- Two hundred and forty five patients consented to participate in the study; however 63 failed to complete the enrolment process. Of those who did complete the enrolment process 71.2% (57/80) and 71.6% (73/102) of Intervention and Control Patients respectively completed the study.
- Patients in the Intervention Group received on average 1.5 ± 0.6 tailored education sessions and a total of 106 ± 44 minutes of education.
- The most common topics addressed during the education sessions were hypoglycaemia, hyperglycaemia, carbohydrates and diabetes medications.
- Patients in the Intervention Group reported significantly greater knowledge and understanding of diabetes and its management than Control patients at the completion of the study.
- Over the course of the three DMEP follow-up sessions, Intervention pharmacists identified 165 issues requiring intervention (2.89 per patient); 37.6% related to lifestyle, 33.6% related to medications, and 26% related to disease.
- For the Intervention Patients
 - HbA1c fell from $8.35 \pm 0.20\%$ at baseline to $7.87 \pm 0.22\%$ at exit (-0.48% ; $p=0.003$) for those patients with a baseline HbA1c $> 7\%$
 - Mean systolic BP dropped from 137.8 ± 2.4 mmHg at baseline to 131.2 ± 2.2 mmHg at exit (-6.2 mmHg; $p<0.02$)
 - Weight fell from 84.9 ± 3.7 kg at baseline 83.9 ± 3.5 kg at exit (-1 kg; $p = 0.038$), and the BMI from 31.2 kg/m² to 29.2 kg/m² (-1.6 kg/m²; $p = 0.02$)
- After adjusting for baseline differences between Intervention and Control patients significant improvements in LDL cholesterol (-0.18 mmol/L 95% CI $-0.36, -0.0009$) and HDL cholesterol (0.21 mmol/L; 95% CI $0.04, 0.39$) levels were seen. Whilst, the reductions in systolic BP (-6.3 mmHg; $p = 0.054$) and weight (-0.87 kg; $p = 0.09$) showed strong trend towards a benefit from the Intervention.

- Significant reductions in the frequency of hyper- and hypo-glycaemic episodes were seen in the Intervention Group, which correlated with a significant increase in self-reported knowledge and understanding of hyper- and hypoglycaemia amongst Intervention patients compared to Controls.
- At the completion of the study there was significantly greater willingness amongst Intervention patients compared to Controls to work toward improving their diabetes care.
- Patients in the Intervention Group recorded lower scores in all six dimensions of the Diabetes Symptoms Checklist-Revised at the completion of the study compared to Control patients; with the changes statistically significant in two suggesting a better level of well-being.
- Based on responses to the SF-36 Short Form questionnaire Intervention patients demonstrated higher scores across all dimensions except “Role-Physical”. The improvement only reach statistical significant for Social Functioning; although based on the one SEM criteria clinically significant improvements were achieved in the dimensions of Physical Functioning, Vitality, Social Functioning, Role – Emotional and Mental Health.
- Patients reported great satisfaction with the DMEP, citing accessibility to the program, improvements in their knowledge about diabetes, and ongoing support in the management of their diabetes as major benefits.
- Pharmacists also expressed great satisfaction with their involvement in the delivery of DMEP and saw an opportunity to extend their role in diabetes care in the future.
- The Intervention was not associated with any statistically significant changes in health resource utilisation, although there were some reductions in Medicare and HIC expenditure, the acuity of hospital admissions and duration of hospital stay.
- The pharmacoeconomic benefits of the study are summarised in the Addendum entitled: “Economics of Providing the DMEP Service.”

1.5 Conclusions

The Diabetes Mellitus Education Program (DMEP) demonstrated that community pharmacists can enhance patients’ knowledge and understanding of

their diabetes and its management. Further that its can deliver meaningful outcomes to participants, namely a reduction in hypo- and hyper-glycaemic episodes, which translate into improvement in quality of life. The cost of avoiding hypo- and hyper-glycaemic episodes was low; supporting the notion that the DMEP is a clinically and cost effective professional service which may be implemented in a wide range of community pharmacies in Australia. The patients and pharmacists involved in the DMEP were very satisfied with education and follow-up sessions provided as part of the program. Further they felt that such a community pharmacy-based program should be more widely available, and expressed a preparedness to participate in such a program on an ongoing basis.

Community pharmacists' role in patient education has been acknowledged by patients and health care professionals alike. It is also acknowledged that diabetes education is an ongoing process, designed to support patients in self-management of their disease. The DMEP allows community pharmacists to be engaged in this process of ongoing care; assisting patients achieve the best outcomes from their disease management. To maximise their success and professional satisfaction, pharmacists who wish to participate in this process should undergo specialised training in diabetes education and management.

Community pharmacies provide an ideal environment for the provision of enhanced pharmacy services. Pharmacists are ranked second only to doctors as sources of information on disease management. Whilst the provision of disease state management services, such as the DMEP, may be confronting to some traditional community pharmacy clients, their uptake by patients is likely to be driven by the convenience of attending a community pharmacy and patients' perceived health benefits derived from participating in such programs. Given self-management is the cornerstone of diabetes management, and that this is greatly enhanced through patient education, it appears likely that future provision of extended services, such as the DMEP, would be adopted and supported by patients in Australian community pharmacies. Furthermore, as was the case with the Pharmacy Diabetes Care Program, subsidisation by the

Australian Government would enable widespread uptake of the DMEP by community pharmacy.

In conclusion, DMEP services implemented in this study have the potential to contribute to improved patient self-efficacy in their management of their diabetes, and with that associated improvements in health outcomes and quality of life.

2. BACKGROUND

The number of people with diabetes worldwide has tripled since 1985¹. This diabetes epidemic particularly relates to type 2 diabetes¹. In Australia, one in four people, 25 years and over, has diabetes or a condition of impaired glucose metabolism.¹

Diabetes is of concern in Australia from health, economic and societal points of view. In economic terms, the annual cost to the nation is more than \$3 billion dollars¹. From a health view point, diabetes and impaired glucose metabolism, coupled with obesity, dyslipidaemia and hypertension, constitute a significant threat in terms of the socioeconomic burden of cardiovascular disease and diabetic complications for Australia.² Once diagnosed, type 2 diabetes represents a chronic disease the long-term management of which poses significant challenges for our health care system.²

As the number of cases of diabetes and the cost of care increases, there will be increased pressure on the health care system to provide more intensive care to more patients with diabetes.² However, one of the barriers to optimal care of patients with type 2 diabetes is poor patient adherence to treatment. As diabetes management is reliant on patients being involved in their own care, patient education is one way of overcoming this barrier.

Patient education is seen as an essential component of diabetes management, as people with diabetes need to have the knowledge and develop the skills necessary to enable them to become “experts” in self-care.³ Patient empowerment should be the aim of patient education. A multidisciplinary approach to education is vital in achieving this aim; it enables patients to make informed choices about their self care options.³

A number of high profile education programs which aim to better educate diabetes sufferers on the management of their condition are in place around Australia. These programs have been developed by Diabetes Australia, Divisions of General Practice and pharmaceutical care providers.

It has been suggested that the Australian health care system will not be able to afford intensive management of type 2 diabetes delivered solely by one group of health care providers.² A team approach has been hailed as an effective way of minimising the burden of diabetes management on the Australian health care system. Community pharmacists are ideally placed to assist in the education of individuals at risk of, or who have diabetes, because they are accessible, available and in frequent contact with the public.²

Research suggests that the primary health care consultation rate in Australian pharmacies may be as high as 43 million per year. Visits to the community pharmacy therefore appear to offer an excellent opportunity to undertake screening, education and referral of individuals at risk of diabetes.²

2.1 Education Programs

2.1.1 Educational Interventions

The Task Force to Review and Revise the National Standards for Diabetes Self-Management Education Programs⁴ defines:

Diabetes self-management education (DSME) as an interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). This process includes:

1. Assessment of the individual's specific education needs
2. Identification of the individual's specific diabetes self-management goals
3. Education and behavioural intervention directed towards helping the individual achieve identified self-management goals
4. Evaluation of the individual's attainment of identified self-management goals.

Steed et al have indicated that many early interventions to improve health outcomes in diabetic patients focused on improving the patients' knowledge; in the belief that improved knowledge would lead to enhanced adherence. It is now recognised that whilst knowledge of one's disease and its management is important, alone it is often insufficient to effect behavioural change and thus improve clinical outcomes.⁵ Thus a range of interventions are employed to enhance diabetes outcomes, including education, self management and psychological interventions, as demonstrated in the activities involved in DMSE process outlined above. Table 2.1 below provides the definitions used by Steed et al in their systematic review of psychosocial outcomes in diabetic patients following education, self-management and psychosocial interventions. It provides a guide to the scope of diversity of the components which may make up any given diabetes educational intervention.⁵ It is not surprising then that the benefits reported vary between and within studies which seek to assess the role of education in influencing patient outcomes and patient management of diabetes.

Table 2.1: Coding of Diabetes Education Intervention Components⁵

Code	Component description
GE	General education: Basic provision of information, commonly using didactic techniques. This code was also used when the only description given was education program.
GD	General discussion: Discussion between participants within a group. Can be facilitated by professional or lay leaders.
ST	Skills training: Teaching of practical skills such as use of blood sugar results, meal planning through demonstration and patient participation.
B	Behavior therapy: Use of behavioral techniques such as goal setting, reinforcement, modeling, reward systems, alteration of environmental cues.
PS	Problem solving: Identification of problems or barriers to behavior and strategies to overcome them. Includes both practical and psychosocial problems. Focus should be on patient problem solving rather than by health care professionals.
C	Cognitive therapy: Teaching or use of cognitive techniques to influence cognition's, e.g. challenging beliefs, considering role of thoughts and emotions, counseling and psychotherapy. Where the term coping skills was used, and it did not adhere to definition of problem solving above, it was coded as cognitive therapy.
SSup	Social support: Teaching techniques to specifically help participants improve social support, e.g. where to go for extra support, communication skills. Simple support groups were not coded as this.
R	Relaxation: Actual practice of relaxation, may include imagery or distraction techniques.
Bio	Biofeedback: Use of biological feedback to assist relaxation.
RP	Relapse prevention: Discussion of how to maintain behavior in the future and prevent relapses.
D	Diet: Participants prescribed a specific weight loss plan as part of intervention. Advice on healthy eating diet and related goal setting was not coded.
E	Exercise: Specific exercise sessions as part of intervention. Advice to increase exercise and related goal setting was not coded.
Mis	Miscellaneous: Where a term is used but not described in sufficient detail to code as any of the above, e.g. stress management.

Note: Coding for all components was based on descriptions available from the published literature.

A number of systematic reviews and meta-analyses have been undertaken to assess the benefits of education on diabetes management and outcomes.⁵⁻⁷ A common amongst the findings of these studies is that documentation of actual

nature of the intervention is often inadequate, and assumptions as to its nature are often made on the basis of the outcomes measured.

2.1.2 Outcome Measures

The effectiveness of educational interventions is often assessed based on such outcome measure as:

- Improved patient knowledge
- Improved glycaemic control
- Improvement in patient adherence to self-monitoring and treatment
- Reduction in risk factors (e.g. lipids, blood pressure, weight, smoking)
- Reduction in short and long-term complications
- Changes in the rate of prescription of antidiabetic medications
- Reduction in health utilisation
- Improvements in well-being and quality of life.⁷

Variations observed in outcomes between studies may arise due to sub-population of diabetes patients in the studies, rates of attrition, patients' baseline characteristics (e.g. HbA1c, blood pressure, lipid levels, BMI, use of antidiabetic medications, level of self-monitoring of blood glucose levels), the nature of the interventions applied, the level of follow-up, the duration of the intervention and the time at which the benefits are assessed. For example, Norris et al concluded the following from their meta-analysis of the benefits of self-management education for adults with type 2 diabetes:

“Self-management education improves GHb (HbA1c) levels at immediate follow-up, and increased contact time increases the effect. The benefit declines 1–3 months after the intervention ceases, however, suggesting that learned behaviours change over time. Further research is needed to develop interventions effective in maintaining long-term glycaemic control.”⁸

Furthermore, there is often a lack of correlation between outcome measures. For example improvements in glycaemic control, as measured by a reduction in HbA1c levels have shown poor correlation with improvements in patients' quality of life scores. In the case of quality of life, outcomes achieved can be influenced by the specific measure used in the study (i.e. generic or disease specific). Steed et al⁵ report that studies using the SF-36 Short Form questionnaire report benefits less frequently than those using a diabetes specific measure. In the case of long-term complications many studies, the duration of many studies is too short to allow detection of changes in the incidence of such complications.⁷

2.1.3 Structure

The currently available literature supports the use of group-based education interventions for patients with type 2 diabetes.^{7,9-11} However, considerably more research has been undertaken to assess the benefits of group-based interventions than those of individualised education programs.

Current research emphasises that health care providers need to adopt a more person/patient-centred counselling style in the education of diabetes patients.¹¹ Patient education is a necessary antecedent to behavioural change.¹² Specifically, it has been suggested that changes in attitude and motivation via integrated education are needed to achieve metabolic control⁶, and therefore that individually-based education which seeks to address personal needs may be an improved way of affecting this change. Some research suggests people with diabetes should be taught at a time and place conducive to learning, as an outpatient in a nationally recognised program of diabetes education classes.⁴ However, other research has suggested that it is best to maximise the time spent on topics immediately relevant to the patient's diabetes.⁴ Therefore, individually tailored-programs can provide for such timely information in the right setting.

2.1.4 The Value of Education

The UKPDS 65 researchers have reported that the use of aggressive efforts to lower blood glucose levels for the treatment of type 2 diabetes is paramount.¹³

This UKPDS 65 study established that retinopathy and nephropathy are benefited by lowering blood glucose levels to achieve a median HbA1c of 7%; reducing the overall microvascular complication rate by 25%. Additionally, the study provided evidence that hyperglycaemia is the major contributor to microvascular disease and its associated risk of cardiovascular complications. For every percentage point reduction in HbA1c, there is a 25% reduction in diabetes-related death, a 7% reduction in all-cause mortality, and an 18% reduction in combined fatal and non-fatal myocardial infarction.¹³

The UKPDS was a landmark diabetes study proving the value of metabolic control. Health care professionals and patients alike need to treat diabetes seriously. It is incumbent on the health care system to provide the necessary resources to expedite and optimise disease management in diabetes patients. The acceptance of the current disadvantageous and dangerous status quo in people with diabetes should no longer be tolerated. Gaede and Pedersen¹⁴ in their review of the multi-targeted and aggressive approach to the treatment of high risk patients with type 2 diabetes state: “The treatment algorithms for multifactorial therapeutic packages do not harbour any revolutionizing novel drugs or previously untested behaviour modelling, but the success criteria seem to include an individualized and stepwise introduction of target-driven polypharmacy and simple but focused behaviour modelling with continuous education, motivation and trouble-shooting for treatment barriers identified for the patient and the care giver.” Reinforcing and extending the education of the patient is pivotal in this aggressive approach, a statement that has been echoed by research findings below.

Heisler et al¹⁵ postulated that knowledge of one’s actual target health outcomes, such as HbA1c, is a pre-requisite for effective patient involvement in managing their diabetes. Of 686 US adults with type 2 diabetes surveyed, 66% reported they did not know their HbA1c, further of those that said they did only 25% could accurately report the value.¹⁵ Knowledge of HbA1c was associated with more formal education and higher evaluations of providers’ thoroughness of communication. Further, respondents who knew their HbA1c had higher likelihood of accurately assessing their diabetes control. However, HbA1c

knowledge was not associated with the respondents' level of diabetes care self-efficacy or reported self-management behaviours.¹⁵

Polonsky et al¹⁶ agree that learning about HbA1c results may inspire patients to improve self care behaviours and metabolic control. Alarming, of 176 participants in their study, only 38.4% believed they had ever had their HbA1c tested. Amongst those who stated their HbA1c had be checked less than a quarter (15.3%) reported a result value that was within the possible range of HbA1c results.

In a supplementary study, Polonsky et al¹⁷ conducted a 2 hour educational workshop on HbA1c, after which patients completed a questionnaire based on understanding and experience with testing of HbA1c. Patients were administered the same questionnaire 3 months after the educational workshop. Their data suggests that enhancing HbA1c awareness may promote better diabetes management.

A study by Ko et al¹⁸ provides evidence of the long term effectiveness of structured type 2 diabetes education programs. They studied 547 hospitalised diabetic patients and allocated them into 2 groups. The intervention group (n = 243) underwent a structured education program, while the control group had no systematic education. After a 4 year follow-up, the mean glycaemic control status for those patients who undertook the education program was significantly better than control group. Patients in the intervention group had lower HbA1c levels, and better self blood glucose monitoring, diet control status and exercise frequency compared with controls.¹⁸

2.1.5 The Role of the Pharmacist in Diabetes Education

It has been reported that general practitioner can provide effective diabetes management and they that may achieve metabolic control as good as their hospital colleagues.¹⁹ However, satisfactory follow-up in primary care setting is far from optimal and cannot be guaranteed. Involvement of appropriately trained specialists and/or multidisciplinary speciality teams may reduce length of stay,

improve glycaemic control and improve outcomes for hospitalised patients. However, out-of-hospital care is an equally important part of the management of diabetes, with research showing that unstructured care in the community is associated with poorer quality of patient follow-up, less effective glycaemic control and greater mortality than in-hospital care.¹⁹

Research suggests that health care professionals in the primary care sector are now responsible for providing much of the ongoing management for patients with diabetes. The transfer of this responsibility to general practitioners without adequate support however may lead to adverse results for patients.¹⁹ In fact, it has been suggested that the Australian health care system could not afford intensive management of type 2 diabetes delivered solely by general practitioners.²

Community pharmacists are one health care group which has ready contact with patients who may play an integral role the primary care of diabetes sufferers. Community pharmacists are ideally placed to assist in the education of individuals at risk of, or who have, diabetes because they are accessible, available and in frequent contact with the public.²

Campbell and Bennett²⁰ have reported on the positive impact that pharmacists play as part of the diabetes management team. Specifically, the fact that when a pharmacist is a member of the diabetes care team patients report feeling better and having fewer health problems.²⁰ They comment that evidence from the American Pharmaceutical Association suggests pharmacists agree that they have a role to play and are keen to be part of a team when it comes to managing diabetes patients.

Community pharmacists are placed to take an active role in diabetes education with because they can interact readily with other members of the disease state management team as general practitioners, dieticians, nurses, and physical therapists. This role may include participating in community classes for patients and family, educating other members of the health care team, providing one-to-one education and counselling of patients and providing necessary supplies.²¹ It

is recognised that pharmacists have the skills to become diabetes educators.²² The pharmacist's role in the diabetes care team is confirmed in Standard 5 of the US National Standards for Diabetes Self-Management Education Programs.⁴

Standard 5

*DSME will involve the interaction of the individual with diabetes with a multifaceted education instructional team, which may include a behaviorist, exercise physiologist, ophthalmologist, optometrist, **pharmacist**, physician, podiatrist, registered dietitian, registered nurse, other health care professionals, and paraprofessionals. DSME instructors are collectively qualified to teach the content areas. The instructional team must consist of at least a registered dietitian and a registered nurse. Instructional staff must be Certified Diabetes Educators (CDEs) or have recent didactic and experiential preparation in education and diabetes management.*

The Task Force to Review and Revise the National Standards for Diabetes Self-Management Education Programs states "The multidisciplinary team utilized in DSME is one in which the different team members retain their individual disciplinary identity, work interdependently, consult with one another, and have shared goals. The team should have a collective combination of expertise in medical treatment, medical nutrition therapy, teaching skills, and behavioural psychology. It is essential in this collaborative and integrated team approach that individuals with diabetes assume an active role in their care."⁴

Diabetes care models implemented by pharmacists in the US and Australia have demonstrated clinically significant improvements in HbA1c and fasting blood glucose levels in intervention groups compared to control groups.² Integral to this outcome, has been the provision of diabetes self-management education and coaching to assist in the empowerment of the patient.² Pharmacists can be trained to educate and motivate their diabetic patients take charge of their condition.^{20,22}

Pharmacists can be an active and contributing member of the extended diabetes education team. This has been demonstrated by their commitment to developing specific diabetes education programs.

2.2 Types of Education Programs

Diabetes can often be prevented or controlled using cost effective intervention strategies¹.

Diabetic patient education has been shown to be associated with fewer complications and hospitalisations, healthier patients and longer life expectancy.²¹ Education is an essential component of management, as people with diabetes need to develop the skills to enable them to become experts in self-care.³

The International Diabetes Institute in Caulfield General Medical Centre, Melbourne, is the largest diabetes treatment centre in Australia, caring for 8000 clients a year on an annual budget of AUD 9 million. Individual appointments are available for people with type 1 and type 2 diabetes, with specialist diabetes physicians, diabetes nurse educators and dieticians. In terms of education, the centre offers seminar programs, supermarket tours, monthly support groups, counselling, books, videos and journals about diabetes.¹

Diabetes Australia is the peak consumer body representing people with diabetes in Australia, and also provides community programs, camps for children with diabetes and develops educational resources about diabetes and diabetes prevention.¹

General Practitioners provide a comprehensive level of patient care. During consultations they can assess risk factors and perform finger prick glucose testing if required. They can also raise awareness of the risks associated with certain behaviours (e.g. being overweight or smoking) and help to modify them.² However, it is important to note that the proportion of consultations in which general practitioners undertake preventative activities for cardiovascular disease

and diabetes is still relatively infrequent. It has been suggested that the main focus of medical attention is still directed at treating the consequences of disease, rather than preventative measures such as assessing and modifying risk factors for these conditions.^{2, 23-25}

The Sugar Care program is an example of a pharmacy-based diabetes care program in Australia.²⁶ This program consists of a series of modules that educate the pharmacist in various areas of specialised diabetes care including provision of a full medication review service, patient education on lifestyle factors, prompting regular medical checks and examining patient progress. Developed by the University of Sydney, Faculty of Pharmacy, it offers a diabetes care model for pharmacists providing such services in the community setting.

From research which has examined the prevalence, type and effectiveness of education programs a number of general observations can be made. Predominately, these diabetes education programs are based on group-learning principles.

In a July 1st 2005 a newspaper article reported that United Kingdom researchers had found group-based training to be the most effective way of delivering education to patients with type 2 diabetes.⁹ Group education programs were said to lead to improvement in HbA1c levels and systolic BP control, and a reduction in the need for diabetes medication. The researchers reviewed 11 studies which included 1532 patients with type 2 diabetes. Equal numbers of men and women aged between 51-65 years participated and the studies compared outcomes in patient receiving group education with either patients receiving individual education or those receiving routine treatment but still awaiting education. HbA1c levels were found to be 1.4% lower at 4-6 months and 1% lower at one year post-education amongst patients who underwent group education compared with the other interventions. Fasting BGL's at 12 months were on average 1.2 mmol/L lower in the group of patients who underwent group education. Systolic BP at 4 to 6 months was also reduced by 5 mmHg. From their review the researchers concluded that group-based model is a cost effective means for the provision of diabetes education.⁹

Deakin et al in their systematic review entitled “Group based training for self-management strategies in people with type 2 diabetes mellitus” concluded that Group-based training for self-management strategies in people with type 2 diabetes is effective by improving fasting BGLs, HbA1c and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication.¹⁰ They reported that for every five patients attending a group-based education program, one patient would be expected have a reduction of their diabetes medication.¹⁰

Hornsten et al¹¹ evaluated whether an educational intervention, focusing on a patient’s personal understanding of their illness was more effective than care given according to national guidelines for diabetes care. The intervention group (n=44) had 10 group sessions addressing themes related to patients’ personal understanding of their illness versus a control group (n=60). Nurses educated patients in theories about illness/wellness experiences and participated in group sessions at which various caring strategies related to the patient’s individual needs and understandings were reflected upon. At a one year follow-up, the intervention group showed lower HbA1c levels (mean difference of -0.94%), lower triglyceride levels (mean difference of -0.52mmol/L) and higher high density lipoprotein levels (mean difference +0.15mmmol/L). It appears therefore, that interventions which focus on patient understanding are effective in improving diabetes clinical indicators.

Raji et al²⁷ completed a study to determine whether a single intensive group education program improved HbA1c levels when compared with passive education programs. For 106 patients all with HbA1c levels greater than 8.5%, education was provided either intensively (n=50) or passively (n=56). The patients in the intensive education group received three and a half days of structured curriculum from a physician, nurse, nutritionist, pharmacist, exercise physiologist, and a social worker. The passive education group received material every 3 months sent to them by mail, which provided basic information on topics related to diabetes management. Both groups had a significant decline ($p<0.03$) in HbA1c when compared with a matched a control group (mean difference of -1.2%) who received no education. Surprisingly however, the

researchers discovered no differences in HbA1c levels between the groups at any evaluation time, suggesting that intensive or passive methods of delivering patient education had similar effects on improving HbA1c (-2% intervention, -1.9% passive).²⁷

The positive results of group-based education programs are further echoed by researchers who argue that lifestyle interventions are generally more effective in group settings, with positive outcomes noted especially for weight loss.^{6, 7, 10, 28}

An example of a more individualised approach to education was taken with the Fremantle Diabetes Study.²⁹ In this study researchers examined the effect of a pharmaceutical care (PC) program on vascular risk in type 2 diabetic patients. One hundred and ninety eight community based patients were randomised to PC (n=92) or usual care (n=88). PC patients had face-to-face, goal directed, medication and lifestyle counselling at baseline, 6 months, 12 months plus 6 weekly telephone assessments and provision of other educational material. Clinical, biochemical and medication related data were regularly sent to patients' clinicians. The main outcome of notation here was a measurable change in HbA1c. The nine steps of good PC practice were followed in each case. Specifically developing a pharmacist-patient relationship, collecting, analysing and interpreting relevant information, listing and ranking drug related problems, establishing pharmaco-therapeutic outcomes with patients, determining feasible alternatives, selecting the best pharmaco-therapeutic solution, designing a therapeutic monitoring plan, implementing individual regimen and monitoring plans and follow up. The PC patients showed lowered HbA1c by 0.5 % over 12 months from baseline. Systolic and diastolic BP fell to a greater extent over 12 months in PC patients where the mean systolic reduction was 14 mmHg. From this study, it can be concluded that individualised approaches do provide for effective management of diabetes clinical indicators.

Similar results were found in a study undertaken by Garrett and Bluml³⁰ involving multi-site community pharmacies providing diabetes care services to 256 patients. The provided services included scheduled consultations, clinical goal setting, outcome monitoring and collaborative drug therapy management.

Over the initial year of the program HbA1c mean decreased from 7.9% to 7.1% and the mean systolic blood pressure decreased from 136.2mmHg to 131.4mmHg. During the same period eye examination rates increasing from 46 to 82%, and foot examination rates increasing from 38 to 80%, together with an increase in influenza vaccination rates increased from 52% to 77%.

The results of a study undertaken by Reiber et al³¹ indicate that selected self-management and self-efficacy programs for diabetic patients lead to improved health status. These programs have also been shown to have similar effects on other chronic disease states.

Other educational programs have utilised technology in the hope of achieving better outcomes. For example, Glasgow and Bull³² conducted a study to assess the actual and potential positive outcomes on the self-management of diabetes using the following:

1. Handheld, portable or mobile devices
2. Automated telephone disease management systems
3. CD-rom programs
4. The internet.

Results showed that when these information and technology tools are used alone they do not provide for a more positive outcome in patient self-management. Rather, it was suggested that their optimal use is to supplement other forms of patient education.³² This outcome is somewhat contradicted by Izquierdo et al. who showed that diabetes education via telemedicine and in person were equally effective in improving glycaemic control (conducted with the help of a diabetes nurse educator and dietician).³³

These results help to demonstrate the difficulty in determining the most effective type of educational model for diabetes management. Whilst the current literature favours group versus individual educational programs, it must be appreciated that there has been much criticism directed against studies which have sought to assess the influence of education on diabetes management and outcomes.⁶⁻⁸ A number of limitations, including both methodological issues and

ill attention to conceptual issues, have been cited as contributors to the mixed results observed.

From a methodological perspective, Loveman et al ⁷ describes several factors that can contribute to the limitations of education-based studies which make comparison of outcomes difficult. These factors include the number of hours of contact hours provided for each intervention; variations in how many patients receive medications throughout a study; length of study and attrition rates. There is the suggestion that because of variations in intervention design, and such methodological limitations, that it is not possible to reach any firm conclusions with respect to the most appropriate educational interventions to achieve significant long lasting effects on disease state management.

Conceptual issues present another factor integral to the success of educational studies and these generally include those personal elements of the patient. It has been suggested that although intensive treatment can improve metabolic control, changes in attitude and motivation are needed to achieve metabolic control. Improved personal attitudes and motivations are seen to be more effective than knowledge in improving metabolic control.⁷ Researchers⁸ state that in order to achieve any change in clinical outcomes, behavioural and attitudinal changes need to be made and that education can provide for this change in motivation by addressing patient needs.

While it is well understood that doctors, nurses and other health professionals do not deal with disease alone, but with individuals who are ill or concerned about their health, there are few studies that have outcomes that address patient satisfaction, anxiety, adherence to treatment, symptom resolution and physiological and functional status, rather than just statistics.³⁴ If education is to be truly effective, patients should acknowledge that they have diabetes and should be able to vent feelings about it. Emotional responses may include denial, anger, anxiety and depression and therefore pharmacists may direct patients towards positive coping strategies, as well as utilising these parameters in educational programs.⁶

Steed et al ⁵ revealed that psychological well-being and quality of life may improve following self-management or educational interventions and pay particular notation to the fact that the incidence of factors such as depression and anxiety are reportedly higher for individuals with diabetes than the general population. Further studies have reported that the incidence for depression and anxiety for individuals with diabetes is 41% and 49% respectively. Coupled with this, quality of life is also reported to be lower for individuals with either type 1 or type 2 diabetes than in the general population.⁵ Addressing these conceptual issues in research may mean that subjects with lesser degrees of depression and anxiety, higher energy and more positive well being are more likely to improve HbA1c results.³⁵

Therefore it appears that if education models regarding diabetes management are to be most effective, attention to factors that influence how patients behave and therefore monitor their disease need to be better understood.

2.2.1 Factors Influencing a Patient's Behaviour in Monitoring Their Disease and Its Management

Trimmer and Voltis-Thomas²¹ recommend that the first step in implementing an educational program is to collect information that may influence patients' ability to learn diabetes self-care behaviours. This information includes a medical and social history (to identify household members who may assist), an assessment of patient knowledge, and visual, reading and motor skills.

Studies³ have revealed that many participants in educational programs do not have sufficient understanding of the treatment targets for which they should aim in order to achieve optimal diabetic control. Changes in a patient's behaviour towards their involvement in the monitoring and management their diabetes, are likely to occur patients possess a greater understanding of such things as blood sugar, blood pressure and cholesterol levels which are associated with optimal diabetes control and better treatment outcomes. Many study participants comment that they have never been informed of the target levels should be aiming for to ensure the best treatment outcomes.³

Lack of engagement of patients in the management of their diabetes is highlighted in an article published in the “Melbourne Weekly Magazine” dated 27th July 2005. The author, Paul Edwards, reported that only 7% of diabetic patients were found to be fully adherent to all aspects of their anti-diabetic regimen which included adherence to medication, diet, exercise and self monitoring of blood glucose.¹ Harris ³⁶ reported the alarmingly finding that amongst a cohort of 1480 patient with type 2 diabetes that 29% of patients treated with insulin, 65% of those treated with oral agents and 80% of those treated with diet alone either never monitored their blood glucose or monitored it less than once per month.

Clemet et al ³⁷ emphasise that knowledge, psychomotor skills, preferred learning styles, psychological status, stress factors that impair learning, social/cultural/religious beliefs, literacy skills, readiness to learn, age, mobility, visual acuity, hearing loss and dexterity are all important in the learning process and influence patients’ understanding their diabetes and its management. Rhee et al ³⁸ (n=605) reported that the most commonly cited barriers to diabetes education by patients were poor vision (74%), reading problems (29%), hearing problems and poor English language skills (11%). Following adjusted analysis, patients with a perceived barrier to education were more likely to be older, male and less scholastically educated. Furthermore, the researchers suggested that higher HbA1c levels are commonly associated with a greater chance of reporting an education barrier. Therefore, if education programs are to be successful these personal patient barriers need to be addressed, something which standardised educational programs do not target.

There is little doubt that patient engagement is critical to achieving diabetes treatment goals.³⁹ As such, there is also the influence of appointment keeping with members of the professional health care team and adherence to medications. Rhee et al ⁴⁰ reported on the outcomes of 1560 patients who after one year of, on average five educational visits, an average medication adherence rate of 89%, had a fall of 1.17% in their HbA1c levels. These researchers concluded that patients who keep more appointments had more substantial improvements in their HbA1c levels. Their findings are supported by

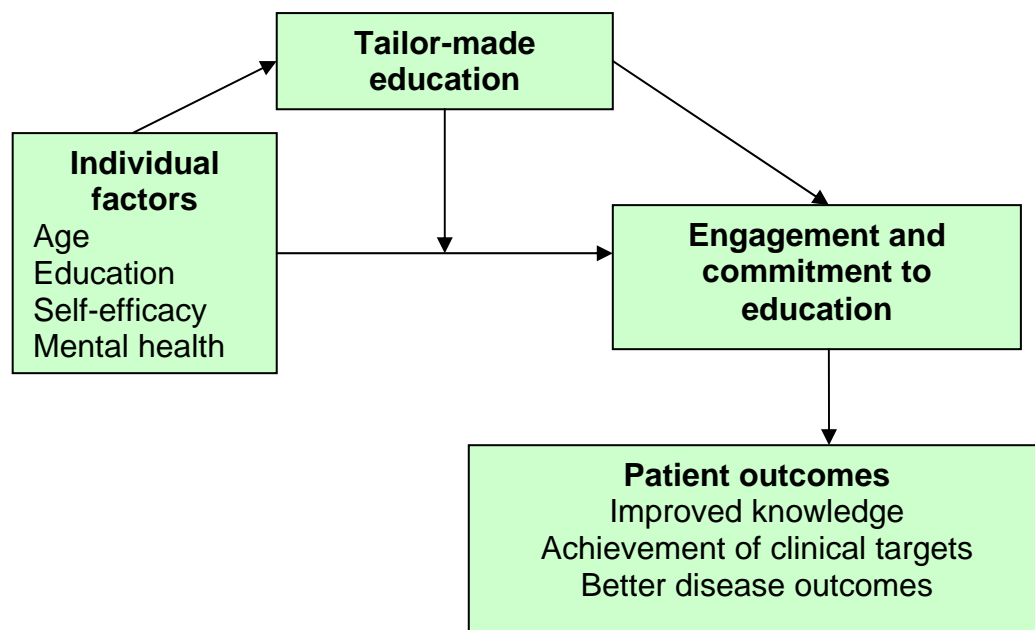
the finding fewer physicians visits by diabetic patients is associated with lower rates of self-monitoring of blood glucose.⁴¹ Therefore, it appears that any educational intervention program needs to engage patients and increase their levels of commitment to the program if they are to achieve the best possible outcomes.

2.3 Developing a Model for Educating Diabetes Patients

Whilst there is broad agreement on what constitutes high quality health care for diabetes patients, there is little consensus on the most efficient way of delivering it. The American Diabetes Association's, Healthy People 2010 ⁶ goal is to increase to 60% (from 40%) the proportion of individuals with diabetes who receive formal diabetes education, but the question remains on how to match education, proven to be effective in maintenance and control of diabetes, with the various patient factors that influence the effectiveness of this education. One option is the provision of tailored of education to meet the individual patient's needs.

Tailored education programs are more likely to address personal needs of the individual patient and to deal with patients' personality differences. Further, they are likely to offer an environment which is more conducive to education via the establishment of a more personal relationship with the educator. By focusing attention on these factors, which may influence adherence to the educational programs, there is a greater likelihood of motivating the patients to return to their educators for scheduled appointments and to seek further advice; thus engaging patients in their education on the self-management of their diabetes. The relationship between factors which affect engagement and commitment to education and thereby influence patient outcomes is diagrammatically represented below.

Figure 2.1: The Role of Tailored Education Programs in Influence Patients' Engagement in their Diabetes Management



From a review of the literature it would appear that individualised patient education programs offer advantages in motivating patients to become engaged in their our disease management. At this time then there is a need to develop a model for diabetes education within the community pharmacy setting which allows tailoring of the education provided based on the individual patient's needs, as assessed by their current knowledge of their disease and its management. It is hoped that by specifically focussing on patient knowledge deficits that a tailored program will offer greater efficiencies and have a higher level of patient acceptance acceptability than a "standardised education program".

It is expected that such the tailored education program proposed in this study will result in:

1. Improved patient knowledge of diabetes, its consequences and management
2. Improved patient compliance with diabetes treatment and monitoring regimens
3. Increased number of patients achieving desired blood glucose and HbA1c levels and reduced incidence of hyper- and hypo-glycaemic attacks
4. Reduce health care resource consumption
5. The development of a diabetes education model which may be implemented in community pharmacies around Australia.

It is envisaged that the tailored diabetes mellitus education program will result in improvement in patients' quality of life through a greater patient understanding of and participation in the achievement of pre-determined clinical targets. Achievement of treatment targets has the potential to significantly reduce health care expenditure reducing the risk of diabetes complications and thus their associated costs.

3. METHODS

3.1 Setting

The project was undertaken in Perth, Western Australia and involved eight metropolitan pharmacies each of which were National Diabetes Supply Scheme (NDSS) sub agencies (refer to Section 3.5). Pharmacies were eligible to receive Continuous Quality Improvement (CQI) credit points at a rate of one point for every 10 hours involvement in the research project. Individual project pharmacies were remunerated for provision of service. Prior to the commencement of the study, metropolitan Divisions of General Practice were contacted to explain the aims and structure of the project, and to enlist their support and cooperation (Appendix 1).

3.2 Research Design

The research design of the DMEP Study (Figure 3.1) aimed to address the two professional components of the service delivery model as follows:

i) Customised Diabetes Education Session. Based on identified deficiencies in patients knowledge of diabetes and its management, tailored one-on-one education sessions were delivered by pharmacists trained in diabetes education.

ii) Ongoing Patient Monitoring and Education. Structured series of follow-up sessions undertaken at regular intervals in the pharmacy during which:

- The level of attainment of therapeutic targets was assessed
- The reasons for non-attainment of targets and poor glycaemic control identified, and strategies devised to overcome these
- The level of non-compliance with pharmacological and non-pharmacological treatments and barriers to compliance were assessed, and strategies devised to overcome these
- Drug-related problems were identified and addressed either directly with the patients or through referral to their general practitioner

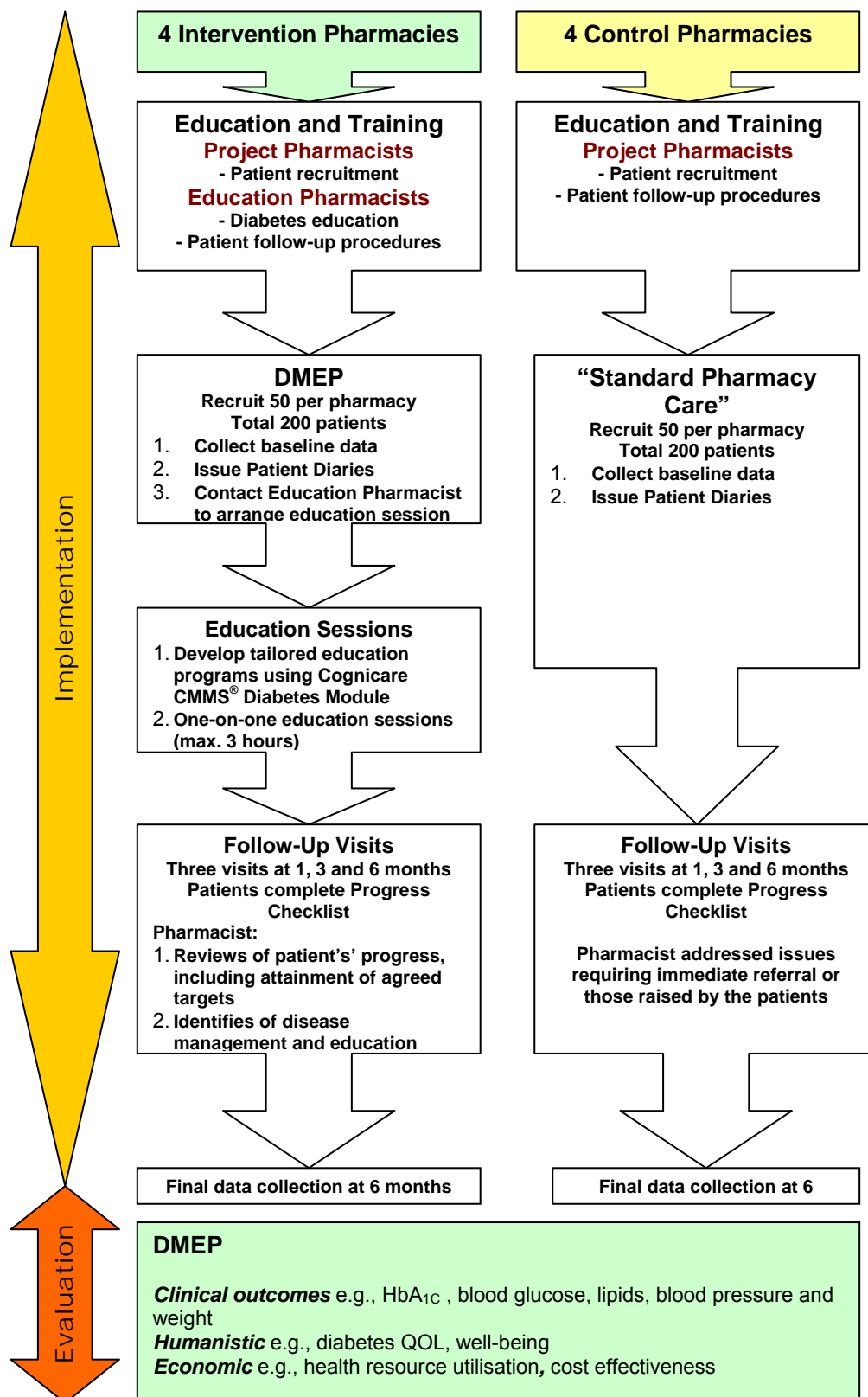
- Further education on the condition, medication, and lifestyle issues was provided
- Patients were reminded of the need for follow-up checks for complications related to diabetes
- Referrals were made as appropriate to healthcare professionals

3.3 Patients

A target total of 400 Type 2 diabetic patients were to be enrolled into the study - 200 into the control group and 200 in the intervention group. Each pharmacy was responsible for recruiting 50 patients with Type 2 diabetes mellitus. Patients eligible for the study were those aged 18 years or older, with the diagnosis of Type 2 diabetes (NIDDM) for which they are receiving drug therapy. Pregnant females were excluded from the study, as were patients from non-English speaking backgrounds, those with intellectual or mental impairment and those highly dependent on medical care such as the chronically disabled.

Patients were recruited at the time of presentation of a prescription for an antidiabetic medication (either an oral hypoglycaemic agent and /or insulin). At this time the aims and structure of the study were explained to the patient and they were invited to become a participant. If they agreed to participate in the study they were asked to give written informed consent (Appendix 2), which included permission to contact their general practitioner to discuss their progress and obtain relevant clinical and laboratory data, and to access their Medicare and Pharmaceutical Benefits records through the Health Insurance Commission and hospital attendance information through the Western Australia Data Linkage Unit. They were informed that they may withdraw from the study at any time without penalty.

Figure 3.1: DMEP Research Schema



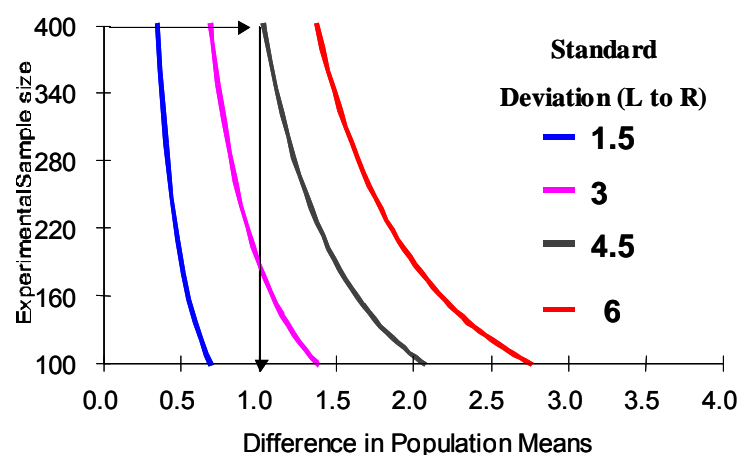
3.4 Sample Size

Literature values for the standard deviation for a population of Blood Sugar Levels (BSLs) are 2.0 for fasting BSLs and 3.5 for the random BSL^{41,42} and 1.6-2.5 for the glycosylated haemoglobin, HbA_{1C}.^{41,42}

Thus we wished to ensure that differences as small as 1 unit (1% in an average HbA_{1C} of 9%; or 1mmol/L in a BSL of 8.0mmol/L) would be detected as we predict that the intervention arm of the project will make a change of at least 1 unit for these parameters.

In order to achieve this, a sample size of 400 was required. This would detect a difference of 1 unit (with a power of 90%) in any population with a standard deviation of 4.5 or less. If the standard deviation of the sample is less than 4.5, then the sample size will detect smaller differences and if the standard deviation is greater than 4.5, then the sample size will detect only larger differences (see Figure 3.2). Where drop-outs occurred the plan was to recruit additional subjects.

Figure 3.2 Sample Estimates



3.5 Recruitment of Pharmacies

National Diabetes Supply Scheme (NDSS) sub agencies were chosen to ensure an adequate number of patients with type 2 diabetes for recruitment purposes. The managing pharmacists from all Perth metropolitan NDSS sub agencies were contacted by phone initially. At this time a brief overview of the project was given and the pharmacist was asked whether or not they would consider participating in a pilot study of customised education programs for Type-2 diabetes patients. Those pharmacists expressing a willingness to further consider participation were sent a project synopsis and an invitation to attend an information session at the School of Pharmacy (Appendix 3).

Issues addressed at this session included: the study protocol, anticipated improvement in outcomes of disease state management, health economic benefits, and the development of a model for disease management programs within community pharmacy. The meeting presentation outlined the rationale for the study in the context of the findings of the Australian Diabetes, Obesity and Lifestyle Study (AusDIAB), with regard to the role of the pharmacist in educating current diabetics and the population at large, in the nature and incidence of the disease, complications arising from poor disease management and goals and strategies for improved management. The anticipated benefit of an individually-tailored patient education program based on an initial assessment of the patient's knowledge and focussing on a patient's knowledge deficits compared to the use of "standardised education programs" was explored and any queries regarding the role of the project pharmacies were addressed. At the conclusion of the meeting pharmacists were invited to complete an expression of interest pro forma which collected demographic information such as contact details, staffing levels and space availability. It was considered advantageous for a successful study outcome if project sites also had a dedicated patient counselling area and two or more pharmacists on duty for most of the trading hours. Based on pharmacist feedback, those pharmacies chosen to participate

in the study were sent a letter advising them of their selection. Four control and four intervention sites were chosen. All project pharmacies were required to complete a Research Agreement acknowledging their responsibilities to the project (Appendix 4). To ensure a successful study outcome and in order to facilitate uniformity in the delivery of patient education at the intervention sites it was decided to employ three independent pharmacists (Education Pharmacists) to undertake this task.

3.6 Pharmacy Randomisation

Pharmacies which expressed interest in participating in the study were allocated into either the Intervention or Control Groups using a list of random numbers. They were then matched according to their geographical location and the socioeconomic status of their clientele. Four matched pairs of matched pharmacies were then selected. To avoid potential bias Control and Intervention pharmacies were not allocated from within the same Division of General Practice.

3.7 Project Pharmacists' Training Sessions

Funding was allocated within the budget to cover employment of locums to allow the nominated Project Pharmacists to attend an eight-hour training day. The three Education Pharmacists also attended. The training session was also used as an opportunity to trial the study's patient documentation for document length, completeness of materials covered, comprehension, space allocation and clarity of meaning and to obtain feedback of participant acceptance and understanding.

Areas covered by the training program included patient recruitment and initial interview. Having reviewed the selection criteria and the format of the Patient Information Sheet and Consent Form (Appendix 2) the pharmacists then worked collaboratively in two groups to develop a standard approach that could be used for recruitment of subjects into either the Control or Intervention arm of the project. The group effort was then evaluated and suggestions for improvement considered.

Education pharmacists underwent a further eight hours of intensive diabetes education training for their role in the project. This training day was conducted by an accredited diabetes educator, and focused on techniques of getting complex concepts such as the mode of action of antidiabetic medications across to patients. The day also included hands on training with the Cognicare® Solutions Ltd CMMS software package diabetes module. The Cognicare diabetes software was used to customise each patient's diabetes education program, based on their response to the selected questions embedded within the modified version of the DPAQ (Appendix 5) and will be discussed in more detail below.

3.8 Research Instruments for Data Collection

3.8.1 A Modified Version of the Diabetes Patient Assessment Questionnaire (DPAQ).²⁰

The Diabetes Patient Assessment Questionnaire (DPAQ)²⁰ documents whether the patient has seen certain specialists, has undergone various evaluations (dilated pupil exam, foot exam, etc.), or has received appropriate counselling (on nutrition, exercise, self-monitoring of blood glucose). Patients indicate the types of treatment they are receiving, their latest blood glucose values, and related information. The questionnaire provides a wealth of information that the pharmacist can use in determining whether certain aspects of diabetes management need attention, perhaps by other members of the health care team.

The questionnaire was modified for the purpose of this study to obtain the following information:

Patient Data

1. Patient demographics

- Gender, age, weight, height
- 2. Past medical history
- 3. Social history
 - Smoker status, alcohol intake

Diabetes Management Data

1. Duration of disease
2. Symptomatology
3. Complications
4. Management
5. Education History
6. Patient's disease knowledge and understanding
7. Level of monitoring (self and by doctor)

Laboratory Data

1. Fasting blood glucose
2. HbA_{1C}
3. Lipids
4. Urine protein
5. Blood pressure

Treatment for Diabetes

1. Diet
2. Lifestyle
3. Medications

3.8.2 Education Log

The Education Log (Appendix 6) was used to record the following information related education sessions: the date and duration of the education sessions, the topics covered (list as per Appendix 7) and specific issues discussed, printed materials provided and comments on the sessions (including patient feedback and pharmacists' reflections on positives and negatives of the sessions).

3.8.3 Quality of Life (QOL) Questionnaires

Two quality of life instruments were used for the study, the Type diabetes specific Diabetes Symptoms Checklist – Revised and generic measure SF-36 (Australia/New Zealand version).

3.8.3.1 Diabetes Symptoms Checklist – Revised (DSC-R)

At the same time, the patient also completed a quality of life assessment known as the validated Type 2 **Diabetes Symptoms Checklist** (DSC-R). This DSC-R was used to assess both the occurrence and the perceived burden of the physical and psychosocial symptoms related to type 2 diabetes and its possible complications. The DSC-R is reported to be the only scale that evaluates physical symptoms in a broad and comprehensive manner⁴³ (Appendix 8).

3.8.3.2 SF-36 Health Survey

The **SF-36** (Australia/ New Zealand version) questionnaire was also administered to determine a more general assessment of QOL. SF-36 measures 8 dimensions of health:

- Physical functioning
- Role limitations due to physical health (role-physical)
- Body pain
- General health perceptions
- Vitality
- Social functioning
- Role limitations due to emotional problems (role-emotional)
- Mental health

It provides a score for each dimension, as well as summary scores for mental and physical health and a single health utility score (Appendix 9).

3.8.4 Patient Diary

Patients were provided with a diary which included written information on diabetes and its management, their medication regimen, dates for prescription

refills, dates for follow-up visits and general practitioners' appointments (Appendix 10). Patients were asked to record in their diary, any symptoms or complications they experienced, together with their management, any missed doses, visits to their general practitioner or hospital attendances, which were diabetes-related. They were also be asked to record all blood glucose levels (BGL) and a weekly weights. These diaries were provided at the initial visit and at the 3-month follow-up visit.

3.8.5 Progress Checklist

At each of the follow-up visits, 1, 3 and 6 months, Intervention and Control patients were asked to complete a Progress Checklist (See Appendix 11). The Progress Checklist was adapted from the Diabetes Care Profile version 2.0 produced by the Michigan Diabetes and Research Center, University of Michigan, which was published in 1998. It contained questions relating to the patient's:

- glycaemic control and reasons for hyperglycaemic and hypoglycaemic episodes
- compliance with diet, lifestyle and drug therapy, and reasons for non-compliance
- pattern of self-monitoring of blood sugar levels and the barriers to monitoring
- achievement of treatment targets including weight, blood pressure, smoking cessation, lipids and HbA_{1c}
- concerns about their diabetes management
- understanding of diabetes-related topics

In the Intervention Group the patient's responses to these questions were used to identify issues for which actions were decided upon (see definition below) and a management plan agreed upon with the patient, and documented in their diabetes diaries. In the Control Group, only issues raised by the patients at the time of the follow-up visits were addressed, as part of "standard pharmacy care".

Definition of an Action:

“Include details on any of the following – reassessment of treatment target, patient education, patient counseling, referral to other health care professionals, dietary advice, exercise or smoking cessations, medication adherence assistance and assistance with disease monitoring.”

3.9 Federal and State Government Health Information Release Documents

Information regarding health resource utilisation was obtained from the Health Insurance Commission Information Release Section and the WA Data Linkage Unit following approval from the relevant Ethics Committees (Appendix 12). Data requested included Medicare (general practitioner visits, pathology tests, (BGL, HbA_{1c}, and serum lipids) and Pharmaceutical Benefits information pertaining to the 6 months prior to the study, the 6 months of the study and 6 months after the study, and attendance at Accident and Emergency Departments and admissions to WA public hospitals and mortality data.

3.10 Study Protocol

3.10.1 Advertising

Posters (Appendix 13) inviting patients with Type 2 Diabetes Mellitus to avail themselves of the opportunity to learn how to better manage their diabetes were displayed within the project pharmacies. Advertising flyers (A5 versions of the poster) were placed into all pharmacy packaging used for dispensed medication to make patients aware of the project and to invite them to participate. Similarly worded advertisements were lodged in a Health Supplement of the Western Australian daily newspaper and as part of a feature article in local community newspaper (Appendix 14) and on the electronic news service of Curtin University of Technology.

As part of in-store promotions of Diabetes Awareness Week, the Education Pharmacists spent three hours in Intervention pharmacies promoting the project to customers.

Letters (Appendix 15) informing general practitioners of the aim and scope of the project were sent to Divisions of General Practice and to individual Medical Practices with the areas in which the Project Pharmacies were located. General Practitioners were invited to nominate patients whose diabetes management they thought would benefit from further diabetes education.

3.10.2 Control Group (“Standard Pharmacy Care”)

3.10.2.1 Initial Enrolment Visit

The patient was given a copy of the Patient Information Sheet to read and the Project Pharmacist answered any questions the patient may have had about the study. If the patient wished to participate in the study, they were asked to complete the Patient Consent Form. After obtaining written informed consent each participant was allocated an unique Participant Study Code. The patient then completed the three questionnaires, following relevant explanation by the pharmacist. The instruments used were:

- The modified version of the Diabetes Patient Assessment Questionnaire
- SF-36 (Australia/ New Zealand version)
- Diabetes Symptom Checklist (DSC-R)

The Project Pharmacist then gave the patient the *“Diabetes Diary –Entry to 3 month”* explaining its purpose. An appointment was made for the patient to return in one month time to review their diary entries. The pharmacist then completed the *Notification of Patient Enrolment Form* (Appendix 16) and sent this to the Project Officer at Curtin University of Technology. The patient’s

general practitioner was sent a letter advising them of the patient's involvement in the study (Appendix 17).

3.10.2.2 One and Three-Month Follow-Up Visits

The Pharmacist phoned the patient the day prior to their appointment to reconfirm attendance. The patient's diary entries were reviewed and the patient was encouraged to continue using it. They were asked if they had any concerns or if they required any further information from the pharmacist. If any serious concerns about patient's health were raised, then the pharmacist would refer the patient back to their general practitioner, as per normal practice. If this action was taken, then this intervention was to be notated in the patient's diary. Patients in the Control Group then received standard patient counselling as appropriate. All services provided by the pharmacist were documented. The patient then completed the Progress Check List Questionnaire. At the 3-Month follow up visit, The "*Diabetes Diary – Entry to 3 months*" was retained by the pharmacist and the "*Diabetes Diary – 3 to 6 months*" issued.

3.10.2.3 Six-Month (Study Exit) Visit

Again the patient's diary entries were reviewed and the diary retained by the pharmacist. If any serious concerns about patient's health were raised, then the pharmacist would refer the patient back to their general practitioner. A photocopy of the current month's Blood Glucose Level record from the diary was given to the patient. The patient then completed the Progress Check List and the three entry questionnaires, namely:

- A modified version of the Diabetes Patient Assessment Questionnaire
- SF-36 (Australia/ New Zealand version)
- Diabetes Symptom Checklist (DSC_R)
-

The patient was thanked for their involvement in the study. The participant's general practitioner was contacted to obtain the results of relevant laboratory tests (Appendix 18) and a print out of their dispensed medications obtained from

the Project Pharmacy records. All of the participant's documentation was returned to the Project Officer.

3.10.3 Intervention Group

(DMEP – tailored education, progress assessment, identification of and interventions to overcome barriers to adherence)

3.10.3.1 Initial Enrolment Visit

The patient was given a copy of the Patient Information Sheet to read and the Project Pharmacist answered any questions the patient may have had about the study. If the patient wished to participate in the study, they were asked to complete the Patient Consent Form. After obtaining written informed consent each participant was allocated an unique Participant Study Code. The patient then completed the three questionnaires, following relevant explanation by the pharmacist. The instruments used were:

- A modified version of the Diabetes Patient Assessment Questionnaire
- SF-36 (Australia/ New Zealand version)
- Diabetes Symptom Checklist (DSC-R)

The patient was advised of the name of their Educator Pharmacist and that they would be contacted by the pharmacist to commence one-on-one education sessions once the data from the questionnaires had been entered into the Cognicare CMMS software and analysed (Appendix 19). An assessment of cardiovascular risk would be undertaken and strategies to address identified risk factors (e.g. obesity, smoking) implemented as part of the education program.

The project pharmacist then completed the *Notification of Patient Enrolment Form* and sent this together with the completed questionnaires to the Project Officer who was responsible for contacting the relevant Educator Pharmacist, to arrange data entry and analysis. When data entry was finalised, the Education Pharmacist contacted the patient to arrange a suitable time for the patient to attend their first individualised (tailored) education session at the Project

Pharmacy. The patient's general practitioner was sent a letter advising them of the patient's involvement in the study. At the completion of the education sessions (up to a maximum of three hours) the Educator Pharmacist made an appointment for the participant to return for the 1-month visit (post education).

3.10.3.2 Customised Education Program

Within the modified DPAQ were embedded questions to assess the patient's current understanding of the diabetes and the level of their diabetes care. The responses to these questions were entered into the Cognicare CMMS Diabetes Care[®] module by the Educator Pharmacist; this allowed the development of an individualised (tailored) diabetes education program for each patient. This program was transcribed to the patient's Education Log. Once the data analysis was completed the Educator Pharmacist contacted the patient to organise their first education session at the Project Pharmacy. At the completion of a maximum of three hours of education the pharmacist in collaboration with the patient established the intervention targets that the patient would endeavour to achieve over the following six month period.

Typical interventions included setting targets for the following parameters: BGL, HbA_{1c}, Weight, Exercise, Diet, Smoking Cessation, Blood Pressure and Cholesterol, Eye and Foot Care.

3.10.3.3 Educational Resources

The patient education material used in the study were based on Diabetes Fact Sheets produced by the International Diabetes Institute (Appendix 20), Diabetes Australia, and Pharmacy Self-Care, together with information from the "Therapeutic Guidelines: Endocrinology" published by Therapeutic Guidelines Limited, and the National Prescribing Service (NPS).

Additional material for life-style behavioural modification was sourced from “Quit WA”, National Heart Foundation, NPS Management of Type 2 Diabetes Mellitus in General Practice, Dyslipidaemia, Hypertension, and Heart Failure, and “The Pharmacists’ Guide to Diabetes” (Bayer Pharmacy Support Program).

3.10.3.4 One and Three-Month Follow-Up Visits

The Education Pharmacist phoned the patient the day prior to their appointment to reconfirm attendance. The patient’s diary entries were reviewed and the patient was encouraged to continue using it. If any serious concerns about patient’s health were raised, then the pharmacist would refer the patient back to their general practitioner, as per normal practice. The patient was asked to complete a Progress Check List and their progress was assessed. The pharmacist reviewed the individual’s agreed treatment targets, reinforcing any educational aspects considered necessary and addressing any patient issues or concerns that may have been raised. Strategies to address issues affecting their ability to comply with drug and non-drug therapy were provided. Wherever necessary the patients were referred back to their general practitioner for review of their diabetes management. All issues identified and acted upon were documented in the intervention log in the patient’s diary. At the 3-Month follow up visit, The “*Diabetes Diary – Entry to 3 months*” was retained by the Pharmacist and the “*Diabetes Diary – 3 to 6 months*” issued.

3.10.3.5 Six-Month (Study Exit) Visit

The Educator Pharmacist phoned the patient the day prior to their appointment to reconfirm attendance. The patient’s diary entries were reviewed and the diary was retained by the pharmacist. If any serious concerns about patient’s health were raised, then the pharmacist would refer the patient back to their general practitioner. A photocopy the current month’s blood glucose levels from the diary was given to the patient. The pharmacist then reviewed the individual’s agreed treatment targets, reinforcing any educational aspects considered necessary and addressing any patient issues or concerns that may have been

raised. A copy of the most recent “Patient Diabetes Management Health Targets” was given to the Project Pharmacist for pharmacy reference and follow-up at subsequent visits by the patient to the pharmacy. The patient then completed the Progress Check List and the three entry questionnaires, namely:

- The modified version of the Diabetes Patient Assessment Questionnaire
- SF-36 (Australia/ New Zealand version)
- Diabetes Symptom Checklist (DSC-R)

The patient was thanked for their involvement in the study. The patient’s general practitioner was contacted to obtain the results of relevant laboratory tests and a print out of their dispensed medications obtained from the project pharmacy records.

3.11 DMEP Study - Communication with Pharmacists

The Chief Investigator and Project Officer used a range of communication strategies to ensure that the project pharmacists were kept well informed of the latest developments in the study, to obtain regular feedback and to provide ongoing support to the pharmacists. Methods employed included regular telephone calls, facsimiles, emails, visits to the pharmacies and regular face to face feedback sessions for all project and educator pharmacists involved to ascertain any problems with methodology and materials, recruitment and retention of participants etc and to share ideas and strategies.

3.12 Intervention Patient – Follow-Up Satisfaction Survey

A questionnaire (Appendix 21) was developed to investigate the patient’s experience of, and satisfaction with, the Customised Diabetes Education Program. It was implemented at the conclusion of all patient involvement in the 6 months of the study. Initially all participants were contacted by telephone and asked to complete the survey. Where contact was unable to be made after

three attempts using this method, the patient was contacted by mail. A covering letter was enclosed with the questionnaire and a reply-paid, self-addressed envelope included for return of the completed questionnaire.

The survey instrument included items relating to participants' opinions about the following:

- Their understanding of their diabetes pre and post education and which aspects of the education they found most and least useful
- The quality of the individualised diabetes education received from the pharmacist and the follow up reinforcement program
- Their preference for receiving education from a pharmacist and / or another health care professional
- The preferred method of delivery of the education

Open ended questions to determine reasons for their opinion of the quality of the education and the follow up services and their preference for a particular method of education were also included.

Question 14 to 16 of the survey sought feedback on the respondents' opinions as to whether pharmacy-based diabetes education and advice should be available, how often they thought that they would use such a service, on an continual basis and whether they would be willing to pay for it.

3.13 Project Pharmacists Follow-Up Satisfaction Survey

To investigate the experiences and level of satisfaction with their involvement in the Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study), all Education, Control and Intervention Pharmacists were invited to attend a focus group meeting at the conclusion of the period of patient recruitment and data collection. The focus group discussions, which lasted about 75 minutes, were audio taped for accuracy of recording the discussion contents. Discussions were lead by the Chief Investigator using a semi structured questionnaire (Appendix 22) that covered topics including:

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

- Training and support throughout the project
- Impediments to recruitment and retention of participants
- Logistical project issues
- Feedback from all
- Study outcomes for relevant stakeholders

3.14 DMEP Study - Evaluation of the Service

The ECHO ⁴⁴ (economic, clinical and humanistic outcomes) model was used to evaluate the service. The ECHO parameters utilised in this study are indicated in Table 3.1.

Null Hypotheses:

H₀: There will be no significant difference between Intervention and Control Groups pre- and post intervention in:

1. Patients' knowledge of diabetes and its management
2. Compliance with diabetes treatment and monitoring regimens
3. The number of patients achieving desired blood glucose and HbA1c levels
4. The incidence of hyper- and hypoglycaemic attacks
5. Quality of Life and well-being scores
6. Consumption of health resources

Table 3.1: Evaluation of the Service

Outcomes	Measures
Clinical	HbA _{1c} Blood pressure (BP) – systolic and diastolic Total Cholesterol (TC) High Density Lipoproteins (HDL) Triglycerides (Trig) Body weight Body mass index
Humanistic	Diabetes Symptoms Checklist (DSC-R) SF 36 Patient satisfaction questionnaire (DMEP)
Economic	Health system costs Cost effectiveness Cost utilisation

3.15 DMEP Study – Quality Control

Adherence to protocols was monitored with meetings with the project pharmacists and during visits to each pharmacy by the project officer. Patient data files were checked for accuracy and completeness to ensure the quality of the data.

3.16 Statistical Analysis

3.16.1 Demographic Characteristics, Diabetes History, Clinical and Humanistic Data

Data analysis was conducted using SPSS 12.0TM and STATA version 9.0TM. All control patients and all intervention patients were included in the analysis at baseline. All Control Group patients who completed the baseline and exit (6 month visit) questionnaires and all Intervention Group patients who completed the educational program and the three follow-up sessions were included in the

post-intervention analysis. Non-normally distributed variables were log-transformed where appropriate. The level of significance for all tests was set at $p < 0.05$.

Differences between the Control Group and Intervention Group at baseline were assessed using Pearson chi-squared tests of association for categorical variables and an independent t-test or a Mann Whitney U test for normally and non-normally distributed continuous variables respectively.

Within-group differences between baseline and post-intervention were assessed using paired t-tests for normally distributed differences, Wilcoxon signed rank test for non-parametric differences and McNemar's test and the Fisher exact test for categorical data. Differences between the control and intervention groups at exit were assessed using linear regression with adjustment for baseline values. Binary or ordinal logistic regression was used to assess differences between groups for categorical variables. Robust standard errors were used in all regression analyses to adjust for clustering within pharmacies. Interaction terms between baseline values and treatment group were also assessed but were removed from the model if non-significant.

Analysis was performed using only those subjects who completed the study rather than on an intention-to-treat basis. The authors acknowledge that using this "completers-only" approach has the potential to introduce selection bias due to differential rates of attrition in the two groups. However, the percentage of subjects who completed the study was not different in the Control and Intervention Groups (58% versus 48%, $p = 0.12$). In addition since the proportion of subjects who completed the study was slightly higher in the Control Group than in the Intervention Group, suggesting that the Control Group may have been more motivated compared to the intervention group, any potential selection bias would be likely to have reduced the estimated beneficial effects of the intervention.

3.16.2 Quality of Life

Changes in quality of life scores were assessed for both statistical and clinical significance. The latter was undertaken for the results of the SF-36 questionnaire, using the SEM-based criterion proposed by Wrywich et al.⁴⁶ Using the SF-36 norms for the state of Western Australia⁴⁷ for persons aged 55 to 64 years (Appendix 23) and the reliability estimates for SF-36 scales in patients with diabetes⁴⁸ (Appendix 24), it was possible to estimate the SEM for each of the SF-36 dimensions by multiplying the standard deviation of the dimension score by the square root of one minus its reliability coefficient, as shown below:

$$\text{SEM} = \sigma_x \sqrt{1 - r_x} \quad \text{Where } \sigma_x \text{ is the standard deviation and } r_x \text{ is the reliability coefficient}$$

Changes in SF-36 dimension scores were then deemed to be potentially clinically significance is they exceed one SEM.

3.16.3 DMEP Study - Economic Analysis

The economic impact of the DMEP will be evaluated using the following three approaches:

3.16.3.1 Analysis of Health System Costs

The cost of health service utilisation by patients in the two groups was calculated from the hospital admissions, Medicare and PBS data. The cost of the following health resources were examined: hospital admissions, GP and specialist consultations, diagnostic investigations and pharmaceuticals. Total health system costs were compared for both groups to determine if the DMEP has achieved cost savings in the use of health services.

3.16.3.2 Cost-Effectiveness Analysis

The incremental net cost per patient of the DMEP was calculated. Program costs will include the costs to pharmacies of implementing the program, as well as costs to patients in participating in the program. Incremental net costs were calculated by subtracting any cost savings in the use of health services from the

costs of implementing the program. The incremental net cost per patient of the DMEP will be compared with any incremental changes in metabolic control to assess if the program offers an attractive cost-effectiveness profile.

3.16.3.3 Cost-Utility Analysis

A cost-utility analysis of the DMEP was conducted using the SF-36 data as the basis for calculating any gain in quality adjusted life years (QALYs) for patients in each group. The SF-36 data was transformed into the SF-6D, and a preference-base single measure of health will be calculated using the preferred Brazier model.⁴⁸ Change in QALYs was calculated for both groups, and the cost per QALY of the intervention and control groups will be compared to assess the cost-effectiveness of the DMEP. A sensitivity analysis will test the effect on cost per QALY of different assumptions regarding duration of health-related changes.

4. RESULTS

4.1 Recruitment

A total of 245 patients agreed to participate in the study, that is, they provided informed written consent and were provided with the entry questionnaire. Of these 121 (Intervention Group 57; Control 64) completed all facets of the study. A further nine patients (all Controls), who failed to attend all of the follow-up sessions at 1, 3 and 6 months of the study completed both the entry and exit questionnaires.

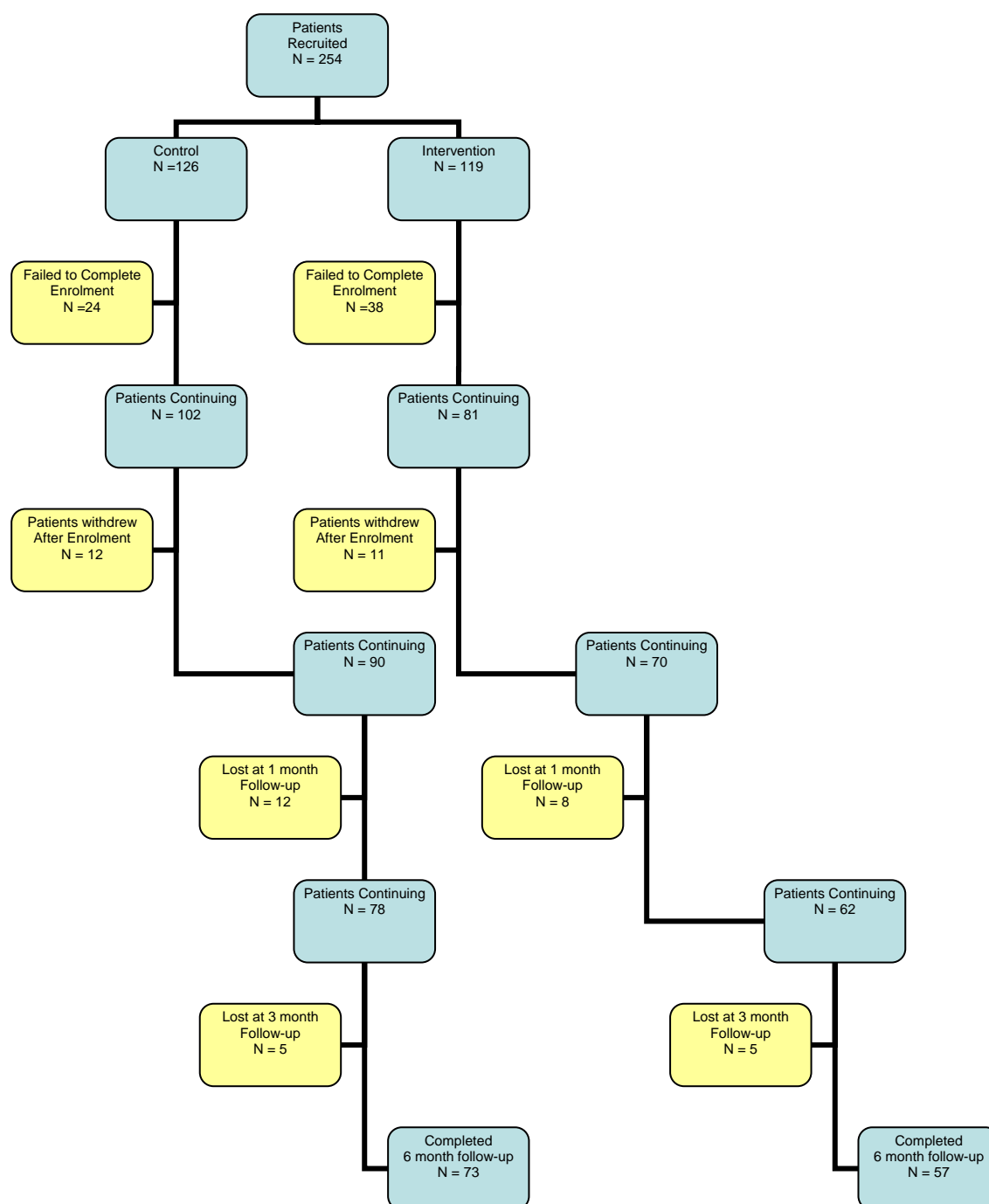
The total number of patients that were recruited in each of the Intervention and Control pharmacies are shown in Table 4.1, together with the stages at which patients withdrew from the study or were lost to follow-up (see also Figure 1).

Table 4.1: Record of Study Recruitments and Withdrawals

Pharmacy	Recruited	Point at which Patients were lost to Follow-up				Completed 6 month follow-up
		Failed to return entry questionnaires	Withdrew after entry	1 month follow-up session	3 month follow-up session	
Intervention Groups						
I1	19	9	2	1	2	5
I2	51	12	6	2	1	30
I3	17	9	1	0	1	6
I4	32	8	2	5	1	16
Total	119	38	11	8	5	57
Control Groups						
C1	12	0	11	0	1	9*
C2	28	4	5	4	1	14
C3	49	4	3	2	0	40
C4	37	16	1	6	2	12 [#]
Total	126	24	21	12	4	73

* 8 completed entry and exit questionnaires, but not follow-up sessions [#] 1 completed entry and exit questionnaires, but not follow-up sessions

Figure 4.1: Recruitment and Retention of Control and Intervention Patients



4.1.1 Patient Withdrawals

The large number of patient withdrawals had a significant negative impact on the power of the study. The reasons given for patients withdrawing from the study included paper work proved too daunting, change of personal circumstances, loss of enthusiasm, illness and travel.

4.2 BASELINE DATA

4.2.1 Patient Demographics

The demographics of all patients who completed entry questionnaires are shown below in Table 4.2. The groups were well matched in terms of gender, age and level of education. They were also well matched in relation to the patients' duration of diabetes, with the majority of the patients in both groups having the disease for 3 years or more. The majority of patients in both groups were non-smokers.

Table 4.2: Demographic Data

Demographics	n	Control	n	Intervention	n	Overall	p-value
Gender (M/F)	114	54/60	73	38/45	197	92/105	0.83
Age (years) [Mean±SE]	111	64.3±1.02	83	64.0±1.26	194	64.2±1.13	0.82
Level of Education							
Primary school	102	5.9%	77	11.7%	179	8.4%	0.08
Year 10		50.0%		35.1%		43.6%	
Year 12		29.4%		41.6%		34.6%	
Bachelor degree		8.8%		10.4%		9.5%	
Postgraduate degree		5.9%		1.3%		3.9%	
Duration of Diabetes							
< 1 year	110	10.9%	82	4.9%	192	8.3%	0.40
1-2 years		10.0%		13.4%		11.5%	
3-5 years		20.0%		19.5%		19.8%	
6-10 years		28.2%		36.6%		31.8%	
>10 years		30.9%		25.6%		28.6%	
Smoking Status							0.33
Current Non-smoker	111	85.6%	81	80.2%	192	83.3%	

Table 4.3 shows comparative data for the Control and Intervention Group patients' lipid levels, blood pressures, weights, heights, BMIs and smoking status. Across all of these parameters the two groups were well matched. Patients in both groups demonstrated less than optimal lipid levels, systolic blood pressures and weight control.

Table 4.3: Baseline Laboratory and Clinical Data

Clinical Data		n	Baseline Mean \pm SE	Difference	Intervention vs. Control p value
Systolic BP (mmHg)	Intervention	30	137.8 \pm 2.4	-3.0 \pm 3.1	0.33
	Control	23	131.3 \pm 3.1		
Diastolic BP (mmHg)	Intervention	30	79.2 \pm 1.4	-1.3 \pm 1.6	0.42
	Control	23	75.7 \pm 1.6		
Total Cholesterol (mmol/L)	Intervention	35	4.54 \pm 0.17	0.23 \pm 0.20	0.27
	Control	35	4.74 \pm 0.19		
HDL (mmol/L)	Intervention	34	1.23 \pm 0.05	0.05 \pm 0.06	0.42
	Control	33	1.24 \pm 0.05		
LDL (mmol/L)	Intervention	21	2.41 \pm 0.22	0.26 \pm 0.21	0.22
	Control	21	2.79 \pm 0.19		
Triglycerides (mmol/L)	Intervention	34	1.95 \pm 0.19	0.09 \pm 0.28	0.76
	Control	34	2.15 \pm 0.25		
Weight (kg)	Intervention	81	85.4 \pm 2.37	1.55 (-4.69, 7.79)	0.62
	Control	110	84.9 \pm 2.09		
Height (cm)	Intervention	80	166.9 \pm 1.00	-0.23 (-3.13, 2.66)	0.88
	Control	109	167.1 \pm 1.05		
BMI (kg/m ²)	Intervention	80	31.2 \pm 0.71	0.85 (-1.00, 2.69)	0.37
	Control	108	30.3 \pm 0.61		

4.2.2 Diabetes Control and Complications

The groups were well matched on the basis of the frequency of HbA1c monitoring and their last reported HbA1c levels (Control $7.50 \pm 0.16\%$ vs. Intervention $7.34 \pm 0.18\%$; $p = 0.51$), although within the subgroup of patients with initial HbA1c less than or equal to 7% those in the Intervention Group had significantly lower levels (Intervention $6.26 \pm 0.12\%$ vs. Control $6.61 \pm 0.09\%$; $p = 0.026$). In the case of diabetes control, the average reported last fasting blood glucose level for the patients in the Intervention Group was lower than that for those in the Control Group, however the difference was not statistically significant based on the available data [$p = 0.17$] (Table 4.4). This lower average fasting blood glucose (FBG) is consistent with the slightly lower average HbA1c seen in the Intervention Group.

Table 4.4: Diabetes Control at Baseline

Clinical Data	n	Control	n	Intervention [Number (%)]	p value
HbA1c measured					
Yes	57	52.8%	41	51.2%	0.35
No	5	4.6%	8	10.0%	
Not sure	46	42.6%	32	38.8%	
Clinical data		(Mean \pm SE)		(Mean \pm SE)	
Last HbA1c value (%)	36	7.50 ± 0.16	41	7.34 ± 0.18	0.51
Patients with HbA1c \leq 7%	16	6.61 ± 0.09	15	6.26 ± 0.12	0.026
Patients with HbA1c $>$ 7%	20	8.25 ± 0.22	24	8.35 ± 0.20	0.91
Last FBG (mmol/L)*	21	8.19 ± 0.64	17	6.83 ± 0.73	0.17

* Patient self-reported test results

The two groups were well matched in regards to the frequency of hyperglycemic episodes and symptoms (Table 4.5). They were also well matched in regards to the frequency of hypoglycaemic episodes, and occurrence and nature of hypoglycaemic symptoms, however the proportion of patients hospitalized as a consequence of hypoglycaemia was considerably higher in the Control Group, however just failing to reach statistical significance ($p = 0.053$).

Table 4.5: Reported Level of Diabetes Control, Symptoms and Complications at Baseline

	n	Control [Number (%)]	n	Intervention [Number (%)]	p value
Average number of hyperglycaemic symptoms in past month	110	2.02±0.19	83	2.19±0.20	0.53
Days in the last month with symptoms of hyperglycaemia					
Not at all	109	41 (37.6)	81	30 (37.)	0.64
1-3 days		19 (17.4)		9 (11.1)	
4-6 days		10 (9.2)		8 (9.9)	
7-12 days		10 (9.2)		5 (6.2)	
> 12 days		14 (12.8)		12 (14.8)	
Don't know		15 (13.8)		17 (21.0)	
Average number of hypoglycaemic symptoms in past month	114	2.21±0.16	83	2.65±0.21	0.26
Hypoglycaemia attacks in the last month					
0 times	111	71 (66.7)	82	50 (61)	0.95
1-3 times		21 (18.9)		17 (20.7)	
4-6 times		4 (3.6)		5 (6.1)	
7-12 times		3 (2.7)		2 (2.4)	
> 12 times		1(0.9)		1 (1.2)	
Don't Know		8 (7.2)		7 (8.5)	
Severe hypoglycaemia reactions in last year					
0 times	111	91 (82)	81	70 (86.4)	0.59
1-3 times		10 (9.0)		5 (6.2)	
4-6 times		4 (3.6)		1 (1.2)	
7-12 times		0 (0)		0 (0)	
>12 times		0 (0)		1 (1.2)	
Don't know		5 (4.5)		4 (4.9)	
Patients carrying glucose tablets or sweets to treat low blood sugars	109	44 (40.4)	83	34 (41.0)	0.93
Percentage of patients ever hospitalized due to hypoglycaemia	111	5 (4.5)	81	0 (0)	0.053
Percentage of patients who had lost consciousness secondary to hypoglycaemia	110	6 (5.5)	81	1 (1.2)	0.125
Percentage of patients who had suffered a seizure	110	0 (0)	92	0 (0)	-

A larger proportion of patients in the control group reported loss of consciousness secondary to hypoglycaemia (5.5% vs 1.2%; $p = 0.125$) and the need for hospitalization as a result of hypoglycaemia (4.5% vs 0%; $p = 0.053$) compared to those in the Intervention Group, these differences were not statistically significant. A similar proportion of patients in both groups reported having sweets or glucose tablets in case of hypoglycaemic episodes (40.4% vs 41.0%, $p = 0.93$).

The only significant difference identified amongst the patients' diabetes-related complications was the more frequent occurrence of post-prandial nausea amongst the patients in the Intervention Group ($p = 0.04$) [Table 4.6]. The relevance of this finding to the outcomes of the study is unclear.

Table 4.6: Diabetes-Related Complications

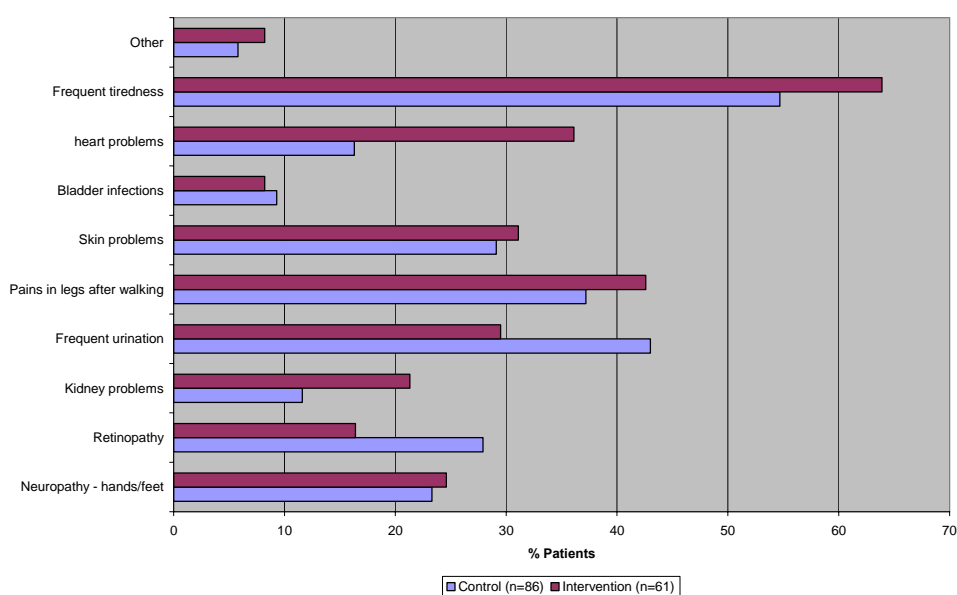
Diabetes-Related Complications	n	Control [Number (%)]	n	Intervention [Number (%)]	p value
Numbness or tingling in hands or feet in the last month	111	50 (45)	82	42 (51.2)	0.396
Any signs of eye damage or disease	105	19 (18.1)	75	9 (12)	0.19
Frequent "heartburn" or acid reflux problems	110	31 (28.2)	80	22 (27.5)	0.92
Postprandial bloating					
Never		50 (46.3)		30 (38.5)	
Sometimes	108	47 (43.5)	78	38 (48.7)	0.63
Often		10 (9.3)		8 (10.3)	
Always		1 (0.9)		2 (2.6)	
Postprandial nausea					
Never		68 (68.0)		39 (52.0)	
Sometimes	100	31 (31.0)	75	32 (42.7)	0.04
Often Always		1 (1.0)		4 (5.3)	
Frequent constipation	110	25 (22.7)	82	14 (17.1)	0.34
Problems with sexual dysfunction	104	43 (41.3)	75	32 (42.7)	0.86
Erectile dysfunction in males	51	33 (64.7)	39	23 (59.0)	0.58
Vaginal dryness in females	55	21 (38.2)	39	15 (38.5)	0.98
Frequent vaginal yeast infections in females	54	7 (13.0)	41	5 (12.2)	0.91

In response to the question “do you suffer from any diabetes complications, the positive response rates in both the Control and Intervention Groups were similar (62.9% vs 61.6%; $p = 0.848$). The types and frequency of complications reported by the patients in both groups are shown in Tables 4.6 and 4.7, and Figure 4.2.

Table 4.7: Self-Reported Frequency and Type of Diabetes Complications

	n	Control [Number (%)]	n	Intervention [Number (%)]	p value
Any diabetes complications					
Yes	97	61 (62.9)	73	45 (61.6)	0.85
No		23 (23.7)		16 (21.9)	
Not sure		13 (13.4)		12 (16.4)	
Average number of diabetes related complications including neuropathy, retinopathy or other eye symptoms, kidney problems, frequent urination, pain in legs after walking, skin problems, bladder infections, heart problems, frequent tiredness, other (See Figure 4.2)	86	1.95±0.17	61	2.07±0.22	0.67

Figure 4.2: Reported Diabetes Complications



4.2.3 Diabetes Management

4.2.3.1 Pharmacological

The modified Diabetes Patient Assessment Questionnaire contained a number of questions regarding medication use, both general (e.g. Q 79. “Do you take any oral medicines to treat your diabetes?”, and Q83. “Do you take medicines for high blood fats (cholesterol, triglycerides)?”, together with specific questions asking the patients to name the medications taken. The results from these questions are presented below.

The two groups were well matched with regards to the proportion of patients using insulin (Intervention 16.9% vs Control 19.3%; $p=0.67$). They were also well matched in regards to the number of oral hypoglycaemic agents taken per patient (Control average 2.75 vs. Intervention average 2.83, $p=0.63$), but not in terms of the proportion of patients receiving these agents (Table 4.8). One hundred percent of patients in the Intervention Group were receiving at least one oral hypoglycaemic compared with 92.5% of patients in the Control Group ($p=0.01$). Of the eight control patients who were not taking an oral hypoglycaemic two were using insulin for glycaemic control.

Table 4.8: Proportion of Patients Taking Pharmacological Agents for the Management of Diabetes and its Complications

Medications	n	Control [Number (%)]	n	Intervention [Number (%)]	p-value
Insulin	109	21 (19.3)	83	14 (16.9%)	0.67
Average number of oral hypoglycaemic agents taken		2.75±0.14		2.83±0.11	0.63
Oral hypoglycaemic agents	107	99 (92.5)	83	83 (100.0)	0.01
Antihypertensive agents	110	67 (60.9)	82	52 (63.4)	0.72
Lipid lowering agents	109	56 (51.4)	82	53 (64.6)	0.07
Medication for diabetes complications	103	12 (11.7)	76	9 (11.8)	0.97

The only significant difference in antidiabetic drug usage was seen with acarbose (Table 4.9), where five patients in the Control Group were receiving the drug compared to none in the Intervention Group ($p = 0.04$). All other classes of antidiabetic medications were represented in Intervention and Control patients and there were no significant differences in frequency of use.

Table 4.9: Antidiabetic Agents

Antidiabetic Agents		n	Baseline [Number (%)]	p value
Insulin	Intervention	55	10 (18.2)	0.74
	Control	69	11 (15.9)	
Sulfonylureas	Intervention	55	37 (67.3)	0.17
	Control	69	38 (55.1)	
Metformin	Intervention	55	45 (81.8)	0.50
	Control	69	53 (76.8)	
Glitazones	Intervention	55	1 (1.8)	0.26
	Control	69	0 (0.0)	
Acarbose	Intervention	55	0 (0.0)	0.04
	Control	69	5 (7.2)	

The two groups were also well matched in the proportion of patients who were receiving antihypertensive medication, lipid lowering agents and medication for other diabetes complications (Table 4.8). Tables 4.10 and 4.11 show the patterns of prescribing of lipid lowering and antihypertensive medications were similar between the two groups.

Table 4.10: Lipid Lowering Agents

Lipid-Lowering Agents		n	Baseline No. Patients (%)	p value
Statins	Intervention	55	32 (58.2)	0.142
	Control	69	31 (44.9)	
Fibrates	Intervention	55	1 (1.8)	0.679
	Control	69	2 (2.9)	

Table 4.11: Antihypertensive Agents

Antihypertensive Agent		n	Baseline No. Patients (%)	p value
Thiazide diuretics	Intervention	55	3 (5.5)	0.47
	Control	69	2 (2.9)	
Potassium sparing diuretics	Intervention	55	1 (1.8)	0.26
	Control	69	0 (0.0)	
Loop diuretics	Intervention	55	0 (0.0)	0.37
	Control	69	1 (1.4)	
Thiazide plus potassium sparing diuretic	Intervention	55	2 (3.6)	0.43
	Control	69	1 (1.4)	
β-blockers	Intervention	55	12 (21.8)	0.54
	Control	69	12 (17.4)	
ACE Inhibitors	Intervention	55	22 (40)	0.27
	Control	69	21 (30.4)	
ACEI plus diuretic	Intervention	55	6 (10.9)	0.48
	Control	69	5 (7.2)	
AT II Receptor Antagonists	Intervention	55	3 (5.5)	0.34
	Control	69	7 (10.1)	
AT II Receptors Antagonists plus diuretic	Intervention	55	2 (3.6)	0.58
	Control	69	4 (5.8)	
Calcium Channel Blockers	Intervention	55	12 (21.8)	0.99
	Control	69	15 (21.7)	
α-blockers	Intervention	55	0 (0.0)	0.37
	Control	69	1 (1.4)	

Seventy-six percent of patients in the Control Group and 74.7% of those in the Intervention Group reported other co-morbidities ($p = 0.84$), with a similar proportion taking medication for these conditions (Control 70.6% vs Intervention 75.0%; $p = 0.51$). Medication taken for these complications included anticoagulants and antiplatelet agents, nitrates and antiarrhythmics. These were used by similar proportions of patients in both groups (Table 4.12).

Table 4.12: Other Medications Taken for Diabetes Complications

Other Medications		n	Baseline No. Patients (%)	p value
Warfarin	Intervention	55	3 (5.5)	0.47
	Control	69	2 (2.9)	
Antiplatelet agents	Intervention	55	14 (25.5)	0.34
	Control	69	23 (33.3)	
Antiarrhythmic agents	Intervention	55	2 (3.6)	0.43
	Control	69	1 (1.4)	
Nitrates	Intervention	55	1 (1.8)	0.87
	Control	69	0 (0.0)	

A similar proportion of patients in both the Control and Intervention groups reported use of herbal remedies, vitamins and minerals and natural products (See Table 4.13).

Table 4.13: Complementary Medicines

Complementary Medicines		n	Baseline No. Patients (%)	p- value
Herbal remedies	Intervention	75	14.7%	0.53
	Control	110	18.2%	
Vitamin & mineral supplements	Intervention	78	30.8%	0.88
	Control	111	29.7%	
Natural products	Intervention	72	18.1%	0.60
	Control	106	15.1%	

Patients were asked a series of questions to assess whether their doctor or pharmacist had provided them with advice on how and when to take their medication, and how to store it. Further, they were asked if they currently had any questions about their medications. Lastly, they were asked about their compliance with their medications. The responses to these questions are shown in Table 4.14. Impressive amongst the responses was the high level of reported compliance with medical therapy.

Table 4.14: Medication Knowledge and Compliance

	n	Controls [Number (%)]	n	Intervention [Number (%)]	p value
Advised on how and when to taken medications	110	107 (97.3)	83	80 (96.4)	0.725
Advised on how to store medication	108	85 (78.7)	82	56 (68.3)	0.104
Any questions about medications	105	13 (12.4)	80	8 (10.0)	0.613
Take medications regularly at the correct time	107	94 (87.9)	80	75 (93.8)	0.176

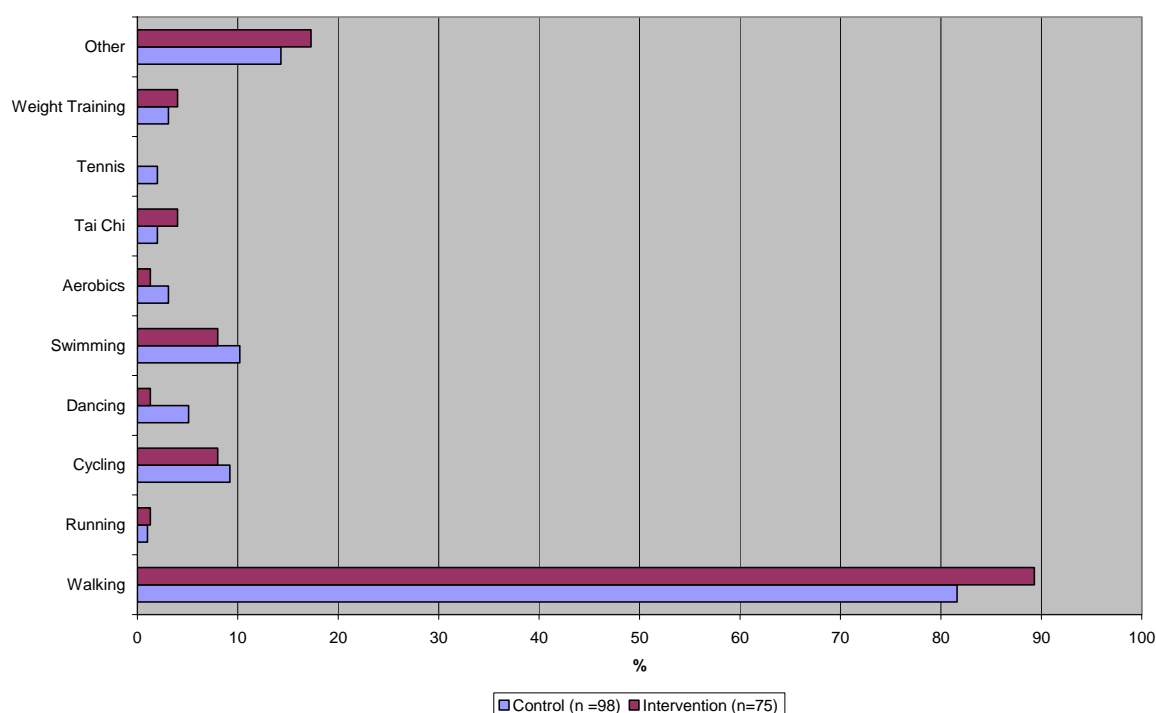
4.2.3.2 Non-Pharmacological

Table 4.15 shows the data on non-pharmacological interventions (lifestyle measures) used by patients in the study. The proportion of patients who had met with dieticians to have a nutritional program prescribed was slightly higher in the Control Group, however the difference was not statistically significant (43.1% vs 33.7%; $p = 0.19$). The Control patients showed a trend towards being more likely to limit their calorie intake (34, 51.5%) compared to the Intervention patients (13, 33.3%). The proportion of patients consuming alcohol was no different in the Intervention Group (41.0%) compared to the Control Group (36.8%; $p = 0.56$), and the reported average weekly consumption was the same (7.6 drinks per week). The level and duration of exercise undertaken by subjects in both groups was similar, as shown in Table 4.15.

Table 4.15: Non-Pharmacological Interventions for the Management of Diabetes and its Complications at Baseline

	n	Control No. Patients (%)	n	Intervention No. Patients (%)	p-value
Nutrition					
Met with a dietician and had a nutrition program prescribed	109	47 (43.1)	83	28 (33.7)	0.19
Limits calorie intake	66	34 (51.5)	39	13 (33.3)	0.07
Counts carbohydrates	65	11 (16.9)	34	8 (23.5)	0.43
Alcohol					
Consumes alcohol	106	39 (36.8)	78	32 (41.0)	0.56
Number of alcoholic drinks consumers per week (Mean±SE)	37	7.65±1.57	27	7.56±1.19	0.94
Physical Activity					
Level of physical activity					
None	109	16 (14.7)	81	12 (14.8)	0.84
Sometimes weekly		19 (17.4)		12 (14.8)	
Weekly		14 (12.8)		8 (9.9)	
Sometimes daily		20 (18.3)		20 (24.7)	
Daily		40 (36.7)		29 (35.8)	
Duration of exercise (hr/week)					
No time	106	14 (13.2)	82	13 (15.9)	0.46
Up to 1 hour		33 (31.1)		17 (20.7)	
1 – 2 hours		17 (16.0)		10 (12.2)	
2 – 3 hours		8 (7.5)		12 (14.6)	
3 – 4 hours		9 (8.5)		10 (12.2)	
4 – 5 hours		8 (7.5)		9 (11.0)	
5 – 6 hours		7 (6.6)		3 (3.7)	
More than 6 hours		10 (9.4)		8 (9.8)	

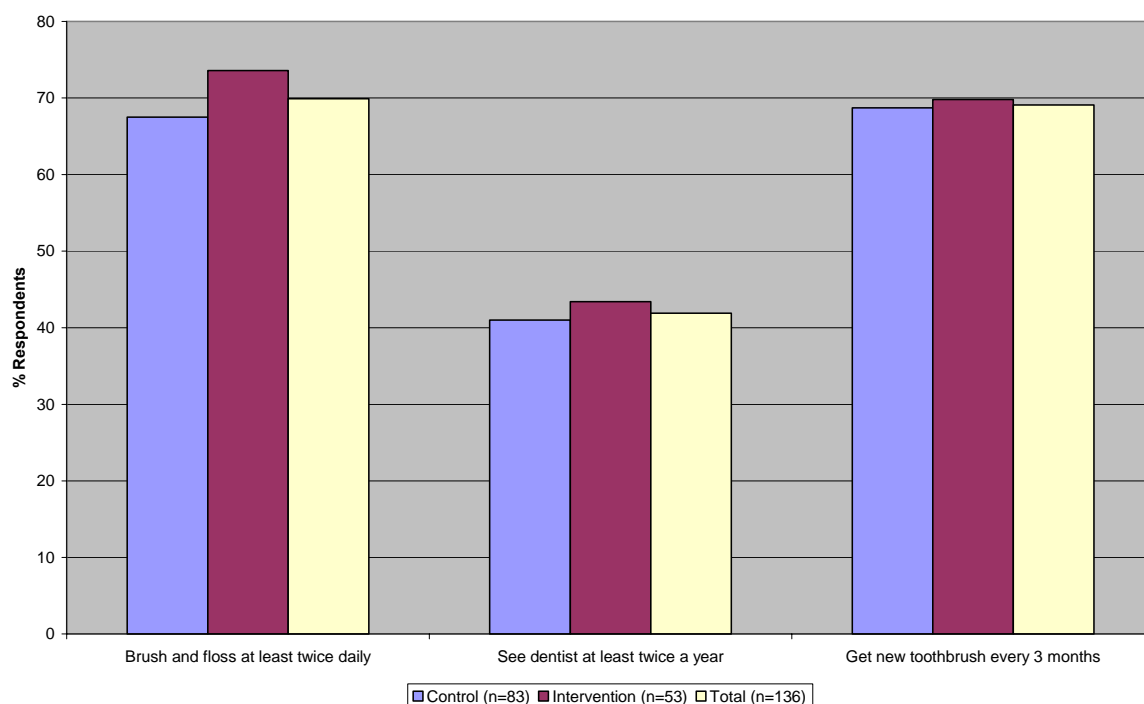
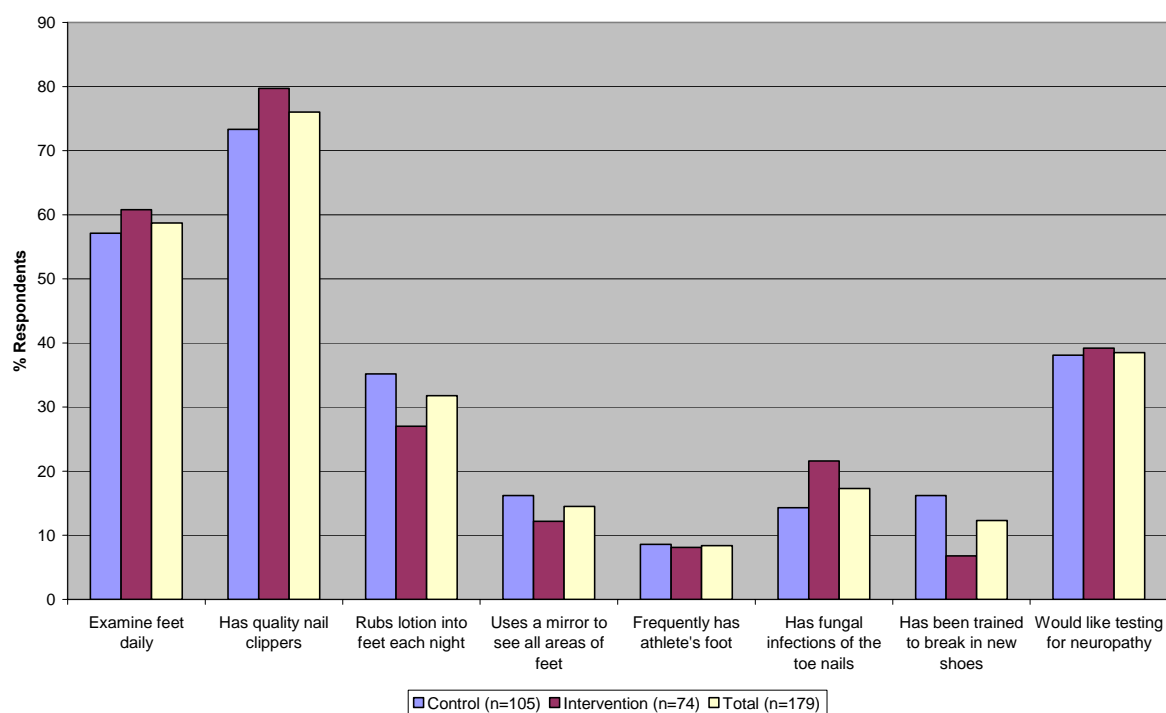
There was no statistical difference in the distribution of the physical activities undertaken by patients in the two groups ($p=0.67$). Walking was the most popular form of physical activity in both groups, undertaken by 81.6% of patients in the Control Group and 89.3% of those in the Intervention Group.

Figure 4.3: Types of Exercise Undertaken

As patients with diabetes often suffer dental and foot problems, training in the preventative care is encouraged. The data in Table 4.16 and Figures 4.4 and 4.5 demonstrate that the level of training in both these areas was comparable between the two groups.

Table 4.16: Training in Preventative Dental and Foot Care

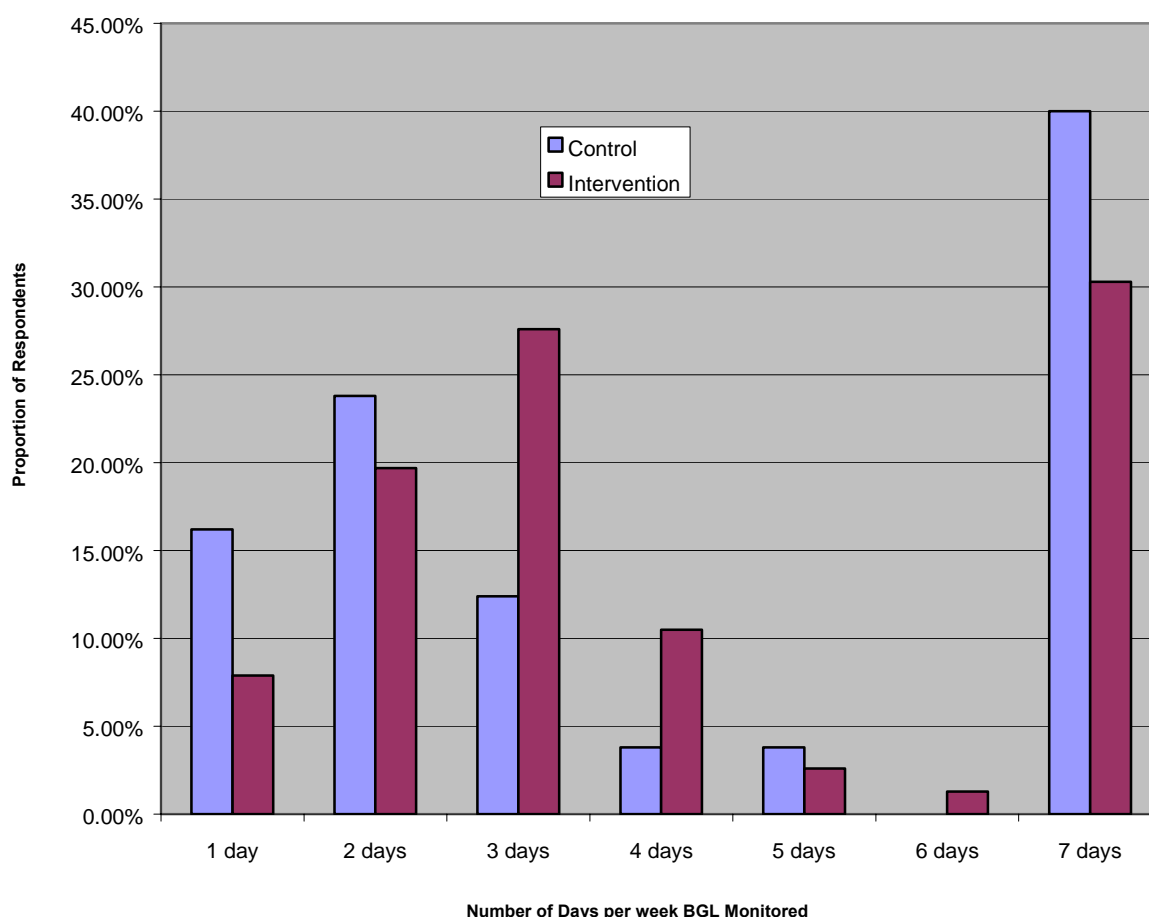
	n	Control [Number (%)]	n	Intervention [Number (%)]	p value
Trained in preventative dental care					
Yes	108	31 (28.7)	79	22 (27.8)	0.75
No		64 (59.3)		50 (63.3)	
Not Sure		13 (12.0)		7 (8.9)	
Trained in preventative foot care - Yes	110	56 (50.9)	82	38 (46.3)	0.53

Figure 4.4: Baseline Data on Dental Care**Figure 4.5: Baseline Data on Foot Care**

4.2.3.3 Patient Self Monitoring

Self-monitoring is an important component of diabetes management. The proportion of patients self-monitoring blood sugar levels was similar in both groups; exceeding 95% ($p=0.44$) [Table 4.17]. However the number of days per week that monitoring was carried out differed ($p = 0.03$), but not the number of times per day ($p=0.35$). Thus, although the average number of days per week on which blood glucose monitoring took place was no different, Control patients were more likely to test their blood sugar levels either every day of the week or twice a week, compared to Intervention patients who were more likely to test their levels either three times weekly or every day (see Figure 4.6),

Figure 4.6: Number of Days of Blood Glucose Monitoring at Baseline



The proportion of patients with their own blood glucose meter was comparable between the groups.

Table 4.17: Blood Glucose, Body Weight and Blood Pressure Monitoring at Baseline

Blood Glucose Monitoring	N	Control [Number (%)]	n	Intervention [Number (%)]	p-value*
Self-monitor blood sugars	108	105 (97.2)	81	77 (95.1)	0.44
Days per week blood sugars are monitored					
1 day	105	17 (16.2)	76	6 (7.9)	0.03
2 days		25 (23.8)		15 (19.7)	
3 days		13 (12.4)		21 (27.6)	
4 days		4 (3.8)		8 (10.5)	
5 days		4 (3.8)		2 (2.6)	
6 days		0 (0)		1 (1.3)	
7 days		42 (40.0)		23 (30.3)	
Average (\pm SE)		4.15 \pm 0.24		4.05 \pm 0.25	0.77 [#]
Times per day blood sugars are monitored					
One	106	28 (24.6)	77	21 (27.3)	0.35
Two		48 (45.3)		31 (40.3)	
Three		16 (15.1)		14 (18.2)	
Four		11 (10.4)		9 (11.7)	
Five		0 (0)		2 (2.6)	
Six		3 (2.8)		0 (0)	
Average (\pm SE)	106	2.21 \pm 0.11	77	2.22 \pm 0.12	0.94 [#]
Blood sugar levels recorded	109	78 (71.6)	82	60 (73.2)	0.20
Blood glucose meter for self monitoring	111	107 (96.4)	82	79 (96.3)	0.98
Weight Monitoring					
Have bathroom scale for weekly weighting	110	87 (79.1)	82	64 (78.0)	0.86
Weight changed in past few months	110	60 (54.6)	83	38 (45.8)	0.47
Blood Pressure Monitoring					
Self-monitor blood pressure	110	30 (27.3)	82	22 (26.8)	0.94

* Pearson Chi-Squared unless otherwise stated; [#] t-test for Equality of Means

A similar proportion of patients in each group had bathroom scales to undertake weekly weighing, and whilst a large proportion of patients in the Control Group (54.6% vs 45.8%) reported weight loss in the past month, the difference was not statistically significant. Just fewer than 30% of patients in both groups reported self-monitoring of blood pressure at home.

4.2.3.4 Diabetes Support Networks

At baseline, a similar proportion of subjects in the Control and Intervention Groups were members of Diabetes Australia (See Table 4.18), however a significantly larger proportion of subjects in the Intervention Group (13.4%) were part of a diabetes support group compared to controls (2.8%; $p = 0.006$), which reflected the fact that one of the intervention pharmacies operated its own diabetes support group.

Table 4.18: Patients' Membership of Diabetes Support Organisations and Groups

	n	Control [Number (%)]	n	Intervention [Number (%)]	p- value
Member the Western Australian branch of Diabetes Australia	109	83 (76.1)	81	65 (80.2)	0.50
Like information about joining Diabetes Australia	31	15 (48.4)	20	10 (50.0)	0.91
Member of a local diabetes support group	107	3 (2.8)	82	11 (13.4)	0.006

4.2.4 Patient Knowledge, Training and Education

Patients were asked a series of questions related to recognition and treatment of both hyperglycaemia and hypoglycaemia (See Table 4.19). Overall, the results suggested that the patients in the Control Group tended to be more knowledgeable than those in the Intervention Group in regards to hyper- and hypo-glycaemia. There were statistically significant differences observed in regard to the patients' knowledge of what signs should prompt immediate medical care in the case of hypoglycaemia (Control 69% vs Intervention 52%; $p = 0.015$), and hypoglycaemia knowledge overall (Control 2.17 vs Intervention 1.87; $p = 0.047$).

Table 4.19: Patient Knowledge of Hyperglycaemia and Hypoglycaemia

	Control		Intervention		p-value
	n	[Number (%)]	n	[Number (%)]	
<i>Knowledge of hyperglycaemia and it management</i>					
Can recognize the symptoms of high sugar levels (hyperglycaemia)	111	76 (68.5)	81	49 (60.5)	0.25
Knows how to treat hyperglycaemia symptoms	110	67 (60.9)	79	39 (49.4)%	0.11
Knows what signs should prompt immediate medical care	109	66 (60.6)	78	37 (47.4)	0.075
Overall knowledge rating on hyperglycaemia (Scale 0-3)	109	1.83±0.12	78	1.51±0.14	0.09
<i>Knowledge of hypoglycaemia and it management</i>					
Knows how to recognize low blood sugar levels (hypoglycaemia)	108	88 (81.5)	81	59 (72.8)	0.16
Knows how to treat the symptoms of hypoglycaemia	110	84 (76.4)	80	55 (68.8)	0.24
Knows what signs should prompt immediate medical care	108	75 (69.4)	79	41 (51.9)	0.015
Overall knowledge rating on hypoglycaemia (Scale 0-3)	108	2.17±0.11	79	1.87±0.14	0.047

The proportion of patients who had received training in the use of a glucagon emergency kit was higher amongst the Control Group (5.4% vs 0%; $p = 0.054$), but this is simply a reflection of the fact that all five patients who had glucagon kits for emergency use were all in the Control Group. In regards to general diabetes education, nutritional training and training on how to obtain finger prick samples, the groups were well matched (See Table 4.20). More patients in the Intervention Group (68.0%) showed a tendency to be more interested in

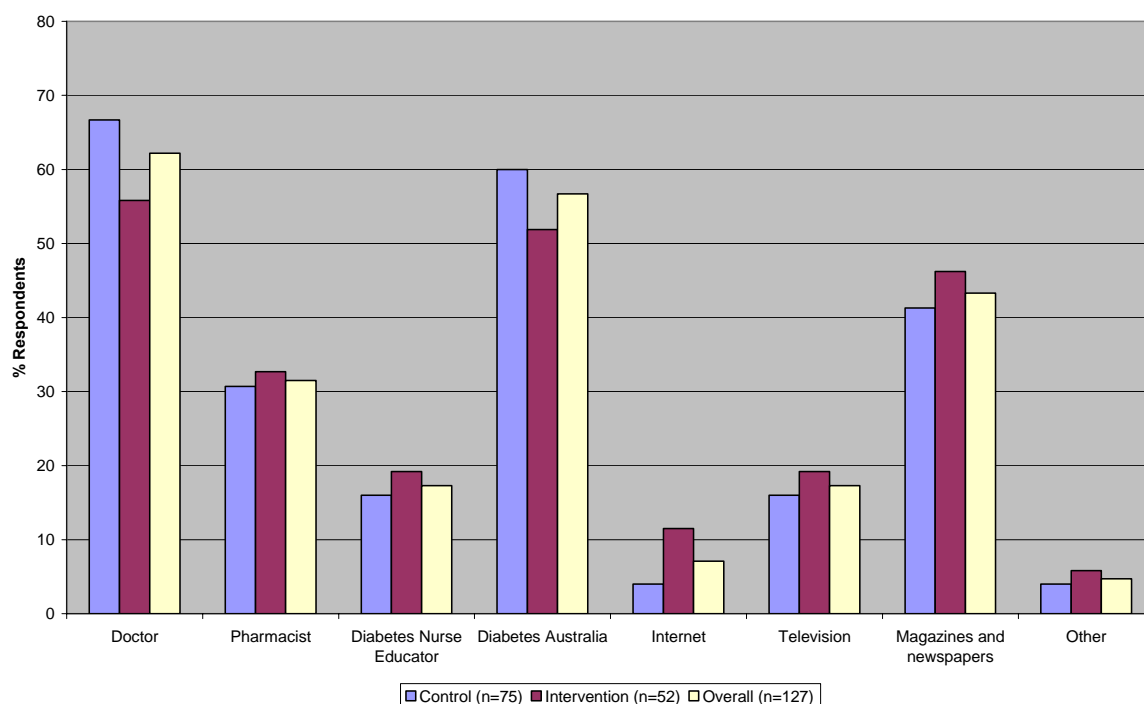
receiving further reading material on diabetes than those in the Control Group (53.7%; $p = 0.051$)

Table 4.20: Patient Training and Education in Diabetes Management

Patient Training and Education	n	Control [Number (%)]	n	Intervention [Number (%)]	p value
Trained to use a glucagon emergency kit	81	5 (6.2)	58	0 (0)	0.054
Trained in how to plan your meals with diabetes	108	58 (53.7)	81	39 (48.2)	0.45
Received any form of diabetes education	111	78 (70.3)	81	68 (84.0)	0.03
Duration of education program					
≤2 hours	79	31 (39.2)	69	26 (37.7)	0.05
2-4 hrs		20 (25.3)		7 (10.1)	
4-8 hrs		6 (7.6)		12 (17.2)	
several days		13 (16.5)		18 (26.1)	
Other		9 (11.4)		6 (8.7)	
Met with a Certified Diabetes Educator	111	65 (58.6)	82	57 (69.5)	0.26
Can demonstrate how to use glucose meter	111	107 (96.4)	81	80 (98.8)	0.31
Trained in how to easily obtain a drop of blood for glucose testing	111	97 (87.4)	78	64 (82.1)	0.31
Would like educational reading materials about diabetes	108	58 (53.7)	78	53 (67.9)	0.051
Keeps up to date with diabetes management	111	68 (61.3)	81	47 (58.0)	0.65

Patients were asked whether they kept up-to-date with diabetes management. Approximately 60% of respondents in both groups stated “yes”. When asked what means they used to keep up-to-date, the most common responses were information from their doctor, Diabetes Australia, and magazines and newspapers (Figure 4.7).

Figure 4.7: Sources of Information Use by Participants for Keeping Up-to-date on Diabetes Management



Patients were asked to rate their understanding of a number of diabetes-related topics, including overall diabetes care on a scale of 1 to 5 (1 = poor and 5 = excellent). The results of these self-assessments are shown in Table 4.21. Using t-test for Equality of Means analysis the only statistically significant difference in the patients' self-assessment of their understanding was in the area of using the results of blood sugar in monitoring in managing their diabetes (Control 3.56 vs Intervention 3.24; $p = 0.043$)

Table 4.21: Patients' Rating of Their Understanding of Diabetes Related Topics

Please rate your understanding of the following topics (Poor = 1, Excellent = 5)	Control (mean ± SE)	Intervention (mean ± SE)	P value
Overall diabetes care	3.21±0.10	3.16±0.10	0.326
Coping with stress	3.33±0.11	3.16±0.10	0.276
Diet for blood sugar control	3.38±0.11	3.28±0.10	0.539
Role of exercise in diabetes care	3.53±0.10	3.61±0.10	0.591
Diabetes medicines you are taking	3.70±0.11	3.49±0.11	0.190
How to use the results of blood sugar monitoring	3.56±0.11	3.24±0.11	0.043
How diet, exercise & medicines affect blood sugar levels	3.53±0.10	3.39±0.11	0.353
Prevention & treatment of high blood sugar	3.29±0.11	3.06±0.12	0.157
Prevention & treatment of low blood sugar	3.24±0.12	2.97±0.12	0.124
Prevention of long term complications of diabetes	3.09±0.12	2.95±0.11	0.388
Foot-care	3.18±0.12	3.25±0.11	0.715
Retinopathy	3.36±0.12	3.29±0.12	0.649
Benefits of improving blood sugar control	3.55±0.10	3.38±0.10	0.237
Pregnancy and diabetes	2.14±0.14	2.41±0.19	0.289

4.2.5 Level of Diabetes Care

Table 4.22 provides information on the level of patient care provided to patients within the two groups. The data do not demonstrated any significant differences in the level of follow-up for diabetic complications amongst the two groups.

Table 4.22: Monitoring for Diabetes-Related Complications

Monitoring (Testing Undertaken)	n	Control	n	Intervention	p-value
Feet examined in the last year	108	56 (51.9)	76	37 (48.7)	0.67
Eye evaluation by specialist in last year	110	79 (71.8)	81	52 (64.2)	0.26
Dilated pupil eye examination	110	65 (60.2)	81	47 (58.0)	0.54
Urine examination for protein					
Yes	109	42 (38.5)	80	32 (40.0)	0.26
No		11 (10.1)		14 (17.5)	
Not sure		56 (51.4)		34 (42.5)	
Bone density estimation (Females only)	60	21 (35.0)	45	14 (31.1)	0.68

As part of the modified DPAQ patients were asked to assess their current level of diabetes care and their willingness to improve it using the following two questions:

- Q45.How do you feel about you diabetes care?
- Q46: How do you feel about working to improve your diabetes care?

The results of these assessments are shown in Table 4.23, and demonstrate that the majority patients in both groups rated their diabetes care as average to good; and both had a similar willingness to work towards improving their level of diabetes care.

Table 4.23: Patients' Assessment of Their Level of Diabetes Care

Question	n	Control [Number (%)]	n	Intervention [Number (%)]	p value*
Q45.How do you feel about you diabetes care?					
Good	109	50 (45.9)	83	35 (42.2)	0.58
Average		45 (41.3)		40 (48.2)	
Poor		14 (12.8)		8 (9.6)	
Q46. How do you feel about working to improve your diabetes care?					
Yes	107	73 (68.2)	82	48 (58.5)	0.24
Bit sceptical		17 (15.9)		21 (25.6)	
Not sure		17 (15.9)		13 (15.9)	

* Pearson Chi-square

4.2.6 Quality of Life Assessments

Two instruments were used to assess the patients' quality of life; the Type 2 Diabetes Symptoms Checklist (DSC_R) and the SF-36. The DSC_R was used to assess the impact of diabetes on the patients' physical functioning. The SF-36 was used to assess the patients' quality of life in general.

4.2.6.1 Diabetes Symptom Checklist (DSC_R)

Patients were asked to complete a Type 2 Diabetes Symptoms Checklist (DSC_R) as a quality of life (QOL) assessment (Appendix 8). The DSC_R was used to assess the impact of diabetes on the patients' physical functioning. The DSC_R is reported to be the only scale that evaluates physical symptoms in a broad and comprehensive manner.¹¹ The DSC_R is comprised of 34 questions, the scores from which are used to calculate composite scores across 6 dimensions. The comparative data for the individual questions are shown in Table 4.24. The only significant differences between the control and interventions groups were seen in the areas of moodiness and numbness in the hands. In both instances the Control Group had higher symptoms scores (moodiness: Control 1.96 vs Intervention 1.61, $p = 0.018$; numbness in the hands: Control 1.62 vs Intervention 1.35, $p = 0.046$). These results however had no impact on the patients' symptom scores as assessed by the 6 dimensions and their four subdivisions in the DSC_R (Table 4.25 and Figure 4.8).

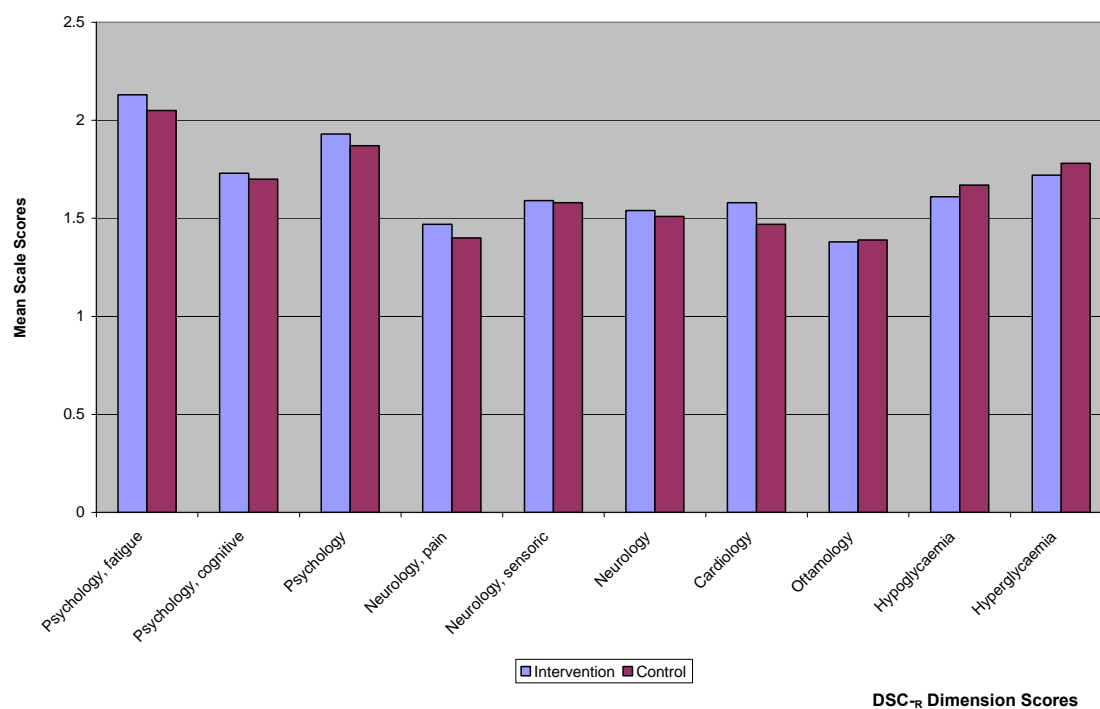
Table 4.24: DSC_R Individual Question Scores

DSC _R Question		Group	n	Mean	SD	p value
1	Lack of strength/energy	Control	105	2.28	1.05	0.87
		Intervention	83	2.25	1.11	
2	Aching calves when walking	Control	105	1.75	1.10	0.65
		Intervention	83	1.83	1.23	
3	Numbness in the feet	Control	105	1.71	1.14	0.49
		Intervention	82	1.83	1.10	
4	Overall sense of fatigue	Control	104	2.16	1.20	0.61
		Intervention	83	2.25	1.16	
5	Shortness of breath at night	Control	105	1.3	0.71	0.19
		Intervention	83	1.45	0.84	
6	Sleepiness or drowsiness	Control	105	2.09	1.14	0.46
		Intervention	83	2.22	1.07	
7	Difficulty concentrating	Control	105	1.65	1.02	0.72
		Intervention	83	1.7	0.96	
8	Moodiness	Control	105	1.96	1.06	0.02
		Intervention	83	1.61	0.90	
9	Numbness in the hands	Control	105	1.62	1.06	0.04
		Intervention	83	1.35	0.69	
10	Persistently blurred vision	Control	105	1.45	0.84	0.82
		Intervention	83	1.42	0.68	
11	Tingling sensation in limbs at night	Control	106	1.52	0.86	0.30
		Intervention	83	1.66	1.00	
12	Very thirsty	Control	106	1.82	1.12	0.66
		Intervention	83	1.75	1.14	
13	Palpitations or pain in the chest	Control	106	1.37	0.68	0.34
		Intervention	83	1.47	0.75	
14	Deteriorating vision	Control	106	1.52	0.85	0.82
		Intervention	82	1.49	0.67	
15	Burning pain in calves at night	Control	106	1.25	0.75	0.83
		Intervention	83	1.27	0.69	
16	Dry mouth	Control	106	2.05	1.20	0.95
		Intervention	83	2.04	1.18	
17	Increasing fatigue during the day	Control	106	2.07	1.10	0.53
		Intervention	83	2.17	1.12	

DSC _R Question		Group	n	Mean	SD	p value
18	Flashes/black spots in field of vision	Control	106	1.41	0.71	0.67
		Intervention	83	1.36	0.69	
19	Irritability just before a meal	Control	106	1.22	0.59	0.16
		Intervention	83	1.36	0.77	
20	Fatigue when getting up	Control	106	1.74	1.02	0.50
		Intervention	83	1.84	1.15	
21	Shooting pains in legs	Control	105	1.4	0.77	0.57
		Intervention	83	1.47	0.89	
22	Fluctuating clear/blurred vision	Control	105	1.37	0.75	0.36
		Intervention	83	1.47	0.72	
23	Frequent voiding	Control	106	1.47	1.04	0.25
		Intervention	83	1.33	0.70	
24	Pains in breast/heart region	Control	106	1.29	0.60	0.54
		Intervention	83	1.35	0.65	
25	Burning pain in legs during the day	Control	105	1.22	0.69	0.53
		Intervention	83	1.29	0.80	
26	Tingling or prickling in hands or feet	Control	106	1.59	1.00	0.10
		Intervention	83	1.4	0.64	
27	Easily irritated or annoyed	Control	106	1.83	1.04	0.87
		Intervention	83	1.86	1.01	
28	Sudden deterioration in vision	Control	106	1.19	0.52	0.80
		Intervention	83	1.17	0.54	
29	Odd feeling in legs or feet when touching	Control	106	1.42	0.86	0.96
		Intervention	83	1.42	0.84	
30	Shortness of breath during exercise	Control	106	1.92	1.07	0.39
		Intervention	83	2.06	1.08	
31	Dull head	Control	106	1.54	0.84	0.44
		Intervention	83	1.45	0.77	
32	Drinking a lot	Control	106	1.78	1.18	1.00
		Intervention	83	1.78	1.15	
33	Difficulty staying attentive	Control	106	1.52	0.80	0.79
		Intervention	83	1.55	0.98	
34	Tingling or pricking in legs or feet	Control	106	1.65	0.99	0.13
		Intervention	83	1.89	1.13	

Table 4.25: Results of the Diabetes Symptoms Checklist Assessments at Baseline

DSC _R Dimension and Sub-division Scores	n	Control	n	Intervention	Difference (95% CI)	p-value
Psychology	72	1.87	52	1.93	-0.27 (1.73, 2.02)	0.63
<i>Psychology, fatigue</i>	69	2.05	52	2.13	-0.08 (-0.36, 0.19)	0.55
<i>Psychology, cognitive</i>	72	1.70	50	1.73	-0.03 (-0.23, 0.18)	0.79
Neurology	73	1.51	51	1.54	-0.03 (-0.21, 0.15)	0.75
<i>Neurology, pain</i>	69	1.40	51	1.47	-0.06 (-0.25, 0.13)	0.74
<i>Neurology, sensoric</i>	73	1.58	51	1.59	-0.01 (-0.21, 0.19)	0.95
Cardiology	72	1.47	50	1.58	-0.11 (-0.27, 0.05)	0.17
Oftamology	70	1.39	50	1.38	0.003 (-0.15, 0.16)	0.97
Hypoglycaemia	69	1.67	50	1.61	0.05 (-0.16, 0.27)	0.62
Hyperglycaemia	71	1.78	49	1.72	0.06 (-0.21, 0.32)	0.67

Figure 4.8: Baseline Mean Diabetes Symptom Checklist Scores

4.2.7.2 SF-36 Short Form Health Survey (Australia/New Zealand)

As can be seen from the data presented in Table 4.26, there were no discernible differences in the baseline assessments of quality of life of the patients in the control and interventions groups across any of the 8 dimensions of the SF-36.

Table 4.26: Results of SF-36 Assessments at Baseline

Domains	Control			Intervention			p value
	n	Mean	SD	n	Mean	SD	
Physical Functioning	72	63.3	27.1	54	66.9	24.0	0.35
Role – Physical	74	58.4	44.3	53	64.5	40.0	0.34
Bodily pain	75	66.1	29.3	53	65.7	27.5	0.92
General health	75	57.9	21.6	52	54.0	22.4	0.92
Vitality	75	54.7	23.6	54	51.6	21.5	0.35
Social functioning	75	75.5	28.0	55	77.7	28.0	0.57
Role – emotional	74	75.2	37.9	53	69.8	39.1	0.35
Mental Health	54	73.1	18.6	54	71.0	20.0	0.45

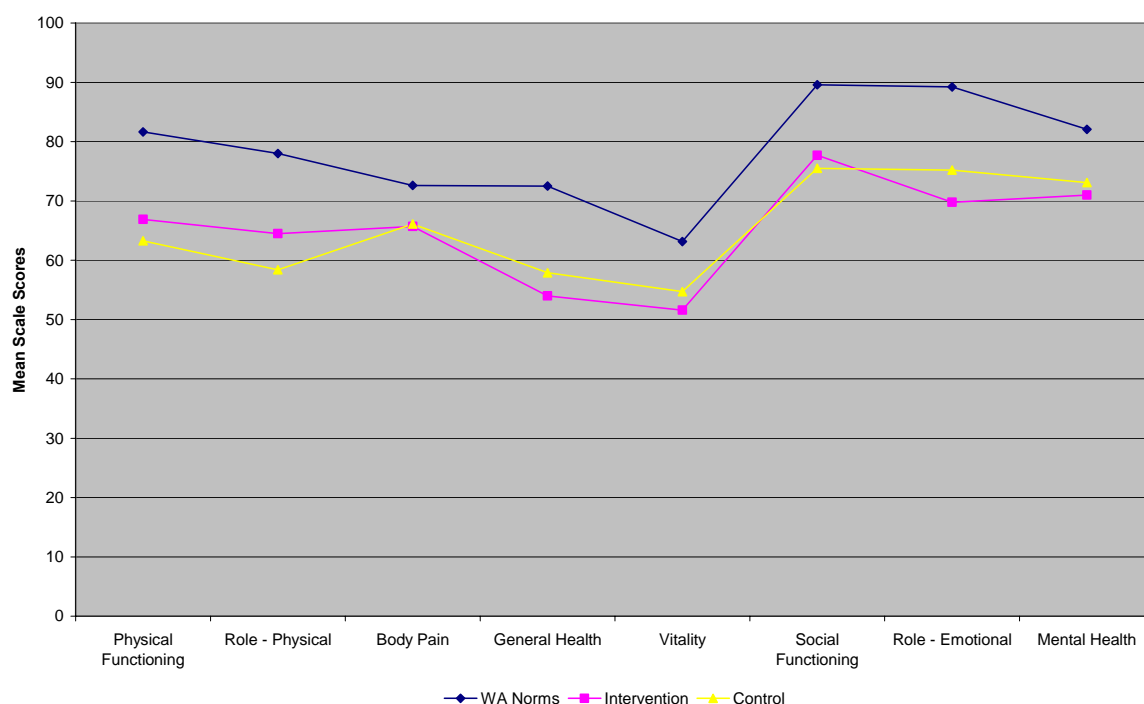
Table 4.27 contains the mean SF-36 scores for the Australian population. It is apparent from these data that SF-36 scores fall with increasing age, as would be expected as the physiological and pathological ageing impact on people's quality of life. The average age of the study population was just over 64 years, meaning the group lay just on the border of 'Older Age', which is reflected in their SF-36 scores. Participants in the study had lower SF-36 scores in the general health and vitality domains compared to the Australian average. This result probably reflects the health impact of the chronic disease(s) in the study population.

Table 4.27: Mean and Standard Deviation (SD) of SF-36 Scales

Australian Population in 1995						
Source: C Stevenson (1996) SF-36: <i>Interim Norms for Australian data</i> . Canberra AIHW						
SF—36 Scale	Young		Mid-age		Older	
	Mean	SD	Mean	SD	Mean	SD
Physical Functioning	90.9	17.5	83.5	21.4	57.3	28.8
Role Physical	86.7	28.7	84.2	32.4	56.0	42.8
Body Pain	82.1	20.8	77.8	23.5	65.4	28.6
General Health	73.9	19.5	73.5	20.0	61.1	22.4
Vitality	63.4	18.9	64.8	18.3	57.4	21.4
Social Functioning	84.0	20.0	86.5	20.8	77.3	27.7
Role Emotional	84.6	29.9	86.9	29.0	72.1	37.0
Mental Health	73.0	15.8	75.2	15.4	75.3	17.3

Figure 4.9 shows the SF-36 scores for the patients in the Intervention and Control Groups in comparison with the Western Australian norms scores for persons aged 55-64 years, as established in 1995. In this comparison the patients in both groups (Intervention and Control) had lower average scores than the general population in Western Australia.

Figure 4.9: SF-36 Scores for the Intervention and Control Groups compared with the Western Australian Norms (1995) for Persons Aged 55-64 Years



4.3 DMEP – Diabetes Mellitus Education Program

The DMEP program consisted of two components; the tailored education sessions and the follow-up sessions at 1, 3 and 6 months. During the follow-up sessions patients completed a progress checklist, their treatment goals were reviewed and issues raised by the patient and identified by the pharmacist were addressed. In contrast the patients in the Control group did not receive the educational sessions, however they were followed up at 1, 3 and 6 months, at which time they completed a progress checklist and the pharmacist addressed any issues that the patient raised. Presented below is a summary of the activities undertaken in the educational sessions and during the follow-up visits.

4.3.1 Educational Interventions

Information from the Modified DPAQ questionnaire for each patient was entered into the Diabetes Care module of Cognicare Australia Limited CMMS software

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

package to develop an individualized education program. The education plan synthesized using the package was then used as the basis for each patient's education program, which was further tailored dependent on each individual patient's request for information.

A total of 70 patients entered the educational phase, however only 62 completed the education sessions and progressed to the follow-up phase of the program. Of these 62 patients, complete data sets on the educational activities provided was available for analysis for 58. These patients received a total of 88 education sessions or 1.52 ± 0.63 per patient. Each patient received a total of 106 ± 44 minutes of one-on-one education.

The educational topics were divided into 17 major areas as defined in Table 4.28. The most common topics that were required to be covered in the educational sessions were Hypoglycaemia (n = 41, 10.4%), Hyperglycaemia (40; 10.1%), The Carbohydrate Connection (40; 10.1%) and Tablets for Your Diabetes (35; 8.8%) [Table 4.29 and Figure 4.10]. The modules which were required the least in ascending order were Impaired Glucose Tolerance (0.8%), Insulin (2.0%), and The Diabetes Travel Guide and Sugar Substitutes & Artificial Sweeteners (both 2.8%). Information on smoking cessation was specifically asked for by seven patients (n=58; 12.1%) which was over 60% of the self-reported smokers within in the group. Education on smoking cessation was recorded under Investing in Good Health for the Future.

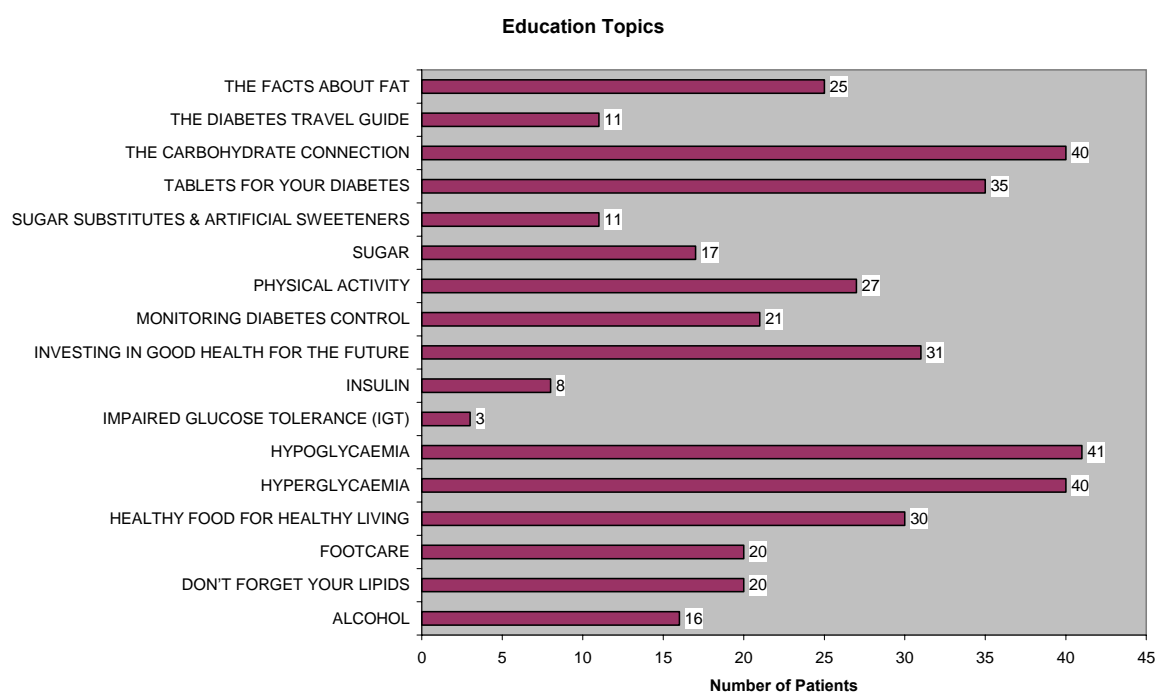
Figure 4.10: Education Modules Covered During Patient Education Sessions

Table 4.28: Educational Modules and Their Content

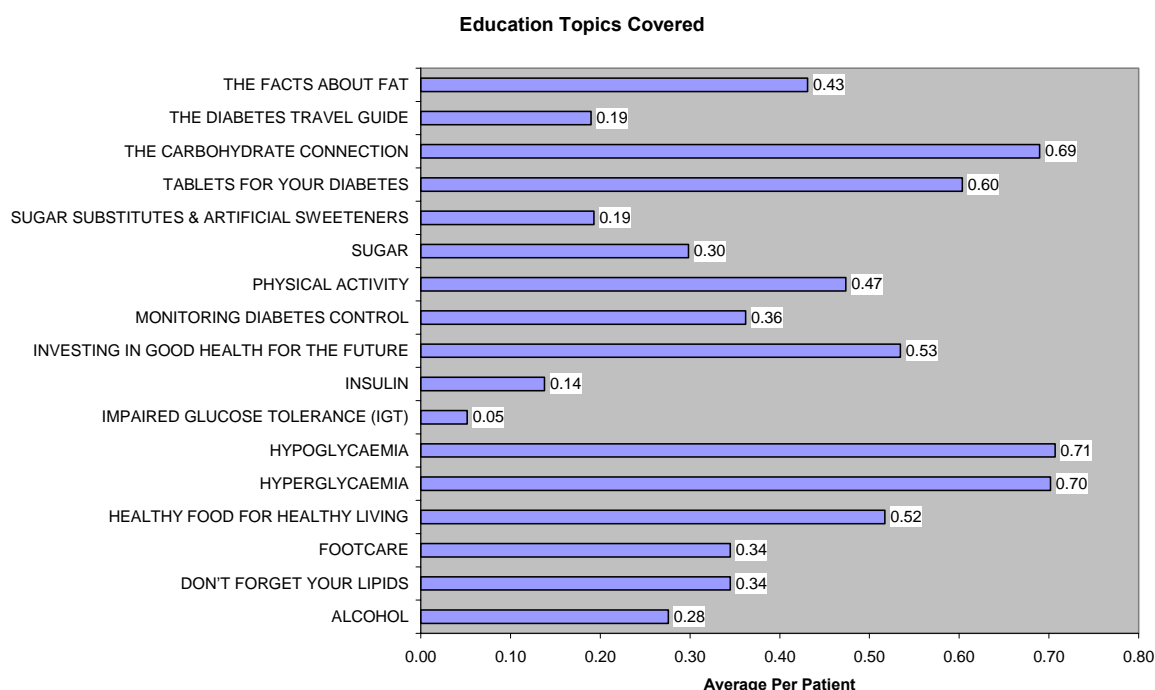
EDUCATION MODULE	CONTENT
Alcohol	<ul style="list-style-type: none"> • Things to remember about consuming alcohol when you suffer from diabetes
Don't forget your lipids	<ul style="list-style-type: none"> • What are lipids? • Different types of lipids • Why should lipids be checked?
Foot care	<ul style="list-style-type: none"> • Circulation • Nerve supply • Daily foot care • First aid • Podiatrists
Healthy food for healthy living	<ul style="list-style-type: none"> • Using the healthy food pyramid • Putting the pyramid into practice
Hyperglycemia	<ul style="list-style-type: none"> • What is it? • What are the symptoms? • What causes it?
Hypoglycemia	<ul style="list-style-type: none"> • What is it? • What causes it? • What are the symptoms? • How to treat? • How can it be prevented?
Impaired glucose tolerance (IGT)	<ul style="list-style-type: none"> • What is it? • What happens in the body with IGT? • How is it treated?
Insulin	<ul style="list-style-type: none"> • Storage and Delivery • Expiry Dates • Injection sites and Injection times • Dose adjustments
Investing in good health for the future	<ul style="list-style-type: none"> • How healthy is your lifestyle • Medical check-up
Monitoring diabetes control	<ul style="list-style-type: none"> • Blood testing: why, how, when & how to record • Obtaining blood testing supplies • Glucometers • HBA1C (Glycated Haemoglobin)
Physical activity	<ul style="list-style-type: none"> • Why it is important • Getting started • Activity ideas
Sugar	<ul style="list-style-type: none"> • How much is a "small amount"? • Types of sugars
Sugar substitutes & artificial sweeteners	<ul style="list-style-type: none"> • Types of sugar substitutes
Tablets for your diabetes	<ul style="list-style-type: none"> • Sulphonylureas • Meglitinides • Biguanides • Acarbose • Thiazolidinediones
The carbohydrate connection	<ul style="list-style-type: none"> • What are carbohydrates? • Which are the best? • How much carbohydrate? • Fibre
The diabetes travel guide	<ul style="list-style-type: none"> • The travel checklist • Packing • In flight • Changes to meals • Handy hints
The facts about fat	<ul style="list-style-type: none"> • Fat & Diabetes • Types of fat • Where are fats found • How to reduce fat

Outside of the topics listed in Table 4.28, two patients sought education on Medic Alert, one on the Diabetes Advice Line and one on diabetes in pregnancy. This last patient was a young female planning to commence a family in the near future.

Table 4.29: Educational Modules Provided

Education Topic	Total times presented	% of total topics discussed	Frequency of presentation (Ave/patient)	SE
Alcohol	16	4.0%	0.28	0.06
Don't Forget Your Lipids	20	5.1%	0.34	0.06
Foot care	20	5.1%	0.34	0.06
Healthy Food For Healthy Living	30	7.6%	0.52	0.07
Hyperglycaemia	40	10.1%	0.70	0.06
Hypoglycaemia	41	10.4%	0.71	0.06
Impaired Glucose Tolerance (IGT)	3	0.8%	0.05	0.03
Insulin	8	2.0%	0.14	0.05
Investing In Good Health For The Future	31	7.8%	0.53	0.07
Monitoring Diabetes Control	21	5.3%	0.36	0.06
Physical Activity	27	6.8%	0.47	0.07
Sugar	17	4.3%	0.30	0.06
Sugar Substitutes & Artificial Sweeteners	11	2.8%	0.19	0.05
Tablets For Your Diabetes	35	8.8%	0.60	0.06
The Carbohydrate Connection	40	10.1%	0.69	0.06
The Diabetes Travel Guide	11	2.8%	0.19	0.05
The Facts About Fat	25	6.3%	0.43	0.07

The frequency of delivery of each of the education modules is shown in Figure 4.11.

Figure 4.11: Frequency of Delivery of Individual Education Modules

During the educational sessions, a number of clinical issues were identified by the educator pharmacists which prompted them to make recommendations for changes to the patient's drug therapy and/or referrals to other health professionals. Examples of these included:

- Referring a patient to her general practitioner because of sores on her legs. Her doctor felt that they were infected and prescribed antibiotics.
- Development of a plan to monitor the effects of a reduction in a patient's Amaryl[®] dose due to recurrent hypoglycaemic episodes, and possible change in the patient's Diaformin[®] dosage regimen.
- Provision of information on the association of dementia with Zocor[®]

4.3.2 Follow-Up Sessions

All 57 Intervention Group patients completed the three follow-up sessions. In contrast, the three sessions were only completed by 61 of the 70 Control Group patients. The remaining nine patients completed the baseline and exit surveys, and hence their data was used in the final analysis.

During the Intervention Group follow-up visits a total of 165 issues were raised or detected and acted upon by the educator pharmacists (an average of 2.89 per patient). In contrast the number of issues acted upon in the Control Group was 22 (an average of 0.36 per patient). The types of issues identified and actions taken are summarized in Tables 4.30 and 4.31 below.

In the Control Group the majority (13/22; 59%) of the issues documented related to lifestyle, in particular weight loss, diet and exercise (Figure 4.12). As a result, the majority of the actions taken by the pharmacists in the Control arm of the study were education based; for example providing advice on what exercise should be undertaken (See Table 4.31). There were however three patients for who the pharmacists suggested follow-up by their general practitioner. One of these patients was suffering from sleep apnoea, a second was feeling “sick” whilst eating and the last had had a number of low BGLs following consumption of the evening meal. It was suggested to a fourth patient that they make an appointment with their eye specialist because of deteriorating vision. The only drug related issue in the Control arm involved the pharmacist obtaining a special insulin delivery device for a patient.

Table 4.30: Issues Identified During the 1, 3 and 6 Month Follow-up Sessions

Issues	Intervention Group		Control Group	
	No.	%	No.	%
Drug Related Issues				
Mechanism of drug action	12	7.3	-	-
Additional drug required	1	0.6	-	-
Drug related problems	24	14.5	-	-
Drug administration devices	1	0.6	1	4.5
Medication compliance	1	0.6	-	-
Disease Related Issues				
Diabetes management	2	1.2	-	-
Diabetes Support	3	1.8	-	-
Blood Glucose Monitoring	7	4.2	1	4.5
Diabetes Complications	14	8.5	1	4.5
Blood pressure target	1	0.6	-	-
Disease knowledge	1	0.6	-	-
Glycaemic control	9	5.5	2	9.1
Disease state management	6	3.6	-	-
Lifestyle Issues				
Weight loss	12	7.3	3	13.6
Alcohol	5	3.0	-	-
Smoking cessation	7	4.2	-	-
Diet	25	15.2	4	18.2
Exercise	9	5.5	6	27.3
Foot care	4	2.4	-	-
Concomitant Diseases				
Concomitant disease	12	7.3	2	9.1
Miscellaneous				
Other	6	3.6	1	4.5
Stress	3	1.8	1	4.5
Total	165	100	22	100

Table 4.31: Actions and Interventions Undertaken in Response to Issues Identified During the 1, 3 and 6 Month Follow-up Sessions

Actions and Interventions	Intervention		Controls	
	Number	%	Number	%
Pharmacists Interventions				
OTC prescribing	11	6.7	-	-
Pharmacists' Interventions	18	10.9	1	4.5
Drug Information	3	1.8	-	-
Educational Interventions				
Alcohol consumption	5	3.0	-	-
Drug usage	9	5.5	-	-
Weight reduction	6	3.6	1	4.5
Smoking cessation	7	4.2	-	-
Diet education	24	14.5	3	13.6
Diabetes	8	4.8	-	-
Patient care	3	1.8	-	-
Travel	1	0.6	-	-
Foot care	2	1.2	-	-
Monitoring advice	4	2.4	1	4.5
Referrals				
Allied health care professional referral	10	6.1	2	9.1
GP Referral	28	17.0	4	18.2
Weight loss organizations	1	0.6	-	-
Diabetes educator referral	2	1.2	-	-
Disease State Management				
Therapeutic target setting	4	2.4	-	-
Exercise advice	9	5.5	9	40.9
Miscellaneous				
Other	10	6.1	-	-
Unknown	-	-	1	4.5
Total	165	100.0	22	100

Figure 4.12: Issues identified during the follow-up sessions (1, 3 and 6 months) in the Control Group

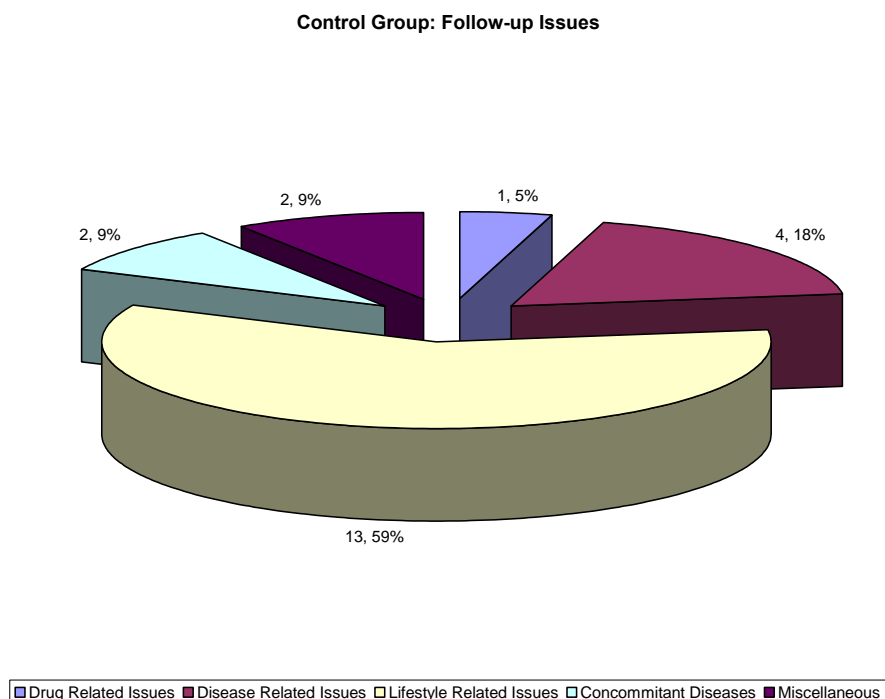
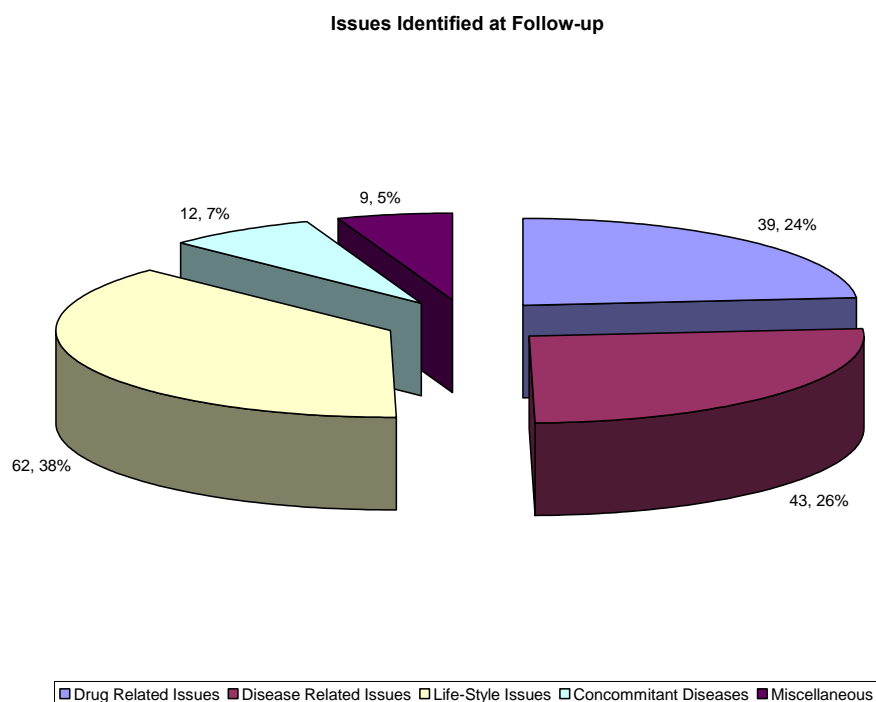


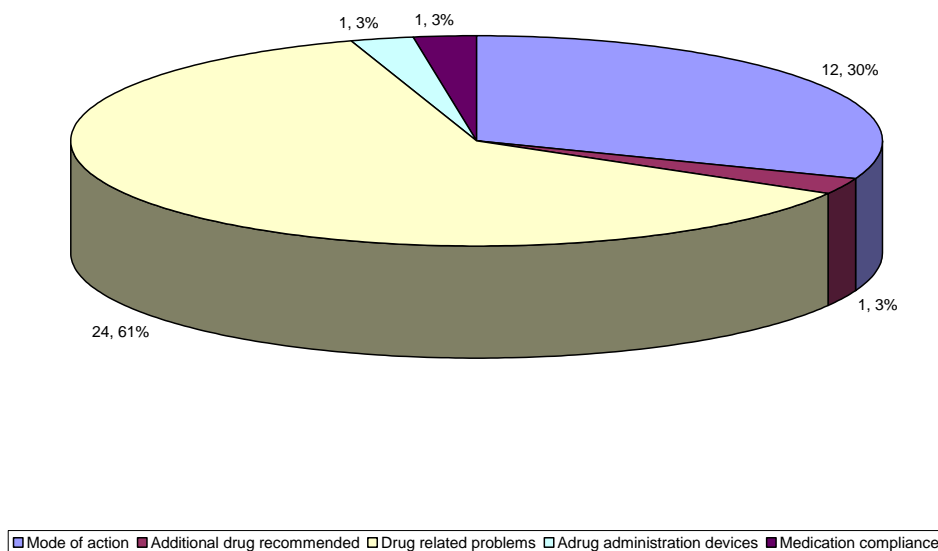
Figure 4.13 shows the distribution of the issues identified during the follow-up sessions of patients within the Intervention Group. Whilst lifestyle issues were again the most common issues identified (as in the Control Group), many more drug related and disease related issues were identified and acted upon. The drug related issues included general enquires about how the patients' medications worked and questions on potential adverse effects. They also included the identification of a number (24) of drug related problems including suspected drug toxicity. Examples include; diarrhoea in a patient taking metformin, hypoglycaemia in a patient taking Amaryl[®], the use of Moduretic[®] in a patient taking Diamicron[®]; drug duplication in the case of a patient taking Diaformin[®] and Diabex[®]; and therapeutic failure in the case of a patient using large quantities of artificial tears but still suffering from sore dry eyes. Other examples of drug related issues included medication compliance problems and the need to replace a faulty insulin pen (See Figure 4.14).

Figure 4.13: Issues Identified during the Follow-up Sessions of Intervention Patients



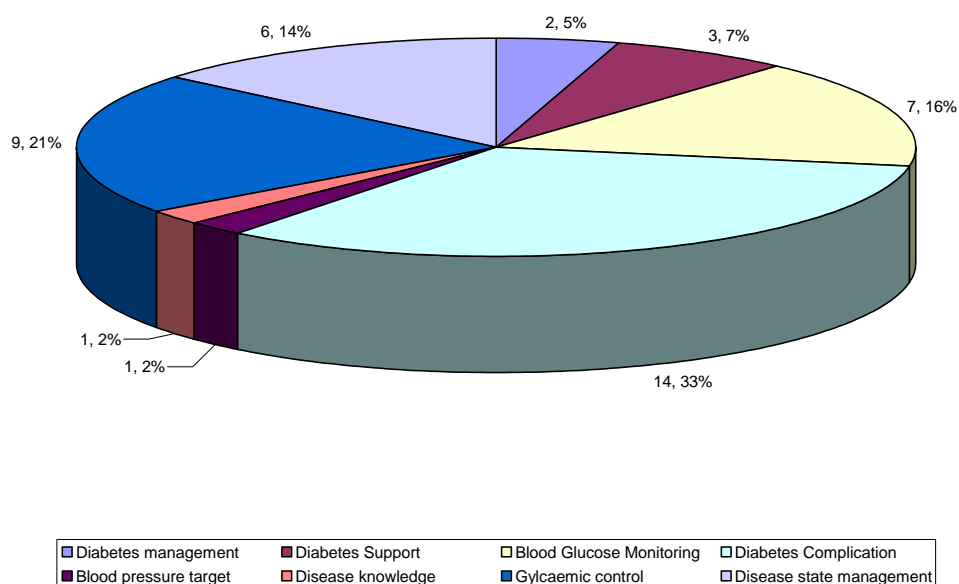
Actions and interventions (See Table 4.31) undertaken to address these drug related issues included referral of patients back to their doctors for review of their medications related to a specific issue (e.g. review of Lexapro® in a patient who indicated that the drug made them hungry, a patient taking two formulations of metformin), and specific recommendations by the pharmacists for changes to the patients' drug therapy (e.g. reducing the dose of Amaryl® in a patient suffering hypoglycaemic episodes, substitution of Solprin® for Aspro Clear® to reduce the cost to the patient, possible introduction of an antidepressant drug for a patient whose husband had recently passed away, cessation of quinine). Advice was also given concerning when to take medications in relation to food (e.g. Diaformin® after food) and the dosage of OTC medications (e.g. paracetamol 1g qid for a patient with bursitis). Education was provided for those patients who were unsure how their diabetes medicines worked.

Figure 4.14: Drug Related Issues Identified During the Follow-up Session of Intervention Patients



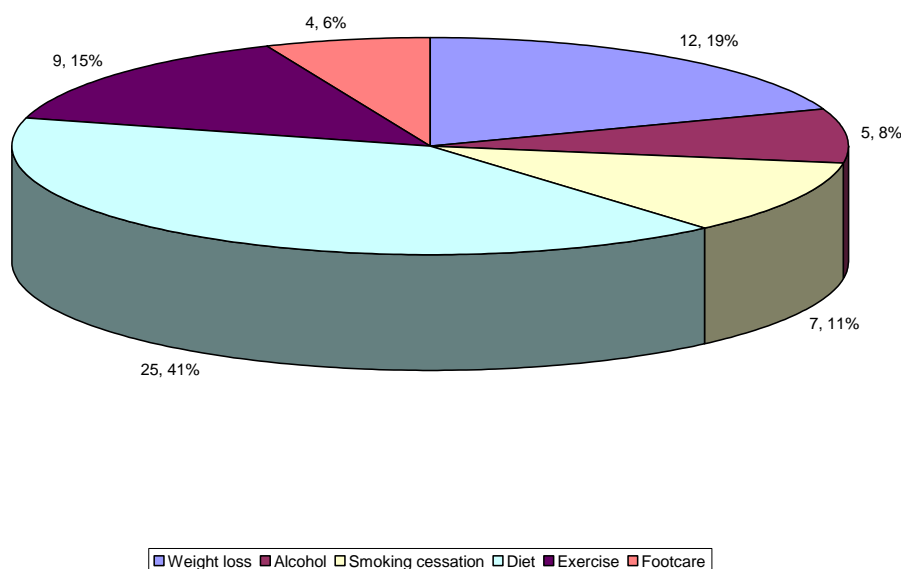
The disease related issues included poor glycaemic control, timing and frequency of blood glucose monitoring, poor control of serum lipids, setting of therapeutic targets, need for HbA1c monitoring, diabetes complications (e.g. burning feet, deteriorating vision, impotence) and need for further diabetes education. These issues prompted a diverse range of pharmacist actions and interventions (See Figure 4.15). These included referral of patients to their general practitioner and other healthcare professionals including eye specialists, optometrists, podiatrists, and diabetes educators (who the patient had previously seen, for clarification of previous advice). Where appropriate, patients were provided with information about diabetes support networks, such as Diabetes Australia and local diabetes support groups. In the case of diabetes complications, apart from referral for further assessment and treatment, the project pharmacists also suggested treatments such as magnesium for leg cramps, cranberry juice for the prevention of recurrent urinary infections, Blackmores Macu Vision® for a patient with eye problems, and dressings for a leg ulcer. Further education on specific diabetes related topics was also provided, such as HbA1c – what is it and why is it monitored.

Figure 4.15: Disease Related Issues Identified During the Follow-up Sessions of Intervention Patients



There were a total of 62 lifestyle issues identified during the following sessions, with inappropriate diet being the most commonly identified problem (25, 41%) as shown in Figure 4.16. Most of these problems were addressed through further education, advice on diet (reduce fat and carbohydrate intake, increased fibre intake, the appropriate timing of meals and snacks), exercise (type, frequency and duration), weight reduction (setting realistic targets, benefits of diet and exercise), alcohol consumption and smoking cessation (Quit program and nicotine replacement therapy), and where appropriate referral of patients to a dietician.

Figure 4.16: Lifestyle Issues Identified During the Follow-up Sessions of Intervention Patients



Twelve of the issues identified during the follow-up sessions related to conditions other than the patient's diabetes, including sore eyes, back pain, anaemia ("low iron stores"), asthma, joint pain, a broken thumb, sinus infection, possible depression, knee pain, diverticulitis and oesophageal reflux. All of these problems resulted in the pharmacist referring the patients to see their general practitioner (10) or other health care professionals (dietician 1, physiotherapist 1).

The nine remaining issues identified were classified as miscellaneous, three related to stress management and amongst the 'other' issues one related to the provision of a card to fit into a patient's purse alerting others that she is a diabetic. Figure 4.17 summarizes the actions and interventions undertaken as a result of the issues identified during the follow-up sessions. Figures 4.18 to 4.21 provide summaries of activities undertaken within the categories of pharmacist interventions, educational interventions, referrals and disease state management for Intervention patients.

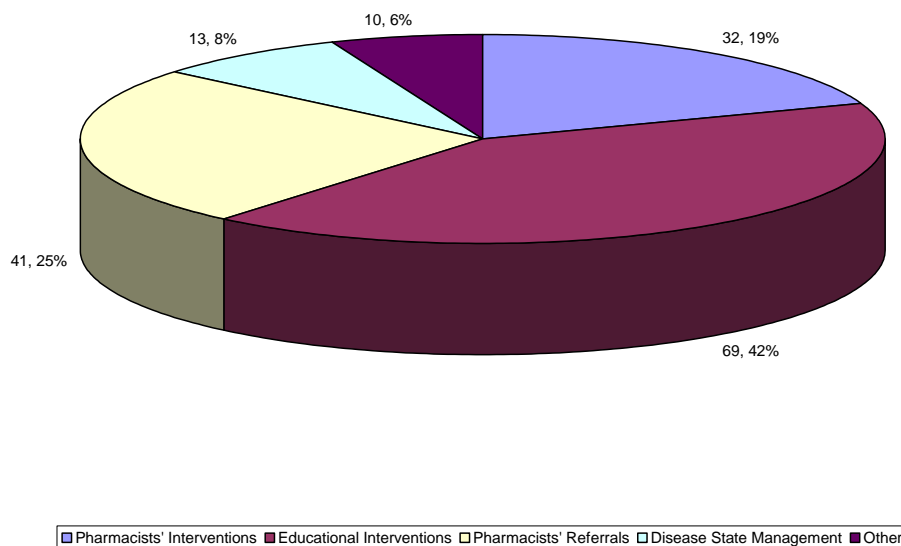
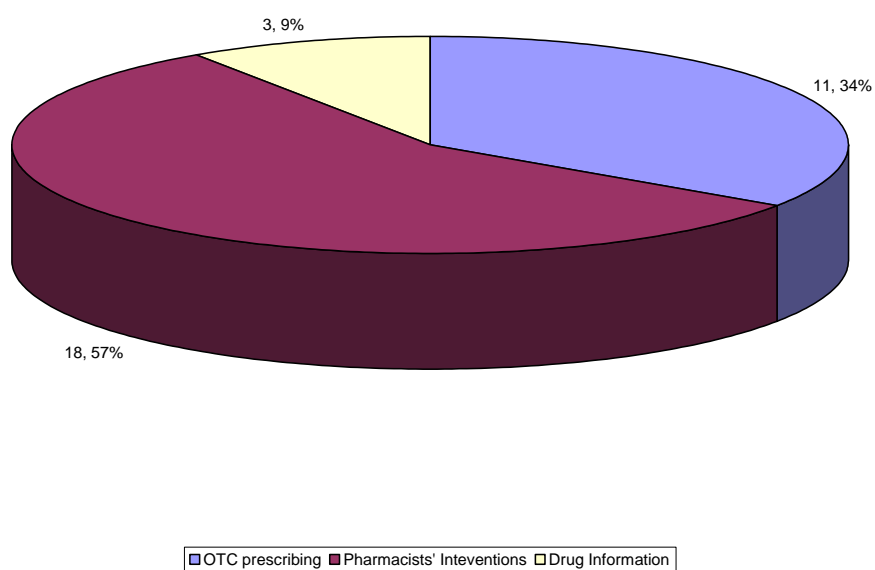
Figure 4.17: Actions and Interventions Undertaken for Intervention Patients**Figure 4.18: Pharmacist Interventions Arising from the Follow-up Sessions for the Intervention Patients**

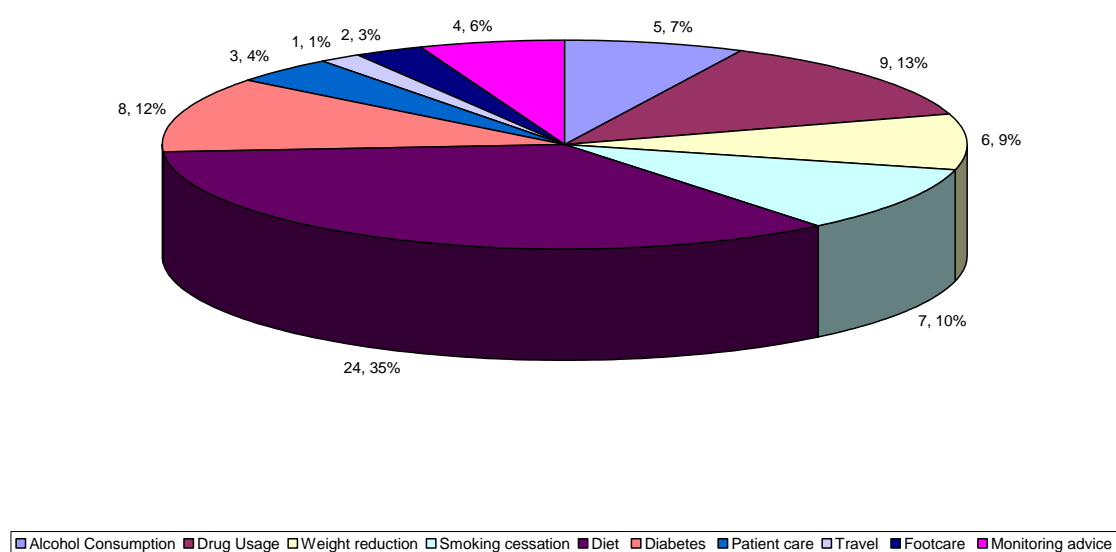
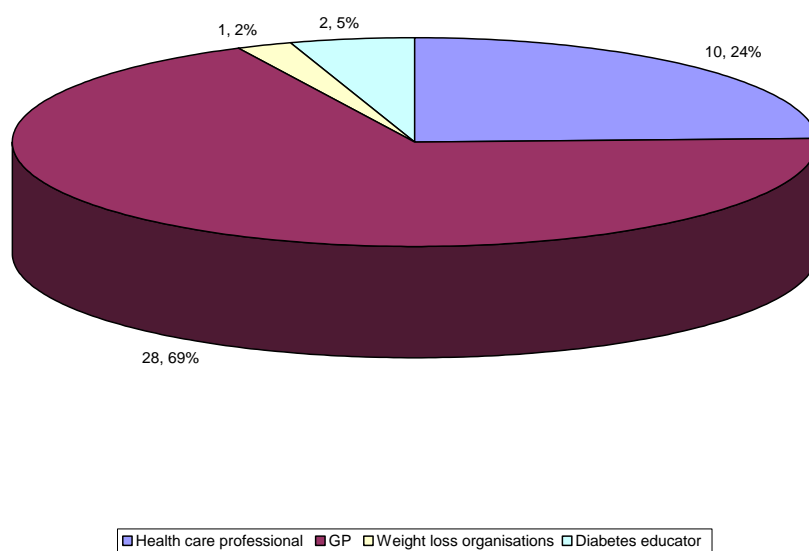
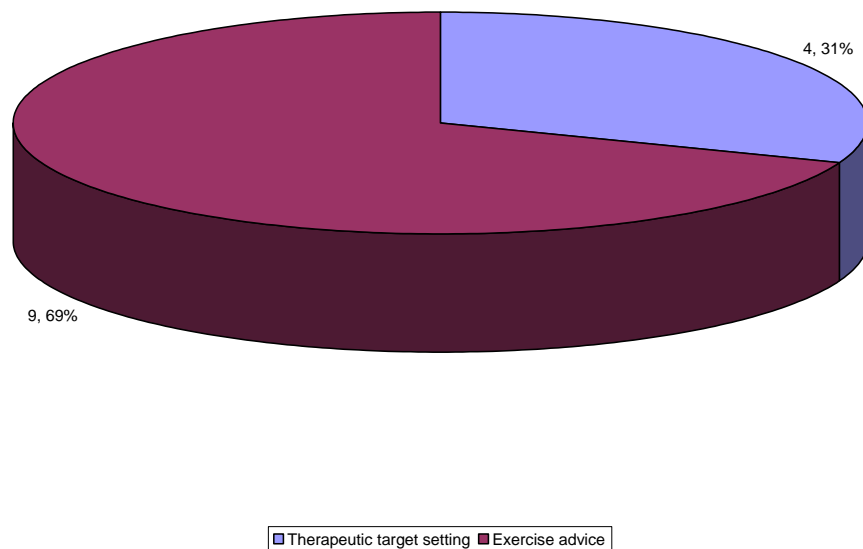
Figure 4.19: Educational Interventions Provided to Intervention Patients**Figure 4.20: Health Care Professional and Other Referrals Recommended for Intervention Patients**

Figure 4.21: Disease State Management Recommendations Made for Intervention Patients



4.4 DMEP Outcomes

The final cohort was made up of 78 Control patients (males 41; females 37) and 56 Intervention patients (males 27; females 29; $p = 0.67$); a total of 134.

4.4.1 Educational Outcomes

Patients had up to a maximum of three educational sessions using the Cognicare CMMS software diabetes care module. These sessions focused on educational deficits identified from their responses to the modified DPAQ. Patients were presented with the assessment of their education needs and asked on which of the topics identified they would like further education, and if they felt they had other unidentified educational needs.

Hyperglycaemia and hypoglycaemia were two of the most common topics addressed during the educational sessions with 40 of 58 (69%) and 41 of 58 (71%) of patients being educated on the two topics respectively. This focus on high and low blood sugar levels was reflected in an enhanced ability to recognize the symptoms of both hypoglycaemia and hyperglycaemia, and how to treat the symptoms of both, when to seek immediate medical care and patients' rating of their overall knowledge of the topics. Intervention patients had higher scores than Control patients at the completion of the study in all of these areas. The differences were, however, only statistically significant using univariate analysis in the case of "recognition of when to seek immediate medical care" (hyperglycaemia, $p = 0.01$; hypoglycaemia $p = 0.02$) (Table 4.32a). However, analysis of intra-group changes baseline versus final revealed highly significant differences in the scores for all topics and overall assessment of knowledge within the Intervention Group ($p < 0.001$; Table 4.32 b), with similar, but less significant changes in the Control Group, except in the case of recognition of hypoglycaemia and the need for medical care with hyperglycaemia.

Table 4.32a: Influence of DMEP on Patients' Knowledge of Hyperglycaemia and Hypoglycaemia: Between Group Changes

		Baseline			Final		
		N	Yes n (%)	*p- value	N	Yes n (%)	*p- value
<i>Knowledge of hyperglycaemia and its management</i>							
Can recognize the symptoms of high sugar levels (hyperglycaemia)	Intervention	81	49 (60.5)	0.25	54	48 (88.9)	0.36
	Control	111	76 (68.5)		77	64 (83.1)	
Knows how to treat hyperglycaemia symptoms	Intervention	79	39 (49.4)	0.11	54	47 (87.0)	0.12
	Control	110	67 (60.9)		75	57 (76.0)	
Knows what signs should prompt immediate medical care	Intervention	78	47 (47.4)	0.08	54	49 (90.7)	0.01
	Control	109	66 (60.6)		75	55 (73.3)	
Overall knowledge rating on hyperglycaemia (Scale 0-3)	Intervention	78	1.51±0.15	0.09	52	1.73±0.16	0.36
	Control	109	1.83±0.12		64	1.54±0.14	
<i>Knowledge of hypoglycaemia and its management</i>							
Knows how to recognize low blood sugar levels (hypoglycaemia)	Intervention	81	59 (72.8)	0.16	55	52 (94.6)	0.22
	Control	108	88 (81.5)		77	68 (88.3)	
Know how to treat the symptoms of hypoglycaemia	Intervention	80	55 (68.8)	0.24	55	54 (98.2)	0.08
	Control	110	84 (76.4)		76	69 (90.8)	
Knows what signs should prompt immediate medical care	Intervention	79	41 (51.9)	0.015	55	54 (98.2)	0.02
	Control	108	75 (69.4)		72	62 (86.1)	
Overall knowledge rating on hypoglycaemia (Scale 0-3)	Intervention	79	1.87±0.14	0.047	55	1.93±0.15	0.37
	Control	108	2.17±0.11		70	1.75±0.13	

* Pearson Chi-Square for categorical data, t-test for equality of mean of descriptive differences

Table 4.32b: Influence of DMEP on Patients' Knowledge of Hyperglycaemia and Hypoglycaemia: Within Group Changes

	Δ for Controls	p-value	N	Δ for Intervention	p-value	N
<i>Knowledge of hyperglycaemia and its management</i>						
Can recognize the symptoms of high sugar levels (hyperglycaemia)	19.7%	0.003	76	35.8%	<0.001	53
Knows how to treat hyperglycaemia symptoms	16.2%	0.01	74	42.3	<0.001	52
Knows what signs should prompt immediate medical care	12.3%	0.07	73	46.2%	<0.001	52
Overall knowledge rating on hyperglycaemia (Scale 0-3)	0.44 \pm 0.17	0.005	78	1.23 \pm 0.19	<0.001	56
<i>Knowledge of hypoglycaemia and its management</i>						
Knows how to recognize low blood sugar levels (hypoglycaemia)	8.0%	0.11	75	23.6%	<0.001	55
Knows how to treat the symptoms of hypoglycaemia	13.5%	0.004	74	27.8%	<0.001	53
Knows what signs should prompt immediate medical care	14.5%	0.008	53	43.4%	<0.001	53
Overall knowledge rating on hypoglycaemia (Scale 0-3)	0.40 \pm 0.13	0.008	78	0.96 \pm 0.16	<0.001	56

The use of logistical regression analysis (Table 4.33) demonstrated a significant effect on patients' knowledge for the tailored education intervention. This was true in the case of hyperglycaemia, for knowing when to seek immediate medical care, for the overall knowledge rating, and for all four parameters in regards to hypoglycaemia.

Table 4.33: Effect of the DMEP on Patients' Knowledge of Hyperglycaemia and Hypoglycaemia

	Effect Intervention vs Control [Odds Ratio (95% CI)]	p- value	N
<i>Knowledge of hyperglycaemia and its management</i>			
Can recognize the symptoms of high sugar levels (hyperglycaemia)	1.76 (0.98, 3.17)	0.058	129
Knows how to treat hyperglycaemia symptoms	2.72 (0.82, 9.00)	0.10	126
Knows what signs should prompt immediate medical care	4.23 (1.83, 9.76)	0.001	125
Overall knowledge rating on hyperglycaemia (Scale 0-3)	2.69 (1.39, 5.20)	0.003	134
<i>Knowledge of hypoglycaemia and its management</i>			
Knows how to recognize low blood sugar levels (hypoglycaemia)	3.50 (1.64, 7.47)	0.001	130
Knows how to treat the symptoms of hypoglycaemia	9.0 (2.02, 40.0)	0.004	131
Knows what signs should prompt immediate medical care	16.8 (4.59, 61.4)	<0.001	122
Overall knowledge rating on hypoglycaemia (Scale 0-3)	5.40 (2.39, 12.19)	<0.001	134

* Regression analysis on exit variables with adjustment for baseline and clustering

The data presented in Tables 4.34a and 4.34b relate to the education and training of the study participants about diabetes in general and in relation to specific diabetes related issues. Comparison of changes between the groups (Table 4.34a) demonstrated that Intervention patients clearly identified that their involvement in the DMEP had provided them with diabetes education (Intervention 100% positive response vs Control 80.3%, $p = 0.001$), and that this education was of greater duration than those patients in the Control Group ($p = 0.011$). Similarly, it showed that patients in the Intervention Group were less inclined to want further reading information on diabetes, presumably due to their enhanced education. Comparison of changes within groups (Table 4.34b), showed similar outcomes, more Intervention patients had received diabetes education ($p = 0.002$) and had met with a "Certified Diabetes Educator" ($p = 0.03$), had longer duration of training ($p = 0.08$), and had been trained in planning meals ($p = 0.08$). Further there was a reduced proportion of Intervention patients desiring further reading materials on diabetes ($p < 0.001$).

Table 4.34a: Influence of the DMEP on Patient Training and Education in Diabetes Management: Between Group Changes

Patient Training and Education		N	Baseline Yes n (%)	*p value	N	Final Yes n (%)	*p value
Trained to use a glucagon emergency kit	Intervention	58	0 (0)	0.054	19	1 (5.3)	0.69
	Control	81	5 (6.2)		61	2 (3.3)	
Trained in how to plan your meals with diabetes	Intervention	81	39 (48.2)	0.45	56	33 (58.9)	0.99
	Control	108	58 (53.7)		78	46 (59.0)	
Received any form of diabetes education	Intervention	81	68 (84.0)	0.03	54	54 (100)	0.001
	Control	111	78 (70.3)		76	61 (80.3)	
Duration of education program	Intervention	69	26 (37.7)	0.05	55	5 (9.1)	0.011
	Control	79	31 (39.2)		61	22 (36.1)	
	Intervention	69	7 (10.1)		55	17 (30.9)	
	Control	79	20 (25.3)		61	13 (21.3)	
	Intervention	69	12 (17.2)		55	9 (16.4)	
	Control	79	6 (7.6)		61	10 (16.4)	
	Intervention	69	18 (26.1)		55	19 (34.5)	
	Control	79	13 (16.5)		61	11 (18.0)	
	Intervention	69	6 (8.7)		55	5 (9.1)	
	Control	79	9 (11.4)		61	5 (8.2)	
Met with a Certified Diabetes Educator	Intervention	82	57 (69.5)	0.26	55	42 (76.4)	0.098
	Control	111	65 (58.6)		77	45 (58.4)	
Can demonstrate how to use glucose meter	Intervention	81	80 (98.8)	0.31	56	55 (98.2)	0.76
	Control	111	107 (96.4)		77	75 (97.4)	
Trained in how to easily obtain a drop of blood for glucose testing	Intervention	78	64 (82.1)	0.31	56	47 (83.9)	0.21
	Control	111	97 (87.4)		78	71 (91.0)	
Would like educational reading materials about diabetes	Intervention	78	53 (68.0)	0.051	52	9 (17.3)	0.001
	Control	108	58 (53.7)		75	39 (52.0)	
Keeps up to date with diabetes management	Intervention	81	47 (58.0)	0.65	56	41 (73.1)	0.33
	Control	111	68 (61.3)		78	63 (80.8)	

*Pearson Chi-Square

Table 4.34b: Influence of the DMEP on Patient Training and Education in Diabetes Management: Within Group Changes

	Δ for Controls	p-value*	N	Δ for Intervention	p-value*	N
Trained to use a glucagons emergency kit	2.1%	0.32	48	6.3%	0.32	16
Train in how to plan your meals with diabetes	2.7%	0.65	74	11.1%	0.08	54
Received any form of diabetes education	8.0%	0.08	75	18.9%	0.002	53
Duration of education (categorical data)	0.10±0.17	0.76	52	0.27±0.14	0.08	45
Met with Certified Diabetes Educator	6.0%	0.21	67	12.2%	0.03	49
Trained about how to obtain easily a drop of blood for glucose testing	6.5%	0.06	77	7.6%	0.10	53
Would like educational materials about diabetes	-1.4%	0.82	74	-50.0%	<0.001	50

* p-values for categorical variables based upon Wilcoxon matched pairs signed rank tests, descriptive differences from t tests. Binary responses assessed using McNemars tests.

The significant effect of the DMEP in these areas was confirmed by regression analysis (Table 4.35), which showed that patients in the Intervention Group were more likely to have received some form of diabetes education, and that this education was of longer duration than those patients in the Control Group. Further, Intervention patients were less likely to desire further reading information on diabetes, presumably because they felt their education needs had been met.

The absence of significant differences in level of training in areas such as the use of glucagon emergency kits, planning meals and how to easily obtain a drop of blood for testing, reflect the fact that such areas of training were not intrinsic components of the DMEP.

Table 4.35: Effect of the DMEP on Patient Training and Education in Diabetes Management

	Effect Intervention vs Control* [Odds Ratio (95% CI)]	p-value	n
Received any form of diabetes education	22.7 (2.2, 234.4)	0.009	75
Duration of education program (Increased)	2.83 (1.78, 4.53)	<0.001	82
Met with a Certified Diabetes Educator	1.81 (0.66, 4.93)	0.25	130
Trained about how to easily obtain a drop of blood for glucose testing	0.60 (0.20, 1.84)	0.37	130
Would like educational reading materials about diabetes	0.12 (0.05, 0.29)	<0.001	124

* Regression analysis on exit variables with adjustment for baseline and clustering

The results presented in Table 4.36 clearly demonstrated that the patients in the Intervention Group rated their knowledge across a range of diabetes related topics higher than their Control Group counterparts. The only exception to this was the topic of “Diabetes and Pregnancy”, given that the average age of the patients in the study was over 64 years of age; there is little surprise that few participants actually requested information on this topic. In fact, only one respondent did so, a woman in her early 30’s who was planning to start a family.

Table 4.36: Patients' Rating of Their Understanding of Diabetes Related Topics: Between Group Changes

Rating of Understanding (Poor = 1, Excellent = 5)	Groups	N	Baseline Mean (\pm SE)	p value [#]	N	Final Mean (\pm SE)	p value [#]
Overall diabetes care	Intervention	81	3.16 (0.10)	0.326	56	4.23 (0.11)	0.005
	Control	109	3.21 (0.10)		78	3.79 (0.11)	
Coping with stress	Intervention	80	3.16 (0.10)	0.276	55	3.89 (0.13)	0.065
	Control	108	3.33 (0.11)		78	3.56 (0.12)	
Diet for blood sugar control	Intervention	82	3.28 (0.10)	0.539	56	4.27 (0.09)	0.000
	Control	109	3.38 (0.11)		78	3.65 (0.13)	
Role of exercise in diabetes care	Intervention	77	3.61 (0.10)	0.591	56	4.29 (0.10)	0.006
	Control	108	3.53 (0.10)		71	3.86 (0.11)	
Diabetes medicines you are taking	Intervention	80	3.49 (0.11)	0.190	55	4.35 (0.10)	0.012
	Control	109	3.70 (0.11)		75	3.96 (0.11)	
How to use the results of blood sugar monitoring	Intervention	79	3.24 (0.11)	0.043	56	4.39 (0.10)	0.001
	Control	108	3.56 (0.11)		76	3.84 (0.13)	
How diet, exercise & medicines affect blood sugar levels	Intervention	80	3.39 (0.11)	0.353	55	4.39 (0.08)	0.007
	Control	111	3.53 (0.10)		76	4.01 (0.11)	
Prevention & treatment of high blood sugar	Intervention	80	3.06 (0.12)	0.157	56	4.25 (0.09)	0.000
	Control	110	3.29 (0.11)		76	3.61 (0.13)	
Prevention & treatment of low blood sugar	Intervention	79	2.97 (0.12)	0.124	56	4.27 (0.10)	0.000
	Control	108	3.24 (0.12)		74	3.70 (0.12)	
Prevention of long term complications of diabetes	Intervention	77	2.95 (0.11)	0.388	56	4.20 (0.11)	0.001
	Control	106	3.09 (0.12)		76	3.62 (0.14)	
Foot care	Intervention	81	3.25 (0.11)	0.715	56	4.30 (0.73)	0.000
	Control	109	3.18 (0.12)		76	3.71 (0.12)	
Retinopathy	Intervention	80	3.29 (0.12)	0.649	56	4.36 (0.10)	0.002
	Control	111	3.36 (0.12)		76	3.88 (0.09)	
Benefits of improving blood sugar control	Intervention	80	3.38 (0.10)	0.237	56	4.45 (0.09)	0.000
	Control	110	3.55 (0.10)		77	3.86 (0.12)	
Pregnancy and diabetes	Intervention	34	2.41 (0.19)	0.289	15	3.07 (0.35)	0.151
	Control	83	2.14 (0.14)		58	2.43 (0.19)	

[#] t-test for Equality of Means

4.4.2 Clinical Outcomes

An integral part of the DMEP was to educate patients about the importance of attaining certain physiological end-points (e.g. fasting blood glucose, HbA1c) in order to achieve better diabetes control and to reduce the risk of long-term complications.

Table 4.37: Treatment Targets in Diabetes Management⁵⁰

Indicator	Target
blood glucose	fasting level: < 6 mmol/L random level: 4 to 8 mmol/L
HbA1c	≤ 7%
LDL cholesterol [NB1]	≤ 2.5 mmol/L
HDL-cholesterol	≥ 1 mmol/L
total cholesterol	<4 mmol/L
triglycerides	<2 mmol/L
cholesterol/HDL-cholesterol ratio	≤ 4.5
blood pressure	130/80 mm Hg or less (<125/75 mm hg with proteinuria exceeding 1 g/day)
body mass index	≤ 25 kg/m ²
urinary albumin excretion	<20 micrograms/minute timed collection <20 mg/L spot collection
albumin to creatinine ratio in morning urine	<2.5 micrograms/mmol (males) <3.5 micrograms/mmol (females)
smoking	zero
alcohol intake	≤ 2 (≤ 1 for females) standard drinks per day
exercise program	at least 30 minutes walking (or equivalent) 5 or more days per week

NB1: For any serum lipoprotein concentration, patients with diabetes have more coronary disease than those patients without diabetes. This increased risk may be due partly to qualitative differences in the lipoprotein fractions, or to the presence of other proatherosclerotic metabolic changes. The dyslipidaemia of type 2 diabetes is usually associated with elevated fasting triglycerides, which are associated with a higher proportion of small dense LDL particles. Small dense LDL particles are more susceptible to oxidation, and are highly atherogenic.

Source: Therapeutic Guidelines: Endocrinology, 2004

The education and follow-up sessions, during which treatment targets were discussed and reviewed, were designed to assist patients to achieve the best

possible control of their diabetes. The ideal therapeutic targets for all patients in the study were those set-out in the Therapeutic Guidelines: Endocrinology, 2004 as illustrated in Table 4.37 above. During the follow-up sessions patients in both arms of the study completed a Progress Checklist (See Appendix 11), which sought to identify barriers to their attainment of their therapeutic targets. In the intervention arm of the study these Progress Checklists were reviewed by the educator/project pharmacists, the patients were interviewed and strategies were put in place to address the issues identified. In the control arm of the study, the project pharmacists provided “standard care”, addressing the issues raised by the patient in a more general way. The changes seen in the clinical and physiological markers of the patients’ diabetes control from baseline to the completion of the study are shown in Table 4.38 below.

Within the Control Group there were statistically significant reductions in the patients’ total cholesterol (-0.28mmol/L , $p = 0.04$), triglycerides (-0.55mmol/L , $p = 0.001$) and weight (-1kg , $p = 0.049$) over the duration of the study. A small, but statistically non-significant reduction was also seen in the mean HbA1c of the Control group (-0.23% , $p = 0.41$). However, in the sub-group of Control patients whose baseline HbA1c was $\leq 7\%$ their mean HbA1c increased by 0.43% ($p = 0.07$); in contrast it fell by 0.15% amongst those Control patients with a baseline HbA1c $> 7\%$. Further, there was a minor decrease in mean LDL cholesterol level (-0.02mmol/L) within the Control group over the course of the study, together with a small reduction in the mean BMI (-0.5kg/m^2). The proportion of non-smokers within the group increased from 85.6% at baseline to 90.8% at the completion of the study.

However, the Control Group showed a slight increase in both the mean systolic (4mmHg , $p = 0.25$) and diastolic (1mmHg , $p = 0.70$) blood pressures, whilst the mean HDL cholesterol fell 0.02mmol/L ($p = 0.57$) over the duration of the study.

Table 4.38: Influence of the DMEP on Clinical and Laboratory Markers of Physiological Health: Within Group Changes

		N	Baseline Mean ±SE	Final Mean ±SE	Baseline vs. Final p value*
HbA1c (%)	Intervention	39	7.34±0.18	7.28±0.28	0.74
	Control	36	7.50±0.16	7.27±0.17	0.41
HbA1c (≤ 7%) (%)	Intervention	15	6.26±0.12	6.49±0.21	0.11
	Control	16	6.51±0.09	6.94±0.24	0.07
HbA1c (>7%) (%)	Intervention	24	8.35±0.20	7.87±0.22	0.003
	Control	20	8.25±0.22	8.06±0.31	0.49
Systolic BP (mmHg)	Intervention	30	137.8±2.4	131.2±2.2	0.02
	Control	23	131.3±3.1	135.3±3.1	0.26
Diastolic BP (mmHg)	Intervention	30	79.2±1.4	77.4±1.2	0.23
	Control	23	75.7±1.6	76.4±1.8	0.70
Total Cholesterol (mmol/L)	Intervention	35	4.54±0.17	4.26±0.13	0.07
	Control	35	4.74±0.19	4.46±0.18	0.04
HDL (mmol/L)	Intervention	34	1.23±0.05	1.27±0.05	0.36
	Control	33	1.24±0.05	1.22±0.05	0.57
LDL (mmol/L)	Intervention	21	2.41±0.22	2.37±0.17	0.76
	Control	21	2.79±0.19	2.77±0.18	0.94
Triglycerides (mmol/L)	Intervention	34	1.95±0.19	1.72±0.14	0.08
	Control	34	2.15±0.25	1.60±0.21	0.001
Weight (kg)	Intervention	47	84.9±2.8	83.0±2.7	0.038
	Control	53	84.9±3.7	83.9±3.5	0.049
BMI (kg/m ²)	Intervention	50	31.2±0.6	29.6±0.8	0.02
	Control	70	30.3±0.7	29.8±0.7	0.10

* t-test for Equality of Means

Within the Intervention Group statistically significant reductions were seen in the patients' weight (-1.9kg, $p = 0.038$) and BMI (-1.6kg/m², $p = 0.02$). The mean HbA1c level decreased by (-0.06%, $p = 0.74$) for the group as a whole, however within the sub-group of patients whose HbA1c was > 7% at baseline it decreased

by 0.48% ($p = 0.003$), whilst it increased by 0.23% ($p = 0.11$) in the sub-group with baseline HbA1c levels $\leq 7\%$. Unlike in the Control Group, there was a statistically significant decrease in mean systolic BP (-6.6mmHg , $p = 0.02$) and a fall in diastolic BP (-1.8mmHg , $p = 0.23$). There was also an overall improvement in the patients' lipid profile, with reductions in total cholesterol (-0.28mmol/L , $p=0.07$), LDL cholesterol (-0.04mmol/L , $p = 0.76$) and triglycerides (-0.23 , $p = 0.08$), and an increase in HDL cholesterol (0.04 , $p = 0.36$), however the changes were not statistically significant on univariate analysis. The proportion of non-smokers also rose from 80.1% to 81.2%.

To assess the effect of the intervention, multivariate regression analysis was undertaken (Table 4.39). This analysis demonstrated that intervention had statistically significant effect on patients' LDL cholesterol and triglycerides levels, and illustrated a strong trend toward improvements in both systolic BP ($p = 0.054$) and weight ($p = 0.09$).

Table 4.39: Effect of the DMEP on Physiological Markers of Health

	Effect: Intervention vs Control* (95% Confidence Intervals)	p-value	n
Hba1c $\leq 7\%$	$\beta = -0.15 (-0.68, 0.38)$	0.52	31
Hba1c $> 7\%$	$\beta = -0.27 (-1.17, 0.64)$	0.51	44
Systolic BP	$\beta = -6.3 (-12.8, 0.15)$	0.054	53
Diastolic BP	$\beta = -0.46 (-5.94, 5.02)$	0.85	53
Cholesterol	$\beta = -0.09 (-0.37, 0.18)$	0.46	70
HDL	$\beta = 0.05 (-0.04, 0.15)$	0.24	67
LDL	$\beta = -0.18 (-0.36, -0.0009)$	0.049	42
Log triglycerides	$\beta = 0.17 (0.009, 0.33)$	0.041	68
Weight	$\beta = -0.87 (-1.93, 0.18)$	0.09	100
BMI	$\beta = -0.30 (-0.76, 0.16)$	0.17	120

* Regression analysis on exit variables with adjustment for baseline and clustering

The smaller that desired number of patients completing the study and the unavailability of clinical data for all those that did reduced the power of the study, and its ability to demonstrate statistically significance differences.

When multivariate regression analysis which included the group*baseline interaction in the model was undertaken HDL was the only variable for which there was a significant group * baseline interaction (Table 4.40)

Table 4.40: Effect of the DMEP on HDL Cholesterol Levels

	Effect :Intervention vs Control* (95% Confidence Intervals)	p-value	n
HDL	$\beta_{\text{group}} = 0.22 (0.04, 0.39)$ $\beta_{\text{group*baseline}} = -0.002 (-0.004, -0.0002)$ $\beta_{\text{group} + \text{group*baseline}} = 0.213 (0.04, 0.39)$	0.02 0.032 0.023	60

* Multivariate Regression (Outcome=Post-Intervention; Group, Baseline and Group*Baseline as Predictors) with Robust Errors

4.4.3 Diabetes Control and Complications

As an indicator of best practice, the proportion of patients who had had their HbA1c measured rose significantly in the Intervention Group compared to the Control Group from baseline to the completion of the study (Table 4.42). At the same time there was a small reduction in the mean HbA1c levels in both groups, with the reductions more marked within the subgroups of patients with baseline HbA1c > 7%, as discussed above in the previous section.

The mean fasting blood glucose level for the Control Group was 1.36mmol/L higher than that of the Intervention Group at baseline, and fell by 1mmol/L across the course of the study. In contrast, there was a slight increase in the mean fasting blood glucose level of the Intervention Group (0.12mmol/L); however both the baseline and final levels were within the 6-7mmol/L range. The differences between the two groups failed to reach statistical significance ($\beta = -1.03 [-2.11, 0.05; p = 0.06]$).

Table 4.41: Diabetes Control: Between Group Changes

Clinical Data		N	Baseline n (%)	p value*	N	Final n (%)	p value*
HbA1c measured							
Yes	Intervention	80	41 (51.2)	0.35	54	47 (87.0)	0.01
	Control	108	57 (52.8)		76	42 (55.3)	
No	Intervention	80	8 (10.0)		54	2 (3.7)	
	Control	108	5 (4.6)		76	6 (7.9)	
Not sure	Intervention	80	32 (38.8)		54	5 (9.3)	
	Control	108	46 (42.6)		76	28 (36.8)	
Clinical data		N	(Mean ± SE)	p value[#]	N	(Mean ± SE)	p value[#]
Last HbA1c value (%)	Intervention	41	7.34±0.18	0.51	25	7.28±0.28	0.98
	Control	36	7.50±0.16		24	7.27±0.17	
Last fasting plasma glucose (mmol/L)*	Intervention	17	6.83±0.73	0.17	8	6.95±0.37	0.74
	Control	21	8.19±0.64		19	7.19±0.67	

* Pearson Chi-Square, [#]t-test for Equality of Means

The tighter level of glycaemic control as indicated by the narrower range of fasting blood glucose levels in the Intervention Group, was reflected in a significant difference in both the number of hyperglycaemic and hypoglycaemic episodes experienced by patients in the Intervention Group in the last month of the study (Table 4.43 and 4.44). The proportion of patients reporting no hyperglycaemic episodes in the last month increased from 46.9% to 70.9% in the Intervention Group compared to an increase from 43.6% to 49.9% in the Control Group. Over the same period, patients in both groups reported a reduction in the number of days where symptoms of hyperglycaemia experienced; with a significant reduction in the Intervention Group compared to the Control Group ($\beta = 0.58$, 95% CI 0.16, 0.97; $p=0.004$). Interestingly, the number of hyperglycaemic symptoms experienced declined in both the Intervention and Control Groups, but the differences within and between groups were not statistically significant.

Table 4.42: Hyperglycaemic Episodes – Number and Frequency: Between Group Changes

Hyperglycaemia	Group	Baseline			Final		
Average number of hyperglycaemic symptoms in past month							
		N	Mean ± SE	p value [#]	N	Mean ± SE	p value [#]
	Intervention	83	2.19±0.20	0.53	55	1.70±0.22	0.99
	Control	110	2.02±0.19		77	1.70±0.22	
Days in the last month with symptoms of hyperglycaemia							
		N	Yes [n (%)]	p value [*]		Yes [n (%)]	p value [*]
Not at all	Intervention	81	30 (37.0)	0.85	55	39 (70.9)	0.16
	Control	109	41 (37.6)		77	38 (49.4)	
1-3 days	Intervention	81	9 (11.1)		55	8 (14.5)	
	Control	109	19 (17.4)		77	14 (18.2)	
4-6 days	Intervention	81	8 (9.9)		55	3 (5.5)	
	Control	109	10 (9.2)		77	8 (10.4)	
7-12 days	Intervention	81	5 (6.2)		55	1 (1.8)	
	Control	109	10 (9.2)		77	4 (5.2)	
> 12 days	Intervention	81	12 (14.8)		55	1 (1.8)	
	Control	109	14 (12.8)		77	7 (9.1)	
Don't know	Intervention	81	17 (21.0)		55	3 (5.5)	
	Control	109	15 (13.8)		77	6 (7.8)	

[#] t-test for Equality of Means; ^{*} Pearson Chi-Square

The proportion of patients within the Intervention Group who reported no hypoglycaemic episodes during the last month rose from 66.7% at baseline to 77.8% at the completion of the study, compared to a decline from 71.8% to 65.8% in the Control Group. As was the case with hyperglycaemic episodes, patients in the Intervention Group reported fewer episodes of hypoglycaemia during the final month of the study compared to those in the Control Group ($p = 0.06$), however the frequency of severe hypoglycaemic reactions in the past year was not significantly different between the groups ($p = 0.47$). This may be due to the fact that the study duration was only 6 months. In both groups, the number of hypoglycaemic symptoms experienced also fell from baseline.

Table 4.43: Hypoglycaemic Episodes – Nature, Frequency and Severity: Between Group Changes

	Group	Baseline			Final		
Average number of hypoglycaemic symptoms in past month							
		N	Mean ± SE	p value [#]	N	Mean ± SE	p value [#]
	Intervention	83	2.65±0.21	0.23	56	1.34±0.23	0.64
	Control	114	2.21±0.16		78	1.20±0.18	
Hypoglycaemia episodes in the last month							
		N	Yes [n (%)]	p value [*]	N	Yes [n (%)]	p value [*]
0 times	Intervention	82	50 (66.7)	0.95	54	42 (77.8)	0.06
	Control	111	74 (71.8)		76	50 (65.8)	
1-3 times	Intervention	82	17 (22.7)		54	11 (20.4)	
	Control	111	21 (20.4)		76	21 (27.6)	
4-6 times	Intervention	82	5 (6.7)		54	0 (0.0)	
	Control	111	4 (3.9)		76	2 (2.6)	
7-12 times	Intervention	82	2 (2.7)		54	0 (0.0)	
	Control	111	3 (2.9)		76	1 (1.3)	
> 12 times	Intervention	82	1 (1.3)		54	0 (0.0)	
	Control	111	1 (1.0)		76	0 (0.0)	
Don't know	Intervention	82	7 (8.5)		54	1 (1.9)	
	Control	111	8 (7.2)		76	2 (2.6)	
Severe hypoglycaemic reactions in last year							
0 times	Intervention	81	70 (90.9)	0.59	56	52 (92.9)	0.47
	Control	111	91 (85.9)		76	69 (90.8)	
1-3 times	Intervention	81	5 (6.5)		56	4 (7.1)	
	Control	111	10 (9.4)		76	3 (3.9)	
4-6 times	Intervention	81	1 (1.3)		56	0 (0.0)	
	Control	111	4 (3.8)		76	2 (2.6)	
7-12 times	Intervention	81	0 (0.0)		56	0 (0.0)	
	Control	111	1 (0.9)		76	0 (0.0)	
> 12 times	Intervention	81	1 (1.2)		56	0 (0.0)	
	Control	111	0 (0.0)		76	1 (1.3)	
Don't know	Intervention	81	4 (4.9)		56	0 (0.0)	
	Control	111	5 (4.5)		76	1 (1.3)	

[#] t-test for Equality of Means; ^{*} Pearson Chi-Square

Multivariate regression analysis demonstrated improvement in glycaemic control based on all of the parameters discussed above, with statistically significant reductions in the risk of patients suffering hyperglycaemic (OR 0.34; 95% CI

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

0.22, 0.52) and hypoglycaemic episodes (OR 0.54; 95% CI 0.34, 0.86) in the Intervention Group compared to the Control Group (Table 4.44).

Table 4.44: Effect of the DMEP on the Number, Nature and Frequency of Hyperglycaemic and Hypoglycaemic Episodes

	Effect Intervention vs Control* (95% Confidence Intervals)	p-value	n
Average number of hyperglycaemic symptoms in past month	OR = 0.94 (0.51, 1.76) β = -0.09 (-0.62, 0.44)	0.86 0.71	134
Days in the last month with symptoms of hyperglycaemia	OR = 0.34 (0.22, 0.52) β = -0.61 (-1.03, -0.19)	0.001 0.005	121
Average number of hypoglycaemic symptoms in past month	OR = 0.86 (0.59, 1.26) β = -0.09 (-0.59, 0.41)	0.44	134
Hypoglycaemia attacks in the last month	OR = 0.54 (0.34, 0.86) β = -0.16 (-0.27, -0.06)	0.009 0.009	126
Severe hypoglycaemia reactions in last year	OR = 0.92 (0.47, 1.82) β = -0.05 (-0.14, 0.04)	0.81 0.235	129

* Regression analysis on exit variables with adjustment for baseline and clustering

As can be seen from the data presented in Table 4.45, there were no differences in the proportion of patients within the two groups who had been hospitalized, lost consciousness or had had a seizure as a consequence of hypoglycaemia. However this may simply reflect the lack of sensitivity of the survey instrument (modified DPAQ) to demonstrate such changes, as the questions posed ask about “ever suffering” rather than frequency of such events.

As an indicator of best practice, the proportion of patients in both groups who reported carrying glucose tablets or sweets to treat low blood glucose levels increased at the conclusion of the study compared to baseline.

Table 4.45: Hypoglycemic Episodes – Management and Outcomes: Between Group Changes

Hypoglycaemia Treatment and Outcomes	Group	Baseline			Final		
		N	Response n (%)	p value*	N	Response n (%)	p value*
Percentage of patients carrying glucose tablets or sweets to treat low blood sugars							
	Intervention	83	34 (41.0)	0.93	56	25 (44.6)	0.40
	Control	109	44 (40.4)		73	38 (52.1)	
Percentage of patients ever hospitalized due to hypoglycaemia							
	Intervention	81	0 (0.0)	0.053	56	0 (0.0)	0.23
	Control	111	5 (4.5)		73	2 (2.6)	
Percentage of patients who had lost consciousness secondary to hypoglycaemia							
	Intervention	81	1 (1.2)	0.12	56	1 (1.8)	0.31
	Control	110	6 (5.5)		78	4 (5.1)	
Percentage of patients who had suffered a seizure secondary to hypoglycaemia							
	Intervention	92	0 (0.0)	-	54	0 (0.0)	-
	Control	110	0 (0.0)		78	0 (0.0)	

* Pearson Chi-square

Table 4.46 below shows the Intervention and Control patients' responses at baseline and at the conclusion of the study to questions regarding specific diabetes complications. At baseline there was a significant difference in the proportion of patients in the two groups experiencing postprandial nausea, however this was not evident at the completion of the study. There was a significantly larger proportion of patients in the Intervention Group compared to the Control Group reporting eye problems at the completion of the study (26.9% vs 14.7%; $p = 0.04$). Overall, patients in both groups reported fewer diabetic complications, which in the Intervention Group at least, may have reflected a better understanding of what is a diabetes complication (Table 4.47).

Table 4.46: Reported Incidence of Diabetes Complications: Between Group Changes

Complications	Group	Baseline			Final			
		N	n (%)	p value*	N	n (%)	p value*	
Numbness or tingling in hands or feet in the last month	Intervention	82	42 (51.2)	0.40	55	20 (36.4)	0.92	
	Control	111	50 (45.0)		78	29 (37.2)		
Any signs of eye damage or disease	Intervention	75	9 (12.0)	0.41	52	14 (26.9)	0.04	
	Control	105	19 (18.1)		75	11 (14.7)		
Frequent "heartburn" or acid reflux problems	Intervention	80	22 (27.5)	0.92	54	10 (18.5)	0.62	
	Control	110	31 (28.2)		77	17 (22.1)		
Postprandial bloating	Never	Intervention	78	30 (38.5)	0.63	53	28 (52.8)	0.48
		Control	108	50 (46.3)		78	36 (46.2)	
	Sometimes	Intervention	78	38 (48.7)		53	21 (43.6)	
		Control	108	47 (43.5)		78	34 (39.6)	
	Often	Intervention	78	8 (10.3)		53	2 (3.8)	
		Control	108	10 (9.3)		78	7 (9.0)	
	Always	Intervention	78	2 (2.6)		53	2 (3.8)	
		Control	108	1 (0.9)		78	1 (1.3)	
Postprandial nausea	Never	Intervention	75	39 (52.0)	0.04	54	40 (74.1)	0.19
		Control	100	68 (68.0)		72	51 (70.8)	
	Sometimes	Intervention	75	32 (42.7)		54	12 (22.2)	
		Control	100	31 (31.0)		72	21 (29.2)	
	Often	Intervention	75	4 (5.3)		54	2 (3.7)	
		Control	100	1 (1.0)		72	0 (0.0)	
Frequent constipation	Intervention	82	14 (17.1)	0.34	56	9 (16.1)	0.96	
	Control	110	25 (22.7)		76	12 (15.8)		
Erectile dysfunction in males	Intervention	39	23 (59.0)	0.58	28	18 (64.3)	0.47	
	Control	51	33 (64.7)		40	29 (72.5)		
Vaginal dryness in females	Intervention	39	15 (38.5)	0.98	26	8 (30.8)	0.38	
	Control	55	21 (38.2)		36	15 (41.7)		
Frequent vaginal yeast infections in females	Intervention	41	5 (12.2)	0.91	27	2 (7.4)	0.81	
	Control	54	7 (13.0)		34	2 (5.9)		

* Pearson Chi-Square

Table 4.47: Reported Diabetes Complications – Occurrence and Number: Between Group Changes

Diabetes Complications	Groups	Baseline			Final		
		N	Response n (%)	p value*	N	Response n (%)	p value*
Any diabetes complications							
Yes	Intervention	73	45 (61.6)	0.84	44	27 (61.4)	0.055
	Control	97	61 (62.9)		67	38 (56.7)	
No	Intervention	73	16 (21.9)		44	16 (36.4)	
	Control	97	23 (27.3)		67	18 (26.9)	
Not sure	Intervention	73	12 (16.4)		44	1 (2.3)	
	Control	97	13 (13.4)		67	11 (16.4)	
Average number of diabetes related complications including neuropathy, retinopathy or other eye symptoms, kidney problems, frequent urination, pain in legs after walking, skin problems, bladder infections, heart problems, frequent tiredness, other (See Figure 4.22)							
		N	Mean ± SE	p value#	N	Mean ± SE	p value#
	Intervention	61	2.07±0.22	0.67	37	1.42±0.22	0.29
	Control	86	1.95±0.17		55	1.14±0.14	

* Pearson Chi-Square for categorical data; # t-test for Equality of Means for descriptive differences

Analysis of the changes within the groups demonstrated that there was a significant reduction in the proportion of patients in the Intervention Group who reported suffering tingling or numbness at the completion of the study compared to baseline (-14.8%; $p = 0.02$). There was also a reduction in the proportion of patients in the Control Group reporting the same symptoms (-10.3%), however this did not reach statistical significance ($p = 0.06$). There were no other significant intra-group changes in the reported complications, including the reduction in reported incidence of post-prandial nausea in the Intervention Group ($p = 0.07$).

The regression analysis of the final results, taking into account baseline variables and clustering, demonstrated a reduced likelihood for patients in the Intervention Group suffering diabetes complications, with the exceptions of frequent constipation and vaginal dryness in females, as illustrated by an odds ratio or a beta value of less than 1. Frequent “heartburn” or acid reflux problems

showed the greatest reduction (OR = 0.29; 95% CI 0.07, 1.14; p=0.08), however this and the other changes did not attain statistical significance (Table 4.48).

Figure 4.22: Reported Rate of Occurrence of Diabetes Complications at Exit

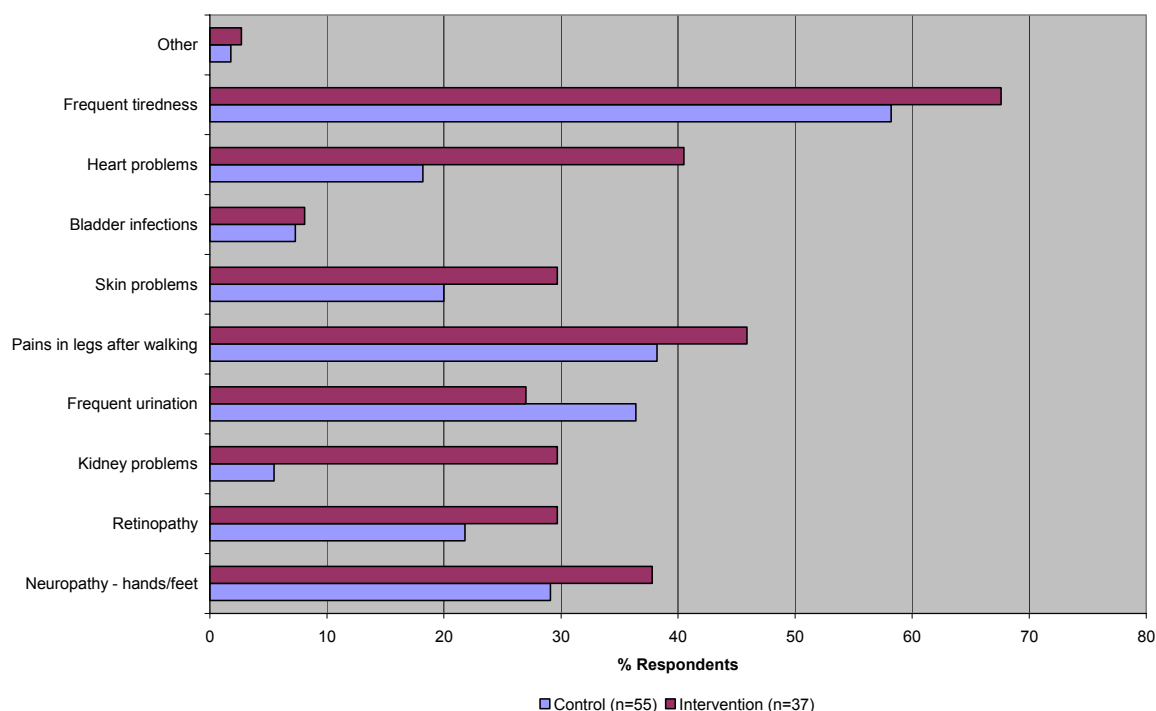


Table 4.48: Effect of the DMEP on Rate of Occurrence of Diabetes Complications

Complication	Effect: Intervention vs Control* (95% Confidence Intervals)	P value	n
Numbness or tingling in hands or feet in the last month	OR = 0.85 (0.30, 2.36)	0.75	131
Any signs of eye damage or disease	OR = 0.82 (0.44, 1.52)	0.53	120
Frequent "heartburn" or acid reflux problems	OR = 0.29 (0.07, 1.14)	0.08	131
Postprandial bloating	OR = 0.77 (0.41, 1.44)	0.42	124
Postprandial nausea	OR = 0.80 (0.40, 1.58)	0.52	109
Frequent constipation	OR = 1.07 (0.37, 3.18)	0.89	131
Erectile dysfunction in males	OR = 0.95 (0.44, 2.04)	0.89	65
Vaginal dryness in females	OR = 0.57 (0.27, 1.20)	0.14	60
Frequent vaginal yeast infections in females	OR = 1.51 (0.19, 11.97)	0.70	59
Average number of diabetes complications	β = 0.19 (-0.27, 0.65)	0.42	134

* Regression analysis on exit variables with adjustment for baseline and clustering

4.4.4 Diabetes Management

4.4.4.1 Pharmacological

Table 4.49 below shows the comparative changes in the pharmacological management of the patients in the Intervention and Control Groups over the duration of the study. In general, there was an increase in the level of drug use in the Intervention Group for all categories of medicines listed with the exception of oral hypoglycaemic agents, where the proportion of users fell from 100% at base to 95.6% at the completion of the study.

Table 4.49: Pharmacological Agents for the Management of Diabetes and Its Complications: Between Group Comparisons

Diabetes Treatment	Group	N	Baseline n (%)	p- value*	N	Final n (%)	p- value*
Insulin users	Intervention	83	14 (16.9)	0.67	55	12 (21.8)	0.34
	Control	109	21 (19.3)		78	12 (15.4)	
Oral hypoglycaemic users	Intervention	83	83 (100)	0.01	49	47 (95.9)	0.27
	Control	107	99 (92.5)		75	68 (90.7)	
Average number of oral hypoglycaemic drugs taken	Intervention	83	2.83±0.11	0.63	49	1.94±0.18	0.82
	Control	107	2.75±0.14		75	2.00±0.18	
Antihypertensive users	Intervention	82	52 (63.0)	0.72	55	41 (74.5)	0.13
	Control	110	67 (61.0)		76	47 (61.8)	
Lipid treatment	Intervention	82	53 (64.6)	0.07	55	37 (67.3)	0.03
	Control	109	56 (51.4)		76	37 (48.7)	
Medication for diabetes complications	Intervention	76	9 (11.8)	0.97	55	10 (18.2)	0.04
	Control	103	12 (11.7)		76	5 (6.6)	
Any other medical conditions	Intervention	79	59 (74.7)	0.84	50	38 (76.0)	0.08
	Control	104	79 (76.0)		74	45 (60.8)	
Medication for other conditions	Intervention	80	60 (75.0)	0.51	55	45 (81.8)	0.27
	Control	109	77 (70.6)		76	56 (73.7)	

* Pearson Chi-Square

The decline in oral hypoglycaemic use was accompanied by an increase in the proportion of patients receiving insulin from 16.9% to 21.8%, however the level of use of insulin in the Intervention and Control Groups was not significantly different at the end of the study (21.8% vs 15.4%; $p=0.34$). Based on univariate analysis, a statistically significant difference was demonstrated in the use of lipid treatments ($p=0.03$) and medications for diabetes complications ($p=0.04$) in Intervention Group compared to the Control Group at the completion of the study. However, using regression analysis on exit variables with adjustment for baseline and clustering, only the increase of use of medications for diabetes complications was demonstrated to be significant (Table 4.50).

Table 4.50: Effect of the DMEP Intervention on Medication Usage

Diabetes Treatment	Effect Intervention vs Control* (95% Confidence Intervals)	p value	n
Insulin users	Two new users in intervention group	N/A	132
Oral hypoglycaemic users	OR = 0.76 (0.16, 3.56)	0.73	119
Average number of oral hypoglycaemic drugs taken	$\beta = -0.12$ (-0.41, 0.16)	0.39	134
Antihypertensive users	OR = 1.40 (0.74, 2.64)	0.30	129
Lipid treatment	OR = 0.92 (-0.10, 1.94)	0.08	128
Medication for diabetes complications	OR = 3.97 (1.18, 13.34)	0.03	123
Any other medical conditions	OR = 7.91 (1.53, 40.97)	0.01	116
Medication for other conditions	OR = 1.68 (0.32, 8.85)	0.54	128

* Regression analysis on exit variables with adjustment for baseline and clustering

Table 4.51 below shows the levels of use of the various antidiabetic medications at the beginning and the completion of the study. The only change which occurred during the course of the study that was statistically significant was in the Control Group where six patients were commenced on a glitazone ($p = 0.03$). The difference in acarbose use seen at baseline was maintained throughout the study.

Table 4.51: Changes in Antidiabetic Agent Usage

Antidiabetic Agents		N	Baseline n (%)	N	Final n (%)	p value Within Groups#	p value Between Groups*
Insulin	Intervention	55	10 (18.2)	55	12 (21.8)	0.81	0.40
	Control	69	11 (15.9)	69	11 (15.9)	1.00	
Sulfonylureas	Intervention	55	37 (67.3)	55	33 (60.0)	0.55	0.18
	Control	69	38 (55.1)	69	33 (47.8)	0.49	
Metformin	Intervention	55	45 (81.8)	55	44 (80.0)	1.00	0.81
	Control	69	53 (76.8)	69	54 (78.3)	1.00	
Glitazones	Intervention	55	1 (1.8)	55	2 (3.6)	1.00	0.26
	Control	69	0 (0.0)	69	6 (8.7)	0.03	
Acarbose	Intervention	55	0 (0.0)	55	0 (0.0)	1.00	0.04
	Control	69	5 (7.2)	69	5 (7.2)	1.00	

Fisher's exact test; * Pearson Chi-Square

There were no statistically significant changes in the use of the various classes of antihypertensive agents during the course of the study as demonstrated by the data presented in Table 4.52. The most commonly prescribed classes of agents at the commencement of the study were ACE inhibitors, β -blockers and calcium channel blockers, and these remained so at the completion of the trial. Agents acting on the renin-angiotensin-system (RAS), ACE inhibitors, angiotensin receptor antagonists and combination products containing these agents were prescribed to approximately 60% of patients in the Intervention Group at the commencement (60.0%) and completion (59.9%) of the study, and just over 50% of patients in the Control Group (commencement 53.5%; completion 52.1%).

Table 4.52: Changes in Antihypertensive Agent Usage

Antihypertensive Agents		n	Baseline n (%)	n	Final n (%)	p value Final vs Baseline [#]	P values Final vs Final [*]
Thiazide diuretics	Intervention	55	3 (5.5)	55	3 (5.5)	1.00	0.05
	Control	69	2 (2.9)	69	0 (0.0)	0.49	
Potassium sparing diuretics	Intervention	55	1 (1.8)	55	0 (0.0)	1.00	N/A
	Control	69	0 (0.0)	69	0 (0.0)	1.00	
Loop diuretics	Intervention	55	0 (0.0)	55	1 (1.8)	1.00	0.87
	Control	69	1 (1.4)	69	1 (1.4)	1.00	
Thiazide plus potassium sparing diuretic	Intervention	55	2 (3.6)	55	2 (3.6)	1.00	0.11
	Control	69	1 (1.4)	69	0 (0.0)	1.00	
β-blockers	Intervention	55	12 (21.8)	55	13 (23.6)	1.00	0.39
	Control	69	12 (17.4)	69	12 (17.4)	1.00	
ACE Inhibitors	Intervention	55	22 (40)	55	16 (29.1)	0.31	0.85
	Control	69	21 (30.4)	69	19 (27.5)	0.85	
ACEI plus diuretic	Intervention	55	6 (10.9)	55	7 (12.7)	1.00	0.09
	Control	69	5 (7.2)	69	3 (4.3)	0.72	
Angiotensin II Receptor Antagonists	Intervention	55	3 (5.5)	55	8 (14.5)	0.20	0.67
	Control	69	7 (10.1)	69	12 (17.4)	0.32	
Angiotensin II Receptors Antagonists plus diuretic	Intervention	55	2 (3.6)	55	2 (3.6)	1.00	0.82
	Control	69	4 (5.8)	69	2 (2.9)	0.68	
Calcium Channel Blockers	Intervention	55	12 (21.8)	55	9 (16.4)	0.62	0.35
	Control	69	15 (21.7)	69	16 (23.2)	1.00	
α-blockers	Intervention	55	0 (0.0)	55	0 (0.0)	1.00	0.37
	Control	69	1 (1.4)	69	1 (1.4)	1.00	

Fisher's exact test; * Pearson Chi-Square

The use of lipid lowering agents changed little throughout the course of the study as shown by the data presented in Table 4.53. The proportion of patients in the Intervention Group who were receiving a statin increased slightly, whilst the

proportion in the Control Group fell, with the difference between the groups (16.5%; $p=0.07$) approaching statistical significance.

Table 4.53: Changes in Lipid- Lowering Agent Usage

Lipid Lowering Agents		N	Baseline n (%)	N	Final n (%)	p value Within Groups [#]	p value Between Groups [*]
Statins	Intervention	55	32 (58.2)	55	33 (60.0)	1.00	0.07
	Control	69	31 (44.9)	69	30 (43.5)	1.00	
Fibrates	Intervention	55	1 (1.8)	55	0 (0.0)	1.00	0.20
	Control	69	2 (2.9)	69	2 (2.9)	1.00	

Fisher's exact test; * Pearson Chi-Square

There were no significant changes in the use of coagulation/blood forming agents (Table 4.54) or other cardiovascular agents (Table 4.55) in either the Intervention or Control Groups over the course of the study.

Table 4.54: Changes in Coagulation/Blood Formation Agent Usage

Coagulation/Blood Formation Agents		N	Baseline n (%)	N	Final n (%)	p value Within Groups [#]	p value Between Group [*]
Warfarin	Intervention	55	3 (5.5)	55	3 (5.5)	1.00	0.47
	Control	69	2 (2.9)	69	2 (2.9)	1.00	
Antiplatelet agents	Intervention	55	14 (25.5)	55	14 (25.5)	1.00	0.77
	Control	69	23 (33.3)	69	16 (23.2)	0.26	

Fisher's exact test; * Pearson Chi-Square

Table 4.55: Changes in the Usage of Other Cardiovascular Agents

Other Cardiovascular Agents		N	Baseline n (%)	N	Final n (%)	p value Within Groups [#]	p value Between Group [*]
Antiarrhythmic agents	Intervention	55	2 (3.6)	55	2 (3.6)	1.00	0.431
	Control	69	1 (1.4)	69	1 (1.4)	1.00	
Nitrates	Intervention	55	1 (1.8)	55	1 (1.8)	1.00	0.841
	Control	69	0 (0.0)	69	1 (1.4)	1.00	

Fisher's exact test; * Pearson Chi-Square

The reported use of herbal medicines decreased in both the Intervention (-12.4%) and Control (-3.7%) groups over the course of the study, with a significantly smaller proportion of patients using herbals in the Intervention Group compared to the Control Group at the completion of the trial ($p=0.03$) [Table 4.56]. In contrast, the self-reported use of vitamins/minerals and natural products increased; more so in the Intervention Group than the Control Group. Using regression analysis to assess the effect of the intervention, the increase in the use of natural products was found to be significant, with Intervention patients 2.75 times more likely to be using a natural product (Table 4.57).

Table 4.56: Changes in Complementary Medicines Usage

Complementary Medicines	Group	N	Baseline n (%)	N	Final n (%)	p value Within Groups [#]	p value Between Group [*]
Herbal remedies	Intervention	75	11 (14.7)	44	1 (2.3)	0.054	0.03
	Control	110	20 (18.2)	76	11 (14.5)	0.55	
Vitamin/Minerals	Intervention	78	24 (30.8)	53	21 (39.6)	0.35	0.25
	Control	111	33 (29.7)	77	23 (29.9)	1.00	
Natural Products	Intervention	72	13 (18.1)	47	12 (25.5)	0.36	0.18
	Control	106	16 (15.1)	71	11 (15.5)	1.00	

* Pearson Chi-Square

Table 4.57: Effect of the DMEP on Complementary Medicines Usage

Complementary Medicines	Effect Intervention vs Control* [Odds Ratio (95% CI)]	p value	N
Herbal Remedies	0.14 (0.01, 2.34)	0.17	114
Vitamin/Minerals	1.42 (0.62, 3.27)	0.41	127
Natural Products	2.75 (1.01, 7.50)	0.048	111

* Regression analysis on exit variables with adjustment for baseline and clustering

As was the case at baseline, patients were asked a series of questions to assess whether their doctor or pharmacist had provided them with advice on how and when to take their medication, and how to store it. Further, they asked if they currently had any questions about their medications. Lastly, they were asked about their compliance with their medications. The responses to these questions are shown in Table 4.58. Impressive amongst the responses was the very high level of reported compliance with medications and the fact that over 95% of patients had received advice on how and when to take them. What was interesting in these results was the fall in the proportion of patients who had further questions about their medication; -8.2% in the Intervention Group ($p = 0.07$) and -4.3% in the Control Group ($p = 0.46$), which suggests beneficial effects from a) being involved in the trial and b) receiving tailored education as part of the Intervention arm, despite the results not achieving statistical significance.

Table 4.58: Changes in Medication Knowledge and Compliance

	Group	n	Baseline	n	Final	p value Within Groups [#]	p value Between Groups [*]
Advised on how and when to taken medications	Intervention	83	80 (96.4)	56	54 (96.4)	1.00	0.39
	Control	110	107 (97.3)	76	75 (98.7)	0.64	
Advised on how to store medication	Intervention	82	56 (68.3)	56	45 (80.4)	0.12	0.43
	Control	108	85 (78.7)	76	65 (85.5)	0.26	
Further questions about medications	Intervention	80	8 (10.0)	55	1 (1.8)	0.08	0.12
	Control	105	13 (12.4)	74	6 (8.1)	0.46	
Take medications regularly at the correct time	Intervention	80	75 (93.8)	53	52 (98.1)	0.40	0.32
	Control	107	94 (87.9)	75	71 (94.7)	0.19	

Fisher's exact test; * Pearson Chi-Square

4.4.4.2 Non-Pharmacological

Tables 4.59 through 4.62 contain data on the changes in non-pharmacological interventions (lifestyle measures), which are important in the management of patients with diabetes, that occurred during the course of the study. As was the case at the commencement of the trial, the proportion of patients who had met with dieticians to have a nutritional program prescribed was higher in the Control Group, however the difference was not statistically significant (44.7% vs 30.4%; $p = 0.09$). Regression analysis also failed to demonstrate a significant difference (OR 0.57; 95% CI 0.17, 1.90; $p = 0.36$) [Table 4.61]. What was interesting was that the proportion of patients reporting limiting calorie intake in the Intervention Group fell from 33.3% at baseline to 22.2% at the conclusion of the study, whilst that in the Control group increased slightly (2.2%), which resulted in a statistically significant difference between the two groups ($p = 0.01$). A similar trend was seen in the proportion of patients reporting that they count carbohydrates.

Table 4.59: Nutritional Practices: Between Group Changes

<i>Nutrition</i>	Groups	Baseline			Final		
		N	Response n (%)	p-value*	N	Response n (%)	p-value*
Met with a dietician and had a nutritional program prescribed	Intervention	83	28 (33.7)	0.19	56	17 (30.4)	0.09
	Control	109	47 (43.1)		76	34 (44.7)	
Limits calorie intake	Intervention	39	13 (33.3)	0.07	27	6 (22.2)	0.01
	Control	66	34 (51.5)		41	22 (53.7)	
Counts carbohydrates	Intervention	34	8 (23.5)	0.43	28	4 (14.3)	0.48
	Control	65	11 (16.9)		43	9 (20.9)	

* Pearson Chi-Square

The proportion patients consuming alcohol was slightly higher in the Intervention Group compared to the Control Group at the commencement of the study, however this trend had reversed by its completion (Table 4.60). Regression analysis did not demonstrate any significant effect of the intervention on drinking habits (Table 4.61). What was interesting however, was the fact that while a higher proportion of patients in the Control Group reported consuming alcohol at the end of the study, they reported consuming less alcoholic drinks per week. This may simply be a reflection of the small number of patients who completed this question on exiting the study, rather than a true change.

Table 4.60: Alcohol Consumption: Between Group Changes

<i>Alcohol</i>	Groups	Baseline			Final		
		N	Response n (%)	p-value	N	Response n (%)	p-value
Consumes alcohol	Intervention	78	32 (41.0)	0.56*	50	18 (36.0)	0.44*
	Control	106	39 (36.8)		77	33 (42.9)	
Number of alcoholic drinks consumed per week (Mean ± SE)	Intervention	27	7.56±1.19	0.94 [#]	19	7.47±1.42	0.34 [#]
	Control	78	7.65±1.57		28	5.57±0.73	

* Pearson Chi-Square for categorical data; [#] t-test for Equality of Means

Whilst the frequency and duration of exercise undertaken by patients in the Intervention Group increased over the course of the study compared to the Control Group, these changes did not attain statistical significance (Tables 4.61 and 4.62). However, in view of the improvement in the glycaemic control, weight and blood pressure of patients in the Intervention Group they appear to have had clinical benefits.

Table 5.61: Effect of DMEP on Non-Pharmacological Interventions

	Effect Intervention vs Control* (95% Confidence Intervals)	p value	n
Met with a dietician and had a nutritional program prescribed	OR=0.57 (0.17, 1.90)	0.36	130
Consumes alcohol	OR=0.94 (0.47, 1.87)	0.86	120
Average number of drinks per week	β =0.14 (-0.21, 0.49)	0.37	39
Frequency of Exercise (scale 1 to 5)	β =0.09 (-0.23, 0.43)	0.50	132
Duration of Exercise Hrs/wk (scale 1-8)	β =0.54 (-0.24, 1.32)	0.15	123
Number of exercise activities undertaken	OR=0.77 (0.55, 1.07)	0.13	134

* Regression analysis on exit variables with adjustment for baseline and clustering

Table 4.62: Exercise Patterns: Between Group Changes

	Group	Baseline			Final		
		N	Response n (%)	p-value*	N	Response n (%)	p-value*
Level of physical activity							
None Sometimes weekly Weekly Sometimes daily Daily	Intervention	81	12 (14.8)	0.84	56	11 (19.6)	0.22
	Control	109	16 (14.7)		78	13 (16.7)	
	Intervention	81	12 (14.8)		56	8 (14.3)	
	Control	109	19 (17.4)		78	11 (14.1)	
	Intervention	81	8 (9.9)		56	2 (3.6)	
	Control	109	14 (12.8)		78	12 (15.4)	
	Intervention	81	20 (24.7)		56	14 (25.0)	
	Control	109	20 (18.3)		78	21 (26.9)	
	Intervention	81	29 (35.8)		56	21 (37.5)	
	Control	109	40 (36.7)		78	21 (26.9)	
Duration of Exercise (hr/week)							
No time Up to 1 hour 1 – 2 hours 2 – 3 hours 3 – 4 hours 4 – 5 hours 5 – 6 hours More than 6 hours	Intervention	82	13 (15.9)	0.45	48	4 (8.3)	0.35
	Control	106	14 (13.2)		77	11 (14.3)	
	Intervention	82	17 (20.7)		48	8 (16.7)	
	Control	106	33 (31.1)		77	20 (26.0)	
	Intervention	82	10 (12.2)		48	9 (18.8)	
	Control	106	17 (16.0)		77	13 (16.9)	
	Intervention	82	12 (14.6)		48	3 (6.3)	
	Control	106	8 (7.5)		77	9 (11.7)	
	Intervention	82	10 (12.2)		48	9 (18.8)	
	Control	106	9 (8.5)		77	8 (10.4)	
	Intervention	82	9 (11.0)		48	5 (10.4)	
	Control	106	8 (7.5)		77	2 (2.6)	
	Intervention	82	3 (3.7)		48	3 (6.3)	
	Control	106	7 (6.6)		77	4 (5.2)	
	Intervention	82	8 (9.8)		48	7 (14.6)	
	Control	106	10 (9.4)		77	10 (13.0)	

* Pearson Chi-Square

The level of training in both preventative dental and foot care remained less than optimal at the completion of the study. However the proportion of patients providing a positive response to both rose slightly in both the Intervention and Control Groups over the duration of the study, although the changes did not reach statistical significance on univariate analysis (Table 4.63 and Figure 4.23). Regression analysis demonstrated a positive effect from the intervention on training in preventative foot care, which was part of the educational intervention, however this did not achieve statistical significance (OR 1.34, 95% CI 0.81, 2.23; $p = 0.25$) (Table 4.64). Dental care was not specifically covered in the educational program.

Table 4.63: Training in Preventative Dental and Foot Care: Between Group Changes

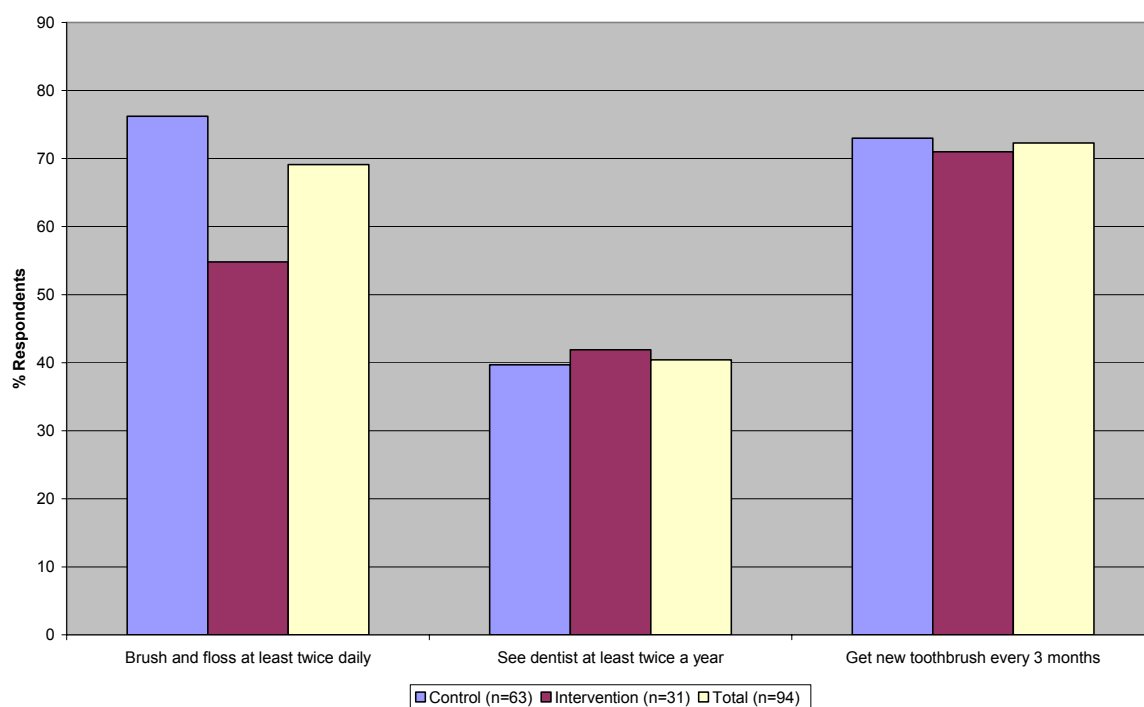
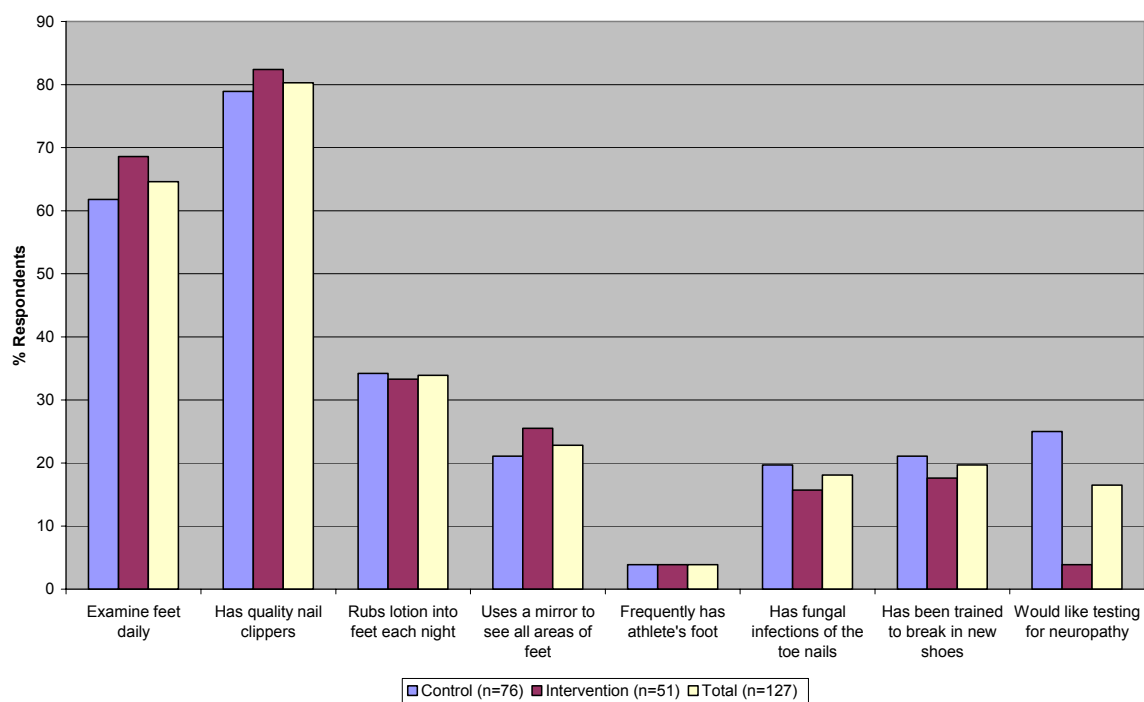
	Group	N	Baseline n (%)	p value*	N	Final n (%)	p value*
Trained in preventative dental care							
Yes	Intervention	79	22 (27.8)	0.75	51	16 (31.4)	0.19
	Control	108	31 (28.7)		73	25 (34.2)	
No	Intervention	79	50 (63.3)		51	30 (58.8)	
	Control	108	64 (59.3)		73	33 (45.2)	
Not Sure	Intervention	79	7 (8.9)		51	5 (9.8)	
	Control	108	13 (12.0)		73	15 (20.5)	
Trained in preventative foot care							
	Intervention	82	38 (46.3)	0.53	55	32 (58.2)	0.52
	Control	110	56 (50.9)		78	41 (52.6)	

* Pearson Chi-Square

Table 4.64: Effect of the DMEP on Dental and Foot Care Training

	Effect Intervention vs Control [Odds Ratio (95% CI)]	p value	n
Trained in preventative dental care	0.80 (0.49, 1.31)	0.38	92
Trained in preventative foot care	1.34 (0.81, 2.23)	0.25	132

* Regression analysis on exit variables with adjustment for baseline and clustering

Figure 4.23: Exit Data on Dental Care**Figure 4.24: Exit Data on Foot Care**

4.4.4.3 Patient Self-Monitoring

At the commencement of the study the proportion of patients who were engaged in self-monitoring of blood sugar levels exceeded 95% in both groups, affording little opportunity for improvement. Despite this there was a small increase in the proportion of patients self-monitoring blood sugar levels in the Intervention Group (95.1% to 98.2%) during the study, while this fell slightly for the Control Group (97.2% to 96.2%).

Table 4.65: Blood Sugar Monitoring: Between Group Changes

	Group	N	Baseline n (%)	p-value	N	Final n (%)	p-value
Blood Glucose Monitoring							
Self-monitor blood sugars	Intervention	81	77 (95.1)	0.44*	55	54 (98.2)	0.50*
	Control	108	105 (97.2)		78	75 (96.2)	
Days per week blood sugars are monitored							
None	Intervention	76	0 (0)	0.03*	55	0 (0)	0.15*
	Control	105	0 (0)		76	1 (1.4)	
1 day	Intervention	76	6 (7.9)		55	5 (9.1)%	
	Control	105	17 (16.2)		73	10 (13.7)	
2 days	Intervention	76	15 (19.7)		55	12 (21.8)%	
	Control	105	25 (23.8)		73	9 (12.3)	
3 days	Intervention	76	21 (27.6)		55	11 (20.0)	
	Control	105	13 (12.4)		73	8 (11.0)	
4 days	Intervention	76	8 (10.5)		55	4 (7.3)	
	Control	105	4 (3.8)		73	6 (8.2)	
5 days	Intervention	76	2 (2.6)		55	1 (1.8)	
	Control	105	4 (3.8)		73	9 (12.3)	
6 days	Intervention	76	1 (1.3)		55	0 (0)	
	Control	105	0 (0)		73	2 (2.7)	
7 days	Intervention	76	23 (30.3)		55	22 (40.0)	
	Control	105	42 (40.0)		73	28 (38.4)	
Mean (±SE)	Intervention	76	4.05±0.25	0.77#	55	4.31±0.31	0.36#
	Control	105	4.15±0.24		73	4.51±0.28	

* Pearson Chi-Square for categorical data; [#] t-test for Equality of Means

Table 4.65 contd: Blood Sugar Monitoring: Between Group Changes

<i>Blood Glucose Monitoring</i>	Group	n	Baseline	p-value	n	Final	p-value*
Times per day blood sugars are monitored							
<div>One</div> <div>Two</div> <div>Three</div> <div>Four</div> <div>Five</div> <div>Six</div> <div>Seven</div>	Intervention	77	21 (27.3)	0.35	55	17 (30.9)	0.63
	Control	106	26 (24.6)		77	24 (31.1)	
	Intervention	77	31 (40.3)		55	19 (34.5)	
	Control	106	48 (45.3)		77	29 (37.8)	
	Intervention	77	14 (18.2)		55	8 (14.5)	
	Control	106	16 (15.1)		77	14 (17.6)	
	Intervention	77	9 (11.7)		55	7 (12.7)	
	Control	106	11 (10.4)		77	9 (12.2)%	
	Intervention	77	2 (2.6)		55	2 (3.6)%	
	Control	106	0 (0)		77	0 (0)	
	Intervention	77	0 (0)		55	1 (1.8)	
	Control	106	3 (2.8)		77	1 (1.4)	
	Intervention	77	0 (0)		55	1 (1.8)	
	Control	106	0 (0)		77	0 (0)	
<i>Average (±SE)</i>	Intervention	77	2.22±0.12	0.94 [#]	55	2.36±0.19	0.36 [#]
	Control	106	2.21±0.11		77	2.16±0.13	
Blood sugar levels recorded							
	Intervention	82	60 (73.2)	0.20	55	51 (92.7)	0.03
	Control	109	78 (71.6)		77	59 (76.6)	
Blood glucose meter for self monitoring							
	Intervention	82	79 (96.3)	0.98	51	50 (98.0)	0.36
	Control	111	107 (96.4)		78	74 (94.9)	

* Pearson Chi-Square for categorical data, [#]t-test for descriptive data

Patients in both groups had increased the number of days per week on which they tested their blood sugar levels. However, whilst the number of times per day patients checked their blood sugars showed a slight increase in the

Intervention Group, this decreased slightly in the Control Group. These changes in the intensity of monitoring were not statistically significant.

There was a significant difference in the proportion of patients who recorded their blood sugar levels between the Intervention and Control Groups at the completion of the study (92.7% vs 76.6%, $p = 0.03$), which may reflect the fact that many patients in the Intervention Group received education on the importance of glucose monitoring (refer to Section 4.3.1).

At baseline the two groups were well matched, both in relation to having bathroom scales on which to weigh themselves weekly and change of weight over the past few months (Table 4.66). Whilst this was true of the former parameter at the completion of the study, a larger proportion of patients in the Intervention Group reported recent weight change (Intervention 60.7% vs Control 37.7%; $p = 0.03$). The effect of the intervention on weight change has previously been demonstrated by the differences in weight change within the Intervention (-1.68 ± 0.77 kg; $p = 0.03$) compared with the Control (-0.42 ± 0.40 kg; $p = 0.29$) Groups. It was confirmed by regression analysis that showed that Intervention patients were 3.82 times more likely to report weight change (95% CI 1.72, 8.52; $p = 0.001$) compared to Control patients.

Table 4.66: Self-Monitoring of Weight and Blood Pressure: Between Group Changes

Self-Monitoring	Group	N	Baseline n (%)	p value	N	Final n (%)	p value
Weight Monitoring							
Have bathroom scale for weekly weighing	Intervention	82	64 (78.0)	0.86	56	45 (80.4)	0.12
	Control	110	87 (79.1)		78	70 (89.7)	
Weight changed in past few months	Intervention	83	38 (45.8)	0.47	56	34 (60.7)	0.03
	Control	110	60 (54.6)		77	29 (37.7)	
Blood Pressure Monitoring							
Self-monitor blood pressure	Intervention	82	22 (26.8)	0.94	55	11 (20.0)	0.04
	Control	110	30 (27.3)		77	28 (36.4)	

* Pearson Chi-Square

Self-monitoring of blood pressure saw the opposite trend emerge, with a greater proportion of patients in the Control Group than the Intervention Group self-monitoring their blood pressure at the conclusion of the study ($p = 0.04$)

4.4.4.4 Diabetes Support Networks

The proportion of patients in the Control and Intervention Groups who were members of Diabetes Australia increased by 3.5% over the course of the study and membership of a local diabetes support group by about 1.5% (See Table 4.67), neither of which were statistically significant.

Table 4.67: Patients' Membership of Diabetes Support Organizations and Groups: Between Group Changes

Memberships and Support	Group	n	Baseline	p value	n	Final	p value
Member the Western Australian branch of Diabetes Australia	Intervention	81	65 (80.2)	0.50	56	47 (83.9)	0.52
	Control	109	83 (76.2)		78	61 (79.5)	
Like information about joining Diabetes Australia	Intervention	20	10 (50.0)	0.91	10	1 (10.0)	0.35
	Control	31	15 (48.4)		25	6 (24.0)	
Member of a local diabetes support group	Intervention	82	11 (13.4)	0.006	54	8 (14.8)	0.03
	Control	107	3 (2.8)		74	3 (4.1)	

* Pearson Chi-Square

4.4.5 Level of Diabetes Care

The level of patient care was assessed based on a number of physiological and process markers, together with patients' own assessment of their level of care and their desire to change it. A number of physiological and process markers have already been discussed, presented below is data relating to monitoring for diabetes complications, namely those involving the feet, eyes, kidneys and bone (Table 4.68).

The level of monitoring for diabetes complications improved in the case of feet and eye examinations, and the testing of the urine for protein, however increases occurred in both groups and were not statistically significant. The proportion of females who reported monitoring of their bone density fell marginally in both groups, but again this decline was not statistically significant.

Table 4.68: Monitoring for Diabetes-Related Complications: Between Group Changes

Monitoring	Group	N	Response n (%)	p- value*	N	Response n (%)	p- value*
Feet examined in the last year							
Yes	Intervention	76	37 (48.7)	0.67	55	34 (61.8)	0.62
	Control	108	56 (51.9)		73	42 (57.5)	
Eye evaluation by specialist in past year							
Yes	Intervention	81	52 (64.2)	0.26	55	36 (65.5)	0.27
	Control	110	79 (71.8)		78	58 (74.4)	
Dilated pupil eye examination							
Yes	Intervention	81	47 (58.0)	0.54	55	43 (78.2)	0.27
	Control	110	66 (60.2)		74	50 (67.6)	
Urine examination for protein (microalbuminuria)							
Yes	Intervention	80	32 (40.0)	0.26	53	24 (46.2)	0.88
	Control	109	42 (38.5)		78	38 (48.7)	
No	Intervention	80	14 (17.5)		52	2 (3.8)	
	Control	109	11 (10.1)		78	4 (5.1)	
Not sure	Intervention	80	34 (42.5)		52	26 (50.0)	
	Control	109	56 (51.4)		78	36 (46.2)	
Bone density estimation (Females only)							
Yes	Intervention	45	31.1%	0.68	27	29.6%	0.97
	Control	60	35.0%		40	30.0%	

* Pearson Chi-Square

Patients were asked as part of the modified DPAQ to assess their current level of diabetes care and their willingness to improve it using the following two questions:

- Q45: How do you feel about your diabetes care?
- Q46: How do you feel about working to improve your diabetes care?

The results of the changes in response to these questions from baseline to the completion of the study are shown in Table 4.69. What the data show is that patients in the Intervention Group generally felt better about their diabetes care, and that they were more prepared to work towards improving it. Regression analysis demonstrates a positive effect of the intervention in relation to both of these issues, however this was only statistically significant for the latter (Table 4.70).

Table 4.69: Patients' Assessment of Their Level of Diabetes Care and Their Willingness to Improve It: Between Group Changes

Question	Group	n	Baseline	p value	n	Final	p value
How do you feel about your diabetes care?							
Good	Intervention	83	35 (42.2)	0.58	56	41 (73.2)	0.18
	Control	109	50 (45.9)		78	45 (57.7)	
Average	Intervention	83	40 (48.2)		56	29(23.2)	
	Control	109	45 (41.3)		78	13 (37.2)	
Poor	Intervention	83	8 (9.6)		56	2 (3.6)	
	Control	109	14 (12.8)		78	4 (5.1)	
How do you feel about working to improve your diabetes care?							
Yes	Intervention	82	48 (58.5)	0.24	55	44 (80.0)	0.20
	Control	107	73 (68.2)		76	50 (65.8)	
Bit sceptical	Intervention	82	21 (25.6)		55	5 (9.1)	
	Control	107	17 (15.9)		76	13 (17.1)	
Not sure	Intervention	82	13 (15.9)		55	6 (10.9)	
	Control	107	17 (15.9)		76	13 (17.1)	

* Pearson Chi-square

Table 4.70: Effect of the DMEP on Patients' Attitudes to Their Diabetes Care

Question	Effect* Intervention vs Control [Odd Ratio (95% CI)]	p-value	n
How do you feel about your diabetes care? (1=Good, 2=average, 3=poor)	0.51 (0.19, 1.43)	0.20	132
How do you feel about working to improve your diabetes care? (1=Yes, 2=bit sceptical, 3=Not sure)	0.38 (0.19, 0.76)	0.006	128

* Regression Analysis on Exit variables with Adjustment for Baseline and Clustering

4.4.6 Quality of Life Assessments

At the 6 month follow-up session participants in the study were asked to complete the DSC-R and SF-36 questionnaires as they did when they entered the study. The results of these assessments are shown below.

4.4.6.1 Diabetes Symptom Checklist (DSC-R)

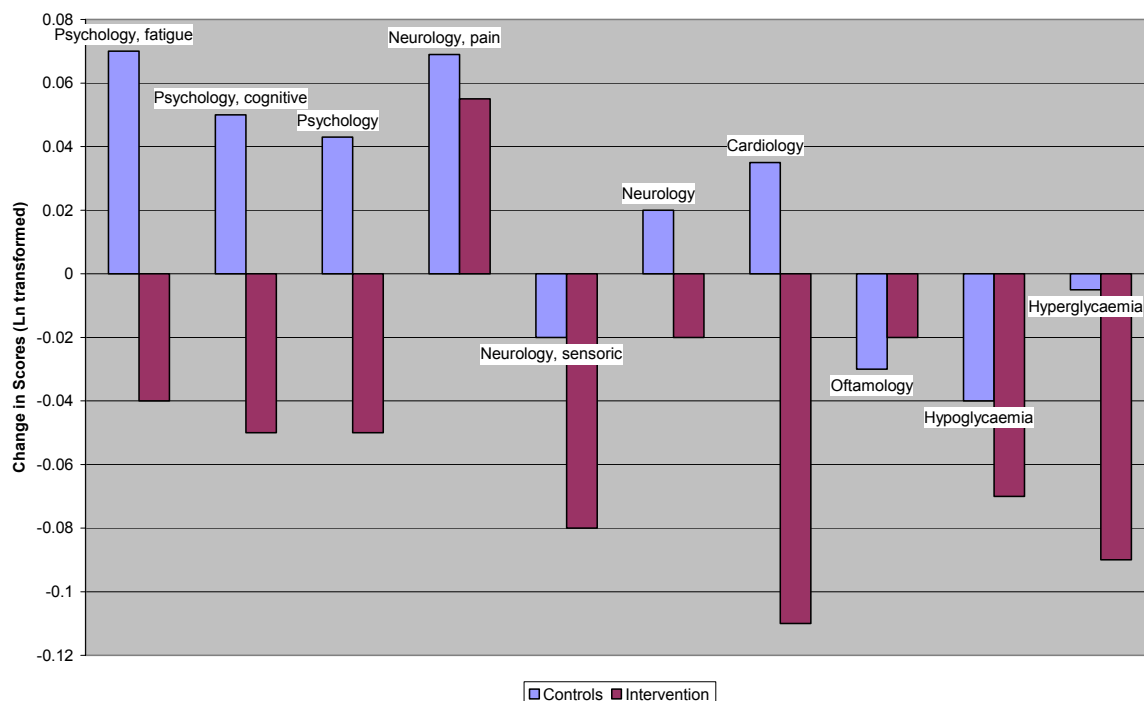
The results of the patients' assessment of the impact of their diabetes on their physical functioning based on the DSC-R scores is shown in Table 4.71. The scores generally decreased across all dimensions compared to baseline in both groups, indicating an improvement in the patients rating of their well-being. There was, however, a greater degree of improvement in the Intervention Group compared to the Control Group. Intervention patients recorded lower scores in four out of six dimensions and three out of the four sub-divisions compared to Control patients at the completion of the study compared with a total of three at baseline; Figure 4.25). Univariate analysis, demonstrated a highly significant difference in hyperglycaemia scores between the two groups (Control 1.67 vs. Intervention 1.42; Difference -0.25, 95% CI 0.02, 0.48; $p = 0.036$).

Table 4.71: Changes Diabetes Symptom Checklist Scores Within and Between Groups

Dimensions and Sub-divisions ^{1,2}		n	Baseline Mean ±SE	n	Final Mean ±SE	Baseline vs. Final p value*	Intervention vs. Control p value†
Psychology	Intervention	83	1.93±0.08	52	1.78±0.09	0.47	0.26
	Control	106	1.87±0.07	72	1.93±0.09	0.41	
Psychology, fatigue ¹	Intervention	83	2.13±0.11	52	1.96±0.11	0.76	0.23
	Control	106	2.05±0.09	69	2.15±0.11	0.21	
Psychology, cognitive ¹	Intervention	83	1.73±0.08	50	1.62±0.08	0.52	0.26
	Control	106	1.70±0.07	72	1.74±0.09	0.39	
Neurology	Intervention	83	1.54±0.07	51	1.53±0.09	0.52	0.89
	Control	106	1.51±0.06	73	1.51±0.07	0.45	
Neurology, pain ²	Intervention	83	1.47±0.08	51	1.61±0.12	0.52	0.38
	Control	106	1.40±0.06	69	1.49±0.09	0.048	
Neurology, sensoric ²	Intervention	83	1.59±0.07	51	1.46±0.09	0.05	0.54
	Control	106	1.58±0.07	73	1.54±0.08	0.33	
Cardiology	Intervention	83	1.58±0.06	50	1.39±0.07	0.008	0.39
	Control	106	1.47±0.05	72	1.48±0.08	0.77	
Oftamology	Intervention	83	1.38±0.05	50	1.38±0.11	0.06	0.62
	Control	106	1.39±0.06	70	1.33±0.06	0.62	
Hypoglycaemia	Intervention	83	1.61±0.08	50	1.44±0.11	0.26	0.14
	Control	106	1.67±0.07	69	1.64±0.08	0.68	
Hyperglycaemia	Intervention	83	1.72±0.09	49	1.42±0.08	0.04	0.036
	Control	106	1.78±0.09	71	1.67±0.08	0.80	

¹ subdivisions of psychology, ² subdivisions of neurology

* t-test for Equality of Means

Figure 4.25: Changes in DSC-R from baseline to exit

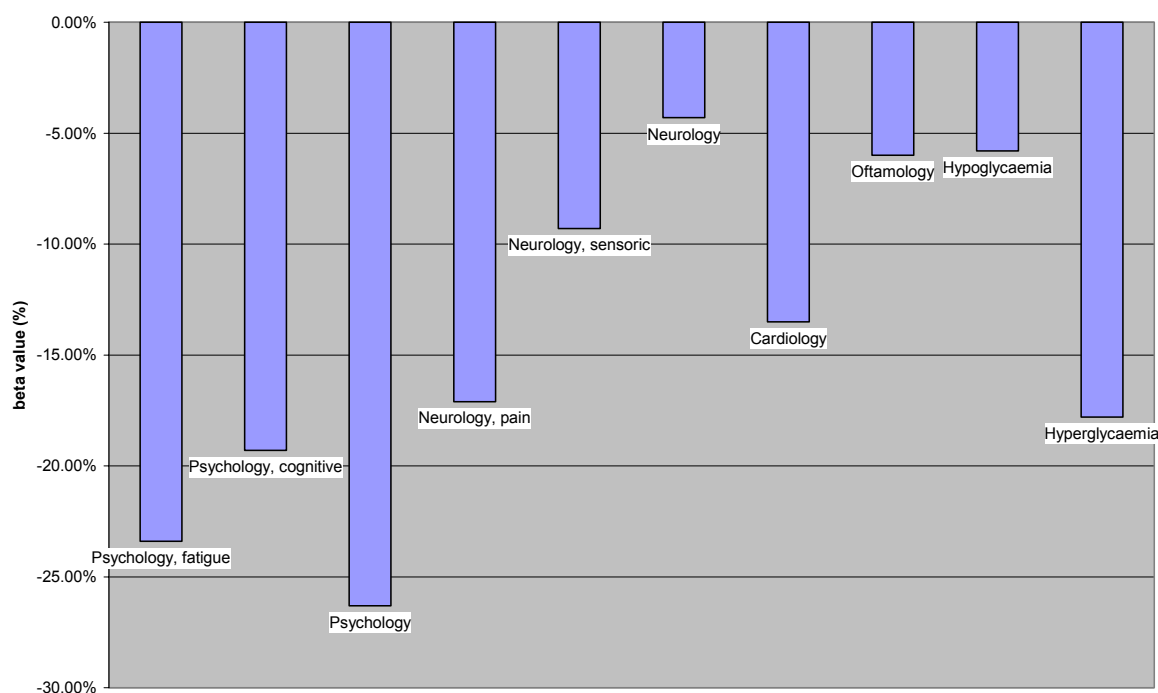
Note: Psychology has the sub-divisions of fatigue and cognition, and Neurology has the sub-divisions of pain and sensoric

Regression analysis with group and baseline interaction included demonstrated a significant benefit of the intervention in the dimension “Psychology ($p=0.001$)” and its two subdivisions “Psychology, pain” ($p<0.001$); “Psychology, cognitive” ($p=0.01$); and the sub-division of “Neurology, pain” ($p=0.039$) (Table 4.72). The analysis did reveal that there was a worsening in the Intervention patients’ assessment in the sub-division of “Neurology, pain”; however this was true of the patients in the Control Group, and their decline was even greater (Figure 4.25). In fact it demonstrated that across all dimensions there was a reduction in DSC-R scores, hence self-assessed improved well-being, in the Intervention Group compared to the Control Group (Figures 4.25 and 4.26).

Table 4.72 Effect of the Intervention on DSC_R Scores - Regression Analysis with Group*Baseline Interaction Included

	Overall group effect (Intervention vs Control)	p-value	n
Psychology, fatigue (ln transformed)			
Group + (Group x baseline)	$\beta = -0.27$ (-0.364, -0.170)	<0.001	122
Percentage change (e^{β})	-23.4% (-30.5, -15.7)		
Psychology, cognitive (ln transformed)			
Group + (Group x baseline)	$\beta = -0.21$ (-0.36, -0.07)	0.01	122
Percentage change (e^{β})	-19.3% (-30.2, -6.7)		
Psychology (ln transformed)			
Group + (Group x baseline)	$\beta = -0.305$ (-0.43, -0.18)	0.001	124
Percentage change (e^{β})	-26.3% (-35, -16.5)		
Neurology, pain (ln transformed)			
Group + (Group x baseline)	$\beta = -0.187$ (-0.362, -0.012)	0.039	120
Percentage change (e^{β})	-17.1% (-30.4, -1.2)		
Neurology, sensoric (ln transformed)			
Group + (Group x baseline)	$\beta = -0.098$ (-0.329, 0.133)	0.35	124
Percentage change (e^{β})	-9.3% (-28.0, 14.2)		
Neurology (ln transformed)			
Group + (Group x baseline)	$\beta = -0.044$ (-0.177, 0.089)	0.46	124
Percentage change (e^{β})	-4.3% (-16.2%, 9.3%)		
Cardiology (ln transformed)			
Group + (Group x baseline)	$\beta = -0.145$ (-0.42, 0.13)	0.26	122
Percentage change (e^{β})	-13.5% (-34.4, 14.1)		
Oftamology (ln transformed)			
Group + (Group x baseline)	$\beta = -0.06$ (-0.63, 0.51)	0.80	120
Percentage change (e^{β})	-6.0% (-46.8, 65.9)		
Hypoglycaemia (ln transformed)			
Group + (Group x baseline)	$\beta = -0.06$ (-0.46, 0.34)	0.735	119
Percentage change (e^{β})	-5.8% (26.8%, 40.5)		
Hyperglycaemia (ln transformed)			
Group + (Group x baseline)	$\beta = -0.196$ (-0.476, 0.084)	0.14	120
Percentage change (e^{β})	-17.8% (-37.8, 8.8)		

Figure 4.26: Diabetes Symptoms Checklist: Overall Group Effect (Intervention vs Control)



4.4.6.2 SF-36 Short Form Health Survey

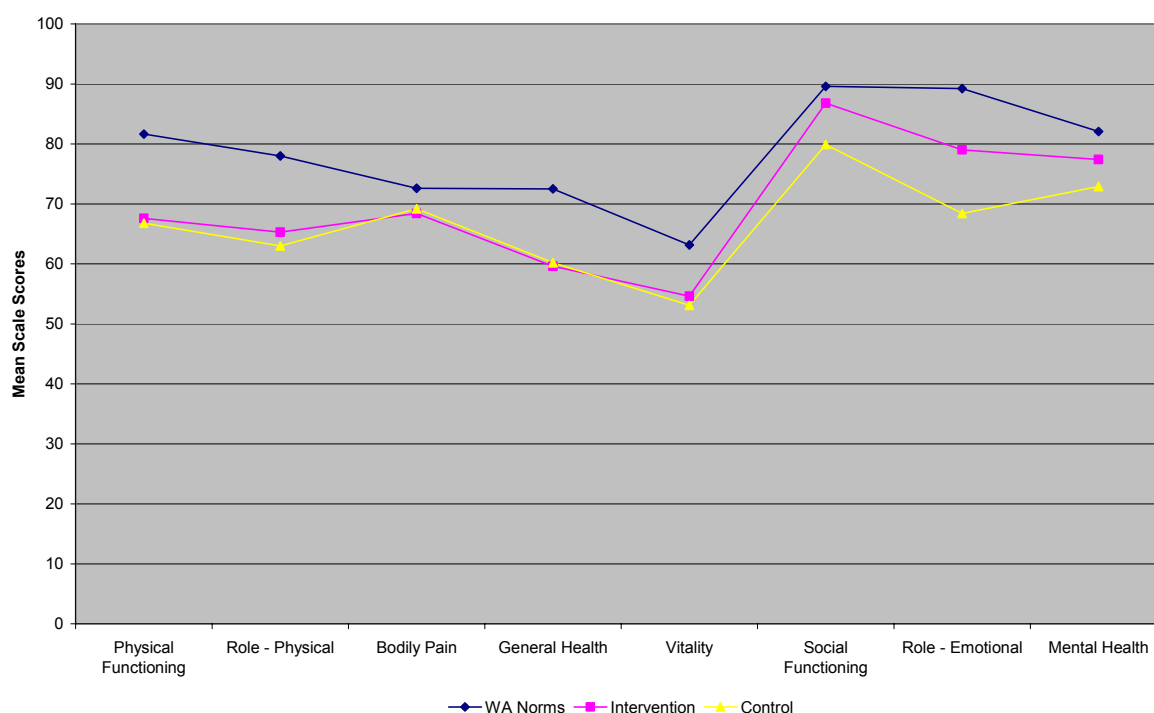
The results of the patients' assessment of their quality of life using the SF-36 questionnaire at the completion of the study are shown in Tables 4.73 and 4.74. The results show that with the exception of the dimensions Vitality (-2.6 ± 1.9) and Mental Health (-1.5 ± 1.8) for the Control Group and Role – physical (-3.1 ± 5.4) and Bodily pain SF7 only (-1.1 ± 2.9) in the Intervention Group, there were increases in the SF-36 scores in both groups across multiple dimensions. While the patients in the Intervention Group scored higher across seven of the 10 dimensions or their sub-divisions compared with those in the Control Group, none of the differences were statistically significant on univariate analysis. Figure 4.27 shows the comparative SF-36 scores compared to the Western Australian norms for persons aged 55-64 years, clearly demonstrating that patients in both groups had a reduced quality of life compared to the general population.

Table 4.73: Changes in SF-36 Scores Within and Between Groups

Dimensions and Sub-divisions ¹		n	Baseline Mean ±SE	n	Final Mean ±SE	Baseline vs. Final p value*	Intervention vs. Control p value†
Physical functioning	Intervention	80	66.9±2.7	54	67.6±3.5	0.95	0.85
	Control	106	63.3±2.6	72	66.8±2.8	0.81	
Role – Physical	Intervention	77	64.5±4.6	53	65.3±5.3	0.56	0.75
	Control	105	58.4±4.3	74	63.0±4.8	0.23	
Bodily pain SF7 only ¹	Intervention	81	49.9±2.6	54	49.8±3.3	0.89	0.56
	Control	107	48.8±2.5	75	52.2±2.6	0.94	
Bodily pain SF8 only ¹	Intervention	81	57.0±2.5	54	59.6±3.2	0.70	0.78
	Control	107	57.0±2.3	75	58.4±2.7	0.27	
Bodily pain	Intervention	82	65.7±3.0	53	68.4±3.9	0.89	0.88
	Control	107	66.1±2.8	75	69.2±3.0	0.31	
General health	Intervention	79	54.0±2.5	52	59.6±3.1	0.34	0.86
	Control	108	57.9±2.1	75	60.2±2.3	0.61	
Vitality	Intervention	82	51.6±2.4	54	54.6±3.0	0.77	0.71
	Control	108	54.7±2.3	75	53.1±2.6	0.17	
Social functioning	Intervention	82	77.7±3.1	55	86.8±2.9	0.06	0.09
	Control	108	75.5±2.7	75	79.9±2.8	0.61	
Role – Emotional	Intervention	79	69.8±4.4	53	79.0±5.0	0.22	0.13
	Control	106	75.2±3.7	74	68.4±4.7	0.01	
Mental Health	Intervention	82	71.0±2.2	54	77.4±2.5	0.15	0.18
	Control	108	73.1±1.8	54	72.9±2.2	0.15	

Table 4.74: Changes in SF-36 Scores within Groups from Baseline to Exit

Dimensions and Sub-divisions ¹	Δ for Controls	p-value	n	Δ for Intervention	p-value	n
Physical functioning	0.4±1.7	0.81	72	0.2±2.8	0.95	54
Role – Physical	5.6±4.7	0.23	74	-3.1±5.4	0.56	53
Bodily pain	0.2±2.1	0.94	75	0.5±3.2	0.89	54
Bodily pain SF7 only ¹	2.4±2.1	0.27	75	-1.1±2.9	0.70	54
Bodily pain SF8 only ¹	2.1±2.1	0.31	75	0.4±2.7	0.89	53
General health	0.9±1.7	0.61	75	2.4±2.5	0.34	52
Vitality	-2.6±1.9	0.17	75	0.8±2.9	0.77	54
Social functioning	1.3±2.6	0.61	75	6.6±3.5	0.06	55
Role – Emotional	11.7±4.6	0.01	74	6.9±5.6	0.22	53
Mental Health	-1.5±1.8	0.15	54	3.3±2.2	0.15	54

Figure 4.27: SF-36 Scores for the Intervention and Control Groups compared with the Western Australian Norms (1995) at Exit

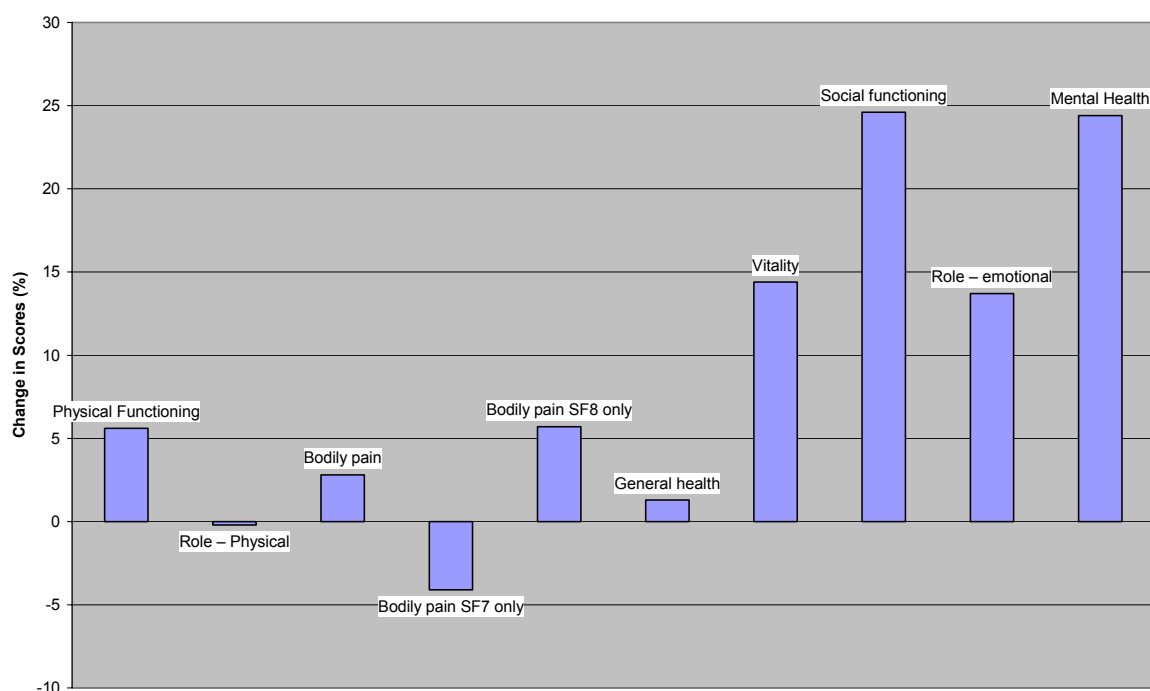
Source: Daly A. SF-36 norms for the state of Western Australia. Western Australian Health Survey 1997, Number 5.

Regression analysis incorporating group*baseline interaction confirmed the positive effect of the intervention on patients' quality of life (Intervention vs Control) with positive changes seen in all dimensions with the exceptions of Role – physical and Bodily pain SF7 only (Table 4.75 and Figure 4.28). However, the only change which was statistically significant occurred in the dimension of Social Functioning ($\beta=24.6$, 95% CI: 6.9, 42.2, $p = 0.013$).

Table 4.75: Effect of the DMEP on SF-36 Scores - Regression Analysis with Group*Baseline Interaction Included

	Overall Group Effect Intervention vs Control (95% Confidence Intervals)	p-value	n
Physical functioning	$\beta=5.6(-21.2, 32.4)$	0.64	126
Role – Physical	$\beta=-0.20(-9.7, 9.3)$	0.96	127
Bodily pain	$\beta=2.81(-21.2, 26.8)$	0.79	129
Bodily pain SF7 only *	$\beta=-4.1(-24.5, 16.2)$	0.65	129
Bodily pain SF8 only *	$\beta=5.7(-15.8, 27.3)$	0.55	128
General health	$\beta=1.3(-12.7, 15.4)$	0.83	127
Vitality	$\beta=14.4(-2.6, 31.5)$	0.09	129
Social functioning	$\beta=24.6 (6.9, 42.2)$	0.013	130
Role – Emotional	$\beta=13.7(-14.0, 41.4)$	0.28	127
Mental health	$\beta=24.4(-23.0, 71.8)$	0.26	129

*Not included in the assessment of clinical significance as there were no norm data

Figure 4.28: Changes in SF-36 Scores - Intervention vs Control

4.4.7 Clinical Significance

The benefit of an intervention can not always be judged on statistical significance alone, more important to patients, health practitioners and governments is the clinical significance of the intervention. That is, is the change observed likely to result in improved patient outcomes, without unnecessary risk and excessive cost, such that it would justify a change in management? To evaluating the potential clinical significance of the DMEP intervention the following strategy was adopted:

An assessment of changes in health-related quality of life using the one-SEM criterion.

The results of this assessment are presented below, together with an explanation of the assessment process.

4.4.7.1 Clinical Significance of the Quality of Life Changes

The minimal clinically important difference (MCID) has been defined by Jaeschke *et al.*⁵² as “the smallest difference in a score of an instrument of interest that patients perceive to be beneficial and that would mandate, in the absence of troublesome side effects and excessive costs, a change in the patient’s management.” In the case of the SF-36 MCIDs are yet to be determined, however Wrywich *et al.*⁴⁶ have proposed that SEM-based criterion may be useful for identifying meaningful intra-individual changes in Health-Related Quality of Life (HRQoL). The SEM or standard error of the measurement takes into account the reliability of a particular test to identify a true difference. Based on results from a study where changes in clinical status were correlated with SEM-based changes in Chronic Respiratory Disease Questionnaire (CRQ) and the SF-36 scores, they have proposed the use of one-SEM as a measure of clinical significance. Using the SF-36 norms for the state of Western Australia⁴⁷ and the reliability estimates for SF-36 scales in patients with diabetes⁴⁸, it was possible to estimate the SEM for each of the SF-36 dimensions by multiplying the standard deviation of the dimension score by the square root of one minus its reliability coefficient, as shown below:

$$\text{SEM} = \sigma_x \sqrt{1 - r_x} \quad \text{Where } \sigma_x \text{ is the standard deviation and } r_x \text{ is the reliability coefficient}$$

The results of these estimates are shown in Table 4.76.

Table 4.76: SF-36 Norms for Western Australian Persons Aged 55-64 years, with Calculated Standard Errors of Measurement

	Mean Scores ^a	Standard deviation ^a	Reliability Coefficient*	SEM
Physical functioning	81.65	21.23	0.93	5.61
Role – Physical	78.04	34.50	0.85	13.36
Bodily pain	72.56	26.24	0.86	9.82
General health	72.48	21.49	0.76	10.52
Vitality	63.16	20.91	0.86	7.82
Social functioning	89.60	20.66	0.86	12.64
Role – Emotional	89.22	26.57	0.81	11.58
Mental Health	82.08	15.44	0.88	5.35

^a Daly A. SF-36 norms for the state of Western Australia. Western Australian Health Survey 1997, Number 5.

* For people with diabetes. Ware JE et al. SF-36® Health Survey. Manual and Interpretation Guide. Lincoln:QualityMetric Inc., 2002, 7:8.

Using Wrywich *et al* one-SEM criterion and the differences in the SF-36 scores of the Intervention and Control Groups as shown by the regression analysis, the increases in five (Physical Functioning, Vitality, Social Functioning, Role – Emotional and Mental Health) of the eight dimensions are likely to be clinically significant. This would seem in keeping with reduction in DSC-R scores (a number of which were statistically significant) observed in the Intervention Group across all domains.

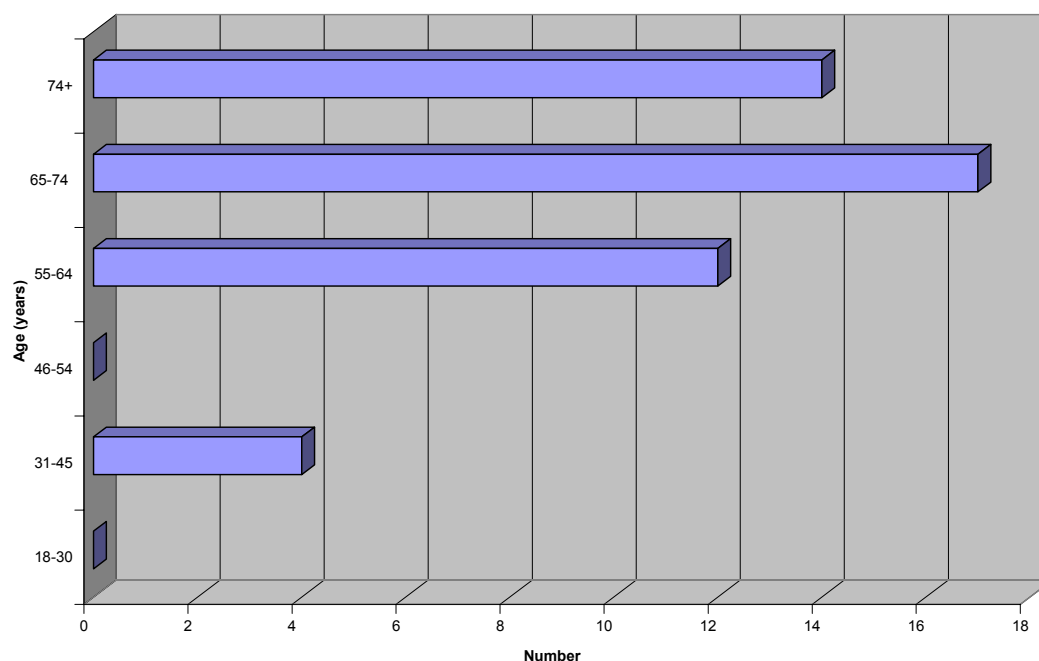
4.4.8 Patient Satisfaction Survey

4.4.8.1 Demographics

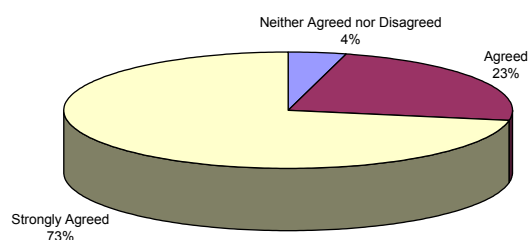
An attempt was made to interview all patients who completed the Intervention arm of the study (n = 57). Of these four were unable to be contacted (phone numbers had changed), two were away on holidays and four did not wish to participate in the survey; leaving 47 respondents. This group was composed of

22 females and 25 males, the majority of whom were aged 55 years or older (Figure 4.29).

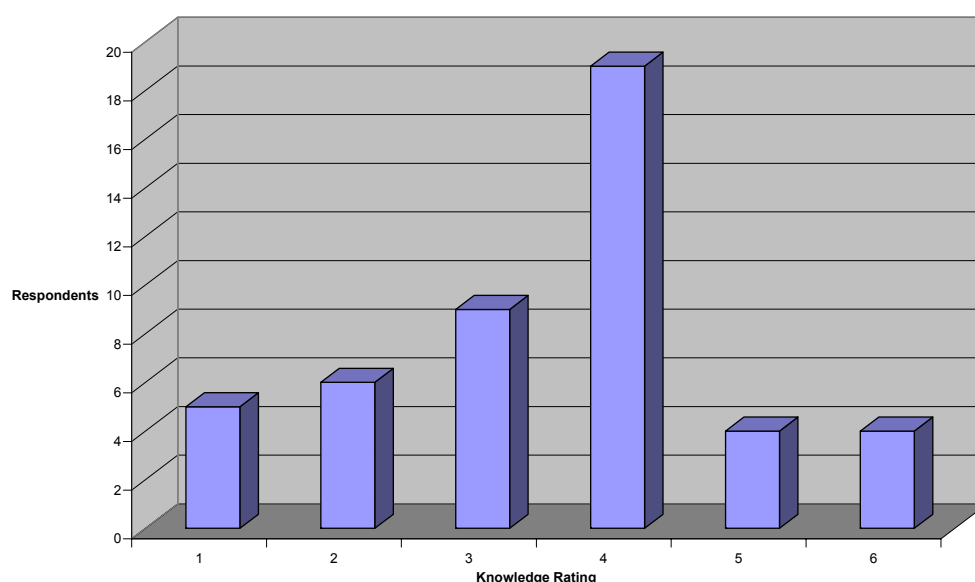
Figure 4.29: Age of Survey Respondents



Respondents were extremely positive in regards to the pharmacist's role in providing diabetes education. The majority of patients stating they agreed (11; 23.4%) or strongly agreed (34; 72.3%) with pharmacists providing diabetes education (Figure 4.30). This was particularly encouraging given that 38 (80.9%), had received diabetes education before enrolling in the DMEP study.

Figure 4.30: Patients' Opinions of Pharmacists Providing Diabetes Education

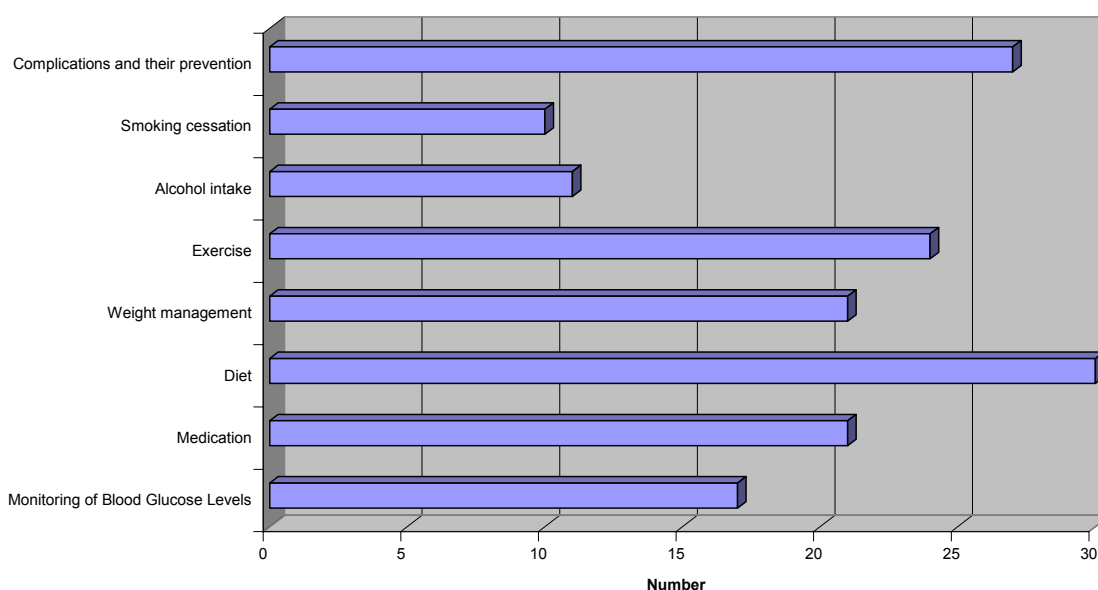
Patients were asked to rate their understanding of their diabetes before their participation on a 1 to 6 Likert scale, where 1 = nothing and 6 = everything. The mean response score was 3.49 ± 1.31 indicating a self-assessed above average understanding of diabetes amongst the patients at entry into the study (Figure 4.31).

Figure 4.31: Patients' Self-Assessment of Their Diabetes Knowledge Pre-Study

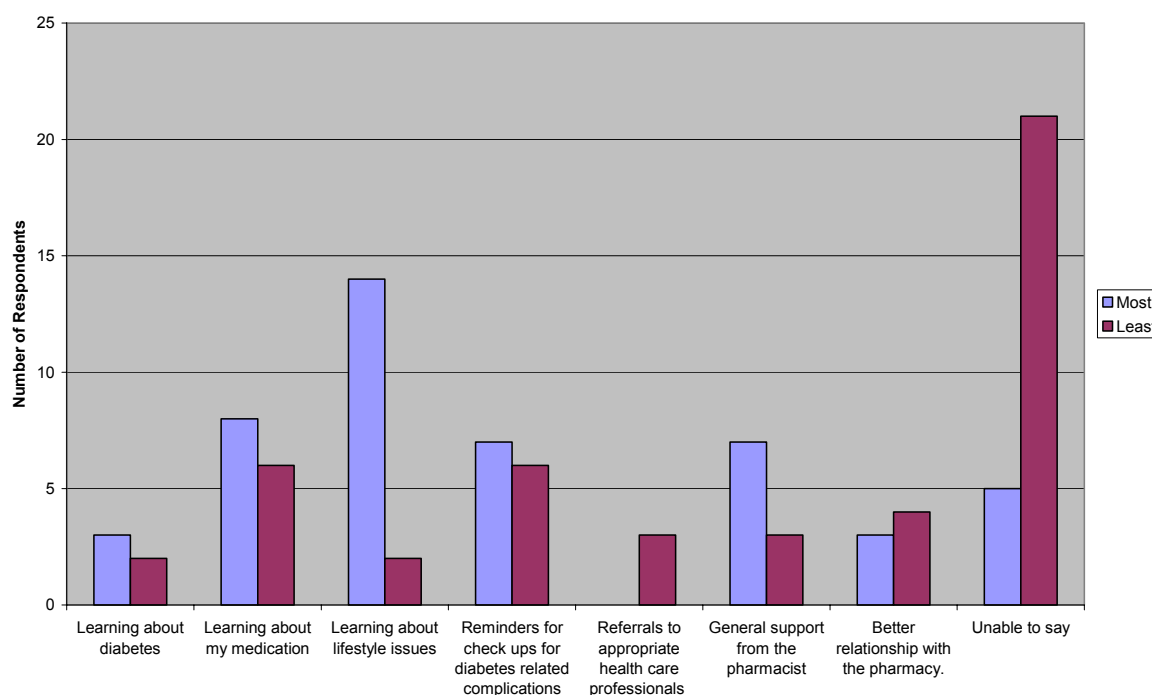
4.4.8.2 Impact of the Service

Respondents reported knowing more about a wide range of topics related to diabetes and its management as a result of participating in the study as shown in Figure 4.32. One respondent made comment that the education sessions made them “*aware of pharmacists’ knowledge*”, whilst another commented on increased awareness of “*medicine interactions*”.

Figure 4.32: Areas in which Patients Reported Knowledge Gains



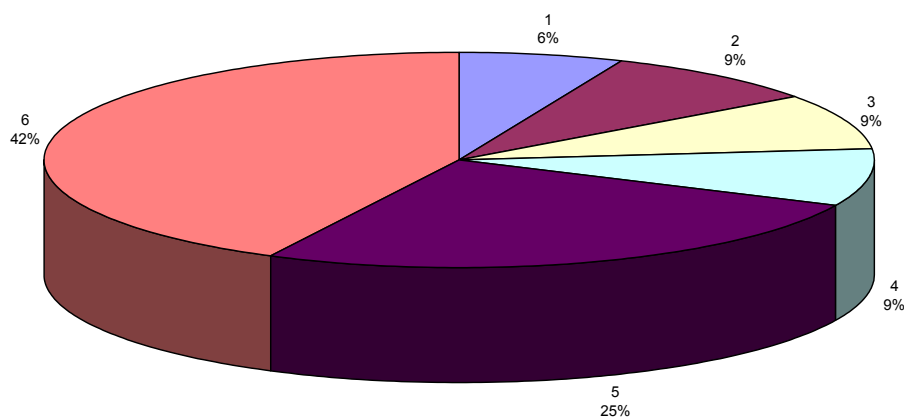
When asked about what aspects of the DMEP delivered in the pharmacy they found the most and least useful there was a mixture of responses. The key positive aspects appeared to be learning about “lifestyle issues”, “learning about my medications”, “reminders for check-up for diabetes-related complications” and the general support from the pharmacist (Figure 4.33). Although, “learning about my medications” and “reminders for check-ups for diabetes-related complications” also featured amongst the least useful aspects.

Figure 4.33: Most and Least Valued Components of the DMEP

An extremely positive outcome from this evaluation was the fact that four times more respondents were unable to identify the least useful aspect (44.7%) than those who failed to identify the most useful (10.6%).

Using a 6 point Likert scale (where 1 = of absolutely no use and 6 = extremely valuable/useful) respondents were asked to rate the usefulness of the follow-up visits at 1, 3 and 6 months after the education phase to assess whether they provided additional value. The mean score for the sessions was 4.66 ± 1.61 indicating that the patients valued the sessions highly (Figure 4.34).

Figure 4.34: Value of Post-Education Follow-Up Sessions
 (1 = of absolutely no use; 6 = extremely useful)



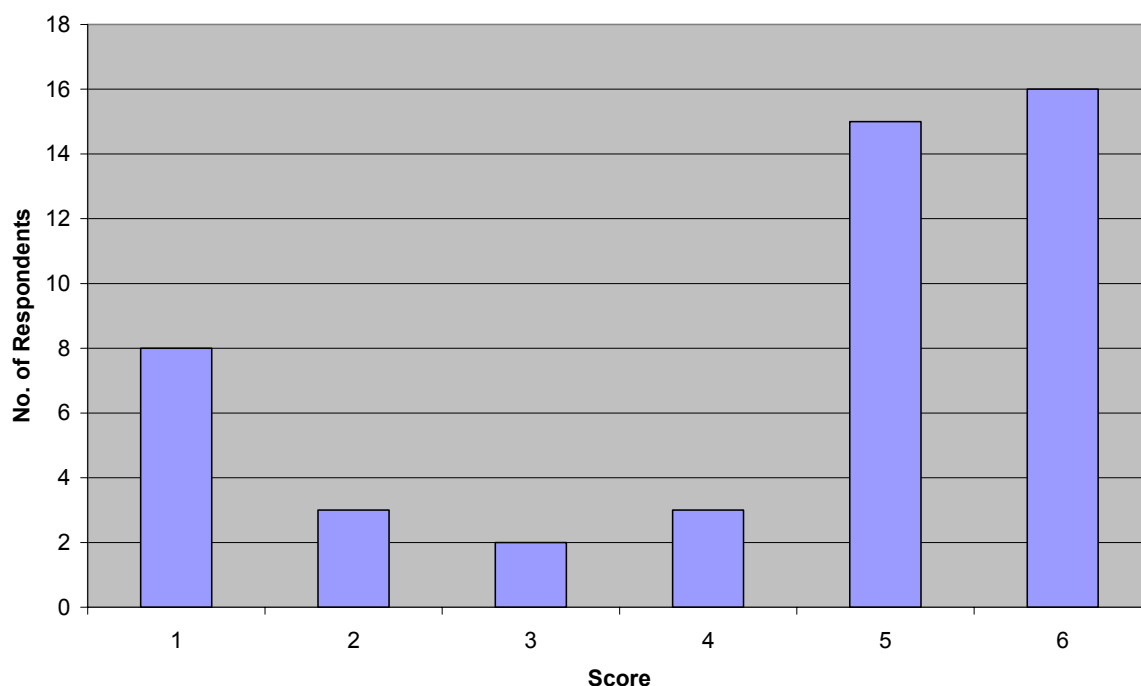
As part of the DMEP service patients were provided with a diary which contained information about diabetes and its management, a lists of their therapeutic targets and their medications, together with appointment dates. As part of the study protocol they were asked to record the BGLs and weights in the diaries, together with reasons for medication non-compliance. As part of this survey they were asked to rate the usefulness of having a diary in which to monitor their diabetes management. Again a 6 point Likert scale was used where 1 = of absolutely no use and 6 = extremely valuable/useful. The respondents rated the diary highly with their mean score being 4.32 ± 1.85 (Figure 4.35). There was however a number of suggestions offered to improve the diaries including:

“Need more/different time slots per day”

“More electronic – link to computer”

“More space at the end for comments”

“Column for what was eaten if the BGL reading is high”.

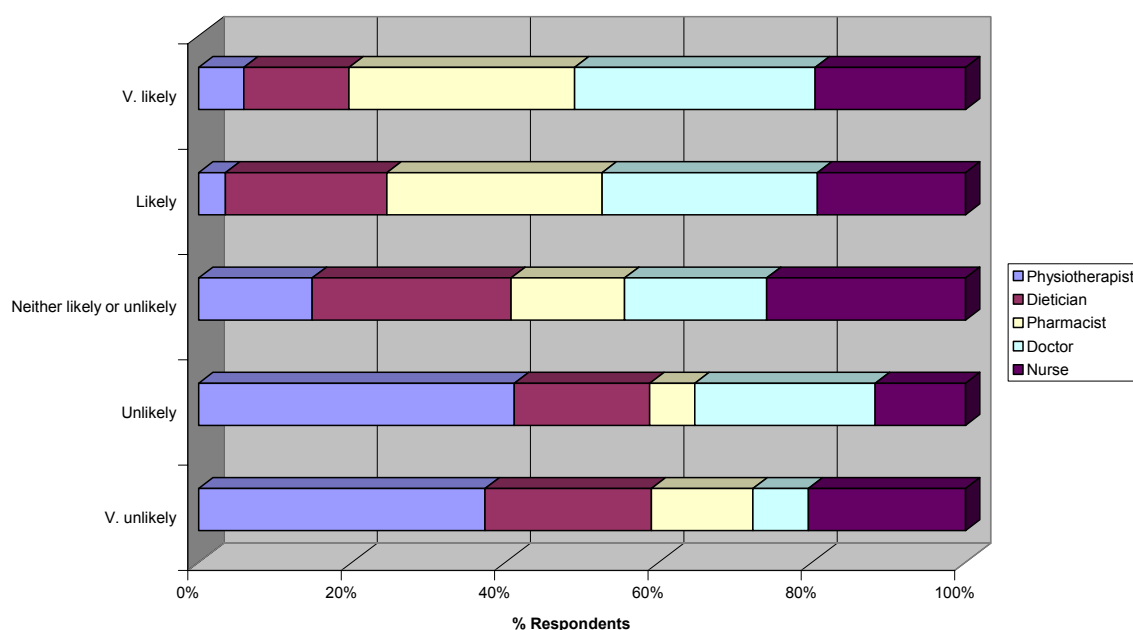
Figure 4.35: Patients' Ratings of the Patient Diaries

Where 1 = of absolutely no use and 6 = extremely valuable/useful

4.4.8.3 Provider Preference

When asked who they would prefer to provide them with diabetes education, patients gave pharmacists the highest approval rating (15; 31.9%), followed by diabetes educator/nurse (14; 29.8%), general practitioners (10; 21.3%) and specialists (5; 10.6%). The remaining three (6.4%) respondents cited the Internet or books as their preferred source of information.

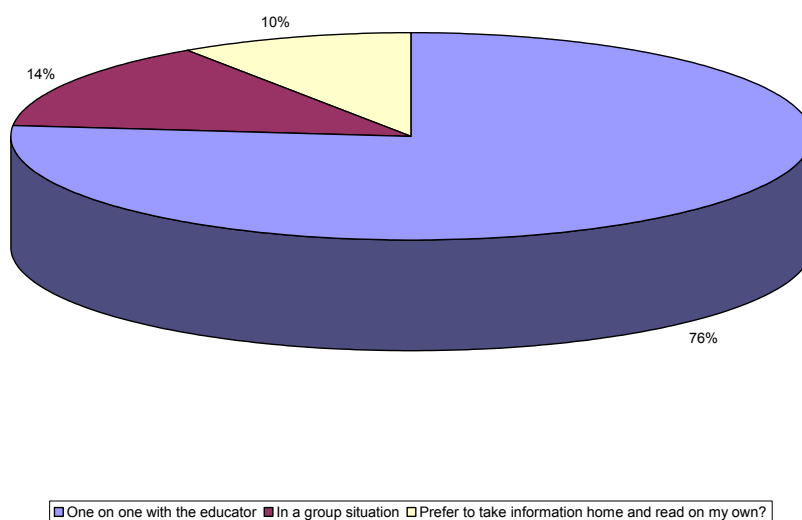
On the specific topic of lifestyle, patients were asked to rank the likelihood of them obtaining information about lifestyle issues from various healthcare professionals. In this assessment pharmacists rate higher than all other health professionals with the exception of doctors (Figure 4.36).

Figure 4.36: Likely Sources of Information on Lifestyle

In response to the question “How do/would you prefer to receive diabetes education?” the majority of respondents (36; 76.6%) preferred one-to-one sessions with the educator (Figure 4.37). Comments from those who stated they would prefer to take information and read in their own time included:

“Good if you get a problem”

“Can reinforce what you have already learnt”

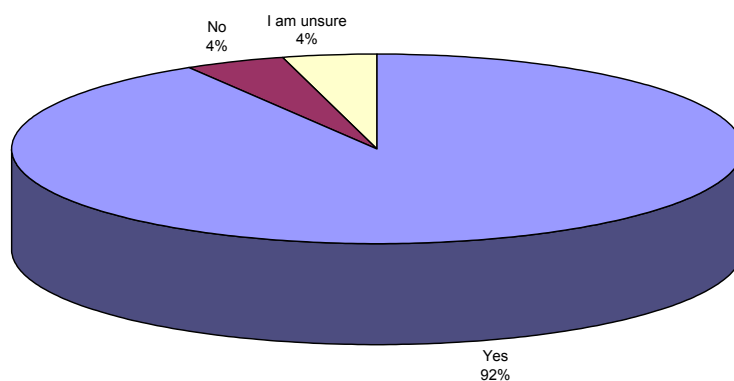
Figure 4.37: Preferred Education Format/Setting

4.4.8.4 Need for The Service

In an attempt to assess perceived need, patients were asked how valuable they felt the education (DMEP) service would be for people in the community with type 2 diabetes. Respondents were asked to rate its importance on a 6 point Likert scale where 1 = of absolutely no use and 6 = extremely useful. The response to this question was overwhelmingly positive with a mean score of 5.74 ± 0.49 ; the majority (36; 76.6%) of respondents rating the service as extremely useful.

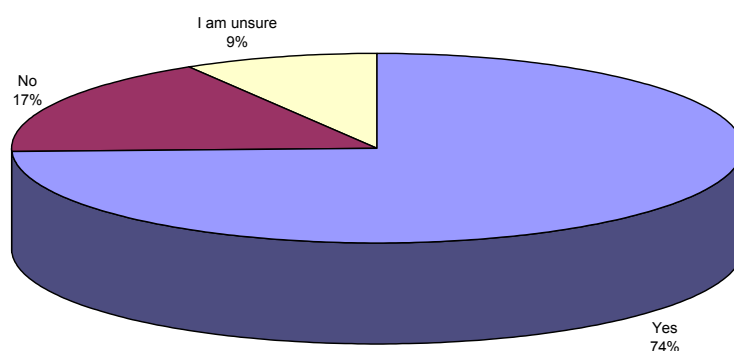
When asked if a pharmacy-based education and advice service for diabetic patients should be available on a regular basis, the overwhelming majority of respondents (43; 91.5%) said “yes” (Figure 4.38).

Figure 4.38: Should Pharmacy-Based Diabetes Education and Advice be Available on a Regular Basis?



Thirty-five (74.5%) of the patients asked if they would continue to use the service in the future if it were available said “yes” (Figure 4.39).

Figure 4.39 Patients' Willingness to Continue Long-Term with the DMEP



In response to the question “how often would you use the service if it were available?” there were mixed responses (Figure 4.40), however a strong preference was shown for 3 monthly sessions. Of those who stated they would use the service if available in the future 22 of 39 (56.4%) were prepared to pay for the service. When asked how much they would be prepared to pay responses ranged from unsure through AUD 5.00 to AUD 40.00 per hour (Figure 4.41).

Figure 4.40: Preferred Frequency of Follow-Up Sessions

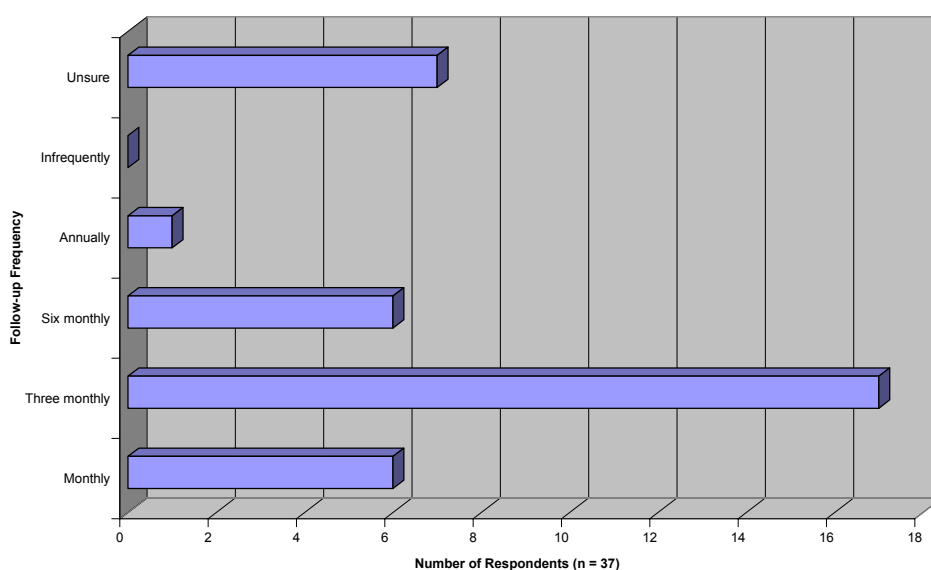
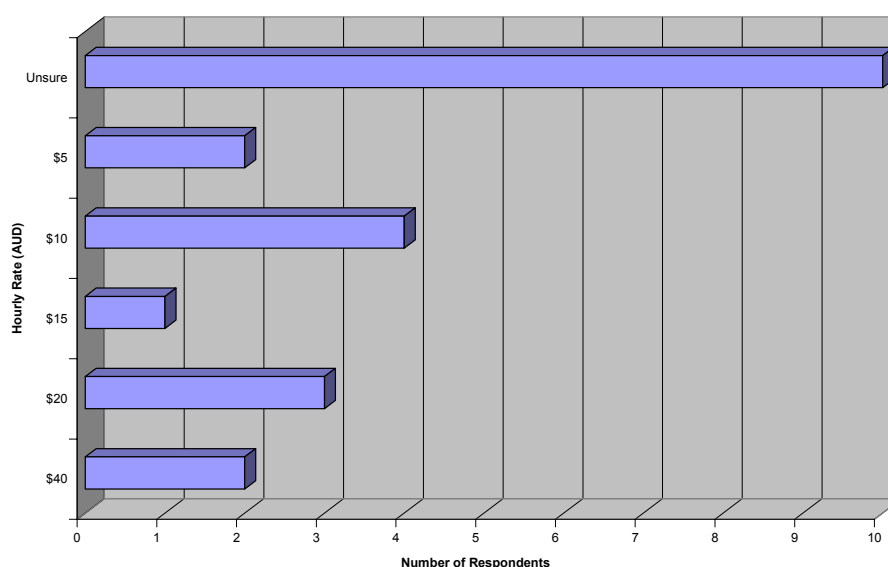


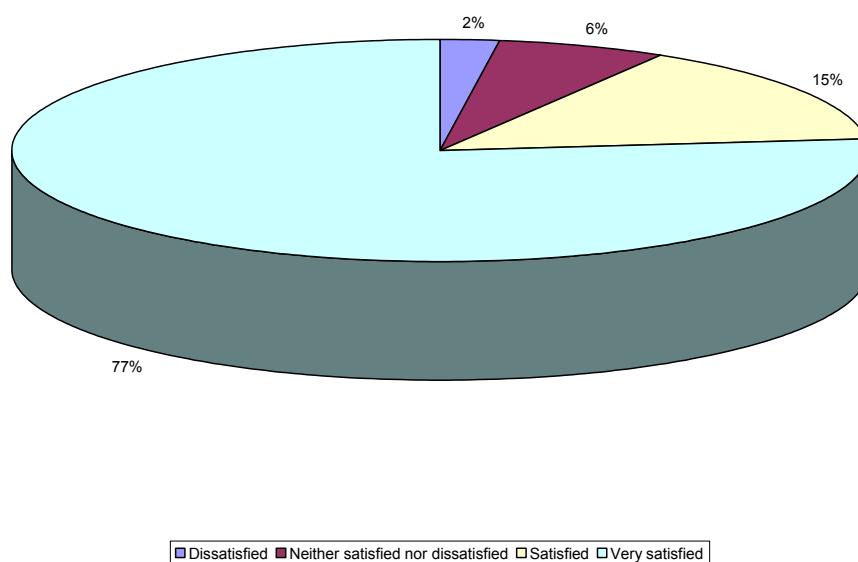
Figure 4.41: Patients Preparedness to Pay (Hourly Rate)



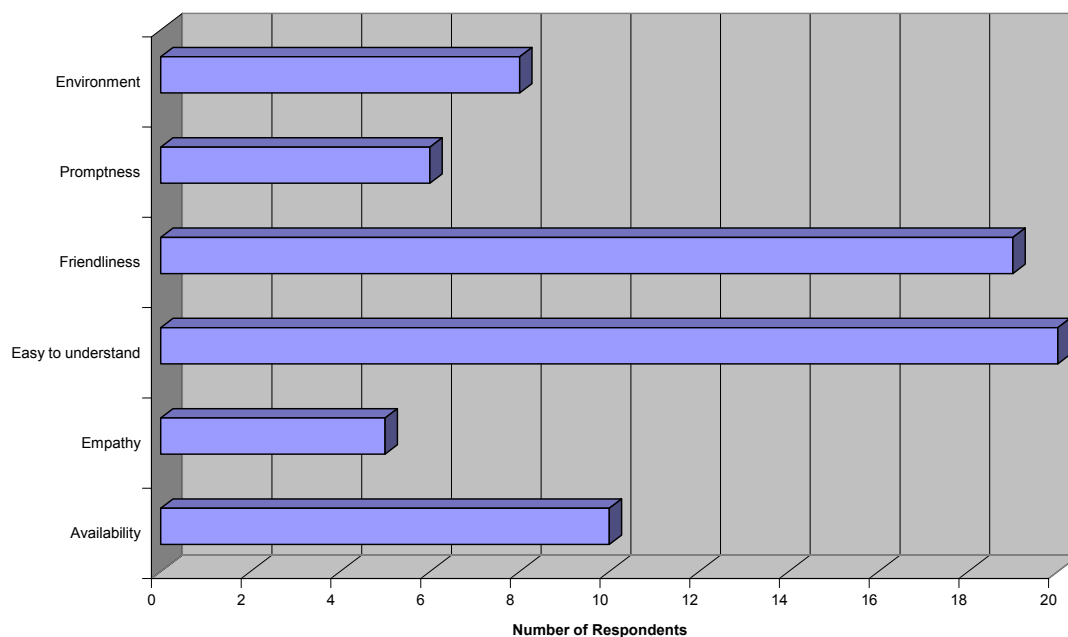
4.4.8.5 Patient Satisfaction

Patients were asked to rank their level of satisfaction with the education and follow-up session provided by the pharmacist on a 5 point Likert scale, where 1 = very dissatisfied and 5 = very satisfied. The overwhelming majority of respondents stated that they were highly satisfied with the service with which they were provided (Figure 4.42).

Figure 4.42: Satisfaction Rating of the DMEP



Unprompted reasons given for the high level of satisfaction included the information provided was “easy to understand” (n = 20), “friendliness” (19) of the pharmacist providing the service, “availability” of the service (10), the “environment” (8) in which the service was provided, the “promptness” (6) of the service provision and the “empathy” (5) shown by the pharmacist (Figure 4.43).

Figure 4.43: Factors Associated with High Ratings of Patient Satisfaction

Based on their experience of being involved in the study, the majority of respondents (93.6%) either agreed (13; 27.7%) or strongly agreed (31; 65.9%) with the concept of pharmacists providing diabetes education services.

4.4.9 Pharmacist Satisfaction Evaluation

A focus group meeting involving project pharmacists from the intervention and control pharmacies, as well as diabetes education pharmacists was held in May 2005, to obtain feedback on the DMEP program. The facilitator worked through a semi-structured questionnaire with input from all pharmacists. An audiotape recording was made of the meeting and presented below is a synopsis of the pharmacists' comments and suggestions.

4.4.9.1 Project Pharmacist Training Prior to Embarking on Recruitment Phase (Explanation of the Aims of the Study)

Pharmacists reported that the 2 days of training received, adequately prepared them to confidently explain the project to potential participants and to equip them to answer their questions regarding diabetes management. With their training they were able to promote the advantages of the program to participants who would be allocated to the Intervention Arm of the study. It was perceived as more difficult to recruit patients into the Control Arm of the study as there were no individual educational benefits for such patients. Nevertheless, the patients who enrolled as control patients inherently were more motivated to improve their diabetes management and this may influence degrees of difference detected between the two arms of study.

4.4.9.2 Time Required to Recruit Patients

For intervention sites, it usually took between 10 to 15 minutes for the pharmacist to get agreement from a patient to enter the study. In some instances, this may have followed a period of discussion between patient and pharmacy assistant (especially assistants with special training in diabetes services) who could outline the project basics, promoting the study benefits.

The enrolling pharmacists felt that the key to a patient agreeing to participate was being able to demonstrate to them clear health benefits that would flow from the study such as learning more about their diabetes. However, it was acknowledge that some participants were also motivated by altruistic reasons, such as the idea that their participation may help other with diabetes in the future. Particularly, if the study could show the Federal Government a health benefit from the service, which may lead to funding for such a service. The project pharmacists reported aspects of the program which appealed to participants in the Intervention Arm were as follows:

- Education was streamlined, individualised and available at the pharmacy that they visited regularly

- Gaining accessibility to other available diabetes education programs could be problematic and also it was sometimes difficult to get into these programs
- Tailored rather than a generic education program was well received. Identifying the educational areas that they knew nothing or little about was important.

4.4.9.3 Recruitment of Control Participants

The time involved in recruiting patients varied dependent on which arm of the study they were in; Intervention or Control. Pharmacists reported that showing the prospective participants the Information Sheet and explaining the protocol of the program and then having the patient sign the Patient Consent Form took about 10-15 minutes. In the case of patients enrolled into the Control Arm of the study, if they stayed in the pharmacy to complete the entry questionnaires then it would take another hour to do so. This also included calculation of BMI, weight check and explanation of the diary by the Project Pharmacist. In the Intervention Pharmacies it was estimated that it took about half an hour to explain the questionnaire format and discuss the various aspects of the diary.

Some participants joined the study having heard about it previously prior to being approached to participate. They had heard about the project from other members of their Diabetes Support group, at meetings. The Project Pharmacists felt that if this model were to be adopted as a service for pharmacy delivery in the future then a viable option to promoting the program would be to use well-trained pharmacy assistants to outline the service to the patient prior to the patient speaking to the pharmacist.

4.4.9.4 Participant Motivation

Project Pharmacists from the control pharmacies believed that the patients that agreed to participate in this arm of the study were usually more highly motivated

in their disease management. People approached said either a definite **“yes”** or **“no, they couldn't be bothered”**, and these latter patients were generally people who the pharmacist felt would benefit from better disease management.

Some customers, loyal to the pharmacy appear to have felt obliged to say **“yes”** to participate and then withdrew; some customers' loyalty to the pharmacy meant they persevered with the program. It was more common for participants not loyal to the pharmacy to drop out of study more readily. Loyalty to the pharmacy may also be the reason some patients completed the study although they may have struggled with it at times.

It was felt that a person's intention to participate in the study was basically personality driven. The Project Pharmacists felt the fact that the pharmacy was in the Intervention or Control arm of the study had very little effect on the participants' intention to participate.

4.4.9.5 Questionnaires

The amount of material in the questionnaires to be completed on entry was slightly daunting for participants. It was felt that the questionnaires were “paper intensive”. The paper work was a screen to entering the study especially for those whose first language is not English. For this reason, in some pharmacies people with known English difficulties were not approached to enter the study.

So as not to create a barrier to study participation, the Project Pharmacists thought that a maximum of four pages of questions would be preferable. The consensus was it should only take about 20-30 minutes to complete and that people would be prepared to sit down and complete this amount at entry. It was thought it would be easier to market the service if there was less paperwork to be completed at enrolment. Pharmacists believed that the questionnaire should include a medical profile and easily accessible data but perhaps not data such as HbA1c. Simpler, familiar, easy to locate clinical information should be requested so participants could **“learn to walk before they ran”**. They felt that

discussion of more complex information could be introduced later in the program timeframe.

Pharmacists reiterated the need to reassure participants that it was OK to tick "**unsure**" in response to some questions. If this were to be provided as an on-going pharmacy service then it would be easier to market as there would be no need to use quality of life tools, such as the SF-36 questionnaire.

4.4.9.6 Diaries

Project pharmacists believe that the diary should be A5 rather than A4 so it is more compact and focussed, easier to carry around and hence more likely to be utilised. Possibly it should be only a few (or 2-3) pages in length, including items such as weight recording, BGL and doctors' appointments. Although the information pages, including patient goals, were valued by participants, it was believed that these should have been separated out as a discrete booklet so core material to be recorded or monitored doesn't get "lost". A general comment was that the method of recording BGLs should be rethought – use of Accucheck® monitor or similar and subsequent downloading onto pharmacy software so that it can be printed out and given back to patients. It was thought that another format for the requesting Clinical data from GP or specialist should be investigated and used. Consistency of format could be improved.

4.4.9.7 Cancellation of Appointments

Despite the fact that participants were phoned as a reminder prior to appointments, participants would often fail to attend the assigned times. Missed appointments were rebooked or rescheduled to accommodate holidays, illness, etc. If participants decided to withdraw from the project they usually notified the project pharmacist and returned the remaining project material. The process of appointment reminder phone calls was reported to be time consuming but it was

felt that phoning to reconfirm appointments was an essential component of the process.

The Project Pharmacists reported that some people, who were not regular customers, and who had withdrawn from the project, did not return to the pharmacy for other services. Further, regular customers who were not compliant with the project protocol would exhibit **“avoidance”** behaviour towards project pharmacists.

For the education program to work efficiently **“the process is best served by allocating a dedicated time to carry out tasks without interruptions”**. Additional staffing levels make the process easier to manage so the pharmacist can be dedicated to recruitment and education in disease state management.

4.4.9.8 Follow-Up Sessions

Most pharmacists thought participants were happy to return for follow up sessions (at 1, 3, and 6 months) because they were aware it formed part of the study protocol, they were expected to attend and were happy to come back as they were learning a great deal through the process.

The process of scheduling follow-up sessions was seen to provide feedback to patients, and enhance pharmacist-patient relationship in providing expert attention. The fact that all sessions were free of charge was an added incentive.

As the government was funding the project, intervention patients **“valued the service, and considered it a privilege, not a chore”**.

4.4.9.9 Consultant versus Regular Pharmacist in Delivery of Service

In intervention pharmacies the participants appreciated that the regular pharmacists had organised for them to receive expert one-on-one consultations,

regarding their diabetes. The regular pharmacist's involvement in their recruitment into the project provided a tangible link to the consultant educator. Added benefit could be seen if the pharmacist dispensing the patients' prescriptions also delivered the education because it provided an opportunity to "touch base" and reinforce points raised or goals set during education sessions. Some Project Pharmacists felt disengaged in the education process, as the educator attended the pharmacy on their day off so there was no opportunity in these circumstances to carry out a face to face briefing session with the pharmacist educator, post appointment. They would have preferred greater involvement and linkage between recruitment and appointments within the pharmacy, feeling that if they had been more involved then discussions with the participants from their pharmacy could have been more specific when dispensing a prescription for them.

Similar problems would exist where the pharmacy employs multiple pharmacists and highlights the need for a system of summaries of appointments and the issues reviewed, that could be flagged in patient computer records and discussed with other pharmacists working at the pharmacy.

4.4.9.10 Patient Feedback

The more self-motivated the patient the more they appeared to benefit from the program, and they had a greater understanding of why they do certain tasks such as record their BGLs. Pharmacists got positive feed back from patients. Outcomes still improved for the **"well informed"** patients (e.g. weight loss) and problems were identified in these patients.

In completing the questionnaires, the control and intervention patients would comment on various aspects of the questions, triggering them to take a closer look at their disease, to **"take stock"** of their situation. It identified issues they knew little about. Questionnaires provided triggers for them to talk with their GP regarding HbA_{1c} levels and testing, and to open discussions with the GP

regarding BGLs. Previously some patients had never shown BGL results to the GP or realised why it was necessary to monitor them.

4.4.9.11 General Practitioner/Specialist Communications

The project did not raise many comments from GPs. Two pharmacists commented that while they did not have any direct comments from local GPs, their patients informed them that they had mentioned their participation in the study to their doctors who told these patients they thought it was a good idea to be participating in the process.

One GP told the patient that he would not provide HbA_{1c}, lipid levels and other tests results to the patient for him to give to the pharmacist. Another GP would not provide a report of the patient's clinical results without a payment of an AUD 200 fee. One GP raised the issue that obtaining laboratory data would be seen as Medicare fraud if the test was carried out for purpose of the study. However GPs were only asked to test in accordance with best practice standards, and were only asked to provide results that they already had.

The head of diabetes educators and individual diabetes educators were initially apprehensive of the study, but were subsequently reasonably satisfied when they realised that pharmacists were not trying to "***steal their turf***". They were happy that pharmacists were identifying knowledge deficits and thereby complementing their work. The diabetes educators in Mandurah were extremely supportive and sent patients to join the study. In the future this might become a source of referrals for pharmacy education programs.

4.4.9.12 Common Themes in Program Outcomes

The tailored education program was an appealing concept to study participants. Even though all participants were treated as individuals, there were some reoccurring themes such as weight loss and the need for a program of exercise that the patient was prepared to put into practice on a regular basis. Comment was made that patients should be encouraged to acknowledge and gain positive feedback and motivation from small increments of positive change and to set realistic goals for themselves. The patients appeared to gain motivation from their regular follow up visits to the pharmacy. They were pleased that someone was taking an interest in their BGL. The pharmacists felt that the use of the Medisense® software reporting package would further enhance this process so the patient can plot how many times their levels were high, low or within normal range.

Pharmacists found that many patients were not familiar with the following concepts:

1. What diabetes means in terms of a disease state and what it means not to have diabetes
2. Type 1 and Type 2 diabetes
3. Insulin resistance
4. How their drugs work and why they take them
5. Where glucose fits into their management and treatment of their disease or why they measure their blood glucose levels.

It was felt that better understanding of these issues resulted in better patient concordance with therapy and lifestyle modifications.

4.4.9.13 Patient Payment for Service

Some of the pharmacists thought that patients would not want to pay for their education service as the current culture of service provision by pharmacy does not foster such a concept. Others thought willingness to pay may be demographic and social status dependent, and some patients may be happy to pay a fee for service if they can see tangible benefits for their disease management through weight loss etc.

Educator pharmacists felt that irrespective of health benefits and improvement in their disease management, for some elderly patients especially, the process had helped them overcome feelings of isolation and given them a sense of belonging to a community. This is a positive aspect of the service that needs to be promoted when seeking funding for it.

It was suggested that in the future patients may sit at a terminal to complete a questionnaire to identify their educational deficiencies and they may then select educational units to which they could listen individually or they might opt for an individual face-to-face educational session with a pharmacist.

4.5 Health Resource Utilization

The health resource utilisation focused on medical and related consultations, investigations, hospital attendances and admissions. After obtaining written consent from each patient Medicare (MBS) and Pharmaceutical Benefit Scheme data was obtained from the Health Insurance Commission and mortality, emergency department attendances and hospital admissions data from the Western Australian Data Linkage Unit (WADLU). Health resource utilisation was compared in the following three periods:

- . • Period 1 (Pre-Study Period): 6 months prior to the study
- . • Period 2 (Study Period): 6 months of the study
- . • Period 3: (Post-Study Period): 6 months after the completion of the study.

4.5.1 Completeness of the Data

There were 132 patients who finished the study (76 controls and 56 in the Intervention group). A number of subjects had to be omitted from the analysis due to incomplete data as outlined below.

1) Hospital morbidity data (Diagnoses and Length of stay)

The data for hospital morbidity was analysed using a 6-month follow-up period since there were 24 patients with total follow up period less than 12 months (last record of hospital admission provided by the WADLU 26th May 2005). There were three subjects with incomplete 6-month follow-up data (Period 3), but who had complete data for the other 2 periods.

2) PBS and Medicare data

Despite a request for data to span the period 6 month pre-enrolment to 12 months post-enrolment the PBS and MBS data provided by the Health Insurance Commission for all patients finished on or before the 30th June 2005. This meant that the data sets for a number of the participants in the study were incomplete as

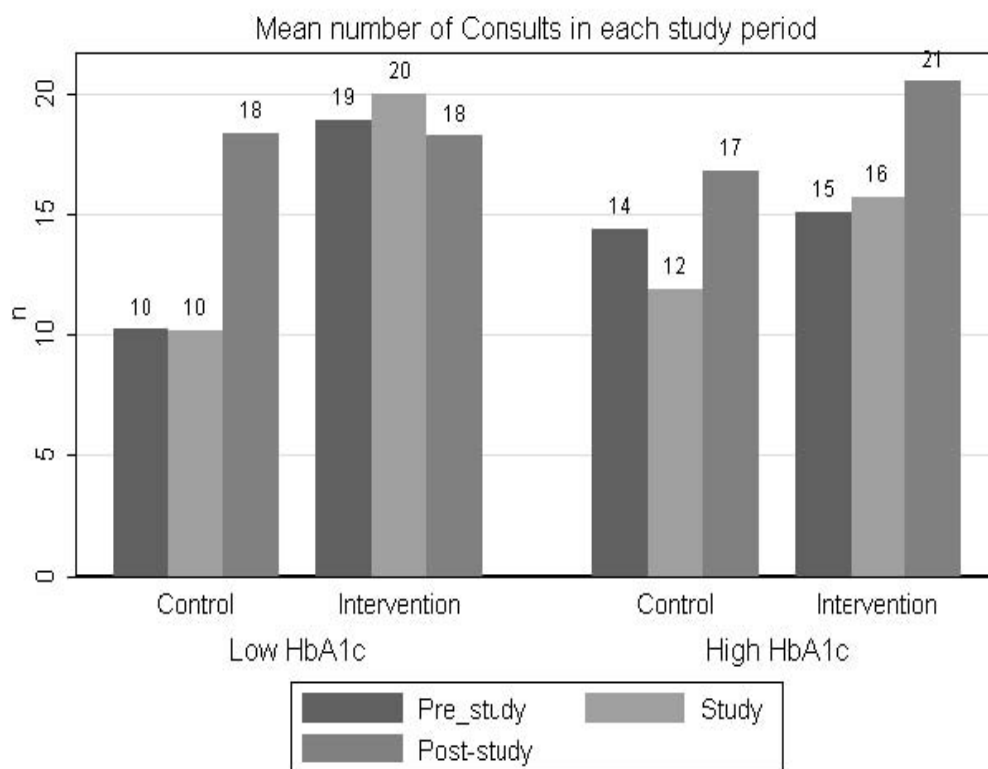
detailed below:

- Three patients started the study after 30/06/2004 and were excluded from the Pre- study period.
- Sixteen patients had incomplete Study period data (i.e. completed the study after 30/06/2004) and were therefore omitted from the Study period analysis.
- Seventy-four patients had incomplete Follow up period data (i.e. their 6-month follow up date was after 30/06/2004) and were therefore omitted from the Follow-up period analysis.

4.5.2 Medical Consultations

Medicare data was used to quantify the utilisation of outpatient health resources.

Figure 4.44: Mean Number of Medicare-Rebated Services Utilised



Figures 4.44-4.46 and Table 4.77 summarise use Medicare-rebated services utilised by patients in the Intervention and Control Groups, both as a whole and within the sub-groups of patients with low baseline HbA1c ($\leq 7\%$) levels and high

HbA1c (> 7%) levels. Using Mann-Whitney tests no significant differences in the utilisation of these resources was demonstrated between any of the groups.

Figure 4.45: Frequency Histograms for Medicare-Rebated Consultations for Patients with Low Baseline HbA1c Levels

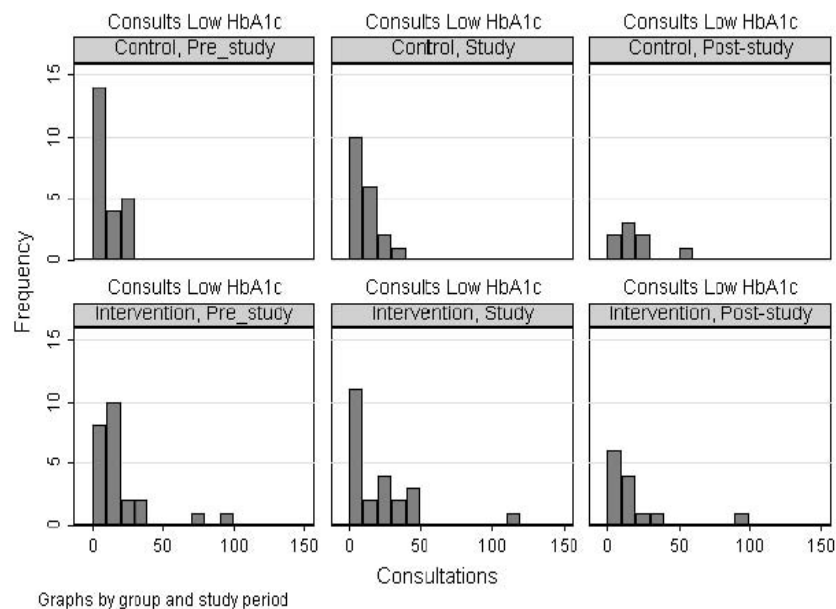


Figure 4.46: Frequency Histograms for Medicare-Rebated Consultations for Patients with Low Baseline HbA1c levels

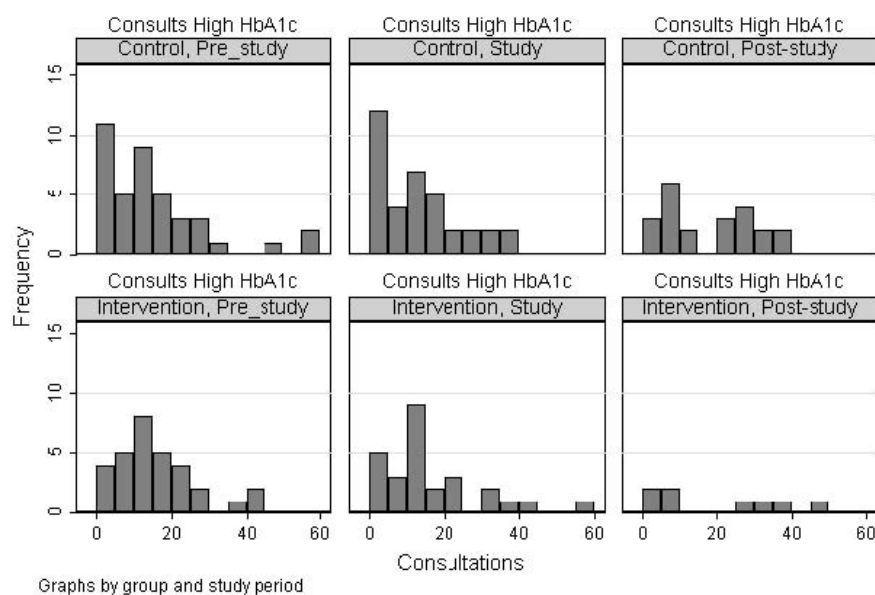


Table 4.77: Medicare-Rebated Medical Consultations

	All Patients			Low HbA1c			High HbA1c		
	Period 1	Period 2	Period 3	Period 1	Period 2	Period 3	Period 1	Period 2	Period 3
Control Group									
No. Patients	73	65	34	23	19	8	40	36	22
Consultations	1039	740	574	235	194	147	575	428	370
Median	12	10	16	8	9	16	12.5	10	17
Minimum	0	0	0	0	0	0	0	0	0
Maximum	112	38	51	30	38	51	57	38	40
Intervention Group									
No. Patients	56	51	21	24	23	13	31	27	8
Consultations	920	884	401	453	460	237	467	424	164
Median	13.5	12	11	14	11	11	13	12	19
Minimum	0	0	0	0	0	0	0	0	0
Maximum	99	113	93	99	113	93	44	60	50
<i>p values</i>	0.38	0.17	0.75	0.18	0.26	0.49	0.60	0.28	0.64

Poisson regression analysis was undertaken to assess the effect of the Intervention on the number of consultations. Results were reported as incident rate ratios (IRR), i.e. relative increase in number of consultations for the Intervention Group versus the Control Group (Table 4.80); and where an $IRR < 1$ suggests a reduction in the number of consultations. As can be seen from the results presented in Table 4.78, with the exception of the Period 2 vs Period 1 comparison for those patients with low HbA1c's the Intervention was associated with reductions in the number of consultations in all other cases, however these changes failed to attain statistical significance.

Table 4.78: Effect of the Intervention on the Number of Consultations

	Sub-Group	IRR	SE	z	p-value	95% Confidence Intervals	
Period 2 vs Period 1	Low HbA1c	1.12	0.17	0.77	0.44	0.83	1.52
	High HbA1c	0.87	0.32	-0.39	0.70	0.42	1.79
Period 3 vs Period 1	Low HbA1c	0.79	0.16	-1.11	0.27	0.53	1.19
	High HbA1c	0.61	0.25	-1.22	0.22	0.28	1.35
Period 3 vs Period 2	Low HbA1c	0.70	0.14	-1.82	0.07	0.48	1.03
	High HbA1c	0.54	0.22	-1.51	0.13	0.24	1.20

4.5.3 Investigations

The influence of the Intervention on the number of investigations performed was assessed using the Medicare data. Figures 4.47 and 4.48 shows the frequency of investigations undertaken for patients with low and high baseline HbA1c levels.

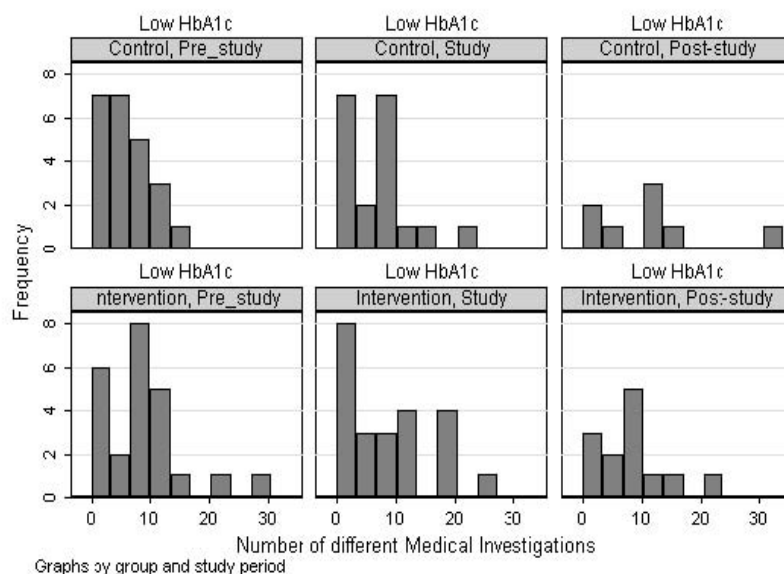
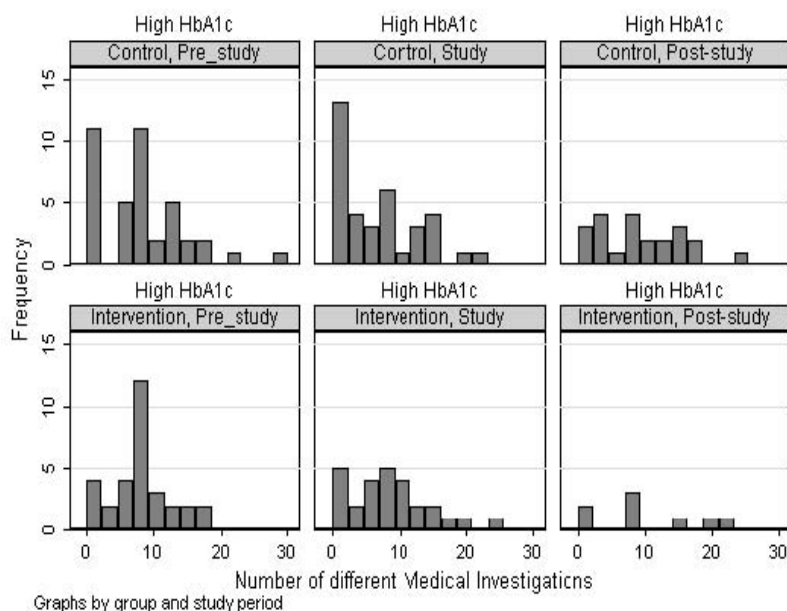
Figure 4.47: Frequency of Investigations Undertaken for Patients with Low Baseline HbA1c levels

Figure 4.48: Frequency of Investigations Undertaken for Patients with High Baseline HbA1c levels



As can be seen from the data presented in Table 4.79 patients in the Intervention Group had more investigations than those in the Control Group during the 6 months prior to the study and the 6 months of the study, although the differences were not statistically significant. In the 6 month post-study period the reverse was true in the case of “All Patients” and those with “Low HbA1c”; however again the differences were not statistically significant.

Table 4.79: Number of Investigations Undertaken

	Number of Investigations [mean±SE]		No. of Patients		p value
	Controls	Intervention	Controls	Intervention	
Period 1 (Pre-study)					
All Patients	7.4 ± 0.8	8.1 ± 0.8	73	56	0.25
Low HbA1c alone	5.8 ± 0.95	8.6 ± 1.4	23	24	0.12
High HbA1c alone	7.7 ± 1.0	8.0 ± 0.85	40	31	0.58
Period 2 (Study Period)					
All Patients	6.5 ± 0.7	8.2 ± 0.9	65	51	0.15
Low HbA1c alone	6.0 ± 1.3	8.2 ± 1.5	19	23	0.36
High HbA1c alone	6.6 ± 1.05	8.6 ± 1.2	36	27	0.18
Period 3 (Post-study)					
All Patients	9.3 ± 1.3	8.6 ± 1.5	34	21	0.79
Low HbA1c alone	11.5 ± 3.8	7.8 ± 1.7	8	13	0.36
High HbA1c alone	9.1 ± 1.4	10.0 ± 2.9	22	8	0.76

Regression analysis was undertaken to compare changes in number of investigations as a result of the Intervention. This involved the use of generalised estimating equations using Poisson regression with an exchangeable correlation structure, use of scaling and robust standard errors. Although the Intervention appeared to result in an increase in the number of investigations undertaken during the study period (Period 2), both in patients with low and high HbA1c, the differences did not attain statistical significance. Comparison between the number of investigations performed post-study and pre-study (Period 3 vs Period 1), and post-study and during the study (Period 3 vs Period 2) showed a reduction in the number of investigations as a result of the Intervention, however again the differences did not attain statistical significance (Table 4.80)

Table 4.80: Effect of the Intervention of Investigation Rates – Regression Analysis

	Subgroup	IRR	SE	z	p-value	95% Confidence Intervals	
Period 2 vs Period 1	Low HbA1c	1.09	0.16	0.62	0.53	0.82	1.45
	High HbA1c	1.09	0.34	0.27	0.78	0.59	1.99
Period 3 vs Period 1	Low HbA1c	0.81	0.15	-1.18	0.24	0.57	1.15
	High HbA1c	0.80	0.25	-0.71	0.48	0.44	1.47
Period 3 vs Period 2	Low HbA1c	0.74	0.14	-1.58	0.11	0.51	1.07
	High HbA1c	0.73	0.23	-0.98	0.33	0.39	1.36

4.5.4 Medications

The Pharmaceutical Benefits Scheme data was used to assess the influence of the Intervention on medication usage. This data is unfortunately incomplete, in that it only provides information on those medications for which the dispensing pharmacist receives re-imbursement from the Health Insurance Commission. Figure 4.49 shows the changes in individual patient's medication usage over the duration of the study. The data presented in Table 4.81 shows that patients in the Control Group on average received fewer PBS medications than those in the Intervention Group, and that those with high HbA1c's received more than those with low HbA1c's, however the differences were not statistically significant.

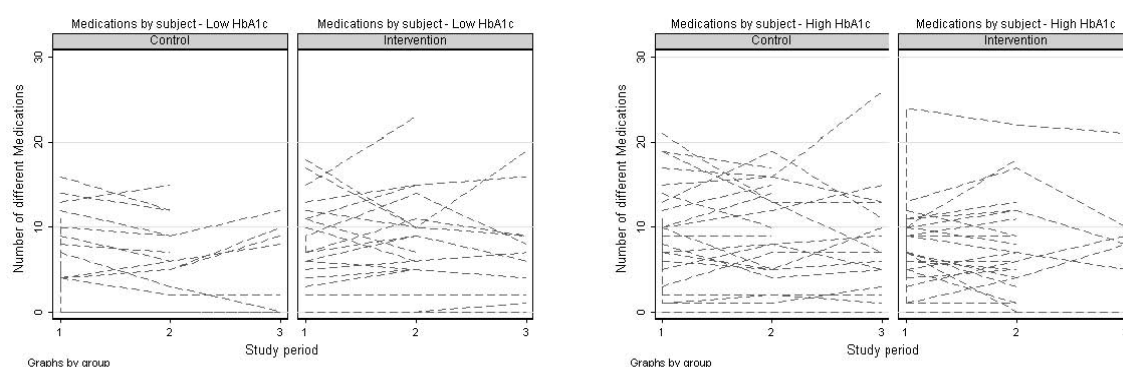
Figure 4.49: Changes in PBS Medication Usage

Table 4.81: PBS Medication Usage

	Number of different Medications (mean ± SE)		Number of Patients		p value
	Controls	Intervention	Controls	Intervention	
Period 1 (Pre-study)					
All Subjects	6.1 ± 0.7	6.7 ± 0.7	73	56	0.34
Low HbA1c alone	5.8 ± 1.1	6.8 ± 1.2	23	24	0.58
High HbA1c alone	6.0 ± 1.0	6.9 ± 0.9	40	31	0.29
Period 2 (Study period)					
All Subjects	5.6 ± 0.7	6.9 ± 0.8	65	51	0.25
Low HbA1c alone	5.3 ± 1.1	7.0 ± 1.3	19	23	0.38
High HbA1c alone	5.6 ± 1.0	7.1 ± 1.2	36	27	0.25
Period 3 (Post-study)					
All Subjects	6.3 ± 1.1	6.8 ± 1.3	34	21	0.77
Low HbA1c alone	5.1 ± 1.8	6.2 ± 1.7	8	13	0.85
High HbA1c alone	6.1 ± 1.4	7.6 ± 2.4	22	8	0.57

Regression Analysis was undertaken to assess the effect of the Intervention on changes in medication use. This involved the use of generalized estimating equations using Poisson regression with an exchangeable correlation structure, use of scaling and robust standard errors. Results were expressed as IRRs (Table 4.82). As was the case for “Investigations” the Intervention was associated with a greater usage of medications during the study period (Period 2 vs Period 1); however this effect was not sustained after the study (Period 3 vs Period 1 and Period 3 vs Period 2). Differences seen however were not statistically significant.

Table 4.82: Effect of the Intervention on the Use of PBS Medications – Regression Analysis

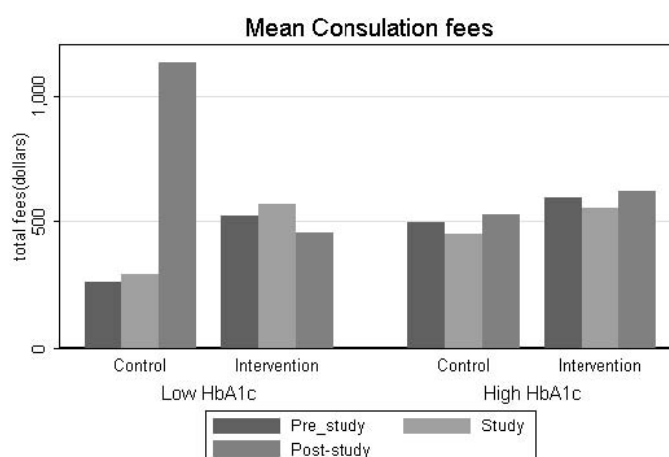
	Sub-Group	IRR	SE	z	p-value	[95% Conf. Interval]	
Period 2 vs Period 1	Low HbA1c	1.10	0.09	1.09	0.28	0.93	1.30
	High HbA1c	1.07	0.36	0.19	0.85	0.55	2.06
Period 3 vs Period 1	Low HbA1c	0.98	0.14	-0.13	0.89	0.74	1.30
	High HbA1c	0.95	0.32	-0.14	0.89	0.49	1.85
Period 3 vs Period 2	Low HbA1c	0.89	0.12	-0.82	0.41	0.68	1.17
	High HbA1c	0.87	0.291	-0.43	0.67	0.45	1.67

4.5.5 Medicare Costs

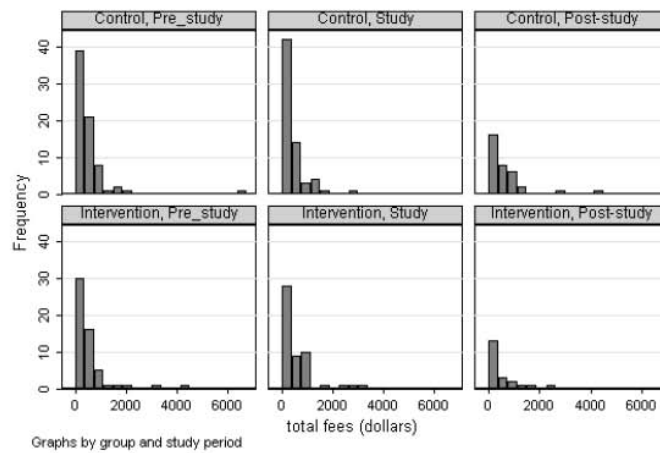
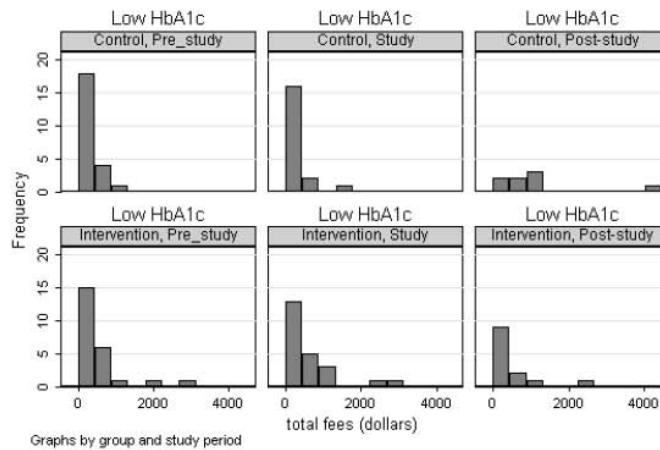
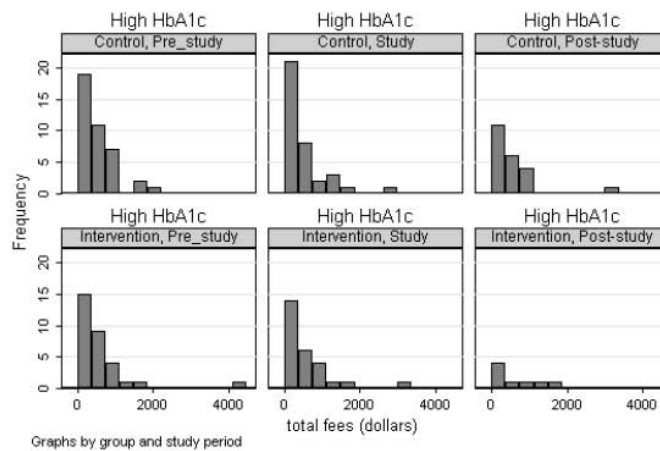
Changes in Medicare item costs over the period of the study are shown in Table 4.83 for the Control and Intervention groups and Figures 4.50 and 4.51 for the subgroups of patients with low and high baseline HbA1c levels. Univariate analysis using Mann-Whitney tests failed to demonstrate any statistically significant effect of the Intervention on Medicare item costs.

Table 4.83: Medicare Expenditure

	Cost in AUD (mean±SE)		Number of Patients		p value for difference
	Controls	Intervention	Controls	Intervention	
Period 1 (Pre-study)					
All Subjects	\$490± 96	\$553± 103	73	56	0.46
Low HbA1c alone	\$259 ± 56	\$523 ± 147	23	24	0.16
High HbA1c alone	\$498 ± 82	\$594 ± 148	40	31	0.83
Period 2 (Study period)					
All Subjects	\$388 ± 62	\$548 ± 99	65	51	0.23
Low HbA1c alone	\$293 ± 91	\$568 ± 152	19	23	0.23
High HbA1c alone	\$453 ± 98	\$552 ± 136	36	27	0.45
Period 3 (Post-study)					
All Subjects	\$667 ± 153	\$519 ± 143	34	21	0.48
Low HbA1c alone	\$1133 ± 503	\$457 ± 188	8	13	0.13
High HbA1c alone	\$526 ± 138	\$620 ± 231	22	8	0.71

Figure 4.50: Medicare-Rebated Consultation Fees for the Sub-Groups of Patients with Low and High baseline HbA1c Levels

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

Figure 4.51: Distribution of Medicare Expenditure Pre-, During and Post-Study**All Patients****Low HbA1c****High HbA1c**

The effect of the Intervention on changes in Medicare item costs was assessed using generalized estimating equations using Poisson regression with robust standard errors to account for clustering within pharmacies. Results are presented as changes in dollars spent due to the intervention (Table 4.84). The Intervention was associated with a reduction in Medicare expenditure during all comparator periods, however these reductions were not found to be statistically significant.

Table 4.84: Effect of the Intervention on Medicare Expenditure – Regression Analysis

	Sub-Group	Regression Coefficient	SE	z	p-value	[95% Conf. Interval]	
Period 2 vs Period 1	Low HbA1c	-24.4	138.8	-0.18	0.86	-296.4	247.5
	High HbA1c	-107.4	253.1	-0.42	0.67	-603.4	388.6
Period 3 Vs Period 1	Low HbA1c	-260.7	216.6	-1.20	0.23	-685.2	163.8
	High HbA1c	-275.9	362.9	-0.76	0.45	-987.2	435.6
Period 3 Vs Period 2	Low HbA1c	-277.5	208.6	-1.33	0.18	-686.2	131.2
	High HbA1c	-292.7	322.9	-0.91	0.36	-925.7	340.3

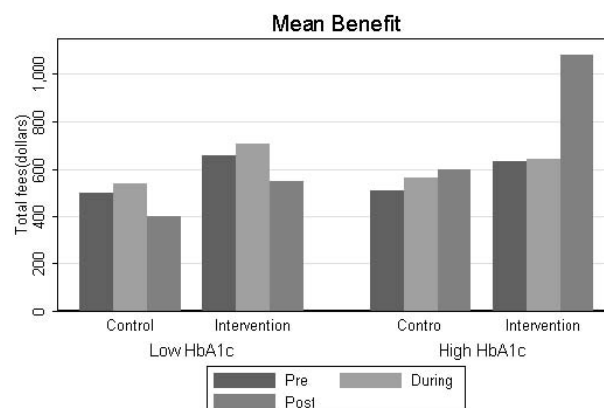
4.5.6 Medication Costs

Changes in the costs of medications provided through Pharmaceutical Benefits Scheme (PBS) over the period of the study are shown in Table 4.85 for the all Control and Intervention patients and Figures 4.52 and 4.53 for the subgroups of patients with low and high baseline HbA1c levels. Whilst the mean cost of PBS medications per patient were generally higher amongst Intervention patients, univariate analysis using Mann-Whitney tests failed to demonstrate any statistically significant difference in the changes in medication costs across the period of the study (Table 4.85).

Table 4.85: PBS Medication Costs

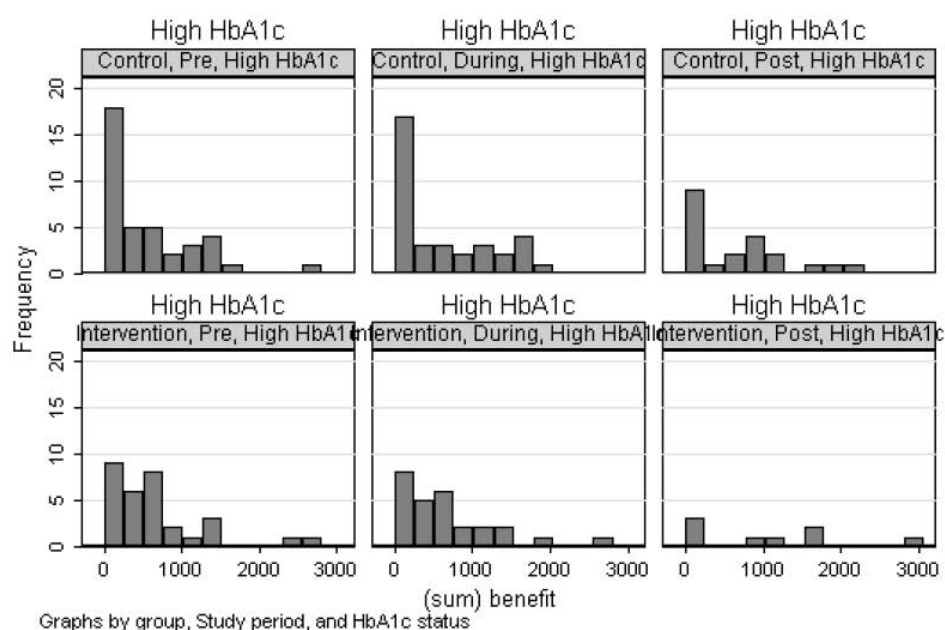
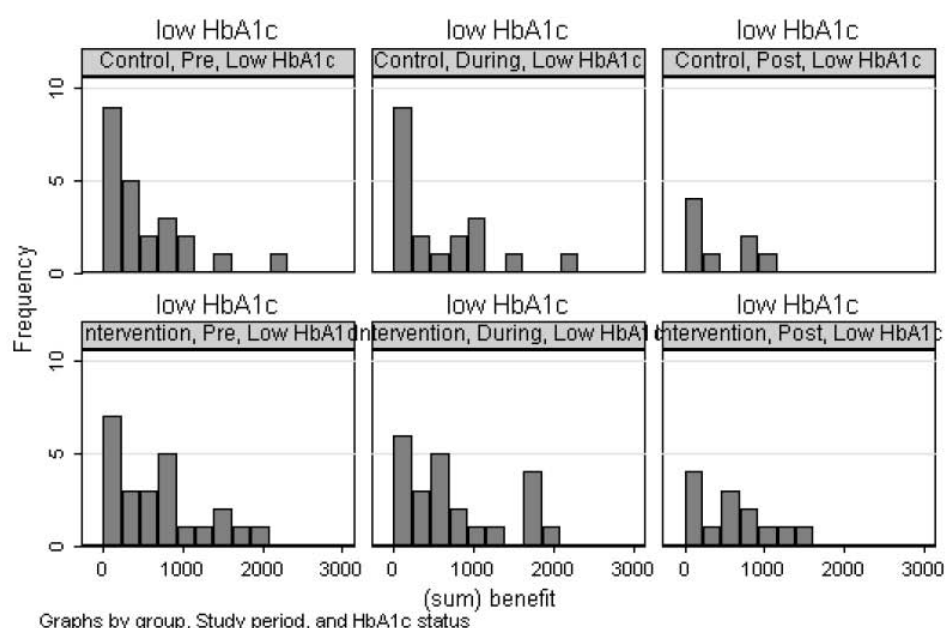
	Cost per Patient in AUD (mean ± SE)		Number of Patients		p value for difference
	Controls	Intervention	Controls	Intervention	
Period 1 (Pre-study)					
All Subjects	\$515 ± 67	\$634±84	73	56	0.22
Low HbA1c alone	\$502 ± 116	\$659 ± 122	23	24	0.37
High HbA1c alone	\$512 ± 98	\$635 ± 119	40	31	0.24
Period 2 (Study period)					
All Subjects	\$678 ± 140	\$658 ± 92	65	51	0.41
Low HbA1c alone	\$541 ± 148	\$707 ± 140	19	23	0.44
High HbA1c alone	\$563 ± 112	\$641 ± 126	36	27	0.39
Period 3 (Post-study)					
All Subjects	\$564 ± 107	\$754 ± 171	34	21	0.40
Low HbA1c alone	\$397 ± 161	\$550 ± 137	8	13	0.54
High HbA1c alone	\$597 ± 143	\$1087 ± 375	22	8	0.26

* Mann-Whitney

Figure 4.52: Mean PBS Medication Costs for Patients with Low and High Baseline HbA1c Levels

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

Figure 4.53: Distribution of PBS Expenditure for Patients with Low And High Baseline HbA1c Levels Pre-, During and Post-Study



Regression analysis was undertaken to assess the effect of the Intervention on changes in PBS medication costs, again using generalized estimating equations with robust standard errors to account for clustering within pharmacies. From the data presented in Table 4.86 it can be seen that although the Intervention tended to

result in higher medication costs the effect was not statistically significant.

Table 4.86: Effect of the Intervention on PBS Medication Costs – Regression Analysis

	Sub-Group	Regression Coefficient	SE	z	p-value	[95% Conf. Interval]	
Period 2 vs Period 1	Low HbA1c	17.1	166.9	0.10	0.92	-310.2	344.4
	High HbA1c	-126.5	328.2	-0.39	0.70	-769.8	516.8
Period 3 vs Period 1	Low HbA1c	93.4	102.4	0.91	0.36	-107.4	294.1
	High HbA1c	222.2	423.0	0.53	0.60	-606.9	1051.3
Period 3 vs Period 2	Low HbA1c	32.09	102.5	0.31	0.75	-168.9	232.9
	High HbA1c	160.92	424.1	0.38	0.70	-670.4	992.2

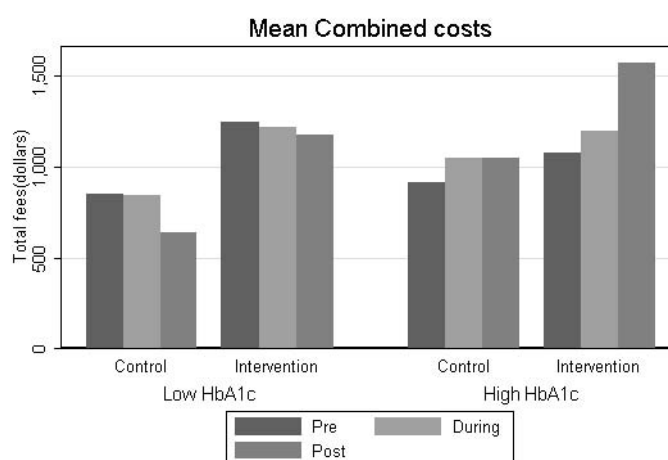
4.5.7 Combined Costs (Scheduled fees from Medicare data + Benefit from PBS data)

Changes in the costs of total treatment costs; i.e. those costs accrued through medical care (Medicare costs) and those the use of medications (PBS costs) over the period of the study are shown in Table 4.87 for the Control and Intervention groups and Figures 4.54 and 4.55 for the subgroups of patients with low and high baseline HbA1c levels. Whilst the mean total cost per patient were generally higher amongst Intervention patients, univariate analysis using Mann-Whitney tests failed to demonstrate any statistically significant difference in the changes in total costs across the period of the study (Table 4.87 and Figure 4.54).

Table 4.87: Combined Medicare and PBS Costs

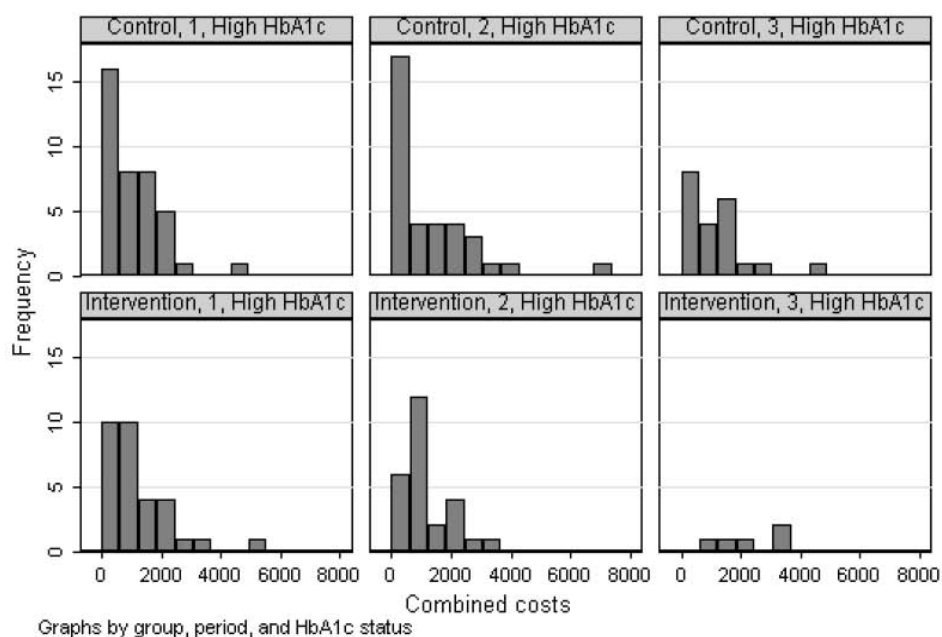
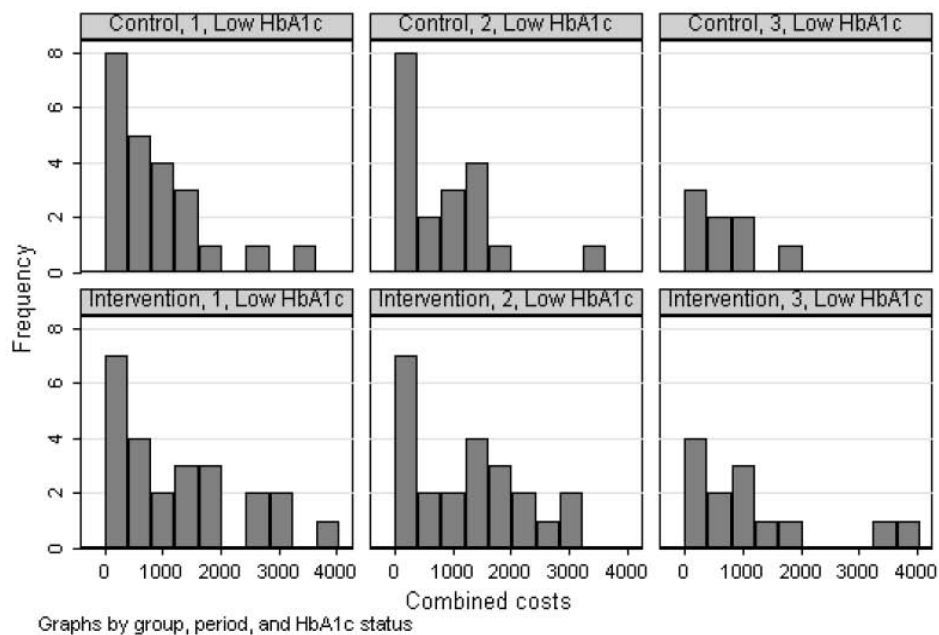
	Total Costs Per Patient in AUD (mean ±SE)		Number of Patients		p value for difference
	Controls	Intervention	Controls	Intervention	
Period 1 (Pre-study)					
All Subjects	\$978 ± 135	\$1133 ± 134	73	56	0.23
Low HbA1c alone	\$854 ± 176	\$1249 ± 235	23	24	0.27
High HbA1c alone	\$918 ± 158	\$1080 ± 157	40	31	0.25
Period 2 (Study period)					
All Subjects	\$1084 ± 171	\$1185 ± 161	65	51	0.37
Low HbA1c alone	\$846 ± 203	\$1223 ± 203	19	23	0.20
High HbA1c alone	\$1048 ± 197	\$1196 ± 250	36	27	0.51
Period 3 (Post-study)					
All Subjects	\$940 ± 158	\$1329 ± 288	34	21	0.48
Low HbA1c alone	\$641 ± 206	\$1178 ± 355	8	13	0.42
High HbA1c alone	\$1050 ± 220	\$1575 ± 507	22	8	0.45

*Mann Whitney tests

Figure 4.54: Mean Total Costs for Patients with Low and High Baseline HbA1c Levels

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

Figure 4.55: Distribution of Treatment Costs for Patients with Low And High Baseline HbA1c Levels Pre-, During and Post-Study



Regression analysis was undertaken to assess the effect of the Intervention of changes in total costs, again using generalized estimating equations with robust standard errors to account for clustering within pharmacies, but also taking into

account clustering within individuals. The data presented in Table 4.88 shows a mixed effect of the Intervention on total treatment costs, with total costs falling amongst patients with high baseline HbA1c's, but generally increasing for those with low HbA1c's. These changes however were not statistically significant.

Table 4.88: Effect of the Intervention on Total Treatment Costs – Regression Analysis

	Sub-Group	Regression Coefficient	SE	z	p-value	[95% Conf. Interval]	
Period 2 vs Period 1	Low HbA1c	-27.9	95.1	-0.29	0.77	-214.3	158.5
	High HbA1c	-244.2	393.1	-0.62	0.54	-1014.8	526.4
Period 3 vs Period 1	Low HbA1c	143.2	128.27	1.11	0.27	-109.07	395.4
	High HbA1c	-73.1	403.6	-0.18	0.86	-864.0	717.9
Period 3 vs Period 2	Low HbA1c	171.1	160.7	1.06	0.29	-143.9	486.2
	High HbA1c	-45.1	365.7	-0.12	0.90	-761.9	671.6

4.5.8 Hospital Admissions

Emergency and elective hospital admission data was obtained from the WADLU. Unfortunately the data provided was incomplete for 24 patients for the 6 month post-study follow-up period (Period 3), and hence their data were omitted from the data analysis. Figure 4.56 shows the categories of diagnoses made during the Intervention and Control patients' hospital admissions. Table 4.89 contains further data on the number of diagnoses made within the sub-categories of "Non-insulin dependent diabetes [E11]", "Diseases of the circulatory system [I00I99]" and "Diseases of the genitourinary system, structure and function [N00N99]".

Figure 4.56: Diagnoses Made During Hospital Admissions for Intervention and Control Patients

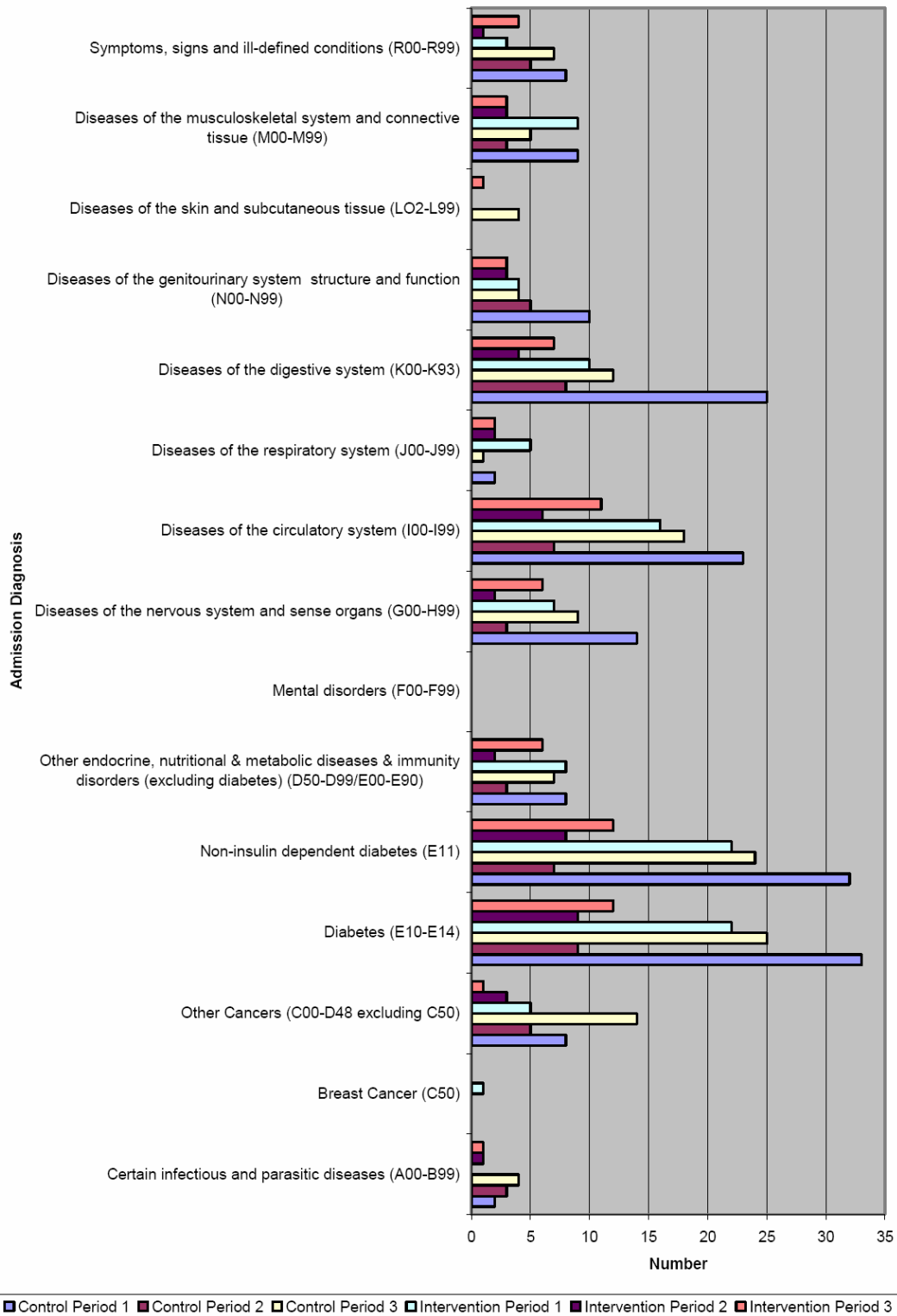


Table 4.89: Diagnoses Made During Hospital Admissions by Category and Sub-Categories

Diagnostic Categories	Control (n=76)			Intervention (n=56)		
	Pre - Study	During study	Post - Study	Pre- Study	During study	Post - Study
Certain infectious and parasitic diseases (A00-B99)	2	3	4	0	1	1
Breast Cancer (C50)	0	0	0	1	0	0
Other Cancers (C00-D48 excluding C50)	8	5	14	5	3	1
Diabetes (E10-E14)	33	9	25	22	9	12
Non-insulin dependent diabetes (E11)	32	7	24	22	8	12
<i>Non-insulin Dependent Diabetes Sub-categories</i>						
NIDDM Coma	0	0	0	0	0	0
NIDDM ketoacidosis (E11.1)	0	0	0	0	0	0
NIDDM Renal complications (E11.2)	2	0	2	0	0	0
NIDDM Ophthalmic complications (E11.3)	7	2	4	4	0	3
NIDDM Neurologic complications (E11.4)	0	0	4	0	0	0
NIDDM Peripheral circulatory complications (E11.5)	1	0	1	0	0	0
NIDDM Other specified complications (E11.6)	2	1	3	1	0	0
NIDDM Multiple complications (E11.7)	8*	1	7	1*	1	7
NIDDM Unspecified complications (E11.8)	1	0	0	0	0	0
NIDDM without complications (E11.9)	15	4#	9	17	7#	3
Other endocrine, nutritional & metabolic diseases & immunity disorders (excluding diabetes) (D50-D99/E00-E90)	8	3	7	8	2	6
Mental disorders (F00-F99)	0	0	0	0	0	0
Diseases of the nervous system and sense organs (G00-H99)	14	3	9	7	2	6
Diseases of the circulatory system (I00-I99)	23	7‡	18	16	6‡	11

	Control (n= 76)			Intervention (n=56)		
Diagnostic Categories	Pre - Study	During study	Post - Study	Pre- Study	During study	Post - Study
<i>Sub-categories of diseases of the circulatory system</i>						
Acute/chronic rheumatic fever or heart disease (I00-I09)	0	0	0	2	0	0
Hypertensive Diseases (I10-I15)	12	4	9	6	2	9
Ischaemic Heart disease (I20-I25)	7	2	3	5	2	1
Pulmonary Heart disease (I26-I28)	0	0	0	1	0	0
Other forms of Heart disease (I30-I52)	0	0	0	1	0	0
Cerebrovascular disease (I60-I69)	3	0	2	0	0	2
Diseases of arteries, arterioles and capillaries (I70-I79)	2	1	0	0	1	0
Diseases of veins, lymphatic vessels and lymph nodes (I80-I89)	2	1	0	0	1	0
Other and unspecified disorders of the circulatory system (I95-I99)	2	1	0	0	1	0
Diseases of the respiratory system (J00-J99)	2	0	1	5	2	2
Diseases of the digestive system (K00-K93)	25	8	12	10	4	7
Diseases of the genitourinary system structure and function (N00-N99)	10	5	4	4	3	3
<i>Sub-categories of genitourinary system</i>						
Other diseases of urinary system including cystitis, NM dysfunction, bladder, urethral (N30-N39)	4	3	1	0	2	2
Diseases of male genital organs (N40-N49)	2	3	1	2	1	0
Diseases of female genitourinary tract other (N70-N98)	4	0	0	1	1	0
Diseases of the skin and subcutaneous tissue (L02-L99)	0	0 _σ	4	0	2 _σ	1
Diseases of the musculoskeletal system and connective tissue (M00-M99)	9	3	5	9	3	3
Symptoms, signs and ill-defined conditions (R00-R99)	8	5	7	3	1	4

* Hospital admissions (Control n = 5 vs Intervention n = 1; p = 0.05)

Emergency Admissions (Control n = 0 vs Intervention n = 2; p = 0.01)

‡ Emergency Admissions (Control n = 0 vs Intervention n = 2; p = 0.01)

σ Hospital admissions (Control n = 0 vs Intervention n = 2; p = 0.01)

The **DMEP Study** is funded by the Australian Government Department of Health & Ageing as part of the Third Community Pharmacy Agreement.

Univariate analysis was undertaken on the data for Intervention and Control patients, and also for the sub-groups of patients with low ($\leq 7\%$) and high ($> 7\%$) baseline HbA1c values, both for elective and emergency admissions. The results of these analyses are contained in Appendix 25. The number of admissions under most categories was small limiting the power of the analysis.

In the case of the combined groups; significant differences were seen in the frequency of hospital admissions under the category of “NIDDM Multiple complications [E11.7]” during the pre-study period (Period 1). While during the study period (Period 2) significant differences were seen in the Emergency Admissions for “Diseases of the circulatory system [I00-I99]” and “NIDDM without complications [E11.9]” and hospital admissions for “Diseases of the skin and subcutaneous tissue [L02-L99]”.

Amongst the subgroup of patients with low baseline HbA1c levels statistically significant differences seen between the Intervention and Control Groups in Pre-Study Period - Hospital Admissions under the category of “Total number of diagnoses” (Intervention 20/26 vs Control 10/25; $p = 0.05$). Amongst the subgroup of patients with high HbA1c’s statistically significant differences seen between the Intervention and Control Groups in Pre-Study Period - Hospital Admissions under the category of “Diagnosis for diseases of the circulatory system [I00-I99]” (Intervention 0/31 vs Control 6/41; $p = 0.045$).

Regression analysis utilizing generalised estimating equations using a Poisson distribution for count data, exchangeable correlation structure, scaling and robust standard errors was undertaken to assess the effect on the Intervention of the on the total number of diagnoses made during hospital admissions. This analysis was repeated for admissions including diagnoses under the category of “Diabetes Diagnoses (E10-E14)”. The data was presented as estimated IRR’s, where an IRR < 1 implies a reduction in counts.

Table 4.90 contains data on the effect on the Intervention on the total number of diagnoses made during hospital admissions. In all comparisons (Period 2 vs Period

1; Period 3 vs Period 1 and Period 3 vs Period 2) the IRR's were less than 1, indicating a fall in the number of diagnoses made, however the differences failed to reach statistical significance. The same was true for admissions under the category of "Diabetes Diagnoses [E10-E14]" (Table 4.91), but again the differences did not attain statistical significance.

Table 4.90: Impact of the Intervention on Total Number of Diagnoses amongst Elective Admissions

	Sub-Group	IRR	SE	z	p-value	[95% Conf. Interval]	
Period 2 vs Period 1	Low HbA1c	0.81	0.50	-0.34	0.74	0.24	2.74
	High HbA1c	0.39	0.30	-1.24	0.22	0.09	1.73
Period 3 vs Period 1	Low HbA1c	0.58	0.34	-0.92	0.36	0.18	1.85
	High HbA1c	0.28	0.26	-1.38	0.17	0.05	1.69
Period 3 vs Period 2	Low HbA1c	0.72	0.44	-0.54	0.59	0.21	2.39
	High HbA1c	0.35	.34	-1.08	0.28	0.05	2.38

Table 4.91: Effect of the Intervention on Total Number of Diabetes Diagnoses [E10-E14] amongst Elective Admissions

	Sub-Group	IRR	SE	z	p-value	[95% Conf. Interval]	
Period 2 Vs Period 1	Low HbA1c	0.65	0.54	-0.52	0.60	0.13	3.28
	High HbA1c	0.52	0.52	-0.65	0.52	0.07	3.70
Period 3 vs Period 1	Low HbA1c	0.56	0.44	-0.74	0.46	0.12	2.65
	High HbA1c	0.45	0.49	-0.73	0.47	0.05	3.84
Period 3 Vs Period 2	Low HbA1c	0.86	0.63	-0.21	0.83	0.21	3.55
	High HbA1c	0.69	0.76	-0.34	0.74	0.08	5.85

4.5.9 Length of Hospital Stay

The length of hospital stay (LOS) data for the three periods – 6 month pre-study (Period 1), 6 months of the study (Period 2) and 6 months after the completion of the study (Period 3), are shown in Table 4.92. The only significant difference demonstrated amongst the groups using univariate analysis was a shorter LOS during the study period for those patients in the Control Group with low baseline HbA1c's (Control 0.08 days vs 0.54 days; $p = 0.02$).

Table 4.92: Length of Hospital Stay

	Length of stay (mean & range) [days]		Number of Patients		p value for difference
	Controls	Intervention	Controls	Intervention	
Period 1 (Pre-study)					
All Subjects	0.39 (0-10)	0.80 (0-32)	76	56	0.93
Low HbA1c alone	0.20 (0-2)	1.71 (0-32)	25	24	0.16
High HbA1c alone	0.29 (0-3)	0.13 (0-2)	41	31	0.34
Period 2 (Study period)					
All Subjects	0.49 (0-11)	0.45 (0-3)	76	56	0.45
Low HbA1c alone	0.08 (0-2)	0.54 (0-3)	25	24	0.02
High HbA1c alone	0.54 (0-7)	0.35 (0-3)	41	31	0.42
Period 3 (Post-study)					
All Subjects	1.30 (0-27)	0.57 (0-6)	73	56	0.43
Low HbA1c alone	0.57 (0-5)	0.71 (0-6)	23	24	0.61
High HbA1c alone	1.83 (0-27)	0.45 (0-3)	40	31	0.58

* Mann-Whitney tests

To assess the effect of the Intervention on the LOS regression analysis was undertaken. Estimates were obtained using generalised estimating equations (to account for clustering within individuals) with an exchangeable correlation structure and robust standard errors to account for clustering of pharmacies. The data from these analyses are shown in Table 4.93. A significant effect of the Intervention on the mean LOS was seen amongst those patients with high baseline HbA1c levels in the 6 month post-study period (Period 3 vs Period 1: regression coefficient = 2.62; $p = 0.044$; Period 3 vs Period 1: Regression coefficient = - 2.13; $p = 0.025$).

Table 4.93: Effect of the Intervention on the Mean Length of Hospital Stay

	Sub-Group	Regression Coefficient	SE	z	p-value	[95% Conf. Interval]	
Period 2 vs Period 1	Low HbA1c	-0.49	0.60	-0.81	0.42	-1.67	0.69
	High HbA1c	-1.75	1.08	-1.63	0.10	-3.86	0.36
Period 3 vs Period 1	Low HbA1c	-1.35	0.80	-1.70	0.09	-2.92	0.21
	High HbA1c	2.62	1.30	-2.01	0.044	-5.16	-0.07
Period 3 vs Period 2	Low HbA1c	-0.87	0.59	-1.47	0.14	-2.02	0.29
	High HbA1c	-2.13	0.95	-2.24	0.025	-3.99	-0.27

4.6 Pharmacoeconomic Evaluation

The results of the pharmacoeconomic evaluation of the DMEP service are presented in the addendum entitled: “Economics of Providing the DMEP Service.”

5. DISCUSSION

5.1 DMEP

The Diabetes Mellitus Education Program (DMEP) was designed to provide patients with type 2 diabetes with diabetes education tailored to meet their needs, together with ongoing follow-up to support these patients to achieve their therapeutic goals. The program involved an initial consultation during which information on the patient's diabetes knowledge was obtained. This information was then entered into the Cognicare CMMS[®] Diabetes Module, from which an education plan was devised for the patient. The patient was then provided with one-on-one education sessions (to a maximum of 3 hours) within a community pharmacy by a pharmacist trained in diabetes education. Following the education sessions, the patient had three follow-up visits over a period of 6 months to monitor their progress, provide further education and address any management issues. The program was successfully implemented in four intervention pharmacies in the Perth metropolitan area, Western Australia. A total of 245 patients agreed to participate in the study, in that they provided written informed consent and completed the entry questionnaires. However only 121 (Intervention Group 57, Control Group 64) completed all facets of the study. The number of participants in the study was well below the recruitment target, and has limited the statistical significance of some of the findings. Reasons for lower than expected enrolment included;

- participation of potential candidates in other diabetes studies (notably the Fremantle Diabetes Study and a type 2 diabetes study being conducted through Sir Charles Gairdner Hospital),
- the large number of patients allocated for recruitment to each pharmacy (50 patients; pharmacies in the Pharmacy Diabetes Care Program often had difficulty recruiting 10 patients),
- burden to the participants of the enrolment paperwork, and
- lack of perceived benefit, particularly amongst potential Control patients.

Unlike the Pharmacy Diabetes Care Program study, patients were not provided with a glucometer for their participation in the study.²

The groups were well matched in terms of gender, age and level of education, diabetes history and smoking history. They were also well matched on all clinical parameters (HbA1c, fasting blood glucose, blood pressure, lipids, weight and BMI). With the exception of LDL cholesterol in the Intervention Group and triglycerides in the Control Group, the mean values were all in excess of the Treatment Targets set out in the Therapeutic Guidelines: Endocrinology, 2004.⁵⁰ The average HbA1c levels for the Intervention and Control Groups were $7.34 \pm 0.18\%$ and $7.50 \pm 0.16\%$ respectively; which although not ideal, when considered with the other clinical parameters suggests that both groups had reasonably well controlled disease at baseline. In fact BMI, and hence weight, showed the greatest deviation from desired levels (Intervention Group + 6.2 kg/m^2 ; Control Group + 5.3 kg/m^2).

Patients in both groups reported similar number and frequency of hypoglycaemic and hyperglycaemic reactions, although hyperglycaemia was more prominent in both groups. This is not surprising, as the risk from hypoglycaemia at any HbA1c level for type 2 diabetics is approximately 10 times less than the risk for type 1 diabetes.⁵⁴ Phillips and Phillipov state “Many patients with type 2 diabetes are overly concerned about hypoglycaemia. It is unusual for someone with type 2 diabetes to require hospital attendance/admission for hypoglycaemia and the majority of such episodes are for type 1 diabetes.”⁵⁴ Less than 10% of patients in both the Intervention and Control Groups reported hospital admission due to hypoglycaemia in the last year.

The Groups were also well matched for diabetes complications, with 61.6% (45/73) Intervention patients and 62.9% (61/97) of Control patients responding “yes” to the presence of any diabetes complications. Amongst the specific complications enquired about the only difference was seen in the incidence of postprandial nausea, which was more prominent (48% vs 32%) amongst the Intervention patients; the reason for this is unclear.

The pharmacological management of both groups was comparable, with the only significant difference existing in the proportion of patients receiving an oral hypoglycaemic agent (Intervention 100% vs Control 92.5%; $p = 0.01$). A similar

proportion of patients were receiving treatment for hypertension, hyperlipidaemia and diabetes complications. Agents acting on the renin-angiotensin-system (i.e. ACE inhibitors and angiotensin II receptors antagonists) were prominent amongst the hypertensive medications used (prescription rates of 60% (33/55) and 53.7% (37/69) in the Intervention and Control Groups, respectively). However given that these agents are recommended first-line antihypertensive agents⁵⁵ for diabetic patients because of their renoprotective effects, their degree of use, may be less than optimal. So too may be the use of lipid lowering agents (used in 51.4 % of Control and 64.6% of Intervention patients), given recent evidence to suggest that they can reduce the incidence of cardiovascular events in diabetic patients, irrespective of their lipid levels.⁵⁶ However, such widespread use is constrained by the Pharmaceutical Benefit Scheme eligibility criteria. Aspirin prophylaxis is recommended for diabetic patients aged greater than 30 years with at least one additional cardiovascular risk factor.^{57,58} Given the fact that no patient in the study was aged less than 30 years, the frequency of use of antiplatelet agents might have been expected to be higher (Intervention 25.5% [14/55]; Control 33.3% [23/69]). Use of complementary medicines was comparable between the Intervention and Control Groups. The majority (>95%) of patients in both groups stated they had been told how and when to take their medications, and greater than 85% of patients in both groups reported taking the medications regularly at the correct time.

The two groups were well matched in relation to diet, alcohol consumption and physical activity; all of which are critical to good diabetes control. They were also well matched with regards to training in preventative foot and dental care, however the level of training in both these areas was less than ideal (i.e. 100%).

Patient self-monitoring is seen as critical in attaining good patient outcomes in diabetes management.⁵⁹ The degree of self-monitoring between the two groups was comparable with regards to blood glucose levels, weight and blood pressure. BGL monitoring was the most commonly form of self-monitoring with over 95% of patients in both groups regularly monitoring their BGLs (~ twice daily; ~ 4 days per week). Patients in both groups were common members of the Western Australian Branch of Diabetes Australia, however a significantly larger

proportion of patients in the Intervention Group were also members of a local diabetes support group (13.4% [11/82] vs 2.8% [3/107]; $p = 0.006$). The latter is related to the fact that one of the Intervention pharmacies operated its own diabetes support group.

At enrolment a significantly larger proportion of patients in the Intervention Group reported having received some form of diabetes education (84.0% vs 70.3%; $p = 0.05$), which was of longer duration ($p = 0.05$) than those in the Control Group. Despite this, the groups did not display any significant differences in their knowledge of a wide range of diabetes related topics, including the treatment and prevention of hyperglycaemia and hypoglycaemia.

The frequency of monitoring for diabetes-related complications is seen as a process indicator of the quality of diabetes care.⁶⁰ It is recommended that diabetic patients should have their feet examined every 6 months, their eyes every 1-2 years (more frequently if there is retinopathy) and have their urine checked for protein annually.^{50,61} Whilst the patients in the Intervention and Control groups were well matched in terms of ongoing monitoring for diabetes complications, the monitoring rates reported were below optimal target. Patients' satisfaction with their level of diabetes care was similar for both groups (majority of patients stating it was average or good), and patients in both Groups shared a similar willingness to improve their diabetes care.

Based on the results of their Diabetes Symptom Checklist and SF-36 Health Survey forms, patients in both groups were well matched in terms of their level of disability from the disease, and the impact of diabetes on their quality of life. This is consistent with their similar levels of diabetes complications which have been shown to influence quality of life.

5.2 Educational Interventions

The goal of diabetes self-management education is to engage in an interactive, collaborative and ongoing process between the person with diabetes or prediabetes and the educator with the objective of supporting self-management and ultimately improving patient outcomes.⁶² The process includes:

- Assessment of the individual's specific education needs.
- Identification of the individual's specific diabetes self-management goals.
- Education and behavioural intervention directed toward helping the individual achieve identified self-management goals.
- Evaluation(s) of the individual's attainment of identified self-management goals.
- Proper documentation of all education encounters.⁶²

The DMEP was designed in such a way as to meet this goal through initial individualised education sessions, and ongoing follow-up designed to support self-management.

There were a wide range of topics addressed during the one-on-one education sessions. The most common related to glycaemic control and included;

- hypoglycaemia (41/58; 71% of patients) and hyperglycaemia (40; 69%),
- the carbohydrate connection (40; 69%), and
- oral hypoglycaemic agents (35; 60%) and insulin (8/10; 80%).

This focus is consistent with the findings of Heisler et al, who reported that in 1098 educational encounters with Type 2 diabetes, educators most commonly addressed glycaemic control (62%).¹⁵

There was also a strong focus on risk factor reduction through diet and lifestyle change. Topics addressed in the diet area include:

- “Healthy Food for Healthy Living” (30; 52%),
- “The Facts about Fat” (25; 43%)
- “Don’t Forget your Lipids” (20; 34%), and
- “Sugar” (17; 29%).

Topics addressed in the lifestyle area were:

- “Investing in Good Health for your Future” (31; 53%),
- “Physical Activity” (27; 47%), and
- “Alcohol” (16; 28%).

The need for ongoing monitoring in the management of diabetes was also addressed in the module “Monitoring Diabetes Control” which was presented to

21 of 58 (36%) patients. Information on smoking cessation was specifically asked about by seven patients or 60% of the smokers in the group.

During the follow-up visits educational interventions were also common, accounting for 42% (69/165) of the pharmacists' interventions. During these sessions the pharmacists assessed the patients' diabetes care and implemented strategies to address management issues. On 41 occasions, these strategies included referral of the patient to their general practitioner (28), other health care professional (10), diabetes educator (2) or weight loss organisation (1). Campbell writes "One of the most important roles that a pharmacist can assume in improving the care of diabetes patients is an extension of the assessment role, and that is to determine the patient's needs and then refer the patient to appropriate diabetes health care providers."⁶⁴ White and Campbell⁶⁵ have suggested that "Building a referral network also serves to identify the pharmacist as a skilled member of the diabetes care team." They further go on to say "Physicians and therapists will be more likely to refer their patients to the pharmacy that has built a reputation for providing knowledgeable care and a full line of diabetes products and devices."⁶⁵

5.3 Study Outcomes

5.3.1 Educational Outcomes

Many patients with diabetes are not knowledgeable about their disease or about proper self-management.⁶⁶ Because of this they may not view diabetes care as a priority in their lives. They may not believe that the long-term complications are avoidable and that they may be at risk of these despite being asymptomatic. Further they may be confused about exactly how their diabetes should be managed. A lack of understanding about their disease, its consequences and its management, may lead patients to minimise their interactions with health care providers, especially in the early phase of the disease and to put little effort into their own self-care. In doing so, such patients risk poor metabolic control and the more rapid onset of long-term complications. Education is the key to addressing this problem. This is acknowledged by the Global Partnership for Effective

Diabetes Management which has included in its 10 step plan to improve patients' glycaemic control the recommendation "Implement a multi- and interdisciplinary team approach to diabetes management to encourage patient education and self-care and share responsibility for patients achieving glucose goals."⁶⁷

Implementation of the DMEP resulted in enhanced patient knowledge across a wide range of diabetes related topics. In the education sessions there was a strong emphasis on glycaemic control, which was reflected in the Intervention patients' higher rating of their knowledge of both hypoglycaemia and hyperglycaemia and their management. Control patients also rated their knowledge in this area higher at the completion of the study, which may reflect influence of the education material provided on "Blood Sugar" in their Patient Diaries (refer to Appendix 10). However, logistical regression analysis demonstrated a clear effect of the tailored education sessions.

As expected, patients in the Intervention Group reported higher rates and longer durations of diabetes education at the completion of the study compared to those in the Control Group. They also reported a significantly lower preference to receive further reading material on diabetes, which may be used as a marker of their satisfaction with their education.

5.3.2 Clinical Outcomes

The impact of the DMEP on patient care was assessed using a number of clinical, process and humanistic indicators.

HbA1c was used as the primary indicator of glycaemic control for the study, as reductions in HbA1c levels have been to be associated with reduced complication rates.^{68,69} The changes observed in HbA1c levels were small and comparable between the Intervention and Control Groups, which might be expected given that the mean baseline HbA1c level in the Intervention and Control Groups were 7.34% and 7.50%, respectively. Choe et al⁷⁰, in their study evaluating the effect of case management by a clinical pharmacist on glycaemic

control and preventive measures in patients with type 2 diabetes mellitus, found that effectiveness of the intervention was influenced by the baseline HbA_{1c} (Table 5.1). They found that for patients with baseline HbA_{1c} of 8% no improvement could be attributed to the intervention. This might in part be explained by the fact that HbA_{1c} targets other than $\leq 7\%$, are advocated under certain circumstance as illustrated in Table 5.2.

Table 5.1: Influence of Baseline HbA_{1c} on the Effect of Pharmacists' Interventions⁷⁰

Baseline HbA _{1c} Level, %	Decrease in HbA _{1c} Level, mean %*		
	Control Group	Intervention Group	Improvement Attributable to Intervention
8.0	0.2	0.2	0.0
9.0	0.4	0.8	0.4
11.0	1.5	2.9	1.4
13.0	2.3	5.9	3.6

*Based on the calculation of posterior values using linear regression models.

Subgroup analysis revealed that Intervention patients with baseline HbA_{1c} > 7%, had a 0.43% decline in their HbA_{1c} levels ($p = 0.003$) from baseline, which was 0.27% greater than that seen in Control patients ($p = 0.51$). The inter-group difference was not statistically significant.

Table 5.2: Guidelines for Glycaemic Management Based on HbA_{1c}⁵⁴

HbA1c (%)	AACE 2002 ¹²	VA 2003 ¹³	ADA 2004 ¹⁴	DA/RACGP 2004 ¹
4.0–5.9	Normal	Normal	Normal	Normal
6.0–6.5	Target			
6.6–6.9	Action	Target A ^a	Target	Target
7.0–7.9		Target B ^b	Action	Action
8.0–8.9		Target C ^c		
≥9.0		Action		
a = absent/mild microvascular complications and life expectancy >15 years b = moderate microvascular complications and life expectancy at least 5 years, or absent/mild microvascular complications and life expectancy 5–15 years c = advanced microvascular complications or life expectancy <5 years				

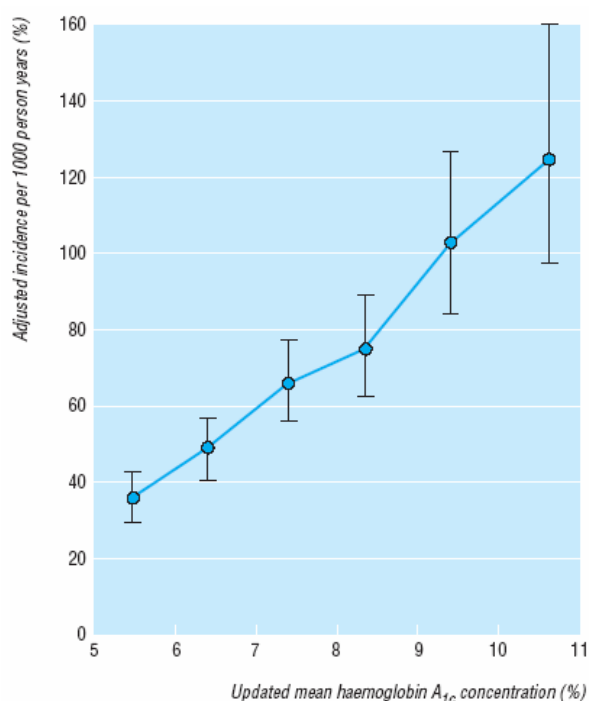
¹²American Association of Clinical Endocrinologists, ¹³ Veteran's Affairs, ¹⁴American Diabetes Association,

¹Diabetes Australia / Royal Australian College of General Practitioners

As was the case in the Pharmacy Diabetes Care Program², there was a decline in the HbA1c in Control Group. This may be attributed to the patients' enrolment in the study resulting in a request for clinical data, which may have triggered a review of the patients care by their doctor. Further, there is evidence which demonstrates increasing patients' awareness of HbA1c and its desired target levels can significantly influence glycaemic control.^{25,71,72}

Notwithstanding the small reductions in HbA1c levels, the potential clinical significance of these reductions should not be undervalued. This is supported by the fact that the effect of HbA1c reduction on the risk of diabetes complications has no threshold (Figure 5.1); a 0.5% reduction in HbA1c equates to an estimated reduction in the risk of stroke and myocardial infarction of 12% and 7%, respectively. Further, the importance of the reduction in HbA1c is also reflected by a significant reduction in the episodes and symptoms of hyper- and hypo-glycaemia reported by patients in the Intervention Group. These latter findings also correlate well with the Intervention patients' higher rating of their knowledge of the short-term complications of hyperglycaemia and hypoglycaemia, and their management compared with the Control Group.

Figure 5.1: Influence of HbA1c on Diabetes Endpoints

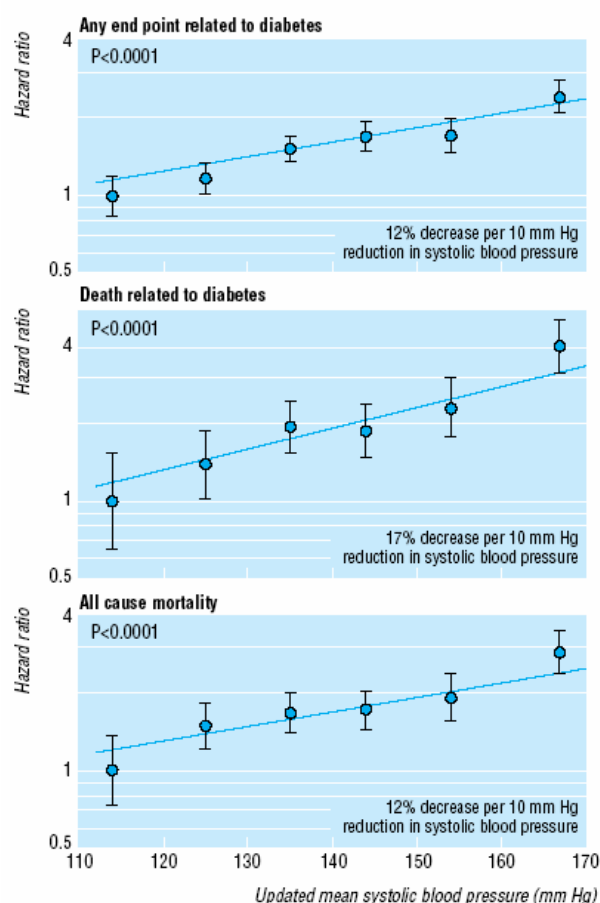


Incidence rate and 95% confidence intervals for any end point related to diabetes by category of updated mean haemoglobin A_{1c} concentration, adjusted for age, sex, and ethnic group, expressed for white men aged 50-54 years at diagnosis and with mean duration of diabetes of 10 years.

(Source: UKPDS. BMJ 2000 ; 321 :401-12)⁷⁴

Patients in the Intervention Group demonstrated positive changes in all other clinical markers (BP, lipids, weight and BMI), with the exception of triglycerides compared to their Control counterparts. Assuming that the same level of variability would have existed in the missing patient results, failure to obtain clinical data for all of the patients who completed the study may have limited the study's ability to demonstrated statistical significance of the changes. For example, there was reduction in systolic BP of 6.3 mmHg, based on the data of 54 patients with matched data, however this failed to attain statistical significance ($p = 0.054$). Such a reduction in systolic BP is however highly clinically significant as evidenced by the data presented in Figure 5.2. As is the case with HbA1c, there is no threshold effect with systolic blood pressure, hence the lower the pressure the lower the risk.

Figure 5.2: Influence of Systolic BP on Diabetic Complications

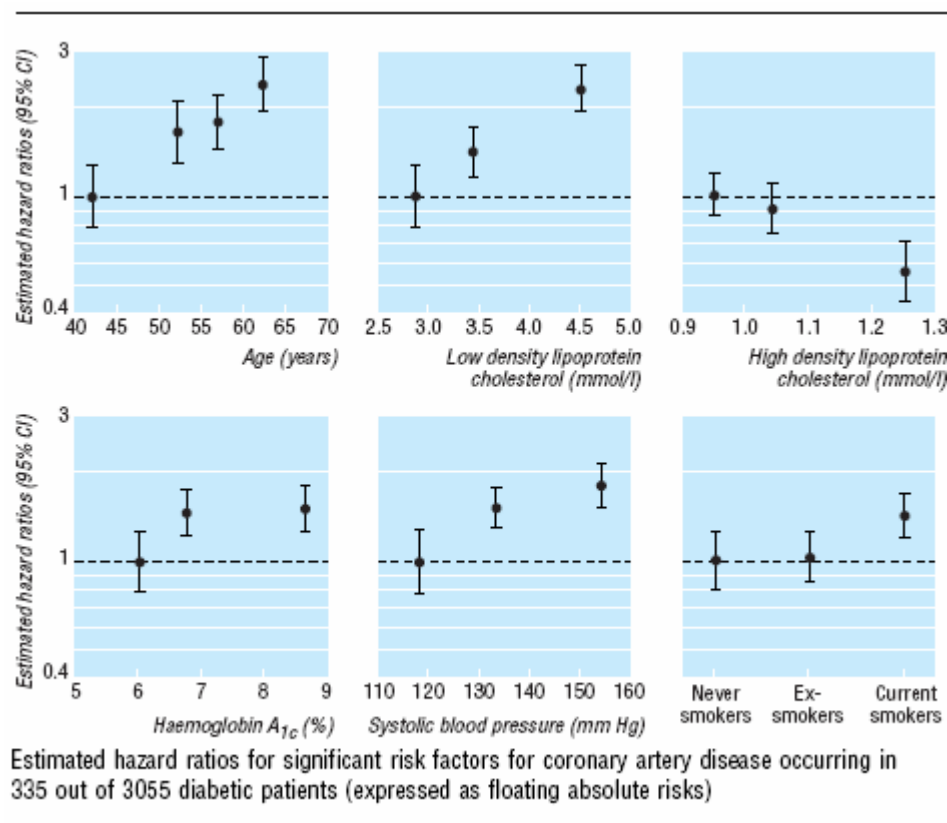


Hazard rates (95% confidence intervals as floating absolute risks) as estimate of association between category of updated mean systolic blood pressure and any end point related to diabetes, death related to diabetes, and all cause mortality with log linear scales. Reference category (hazard ratio 1.0) is systolic blood pressure <120 mm Hg; P value reflects contribution of systolic blood pressure to multivariate model. Data adjusted for age at diagnosis, ethnic group, smoking status, presence of microalbuminuria, haemoglobin A1c, high and low density lipoprotein cholesterol, and triglyceride.

(Source: UKPDS 36. BMJ 2000; 321:412–9)⁷³

The prevention of diabetes complications requires a multifaceted approach; it is more than simply glycaemic control. Close attention must also be paid to BP and lipid control, weight reduction and lifestyle changes such as diet, exercise, alcohol consumption and smoking cessation. Figure 5.3 below illustrates the effects of a number of these on the risk of coronary artery events in diabetic patients. What is evident from this data is that in assessing the effect of any intervention on diabetes outcomes cumulative benefits should be considered. The UKPDS risk engine⁴⁵ provides a means of assessing that cumulative benefit by taking into account age, sex, duration of diabetes, history of atrial fibrillation, smoking history, HbA1c, systolic blood pressure, total cholesterol and HDL-cholesterol.

Figure 5.3: UKPDS: 23 – Estimated Hazard Ratios for Coronary Artery Disease



(Source: UKPDS 23. BMJ 1998; 316: 823–8)⁷⁵

Small changes in HbA1c, systolic BP, total cholesterol and HDL can translate into significant changes individual patient's absolute risk of myocardial infarction (both fatal and non-fatal) and stroke (both fatal and non-fatal). Having calculated the absolute risk reduction (ARR) it is then possible to determine the number needed-to-treat (NNT). The NNT defines the treatment-specific effect of an intervention and McQuay and Moore⁵¹ suggest it as a currency for making decisions about individual patients. For example, the UKPDS study, on which current clinical management of type 2 diabetics is based, demonstrated intensive treatment reduced the AR of any of a range of 21 endpoints by 3.2%, which translates into a NNT = 31 for 10 years. In that study the difference was predominantly due to reduction in the microvascular complication, retinopathy requiring photocoagulation. Cardiovascular events were not significantly reduced; although there was a trend towards reduction in total myocardial infarction, 14.2% v 16.3%, $p=0.052$.⁷⁶ Table 5.3 below summarises the benefits of treating hypertension in people over the age of 60 years; the NNT are for 5 years.⁷⁷

Table 5.3: Number Needed-to-Treat for Hypertensive Patients Aged Over 60 years⁷⁷

	NNT	
	High Quality Trials	All Trials
Cardiovascular mortality	52	58
Cardiovascular mortality & morbidity	18	21
Cerebrovascular mortality	183	193
Cerebrovascular mortality & morbidity	43	46
CHD mortality	78	88
CHD mortality & morbidity	61	68

(Source: Treatment of Hypertension in the elderly. Bandolier Journal. Accessed at: <http://www.jr2.ox.ac.uk/bandolier/band15/b15-9.html>)⁷⁷

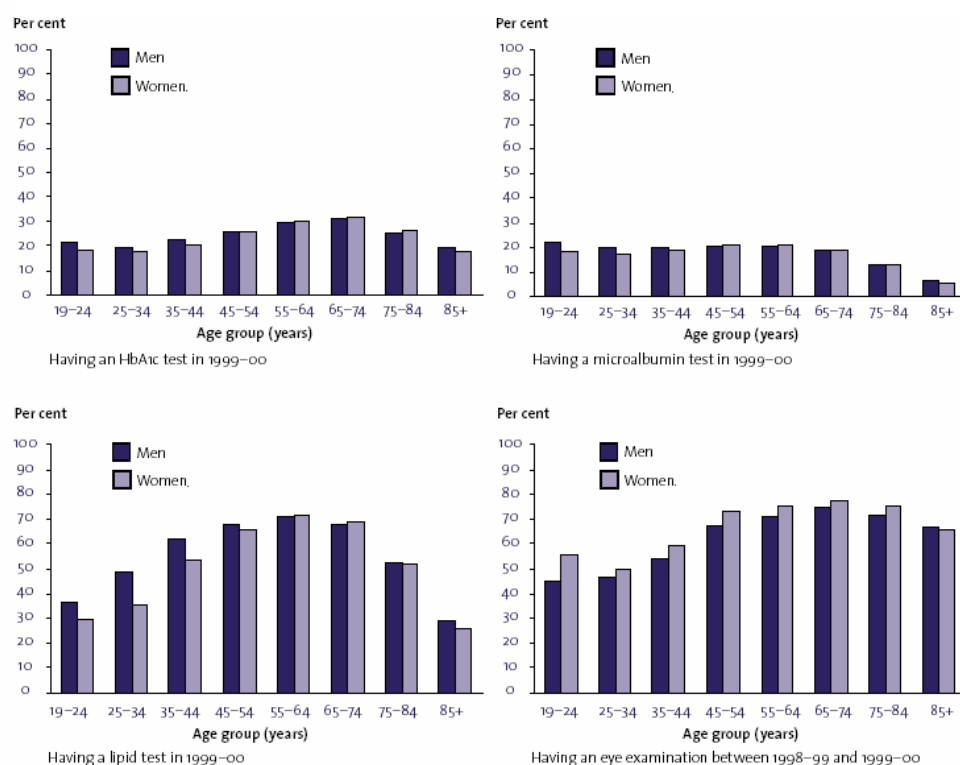
As this study failed to demonstrate statistically significant differences in HbA1c, total cholesterol or systolic BP; and the data analysis was not undertaken on an

intention-to-treat basis; calculation of risk reduction using the UKPDS risk engine was deemed inappropriate. Such an approach would have however allowed a comparison of the intervention worth compared those currently included as part of best practice.

5.3.3 Patient Care

The level of adherence to testing guidelines may be used as an indicator of the quality of the process of patient care. As HbA1c levels reflect chronic glycaemic control and correlate with the risk of diabetes related complications, routine measurement of these levels is seen as critical to good diabetes management. It is recommended that HbA1c levels are monitored twice yearly, however compliance with this and other minimum testing guidelines has been less than optimal in Australia⁷⁸ (see Figure 5.4). A positive result of the intervention was the increase in the proportion of patients reporting that their HbA1c had been measured at the completion of the study (Intervention 87.0% vs Control 55.3%; $p=0.01$); up 36.8% in the Intervention Group from baseline ($p=0.001$).

Figure 5.5: Adults Identified with Diabetes Meeting the Minimum Frequency for Selected Tests⁷⁸



Source: Health Insurance Commission 2001.

Self-monitoring of blood glucose (SMBG) levels is also seen as crucial element of diabetes care. It is considered a tool for guiding patients' and health care providers' actions regarding dietary changes, physical activity, and pharmacological therapy.¹⁷ There is now considerable evidence to support the benefits of SMBG in type 2 diabetes, and that the more frequent the testing the better the effect on glycaemic control as adjudged by HbA1c levels.⁷⁹ In the current study there was a high level of SMBG testing in both groups at baseline (> 95% of patients regularly monitoring BGLs) which afforded little opportunity for improvement. One positive effect of the intervention however was the increase in the proportion of patients who were recording their BGLs at the completion of the trial (Intervention – Final 92.7% vs Baseline 73.2%, $p = 0.004$, and Control – Final 76.6%, $p = 0.03$). The data recorded can be used by the patient and their health care providers to assess and adjust their diabetes management.

Davidson states barriers to the effective use of self-monitoring include “1) poor patient adherence, 2) limited access to supplies, 3) incomplete patient education (how to perform self-testing, understanding glycaemic targets, actions to be taken based on results), and 4) lack of specific recommendations for timing and frequency.”⁸⁰ Patient adherence with SMBG and access to supplies did not appear to be issues in this study; while the patient education sessions addressed barriers 3 and 4.

The intervention appeared to have no effect on the level of monitoring for foot, eye or renal complications (urinary protein) over the course of the study. However, as the questions used to assess this asked about whether or not such tests had been performed in the past year, and the intervention lasted only 6 months, such changes may not have been detectable.

Patients in the Intervention Group tended to have a better level of satisfaction with their diabetes care overall than those in the Control Group (OR 0.51, 95% CI: 0.19, 1.43; $p = 0.20$). More importantly the intervention appeared to have an empowering effect, with Intervention patients demonstrating a greater willingness to work towards improving their diabetes care (OR 0.38; 95% CI

0.19, 0.76; $p = 0.006$). This latter finding is significant based on the findings of O'Connor et al who found that amongst 617 adult diabetics with a baseline $\text{HbA1c} \geq 7\%$, that patient's readiness to change independently predicts change in HbA1c .⁸¹

5.3.4 Quality of Life

There is good evidence that quality of life can be significantly impaired by the development of diabetes complications and by frequent hypo- or hyperglycaemia.⁸²⁻⁸⁵ In this study, the intervention was associated with improvements in the patients' quality of life as assessed using the Diabetes Symptoms Checklist Revised (DSC-R) in all dimensions, with patients in the Intervention Group recording lower scores (reflecting better well being) than those in the Control Group. Statistically significant differences were demonstrated in the dimension of "Psychology" and its sub-divisions fatigue and cognitive, and "Neurology" sub-division of pain". Such changes are consistent with the significant reduction in the reported episodes of hypo- and hyperglycaemia in the Intervention Group. For example chronically elevated blood sugar levels may lead to persistent fatigue, which may contribute to dysphoria.⁴³ Frequent hypoglycaemia episodes on the other hand can be exhausting, debilitating, discouraging and may arouse significant anxiety. Van der Does et al have suggested that better glycaemic control is associated with fewer symptoms, better mood and better well-being.⁸⁶ They demonstrated a significant, albeit weak relationship between HbA1c and scores on the DSC-R hyperglycaemic and the neuropathic dimensions. In general, studies investigating the relationship between diabetes control (HbA1c) and subjective well-being have found low correlations, if any, although there is better evidence that patients with diabetes associated complications (e.g. neuropathy, retinopathy, nephropathy) generally have lower levels of quality of life compared to those without complications.⁸⁷

Quality of life as assessed using the Short Form (SF-36) Health Survey demonstrated a statistically significant benefit of the intervention in the dimension of "Social Functioning". This finding is consistent with reduction in

hypo- and hyper-glycaemic episodes, and the patient self reported reduction in diabetes complications. The significant changes in the DSC-R scores also lends support to clinical significance of the improvements seen in Physical Functioning, Vitality, Social Functioning, Role – Emotional and Mental Health as assessed using Wrywich *et al*'s one-SEM criterion.⁴⁶

The UKPDS 37⁸⁸ examined the influence of improved blood glucose and blood pressure control, diabetic complications and hypoglycaemic episodes on the quality of life of patients with type 2 diabetes. The conclusions from this study were that diabetes complications affected quality of life, whereas therapeutic interventions shown to reduce the risk of complications had no effect.⁸⁸ Davis *et al*, from a survey of 861 patients with type 1 or type 2 diabetics, found that quality of life and health-related utility were inversely related to the severity and frequency of hypoglycaemic episodes.⁸⁹ Lundkvist *et al* also reported a negative effect of hypoglycaemia amongst a group of 309 type 2 diabetes patients aged 35 years or older. Patients who had experienced hypoglycaemic symptoms (115, 37%) in the previous month were more affected by their diabetes, reported lower general health and were more anxious, than those who had not suffered hypoglycaemia.⁹⁰ Goddiijn *et al*, in a longitudinal study of type 2 diabetics found that a reduction in hyperglycaemic symptoms was associated with an improvement in health-related quality of life.⁹¹ Kleefstra *et al* demonstrated in a group of 1006 type 2 diabetes patients that hyperglycaemic symptoms, as assessed using the Rand-36 questionnaire, had a negative effect on scores across all dimensions, however this was not true of HbA1c.⁹² Based on the findings of these studies and the fact that patients in the Intervention Group reported suffering fewer hypo- and hyper-glycaemic episodes, the positive effects of the intervention on patients' self-reported quality of life are to be expected and are likely to be clinically significant.

5.4 DMEP - Patient Satisfaction

Responses to the DMEP Patient Satisfaction Survey demonstrated a high level of satisfaction with their interactions with the pharmacists, the location of the service provider and the service impacts, such as understanding of certain aspects of diabetes management (e.g. medications, diet, exercise and how to deal with diabetes). Patients were strongly supportive of the pharmacist's role in diabetes education. They listed amongst the most valuable components of the DMEP service:

- learning about lifestyle issues,
- learning about medication,
- reminders about the need for check-ups for diabetes-related complications, and;
- general support from the pharmacist.

They highly valued both the educational sessions and the follow-up sessions, and rated pharmacists as their preferred provider of diabetes education. Their high level of satisfaction with the service centred around the information provided was easy to understand, the pharmacist was friendly and empathic, and the service was accessible and timely. There was an overwhelming belief amongst patients that the service should be more generally available. There was also a willingness to continue to utilise the service if it were available and to pay for it. The DMEP service provided addresses many of the identified barriers to optimal diabetes care. With its foundation of tailored patient education, delivered to patients within community pharmacies, together with follow-up sessions to support patient self-management it empowers patients, enhances their self efficacy and motivation which, in turn, is reflected in better patient outcomes.

5.5 DMEP - Pharmacist Feedback and Satisfaction

The Project Pharmacists overwhelmingly supported the study and could appreciate community pharmacists could have an extended role in care of their patients with diabetes. Feedback to the pharmacists, from the patients who participated in the DMEP, that the education was streamlined, individualised,

and that it was delivered in the pharmacy were positive motivators. Patients also commented that gaining access to other diabetes education programs could be problematic, providing pharmacists with an appreciation of an unmet need.

The model of using independent pharmacist diabetes educators, was well received, although some of those interviewed felt that they were disengaged from the program because of this. It appeared from the discussion that ensued that communication of what education had been provided and what plans had been made was the major issue, and that this could be addressed through better communication, in particular the use of electronic patient records.

Feedback on recruitment barriers suggests the volume and time required to complete the baseline paperwork were significant contributing factors. It was also felt that patients who were the most motivated, were the most likely to complete the project. The latter is a common criticism of many studies; however, it reflects personal preference and is not easily controlled for. The former reflects the need to record data as part of the research process, and as such should not be seen as an impediment to implementation of a practical, sustainable DMEP service.

A multidisciplinary, collaborative approach to the care of patients with diabetes is now acknowledged as the prefer model.⁶⁸ The range of services that can be provided by pharmacists within this model may include:

- diabetes screening
- diabetes supplies
- diabetes education
- medication counseling
- drug administration assistance
- medication management reviews
- outcome monitoring
- prescribing of therapeutic agents

5.6 Economic Analysis of the DMEP

5.6.1 Health Resource Utilization

The measure of the effectiveness of any intervention is its ability to improve disease control, reduce disease complications and enhance patients' quality of life. In doing so it is inevitable that there will be changes in the patterns of health resource utilisation. For example, poor compliance and inadequate monitoring are often cited as causes of sub-optimal outcomes in the treatment of diabetes. Hence, it might be expected that an intervention aimed at improving diabetes management may results (at least initially) in an increased in expenditure on medication (as a result of enhanced compliance) and an increase in GP consultations and investigations (as a result of compliance with best practice, e.g. HbA1c levels). At the same time, better disease controlled would be expected to result in fewer episodes of hypoglycaemia and hyperglycaemia, and a reduction in long-term diabetes complications. These improvements should be manifested in a reduced need specialist consultations and hospitalisations.

The health resource utilisation evaluation of the DMEP service was limited in part by the number of patients who completed the study, but also by incomplete follow-up data provided by both the HIC and the WADLU. Notwithstanding these limitations the results obtained consistent evidence of a positive effect of the DMEP on health resource utilisation. Medication usage and investigation rates increased during the 6 months of the Intervention, but then fell relative to the Control Group in the 6 month follow-up period. The changes were associated with an increase in medication expenditure, but a fall in overall costs (Medicare plus PBS), there was also a fall in hospital admission acuity (as evident by the number of diagnoses) and the length of hospital stays (although only the latter achieve statistical significance). Sidorov et al reported similar findings from a study involving 6,799 patients with a diagnosis of diabetes 45.9% who were enrolled into a disease management program and 54.1% who were not.⁹³ They reported an annual reduction in health claims of USD 1294.32 (AUD 1738.55) amongst DSM group patients. There were also reductions in the number of hospital admissions (0.12 per patient per year), days in hospital (0.56 days per

patient per year), but a higher number of primary care visits (8.36 vs 7.78; $p < 0.05$).

5.6.2 Pharmacoeconomic Evaluation

The results of the pharmacoeconomic evaluation are discussed in the Addendum entitled: “Economics of Providing the DMEP Service.”

5.7 DMEP Success

There have been numerous studies which have investigated the benefits of pharmacist involvement in diabetes care programs.^{2,94-109} Integral to all of these studies is some component of patient education. However none have used tailored patient education as the platform from which the service is built. All patients involved in the Intervention arm of DMEP study had their educational needs assessed at the time of enrolment, and an individualised education program was developed with the aid of a commercially available diabetes care software package. The tailored education program was delivered in a series of one-on-one sessions within the community pharmacies. The education program was then complemented by a series of follow-up sessions involving monitoring of patient progress, patient education, goal setting, identification and resolution of drug related problems and where necessary referral of the patients to other health care providers. These all form part of the pharmaceutical care model, and are seen as essential components of pharmacists’ contribution to diabetes care.⁶⁴⁻⁶⁶

The aims of the DMEP were to improve patients’ knowledge and understanding of diabetes and its management, and in doing so improve metabolic control, and reduce the incidence of short and long-term diabetes complications, enhance patients’ quality of life and reduce health care costs. It is reasonable to say that the majority of these aims were achieved, albeit to differing degrees.

Education is seen as an essential component of diabetes management, as people with diabetes need to develop the skills to enable them to become experts in self care. A multidisciplinary approach to education is vital in enabling people to make informed choices about their self care options.⁶⁸ The positive impact of educational interventions varies between and within studies seeking to identify the role of education in influencing self-management of diabetes and the subsequent effects on the achievement of desired blood glucose and HbA1c levels, the reduced incidence of hypo- and hyper-glycaemic episodes and consumption of health care resources. Patients receiving the DMEP service reported greater improvement in their knowledge and understanding of diabetes and its management compared to those who did not. Noteworthy is the fact that hypoglycaemia and hyperglycaemia were the most common topics addressed during the education sessions. Patients in the Intervention Group reported significantly improved knowledge of these topics and this translated into a lower frequency of hypoglycaemic and hyperglycaemic episodes in this group. Patients in the Intervention Group also reported improvements in well being, that are consistent with a reduction in such episodes.⁸⁹⁻⁹¹

Further, this reduction in hypoglycaemic and hyperglycaemic episodes would be expected to translate into health savings. Lundkvist et al from a study involving 309 type 2 diabetics reported that direct and indirect costs of hypoglycaemia per patient with hypoglycaemia symptoms were USD 12.90 (AUD 17.33) and USD 14.10 (AUD 18.95) per month, respectively.⁹⁰

The changes in clinical parameters in this study (with the exception of HDL levels) whilst failing to reach statistical significance, were in keeping with findings of other community pharmacy based, pharmacist-delivered diabetes programs, where improvements in clinical outcomes have been reported.^{2,29,94-97} Within the subgroup of Intervention patients with a baseline HbA1c > 7%, there was a 6% (0.48/8.35) improvement from baseline in final HbA1c after 6 months. This result was similar in magnitude to those attained in the SugarCare study⁹⁷ (6%; 0.5/7.9) and by Clifford et al.²⁹ in a 12 month pharmacist delivered pharmaceutical care program for type 2 diabetes. It was however about half of that observed in the Pharmacy Diabetes Care Project (PDCP) [11%; 1.0/8.9]² in

which patients were enrolled in a 6 month community pharmacy-base disease state management program. That study produced improvements in HbA1c similar to those reported by Cranor et al.,⁹⁴ and Wermeille et al.⁹⁵ Differences in the results obtained may be explained in part by the differing baseline HbA1c levels. As discussed previously, Choe et al reported the significance of pharmacists' interventions was dependent on the patient's initial level of glycaemic control.⁷⁰

The change in systolic BP (-6.3mmHg or -5%) attributed to the Intervention only just failed to achieve statistical significance ($p = 0.054$). This change was greater in magnitude than that seen in the PDCP² (-1%; 2mmHg/135mmHg), but less than that reported by Clifford et al²⁹ 9% (14mmHg/157mmHg). These differences may in part be related to differences in baseline BP control, and the duration of the intervention. The three studies showed similar declines in total cholesterol amongst Intervention patients (-0.28 mmol/L, -0.22 mmol/L² and -0.30 mmol/L²⁹), and increases in HDL cholesterol (0.04 mmol/L, 0.01 mmol/L² and 0.03 mmol/L²⁹).

The clinical significance of these changes is illustrated by their cumulative effect on cardiovascular risk. Clifford et al reported a 4.8% reduction in the 10 year risk of a patient suffering a first CHD event.²⁹ The clinical relevance of this reduction is better appreciated by calculating the NNT, which in the case of the Clifford et al²⁹ study was 21 for 10 years to prevent one event.

Factors such as the setting, nature and intensity of the intervention delivered by the pharmacist can influence such interventions impact on patient care. As pointed out by Krass et al 'the majority of trials of diabetes care models delivered by pharmacists either in clinic or community settings have utilised varied and complex interventions comprising a combination of the following: diabetes self-management education and coaching to assist in empowerment of the patient^{97,100,111-113}; monitoring and promoting patient adherence with medication and other components of self-management (e.g., prescription refills)^{97,114}; monitoring and documenting easily measurable key clinical outcome measures, such as blood glucose levels^{97,100,108,111,113,114}; blood pressure^{97,100,113}; lipid levels

97,100,108,113; reminding patients of the importance of regular examinations for the presence of diabetic complications, e.g., eye and feet examinations^{60,97,113}; and ensuring the quality and evidence-based use of medications^{97,100,108,110-112,114,115}.” The difficulty then is to determine which of the components of the intervention have made a contribution to the effectiveness of the service.

The Global Partnership for Effective Diabetes Management in their article entitled: “Improving glucose management: Ten steps to get more patients with type 2 diabetes to glycaemic goal” makes the following statement:

“Physicians and other PCPs (primary care providers) should recognise their important role in enabling and empowering patients to take control of their condition by providing effective communication, education and support, including the use of positive language, and by encouraging patient self-management.”⁶⁸

The DMEP embraced these principles both in its structure and the manner in which it was delivered as evidenced by feedback provided by those who received the service.

The results of the DMEP study provide evidence to support patients’ acceptance of community pharmacists as effective diabetes educators, and complements evidence that other health care professions support the pharmacist’s role as an educator. Further, the results add support to the role of community pharmacists as highly trained and accessible health care professionals in the delivery of effective disease state management services for diabetes. The DMEP study provides evidence of the effectiveness of tailored education programs and a high level of patient satisfaction. It also demonstrates patients’ desire to be supported in their diabetes management through regular follow up sessions.

The DMEP study is unique in that it employed pharmacists trained to be diabetes educators, to deliver a diabetes disease state management service in

community pharmacies. It differs from other community pharmacy-based studies in that all patients were provided with individualised diabetes education at entry into the study. The aim in doing this was to improve patients' knowledge and understanding of their disease and its management, thus empowering them to become more involved in their own self-management. The results of the study further strengthen the evidence base for the value of diabetes disease state management services delivered in community pharmacy.

5.8 Study Limitations

It should be noted that there were certain limitations associated with this study.

Firstly, the number of patients recruited into the study was below its target of 400, and there was a substantial attrition rate. Further, difficulties were encountered in obtaining clinical data for a number of patients from their general practitioners, which meant the ability of the study to demonstrate statistically significant changes in clinical outcomes was further compromised.

Secondly, HbA1c levels were not used as a selection criterion, as was the case in the recent Pharmacy Diabetes Care Program study; as a consequence approximately 40% of patients both in the Intervention and Control Groups had $\text{HbA1c} \leq 7\%$, which limited the potential of the study's intervention to demonstrate statistically significant improvement in outcomes in the timeframe of the study. Interventions involving patients with the poorest glycaemic control provide the greatest opportunity to demonstrate such improvements.

Thirdly, the educational material provided in the form of the patient diaries and the requirement for patients to complete a Progress Checklist at each of the follow-up sessions in the Control arm of the study had the potential to improve patient knowledge and change patient behaviour. The former is illustrated by the Control Patients reported improved knowledge of hypoglycaemia and hyperglycaemia.

Fourthly, in applying Wrywich *et al*'s one-SEM criterion, the reliability coefficients used were obtained from a survey undertaken of a subgroup of Americans with diabetes, and as such should be only considered of indicative of those which may be obtained if a similar subgroup of Australians were surveyed.

5.9 Conflict of Interest

Mr Jeffery Hughes is a Director of Cognicare Solutions Limited the providers of CMMS[®] Diabetes Care software.

6. CONCLUSIONS

The Diabetes Mellitus Education Program (DMEP) demonstrated that community pharmacists can enhance patients' knowledge and understanding of their diabetes and its management. Further that its can deliver meaningful outcomes to participants, namely a reduction in hypo- and hyper-glycaemic episodes, which translate into improvement in quality of life. The cost of avoiding hypo- and hyper-glycaemic episodes was low; supporting the notion that the DMEP is a clinically and cost effective professional service which may be implemented in a wide range of community pharmacies in Australia. The patients and pharmacists involved in the DMEP were very satisfied with education and follow-up sessions provided as part of the program. Further they felt that such a community pharmacy-based program should be more widely available, and expressed a preparedness to participate in such a program on an ongoing basis.

Community pharmacists' role in patient education has been acknowledged by patients and health care professionals alike. It is also acknowledged that diabetes education is an ongoing process, designed to support patients in self-management of their disease. The DMEP allows community pharmacists to be engaged in this process of ongoing care; assisting patients achieve the best outcomes from their disease. To maximise their success, pharmacists who wish to participate in this process should undergo specialised training in diabetes management, and guidelines for the provision of such services should be developed against which benchmarking and accreditation could be based, in the same way as they exist in the United States. Further, emphasis should be placed on information technology solutions which can assist community pharmacists deliver such services. Such solutions should include software to assist pharmacists identify individual patient's educational needs, deliver diabetes educations, establish care plans, monitor patient progress, and document services provided and interventions made.

Community pharmacies provide an ideal environment for the provision of enhanced pharmacy services. Pharmacists are ranked second only to doctors as sources of information on disease management. Whilst, the provision of diabetes educational services, such as the DMEP, may be confronting to some traditional community pharmacy clients their uptake by patients is likely to be driven by the convenience of attending a community pharmacy and patients perceived health benefits derived from participating in such programs. Given self-management is the cornerstone of diabetes management, and that this is greatly enhanced through patient education, it appears likely that future provision of extended services, such as the DMEP, would be adopted and supported by patients in Australian community pharmacies. Furthermore, as was the case with the Pharmacy Diabetes Care Program, subsidisation by the Australian Government would enable widespread uptake of the DMEP by community pharmacy.

In conclusion, DMEP services implemented in this study have the potential to contribute to improved patient self-efficacy in their management of their diabetes, and with that associated improvements in health outcomes and quality of life.

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8. APPENDICES

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APPENDIX 1

Letter for Divisions of General Practice

March 2003

Dear

My research group is about to undertake a study at selected metropolitan community pharmacies. The title of the project is *Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules*. I am contacting Divisions of General Practice to explain the aims and structure of the project, and I hope to enlist their support and cooperation.

The aim of this study is to evaluate patient specific diabetes mellitus education programs for community pharmacists that would form part of a disease management program.

The expected results of this tailored education program are:

1. Improved patient knowledge of diabetes, its consequences and management
2. Improved patient compliance with treatment and monitoring regimens
3. Increased number of patients achieving desired blood glucose and Hb_{1Ac} levels and reduced incidence of hypo- and hyper-glycaemic episodes
4. Reduced health care resource consumption
5. Development of a diabetes education model, which may be implemented in community pharmacies around Australia

The study will be undertaken at 8 Perth metropolitan community pharmacies- 4 control and 4 intervention sites, based on their geographical location. Control and intervention pharmacies will be allocated from different Division of General Practice to avoid any possible bias. These groups will be matched based on patient demographics, socio-economic status and the duration and severity of their diabetes. Each pharmacy will be responsible for recruiting 50 diabetic patients. If a patient agrees to participate in the study they will be asked to give written informed consent, which will include permission to contact their general practitioners to discuss their progress and obtain relevant clinical and laboratory data, and to access the Medicare and Pharmaceutical Benefits records through the Health Insurance Commission.

After obtaining written informed consent, the pharmacist will interview the patient to obtain the following initial information: patient demographics, diabetes history (date of diagnosis, treatment, complications, level of control, previous diabetes education), other past medical history, medication history, history of drug allergies, and social history. The patients will then be asked to complete a diabetes questionnaire (designed to assess patient's knowledge and identify education needs) and a Quality of Life questionnaire. Patients in the control group will then receive standard patient counselling and be provided with a diary to be completed.

Patients in the intervention group will receive a tailored education program based on the results of their diabetes questionnaire. The education program will consist of a maximum of three one-hour sessions conducted in the pharmacy over a period of 1 month. An assessment of cardiovascular risk will be undertaken and strategies to address identified risk factors (e.g. obesity, smoking) will be implemented.

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At follow-up interviews (1, 3 and 6 months) the patient's diary will be reviewed for completeness and their progress will be assessed using a standard progress questionnaire. Patients in the control group will be asked if they have any concerns or if they required any further information. Where issues raised by the patient are deemed significant the pharmacist will refer the patient to their general practitioner. All services provided by the pharmacist during the follow-up visit will be documented. At the 6-month visit patients in each group will be asked to again complete the diabetes questionnaire and QOL assessment.

Patients will be provided with a diary which will include written information on diabetes and its management, their medication regimen, dates for prescription refills, dates for follow-up visits and doctors appointments. Patients will be asked to record any symptoms or complications they experience, together with their management, any missed doses, visits to their doctor or hospital attendances that were diabetes related in their diary. They will also be asked to record all BGL measurements and a weekly weight.

Information regarding health resource utilisation will be obtained from the Health Insurance Commission Information Release Section. Data requested will include Medicare (doctor visits, hospital attendances, pathology tests (BGL, HbA_{1c}, serum lipids and urinalysis) and Pharmaceutical Benefits information pertaining to the 6 months prior to the study, the 6 months of the study and 6 months after the study.

I hope that doctors within this Division of General Practice will give this research their support and cooperation. Should you have any queries my contact details are as follows:

Mr. Jeff Hughes,

Senior Lecturer, School of Pharmacy, Curtin University of Technology

GPO Box U 1987, Perth WA 6845

Phone 9266 7367 Fax 9266 2769 (Attention: Jeff Hughes)

Email J.D.Hughes@curtin.edu.au

Yours sincerely,

Mr. Jeff Hughes, Principal Investigator

Mr. Mark Coles, Secondary Investigator

APPENDIX 2



Project Title: Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study)

INFORMATION SHEET

You are being invited to take part in a research study. Before you make your decision, it is important for you to understand why the research is being done and what it would involve. Please take as much time as you need to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information.

The aim of this study is to assess the impact of community pharmacy based diabetes education programs on the outcome of diabetes management in patients with Type 2 diabetes mellitus as measured by blood sugar level control and complication rates. For example, complications such as heart, kidney, foot or eye problems or nerve damage.

You have been invited to participate in this study because you are aged 18 years or over, and receiving a medication for the treatment of type 2 diabetes during the period of May 2003 and February 2005.

It is your decision whether or not to take part. If you decide to take part you can still withdraw at any time, without giving a reason. If you decide not to participate, or decide later to withdraw, it will not affect the standard of further care you would receive. If you do decide to take part you will be asked to sign a consent form. You will be given this information sheet to keep and you will receive a copy of your signed consent form.

If you agree to participate in the study you will be interviewed using structured questionnaires to obtain information about your knowledge of your disease and its management. Further, you will be asked to complete two questionnaires to assess what impact your diabetes has had on your quality of life. This process should take no longer than 30 minutes. You will then be assigned into one of two groups – Group A, which will receive a tailored education program (based on the results of the initial questionnaires) and Group B, which will receive standard pharmacy care. The tailored education program will involve three sessions (approximately 1 hour duration) during the first month of the study to be conducted in the pharmacy. Patients in both groups will need to attend follow-up appointments (approximately 30 minutes duration) after 1, 3 and 6 months.

To further evaluate the benefits of the service, it is planned to undertake a comparison of the health resource consumption (E.g. number of doctors visits, hospital admissions, etc) between patients in the control group and those in the intervention group. To facilitate this we will require permission to contact your general practitioner to discuss your progress and obtain relevant clinical and laboratory data, and permission to access your Medicare (E.g. number of visits to doctors) and Pharmaceutical Benefits (E.g. prescription records) data held by the Health Insurance Commission (HIC). If you were willing to participate in this study we would seek your permission to access your HIC records for the duration of the study. We would seek also your permission to access data held by the

APPENDIX 2

pharmacy that relates to your medications and treatment of diabetes (Eg. National Diabetes Services Scheme supplies).

A possible benefit of participating in the study is an improved control of your diabetes through enhanced knowledge of the disease and its management. This should translate into a possible reduction in your use of health care resources and an improvement in your quality of life.

This study is a non-interventional study, and hence poses no additional hazards to you.

The study records will be kept in the School of Pharmacy during the period of this study and in a locked archive for 5 years from the time the study is closed, and will be destroyed at that time. Only the investigators of the study will be able to see your records. Personal data, which may be sensitive, (eg. name, date of birth) will be collected and processed but only for research purposes in connection with this study. All the data will be de-identified with no reference on the completion of data collection.

This study will be carried out in accordance with the principles specified by the “National Statement on Ethical Conduct in Research involving Humans”. The Curtin University of Technology Human Research Ethics Committee has reviewed and approved the study.

If you have any questions or concerns now or at any time about the study, you should contact us on the numbers listed below:

- Jeff Hughes, School of Pharmacy, Curtin University 9266 7367
- Jenny Wilkinson, School of Pharmacy, Curtin University 9266 7419
- Shelley Kinsella, School of Pharmacy, Curtin University 9266 2531

If you want to discuss the study with someone who is not directly involved in this study (for example, any issues about the information you have received, the conduct of the study or your rights as a participant, or a complaint you have), you can contact the Curtin University Human Research Ethics Committee Secretariat on 9266 2784.

APPENDIX 2

STUDY CODE			:		
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Patient Consent Form

**Project Title: Customised Education Programs for Patients with Diabetes Mellitus –
Use of Structured Questionnaires and Education Modules (DMEP Study)**

Patient name:

Phone:

Address:

1. I have been given a full explanation of the purpose of the study, the procedures involved and what is expected of me. I understand and accept the nature of the study that has been explained to my satisfaction by (pharmacist)
2. I understand that my participation in the study is voluntary and that I may withdraw from the study at any time without penalty
3. I am over the age of 18 years
4. I understand that all information received will be treated with the strictest confidence and there will be no reference to personal details whatsoever, and that following completion of data analysis all patient records will be de-identified.
5. I have been given and read a copy of the information sheet and this consent form
6. I freely give my consent to participate in the study, investigating the effectiveness of a community pharmacy based education and follow-up program in assisting patients manage their raised blood glucose and attain their treatment goals.
7. I further give my consent for the Project Supervisor, Jeff Hughes, Senior Lecturer, School of Pharmacy, to contact my general practitioner to discuss my progress and obtain relevant clinical and laboratory data and to access my Medicare and Pharmaceutical Benefits records for the period of the study for the purpose of obtaining data to be used in evaluating the effectiveness of the program. I also give my consent for him to access data held by the pharmacy that relates to my medications and treatment of diabetes.

Signature: _____

Date:

Witness: _____

Name:

Date:

Thank you for agreeing to participate in this study

APPENDIX 2

STUDY CODE	C		:		
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Patient Consent Form*(PATIENT'S COPY)*

**Project Title: Customised Education Programs for Patients with Diabetes Mellitus –
Use of Structured Questionnaires and Education Modules (DMEP Study)**

Patient name: _____ Phone: _____

Address: _____

1. I have been given a full explanation of the purpose of the study, the procedures involved and what is expected of me. I understand and accept the nature of the study that has been explained to my satisfaction by _____ (pharmacist)
2. I understand that my participation in the study is voluntary and that I may withdraw from the study at any time without penalty
3. I am over the age of 18 years
4. I understand that all information received will be treated with the strictest confidence and there will be no reference to personal details whatsoever, and that following completion of data analysis all patient records will be de-identified.
5. I have been given and read a copy of the information sheet and this consent form
6. I freely give my consent to participate in the study, investigating the effectiveness of a community pharmacy based education and follow-up program in assisting patients manage their raised blood glucose and attain their treatment goals.
7. I further give my consent for the Project Supervisor, Jeff Hughes, Senior Lecturer, School of Pharmacy, to contact my general practitioner to discuss my progress and obtain relevant clinical and laboratory data and to access my Medicare and Pharmaceutical Benefits records for the period of the study for the purpose of obtaining data to be used in evaluating the effectiveness of the program. I also give my consent for him to access data held by the pharmacy that relates to my medications and treatment of diabetes.

Signature: _____ Witness: _____

Date: _____ Name: _____

Thank you for agreeing to participate in this study Date: _____

APPENDIX 3

Pharmacy Letter of Invitation

March 14th 2003.

Dear **Pharmacist <Name>**

We would like to invite your National Diabetes Supply Scheme sub agency pharmacy to participate in a pilot study of customised education programs for your type-2 diabetes patients. Three pharmacists, employed as part of this research project, will facilitate the educational component, using structured questionnaires and education modules. To enable us to more fully explain the various aspects of the study, and to address any queries regarding your role in the project, we extend an invitation to you to attend an information evening at the School of Pharmacy on Tuesday March 25th at 7.30 pm.

The primary investigator for the project is Mr. Jeff Hughes, Senior Lecturer at the School of Pharmacy, Curtin University and the funding grant is from the Third Community Pharmacy Agreement Research and Development Grants program. The aim of this study is to evaluate patient specific diabetes mellitus education programs for community pharmacists that would form part of a disease management program. Existing pharmacy-based diabetes patient education programs frequently involve standardised assessments, intensive counseling by the pharmacist and group education. As compared to the use of “standardized education programs” a tailored approach focuses specifically on patient knowledge deficits. In doing so, such programs offer greater efficiencies and are likely to have a higher level of patient acceptance. Such programs have the potential to significantly reduce health care expenditure through improving patient compliance rates and achievement of treatment targets thus reducing complications and their associated costs.

The study will be undertaken at 8 subagent pharmacies located in the metropolitan area, at 4 control and 4 intervention sites. It is envisaged that the project will take 9 to 12 months to complete, with each patient being involved over a 6-month period. Pharmacists in each site will undergo a one-day training program. This training program will include patient recruitment and consent, assessment of patient knowledge, educational strategies to be employed and documentation requirements. As well as pharmacist remuneration for their involvement, pharmacies will receive Continuous Quality Improvement (CQI) credit points at a rate of one point for every 10 hours involvement in the research project. Prior to the commencement of the study, metropolitan Divisions of General Practice will be contacted to arrange a meeting to explain the aims and structure of the project, and to enlist their support and cooperation.

APPENDIX 3

Each pharmacy will be responsible for recruiting 50 patients with Type 2 diabetes. Patients will be recruited when they present a prescription for an antidiabetic medication. At this time the pharmacist will discuss the aims and structure of the study to the patients, they will be invited to become a participant and to complete the initial questionnaire. Control and intervention groups will be matched based on patient demographics, socio-economic status and the duration and severity of their diabetes. Control and intervention pharmacies will not be allocated from within the same Division of General Practice to avoid any possible bias.

We hope you will consider participation by your pharmacy in this project. For catering purposes, please advise either Jeff Hughes (9266 7367) or Jenny Wilkinson (9266 7419) by 20th March, whether you are able to attend the information session on March 25th.

Yours sincerely,

Jeff Hughes and Jenny Wilkinson

APPENDIX 4

Research Agreement between Project Pharmacy and Investigators

Customised Education Programs for patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study)

In agreeing to participate in the abovementioned study I understand my obligations to be as follows:

1. To actively promote the study within my pharmacy
2. To recruit fifty (50) subjects aged 18 years or older with type 2 diabetes mellitus who are currently receiving drug treatment for this condition
3. To explain to all eligible subjects the study's aims of the and requirements for their involvement, and to obtain informed written consent from those subjects willing to participate in the study
4. To complete all documentation (consent forms, DPAQ, DSC-R, SF-36, progress checklists, intervention records) as outlined in the study protocol and to provide this documentation to the project supervisor as outlined in study schedule
5. To notify the project supervisor when each subject is enrolled into the study as per the study protocol; and to notify the subject's general practitioner of the same.
6. To provide invoices for patient for activities undertaken as part of the study as per study protocol on the last day of each month
7. To provide assess to patients' dispensing records for the period 6 months prior to, during and 6 months after the study period, where complete data is not available through the HIC records.
8. To provide assess to patient's National Diabetes Services Scheme supply records for the period 6 months prior to, during and 6 months after the study period.

Furthermore I understand that at the completion of the study that all of the protocols and educational materials used in the study will be made available to my pharmacy and that the pharmacy will be provided with an executive summary of the results of the study.

Name: _____

Pharmacy: _____

Address: _____

Signature: _____ Date: _____

Witness: _____ Date: _____

APPENDIX 5

Diabetes Patient Assessment Questionnaire

PATIENT DATA

Name (Mr/ Mrs/ Ms/ Dr) _____

Address _____

_____ Postcode _____

Phone Number: Home (08) _____ Work (08) _____

Date of Birth: _____ Gender ☐ Male ☐ Female
(day/month/year)

Medicare Number _____

What is the last level of education completed by you? (Tick appropriate response)

☐ Primary school ☐ Year 10 (Junior) ☐ Year 12 (Leaving)

☐ Bachelor university degree ☐ Post-graduate university qualification

Who is your general practitioner?

Address and phone number of general practitioner, if known:

Phone Number: (08) _____

DIABETES MANAGEMENT DATA

When did you last see your general practitioner about diabetes? Month/Year

Have you been seen by a specialist in diabetes care? ☐ Yes ☐ No

If so, please state the name of the specialist _____

When did you last see your specialist about diabetes? Month/Year _____

Do you have a full medical check-up at least once a year? ☐ Yes ☐ No

How long have you had diabetes?

☐ Less than 1 year ☐ 6-10 years

☐ 1-2 years ☐ more than 10 years

APPENDIX 5

☐ 3-5 years

In the last month have you had any of the following symptoms? (Tick as many as apply)

☐ Increased thirst (polydipsia)

☐ Blurred vision

☐ Increased urination (polyuria)

☐ Fatigue

☐ Increased hunger (polyphagia)

☐ Itching

☐ Recurrent or poorly healing infections

☐ Weight gain

☐ Weight loss

☐ No symptoms

How many days in the last month have you had high blood sugar levels with symptoms such as thirst, dry mouth and skin, increased sugar in urine, less appetite, nausea or fatigue?

☐ 0 days

☐ 7-12 days

☐ 1-3 days

☐ more than 12 days

☐ 4-6 days

☐ Don't know

Do you know

a) How to recognize these symptoms of hyperglycaemia? ☐ Yes ☐ No,

b) When to treat them?

☐ Yes ☐ No and

c) What signs should prompt immediate medical care? ☐ Yes ☐ No

Have you ever been hospitalised for a high blood sugar level? ☐ Yes ☐ No

If yes, when *was the last time?* _____ Month/year

In the last month have you had any of the following symptoms? (Tick all that apply)

☐ Increase heart rate (tachycardia)

☐ Tremulousness

☐ Awareness of your heartbeat (Palpitations)

☐ Sweating

☐ Dizziness

☐ Hunger

☐ Inability to concentrate

☐ Impaired motor function

☐ Confusion

☐ Headache

☐ Double vision (Diplopia)

☐ Restlessness

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Do you know:

a) How to recognize these symptoms of hypoglycaemia? ☐ Yes ☐ Nob) When to treat them? ☐ Yes ☐ No andc) What signs should prompt immediate medical care? ☐ Yes ☐ No

How many times in the last month have you had low blood sugar reactions with symptoms such as sweating or weakness etc?

☐ 0 ☐ 7-12 times☐ 1-3 times ☐ more than 12 times☐ 4-6 times ☐ Don't know

How many times in the last year have you had severe low blood sugar reactions such as passing out or needing help to treat the reaction?

☐ 0 ☐ 7-12 times☐ 1-3 times ☐ more than 12 times☐ 4-6 times ☐ Don't knowDo you carry glucose tablets to treat low blood sugar? ☐ Yes ☐ NoHave you ever been hospitalised for hypoglycaemia? ☐ Yes ☐ No

If yes, when was the last time? _____ Month/Year

Have you ever lost consciousness from hypoglycaemia? ☐ Yes ☐ NoHave you ever had a seizure? ☐ Yes ☐ NoIf currently being treated with insulin or Sulfonylureas do you have a glucagon emergency kit? ☐ Yes ☐ No ☐ Not ApplicableIf yes, is the kit in date? ☐ Yes ☐ No ☐ Not sureHave you been trained to use a glucagon emergency kit? ☐ Yes ☐ NoHave you had your feet examined in the last year? ☐ Yes ☐ No

If yes, when? _____ Month/Year

Have you experienced numbness or tingling in hands or feet in the last month?

☐ Yes ☐ NoHave you been evaluated by an ophthalmologist in the past year? ☐ Yes ☐ No

If yes, when? _____ Month/Year

APPENDIX 5

Have you had a dilated pupil eye examination? ☐ Yes ☐ No ☐ Not sure

Date of last examination Month/Year _____

Results of examination: Any signs of retinopathy? ☐ Yes ☐ No ☐ Not sure

Do you report any changes in vision to your doctor? ☐ Yes ☐ No

Has someone spent time teaching you how to plan your meals with diabetes?

☐ Yes ☐ No

Do you take any of the following?

herbal remedies ☐ Yes ☐ No,

vitamins ☐ Yes ☐ No *or*

any natural products ☐ Yes ☐ No

Name(s) of Products:

Are you a non-smoker ☐ Yes ☐ No

If you smoke, how many tobacco products do you smoke per day?

Would you be interested in attending a smoking cessation program?

☐ Yes ☐ No

Do you exercise regularly? ☐ Yes ☐ No

Have you received any diabetes education? ☐ Yes ☐ No

What was the duration of the education program? (Tick applicable response)

☐ 2 hours or less; ☐ 2-4 hrs; ☐ 4-8 hrs; ☐ Several days; Other _____

APPENDIX 5

Please rate your understanding of the following topics. Circle one answer for each.

	Poor		Good		Excellent
	1	2	3	4	5
Overall diabetes care	1	2	3	4	5
Coping with stress	1	2	3	4	5
Diet for blood sugar control	1	2	3	4	5
Role of exercise in diabetes care	1	2	3	4	5
Diabetes medicines you are taking	1	2	3	4	5
How to use the results of blood sugar monitoring	1	2	3	4	5
How diet, exercise & medicines affect blood sugar levels	1	2	3	4	5
Prevention & treatment of high blood sugar	1	2	3	4	5
Prevention & treatment of low blood sugar	1	2	3	4	5
Prevention of long term complications of diabetes	1	2	3	4	5
Footcare	1	2	3	4	5
Retinopathy	1	2	3	4	5
Benefits of improving blood sugar control	1	2	3	4	5
Pregnancy and diabetes	1	2	3	4	5

Have you met with a Certified Diabetes Educator (nurse, dietitian or pharmacist) about your diabetes treatment? ☐ Yes ☐ No ☐ Not sure

How do you feel about your diabetes care? ☐ Good ☐ Average ☐ Poor

How do you feel about working to improve your diabetes care?

- ☐ I feel ready ☐ I am not sure
☐ I am a bit sceptical or need more information

Do you have a Medic Alert tag or bracelet? ☐ Yes ☐ No

Do you have a bathroom scale to weigh yourself weekly? ☐ Yes ☐ No

Has your weight changed in the past few months? ☐ Yes ☐ No ☐ Not sure

Do you test your blood sugar levels? ☐ Yes ☐ No

- a) How many days a week do you test your blood sugar levels? ____ days/week
b) On the days you test, how many times do you test your blood sugars?
____ times /day
c) Do you keep a record of your blood sugar test results?
d) ☐ Yes ☐ No ☐ Only unusual values

Do you have a blood glucose meter to self-monitor blood glucose levels?

☐ Yes ☐ No

If yes, what kind of meter?

APPENDIX 5

Can you demonstrate how to use it? ☐ Yes ☐ No

Have you been trained about how to easily get a drop of blood? ☐ Yes ☐ No

Do you belong to the Western Australian branch of Diabetes Australia?

☐ Yes ☐ No

If No, would you like information about joining? ☐ Yes ☐ No

Would you like any educational reading materials about diabetes? ☐ Yes ☐ No

Do you keep up to date with current treatment and recent advances in diabetic management? ☐ Yes ☐ No

If you answered Yes, through which of the following means is this achieved?

☐ Doctor, ☐ Pharmacist, ☐ Diabetes Nurse Educator, ☐ Diabetes Australia,

☐ Internet, ☐ Television, ☐ Magazines and newspapers

Do you frequently have "heartburn" or acid reflux problems? ☐ Yes ☐ No

Do you feel bloated or nauseated after you eat a meal? ☐ Yes ☐ No

Are you frequently constipated? ☐ Yes ☐ No

Do you have any problems with sexual function? ☐ Yes ☐ No

If you are a man, do you have erectile dysfunction (impotency)? ☐ Yes ☐ No

If you are a woman, do you have vaginal dryness? ☐ Yes ☐ No

If you are a woman, do you have frequent vaginal yeast infections? ☐ Yes ☐ No

Have you been trained in preventative dental care? ☐ Yes ☐ No ☐ Not sure

Do you brush and floss at least twice a day? ☐ Yes ☐ No

Do you see a dentist at least twice a year? ☐ Yes ☐ No

Do you get a new toothbrush at least every 2 weeks? ☐ Yes ☐ No

Have you been trained in preventative foot care? ☐ Yes ☐ No

Do you examine your feet daily? ☐ Yes ☐ No

Do you have a quality pair of nail clippers? ☐ Yes ☐ No

Do you rub lotion on your feet each night? ☐ Yes ☐ No

Do you have a mirror to help you see all areas of your feet? ☐ Yes ☐ No

Do you frequently have athlete's foot? ☐ Yes ☐ No

Do you have fungal infections of your toenails? ☐ Yes ☐ No

Have you been trained as to how to break in a new pair of shoes? ☐ Yes ☐ No

Would you like me to test your feet for neuropathy? ☐ Yes ☐ No

Do you take a daily multivitamin that is high in antioxidants?

☐ Yes ☐ No ☐ Not sure

APPENDIX 5

Would you like information about the need for vitamins C and E, folic acid, magnesium, zinc, selenium, chromium, calcium, B vitamins? ☐ Yes ☐ No

Do you take any "natural" or "herbal" remedies for diabetes? ☐ Yes ☐ No

If yes, please list: _____

Do you suffer from any diabetes complications? ☐ Yes ☐ No

If yes, which ones? _____

Please tick any of the following that you have:

- | | |
|--|---|
| <input type="checkbox"/> Neuropathy in hands or feet | <input type="checkbox"/> Skin problems |
| <input type="checkbox"/> Retinopathy or other eye problems | <input type="checkbox"/> Bladder infections |
| <input type="checkbox"/> Kidney problems | <input type="checkbox"/> Heart problems |
| <input type="checkbox"/> Frequent urination | <input type="checkbox"/> Frequently tired |
| <input type="checkbox"/> Pain in legs after walking | |
| Other (please list) _____ | |

LABORATORY VALUES

Have you had your hemoglobin A1c (HbA1c, glycosylated hemoglobin) level measured? ☐ Yes ☐ No ☐ Don't know

If yes, what was the last value? _____ %

When was it last measured? (Month/Year) _____

What was your last fasting plasma glucose value? ☐ Don't know; or _____ mmol/L

Have you ever been tested for protein in your urine (microalbuminuria)?

☐ Yes ☐ No ☐ Don't know

Have you ever had ketones in your blood or urine? ☐ Yes ☐ No ☐ Don't know

What are the values for your blood pressure?

[Blood pressure goal is <130 (systolic)/85 (diastolic) mmHg]

Systolic _____ Diastolic _____ ☐ Don't know

What are your blood lipid (fat) values?

HDL _____ LDL _____ Total cholesterol _____

Triglycerides _____ ☐ Don't know

When were your blood lipid values last tested? (Month/Year) _____

Please state your weight: _____ Kg.

Your height: _____ cm. (or _____ ft. _____ inches)

(BMI can be calculated from these values _____) [Pharmacist will fill in]

If you are a woman, have you had a bone density screening (for osteoporosis)?

APPENDIX 5

☐ Yes ☐ No

Date of last screening Month/Year _____

TREATMENT FOR DIABETES

Have you met with a dietitian and had a nutrition program prescribed? ☐ Yes ☐ No

If yes, do you limit calories? ☐ Yes ☐ No

If yes, do you count carbohydrates? ☐ Yes ☐ No

Do you consume alcohol? ☐ Yes ☐ No

If yes, how many drinks per week _____?

Beer _____ (full/medium/light strength) Wine _____ Spirits _____

(Circle which type of beer)

Do you exercise

☐ Sometimes- daily

☐ Sometimes- weekly

☐ Yes- daily

☐ Yes- weekly

☐ No

What length of time do you spend exercising each week?

☐ None

☐ 3-4 hours

☐ Up to 1 hour

☐ 4-5 hours

☐ 1-2 hours

☐ 5-6 hours

☐ 2-3 hours

☐ more than 6 hours

What type of exercise:

☐ Walking ☐ Running ☐ Cycling ☐ Dancing ☐ Swimming ☐ Aerobics

☐ Tai Chi ☐ Tennis ☐ Weight training ☐ Other _____

Do you inject insulin to treat your diabetes?

☐ Yes ☐ No

If yes, which type of insulin and how much and how often do you inject?

Insulin type _____

(Insulin types include NPH, Regular, Humalog, Ultralente, Lente or Mixtures)

Daily number of units _____ Injections /day _____

Do you take any oral agents to treat your diabetes?

☐ Yes ☐ No

If YES, circle the medications you take and fill in the dose and how often you take them.

Glipizide (Melizide, Minidiab), or glimepiride (Amaryl) or Glibenclamide (Glimel, Daonel) or Gliclazide (Diamicron, Nidem) _____

Metformin (Diabex, Diaformin, Glucohexal, Glucomet, Glucophage)

Acarbose (Glucobay)

APPENDIX 5Pioglitazone (Actos) or Rosiglitazone (Avandia)

Repaglinide (NovoNorm) _____

Has your pharmacist or doctor told you:

How and when to take your medications?

☐ Yes ☐ No

How to store your medications?

☐ Yes ☐ No

Do you have any questions about your medications?

☐ Yes ☐ NoDo you take your diabetic medication regularly at the correct time? ☐ Yes ☐ No

Do you take any medications to treat high blood pressure?

☐ Yes ☐ NoIf yes, please list the medication's name(s):

Do you take any medications to treat high blood fats (cholesterol, triglycerides)?

☐ Yes ☐ NoIf yes, please list the medication's name:

Do you take any medications to treat diabetes complications?

☐ Yes ☐ NoIf yes, please list the medication's name(s):

Do you currently, or have you in the past, suffered from any other medical conditions?

☐ Yes ☐ NoIf yes, please list all of the conditions:

Do you take any medications to treat any other conditions?

☐ Yes ☐ NoIf yes, please list all of the medications:

Do you have any allergies to medicines?

☐ Yes ☐ NoIf yes, please list all of the medication to which you are allergic:

APPENDIX 5

If you are a female and between 17 to 45 years of age:

Are you now or planning to become pregnant in the near future? ☐ Yes ☐ No

If yes:

Have you ever had an infant 4kg (9 lbs) or greater? ☐ Yes ☐ No

Any history of toxemia, stillbirth or other complications of pregnancy? ☐ Yes ☐ No

OTHER TOPICS

Please list any other healthcare issues that you would like to discuss:

1. _____
 2. _____
 3. _____
 4. _____
-

FOR EDUCATOR'S USE:

TOPICS THAT NEED ATTENTION:

TREATMENT PLAN:

Short-term plan:

Next appointment _____

Information needed from physician:

Other: _____

Long-term plan:

Dates of Interventions

APPENDIX 6

PATIENT EDUCATION LOG

Patient Name: _____ Patient Code: _____ Pharmacist: _____

Date of Enrolment: _____ Contact Details: _____

Education Topics Identified		Discussion Dates (Session Number)		
1.	_____			
2.	_____			
3.	_____			
4.	_____			
5.	_____			
6.	_____			
7.	_____			
8.	_____			
9.	_____			
10.	_____			

Schedule of Education Sessions

Number	Date (if not required mark as N/R)	Time
1	_____	_____
2	_____	_____
3	_____	_____

APPENDIX 6**Education Session 1 (Patient ID: _____ Date: _____ Time: _____)**

Topic	Issues Discussed (Complete when the education for a particular topic is tailored specifically for an individual patient. Where standard material is covered annotate – “Standard”)	Comments (Report any feed-back from the patient and your opinion of how the session went)	Written Material Provided (Type & Source)	Time Taken (in 15min blocks)

APPENDIX 6**Education Session 2 (Patient ID: _____ Date: _____ Time: _____)**

Topic	Issues Discussed (Complete when the education for a particular topic is tailored specifically for an individual patient. Where standard material is covered annotate – “Standard”)	Comments (Report any feed-back from the patients and your opinion of how the session went)	Written Material Provided (Type & Source)	Time Taken (in 15min blocks)

APPENDIX 6**Education Session 3 (Patient ID: _____ Date: _____ Time: _____)**

Topic	Issues Discussed (Complete when the education for a particular topic is tailored specifically for an individual patient. Where standard material is covered annotate – “Standard”)	Comments (Report any feed-back from the patients and your opinion of how the session went)	Written Material Provided (Type & Source)	Time Taken (in 15min blocks)

APPENDIX 7

DIABETES MELLITUS EDUCATION PROGRAM (DMEP)

CUSTOMISED EDUCATION

PATIENT NAME: _____ PATIENT CODE: _____

EDUCATION MODULES AVAILABLE FOR REVIEW

EDUCATION MODULE	CONTENT
Alcohol	<ul style="list-style-type: none"> Things to remember about consuming alcohol when you suffer from diabetes
Don't forget your lipids	<ul style="list-style-type: none"> What are lipids? Different types of lipids Why should lipids be checked?
Footcare	<ul style="list-style-type: none"> Circulation Nerve supply Daily foot care First aid Podiatrists
Healthy food for healthy living	<ul style="list-style-type: none"> Using the healthy food pyramid Putting the pyramid into practice
Hyperglycemia	<ul style="list-style-type: none"> What is it? What are the symptoms? What causes it?
Hypoglycemia	<ul style="list-style-type: none"> What is it? What causes it? What are the symptoms? How to treat? How can it be prevented?
Impaired glucose tolerance (IGT)	<ul style="list-style-type: none"> What is it? What happens in the body with IGT? How is it treated?
Insulin	<ul style="list-style-type: none"> Storage and Delivery Expiry Dates Injection sites and Injection times Dose adjustments
Investing in good health for the future	<ul style="list-style-type: none"> How healthy is your lifestyle Medical check-up
Monitoring diabetes control	<ul style="list-style-type: none"> Blood testing: why, how, when & how to record Obtaining blood testing supplies Glucometers HBA1C (Glyco-Haemoglobin)
Physical activity	<ul style="list-style-type: none"> Why it is important Getting started Activity ideas
Sugar	<ul style="list-style-type: none"> How much is a "small amount"? Types of sugars
Sugar substitutes & artificial sweeteners	<ul style="list-style-type: none"> Types of sugar substitutes
Tablets for your diabetes	<ul style="list-style-type: none"> Sulphonylureas Meglitinides Biguanides Acarbose Thiazolidinidiones
The carbohydrate connection	<ul style="list-style-type: none"> What are carbohydrates? Which are the best? How much carbohydrate? Fibre
The diabetes travel guide	<ul style="list-style-type: none"> The travel checklist Packing In flight Changes to meals Handy hints
The facts about fat	<ul style="list-style-type: none"> Fat & Diabetes Types of fat Where are fats found How to reduce fat

APPENDIX 8

Diabetes Symptom Checklist (DSC-R)

Instruction

People with diabetes can experience various discomforting physical and mental symptoms related to their disease. This questionnaire reflects most of the symptoms reported by diabetic patients treated with diet, tablets and/or insulin. Please circle the answer that reflects your experience of symptoms in the past month, today included.

If a symptom did not occur, please circle "No" in the column "DID SYMPTOM OCCUR"

EXAMPLE

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WASTROUBLESOME TO ME				
		not at all	a little	moderately	very	extremely
Sore throat?	No					
	Yes <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	1	<u>2</u>	3	4	5

This answer means:

In the last month I did have a sore throat and it was a little troublesome to me.

How much trouble have these symptoms given you
over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WASTROUBLESOME TO ME				
		not at all	a little	moderately	very	extremely
1. Lack of strength (energy)?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
2. Aching calves when walking?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
3. Numbness (loss of sensation) in the feet?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
4. An overall sense of fatigue?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
5. Shortness of breath at night?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
6. Sleepiness or drowsiness?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
7. Difficulty concentrating?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
8. Moodiness?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
9. Numbness (loss of sensation) in the hands?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
10. Persistently blurred vision (also with glasses on)?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5

How much trouble have these symptoms given you
over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WASTROUBLESOME TO ME				
		not at all	a little	moderately	very	extremely
11. Tingling sensations in the limbs at night?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
12. Very thirsty?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
13. Palpitations or pains in the breast or heart region?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
14. Deteriorating vision?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
15. Burning pain in the calves at night?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
16. Dry mouth?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
17. Increasing fatigue during the course of the day?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
18. Flashes or black spots in the field of vision?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
19. Irritability just before a meal?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
20. Fatigue in the morning when getting up?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5

How much trouble have these symptoms given you
over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WASTROUBLESOME TO ME				
		not at all	a little	moderately	very	extremely
21. Shooting pains in the legs?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
22. Fluctuating clear and blurred vision ?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
23. Frequent voiding?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
24. Pains in the breast or heart region?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
25. Burning pain in the legs during the day?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
26. Tingling or prickling sensations in hands or fingers?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
27. Easily irritated or annoyed?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
28. Sudden deterioration of vision?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
29. Odd feeling in legs or feet when touching?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5

How much trouble have these symptoms given you
over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WASTROUBLESOME TO ME				
		not at all	a little	moderately	very	extremely
30. Shortness of breath during exercise?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
31. Dull head?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
32. Drinking a lot (all sorts of beverages)?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
33. Difficulty staying attentive?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
34. Tingling or prickling sensations in legs or feet?	No Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
Other symptoms:						
35. _____	Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
36. _____	Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5
37. _____	Yes <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1	2	3	4	5

Will you please check if you have answered **all** the questions?

Scoring of the Diabetes Symptom Checklist, DSC-r

Psychology, fatigue: $(dscr1+dscr4+dscr17+dscr20)/4$.

Psychology, cognitive: $(dscr6+dscr7+dscr31+dscr33)/4$.

Neurology, pain: $(dscr2+dscr15+dscr21+dscr25)/4$.

Neurology, sensoric: $(dscr3+dscr9+dscr11+dscr26+dscr29+dscr34)/6$.

Cardiology: $(dscr5+dscr13+dscr24+dscr30)/4$.

Oftalmology: $(dscr10+dscr14+dscr18+dscr22+dscr28)/5$.

Hypoglycemia: $(dscr8+dscr19+dscr27)/3$.

Hyperglycemia: $(dscr12+dscr16+dscr23+dscr32)/4$.

APPENDIX 9

AUSTRALIA/NEW ZEALAND SF-36 FORM

AUSTRALIA/NEW ZEALAND STANDARD SF-36, BOOKLET FORM

SF-36 HEALTH SURVEY

INSTRUCTIONS: This questionnaire asks for your views about your health, how you feel and how well you are able to do your usual activities.

Answer every question by making the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent.....1
Very good2
Good.....3
Fair.....4
Poor.....5

2. Compared to one year ago: how would you rule your health in general now?

(circle one)

Much better now than one year ago.....1
Somewhat better now that one year ago.....2
About the same as one year ago.....3
Somewhat worse now than one year ago.....4
Much worse now than one year ago.....5

AUSTRALIA/NEW ZEALAND STANDARD SF-36, BOOKLET FORM

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No. Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner.	1	2	3
c. Lifting or carrying groceries.	1	2	3
d. Climbing several flights of stairs.	1	2	3
e. Climbing one flight of stairs.	1	2	3
f. Bending, kneeling, or stooping.	1	2	3
g. Walking more than one kilometre.	1	2	3
h. Walking half a kilometre.	1	2	3
i. Walking 100 metres.	1	2	3
j. Bathing or dressing yourself.	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	Yes	No
a. Cut down on the amount of time you spent on work or other activities.	1	2
b. Accomplish less than you would like.	1	2
c. Were limited in the kind of work or other activities.	1	2
d. Had difficulty performing the work or other activities (for example, it took extra effort).	1	2

AUSTRALIA/NEW ZEALAND STANDARD SF-36, BOOKLET FORM

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	Yes	No
a. Cut down on the amount of time you spent on work or other activities.	1	2
b. Accomplish less than you would like.	1	2
c. Didn't do work or other activities as carefully as usual.	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

AUSTRALIA/NEW ZEALAND STANDARD SF-36, BOOKLET FORM

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all..... 1

A little bit..... 2

Moderately..... 3

Quite a bit..... 4

Extremely..... 5

9. These questions are about how you feel things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life.	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt down?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

AUSTRALIA/NEW ZEALAND STANDARD SF-36, BOOKLET FORM

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

Not at all..... 1

A little bit 2

Moderately..... 3

Quite a bit..... 4

Extremely..... 5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people.	1	2	3	4	5
b. I am as healthy as anybody I know.	1	2	3	4	5
c. I expect my health to get worse.	1	2	3	4	5
d. My health is excellent.	1	2	3	4	5

APPENDIX 10

Diabetes Mellitus Study Patient Diary

Diaries were issued at the time of enrolment and at the 3 month follow-up visit

		STUDY CODE				I	1	:		
PATIENT'S NAME										

DIABETES MELLITUS
CUSTOMISED EDUCATION
PROGRAMS

PATIENT'S DIARY

ENTRY TO 3 MONTHS

Please bring your diary with you when you return for your follow-up appointments with the pharmacist after 1, 3, and 6 months. Date enrolled in the study / /

Your **Pharmacist Diabetes Educator** is
Diana / Julie / Shelley

Diary Index

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Diabetes Mellitus Study –Education Appointments

Your Education Pharmacist: Diana / Julie / Shelley has made an appointment with you
on _____ at _____ a.m. / p.m.

Please phone (08) _____ if you are unable to keep your
appointment, preferably ***at least 24 hours in advance*** so an alternative appointment
can be scheduled. Thank you.

Your Education Pharmacist: Diana / Julie / Shelley has made an appointment with you
on _____ at _____ a.m. / p.m.

Please phone (08) _____ if you are unable to keep your
appointment, preferably ***at least 24 hours in advance*** so an alternative appointment
can be scheduled. Thank you.

Your Education Pharmacist: Diana / Julie / Shelley has made an appointment with you
on _____ at _____ a.m. / p.m.

Please phone (08) _____ if you are unable to keep your
appointment, preferably ***at least 24 hours in advance*** so an alternative appointment
can be scheduled. Thank you.

Dear Doctor,

Our project, entitled *Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules*, aims to assess the impact of community pharmacy-based diabetes education programs on the outcome of diabetes management in patients with Type 2 diabetes mellitus. Patients enrolled in this study have given permission to contact their general practitioners to discuss their progress and obtain relevant clinical and laboratory data. It would be greatly appreciated if you would complete the following details from the patient's medical records to assist in the study. Thanking you for your co-operation in this matter.

Mr Jeff Hughes, Senior Lecturer,
School of Pharmacy, Curtin University of Technology,
GPO Box U1987, PERTH WA 6845
Phone: 9266 7367

Clinical and Laboratory Data from Medical Records

Parameter	Date Last Measured	Value/ Result
Haemoglobin A1c	/ /	%
Fasting plasma glucose	/ /	mmol/L
HDL	/ /	mmol/L
LDL	/ /	mmol/L
Total Cholesterol	/ /	mmol/L
Triglycerides	/ /	mmol/L
Blood Pressure	/ /	mm Hg
Bone mineral density	/ /	

What is Type II / Non Insulin Dependent Diabetes?

Diabetes is a condition where the blood has too much sugar or glucose in it.

Why is there too much sugar?

This happens because not enough **insulin** is being produced or the insulin is not working properly. As a result the sugar is not transported from the blood into cells where it is used for energy.

What is glucose?

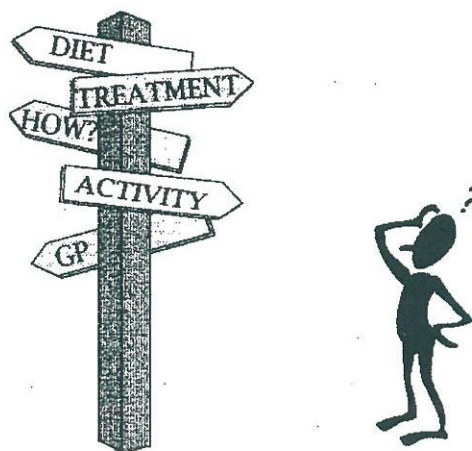
Glucose is a form of sugar. Our bodies use glucose for energy. Glucose comes from our bodies breaking down foods which contain carbohydrates e.g. bread and pasta.

What is insulin?

Insulin is a hormone, produced by the pancreas. It is responsible for helping the glucose enter the cells.

What now?

Talk to your GP about your diabetes, help that you can get e.g. diabetes education and support groups, and the best ways **YOU** can control it.



How did I get Diabetes?

Type II diabetes can affect people over the age of 50 who are;

- ★ Overweight
- ★ Have an immediate relative with Type II Diabetes
- ★ Suffer from high blood pressure

OR

- ★ Who are over 65
- ★ Have heart disease
- ★ Had a very large baby (bigger than 4kg / 9lb) or high blood sugar levels during pregnancy.
- ★ Had a borderline to high blood sugar test

OR

If you are over 35 and are:

- ★ Aboriginal / Torres Strait Islander
- ★ A Pacific Islander
- ★ From the Indian sub continent
- ★ From Chinese cultural background

Can I be cured?

There is no cure for diabetes. But, **YOU** can control it well by;

- ★ Living a health lifestyle.
- ★ Keeping to your treatment.
- ★ Monitoring your blood sugars regularly.
- ★ Seeing your GP on a regular basis.
- ★ Attending all appointments to GPs and other Health Professionals.



Why do I need to see my GP for treatment?

Why is treatment important?

Treatment is important because it controls your blood sugar levels and prevents complications from happening. If your diabetes is not well controlled you are at risk of:

- ★ Fainting or going into a coma
- ★ Damage to your eyes
- ★ Damage to your kidneys
- ★ Poor circulation
- ★ Damage to your feet
- ★ Heart disease or a stroke
- ★ Impotence

Aims of treatment

- ★ To improve the quality of your life.
- ★ To keep your blood sugar level in a suitable range
- ★ To lose weight if you are over weight.
- ★ To stay at an ideal weight.
- ★ Reduce the risk of heart disease.

Types of treatment

- ★ Well controlled diet (see diet information sheet)
- ★ Regular physical activity (see activity sheet)
- ★ Tablets
- ★ Insulin

Don't forget that **YOU** are in ultimate control of your diabetes management. It is up to **YOU** to change your diet, be more active and take any treatment as advised.





What can I eat?



There is no such thing as a rigid “diabetic” diet. But, you have to ***make sure you eat a healthy diet.***

- ★ **Eat food that is low in fat** – e.g. lean meat, low fat milk/yoghurt, fruit and vegetables. This helps you to lose weight if you are over weight or to maintain a healthy weight.
- ★ **Eat food that contains carbohydrates and high fibre** – such as; bread, rice, pasta. These should be the base of every meal as they provide you with glucose (for energy) and stops blood glucose from rising too quickly.
- ★ **Eat less sugar** – perhaps eat it on special occasions e.g. birthdays.
- ★ **Drink less alcohol** – no more than 1 or 2 standard drinks a day and have 1 or 2 drink free days a week. You may prefer not to have alcohol at all.
- ★ **Eat less salt.**
- ★ **Eat regular meals.**

If you are confused or are finding it hard to identify the right foods, ask your GP about seeing a dietician.



What regular checks do I need and why?

Diabetes is a complex condition which can effect different areas of the body. It is important that you have the following checks:

Every 3 months by your GP:

- ★ Weight
- ★ Home blood sugar levels
- ★ Blood pressure
- ★ HbA1c - this measures your average blood glucose levels over the past 3 months.
- ★ Your current treatment.

Every 6 months by your GP / Podiatrist:

- ★ Foot examination.

Every 12 months by your GP or relevant specialist:

- ★ **Kidneys.** Your GP will ask for a microalbumin test, which checks for the amount of protein in your urine, to see if you have any kidney damage.
- ★ **Eyes.** These are checked to see whether damage has been caused to the blood vessels in the back of your eye.
- ★ **Cholesterol.** Heart disease is common in people with diabetes, so it is important to check your levels of cholesterol and keep them controlled.





Blood Sugar.



How do I know if my blood sugar is low?

You will know your blood sugar is low (also known as having a hypo) because you may feel one (or more) of the following:

- ★ Dizzy
- ★ Hungry
- ★ Shaky
- ★ Sleepy
- ★ Sweaty.

Why does this happen?

Low blood sugar can happen for different reasons:

- ★ Skipping a meal or leaving big gaps between meals.
- ★ Eating too little food.
- ★ Drinking too much alcohol.
- ★ Exercising more than normal.
- ★ Taking too much diabetes medicine.

If you think your blood sugar is low, **TEST IT.**

If it is less than 4 mmol/L, eat 15 gms of carbohydrates e.g.;

- ★ 4 teaspoons of sugar
- ★ ½ cup of fruit juice
- ★ 1 cup of fat free or low fat milk.

Follow this with a complex carbohydrate snack e.g. a sandwich.

After 15 minutes test your blood sugar again.

***If you are having trouble with your blood sugar,
see your GP.***

Goals for Diabetes Management

Blood Glucose Level	Fasting: 4 – 5.5 mmol/L
	Random: 4 – 7.8 mmol/L
Glycosylated Haemoglobin (HbA _{1c})	Less than 7 %
Cholesterol	Less than 5.5 mmol/L
Cholesterol/High Density Lipoprotein Cholesterol Ratio	Less than 4.5 mmol/L
Blood Pressure	Less than 130/85 mm Hg
Body Mass Index	Less than 25 where practicable
Urinary Albumin Excretion	Less than 20 µg/min or mg/L
Cigarette Consumption	Zero
Alcohol	Less than 20 g/day
Exercise	At least 20 minutes, a minimum of four times a week

Patient Diabetes Management Health Targets

<i>Issue</i>	<i>Action</i>	<i>Plan</i>

Patient Diabetes Management Health Targets

<i>Issue</i>	<i>Action</i>	<i>Plan</i>

Planned Appointments Diary for Doctors & Other Health Professionals			
Date	Time	Name of Doctor / Health Professional	Reason for Visit (Eg Illness, Diabetes Review, Blood Test, refill prescriptions)

Emergency Appointments with Doctors & Other Health Professionals or Diabetes-related Emergency Attendance at Hospital			
Date	Time	Name of Doctor / Health Professional/ Hospital	Reason for Visit (Eg Illness, Diabetes Review, Blood Test)

Please record between Progress Check Visits with your Pharmacist, all the occasions when you have any of the following reactions

- 1) A **low blood sugar (glucose)** with symptoms such as sweating, weakness, anxiety, trembling, hunger or headache **or**
- 2) A **severe low blood sugar** with symptoms such as passing out or needing help to treat the reaction **or**
- 3) A **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue.

[illegible]

[illegible]

Weekly Weight Measurements		
Target Weight (Kg):		
<i>Please record weight on the same day each week at approximately the same time in clothing of similar weight etc.</i>		
Week	Date	Weight (Kg)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		

Name: _____

Month/Year: _____

BLOOD GLUCOSE LEVELS (mmol/L)

DAY	Date	BREAKFAST			LUNCH			DINNER			Over-night	Remarks eg. Activity, illnesses, diet changes, anxiety, infections
		Before	After	Time after (hours)	Before	After	Time after (hours)	Before	After	Time after (hours)		
SUN												
MON												
TUE												
WED												
THUR												
FRI												
SAT												
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APPENDIX 11

STUDY CODE			:		
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Progress Check List

Date _____ **Visit No.** _____ **Patient** _____

For the following questions, please check the appropriate response.

Q1. How many **times** in the last **month** have you had a **low blood sugar** (glucose) reaction with symptoms such as sweating, weakness, anxiety, trembling, hunger or headache?

- ☐₁ 0 times
☐₂ 1-3 times
☐₃ 4-6 times
☐₄ 7-12 times
☐₅ More than 12 times
☐₆ Don't know

Q2. How many **times** in the last **year** have you had **severe low blood sugar** reactions such as passing out or needing help to treat the reaction?

- ☐₁ 0 times
☐₂ 1-3 times
☐₃ 4-6 times
☐₄ 7-12 times
☐₅ More than 12 times
☐₆ Don't know

Q3. How many **days** in the last **month** have you had **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue?

- ☐₁ 0 days
☐₂ 1-3 days
☐₃ 4-6 days
☐₄ 7-12 days
☐₅ More than 12 days
☐₆ Don't know

Q4. How many **times** in the last **month** have you had visit your **doctor or the hospital** with **diabetes** related problems such as low or high blood glucose, infections or eye problems?

- ☐₁ 0 times
☐₂ 1 time
☐₃ 2-3 times
☐₄ 4-5 times
☐₅ More than 5 times
☐₆ Don't know

APPENDIX 11

For the following questions, please circle the appropriate response. (circle one answer for each line)

Q5. During the past month, how often did your blood sugar become too high because: (circle one answer for each line)						Don't Know
	Never	Sometimes			Often	
a) you were sick or had an infection?	1	2	3	4	5	DK
b) you were upset or angry?	1	2	3	4	5	DK
c) you took the wrong amount of medicine?	1	2	3	4	5	DK
d) you ate the wrong types of food?	1	2	3	4	5	DK
e) you ate too much food?	1	2	3	4	5	DK
f) you had less physical activity than usual?	1	2	3	4	5	DK
g) you were feeling stressed?	1	2	3	4	5	DK

Q6. During the past month, how often did your blood sugar become too low because: (circle one answer for each line)						Don't Know
	Never	Sometimes			Often	
a) you were sick or had an infection?	1	2	3	4	5	DK
b) you were upset or angry?	1	2	3	4	5	DK
c) you took the wrong amount of medicine?	1	2	3	4	5	DK
d) you ate the wrong types of food?	1	2	3	4	5	DK
e) you ate too little food?	1	2	3	4	5	DK
f) you had more physical activity than usual?	1	2	3	4	5	DK
g) you waited too long to eat or skipped a meal?	1	2	3	4	5	DK
h) you were feeling stressed?	1	2	3	4	5	DK

APPENDIX 11

	Never		Sometimes		Always
Q7. How often do you follow the schedule for your meals and snacks?	1	2	3	4	5
List any factors that prevent you following your schedule					
	Never		Sometimes		Always
Q8. How often do you follow the schedule for your medications?	1	2	3	4	5
List any factors that prevent you following your schedule					

	Never		Sometimes		Always
Q9. How often do you follow the schedule for your exercise?	1	2	3	4	5
List any factors that prevent you following your schedule					

	Never		Sometimes		Always
Q10. How often do you follow the schedule for monitoring your blood sugars?	1	2	3	4	5

APPENDIX 11

Q11. When you don't test for sugar as often as you have been told, how often is it because:					
	Rarely		Sometimes		Often
a) you forgot?	1	2	3	4	5
b) you don't believe it is useful?	1	2	3	4	5
c) the time or place wasn't right?	1	2	3	4	5
d) you don't like to do it?	1	2	3	4	5
e) you ran out of test materials?	1	2	3	4	5
f) it costs too much?	1	2	3	4	5
g) it's too much trouble?	1	2	3	4	5
h) it's hard to read the test results?	1	2	3	4	5
i) you can't do it by yourself?	1	2	3	4	5
j) your levels don't change very often?	1	2	3	4	5
k) it hurts to prick your finger?	1	2	3	4	5

Q12. During the last month have you achieved your target weight (or lost weight)

☐₁ yes

☐₂ no

☐₃ Don't know

What is your target weight? _____ kg

What is your current weight? _____ kg

How much weight did you loss? _____ kg

If you are a smoker complete Q 13

Q13. During the last month have you reduced your cigarette use or cease smoking?

☐₁ yes Ceased / Reduced by _____ cigarettes/week

☐₂ no

Q14. During the last month have you had your blood pressure checked?

☐₁ yes

☐₂ no

☐₃ Don't know

If yes, do you know what the reading was ? _____ / _____ mmHg

APPENDIX 11

Q15. During the last 3 months have you had your lipids (cholesterol and/or triglycerides) checked?

☐₁ yes

☐₂ no

☐₃ Don't know

If yes, do you know what the values were?

Cholesterol _____ mmol/L; HDL _____ mmol/L; triglycerides _____ mmol/L

Q16. During the last 3 months have you had your haemoglobin A_{1C} (HbA_{1C}, glycosylated haemoglobin) checked?

☐₁ yes

☐₂ no

☐₃ Don't know

If yes, do you know what the value was? _____ %

APPENDIX 11

Q17. Do you have any concerns about the current management of your diabetes?

☐₁ yes

☐₂ no

If yes please list your concerns

Q18. How do you rate your understanding of:					
	Poor		Good		Excellent
a) diet and blood sugar control	1	2	3	4	5
b) weight management	1	2	3	4	5
c) exercise	1	2	3	4	5
d) use of insulin/tablets	1	2	3	4	5
e) sugar testing	1	2	3	4	5
f) foot care	1	2	3	4	5
g) complications of diabetes	1	2	3	4	5
h) eye care	1	2	3	4	5
i) combining diabetes medication with other medications	1	2	3	4	5
j) alcohol use and diabetes	1	2	3	4	5

APPENDIX 11

Pharmacist Only Use

Actions

Include details on any of the following – reassessment of treatment target, patient education, patient counseling, referral to other health care professionals, advice of diet, exercise or smoking cessations, medication adherence assistance and assistance with disease monitoring

<i>Issue</i>	<i>Action</i>	<i>Plan</i>

APPENDIX 12

Ethics Approvals

The Confidentiality of Health Information Committee (CHIC)

Curtin University of Technology, Human Research Ethic Committee (HREC)

CONFIDENTIALITY OF HEALTH INFORMATION COMMITTEE (CHIC)
An Independent Committee appointed by the Minister for Health in Western Australia

Please address all correspondence to:-

Project Officer - CHIC
Health Information Centre
1st Floor 'C' Block
189 Royal Street
EAST PERTH WA 6004

ph: (08) 9222 4194
fax: (08) 9222 4236

Mr Jeff Hughes
School of Pharmacy,
Curtin University of Technology
GPO Box 1987
PERTH WA 6845

Dear Mr Hughes,

#200433

**Customised education programs for patients with Diabetes Mellitus – Use
of structured questionnaires and education modules (DMEP)**

Date of commencement	01/05/2003
Date of completion	31/12/2005
Researchers accessing identifiable data	Mr Jeff Hughes, Mr Peter Tenni, Mr Mark Coles
Databases to be accessed	Data Linkage Unit, Hospital Morbidity Data System Emergency Department Information System
Ethics approval	Curtin University dated 10/11/03 valid to 19/11/04

Thank you for your letter dated 29/09/2004. The Confidentiality of Health Information Committee (CHIC) reviewed the letter at the meeting held on 13/10/2004.

CHIC acknowledges receipt of the Declarations of Confidentiality for the community pharmacists involved in the project. The Committee has noted the additional expertise added to the research team.

As the committee was satisfied with your response to their concerns about the project, approval is granted for you to proceed with your project subject to and conditional upon compliance with the following points:

- It is the responsibility of the researcher(s) to advise CHIC of any change to the above information or to the design protocol. Major changes to protocol that affect access to and use of data from the Department of Health datasets must be approved by CHIC.
- CHIC has a mandate to monitor the use of any data released for access. Monitoring includes the submission of an annual progress report, and a final report required at the completion of the project. Failure to submit reports may result in termination of access to data.
- CHIC reserves the right to monitor the progress of a project more intensively, as it sees fit. This monitoring may include site visits, interviews or documentation checks.

Please ensure that you provide CHIC with a copy of your Curtin University Ethics Approval renewal, as the current one expires 19/11/2004. Access to the Department of Health Data Collections is contingent on a copy of current Ethics Approval being on CHIC's file.

We wish you well with your project.

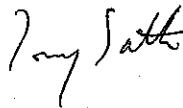
Yours sincerely



Dr David Blackledge

CHAIRPERSON

CONFIDENTIALITY OF HEALTH INFORMATION COMMITTEE



Mr Tony Satti

DIRECTOR GENERAL'S REPRESENTATIVE

18 October 2004

memorandum

To	Jeff Hughes, Pharmacy
From	Max Page, Executive Officer, Human Research Ethics Committee
Subject	PROTOCOL APPROVAL – EXTENSION HR 227/2002
Date	6 October 2004
Copy	

Office of Research and Development

**Human Research Ethics
Committee****TELEPHONE** 9266 2784**FACSIMILE** 9266 3793**EMAIL** s.darley@curtin.edu.au


The Human Research Ethics Committee acknowledges receipt of your Form B progress report for the project *Customised education programs for patients with Diabetes Mellitus - use of structured questionnaires and education modules (DMEP study)*.

Extended approval for this project is for the year to **21/09/2005**.

Your approval number remains **HR 227/2002**. Please quote this number in any further correspondence regarding this project.

Thank you.



 Maxwell Page
Executive Officer
Human Research Ethics Committee

memorandum

To	Jeff Hughes, Pharmacy
From	Max Page, Executive Officer, Human Research Ethics Committee
Subject	Protocol Approval HR 227/2002
Date	22 September 2004
Copy	Graduate Studies Officer, Division of Health Science

Office of Research and Development

Human Research Ethics Committee


TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL s.darley@curtin.edu.au

Thank you for providing additional information for the project "CUSTOMISED EDUCATION PROGRAMS FOR PATIENTS WITH DIABETES MELLITUS - USE OF STRUCTURED QUESTIONNAIRES AND EDUCATION MODULES (DMEP STUDY)".

According to our records, your original response to my letter of provisional approval was received on 22 November 2002, and I approved that the information you provided satisfactorily addressed the points raised by the Committee.

Approval of this project remains for the period of 20/11/2002 to 19/11/2004. The approval number for your project is HR 227/2002. *Please quote this number in any future correspondence.*



 Maxwell Page
Executive Officer
Human Research Ethics Committee

J:\OR\HREC\REG99\HR 227/2002

MINUTE

Curtin

UNIVERSITY OF TECHNOLOGY

To	Jeff Hughes, Pharmacy
From	Max Page, Executive Officer, Human Research Ethics Committee
Subject	PROTOCOL APPROVAL – EXTENSION HR 227/2002
Date	10 November 2003
Copy	

Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784

FACSIMILE 9266 3793

EMAIL t.lerch@curtin.edu.au

The Human Research Ethics Committee acknowledges receipt of your Form B progress report for the project *Customised education programs for patients with Diabetes Mellitus - use of structured questionnaires and education modules (DMEP study)*.

Extended approval for this project is for the year to 19/11/2004.

Your approval number remains **HR 227/2002**. Please quote this number in any further correspondence regarding this project.

Thank you.

Tania Lerch

Maxwell Page
Executive Officer
Human Research Ethics Committee

MINUTE

To	Jeff Hughes, Pharmacy
From	Tania Lerch, Secretary, Human Research Ethics Committee
Subject	MONITORING OF RESEARCH PROJECT - Progress Report and Application for Renewed Approval - HR 227/2002
Date	8 October 2003

Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL t.lerch@curtin.edu.au

Our records indicate that the Human Research Ethics Committee has granted approval for the following project:

Approval No: HR 227/2002

Investigator: Jeff Hughes, Pharmacy

Supervisor:

Project Title: "Customised education programs for patients with Diabetes Mellitus - use of structured questionnaires and education modules (DMEP study)"

Expiry Date: 19/11/2003

In order to comply with the National Health and Medical Research Council *National Statement on Ethical Conduct in Research Involving Humans* it is necessary for the researcher to complete the attached FORM B and return to the address at the foot of this page.

Please ensure that the following directions are adhered to and the FORM B is returned as soon as possible.

1. Please indicate whether the project has been completed/abandoned/not commenced/not funded/or still in progress.
2. Please ensure that **all questions are answered** as appropriate and that signatures are placed where indicated.
3. **ALL RESEARCHERS** must return this form regardless of the stage of the project.

Your co-operation in this matter is very much appreciated.



Tania Lerch
Secretary, Human Research Ethics Committee

Office of Research and Development, Curtin University of Technology, Box U1987 GPO, PERTH WA 6845

To	Jeff Hughes, Pharmacy
From	Max Page, Executive Officer, Human Research Ethics Committee
Subject	Protocol Approval HR 227/2002
Date	22 November 2002
Copy	

Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784

FACSIMILE 9266 3793

EMAIL t.lerch@curtin.edu.au

On behalf of the Human Research Ethics Committee I am authorised to inform you that the project *"CUSTOMISED EDUCATION PROGRAMS FOR PATIENTS WITH DIABETES MELLITUS - USE OF STRUCTURED QUESTIONNAIRES AND EDUCATION MODULES (DMEP STUDY)"* is granted **provisional approval**, subject to further information/clarification of the points raised below. Please forward your response to the Secretary, HREC, C/- Office of Research & Development as soon as possible.


Reviewer comments:

1. The application quotes that the questionnaire to be used in this study will be based on the DPAQ, which suggests that there will be some modification. The applicants will need to submit the modified version of the questionnaire to the HREC executive prior to the commencement of the study.
2. Patient information retrieved from HIC including Medicare numbers and pharmaceutical benefits data is highly sensitive. It may be appropriate to consider a greater level of security for this information while it is in its identifiable form. A simple locked filing cabinet may not be suitable in this instance.
3. Written approval from the head of each Pharmacy or Clinic involved in patient recruitment prior to the commencement of the study should be obtained.
4. Please comment on the exclusion of patients from non-English speaking background(s). The applicants have not provided an explanation for this exclusion criteria, which may significantly bias the sample population. It is well known Mediterranean sub-populations in Perth have a high incidence of diabetes and cardiovascular disease (Fremantle Diabetes Study). Excluding representative populations such as these may bias sample population. Please clarify.
5. Also, please provide further explanation as to the reason to not randomise patients into either control or intervention group within each Pharmacy or Clinic. The applicants intend to 'enrol' patients into either group as allocated per Pharmacy, which presents bias to the study with respect to geographical location, demographics and socio-economic status. Depending on the number of Pharmacies in each geographical region it may not be possible to compensate for these differences. Alternatively, a randomised selection within each Pharmacy or Clinic may avoid these confounders. Please clarify

Final approval will be subject to a satisfactory response to the items above. Provisional approval of this project is for a period of twelve months 20/11/2002 to 19/11/2003.

When the project has finished or if at any time during the twelve months changes/amendments occur, or if a serious or unexpected adverse event occurs, the attached FORM B is to be completed and returned to Ms Tania Lerch, (Secretary, HREC) C/- Office of Research & Development as soon as possible. The approval number for your project is **HR 227/2002**. Please quote this number in any future correspondence.

find attached your protocol details together with the application form/cover sheet.


Maxwell Page
Executive Officer
Human Research Ethics Committee

J:\OR\HREC\REG99\HR 227/2002

Please Note: If information about the authorisation of this project is required, the following standard statement is suggested for inclusion in the information to subjects section of the protocol. *This study has been approved by the Curtin University Human Research Ethics Committee. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784.*

APPENDIX 13

**Do you have
Type 2 Diabetes Mellitus?
We Need Your Help**

- ☐ The School of Pharmacy, Curtin University needs volunteers to participate in a diabetes research study
- ☐ You may be eligible for the study if you:
 - Are aged over 18 years
 - Have been diagnosed with Type 2 Diabetes Mellitus (also known as non-insulin dependent diabetes or NIDDM)
 - Have been receiving anti-diabetic medications on a regular basis

**If you are interested please speak to the
PHARMACIST**

or

**Call the Diabetes Research Group,
School of Pharmacy, Curtin University
9266 7419**

APPENDIX 14

Newspaper Advertisement

Do you have Type 2 Diabetes Mellitus?

We Need Your Help

The School of Pharmacy, needs volunteers to participate in a diabetes research study.

If you are interested and live within the metropolitan area of Perth please speak to one of our project staff who will answer any queries you may have regarding this study and then direct you to our closest participating project pharmacy in your area.

Telephone (08) 9266 7369

CRICOS provider code 003011

1911/CR11118

Curtininnovation

Curtin
UNIVERSITY OF TECHNOLOGY

APPENDIX 15

Information Letter to General Practitioners

April 2003

Dear Doctor

We wish to inform you that our pharmacy is participating in a community pharmacy research project entitled, *Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study)* and to advise you that some of your patients may consent to participate through our pharmacy's involvement in the study.

The aim of this study is to evaluate patient specific diabetes mellitus education programs for community pharmacists that would form part of a disease management program. The expected results of this tailored education program are:

1. Improved patient knowledge of diabetes, its consequences and management
2. Improved patient compliance with treatment and monitoring regimens
3. Increased number of patients achieving desired blood glucose and Hb_{1Ac} levels and reduced incidence of hypo- and hyper-glycaemic episodes
4. Reduced health care resource consumption
5. Development of a diabetes education model, which may be implemented in community pharmacies around Australia

The study is being undertaken at 8 Perth metropolitan community pharmacies- 4 control and 4 intervention sites, based on their geographical location. These groups will be matched based on patient demographics, socio-economic status and the duration and severity of their diabetes. Each pharmacy will be responsible for recruiting 50 diabetic patients. If a patient agrees to participate in the study they will be asked to give written informed consent, which will include permission to contact their general practitioners to discuss their progress and obtain relevant clinical and laboratory data.

After obtaining written informed consent, the pharmacist will interview the patient to obtain the following initial information: patient demographics, diabetes history (date of diagnosis, treatment, complications, level of control, previous diabetes education), other past medical history, medication history, history of drug allergies, and social history. The patients will then be asked to complete a diabetes questionnaire (designed to assess patient's knowledge and identify education needs) and a Quality of Life questionnaire. Patients in the control group will then receive standard patient counselling and be provided with a diary to be completed throughout the study period. Patients in the intervention group will receive a tailored education program based on the results of their diabetes questionnaire. The education program will consist of a maximum of three one-hour sessions conducted in the pharmacy over a period of 1 month. An assessment of cardiovascular risk will be undertaken and strategies to address identified risk factors (e.g. obesity, smoking) will be implemented.

APPENDIX 15

At follow-up interviews (1,3 and 6 months) the patient's diary will be reviewed for completeness and their progress will be assessed using a standard progress questionnaire. Patients in the control group will be asked if they have any concerns or if they required any further information. Where issues raised by the patient are deemed significant the pharmacist will immediately refer the patient to their general practitioner. All services provided by the pharmacist during the follow-up visit will be documented. At the 6-month visit patients in each group will be asked to again complete the diabetes questionnaire and QOL assessment.

Patients will be provided with a diary which will include written information on diabetes and its management, their medication regimen, dates for prescription refills, dates for follow-up visits and doctors appointments. Patients will be asked to record any symptoms or complications they experience, together with their management, any missed doses, visits to their doctor or hospital attendances that were diabetes related in their diary. They will also be asked to record all BGL measurements and a weekly weight.

Should you have any queries please contact either myself at the pharmacy, or the project supervisor at Curtin University. The contact details for the project supervisor are as follows:

Mr Jeff Hughes, Senior Lecturer

School of Pharmacy, Curtin University of Technology

GPO Box U1987, Perth WA 6845

Telephone 9266 7367; Fax 9266 2769

Email: J.D.Hughes@curtin.edu.au

Yours sincerely,

Project Pharmacist

APPENDIX 15

Date

Dear Doctor

In April 2003 we sent you a letter informing you that our pharmacy is participating in a community pharmacy research project entitled, *Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study)*.

Your patient _____ has agreed to participate in this study. At follow-up interviews (1,3 and 6 months post entry into the study) the patient's Diabetes diary will be reviewed for completeness and their progress will be assessed using a standard progress questionnaire. Where issues raised by the patient are deemed significant our project pharmacist will immediately refer the patient to their general practitioner for review.

As part of their informed consent your patient has given permission for the members of the research team to contact their general practitioner to discuss their progress and obtain relevant clinical and laboratory data. Consequently someone from the study's research team may contact you in the future requesting access to this patient information.

Should you require any further information or clarification, please contact either myself at the pharmacy or Mr. Jeff Hughes. The contact details for the project supervisor are as follows:

Mr Jeff Hughes, Senior Lecturer
School of Pharmacy, Curtin University of Technology
GPO Box U1987, Perth WA 6845
Telephone 9266 7367; Fax 9266 2769
Email: J.D.Hughes@curtin.edu.au

Yours sincerely,

Project Pharmacist.

APPENDIX 16

Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study).

STUDY CODE	I / C		:		
-------------------	--------------	--	---	--	--

Notification of Patient Enrolment Form

Name: (Mr/ Mrs/ Ms/ Dr) _____
(Family Name) (Given Name)

Address: _____

Postcode

Phone Number: Home (08) _____ Work (08) _____

Mobile_____

Preferred time to be contacted to arrange any appointments etc.: (please circle)

Morning / Afternoon / Evening / Any time

Email: _____

Date of Birth: _____ **Gender** ☐ Male ☐ Female
(day/month/year)

Patient to return-post the completed questionnaire to pharmacy? ☐ Yes ☐ No

If YES, date received / /

Project co-ordinator advised of enrolment ☐ Yes ☐ No

Date advised _____ & completed patient consent forms and questionnaire
information forwarded

Contact details:

Jenny Wilkinson, Lecturer, School of Pharmacy,

Curtin University of Technology, GPO Box U1987, PERTH, WA. 6845.

Phone 9266 7419; Fax 9266 2769;

Email J.Wilkinson@curtin.edu.au

Date Patient entered study

--	--	--

Proposed Date for 6-month Exit Follow-up

--	--	--

Or Notification of Date of Withdrawal from Study

--	--	--

Exit Questionnaires Completed

☐ Yes ☐ No

Completed Exit Questionnaires Forwarded to Project Co-ordinator

--	--	--

APPENDIX 16

Notes or Comments

[illegible]

APPENDIX 17**Letter of Notification of Enrolment to General Practitioner**

Date

Dear Doctor

In April 2003 we sent you a letter informing you that our pharmacy is participating in a community pharmacy research project entitled, *Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study)*.

Your patient _____ has agreed to participate in this study. At follow-up interviews (1, 3 and 6 months post entry into the study) the patient's Diabetes diary will be reviewed for completeness and their progress will be assessed using a standard progress questionnaire. Where issues raised by the patient are deemed significant our project pharmacist will immediately refer the patient to their general practitioner for review.

As part of their informed consent your patient has given permission for the members of the research team to contact their general practitioner to discuss their progress and obtain relevant clinical and laboratory data. Consequently someone from the study's research team may contact you in the future requesting access to this patient information.

Should you require any further information or clarification, please contact either myself at the pharmacy or the research coordinators at Curtin University. The contact details for the Principal Investigator are as follows:

Mr Jeff Hughes, Senior Lecturer
School of Pharmacy, Curtin University of Technology
GPO Box U1987, Perth WA 6845
Telephone 9266 7367; Fax 9266 2769
Email: J.D.Hughes@curtin.edu.au

The contact details for the Project coordinator are as follows:

Jenny Wilkinson, Lecturer, School of Pharmacy,
Curtin University of Technology, GPO Box U1987, PERTH, WA. 6845.
Phone 9266 7419; Fax 9266 2769;
Email J.Wilkinson@curtin.edu.au

Yours sincerely,

Project Pharmacist.

APPENDIX 18

Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study).

Request for 6 month Clinical Data



Dr «Doctors_Name»
«Doctors_address»

Date

Dear Dr «Doctors_Name»

As you may be aware, your patient,
«Participants_Name» of «Participants_Address»
has been participating in the Diabetes Mellitus Education Program (DMEP) for a period of 6 months. «Participants_Name» agreed to be involved in the study on
«Date_of_Study_Entry».

To complete the study the research investigators require measures for the data listed on the attached request form. We would greatly appreciate it if you would provide the results of routine tests completed. Ideally we would like results of tests performed approximately **6-9 months from the date of the participant's entry** into the study. For comparison we are providing the corresponding baseline measures provided by the patient during the study.

However if in the course of reviewing the patient's records you can also provide "baseline" results for tests performed for these parameters that were obtained on a date closer to that on which the patient entered the study would you please include these also.

Please return the completed data form by fax to the Project Data Manager Mrs. Jenny Wilkinson, at the School of Pharmacy at Curtin University of Technology (08 9266 2769).

A copy of the Patient's Consent Form is included and a copy of the letter to local General Practitioners sent by Project Community Pharmacists in April 2004 advising them of the study's protocol is attached for your information. Please contact me if you wish to discuss any issues.

Thank you,

Jenny Wilkinson, Project coordinator

APPENDIX 18

Customised Education Programs for Patients with Diabetes Mellitus – Use of Structured Questionnaires and Education Modules (DMEP Study).

Request for 6 month Clinical Data



Dr «Doctors_Name»
«Doctors_address»

«Participants_Name»
Code «Pharmacy_Site»
«Date_of_Study_Entry»

GP please fax the completed form to the attention of Diabetes Mellitus Education Program Project Data Manager Mrs. Jenny Wilkinson at 08 9266 2769. Thank you.

<p>Baseline</p> <p>HbA_{1c}: __ __. __ __ % Date: _____</p> <p>Total cholesterol: __ __. __ __ mmol/l Date: _____</p> <p>HDL cholesterol: __ __. __ __ mmol/l Date: _____</p> <p>Triglyceride: __ __. __ __ mmol/l Date: _____</p> <p>Blood Pressure: ____ / ____ mmHg Date: _____</p>	<p>*** 6 Months</p> <p>*** Please provide results of relevant routine tests</p> <p>HbA_{1c}: __ __. __ __ % Date: _____</p> <p>Total cholesterol: __ __. __ __ mmol/l Date: _____</p> <p>HDL cholesterol: __ __. __ __ mmol/l Date: _____</p> <p>Triglyceride: __ __. __ __ mmol/l Date: _____</p> <p>Blood Pressure: ____ / ____ mmHg Date: _____</p>
--	---

APPENDIX 19

Cognicare CMMS® Diabetes Module Cognicare Solutions Limited <http://www.cognicare.com.au/>

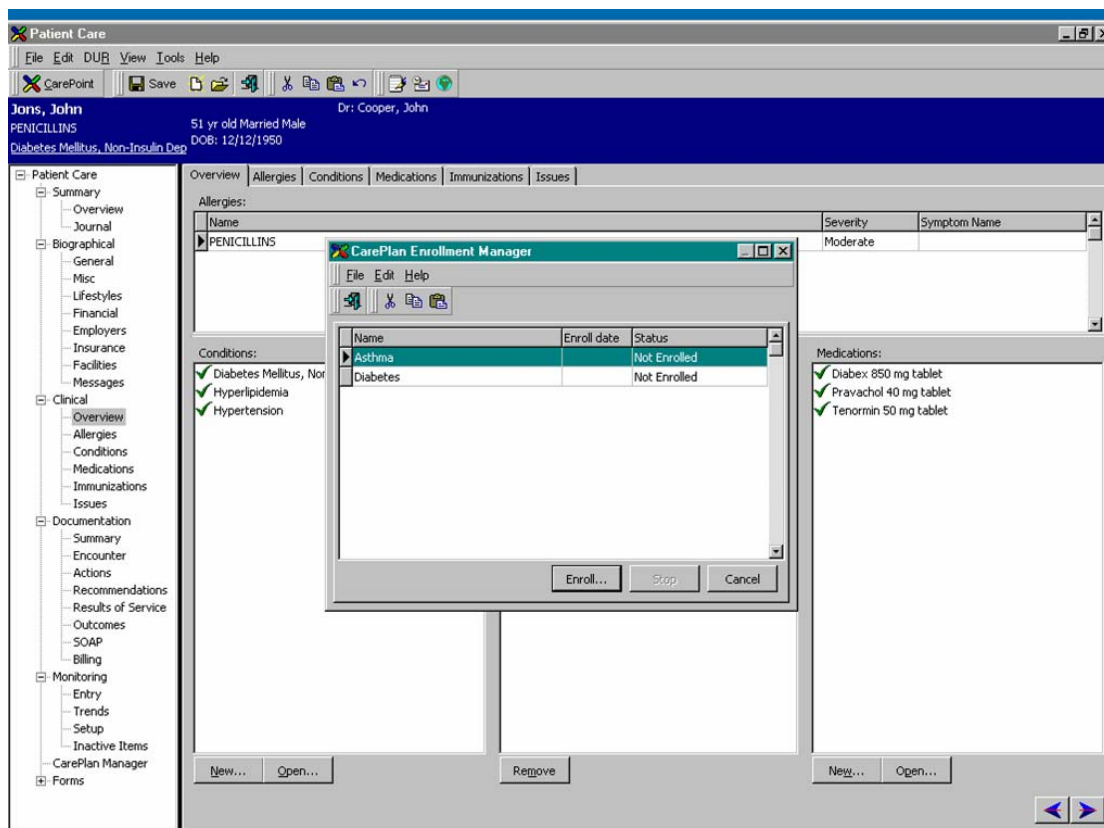


The Cognicare CMMS® Diabetes Module allows the user to:

1. Assess the risk and severity of diabetes through a structured electronic questionnaire
2. Develop an action plan
 - Referral, education, counselling and monitoring components
3. Develop a structure for patient encounters
 - Pre-visit, during visit and post visit tasks

Enrolment Process

Step 1: Choose Disease State Management Module



APPENDIX 19

Step 2: Enter demographic and lifestyle information

Diabetes CarePlan Enrollment - [New]

Required Demographic Information

Full Name: Ethnicity:

Date of Birth: Age: 51 yr Height:

Gender: Weight in pounds:

Dietary Plan:

Tobacco Monitoring

Tobacco Use: Details>>

Pack Years:

Comments:

Tobacco Comments:

Alcohol Monitoring

Alcohol Use: Details>>

Comments:

Alcohol Comments:

Back Next Cancel

Step 3: Complete Family, Medical and Medication Histories

Diabetes CarePlan Enrollment - [New]

Do you have a history of endocrine or eating disorders? ☐ Yes ☒ No

Please choose from the following:

Family History

Diabetes type 1 or Type 2	<input checked="" type="checkbox"/> Brother/Sister	<input type="checkbox"/> Children	<input type="checkbox"/> Grandparent	<input checked="" type="checkbox"/> Parent
Thyroid Problems	<input type="checkbox"/> Brother/Sister	<input type="checkbox"/> Children	<input type="checkbox"/> Grandparent	<input type="checkbox"/> Parent
Heart Problems	<input type="checkbox"/> Brother/Sister	<input type="checkbox"/> Children	<input checked="" type="checkbox"/> Grandparent	<input checked="" type="checkbox"/> Parent
Kidney Problems	<input type="checkbox"/> Brother/Sister	<input type="checkbox"/> Children	<input checked="" type="checkbox"/> Grandparent	<input type="checkbox"/> Parent
Eye Problems	<input type="checkbox"/> Brother/Sister	<input type="checkbox"/> Children	<input type="checkbox"/> Grandparent	<input type="checkbox"/> Parent
Cancer	<input type="checkbox"/> Brother/Sister	<input type="checkbox"/> Children	<input type="checkbox"/> Grandparent	<input type="checkbox"/> Parent

Medications:

Name	Dispensed	Refilled	Refills/Remaining	
Diabex 850 mg tablet	11/25/2002		0/1	
Pravachol 40 mg tablet	11/25/2002		0/1	

Conditions:

Date	Name	ICD9	Res Date	
12/12/1987	Diabetes Mellitus, Non-Insulin Dependent	250		
12/12/1984	Hypertension	401		

Back Next Cancel

APPENDIX 19**Step 4: Complete Diabetes Questionnaire**

Diabetes CarePlan Enrollment - [New]

1. Have you ever been told what type of diabetes you have?

☒ Yes Type of Diabetes: **Diabetes Mellitus Type 2**

☐ No How long have you had diabetes (years)? **15**

2. Do you have a blood glucose meter?

☒ Yes What kind of meter do you use? **Accu-Chek Advantage**

☐ No Can you demonstrate how to use it? ☐ Yes ☒ No


3. Please indicate the symptoms you have experienced in the past month.

<input type="checkbox"/> None	<input type="checkbox"/> Itching	<input type="checkbox"/> Weight loss
<input checked="" type="checkbox"/> Increased thirst (polydipsia)	<input checked="" type="checkbox"/> Blurred vision	<input checked="" type="checkbox"/> Weight gain
<input type="checkbox"/> Increased urination (polyuria)	<input checked="" type="checkbox"/> Fatigue	
<input type="checkbox"/> Increased hunger (polyphagia)	<input type="checkbox"/> Recurrent or poorly healing infections	

4. Do you know how to recognize these symptoms of hyperglycemia, when to treat them and what signs should prompt immediate medical care?

☐ Yes ☒ No

5. Have you ever been hospitalized for high blood sugar?

☒ Yes Please enter the approximate date that you were hospitalized. **11/7/2002** 

☐ No

[Back](#) [Next](#) [Cancel](#)

Step 4: Complete Diabetes Questionnaire contd...

Diabetes CarePlan Enrollment - [New]


6. Please indicate the symptoms you have experienced in the past month.

<input type="checkbox"/> None	<input type="checkbox"/> Dizziness	<input type="checkbox"/> Headache
<input type="checkbox"/> Increase heart rate (tachycardia)	<input checked="" type="checkbox"/> Hunger	<input type="checkbox"/> Double vision (diplopia)
<input type="checkbox"/> Awareness of heartbeat (palpitations)	<input checked="" type="checkbox"/> Inability to concentrate	<input checked="" type="checkbox"/> Restlessness
<input checked="" type="checkbox"/> Tremulousness	<input type="checkbox"/> Impaired motor function	<input type="checkbox"/> Inappropriate behavior
<input checked="" type="checkbox"/> Sweating	<input type="checkbox"/> Confusion	

7. Do you know how to recognize these symptoms of hypoglycemia, when to treat them and what signs should prompt immediate medical care?

☐ Yes ☒ No

8. Have you ever been hospitalized for hypoglycemia?

☒ Yes Please enter the approximate date that you were hospitalized. **11/23/2002** 

☐ No

9. Have you ever lost consciousness from hypoglycemia?

☐ Yes Have you ever had a seizure? ☐ Yes ☒ No

☒ No

10. Do you monitor urine ketones?

☐ Yes ☒ No


[Back](#) [Next](#) [Cancel](#)

APPENDIX 19

Step 4: Complete Diabetes Questionnaire contd...

Diabetes CarePlan Enrollment - [New]

11. If currently being treated with insulin or sulfonylureas does the patient have a glucagon emergency kit? ☐ Yes ☒ No

12. Have you had your feet examined in the last year? ☒ Yes ☐ No Please enter the approximate date of the examination. 4/9/2002 

13. Has the patient experienced numbness or tingling in hands or feet in the last month? ☐ Yes ☒ No

14. Have you been evaluated by an ophthalmologist in the past year? ☐ Yes ☒ No Do you report any changes in vision? ☒ Yes ☐ No

15. Has someone spent time teaching you how to plan your meals with diabetes? ☐ Yes ☒ No

16. Exercise regimen:

Consistent Exercise: Sometimes-daily Amount: Up to 1 hr

Activity: Walking Mobility Status: Mobile

Back Next Cancel

Step 4: Complete Diabetes Questionnaire contd...

Diabetes CarePlan Enrollment - [New]

17. Do you take any herbal remedies, vitamins or any natural products? ☒ Yes ☐ No

18. Blood glucose reading (in mg/dl) 7.4

Last time you had anything to eat or drink 0-2 hours

Back Next Cancel

APPENDIX 19

Step 5: Create Diabetes Care Plan

Diabetes CarePlan Enrollment - [New]

- ☒ Diabetes Basic Program
 - ☐ Type 1 diabetes
 - ☒ Type 2 diabetes
 - ☐ Gestational
 - ☐ Other
 - ☐ Monitoring
 - ☐ Education
- ☒ Increased health care due to diabetes
- ☒ Complications
- ☒ Nutrition Management
- ☐ Exercise Education
- ☐ Pregnancy
- ☒ Hypertension
- ☒ Hyperlipidemia
- ☒ Nontraditional Medications
- ☒ Ketone Monitoring
- ☒ Glucagon Education
- ☐ Foot Care
- ☒ Retinopathy Prevention
- ☐ Inhibited activities related to diabetes symptoms

Back Next Cancel

Step 5: Create Diabetes Care Plan contd...

Diabetes CarePlan Enrollment - [New]

- Diabetes Basic Program
 - ☐ Type 1 diabetes
 - ☒ Type 2 diabetes
 - ☒ Achieve maximum prevention of complications with due regard for patient safety
 - Blood glucose monitoring
 - Hemoglobin A1C monitoring
 - Assess and record subjective diabetes symptoms each visit
 - Evaluate patient's progress in achieving treatment goals
 - Screen for microalbuminuria
 - Reassess the patient
 - Maintain patient blood glucose diary
 - Medication management review
 - Institute/review patient blood glucose diary at each encounter
 - Review medication and any changes to therapy
 - Evaluate cultural influences, health beliefs and behaviors, and socioeconomic factors
 - ☐ Increased health care due to diabetes
 - ☒ Prevent recurrent exacerbations of diabetes and minimize the need for physician and hospital visits
 - Monitor days missed from work or school
 - Monitor last unexpected physician visit
 - Monitor hospitalization
 - Monitor reduced activity days
 - ☐ Complications
 - ☒ Reduce potential complications with diabetes through awareness and prevention
 - Educate the patient on the complications of diabetes
 - Review last ophthalmologist visit date, last foot exam
 - ☐ Nutrition Management
 - ☒ Assist the individual in making changes in nutrition habits leading to improved metabolic control
 - Monitor weight

Back Next Cancel

APPENDIX 19

Step 6: Create a Summary of Review Findings

Diabetes CarePlan Enrollment - [New]

John Jons is a 51 yr old Caucasian Male.

The family history indicates the following: diabetes type 1 or type 2, heart problems, kidney problems.

John Jons is currently taking the following medications: Tenormin 50 mg tablet. This may affect blood glucose.

John Jons has the following conditions: hypertension, hyperlipidemia. This increases the risk of coronary heart disease. Further education and closer monitoring may be beneficial.

John reports that he has been told that he has diabetes mellitus type 2.

John has the Accu-Chek Advantage, and reports he needs assistance in learning how to use the meter.

John reports the following symptoms of hyperglycemia in the past month: Increased thirst (polydipsia), Blurred vision, Fatigue, Weight gain.

Because the patient does not know how to recognize the signs and symptoms of hyperglycemia, he would benefit from education including how to recognize, when to treat them and what signs should prompt immediate medical care.

He was hospitalized on 11/7/2002 for hyperglycemia.

John reports the following symptoms of hypoglycemia in the past month: Tremulousness, Sweating, Hunger, Inability to concentrate, Restlessness.

Because the patient does not know how to recognize the signs and symptoms of hypoglycemia, he would benefit from education including how to recognize, when to treat them and what signs should prompt immediate medical care.

He was hospitalized on 11/23/2002 for hypoglycemia.

He reports never having lost consciousness from hypoglycemia.

He reports never having a seizure in the past.

Print

Back Finish Cancel

Step 7: Transfer data to Care Manager

Patient Care

File Edit DUR View Tools Help

CarePoint Save Open Print Copy Paste Undo Redo

Jons, John 51 yr old Married Male Dr: Cooper, John
PENICILLINS DOB: 12/12/1950
Diabetes Mellitus, Non-Insulin Dep

Plan

- Diabetes
 - Type 2 diabetes
 - Increased health care due to diabetes
 - Complications
 - Nutrition Management
 - Hypertension
 - Hyperlipidemia
 - Nontraditional Medications
 - Ketone Monitoring
 - Glucagon Education
 - Retinopathy Prevention

Summary Create...

John Jons is a 51 yr old Caucasian Male.

The family history indicates the following: diabetes type 1 or type 2, heart problems, kidney problems.

John Jons is currently taking the following medications: Tenormin 50 mg tablet. This may affect blood glucose.

John Jons has the following conditions: hypertension, hyperlipidemia. This increases the risk of coronary heart disease. Further education and closer monitoring may be beneficial.

Pending Worksheets

Date	Status	User	Days in queue
------	--------	------	---------------

Open... Discard

Journal

Date	User	Type	Description	Edit M
------	------	------	-------------	--------

APPENDIX 20

Fact Sheets

<http://www.diabetes.com.au/diabetes.php?regionID=37>

(The Factsheets below require Adobe Acrobat Reader to view them - click on the icon above if you require the viewer)



[How do I know if I have Diabetes?](#) (81kb)



[What is Diabetes?](#) (172kb)



[How does the body control glucose in the blood?](#) (421kb)



[Type 1 Diabetes](#) (226kb)



[Type 2 Diabetes](#) (247kb)



[Gestational Diabetes Mellitus](#) (154kb)



[Impaired Glucose Tolerance](#) (138kb)



[Monitoring Diabetes Control](#) (258kb)



[Physical Activity](#) (402kb)



[Healthy Food for Healthy Living](#) (552kb)



[The Facts About Fat](#) (897kb)



[Don't Forget Your Lipids!](#) (395kb)



[The Carbohydrate Connection](#) (236kb)



[Sugar](#) (116kb)



[Sugar Substitutes](#) (74K)



[Alcohol](#)(274kb)



[Investing in Good Health for the Future](#) (206kb)



[Footcare](#) (290kb)



[Hypoglycemia](#) (677kb)



[Hyperglycemia](#) (262kb)



[Insulin](#) (223kb)



[Tablets for Your Diabetes](#) (235kb)



[The Diabetes Travel Guide!](#) (378kb)



[Food and Diabetes](#) (180kb)

APPENDIX 21

DMEP Study

Intervention Patient Satisfaction Form

Identification Code:

I			
---	--	--	--

Demographic Information (To be completed by interviewer prior to phoning)

Gender Female ☐ Male ☐

Age

☐18-30 ☐31-45 ☐46-54 ☐55-64 ☐65-74 ☐74+

Introduction

Hello, my name is <Name>, from the School of Pharmacy at Curtin

University. Please may I speak to <Name>.

In the past you visited <Name> Pharmacy to take part in our Diabetes Education Program. I wonder if you would be prepared to answer some questions regarding your opinion of the service. It should only take about five minutes of your time.

Enrolment

At the time that the pharmacist first approached you and asked you whether you would be interested in participating in the study:

1.

What was your opinion about **receiving education** about diabetes **from the pharmacist**?

Strongly Disagreed	<input type="checkbox"/>
Disagreed	<input type="checkbox"/>
Neither Agreed nor Disagreed	<input type="checkbox"/>
Agreed	<input type="checkbox"/>
Strongly Agreed	<input type="checkbox"/>

with the idea of a pharmacist helping you to learn more about your diabetes.

2.

Had you previously received Diabetes Education?

Yes ☐ No ☐ Don't Remember ☐

3.

How much did you believe that you **understood about your diabetes at this time**?

Where **1** is understood *nothing at all* and **6** is *everything about* diabetes

1 2 3 4 5 6

APPENDIX 21

Education

4.

From which of the following options would you prefer to receive education about diabetes?

Specialist	↑
General Practitioner	↑
Pharmacist	↑
Diabetes Educator Nurse	↑
Internet/ books	↑
Other	

5.

How do/ would you prefer to receive diabetes education?

One on one with the educator	↑
In a group situation	↑
Prefer to take the information home and read on my own	↑
Why?	

6.

Which of the following aspects were the most useful **and** least useful parts of the education service that you completed in the pharmacy?

	Most	Least
Learning about Diabetes	↑	↑
Learning about my medication	↑	↑
Learning about lifestyle issues	↑	↑
Reminders for follow-up checks for complications related to diabetes	↑	↑
Referrals to appropriate health care		
Professionals	↑	↑
General support from the pharmacist	↑	↑
Better relationship with the pharmacy	↑	↑
Other (specify)		

7.

Which of the following aspects of diabetes and its management have you learnt more about since participating in the study?

Monitoring of Blood Glucose Levels	↑
Medication	↑
Associated Lifestyle Issues (Which issues, tick)	
Diet	↑
Weight Management	↑
Exercise	↑
Alcohol Intake	↑
Smoking Cessation	↑
Complications and their Prevention	↑

APPENDIX 21

Other.....

8.

How likely is it that you would use the following professions to obtain information about lifestyle issues such as diet and weight loss, exercise, alcohol intake and smoking cessation?

	Very unlikely	Unlikely	Neither likely nor unlikely	Likely	Very Likely
Physiotherapist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dietician	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Doctor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nurse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9.

What was your impression of the quality of the education and follow up delivered by the pharmacist?

Very dissatisfied ☐
 Dissatisfied ☐
 Neither satisfied nor dissatisfied ☐
 Satisfied ☐
 Very satisfied ☐

Comments (why?).....

Indicate if any or all of the following are mentioned (unprompted)

Availability Y / N
 Empathy Y / N
 Easy to understand Y / N
 Friendliness Y / N
 Promptness Y / N
 Environment Y / N
 Other

10.

What was your impression of the usefulness of the Follow up sessions at **1, 3 and 6** months after the initial education phase?

Where **1** is of *absolutely no use* and **6** is *extremely valuable / useful*

1 2 3 4 5 6

Any comments you wish to make

11.

How useful was having a diary in which to monitor your diabetes management?

Where **1** is of *absolutely no use* and **6** is *extremely valuable / useful*

1 2 3 4 5 6

APPENDIX 21

WHY?

How could it be improved?

12.

How important do you think this education service is for people in the community with type 2 diabetes?

Where **1** is of *absolutely no use* and **6** is *extremely valuable / useful*

1 2 3 4 5 6

13.

Should pharmacy-based education and advice about diabetes be available to patients on a regular basis?

Yes [↑] No [↑] I am unsure [↑]

14.

Would you continue to use the service if it was available long-term?

Yes [↑] I am unsure [↑]

No [↑]

If the answer is **NO** go to **question 16**

15.

How often would you need to use the service?

Monthly [↑]

Three monthly [↑]

Six monthly [↑]

Annually [↑]

Infrequently [↑]

Unsure [↑]

16.

Would you be willing to pay for the service?

[↑] Yes [↑] No

If Yes-

How much would you be prepared to pay (per hour)?

\$...../hour

17.

At the completion of your involvement in the study after six months :

What was your opinion about **receiving education** about diabetes **from the pharmacist?**

Strongly Disagreed [↑]

Disagreed [↑]

Neither Agreed nor Disagreed [↑]

Agreed [↑]

Strongly Agreed [↑]

APPENDIX 21

Thank you for your time and assistance I have no further questions to ask you **INTERVIEWER'S INTRODUCTION**

Hello my name is <Name> from the School of Pharmacy at Curtin University and I am phoning in regard to the Diabetes Education Program Study in which you participated. This message is for <NAME>. I was wondering if you would be able to spare 5 minutes of your time to answer a few questions about your experience in the study. Your time and assistance would be greatly appreciated.

You can contact me at the University on <Telephone Number> between # and # on # day(s). Or you can leave a message for me to return your call on <Telephone Number>. I look forward to speaking to you. Thank you.

APPENDIX 22

De-brief of Project Site and Educator Pharmacists Involved in DMEP Project - May 2005.

Below are some questions to you may wish to consider, and you may have other ideas/ areas you believe we should consider for value of patient outcome and from the logistics of running the project itself.

Training Prior to Commencement of Project

Support from Project Organisers throughout Study

Advertising

Adequate or not?

Patient Recruitment

Time requirements

Time taken to explain project.

Complexity of materials?

Barriers

Problems in recruiting?

Attrition / Drop out rates

Project Participation & Protocol

Logistics

Space Requirements for Implementation

How many pharmacists do you think would need to be employed at any one time to make the program work in situ without bringing in a dedicated pharmacist educator?

Protocol Aspects

Procedure in pharmacy or complete at home and return? Problem getting returns?

Length and Number of questionnaires

Problems with diary completion ?

Problems with BGL monitoring?

Did you have to reschedule appointments?

Reasons for cancelling?

Lost to follow up? Reasons?

Appropriateness of Frequency of the Follow-up Sessions at 1, 3 and 6 months intervals?

Universal or is there a necessity to tailor to each patient?

Education Materials etc

Adherence intervention- detect any change in patient behaviour just due to fact the patient was coming back to fill in progress check list

Feedback

Patients

Interventions most useful / acceptable to patients

APPENDIX 22

Consumer feed back?

Any patient feedback on the role of pharmacists versus Diabetes Educators – availability and patient rapport.

GPs

Communications with GP's:

Supportive or negative?

Resistance from GP's? Why?

Any other feedback received?

Any collaboration in changes to drug therapy etc for patient?

Other Allied Healthcare Professionals

Feedback from any other allied healthcare professional?

Educators

Challenges involved in effecting behavioural change?

Incremental versus all at once goal setting: How many at any one time?

Outcomes

Patients

Improved self efficacy; self confidence in participation in disease management

Project Pharmacists

Overall pharmacist experience of the program: positive; negative;

Worthwhile area in which to become involved? Or already catered for effectively by other agencies?

Improved knowledge base in diabetes disease state and its management; improvement in customer relationships; improved job satisfaction; changed perception of role of pharmacist in disease state management

Improved self confidence in participation in disease management

Patient appreciation of service- motivational incentive

Educator Pharmacists

Improved knowledge base in diabetes disease state and its management; improved job satisfaction;

Pharmacy

Any business impact and the implications of this for future implementation?

Do you think it would be better for the positive outcome for the pharmacy if the educator was a regular staff member?

Marketing and possible costings?

Referrals to GPs or Other Allied Healthcare Professionals

Any made? Significance? Would the intervention been undertaken without the study?

Impact of Other Diabetes Studies etc

APPENDIX 23

SF-36 Norms for the State of Western Australian

Source: Daly A. SF-36 norms for the State of Western Australia

SF-36 norms for the State of Western Australia

6 Persons aged 55-64 years

	Physical Functioning	Role Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role Emotional	Mental Health
Mean	81.65	78.04	72.56	72.48	63.16	89.60	89.22	82.08
Lower 95% Confidence Limit for the mean	79.95	75.27	70.50	70.75	61.49	88.00	87.13	80.85
Upper 95% Confidence Limit for the mean	83.35	80.78	74.69	84.18	64.83	91.29	91.37	83.31
Number contributing to the mean	605	605	605	605	604	605	605	604
Standard deviation	21.23	34.50	26.24	21.49	20.91	20.66	26.57	15.44
Standard error of the mean	.86	1.40	1.07	.87	.85	.84	1.08	.63
5 th Percentile	30.00	0.00	22.00	30.00	20.00	37.50	0.00	48.00
25 th Percentile	75.00	50.00	52.00	60.00	50.00	87.50	100.00	76.00
50 th Percentile (Median)	90.00	100.00	74.00	77.00	65.00	100.00	100.00	88.00
75 th Percentile	100.00	100.00	100.00	87.00	80.00	100.00	100.0	92.00
95 th Percentile	100.00	100.00	100.00	97.00	90.00	100.00	100.00	100.00
Minimum	0.00	0.00	0.00	0.00	0.00	0.00	0.00	20.00
Maximum	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
% Floor	0.1	10.4	0.4	0.0	0.3	0.1	5.4	0.5
% Ceiling	21.3	64.6	34.1	4.8	1.2	71.9	83.1	7.9

1995 Western Australian Health Survey No 5, June 1997

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SF-36 norms for the State of Western Australia

7 Persons aged 65-74 years

	Physical Functioning	Role Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role Emotional	Mental Health
Mean	76.31	74.19	74.56	70.67	61.90	90.87	88.70	82.52
Lower 95% Confidence Limit for the mean	74.39	71.04	72.27	68.74	59.95	89.18	86.27	81.06
Upper 95% Confidence Limit for the mean	78.24	77.42	76.86	72.59	63.86	92.56	91.21	83.98
Number contributing to the mean	522	522	522	522	522	522	522	522
Standard deviation	22.39	37.14	26.68	22.39	22.73	19.64	28.80	16.96
Standard error of the mean	.98	1.62	1.17	.98	.99	.86	1.26	.74
5 th Percentile	25.00	0.00	22.00	25.00	15.00	50.00	0.00	44.00
25 th Percentile	68.75	50.00	61.00	57.00	50.00	100.00	100.00	76.00
50 th Percentile (Median)	85.00	100.00	84.00	77.00	65.00	100.00	100.00	88.00
75 th Percentile	100.00	100.00	100.00	100.00	90.00	100.00	100.00	100.00
95 th Percentile	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Minimum	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Maximum	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
% Floor	0.0	13.1	1.0	0.3	0.3	0.1	7.1	0.3
% Ceiling	9.8	60.7	40.3	6.0	2.6	75.8	85.0	10.7

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1995 Western Australian Health Survey, No 5, June 1997

APPENDIX 24

SF-36 Reliability Coefficients

Source: Ware JE Jr, et al. SF-36® Health Survey. Manual and Interpretation Guide. Lincoln:QualityMetric Inc., 2002

7:8

SF-36 Health Survey Manual

TABLE 7.3 RELIABILITY ESTIMATES FOR SF-36 SCALES IN MOS SUBGROUPS (N=3,445)

		PF	RP	BP	GH	VT	SF	RE	MH
Age	< 65	.92	.83	.81	.79	.87	.85	.83	.90
	65-74	.92	.86	.85	.78	.86	.84	.82	.88
	≥ 75	.92	.85	.81	.77	.82	.83	.82	.86
Gender	Female	.93	.84	.82	.79	.87	.84	.82	.90
	Male	.92	.84	.82	.77	.85	.87	.84	.89
Race	White	.93	.84	.83	.79	.88	.85	.82	.90
	Black	.93	.82	.80	.76	.83	.82	.82	.89
	Other	.92	.86	.80	.75	.82	.84	.82	.89
Education	< 8	.94	.88	.85	.79	.76	.85	.87	.89
	9-11	.94	.88	.87	.80	.86	.86	.84	.90
	12	.92	.82	.81	.78	.86	.85	.81	.90
	> 12	.92	.83	.80	.77	.88	.85	.82	.90
Poverty Status	Poverty	.94	.86	.85	.79	.85	.82	.86	.90
	Non Poverty	.92	.84	.81	.78	.88	.85	.82	.90
Diagnosis	Hypertension	.93	.84	.83	.77	.86	.84	.81	.87
	Diabetes	.93	.85	.86	.76	.86	.86	.81	.88
	CHF	.92	.82	.83	.78	.87	.90	.87	.84
	MI	.92	.83	.74	.78	.84	.84	.80	.86
	Clinical depression	.93	.84	.82	.79	.86	.82	.77	.86
	Symptomatic depression	.94	.83	.80	.77	.84	.79	.80	.86
Disease Severity	Uncomplicated Medical	.90	.81	.79	.75	.84	.76	.79	.84
	Complicated Medical	.91	.83	.82	.78	.87	.87	.83	.82
	Psychiatric and Uncomplicated Medical	.91	.80	.79	.72	.82	.84	.79	.85
	Psychiatric and Complicated Medical	.93	.70	.75	.65	.80	.72	.81	.88

Note. From "The MOS 36-Item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups" C.A. McHorney et al., in press, *Medical Care*.

APPENDIX 25

Hospital Admission Diagnoses

Univariate analysis

Total number of diagnoses

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	----- Elective -----			----- Emergency -----		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	43	52	86	31	6	48
	0	0	0	0	0	0
	0	0	0	0	0	0
	7	10	17	7	4	14
Intervention	56	56	56	56	56	56
	31	38	43	10	8	26
	0	0	0	0	0	0
	0	0	0	0	0	0
	7	6	9	6	4	12
p-values	0.92	0.52	0.35	0.28	0.75	0.35

Total number of diagnoses

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	----- Elective -----			----- Emergency -----		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	10	10	22	14	0	5
	0	0	0	0	0	0
	0	0	0	0	0	0
	4	10	4	7	0	5
Intervention	24	24	24	24	24	24
	24	20	12	1	4	7
	0	0	0	0	0	0
	0	0	0	0	0	0
	7	6	5	1	4	7
p-values	0.16	0.025	0.29	0.29	0.31	1.00

Total number of diagnoses

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	----- Elective -----			----- Emergency -----		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	23	33	48	16	2	43
	0	0	0	0	0	0
	0	0	0	0	0	0
	7	6	17	5	2	14
Intervention	31	31	31	31	31	31
	7	16	30	9	4	19
	0	0	0	0	0	0
	0	0	0	0	0	0
	4	4	9	6	4	12
p-values	0.34	0.37	0.67	0.64	0.826	0.25

APPENDIX 25

Diagnoses for diabetes

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	8	9	15	7	0	10
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	2	2	1	0	4
Intervention	56	56	56	56	56	56
	6	7	8	2	2	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	3	1	1	2
p-values	0.80	0.75	0.27	0.21	0.10	0.38

Diagnoses for diabetes

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	2	2	4	3	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	0	1
Intervention	24	24	24	24	24	24
	4	3	1	0	1	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	1	1
p-values	0.36	0.31	0.15	0.08	0.31	0.98

Diagnoses for diabetes

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	4	7	8	4	0	9
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	1	2	1	0	4
Intervention	31	31	31	31	31	31
	2	4	7	2	1	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	3	1	1	2
p-values	0.87	0.63	0.90	0.62	0.25	0.28

APPENDIX 25

Diagnoses for NIDDM

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	8	7	14	6	0	10
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	2	2	1	0	4
Intervention	56	56	56	56	56	56
	6	6	8	2	2	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	3	1	1	2
p-values	0.80	0.60	0.36	0.31	0.10	0.38

Diagnoses for NIDDM

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	2	2	3	3	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	0	1
Intervention	24	24	24	24	24	24
	4	3	1	0	1	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	1	1
p-values	0.36	0.31	0.28	0.08	0.31	0.98

Diagnoses for NIDDM

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	4	5	8	3	0	9
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	1	2	1	0	4
Intervention	31	31	31	31	31	31
	2	3	7	2	1	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	3	1	1	2
p-values	0.87	0.74	0.90	0.89	0.25	0.28

APPENDIX 25

Diagnoses for NIDDM_coma

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	56	56	56	56	56	56
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_coma

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_coma

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	31	31	31	31	31	31
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

APPENDIX 25

Diagnoses for NIDDM_ketoacidosis

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	56	56	56	56	56	56
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_ketoacidosis

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_ketoacidosis

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	31	31	31	31	31	31
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

APPENDIX 25

Diagnoses for NIDDM_renal

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	2	1	0	0
	0	0	0	1	0	0
	0	0	0	0	0	0
	0	0	1	1	0	0
Intervention	56	56	56	56	56	56
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	.	.	0.21	0.39	.	.

Diagnoses for NIDDM_renal

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	0	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	1	0	0
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	.	.	.	0.33	.	.

Diagnoses for NIDDM_renal

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	31	31	31	31	31	31
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

APPENDIX 25

Diagnoses for NIDDM_ophthalmic

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	2	2	4	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	0	0
Intervention	56	56	56	56	56	56
	1	0	3	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	2	0	0	0
p-values	0.75	0.39	0.63	0.39	.	.

Diagnoses for NIDDM_ophthalmic

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	2	2	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	2	1	1	0	0
Intervention	24	24	24	24	24	24
	1	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	0	0	0	0
p-values	0.31	0.33	0.14	0.33	.	.

Diagnoses for NIDDM_ophthalmic

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	2	0	2	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	1	0	0	0
Intervention	31	31	31	31	31	31
	0	0	3	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	2	0	0	0
p-values	0.22	.	0.77	.	.	.

APPENDIX 25

Diagnoses for NIDDM_neurologic complications

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	0	0	0	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	4
Intervention	56	56	56	56	56	56
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	0.38

Diagnoses for NIDDM_neurologic complications

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_neurologic complications

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	0	0	0	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	4
Intervention	31	31	31	31	31	31
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	0.38

APPENDIX 25

Diagnoses for NIDDM_circulatory complications

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	1	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	1	0	0	0
Intervention	56	56	56	56	56	56
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	0.38	.

Diagnoses for NIDDM_circulatory complications

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	1	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	1	0	0	0
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	0.31	.

Diagnoses for NIDDM_circulatory complications

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	31	31	31	31	31	31
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

APPENDIX 25

Diagnoses for NIDDM_other specified complications

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	1	1	1	0	2
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	1	1	0	1
Intervention	56	56	56	56	56	56
	0	0	0	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	1	0	0
p-values	.	0.39	0.38	0.83	.	0.21

Diagnoses for NIDDM_other specified complications

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	0	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	1
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values	0.31

Diagnoses for NIDDM_other specified complications

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	1	1	1	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	1	1	0	1
Intervention	31	31	31	31	31	31
	0	0	0	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	1	0	0
p-values	.	0.39	0.38	0.84	.	0.3

APPENDIX 25

Diagnoses for NIDDM_multiple complications

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	5	1	3	2	0	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	1	0	2
Intervention	56	56	56	56	56	56
	0	1	3	1	0	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	1	1	0	2
p-values	0.05	0.83	0.74	0.75	.	0.74

Diagnoses for NIDDM_multiple complications

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	1	1	0	2	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	0	1	0	1
Intervention	24	24	24	24	24	24
	0	1	0	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	0	0	0	1
p-values	0.33	0.98	.	0.16	.	0.98

Diagnoses for NIDDM_multiple complications

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	3	0	3	0	0	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	1	0	0	2
Intervention	31	31	31	31	31	31
	0	0	3	1	0	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	1	1	0	2
p-values	0.13	.	0.75	0.25	.	0.79

APPENDIX 25

Diagnoses for NIDDM_unspecified complications

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	56	56	56	56	56	56
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_unspecified complications

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	24	24	24	24	24	24
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

Diagnoses for NIDDM_unspecified complications

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
Intervention	31	31	31	31	31	31
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
p-values

APPENDIX 25

Diagnoses for NIDDM_without complications

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	3	4	5	2	0	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	1	0	1
Intervention	56	56	56	56	56	56
	5	5	3	1	2	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	1	1	0
p-values	0.24	0.41	0.73	0.75	0.01	0.08

Diagnoses for NIDDM_without complications

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	1	0	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	0	0	0	0
Intervention	24	24	24	24	24	24
	3	2	1	0	1	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	1	0
p-values	0.28	0.15	0.33	.	0.31	.

Diagnoses for NIDDM_without complications

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	1	4	4	2	0	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	1	0	1
Intervention	31	31	31	31	31	31
	2	3	2	1	1	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	1	1	0
p-values	0.41	0.99	0.60	0.73	0.25	0.07

APPENDIX 25

Diagnoses for nervous system and sense organs (G00-H99)

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	4	3	7	3	0	2
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	2	1	1	0	1
Intervention	56	56	56	56	56	56
	2	2	5	1	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	2	1	0	1
p-values	0.90	0.77	0.65	0.48	.	0.72

Diagnoses for nervous system and sense organs (G00-H99)

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	1	2	3	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	0	0
Intervention	24	24	24	24	24	24
	2	1	2	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	0	1
p-values	0.53	1.00	0.61	0.33	.	0.33

Diagnoses for nervous system and sense organs (G00-H99)

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	3	1	3	2	0	2
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	1	1	1	0	1
Intervention	31	31	31	31	31	31
	0	0	3	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	2	1	0	0
p-values	0.22	0.39	0.90	0.73	.	0.21

APPENDIX 25

Diagnoses for diseases of the circulatory system (I00-I99)

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	9	7	9	6	0	9
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	2	2	1	0	4
Intervention	56	56	56	56	56	56
	2	4	7	1	2	4
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	1	2
p-values	0.14	0.77	0.81	0.12	0.01	0.54

Diagnoses for diseases of the circulatory system (I00-I99)

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	1	2	2	3	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	0	1
Intervention	24	24	24	24	24	24
	2	2	3	0	1	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	0	1	1
p-values	0.53	0.98	0.68	0.08	0.31	0.98

Diagnoses for diseases of the circulatory system (I00-I99)

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	6	3	5	3	0	8
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	1	2	1	0	4
Intervention	31	31	31	31	31	31
	0	2	4	1	1	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	1	1	1	2
p-values	0.045	0.89	0.74	0.46	0.25	0.41

APPENDIX 25

Diagnoses for diseases of the digestive system (K00-K93)

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	5	7	11	1	1	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	2	2	1	1	1	1
Intervention	56	56	56	56	56	56
	5	3	6	0	1	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	1	1
p-values	0.43	0.56	0.47	0.39	0.83	0.85

Diagnoses for diseases of the digestive system (K00-K93)

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	1	0	4	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	1	0	0	1
Intervention	24	24	24	24	24	24
	4	2	3	0	1	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	1	0
p-values	0.15	0.15	0.64	.	0.31	0.31

Diagnoses for diseases of the digestive system (K00-K93)

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	2	5	5	0	1	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	0	1	0
Intervention	31	31	31	31	31	31
	1	1	3	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	0	1
p-values	0.73	0.28	0.71	.	0.39	0.26

APPENDIX 25

Diagnoses for diseases of the UG system (N00-N99)

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Pre	Elective During	Post	Pre	Emergency During	Post
Control	76	76	76	76	76	76
	2	4	3	1	1	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	2	1	1	1	1
Intervention	56	56	56	56	56	56
	1	3	0	1	0	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	0	1	0	2
p-values	0.75	0.72	0.13	0.83	0.39	0.41

Diagnoses for diseases of the UG system (N00-N99)

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Pre	Elective During	Post	Pre	Emergency During	Post
Control	25	25	25	25	25	25
	1	0	0	1	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	0	0	1	0	0
Intervention	24	24	24	24	24	24
	1	2	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	0	0	0	0
p-values	0.98	0.15	.	0.33	.	.

Diagnoses for diseases of the UG system (N00-N99)

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Pre	Elective During	Post	Pre	Emergency During	Post
Control	41	41	41	41	41	41
	1	2	1	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	1	1	1	0	0	1
Intervention	31	31	31	31	31	31
	0	1	0	1	0	3
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	0	1	0	2
p-values	0.39	0.73	0.38	0.25	.	0.41

APPENDIX 25

Diagnoses for diseases of the skin and subcutaneous tissue (L02-L99)

High and Low HbA1c combined: n (subjects), n (diagnoses), median, minimum, maximum
> mum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	76	76	76	76	76	76
	0	0	2	0	0	2
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	1	0	0	1
Intervention	56	56	56	56	56	56
	0	2	0	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	0	0	0	1
p-values	.	0.01	0.21	.	.	0.72

Diagnoses for diseases of the skin and subcutaneous tissue (L02-L99)

Low HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	25	25	25	25	25	25
	0	0	1	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	1	0	0	0
Intervention	24	24	24	24	24	24
	0	1	0	0	0	1
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	0	0	0	1
p-values	.	0.31	0.31	.	.	0.33

Diagnoses for diseases of the skin and subcutaneous tissue (L02-L99)

High HbA1c: n (subjects), n (diagnoses), median, minimum, maximum

group	adm_typeEE and study period					
	Elective			Emergency		
	Pre	During	Post	Pre	During	Post
Control	41	41	41	41	41	41
	0	0	1	0	0	2
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	0	1	0	0	1
Intervention	31	31	31	31	31	31
	0	1	0	0	0	0
	0	0	0	0	0	0
	0	0	0	0	0	0
	0	1	0	0	0	0
p-values	.	0.25	0.38	.	.	0.21