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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
AMDR	Acceptable macronutrient distribution range
ANCOVA	Analysis of covariance
BMI	Body mass index
CDA	Canadian Diabetes Association
CHCs	Community health centres
DAS III	Revised Diabetes Attitudes Scale III
DKNB	Diabetes Knowledge form B
DSME	Diabetes self-management education
EASD	European Association for the Study of Diabetes
EDTA	Ethylene diamine tetra-acetic acid
FGDs	Focus group discussions
$HbA1_c$	Haemoglobin $A1_c$
HBM	Health Belief Model
MNT	Medical nutrition therapy
NE	Nutrition education
RCT	Randomised controlled trial
SCT	Social Cognitive Theory
SEMDSA	Society for Endocrinology, Metabolism and Diabetes in South Africa
TPB	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
TTM	Trans-Theoretical Model
Type 2DM	Type 2 diabetes mellitus

CHAPTER 1

INTRODUCTION AND OUTLINE

1.1 BACKGROUND

Type 2 diabetes mellitus (2 DM) is a chronic disease characterised by insulin resistance and relative insulin deficiency.[1,2] The condition is associated with both macro vascular (cardiovascular, cerebrovascular, peripheral vascular disease) and microvascular (retinopathy, nephropathy, neuropathy) complications.[1]

Type 2 DM is increasing in epidemic proportions and is now considered a global public health problem. [3,4] The condition that was traditionally associated with the affluent, nowadays affects populations from all socio-economic levels.[3,4,5] Globally in the year 2000 there were 171 million people with diabetes[3] and the number increased to 366 million in 2011.[4] The number is projected to increase to 552 million in 2030.[4] In addition, the Africa region is expected to have the largest proportional increase in the number of adults with diabetes by 2030.[4] In South Africa, the national prevalence data for the year 2000 by the Medical Research Council of South Africa reported a prevalence of 5.5%.[6] A prevalence of 6.5% is reported in the recent International Diabetes Federation Atlas (5th edition).[7] The increase in prevalence in developing countries has been associated with urbanisation and the resultant shift from the traditional relatively healthy lifestyle to one of diets high in energy and low physical activity with consequent obesity.[8,9]

Type 2 DM is a major cause of premature deaths and morbidity associated with the complications.[10] In the year 2000, 2.9 million deaths globally were attributed to diabetes. This accounted for 5.2% of all deaths and placed diabetes as the fifth leading cause of death.[11] The number of deaths rose to 3.96 million in the year 2010, representing a 6.8% global mortality for all ages.[12] In the African region, diabetes accounted for 6% of deaths in adults.[12] In South Africa, for the year 2000 diabetes was estimated to account for 4.3% of all deaths, ranking diabetes as the seventh leading cause of death for those aged ≥ 30 years.[6] Globally, diabetes is also a leading cause of new cases of end-stage renal disease, lower-limb amputations, blindness and cardiovascular diseases.[10] In Africa[8] and South Africa[6,13] complications of type 2 DM are also common.

Diabetes is one of the world's most important causes of health expenditure and economic loss.[10,14] Globally, in the year 2010, 12% of the total health expenditures were expected to be spent on diabetes.[14] In the United States, individuals with diabetes cost the health care sector approximately 2.3 times more than people without the disease.[15] This makes type 2 DM a significant economic burden and a challenge, especially in developing economies like those of Africa, where resources are limited in addition to conflicting health demands.[8,16]

Preventing diabetes complications is a primary goal of diabetes management.[17,18] Central to preventing the complications is tight glycaemic control[17,19] as well as control of blood pressure[17,20] and management of lipids.[17] Medical nutrition therapy (MNT), physical activity, education and medication are the key elements in the management of diabetes.[17] To keep diabetes under control the person with diabetes needs to effectively take on self-care activities including dietary choices, exercising and glucose monitoring.[21]

Patient education, also referred to as diabetes self-management education (DSME), empowers the person with diabetes with knowledge, skills and motivation that are needed to perform appropriate self-care.[22] DSME has been shown to be effective in improving knowledge, self-care behaviours, glycaemic control and other health outcomes.[23,24,25] The value of diabetes education is evident in research demonstrating that patients who never received diabetes education showed a striking fourfold increased risk of a major complication.[26]

MNT is an integral component of DSME.[17] MNT, both as an independent variable and in combination with other components of DSME, has been shown to be effective in improving health outcomes in individuals with diabetes.[27,28] MNT can assist in decreasing the onset of costly complications of diabetes. In type 2 DM it has the potential of cost savings as a result of decreasing or discontinuing the use of oral hypoglycaemic agents when diet and physical activity can provide the desired outcomes.[29,30]

In recognition of the critical role that nutrition plays in the management of diabetes, evidence based nutrition recommendations have been formulated by various organisations. These include the American Diabetes Association (ADA),[31] the European Association for the Study of Diabetes (EASD)[32] and the Canadian Diabetes Association (CDA)[33] among others. Individuals with diabetes are expected to make dietary changes in line with the recommendations in order to keep diabetes under control. However, since dietary behaviour

change is complex,[34] low adherence [35,36]and the obstacles to dietary adherence [36,37] in people with diabetes are well documented in the literature. In addition, dietary self-management is cited as one of the most difficult among diabetes self-care areas.[38,39]

1.2 STATEMENT OF THE PROBLEM

Individuals of low socio-economic status are among the groups noted to experience worse long term diabetes management outcomes,[40,41,42] This is also true for South Africa.[13] This is attributed to more socio-economic barriers to self-care, including limited access to continuous quality care.[43,44,45] Therefore, the diabetic populations from resource limited settings need special attention and effective feasible diabetes management strategies.

Patient education is essential in the management of diabetes. It is also considered a feasible strategy due to its low technical complexity, low capital requirements and cultural acceptability.[46] However, in many countries its full potential is not being realised as many individuals with diabetes are not receiving adequate education.[47,48] In developing countries such as those in Africa, structured and comprehensive diabetes education is limited and almost non-existent in some cases.[49] Due to large numbers of patients in most clinics, consultation times are very short leaving little or no time for patient education.[49] Empirical observations of some clinics in South Africa indicated that patients receive brief education during consultations complemented with some education in the outpatient waiting room as they waited to see a health professional.[50] This form of education may not adequately equip the diabetic individual with the necessary knowledge, skills, attitudes and motivation to accurately perform self-care behaviours. There is therefore need for systematic education that ensures that the diabetic individual is well equipped to make informed decisions concerning the management of their condition.[51]

World-wide, MNT is recognised as fundamental in the management of diabetes. However, despite the established role of MNT in enhancing diabetes control, its contribution to diabetes management in Africa, including South Africa, is not well established. There is a paucity of structured nutrition education programmes for individuals with diabetes. In addition, poor dietary adherence and the associated barriers in people with type 2 DM from a resource limited setting has been reported in South Africa.[52] Given that dietary adherence is reported to be one of the most difficult among diabetes self-care areas,[38,39] effective nutrition education is necessary to assist diabetic individuals in overcoming barriers to dietary self-care. Education

that is culturally relevant,[53,54] and tailored to the needs and abilities[55,56] of the patient has been shown to be effective in improving health outcomes.

There is therefore a need to establish whether a nutrition education intervention that is relevant to the culture and the needs of a resource limited population is effective in improving diabetes health outcomes.

1.3 PURPOSE OF THE STUDY

The aim of this study was to develop a culturally acceptable nutrition education programme that was tailored to the needs of adults with type 2 DM and to evaluate the programme's effectiveness in improving health and associated outcomes.

1.4 SIGNIFICANCE OF THE STUDY

MNT and education are essential components of care and management of type 2 DM. However, there is a paucity of data on the contribution of nutrition education to diabetes management and health outcomes in Africa, including South Africa. No study in South Africa has specifically investigated the effect of a tailored NE programme on health outcomes. This study thus fulfils a research need. The study provides insight into the issues that need to be addressed in an NE programme specific for diabetic adults in a resource limited setting. The information generated contributes to a better understanding of the factors that need to be considered in the nutritional management of diabetes. This includes the planning and provision of NE that is tailored to the needs of diabetic adults in a resource limited setting. The study also provides a needed insight as to whether a tailored NE is effective in improving health and associated outcomes. Factors that contributed to the NE programme success and those that might need adjustment were identified. This would constitute a data base valuable to health professionals in planning relevant and appropriate interventions for this population group. The study also provides evidence that could motivate policy makers and managers of health facilities to support and facilitate patient education activities.

The study might also pave way for other such studies in an effort to curb the burden of diabetes complications in Africa, including South Africa. A NE programme that improves health outcomes can contribute to a reduction in the burden associated with diabetes. This is critical in South Africa where diabetes is a significant health and economic burden.[6]

The study involved a diabetic population with limited access to nutrition and other health services. Given that diabetes self-management education is a right for all according to the International Diabetes Federation position statement,[57] the patients in this study should therefore have the therapeutic benefits of participating in the NE.

1.5 THESIS OUTLINE

This section presents the outline of the rest of the thesis. The thesis reference lists are presented at the end of a section or chapter.

CHAPTER 2

The literature that was reviewed is presented. A reference list for chapters 1 and 2 appears after this chapter.

CHAPTER 3

In this chapter an overview of the study methodology is presented as the study was done in phases. A reference list for the chapter is presented at the end of the chapter.

CHAPTER 4

This chapter presents the first phase of the study that was conducted using qualitative methods. The phase entailed assessing and presenting the nutrition education needs and preferences of type 2 diabetic adults. A reference list for the chapter is presented at end of the chapter.

CHAPTER 5

The chapter presents phase 2 of the study which dealt with the planning of a tailored NE programme. A reference list for the chapter is presented after the chapter.

CHAPTER 6

This chapter presents the aim, objectives, hypotheses and methodology for phase 3. Phase 3 entailed the implementation and evaluation of the planned NE programme.

CHAPTER 7

This chapter presents the results for phase 3.

CHAPTER 8

This chapter presents the discussion of the results for phase 3, and includes the conclusion and recommendations for this phase. A reference list for chapters 6, 7 and 8 is presented at the end of this chapter.

CHAPTER 9

Chapter 9 presents the executive summary, general conclusions and recommendations for the study as a whole. A reference list for the chapter is presented at the end.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

This literature review aimed to investigate and report the relevant information necessary to plan an effective NE programme for adults with type 2 DM in resource limited settings. The literature is limited to studies of type 2 DM. The literature review is presented as follows:

- a synopsis of the general background of diabetes (pathogenesis, prevalence, aetiology and impact)
- diabetes management goals and strategies
- the evidence for MNT effectiveness
- MNT recommendations and strategies for type 2 DM
- key considerations in planning an effective NE programme for type 2 DM individuals from resource limited settings.

The information sources that were used for this review included journal articles, conference proceedings and books. Data bases that were used included the Medline, PubMed and Cumulative Index to Nursing and Allied Health (CINAHL). The internet was also used. The literature review was limited to English materials dating from 1990 to 2012.

Key words used for literature search were: Type 2 diabetes mellitus, resource limited/poor, diet, nutrition education, medical nutrition therapy, Africa, South Africa, diabetes knowledge, attitudes, haemoglobin A_{1c}

2.2 PATHOGENESIS OF TYPE 2 DIABETES MELLITUS

Type 2 DM is a chronic disease that develops gradually. The condition was previously predominantly diagnosed in the middle and later life.[58] However, it is now increasingly affecting children and adolescents.[59,60]

Type 2 DM is characterised by a dual defect of insulin action (insulin resistance) and beta-cell secretory dysfunction of a non-autoimmune origin.[61] Hyperisulinemia and impaired glucose tolerance (IGT) precede the development of type 2 DM.[61, 62] Hyperinsulinism indicates insulin resistance, a condition characterised by impaired response of insulin on carbohydrate, lipid,

and protein metabolism.[61] The impairment of insulin action in major target organs such as the liver and muscles is a common pathophysiologic feature of type 2 DM.[2, 63] Insulin resistance shows familial aggregation[61] and is associated with obesity, particularly intra-abdominal obesity and a sedentary lifestyle.[61,63] Excess abdominal fat mass is associated with increased release of free fatty acids to the liver and the circulatory system. The increased free fatty acids contribute to increased insulin resistance in the liver and muscles.[62,63]

When insulin action decreases the system usually compensates by increasing beta-cell function and increased insulin secretion.[62,63] However, with time, the high rate of insulin secretion cannot be maintained, a state associated with a decline in beta-cell function.[62,63] A progressive deterioration of the beta-cell function and subsequent decline in the insulin-secreting ability leads to fasting hyperglycaemia and type 2 DM.[62,63] Both gluco-toxicity (toxic effects of elevated plasma glucose concentrations over time) and lipotoxicity (toxic effects of chronically elevated free fatty acids) are implicated in the beta-cell dysfunction.[62,63]

2.3 AETIOLOGY/RISK FACTORS FOR TYPE 2 DIABETES MELLITUS

Type 2 DM is caused by a combination of genetic and environmental factors.[2,64] Although the genetic component is considered essential in the development of type 2 DM, the activation of a genetic predisposition requires the presence of adverse environmental and behavioural factors especially those associated with lifestyle.[64] Overweight, abdominal obesity, physical inactivity, increasing age are important risk factors in the development of the condition.[2,64]

2.3.1 Genetic factors

Type 2 DM has a strong genetic predisposition.[64] A positive family history confers a 2.4 fold increased risk for the condition.[62] About 15-25% of first degree relatives of patients with type 2 DM develop impaired glucose tolerance or diabetes.[63] The higher concordance rates between monozygotic twins (35-58%) compared with dizygotic twins (17-20%) observed in individuals older than 60 years is further evidence for the genetic involvement.[63]

2.3.2 Obesity

Increased obesity (particularly abdominal) is the most important risk factor for type 2 DM.[64] Studies have shown obesity to be a strong predictor of type 2 DM development.[64] Notable of the studies is the Nurses' Health Study that followed over 84,000 female nurses for 16

years.[65] In that study, being overweight or obese was shown to be the single most important predictor of type 2 DM.[65] Interventions directed at reducing overweight and obesity have also been shown to lead to a reduction in the incidence of type 2 DM in high risk individuals.[66] Obesity promotes the development of insulin resistance and the metabolic syndrome and ultimately type 2 DM.[5]

2.3.3 Environmental and lifestyle factors

Low levels of physical activity and high-energy diets are the major contributors to obesity and type 2 DM.[5,65] In developing countries including those in Africa, rapid urbanisation and nutrition transition together with an increased sedentary lifestyle are a major drive to type 2 DM, the associated obesity and other non-communicable diseases.[9,16,67,68] Globalisation is the root cause underlying the aforementioned changes.[67,68] The nutrition transition entails a shift from the traditional relatively healthy lifestyle to one of more unhealthy diets (energy dense, high in fat, salt and sugar and low in fibre) coupled with low physical activity, which leads to obesity.[68] The changes in diet include: decreases in staple foods rich in starch and dietary fiber and increased consumption of processed foods; increases in foods from animal origin rich in total fat and saturated fatty acids; decreases in plant protein sources such as legumes; increases in carbonated sweetened beverages; and increases in salt intake as well as added sugar, fats and oils in preparation of food.[68] The low physical activity is as result of a shift from labour-intensive occupations and leisure activities to less labour intensive ones associated with urbanisation and technological advancement.[67,68] Smoking, excess alcohol consumption[67] and poverty also increase the risk of type 2 DM.[5,67]

2.4 PREVALENCE OF DIABETES

2.4.1 Global prevalence

Globally in developed as well as developing countries, diabetes mellitus on the increase has reached epidemic levels in several populations. This is especially true for type 2 DM that accounts for 90-95% of the cases.[58]

Global estimates over the years indicate a marked rise in the prevalence of diabetes. King et al reported a global estimate of 135 million adults with diabetes in 1995 and an expected increase to 300 million by the year 2025.[69] Estimates by Wild et al indicated that in the year 2000, there were 171 million people with diabetes and the number was projected to increase

to 336 million by 2030.[3] Recent estimates from the International Diabetes Atlas (5th edition) indicate 366 million in the age group 20-79 years are living with diabetes and the number is projected to increase to 552 million in the year 2030.[4] The magnitude of increase has continuously being projected to be higher in developing countries than developed countries.[3,4,69] According to the most recent estimates most people with diabetes are now living in low-and middle-income countries.[4] A demographic difference in prevalence is observed between developed and developing countries. In developing countries the majority of individuals with diabetes are in the 45-65 years age bracket, while in the developed countries they are in the age category of 65 years and above.[3,69]

The prevalence of type 2 DM has been reported to be higher in populations of low socio-economic status in developed countries.[70,71,72] Prevalence data based on the socio-economic gradient in populations in developing countries are limited. A systematic review and meta-analysis by Hwang et al has however reported a dramatic rise in rural diabetes prevalence in low-income and middle-income countries.[73]

2.4.2 Prevalence in Africa

Data on the epidemiology of diabetes are limited. A review by Motala et al in the year 2003 indicated that the prevalence of type 2 diabetes in Africa has increased over the past two decades.[74] The reported rates varied from low in both rural and urban communities in West African countries and Tanzania in East Africa. Moderate rates were reported in some communities in South Africa (4.8%-8%) and Sudan (3.4-8.3%), and high among urban communities of Cairo (13.5%, 20%) and populations of mixed Egyptian ancestry in Northern Sudan (10.4%).[74] A more recent review by Hall et al for Sub-Saharan Africa reported low prevalence rates in rural Uganda (0.6%), moderate rates for Ghana (6.4%), Nigeria (2.5-7.9%), South Africa (3.9-8.8%) and a high rate for Zimbabwe (10%).[75] Moderate rates were noted for rural Kenya (2.2-5%) and high rates for the urban areas (12%).[75] This classification is reported according to the article.

2.4.3 Prevalence in South Africa

In South Africa as in the rest of the world, diabetes mellitus is common and affects individuals across all population groups.[76] Previous data show estimates of type 2 DM varying between 3% and 28.7 %.[77] The highest prevalence was found among the elderly

coloured community of Cape Town (28.7%)[78] and the Indian community of Durban (13%).[79] Data for the year 2000 by the Medical Research Council of South Africa showed a prevalence of 5.5%.[6] The current Diabetes Federation Atlas shows a prevalence of 6.5% in South Africans aged between 20 and 79 years. One study reported in the review by Hall et al for a rural area in Limpopo showed a prevalence of 8.8%.[75] The increase in prevalence in Africa and other developing countries is attributed to urbanisation, and adapting to a more westernised lifestyle with the resultant increase in obesity.[8,16]

2.5 IMPACT OF DIABETES

2.5.1 Economic costs

The chronic nature of diabetes, the associated severe complications and the means required to control them makes diabetes a costly disease. In the year 2010 it was estimated that the global annual direct health care costs for individuals with diabetes was 376 billion USD.[14] In most low income countries the bulk of diabetes expenditure is borne by the individual and/or their families.[80] For example in Sub-Saharan Africa, the majority of diabetes care is paid for by the patient or family.[81] It has also been observed that the socioeconomically disadvantaged groups, both in developed and developing countries bear a disproportionate economic burden as they spend a higher proportion of family income on diabetes care.[82,83]

Diabetes takes a toll on individuals, family and society through indirect costs such as lost productivity due to illness, absenteeism, disability, premature retirement and premature mortality.[80] This is especially a concern in developing countries where most people with diabetes are in the economically active age.[69]

2.5.2 Morbidity and mortality

Diabetes is one of the major causes of premature deaths.[10] It was estimated to be the cause of 5.2% of deaths globally in the year 2000,[11] and 6.8% in the year 2010.[12] It is a leading cause of new cases of end-stage renal disease, lower-limb amputations, blindness and cardiovascular diseases.[10] In Africa data on diabetes related deaths and complications are limited. A review by Mbanya and Sobngwi found that micro-vascular complications are highly prevalent and occur early during the disease course.[84]A more recent review on chronic complications in Africa confirms microvascular complications are common, especially retinopathy and foot ulceration.[85] Data on macro-vascular complications in Africa are also

limited, but available data indicate diabetes related cardiovascular complications are becoming more common.[85]

In South Africa diabetes micro-vascular complications are also common.[6,86] Diabetes is also among the leading causes of deaths in South Africa. It was ranked as the tenth leading cause of death among people of all ages and seventh for those aged ≥ 30 years in the South African population in the year 2000.[6]

2.5.4 Quality of life

Diabetes affects people's physical and social functioning and their perceived physical and mental well-being.[87] The presence of diabetes related complications and dietary restriction, stress, pain and anxiety associated with diabetes are reported to affect the patient's health-related quality of life.[87]

2.6 DIABETES MANAGEMENT GOALS

The overall goal of diabetes management is achieving the best possible glycaemic control to delay or arrest macro-vascular and micro-vascular complications.[17] Since individuals with type 2 DM have a 2-4 fold increase in cardiovascular disease (CVD) risks,[88] blood pressure control and the control of blood lipids are also important management goals.[17]

2.6.1 Blood glucose control

Evidence from epidemiological observation studies and clinical trials support the value of lowering blood glucose in reducing the risks of diabetes complications and mortality. The United Kingdom Prospective Diabetes Study (UKPDS), a longitudinal observation of 3642 type 2 DM individuals, showed that each 1% decrease in HbA_{1c} averaged over 10 years of follow-up was associated with a 21% decrease in mortality related to diabetes ($p < 0.0001$). In the same study a 1% decrease in HbA_{1c} averaged over time was associated with a 37% risk reduction in microvascular complications ($p < 0.0001$).[19] In the UKPDS[89] sub-study and Kumamoto[90] study, intensive blood glucose control with pharmacological agents resulted in significant reductions in micro-vascular complications. However, it is worth noting that intensive therapy was associated with increased risk of hypoglycaemia and weight gain.[20]

Literature clearly points to the significance of achieving good glycaemic control.

Glycosylated haemoglobin specifically A1C is the primary target for glycaemic control[17] as it provides the best available index of diabetes overall control and is shown to predict the risk for microvascular complications.[91] The American Diabetic Association (ADA) recommends HbA_{1c} levels below 7%,[17]and these have also been adopted in South Africa.[92]

2.6.2 Blood pressure control

Hypertension occurs twice as frequently in people with diabetes as in those without diabetes.[93] The presence of hypertension in type 2 DM substantially increases the risk for CVD, nephropathy and retinopathy.[93,94] Evidence from studies do support blood pressure control as a means to reducing complications in type 2 DM. The UKPDS sub-study demonstrated that tight blood pressure control reduced the risks of micro-vascular complications by 37% and death from type 2 diabetes-related diseases by 32%.[20]

2.6.3 Lipid control

Type 2 DM is associated with a cluster of dyslipidemia that include elevated triglycerides, low HDL and small dense LDL cholesterol.[95,96] These lipid abnormalities contribute to the increased risk of CVD observed in the patients.[95,96] Lipid control is therefore considered an essential element of the multifactorial approach to preventing CVD in type 2 DM.[17] Significant reductions in cardiovascular events in type 2 DM have been demonstrated with pharmacological interventions.[97,98] Lifestyle interventions that included diet, have also shown significant improvements in lipids and the associated CVD risk.[99,100]

2. 7 DIABETES MANAGEMENT STRATEGIES

Diabetes management involves medical nutrition therapy (MNT), physical activity, medication, self management education and blood glucose monitoring.[17,101]

2.7.1 Pharmacological treatment

Lifestyle changes (diet and physical activity) are central to diabetes care, and in most cases have been the initial therapy for type 2 DM. However, due to the progressive nature of type 2 DM lifestyle interventions are seldom sufficient on their own to maintain glycaemic control without pharmacological agents.[102] In recognition of this the ADA recommends early intervention with metformin in combination with lifestyle changes, with timely augmentation with additional agents (including insulin) as a means of achieving and maintaining

recommended levels of glycaemic control.[17]

2.7.2 Physical activity

Physical activity is recognised as an important component of diabetes management and a vital complement to MNT.[17,101] Regular physical activity has been shown to improve blood glucose control, contribute to weight loss and its maintenance, reduce cardiovascular risk factors and to improve overall well being.[103,104] The ADA recommends regular aerobic physical activity of at least 150 minutes per week for moderate-intense physical activity or 90 minutes per week of vigorous physical activity. In the absence of contra-indications individuals with type 2 DM are also encouraged to undertake resistance physical activity for at least three times per week.[17]

2.7.3 Patient education

Diabetes self-management education (DSME) is an essential element of diabetes management.[17] Diabetes education is the process of providing the person with diabetes with the knowledge, skills and motivation needed to perform self-care.[22] The goals of self-management education are to optimise metabolic control, prevent complications and optimise quality of life, while keeping costs acceptable.[17]

To be able to make informed choices about diabetes self-management (medication taking, dietary choices, physical activity and blood glucose monitoring) individuals with diabetes need to receive structured self-management education.[22,51] In recognition of the importance of patient education, standards for DSME have been set by various diabetes organisations, including the International Diabetes Federation[105] and the ADA.[22] These organisations recommend patient education upon diagnosis, continuing education and regular assessments.[22,105] A large body of literature, including meta-analyses and systematic reviews, has demonstrated that diabetes patient education improves knowledge, self-care behaviours, glycaemic control and other health outcomes in diabetes management.[23,24,25,106,107]

DSME has been shown to reduce medical costs in developing countries in the short-term.[30] It is considered feasible due to the low technical complexity, low capital requirements and cultural acceptability, and therefore recommended as a high priority intervention area in developing countries.[46]

2.7.4 Medical Nutrition Therapy

Medical nutrition therapy is an integral component of diabetes treatment and self management education.[17] According to the ADA the goals of MNT for the diabetic patient are: (i) to achieve and maintain recommended metabolic outcomes, including glucose and HbA_{1c}, lipid and lipoprotein profiles, blood pressure and body weight, (ii) prevent or slow the rate of development of complications by modifying nutrient intake and lifestyle, and (iii) to address individual nutrition needs, taking into account personal and cultural preferences and willingness to change.[31]

2.7.4.1 Effectiveness of medical nutrition therapy in diabetes management

Evidence from literature supports the value of MNT in improving health outcomes in diabetes. A review by Pastors et al reported evidence from randomised controlled trials, observational studies, meta-analyses and systematic reviews.[27] Notable among the clinical randomised studies included in this review was the UKPDS in which nutrition counselling had been the primary intervention in the first three months in the newly diagnosed type 2 DM.[108] In that study, the mean HbA_{1c} decreased by 1.9% and there was an average weight loss of ~ 5kg after three months.[108] Another of the clinical studies reviewed was by Franz et al which concluded that intensive MNT provided by dietitians decreased HbA_{1c} by 1.9% in newly diagnosed type 2 DM, and by 0.9% in type 2 DM with an average duration of the disease of four years.[109] Among the meta-analyses, Brown et al concluded that nutrition therapy alone had the largest significant impact on weight loss and metabolic control.[110]

Evidence also exists from other studies and reviews. A review by Asha et al observed that MNT as a component of DSME improved health outcomes in individuals with type 2 DM.[25] A study by Miller et al reported significant improvements in HbA_{1c} and knowledge in elderly patients who participated in a NE programme conducted over eleven weeks.[111] Shabbidar et al observed significant improvements in HbA_{1c} and body mass index (BMI) in type 2 DM after 12 weeks of NE intervention.[28] In a prospective non-controlled study, Lemon et al found a 1.7% decrease in HbA_{1c} over six months in 54% of newly diagnosed type 2 DM.[112] The study also reported a weight loss averaging 2.8 kg and improvements in blood pressure, total cholesterol and triglycerides.[112]

Some studies have observed significant improvements in other outcomes, but non-significant

improvements in glycaemic control. Campbell et al observed positive significant outcomes for dietary compliance and dietary intake (low total fats and saturated fat, high fibre) and total blood cholesterol, but not for glycaemic control.[113] Another study by Anderson-Loftin et al noted significant improvement in BMI and dietary fat behaviour in an intervention for patients in a rural environment where availability of low-cost, low fat food choice was limited, but non-significant improvements in glycaemic control.[114]

This evidence indicates that MNT makes a significant contribution to diabetes control. It also suggests that its impact on glycaemic improvement is greater at initial diagnosis but it continues to be effective at any stage of the disease process.[27] It also suggests that MNT can improve other outcomes even without significant improvements in glycaemic control and this could relate to the extent of beta-cell dysfunction. However, the reduction in cardiovascular risks such as blood cholesterol, saturated fat intake and weight loss still justifies the interventions.

2.7.4.2 Nutrition recommendations for type 2 diabetes mellitus

In general, healthy eating recommendations for the general population are considered appropriate for individuals with type 2 DM.[31,32,33] and in some countries like Canada they form part of the nutrition recommendations for diabetes management.[33] Specific evidence based nutrition guidelines have also been formulated by various organisations. Table 2.1 presents a summary of nutrition recommendations for diabetes from selected diabetes professional organisations. Data on nutrition guidelines for the management of diabetes in Africa are limited. In South Africa, recent guidelines for type 2 DM by the Society for Endocrinology, Metabolism and Diabetes in South Africa (SEMDSA)[115] provide specific dietary guidelines which are in line with those of the international organisations.

2.7.4.2.1 Macronutrients

Macronutrient combination

There is a general consensus that currently there is no established optimal macronutrient mix for the management of diabetes.[31,33] The ADA and CDA recommend macronutrient intake as for the general population that are based on the dietary reference intakes of the acceptable macronutrient distribution range (AMDR).[32,33] The AMDR include 45-65% energy from carbohydrates, 10-35% energy from proteins and 20-35% energy from fats.[116] As seen in

Table 2.1 the various organisations presented have adopted macronutrients within the AMDR. The levels of carbohydrates, proteins and fats recommended are similar or comparable.

Carbohydrates

Carbohydrate is the major nutrient that determines postprandial glucose levels.[116] Both the amount and the type of carbohydrate affect postprandial glucose response.[117]

A summary of the specific guidelines with regard to carbohydrates as stipulated by the various organisations is presented below:

- the need to monitor carbohydrate intake as a strategy to achieving glycaemic control through carbohydrate counting, exchanges or experienced based estimation[31,115]
- consistency in carbohydrate intake, meal spacing and regularity in meal consumption to help in glucose control[33]
- carbohydrate quantities, sources and distribution throughout the day be selected to facilitate near-normal long-term glycaemic control[32]
- sucrose and sugar containing foods: allowed in the context of a healthy diet, (i) and be substituted for other carbohydrates,[31] (ii) but restricted to less than 10%[32,33,115]
- low glycaemic foods: an effect of 0.43% on HbAlc by low glycaemic foods has been reported.[32] However, there is no consensus concerning the use of glycaemic foods. The CDA and EASD encourage the use of glycaemic foods in the management of diabetes while the ADA and SEMDSA state that low glycaemic foods may provide benefits over that observed when total carbohydrate content is considered alone. The ADA stand is based on the fact that there is no evidence for long term benefits of low glycaemic foods[31]
- carbohydrate sources that include whole grains, low fat milk, fruits and vegetables and legumes are encouraged.[31,32,33,115]

Proteins

The recommendations for proteins for individuals with normal renal function are based on those of the general population and are mainly based on typical intakes; 10-20 %[32] and 15-20%.[31,33,115]

Fats and cholesterol

Individuals with diabetes have an increased risk for cardiovascular diseases.[88] This is the basis

for all the guidelines reviewed emphasising the limiting of saturated fats (<7-10% total energy) and minimising the intake of *trans* fatty acids. The guidelines also recommend the consumption of fish as a source of omega three fatty acids. The ADA and EASD also give specific guidelines for the level of dietary cholesterol intake < 200 mg/day and < 300 mg/day respectively.

Table 2.1: Summary of nutrition recommendations for diabetes by various diabetes organisations

Dietary component	**ADA**[31] 2008	**CDA**[33] 2008	**EASD**[32] 2004	**SEMDSA**[115] 2012
Carbohydrates energy (%)	45-65	45-60	45-60	45-60
Sucrose energy (%)	Not specified	≤ 10	≤ 10	≤ 10
Protein energy (%)	15-20	15-20	10-20	15-20
Fats energy (%)	<35%	<35%	<35%	<35%
Saturated fats energy (%)	< 7	< 7	< 10 including trans fatty acids < 8 if LDL elevated	< 7
Trans-fats	Minimise	Minimise		Minimise
Polyunsaturated fats energy (%)	Not specified	<10	<10	<10
Monounsaturated fats energy (MUFA) (%)	60-70 Carbohydrate plus MUFA	Not specified	10-20	Not specified
Omega-3 fatty acids	2-3 fish servings/week	Foods rich in Omega 3	2-3 fish servings/week	≥ 2 fish servings/week
Fibre/day	14g/1000 kcal	25-50g	> 40g (20g/1000kcal) ~50% soluble	25-50g
Cholesterol (mg)	< 200	Not specified	< 300	Not specified
Sodium (mg)	< 2300	Not specified	Not specified	< 2300

- ADA: American Diabetes Association
- CDA: Canadian Diabetes Association
- EASD: European Association for the Study of Diabetes
- SEMDSA: Society for Endocrinology, Metabolism and Diabetes in South Africa

Fibre

There is a general consensus that a high fibre intake up to 50 g/day (including soluble fibre) is

beneficial in controlling blood glucose and improving the lipid profile.[31,32,33] This is the basis for recommending higher intakes than for the general population (25-50 g/day) by most of the organisations reviewed (Table 2.1). In addition, the EASD specifies the proportion that needs to be contributed by soluble fibre. The ADA recommends fibre intake as for the general population (14g/1000 kcal/day) as the priority target.

2.7.4.2.2 Micronutrients

There is a general consensus on the lack of evidence for supplementation with mineral or vitamin supplements unless for those with underlying deficiencies or special population groups such as pregnant women.[31,32,33,115] Diabetic individuals, similar to the general population, are encouraged to consume a variety of foods from the various food groups to meet their needs for micronutrients.[31,32,33,115] The recommended sodium intake of 2300 mg/day by the ADA and SEMDSA is as for the general population.[118]

2.7.4.2.3 Energy balance and weight management

Approximately 80% of individuals with type 2 DM are overweight or obese with insulin resistance.[119] MNT should therefore emphasise lifestyle changes that lead to decreased energy intake and increased expenditure through physical activity to enhance weight loss[17,31,32] Even modest weight loss has been shown to improve insulin resistance and glycaemic control,[120,121] and lower lipids and blood pressure.[121]

2.7.4.3 Barriers to dietary adherence

Eating behaviours are acquired over a lifetime and are based upon strong and entrenched preferences making dietary behaviour change complex and difficult for many individuals.[34,122] In individuals with diabetes, dietary self-management is cited as one of the most difficult compared with other areas of self-care.[35,36,38]

The most frequently cited barriers to dietary change in individuals with diabetes include cost of diet, time pressures, competing priorities, social events, negative emotions and difficulty resisting temptations.[36,37,123] In a study with low-income individuals with type 2 DM, cost, limited portions, decrease in the quality of life, lack of family support and difficulty during holidays and special occasions were cited as the barriers to following dietary recommendations.[37] Nthageni et al reported poor understanding of diabetes, cost and taste of

foods, unavailability of appropriate foods, and inadequate, inaccurate as well culturally inappropriate dietary advice as barriers to dietary compliance among black type 2 diabetic patients in a resource limited setting in South Africa.[52] Glasgow suggests the need for exploring these barriers and using strategies such as problem solving to assist patients overcome the barriers.[124] There is therefore need for identifying barriers to dietary change and consequently addressing them during patient education in order to help diabetic individuals make positive dietary changes.

2.8 DEVELOPING AN EFFECTIVE NUTRITION EDUCATION PROGRAMME

Nutrition education has been defined as "Any set of learning experiences designed to facilitate the voluntary adoption of eating and other nutrition-related behaviours conducive to health and well-being".[125] Since dietary management is cited as one of the most difficult self-care areas, there is need for effective nutrition education that can assist diabetic individuals overcome the barriers to dietary self-care. The key issues that need consideration in designing an effective nutrition education programme for individuals with type 2 DM are discussed below.

2.8.1 Appropriate goals and outcomes

Appropriate dietary behaviour change is the primary goal of nutrition education.[125,126] This is congruent with that of DSME of behaviour change as the primary goal.[127] Therefore, effective nutrition education for individuals with diabetes should lead to a positive change in dietary behaviour[126,128] as reflected in healthy food choices and eating habits.[125,126] The expected outcomes of the change are improved glycaemic control, improved blood lipid profile and blood pressure.[129] Potential mediating factors including knowledge, attitudes and skills related to diabetes and diet are also expected to improve.[128]

2.8.2 Target group tailored intervention

Education programmes must be matched to the needs and abilities of the patient if they are to be effective.[125,126,130] Messages and materials that are customised to address the unique needs and concerns of specific patients have been shown to be effective in changing health-related behaviours.[55,56]

In order to design a targeted education programme, a needs assessment is recommended.[125,126]

This activity helps in providing a better understanding of the target group in such aspects as knowledge, attitudes, barriers and facilitators to behaviour change and needs and preferences for diabetes education.[131,132]

Different methods can be used to conduct a needs assessment.[133] However, the use of focus groups has been a major strategy in developing or adapting self-management interventions especially in low income and minority groups.[131,132] The informal style of focus groups is conducive to identifying barriers to care, exploring health beliefs, identifying education needs and in gathering information to improve intervention programmes.[131] The synergy promoted by the group interaction produces ideas and statements which could not be generated with other types of methods. Respondents can qualify, clarify and build upon responses thus conveying more thoughtful and in-depth information.[131,134]

2.8.2.1 Literacy level

A high proportion of low income populations have low literacy levels.[43,44] Therefore, the education programme content should be simple to increase comprehension and compliance.[53] Zeimer et al demonstrated that a simple meal plan method emphasising healthy food choices was effective in improving glycaemic control in African Americans with type 2 DM.[135]

Strategies and educational materials that enhance understanding should be incorporated. These include use of visual materials, action oriented teaching, repetition of key concepts and skills and facilitation of frequent timely feedback[136] and focusing on few but important dietary concepts.[114] Other strategies include minimal reading activities such as group discussions, demonstrations and videos,[54] and visits to real world settings such as grocery stores.[137,138]

2.8.2.2 Socio-cultural context

Attitudes and beliefs about foods tend to reflect cultural values. Cultural food practices not only affect taste preferences but also shopping habits, manners, communication and personal interactions.[34,122] Social influences are also important determinants of food choices. Family and friends provide a source of modeling and peer pressure for consuming particular foods or trying new foods.[34,122] Therefore consideration of the socio-cultural context of the target group is crucial to increasing programme acceptance and effectiveness.[139]

Several studies have demonstrated that culturally sensitive interventions are effective in improving glycaemic control and dietary behaviours.[53,54,114] Aspects that have been used in diabetes patient education to increase cultural relevance include using preferred language, integrating cultural dietary preferences into healthy dietary strategies, integrating cultural traditions associated with food such as family gatherings, incorporating family members,[53,137] using ethnic food models to teach meal planning,[53,114] and using cultural familiar experiences such as drama.[136]

2.8.2.3 Locality of the nutrition education programme

Patients with low income and low educational attainment tend to have low education programme attendance rates,[140] and high attrition rates.[141] A convenient locality that is easily accessible by public transport can minimise the transport problem, which is often cited as a barrier to participation in patient education programmes.[43]

Most education programmes tend to be provided in outpatient clinic settings.[139] However, the use of community settings such as schools, churches, community centres is becoming common especially for underserved populations.[53,54,114,137] These settings may be more convenient and familiar for the participants and could be a strategy to help them overcome the socio-economic barriers to participation.[139]

2.8.3 Appropriate implementation approaches and strategies

2.8.3.1 Active involvement of the learner/patient

Diabetes care responsibility primarily lies with the individual with diabetes.[21] To acquire the knowledge, skills and attitudes necessary for appropriate self-care behaviours, including the diet, he/she needs to be actively involved in the learning and decision making processes. Active involvement of the leaner as compared with the didactic teaching approach has been shown to be more effective in improving diabetes self-management outcomes.[23,44,142,143]

Strategies that actively engage the learner in the learning and decision making processes in diabetes education, include hands-on activities such as meal preparation,[53,114,136] collaborative goal setting and problem solving,[136] cognitive reframing,[136,107] group discussions,[53,144] story telling,[53] and role playing.[144]

2.8.3.2 Behaviour focused approach, based on appropriate theories/models

Research indicates that the correlation between knowledge and behaviour change is low[23,142] and that education programmes that incorporate behaviour change strategies are more effective in changing behaviour.[145,146,130] Therefore nutrition education programmes for individuals with diabetes must go beyond knowledge and target dietary and other nutrition related behaviours.

To help individuals change dietary and other health behaviours several factors are suggested as the targets for intervention. Cotento et al recommend the addressing of psychosocial factors that are antecedents of behaviour such as personal factors (attitudes and beliefs), behavioural capabilities (knowledge and skills) as well as environmental factors that facilitate or impede change.[145] In interventions for individuals with diabetes, Peyrot and Rubin suggest targeting the following: (i) motivators (factors that predispose one to action such as, perceived need, perceived benefits of treatment, outcome expectancies, rewards/incentives and cues to action), (ii) inhibitors/facilitators (barriers or resources for actions), (iii) intentions (ready to change and goal to work towards), and (iv) triggers (events that shift a person from being predisposed to action into an action state).[147]

Behaviour change is a complex process; therefore in planning any behavioural intervention programme, a theoretical foundation is recommended[126,146,143] Theory helps us better understand the relationships among factors that influence behaviour change.[126] Appropriate use of education and behaviour change theories helps to ensure congruence between planned interventions and expected outcomes.[133]

The most commonly used theories in diabetes education include the Health Belief Model (HBM), the Theory of Planned Behaviour (TPB), the Social Cognitive Theory (SCT) and the Trans-Theoretical Model (TTM). These theories and their application in diabetes education are discussed below.

2.8.3.2.1 Health Belief Model

The Health Belief Model emphasises perceived threat as a motivating force and perceived benefits (less barriers) as providing a preferred path to action.[148] It purports that readiness to take an action to avoid a condition/illness is more likely to the extent that people (i) perceive

themselves as threatened by the condition (which is dependent on the perceived personal susceptibility and severity of the condition), (ii) perceive benefits in following the recommended course of action, (iii) perceive barriers (concrete and psychological costs) of following the health recommendations to be low, and (iv) believe they have the ability to perform the recommended behaviour successfully.[148]

The HBM as applied to dietary adherence for diabetes management includes beliefs about personal susceptibility to secondary complications of diabetes, severity of diabetes and its complications, the belief that dietary adherence will render benefits in preventing the complications, the perception that barriers and other costs related to dietary adherence are not excessive and that they have the ability to make the recommended dietary changes.[149]

2.8.3.2.2 Trans-Theoretical Model (TTM)

The Trans-Theoretical Model views behaviour change as a process in which individual's progresses through a series of distinct stages of change.[150] These stages include (i) pre-contemplation: not intending to change in the foreseeable future, (ii) contemplation: not prepared to take action at present, but intending to within the next six months, (iii) preparation: actively considering changing behaviour immediately or within the next month, (iv) action: actually made a behaviour change in the recent past within six months or less, (v) maintenance: behaviour changed for greater than six months and is working to sustain the change, and (vi) termination: the person has zero temptation and the ability to resist relapse. The use of the model is useful in eliciting behaviour change if the education matches the stage and addresses individual needs.[150]

Vallis et al utilised the model in a randomised controlled trial to distinguish diabetes related characteristics of individuals at different stages of change towards more healthy low fat diets. In that study, overweight individuals with type 2 diabetes identified in the action stages (action and maintenance) had healthier eating behaviours than those in the pre-action stages (pre-contemplation, contemplation and preparation).[151]

2.8.3.2.3 Social Cognitive Theory (SCT)

The Social Cognitive Theory describes learning as a reciprocal inter-action between an individual's cognitive processes, environment and behaviour (reciprocal determinism).[152] This

is the basis for including both environmental and individual level interventions. Key concepts of the SCT include (i) reinforcement (reinforcement can be accomplished directly through verbal feedback, through social modelling or through self–management, (ii) expectations, (iii) expectancies (values that people place on an expected outcome). The more highly valued the expected outcome, the more likely the person will perform the needed behaviour, (iv) behaviour capability (knowledge and skills necessary to perform a behaviour). This construct emphasises that the individual must first know the behaviours and how to perform them and hence the need for clear instruction and training, and (v) self-efficacy (confidence in one's ability to successfully perform a specific behaviour). Self efficacy can be increased through skills mastery, through modelling and social persuasion.[133]

The SCT model was utilized by Miller et al to target personal characteristics (knowledge, skills and health beliefs) and behaviour itself in a nutrition education intervention for type 2 DM.[111] The intervention incorporated activities to strengthen knowledge and skills and included weekly goal setting and rewards to facilitate and reinforce behaviour change. The study observed improvements in HbA_{1c}. In another study Garret et al targeted the self-efficacy construct and used vicarious experience and verbal persuasion as methods of increasing self-efficacy.[153] The study observed improvement in the outcomes measured (knowledge, feeling of control and behaviour). However, glycaemic control was not evaluated.[153]

2.8.3.2.4 Theory of Planned Behaviour (TPB)

The Theory of Planned Behaviour is an extension of the Theory of Reasoned Action (TRA).[133] The TRA purports that an individual's intention to perform a given behaviour is a function of their attitudes (anticipated outcomes of a behaviour and values placed on these outcomes) toward performing the behaviour and the normative beliefs about what relevant others think they should do, weighted by the motivation to comply with those others. The TPB has an additional concept of perceived behavioural control. This construct points out that behavioural intent and behaviour are also influenced by the degree of control people feel they have over circumstances or in being able to perform the behaviour. The more favourable the attitude and subjective norm with respect to a behaviour and the greater the perceived degree of control, the stronger the individuals intentions to perform the behaviour.[133] Chapman et al used the TPB theory with older diabetic adults. They found that the intention to consume certain high fat foods was strongly related to subjective norms, attitudes towards dietary

adherence and perceived control.[149]

2.8.3.3 Mode and format of programme delivery

Education programmes could be delivered using a face to face approach, written material, telephone and electronic methods. The face to face method is the most commonly used[107,143] and the one associated with better health outcomes in diabetes self management education programmes,[24,107] even among the disadvantaged populations.[44]

Individual and group approaches have both been used in diabetes patient education at approximately equal frequencies.[154] However, very few studies have directly compared the effectiveness of group versus individual formats for delivering a specific intervention. Rickheim et al in a randomised controlled trial, comparing the effectiveness of the two approaches found that glycaemic control improved in both groups, but with slightly more reduction in HbA_{1c} in the group setting.[155] Both the group and individual interventions also showed improvements in body weight, psychosocial adjustments, mental health and attitudes towards diabetes, thus supporting the conclusion that group sessions are as effective as individual settings in educating adults with diabetes. Another randomised controlled trial, comparing group education versus individual consultations delivered as routine diabetes care in type 2 diabetics over a period of two years, observed better health outcomes in the group participants. They sustained their levels of HbA_{1c} while the levels of those in individual settings worsened. They also increased HDL cholesterol levels and reduced their BMI and triglyceride levels.[156] A systematic review by Deakin et al concluded that group DSME is effective in improving fasting blood glucose levels, $HbA_{1c,}$ diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication.[157]

Norris et al in their systematic review observed that group delivery was more effective for lifestyle programmes.[23] However, group versus individual delivery was found not to be a statistically significant predictor of glycaemic control in a meta-analysis by Norris et al.[158] Clement's review of diabetes self-management education observed that small groups and one-on one education might be equally effective in enhancing self-care behaviours and glycaemic control, and suggested that an optimum programme is the one that uses both formats.[159] Similarly, Brown concluded that a combination of group and one-on one approaches achieved higher knowledge gains in DSME programmes and the author suggests the use of small

groups of ten participants or less.[146]

A careful combination of the two mentioned approaches could derive more benefits than that offered by either alone. Group processes encourage change in beliefs and values as members share their knowledge, beliefs and skills and use the experience of others as a model.[159,160] In a group setting individuals can obtain emotional support from people with similar experiences.[161] Group education is also cost effective and efficiently utilises scarce resources.[138,162]

One-on one education allows better tailoring to each individual's needs and better interaction based on non-verbal signals.[160,162] Therefore it is useful for exploring long term intrapersonal problems[161] or initial education when educational objectives need to be strictly selected, especially in the presence of severe emotional distress.[160]

A combination of the two approaches was utilised by Rosal et al in a diabetes self-management education programme for low-income Spanish speaking patients. An initial individual one hour session was followed by ten weekly group sessions and an extra two 15-minutes individual sessions during the ten-week period. The study found significant improvements in glycaemic control.[136] Wilson has suggested some ways of combining the two approaches: the use of telephone contacts by the educator to follow-up on progress and providing individual counselling after or in between group sessions,[162] the latter is more feasible in resource limited settings.

2.8.3.4 Provision of social support

Social support is an important element in dietary behaviour change.[122,163] Social interactions can provide good models for healthy eating and feedback that can reinforce or modify one's self-evaluation. Peers, family and professionals can provide emotional support as well as challenge patients, stereotype or negative expectations regarding proposed change.[163] Social persuasion helps in enhancing confidence in individuals, and can assist diabetic individuals improve their self-care behaviours.[164]

2.8.3.5 Suitable programme duration and contact time

There is very little guidance from the literature on the appropriate dosage (length and contact

time) for diabetes education interventions. A few studies however, do point to the fact that a sufficient duration and contact time are necessary for a programme to be effective. A meta-analysis by Norris et al observed that glycosylated hemoglobin levels decreased with increased contact time between the participant and educator.[158] Similarly, Brown et al in a study of dosage effects of diabetes education for Mexican Americans, observed that individuals who attended more sessions had greater improvements in metabolic control.[137] In another study, the same authors observed a maximum benefit effect of DSME on glycaemic control at six month for Mexican-Americans.[54] A systematic review by Glazier et al concluded that interventions for the socially disadvantaged including low-income groups should be of high intensity (> 10 contact hours) and delivered over a long duration (≥ 6 months).[44]

2.8.3.6 Follow-up intervention

Maintenance of outcomes in individuals with diabetes is a challenge, and more so in minority groups and those of low income.[43] The meta-analysis of trials by Norris et al showed that the benefits of diabetes self management education decline one to three months after the intervention.[158] Similarly a meta-analysis by Brown observed that metabolic control improved between one and six months, but decreased to the levels of one month after six months.[165] Therefore, it appears that follow-up intervention is necessary to maintain the achieved outcomes.[23,158,159] Among the methods used for follow-up intervention include telephone calls and additional group sessions at periodic intervals to reinforce previously learned self-management information and to provide social support.[54]

2.8.4 Competent educator

An effective NE programme is the one delivered by a competent educator.[125,126] Personal competency characteristics of successful nutrition educators include strong skills in interpersonal relationships, communication, listening and interviewing skills,[125,143] as well as skills in behaviour change.[22,125] In addition, the basic competencies of the dietetic/nutrition profession are necessary. These include understanding the fundamentals of the food and nutrition science, including knowledge of physiological and psychological determinants of eating behaviour and an understanding of the environmental and social implications of the food system.[125] A registered dietitian is the professional recommended to conduct nutrition education for individuals with diabetes.[22,31,32,33,166] However, in many settings this category of

a professional is not adequate or available. Therefore other health professionals should be trained to offer the nutritional education.[167] Trained peer educators could also be utilised to deliver NE.[168,169]

2.8.5 Appropriate nutrition education content and approach

The content of the NE should be based on assessed individual/group needs[22,126] In newly diagnosed individuals initial self-management education (survival skills) is necessary. This includes basic meal planning and physical activity guidelines, signs and symptoms and prevention of hypoglycaemia for those on medication, nutritional management during short illness and blood glucose monitoring.[170] Thereafter, the topics/content that are emphasised, should be based on the patient's lifestyle, level of nutrition knowledge, and experience in planning, purchasing and preparing meals. Suggested essential nutrition education topics include among others sources of carbohydrates, proteins and fats, nutrition labels, modification of fat intake, grocery shopping guidelines, guidelines for eating out and on special occasions, behaviour modification techniques and tips for problem solving.[170] Appropriate meal planning approaches that enhance motivation and adherence to diet are necessary.[170] The plate model is one visual approach to planning meals.[171] The approach has been shown to improve the understanding of meal planning principles and the ability to plan healthy meals in individuals with type 2 DM in underserved populations.[172] This meal planning approach could be useful in resource limited settings as it is simple, versatile and it promotes understanding and memory retention.[171]

2.9 EVALUATING NUTRITION EDUCATION PROGRAMMES

Evaluation has in its simplest form been defined as the process of determining the value or worth of an enterprise[126] or the measurable determination of the value or degree of success in achieving specific objectives.[173] In broader terms and in reference to programmes, it has been defined as the rigorous, science based collection of information about programme activities, characteristics, outcomes and impact that determines the merit or worth of a specific programme or intervention.[174] Evaluation through systematic data collection establishes the effectiveness of a programme in achieving its originally stated objectives and the extent to which observed changes are attributable to the programme. [175] Therefore, evaluation goes beyond monitoring, the routine tracking and reporting of priority information about a programme and its intended outputs and outcomes.[174] Monitoring however does provide

contextual information[176] and some basic data for evaluation.[175]

Planning for evaluation is an important part of programme planning.[126,177] The reasons for undertaking programme evaluation include the following:

- To determine whether the programme goals and objectives have been achieved[126,177]
- Judgment on whether the programme contributed to the desired effects on targeted behaviour, mediating variables of behaviour, physiological variables and other variables[126]
- Determine whether the programme was implemented as planned or not and the reasons[126]
- To determine whether the programme (content, strategies and activities) were suitable for the target group and if they contributed to the achievement of the goal and objectives.[126]

2.9.1 Types of evaluations

The types of evaluations used for health promotion/education programmes are generally grouped into the following categories:
(i) Formative evaluation, (iii) process evaluation, and (iii) summative evaluation.[126,177,178, 179]

2.9.1.1 Formative evaluation

Formative evaluation is primarily used during the programme development stages (pre-intervention).[126,173] This evaluation functions to improve the programme prior to implementation. Information gathered is used to identify problems and the changes needed to improve processes, methods and procedures.[180] Formative evaluation can include pilot testing of programme components, activities and materials.[126,133]

2.9.1.2 Process evaluation

Process evaluation is conducted during the programme implementation stage.[126,133,177,181] The purpose of process evaluation is to assess how well a programme is being implemented relative to the plan.[126,177,180] Aspects that can be assessed include participants recruitment and maintenance of participation (programme reach), the magnitude of exposure to the programme activities and materials, barriers and problems,[126,178] and the participants judgment of the programme.[126]

Process evaluation data assist in the interpretation of the results[126,180] and/or understanding of the relationship between specific programme elements and programme outcomes.[181] The data can also provide information on the feasibility and acceptability of an intervention to the provider and the users (participants).[180] Process evaluation also contributes to the external validity of an intervention.[180] Process evaluation is considered to be important in randomised controlled trials.[180]

2.9.1.3 Summative evaluation

Summative evaluations provide information on the effects of the programme.[126,133,177,179] These evaluations are done at the end of end of the programme[126,133,179] and for ongoing programmes.[179] Outcomes and impact evaluations are considered summative evaluations.[126,133,177,179] However, in the literature the two terms are used differently or interchangeably. Contento indicates that while both impact and outcome evaluations show the effect of an intervention, the impact evaluation uses a more systematic design, and provides more definitive evidence that the effects obtained are due to an intervention.[126] Some authors consider impact evaluation as the initial effect of a programme on proximal targets of change or the immediate/intermediate observable effects of a programme such as knowledge, attitudes and behaviour and outcome evaluation as the consequent effect of a programme on health outcomes corresponding to the goal or target (long-term).[133,178] Others view outcome evaluation as dealing with the immediate and intermediate goals and the impact evaluation dealing with the ultimate goal of the programme (long-term).[174,182] Therefore, there is no consensus on the two types of evaluations. For the purpose of this study outcome evaluation is used. This is based on the definition of an outcome as a "measurable product and the changed state or condition as a consequence of health care over time"[127] irrespective of whether it is short term, intermediate or a long term outcome.

2.9.2 Considerations for nutrition education programme evaluations

Nutrition education programmes should be evaluated for both process and outcomes.[126] The following are considerations for planning process and outcome evaluations:[126]

2.9.2.1 Process evaluation

Data collected for process evaluation depends on the size of the programme, the aspects to be evaluated and the available resources. Data can be collected through interviews with key

individuals or discussions with group participants or observations. Appropriate tools should be designed for data collection.

2.9.2.2 Outcome evaluation

In the planning of outcome evaluations the following considerations are necessary:

- Clarification of outcomes to be evaluated:
  The goals and objectives are the basis for the outcomes to be evaluated. The outcomes selected should be based on the purpose, duration and power of the intervention. NE programmes can be evaluated on short-term outcomes (mediators of behaviour), medium term outcomes (behaviour goals), and long-term outcomes (physiological and environmental supports).
- Identifying potential indicators and measures of outcome effectives:
  Appropriate indicators and measures for effectiveness should be clarified for each outcome. Indicators are ways to operationalise theoretical constructs, activities and behaviours in order to identify that change has occurred, for example 'increase in fruits and vegetable intake'. Measures are the tools to use for evaluating the change for example, questionnaires and 24 hour diet recalls.
- Selecting, adapting or designing instruments for measuring programme effectiveness
- Constructing an appropriate evaluation plan to measure impacts
- Designing the methods for collecting the evaluation data.

2.10 SUMMARY

Type 2 DM is a major public health problem with a substantial burden globally and in South Africa. The complications associated with type 2 DM are a major cause of morbidity and mortality. Preventing or delaying the complications is a primary goal of diabetes management. Tight glucose control, in conjunction with blood pressure control and blood lipid management is fundamental to preventing the microvascular and macrovascular complications of type 2 DM.

DSME is critical to empowering individuals with type 2 DM manage their condition effectively. Appropriate lifestyle modifications (diet and physical activity) are also essential and pharmacological agents may be necessary.

MNT by itself or in conjunction with DSME is effective in improving outcomes in diabetes. However, NE is a challenge since dietary behaviour change is complex and diabetic individuals find dietary-self-care to be one of the most difficult self-care areas. Effective NE is needed to assist diabetic individuals overcome the barriers to dietary self-care.

A comprehensive need assessment is essential for the planning of NE that is tailored to the needs and abilities of the patient(s). The use of a behaviour focused approach based on appropriate theory, incorporating learner centred activities and the use of appropriate NE implementation strategies and approaches are important aspects of an effective NE programme. Increased contact time with the educator and suitable NE programme duration are also essential elements for an NE programme. The effectiveness of an NE programme should be established through appropriate outcome assessments in the light of suitable process evaluations. The effectiveness of a tailored NE programme for type 2 DM in resource limited settings needs to be established.

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CHAPTER 3

METHODOLOGY OVERVIEW

3.1 INTRODUCTION

As stated in the introduction, the purpose of this study was to develop a nutrition education (NE) programme that would be culturally relevant and tailored to the needs of adults with type 2 DM in a resource limited setting of the Moretele sub-district, and to evaluate the programme's effectiveness on health outcomes. To achieve this goal, the study was conducted in three different phases using a mixed methods research approach. This chapter gives an overview of the methodology applied in the study. The particular methods applied in the specific phases are extensively discussed in chapters 4, 5 and 6 respectively. This chapter also discusses the study setting and gives the definitions of terms pertaining to the study as a whole.

3.2 RESEARCH PERSPECTIVE

3.2.1 Research approach

The study was done in three phases. The phases were (i) needs assessment (phase1), (ii) planning of the NE programme (phase 2), and (iii) implementation and evaluation of the NE programme (phase 3). The research questions addressed in the three phases were as follows:

Question 1

What are the needs for NE in adults with type 2 DM in the Moretele sub-district?

Question 2

What are the features (components, activities) of a tailored, cultural relevant NE programme for adults with type 2 DM in the Moretele sub-district?

Question 3

What is the effect of the tailored NE programme on health and associated outcomes of adults with type 2 DM in the Moretele sub-district?

A mixed-methods research design, encompassing both quantitative and qualitative research domains, was used. [1,2] A combination of approaches was selected as neither alone could address the study research questions adequately.[2,3] The qualitative approach was appropriate for assessing the needs for NE and the preferred features of an NE programme (research

question 1). The qualitative method allowed participants in the study to give views in their own words, rather than as a choice between pre-determined responses. This allowed the researcher to obtain an understanding of the NE needs from the participants' perspective.[4] Research question 3 (phase 3) aimed to ascertain the effects of the NE programme on specified outcomes. Therefore a quantitative approach that quantifies phenomena and describes variables in a causal-effect relationship was appropriate.[4] Research question 2 dealt with the planning of the tailored NE and did not require an empirical investigation.

3.2.2 Research phases

The research phases were conducted sequentially with a consecutive phase being dependent on the previous phase(s). Therefore, the third phase depended on the first and second phases, while the second depended on the first phase. The results from each phase were analysed and discussed separately and then integrated at the end in the summary (see chapter 9).

3.2.2.1 Phase 1: Nutrition education needs assessment

Phase 1 was the needs assessment phase. The overall goal of the phase was to explore and describe the nutrition education needs of adults with type 2 DM in the study setting. A qualitative research approach based on an interpretive phenomenological[5] design was used.

Participants in phase 1 included adults (males and females) with non-insulin dependent type 2 DM and the health professionals serving them at the community health centres (CHCs). A convenience purposive[6,7] sample was used with the patients. All health professionals who met the inclusion criteria and agreed to participate were included.

Data were collected using focus group discussions with the diabetic patients and self-administered questionnaires for the health professionals. Data were analysed using frame work analysis based on Krueger's approach in combination with that of Richie and Spencer.[8] This phase is discussed in chapter 4.

3.2.2.2 Phase 2: Planning the nutrition education programme

The aim of this phase was to plan a NE programme that would be culturally relevant and tailored to the needs of adults with type 2 DM in the study setting. The specific objective was to determine the NE features (appropriate theoretical models/theory, NE components,

curriculum and content, activities, teaching approaches, etc.) based on the needs assessment and evidence from the literature. The phase also included preparations for the implementation of the NE programme.

Results from phase 1 (NE needs assessment) and evidence from the literature were used to plan the NE programme. Preparations for implementation involved consultations with collaborators, development and pilot testing the education tools/materials and questionnaires for outcome measurements, as well as the training of the facilitators. Phase 2 is discussed in chapter 5.

3.2.2.3 Phase 3: Implementation and evaluation of the nutrition education programme

The purpose of phase 3 was to implement the planned NE programme and to evaluate the programme's effectiveness on glycaemic control (primary outcome) and other specific outcomes (dietary behaviours, body mass index, lipid profile, diabetes knowledge and the attitudes toward diabetes and its treatment) (secondary outcomes) in adults with type 2 DM in the study setting.

A randomised controlled trial (RCT) using two groups was implemented. The RCT is the most scientifically rigorous method of hypothesis testing and is regarded as the gold standard for testing the effectiveness of interventions.[9] One group (intervention) received the NE intervention while the other group (control) received usual medical care. Both groups received the same education materials. The groups were followed up to 12 months. Outcomes were assessed at baseline, six months and 12 months. Post-intervention data were analysed for the participants who completed the study. An intention to treat analysis[10] was also done for HbA_{1c} that served as the primary outcome.

The NE programme process evaluation was undertaken using both qualitative and quantitative approaches. Data from the process evaluation assisted in an assessment on the extent of the NE programme implementation, and gave insight on the participants experience with the programme. The results were used to explain the outcomes.[11,12]

The outcomes were grouped into primary and secondary outcomes. The primary outcome is considered to be the most important, and is the one usually used to calculate the sample

size,[13] as was done in this study. Glycosylated haemoglobin (HbA_{1c}) was the primary outcome in this study since glycaemic control is the main goal of diabetes management. The HbA_{1c} test is considered the gold standard for testing glycaemia as it has been shown to predict the risk for the development of chronic complications in diabetes.[14] All other outcomes that were measured were considered secondary outcomes. These included blood pressure, blood lipids, BMI, dietary behaviours (dietary intake and food related practices), diabetes knowledge and the attitudes toward diabetes and its treatment. Outcomes were also grouped according to the outcome categories of diabetes self-management education (DSME) (see Table 3.1 for DSME based outcomes). These include immediate, intermediate, post-intermediate and long-term outcomes.[15] The immediate outcomes were diabetes knowledge and the attitudes toward diabetes and its treatment. Dietary behaviours were the intermediate outcomes while post-intermediate outcomes were HbA_{1c}, blood pressure, blood lipids and BMI. These post-intermediate outcomes were also referred to as clinical outcomes. Long-term outcomes were not assessed in this study.

A conceptual framework of the study is graphically presented in Figure 3.1. The definitions of the main concepts of the conceptual framework are given in Table 3.1. Figure 3.2 graphically presents the study phases.

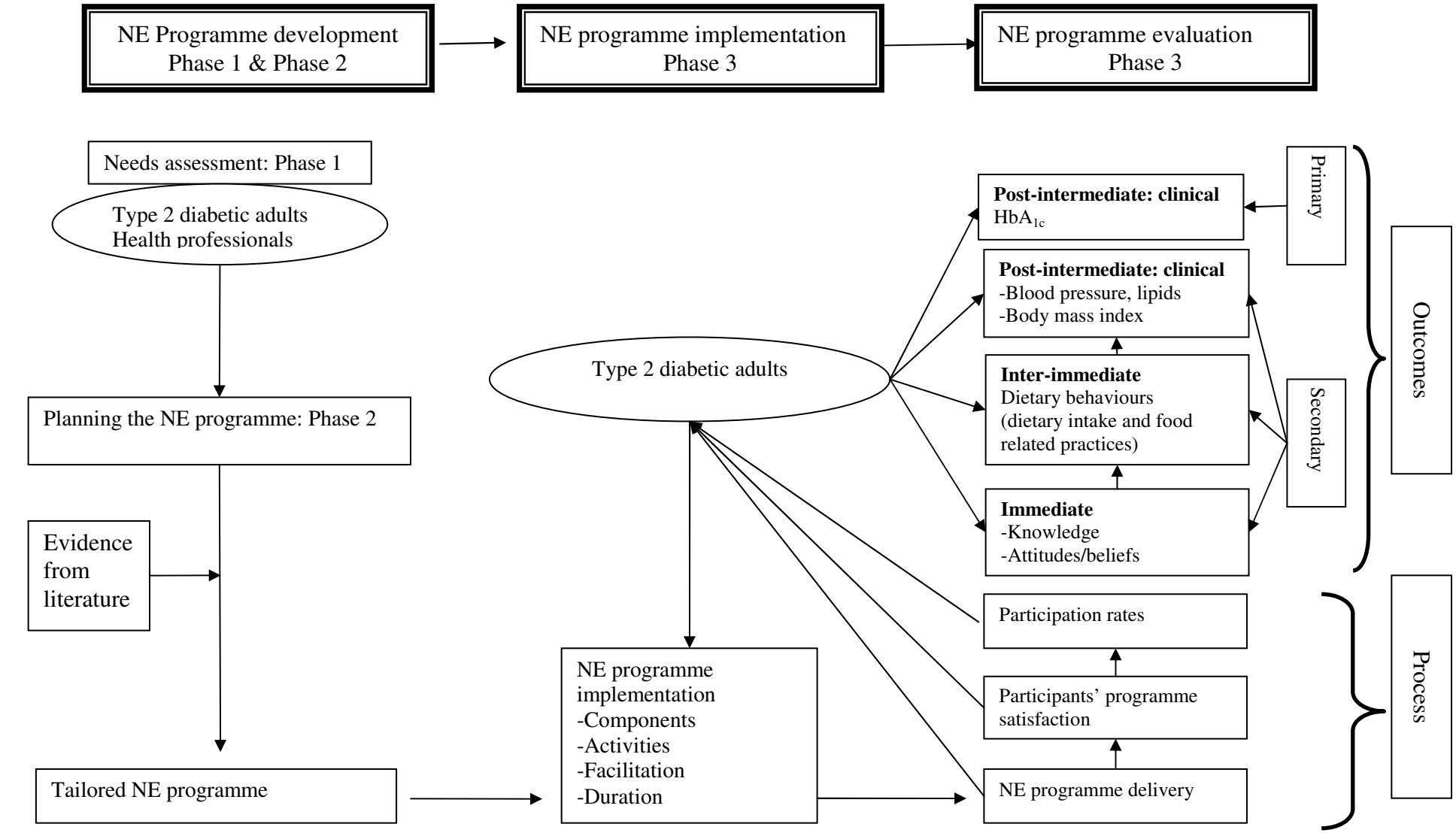

Figure 3.1: Conceptual framework of the study

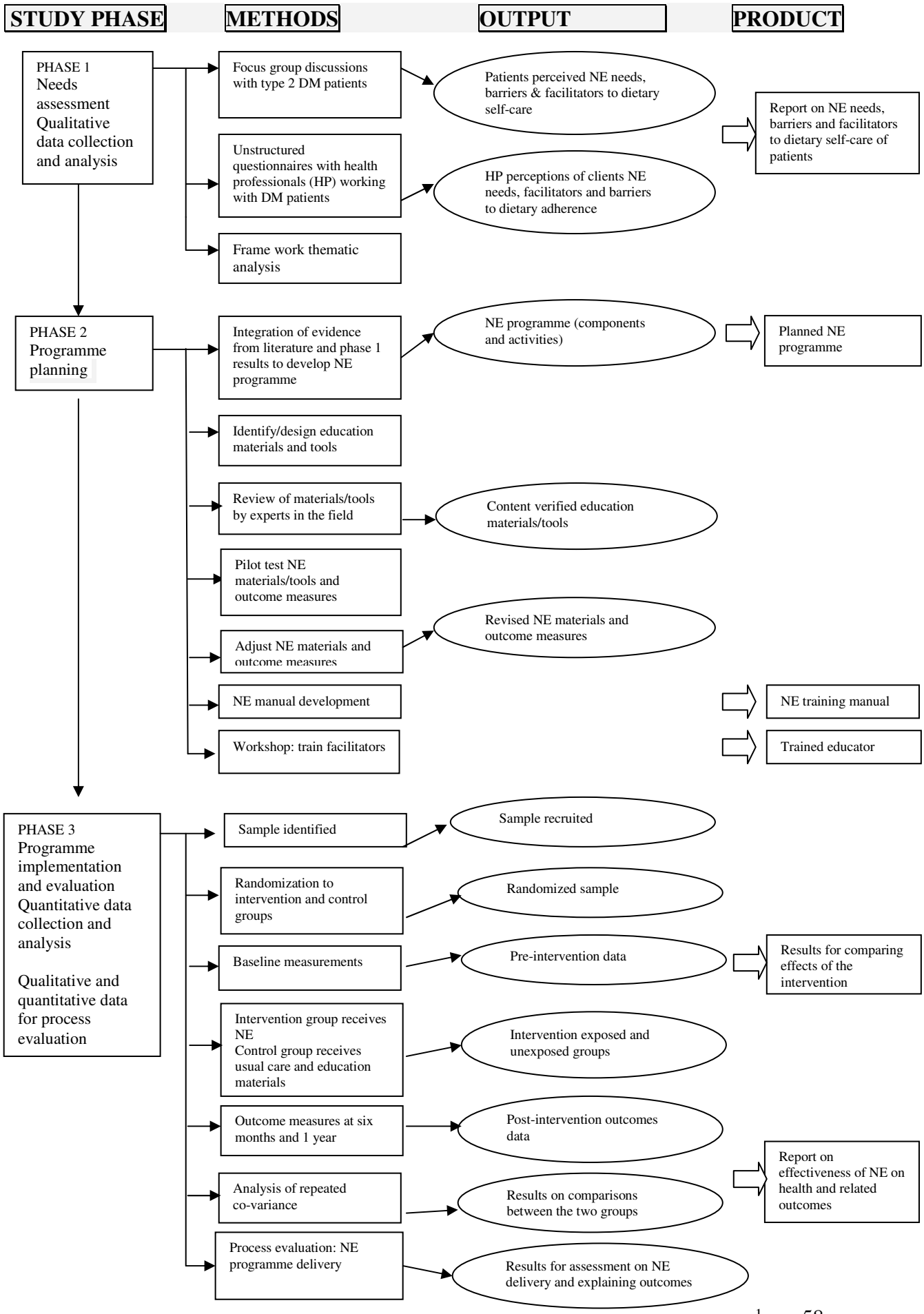

Figure 3.2: **Schematic outline of the study phases.** Format adapted with modification from Creswell.[1]

3.3 STUDY SETTING AND POPULATION

The study was done in two CHCs, Makapanstad and Mathibestad, in the Moretele sub-district, North West Province, South Africa. The CHCs are approximately 10 km apart and are situated about 80 km north-west of Tswane Metropolitan, Gauteng. Figure 3.3 shows the location of the study site.

Moretele sub-district is divided into 22 wards (sections)[16] and has a population of 184 242 people as per the recent (2011) national census.[17] The average annual household income in the sub-district is R 35 467 (~ R 3000 per month/USD 340). For adults aged 20 years and above, about 10 000 (~9%) have no formal education and approximately 4 900 (~5%) have an education level above matriculation (grade 12). The unemployment rate in the sub-district is 45%.[17] The sub-district has 24 health clinics (two of which are mobile), which are served by one dietitian.[18]

The CHCs are managed by professional nurses. General physicians visit the CHCs three times per week to consult with referred cases. Health education at the CHCs (including nutrition) is mainly done by nursing professionals. At the time of the study (2009 to 2011), approximately 160 diabetic patients per CHC were attending on a regular basis as per diabetes registries at the CHCs.

The study population consisted of male and females, aged 40 to 70 years and with non-insulin dependent type 2 DM attending the two CHCs. Thirty one and 82 patients participated in phases 1 (see chapter 4, section 4.7) and 3 (see chapter 7, section 7.2) respectively.

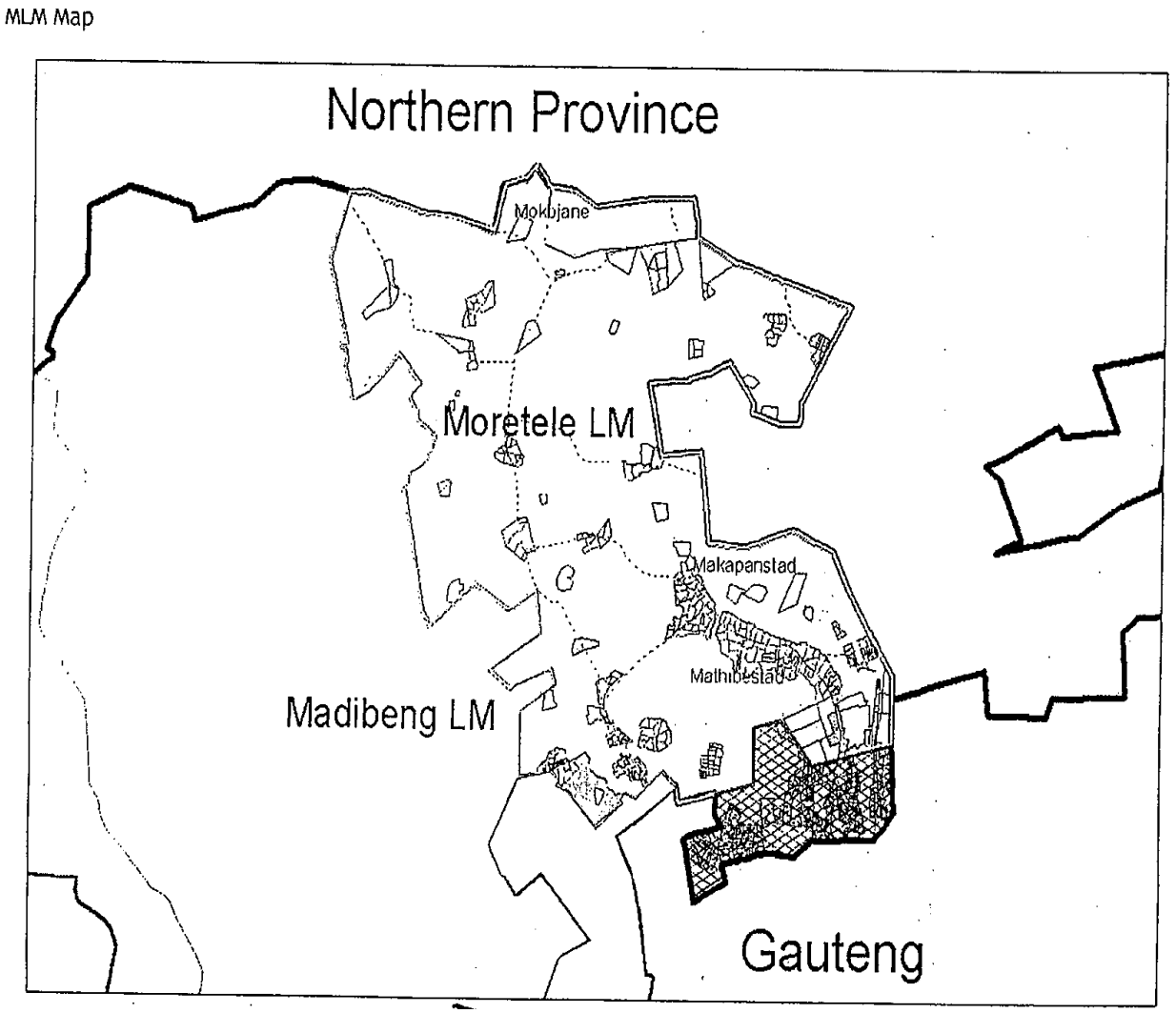

Figure 3.3: Moretele local municipality map showing the study setting[16]

3.4 ETHICAL APPROVAL AND CONSIDERATIONS

Ethical approval for the study was obtained from the Research Ethics Committee, Faculty of Health Sciences, University of Pretoria. Approval was obtained in two stages. Firstly, for the NE programme development (phases 1and 2) [number 164/2008 (Appendix 1)] and secondly for phase 3 (implementation and evaluation of the NE programme) [number 215/2009 (Appendix 2)]. The reason for obtaining ethical approval in stages was because the implementation and evaluation of the NE programme could not be described fully before the actual programme had been developed.

Permission to undertake the study in the study site was granted by the Department of Health, North West Province, South Africa.

Informed consent was obtained from all participants in all the phases. Participants were given information about the study in the preferred language. Those who were willing to participate were requested to give written informed consent or verbal consent in the presence of a witness if they were not able to read or write. Appendices 3 and 4 give the participant information and informed consent documents for phase 1 and 2. Appendix 5 gives the participant information and informed consent for phase 3.

Participants' anonymity was ensured through using a study number which had no relationship with the participant in all data collection documents. For example, in phase 3 the study number consisted of the age-gender strata (1 to 4), followed by initials for the surname and name, and a number indicating the order of recruitment (01 to 82).

Participants were reimbursed for transport costs and were offered healthy snacks after each of the NE sessions or outcome assessments at the CHCs. In phase 3, after all data collection had been completed, the control group participants were also offered a 3.5 hour education session covering key principles of the NE programme. All participants who completed the phase were issued with a participation certificate.

3.5 DELIMITATIONS OF THE STUDY

The study was undertaken in a community set-up and in a resource limited setting of the Moretele sub-district, North West Province, South Africa. The study had an African

ethnicity focus that was dictated by the study location. In addition, only adults aged 40 to 70 years with type 2 DM and on oral hypoglycaemics were involved.

3.6 ASSUMPTIONS

The assumptions for this study were as follows:

- the participants would be honest in providing the information solicited from them,
- the NE programme would be delivered uniformly and consistently across the sessions and the two CHCs,
- changes in seasons over the study period would not influence changes in dietary behaviours,
- there would be no contamination between the intervention and control groups.

3.7 DEFINITION OF KEY CONCEPTS

Definitions of terms in this chapter pertain to the general terms in the overall study and the main concepts in the conceptual framework. Additional operational definitions of the specific outcomes that were measured are presented in chapter 6 (Table 6.3).

Table 3.1: Definition of key concepts

Concept	Description and /or operational definition
Resource limited setting	A geographical or structural location with limited infrastructure (facilities and services) and highly skilled labour force such as health professional specialists. Majority of individuals from these settings have low income and material wealth. In the South African context, a resource limited setting hospital/clinic would mainly serve individuals or households who qualify for some subsidy for the service offered in a hospital, based on the level of their income and assets. This includes the following categories: H0 (social pensioners and the formally unemployed) who receive full subsidy, H1 (individuals or households with an income of less than R36 000 and R50 000 per annum respectively) who receive a partial subsidy.[19] Majority of patient participants in this study were in the H0 category.
Nutrition education programme	A planned and coordinated group of activities and procedures aimed at improving dietary and related health behaviours
Needs assessment	The process of determining the perceived or observed problems and issues of concern or interest related to diabetes and diet

Continued/…….

Table 3.1: Definition of key concepts continued

Concept	Description and /or operational definition
Tailored	Intervention based on specific characteristics of the participants and data obtained from them
Culturally appropriate	Based on formation obtained from the participants, use of the local language, use of familiar and acceptable foods and locally accessible intervention sites
Effectiveness	The extent to which the intervention does what it is intended to do 'in the field' or 'in the real world.'[20]
Diabetes self-management education (DSME)	Ongoing process of facilitating the knowledge, skill and ability necessary for diabetes self-care.[21]
Outcome	A measurable product and the changed state or condition as a consequence of health care over time.[15]
Evaluation	The measurable determination of the value or degree of success in achieving specific goals/objectives.[22] In this study it involved measuring outcomes pre and post-NE intervention to determine the effectiveness of the NE in improving health outcomes.
Process evaluation	Determination of how well a programme is being implemented relative to the plan.[11] It also includes the participants' judgement of the programme. In this study it involved collection of data on the number of NE sessions and activities implemented, duration of NE sessions, number of participants attending sessions etc. These were compared with what had been planned. Data on participants experience with the programme were also collected to determine participants' programme satisfaction.
DSME based outcomes Immediate outcomes	Learning (self-care knowledge and skills to achieve self care) is the immediate outcome. It can be assessed by testing or direct observation.[15] In this study diabetes knowledge and the attitudes towards diabetes and its treatment were the immediate outcomes.
Intermediate outcomes	Results over a period of time. Behaviour change such as change in eating behaviour is the intermediate outcome. It can be measured through self-report, such as using a 24 hour diet recall[15] as used in this study.
Post-intermediate outcomes	Results over time and are as a result of the interaction of DSME, participant self-management and clinical management. Clinical status (such as levels of HbA_{1c}, blood pressure, body mass index and lipids) is the post-intermediate outcome. Clinical status can be measured with laboratory and procedural testing.[15] These were evaluated in this study.
Professional nurse	A person who is qualified and competent to independently practise comprehensive nursing in the manner and the level prescribed, and who is capable of assuming responsibility and accountability for such practice.[23]
Auxiliary nurse	A person educated to provide elementary nursing care.[23]

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CHAPTER 4

PHASE 1: NUTRITION EDUCATION NEEDS ASSESSMENT

4.1 INTRODUCTION

As reported in the literature review (chapter 2, section 2.8.2) a comprehensive needs assessment is fundamental to the planning of education programmes that are tailored to the needs and abilities of the patient. In view of this, a needs assessment was undertaken with type 2 DM patients and the health professionals' serving them. This chapter discusses the NE needs assessment (i.e. the phase 1 of the study) by referring to:

- Aim and objectives
- methods
- results and discussion
- strengths and limitations of the phase
- conclusions for the phase
- recommendations for planning the NE programme.

4.2 AIM AND OBJECTIVES

The aim of phase 1 was to explore and describe the nutrition education needs and preferences of adults with type 2 DM in the Moretele Sub-District, North West Province (South Africa) to guide the development of a tailored NE programme.

The specific objectives were to:

i) establish the current understanding of diabetes and its management by the patients,
ii) examine the patients self-reported dietary practices and dietary adherence,
iii) explore the factors that could impact NE, i.e. the perceived barriers and facilitators to dietary compliance,
iv) elicit recommendations for content and preferred education approaches for a NE programme.

4.3 METHODS

4.3.1 Study design

An interpretive phenomenological approach in the qualitative domain was used. The goal of phenomenology is to understand the world as it is experienced by the individual.[1,2,3] The

philosophical underpinnings of interpretive phenomenology are as follows: firstly, the meanings embedded in common life practices are not always apparent to the participants, but can be obtained from the narratives produced by them. Secondly, expert knowledge on the part of the researcher is a valuable guide to the inquiry. Therefore, the meanings obtained from an inquiry are a blend of those articulated by the participants and the researcher.[2]

4.3.2 Setting

Makapanstad and Mathibestad Community Health Centres (CHCs) in the Moretele sub-district, North West Province (South Africa) as discussed in chapter 3 section 3.4.

4.3.3 Population and sampling

The participants were male and females adults with type 2 DM receiving health care at the two CHCs and the health professionals serving them at these CHCs.

4.3.3.1 Inclusion criteria

Diabetic patients

- Aged between 40 and 65 years
- Not on insulin therapy
- At least one year living with diabetes.

Health professionals

- Should have worked for at least six months with the diabetic patients at the mentioned CHCs.

4.3.3.2 Sampling

Convenience purposive sampling[4,5] was done for the diabetic patients. This involved selecting those patients who were available and willing to participate (convenience sample),[5] while purposively selecting those who were likely to be information rich[5] based on the duration of diabetes (at least one year). All patients attending the clinics during the study period and who met the inclusion criteria were included if they were able and willing to discuss about their diabetes in a group format. The participants were recruited during their monthly clinic attendance. They were approached individually by the researcher assisted by a field worker

and requested for permission to look at their files and to ask them a few questions. Eligible participants were invited to participate in the study and if they consented they were given an appointment date written on a card. Six to ten patients[6] were targeted to participate per focus group, therefore a total of 12 participants were recruited to allow for non-attendance. All health professionals who met the inclusion criteria were requested to participate in the study.

Ethical clearance was obtained from the Research Ethics Committee of the Faculty of Health Sciences, University of Pretoria (number 164/2008) as reported in chapter 3 section 3.4.

4.4 DATA COLLECTION

Data collection was done in February until May 2009. Focus group discussions (FGDs) were used for the diabetic population. Self-administered questionnaires were used with the health professionals.

4.4.1 Focus group discussions

A semi-structured interview guide (Appendix 6) with open ended questions was used to generate information in the FGDs. [7] A qualified dietitian, who was experienced in group facilitation, moderated the FGDs in the local dialect (isiTswana). A trained Tswana speaking field worker took detailed field notes and also audio-taped the sessions. The researcher was also present in all the focus group discussions.

Before commencing the FGDs, the moderator explained the purpose and the details of the study to the participants. The participants were given an opportunity to ask questions whereafter informed consent was obtained (written or verbal in the presence of a witness). A brief socio-demographic questionnaire (Appendix 7) was then administered to each participant by the moderator.

Four to ten diabetic patients participated in each FGD that was held at the CHCs. FGDs were conducted until no new information emerged from consequent groups,[6,8] totalling five groups. The FGDs took place in a quiet room in each of the CHCs. The environment was relaxed and non-threatening to allow maximum participation. The sitting arrangement allowed maximum opportunity for eye to eye contact between the moderator and participants.[8] The moderator explained the course of the discussions, the ground rules and the importance of each

participant's contribution. The role of the field worker and the researcher was explained. The use of the two audiotape recorders was also explained.[8]

During each FGD questioning progressed logically. Probes and cues were used to stimulate independent responses and expansion of ideas and comments.[8] The FGDs took one and half to two hours.[8,6] Debriefing between the research team (researcher, moderator, field worker and one study leader) was done after each FGD to discuss and clarify any arising issues.[7,9]

4.4.2 Questionnaires

A self-administered questionnaire, containing a total of 14 open ended questions, was used with the health professionals. Two of the questions in addition had a closed ended question (Appendix 8). The questions addressed four broad areas, namely adherence to dietary recommendations by patients, barriers and facilitators to dietary adherence of patients and recommendations for a NE programme.

The questionnaires were distributed to 14 health professionals who met the inclusion criteria and gave informed consent. The health professionals were given a time frame to fill out the questionnaires at their convenience. The researcher personally collected the questionnaires and checked them for completeness.

4.5 DATA PREPARATION AND ANALYSIS

Data from focus group interviews were transcribed verbatim in the isiTswana language by an experienced transcriptionist and then translated into English. The moderator independently transcribed some of the tapes and translated them into English to confirm the accuracy and completeness of the transcribed and translated text. The hand written field notes were also used to confirm data and complement the texts, allowing a fuller analysis of the data.[7,6]

Data were analysed using framework analysis according to Krueger's approach in combination with that of Ritchie and Spencer.[6] Framework analysis uses a thematic approach, in which the themes are allowed to develop both from the research questions and from the narratives of the participants.[6] The steps in the framework approach were applied in the data analysis process. These include i) familiarisation, ii) identifying a thematic framework, iii) indexing and charting, and iv) mapping and interpretation (Figure 4.1).

Familiarisation: The transcribed text and the text from the health professionals' responses were read through several times by the researcher to make sense of the whole data before breaking it into parts.[6] Key ideas and recurrent themes were listed during this process.[10]

Thematic framework identification: Key issues, concepts and themes through which data could be examined and referenced with were identified.[10] The framework was based on the research objectives and emergent issues from the participants' accounts.[10] Ideas and concepts related to the research objectives were identified in the text and were written on the text margins in form short phrases or concepts, and starting to develop categories.[6] A list of the index data (codes) was thereafter compiled.[10]

Indexing: All scripts were systematically coded based on the thematic framework. This involved making comparisons within and between cases and making judgement on their meaning. The codes were recorded on the margins of the transcript.[6,10]

Charting: Quotes from the coded data were lifted from their original context and placed in the appropriate thematic content, through cutting and pasting. Similar quotes were grouped together.[6] Charts were constructed per each theme and separately for the patients and health professionals.

Mapping and interpretation: The charts were reviewed to identify the dimensions of the issues under investigation.[10] The meaning of individual quotes, the relationship between them and the data as a whole was sought.[6] Key themes and categories were identified.[10] Frequency, extensiveness, specificity and intensity of participants' comments were used to isolate the major categories and to explain the data.[6] Citations from the participants were used to demonstrate the link between the data and the results.

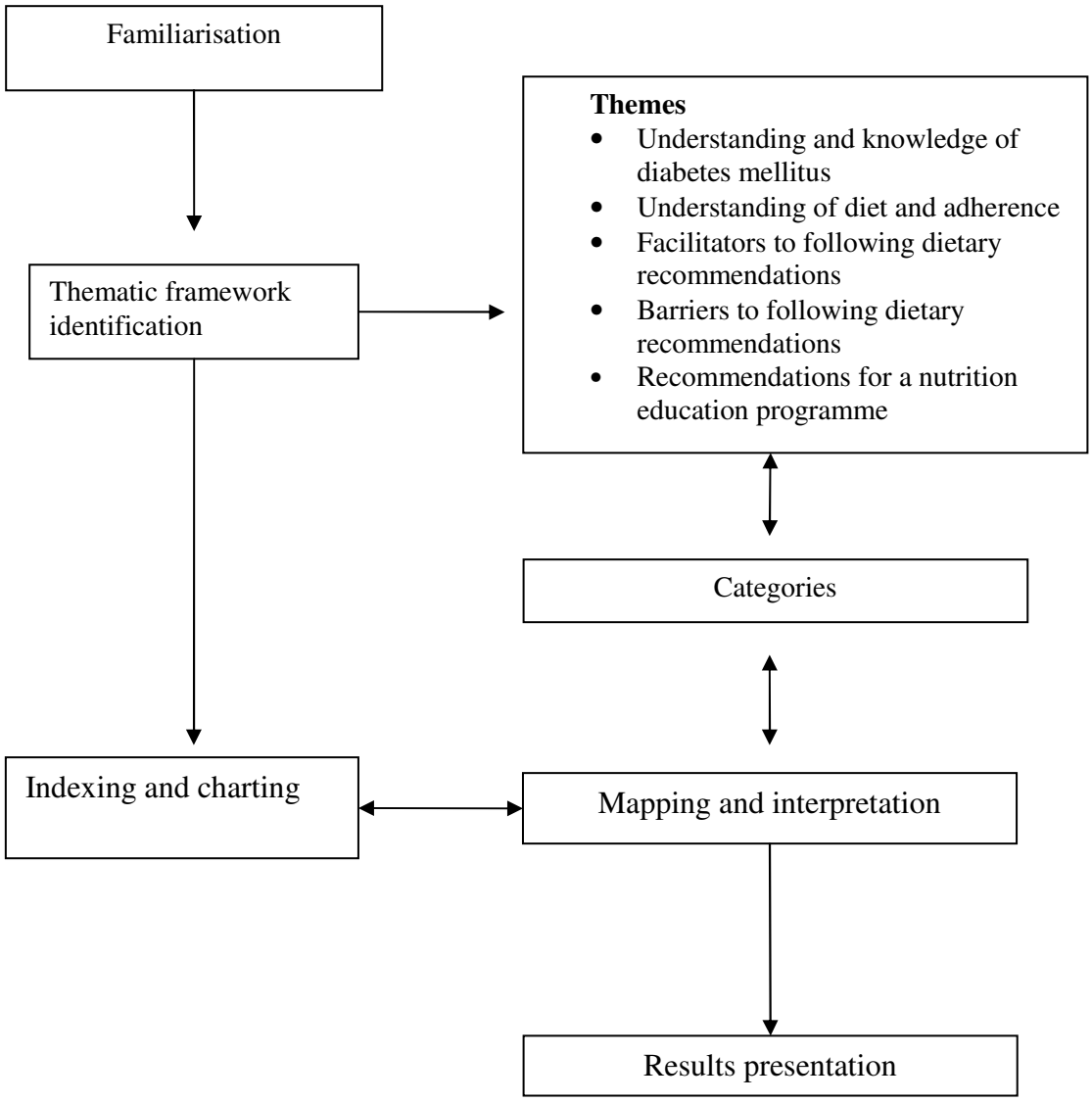

Figure 4.1: **Data analyses process (adapted from Krueger and Ritchie & Spencer[6])**

4.6 TRUSTWORTHINESS OF THE DATA

Polit and Beck have defined trustworthiness as "the degree of confidence qualitative researchers have in their data" as assessed using the criteria of credibility, transferability, dependability and confirmability.[11] Trustworthiness of the data was ensured through the following ways:

- Obtaining data until theoretical saturation occurred (no new information from consecutive focus groups)[6,9]
- Using two different sources of information: the patients and health professionals
- Referential adequacy:[11] audio tapes and field notes were used to document the

findings

- Using the moderator to confirm the transcribed and translated data.

4.7 SOCIO-DEMOGRAPHIC DESCRIPTION OF THE STUDY PARTICIPANTS

A total of 31 patients with type 2 DM and ten health professionals respectively participated in the study. Table 4.1 presents the socio-demographic characteristics of the patients. The majority of the patients were females (90.3%). The patients' mean age was 55.7 years (range 41 to 65 years). Their mean duration of disease was 7.6 years (range 1 to 20). The highest proportion of the participants (48%) had seven to nine years of schooling. About a third (35.5%) of the participants were pensioners. Of the non-pensioners, the majority (85%) were unemployed. Table 2 presents the demographic characteristics of the health professionals. All the health professionals were female nurse practitioners. The majority of these professionals (80%) had worked in the CHCs for more than two years.

Table 4.1: Socio-demographic characteristics of patients (N=31)

Socio-demographic characteristic	n	(%)
Age (years)		
40-49	8	25.8
50-59	10	32.3
60-65	13	41.9
Gender		
Female	28	90.3
Males	3	9.7
Education level		
None	3	9.7
Grade 1-6	8	25.8
Grade 7-9	15	48.3
Grade 10-12	3	9.7
Post grade 12	2	6.5
Employment status		
Full time	1	3.2
Part-time	2	6.5
Unemployed	17	54.8
Pensioner	11	35.5
Duration of disease since diagnosis (years)		
1-4	16	51.6
5-9	4	12.9
10-15	8	25.8
16-20	3	9.7
Management of diabetes		
Diet alone	0	-
Diet and oral hypoglycaemic agents	31	100%

Table 4.2: Demographic characteristics of health professionals (N=10)

Biographic characteristic	n	%
Profession		
Nursing	10	100
Professional	7	70
Auxiliary	3	30
Gender		
Female	10	100
Duration worked at clinic (years)		
0.6-1	2	20
2-5	4	40
6-10	0	0
11-20	3	30
21-25	1	10

4.8 RESULTS

The results of the needs assessment are organised as per the five broad themes that were generated from the study objectives and the participants' narratives. The results for patients participants are reported as per the focus groups (N=5). Selections of participants' citations are presented to support the results. The quotes from patients are presented as group (Gp), participant number and number of participants in the group. For example Gp 1, P1/4 indicates group 1, participant number 1 in a group of 4 participants. Citations from health professionals are presented as HP and the number allocated to the health professional (N=10), e.g. HP3 indicates health professional assigned number 3.

4.8.1 Understanding of diabetes mellitus and its treatment

Information on the understanding of diabetes and its treatment was obtained through asking patients' their views about diabetes in relation to risk factors/causes, complications, seriousness and its management. The results indicated that the patients were aware of some aspects of DM but some critical aspects were lacking. For example, in none of the focus groups was overweight/obesity mentioned as a risk factor for diabetes nor was heart diseases mentioned as a complication of the disease. Knowledge deficits were also observed in the form of inaccurate information (misinformation) and/or incomplete information. Misinformation on the causes/risk factors of the disease ranked the highest (four groups). Among the factors indicated as causes included diet (sugar, sweet foods) and stress. The following comments by the participants illustrate the confusion concerning the causes of diabetes:

> *"Diabetes is caused by the pancreas, when the pancreas is unable to break down the food"* [Gp 3, P6/8],
>
> "*I was confused because I grew up not eating sugar"* [Gp 2, P4/10],
>
> *"While the heart is pumping because of the problems you have diabetes easily gets you"* [Gp 3, P2/8],
>
> *"It is caused by family problems or your own problems that you do not share with others"* [Gp 4, P3/4].

The following participants' comments illustrate their awareness of the management strategies:

> "*It needs one to eat the proper foods*" [Gp 1, P1/5],
>
> "*You are not supposed to be seated all the time, you should walk some distance*"

[Gp 4, P2/4],

"You have to take your medication and not to be too much stressed" [Gp 3, P2/8].

In two focus groups the participants seemed to believe there could be a cure for their condition and that the current treatment is not effective as illustrated by the following comments:

"A *grant and medicine that can help treat this disease"* [Gp 3, P1/8],

"We would appreciate if they could make medicine that will make us better'' [Gp 2, P4/10],

"We wish they could add something to the treatment of this illness that could help us" [Gp 3, P2/8].

Three of the groups viewed diabetes a serious condition needing proper treatment:

"If a person has diabetes, he or she should consider the matter serious and seek treatment" [Gp 4, P2/4],

"Diabetes is very dangerous, it kills" [Gp 2, P2/10],

"Diabetes is a kind of disease that needs care" [Gp 3, P3/8].

However, some of the participants expressed the seriousness of disease in terms of the symptoms and metabolic consequences experienced:

"It is dangerous, it makes you feel hungry" [Gp 1, P2/5],

"It makes me have headache" [Gp 2, P4/10],

"Diabetes is dangerous, I used to have a big body, but due to diabetes I lost some of the weight" [Gp 3, P1/8].

4.8.2 Understanding of diet and adherence

Information on the understanding of diet and adherence was generated by asking patients what they had been taught or knew about diet and their current dietary practices. All the focus groups seemed to be aware of most dietary recommendations as per the South African national guidelines for diabetes[12] and the Food Based Dietary Guidelines[13] as indicated by the following comments by participants:

"We are not supposed to eat oily and fatty foods; we may eat fruits, beans and vegetables" [Gp 2, P2/10],

"If you use sugar it must be just little, even salt" [Gp 4, P4/4],

"You must eat smaller amount of food" [Gp 1, P3/5],

"You should eat a lot of vegetables" [Gp 5, P1/4].

The recommendations for limiting alcohol intake and intake of adequate water were not strongly emphasised as each was mentioned by one participant only.

Limiting sugar and fat intake was considered important as indicated by the reported foods choices and past dietary changes. All the groups mentioned having reduced fat in cooking and reducing sugar intake:

"*I used to use a lot of oil in cooking but now I boil all my vegetables and use a little oil in cooking other foods"* [Gp 5, 4/4],

"We no longer use oil, we cook with water" [Gp 4, P3/4],

*"I do not use sugar anymor*e" [Gp 2, P2/5].

Despite the reported reduction in fat intake, the use of saturated fats and high fat products was identified in two of the focus groups:

"I use full cream milk" [Gp 5, P3/4],

"I use a little holsum (palm oil) in cooking" [Gp 5, P2/4],

"I use some butter after boiling the vegetables" [Gp 4, P3/4].

Participants in three focus groups indicated that they had reduced food portion sizes. The reduction of the portion sizes was however associated with not feeling satisfied (hunger feelings). Participants in two groups indicated they had not changed food portion sizes.

"*I stopped eating a lot, at first I would feel hungry but now I am getting used"* [Gp 2, P6/10],

"I like brown pap (stiff sorghum porridge) but it does not make me full as I have to eat a small amount" [Gp 1, P4/5],

"Not much has changed, I eat amounts like other people" [Gp 5, P6/10],

"I eat the normal food portions" [Gp 4, P4/4].

There seemed to be a confusion concerning meal frequency and portion sizes as expressed by the following comments by some participants:

"We are supposed to eat very little at a time within a short period, sometimes when you are supposed to eat you are still full and that causes sugar to go high" [Gp 2, P3/10],

"I may eat now and within a short time I want to eat again so I can have energy to do chores" [Gp 4, P2/4],

"I used to eat in the mornings and the next time I will eat at one o'clock or evening, now I have to eat because you cannot stay with an empty stomach" [Gp 1, P3/5],

"We are not supposed to eat to our full stomach" [Gp 2, P2/10].

Eating balanced meals seemed not to be an important aspect as none of the groups mentioned consuming a combination of all foods groups. Starchy foods were the most commonly mentioned as consumed, followed by milk, fruits and meat. Vegetables seemed not to be consumed regularly. Legumes, apart from peanut butter spread were not mentioned in any of the groups.

"Most of the times I eat porridge" [Gp 4, P2/4],

"Supper I will eat pap (stiff maize meal porridge) or rice with meat or sometimes vegetables or milk " [Gp 3, P3/8],

"I eat mabela (sorghum) meal, at lunch I eat brown bread; I also sometimes eat apple for snacks" [Gp 1, P5/5],

"In the morning two slices of bread with some peanut butter and tea with low fat milk, around ten o'clock pap or bread, sometimes with fish, an apple around 2 0'clock, then supper brown or white pap" [Gp 5, P4/4].

Fruits especially apples were regarded as important snacks foods but many participants (four groups) expressed problems in having adequate fruits:

"W*e eat snacks like apples when they are available, when we have money"* [Gp 5, P4/4],

"*We are unable to buy enough foods like fruits"* [Gp1, P2/5],

"I eat apples (green) sometimes; I do not eat every day because I do not have money" [Gp2, P1/10].

Consumption of starchy foods higher in fibre appeared to be important in all the groups. However, it was noted that the higher fibre options were interchangeably used with the lower fibre options by some participants:

"*I normally use brown bread"* [Gp 3, P3/8],

"I now eat mabele (sorghum) porridge" [Gp 4, P2/4],

"*I eat jungle oats in the morning*" [Gp 1, P3/5],

"*I eat brown or white pap (stiff maize meal porridge), sometimes brown rice"* [Gp 5, P3/5].

Misconceptions about the role of food were identified in three focus groups as indicated by the following patients' statements:

"You must give yourself less food hence a lot of people die and become blind due to diabetes" [Gp 1, P1/5],

'Its is dangerous (disease) because it needs you to eat" [Gp 3, P4/8],

"Hence we loose weight because we cannot just eat anything" [Gp 4, P2/4].

The health professionals were asked their views of their patients' adherence to dietary recommendations with regard to the proportion following or not following recommendations (closed ended question), and areas they found easy or difficult to adhere to (open ended questions). Table 4.3 gives a summary of the health professionals' views about the patients' adherence to dietary recommendations. Five indicated that half of the patients did not adhere to dietary recommendations while three indicated the majority did not adhere to the recommendations per se.

Health professionals reported that patients found it easy to use less sugar but found food portion control as the most difficult aspect of dietary adherence. Other areas indicated as patients' having difficulties included consuming adequate fruits and vegetables and balanced meals. This is in agreement with what was found among the patient group.

Table 4.3: Health professionals' perspective on patients' adherence to dietary recommendations (N=10)

Adherence aspect	Sub-category	n
Proportion of patients not adhering to dietary recommendations	Half	5
	Majority	3
	Quarter	2
Dietary recommendations that patients find easy to follow	Eating three meals per day	1
	Not using a lot of sugar in tea	4
	Using less sugar rather than no sugar	4
	Using correct cooking methods	1
Dietary recommendations that patients find difficult to follow	Eating smaller portions	5
	Using whole meal products	2
	Using low fat products	4
	Including snacks	3
	Consuming balanced diet	5
	Consuming adequate fruits and vegetables	4

4.8.3 Barriers to adhering to dietary recommendations

Information on barriers to dietary adherence was generated through asking patients questions regarding the problems they experienced while making dietary changes and what hindered them from making other changes they deemed desirable. Health professionals were asked questions on the factors they thought interfered and/or discouraged dietary adherence by patients. Eight barriers to following dietary recommendations were identified as is shown in Table 4.4. Some of the barriers were similar among the patients and health professionals while others differed. Financial constraints including food insecurity was the major barrier identified by the two groups. All the patient groups (n=5) and all health professionals cited it as a barrier.

The social context was another barrier cited by the two groups of participants. Family meal arrangement was seen as a barrier either due to the fact that some patients were not the ones in charge of food purchasing or preparation or their condition was viewed as needing different foods. Health professionals viewed social functions (ceremonies) and cultural beliefs as precipitators or underlying forces to inappropriate dietary practices. This was not cited in the patient group.

Barriers related to self-care were cited by both the patients and health professionals with some aspects being similar while others differed. Denial of disease and use of other remedies was common in both groups. Self-care barriers cited by patients only included helplessness from lack of control despite perceived adherence, forgetting to eat and the belief that dietary change is difficult. Cravings and temptations as a barrier was mentioned by health professionals only.

Barriers related to perceived effects of the required dietary changes emerged from the patient group. Two of the focus groups indicated that special foods were needed and three groups indicated that the foods were tasteless and the diet restrictive. Hunger was cited to be related to the disease as well as to the requirement to eat small food portions and therefore seen as a barrier.

Access to appropriate foods and cost of appropriate foods were barriers identified by both groups and were associated with the physical environment. Participants cited high cost of foods and the unavailability of healthy foods in the local markets as impediments to dietary compliance. In addition, health professionals cited inconsistent availability of water as a barrier to home gardening and hence vegetable access.

Some patients (n=4) indicated that the education they were offered at the clinic was not comprehensive and it was too generalised as it was offered together with patients with other conditions. Health professionals cited poor understanding of the disease and diet due to low literacy levels as a barrier to adherence to dietary recommendations

Table 4.4: Summary of barriers to following dietary recommendations

Barrier category	Sub-category	Ethnographic descriptions
Financial constraints and food insecurity	Lack of money and food/poverty/unemployment	*"We do not have money to buy the right foods for our illness"* [Gp 3, P2/8] *"Sometimes it is not a question of tablets but a lack of food"* [Gp 4, P2/4] "*Because of unemployment and poverty the people are unable to buy the food they are taught to eat"* [HP 5] *"Not all patients afford to buy the food they are supposed to eat"* [HP 3]
	Need for grants and food parcels	*"Grants so we can buy foods specific for diabetes"* [Gp2, P1/8] *"We would like help with social grants and food parcels such as maize meal, beans and milk"* [Gp 5, P1/4] *"The government should provide food parcels, so that people do not loose courage"* [HP 3]
Social context	Conflict between family meal arrangements	*"Our children cook for us, they like oily food"* [Gp 2, P1/10] *"I am the only one with diabetes, they do not eat what I eat"* [Gp 1, P3/5] *"They eat whatever the family members are eating because some of them are not the ones who cook"* [HP 3]
	Ceremonies	"D*uring ceremonies they are tempted to eat a lot of sweets and large quantities, they always indulge"* [HP 7] *"Majority state they crave for sweet foods especially during wedding ceremonies"* [HP 4]
	Cultural beliefs	*"Believe they are bewitched"* [HP 2]
Self care and adherence	Helplessness and frustration due to lack of control despite adherence	*"I try to be on diet, but my weight remains the same"* [Gp 1, P2/5] *"Some people are loyal to the treatment only to find there is no change"* [Gp 3, P1/8]
	Forgetting to eat	*"We work in such a way that we forget to eat"* [Gp 1, P3/5]
	Use of other remedies	*"I also used herbal medicine but it did not work"* [Gp 2, P6/10] *"Beliefs as most of them tend to use home remedies forgetting taking medicine and correct diet"* [HP 10]
	Denial of disease	*"It's been long with this illness, I did not want to accept the situation"* [Gp2, P4/10] *"Denial makes them not disclose the condition, thus eat whatever is offered"* [Gp2, P4/10]

Continued/……

Table 4.4: Summary of barriers to following dietary recommendations continued

Barrier category	Sub-category	Ethnographic descriptions
Dietary changes and implications	Special foods	*"If it is possible one should have foods different from other family members, this will help you follow the rules"* [Gp 5, P4/4,]
	Tasteless foods & drinks	*"We are not used to these tasteless foods"* [Gp 3, P1/8] "*I felt the change because we no longer enjoy nice food"* [Gp 4, P2/4] *"I stopped taking tea as it is tasteless without sugar"* [Gp 5, P1/4].
	Restrictive diet	"*Only that I cannot have cold drinks"* [Gp 5, P3/4] *"We have cut out a lot of things"* [Gp 3, P2/8]
Physiological	Hunger	*"Food is important in this illness because we feel hungry more often"* [Gp 3, P1/8] *"I eat more food than expected because I feel hungry all the time"* [Gp 1, P5/5] *"I have to eat small amount, thus I do not feel full"* [Gp1, 1/5]
Structural/ environmental	Expensive foods/ access to appropriate foods	*"The foods that are good for us are expensive and sometimes we do not get them in the shops"* [Gp 4, P1/4] "*They do not have enough money to buy low fat food, because they are expensive"* [HP 8]
	Access to appropriate foods	*"I have to get the right cheese and it is difficult because it is far where I can get it"* [Gp 3, P2/8] *"They are unable to do self gardening because of lack of water"* [HP 5] *"Environmental issues, for example low fat products are not always available"* [HP 2]
Incomprehensive and generalised education	Education not specific for diabetics	*"On the other hand things are being generalised as we are taught with other conditions"* [Gp 1, P1/5]
	Not offered full information	*"When we are with patients with other diseases we are not given full information"* [Gp 3, P3/48] "*We usually do get full explanations*" [Gp 5, P/5]
Poor understanding of disease	Low education level	*"Low level of education, thus they cannot understand fully'*[HP 2] *"Educational background, many are not educated*" [HP 6]

4.8.4 Facilitators to following dietary recommendations

Information on facilitators to dietary adherence was generated through asking patients questions on what helped them or would help them follow dietary advice. Health professionals were asked to explain the factors that contributed or could contribute to patients' adherence to dietary recommendations.

Table 4.5 summarises the facilitators to following dietary recommendations as expressed by the patients and health professionals.

Table 4.5: Summary of facilitators to following dietary recommendations

Facilitator category	Sub-category	Ethnographic descriptions
Education	Knowledge of suitable and unsuitable foods	*"We were advised on what to eat and not eat"* (Gp 4, P1/4)
	Guidelines with meal plan	*"I changed the way I used to eat and followed how it was organised in the certificate from hospital, my sugar went down"* [Gp 2, P6/10]
	Knowledge about disease	*"We are given good advice at the clinic"* [Gp 1, P3/5] *"Knowledge about diabetes and the right foods"* [HP 8]
Social support	Support by family	*"We are being supported by our children"* [Gp 3, P1/8] *"Family support, the family eats the same food, thus no feeling of isolation"* [HP 1]
	Support by health professionals	*"If you come across a question bring it to the clinic for the sister's explanation"* [Gp 3, P2/8] *"Encouragement by health professionals during individual consultations"* [HP 7]
	Peer support group	*"Having support groups where they can share experiences"* [HP 3]

Social support from family and health professionals and the knowledge acquired through education were identified as major facilitators to following dietary recommendations by both the patients and health professionals. Knowledge of the appropriate and inappropriate foods was considered an important aspect in the dietary self-care. In one of the groups a participant stated that a written meal plan assisted in following the recommendations.

Health professionals recommended formation of support groups (peer groups) as they felt this would facilitate appropriate self-care through sharing experiences.

4.8.5 Recommendations for a nutrition education programme

Patients were asked about the kind of information they had received in the past and the extra information they would need; how they would like the information to be given and by whom; when, how often and where they would like to receive the information and other suggestions for a NE programme. Health professionals were asked to give their suggestion for content, delivery format, facilitator, teaching materials, venue and frequency of meetings and additional suggestions.

Table 4.6 presents the recommendations for the NE programme as suggested by the patients and health professionals. Both groups recommended topics related to the disease and diet. The patient group was not explicit with respect to nutrition topics. The health professionals gave a wide range of nutrition topics, including balanced diet, portion size control, meal distribution, starches and the role of food in the management of disease.

Table 4.6: Summary of recommendations for a nutrition education programme

Category	Sub-category	Ethnographic descriptions
Content	**Disease related**	
	Causes of diabetes and symptoms of hyper/hypoglycaemia	*"The real cause of the disease should be explained"* [Gp 4, P3/4] *"Know more about the causes of the disease and what symptoms to look for, some people have different symptoms"* [Gp 3, P2/8] *"We would like to know why we have symptoms different from other people with diabetes"* [Gp 2, P7/10]
	Complications of diabetes	*"It would be good to be reminded of the problems that are caused by diabetes"* [Gp 4, P1/4] "*Education about their condition and the complications"* [HP 7]
	Diet related	
	Appropriate and inappropriate foods	*"Know more about food as we have problem getting the right kind of food"* [Gp 2, P1/10] "*More about food and what not to eat"* [Gp 5, P1/4]
	Balanced diet	*"Eating healthy, well balanced diet"* [HP 5] *"Advice to eat fruits especially those suitable for their condition"* [HP 9]
	Portion size control	"*Emphasise on reducing the amount of food they are eating*" [HP 3]

Continued……./

Table 4.6: Summary of recommendations for a nutrition education programme continued

Category	Sub-category	Ethnographic descriptions
Delivery format	Group	*"I would like to be taught together with others"* [Gp 1, P3/5] "*When we are together we give each other advice*" [Gp 4, P1/4] *"Clients understand better if given information in a group, individual can threaten them*" [HP 5]
	Both group and individual	"*Group helps to teach many of them, individual helps to open up issues they will not in a group*" [HP 6]
Teaching method	Participatory methods	"*Discussion is better if used together with demonstrations, discussions help in dealing with common problems*" [HP 10] "*Demonstrations for them to see examples of foods and amounts to serve"* [HP 7] *"They should be given tasks to do concerning their condition"* [HP 5]
Teaching material	Written materials (posters & pamphlets)	"*Some give us information but we forget, when I have a pamphlet, my children can help me"* [Gp 3, P1/8] *"It is good to be given pamphlets because we have children at home"* [Gp 4, P1/4] *"Pamphlets they can see pictures or information and share with family"* [HP 7]
Educator	Health professional	*"Anyone like a doctor or nurse"* [Gp 5, P2/4]*"*
	Health professional/community health worker and peers	*"They do not participate well if someone from higher levels is not involved"* [HP 10] *"Peers will be useful as they have a lot of influence"* [HP 4]
Venue	Community accessible sites	"*We prefer the clinic, if you call people to another place, they might not come"* [Gp 1, P1/5 *"Education at the clinic or school"* [HP 2]
Day of the week	Week days	"*Any day except Saturday and Sunday*" [Gp 3, P1/8]
Special issues	Involve family members	*"Our children should be involved in the lessons because they cook for us"* [Gp 2, P2/10] *"Educate family members about the disease and its treatment*" [HP 1]
	Diabetes specific and comprehensive education	*"When we are with other diseases we are not given full information"*[Gp5, P4/4] *"We prefer a person who can tell us about diabetes only"* [Gp 4, P2/4]
	Educator knowledgeable about the disease	"*Someone who knows about the disease, like a doctor or nurse*" [Gp 4, P3/4] "*The information can be given by experts*" [HP 7]
	Appropriate language	*"Use their local language as most do not understand English or use an interpreter"* [HP 8]

The majority of the patient groups (n=4) preferred delivery of education through group format, while one group indicated either group or individual format. The majority of the health professionals (n=7) recommended a combination of both group and individual formats. The patients' preference on group format seemed to be based on the practice at the clinics: *"we are usually taught in a group"*. The patients viewed the group setting as a place to learn from one another: *"when we are together we give each other advice"*. The health professionals viewed the group format as less threatening to the patients, hence encouraging better participation while the individual format would help them disclose issues they would not share in a group.

The patients perceived the health professional as the best person suited to deliver the education. The majority (n=6) of the health professionals indicated that the health professional or community worker in conjunction with a peer would be best suited to offer the education. They felt a health professional or community worker would be viewed by patients as a person with authority and this would encourage participation in the NE while a peer would influence learning through sharing experiences.

The patients viewed the clinic as the best venue for receiving the education and week days as the suitable time to receive the education. However, they were vague concerning the frequency of meetings. The health professionals gave a wide range of suggestions for the frequency of meetings with half of them (n=5) indicating once per week. However, only one gave the reason for the suggestion: "*they do not like coming often due to finances*".

Posters and pamphlets were mentioned by the patients and health professionals as materials suitable for use in the education. Pamphlets were seen as materials useful even for those without diabetes and for use at home with the help of family members. Health professionals viewed participatory methods such as discussions and demonstrations as the best teaching methods.

The patients and health professionals made other recommendations, e.g. inclusion of family members in the education, and punctuality of the educators. The patients also recommended education specific to diabetes and a competent educator. The health professionals recommended use of the local language or an interpreter, and the inclusion of motivational activities such as competitions.

Table 4.7 presents a summary of the findings on the five themes (paragraphs 4.8.1-4.8.5).

Table 4.7: Summary of the findings on all the themes

Theme	Findings
Understanding of diabetes and its treatment	• Awareness of most aspects related to management strategies • Disease knowledge deficits and misconceptions related to causes/risks factors, complications and nature of the disease
Understanding of diet and adherence	• General awareness of most dietary recommendations • Reported dietary changes and intake indicated some appropriate dietary changes and some extent of adherence **Reported/observed problems** • Unbalanced diets • Food portion control and confusion on meal frequency • Unsatisfactory intake of vegetables and fruits • Lack of consumption of legumes • Intake of saturated fats • Misconceptions on the role of food in diabetes • Inappropriate management of hypoglycaemia

Barriers to dietary adherence	• Financial constraints and food insecurity
	• Social environment
	  ◦ Family meal arrangements
	  ◦ Ceremonies
	• Perceived impact of dietary changes
	  ◦ Tasteless foods and restrictive diet
	  ◦ Special foods needed
	• Self-care and adherence challenges
	  ◦ Frustrations related to perceived negative results even with dietary adherence
	  ◦ Use of non-conventional treatments
	• Physiological: hunger associated with the recommendation to eat smaller food portions and the disease
	• Access to appropriate foods related to the physical environment and cost of food
	• Generalised and incomprehensive education
	• Poor understanding of disease

Facilitators to dietary adherence	• Support from family and health professionals • Empowerment through education
Recommendations for a NE programme	• Content on disease and diet • Group delivery format • Diabetes specific and comprehensive education • Participatory methods • Competent educator • Health professional or health professional in conjunction with a peer • Written materials such as pamphlets and posters • Venue: clinic or school • Involvement of family members • Local language or English with local language interpretation

4.9 DISCUSSION

This qualitative phase of the study aimed at establishing the nutrition education needs of type 2 diabetic patients as perceived by patients and their health care providers. The study phase highlights the problems and issues of concern related to diabetes and diet, and the preferences for NE from the view point of the participants. The results obtained provided insight for planning a NE programme that would be tailored to the needs and abilities of the patients. The results are discussed as per the study objectives, namely the current understanding of diabetes and its management, the self-reported current dietary practices and perceived dietary adherence, the factors that could impact the NE (barriers and facilitators to dietary compliance), and recommendations for content and preferred education approaches for the NE programme.

4.9.1 Understanding of diabetes mellitus and its treatment

Patients in this study demonstrated some knowledge about the disease and its treatment but not in totality. Knowledge deficits and misconceptions about the causes, metabolic consequences, complications and the relationship between diet and disease were common. This finding confirms previous reports regarding patient knowledge of disease and its treatment.[14,15,16,17,18,19] The inaccuracy and deficiency in knowledge may be due to lack of specific and comprehensive education as indicated by the patients and poor understanding related to low literacy levels. Though knowledge by itself does not necessarily lead to improved self-care behaviours or outcomes,[20] an understanding of the disease, its course and treatment and how all these interact are pre-requisites for effective self-care.[21,22] Some studies have also demonstrated a positive relationship between disease knowledge and self-care behaviours.[22,23] This clearly demonstrates a need for improving the basic knowledge about the disease and its treatment. The fact that patients' recommended topics about the disease (causes, metabolic consequences, the differences in symptoms and problems associated with the disease) to be included in the NE further confirms a perception of inadequate knowledge about the disease. In addition, the health professionals also recommended content on the disease for the NE programme, and also indicated poor knowledge of the disease as a factor contributing to poor dietary adherence.

4.9.2 Diet knowledge, dietary practices and adherence

An interesting finding from the assessment is that the majority of the patients seemed aware of the dietary recommendations and also indicated they had made dietary changes in line with the recommendations.[12,13] Despite these results, the majority (80%) of the health professionals indicated that half or more of their patients did not adhere to the dietary recommendations all the time. In addition, self-reported dietary practices also revealed the following problems: insufficient intake of fruits and vegetables, food portion size control, consumption of unbalanced meals and a lack of consumption of legumes. Other problems included irregularity of meals, the use of saturated fats and misconceptions about snacks. The problem of food portion control was cited in a study with a similar context.[17] Notable also is that most of these problems observed in the patients' reported dietary practices are similar to those reported by health professionals. Health professionals particularly emphasised the problem of food portion control. This result was observed in the study by Shultz et al involving diabetes educators and type 2 diabetic patients. [24] The findings thus indicated a gap between dietary recommendations awareness and practice which could be attributed to the barriers identified in this population.

Inadequate intake of fruits and vegetables in this study population confirmed a problem identified by other studies in developed countries[25] as well as in developing countries.[18]

4.9.3 Barriers and facilitators to adhering to dietary recommendations

The results on barriers to following dietary recommendations revealed personal and environmental factors that made it difficult for patients to make dietary changes or to adhere to dietary recommendations. Financial problems, food insecurity as well as the cost of appropriate foods were strongly emphasised by the patients and the health professionals. This is an expected result as the majority of the patients were unemployed. The findings on financial constraints and the cost of foods were in line with other previous studies.[17,26,27,28]

Absence of support in the social environment can cause difficulties for the diabetic patients when coping with illness in everyday life.[29] Family dietary behaviour was seen as a challenge due to family food preferences, food selection and preparation. Patients expressed reluctance by family members to make dietary changes since they were considered to be only for the diabetic person. This result was similar to other studies with different cultures.[24,26,27,30,31,32]

Notably, social functions such as ceremonies, were a barrier cited only by the health professionals. Though this might not be seen as an issue by the patients, this information forms a platform for exploring the barrier with the patients. Some studies have indicated that patients find it difficult to adhere to diet during special occasions.[31]

The physical environment was seen as a barrier to accessibility and availability of healthful foods. This related to the distant location of supermarkets/grocery stores with variety and appropriate products, and high cost of healthy foods in the local shops[28,30] and inconsistent availability of water that discourages gardening. This was an important finding since geographical areas such as neighbourhoods could influence the ability of the target audience to implement received nutrition messages.[33]

Barriers that have also been identified in other studies included generalised and incomprehensive education,[30,34,35] feeling hungry, small food portion sizes,[24,31] taste of food, restrictive diet,[36] forgetting to eat[34] and inadequate knowledge of the disease and diet.[17,34]

Two key facilitators to following dietary recommendations emerged from the two groups of participants: social support (family and health professionals) and knowledge obtained through education. These findings have been reported in other studies[37] with diabetic patients and they indicated that patients in this study valued education. Carbone et al in a study of perspectives of Latino patients and their health care providers about diabetes self-management, found similar results about support by family and health professionals.[26] A review by Gallant reported a modest positive relationship between social support and chronic disease self-management especially in diabetes. Dietary behaviours were indicated particularly to be susceptible to social influences. [38] Other studies have also shown a positive relationship between social support and self-care behaviours.[29,32] This finding has important implications in planning care for this study population.

Overall, the family was seen both as a barrier and facilitator to dietary self-management by the two groups of participants, a result also reported by Carbone et al.[26]

4.9.4 Recommendations for a nutrition education programme

Patients and health professionals demonstrated an interest in having a NE programme and gave several suggestions on the kind of programme they preferred. Patients had clear recommendations concerning certain aspects of the programme while they had difficulty articulating others.

A surprising finding concerning the topics for the NE was that the majority of the patients' strongly emphasised topics related to the disease, while they were not explicit with topics on diet as indicated by such statements "any information that can help us feel better", "more about food". This finding could be attributed to the fact that the patients perceived themselves more deficient in knowledge about the disease than diet. In addition, the fact that many suggested provision of grants or food parcels for helping them follow dietary recommendations might be an indication that food insecurity was seen as the major issue that needed to be addressed. The patients also found it difficult to recommend preferred teaching methods. Other studies using focus groups have also found an inability of patients to articulate the content of an education programme.[39,40] The study by Benavides-Vaello et al found that patients who had not been exposed to diabetes education found it difficult to define what they needed to know and how best they could learn.[39] This could be true for this study population who indicated they were not offered diabetes specific education since they were taught with patients with other chronic diseases.

The health professionals suggested a range of topics both related to the disease and diet, most of which reflected the problems identified in the dietary practices and knowledge of the patients.

Patients envisioned a programme at the clinic as this was seen as a familiar and accessible site. They also preferred group education as they could learn from each other. This finding has been reported in other studies.[36,41] The health professionals concurred with the group education format; though the majority suggested a combination of both the individual and group delivery format as each has its unique potential in enhancing learning. A combination of the two approaches is supported in interventions to promote diabetes self-management.[42] Knowledgeable educators such as a health professional and specific but comprehensive education were indicated as desirable characteristics of the programme by the patients. This

finding has been cited in other studies.[35,41,43,] The health professionals also indicated that inclusion of a peer educator would further enhance learning, a finding that has been reported by other studies.[35]

Written material, especially pamphlets, were seen as useful reinforcements of knowledge at home with the help of family. This finding has been observed in other studies.[35,41] A notable finding was the recommendation for including family members in the education; a suggestion that was also articulated by the health professionals. This finding is consistent with other studies with type 2 diabetic patients.[35,41]

4.10 STRENGTHS AND LIMITATIONS OF PHASE 1

The use of patients as well as their healthcare providers is an important strength of this study. Similar views added weight to the issue at hand while divergent views complemented those of the patients. The divergent information also created a platform for further exploration of the issues with the patients. The health professionals also provided insight on some issues that patients had difficulty articulating.

The sample that was used had few male participants compared to females and hence may not be a representation of the population. This may limit the generalisability of the results.

The use of interviews with the health professionals, as planned initially, would probably have given deeper insight to the issues at hand than the open ended questionnaires. This is because with interviews one is able to probe and clarify issues.[44,45] However, work schedules and limited staff at the clinics made it difficult to arrange for interviews. Open ended questionnaires thus provided an alternative method where the health professionals could give their views at their convenience.

In the exploration of dietary practices, the reported dietary changes were not quantitatively verified. The report on dietary intake was mainly on the type of foods and frequency of consumption and not the exact amounts of foods or drinks consumed. Thus the reported reduction of intake of sugar, fats, salt and portion sizes could be subjective. However, since the objective of the study was to have an insight of the nutritional issues that warrant intervention, the qualitative analysis of dietary practices was deemed sufficient.

An evaluation of the patients' weight status based on the body mass index would have given an indication of the participants energy balance. The information could guide on specific goals with regard to energy intake and weight status for the NE. It could also act as a proxy for gauging the reported dietary changes and/or dietary adherence.

A validation of the results with the participants would further have contributed to the trustworthiness of the data[46] as well as serve the purpose of clarifying issues that could be unclear such as on the reasons for the lack of consumption of legumes.

4.11 CONCLUSION ON PHASE 1

The aim of phase 1 was to assess the needs and preferences for nutrition education, as well as the factors that could impact on NE in adults with type 2 DM in a resource poor setting as were perceived by the patients and the health professionals serving them.

The findings from this study phase revealed knowledge deficits and misconceptions about diabetes and its treatment by the patients. They also reported unsatisfactory dietary practices including inappropriate consumption of fruits and vegetables, unbalanced diets and problems with food portion control despite the general awareness of the dietary recommendations.

The numerous barriers identified in this study were likely to be the major factors contributing to the gap between awareness and practice. These barriers were mainly in the personal, socio-economic and physical environment domains. The major barrier to dietary adherence was financial constraints and the associated food insecurity. Social support was the major facilitator to following dietary recommendations, with family support being seen as both a barrier and a facilitator.

Participants in this study showed interest in a NE programme, and gave specific recommendations, including content related to the disease and diet, the clinic as the preferred site, group education, a competent educator, diabetes specific and comprehensive education, provision of pamphlets and inclusion of family members. The health professionals' input complemented the recommendations of patients.

4.12 RECOMMENDATIONS FOR PLANNING THE NUTRITION EDUCATION PROGRAMME

In the planning of the NE programme the knowledge gaps and dietary practise problems should be addressed. The NE programme should also include strategies to address the barriers as well as the facilitators to dietary adherence and incorporate the suggestions for an NE programme. The implementation of this recommendation is discussed in chapter 5.

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CHAPTER 5

PHASE 2: PLANNING THE NUTRITION EDUCATION PROGRAMME

5.1 INTRODUCTION

Structured and comprehensive education is recommended in order to equip diabetic individuals with the necessary knowledge, skills, attitudes and motivation to perform required self-care behaviours effectively.[1,2]

This phase describes the process that was used to develop a NE programme for adults with type 2 DM and also presents the programme that was designed. The phase followed on phase 1, reported in chapter 4. In phase 1, the nutrition education needs of the patients were identified. The data from phase 1 were used in this phase (2) to plan the NE programme.

5.2 AIM

The aim of this phase was to plan a NE programme that would be culturally relevant and tailored to the needs of adults with type 2 DM in the Moretele sub-district, North West Province (South Africa).

5.3 METHOD

The results from the NE needs assessment (phase 1, chapter 4) and evidence from literature were used in designing the NE programme. The process was guided mainly by the steps for designing theory based nutrition education by Contento.[3] The steps that were used include:

- analysis of the needs and identification of behaviour(s) of focus
- statement of programme goal and objectives[4]
- identifying the relevant potential mediating factors for the behaviour (s)
- selection of theory
- selection of programme components and statement of educational goals and objectives
- selection of strategies/activities for addressing potential mediators of behaviour
- designing evaluation
- preparation for NE implementation.

Each of these steps is discussed as part of the process of the NE programme planning.

5.4 PROCESS

5.4.1 Analysis of the needs and identification of behaviour(s) of focus

5.4.1.1 Analysis of needs

The analysis of the NE needs in phase 1 of the study (chapter 4, Table 4.7*)* revealed the following:

- inadequate knowledge and misconceptions about diabetes and its treatment
- consumption of unbalanced diets
- insufficient vegetable and fruit intake
- problems with food portion control (consumption of large amounts) especially starchy foods
- lack of consumption of legumes
- confusion about meal frequency and meal irregularities
- intake of saturated fats
- a number of barriers to dietary modification and adherence (financial constraints, food insecurity, cost of appropriate foods, small food portion sizes, generalised and incomprehensive education, unavailability of appropriate foods, conflicts in family meal arrangements)
- some facilitators to following dietary recommendations (support from family and health professionals and knowledge obtained through education)
- several suggestions for a NE programme on content, mode of delivery, type of educator, venue and other recommendations.

5.4.1.2 Identification of behaviours of focus of the nutrition education programme

As stated earlier in the literature review (section 2.8.1), behaviour change is the unique outcome measurement for DSME[5], and appropriate dietary behaviour change being the primary goal of nutrition education.[3] The reason for focusing on behaviour is based on the evidence that behaviour is one of the major determinants of health[6,7] and that changes in behaviour do influence health status.[6] In addition, research evidence suggests that knowledge though necessary, by itself is not sufficient in improving health outcomes.[8,9]

The major dietary behaviours selected that the NE programme would address were:

- intake of vegetables and fruit

- starchy foods portion control
- intake of balanced meals, including legumes.

These dietary behaviours were selected as they were the major problems observed from the patients' self-reported dietary intake and also reported by the health professionals in the needs assessment (chapter 4, section 4.8.2). They were also deemed likely to have the greatest impact on the primary outcome (HbA_{1c}).

5.4.2 Statement of the goal and objectives of the NE programme

Based on the overall outcomes expected and the major behaviours to be targeted, the goal and objectives of the NE programme were formulated as discussed below.

5.4.2.1 Goal

The goal of the NE programme was to improve glycaemic control and other clinical outcomes (BMI, lipid profile, blood pressure) through improved dietary behaviours and behaviour mediating factors.

5.4.2.2 Objectives

The specific objectives were to:

(i) increase vegetable and fruit intake
(ii) decrease starchy food intake (servings per day)
(iii) enhance balance in meals including the use of legumes
(iv) improve knowledge and attitudes related to diabetes and its management aimed at improving dietary behaviours.

5.4.3 Potential mediators of behaviour change

The factors likely to mediate (facilitate or impede) the behaviours of focus, i.e. potential mediators, were identified from the needs assessment, the theoretical framework selected and evidence from the literature. Potential mediators of behaviour are classified into two major categories: person-related psychosocial mediators (beliefs, attitudes, behaviour capabilities) and environmental-related factors (physical/structural and social). These are the primary targets of NE.[1] Table 5.1 shows the identified potential person-related and environmental-related mediators of behaviour in this study. Motivational factors include beliefs and attitudes

that enhance readiness to change. Action mediators include knowledge, cognitive and behavioural skills which can lead to self-efficacy, thereby enhancing behaviour change initiation and maintenance.[3]

Table 5.1: Potential person-related and environmental mediators of behaviour in the target group

Person-related factors	
Motivational factors	**Action mediators**
• Belief: for example that diet is important in the management of diabetes • Perceived benefits/outcome expectations: for example eating the right foods makes participants feel better or have blood glucose under control • Reduction of the perceived barriers (such as food costs, tasteless meals, unavailability of appropriate foods, small food portion sizes etc. as identified in the needs assessment) • Attitude: for example perceived seriousness of diabetes and that it is a disease that needs proper care to prevent complications	• Knowledge about disease, relationship between diet and disease and the dietary recommendations. This includes knowledge about food groups, healthful foods, meal balance, cooking methods and recommended servings of various food groups and portion sizes • Food and nutrition skills. Skills in selecting and preparing appropriate meals that have variety, are balanced and tasty. Skills in food portion estimation and skills to decreasing the cost of meals • Self-regulation skills Skills in dealing with barriers or difficult situations. Goal setting and self monitoring skills
Environmental-related factors	
Motivational factors	**Action mediators**
• Support from family, educators and health professionals	• Availability and accessibility of appropriate foods • Support from family, educators and health professionals

5.4.4 Theory selection

The NE was planned to incorporate both motivational (pre-action phase) and action phase activities. The aim of the motivation phase is to facilitate the intention to act (behavioural intention), therefore the NE strategies focused on 'why take action'. The action phase aims at facilitating initiation of action and its maintenance. Therefore, the NE strategies would focus on 'how to take action.' Behaviour capabilities (knowledge and skills) and self-regulatory skills are important in this phase.[3]

Concepts from a combination of theories[10] were utilised to create an eclectic theoretical framework for the NE programme. The theories included the Social Cognitive theory (SCT)[11] as the major theoretical framework, the Knowledge Attitude Behaviour (KAB) model[12,13] and the Health Belief Model (HBM).[14]

The SCT proposes that behaviour, personal factors and the environment interact to explain and predict behaviour. This theory was selected for the following reasons: (i) both person-related factors and environmental factors were found to influence dietary behaviours of the target audience, (ii) it is useful both in the motivational and action phases,[3] and (iii) other studies in people with type 2 diabetes have used the theory successfully.[15,16,17] The constructs in the SCT selected for utilisation were outcome expectations, behaviour capabilities, self-regulation, self-efficacy, observational learning/modelling and social support. The SCT, however, does not adequately address attitudes and beliefs, therefore principles from the KAB and some constructs from HBM were incorporated.

The KAB model proposes that as people acquire and accumulate knowledge their attitudes change. A change in attitude then leads to a change in behaviour.[12,13] In providing information about diabetes and its treatment, misconceptions and knowledge deficits would be addressed. In addition, information on food intake, the benefits of following a healthy eating pattern and how to reduce barriers to healthy eating were expected to improve knowledge. Overall, accumulation of knowledge was expected to lead to more positive attitudes towards diabetes and diet, and consequently act as a motivator to making positive dietary changes and other diabetes self-care activities.

The HBM constructs incorporated in the theoretical model of this study were perceived severity of disease and consequent perceived threat and cues to action as motivating forces to initiating positive dietary and related behaviour changes.

Table 5.2 shows the theories, constructs used, their definition and how they were to be applied in the NE programme. Figure 5.1 shows the conceptual framework for the integrated theoretical constructs.

Table 5.2: Theories, constructs and their application in the nutrition education programme

Theory/Model	Construct	Definition	Application
Social Cognitive Theory	Outcome expectations	Beliefs about the likely outcomes of certain behaviours[18]	Activities and messages to enhance positive outcomes or benefits and to reduce the perceived barriers. This would include: • discussing the benefits of healthy eating to overall health and for diabetes control • discussing the importance of controlling portion sizes for diabetes control • discussing the relationship between nutrients and metabolic outcomes, e.g. carbohydrate and blood glucose • discuss how to reduce the perceived barriers such as cost or availability of healthful foods
Social Cognitive Theory	Behavioural capability	Knowledge and skills needed to perform behaviour[3,11,18] such as diabetes dietary-self care	Provide information, for example on: • what constitutes a healthy diet • recommended servings for food groups such as fruit and vegetables, etc. Provide opportunity to observe task being performed through demonstrations Provide opportunity for skill mastery such as: • practise portioning different food groups • vegetable gardening
Social Cognitive Theory	Self-efficacy	A person's perceived confidence to perform a particular behaviour[3]	• Demonstrations to observe educator and others doing a task such as portioning foods • Provide opportunity for problem solving to deal with barriers (in group) • Educator encouragement to the participants (social persuasion) • Provide opportunity for skill mastery such as practise portioning different foods, preparing a healthy dish and label reading

Continued/…….

Table 5.2: Theories, constructs and their application in the nutrition education programme continued

Theory/Model	Construct	Definition	Application
Social Cognitive Theory	Self-regulation	Gaining control over own behaviour through monitoring and adjusting it[18]	Provide instructions and opportunities to develop skills in self-control: • participants to evaluate their current dietary practices and monthly blood glucose against recommendations or goals • setting goals for intended behaviour • discussions on how to deal with challenging situations/barriers
Social Cognitive Theory	Social support	Guidance and encouragement from peers, family and programme facilitators[3]	• Small group education • Involvement of family members (some sessions) • Verbal encouragement and support by facilitators
Social Cognitive Theory	Observational learning/modelling	Behavioural acquisition that occurs by watching the actions and outcomes of others[11]	Demonstration by educator followed by some participants doing the action
Social Cognitive Theory	Reinforcement	Responses to behaviour that encourage or discourage recurrence[11] Strengthening through multiple exposure[3]	• Educators compliment positive behaviour • Review learnt content • Provide handouts
Health Belief Model	Cues to action	Internal or external events that are reminders for taking action[18]	• Provide reminders about the behaviour using written education material (fridge/wall flyer) • Use active voice in the flyer
Health Belief Model	Perceived severity	Belief that one is susceptible to the sequelae of an illness/condition[18]	State diabetes is a serious disease that has no cure. If not properly controlled it can lead to other complications
Knowledge Attitude Model	Knowledge and attitude	Knowledge: • understanding of basic facts or procedures that enhance ability to act (instrumental or how-to knowledge) • An understanding of the reason(s) for making change in behaviour (why-to knowledge)[3] Attitude: Positive and negative beliefs about certain behaviours or condition[3]	Provide comprehensive information that will: • correct misinformation and address knowledge deficits • enhance dealing with barriers

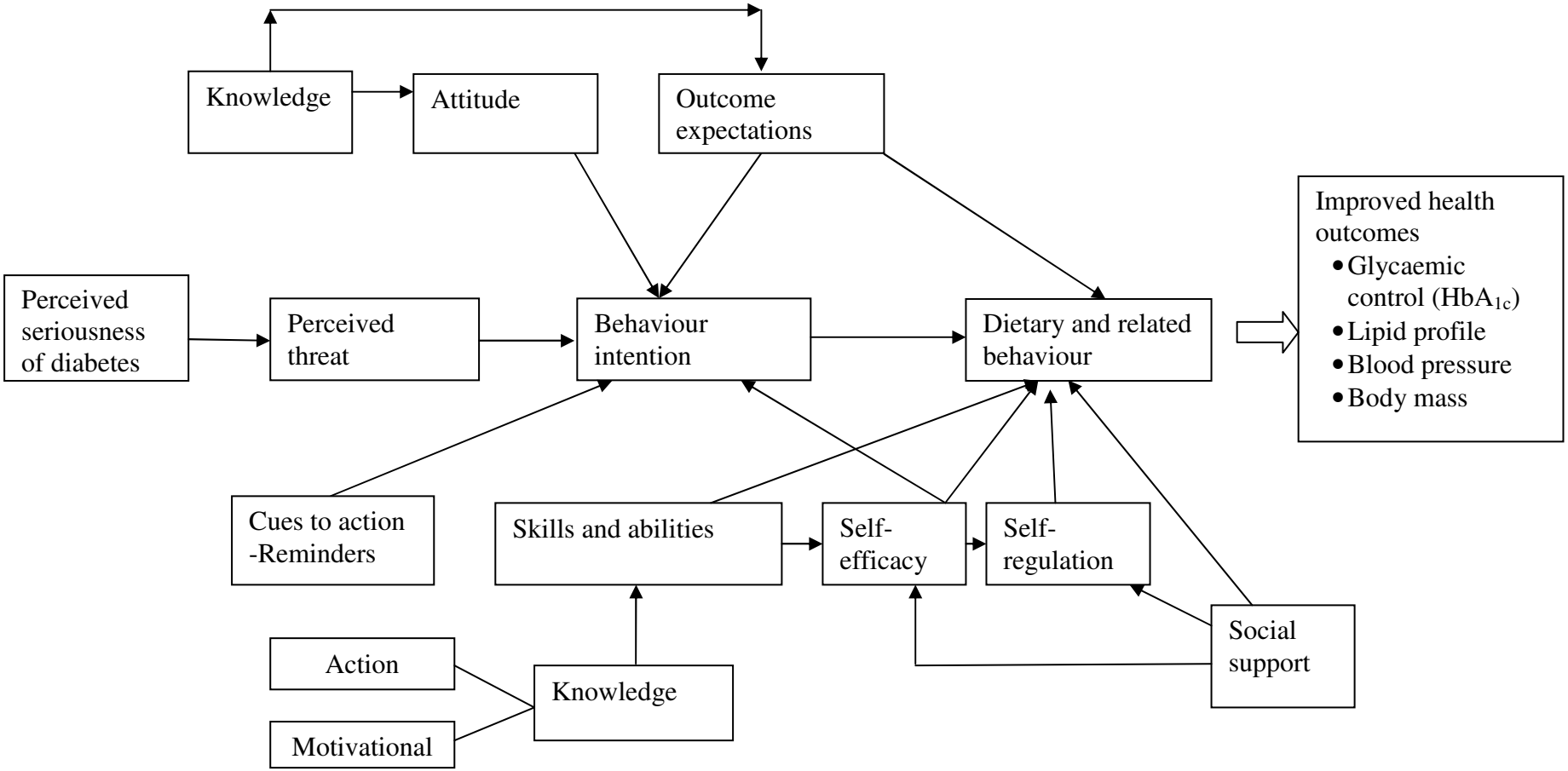

Figure 5.1: Eclectic conceptual framework of the integrated theoretical constructs of the Social Cognitive Theory, Knowledge Attitude Behaviour and Health Belief Models for the nutrition education programme

5.4.5 Selection of programme components and statement of educational goals and objectives

5.4.5.1 Programme components

The programme was planned to have four (4) components/deliverables (Table 5.3):

- Curriculum component: group education sessions to cover the curriculum content on a bi-weekly basis for eight weeks
- Group follow-up intervention sessions that would follow after the curriculum had been taught, initially on a monthly basis, then on a bi-monthly base up until one year. The follow-up sessions were aimed at reinforcing the self-management information learnt during the curriculum, providing social support and minimising the loss to follow-up[19]
- Vegetable gardening demonstration incorporated in the group sessions (weekly and monthly)
- Printed education materials in form of handouts (pamphlet and fridge/wall flyer).

Table 5.3: **Nutrition education programme components**

Component	Period	Duration	Activity
Curriculum/group education	1st four months	Bi-weekly meetings: 2-2.5 hours each Total 8 weeks (16-20 hours)	Curriculum content coverage
Group follow-up intervention sessions	5-8 month 9-12 months	Monthly meetings: 1.5 hours each Total 4 months (6 hours) Alternate month meetings: 1-1.5. hours each (10th & 12th month) Total 2 months (3 hours)	• Facilitated review of learned content • Problem solving • Social support (unstructured)
Vegetable gardening	One session each during the curriculum, monthly and bi-monthly meetings	-	Demonstration on sowing/transplanting and maintaining selected vegetables (a collaboration with the Department of Agriculture)
Printed education material handouts	To be provided as handouts at the end of the curriculum	-	Use at home together with family

Table 5.4 shows the features (content and related activities) of the NE curriculum. The content of the curriculum was based on what both groups of participants expressed as the areas of need and/or suggestions as well as gaps and problems identified by the researcher. The major sources of information used for planning the content included the International Diabetes Federation,[20] the American Diabetes Association (ADA) nutrition recommendations,[21] medical nutrition therapy for diabetes by Franz,[22] the guidelines for type 2 DM management by the Society for Endocrinology and Diabetes for South Africa,[23] and the South African Food Based Dietary guidelines.[24]

The education materials (handouts) are discussed together with other education materials (see section 5.3.7).

Table 5.4: **Nutrition education programme curriculum**

Session	Topic	Content and activities
1	What is diabetes mellitus?	Nature of disease[20,22] Causes/risk factors, types Symptoms and metabolic consequences Complications Address misconceptions
2	Treatment of diabetes	Diet, exercise medication and their roles in treatment[22] Aim for treatment and targets for good control[21,22,23] Causes, symptoms and management of hypoglycaemia & hyperglycaemia[22] **Activity**: Reflection[a] on current practices, baseline laboratory results and monthly glucose results, goal setting and group discussion
3	Dietary guidelines*	Healthy eating based on South African Dietary guidelines Focus on variety and balance[24] Specific guidelines for starch, vegetables, fruits and meats and alternatives (additional information with respect to diabetes) **Activity**: Reflection on current dietary practices plus goal setting and group discussion
4	Improving vegetable supply through gardening**	Vegetable gardening demonstration (sowing and transplanting vegetables) **Activity**: Discussions on barriers to vegetable intake and gardening, goal setting
5	Dietary guidelines continued: fats, salt, sugar and water*	Specific guidelines for each food group[24] **Activity** Label reading of products on display Reflection on current practices related to dietary guidelines and label reading , goal setting and group discussion
6	Meal planning: portions and meal frequency	Discussion on importance of portion control[21,22] Guidelines for meal pattern and portion sizes **Demonstration**: portion sizes (household measures, plate model,[25] Zimbabwe hand jive[26]) **Activity** • Practise portioning various commonly used foods • Discussion about portion sizes and associated issues such as hunger • Reflection on food portioning , goal setting and group discussion
7	Meal planning: principles	Planning meals on a limited budget, emphasise variety and balance within available resources[24] **Activity**: • Group identify strategies that could be used to plan healthy meals within their resources • Do costing for sample meals of commonly consumed foods • Plan a day's menu based on available resources and calculate the cost • Reflection and group discussion
8	Meal preparation: healthy cooking with diabetes* Integration of sessions and evaluation	Cooking demonstration **Activity:** group cooking, meal tasting and group discussion

* Attendance of family member ** To continue during monthly/bi-monthly meetings

[a] Active self-exploration and appraisal. For example of current dietary and related practices in the light of information provided such as dietary guidelines/recommendation.

5.4.5.2 Statement of the educational goals and objectives

The major education goals for the NE programme were:

- To increase the awareness on the importance of keeping diabetes under control and the important role of dietary and related behaviours in its management through the curriculum, follow-up meetings and education materials
- To increase the motivation to keep diabetes under control through dietary and related behaviours via the curriculum, follow-up meetings and education materials
- To increase the awareness on the importance of vegetable and fruits, balanced meals and food portion control in the control of diabetes and overall health through the curriculum, follow-up meetings and education materials
- To increase the motivation to: increase the consumption of vegetables and fruits, consume balanced meals, control food portion sizes through the curriculum, follow-up meetings and education materials
- To facilitate the ability to act (consume more vegetables and fruits, control food portions and consume balanced diets) by providing opportunity to: gain knowledge related to diabetes and diet, practise food related skills and gain skills in problem solving through the curriculum, follow-up meetings and vegetable gardening demonstration.

The learning objectives for the curriculum (the major NE component) are presented in the training manual (Appendix 12).

5.4.6 Theory-based strategies and activities for addressing potential mediators of behaviour

A strategy is an approach for achieving a specific target such as a programme's goal and objectives.[4] Theory-based strategies are the ways used to address the potential mediators of behaviour change, while educational activities are the ways in which the strategies are carried out in practice.[3] Table 5.5 presents a summary of the strategies and activities planned to address the various potential mediators of behaviour change.

Table 5.5: Summary of strategies for addressing the potential mediators of behaviour change

Strategies	Potential behaviour mediator/theory construct addressed	Application (activities/messages/learning experiences)
Goal setting	Self-regulation/self-control	• Participants to reflect on current practises in the light of information/guidelines provided; set goals related to a specific dietary behaviour such as vegetable and fruit intake based on their current intake and the recommendations
Provide information about outcome expectations ("why-to" information) and persuasive communication about positive outcomes	• Knowledge, attitudes and beliefs • Outcome expectations/perceived benefits	• Discuss the benefits of healthy eating /balanced meals to overall health and for diabetes control • Discuss the benefits of food portion control in the control of diabetes and other benefits
• Provide "how-to" information • Action oriented sessions and skills building • Facilitated discussions • Guided practise	Behaviour capability: skills in food and nutrition	Provide information for example on: • what constitutes a healthy and balanced diet • recommended servings for food groups such as fruit and vegetables, etc. Group discussions and activities
Guided practice to encourage mastery of skills	Self-efficacy	Demonstration of desired behaviour such as portioning foods followed by participants practising food portioning
Decrease perception of barriers or negative outcomes	• Perceived barriers to dietary self-care • Self-efficacy • Outcome expectations	• Group discussions on barriers and strategies that could be used • Tips on healthy eating on a limited budget • Activities such as meal planning on a limited budget and vegetable gardening demonstration to encourage growing of own vegetables
Provide reinforcements	Reinforcement	Verbal praise for accomplishments
Provision of social support	Social support	Group activities and creating supportive group environment Involving family members in some sessions
Provision of cues to appropriate dietary and related behaviours	Cues to action	Messages on the fridge/wall flyer on the desirable behaviour
Opportunity for learning through observation	Observational learning/modelling	Demonstrations by facilitator and observing other participants doing the task
Consciousness raising on the seriousness of diabetes	Perceived severity	Messages such as diabetes is a serious disease with no cure, if not kept under control can lead to serious complications
Problem solving opportunities	• Skills in dietary behaviour and self-regulation • Perceived barriers to dietary self-care	• Group discussions of on-going barriers and ways of dealing/coping with the barriers

5.4.7 Selection and designing of education materials and tools

To cater for the low literacy levels of the target group (84 % below grade 9 level of education, chapter 4, Table 4.1), visual tools and materials such as real foods, empty food containers and coloured flip charts were chosen as teaching aids.

The South African Food Based Dietary Guidelines flip chart[24] was selected for teaching the dietary principles. The tool was selected for the following reasons: firstly, the guidelines have been tested and used in different South African populations even in rural areas.[27] Secondly, the dietary principles are in line with those for the management of diabetes. Lastly, as a strategy to show and convince the participants and their families that people with diabetes do not have to eat differently from what the general population is encouraged to eat. However, additional information specific to diabetes was prepared in guidelines where it was felt necessary. This included the guidelines on starchy foods and vegetables and fruits. In conjunction with the dietary guidelines the plate model,[25] Zimbabwe hand jive[26] and common household measures were chosen for teaching food portion sizes. The Zakhe education flip chart[28] was adapted with some modification for teaching the basics of diabetes and its treatment. The tool has previously been used in a rural area in Kwazulu-Natal (South Africa).[28,29] 'Zakhe' in Zulu means 'rebuild yourself.'

Printed education materials to be issued as handouts for use at home were designed. They were intended to reinforce the information received during the group education sessions and to act as constant reminders of the desired behaviours.[30] They would cater for the need expressed by the target audience for written materials to use at home with the help of family members. The materials included a pamphlet (Appendix 9) and a fridge/wall flyer (Appendix 10). The pamphlet was designed to mainly address the observed knowledge gaps related to diabetes and its treatment. The flyer was designed to mainly address dietary and related behaviours.

The principles on design and content of print material[31] were utilised in the development of the handouts. These included using short, simple words and sentences and legible print and headings. Colour and pictures to augment text,[30,31,32] questions to help recall key points as well as the use of an active voice to enhance action taking[32] were also applied. Messages to enhance motivation to take action ("why-to" information), those that showed the desired

behaviour ("how-to" information) and those that addressed some of the identified barriers were included.[3]

The modified education tool and the handouts were reviewed by dietitians working in the field of diabetes or who had previously worked in the field, those who had previously worked in a site similar to the study site and one of the study leaders. This was an aspect of formative evaluation that was done to ensure that the content of the education materials and its presentation was appropriate for the intended audience. Some of the feedback obtained from the review included the following: (i) information was accurate and relevant, (ii) the materials were simple and easy to use, (iii) the colour and pictures were deemed sufficient to create interest in participants or readers, and (iv) the use of "you can do this" on the pamphlet and poster would encourage readers to take action towards the desired dietary behaviours. Additional suggestions on practical information, for example on encouraging consumption of adequate water through carrying water when travelling, were incorporated.

5.4.8 Designing of process and outcome evaluation

Process and outcome (a form of summative evaluation) evaluations were planned for evaluating the NE programme. The process evaluation aimed at establishing whether the NE was implemented as planned and the participants experience with the programme.[1,33,34] Table 5.6 presents the indicators and measures identified for the process evaluation.

Table 5.6: Indicators and measures for the process evaluation

Indicator	Tool
NE participation rates	Attendance register
Number of sessions held	Observation form
NE session length	Observation form
NE session deliverer	Observation form
Participants' experience with the curriculum component	Open ended questionnaire with one closed ended question (see chapter 6, section 6.5)
Participants' experience with the overall NE programme (activities, content, duration, education materials, overall delivery and perceived benefits) at the of the study (12 months)	Semi-structured focus group discussions (see chapter 6, section 6.5)

The outcome evaluation aimed at establishing the effects of the NE[3] based on the goal and objectives. The outcomes would be assessed at three levels, namely (i) short-term/immediate outcomes or the mediators of behaviour change[3,5] which included knowledge and attitudes, (ii) intermediate/medium term outcomes[3,5] which included dietary behaviours, and (iii) post-intermediate outcomes[5] which in this study were the clinical outcomes (Haemoglobin A_{1c}, BMI, lipid profile and blood pressure). Appropriate tools for assessing various outcomes were selected or designed. The features of the tools and the outcome measures are given in chapter 6 section 6.4

5.4.9 Preparation for the implementation of the nutrition education programme

This step entailed identification of appropriate session facilitators and their training, consulting with collaborators and stake holders and pilot testing of the outcome measuring tools and education materials. In this study, collaborators were the organisations serving the target population and therefore viewed as partners, while stakeholders were the individuals or group of individuals who would be affected or could affect the NE programme (i.e. the target group).

5.4.9.1 Identification of nutrition education sessions' facilitator

The target group expressed the preference for a competent health professional to educate them. Therefore a dietitian was seen as the most suitable person to deliver the NE and the one typically recommended to provide NE for individuals with diabetes.[1,35] The language barrier and the need for the NE to be cultural appropriate limited the researcher from being the primary facilitator of the NE programme. Therefore the sub-district dietitian, who served the community health centres (CHCs) and spoke the local language, was identified as the most suitable person to facilitate the NE sessions. For the vegetable gardening sessions, the horticulture officer from the sub-district was identified as the person suitable to deliver the sessions due to expertise in the subject matter and familiarity with the environmental conditions, as well as the challenges with vegetable growing in the setting. In addition, a community health worker was deemed necessary for providing support during the NE group activities.

5.4.9.2 Consultations with stake holders and collaborators

Prior to finalising the components of the NE programme and consultations with identified facilitators, consultations with the target group/stakeholders were done to confirm whether a vegetable gardening component would be acceptable. This was done with eleven type 2 diabetic patients from the two CHCs who had participated in the needs assessment (phase 1). Data were collected through individual interviews that were done in the local language by a qualified dietitian. A semi-structured interview guide was used (Appendix 11). All participants who were interviewed indicated they had no formal training on vegetable gardening and they would be interested in receiving that kind of training. Other information deemed useful for the vegetable gardening component was also gathered. This included information on the problems experienced with obtaining or growing vegetables among others. Table 5.7 gives the summary of the information obtained from the interviews.

Table 5.7: Summary of the information obtained from the interviews on vegetable gardening

Item	Item responses (N=11)
Vegetables commonly consumed in the area	• Cabbage, spinach, beetroot, carrots, potatoes, onions • Local vegetables during summer
Source of vegetables: interviewees and community	• Own garden and purchase (n=6) • Purchase (n=5) • Most people in the area do not grow own vegetables they purchase
Place of vegetable purchase	• Mostly from neighbours and local shops • Occasionally supermarkets (2-3 times per month) due to distance
Problems with obtaining vegetables	• Vegetables from own gardens not available through the year • Vegetables for purchase not always available in local shops or neighbours • Few local shops sell vegetables • Supermarkets are the only places with most types but distance limits shopping trips • Cost (expensive)

Vegetables commonly grown in the area	• Spinach, cabbage
	• Other vegetables like beetroot, onion, carrots, and green peppers are grown by few people. Reasons given:
	  •some vegetables like carrots do not perform well
	  •lack of information on how to grow the vegetables

Problems experienced in growing own vegetables by interviewees and the community	• Availability of seed/seedlings • Finances to buy seed and fertiliser • Pest especially in cabbages • Water not always available • Destruction of vegetables by livestock (chicken and goats) in case of no fence
Previous training on vegetable gardening	• No formal training (n=11) • Learnt from other people (neighbours/parents) and school

Interest in receiving training on vegetable gardening	• All interested and indicated that other people with diabetes would be interested. Reasons given:
	  • had not received such training before
	  • learn how to grow other vegetables not grown
	  • learn how to start growing own vegetables
	  • to improve on current practices
	  • to be able to teach others

Additional training/information needed	• How to recycle water to use in vegetable gardens • Fertilisers • Making own manure/compost • Managing of pest

Consultations with the management of the Moretele sub-district Departments of Health and Agriculture (collaborators) respectively were done in regard to the participation of identified personnel in the facilitation of the NE sessions. Consequent to support by management, several consultations with the relevant persons were done. In addition, a visit to the sites (CHCs gardens) where the vegetable gardening demonstrations would take place, was done by the sub-district horticultural officer, accompanied by the researcher to confirm the feasibility and logistics of delivery of the component.

Consultations were also done with the CHCs managers for identifying a suitable community health worker to assist the dietitian with the NE sessions. No suitable person could be identified. Therefore, a final year nutrition and food science university student, who lived in the study area, was identified as a suitable option (appointed as a field worker).

5.4.9.3 Translation of the outcome measurement tools

The tools selected for assessing diabetes knowledge questionnaire (DKNB)[36] and the attitudes towards diabetes and its treatment (DAS III)[37] (see chapter 6, sections 6.4.4 and 6.4.5) which had been designed in English, were translated into the local language (isiTswana). Before translation, and in consultation with dietitians in the field of diabetes and those who had worked in an area similar to the study setting, terms not normally used in the South African context or those that would be difficult to get appropriate local idioms for, were simplified to familiar terms. For example “tight control” in the diabetes attitudes scale was changed to “good control”. The recommended procedure of translation was followed.[38] A professional bi-lingual translator translated the questionnaires to the isiTswana idiom. The questionnaires were then back translated by the final year university student (appointed field worker) from the study site and confirmed by a Tswana speaking qualified dietitian. The differences between the English version and the isiTswana version were verified and resolved before the version for field testing was finalised.

5.4.9.4 Pilot testing of the education tools and outcome measures

Formative evaluation was done as part of piloting that aimed at testing the appropriateness of outcome measures and one education tool before their use in the study. Ten type 2 diabetic patients from the Rekopanswe clinic in the Moretele sub-district participated in the pilot study. These patients had similar inclusion criteria as those to be used in the main

study. The pilot study tested the translated DKNB and the DAS III questionnaires (see section 5.4.9.3) and the modified diabetes basics flip chart (see section 5.4.7) for their understandability. The questionnaires which were originally developed for self-administration were also tested for the most appropriate administration method. A registered dietitian, assisted by the appointed field worker, did the pilot testing in the local language. The researcher was present during the pilot testing.

No problems were indicated with the education tool in regard to the understanding of the content. However, for one page a suggestion to use bolder colour to improve on visibility was made. For the questionnaires, few questions had to be rephrased to enhance their understanding. Some terms which patients were not familiar with, had to be replaced or a suitable description had to be used. For example, for the term “type 1 diabetes” in the DAS III questionnaire, “type of diabetes that needs insulin” was used.

Interviewer administration of the questionnaires was found to be the most appropriate method of administering the questionnaires as it could cater for all levels of literacy.

5.4.9.5 Development of a training manual

A training manual with detailed explanations for each session was developed by the researcher to assist in the facilitation of the NE sessions. The manual included information on the outcomes expected for each session (learning objectives), the outline and content for each session, the activities for the facilitator and participants, as well as the materials needed (Appendix 12). The aim of the manual was to ensure the intended information and activities were delivered correctly, consistently and in a structured manner.

5.4.9.6 Training the facilitators

The sub-district dietitian and the appointed field worker participated in a one half day workshop with the researcher where discussions on the NE session’s expectations, the use of the training manual and education tools were done. In addition, demonstrations on some parts of some sessions were done and questions related to facilitation were discussed at length. During the workshop a copy of the training manual was provided plus an A4 size copy of the flip chart on the basics of diabetes.

5.5 SUMMARY

This phase aimed at planning a tailored NE programme for adults with type 2 DM in a resource limited setting. Data from the needs assessment done in phase 1, as well as evidence from the literature, were used as the base for planning the NE programme. The NE programme goal and objectives, the target behaviours and the potential mediators of the behaviours as well as the theoretical framework for the NE were identified. In the programme design, the components of the NE as well as the strategies and activities to address behaviour mediators for each component were selected. The manner for evaluating the NE programme, including the measures to use, was determined. Finally, preparations for the implementation of the NE were done, which included consultations with relevant stakeholders, training of the facilitators and pilot testing of the education tools and the relevant outcome measures.

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PHASE 3: IMPLEMENTATION AND EVALUATION OF THE NUTRITION EDUCATION PROGRAMME

CHAPTER 6: AIMS, OBJECTIVES AND METHODS OF PHASE 3

6.1 INTRODUCTION

Phase 3 was the last phase of this study. Phases 1 and phase 2 were prerequisites for this phase. In phase 1 (qualitative) the NE needs of adults with type 2 DM in the study setting were identified. In phase 2 the needs assessment results were used to plan a tailored NE programme.

Phase 3 entailed the implementation and evaluation of the NE programme. The phase was a quantitative study, with a qualitative part embedded for the NE programme process evaluation. The phase is presented in three chapters, namely chapter 6 (aim, objectives and method), chapter 7 (results) and chapter 8 (discussion, conclusions and recommendations). The references for this phase (chapters 6 to 8) appear at the end of chapter 8.

This chapter (6) discusses the following:

- aim, objectives and hypotheses
- methods: study setting, study design, sample and participants flow through the study, measurements (outcomes and other variables), data management and analyses
- validity and reliability of the measurements
- implementation and process evaluation of the NE programme.

6.2 AIM, OBJECTIVES AND HYPOTHESES

6.2.1 Aim

The purpose of this phase was to implement a NE programme that had been developed for type 2 DM adults in a resource limited setting of the Moretele sub-district, North West Province (South Africa) and to evaluate the programme's effectiveness on glycaemic control and other health outcomes (BMI, blood pressure, lipid profile, dietary behaviours, diabetes knowledge and the attitudes towards diabetes and its treatment).

6.2.2 Objectives

General objectives (6.2.2.1) and specific outcomes objectives were formulated (6.2.2.2).

6.2.2.1 General objectives

- The implementation of the NE programme at the two CHCs.
- The evaluation of the programme's effectiveness at six and 12 months on the following outcomes:
    - (i) clinical status: Haemoglobin A_{1c} ($HbA_{1c)}$ (primary outcome), BMI, blood pressure and lipid profile
    - (ii) dietary behaviours
    - (iii) diabetes knowledge
    - (iv) attitudes towards diabetes and its treatment.

6.2.2.2 Specific outcome objectives

Primary outcome objective

- To determine the differences between the intervention and control groups at six months and 12 months for $HbA_{1c.}$

Secondary outcome objectives

- To determine the differences between the intervention and control groups at six months and 12 months for the secondary outcomes: dietary behaviour, BMI, lipid profile, blood pressure, diabetes knowledge and attitudes towards diabetes and its treatment.
- To determine the differences between the intervention and control groups in the proportion of participants who achieved HbA_{1c} levels of less than 7%.
- To determine the within the groups differences at six months and 12 months for HbA_{1c} and the secondary outcomes.

The between group difference in outcomes was the primary interest and focus of this study.

6.2.3 Research hypotheses

6.2.3.1 The intervention group would have significantly lower HbA_{1c} levels at six months compared with the control group, and would sustain significantly lower levels at 12 months compared with the control group.

6.2.3.2 The intervention group would have significantly better outcomes in the secondary outcomes (blood lipid levels, BMI, blood pressure, dietary behaviours, diabetes knowledge and attitudes towards diabetes and its treatment) at six months and would sustain significantly better outcomes at 12 months compared with the control group.

6.2.3.3 The intervention group compared with the control group would have significantly more participants achieving the HbA_{1c} targets (<7%) at six months and at 12 months.

6.2.3.4 The intervention group would have significantly better within group improvements for the primary and secondary outcomes at six and 12 months compared with the control group.

6.3 METHOD

The study received ethical approval from the Research Ethics Committee, Faculty of Health Sciences, University of Pretoria (number 215/2009) as discussed in Chapter 3, section 3.4.

6.3.1 Study design

A randomised controlled clinical trial using two groups was implemented. One group (intervention) received the intervention which consisted of structured face to face NE and education materials (pamphlet and fridge/wall poster). The other group (control) only received the education materials. Both groups received usual medical care at their respective community health centres (CHCs). The effectiveness of the intervention was evaluated at six months and 12 months.

6.3.2 Setting

The study was done in the two CHCs (Makapanstad and Mathibestad) in Moretele sub-district, North West Province (South Africa) as discussed in chapter 3, section 3.3.

6.3.3 Population and sampling

The population consisted of adults (male and females) with type 2 DM.

6.3.3.1 Inclusion criteria

Patients were included in the study if they met the following criteria:

- aged between 40 and 70 years

- at least one (1) year living with of diabetes
- blood sugar levels of 10 mmol/L or above in two occasions in the last six months and consequent HbA_{1c} levels ≥8% after blood analysis
- regular attendance of the diabetic clinic according to patient record.

6.3.3.2 Exclusion criteria

Patients were excluded in the study if they were:

- on insulin therapy
- pregnant
- in full time employment (full time work commitment would interfere with the attendance of the NE sessions)
- planning to move from area of study during the study period.

6.3.3.3 Sample size and sample selection

A total sample of 72 patients (36 per group) was required to detect a 1 % difference in HbA_{1c} (SD of 1.5 and a power of 80%) at six months. To allow for a 10% attrition rate, 80 patients were needed. Recruitment into the study was done face to face during participants' monthly clinic attendance. A two stage process was used to select the sample. Patients who met all the inclusion criteria before the HbA_{1c} analysis and were willing to participate in the study (by signing informed consent) were initially selected. After the HbA_{1c} analysis only those who met the criterion of HbA_{1c} levels of ≥8% were included in the final sample.

6.3.3.4 Randomisation

Participants were randomised into either the intervention or control group using block randomisation[1,2] in blocks of varying sizes (two to six) using a computer generated random schedule. Randomisation was done by participant irrespective of clinic. The participants were stratified based on sex and age. Allocation concealment using sealed sequentially numbered opaque envelopes with the randomisation code was done. Each stratum had its own set of the sequentially numbered envelopes. Upon confirmation of a participant's eligibility, the next envelope in sequence (for their specific stratum) was opened and the treatment allocation entered on a randomisation list. The patient identifier (study number) was written on the

envelope. The list of the participants and the treatment allocation was kept in a secure place by the researcher.

The health professionals serving the participants at the CHCs and those involved in blood specimen collection were masked to the treatment groups. Figure 6.1 shows the participant flow throughout the study.

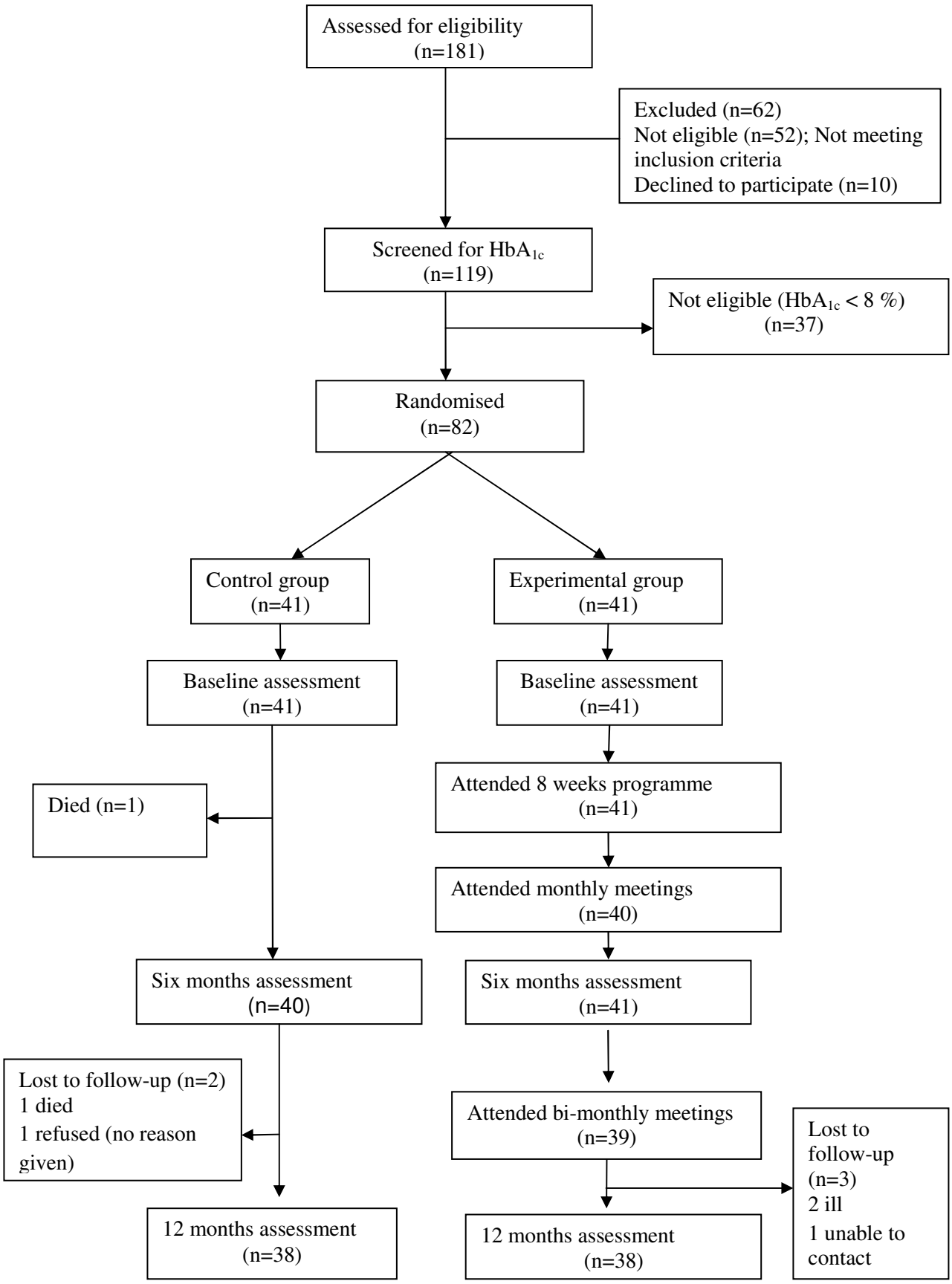

Figure 6.1: Flow of participants through the study

6.3.4 Pilot study

Five (5) participants were used to pilot test the research procedure (Table 6.1). The data for these participants were included with the rest of the sample.

Table 6.1: Protocol for baseline and post intervention assessment for intervention and control groups

Welcome, introductions and appreciation of participants' attendance
↓
Information in isiTswana and English
↓
Informed consent (written or witnessed)*
↓
Blood samples (HbA_{1C} & lipids)
↓
Allocation of study number*
↓
Collecting demographic data*
↓
Measurement of blood pressure
↓
24 hour diet recall
↓
Completion of diabetes knowledge (DKN) questionnaire
↓
Completion of diabetes attitudes scale (DAS)
↓
Measurement of height
↓
Measurement of weight
↓
Refreshments
↓
Payments of transport
↓
Next appointment (typed cards)

* Only at baseline assessment

6.4 MEASUREMENTS

Measurements of outcomes were done for both groups at baseline, six months and one year. Participants' socio-demographic data and diabetes medication use were also obtained (see below). Outcome assessments were done on different days for the intervention and control groups. The researcher, an appointed field worker (final year nutrition & food science university student) and a qualified dietitian (only for baseline data) were involved in the collection of data. Blood samples were collected by professional nurses working at the CHCs. Data capturing commenced in April 2010 and ended in November 2011.

6.4.1 Socio-demographic data and diabetes medication

A structured interviewer administered questionnaire was used to collect socio-demographic data (Appendix 13). Medications prescribed for the control of diabetes were obtained from the patients' records at baseline and post-intervention.

6.4.2 Clinical data outcomes

The clinical data capturing form is presented in appendix 14.

6.4.2.1 Body mass index

Weight and height were measured using standard techniques with participants barefooted and in light clothing.[3] Weight was measured twice to the nearest 0.1 kg using a calibrated electronic scale (Seca 208). Height was measured twice to the nearest 0.1 cm using a portable stadiometer (Seca 214). The mean of each of the weight and height measurements were used for calculations. Each participant's BMI (kg/m^2) was calculated by dividing the average of the body weight in kilograms by the square of the subject's height in meters.[4]

6.4.2.2 Blood pressure

Blood pressure was measured according to standard guidelines[5] using an electronic blood pressure monitor (Omron 705CP). Measurements were done with the participant seated, with right arm supported on a table and after a rest of five minutes. A large cuff (15 cm-rubber bladder) was used for those with a mid-arm circumference of 32 cm or greater. Two measurements were taken and in case there was a difference of more than 5 mm Hg between the readings, one or two more measurements were taken. The mean of the two closest measurements was used to determine mean blood pressure.

6.4.2.3 Haemoglobin A1C and lipid profile

Non-fasting venous blood samples were collected. EDTA tubes were used for HbA_{1c} and plain clotting tubes for the lipid samples. The blood specimens were transported on ice for analysis at the Steve Biko Academic Hospital Core laboratory of the National Health Laboratory Services (Pretoria) within six hours of being drawn.

The HbA_{1c} reagent kit, used in conjunction with SYNCHRON LX®, Unicel® DxC 600/800 system(s), SYNCHRON systems HbA_{1c} calibrators and SYNCHRON® systems haemolysing reagent, were used to quantitatively determine HbA_{1c} concentration as a percentage of total haemoglobin in human whole blood.[6] The HbA_{1c} results from the laboratory used are traceable to the International Federation of Clinical Chemistry (IFCC) calibrators.[6]

A full lipid profile was done (total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides).The lipid profile was determined by using reagents for the specific lipid with SYNCHRON LX®, Unicel® DxC 600/800 system(s) and SYNCHRON systems lipids calibrators.[7]

6.4.3 Dietary behaviours

Three face-to-face 24 hour diet recalls (two week days and one weekend day) on non-consecutive days were used to collect dietary intake using a researcher designed form (Appendix 15). Data on vegetable gardening was also obtained using the same form. Food models (fruits), bean bag mounds[8] and commonly used household measures (cups, glasses, spoons, bowls etc.) were used to assist participants in estimating consumed food/fluids portions. The household measures (cups, bowls and glasses) were standardised and graduated based on the standard cup measurements. The spoons were of known standard spoons or cups measurements equivalents. The standard half cup was used to determine the number of servings for starchy foods, vegetables and cut fruits.

A food change questionnaire,[9] constructed by the researcher, assessed the participants' perceived dietary changes at six and 12 months. The perceived dietary changes were assessed after the completion of the three 24 recalls at each of the assessment periods. The dietary practices assessed were based on the NE content (including the written materials provided) and the goal and objectives of the NE programme. Participants were asked to indicate whether

they had “increased”, “decreased”,” no change” or “not applicable” their intake for 16 items (food and dietary practices). Additional four (4) items assessed the frequency of performing behaviour related to reducing fat during preparation and consumption of meat items by indicating, “all the time”, “most times”, “sometimes”, “ never” or “not applicable” (Appendix 16).

6.4.4 Diabetes knowledge

The diabetes Knowledge Form B scale (DKNB)[10] was used to measure diabetes knowledge (Appendix 17). The DKNB questionnaire has previously been used in South Africa.[11] The DKNB is a standardised questionnaire comprising 15 questions sampling knowledge in five broad areas: basic physiology, hypoglycaemia, food groups, sick day management and general diabetes care. The scores are expressed as raw scores out of 15, or as a percentage of correct answers. Each item was assigned a score of one (1) for a correct response or zero for incorrect response. For items 13 to 15, which had more than one correct answer, a score of one was assigned if all the answers were correct.

The questionnaire was face to face interviewer administered in the local language at baseline. At the six and 12 months assessments, it was self-administered by participants deemed to have adequate reading capabilities [30% (≥ 9 years of schooling)] (due to unavailability of one of the interviewers). It was interviewer administered for the rest of the participants. The self-administration of the questionnaire was done in a group set-up (three to seven participants). The field worker clarified the instructions and was available for any other clarifications.

6.4.5 Attitudes toward diabetes and its treatment

The Revised Diabetes Attitudes Scale-III (DAS-III)[12] was used to assess the participant’s attitudes towards diabetes and its treatment (Appendix 18). The scale is suitable for comparisons across groups and for the evaluation of education programmes.[12] The scale has five sub-scales (constructs) and 33 Likert scale items (5-strongly agree, 4-agree, 3-neutral, 2-disagree and 1-strongly disagree). This standardised questionnaire measures attitudes with regard to the need for special training for professionals, seriousness of type 2 diabetes, the value of tight glucose control, psychosocial impact of diabetes and patient autonomy. The scale has previously been used in South Africa.[13]

The questionnaire was face to face interviewer administered in the local language at baseline. At the six and 12 months assessments, the questionnaire was self-administered by participants deemed to have adequate reading capabilities [30% (≥ 9 years of schooling)] (due to unavailability of one of the interviewers). It was interviewer administered for the rest of the participants. The self-administration of the questionnaire was done in a group set-up (three to seven participants). The field worker clarified the instructions and was available for any other clarifications.

Table 6.2 gives the operational definitions of the measured outcomes and their targets or cut off points.

Table 6.2: Operationalisation of the variables measured in phase 3

Variable	Operational definition	Target/cut off values
Clinical status	Health condition as assessed through biochemical indicators, blood pressure and anthropometric measurements	-
HbA_{1c} (%)	A biochemical measure that assesses glycaemia for the preceding 2-3 months.[14]	< 7 [15]
Lipid profile	The levels of total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides in the blood	
Total cholesterol (mmol/L)		< 4.5[15]
LDL-cholesterol (mmol/L)		< 2.5[15]
HDL-cholesterol (mmol/L)		> 1.2 (women) > 1 (men)[15]
Blood pressure (mmHg)		< 130/80[15]
Triglycerides (mmol/L)		< 1.5[15]
Body mass index (BMI) (kg/m^2)	A measurement representing the ratio of a person's body weight to his/her height used to classify underweight, overweight and obesity. It is obtained by the weight in kilograms divided by the square of the height in meters.[4]	Underweight < 18.5 Normal 18.5-24.99 Overweight ≥ 25 Obese ≥ 304 Target < 25[15]
Dietary behaviours	-Dietary intake: food types, amounts and nutrient composition (cholesterol, sodium and fibre), total energy and the macronutrient distribution and consumption of fruits and vegetables -Food related practices such as vegetable gardening, food selection and preparation	
Meal balance	A meal that contains food groups that contribute to macronutrients in the appropriate proportions and includes vegetables and fruits. Legumes were encouraged as a means to improving meal balance.	Acceptable macronutrient distribution range (AMDR); carbohydrates 45-65%; Proteins 10-35%; Fats 20-35%[16]
Macronutrient contribution to energy (%)		Total fat ≤ 30[17] Saturated fatty acids < 7[18] PUFA < 10[19] MUFA 10[17] Protein 10-20[19] Total carbohydrates 45-65[18] Sucrose 10%[19]
Cholesterol (mg/day)		< 200 [18]

- PUFA: Polyunsaturated fatty acids
- MUFA: monounsaturated fatty acids

Continued/…….

Table 6.2: Operationalisation of the variables measured in phase 3 continued

Variable	Operational definition	Target/cut off values
Sodium chloride (mg/day)		< 2300 [18]
Fibre (g/day)		25[17]
Starchy foods	Grains, tubers and roots	6-11 servings per day[20]
Fruits and Vegetables		5 servings per day[21]
Diabetes knowledge	Understanding of diabetes and its management	Poor (<7.5/<50%), average (8-10), good (11-15) out of a total score of 15
Attitudes towards diabetes & its treatment	Specific beliefs concerning diabetes or its treatment	< 3-Negative (specific sub-scale) > 3-positive (specific sub-scale) =3 neutral[22]

6.5 PROGRAMME ATTENDANCE AND PROCESS EVALUATION

An attendance register was used to obtain data on the attendance of the NE sessions' by the participants. The NE programme process evaluation was done through feedback from the participants as well as the researcher's observations during the NE sessions and reflection. A debriefing with the facilitators (sub-district dietitian and the field worker) was done at the end of each session. Participants' feedback was obtained at the eighth week and after the 12 months outcome assessment.

At the eighth week a short questionnaire with open ended questions and one closed ended question (Appendix 19) was used. The assessment was done to evaluate participants' satisfaction with the curriculum component and to elicit suggestions for the monthly meetings and/or other suggestions which could help improve the NE programme delivery. The field worker explained each question to the participants in a group using the local language, after which each participant filled out the questionnaire. Those who had difficulties with writing were assisted. At 12 months, focus group discussions (FGDs) were done within the five groups used for the NE sessions. A semi-structured interview guide was used (Appendix 20). The sessions were facilitated in the local language by the field worker, who also took notes. All the sessions were tape recorded. The FGDs lasted between one and two hours.

6.6 DATA MANAGEMENT AND ANALYSIS

6.6.1 Data management

All data were coded and captured by the researcher personally. The 24 hour diet recalls data were input into the FoodFinder3® diet analysis software. After analysis, the data were exported to the EXCEL spread sheets. All other data (including the number of servings for starchy foods and fruits and vegetables) were first captured on to EXCEL spread sheets before being imported to the statistical analysis package. The researcher checked and cleaned the data before analysis.

6.6.2 Data analysis

As mentioned above, the FoodFinder3® diet analysis software was used to analyse the 24 hour diet recalls. The software, a product of the Medical Research Council (South Africa) contains the most current data base for South African foods.

Stata® software version 11.1 (Stata Corp, College Station, TX, USA) was used for all statistical analysis of the quantitative data. The analysis of post-intervention outcomes was done for those participants who completed the assessments (Figure 6.1). In addition, an intention to treat analysis was done for the primary outcome (HbA_{1c}) using the last observed response (carry forward).[23]

Continuous variables for each group (intervention and control) were assessed for normality, using the Shapiro-Wilk test complemented with histograms. Tests for differences in baseline characteristics for the two groups were based on a Chi-square (Fischer's exact if n<5) test for categorical variables, *t*-test for normally distributed continuous variables, and the Mann-Whitney test for skewed continuous variables. The baseline characteristics were summarised and presented as means ± standard deviations for normally distributed continuous variables, as medians and interquartile ranges for skewed continuous variables, or as numbers and percentages for categorical variables.

An analysis of co-variance (ANCOVA) was done to compare the intervention and control groups on the measured outcomes post-intervention, using the baseline values as covariates as well as adjustments for age, gender and clinic. Triglycerides were normalised through logarithmic transformation[24] before the analysis. Rank ANCOVA[25]was used for dietary intake

as the majority of the data were skewed. Regression diagnostics[26] were first performed to assess any unusual observations (outliers, leverage and influence) in the measured outcomes. A paired *t*-test for normally distributed variables and the Wilcoxon matched paired signed rank test for skewed data were used to test the within group changes from baseline to post-intervention. The level of significance for all tests was set at $\alpha < 0.05$ for a two-tailed test.

Comparisons for energy intake were done for the genders combined as there were no significant differences between the groups for intake by gender. The DAS III sub-scales and their scores were computed as per guidelines by the Michigan Diabetes Research and Training Centre. [27] Cronbach's alpha was calculated for each of the DAS III sub-scales at baseline to assess the internal reliability of the items. Items that did not contribute to internal consistency were omitted in the final analysis.

Data for programme process evaluation, which were mainly qualitative, were analysed using a combination of Krueger's and Richie & Spencer framework approach discussed in chapter 4 (section 4.5). The tape recorded data were first transcribed verbatim and then translated into English by the field worker who conducted the FGDs.

6.7 VALIDITY AND RELIABILITY OF THE MEASUREMENTS

Measures that were implemented to ensure validity and reliability of the data included the following:

i) The use of standardised questionnaires: the DKNB scale [10] for assessing diabetes knowledge and DAS III scale[12] for assessing the attitudes towards diabetes and its treatment. These questionnaires have previously been used in South Africa.[11,13]
ii) Making the questionnaires available in the local language to allow better understanding of the questions. As discussed in chapter 5 section 5.4.9.3, the questionnaire translations were done using the recommended procedures.[28] (English into the idiom of the community, then back translation into English by a second translator, finally comparisons and appropriate adjustments were done).
iii) The food change questionnaire generated by the researcher was assessed for content validity and appropriateness by one of the study leaders before implementation.
iv) Pre-testing the data collection tools to ensure accurate and relevant data. This was done with a population similar to the study population (chapter 5, section 5.4.9.4).

v) Pretesting the data collection process (section 6.3.4).

vi) Regular calibration of instruments: the weighing scale and blood pressure monitor

vii) Appropriate training of the field worker and the registered dietitian.

viii) Regular debriefing with personnel who collected data on measurements procedures and techniques to ensure standards were maintained.

ix) Checking the inter-rater agreement between the researcher (used English) and the field worker (used the local language) for the 24 hour recall interview for a sample of participants conversant with English (three per each time period). Both interviewers were blinded to the results of the other person. The participants involved were also not aware that their 24 hour recall interview would be done twice (by the different interviewers). In all the cases there was 100% agreement in the reported meals, food items and portion sizes, except in one case where starch portions differed by a small margin (0.25 of a standard cup for one meal).

6.8 THE NUTRITION EDUCATION PROGRAMME IMPLEMENTATION

6.8.1 Intervention

The details of the NE programme are given in chapter 5. Briefly, the overall goal of the NE programme was to improve glycaemic control (HbA_{1c}) and other clinical outcomes (BMI, blood lipids, blood pressure) through improved dietary behaviours and behaviour mediating factors (chapter 5, section 5.4.2.1). Specifically, the NE programme aimed to (i) reduce starchy food intake (number of servings/day), (ii) increase vegetable and fruit intake, (iii) improve meal balance, and (iv) improve knowledge about diabetes and its management and attitudes toward diabetes and its treatment (chapter 5, section 5.3.2.2). A combination of constructs from the Social Cognitive Theory, Health Belief Model and the Knowledge Attitude Behaviour theories/models of behaviour change were used (chapter 5 section, 5.4.4 & Figure 5.1).

The NE programme was implemented as follows: eight weekly sessions each lasting 2 to 2.5 hours to cover the curriculum (Table 6.4), followed by follow-up sessions; four monthly meetings and two bi-monthly meetings each lasting 1.5 hours (Table 6.5), and the provision of written materials for use at home (pamphlet and wall/fridge poster) (chapter 5, section 5.4.7 paragraph 3). The total programme contact time was 26.5 hours for the combined weekly and monthly meetings.

The NE sessions were conducted at the two CHCs in five groups of six to ten participants. The first group commenced in June 2010. The last meeting was held in September 2011 with the last group. To prevent contamination between the intervention and control group participants, the NE sessions were held in a block separate from the one where patient consultations were done in each CHC. Participants were also requested not to share information with other patients.[29]

Weekly NE sessions were facilitated initially by the sub-district dietitian (25%), thereafter by the appointed field worker (65%) and the researcher (10%). The dietitian and the field worker (see chapter 5 section 5.4.9.5) had been trained to facilitate the sessions. A training manual (see chapter 5 section 5.4.9.6) was used to ensure uniform information and delivery. The local language was used in all the sessions facilitated by the dietitian and the field worker (90%), while English with local language translations were used for those delivered by the researcher (10%). The majority (95%) of the follow-up meetings were facilitated by the field worker with the assistance of the researcher. The researcher was present at all the sessions to observe the delivery and interactions between the facilitator and participants, and to address any questions.

6.8.1 Participants' follow-up in both groups

Participants in both groups were given cards with written appointment dates. Additional measures included telephonic reminders to participants or their relatives/friends and also using participants in the same group residing in the same area. If a participant did not turn up either for the education session or assessment, they would be telephoned to find out the reason for not attending. For the education sessions, they would be requested to attend the next session and for assessment they would be given a new appointment. For those without telephones, a participant in the same group residing in the same area would be requested to remind them to come for the next education session or assessment.

The control group participants who had telephones were telephoned two weeks prior their sixth and 12 months' assessments as a reminder.

Table 6.3: The nutrition education curriculum as implemented

Session	Topic	Content, activities and *teaching aids* (italics)
1	What is diabetes mellitus?	Nature of disease (explanation of what happens when one has diabetes, including body's response to food in diabetic/non-diabetic states, insulin action) Causes/risk factors, types Symptoms and complications *Diabetes basics flip chart(Living with diabetes)*
2	Treatment of diabetes	Diet, exercise medication and their roles in treatment Aim for treatment and targets for good control Causes, symptoms and management of hypoglycaemia & hyperglycaemia *Diabetes basics flip chart(Living with diabetes)* Reflection on current practises and group discussion
3	Dietary guidelines: healthy eating; mixed meals (balanced nutrition)	- Healthy eating: importance of regular and varied meals -Overview of food groups and their role in the body -Specific guidelines for starch, vegetables, fruits and meats and alternatives (additional information with respect to diabetes) -Guided discussion on improving dietary variety. Reflection on current dietary practices and group discussion *South African dietary guidelines flip chart*
4	Improving vegetable supply through gardening	-Discussion on barriers to vegetable and fruit intake and on how to improve vegetable and fruits availability -Vegetable gardening demonstration : sowing and transplanting selected vegetables* -Guided tour of the CHCs' previously established vegetable gardens *South African dietary guidelines flip chart*
5	Dietary guidelines continued: fats, salt, sugar and water**	Specific guidelines for each food group **Group activity** -label reading of products on display *South African dietary guidelines flip chart* *Empty food containers* *Raw foods (chicken & meat)* Reflection on current practices related to dietary guidelines and label reading plus group discussion

Continued/…….

Table 6.3: The nutrition education curriculum as implemented continued

Session	Topic	Content, activities and *teaching aids* (italics)
6	Meal planning: portions and meal frequency	-Facilitated group review of the effect of food on blood glucose -Discussion on importance of food portion control and regular meals Guidelines for portion sizes **Demonstration**: portion sizes (household measures, Zimbabwe hand jive, plate model) **Group activity** Practice portioning various commonly used foods Discussion about portion sizes and associated issues such as hunger Reflection and group discussion *-Plate model & Zimbabwe hand jive flip charts* *-Cooked foods displays*
7	Meal planning: principles	Planning meals on a limited budget, emphasise on variety and balance within available resources **Group activity**: • costing of sample meals of foods commonly consumed in the community • -formulation of cheap mixed/balanced meals for foods commonly consumed in the community Group discussion and group goal setting *Sample menus handouts*
8	Meal preparation: healthy cooking with diabetes Integration of sessions and evaluation Hand outs: pamphlet and fridge/wall poster	Importance of legumes in general and in diabetes Cooking demonstration and group cooking (one legume & one commonly consumed vegetable) Meal tasting and group discussion *Recipe handouts*

* Only done in one group
** Attendance of family member

- In 6 of the sessions, 5-10 minutes of indoor group physical activity (stretches, on-spot jogging and /or jogging around the room) after the NE sessions were done to encourage physical activity at individual level.

(See the planned NE curriculum; Chapter 5, Table 5.4)

Table 6.4: Activities of the monthly and bi-monthly meetings

Meeting	Activities
Monthly meetings (4 meetings, 1.5 hours each)	• Facilitators informally assessing participants well being • Participants discussing results of their monthly blood glucose results • Participants sharing their successes and barriers to dietary self-management and related issues • Group discussions on how to deal with barriers • Facilitators addressing any arising issues • Structured review of learnt content: asking questions from specific topics and generating a discussion then facilitators summarising
Bi-monthly meetings (2 meetings, 1.5 hours each)	First meeting: • Facilitators informally assessing participants well being • Facilitators addressing any arising issues • Feedback on HbA_{1c} levels and lipid profile • Group discussions on how to improve glucose control and lipid profile
	Second meeting • Facilitators informally assessing participants well being • Participants discussing results of their monthly blood glucose results • Participants sharing their successes and barriers to dietary self-management and related issues • Group discussions on how to deal with barriers • Facilitators addressing any arising issues

CHAPTER 7

RESULTS FOR PHASE 3

7.1 INTRODUCTION

This chapter reports the participants' socio-demographic characteristics, baseline and post-intervention outcomes, programme participation rates and the programme process evaluation. The results of the quantitative data are either presented as means ± standard deviations (SD) for normally distributed continuous variables, as medians and interquartile ranges for skewed continuous variables, or as numbers and percentages for categorical variables. The analysis of covariance (ANCOVA) results for the clinical outcomes and diabetes knowledge scores are presented as adjusted means and standard errors and the change (beta) plus 95% confidence interval (CI) for the covariates. For dietary outcomes where rank ANCOVA was used, results are given as medians and interquartile ranges and post-intervention *p*-values for the rank ANCOVA. Results for attitudes towards diabetes and its treatment are presented as means ± SD for baseline data and adjusted means and standard errors for post-intervention data.
The results for the qualitative data are presented as themes and sub-themes that are supported by ethnographic descriptions.

7.2 PARTICIPANTS SOCIO-DEMOGRAPHIC CHARACTERISTICS'

A total of 82 (71 females) type 2 diabetic patients participated in the study. Fourteen of these patients (17%) had participated in phase 1 of the study. All the participants were of black ethnicity. The mean age of the patients was 58.8±7.7 years. Table 7.1 shows the participants' socio-demographic characteristics per group (intervention and control). The majority in both groups were unemployed (>80%) with a high proportion depending on pension (>45%) or other forms of grants (>14%) for their livelihood. More participants in each group, 43.9% and 39% for the intervention and control groups respectively, had an education level of grade 7 to 9 (pre-matriculation level). The majority of participants in both groups were married (>60%) and were living with family (> 90%). All participants were on oral hypoglycaemic agents with the majority in both groups (>70%) being on a combination of biguanides and sulphonylureas. There were no significant differences between the intervention and control groups for the socio-demographic characteristics.

Table 7.1: Participants' socio-demographic characteristics: comparisons between the intervention and control groups (N=82)

Variable	Group				P-value[c]
	Intervention (n=41)		Control (n=41)		
Age (yrs)	59.4±6.9		58.2±8.0		0.66
Diabetes duration (yrs)	5 (3-9)[a]		7 (4-10)[a]		0.37
Gender					
Male	5 (12.2)[b]		6 (14.6)		0.75
Female	36 (87.8)		35 (85.4)		
Age-gender					
Males: 40-60 yrs	2 (4.9)		3 (7.3)		1.0
Males 61-70 yrs	3 (7.3)		3 (7.3)		
Females 40-60 yrs	20 (48.8)		19 (46.4)		
Females 61-70 yrs	16 (39)		16 (39)		
Marital status					
Single	6 (14.6)		6 (14.6)		0.69
Married	25 (61)		28 (68.3		
Widowed	6 (14.6)		6 (14.6)		
Separated/divorced	4 (9.8)		1 (2.5)		
Living situation					
Live with family	37 (90.2)		39 (95.1)		0.54
Live alone	3 (7.3)		2 (4.9)		
Other	1 (2.5)		0		
Education level					
No formal education	2 (4.9)		5 (12.2)		0.69
Grade 1-6	11 (26.8)		11 (26.8)		
Grade 7-9	18 (43.9)		16 (39.0)		
Grade 10-12	7 (17.1)		8 (19.5)		
Post grade 12	3 (7.3)		1 (2.5)		
Employment status					
Employed	2 (4.9)		6 (14.6)		0.26
Not employed	39 (95.1)		35 (84.4)		
Source of finance					
Husband/wife	8 (19.5)[b]		6(14.6)		0.9
Relative	2 (4.9)		2 (4.9)		
Piece jobs	2 (4.9)		3 (7.3)		
Pension	22 (53.7)		19 (46.3)		
Other grants	6 (14.6)		9 (22)		
No answer	1 (2.5)		2 (4.9)		
Participation by clinic	**Clinic 1**	**Clinic 2**	**Clinic 1**	**Clinic 2**	0.67
	21	20	23	18	

[a] Median and interquartile range in parenthesis
[b] Number (n) and percentage in parenthesis and all such values
[c] Based on chi squared, Fischer's exact if n<5

7.3 OUTCOMES

7.3.1 Differences between the intervention and control groups from baseline to six and 12 months

7.3.1.1 Clinical outcomes

Table 7.2 shows the baseline and post-intervention clinical outcomes and diabetes medication for the intervention and control groups for the unadjusted data. There were no significant group differences in the use of glucose lowering medication at baseline, six months and 12 months. There were no significant differences between the groups for HbA_{1c}, body mass index, systolic blood pressure, diastolic blood pressure, total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides at baseline. Post-intervention, only HbA_{1c} at six months showed a significant difference between the groups (1.2% mean difference, p=0.038; 95% CI -2.3 to 0.6). This difference was however no longer significant after adjusting for baseline values and independent variables (gender, clinic and age) (0.62% mean difference, p=0.15, 95% CI -0.22 to 1.5) (Table 7.3). The number of participants who achieved the targets for HbA_{1c} (< 7%) was higher in the intervention group (4 vs. 1, p=0.20) at six months and (4 vs.1, p=0.36) at 12months but this was non-significant (Table 7.2).

Regression diagnostics for the clinical and other outcome variables did not show any data that significantly influenced the results, therefore ANCOVA included all observations. Table 7.3 shows the diagnostics results for the primary outcome (HbA_{1c}) as an example. Table 7.4 shows the adjusted means and effects of the baseline co-variates and other independent variables (age, gender, clinic) on the clinical outcomes post-intervention. Baseline values had a highly significant effect on all measured clinical outcomes (p=0.000) at six and 12 months with higher values predicting higher levels of the post-intervention outcome.

The control group had higher HbA_{1c} levels than the intervention group at six months and 12 months respectively (+ 0.62%, p= 0.15, 95% CI -0.22 to 1.5; + 0.67%, p=0.16, 95% CI -0.27 to 1.6), but this was not significant. The intention to treat analysis (using last observation carried forward) showed a similar trend and treatment effects values close to those obtained with participants completing the assessments analysis (+ 0.64%, p=0.13, 95% CI -0.19 to 1.5 at six months; + 0.63%, p=0.16, -0.26 to 1.5 at 12 months). The control group had a higher BMI, total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides at the two time periods compared with the intervention group, but in all cases it was not significant. Systolic

and diastolic blood pressure at six months were lower in the control group than in the intervention group (-4 mmHg, p=0.3, 95% CI -12.5 to 3.9 and -0.15 mmHg, p=0.95, 95% -4.5 to 4.2), but this was non-significant. Systolic blood pressure, diastolic blood pressure and BMI at six and 12 months decreased more in females than males, but this was not significant.

Table 7.2: **Clinical outcomes and diabetes medication: differences between the intervention and control group from baseline to post-intervention**

	Baseline				**Six months**				**Twelve months**			
	Intervention group (n = 41)	**Control group** (n = 41)	**Difference in means (95% CI)**	**P value**	**Intervention group** (n = 41)	**Control group (n = 40)**	**Difference in means (95% CI)**	**P value**	**Intervention group** (n = 38)	**Control group** (n = 38)	**Difference in means (95% CI)**	**P value**
HbA_{1c} (%)	10.8±1.8	11.4±2.2	0.6 (-1.5-0.3)	0.17	9.4±2.3	10.6 ±2.5	1.2 (-2.2--0.06)	0.038	9.6±2.2	10.7±2.5	1.1 (-2.1-0.03)	0.058
HbA_{1c} < 7%					4 (9.8)[a]	1 (2.5)		0.2[b]	4 (11.1)	1 (2.6)		0.36[b]
Body mass index (kg/m^2)	31.5±7.0	30.4±6.8	1.1 (-2.1-4.1)	0.50	31.0±6.7	30.3±7.1	0.7 (-2.3-3.8)	0.63	30.9±6.8	30.4±7.0	0.5 (-2.7-3.6)	0.79
Systolic BP (mmHg)	142.9 ± 22.9	143.3± 28	4.0 (-11.4-10.9)	0.97	134.0±23.2	130.0±25.2	4.1 (-6.7-14.8)	0.45	141.2 ± 22.6	141.2 ± 28.3	0.08 (-11.6-11.8)	0.99
Diastolic BP (mmHg)	84.3±11.7	84.5±11.7	0.2 (-5.5-5.1)	0.93	78.9±11.4	78.0 ±11.3	0.00 (-5.0-5.0)	0.99	80.1 ± 11.8	82.6 ± 13.0	2.5 (-8.1-3.2)	0.38
Total blood cholesterol (mmol/L)	4.8 ± 1.2	4.9 ± 0.9	0.1 (-0.6-0.4)	0.65	4.4 ± 0.9	4.6 ± 0.9	0.2 (-0.6-0.2)	0.26	4.7 ± 0.9	4.9 ± 0.9	0.2 (-0.6-0.2)	0.25
LDL-cholesterol (mmol/L	3.0 ± 0.9	3.1± 0.9	0.1 (-0.5-0.3)	0.51	2.6 ± 0.7	2.8 ± 0.8	0.2(-0.5-0.6)	0.3	2.8 ±0.8	3.0 ±0.8	0.2 (-0.6-0.2)	0.25
Triglycerides (mmol/L)	1.36[c] (1.1-1.6)	1.4 (1.2-1.6)	0.04	0.66[d]	1.3 (1.1-1.6)	1.5 (1.3-1.8)	0.2	0.23[d]	1.5 (1.3-1.8)	1.7 (1.4-1.9)	0.2	0.50[d]
Oral hypoglycaemics Biguanides Sulphoynlureas + biguanides Sulphonylureas	 8 (19.5)[a] 29 (70.7) - 4 (9.8)	 7 (17.1) 29 (70.7) - 5 (12.2)	-	0.92[b]	 9 (22) 28 (68.2) - 4 (9.8)	 7 (17.5) 28 (70)5 - 5 (12.5)	-	0.84[b]	 9 (23.7) 25 (65.8) - 4 (10.5)	 6 (15.8) 29 (76.3) - 3 (7.9)	-	0.60[b]
Change in oral hypoglycemics No change Increased dose or number Decreased dose or number	 - 	 - 	 - 	 - 	 38 (92.7) 0 3 (7.3)	 39 (97.5) 1 (2.5) 0	 - 	 0.26[b] 	 35 (92.1) 3 (7.9) 0	 30 (79) 7 (18.4) 1 (2.6)	 - 	 0.11[b]

[a] Number (n) and percentage in parenthesis
[b] Based on chi square test or Fischer's exact test (if n<5); All other p-value based on *t*-test
[c] Geometric mean and 95% confidence interval in parenthesis
[d] Based on log transformed variable

Table 7.3: Regression diagnostics: residual, leverage and influence for HbA_{1c} at six and 12 months as per observations (participants ID number)

Item/time period	Measure				High for > 3 measures	P-value[d]
	Residual[a] absolute (rstu)	Leverage[b]	Influence[c]			
			Cook's D	Absolute (DFITS)		
Cut offs	>2	>(2k+2)n	>4/n	2*sqrt(k/n)		
Values	-	0.148	0.0493	0.496		
Six months (n=81)	74, 73, 29, 79, 16, 35, 31	74, 24, 57	74, 73, 29, 16	74, 25, 73, 79, 16, 45, 35, 37	74, 73, 16	0.08
12 months (n=76)	74, 73	74	74, 73	74, 25, 73, 29, 24, 76, 57	74, 73	0.08

K is the number of predictors
n is the number of observations

[a] Shows outliers; outliers have a large residual
[b] Measure of how far an observation deviates from the mean of that variable
[c] A product of leverage and outlierness. An influential observation substantially changes the estimate of coefficients.[26]
[d] Value based on analysis after removing observations with high measures of influence

Table 7.4: **Clinical outcomes: adjusted means and effects of baseline values and independent variables on post-intervention outcomes**[a]

Outcome/ Time period	Adjusted mean (SE)		Treatment (control vs. intervention)		Baseline covariate		Age		Female vs. male		Clinic 2 vs. clinic 1	
	Inter-vention	Control	Change (95% CI)	P value	Change (95% CI)	P value	Change (95% CI)	P value	Change (95% CI)	P value	Change (95% CI)	P value
HbA_{1c} (%)												
Six months (n=81)	9.70 (0.3)	10.3 (0.3)	0.62 (-0.22- 1.5)	0.15	0.82 (0.62- 1.03)	0.000	-0.06 (-0.1- -0.01)	0.031	1.56 (0.32- 2.8)	0.014	0.15 (-0.65- 0.96)	0.71
ITT (n=82)	9.67 (0.29)	10.3 (0.29)	0.64 (-0.19- 1.5)	0.13	0.74 (0.54- 0.96)	0.000	-0.06 (-0.12- -0.01)	0.032	1.57 (0.34- 2.8)	0.013	0.27 (-0.56- 1.1)	0.51
12 months (n=76)	9.8 (0.3)	10.5 (0.3)	0.67 (-0.27- 1.6)	0.16	0.55 (0.32- 0.78)	0.000	-0.06 (-0.11- 0.01)	0.08	-0.55 (-1.9- 0.8)	0.37	0.70 (-0.25- 1.7)	0.15
ITT (n=82)	9.8 (0.3)	10.4 (0.3)	0.63 (-0.26- 1.5)	0.16	0.57 (0.34- 0.80)	0.000	-0.06 (-0.12- 0.003)	0.06	-0.52 (-1.9- 0.81)	0.44	0.55 (-0.34- 1.5)	0.22
Body mass index (kg/m^2)												
Six months	30.5 (0.2)	30.8 (0.2)	0.29 (-3.0- 0.88)	0.33	0.98 (0.94- 1.0)	0.000	-0.03 (-0.07- 0.01)	0.14	-0.72 (-1.6- 0.16)	0.11	-2.8 (-0.89- 0.32)	0.35
12 months	30.5 (0.3)	30.9 (0.3)	0.37 (-0.4- 1.1)	0.34	0.96 (0.91- 1.0)	0.000	-0.04 (-0.09- 0.01)	0.12	-0.48 (-1.6- 0.64)	0.40	-0.91 (-1.7- 0.12)	0.024
Total cholesterol (mmol/L)												
Six months	4.4 (0.1)	4.6 (0.1)	0.17 (-0.09- 0.44)	0.19	0.57 (0.43- 0.69)	0.000	0.01 (-0.01- 0.03)	0.34	-0.02 (-0.41- 0.36)	0.89	0.21 (-0.5- 0.47)	0.12
12 months	4.75 (0.1)	4.81 (0.1)	0.06 (-0.23- 0.36)	0.67	0.67 (0.51- 0.83)	0.000	-0.13 (-0.34- 0.01)	0.17	-0.41 (-0.83- 0.01)	0.053	-0.07 (-0.36- 0.22)	0.62
LDL-cholesterol (mmol/L)												
Six months	2.66 (0.08)	2.74 (0.08)	0.08 (-0.15- 0.31)	0.49	0.69 (0.56- 0.83)	0.000	-0.001 (-0.01- 0.01)	0.86	-0.09 (-0.43- 0.24)	0.58	0.07 (-0.16- 0.29)	0.57
12 months	2.87 (0.08)	2.97 (0.08)	0.1 (-0.13- 0.33)	0.40	0.73 (0.59- 0.87)	0.000	-0.01 (-0.02- 0.01)	0.39	-0.07 (-0.4- 0.26)	0.68	-0.07 (-0.32- 0.16)	0.56
HDL-cholesterol (mmol/L)												
Six months	0.99 (0.02)	1.02 (0.03)	0.02 (-0.05- 0.09)	0.52	0.77 (0.64- 0.91)	0.000	-0.001 (-0.01- 0.004)	0.78	0.01 (-0.1- 0.12)	0.85	0.03 (-0.04- 0.10)	0.36
12 months	1.02 (0.03)	1.07 (0.03)	0.05 (-0.04- 0.13)	0.28	0.8 (0.64- 0.96)	0.000	-0.004 (-0.01- 0.002)	0.18	0.04 (-0.9- 0.16)	0.53	0.03 (-0.05- 0.12)	0.44

[a]Based on analysis of covariance SE: Standard error ITT: Intention to treat analysis

Continued/……

Table 7.4: **Clinical outcomes: adjusted means and effects of baseline values and independent variables on post-intervention outcomes continued**[a]

Outcome/Time period	Adjusted mean (SE)		Treatment (control vs. intervention)		Baseline covariate		Age		Female vs. male		Clinic 2 vs. clinic 1	
	Inter-vention	Control	Change (95% CI)	P[a] value	Change (95% CI)	P[a] value	Change (95% CI)	P[a] value	Change (95% CI)	Pa value	Change (95% CI)	P[a] value
Triglycerides (mmol/L)[b]												
Six months	1.3	1.5	1.124 (0.97- 1.31)	0.13	2.31 (1.95-2.72)	0.000	0.99 (0.99- 1.00)	0.66	1.04 (0.82-1.32)	0.73	1.06 (0.90- 1.25)	0.45
12 months	1.5	1.7	1.056 (0.90- 1.23)	0.49	1.95 (1.64-2.30)	0.000	1.006 (1.001- 1.011)	0.015	0.85 (0.66- 1.10)	0.22	1.027 (0.87-1.212)	0.75
Systolic BP (mm Hg)												
Six months	134.1 (2.9)	129.8 (2.9)	-4.3 (-12.6- 3.9)	0.30	0.61 (0.43- 0.78)	0.000	0.2 (-0.38- 0.78)	0.50	-8.2 (-20.2- 3.77)	0.18	-1.2 (-9.4- 7.0)	0.77
12 months	141.1 (2.9)	141.3 (2.9)	0.18 (- 8.1- 8.4)	0.97	0.68 (0.51- 0.85)	0.000	0.49 (-0.08- 1.05)	0.09	-1.46 (-13.2- 10.3)	0.80	-3.31 (-11.6- 4.9)	0.43
Diastolic BP (mmHg)												
Six months	78.97 (1.52)	78.8 (1.54)	-0.15 (-4.5- 4.2)	0.95	0.46 (0.28- 0.64)	0.000	0.13 (-0.16- 0.41)	0.39	-5.6 (-11.9- 0.81)	0.09	-0.53 (-4.9- 3.8)	0.81
12 months	80.1 (1.6)	82.7 (1.6)	2.59 (-1.89-7.0)	0.25	0.61 (0.42- 0.8)	0.000	0.28 (-0.01- 0.58)	0.06	-1.49 (-7.9- 4.9)	0.65	-0.43 (-4.9- 4.1)	0.85

[a]Based on analysis of covariance
[b] Based on log transformed variable; means as geometric means & change (95% CI) as a ratio
SE: Standard error

Figures 7.1 and 7.2 respectively show the individual and group (mean ±2 standard errors) response from baseline to 12 months for HbA_{1c} for the intervention and control groups. The individual responses show a similar trend of a decline up to six months then an increase up to 12 months in the two groups for the majority of the participants. The group response shows a decline in the mean HbA_{1c} up to six months then a slight increase after six months until 12 months. The intervention group had a greater decrease in mean HbA_{1c} levels and a narrower 95% confidence interval. The two groups sustained mean HbA_{1c} levels lower than the baseline levels.

Figure 7.3 shows the trends in the mean BMI from baseline to post intervention for the intervention and control groups. Both groups had a decline up to six months, with the intervention group having a slightly greater decline than the control group. After six months, the intervention group had a further slight decline while the control group had an increase up to 12 months. At 12 months, the intervention group had a BMI lower than the baseline value while in the control group it was similar to the baseline levels.

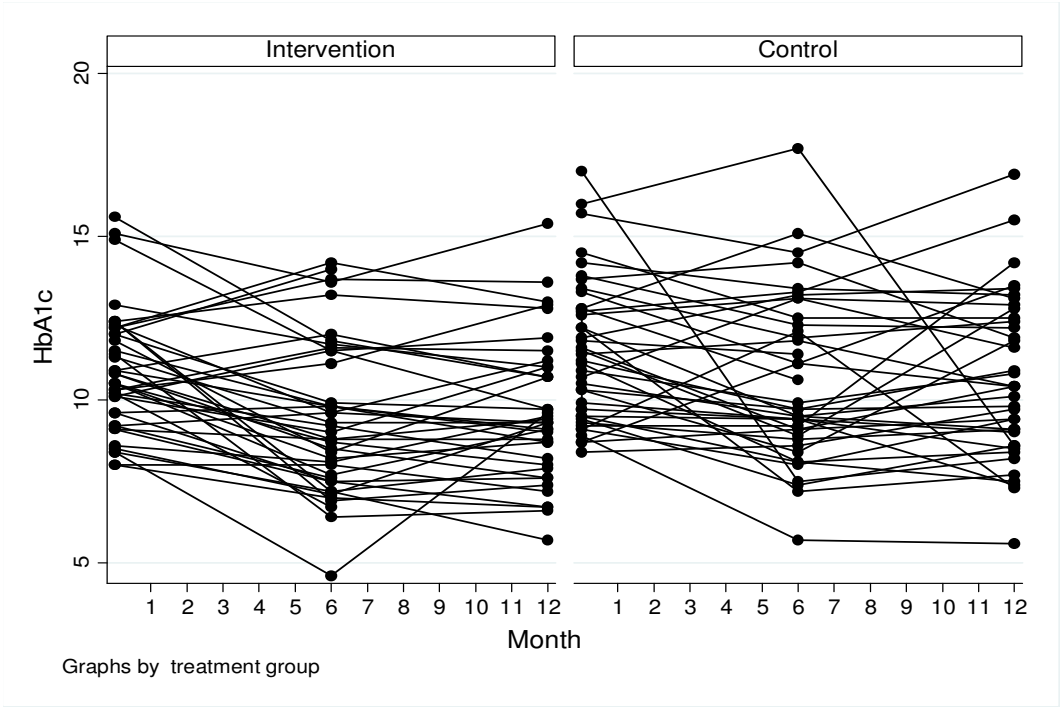

Figure 7.1: Individual response profiles for HbA_{1c} levels by treatment group

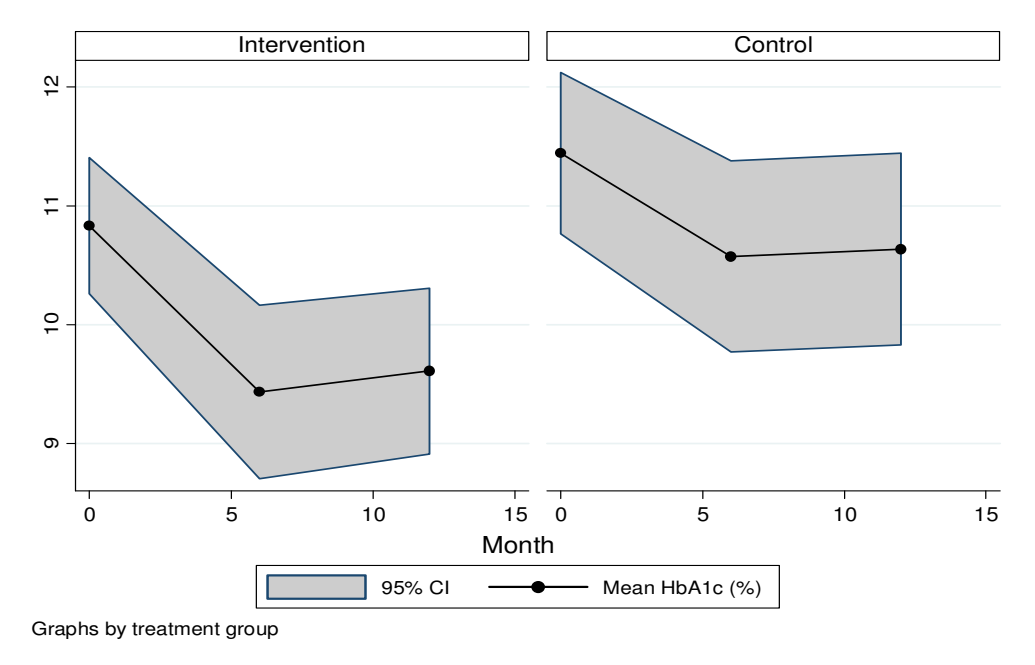

Figure 7.2: Mean HbA_{1c} and standard error plots from baseline to 12 months; shaded area represent ±2 standard errors

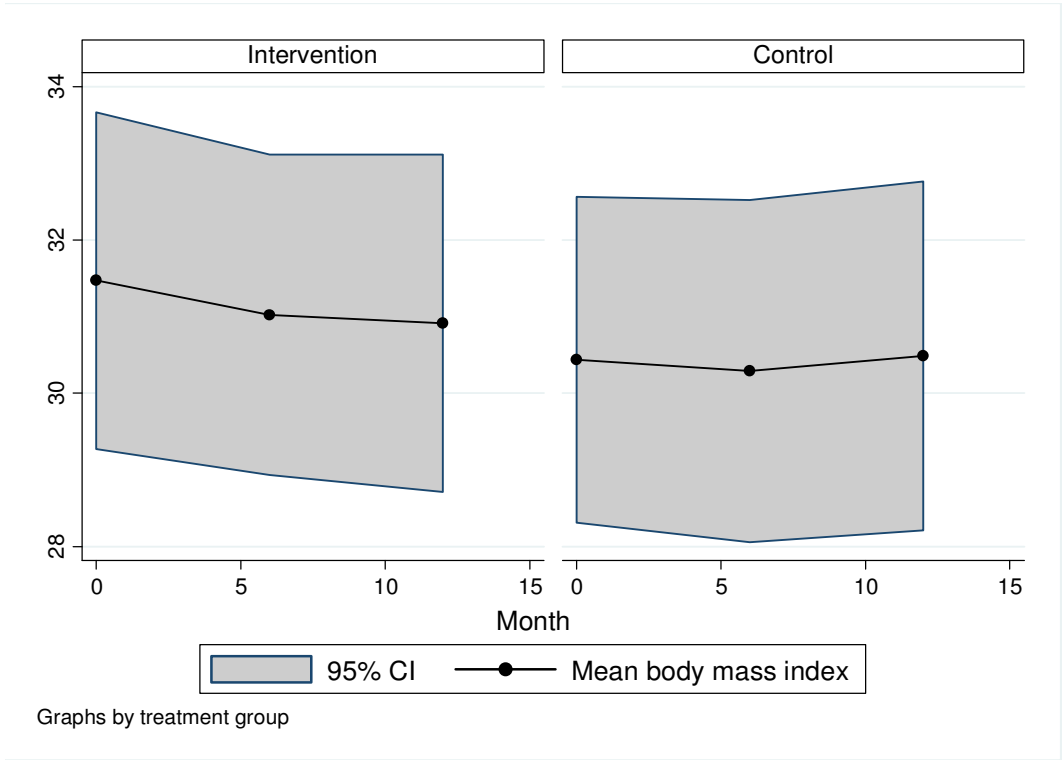

Figure 7.3: Mean body mass index and standard error plots from baseline to 12 months; shaded area represents ±2 standard errors

7.3.1.2 Dietary outcomes

7.3.1.2.1 Dietary intake and food related practices

The dietary outcomes in this section are based on the results of the three 24 hour recalls (chapter 6, section 6.4.3). Table 7.5 shows the baseline and post-intervention dietary outcomes for the intervention and control groups. Baseline dietary outcomes were similar apart from the median percentage energy from total fat and polyunsaturated fats which were significantly higher in the control group [18.5% (15.6, 23.7) vs. 16.4% (12.9, 20.9), p=0.044] and [5.8 % (4.5, 7.9) vs. 5.0 % (3.6, 5.7), p=0.038] respectively. Post-intervention, the control group had a significantly higher intake of starch (servings) at six months and 12 month (p=0.005 and p=0.017) respectively for the adjusted values. The proportion of participants undertaking vegetable gardening significantly increased in the intervention group at six months (p= 0.003) and 12 months (p=0.0006) compared with the control group.

The control group had a higher intake of energy, percentage energy from total fats and all the fatty acids at six and 12 months, but this was non-significant. The intervention group had a higher but non-significant intake of percentage energy from proteins in the two time periods. The control group had a lower intake of vegetables and fruits at six and 12 months, but this was not significant.

Figures 7.4, 7.5 and 7.6 show the trends in the median intake for energy, starch servings and vegetable and fruits servings respectively. The intakes for energy and starch declined up to six months and then slightly increased after six months in both groups up to 12 months. The decline was greater in the intervention group for the two outcomes. At 12 months the intervention group sustained lower values than baseline levels for energy and starch intake, while the control group sustained lower than the baseline values for energy only. The median intake of vegetables and fruits increased in both groups until six months, with the intervention group having a greater increase than the control group. After six months the intake of vegetables and fruits further increased in the intervention group though to a lesser extent than up to six months, while it declined in the control group.

Table 7.5: Dietary outcomes: differences between the intervention and control groups from baseline to post-intervention

Outcome	Baseline			Six months			Twelve months		
	Intervention Group (n = 41)	Control group (n = 41)	P[a] value	Intervention Group (n = 41)	Control group (n = 40)	P[b] value	Intervention Group (n = 38	Control Group (n = 38)	P[b] value
Energy (KJ/day)	7212.0[d] (6255.0-8306.0)	7187.0 (5395.0-8097.0)	0.71	5940.1 (5067.9-7000.5)	6506.4 (5546.8-7016.1)	0.11	5977.0 (5351.0-6801.0)	6998.0 (5492.0-8059.0)	0.055
Carbohydrate energy (%)	67.2 (64.6-72.2)	66.4 (62.3-70.7)	0.27	69.0 (63.2-72.9)	68.6 (64.5-71.1)	0.78	69.1 (63.9-74.6)	67.8 (64.5-69.8)	0.45
Added sugar energy (%)	2.2 (1.4- 4.8)	2.5 (0.5- 4.3)	0.45	1.6 (0.4- 2.8)	2.3 (0.6- 4.3)	0.22	2.3 (1.2- 3.6)	2.0 (0.8- 4.4)	0.80
Protein energy (%)	13.8 (12.9-15.8)	13.4 (12.2-15.3)	0.12	15.0 (13.8-16.4)	13.8 (12.6-16.1)	0.07	14.7 (13.3-16.4)	14.2 (12.5-16.3)	0.96
Fat energy (%)	16.4 (12.9-20.9)	18.5 (15.6-23.7)	0.044	16.0 (13.2-19.2)	17.2 (14.9-19.3)	0.96	16.4 (12.3-19.4)	17.9 (14.2-20.1)	0.33
Saturated fat energy (%)	4.3 (3.2- 6.1)	4.8 (3.7- 6.8)	0.37	4.3 (3.1-6.1)	4.8 (3.6- 6.0)	0.45	4.2 (2.6- 5.6)	4.5 (3.7- 6.6)	0.22
Polyunsaturated fat energy (%)	5.0 (3.6-5.7)	5.8 (4.3-7.9)	0.038	4.6 (3.7-6.4)	5.0 (4.0-6.3)	0.49	4.5 (3.7-6.0)	5.4 (4.3-7.4)	0.21
Monounsaturated fat energy (%)	5.3 (4- 6.3)	5.6 (4.6- 7.7)	0.24	4.6 (3.7- 5.8)	5.0 (4.2- 5.5)	0.82	4.3 (3.5- 6.4)	5.4 (4.1- 6.3)	0.18
Cholesterol (mg)	114.0 (73- 176)	86.0 (46- 161)	0.31	85.0 (50- 182)	71.5 (39.5- 127.0)	0.51	71.5 (36.0- 146.0)	85.5 (58.0-140.0)	0.39
Fibre (g)	20.0 (16.0-24.0)	22.0 (13.0-24.0)	0.87	18.0 (15.0-23.0)	19.5 (15.5-23.5)	0.72	21.0 (19.0-24.0)	20.0 (16.0-27.0)	0.39
Sodium (mg)	2258.0 (1828.0-2694.0)	2212.0 (1508.0-2831.0)	0.64	2301.1 (1825.3-1713.7)	2257.1 (1871.0-2706.0)	0.96	2334.2 (1840.7-2809.1)	2419.9 (1983.0-2827.0)	0.36
Vegetables & fruits (servings)	1.3 (0.7- 2.2)	1.5 (0.8- 2.0)	0.65	2.1 (1.5- 3.0)	1.8 (1.0- 2.9)	0.17	2.3 (0.97- 2.9)	1.7 (1.1- 1.3)	0.48
Starch (servings/std ½ cup)	12.3 (10.5-13.7)	11.8 (9.7-13.5)	0.54	9.3 (8.5-11.2)	10.8 (9.4-12.4)	0.005	9.9 (8.8-11.5)	11.9 (8.7-13.3)	0.017
Vegetable gardening Yes No	 8 (19.5)[e] 33 (80.5	 3 (7.3) 38 (92.7)	0.11[c]	 17(41.5) 24 (58.5)	 5(12.5) 38 (87.5)	0.003[c]	 16 (42.1) 22 (57.9)	 5(13.2) 33 (86.8)	0.005[c]

[a] Based on Mann-Whitney test [b] Based on rank ANCOVA [c] Based on Chi square test (Fischer's exact test for n<5)
[d] Median and interquartile range in parenthesis [e] Number (n) and percentage
std: standard
***NB* ; % energy from macronutrients at baseline do not add to 100% as some energy was contributed by alcohol**

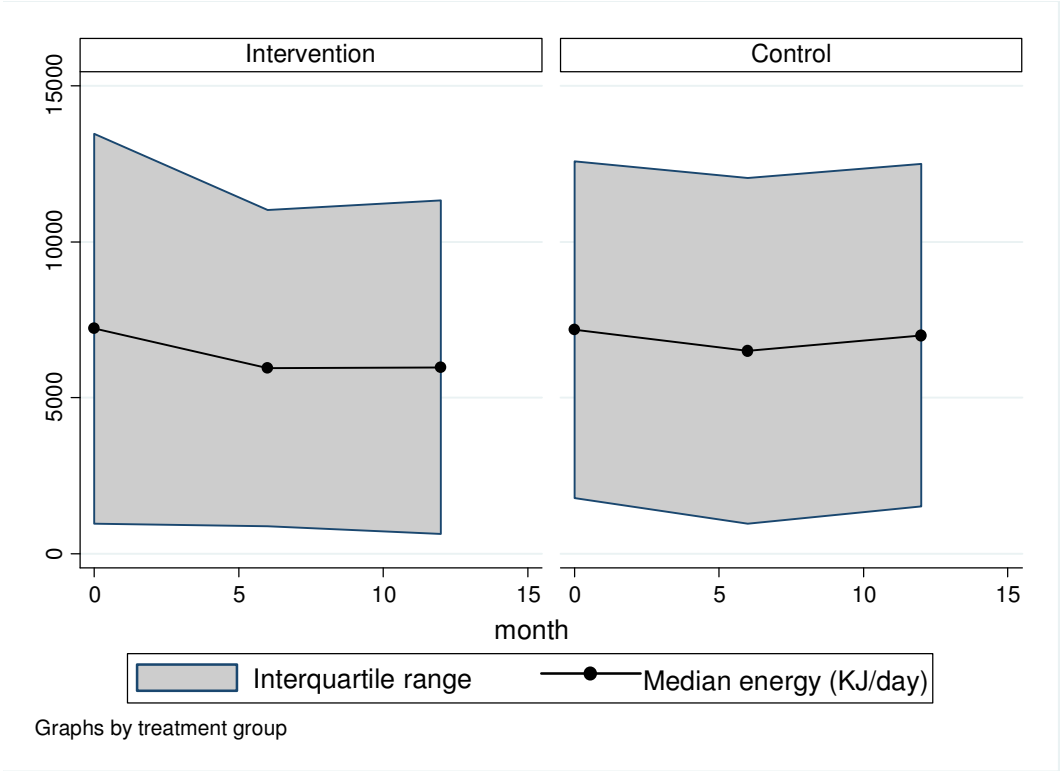

Figure 7.4: Median energy intake and the interquartile range from baseline to 12 months

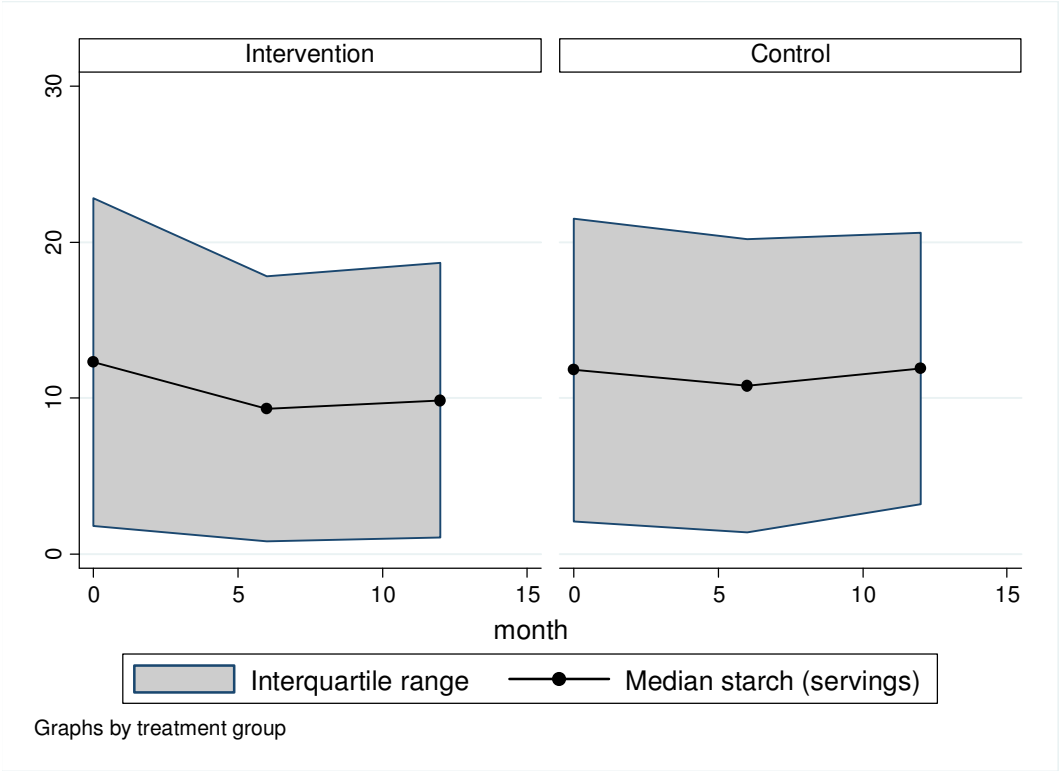

Figure 7.5: Median starch servings and the interquartile range from baseline to 12 months

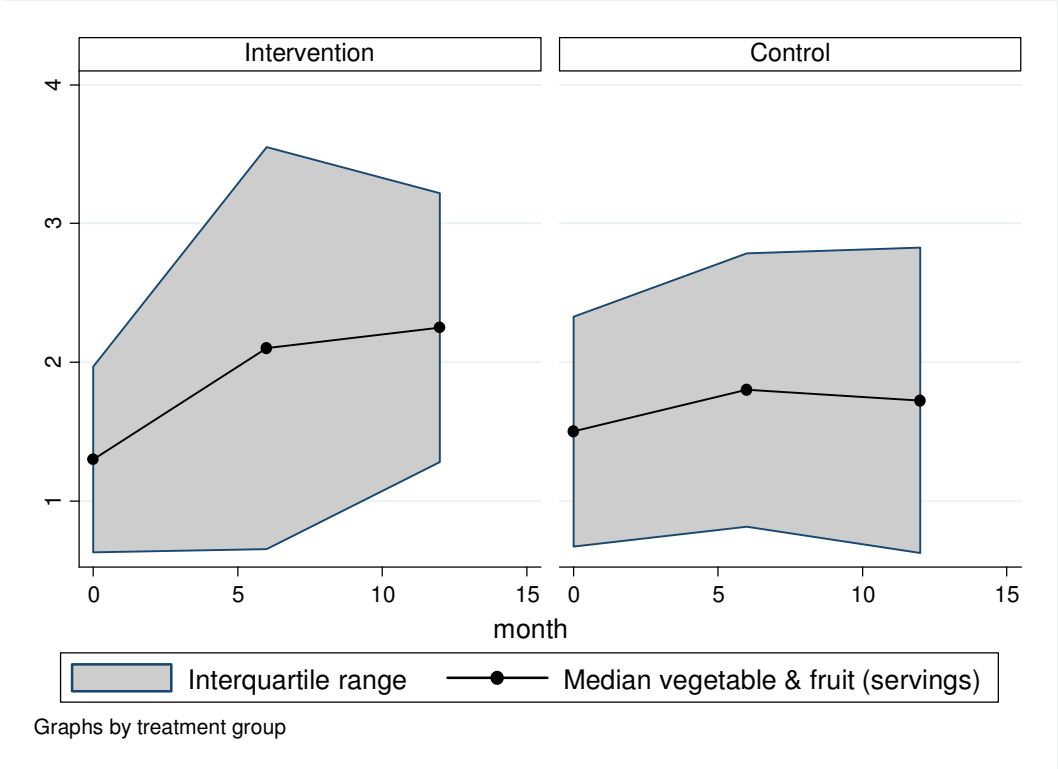

Figure 7.6: Median vegetable and fruit servings and the interquartile range from baseline to 12 months

7.3.1.2.1 Perceived dietary changes

Table 7.6 shows the comparisons for the participants' perceived dietary changes for the intervention and the control groups at six months and 12 months as assessed by the food change questionnaire. A significantly higher proportion of participants in the intervention group than the control group perceived themselves as having reduced the amount of margarine used on bread at the two time periods. A significantly higher proportion of participants in the intervention group perceived themselves as having decreased the intake of starchy foods at six months and increased consumption of legumes at 12 months. More participants' in both groups perceived themselves as having increased consumption of fruits (> 40% at 6 months and > 50% at 12 months). The majority (> 70%) of participants in both groups perceived themselves as having increased the intake of vegetables at 12 months.

The majority (>75%) in both groups perceived themselves as having reduced the intake of starchy foods at the two time periods. The majority of participants in both groups also perceived themselves as having reduced the intake of salt, sugar and fats as depicted by the various dietary practices. The findings on perceived dietary changes confirmed those obtained

through the 24 hour recalls for reductions in starchy food intake (servings/day) and increased consumption of vegetables and fruits in both groups. Starchy food intake decreased in both groups but only significantly in the intervention group. Vegetables and fruits intake increased in both groups but not significantly in either.

The result of a significantly higher proportion of intervention participants reporting increased consumption of legumes do not agree with the results obtained with the 24 hour recalls. The proportion that reported consuming legumes were not significantly different in the two groups (9 vs. 4 at six months, p=0.14) and (11 vs. 10 at 12 months, p=0.80) for the intervention and control groups respectively.

Table 7.6: Participants' perceived dietary changes at six and 12 months

Dietary change category	Six months			Twelve months		
	Intervention (n=41)	Control (n=40)	P value[a]	Intervention (n=36)	Control (n=36)	P value[a]
Fruit intake (amounts & frequency)			0.87			0.39
Increased	18 (43.9)	18 (45)		25 (65.8)[b]	22 (57.9)	
Decreased	9 (22.0)	7 (17.5)		6 (15.8)	4 (10.5)	
No change	14 (34.1)	15 (37.5)		7 (18.4)	12 (31.6)	
Vegetable intake (amounts & frequency)			0.34			0.90
Increased	27 (65.9)	20 (50)		28 (73.7)	27 (71.0)	
Decreased	1 (2.4)	2 (5)		2 (5.2)	3 (7.9)	
No change	13 (31.7)	18 (45)		8 (21.1)	8 (21.1)	
Starch intake (servings)			0.006			0.08
Decreased	40 (97.6)	31 (77.5)		38 (100)	35 (92.1)	
No change	1 (2.4)	9 (22.5)		0	3 (7.9)	
Sugar intake						
Sugar in tea			0.08			0.12
Decreased	30 (73.2)	20 (50)		33 (86.9)	27 (71.0)	
No change	4 (9.8)	10 (25)		0	3 (7.9)	
Do not use	7 (17.0)	10 (25)		5 (31.1)	8 (21.1)	
Sugary foods/drinks			0.06			0.14
Decreased	26 (63.4)	17 (42.5)		33 (86.9)	30 (79.0)	
No change	5 (5.2)	3 (7.5)		3 (7.9)	1 (2.6)	
Do not use	10 923.4)	20 (50)		2 (5.2)	7 (18.4)	
Salt intake						
Salt in cooking			0.43			0.88
Decreased	26 (63.4)	21 (52.5)		30 (79.0)	30 (79.0)	
No change	9 (22)	14 (35)		3 (7.9)	4 (10.5)	
Do not use	6 (14.6)	5 (12.5)		5 (13.1)	4 (10.5)	
Salt at table			0.81			0.62
Decreased	11 (26.8)	5 (12.5)		13 (34.2)	11 (28.9)	
No change	4 (9.8)	3 (7.5)		0	0	
Do not use	26 (63.4)	32 (78)		25 (65.8)	27 (71.1)	

Continued/…….

Table 7.6: Participants' perceived dietary changes at six and 12 months continued

Dietary change category	Six months			Twelve months		
	Intervention (n=41)	Control (n=40)	P value[a]	Intervention (n=36)	Control (n=36)	P value[a]
Fat intake						
Oil in cooking			0.29			0.53
Decreased	29 (70.7)	24 (60)		34 (89.5)	31 (81.6)	
No change	8 (9.5)	7 (17.5)		3 (7.9)	4 (10.5)	
Do not use	4 (9.8)	9 (22.5)		1 (2.6)	3 (7.9)	
Fatty foods consumption			0.43			0.49
Decreased	28 (68.3)	24 (60)		33 (86.9)	29 (76.3)	
No change	6 (14.6)	7 (17.5)		2 (5.2)	4 (10.5)	
Do not use	7 (17.1)	9 (22.5)		3(7.9)	5 (13.2)	
Margarine on bread			0.006			0.002
Decreased	30 (73.2)	17 (42.5)		30 (78.9)	20 (52.6)	
No change	2 (4.8)	11 (27.5)		0	10 (26.3)	
Do not use	9 (22)	12 (30)		8 (21.1)	8 (21.1)	
Removing skin from chicken before cooking			0.18			0.78
All the time	25 (61)	15 (37.5)		23 (60.5)	19 (50.0)	
Most times	5 (12.2)	5 (12.5)		3 (7.9)	3 (7.9)	
Sometimes	2 (4.8)	4 (10)		1 (2.6)	1 (2.6)	
Never	9 (22)	14 (35)		11 (29.0)	14 (36.9)	
Do not use	0	2 (5)		0	1 (2.6)	
Trimming visible fat in meat before cooking			0.60			0.39
All the time	22 (53.7)	17 (42.5)		27 (71.1)	19 (50.0)	
Most times (> 4 times/week)	9 (22)	7 (17.5)		5 (12.1)	8 (21.1)	
Sometimes (<3 times/week)	1 (2.4)	3 (7.5)		1 (2.6)	2 (5.2)	
Never	7 (17.1)	11 (27.5)		5 (13.2)	8 (21.1)	
Do not use	2 (4.8)	2 (5)		0	1 (2.6)	
Legumes intake			0.11			0.013
Increased	21 (51.2)	10 (25)		24 (63.2)	10 (26.3)	
Decreased	3 (7.3)	4 (10)		3(7.9)	7 (18.4)	
No change	16 (39)	25 (62.5)		10(26.3)	20 (52.6)	
Do not use	1 (2.4)	1 (2.5)		1(2.6)	1 (2.6)	
Variety in food choices			0.06			0.11
Increased	26 (64.4)	17 (42.5)		25 (65.8)	18 (21.1)	
No change	15 (36.6)	23 (57.5)		13 (34.2)	20 (52.6)	

[a] Based on chi squared, Fischer's exact if n<5
[b] n and percentage in brackets

7.3.1.3 Diabetes knowledge

Table 7.7 shows the baseline and post-intervention mean diabetes knowledge scores for unadjusted data for the intervention and control groups. The scores are out of a possible maximum of 15. There were no significant differences between the groups in mean diabetes knowledge scores at baseline. Post-intervention the intervention group had significantly higher scores than the control group at both six months [5.95±2.2 vs. 5.1±1.7, p=0.048, 95% CI 0.01 to 1.74] and 12 months [7.1±2.2 vs. 5.1±2.3, p=0.000, 95% CI 0.90 to 3.0] for the unadjusted data. After adjusting for age, gender, clinic and baseline values (Table 7.8) the

control group still had significantly lower mean scores at six months [(-0.95), p=0.033, 95% CI -1.82 to -0.08] and 12 months [(-2.22), p=0.000, 95% CI -3.2 to -1.3].

Table 7.8 shows the adjusted means and the effects of independent variables on the post-intervention diabetes knowledge scores. Gender and clinic did not have a significant influence on diabetes knowledge scores in any of the time periods. Baseline scores had a significant influence at 12 months [(+0.29), p=0.032, 95% CI 0.03 to 0.56], while age had a significant influence at 12 months [(-0.7), p=0.032, 95% CI -0.14 to -0.01].

Figure 7.7 shows the trend in the mean diabetes knowledge scores from baseline up to 12 months. The scores increased steadily in the intervention group up to 12 months while they declined in the control group up to six months and thereafter slightly increased up to 12 months. At 12 months the control group sustained lower scores than those at the baseline. The baseline and post-intervention mean diabetes knowledge scores were all below 50% (mean < 7.5) for both groups indicating poor knowledge of diabetes.

Table 7.9 shows the proportion of participants who obtained correct answers for specific questions per knowledge category. At baseline there were no significant group differences in participants who had correct responses for questions in each knowledge category. Post-intervention the intervention group had significantly more participants getting the correct answer for one item on “the sick day management related to insulin adjustments” at six months [65.9 % vs. 37.5%, p=0.011] and 12 months [52.6% vs. 28.9%, p=0.036] compared with the control group. The group also had significantly more participants getting the correct answer for the normal range of blood glucose [86.8% vs. 42.1%, p=0.000] and the item on general diabetes management [92.1% vs. 71.1%, p=0.000] at 12 months. The intervention group also had more participants obtaining correct responses for the majority of the questions in each knowledge category. The majority of participants (> 70%) in both groups got the item on general management of diabetes correct from baseline to post-intervention. Both groups performed very poorly with regard to the causes of hypoglycaemia, free foods and empty calorie foods throughout the study. Generally in both groups, correct responses were more in the food group knowledge category related to margarine and rice and the normal range of blood sugar. Both groups performed poorly on most items on the knowledge category of basic physiology including insulin action.

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Table 7.7: Diabetes knowledge scores: differences between the intervention and control groups from baseline to post-intervention

Outcome	**Baseline**				**Six months**				**Twelve months**			
	Intervention group (n = 41)	Control group (n = 41)	Difference in means (95% CI)	P value	Intervention group (n = 41)	Control group (n = 40)	Difference in means (95% CI)	P value	Intervention Group (n = 38	**Control Group** (n = 38)	Difference in means (95% CI)	P value
Diabetes knowledge scores	5.3±1.9	5.7±2.2	0.3 (-1.20- 0.62)	0.52	5.95±2.2	5.1±1.7	0.89 (0.01- 1.74)	0.048	7.1±2.2	5.1±2.3	1.95 (0.90- 3.0)	0.000

Table 7.8: Diabetes knowledge scores: adjusted means and effects of baseline values and independent variables on post-intervention outcomes[a]

Diabetes knowledge scores/ Time period	**Adjusted mean (SE)**		**Control vs. intervention**		**Baseline covariate**		**Age**		**Female vs. male**		**Clinic 2 vs. clinic 1**	
	Intervention	Control	Change (95% CI)	P value	Change (95% CI)	P value	Change (95% CI)	P value	Change (95% CI)	P value	Change (95% CI)	P value
Six months	6.0 (0.30)	5.0 (0.31)	-0.95 (-1.82- -0.08)	0.033	0.02 (-0.21- 0.25)	0.83	-0.06 (-0.12- 0.001)	0.058	0.58 (-0.72- 1.88)	0.37	0.04 (-0.88- 0.96)	0.93
12 months	7.2 (0.33)	5.0 (0.33)	-2.22 (-3.2- -1.3)	0.000	0.29 (0.03- 0.56)	0.032	-0.7 (-0.14- -0.01)	0.033	-0.40 (-1.8- 1.02)	0.58	-0.73 (-1.77- 0.30)	0.16

[a] Based on ANCOVA (adjusted for baseline, age, gender & clinic)
SE: standard error

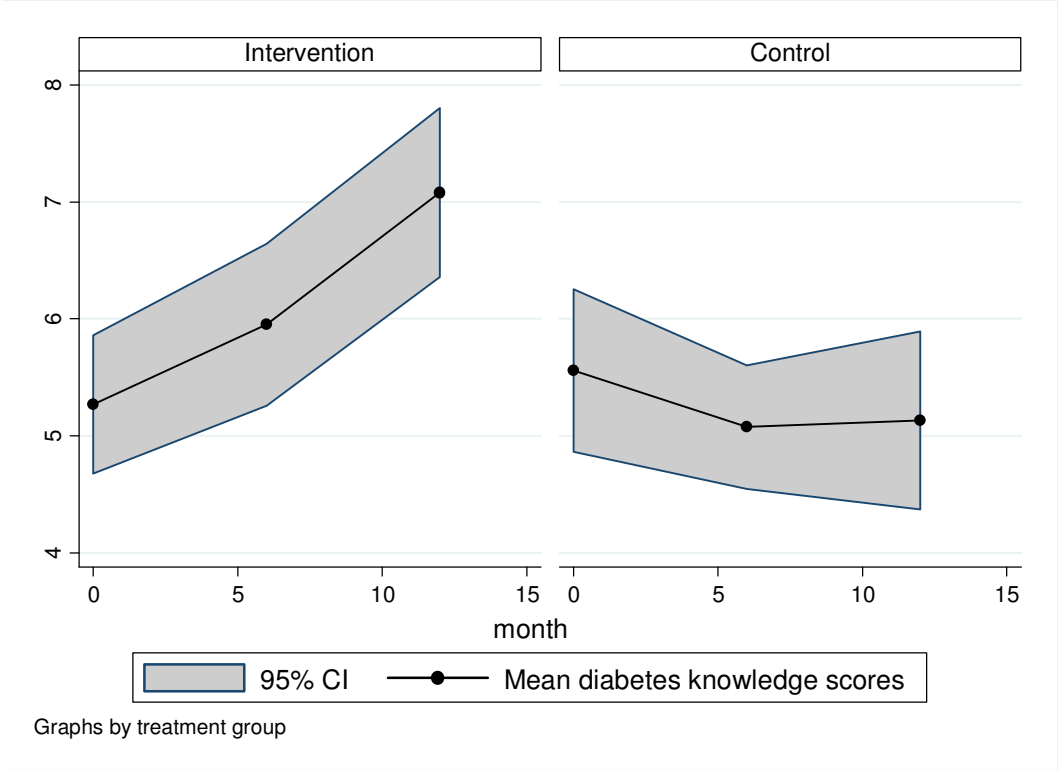

Figure 7.7: Mean diabetes knowledge scores and standard error plots from baseline to 12 months; shaded area represents ±2 standard errors

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Table 7.9: Correct responses for Diabetes Knowledge Form items per knowledge category by group from baseline to post-intervention

Category of knowledge	Baseline			6 months			12 months		
	Interv. (n=41)	Control (n=41	P value[a]	Interv. (n=41)	Control (n=40)	P Value[a]	Interv. (n=38)	Control (n=38)	P Value[a]
Basic physiology of diabetes including insulin action [n (%)]									
When glucose is detected in urine	26 (63.4)	22 (53.7)	0.37	15 (36.6)	11 (27.5)	0.38	25 (65.8)	18 (47.4)	0.11
Best food before prolonged exercise	23 (56.1)	22 (53.7)	0.87	22 (53.7)	18 (45)	0.59	16 (42.1)	18 (47.4)	0.44
High blood or urine sugar level and insulin adjustment	9 (22)	15 (36.6)	0.27	18 (43.9)	13 (32.5)	0.29	18 (47.4)	10 (26.3)	0.06
Why feet care in the elderly	15 (36.6)	16 (39)	0.8	15 (36.6)	17 (42.5)	0.59	15 (39.5)	14 (36.8)	0.8
Normal glycaemia & hypoglycaemia									
Normal range of blood glucose	19 (46.3)	23 (56.1)	0.38	26 (63.4)	21 (52.5)	0.33	33 (86.8)	16 (42.1)	0.000
Cause of hypoglycaemia	10 (24.4)	10 (24.4)	1	9 (22)	11 (27.5)	0.56	6 (15.8)	6 (15.8)	1
When hypoglycaemia is likely to occur	1 (2.4)	0	0.34	2 (4.9)	3 (7.5)	0.62	2 (5.3)	1 (2.6)	0.56
Food group & substitutions									
Margarine	23 (56.1)	23 (56.1)	1	25 (58.5)	22 (55)	0.59	26 (68.4)	22 (57.9)	0.34
Rice	11 (26.8)	13 (31.7)	0.63	24 (58.5)	21 (52.5)	0.48	24 (63.2)	16 (42.1)	0.1
Egg substitution	13 (31.7)	10 (24.4)	0.46	23 (56.1)	16 (40)	0.11	18 (47.4)	17 (44.7)	0.9
Free foods	0	0	1	2 (4.9)	0	0.16	1 (2.6)	2 (5.3)	0.56
Empty calorie /Kilo joule foods	2 (4.9)	3 (7.3)	0.64	5 (12.2)	1 (2.5)	0.09	6 (15.8)	2 (5.3)	0.15
Sick day management									
Insulin adjustment during illness	17 (41.5)	18 (43.9)	0.82	27 (65.9)	15 (37.5)	0.011	20 (52.6)	11 (28.9)	0.036
Illness, poor dietary intake and use of insulin	12 (29.3)	13 (31.7)	0.80	8 (19.5)	5 (12.5)	0.39	15 (39.5)	9 (23.7)	0.14
General diabetes management [n (%)]									
Key to control of DM	37 (90.2)	37 (90.2)	1	36 (87.8)	30 (75)	0.14	35 (92.1)	27 (71.1)	0.000

[a] Based on chi-squared test or Fischer's exact if n<5

Interv. : Intervention

7.3.1.4 Attitudes towards diabetes and its treatment

Table 7.10 shows the mean baseline and post-intervention scores for the attitudes towards diabetes and its treatment for each sub-scale and the Cronbach's alpha (baseline). Out of a total of 33 items, seven that did not contribute to the sub-scales internal consistency were excluded from the analysis. The alpha values ranged from 0.46 to 0.72, with the highest being for the need for special training and the lowest for the psychosocial impact of diabetes. The sub-scales scores which were out of a maximum of five were similar in both groups at baseline.

At baseline the scores for the need for special training, the psychosocial impact of diabetes and patient autonomy sub-scales placed participants in both groups in the positive attitude category (>3), but more weakly for patient autonomy. Scores for the value of tight glucose control were below three (3) in both groups placing participants in the negative attitude category. Scores for the seriousness of diabetes placed the control group in a neutral position and the intervention group in the negative attitude, but closer to the neutral category. Post-intervention only scores for patient autonomy at 12 months were significantly higher in the intervention group (p=0.016), but this did not change the attitude classification and the score was lower than baseline value. There were no changes in the attitudes classification for either group from baseline to post-intervention in most sub-scales (four). Only in the sub-scale on the seriousness of type 2 diabetes there were minor shifts from negative to neutral or close to neutral or vice versa.

Table 7.10: Attitudes toward diabetes and its treatment: differences between the groups from baseline to post-intervention

Sub-scale	Scale characteristics		Baseline				Six months				Twelve months			
	Number of items	Cronbach's alpha	Interv. group (n = 41)	Control group (n = 41)	Difference in means (95% CI)	P Value	Interv. Group (n = 41)	Control group (n = 40)	Difference in adjusted means (95% CI)	P[a] value	Interv. Group (n = 38	Control Group (n = 38)	Difference in adjusted means (95% CI)	P[a] value
Need for special training	5	0.72	4.7±0.41[b]	4.6±0.46	0.04 (-0.15-0.23)	0.69	4.6 (0.07)[c]	4.5 (0.07)	0.01 (-0.23-0.18)	0.82	4.6 (0.08)	4.5 (0.06)	0.16 (0.001-0.38)	0.09
Seriousness of type 2 diabetes	6	0.53	2.9±0.61	3.1±0.59	0.21 (-0.47-0.05)	0.12	3.0 (0.09)	2.8 (0.09)	0.19 (-0.45-0.09)	0.19	3.0 (0.1)	3.3 (0.1)	0.25 (-0.4- -0.55)	0.09
Value of tight control	5	0.57	2.3±0.89	2.6±0.83	0.24 (-0.53-0.23)	0.43	2.6 (0.1)	2.5 (0.1)	0.12 (-0.41-0.17)	0.41	2.6 (0.12)	2.4 (0.12)	0.17 (-0.52-0.17)	0.33
Psychosocial impact of diabetes	4	0.46	4.4±0.71	4.4±0.63	0.01 (-0.28-0.31)	0.87	4.2 (0.09)	4.3 (0.09)	0.05 (-0.21-0.32)	0.6 9	4.3 (0.08)	4.4 (0.08)	0.08 (-0.15-0.31)	0.48
Patient autonomy	6	0.53	3.6±0.51	3.5±0.50	0.14 (-0.07-0.35)	0.19	3.4 (0.07)	3.5 (0.07)	0.08 (-0.13-0.29)	0.48	3.5 (0.08)	3.2 (0.08)	0.27 (-0.48- -0.05)	0.016
Total items	26													

[a] Based on analysis of covariance
[b] Mean ±SD and in all such values
[c] Adjusted mean plus standard error and all such values
Interv.: Intervention

Scores: a mean score of > 3 indicates a positive attitude; < 3 negative attitude; = 3 neutral

7.3.2 Outcomes: differences within the intervention and control groups from baseline to six and 12 months

Table 7.11 shows the outcomes with significant changes within both groups at six months or 12 months or significant changes within one group in the two time periods. Significant reduction in both the intervention and control groups from baseline to six months was demonstrated for HbA_{1c}, systolic blood pressure, diastolic blood pressure, total blood cholesterol and LDL-cholesterol. The decline in HbA_{1c} levels for the intervention group was still significant at 12 months. There was a significant decrease in reported mean energy intake at six months in both groups with the decrease being still significant at 12 months for the intervention group. Vegetable and fruits intake significantly increased in both groups at six months and 12 months. The intervention group had a significant decrease in the mean intake of starch (servings) at the two time periods. The two groups significantly deteriorated in mean triglyceride levels at 12 months (p=0.03) for the intervention group and (p=0.01) for the control group.

Other outcomes with significant changes at six or 12 months in either the intervention or control group (data not presented in table 7.11) included the following: the intervention group had significant improvements in diabetes knowledge scores at 12 months [5.2 ±1.9 to 7.1 ± 2.2) (p=0.000) versus (5.5 ± 2.1 to 5.2 ± 2.2) (p=0.29)] for the control group and BMI [31.5 ±7.0 to 31.0 ± 7.1 (p=0.038)] versus [30.3 ± 6.9 to 30.29 ± 7.1 (p=0.80)] for the control at six months. The control group had a significant decrease in reported cholesterol intake [86 (46-161)] to [71.5 (39.5-127)]mg (p=0.03) versus [114 (73-176)] to [85 (50-182)] mg, (p=0.48) for the intervention group and percent energy from fat [19.7 (6.2) to 17.5 (5.7)] (p= 0.04) versus [17.1 (6.6) to 16.9 (4.6)], p=0.23 for the intervention group) at six months.

Table 7.11: **Changes within the intervention and control groups from baseline to six and 12 months**

Variable	Group	N in the various time periods			Mean± SD			Mean/median change		P-value	
		Base-line	6 mo	12 mo	Baseline	6 mo	12 mo	6 mo	12 mo	6 mo	12 mo
HbA_{1c} (%)	Intervention	41	41	38	10.9 ±1.9	9.4± 2.3	9.6 ± .2	-1.4	-1.3	0.000*	0.000*
	Control	41	41	38	11.4 ±2.2	10.6 ±2.5	10.6 ±2.5	-0.9	-0.81	0.01***	0.06
Systolic BP (mm Hg)	Intervention	41	41	38	142.9 ± 22.9	134 ± 23.1	141.2 ± 22.6	-8.9	-0.4	0.01**	0.91
	Control	41	40	41	143.3± 28	130 ± 25.0	141.2 ± 28.3	-13.3	-0.7	0.000*	0.80
Diastolic BP (mm Hg)	Intervention	41	41	40	84.3 ±11.7	78.9 ±11.4	80.1 ± 11.8	-5.4	-3.7	0.01***	0.05
	Control	41	41	40	84.6 ± 6.5	78.9 ±11.3	82.6 ± 13.0	-5.7	-1.7	0.000*	0.29
Total blood cholesterol (mmol/L)	Intervention	41	41	38	4.8 ± 1.2	4.3 ± 0.9	4.7 ± 0.9	-0.5	-0.1	0.002**	0.58
	Control	41	40	38	4.9 ± 0.9	4.3 ± 0.9	4.9 ± 0.9	-0.35	-0.02	0.000*	0.85
LDL-cholesterol (mmol/L	Intervention	41	41	38	3.0 ± 0.9	2.6 ± 0.7	2.96±0.9	-0.15	-0.37	0.000*	0.14
	Contr.	41	40	38	3.1 ± 0.9	2.8 ± 0.8	3.0±0.8	-0.1	-0.35	0.000*	0.40
Triglycerides (mmol/L)	Intervention	41	41	38	1.3 (1-1.9)[a]	1.3 (0.8-2.2)	1.45 (1.1-2.2)	0	+0.15	0.54	0.02***
	Control	41		38	1.4 (1-1.9)	1.4 (1-1.9)	1.5 (1.3-2.4)	0	+0.2	0.22	0.01***
Dietary intake											
Energy (KJ/day)	Intervention	41	41	38	7212.0[a] (6255.0-8306.0)	5940.1 (5067.9-7000.5)	5977.0 (5351.0-6801.0)	-1123.0	-999.0	0.000*	0.000*
	Control	41	40	38	7187.0 (5395.0-8097.0)	6506.4 (5546.8-7016.1)	6998.0 (5492.0-8059.0)	-2147.0	-381.8	0.000*	0.17
Starch servings (per std ½ cup)	Intervention	41	41	38	12.3 (10.5-13.7)	9.3 (8.5-11.2)	9.9 (8.8-11.5)	-2.5	-2.3	0.000*	0.000*
	Control	41	40	38	11.8 (9.7-13.5)	10.8 (9.4-12.4)	11.9 (8.7-13.3)	-0.82	-0.84	0.07	0.3
Vegetables & fruits servings (per std ½ cup)	Intervention	41	41	38	1.3 (0.7- 2.2)	2.1 (1.5- 3.0)	2.3 (0.97- 2.9)	+0.7	+1.0	0.002**	0.000*
	Control	41	40	38	1.5 (0.8- 2.0)	1.8 (1.0- 2.9)	1.7 (1.1- 3.0)	+0.3	+0.2	0.043**	0.002**

[a] Median and interquartile range in parenthesis mo: months

* p<0.0001 ** p<0.0003 *** p< 0.05

7.4 NUTRITION EDUCATION PROGRAMME PROCESS EVALUATION

7.4.1 Programme participation rates

Table 7.12 shows the NE sessions' attendance rates for the weekly, monthly and bi-monthly sessions for the entire programme. The average meetings attendance through the whole programme was above 80%. Bi-monthly meetings had the highest attendance rates. For the weekly meetings, adherence was considered as an attendance of six or more sessions out of eight. This was achieved by the majority of the participants (80%). Out of this proportion, 39% attended all sessions.

Table 7.12: **Nutrition education programme attendance rates**

Meeting	**Attendance rate (%)**
Weekly	84.5
Monthly meetings	83.3
Bi-monthly meetings	87.7
Attendance of all weekly sessions	39.0
Attendance of ≥ 6 weekly sessions	80.5

The study participant retention rate (intervention and control groups) was 98.8% at six months and 92.7% at 12 months. Overall the study attrition rate was 7.3%.

7.4.2 Programme delivery

Table 7.13 presents the summary of the results for the programme delivery as compared with the planned programme. All the meetings were held at the clinics as planned. All the eight weekly meetings were held as scheduled. For the monthly meetings, two of the groups had three meetings instead of four as one their scheduled meeting times fell in the festive month (after 15th December) and the majority of participants were not available, therefore the meeting was cancelled. All bi-monthly meetings took place as planned.

Approximately 80% of the planned activities were done as had been planned. Vegetable gardening demonstration (sowing and transplanting) and individual goal setting were the main activities that were not executed as planned. The vegetable gardening demonstration was only done in one group. The other four groups only viewed vegetable gardens at the CHCs. Only

one session with family members attending was held out of the three initially planned. The reduction in the number of meetings was due to inadequate space for meeting in one of the clinics. A large room initially allocated for the NE sessions was no longer available.

The sub-district dietitian only facilitated 25% of the NE sessions as opposed to the 100% initially planned. Of the remaining proportion, the majority (65%) of the NE sessions were facilitated by the appointed field worker (a final year nutrition and food science university student) and the remainder (10%) by the researcher. The use of the local language as the sole medium for the NE sessions' facilitation was achieved for the majority (90%) of the sessions (sessions by dietitian and field worker). The remaining proportions of the sessions were facilitated in English accompanied by the local language translation (researcher).

Table 7.13: Comparison of planned programme and actual implementation

Activity/item	Planned	Implemented proportion (%)	Reasons for not achieving target
Curriculum sessions	8 sessions (bi-weekly)	100	Target achieved, but sessions implemented on a weekly basis to avoid prolonging time in the field due to slow recruitments
Monthly meeting	20 (4 x 5 groups)	90	Two groups missed one session. Session cancelled as most participants were not available as meeting time fell in the festive season (December)
Bi-monthly meetings	10 (2 x 5 groups)	100	-
Vegetable gardening demonstration	10 (2 x 5 groups)	6.7	Planned facilitator (Department of Agriculture) not able to participate due to other work related commitments
Monthly topics (8/8)	7/8	87.5	Vegetable gardening not done as planned
Goal setting (Individual & group)	6 sessions in the weekly meetings	66.7	Individual goal setting proved a challenge to participants due to low literacy levels; therefore goals were discussed in group format and individuals encouraged personal implementation

Continued/……

Table 7.13: Comparison of planned programme and actual implementation continued

Activity/item	Planned	Implemented proportion (%)	Reasons for not achieving target
Attendance of family members	15 (3 sessions x 5 groups) 50% participants to bring family (approximately n=20)	33.3 55% of anticipated (11/20)	Inadequate meeting space in one of the clinics, therefore one meeting per group was done Unavailability of family members was reported as the contributing factor
Facilitator	Sub-district dietitian assisted by a community health worker (CHW)	25	Conflicting work demand as there is only sub-district dietitian No suitable CHW could be identified, therefore a university student from the study site was used (appointed as a field worker)
Language of facilitation	Local language	90	Due to unavailability of the dietitian and research assistant in some occasions, the researcher had to facilitate some sessions in English with local language translations
Teaching tools and materials	Flip charts, handouts, raw and cooked foods, empty food containers	100	-

7.2.4.3 Participants' evaluation of the nutrition education programme

Thirty one (individually) and 35 (in five groups) intervention group patients participated in the NE programme process evaluation at eight weeks and 12 months respectively.

Table 7.14 presents the summary of the eight week NE programme evaluation results. All participants indicated they enjoyed the programme very much and were satisfied with the education sessions. They also reported they had learnt something new in response to the question "name one or two things you have learnt from the education sessions". Three participants indicated that the education they received had a positive influence on their blood glucose control, while two suggested that the education be extended to others. In response to the suggestions for topics that could be discussed during the monthly meetings (follow-up sessions), the majority (21/31) indicated that the topics that had been covered during the curriculum (eight weeks) be taught again. Some recommended that all the topics be repeated while others gave specific topics. In the specific topic category, lessons on diabetes including

insulin and food portion sizes were the most cited. Only one participant mentioned the inclusion of a new topic.

Table 7.14: **Summary of participants' nutrition education programme evaluation at eight weeks**

Theme	Sub-theme	Ethnographic description
Programme satisfaction	Enjoyment Liked/not liked	*"Enjoyed very much"* *"Liked everything"*
Knowledge gained	New information	*"I have learnt potatoes and sweet potatoes are starchy foods"* *"I have learnt how much to dish up"* *"I did not know rice is starch"* *"I have learnt I should use less sugar, salt and fats"* *"I have learnt about diabetes and its dangers and how to correct them with food"* *"I have learnt the importance of eating vegetables"* *"I have learnt how to cook lentils"* *"Removing fat from meat before cooking"*
Experience of the weekly sessions	Valuable/ Positive experience	*"I am very happy about what we have learnt, I wish others with diabetes can have the same education"* *"Empowered, I wish lessons could be extended to others"* *"I am satisfied with the lessons; I am so happy my sugar levels have gone down"* *"I am happy, I even saw the benefits, my sugar is now 6 to 8"*
Recommendations for monthly meetings	Content/activities	*"We must repeat all the lessons"* *"Lessons should be repeated so that we may refresh and not forget"* *"We wish to learn more about diabetes, especially on dangers and insulin"* *"Session about amount of food to eat"* *"We could also discuss more about hypertension"*

Table 7.15 shows the results of NE programme evaluation at 12 months. All groups reported they enjoyed the programme and were satisfied with its content and delivery. They also indicated the programme had a positive effect on their overall health and had improved family support. All the groups indicated they had gained some knowledge and also made positive dietary and related behaviour changes as a result of participating in the programme. Some participants felt empowered to share their knowledge with others.

In regard to specific aspects of the programme, the group format was viewed positively as participants could learn from one another, work together and share problems. The numbers of meetings attended were deemed adequate by all the groups except one participant in one group who felt the meetings were not enough. All groups also indicated the timing and duration of the meetings were appropriate as they could do other things after the meetings. Education materials used during the group meetings were viewed useful, easy to follow and informative by all groups. The materials given as handouts were seen as valuable resources for the participants and their families.

Participants in all groups gave a number of reasons for participating in the NE programme to its completion. These include the positive experience in the programme, including the treatment by the facilitators, the benefits accrued and the quest for information about their condition. Some also pointed that reimbursement of transport cost made it easy for them to attend the meetings. All groups indicated they had never attended any other diabetes education programme.

Participants recommended that the same programme be offered to other people with diabetes without change of duration or content. They however recommended that the pamphlet be available in both English and the local language (as for the fridge/wall poster) and the attendance for family members be open and not restricted to a specific session.

Table 7.15: Summary of participants' nutrition education programme evaluation at 12 months

Theme	Sub-theme	Ethnographic descriptions
Programme satisfaction	Enjoyed/liked/did not like	*"We enjoyed everything; you treated us with respect and showed you really care"* *"Very happy with the programme; we are sad it is ending"* *"To me the programme gave me light, I never used to know if I eat too much it is a problem"*
Impact of the NE programme	Well being/health	*" I now feel healthy and look better"* *"High blood and urinating frequently has decreased, I also can sleep the whole night without feeling hungry, I used to wake and eat at night"* *"I now do not live with fear of death because I know I can control diabetes"* *"My sugar used to be 18, nowadays it is less than 10, today it was 8.5 "* *"Blood sugar has reduced, for two months now my sugar is between 4 to 8"* *" Used not to see properly, but now I see, the change in the food I eat has really helped"*
	Changes made	*"I used to eat a lot of fat, but now I use less and remove fat from meat and skin from chicken"* *"I did not like eating beans and cucumbers but now I eat lots of them"* *"I eat more fruits and vegetables, I boil rather than fry foods"* *"I used to eat without caring, I eat better now"* *"I drink lots of water and opt for less sugary foods"* *"We exercise more"*
	Knowledge/skills gained	*" I now know which levels our blood sugar should be, 4 to 8 and not more or less"* *"The importance of monitoring sugar and keeping it under control"* *"I never knew that we should remove fat from meat nor not to cook with too much oil"* *"Now I am able to read food labels"* *"Now we know which fats/oils to buy and how much to use"* *"It is no use taking pills only, you need to eat healthily also"* *"To eat more vegetables than starch"*
	Other effects	*"Family has been supportive; this has helped me to be faithful to the treatment"* *"Now the whole family eats the same"* *"Now I can even teach others"*
Programme delivery	Meetings number & frequency	*"They were right, we were looking forward to the meetings"* *"They were adequate; not too few nor too many"* *"They were not enough"*

Continued/……..

Table 7.15: Summary of participants' nutrition education programme evaluation at 12 months continued

Theme	Sub-theme	Ethnographic descriptions
Programme delivery	Meetings time & duration	*"Just right we never took more than two hours, I had time to do other things after the meeting"* *"We could get our treatment the same day"* *"Time was fine, it should not be too much"* *"We never got bored or impatient"*
	Group format	*"We enjoyed working in a group, everybody was very supportive"* *"We learnt from others things we did not know"* *"We reminded each other because we are not the same, some of us are slow to learn"* *"We shared problems"* *"I realised I am not alone, I met others living with diabetes, since joining the group I accepted my condition"*
	Teaching aids/materials -Flip chart -Fridge/wall poster & pamphlet	*"Very helpful and informative"* *"Very clear and easy to follow as they were explained"* *"Set as a reminder, I often refer to the poster"* *"Helpful not only for ourselves, but for the whole family including children"*
	Food displays Food containers	*"The examples explained more"* *"It was helpful to see rather than being told only"*
Recommendations for future programmes	Changes/additions General recommendations	*" No need for change, you should do as you did for us"* *"You can have the family attendance open, not only one day so that family members can come when they are available"* *"Pamphlets should also be in both languages because not everyone understands English"* *"Please also do this to others; many people with diabetes need such programmes"* *"We feel the programme should continue, if not here somewhere else to help others with diabetes"*
Persistent programme participation	Reasons/motivation	*"The changes we saw, I saw a lot of improvement in my health"* *"Needed more information about diabetes"* *"Educative lessons"* *"I was sick and wanted to find more about my condition"* *"We enjoyed, we were looking forward to the meetings"* *" I did not worry about transport"* *"The way you treated us, you were kind and respectful"*
Prior attendance of diabetes education programme	-	*"No, this is the first one"* *"We never had such lessons before"* *"Previously they used to give a specific day for diabetes at the clinic, the nurses would give us a brief message about diabetes (not longer than 15 minutes)"*

CHAPTER 8

DISCUSSION ON PHASE 3

8.1 INTRODUCTION

Phase 3 aimed at evaluating the effects of a tailored NE programme on glycaemic control as assessed by HbA_{1c} and other specific outcomes (BMI, blood pressure, lipid levels, dietary behaviours, diabetes knowledge and attitudes towards diabetes and its treatment). The study hypothesised that the NE programme would lead to significantly better outcomes in the intervention group at six months and these improved outcomes would be sustained at 12 months.

The discussion is done in the following order:

- Outcomes
    - Clinical
    - Dietary behaviours
    - Diabetes knowledge
    - Attitudes toward diabetes and its treatment
- Process evaluation
- Strengths and limitation of the phase
- Conclusion
- Recommendations.

8.2 OUTCOMES

8.2.1 Clinical outcomes

The first hypothesis related to HbA_{1c} as the primary outcome was that the intervention group would have significantly lower levels than the control group at six months and sustain significantly lower levels at 12 months. The results refute this. HbA_{1c} levels were lower in the intervention group but not significantly lower than in the control group [-0.64% (p=0.15; CI -0.22 to 1.5) at six months and -0.67% (p=0.16; CI -0.27 to 1.6) at 12 months] (Table 7.4).

The non-significant differences in changes in HbA_{1c} results are in agreement with some other studies.[30,31,32] In contrast, other studies have reported significant improvements in HbA_{1c} levels. A study by Miller et al consisting of ten weekly group sessions offered by the same

dietitian found significant differences in HbA_{1c} ($p<0.01$) with older well educated diabetic adults at the end of the intervention.[33] However, in that study no education materials were provided to the control group.[33] Shabbidar et al demonstrated a significant decrease in HbA_{1c} of 1.9±2.1% in the experimental group ($p=0.022$) compared with 0.2% ±2.2 in the control group. The intervention consisted of eleven weekly sessions facilitated by a dietitian.[34] Deakin et al in the diabetes X-PERT programme consisting of six weekly-two hour sessions, found significant differences in HbA_{1c} ($p<0.0001$) at 14 months. This programme was developed and offered by a research dietitian.[35] In another study, Brown et al reported significant improvements in glycaemic control at 12 months ($p= 0.011$) in diabetic patients in a resource limited setting.[36] The study was facilitated by a team of bilingual health professionals (dietitians and nurses) and community health workers. The programme had a total of 52 contact hours and in addition, intervention participants were given educational materials and home glucose monitors. The study was wholly facilitated in the participants' preferred language.[36] However, this study did not monitor changes in diabetes medication. The effects of the medication could therefore have been a confounding factor.

In the above cited significant studies, it is notable that they were all facilitated by a dietitian or with the dietitian as part of the team, even though two of the non-significant ones were facilitated by dietitians. In the current study, the majority of the sessions were facilitated by a final year student not fully in the field of nutrition or dietetics (but in nutrition and food science). The reasons for this were that the sub-district dietitian was not fully available due to conflict in work demands. The researcher is not conversant with the local language and the NE was planned to be culturally appropriate. The facilitation of the NE by the student and not a registered dietitian might have impacted on its delivery, even though every effort was made to ensure delivery as intended. Given the complexity of behaviour change, and that dietary self-care is cited as the most difficult,[37,38] it might be that in this study population who indicated they had not participated in any diabetes specific education before, the role of a dietitian would be crucial. NE offered by a registered dietitian (RD) or where the RD is part of a team compared with a non RD has been shown to significantly improve glycaemic control.[39] In one study where nutrition students (master's level) were used, significant improvement in HbA_{1c} was observed.[40]

Factors that could have resulted in improvements in HbA_{1C} in the control group and hence diluted the NE effects on HbA_{1c} include the following: the two stage recruitment process

which first screened for HbA_{1c} made participants aware that inclusion would be based on higher values of this parameter. The process was necessary as routine HbA_{1c} assessment was not done at the CHCs. The participants also wanted feedback on their laboratory results at baseline and at six months and this information was provided. The fact that they knew their blood glucose was not well controlled and they were participating in a study could have motivated them to make changes based on the information on the education materials they received; the so-called Hawthorn effect. In addition, an increase in glucose lowering medication (dosage and number), though non-significant was higher in the control group.

The other hypothesis related to the HbA_{1c} was the third hypothesis (chapter 6, section 6.2.3.4). This hypothesis stated that the NE would result in significantly more participants in the intervention group than in the control group achieving the target for HbA_{1C} levels (<7%) at six months and 12 months. The findings did not support this hypothesis (Table 7.2). There were more participants in the intervention group who achieved HbA_{1C} target but this was non-significant. The non-significant result is unexpected because the importance of good glycaemic control was greatly emphasised. In addition, participants were given opportunities to discuss their monthly blood glucose results that they obtained from the CHCs. Also, more intervention group participants post-intervention answered the question on "the normal range for blood glucose" of the diabetes knowledge questionnaire correctly indicating more awareness of the blood glucose targets. Berikai et al demonstrated that gain in knowledge of diabetes care targets was associated with achieving the targets for HbA_{1c}.[41] In this study however, knowledge of the blood glucose targets seems not to have effected adequate behaviour change to allow achievement of HbA_{1c} targets. No studies on NE were available for comparisons of the proportion of participants achieving glycaemic targets.

Overall, the NE reduced HbA_{1c} levels by 0.62% at six months and 0.67% at 12 months. This reduction is comparable with other studies. Deakin et al reported a reduction of 0.6% at 14 months in the intervention group.[354] In uncontrolled diet studies, both Leibbrandt et al[42] and Bastiaens et al[43] reported a 0.6% decline in HbA_{1c} at 12 months. The reduction in this study is higher than the net reduction of 0.26% expected at six months in the meta-analysis by Norris et al.[44] Other studies have also reported lower declines in HbA_{1c}: Anderson-Loftin et al[45] reported a group difference of 0.2% at six months while Brown et al[36] reported a 0.39% group difference at 12 months. The reduction in HbA_{1c} levels in this study was however lower than that reported for medical nutrition therapy (MNT) offered by RDs of 0.9% in type 2 diabetes

with an average diabetes duration of four years.[46,47] Although, the average diabetes duration in this study was higher than that reported for the MNT studies, the lower reduction of the HbA_{1c} could probably partly be explained as stated earlier by the fact that the NE was not fully delivered by a RD. Despite the reduction in HbA_{1c} not being statistically significant, it may be of clinical importance in reducing the risk of diabetes related complications. According to the United Kingdom Prospective Diabetes Study (UKPDS)[48] a 1% decrease in A1C resulted in a reduction of 37% for microvascular complications and 21% for deaths related to diabetes. If risk reduction is proportional to HbA_{1c} reduction, then based on the UKPDS, this study would reduce the risk for microvascular complications by 25% and deaths by 14%.

For the other clinical outcomes, the second hypothesis related to secondary outcomes applies (chapter 6, section 6.2.3.2). It was hypothesised that the clinical outcomes for the intervention group would be significantly better at six months than those of the control group, and the improved outcomes would be sustained at 12 months. The findings did not support this hypothesis (Table 7.4). However, the NE programme had positive effects on some clinical outcomes including BMI, total cholesterol, LDL cholesterol and triglycerides.

The BMI decreased more in the intervention group and the group sustained a lower mean BMI than the baseline value at the end of the study. In contrast, the control group sustained baseline levels at the end of the study after an initial decline. The greater reduction in BMI in the intervention group could be explained by a greater reported reduction in energy intake in the group. Though the BMI changes were non-significant, the study achieved some beneficial effects with regard to weight loss, given that some lifestyle studies have reported an increase in weight.[49] In addition, even though the weight loss in both groups was below 5% at the end of the study, it was higher than in the study by Deakin et al that reported a weight loss of 0.3 kg at 4 months and 0.5 kg at 14 months for the experimental group[354] versus 1.1 kg at six months and 0.9 kg at 12 months in this study. It should however be noted that the BMI classification placed both groups in the obese category throughout the study. This confirms the problem with losing weight in people with type 2 diabetes as reported in the meta-analysis of Norris et al.[50]

Non-significant changes in BMI have been reported in some studies.[31,32,42] However, other studies have reported significant reductions in BMI.[30,34,35,40] Though it is not very clear what

contributed to the significant or non-significant changes in these studies, a review of studies on weight loss in diabetes indicate that energy restriction should be a major strategy for weight loss.[51] In addition, a systematic review by Curioni et al reported that a combination of diet and exercise affect and sustain greater weight loss than diet alone in overweight or obese people without diabetes.[52] In the present study, energy intake decreased in both groups, but it seems the decline was not adequate to confer significant weight losses. It might be that the addition of an exercise component could have made the changes in BMI significant.

The non-significant improvements in the lipid profile have been reported in other studies. Deakin et al reported non-significant changes in HDL-cholesterol and LDL cholesterol at 14 months.[35] Huang et al[32] and Leibbrandt et al[42] found non-significant reductions in all lipids parameters at 12 months, while Shabbidar et al[34] found non-significant changes in all the lipids measured at three months. Anderson-Loftin et al[30] at six months, and Brown et al[36] at 12 months found no significant group differences in all lipids measured in participants in low-income and underserved settings. In studies involving diet and physical activity[40] and lifestyle studies in which weight loss was the primary outcome[53,54] non-significant improvements in all lipid parameters were reported.

Despite the non-significant improvements in the lipid profile in this study some positive effects were observed. Firstly, the mean total cholesterol at six months for the intervention group was within the recommendations of the Society of Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA).[15] Secondly, mean triglycerides remained below the cut off[15] at the two time periods for the intervention group and only at six months for the control group. This may be clinically important as triglycerides have an independent effect on the incidence of coronary heart disease.[55] Finally, total cholesterol, LDL-cholesterol and triglycerides tended to be lower in the intervention group at the two time periods. This finding was also observed by Anderson-Lofting et al.[30] However, a tendency for the triglycerides to deteriorate in both groups was noted. This could be attributed to the slight increase in percentage energy from carbohydrates post-intervention. A meta-analysis by Kodama et al comparing the influence of fat and carbohydrates on metabolic profile in type 2 diabetes found that high carbohydrate diets significantly increased fasting triglycerides.[56]

The non-significant changes in blood pressure have been reported in some other studies.[34,35,40] The non-significant improvements in blood pressure may be explained by the non-significant changes in the BMI.

For the within group comparisons, the fourth hypothesis applies (chapter 6, section 6.3.3.4). The hypothesis stated that the intervention group would have significantly better within group primary and secondary outcomes at six months and 12 months compared with the control group. The results support this hypothesis for HbA_{1c} whereby the outcome was significantly better in the intervention group at the two time periods compared with the control group where significant improvements were only at six months (Table 7.11). In addition, BMI significantly reduced in the intervention group at six month (31.5±7.0 to 31.0±7.1, p=0.034 versus 30.3±6.9 to 30.29±7.1, p=0.8 for the control group).

Overall the positive effects of the NE on clinical outcomes could probably be attributed to the greater changes in dietary behaviours observed in the intervention group.

8.2.2 Dietary outcomes

The second hypothesis relating to secondary outcomes, in this case dietary behaviours, was that the intervention group would have significantly better outcomes at six months and these improved outcomes would be sustained at 12 months. The results do not refute this hypothesis (Table 7.5). Some outcomes were significantly better in the intervention group while for some outcomes there were no significant group differences. The NE programme significantly increased the proportion of participants in the intervention group growing own vegetables at six months and 12 months. It also significantly reduced the starchy food intake (servings) in this group. These two dietary behaviours were sustained beyond six months when the effects of diabetes self-management education are reported to start waning off.[57]

The factors likely to have contributed to improvements in vegetable gardening, include a session dedicated to discussing strategies for improving vegetable intake, encouragement to grow own vegetables and a guided visit to the CHCs vegetable gardens. In addition, one of the groups had a demonstration on sowing and transplanting vegetables conducted by the horticulture officer from the sub-district. No study on vegetable gardening within an NE programme for diabetes was available for comparison. Though the increase in participants in the intervention group growing their own vegetable did not result in significant group

differences in vegetable and fruits intake, it might have contributed to the higher intake found in the group. Lombard et al in a study of indigenous people in Northwest New Mexico, including persons with diabetes, found that non-gardeners were likely to eat less vegetable servings per day compared with gardeners.[58] Similarly, Sommerfield et al in a study of older adults found that gardeners were more likely to consume more vegetables compared with non-gardeners.[59] These results are confirmed in the present study in the within group vegetable intake that showed significant improvements in the intervention group at the two time periods compared with the control group [(0.75 to 1.5 median servings, p=0.001 versus 1.2 to 1.3 median servings, p=0.20 at six months) and (0.75 to 1.5 median servings, p=0.003 versus 1.2 to 1 median serving p=0.31 at 12 months)]. Vegetable gardening as a means to improving vegetable intake seems to be important in this population who reported problems with access to vegetables.

The significant reduction of starchy food intake in the intervention group is likely to have occurred due to the following reasons. Firstly, the importance of controlling the amounts of food consumed, especially starchy foods was emphasised. Secondly, guidelines for portioning various food groups in a meal were provided using simple-visual approaches: the plate model[60] and the Zimbabwe hand jive.[61] This also included demonstrations and showing sample meals using culturally appropriate foods. Participants also had a chance to practise the portioning of foods using the guidelines. No published studies assessing starchy foods intake (servings) in people with diabetes were found.

The NE had positive but non-significant effects on other dietary outcomes. Energy intake declined in both groups but more in the intervention group. The non-significant results are in agreement with other studies.[9,35] Huang et al found significant group differences only for participants with HbA_{1c} levels of ≥7%.[32] The greater decline in the intervention group appears to have been effected by the greater reduction in starchy foods intake (servings) since changes in the percentage energy from fats and proteins changed only slightly during the study. The levels of energy decline in the intervention group are comparable to those reported by Huang et al,[32] but higher than those reported by Deakin et al.[35]

Post-intervention changes in energy intake from the macronutrients, fatty acids and added sugar and intakes of fibre, cholesterol and sodium chloride were not significantly different between the groups. This finding is in concordance with other studies.[32,35,42] The reasons for

the non-significant changes in the percentage energy from fats, fatty acids and added sugar could be due to the fact that even at baseline they were far below the recommendations, implying it would be more difficult to reduce the levels. Percentage energy from carbohydrates and proteins tended to increase from baseline to post-intervention in both groups. However, energy intake from proteins was still within the guidelines used in this study (10-20% of total energy intake).

Percentage intakes for energy from carbohydrates at baseline and post-intervention in both groups were above the guidelines used in this study (45% - 65%) (see chapter 6, Table 6.3). The levels in this study were higher than those reported in studies not prescribing a specific carbohydrate contribution to energy intake.9,[32,35,49] The level of carbohydrate intake in the present study (above 65%) would be classified as "high carbohydrate" based on the classification by Wheeler et al in their systematic review of dietary aspects in the management of diabetes.[62] In this review, the authors indicated a non-unanimous agreement on the percentage of energy from carbohydrates shown to confer optimal glycaemic control. In regard to comparisons between moderate intake (40-65%) and high intake (>65%), the review found conflicting results. In one of the reviewed studies with a high carbohydrate prescription of 75% energy (actual participants' intake of 66.3%) compared with a moderate level of 46%, intent to treat analysis showed no significant differences in $HbA_{1c.}$ In the same study, secondary analysis that used the observation immediately prior a participant dropping out or having diabetes medication changed, showed significant group differences with the higher carbohydrate group showing better glycaemic control.[62] A meta-analysis by Kodama et al also reported non-significant differences in HbA_{1c} between high carbohydrates diets (50-73%) with lower-carbohydrate diets (35-50%).[56] Based on the results of these studies, it cannot be concluded that the high carbohydrate intake in this study resulted in the non-significant changes in glycaemic control. The high carbohydrate intake among people with type 2 DM seems to be typical in black communities in resource limited settings in South Africa as similar findings were found by Nthangeni et al.[63] This could be explained by the fact that carbohydrate rich foods are often cheaper.

Cholesterol intake tended to decline in both groups through the study even though the baseline intakes were within the recommendations. Post-intervention fibre intakes were close to the baseline levels and they did not meet the guidelines used in this study (25g/day). Fibre intakes were however higher than those reported in other studies.[9,42]

Vegetable and fruits intake increased in both groups at six months and 12 months, but more so in the intervention group (non-significant). However, none of the groups achieved intakes of the recommended five servings per day. This problem could be related to the barriers to vegetable and fruit intakes reported in chapter 4 (Table 4.7). The non-significant differences in vegetable and fruit intake have been reported in other studies.[31,35,42] However, some studies have reported significant increases in the consumption of vegetables and fruits.[35]

In regard to hypothesis four, in this case relating to dietary intake, the hypothesis was that the intervention group would have significantly better within group outcomes at six months than the control group and these outcomes would be sustained at 12 months. The results support this hypothesis for the starchy food intake whereby the number of servings consumed was significantly lower than baseline levels in the intervention group at the two time periods. Energy intake was also significantly lower at the two time periods for the intervention group, and only at six months for the control group (Table 7.11).

In regard to the goal of enhancing meal balance based on the AMDR and vegetable and fruit intake and legume consumption (chapter 6, Table 6.3), there were no significant group differences in either of the variables from baseline to post-intervention. However, intake of protein improved in both groups and was within the AMDR. Fat intake was much lower than the AMDR while carbohydrates intake was higher than the AMDR throughout the study for both groups. While underreporting of dietary intake cannot be ruled out as this has been observed in obese type 2 DM patients,[64] the pattern of macronutrient intake in this study is similar to that observed in the South African study by Nthangeni et al.[63]

It is noteworthy that some of the participants' perceived dietary changes results agreed with those obtained through the 24 hour recalls. The most notable is the reduction of starchy foods intake (servings) whereby the majority in both groups (>78%) at six months and 12 months perceived themselves as having decreased intake (Table 7.6). This was confirmed through the 24 hour recalls data that showed both groups decreased their starchy food intake. In addition, significantly more participants in the intervention than the control group indicated they decreased the intake of starchy foods at six months (p=0.006) and close to significance at 12 months (p=0.08) (Table 7.6). The results from the 24 hour recalls showed that the intervention group significantly reduced starchy foods intake compared with the control group. Another observation is for the vegetable and fruits intake where more participants in both groups

(Table 7.6) indicated they had increased their intakes, but no significant group differences were observed. These results were confirmed by the 24 hour recalls data. These two results might indicate that the patients perceived themselves as consuming large quantities of starchy foods and inadequate vegetables and fruits. Overall, the majority of the participants in both groups perceived themselves as having made positive dietary changes. The results were supported in most cases by the 24 hour recalls for fat and sugar and not for sodium and legumes intake.

8.2.3 Diabetes knowledge

The second hypothesis related to secondary outcomes also implies to diabetes knowledge. This hypothesised that there would be significant improvements in knowledge at six months and the improvement would be sustained at 12 months for the intervention group. The results support this hypothesis. The NE significantly improved diabetes knowledge scores over the course of the study. The results of this study are in agreement with other studies that found diabetes knowledge to significantly improve in the intervention group.[33,35,36] This finding was also reported in a physical activity and diet study done in South Africa using the same diabetes knowledge measurement tool that was used in the present study.[11] These results add to the evidence found in reviews that diabetes self-management education does improve patients' knowledge about diabetes and its management.[65,66] Factors that could have contributed to improvement in knowledge scores included the use of visual educational tools and materials to explain some concepts, and the local language to enhance participants understanding of information (36 out of a total 40 weekly sessions for the five groups were presented in the local language).

However, even though the mean knowledge scores were significantly higher in the intervention group at the end of the study, they were still in the classification of poor knowledge (<7.5/15 or <50% of correct), which could indicate inadequate comprehension of the disease and its management. In contrast, Rodrigues et al reported that the majority (78%) of participants attending a diabetes education course in Brazil obtained scores higher than eight out of a maximum possible of 15. [67] Even though baseline scores were very low (5.2 or 35% correct), the post-intervention increase (0.75 at six months and 1.8 at 12 months for intervention group) was also low contributing to the low scores at the end of the study. The increase in knowledge scores was lower than those reported in studies using the same diabetes

knowledge measurement scale as the present study. Beeney and Dunn reported a three point increase at three months,[68] while Van Rooijen and colleagues reported a 2.96 and 4.27 point increases at 14 weeks and 12 months respectively for the intervention groups.[11] In studies using different measurement scales, Deakin et al reported a 2.9 and 1.5 increases at four months and 14 months respectively.[35]

The low baseline diabetes knowledge scores (pre-education) are comparable with those reported in other studies especially in developing countries.[13,69,70] The low knowledge scores could be related to the low education level[71,72,73] and previous non-attendance of diabetes education programmes.[73] The low knowledge scores post-intervention could be due to low literacy including health literacy that is associated with low education attainment.[74,75] Low literacy is common in populations with limited resources[76] as was observed in this study. The low literacy could affect the ability to process and understand information.[74] The effect could also be magnified by the fact that the NE was not fully offered in the cultural language. The use of two languages in some sessions (English with local language translations) may have resulted in participants not to fully comprehend some of the content. It could also be that the participants were overwhelmed by the information, given that this was their first time to attend a structured diabetes education programme. Poor knowledge of diabetes even after attending diabetes education has been reported in people with low health literacy compared with those with adequate literacy.[77] A study by Kim et al also demonstrated that after diabetes education, patients with higher health literacy had higher diabetes knowledge scores than those with limited literacy.[75]

In regard to specific knowledge categories of the measuring instrument, poor performance was observed in the basic physiology, including insulin action, causes of hypoglycaemia and items on free foods and empty calorie foods from baseline to post-intervention in both groups. The finding on poor knowledge on the causes of hypoglycaemia after diabetes education was also observed by Beeney and Dunn.[68] This may indicate a challenge in transmitting more seemingly complex preventative-oriented knowledge.[68] The poor knowledge on basic physiology and insulin action has been reported in a South African study.[13] It may reflect inadequate comprehension of the underlying principles of diabetes self-management in many patients in this setting which could negatively impact on self-care activities.

Even though improvement in knowledge does not necessarily translate to improved metabolic outcomes[68,78] an understanding of the disease is a prerequisite to performing appropriate self-care activities. Persell et al demonstrated that a one-point increase on the knowledge scale was associated with following a diabetes diet, blood glucose self-monitoring and regular physical activity.[79]

8.2.4 Attitudes toward diabetes and its treatment

The second hypothesis (related to secondary outcomes), also implies to the attitudes towards diabetes and its treatment. It was hypothesised that the NE would result in significantly greater improvements in the intervention group compared to the control group at six months. In addition, the improvements would be sustained at 12 months. The findings do not support this hypothesis. The non-significant findings have been reported in other studies. Rodrigues et al in a study of 82 diabetic adults attending a diabetes self-care education programme facilitated by health professionals from various fields (nursing, nutrition, psychology, physical education) found no changes in attitudes at the end of the programme.[67] Baradan and colleagues found no significant group differences towards selected attitudes towards diabetes (seriousness and complications) after a diabetes education programme.[80] Similarly, Atak et al found no improvements in attitudes in an education programme delivered by the researcher.[81] Comparisons for specific attitude sub-scales are difficult as different attitudes measuring instruments were used in the above reported studies. There is also a paucity of published data on diabetes education programmes that are more specific to nutrition that measured attitudes towards diabetes and its treatment.

The lack of improvement in the attitudes related to the value of tight glucose control and the seriousness of type 2 diabetes in the intervention group is an unexpected result. This is because the need for keeping blood glucose under control and the consequences of poor control were greatly emphasised during the NE sessions. In addition, a study in Argentina by Galiadino et al found that patients who had previously attended a diabetes course had a higher score on the seriousness of type 2 diabetes indicating a more positive attitude.[82]

The negative attitude measured towards tight glucose control and the neutral attitude about the seriousness of type 2 diabetes found in participants in this study could negatively influence how they received information and their commitment to apply appropriate self-care

activities, and consequently metabolic control. Khattab et al reported that patients with negative attitudes towards diabetes had increased odds of poor glycaemic control.[83] Similarly Clark et al reported that intervention participants who viewed diabetes as less serious showed less improvements on dietary outcomes.[84] Anderson et al found that patients who report high levels of adherence to diabetes care have more positive attitudes toward diabetes and its management.[85]

Even though the DAS III scale was pre-tested, there is a possibility that some participants did not understand some questions properly, as indicated by the low internal consistency in some of the sub-scales compared with those obtained in the original scale by Anderson et al.[12] The Cronbach's alpha in the original scale ranged from 0.65 to 0.8[12] whereas in this study it ranged from 0.47 to 0.7. However, the values in this study are comparable with those reported by Van Rooijen[13] which ranged from 0.41 to 0.62 in a study of type 2 diabetic patients in South Africa. Generally, a Cronbach's alpha of 0.7 to 0.8 is considered satisfactory for group comparisons.[86] Therefore, the alpha values in some of the sub-scales in this study were way below the satisfactory values.

The lack of improvement in the attitudes towards diabetes and its treatment is contrary to the expectations based on the Knowledge Attitude Behaviour (KAB) model used in this study. The KAB model purports that an accumulation of knowledge leads to a change in attitude.[87] It could be that the knowledge acquired by the participants in this study was insufficient to confer a positive effect on attitude. This could be supported by the post-intervention diabetes knowledge scores of less than 50% correct. However, since the magnitude of knowledge accumulation that would confer a change in attitude is not known, it may not be conclusive that insufficient knowledge in this study population led to a lack of improvement in attitudes. It could be that knowledge by itself does not necessarily lead to a change in attitude. It may be that alongside knowledge, directly addressing attitudes could play an important role.[88] This is supported by the study by Cooper et al that used group as a forum for participants to explore their attitudes towards diabetes and its treatment.[89] The study reported significant differences between the intervention and control groups in the attitudes towards diabetes and its treatment.

8.3 NUTRITION EDUCATION PROGRAMME PROCESS EVALUATION

8.3.1 Programme participation

The programme retention rates were high (92.7%) for both the intervention and control groups. These results are comparable with those achieved by Deakin et al[35] of 92.6% at 14 months, and Gaede et al[49] of 93%. The retention rates were higher than those achieved in other studies.[30,34,40] The participation rates per group were also high at 88% in each group. This is higher than those reported by Anderson-Loftin et al of 78% for the experimental group and 56% for the control group.[30] The reasons for the high retention rates could be due to the high enthusiasm for participation observed in all participants (intervention and control) during the baseline data collection. This could be due to the fact that they had never participated in any diabetes specific education programme or received written materials related to their condition before. The reminders for meetings by telephone for whom it was feasible, and the use of other participants to contact those without telephones, probably also contributed to participation. In addition, the reimbursement of transport costs could also have encouraged participation because the transport barrier had been removed. In the words of one participant: "*I did not have to worry about transport*". The provision of healthy refreshments could also have played a role.

8.3.2 Nutrition education sessions

The participation in the NE sessions by the intervention group participants was high for both the weekly and monthly meetings as evidenced by attendance rates of over 80% (Chapter 7, Table 7.12). This is higher than the average of 60% reported in a review of diabetes self-management education for disadvantaged populations.[76] The participants also reported great satisfaction with the programme. Several factors may have contributed to these two positive findings. The delivery of the NE programme in a manner that participants felt their needs were met. This included among others NE content that was viewed useful, group format that was deemed supportive for learning and coping with living with diabetes and the timing of the sessions that was seen as appropriate. The perceived and or /real positive benefits such as improved well being, family support, gained knowledge and achieved dietary and related behaviour changes could also have contributed to the high satisfaction with the NE programme. In addition, the participants expressed that they felt valued and treated with respect. This could indicate that a caring and trusting relationship was established between the participants and the facilitators.

Culturally appropriate diabetes interventions have been shown to improve participation rates.[30,90] Group meetings in this study were considered useful because they could facilitate group activities, provide social support and contribute to effective learning. This result has been demonstrated in other studies.[30,89,90,91]

8.3.3 Programme delivery

The NE programme was delivered as planned for the majority of the aspects (components, format, content, use of education materials/tools/and the number of meetings) while some aspects had to be altered due to situations beyond the researcher's control. The major changes were on the facilitator of the NE sessions and two activities (vegetable gardening demonstration and individual goal setting). The changes on the facilitator and vegetable gardening activity were necessitated by conflict in work demands of these facilitators. This problem, though not anticipated, was related to the inadequacy of specialised personnel especially in this study setting, which is common in resource limited settings.[92,93] The problem of inadequacy of personnel precluded the training or planning of the NE facilitation with more than one person. Despite the challenges, the fact that most of the NE programme was implemented as had been planned demonstrates that conducting a diabetes education programme focusing on diet in a resource limited setting is feasible.

8.4 STRENGTHS AND LIMITATIONS OF PHASE 3

8.4.1 Strengths

Several aspects of this phase contributed to its strength. These included the randomised study design, the low attrition rates, the comprehensive set of outcomes assessed and the monitoring of the changes in glucose lowering medication. The 12-month study period was long enough to observe changes in the measured outcomes and their subsequent sustenance. Other strengths included the tailoring of the NE to participants expressed needs and preferences. The assessment of perceived dietary changes and the comprehensive process evaluation of the NE additionally provided evidence for participants experience with the programme, and insight for future programmes. The use of a student (appointed community worker) facilitator from the study setting was an additional strength as she had the same cultural orientation as the participants.

8.4.2 Limitations

The study power was lower than initially planned. The power calculations showed that 80 patients were needed to show a 1% difference in HbA_{1c} at six months based on an estimated standard deviation of 1.5. Though this sample size was achieved, the standard deviation was greater than anticipated (2.0), implicating a need for more participants than the initial estimate. Although this being the case, challenges with the recruitment made it difficult to obtain additional participants.

Whereas measures were taken to prevent contamination between the participants in the intervention and control groups, such an occurrence cannot be ruled out. Information sharing between participants could have occurred during their monthly CHCs attendance. Such information sharing however is unlikely to lead to a significant change in behaviour.[94] In addition, given the scope (intensity and duration) of the NE programme the "dose" exposure on the control group participants would be low, since the whole NE package was unlikely to be transferred,[94] therefore the effect if any, would not likely be significant.

The lipid profile was assessed on non-fasting blood samples. This could influence the accuracy of the evaluated lipids particularly triglycerides which remain elevated for several hours postprandial.[95] Asking participants to fast before assessments were done was seen as an aspect that could lead to non-compliance in some participants or discourage participation, hence the use of the non-fasting specimens.

The greater number of women compared to men in the study sample could limit generalisation of the results. This gender imbalance is also reported in other studies.[34,40] In this study the imbalance is likely due to the relatively smaller number of males observed to attend the CHCs. This occurrence could be associated with the lower diabetes prevalence rates in males in comparison with females (except in the Indian population) reported in South Africa.[96]

The administration of the questionnaires (DKNB and DASIII) with two different methods (interviewer at baseline and self-administration at six and 12 months), could have influenced the way participants responded to questions, and probably the results. The influence is related to the different cognitive processes that operate in the two administration methods and the

effect of the presence of the interviewer.[97] However, since the methods were equally applied to the intervention and control groups, if there was any effect it would cut across the two groups. In addition, the use of the two administration methods affected less than a third of the participants.

Another limitation of this phase was that the models/theories of behaviour change used were not optimally applied. Specifically the goal setting and self-efficacy constructs of the Social Cognitive Theory (see chapter 5, Table 5.2), which are interrelated[98] were not optimally applied. Firstly, only group goal setting was done as individual goal setting proved a challenge for participants. The lack of participation in the personal goal setting could probably be due to the low literacy levels of the study participants. The lack of personalised goal setting might have hindered the commitment to attaining the goals set in the group, for example of increasing consumption of vegetables and fruits or improving meal balance. Secondly, the construct of self-efficacy was not measured before and after the intervention. Therefore, this study did not ascertain whether there was any improvement in self-efficacy for specific behaviours targeted. The lack of significant results in some of the measured variables could probably be due to non-improvement in self-efficacy. Goal setting[99,100] and self-efficacy[101] have been shown to facilitate dietary and related behaviour changes and even to influence glycaemic control in individuals with diabetes.[102]

8.5 CONCLUSIONS

In this phase a tailored NE programme was implemented and also evaluated on the effects on glycaemic control (HbA_{1c} levels), BMI, blood pressure, lipid profile, dietary behaviours, diabetes knowledge and attitudes towards diabetes and its treatment.

It can be concluded that, the NE programme as implemented in this study over a period of 12 months in adults with type 2 DM, did not significantly improve glycaemic control based on HbA_{1c} levels. However, a positive trend was observed in that the HbA_{1c} levels decreased more in the intervention group and also more participants in the group achieved the HbA_{1c} targets. The NE programme was not effective on other clinical outcomes (BMI, blood pressure, lipid profile), but a positive trend was seen in a greater decrease in BMI, total cholesterol and LDL-cholesterol in the intervention group.

The NE programme significantly improved some dietary outcomes, namely a reduction in the intake of starchy foods (servings) and an increase in proportion of participants growing their own vegetables. Positive but non-significant effects on energy intake and vegetable and fruit consumption were realised. The NE programme did not meet the objective of enhancing meal balance in the study population.

The NE programme significantly improved diabetes knowledge through the study period but had limited effects on the attitudes towards diabetes and its treatment. Therefore, the link between accumulation of knowledge and consequent improvement in attitudes and behaviour change as purported by the KAB model was not confirmed in this study.

The NE programme was acceptable to the participants and was highly valued. Both the intervention and control groups benefited from participating in the study as evidenced by the improvements in some of the outcomes such as the HbA_{1c} and vegetable and fruits intake in both groups and self reported positive changes.

The NE programme to some extent did achieve some of the education goals:

- Firstly, the goal of increasing the awareness and motivation to keep diabetes under control as evidenced by the reductions in HbA_{1c} levels (non-significant);
- Secondly, increasing awareness on the importance of consuming vegetables and fruits increased the consumption thereof (non-significant);
- Lastly, the education goal on increasing the ability to perform specific dietary behaviours was achieved for the starchy foods intake (reduction in the number of servings) and growing own vegetables in the intervention group.

Finally, it is concluded that it is possible to implement a tailored NE programme in a resource limited setting as evidenced by the study retention rates (~93%) and the participants expressed satisfaction with the programme.

8.6 RECOMMENDATIONS

Following the completion of this phase, recommendations for future research are made as follows:

8.6.1 The study to include at least one individual counselling session that would include a goal setting activity (based on clinical and dietary outcome measures). This approach could enhance personal goal setting and the commitment to pursuing the goal.

8.6.2 An assessment of self-efficacy for vegetable and fruit intake be done pre-and post-intervention. This would establish whether the lack of significant improvement in vegetable and fruits intake, despite the significant change in the reported proportion of participants growing own vegetable in the intervention group, was due to low self-efficacy or other factors.

8.6.3 The study to provide structured sessions for participants to explore their attitudes towards diabetes and its treatment. This could include for example giving some attitudinal statements and encouraging participants to discuss them. This would assist in directly addressing the existing attitudes with a goal of improving inappropriate attitudes.

8.6.4 The study to incorporate a structured physical activity component to complement the dietary component in collaboration with relevant collaborators such as physiotherapists.

8.6.5 The NE programme to have dietary energy restriction as an objective so as to address the weight status (obesity) of the participants.

8.6.6 The study to explore the interaction of family support (family attending sessions and participants' self-reported improved family support) with the measured outcomes such as HbA_{1c}. This would establish whether family support has a positive effect on the measured variables.

8.6.7 To improve on the delivery of the vegetable gardening component of the NE programme; an exploration of the most suitable approach to its execution is needed.

8.6.8 The study to perform an intention to treat analysis for all outcomes measures.

8.6.9 Given the poor performance on the diabetes knowledge test and some of the DAS III sub-scales, future studies should develop such tools for low literacy communities or modify and adapt the standardised ones that were used in this study.

8.6.10 The study to test the effectiveness of the NE programme with a younger age group such as 40-55 years who may be more motivated to make dietary changes.

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CHAPTER 9

EXECUTIVE SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

9.1 INTRODUCTION

Diabetes self-management education, including nutrition education (NE), is an essential component of diabetes management. Effective NE can assist individuals with type 2 diabetes mellitus in resource limited settings to improve their dietary self-care; an area cited among the most difficult[1,2] with consequent improvement in health outcomes.

This chapter presents a synopsis of study as a whole, the general conclusions and the recommendations for future research and practice respectively.

9.2 AIM AND OBJECTIVES OF THE STUDY

The purpose of this study was to plan a tailored NE programme for adults with type 2 DM in a resource limited setting and to evaluate the programme's effectiveness on specific health outcomes. The study was undertaken in three phases, each of which had its own aim and objectives.

9.2.1 Phase 1: Needs assessment

This phase aimed at establishing the needs and preferences for NE as well as factors that could impact on the NE. The specific objectives were to (i) establish the current understanding of diabetes and its management by the patients, (ii) examine the patients self-reported dietary practices and dietary adherence, (iii) explore the factors that could impact on NE, i.e. the perceived barriers and facilitators to dietary compliance, and (iv) elicit recommendations for content and preferred education approaches for a tailored NE programme.

9.2.2 Phase 2: Planning the nutrition education programme

The aim of this phase was to plan a NE programme that would be culturally relevant and tailored to the needs of adults with type 2 DM in the study setting. The specific objective was to determine the NE features (appropriate theoretical models/theory, NE components, curriculum and content, activities, teaching approaches, etc.) based on the needs assessment and evidence from the literature.

9.2.3 Phase 3: Implementation and evaluation of the NE programme

The aim of this phase was to implement and evaluate the effectiveness of the NE programme on glycaemic control based on HbA_{1c} and other specific health outcomes (blood lipids, blood pressure, BMI, dietary behaviours, diabetes knowledge and attitudes towards diabetes and its treatment). The specific objectives were to:

- determine the differences between the intervention and control groups for HbA1c (primary outcome) and secondary outcomes (blood lipids, blood pressure, BMI, dietary behaviours, diabetes knowledge and attitudes towards diabetes and its treatment) at six months and 12 months,
- determine the differences between the intervention and control in the proportion of participants achieving HbA_{1c} levels of less than 7% at six and 12 months,
- determine the within the group differences at six months and 12 months for HbA_{1c} and the secondary outcomes.

It was hypothesised that the intervention group would have significantly better outcomes for the primary and secondary outcomes at six months and would sustain the improved outcomes at 12 months. The NE aimed at achieving a 1% change in HbA_{1c} (primary outcome) at six months.

9.3 METHODS

The study was done by employing a mixed research approach in the qualitative and quantitative domains. The study was conducted from February 2009 to November 2011.

Ethical approval for the study was granted by the Research Ethics Committee of the Faculty of Health Sciences, University of Pretoria (number 264/2008 for phases 1 and 2 and number 215/2009 for phase 3).

9.3.1 Study setting and population

The study was done in two community health centres (CHCs), Makapanstad and Mathibestad, in a resource limited setting of the Moretele sub-district, North West Province (South Africa). The study involved patients with type 2 DM, aged 40 to 70 years, not on insulin therapy and at least one year living with diabetes.

9.3.2 Phase 1: Needs assessment

Thirty one (three males) type 2 DM patients (a convenience purposive sample) aged 40 to 65 years, and ten nursing professionals who served the patients at the CHCs, participated in the qualitative NE needs assessment. Focus group discussions were used with the patients and an open ended self-administered questionnaire with the health professionals. Framework analytical approach based on a combination of Kruger and Richie & Spencer[3] approaches was used for data analysis.

9.3.3 Phase 2: Planning the nutrition education programme

The results from the needs assessment (phase 1) in conjunction with literature were used to plan a tailored NE programme. The planned NE had the following features:

- It aimed at improving glycaemic control (HbA_{1c}) and other specific outcomes (blood pressure, BMI, blood lipids) through improved dietary behaviours and behaviour mediating factors (knowledge and skills, attitudes, self-efficacy, etc.)
- Major dietary behaviours of focus were increasing vegetables and fruit intake, reducing starchy foods intake (number of servings) and improving balance in meals (acceptable macronutrient distribution range plus vegetables and fruits intake)
- Underpinned by selected constructs from the Social Cognitive Theory, Health Belief Model and Knowledge Attitude Behaviours theories
- Four programme components: curriculum (eight weekly meetings), follow-up meetings (four monthly and two bi-monthly), vegetable gardening demonstration and education materials (pamphlet and wall/fridge flyer)
- Group delivery at the CHCs
- Use of the local language and local foods
- Involvement of family
- Facilitators: sub-district dietitian and the sub-district horticultural officer (for the vegetable gardening component).

9.3.4 Phase 3: Implementation and evaluation of the nutrition education programme

A randomized controlled trial with 82 (eleven males) type 2 DM patients aged 40 to 70 years and with HbA_{1c} levels of ≥8 mmol/L evaluated the effects of the planned NE programme. Participants were randomised into either the intervention or control groups. The intervention group received the NE which comprised of eight weekly meetings to cover the curriculum,

follow-up meetings (monthly and bi-monthly) and education materials. The control group received the same education materials. Both groups continued with usual medical care at their respective CHCs.

Outcome measurements were done at baseline, six months and 12 months. The outcome assessment was done on different days for the intervention and control groups. The outcomes included HbA_{1c} (primary outcome), full lipid profile, blood pressure, BMI, dietary behaviours (dietary intake and vegetable gardening), diabetes knowledge, and attitudes towards diabetes and its treatment. Three 24 hour recalls (included one weekend day) on non-consecutive days assessed dietary intake. Diabetes knowledge and the attitudes towards diabetes and its treatment were assessed using the diabetes Knowledge Form B scale (DKNB)[4]) and the Revised Diabetes Attitudes Scale-III (DAS-III)[5] respectively. The other outcomes were assessed through standard procedures.

An analysis of covariance (ANCOVA) compared the groups on the measured outcomes using baseline values, age, gender, and clinic as covariates. Rank ANVOVA[6] was used for dietary intake as the data were skewed. A paired t-test or Wilcoxon matched paired signed rank test tested the within group changes. The between group comparison was the major interest of the study. The level of significance for all tests was set at $\alpha < 0.05$ for a two-tailed test.

The evaluation of the NE programme by participants (as part of process evaluation) was done during two time periods. At the end of the curriculum (eighth week), the assessment was done with 31 (out of 41) intervention group participants using a semi-structured questionnaire. After the outcomes had been assessed at 12 months, the programme evaluation was also done using focus group discussions (FGDs) within the five groups that were involved in the NE sessions.

Figure 9.1 diagrammatically summarises the phases.

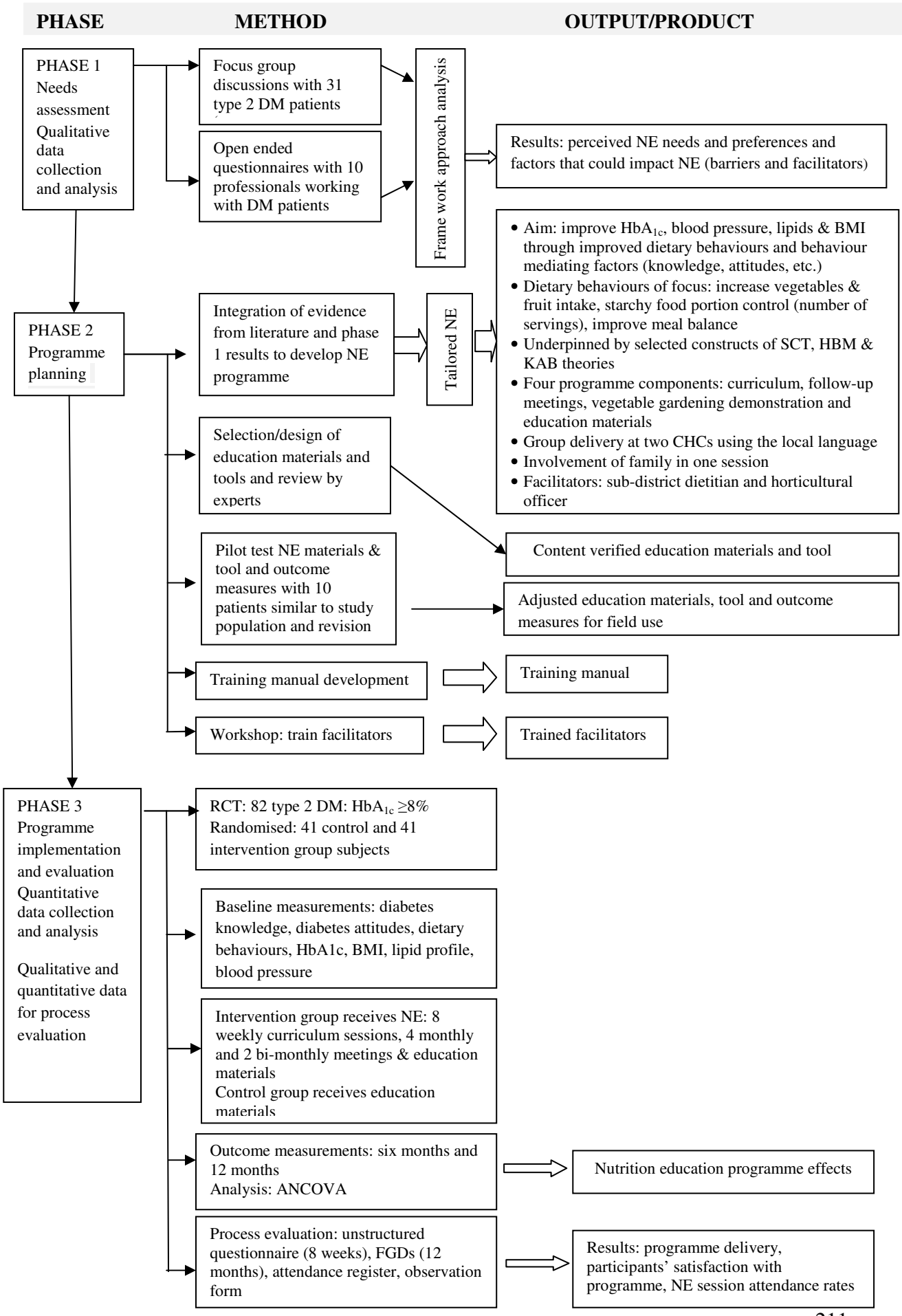

Figure 9.1: **Schematic summary of the study phases**

Nutrition education programme implementation: The NE was implemented in five groups of six to ten participants at the two CHCs. All the sessions (weekly, monthly and bi-monthly meetings) were held according to the planned schedule, except for one monthly meeting in two groups that had to be cancelled due to participants' unavailability. About 80% of the activities were executed as planned. The vegetable gardening demonstration (only done for one group) and individual goal setting (not done) were the major activities not implemented as had been planned. The majority (65%) of the sessions were facilitated by an appointed field worker (a university final year student in nutrition and food science) from the study site. The sub-district dietitian facilitated 25% of the sessions and the researcher 10%. The local language was used in 90% of the sessions and 10% (by the researcher) in English with local language translations.

The NE session's attendance rate was over 80% for both the weekly and monthly/bi-monthly meetings.

9.4 MAIN FINDINGS

9.4.1 Phase 1: Nutrition education needs assessment

The results from phase 1 indicated the following:

- Knowledge deficits and misconceptions existed about diabetes and its treatment, particularly on risk factors/causes.
- Problems with dietary adherence despite a general awareness of the dietary recommendations were experienced by the subjects. This included inappropriate self-reported dietary practices: low consumption of vegetables and fruits, low consumption of legumes, problems with food portion control and unbalanced diets.
- Eight barriers and two major facilitators to following dietary recommendations were identified. The barriers were in the personal, socio-economic and physical/structural environment domains. Financial constraints including the associated food insecurity was the major barrier while social support (family and health professionals) was the major facilitator. However, family was also seen as a barrier to following dietary recommendations due to conflict in family meal arrangements.
- Participants were interested in a NE programme and provided some specific recommendations for preferred approaches and content. This included content related to the disease and diet, group education at the clinic, a competent educator, diabetes

specific education, provision of education materials as handouts and inclusion of family members in the NE.

9.4.2 Phase 3: Implementation and evaluation of the nutrition education programme

9.4.2.1 Participants programme evaluation

The qualitative NE programme evaluation by the participants indicated the following:

- Participants were highly satisfied with the programme delivery (content, facilitation duration, group delivery, education materials, etc.).
- Participants felt they had benefited from participating in the NE programme: new information, improved well being, improved dietary and related practices and increased family support.
- The NE programme was considered valuable and was recommended for other people with diabetes.

9.4.2.2 Effects of the nutrition education programme

The results on the effects of the NE programme are reported for participants who completed the assessments: 81 at six months (41 intervention, 40 control) and 76 at 12 months (38 per group).

9.4.2.2.1 Comparison between groups

The results on the group comparisons are presented for data adjusted for age, gender, clinic and baseline values. However, for dietary intake data, only the *p*-value is for the adjusted data and not the medians since rank ANCOVA was used. The effect of the NE programme for the between the group comparison (the main interest of the study), indicated the following for the intervention group when compared with the control group:

- Non-significant difference in mean HbA_{1c} levels (primary outcome) (-0.62%, p=0.15) at six months and (-0.67%, p=0.16) at 12 months.
- Non-significant differences in other clinical outcomes at six and 12 months respectively: mean BMI (-0.29 kg/m^2, p=0.33; -0.37 kg/m^2, p=0.34), mean total cholesterol (-0.17 mmol/L, p=0.19; -0.06 mmol/L, p=0.67), mean LDL-cholesterol (-0.08 mmol/L, p=0.49; -0.4 mmol/L, p=0.4), mean HDL-cholesterol (-0.02 mmol/L, p=0.52; -0.05 mmol/L, p=0.28), mean triglycerides (mmol/L) [-12.4%, p=0.17; -5.6%,

p=0.49],[1] systolic blood pressure (+4.3 mmHg, p=0.30; -0.18 mmHg, p=0.97) and diastolic blood pressure (+0.15 mmHg, p=0.95; -2.59 mmHg, p=0.25).

- A significant reduction in median starchy food intake (servings) (-1.5, p=0.005) at six months and (-1.0, p=0.017) at 12 months.
- A significant higher proportion of participants grew own vegetables (17/41 vs. 5/40, p=0.003) at six months and (16/38 vs. 5/38, p=0.005) at 12 months.
- Non-significant differences in other dietary outcomes at six and 12 months respectively: median energy intake [-556 KJ/day, p=0.11; -1021 KJ/day, p=0.055], macronutrient distribution (median % energy)[(carbohydrates, +1.4, p=0.78; +1.3, p=0.45), (proteins, +1.2, p=0.07; +0.5, p=0.96), (fats, -1.2, p=0.96; -1.5, p=0.33)], median vegetable and fruits intake (servings) [+0.3, p=0.17; +0.6, p= 0.48] , median fibre intake (-0.5 g, p=0.72; +1 g, p=0.39), median cholesterol intake (+0.5 mg, p=0.51; -1 mg, p=0.39) and median sodium intake (+44 mg, p=0.96; -85 mg, p=0.36).
- Significant difference in diabetes knowledge (+0.95, p=0.033) at six months and (+2.2, p=0.000) at 12 months.
- Non-significant group differences in the attitudes towards diabetes and its treatment.
- A non-significant difference in the number of participants who achieved HbA_{1c} targets (<7%) [4/41 vs. 1/40, p=0.2)] at six months and [4/38 vs. 1/38, p=0.2] at 12 months.

9.4.2.2.2 Within group comparisons

The within group changes are reported for outcomes with significant changes in both the intervention and control groups at six and/or 12 months or in one group at six and 12 months. The results indicated the following:

- A significant reduction in HbA_{1c} at six months (-1.4%, p=0.000 vs. -0.9, p=0.01) for the intervention and control groups respectively and (-1.3%, p=0.000 vs. -0.81, p=0.06) at 12 months for the intervention group.
- Significant reductions in systolic blood pressure (-8.9 mmHg, p=0.01 vs. -13.3 mmHg, p=0.0001), diastolic blood pressure (-5.4 mmHg, p=0.01 vs. -5.7 mmHg, p=0.0004), total cholesterol (-0.44 mmol/L, p=0.002 vs. -0.35 mmol/L, p=0.000) and LDL-cholesterol (-0.2 mmol/L, p=0.000 vs.-0.1 mmol/L, p=0.000) at six months for the intervention and control groups respectively.

[1] Mean difference given as a percentage since beta was a ratio of the geometric mean for the log transformed variable

- A significant reduction in starchy food intake (median servings) [-2.5, p=0.000; -2.3, p=0.000] at six and 12 months respectively for the intervention group.
- A significant increase in the intake of vegetables and fruits (servings) at six months (+0.7, p=0.002 vs. +0.3, p=0.043) and at 12 months (+1, p=0.000 vs. +0.2, p=0.002) for the intervention and control groups respectively.
- A significant reduction in energy intake in both groups at six months (-1272.0 KJ, p=0.000 vs. -680.6 KJ, p=0.000) for the intervention and control groups respectively and at 12 months (-1235.0 KJ, p=0.000 vs. -381.8 KJ, p=0.17) for the intervention group.

9.5 STRENGTHS AND LIMITATIONS OF THE STUDY

9.5.1 Strengths

The major strengths of the study were:

- The use of a mixed research approach (qualitative and quantitative domains) that allowed the research questions to be addressed more appropriately in the given context.
- The use of the health professionals serving the patients as an additional source of data in the NE needs assessment (phase 1). This was useful in providing insight on some issues that patients had difficulty in articulating. Major issues of concern were identified by both groups of participants.
- The development of the NE programme within a contextualized theoretical model (phase 2). This provided insight on the relationship among the factors that could influence dietary and related behaviours in the study participants. The eclectic theoretical model (Social Cognitive Theory, Health Behaviour model and Knowledge Attitude behaviour model) guided in the formulation of intervention strategies that could support the mechanisms of behaviour change. In addition, this theoretical model approach helped in overcoming the limitations of one theoretical model, thereby allowing a more comprehensive targeting of the behaviours of concern.
- The use of a randomised study design to assess the effects of the NE (phase 3).
- The comprehensive set of outcomes assessed in phase 3 and a study period (12 months) that was long enough to observe changes in the outcomes.
- The low programme attrition rates (phase 3).

9.5.2 Limitations

The major limitations of the study were:

- Inadequate study power for phase 3: the sample size used for phase 3 was inadequate to detect a 1% change in HbA_{1c} even though the calculated sample was achieved. This is because the sample standard deviation for HbA_{1c} was greater (2.0) than anticipated (1.5). However, challenges with recruitment limited the inclusion of more participants.
- Sample gender imbalance: male representation in the samples used in both phases 1 and 3 was quite low when compared with females. This could limit the generalisation of the findings.
- The possibility of contamination through information sharing between participants of the intervention and control groups during their monthly CHCs attendance, even though measures were taken to minimise this occurrence. However, the likelihood of such information sharing leading to a significant change in behaviour is minimal.[7] Given the duration and intensity of the NE programme the "dose" exposure on the control participants would be low, since the whole NE package was unlikely to be transferred,[7] therefore the effects if any, would not likely be significant.
- Some constructs of the Social Cognitive Theory, namely goal setting and self-efficacy, were not optimally applied. This could probably have interfered with behaviour change and contributed to a lack of significant findings in some outcomes.

9.6 CONCLUSIONS

The conclusions drawn from the entire study are as follows:

- Limited knowledge about diabetes and its treatment and inappropriate dietary practices (food portion control problems, inadequate consumption of vegetables and fruits, low consumption of legumes and unbalanced diets) in the study population were observed in both phases 1 and 3.
- Nutrition education improved knowledge significantly in the intervention group but not satisfactorily since the mean score at the end of the study was below 50%.
- Nutrition education significantly improved dietary behaviours related to starchy food portion control and the proportion of participants growing own vegetables.
- The nutrition education effected a non-significant reduction of HbA_{1c} levels, total cholesterol, LDL-cholesterol and energy intake and a non-significant increase in vegetables and fruits consumption.

- The nutrition education programme had limited effects on other clinical outcomes (blood pressure, HDL-cholesterol, triglycerides), other dietary outcomes (fibre, sodium, cholesterol) and attitudes towards diabetes and its treatment.
- Both the intervention and control groups benefited from participating in the study as evidenced by some outcomes with significant within group changes.
- The nutrition education programme did not achieve the 1% reduction in HbA_{1c} levels, despite the high programme satisfaction reported by the participants and the high programme participation rates. However, the ~0.6% reduction achieved can be considered as clinically significant. Based on the United Kingdom Prospective Diabetes Study (UKPDS), these levels could reduce microvascular complications by 25%.[8] In addition, a reduction of at least 0.5% in HbA_{1c} in 6 months is considered a beneficial metabolic response by some organisations.[9] A larger sample would be required to prove statistical significance.

9.7 RECOMMENDATIONS FOR FUTURE RESEARCH

On completion of this study the following recommendations for future research are made:

To improve on outcomes:

- The programme should include at least one session for individual counselling that would include a goal setting activity. This could facilitate the participants' ability to set personal goals because of individualised feedback and assistance by the counsellor.
- The nutrition education should directly address the attitudes towards diabetes and its treatment. This could include, for example sharing statements related to diabetes and its treatment and encouraging participants to discuss. This could assist in exploring the existing attitudes with a goal of improving inappropriate ones and/or formation of positive attitudes.
- The nutrition education should incorporate a structured physical activity component to complement the dietary component in collaboration with relevant collaborators such as physiotherapists.

To explore unaddressed or arising issues/problems:

- An assessment of self-efficacy for vegetable and fruit intake should be done pre and post-intervention. This could establish whether the lack of significant improvement in

vegetable and fruits intake, despite the significant change in the reported proportion of participants growing own vegetable in the intervention group, was due to low self-efficacy or other factors.

- An exploration on the barriers to the consumption of legumes and the effective means to improving their consumption in the study participants should be done. Legume consumption was found to be very low pre and post-NE intervention. Even though legume intake was not among the major dietary behaviours of focus, legume consumption was encouraged since they are a cheap source of protein that could assist in improving meal balance. Also, for their beneficial role on blood glucose and blood lipids control.

9.8 RECOMMENDATIONS FOR PRACTICE

On completion of this study the following are recommended for practice:

- Efforts should be made within the limited available resources to provide structured patient education at clinic level in order to improve the knowledge about diabetes and its treatment and overall diabetes self-management of patients. This could be done by training specific staff members as diabetes educators who could offer education at designated periods to newly diagnosed patients as well as those with existing diabetes.
- Formation of diabetes peer support groups (initiated by the CHCs) with a peer leader as was suggested by health professionals in phase 1 of this study. This could provide a forum for providing education and for group members to explore ways of dealing and coping with on-going barriers to dietary and other diabetes self-care areas. The peer leaders could be trained to offer education.
- Provision of appropriate education materials to diabetic patients and their families to capitalise on the need expressed by the study participants. This could complement any other education that is offered.
- Vegetable gardening at household level should be encouraged as a means to improving access to and consumption of vegetables by the diabetic patients. This could be done by the clinics in partnership with the Department of Agriculture.

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APPENDIX 1 & 2

ETHICAL APPROVAL

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* **FWA** 00002567, Approved dd 22 May 2002 and Expires 13 Jan 2012.
* **IRB** 0000 2235 IORG0001762 Approved dd Jan 2006 and Expires 13 Aug 2011.

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Faculty of Health Sciences Research Ethics Committee
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

DATE: 20/11/2009

PROTOCOL NO.	**215/2009**
PROTOCOL TITLE	Implementation and evaluation of a nutrition education programme for adults with type 2 Diabetes Mellitus in a resource poor setting of the Moretele Sub-District (North West Province), South Africa
INVESTIGATOR	**Principal Investigator:** Ms J W Muchiri
SUPERVISOR	Prof. Paul Rheeder & Ms Gerda Gericke
DEPARTMENT	**Dept:** Human Nutrition, Steve Biko Academic Hospital **Phone:** 012-3541235 **Fax:** 012-3541232 **Mobile:** 082 6888275 **E-Mail:** jane.muchiri@up.ac.za
STUDY DEGREE	PhD Dietetics
SPONSOR	South African Sugar Association
CONTACT DEATAILS	**Representative:** Duduzile Muthuli **Phone:** (031) 5087000 **Fax:** (031) 5087191 **E-Mail:** duduzile.mthuli@sasa.org.za
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POSTAL ADDRESS	South African Sugar Association / Kwa_Shukela, 170 Flanders drive, Mount Edgecombe / P.O. Box 700, Mount Edgecombe, KwaZulu-Natal, 4300
MEETING DATE	18 November 2009

This **Protocol** and **Informed Consent** Document were considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria and approved by a quorum of committee members on 18/11/2009

Members of the Research Ethics Committee:

Prof VOL Karusseit	MBChB; MFGP(SA); MMed(Chir); FCS(SA) - Surgeon
Prof JA Ker	MBChB; MMed(Int); MD – Vice-Dean (ex officio)
Dr NK Likibi	MBBCh – Representing Gauteng Department of Health)
Prof TS Marcus	(female) BSc(LSE), PhD (University of Lodz, Poland) – Social scientist
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*Members attended & Feedback at the meeting.

Date: 29/09/2008

PROTOCOL NO.	**164/2008**
PROTOCOL TITLE	Development Of A Nutrition Education Program For Adults With Type 2 Diabetes Mellitus In A Resource Poor Setting Of The Moretele Sub-District (North West Province), South Africa.
INVESTIGATOR	**Principle Investigator:** Mrs J W Muchiri jane.muchiri@up.ac.za
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DEPARTMENT	**Dept:** Human Nutrition **Cell:** 0826888275
STUDY DEGREE	PhD (Human Nutrition)
SPONSOR	None
MEETING DATE OF THIS STUDY	17/09/2008

This **Protocol** and **Informed Consent** and **all the attachments** have been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 17/09/2008 and found to be acceptable

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Dr N K Likibi	MB.BCh; Med.Adviser (Gauteng Dept.of Health)
*Dr T S Marcus	(female) BSc (LSE), PhD (University of Lodz, Poland)
*Mrs M C Nzeku	(female) BSc (NUL); MSc Biochem (UCL, UK)
*Snr Sr J. Phatoli	(female) BCur (Eet.A) BTec (Oncology Nursing Sience)Snr Nursing-Sister
*Dr L Schoeman	(female) BP harm, BA Hons (PSy), PhD
*Dr R Sommers	(female) MBChB; MMed (Int); MPhar.Med;
*Mr Y Sikweyiya	MPH; Master Level Fellowship in Research Ethics; BSC (Health Promotion) Postgraduate Dip in Health Promotion
*Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path), PGCHE
*Dr A P van Der Walt	BChD, DGA (Pret) Director: Clinical Services of the Pretoria Academic Hospital
*Prof C W van Staden	MBChB; MMed (Psych); MD; FCPsych; FTCL; UPLM; Dept of Psychiatry

Dr R Sommers; MBChB; MMed (Int); MPhar.Med.
SECRETARIAT of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, Pretoria Academic Hospital

APPENDIX 3

PARTICIPANTS: INFORMATION LEAFLET AND INFORMED CONSENT (PATIENTS)

Study title: Development of a nutrition education program for adults with non-insulin dependent type 2 diabetes mellitus from a resource poor setting of Moretele Sub-District (North West Province).

Dear Participant

1. INTRODUCTION.

We invite you to participate in a research study. This information leaflet will help you to decide if you want to participate. Before you agree you should fully understand what is involved. If you have any questions that this leaflet does not explain, please do not hesitate to ask the interviewer Jane Muchiri.

2. THE NATURE AND PURPOSE OF THE STUDY.

The purpose of this study is to obtain information that will assist in planning a nutrition education program that addresses the needs and concerns of type 2 diabetic patients from resource poor settings. Type 2 diabetes, is the type of diabetes that normally occurs in adults, usually from 40 years and above. In most cases, insulin is not required for control, but it is managed with diet or diet with tablets. You as a participant are an important source of information on the issues that could be addressed in such a programme. This includes such information as the topics that could be included based on your experience with diabetes and eating, how the information could be conveyed and what would make such a programme successful.

3. EXPLANATION OF THE PROCEDURE TO BE FOLLOWED.

This study will involve interviewing you in a group. You will be asked some questions concerning yourself and your diabetes. You will also be asked some questions concerning what you have learnt about diabetes and eating, the problems you experience and successes, what other information you would like to receive and how the information should be provided.
A tape recorder will be used throughout the session to make sure the information you give is accurately obtained and for review purposes at a later stage.
Your name will not be on the tape.
Participation in the study will take approximately 1.5-2 hours.

3. RISKS AND DISCOMFORT INVOLVED.

There are no risks involved in the study. However, you may experience some discomfort in answering some of the questions that you may find sensitive. Should you feel uncomfortable in answering any question, you are free not to answer the question. The interview will also take up some of your time.

4. POSSIBLE BENEFITS OF THIS STUDY.

Although you may not benefit directly from the study, the results of the study will be used to plan a nutrition education program that addresses the needs and concerns of individuals with type 2 diabetes mellitus from resource poor settings. It is hoped such a program will assist these individuals take better care of their diabetes through healthy eating. In future you could also benefit from such a program.

5. WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your participation in this study is entirely voluntary. You can refuse to participate or stop at any time during the interview without giving any reason. Your withdrawal from the study will not affect you in any way.

6. HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received written approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria and the Department of Health, North West Province. Copies of the approval letters are available if you wish to have them.

7. INFORMATION AND CONTACT PERSON.

The contact person for this study is Jane Muchiri. If you have any questions about this study please contact her on cellular phone 082-6888275. Alternatively you may contact my supervisor, Ms Gericke on office number (012) 354 1291, cellular phone 0836762134.

8. COMPENSATION.

Your participation is voluntary. A contribution towards your transport expenses will be given for your participation.

9. CONFIDENTIALITY.

All information that you give will be kept strictly confidential. Once we have analysed the information no one will be able to identify you. Research reports and articles in scientific journals will not include any information that may identify you or your clinic.

CONSENT TO PARTICIPATE IN THIS STUDY

I consent that the person who asked me to participate in this study has told me about the nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect me in any way.

I have received and signed copy of this informed consent agreement.

Participant's name …… ……. (Please print)

Participant's signature …… Date ……

Investigator's name …… ……. (Please print)

Investigator's signature …… Date ……

Witness's name …… ……. ….. (Please print)

Witness's signature …… …
Date……

VERBAL INFORMED CONSENT.

I, the undersigned, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the participant whom I have asked to participate in the study.

The participant indicates that he /she understand that the results of the study, including personal details regarding the interview will be anonymously processed into a research report The participants indicates that he/she had time to ask questions and has no objection to participate in the interview. He/she understands that there is no penalty should he/she wish to discontinue with the study and his/her withdrawal will not affect him/her in any way. I hereby certify that the client has agreed to participate in the study.

Participant `s name …… ……. (Please print)

Person seeking consent …….. (Please print)

Signature …… ….. Date ……

Witness `s name …… ……. ….. (Please print)

Signature …… ….. Date ……

APPENDIX 4

PARTICIPANTS` INFORMATION LEAFLET AND INFORMED CONSENT FOR HEALTH PROFESSIONALS (PHASE 1)

Study title: Development of a nutrition education program for adults with non-insulin dependent type 2 diabetes mellitus in a resource poor setting of the Moretele Sub-District (North West Province).

Dear Participant

1. **INTRODUCTION.**

We invite you to participate in a research study. This information leaflet will help you to decide if you want to participate. Before you agree you should fully understand what is involved. If you have any questions that this leaflet does not explain, please do not hesitate to ask the researcher, Jane Muchiri.

2. **THE NATURE AND PURPOSE OF THE STUDY.**

The purpose of this study is to obtain information that will assist in planning a nutrition education program that addresses the needs and concerns of type 2 diabetic patients from resource poor settings. You as a participant are an important source of information on the issues that could be addressed in such a program. This includes information such as the topics that could be included based on problems observed in your clients, methods of delivering the education and possible strategies for an effective program.

3. **EXPLANATION OF THE PROCEDURE TO BE FOLLOWED.**

This study will involve you answering questions in a questionnaire. The questionnaire asks some questions concerning your non-insulin dependent type 2 diabetic adult clients. This includes questions about:

- The major problems you have observed in their general self-care and with regard to diet.
- Your perceptions of factors that hinder their dietary adherence and those that would facilitate/motivate adherence.
- Your suggestions on the topics that could be covered in a nutrition education intervention and advice on what would make such a program successful.

Your name will not appear on the questionnaire.
Participation in the study will take approximately thirty minutes.

4 **RISKS AND DISCOMFORT INVOLVED.**

There are no risks involved in the study. Answering the questionnaire will take up some of your time.

5. **POSSIBLE BENEFITS OF THIS STUDY.**

Although you will not benefit directly from the study, the results of the study will be

used to plan a nutrition education program that is tailored to the needs and concerns of individuals with type 2 diabetes mellitus from resource poor settings. It is hoped such a program will assist these individuals improve their dietary self-care with consequent improvements in health outcomes.

6. **WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**

Your participation in this study is entirely voluntary. You can refuse to participate or stop at any time during the interview without giving any reason. Your withdrawal from the study will not affect you in any way.

7. **HAS THE STUDY RECEIVED ETHICAL APPROVAL?**

This study has received written approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria and the Department of Health North West Province. Copies of the approval letters are available if you wish to have them.

8. **INFORMATION AND CONTACT PERSON.**

The contact person for this study is Jane Muchiri. If you have any questions about this study please contact her on cellular phone 082-6888275. Alternatively you may contact my supervisor, Ms Gericke on office number (012) 354 1291, cellular phone 0836762134.

9. **COMPENSATION.**

Your participation is voluntary. No compensation will be given for your participation.

10. **CONFIDENTIALITY.**

All information that you give will be kept strictly confidential. Once we have analyzed the information no one will be able to identify you. Research reports and articles in scientific journals will not include any information that may identify you or your clinic.

CONSENT TO PARTICIPATE IN THIS STUDY

I consent that the person who asked me to participate in this study has told me about the nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect me in any way.

I have received and signed copy of this informed consent agreement.

Participant's name …… ……. (Please print)

Participant's signature …… Date ……

Investigator's name …… ……. (Please print)

Investigator's signature …… Date ……

Witness's name …… ……. ….. (Please print)

Witness's signature …… … Date ……

APPENDIX 5

PATIENT INFORMATION LEAFLET & INFORMED CONSENT (PHASE 3)

TITLE: Implementation and evaluation of a nutrition education program for adults with type 2 Diabetes Mellitus in a resource poor setting of the Moretele Sub-District, North West Province.

INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that if you have a personal doctor, you discuss with or inform him/her of your possible participation in this study, wherever possible. The investigator will be notifying your personal doctor in this regard.

WHAT IS THE PURPOSE OF THIS TRIAL?

You have been diagnosed as suffering from type 2 diabetes mellitus and the investigator would like you to consider taking part in the research on the effect of a nutrition education programme on your blood glucose, blood pressure and the fat content of your blood. The education programme was specifically designed for individuals with type 2 diabetes mellitus in Moretele Sub-District. During the study you will either be in the experimental group or the control group. The experimental group will receive the nutrition education while the control group will receive the usual care at the clinic (consultations with the sisters or doctor and medication).

WHAT IS THE DURATION OF THIS TRIAL?

If you decide to take part you will be one of approximately 80 patients. The study will last for 12 months. You will be asked to visit the investigator 17 times as per the following schedule: nine weekly meetings, followed by meetings once a month for four months, then once every two months until one year. During the visits you will undergo the following:

Visit 1-week 1

- A blood test to establish the glucose and fat content of your blood.
- You will be asked personal questions concerning yourself, your diet (what you eat, the amounts and how often you eat) and diabetes.
- Measuring of your height, weight and blood pressure.

Visit 2: Week 2

- You will be asked questions about your diet.
- Participate in first session of education in a group.

Visit 3, 4, 5, 6, 7, 8, and 9: Week 3, 4, 5, 6, 7, 8 and 9 after the start of the study

- Participate in education sessions in a group.

Visit 10, 11, 12, 13: Week 13, 17, 21,25

- Participate in group problem solving discussions and asking questions
- Participate in group revision of lessons learnt in the past.

Visit 14: Six months after start of study (26th week)

- A blood test to establish the glucose and fat content of your blood.
- Questions concerning your diet (what you eat, the amounts and how often you eat) and diabetes.
- Measuring of your height, weight and blood pressure.
- Individually ask any questions related to diet and diabetes

Visit 15: Week 40

- Individually and in group discuss problems related with diabetes and diet.
- Share experiences on handling issues related to diabetes.

Visit 16: Twelve (12) months after the start of the study

- A blood test to establish the glucose and fat content of your blood.
- Questions concerning your diet (what you eat, the amounts and how often you eat) and diabetes.
- Measuring of your height, weight and blood pressure.

Visit 17: 5 to7 days after 12 month visit

- Questions concerning your diet (what you eat, the amounts and how often you eat).

EXPLANATION OF PROCEDURES TO BE FOLLOWED

You will be requested for permission to check the following information from your file: your age, how long you have had diabetes, your blood glucose results for the last six months and the type of treatment you are receiving. Blood tests to check the glucose control over the last three months and the fat content of your blood will be done. If the glucose levels are high you will continue with the study. You will be asked to answer some questions concerning your illness and diet. Your weight, height and blood pressure will be measured. You will also be taught about diabetes and diet in a group.
It is important that you let the investigator know of any medicines (both prescriptions or over-the-counter medicines), alcohol or other substances that you are currently taking.

HAS THE TRIAL RECEIVED ETHICAL APPROVAL?

This clinical trial Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update:

October 2000), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS TRIAL?

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care. The investigator retains the right to withdraw you from the study if it is considered to be in your best interest. If it is detected that you did not give an accurate history or did nor follow the guidelines of the trial and the regulations of the trial facility, you may be withdrawn from the trial at any time.

IS ALTERNATIVE TREATMENT AVAILABLE?

Alternative treatment in the form of medication is often used to treat type 2 Diabetes Mellitus. If you decide not to take part in this study it is possible that your doctor may treat you with this, or other suitable medication.

MAY ANY OF THESE TRIAL PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

Venipunctures (i.e. drawing blood) are normally done as part of routine medical care and present a slight risk of discomfort. Drawing blood may result in a bruise at the puncture site, or less commonly fainting or swelling of the vein, infection and bleeding from the site. Your protection is that the procedures are performed under sterile conditions by experienced personnel. A total of 40.ml of blood will be collected over the course of the entire study.

The other tests and procedures are not painful. You will have to remove extra clothing and shoes when your weight is being taken. You may experience some discomfort in answering some of the questions that you may find sensitive. Should you feel uncomfortable in answering any question, you are free not to answer the question. The study will also take up some of your time.

WHAT ARE THE RISKS INVOLVED IN THIS TRIAL?

There are no risks involved in this trial.

FINANCIAL ARRANGEMENTS

The investigator will provide payment for all trial procedures and transport.

SOURCE OF ADDITIONAL INFORMATION

For the duration of the trial, you will be under the care of the usual clinic sisters or attending doctor. If at any time between your visits you feel that any of your symptoms are causing you any problems, or you have any questions during the trial, please do not hesitate to contact your clinic.

CONFIDENTIALITY

All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information which identifies you as a patient in this trial.

In connection with this trial, it might be important for domestic and foreign regulatory health authorities and the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, as well as your personal doctor, to be able to review your medical records pertaining to this trial.

Any information uncovered regarding your test results or state of health as a result of your participation in this trial will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this trial but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases in which a law exists compelling us to report individuals infected with communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorized state agency.

INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, Mrs J Muchiri about the nature, conduct, benefits and risks of clinical trial. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the clinical trial.
I am aware that the results of the trial, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a trial report.
I may, at any stage, without prejudice, withdraw my consent and participation in the trial. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Patient's name _____
(Please print)

Patient's signature _____

Date _____

Investigator's name _____
(Please print)

Investigator's signature _____

Date _____

I, Dr/Mrs ……. herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above trial.

Witness's name _____(Please print)

Witness's signature _____

Date _____

VERBAL PATIENT INFORMED CONSENT

I, the undersigned,_____ have read and have explained fully to the patient, named …….. and/or is/her relative, the patient information leaflet, which has indicated the nature and purpose of the trial in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the trial and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the trial at any time for any reason.

I hereby certify that the patient has agreed to participate in this trial.

Patient's Name _____
(Please print)

Investigator's Name _____
(Please print)

Investigator's Signature
Date

Witness's Name _____
(Please print)

Witness's Signature _____
Date _____

APPENDIX 6

FOCUS GROUPS INTERVIEW SCHEDULE

Instructions for the moderator: Use the bracketed information as a cue or probe in case of inappropriate, inadequate or non-response to a question.

A Preliminaries

Please introduce yourself briefly and say a few words about yourself

Please tell us a little bit about your diabetes, for example how long you have had it and how it is treated.

B Factors influencing dietary self-management

1. What is your understanding of diabetes? (For example the causes, its effects and seriousness and how it should be managed).

2. What type of foods are you currently eating? (discuss in meal pattern for example, breakfast, lunch, in between meals(snacks) etc)

3. Are there any changes you have made in the past in the way you eat to take care of your diabetes? If so what changes? (For example the type of foods chosen, cooking methods, number of meals consumed and when they are eaten, quantities of foods consumed, items added to food such as salt, sugar, spreads etc)

4. What problems have you experienced in making these changes? (For example, restrictive meals, temptations, small portion sizes, difficulties in meal selection during special functions, fitting meals into the family meals etc,).

5. Are there any other changes you would want to make in the way you eat? (For example changes in the type and variety of foods consumed, cooking methods, and quantities consumed etc).

   What keeps you from making these changes? (For example lack of family support, cost, lack of variety to select from, lack of time and skills in food preparation, inadequate knowledge on food selection and preparation etc)

6. What would help you make these changes? (For example family support, information on: meal planning on a low budget, demonstrations on portion sizes and healthy meals for diabetics, peer support groups etc)

7. Do you consider the way you eat to be important in controlling diabetes? In which way (s)?

C Nutrition education needs

8. What kind of information about diabetes and diet have you received in the past?

9. What information did you find very helpful? (For example appropriate/inappropriate food choices, portion sizes, label reading, cooking methods, etc)

10 What information did you find not very helpful?

11. What more information would you like to receive in order to take better care of your diabetes? (For example food selection and preparation, label reading, eating out)

12. How would you like to receive this information? (For example in group/individual sessions, discussion, lecture and written material etc)

13 We want to develop an education programme to help individuals with diabetes eat more healthily in order to take better care of their diabetes. What advice would you give us? (For example what information/ topics to be covered, how many days in a month would be suitable, the day(s) of the week that would be suitable, the venue, length per session etc).

APPENDIX 7

SOCIO-DEMOGRAGRAPHIC DATA COLLECTION FORM FOR PATIENTS (PHASE 1)

DATE……..

Respondent number		☐☐☐
Age		☐☐
Education level	None	1 ☐
	St 1-4	2 ☐
	St 5-7	3 ☐
	St 8-10	4 ☐
	Post St 10	5 ☐
Current employment status	None	1 ☐
	Part-time	2 ☐
	Full-time	3 ☐
	Pensioner	4 ☐
Diabetes duration (years)		☐☐
Diabetes management	Diet alone	1 ☐
	Diet and tablets	2 ☐

APPENDIX 8

QUESTIONNAIRE FOR HEALTH PROFFESSIONALS (PHASE 1)

Respondent Number …… Clinic……

Date ……Number of years worked in the clinic…….....

Profession.....

The purpose of this questionnaire is to gather information that will help in planning a nutrition education program that is appropriate and suited to the needs of non-insulin type 2 diabetic individuals in resource poor settings. The information you provide will be treated with confidentiality. The questionnaire will take approximately 20-30 minutes.
Your participation is highly appreciated.

Kindly write your response/answer in the space provided

1. What is your opinion about dietary adherence among the non-insulin dependent type 2 diabetic patients under your care?

   1.1 Do the patients follow the dietary recommendations? ***Please circle one answer***

   A. Fully B. Partially C. No

   Please explain your answer

   ……
   ……
   ……
   ……
   ……
   …….

   1.2 What diet/nutrition recommendations do they find easy to follow?

   ……
   ……
   ……..
   ……
   …….

1.3 What diet/nutrition recommendations do they find difficult to follow?

……

……

……

……

……

……..

1.4 What would you say is the proportion of those not following the dietary recommendations? E.g. majority, a half, a quarter etc.

……

……

1.5 Any additional comments

……

……

……..

……..

2. What factors would you say contribute to adherence or non-adherence to dietary/nutrition recommendations? (for example cultural issues, knowledge, economic status, beliefs & attitudes)

Please explain

2.1 Adherence

……

……

……

……

……

……..

2.2 Non-adherence

……

……

……

……

……..

3 What factors do you think would motivate/encourage them to follow dietary/nutrition recommendations? (For example family/peer support, written material etc.).

Please explain

……
……
……
……
……

4 We are in the process of planning a nutrition education program for individuals with non-insulin dependent type 2 diabetes. What advise would you provide with regard to the following? **Please explain each of the items.**

a. How to set up the nutrition education programme (for example clinic driven, participatory, self-help etc.)

……
……
……
……
……

b. Nutrition messages/content

……
……
……
……
……

c. Delivery methods (for example group, individual)

……
……
……
……
……

d. Teaching methodologies (for example discussions, demonstrations, lectures, peers etc.).

……
……
……
……

e. Teaching aids and resources (for example flip charts, real objects, written materials)

……

……

……

……

f. Frequency and timing of meetings (which day(s) and how many days in a month)

……

……

……

……

g. Facilitator of the sessions/teacher (For example health professional, peers etc).

……

……

……

……

……

h. Any other advice.

……

……

……

……

……

……

APPENDIX 9 & 10
(EDUCATION MATERIALS)

Appendix 9 : **Pamphlet (z fold presentation)**

Appendix 10: **Fridge/wall flyer (English & isiTswana versions)**
(Reduced size)

Faculty of Health Sciences
Department of Human Nutrition

Taking control: Healthy living with diabetes

Do you know the facts?

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Health Sciences

www.up.ac.za

What is diabetes

Diabetes means your blood sugar (glucose) is too high. Glucose comes from the food we eat such as starchy foods (bread, pasta, mealie porridge, rice, and potatoes), sugar and sugary foods, fruits, milk and dry beans.

A substance called insulin, made by an organ called the pancreas, helps glucose get from the blood into the cells. The cells take the glucose and turn it into energy. This energy is needed for doing work.

When you have diabetes, your body has a problem making insulin or using insulin properly. As a result glucose builds up in your blood and cannot get into your cells. This leads to a rise in blood glucose levels and an overflow of glucose into urine.

What are the symptoms of diabetes?

Common symptoms include[1]:

- having to go to the toilet often
- being very thirsty
- feeling very hungry or tired
- losing weight without trying
- sores and cuts that do not heal so easily
- not able to see clearly (blurred vision)
- infections that keep coming back (recurrent infections)

However, some people may not have these symptoms.

What are the types of diabetes?

There are two main types of diabetes[1].

Type 1 diabetes

In type 1 diabetes, the body does not make insulin. People with type 1 diabetes need to take insulin every day.

Type 2 diabetes

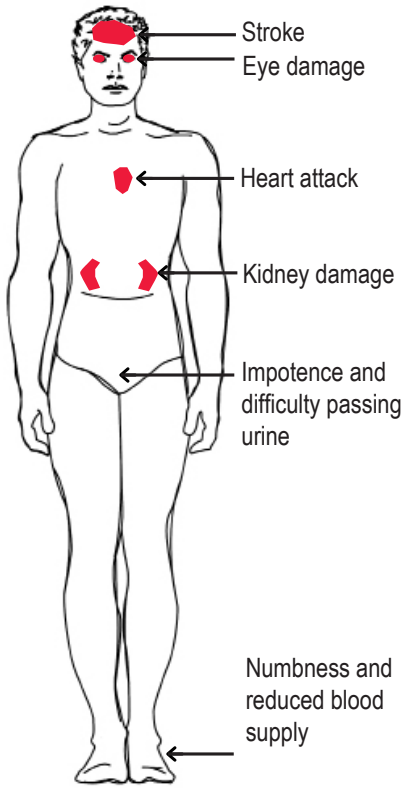
In type 2 diabetes, the body does not make enough insulin, or use insulin well. Type 2 diabetes can be controlled by diet alone. However, some people have to use tablets, insulin or both. This is the most common form of diabetes.

What causes diabetes?

- The exact cause of diabetes is not properly known
- Type 1 diabetes is thought to be caused by viral disease that destroys the cells that make insulin
- Type 2 occurs more frequently in people who are overweight and physically inactive
- Chances of developing diabetes increase if there is a close family member with the disease[1].

Why should you be concerned about diabetes?

Diabetes is a serious disease. It can lead to other health problems. When high levels of glucose are not controlled, they can slowly damage your eyes, heart, kidneys, nerves and feet.



Can diabetes be cured?

At present, there is no cure for diabetes[1].

But good news!! You can control diabetes

Diabetes can be managed

- A person with diabetes can live a normal active life. This is only possible if diabetes is properly controlled.
- Good control means trying to keep your blood sugar levels as near the normal as possible.
  A target of 4-8 mmol/L2 is the guideline, but it is important to discuss your individualised target with your health care team.

To have good control, try to follow all of the following guidelines:

Follow a healthy eating plan every day

Healthy eating means you:

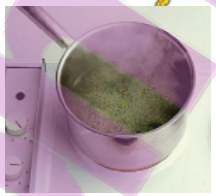
- eat a variety of foods and balanced meals

- include foods that are high in fibre such as whole grains and cereals, vegetables, fruits and dried beans and lentils.

- eat plenty of vegetables and fruits. Have some vegetables with your lunch and supper/ dinner and at least one to two fruits every day.

- choose foods that are low in fat such as skimmed or low fat milk
- reduce the amount of fats in food. For example, cut off fat from meat and remove the skin from chicken before cooking.[3]

- cook foods using low fat cooking methods such as boiling, steaming and grilling



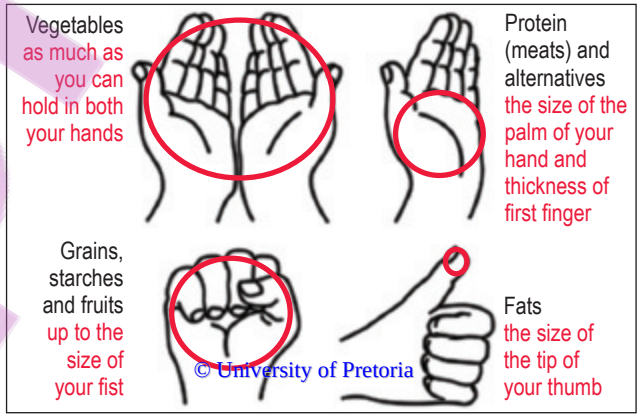
- avoid or reduce intake of sugar, sugary foods and sugary drinks
- use salt sparingly
- eat regular meals and do not skip meals. Eat at least three meals per day (breakfast,lunch and dinner)
- control the amount of food you eat: eat smaller amounts of food at every meal

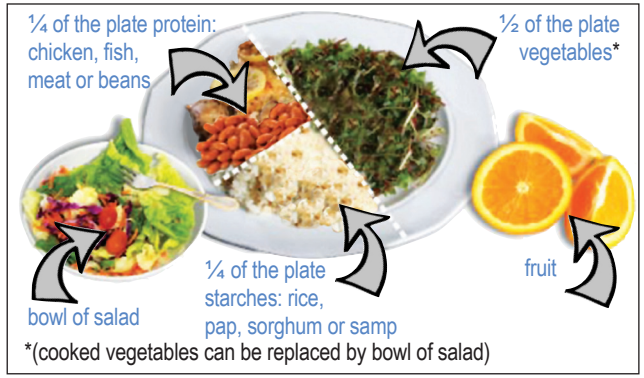
1

- drink plenty of clean water: at least 6-8 glasses per day

How much should I eat?

A guide on the amounts of foods for one meal.





*(cooked vegetables can be replaced by bowl of salad)

Healthy eating helps you:

- better control your blood sugar levels: this reduces the dangers of poorly controlled diabetes.
- reduce the chances of getting other diseases like heart disease
- reduce blood pressure
- loose weight if overweight or maintain a healthy weight
- have proper bowel function because of the high fibre
- feel better

Be physically active

- Being active every day will help keep your blood glucose under control. Your body uses insulin better when you exercise.
- Exercise helps in losing weight and has many other benefits.
- Some ways to exercise include walking, jogging and bicycle riding. Doing gardening and household work are also ways that help in keeping physically active.

If on medication, take medication correctly

It is important to take your medication as prescribed by your health provider.

Have your blood sugar levels checked regularly

You have the facts. Take charge. Be in control

References

1. International Diabetes Federation [Home page on the internet]. About diabetes. [Cited 2010 Jan 15]. Available from: www.idf.org/about_diabetes
2. Society for Endocrinology, Metabolism and Diabetes of South Africa. SEMDSA guidelines for diagnosis and management of type 2 Diabetes Mellitus for primary health care-2009
3. Healthy eating. Changing Diabetes. Diabetes Education. Novo Nordisk

Taking control: Healthy eating with Diabetes

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You can keep diabetes under control through healthy eating and following other management guidelines.

Why healthy eating?

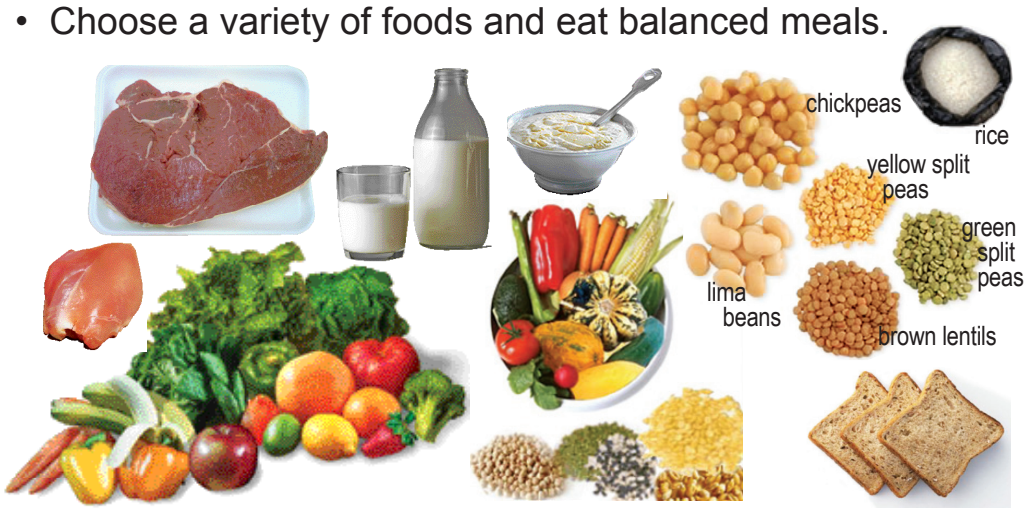
Healthy eating helps you better control your blood sugar levels. This reduces or prevents the problems caused by poorly controlled diabetes. And that is not all.

It helps:

- reduce your chance of getting other diseases like heart disease
- reduce blood pressure
- loose weight if overweight or maintain a healthy weight that helps with the control of your blood glucose levels

How can I eat healthily?

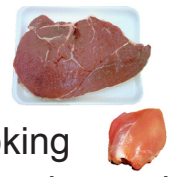
- Choose a variety of foods and eat balanced meals.



- Include foods that are high in fibre. You can do this by choosing vegetables, fruits, whole grain breads and cereals, dried beans and lentils.

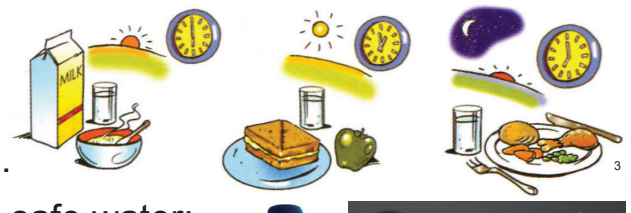
- Eat plenty of vegetables and fruits. You can do this by having some vegetables with your lunch and supper/dinner and at least one to two fruits every day.
- Choose foods that are low in fats such skimmed or low fat milk.

- Reduce the amount of fats in food. You can do this by removing all visible fat from meat and the skin from chicken before cooking.



- Cook foods using low fat cooking methods such as boiling, steaming and grilling.

- Choose foods that are low in sugar and salt.
- Eat regular meals and do not skip meals.
- Control the amount of food you eat. You can do this by eating smaller meals.



- Drink plenty of clean safe water: at least 6-8 glasses per day. You can do this by carrying water with you when you are away from home.

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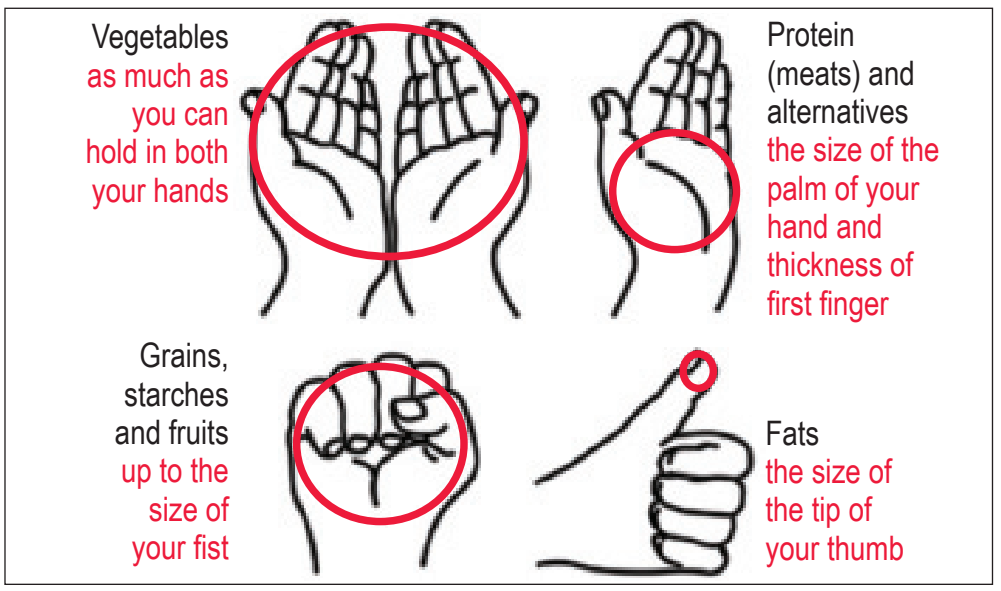
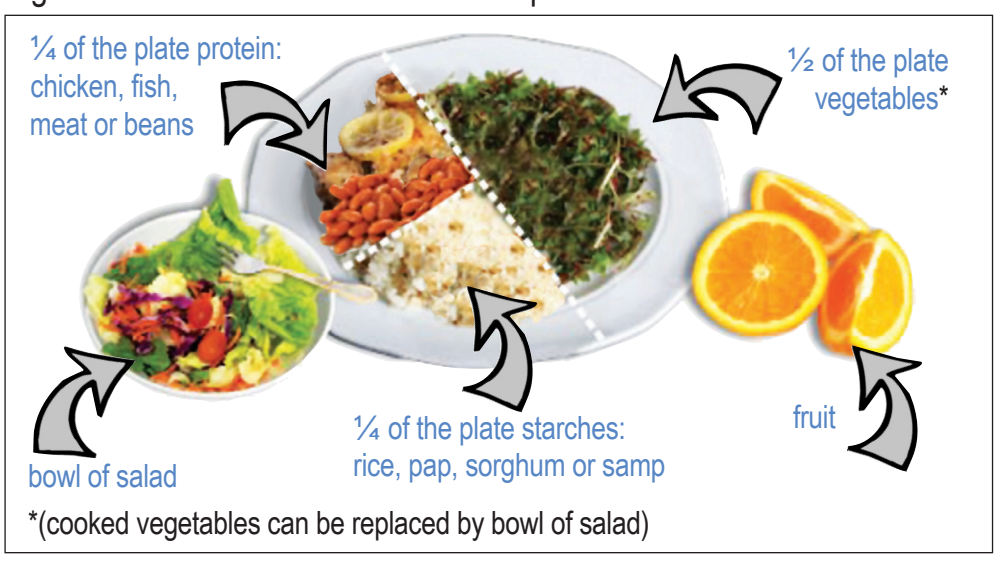
How much should I eat?

A guide on the amounts of foods for one meal.



A guide on the amounts of food on the plate.



*(cooked vegetables can be replaced by bowl of salad)

Healthy eating does not have to be expensive:

You can:

- buy vegetables and fruits in season and those on special offer
- grow your own vegetables and fruits
- collect and use wild traditional vegetables and fruits
- eat dry beans or lentils instead of meat or mix them with meat
- buy fruits instead of cold drinks or fruit juice
- make water your drink of choice

Be physically active

- Being active every day will help keep your blood glucose under control. Your body uses insulin better when you exercise.
- Exercise helps in losing weight and has many other benefits.
- Some ways to exercise include walking, jogging and bicycle riding. Doing gardening and household work are also ways that help in keeping physically active.

Remember also: If on medication, take as instructed. Healthy eating will benefit you and your family.

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Go tsea taolo: Go ja sentle ka bolwetsi ba swikiri

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O ka kgona go tshwarella bolwetsi ba swikiri fa taolong ka go ja sentle le go latela taolo ya ditshupatsela tse dingwe.

Ke ka lebaka la eng re tshwanetse go ja sentle?

Go ja sentle go go thusa go laola seemo sa gago sa madi. Se se fokotsa goba se thibela mathata ao a tlholang ke bolwetsi ba swikiri bo bo laolwang bokoa. E bile ga go felle fao.

E thusa gape go:

- fokotsa sebaka sa gago sa go tsenwa ke malwetsi a go tshwana le bolwetsi ba pelo.
- fokotsa kgatello ya madi.
- fokotsa boima ge e ba boima ba gago bo feta tekano goba wa tshwarella boima bo bo lekaneng boo bo thusang ka taolo ya seemo sa madi a glucose.

Na nka ja jang sentle?

- Kgetha dijo tsa go fapafapana gomme o je dijo tseo di lekaneng. (lokela mmotlolo wa sekotlelo).

- Tsenya dijo tseo di nang le fibre ya ko godimo. O ka dira se ka go kgetha merogo, dienywa, dithoro, marotho le diserele, dinawa tseo di omisitsweng le diletili.

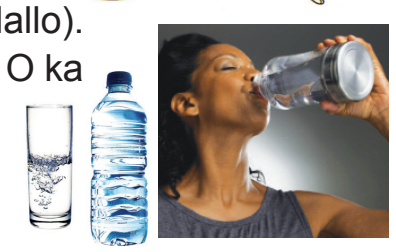
- Eja merogo e mentsi le dienywa.
- O ka dira se ka go tsenya ye meng ya merogo mo dijong tsa gago tsa matena le selalelo le seenywa se le nngwe goba di le pedi letsatsi le lengwe le le lengwe.

- Kgetha dijo tseo di leng kwa tlase ka mafura ja ka lebese leo le sekimilweng kgotsa lebese la mafura a kwa tlase.
- Fokotsa bokalo ba mafura fa dijong. O ka dira se ka go tlosa mafura ao a bonalago mo nameng le matlalong a kgogo pele o apea.

- Apea dijo ka go dirisa mekgwa ya kapeo ya dijo tsa mafura a tlase ja ka go bedisa, go phufulwa le go tshimelwa.

- Kgetha dijo tseo di le go tlase ka swikiri le letswai.
- Eja dijo tsa ka metlha gomme o se ke wa tshedise dijo. O ka dira se ka go ja ga raro ka letsatsi (phitlholo, matena le selallo).

- Laola bokalo ba dijo tseo o di jang. O ka dira jalo ka go ja dijo tse nnyane.
- E nwa meetse a mantsi a a tlhwekileng: digalase tse 6-8 ka letsatsi. O ka dira seo ka go tshwara meetse ge o tloga ko gae.



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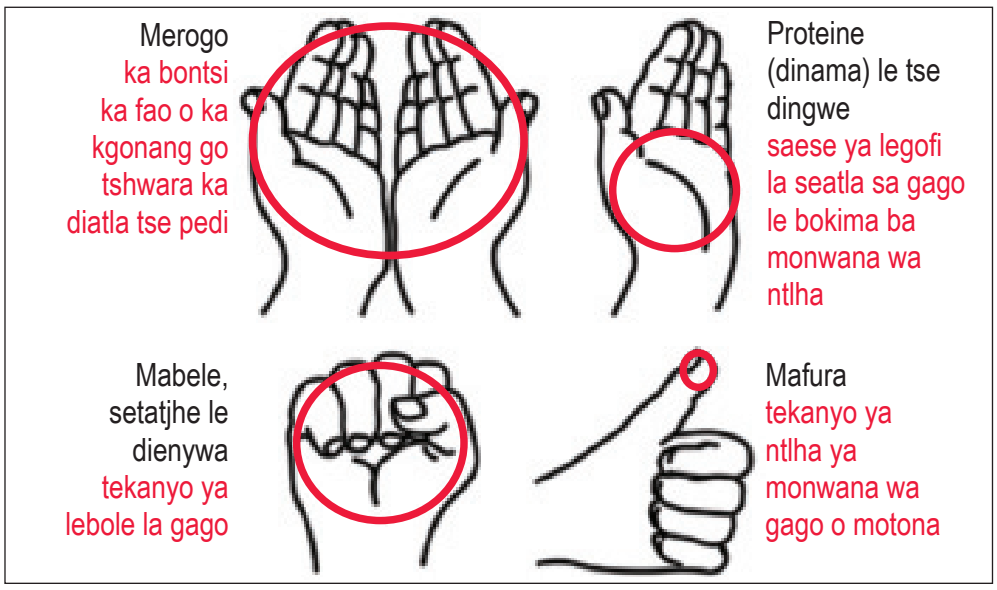
Naa ke tshwanetse go ja dijo tse kaakang?

Tshupatsela ya tekanyetso ya dijo tsa motho a le mong.



Tshupatsela ya tekanyetso yo dijo ka mo poleiting.

*(Digwere tseo di apeilweng di ka emelwa ke mogopo wa salata)

Go ja sentle ga go tlhokegale go ture:

O ka:

- Reka merogo le dienywa tsa setlha seo re leng mo go sona le tseo di rekegago ka theko e kwa tlase.
- bjala merogo le dienywa tsa gago.
- kgoboketsa le go dirisa merogo le dienywa tsa setso tsa kwa nageng.
- eja dinawa tseo di omisitsweng goba dilentili sebakeng sa nama goba o di tlhakanye le nama.
- reka dienywa sebakeng sa dinotsididi goba seno sa dienywa.
- dira meetse kgetho ya gago ya seno.

E ba mafolofolo fa mmeleng

- Go ba mafolofolo letsatsi lengwe le lengwe go tla thusa glucose ya madi gore e laolege.
- Boitshinollo bo thusa go fokotsa boima gomme bona le mehola e meng e mentsi.
- Mekgwa e meng ya go itshinolla e akaretsa go tsamaya, go taboga le go reila paesekela. Go dira nkatana le ditironyana tsa ka mo gae le yona ke mekgwa yeo e thusang go tshwarella go ba mafolofolo mmeleng.

E lellwa le se: ge o dirisa meriana, dira ka fao o laetsweng. Go ja sentle go tla thusa wena le ba lelapa la gago.

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APPENDIX 11

VEGETABLE GARDENING QUESTIONNAIRE (PHASE 2)

Clinic…… **Participant number……..**

1. What vegetables are commonly eaten in this area?

2. Where do you obtain your vegetables from? Specify what vegetables are obtained from each source

   ☐ Own garden

   ☐ Own garden and buying

   ☐ Buying

   ☐ Any other (Specify)…….

3. Where do most people living in this area get most of their vegetables from?

   ☐ Own garden

   ☐ Own garden and buying

   ☐ Buying

   ☐ Any other (Specify)…….

4. If vegetables are purchased, where do you or other people living in this area buy vegetables from?

   ☐ Neighbours

   ☐ Local shops/grocery

   ☐ Supermarket

   ☐ Any other (Specify)…….

5. What problems do you or other people with diabetes experience in obtaining vegetables for consumption?

6. Which vegetables are commonly grown in this area?

7. What problems do you or other people in this area experience in growing your/their own vegetables?

8. Have you ever received any information/education on how to grow your own vegetables?

9. From where did you receive this information?

10. What more information or help would you need to be able to grow vegetables in your own garden?

11. Would you or other people with diabetes be interested in learning how to grow your own vegetables? Please explain.

APPENDIX 12

TRAINING MANUAL

Fakulteit Gesondheidswetenskappe

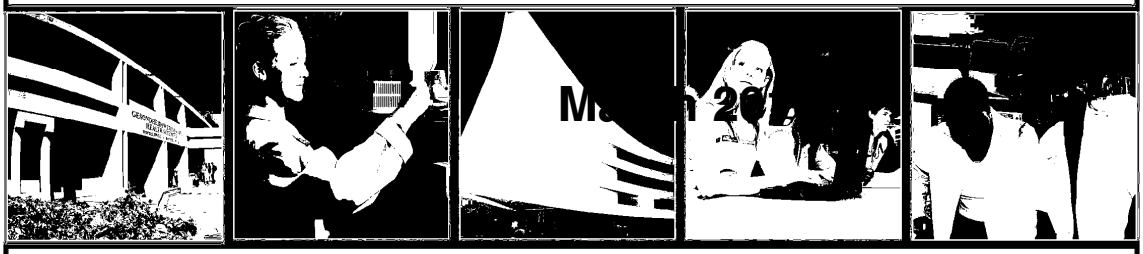
Faculty of Health Sciences

NUTRITION EDUCATION PROGRAMME FOR TYPE 2 DIABETES MELLITUS

TRAINING MANUAL

School of Health Care Sciences

Department of Human Nutrition



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INTRODUCTION

This nutrition education programme is designed for individuals with type 2 diabetes mellitus, specifically those not on insulin therapy. The sessions are designed in a way that allows an active interaction between the facilitator and participants' and the participants themselves.

There are questions at the beginning or during the session. These open ended questions help to draw on what the participants already know about the topic being addressed. There are also questions before the end of each session that help the facilitator gauge the comprehension of the topic for the session.

Before the end of the sessions there is a participant self-assessment and goal setting activity. This is to give participants an opportunity to evaluate their current dietary or other self-management practices against the recommendations/guidelines. Participants' self-assessment forms the basis for setting personal goals and action plans.

TABLE OF CONTENTS

Session 1- Understanding diabetes mellitus

Approximate time required: 2 hours

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
At the end of the session the participant will be able to: • describe diabetes mellitus • explain the role of glucose in the body • explain the role of insulin in the body	1.1 **What is diabetes**? A. Introduction of participants and self. B. Discuss participants' responses on the explanation of diabetes, and then give the explanation using the flip chart. • Diabetes is life long condition in which the blood sugar levels (glucose) become too high. This results either from inability to produce insulin or to use produced insulin properly. Insulin is produced in the pancreas (show on flip chart). It helps glucose to move from the blood stream to the body cells. In other words it opens the cells, just like a key opens a door. This allows glucose into the cells. • To help us understand diabetes, we need to know that our bodies' whether we have diabetes or not need glucose. We need glucose to give us energy to do work. Glucose comes from the foods we eat like starchy foods (bread, sorghum, mealie porridge, rice, potatoes) fruits, sugar and sugary foods, dry beans and milk. When we eat, the food is broken down into glucose. This glucose enters the blood stream. In a person without diabetes, insulin will move the glucose from the blood to the cells, thus lowering the blood glucose. In a person with diabetes there is no insulin being produced, or insulin is not working properly. The cells remain locked or only a few cells are opened, thus glucose cannot enter the cells. The glucose remains in the blood stream leading to high sugar (glucose) levels. It also overflows into urine and is passed out of the body in urine. **Does any one have a question so far?**	Ask participants to describe diabetes in their own words; (Does anyone want to explain to us what diabetes is?) Ask the participants why we need glucose? Ask participants to name the foods that give glucose	Flip chart: diabetes basics

LEARNING OBJECTIVE	PRESENTATION OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to describe the major types of diabetes	**1.2 Types of diabetes, causes/risk factors and characteristics** **A.** As you might already know there are different types of diabetes B. Discuss responses and explain the two major types (Type 1 & Type 2) using the flip chart. Mention also that some pregnant women get another type (gestation diabetes). C. Discuss the responses, addressing any misconceptions as you give the explanations using the flip chart: **Type 1**: Occurs due to destruction of the cells of the pancreas that produce insulin. Thus no insulin is produced. Individuals have to use insulin injections. This type occurs in children and younger people. **Type 2:** Usually occurs in people who are overweight and not active. Insulin is produced but it is not enough or the body does not use it properly. Usually occurs in older people over 35 years. Nowadays being seen in children and young people ***NB***: Chances of getting diabetes increase if there is a family history of diabetes. **Does any one have a question so far?**	Ask the participants: Do you know what the major types of diabetes are? Can any one tell us what causes diabetes? Or what makes people get diabetes?	Flip cart: diabetes basics
The participant will be able explain the symptoms of diabetes	**1.3 Symptoms of diabetes** Discuss response and explain symptoms using flip chart. A. Passing a lot of urine: the kidney is trying to remove excess glucose from the blood B. Excessive thirst: because extra fluid is passed into the kidney to dilute glucose C. Hunger: glucose does not enter the cells D. Tiredness: glucose does not enter the cells, thus not changed into energy E. Weight loss: glucose does not enter the cells; body's fat stores are used for energy. F. Blurred vision: lenses in the eyes take up extra glucose and become swollen and unable to focus	Ask participants to name the signs/symptoms seen or are experienced when one has diabetes	Flip chart: diabetes basics

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	1.3 Symptoms of diabetes H. Fruity breath: due to ketone bodies that are formed as a result of a lot of fat being broken for energy (mainly in type 1) **However**, some people with type 2 diabetes do not experience these symptoms.		
The participant will be able to: explain the complications of diabetes	**1.4. Complications/dangers of diabetes** If diabetes is not treated or well controlled it can cause problems in many parts of the body A. Discuss the responses on complications and use flip chart to further explain or correct any misconceptions. I. Eye problems that can lead to blindness II. Kidney problems: too much blood sugar causes the kidney to overwork. This can result to the kidneys not working properly. III. Heart disease: due to blockage of blood vessels with fat deposits or narrowing of blood vessels, heart attack can occur IV. Stroke: due to blockage of blood vessels supplying the brain V. Nerve damage: excess glucose can cause damage to the blood vessels to the nerves especially to those of the legs. This can cause foot problems, problems with passing urine and manhood (impotence) VI. Foot problems: occurs due to nerve damage and reduced blood supply to the feet. This makes it easy to get ulcers and infections that can lead to amputation. VI. Kidney problems: too much blood sugar causes the kidney to overwork. This can result to the kidneys not working properly.	Ask the participants to give the complications/problem caused by diabetes	Flip chart: diabetes basics

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to: explain the complications of diabetes	VII. Heart disease: due to blockage of blood vessels with fat deposits or narrowing of blood vessels, heart attack can occur VIII. Stroke: due to blockage of blood vessels supplying the brain IX. Nerve damage: excess glucose can cause damage to the blood vessels to the nerves especially to those of the legs. This can cause foot problems, problems with passing urine and manhood (impotence) X. Foot problems: occurs due to nerve damage and reduced blood supply to the feet. This makes it easy to get ulcers and infections that can lead to amputation. **Does any one have a question so far?** **1.5 Assessment and summary** Assess participants' comprehension of content before the end of session. Discuss participants' response and summarise. Inform participants, the topic for next meeting: [treatment of diabetes]	Ask the group to explain: • What diabetes is • The major types of diabetes and their characteristics • Some of the symptoms of diabetes • Some complications of diabetes	Flip chart: diabetes basics

Session 2: Treatment of diabetes

Approximate time required 1.5- 2 hours

LEARNING OBJECTIVE	PRESENTATION-OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to: explain the methods of treating diabetes	2.1 **Treatment of diabetes (strategies)** A. Introduction. Brief on what was covered in the previous session and what will be covered in the session B. The ways in which diabetes is treated Diabetes is managed through meal planning (diet), exercise and medication. I. Meal planning (diet) Why is it important? • Food is broken down into glucose, and hence raises blood sugar levels • Your meal plan (what you eat, how much you eat and when you eat) helps control your blood sugar levels. Eating too much food or foods that are not healthy can cause blood sugar levels to rise. • Following a healthy meal plan is necessary for controlling blood sugar levels and has many other benefits. This will be discussed later. II. Exercise/physical activity Regular exercise (being active) is recommended for all people including those with diabetes. i) Why is exercise important? • Helps in lowering blood sugar levels • Helps control your weight • Improves blood pressure • Lowers high cholesterol • Improves blood flow and circulation • Keeps blood vessels elastic • Helps relieve stress ii) What exercise? Must be suitable for you. Examples are walking, jogging, bike riding etc. Gardening and household chores also help in keeping physically active (show flip chart: be active guideline)	Ask the group to briefly say what was discussed in the last session Ask the group to explain the ways of treating diabetes Ask the group why a meal plan is important in the management of diabetes Ask the group why exercise is important in the management of diabetes ***NB:*** Diabetes can make blood vessels less elastic and cause problems with circulation. overweight increases the risk for heart disease, high blood pressure and insulin not working properly	Flip chart: diabetes basics Flip chart: South African guidelines for healthy eating page 8-9

LEARNING OBJECTIVE	PRESENTATION-OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	iii) How to exercise • Regularly-at least 3-4 times per week for 30-50 minutes • With suitable foot wear • Stop in case you experience any of these problems; chest pain, difficulty breathing, dizziness, chest fullness, joint or muscle pain III.Medication This includes oral medication and insulin injections. i) Oral medications Used in type 2 diabetes. Different types to deal with the problems in type 2. Some help stimulate the pancreas to secrete insulin, others sensitise the body to use insulin properly, and others reduce the production of glucose by the liver. ii) Insulin Insulin injections are used in individuals with type 1 diabetes. Some individuals with type 2 diabetes may also need to use insulin at some stage.	Ask participants what exercise they are involved Ask the participants to say what exercise they plan to do or what more they could do to be physically active Ask participants recall the problem in type 2 diabetes (inadequate production of insulin or insulin not working properly) Ask participants to recall that in type 1 diabetes, no insulin is produced	Flip chart: diabetes basics
The participant will be able to: describe the treatment goals for diabetes	**2.2 Treatment goals** The goal of diabetes treatment is to have the blood sugar levels close to the normal as possible by balancing food intake with physical activity and medication. This means you avoid low or high blood sugar levels. This delays or prevents the complications/dangers of diabetes. • Target blood sugar levels • Before meals (fasting):4-7 mmol/L • 1-2 hours after meals: 5-8 mmol/L Therefore the blood sugar levels that you check at the clinic should be between 4-8	Ask the participants whether they know their blood sugar levels for the previous month	Flip chart: diabetes basics

LEARNING OBJECTIVE	PRESENTATION-OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	• The sugar levels for the last two to three months (called AIC) as we did for the project should be less than 7 • It is also important to have your blood pressure, blood fats such as cholesterol and body weight within the healthy range.	Ask participants to check their laboratory results for their AIC levels and say what they think	Participants laboratory results print out
The participant will be able to: • state the causes and symptoms of high blood sugar levels • describe how to treat high blood sugar levels • describe the strategies they will use to prevent high blood sugar levels	**2.3 Causes of high blood sugar levels** A. Eating too much food B. Forgetting to take oral medication or use insulin or delaying their intake C. Being ill D. Stress **2.3.1 Symptoms of high blood sugar levels** The symptoms of diabetes are experienced when the blood sugar levels are high (show flip chart) Therefore it is important to regularly have your blood sugar levels checked. **2.3.2 Treatment of high blood sugar** If your blood sugar levels are high: A. It may be due to the causes which we have already discussed. Try to identify the cause and correct it. You may need to: ▪ reduce the amount of food ▪ take medication as advised by your health provider ▪ exercise (only when blood sugar levels are below 16 mmol/L) ▪ deal with stress B. Take plenty of water to prevent dehydration C. Visit your health clinic if you are sick or the blood sugars remain high even after making the changes **Is there any question so far?**	Ask participants what can make blood sugar levels to get high Ask the participants how one feels if the blood sugar levels are high Ask participants what they should do if blood sugar levels are high	Flip chart: diabetes basics

LEARNING OBJECTIVE	PRESENTTION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
.	**2.3.3 Goal setting:** preventing high blood sugar levels. In the next 2 weeks • eat smaller amount of foods • choose foods high in fibre, increase vegetables to 2 servings/day • reduce amount of sugar used • take medication as advised • exercise 3 days/week for 30 minutes	Ask participants to say what they plan to do to prevent high blood sugar levels	
The participant will be able to: • explain the causes of low blood sugar levels • describe the symptoms of low blood sugar • explain how to manage low blood sugar levels	**2.4 Causes of low blood sugar** A. Using too much insulin or tablets B. Taking too much alcohol C. Skipping a meal or eating too little food D. Strenuous exercise **2.4.1 Symptoms of low blood sugar** A. Shakiness and dizziness B. Headache and lack of concentration C. Weak knees D. Sweat, extreme hunger E. Pale, irritable and confused **2.4.2 Treatment of hypoglycaemia** A. Use some form of sugar ▪ 2 tsp sugar with milk ▪ 5-6 hard sweets ▪ 2-4 tsp sugar in water ▪ ½ cup fruit juice or regular soft drink ▪ 1 table spoon honey B. Follow with a slowly digested starch such as a sandwich with low fat meat or cheese and vegetable **Self reflection: Causes and management of low blood sugar levels** **Goal setting:** preventing low blood sugar levels. In the next 2 weeks • Take 3 meals per day • Take medication correctly	Ask participants what can make sugar levels to become low Ask the participants what the symptoms of low blood sugar levels are Ask the participants if they have ever experienced low blood sugar levels, what could have been the cause and how they managed it	Flip chart: diabetes basics

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	2.4 Assessment and summary Assess participants' comprehension of content before the end of session. Discuss participants' response and summarise. Inform participants, the topic for next session: [Dietary guidelines]	Ask the participants to explain : • why meal planning is an important treatment for diabetes • why exercise is important in the management of diabetes • the goal of diabetes treatment • Some of the causes of high blood sugar • how they can prevent high blood sugar levels	

Lesson 3: Dietary guidelines
(Variety, starchy foods, fruits and vegetables and meats and alternatives)

Approximate time 2-2.5 hours

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to explain what is healthy eating	**3.1 Introduction: the South African Guidelines for healthy eating** All individuals in South Africa including those with diabetes are encouraged to eat healthily. **A. What does healthy eating mean?** An eating pattern that emphasis variety, regular meals, starchy foods, vegetables and fruit, low fat and low sugar. It also includes physical activity. The South African guidelines for healthy eating have been developed to help us eat more healthily. We shall discuss some of these guidelines in details **B. What are the benefits of healthy eating?** • You won't get sick easily • You won't get tired easily • You are able to do your work well • You have better control of blood sugars • It helps to loose weight if overweight or stay within a healthy weight • It helps reduce blood pressure	Introduce the South African guidelines for healthy eating Ask the participants to explain what they understand by healthy eating Ask the participants to explain some benefits of healthy eating	Flip chart: South African guidelines for healthy eating **(**SA guidelines)
The participant will be able to: • Explain what variety means and the benefits • Describe how they can achieve variety in meals	**3.2. Specific dietary guidelines** **3.2.1 Enjoy a variety of foods** A. What is the meaning of, a variety of foods? • Eating more than one type of food in a meal and different types at various meals e.g. lunch and supper. • A variety of foods combined in one meal is a mixed meal (show flip chart) B. The importance of variety • Makes meals more enjoyable • Helps us get all the nutrients we need. If we eat one type of food we will not get all the nutrients we need to stay healthy	Show flip chart and meals on display and raw foods.	Flip chart pages 4-7 Samples of raw foods and cooked meal(s) to show variety

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to: • Explain what variety means and the benefits • Describe how they can achieve variety in meals	C. Enjoying our food Eating is something we should enjoy. Eating with family and friends should make it a happy event. Variety makes meals more interesting and enjoyable. D. How to add variety to our foods • Include different foods into our meals • Try different cooking methods such as steaming, grilling, boiling • Try affordable vegetables and fruits that have not been used before • Try raw vegetables instead of always cooking vegetables **Does any one have a question so far?** **E. Goal setting:** improving variety in meals	Ask the participants what they can do to bring variety to their meals Ask the participants to decide on one or two things they will do to improve on variety in their meals and tell other members	
The participant will be able to: • explain the importance of starchy foods • describe healthier options of starchy foods	**3.2.2 Make starchy foods the basis of most meals** A. Examples of starchy foods B. Why starch foods should be a part of each mixed meal I. Provision of energy and some nutrients II. Makes one feel satisfied III. Unrefined starchy foods (e.g. coarse maize meal and whole wheat bread) have fibre which helps the bowels function properly (going to the toilet easily). They also help in better control of blood sugars. IV. They are widely available and not expensive C. Mix starchy foods with other foods • Starchy foods do not give everything that the body needs, therefore mix it with other foods such as vegetables, fruits, dry beans, meat, chicken, eggs etc. • Mixing starchy foods with other foods help to better control your blood sugars. D. Best choices of starchy foods include unrefined types and those that are fortified (have more nutrients added	Ask to participants to give examples of starchy foods Ask participants to give examples of unrefined starchy foods	Flip chart SA dietary guidelines pg 12-13

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to explain why the quantities of starchy foods need to be controlled	E. Control the amounts of starchy foods • Starchy foods raise blood sugar levels. Eating too much will cause the sugar levels to get very high. Eat smaller portions and combine with other foods.	Ask the participants why they should not eat too much of starchy foods	Flip chart SA dietary guidelines pg 12-13
The participant will be able to: • Explain the importance of eating fruits and vegetable The participant will be able to: ▪ explain the term "plenty" in respect to vegetables and fruits • describe how they can include vegetables and fruits in their daily meals • describe the relationship between vegetables and fruits and blood glucose	**3.2.3 Eat plenty of vegetables and fruits** A. Why we should eat plenty of vegetables and fruits Discuss benefits as outlined in flip chart • Helps our eyesight • Helps our bodies fight against diseases such as colds • Helps to better control blood sugar • Helps to control blood pressure • Helps our bowels work properly because of fibre • Helps protect the bodies against diseases like heart disease and some cancers B. What does plenty mean? • At least five portions/servings per day. A serving means 1 medium fruit or ½ cup cooked vegetable or ½ cup fruits. • This can be achieved by including one to two fruits per day and having 2 serving spoons of vegetables with your lunch and supper/dinner • Fruit can be eaten with your meals for example breakfast or in between meals • It is important to include both yellow (carrots and pumpkin etc) and green vegetables (morogo, cabbage, spinach, green beans etc) • It is important to eat vegetables from home gardens and the veld C. Do fruits and vegetables raise blood sugars? • Fruits raise blood glucose, therefore eat only one medium fruit at a time • Some starchy vegetables like pumpkin, squash and peas also raise blood glucose to some extent. It is important not to eat too much of them in one meal. • Leafy vegetables such as spinach, cabbage, morogo, lettuce do not raise blood glucose; therefore they can be eaten without controlling the amounts (freely	Ask the participants to explain why it is important to eat fruits and vegetables .	Flip chart SA dietary guidelines pg 20-21

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIIES	MATERIALS
	D. How to prepare vegetables • Wash fresh vegetables and fruits in clean safe water before using • Cook vegetables for a short time in very little water till just tender to preserve nutrients and flavour • Include both cooked and raw vegetables E. Discuss the factors mentioned by the group F. How to cut the costs of fruits and vegetables • Buy vegetables and fruits grown in the area • Buy those in season • Grow own vegetables and fruits to have a constant supply • Collect and use traditional fruits and vegetables • Buy more vegetables when they are cheaper than fruits **Goal setting**: increasing the intake of vegetables and fruits **Goal** : to increase vegetables to at least 2-3 servings per day and fruits to at least one serving per day	Ask the participants the reasons why people do not eat plenty of vegetables and fruits Ask participants whether they think they are eating enough vegetables and fruits. Ask them to identify one or two things they could do to increase their intake of vegetables and fruit	
The participant will be able to: • explain the importance of legumes • describe how they can include legumes into their eating plan	**3.3.4 Eat dry beans, split peas, lentils and Soya regularly** A. Introduction: In the beginning we talked about having a variety of foods and mixed meals. We have talked about starchy foods, vegetables and fruits which form a part of mixed meals. B. We will now look at another group of foods which can form part of mixed meal. C. Show displayed examples	Ask the participants to explain the benefits of eating these	

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTVITIES	MATERIALS
The participant will be able to: • explain the importance of legumes • describe how they can include legumes into their eating plan	D. What is good about these foods (benefits) • They can be used instead of meat • They are rich in protein, iron and other nutrients • They are good extenders of meat • They are not expensive • They help in blood glucose control (soluble fibre) • They help prevent heart disease and cancer • They contain very little fat • Help in proper bowel function E. What does regularly mean? It means at least three times per week. They should be eaten on the days you do not eat meat or fish or chicken. If one never eats meat, fish, chicken, milk or milk they should eat them every day. F. Discuss the reasons given for not eating these foods. Offer suggestions for overcoming the problems G. How to prepare dry beans: explain as given in the flip chart	Ask the participants why they think people do not eat dried beans, split peas and Soya Ask participants if they use dried beans, split peas or soya in their meals Ask the participants to suggest ways they could include them in their meals	Flip chart SA dietary guidelines pg 16-17 Raw samples (in clear plastic bags) of dried beans such as sugar beans, kidney beans, split peas, lentils, Soya beans and Soya meat.
The participant will be to: • explain the importance of these foods • describe how they can make wise economic choices of these foods • describe how they can prepare these foods more healthily	3.3.5 **Chicken fish, meat, milk or eggs can be eaten daily** A. Introduction Chicken, fish, meat, milk and eggs are another group of food that can be included in a mixed meal. B. Why are these foods needed in the body? Discuss participants' responses and give reasons given in flip chart. • They are animal sources of proteins • They help to build muscles, strong teeth and bones	Ask the participants why they think chicken, meat, fish, milk or eggs are needed by the body.	Flip chart SA dietary guidelines pg 18-19

Continued/……..

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be to: • explain the importance of these foods • describe how they can make wise economic choices of these foods • describe how they can prepare these foods more healthily	• Milk, maas, cheese, yoghurt and soft edible should bones of fish (pilchards, sardines) contain a mineral called calcium. Calcium helps in building strong bones and teeth • Chicken, meat and fish contain a mineral called iron. This mineral is necessary for healthy red blood red cells, which carry oxygen in the body. C. Must these foods be eaten every day? Small portions can be eaten every day, but do not have to be eaten every day. A small portion is considered as one chicken thigh, a piece of fish or meat, the size of the palm and thickness of the little finger. About 2 cups of milk or sour milk or yoghurt are needed per person every day Too much of animal based foods increase the chances of heart diseases. This is due to the amount and type of fat (as we shall discuss later). • Eggs and chicken are cheaper alternatives to red meat. However, eat only three to four eggs a week as egg yolk contains some fat. • Choose leaner cuts of meat, cut off all visible fat from meat and remove the skin from chicken before cooking. • Rather boil, stew, microwave, roast or grill meat instead of frying • Liver, kidney and offal are cheap sources of protein but they are also high in fat and cholesterol, they should not be eaten often. • Fish contains a little fat thus it can be substituted for red meat. Fish tinned in water or tomatoes are a better choice than fish tinned in oil. Try not to have fried fish • Traditional foods such as mopani worms, locusts and other insects can also be used. They are a good source of protein and are low in fat	Ask the participants why they think chicken, meat, fish, milk or eggs are needed by the body.	Flip chart SA dietary guidelines pg 18-19

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	Polonies, viennas, sausage meat, salami and bacon are high in fat and salt. If they have to be consumed, it should be occasionally **Goal setting**: selecting and preparing meats, chicken, fish, eggs and milk **Goal**: In the next two weeks; • to choose low fat/skim milk • prepare food with low fat cooking methods • remove skin from chicken • choose low fat meats	Ask participants to say what changes they think they need to make concerning eating or preparing chicken, meat, fish, eggs and milk. Ask them to select one or two things they want to change	

Session 4: Improving vegetable supply through gardening

Approximate time 2 hours

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTVITIES	MATERIALS
The participant will be able to: • explain the importance of producing own vegetables • list the requirements for growing specified vegetables • demonstrate how to prepare seed bed, apply manure/fertiliser, sow or transplant seedlings and control pests • describe how they can maintain their vegetable supply through own vegetable production	A. Today our lesson is on growing our own vegetables B. Discuss participants responses as you highlight the benefits of eating vegetables in general and in sugar control C. Discuss the benefits of growing own vegetables and the reasons why people do not grow vegetable D. Take participants to the demonstration sites and explain the requirements for each of the vegetables as you demonstrate E. Allow participants to be involved in each of the activity F. Give tips on how to maintain constant vegetable supply • staggering the planting • maintenance of moisture • controlling pests **Goal setting**: Increasing vegetable supply • start vegetable garden if not having one in the next one month • Increase number of vegetables produced in the next one month • Collect wild vegetables and use	Ask the participants' to recall the importance of eating plenty of vegetables Ask the participants the benefits of growing their own vegetables Ask the participants if they grow their own vegetables and why people do not grow their own vegetables Ask participants what they can do to increase their vegetable supply through own gardening	Farm tools (fork, spade etc) seedlings of cabbage, spinach & onions Carrot and green bean seeds Fertilisers and pesticides Measuring sticks

Session 5: **Dietary guidelines: fats, sugar, salt and water**

Approximate time 11/2-2 hours

LEARNING OBJECTIVE	PRESENTATATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to: • explain the importance of fats in the body • describe the wise choices of fats and oils • explain why fats should be used sparingly	**5.1 Eat fats sparingly** Content: Some fats are good and others not so good. Too much of any is not healthy A. Do our bodies need fats? Discuss participants' responses and then explain. Yes our bodies need fat: • Fats give us energy and keep us warm • Fats our bodies to absorb some vitamins B. What are the dangers of eating too much fat? Discuss participants responses and then explain • Becoming overweight • Increase in blood cholesterol • Increased chances of getting heart diseases (remember people with diabetes have a higher chance of getting heart disease) C. Which foods are high in fat? Discuss participants' response and make any additional foods. Examples: fried chips and crisps, vetkoek, doughnuts, pies, coffee creamers, drippings from meat, ghee, butter, lard D. Which oils and fats are wise choices? Discuss as per flip chart **NB**: Generally plants contain better types of fats than animals. Exemptions include coconut and palm oil kernel (which are plant sources with "bad" fats) and oily fish (pilchards, tuna, sardine, and mackerel) which have better fats. E. Which fats and oils are less wise choices? Discuss as per flip chart	Ask the participants whether they think our bodies need fats Ask the participants what are the problems caused by eating too much fat Ask the participants to mention some of the foods that are high in fats	Flip chart: SA dietary guidelines pg 22-23

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	F. F Discuss what it means to eat fats sparingly G. Discuss tips to reduce fats including reading food labels **Goal setting**: reducing fats in foods and making healthy fat choices Goal: to trim fat off from meats and removing skin from chicken before cooking all the times -cooking with less fat in every meal	Ask the participants what they will do to: • reduce the fat content of their foods • reduce the unhealthy fat choices	Flip chart SA dietary guidelines pg 22-23
The participant will be able to: • explain why salt should be used sparingly • state foods that are high in salt	**5.2 Use salt sparingly** A. Introduction Most of the salt we eat comes from salt added when preparing, cooking or eating foods (at table) B. Do our bodies need salt? Discuss as per flip chart C. Why do we have to eat salt sparingly? Discuss as per flip chart. D. What foods and products are high in salt? • Sausages, polony, salami, snoek, pizzas, potato crisps, biltong and canned or packet soups • Fast foods and take always such as pies • Stock cubes, marmite, Bovril, salted nuts, sauces	Ask participants why it is important to use salt sparingly	Flip chart pg 24-25
The participant should be able to: • explain why foods, drinks and sugar should be used sparingly • state the foods that are high in sugar	**5.3 Use foods and drinks containing sugar sparingly and not between meals** A. Discuss participants' response on why too much sugar is not good for health, and then explain reasons from flip chart. In addition explain in diabetes less sugar helps in better control of blood glucose B. What are some of the foods that are high in sugar	Ask participants why too much sugar is not good for our health Ask participants to mention foods that are high in sugar Ask participants which foods and drinks they take which contain sugar	Flip chart pg 26-27

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
	C. How should we use foods and drinks with added sugar or sugar? Foods and drinks with a lot of added sugar and sugar itself are better avoided. If they have to be taken it should be **sparingly and as part of a healthy meal**. **Sparingly** means small amounts at a time and as little as possible D. How we can use sugar sparingly? Discuss as per flip chart **Goal setting:** reducing intake of sugar and sugar containing foods **-** not adding sugar to hot beverages or reducing the amounts in the next 2 weeks **-**choosing foods with less sugar **Group activity:** Label reading A. Labels found on food packages help us know which foods are high or low in sugar, salt or fat. It is important to read food labels when buying foods. B. Remember when reading labels, sugar may also be called sucrose or dextrose C. Discuss what to look for in labels: ingredient list, nutrition information panel, nutrient claim 'free, low, high" and words used such 'lite" using examples of packages on display. D. Discuss participants' grouping of products.	Ask participants to mention ways in which they could decrease intake of sugar in foods and drink Ask participants to look at the packets/containers of products on display and place those they think are better choices together (low fat, sugar and salt) and those they think are not good choices together.	Empty packets/ containers of foods that are low or high in fats, sugar or salt
The participant will be able to explain why drinking lots of clean water is important and why drink clean water	**3.3.9 Drink lots of clean safe water** **A.** Introduction: Every part of our body contains large amounts of water. We cannot live without water **B.** Discuss participants' responses and give explanations on the need for water and why the water should be clean as per the flip chart **Note:** Pure fruit juice contains natural sugar (1 glass has amount of sugar equivalent to 6 teaspoons) therefore not a good choice of drink.	Ask participants to explain the reasons why we need water Ask participants why we need clean safe water Ask participants what they can do to ensure they take enough water	Flip chart pg 10-11

Session 6: Meal planning: Food portions/serving sizes and meal frequency

Approximate time: 2 hours

LEARNING OBJECTIVE	PRESENTATION: OUTLINE AND CONTENT	ACTIVITIES	MATERIALS
The participant will be able to: • describe food combinations for meal balance and variety • portion various foods using household tools and parts of the hand	**6.1 Portion sizes** A. Introduction As discussed earlier what you eat, how much you eat and when you eat is important in the control of blood sugar levels. Today we will look at some ways that can help you eat healthily as well as control the amounts of foods you eat B. Discussion on how participants determine portions/amounts and demonstration by one participant how they portion one of the sample meals C. The plate method You can use the plate you normally use for lunch or supper/dinner. Half the plate you fill with vegetables. In the other half you divide into two. Half you fill with starchy foods and the other half with proteins (meat, fish, beans etc). In this way you include different foods as discussed earlier, you eat plenty of vegetables and control the starch and proteins. D. Using your hands You can also uses your hands to help you determine the amount of foods to eat Show the flip chart as you demonstrate with your hands E. Do the actual portioning of foods using the two methods. ***NB***: the fist can be used as a guide for the starch portion for the plate model F. **Group work** : portioning foods G. **Group discussion**: • how the methods for portioning foods can be applied at home • what the participants think about the portion sizes	Ask participants how they determine the amount of foods to eat in a meal Ask one participant to show how they serve a combination of the provided sample foods Show participants the plate model Ask the participants in groups of three to use the two methods to portion provided foods Ask the participants whether they can use any of the methods to help them portion their foods.	Flip chart with plate model & Zimbabwe hand jive Commonly used plate and serving spoons, paper plates Samples of cooked foods. Rice, pap, mashed potatoes, chicken pieces, beef stew, spinach/cabbage/morogo, carrots/pumpkin, samp and beans Samples of pre-plated foods using the plate model.

LEARNING OBJECTIVE	PRESENTATION: OULINE & CONTENT	ACTIVITIES	MATERIALS
The participants will be able to explain the importance of regular meals	**6.2 Number of meals** A. As discussed earlier healthy eating includes eating regular meals B. Meaning of regular At least three meals (breakfast, lunch and supper/dinner) in a day and not skipping meals C. Benefits of eating regular meals • better control of blood sugar levels • you get all the nutrients needed by the body and the energy to work **Are there any questions so far?** **Goal setting:** eating regular meals • to eat at least three meals in a day everyday for the next 2 weeks	Ask the participants why it is important to eat regular meals Ask the participants how many meals they eat in a day and whether they skip any meals Ask the participants to mention ways that can help them eat regular meals	

Session 7: Planning healthy meals on a limited budget

Approximate time 1.5-2 hours

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will be able to: • describe ways in which they can reduce the costs of meals	A. Introduction Healthy eating does not have to be expensive. One can eat healthily even if they do not have a lot of money B. Discuss participants' responses and give the tips for reducing the cost of meals • Buy fruits and vegetables in season or those on offer • Grow your own fruits and vegetables • Collect and use traditional vegetables and fruits • Make water your drink of choice instead of buying cold drinks or juice • Use beans or lentils instead of meat or mix with meat • Carry your own packed lunch when away from home instead of buying lunch • Buy non perishable foods like UHT low fat milk in bulk or powdered low fat milk whenever possible • Do not shop when hungry as this will tempt you to buy things you did not plan for C. Using examples of good mixed meals (Appendix 1) show the cost of the meals D. Do the costing meals of the meals and compare E. Evaluation and goal setting: eating good mixed meals (balanced) Goal: to eat balanced meals in at 1 meal per day for the next two weeks	Ask participant to explain ways that could help some body reduce the costs of Ask some participants to say the foods they ate the previous meals Ask the participants to give examples of balanced meals that they could plan within their budget	

Session 8: Preparing healthy meals

Approximate time 2-2.5 hours

LEARNING OBJECTIVE	PRESENTATION: OUTLINE & CONTENT	ACTIVITIES	MATERIALS
The participant will demonstrate an appreciation of foods prepared using low fat cooking methods The participant will demonstrate an appreciation of lentils (a cheap source of protein) that is not commonly consumed	A. Introduction We have talked about healthy eating as a way of helping in the control blood sugar levels and many other benefits. Some people think that foods that are low in fat or salt or sugar are tasteless. Today we will prepare some foods that we commonly prepare at home and those we may want to start preparing. B. Start discussion on meats and alternatives. Products: boiled meat and lentil curry. Show the trimming of meat before cooking. Show the need to use a spoon when putting oil in a sauce pan when stewing the curry. C. Discuss vegetable preparation. Give reasons why vegetables should generally be prepared last and why they should be cooked for a short time and with very little water or their own water. Show the process of preparing vegetables. D. Allow participants to taste the produced foods in combination with starches E. Allow discussion about the foods	Ask participants to say how they prepare the foods on display Ask some participants to assist in the tasks Ask participants what they could do to prepare tasteful healthy meals.	Ingredients: 2 vegetables, meat, lentils (preboiled), 1 or 2 starches, tomatoes, onions, green pepper, herbs , mixed spices, pepper, curry, powder, cooking oil Kitchen equipments: chopping board, kitchen knives, wooden spoons, serving spoon, sauce pans

APPENDIX 1: Sample meals for cost analysis

Day 1 meals	Amounts consumed	Cost	Day 2 meals	Amounts consumed	Cost
Breakfast Soft porridge with Low fat milk Tea with milk Banana			**Breakfast** Brown bread Margarine, thinly spread Tea with milk Apple		
Lunch Brown bread sandwich with pilchards Margarine thinly spread Orange Water			**Lunch** Rice or sorghum Brown lentil curry with Green beans Banana Tea with milk		
Supper Samp and beans Stewed tomatoes and onion Spinach Pumpkin			**Supper** Stiff maize meal porridge Chicken stew and carrots Boiled morogo Water		

APPENDIX 13

SOCIO-DEMOGRAPHIC DATA FORM (PHASE III)

CLINIC_____

V1	Study number		☐☐☐ 1-3
V2	Age (years)		☐☐ 4-5
V3	**Gender** Male Female	 1 2	☐ 6
V4	**Educational level** None St 1-4 St 5-7 St 8-10 Post 10	 1 2 3 4 5	☐ 7
V5	**Marital status** Single Married Widowed Separated/divorced	 1 2 3 4	☐ 8
V6	**Employment status** Are you working? Yes No	 1 2	☐ 9
V7	**What kind of work do you do?** Selling Domestic Dressmaking Office Other (specify) Not applicable	 1 2 3 4 5 6	☐ 10
V8	**Source of financial support** How do you get money to live? Husband Relatives Piece jobs Pension Friends/disability/grant No answer	 1 2 3 4 5 6	☐ 11
V9	**Living arrangement** Live with family Live alone Other (please specify)	 1 2 3	☐ 12
V10	**Diabetes management** Diet Diet plus tablets	 1 2	☐ 13
V11	Duration living with diabetes (Years)		☐☐ 14-15

APPENDIX 14

CLINICAL DATA AND DIABETES MEDICATION

CLINIC_____

V1	Respondent number	☐☐☐ 1-3
V2	Age	☐☐ 4-5
V3	Weight (kg)	☐☐☐ 6-8
V4	Height (cm)	☐☐☐ 9-11
V5	Body mass index (kg/m^2)	☐☐☐ 12-14
V6	Blood pressure (mmHg)	Systolic ☐☐☐ Diastolic ☐☐☐ 15-20
V7	$HbA1_c$ (%)	☐☐☐ 21-23
V8	Total cholesterol (mmol/L)	☐☐ 24-25
V9	LDL-cholesterol (mmol/L)	☐☐ 26-27
V10	HDL-cholesterol (mmol/L)	☐☐ 28-29
V11	Triglycerides (mmol/L)	☐☐ 30-31

Body mass

1	2

Blood pressure

1 Systolic_____ Diastolic_____	2 Systolic_____ Diastolic_____	3 Systolic_____ Diastolic_____

Diabetes medication (type & dose) (i)……

(ii)……

(iii)……

APPENDIX 15

24 HOUR DIET RECALL AND VEGETABLE GARDENING FORM (1st Meeting)

Day _____ Date_____

Clinic_____ Respondent number ☐ ☐ ☐

PART I: DIET RECALL

Time	**Place**	**Food & type**	**Cooking method**	**List of ingredients (if mixed dish)**	**Amounts (standard cup and spoon measures)**

Did you eat or drink anything else? (Review day to see if any foods/drinks or snacks have been omitted)

PART II: VEGETABLE GARDENING

1. Do you grow your own vegetables?[1]

1	2
Yes	No

2. If so, what vegetables do you grow?

I. .....
II. .....
III. .....
IV. .....
V. .....

3. Do you consume the vegetables you grow?

1	2
Yes	No

4. If so, which ones?

I. .....
II. .....
III. .....
IV. .....
V. .....

4. Do you sell the vegetables that you grow?

1 Yes 2 No

[1] At six months and 12 months: Have you grown vegetables in the last six months?

APPENDIX 16

FOOD CHANGE INTERVIEW SCHEDULE

Clinic…… **Study No……..**

Please for the following items say whether you:

(i) Ate or used more (ii) ate/used less or (iii) amounts eaten or used remained the same, since you joined the diabetes project (study)[2]. For the selected item please explain**.**

Example: used to eat vegetables once/day now, 2 times; used not to eat fruit everyday now I eat 1 or 2 fruits/day, used to eat vegetables only on weekends now I eat everyday, used to use 3 tsp sugar in tea, now I use 1/do not use

No	**Item**	**Ate/used more** **1**	**Ate/used less** **2**	**Amounts eaten/used remained the same** **3**	**Do not use /not applicable** **4**	**Explain your answer**
1	Eating fruits					
2	Eating vegetables					
3	Eating fatty foods					
4	Amount of salt added when cooking food					
5	Amount of salt added to food when eating					
6	Eating salty foods					
7	Adding sugar to tea					
8	Adding sugar to foods					
9	Eating foods or drinks high in sugar					
10	Amount of oil used in cooking					

[2] At 12 months: in the last six months

No	Item	Ate/used more 1	Ate/used less 2	Amounts eaten/used remained the same 3	Do not use /not applicable 4	Explain your answer
11	Amount of margarine used on bread					
12	Amount of margarine added to foods					
13	Amount of dressing used on salads					
14	Amounts of starchy foods eaten at one meal					
15	Eating beans, lentils, dried peas, etc					
16	Eating different type of foods					

For the following items, say what your practices were in the last six months. You do (i) all the time, (ii) most times, (ii) sometimes (iv) never or (v) not applicable

No.	Item	All the time 1	Most times (more than 4 times per week) 2	Sometimes (less than 3 times per week) 3	Never 4	Not applicable 5
1	Remove all fat I can see on meat before cooking					
2	Remove skin from chicken before cooking					
3	Remove all fat I can see on meat before eating					
4	Remove skin from chicken before eating					

APPENDIX 17

DIABETES KNOWLEDGE TEST (DKNB)

INSTRUCTIONS (SELF-ADMINISTRED)

This is a short quiz to find out how much you know about Diabetes Mellitus. There are 15 questions and each has several possible answers. For questions 1 to 12 only one answer is correct. If you know the right answer, circle the letter in front of it. If you do not know the answer, circle the letter in front of "I do not know". Notice that questions 13,14 and 15 have more than one correct answer, so you should circle all the answers you think are correct.

INSTRUCTIONS (INTERVIEWER ADMINISTERED)

This is a short quiz to find out how much you know about diabetes mellitus. There are 15 questions and each has several possible answers. I will ask you each question at a time and tell you the possible answers. Then you will tell me which answer you think is correct, and if you do not know you tell me so. For the first 12 questions only one answer is correct. The last three questions have more than one correct answer, so you will tell me all the answers you think are correct. I will let you know when we get to these questions

Clinic_____- **Study number** ☐☐☐

1-3

1. The key to the control of diabetes is: ☐
(A.) A balance between regular amounts of insulin/tablets, food and exercise
B. The maintenance of low sugar in the urine to prevent hypoglycemia
C. A high protein, high-fibre diet 4
D. I don't know

2. The NORMAL range for blood sugar is: ☐
(A.) 4-8 mmol/l
B. 7-15 mmol/l
C. 2-10 mmol/l 5
D. I don't know

3. Margarine is mainly: ☐
A. Protein
B. Carbohydrate
(C.) Fat 6
D. Mineral and vitamin
E. I don't know

4. Rice is mainly : ☐
A. Protein
(B.) Carbohydrate
C. Fat 7
D. Mineral and vitamin
E. I don't know

5. Glucose is detected in urine when:
A. The build-up of ketones in the urine prevents insulin from working properly
(B) The kidney threshold is passed and glucose spills over into the urine
C. The dose of insulin or diabetic tablets is too large 8
D. I don't know

6 One egg can be substituted for:
(A.) A slice of cheese
B. Half cup of mushroom
C. One slice of bread 9
D. 4 tables spoons of cream

7. A person with diabetes on insulin who becomes ill often needs:
(A.) More insulin
B. Less insulin
C. No insulin 10
D. I don't know

8. The best food for some one with diabetes to eat before prolonged exercise or sport would be:
A. A protein-rich food, like meat
(B.) A carbohydrate, like bread or plain biscuit 11
C. Nothing until afterwards
D. Honey or syrup
E. I don't know

9. People with diabetes should take care of their feet because:
A. After a long period of time, injecting insulin into the legs may cause swelling of the feet
B. Flat feet are commonly associated with diabetes 12
(C.) Older people with diabetes may have poor circulation of blood in this area
D. I don't know

10. When people with diabetes on insulin become ill and unable to eat the prescribed diet:
A. They should immediately stop taking insulin
(B.) They must continue to take insulin 13
C. They should use diabetic tablets instead of insulin
D. I don't know

11. When a person on insulin has a high blood or urine sugar level and ketones were present, they should:
(A.) Increase insulin
B. Decrease insulin 14
C. Keep insulin and diet the same and test blood/urine later
D. I Don't know

12. Low blood sugar is caused by:
(A) Too much insulin
B Too little insulin
C Too little exercise 15
D I don't know

In these last three questions, there is more than one correct answer in each question. Please tell me all the answers you think are correct

13 On a diabetic diet, which of the following can be taken freely (as much as you like)

(A.) Lettuce, celery, cucumber
(B.) Herbs and spices
C. Marmite, Bovril, soup cubes
D. Fresh fruit
E. I don't know

16

14 "Empty energy" is a term used to describe foods which supply energy and no other nutrients. Which of the following are sources of "empty energy"?

A. Fruit juices
B. Margarine
(C.) Soft drinks
(D.) Sugar
E. I don't know

17

15. Hypoglycemia (low blood sugar) is likely to occur if:

(A.) Blood sugar drops too low
B. You miss your normal dose of insulin or tablets
(C.) You miss your meal
D. Blood sugars exceeds 2+
E. I don't know

18

THANK YOU

APPENDIX 18

DIABETES ATTITUDE SCALE 3 (DAS III)

In general I believe that:

		Strongly agree 5	Agree 4	Neutral 3	Disagree 2	Strongly disagree 1	
1	Health care professionals who treat people with diabetes should be trained to communicate well with their patients						☐
2	People who do not need to take insulin to treat their diabetes have a disease that is not very serious						☐
3	There is not much use in trying to have good blood sugar control because the complications of diabetes will happen anyway						☐
4	Diabetes affects almost every part of a diabetic person's life						☐
5	The important decision about diabetes daily care should be made by the person with diabetes						☐
6	Health care professionals should be taught how daily diabetes care affects patient's lives						☐
7	Keeping the blood sugar close to normal can help prevent the complications of diabetes						☐
8	Most people can enjoy life and still keep diabetes under control						☐
9	Health care professionals should help patients make informed choices about their care plans						☐
10	It is important for the nurses and dieticians who teach people with diabetes to learn counseling skills						☐
11	People whose diabetes is treated by just a diet do not have to worry about getting long term complications						☐
12	Almost everyone with diabetes should do whatever it takes to keep their blood sugar close to normal						☐
13	The emotional effects of diabetes are pretty small						☐
14	People with diabetes should have the final say in setting their blood glucose goals						☐
15	Blood sugar testing is not needed for people with type 2 diabetes						☐

16	Low blood sugar reactions make good control too risky for most people						☐
17	Health professionals should learn how to set goals with patients, not just tell them what to do						☐
18	Diabetes is hard because you never get a break from it						☐
19	The person with diabetes is the most important member of the diabetes care team						☐
20	To do a good job, diabetes educators should learn a lot about being teachers						☐
21	Type 2 diabetes is a very serious disease						☐
22	Having diabetes changes a person' outlook on life						☐
23	People with type 2 diabetes will probably not get much benefits from keeping their blood sugars close to normal: that is 4-8 mmols/L						☐
24	People with diabetes should learn a lot about diabetes so that they can be in charge of their own diabetes care						☐
25	Type 2 diabetes is not as serious as type 1 diabetes						☐
26	Keep blood sugar levels close to normal is too much work						☐
27	A person with diabetes can lead a normal life						☐
28	What the patient does has more effect on the outcome of diabetes care than anything that a health professional does						☐
V29	Keeping blood sugar levels close to normal (4-8 mmol/L) makes sense only for people with type 1 diabetes						☐
V30	It is frustrating for people with diabetes to take care of their disease						☐
V31	People with diabetes have a right to decide how hard they will work to control their blood sugar						☐
V32	People who take diabetes pills should be as concerned about their blood sugars as those who take insulin						☐
V33	People with diabetes have the right not to take good care of their diabetes						☐

FORMULAE FOR COMPUTING DAS III SCORES

Scale Name	Scale Equation	Special Instructions
Need for Special Training	Σ (Q1, Q6, Q10, Q17, Q20) / Number of non-missing items	
Seriousness of NIDDM	Σ (Q2, Q7, Q11, Q15, Q21, Q25, Q31) / Number of non-missing items	Reverse scores for Q2, Q7, Q11, and Q15.
Value of Tight Control	Σ (Q3, Q8, Q12, Q16, Q23, Q26, Q28) / Number of non-missing items	Reverse scores for Q3, Q16, Q23, Q26, and Q28.
Psychosocial Impact of DM	Σ (Q4, Q13, Q18, Q22, Q29, Q33) / Number of non-missing items	Reverse scores for Q13.
Patient Autonomy	Σ (Q5, Q9, Q14, Q19, Q24, Q27, Q30, Q32) / Number of non-missing items	

Note: Strongly Agree = 5, Agree=4, Neutral = 3, Disagree=2 and Strongly Disagree=1.

Note: Scoring; Maximum possible =5; Minimum possible =1

Mean scores = 3 Neutral
< 3 Negative attitude
> 3 Positive attitude

APPENDIX 19

PARTICIPANTS' PROGRAMME EVALUATION (END OF EIGHT WEEKS)

Clinic……..

We would like to know what you think or feel about the education sessions we have had so far (the last eight weeks)

1	Did you enjoy the education sessions? 1= I enjoyed very much 2= I enjoyed a little bit 3= No	
2	If you enjoyed, which sessions did you enjoy the most? 1= sessions about diabetes 2= sessions on guidelines for healthy eating 3= session about amount of foods to eat (portion sizes) 4= cooking lentils 5= lesson on vegetable gardening 6=everything	
3	Did you learn any new thing from the education? 1=yes 2=no	
4	If yes name <u>two</u> things that you learnt from the education sessions **……...** **……** …… …… …… …… ……	
5	Do you have any suggestions or comments concerning the sessions we have had so far? …… …….. …… …… …….. ……	
6	Do you have any suggestions on what could be taught or discussed during the monthly meetings **……...** **……...** **……..** **……..** **……..** **……** **……...**	

APPENDIX 20

FOCUS GROUP INTERVIEW GUIDE: NUTRITION EDUCATION PROGRAMME EVALUATION

The moderator: Use the information in brackets to help in probing for information in cases where participants do not respond to a question.
We want you to tell us what you think of the diabetes education programme that you have participated in the last one year

1. Did you enjoy the programme? Please explain
    - What did you enjoy/like most about the programme?
    - What did you not like/enjoy about the programme
2. Did your health/well being get better from the programme? Please explain

3. Tell us what you think about the lessons/topics that were covered (were they helpful, did you learn anything; if yes what did you learn; was the information: enough, not enough or too much)

3.1 What is diabetes?
3.2 Problems/complications of diabetes
3.3 Causes of high and low sugar
3.4 What to do if sugar is high or low
3.5 Treatment of diabetes
3.6 Guidelines to healthy eating for South Africans
3.7 Amount of foods to eat
3.8 Healthy cooking-with lentils

4. Do you think there is some information that you would have liked to know that was not covered in the lessons? Please explain

5. Tell us what you think about the tools and materials used for the lessons. Please explain (Were they useful? Easy/ difficult to follow/read? etc.)
    - Flip charts
    - Cooked and raw foods
    - Food label containers

6. Tell us what you think about the written materials you were given to use at home. Please explain
    - Fridge/wall poster
    - Pamphlet

6.1. Were they useful to you? Please explain
6.2. Were they useful to your family? Explain
6.3 Were they easy to use/read? Explain
6.4 Is there any comments/suggestion you can make concerning the materials?

7. Tell us what you think about the number of meetings (for example too many, just right, not enough). Please explain.

- Meetings done every week (first eight weeks)
- Monthly meetings
- Meetings done every two months

8. Tell us what you think about the time that each lesson took. Please explain
   Too much
   Too little
   Just right
9. Did you like having the lessons in a group? Please explain

10. What do you think about the exercises that were done after each lesson? Please explain

    Very enjoyable; not enjoyable
    Very helpful; not helpful
    Was enough; was not enough
11. What advice would you give us if we were to arrange for another diabetes education programme?
    - Number of meetings
    - Person to teach
    - Written materials
    - Materials for teaching
    - Time for each lesson
    - How to involve family members

12. Have you ever attended diabetes lessons before? Please explain (for example when, where, who was the teacher, was it in group or individual, what was taught)

13. What are the reasons that made you come for the lessons in this programme?

14. What changes have you made in the way you eat and exercise because of attending the education programme? Please explain (for example)

    - The type of foods you eat
    - The amount of foods you eat (starches, fruits, vegetables etc.)
    - How you prepare and cook food
    - The amount of oil/fat used in cooking, spreading, dressings
    - Amount of sugar used in tea or foods
    - Exercise
    - Others