

**A facility-based therapeutic group programme  
versus usual care for weight loss in obese patients  
attending a district hospital in the Cape Metropole**

By

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## ABSTRACT

**Background:** Non-communicable diseases (NCDs) are becoming a threat to South Africa's health and human capacity. Even though there is evidence of NCD surveillance, policy development and population-level interventions for NCDs, there has been minimal investment in secondary and tertiary prevention programmes targeting modifiable risk factors such as unhealthy diet and physical inactivity. A group-based weight loss programme may provide a cost-effective approach to improving outcomes in obese patients with NCDs, in busy government primary health care (PHC) facilities in the Western Cape.

**Aim:** The primary aim of this research was to compare the impact of a six-week facility-based therapeutic group (FBTG) programme with that of usual care on weight loss and reduction in BMI in obese patients with one or more risk factors for the development of NCDs or existing NCDs, attending a district hospital in the Cape Metropole. The secondary aims of this research were firstly, to compare the impact of the FBTG programme with that of usual care on intermediate and modifiable risk factors for NCDs in the target population; and secondly, to characterise the total baseline sample, as well as to compare patients who chose the FBTG programme with patients who chose usual care for baseline characteristics.

**Methods:** A cross-sectional design was used to describe the baseline sample that consisted of 96 FBTG patients and 97 usual care patients. An interviewer administered questionnaire developed for the purposes of this study as well as the hospital database CLINICOM and patients' folders, were used to collect data at baseline and six months on socio-demographic variables, disease status, intermediate risk factors (HbA1c, cholesterol and blood pressure), medication usage, smoking status, weight, body mass index (BMI), waist circumference, weight loss goals, physical activity, dietary intake, NCD risk profiles and stage of change. A quasi-experimental design was used to compare the impact of the two treatments on the mentioned variables. The FBTG programme comprised of a one-on-one dietetic consultation at baseline, followed by weekly group sessions for six weeks and a final one-on-one dietetic follow-up consultation at six months. Usual care patients received standard care that consisted of a one-on-one dietetic consultation at baseline and at six months. The within-group changes were compared between treatment groups for anthropometric measures, intermediate risk factors, dietary intake, physical activity, stages of change and perceived compliance to diet, physical activity, behaviour change and medication adherence. For change in weight and BMI (primary outcome), per protocol

analysis was conducted, as well as two methods of intention-to-treat (ITT) analysis in order to account for missing values.

**Results:** Our baseline sample consisted of mostly middle-aged females of mixed ancestry who have  $10.1 \pm 2.7$  years of formal education and a family income between R0.00 and R4166.66. The majority of patients were from the residential areas of Ocean View (predominantly mixed ancestry) and Fish Hoek (predominantly white), and 54.4% of the baseline sample were employed at recruitment. There were no differences between treatment groups for most socio-demographic measures, however a significantly higher number of patients from Masipumele chose usual care, while there was a trend for patients with higher educational attainment to choose the FBTG intervention. Diabetes, high blood pressure and high cholesterol were highly prevalent in the total sample, while usual care patients with DM had a significantly higher HbA1c than FBTG patients. There were no differences in the number of patients with NCDs, intermediate risk factors and medication usage between treatment groups. The mean BMI of the total sample was  $39.3 \text{ kg/m}^2$  (obese class II), with a mean waist circumference of 117cm. Only 14% of the sample were engaging in formal physical activity, and presented with a number of poor food choices including energy-dense snacks, high fat foods, and refined carbohydrates, and low intake of fruit and vegetables. The majority of the sample was in contemplation stage of change at baseline. Overall, usual care patients presented with a higher NCD risk profile at baseline, as significantly more usual care patients were smoking, had poor glycaemic control, and did not meet the goals of intake of five fruit and vegetables per day and 150 minutes of exercise per week compared to FBTG patients.

Over the six month intervention period, a statistically significant difference between treatment groups was observed for weight change over six months in per protocol analysis (FBTG:  $-2.9 \text{ kg} \pm 5.2$ , usual care  $-1.2 \text{ kg} \pm 3.7$ ), intention-to-treat (ITT) using last observation brought forward (FBTG:  $-2.2 \pm 4.5$ , usual care  $-1.0 \pm 3.3$ ) and ITT using multiple imputation (FBTG:  $-2.8 \pm 4.9$ , usual care  $+0.2 \text{ kg} \pm 9.7$ ). Furthermore, patients in the FBTG with education  $\geq 10$  years lost significantly more weight than usual care patients with the same level of educational attainment. The mean percentage weight loss was 2.6% in FBTG patients and 1.6% in the usual care patients. Thirty-nine percent of FBTG patients and 40% of usual care patients were lost to follow up (LTFU). Patients LTFU tended to be younger and were significantly more educated than completers. Waist circumference reduced by  $-3.7 \text{ cm}$  in FBTG patients, which was significantly greater than the  $-0.6 \text{ cm}$  achieved in usual care patients. Usual care patients experienced a significant reduction in their HbA1c levels, cholesterol and DBP, while FBTG patients experienced a significant reduction in SBP and

DBP only. The within-group change for HbA1c was significantly greater in usual care compared to FBTG patients. Significantly, more FBTG patients participated in formal physical activity and reached the target of 150 minutes of physical activity per week compared to usual care patients. While several significant within-group changes in the intake from indicator food groups were evident in both treatment groups, the within-group changes in dietary intake did not differ significantly between treatment groups. Significantly, more FBTG patients were in the action stage of change by six months compared to usual care patients. Perceived compliance to behaviour change was significantly higher in the FBTG, while there were no differences in compliance scores for diet and physical activity, which were about five and six out 10 respectively.

**Conclusion:** Overall it can be concluded that the multi-component FBTG intervention was more effective than usual care in inducing weight loss (primary outcome). It was also more effective in reducing waist circumference, and improving physical activity levels and stage of change, which may have contributed to the weight loss outcome. Both treatments were effective in improving blood pressure and some food choices. The usual care treatment was more effective in reducing HbA1c, bearing in mind possible bias as a result of missing data. There are indications that the higher intervention dosage within the FBTG may have resulted in greater weight loss.

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### **Candidate contribution**

My role as primary investigator included the planning and facilitation of the intervention, collection and analysis of all data, statistical analysis and write up of the dissertation.

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**Addendum A: Consent forms and assessment questionnaires**

**Addendum B: MDHS Chronic Disease Monitoring Sheet**

**Addendum C: DOH Model of Care for management of NCDs**

## LIST OF ABBREVIATIONS

ADA	American Diabetes Association
AIDS	Acquired immunodeficiency syndrome
BMI	Body mass index
CDE	Centre for Diabetes and Endocrinology
CDM	Chronic disease management
CDU	Chronic Dispensing Unit
CHIPs	Community Health Intervention Programme
CHWs	Community Health Workers
CVD	Cardiovascular disease
DASH	Dietary Approaches to Stop Hypertension
DHA	Docosahexaenoic acid
DM	Diabetes Mellitus
DOH	Department of Health
DOTS	Directly observed therapy, short course
DPP	Diabetes Prevention Program
DPS	Diabetes Prevention Study
EPA	Eicosapentaenoic acid
FAO	Food and Agricultural Organisation
FBH	False Bay Hospital
FBTG	Facility-based therapeutic group
FBDG	Food-based dietary guideline

FFQs	Food frequency questionnaires
GI	Glycaemic index
GPs	General Practitioners
HAPs	High attendance patients
HbA1c	Glycated haemoglobin
HBP	High blood pressure
HDL	High-density lipoprotein
HFCS	High-fructose corn syrup
HIV	Human immunodeficiency virus
ITT	Intention-to-treat analysis
LAPs	Low attendance patients
LTFU	Lost to follow up
LDL	Low-density lipoprotein
MDGs	Millennium Development Goals
MUFA	Monounsaturated fatty acids
MRC	Medical Research Council
NCDs	Non-communicable diseases
NGOs	Non-governmental organisations
PUFA	Polyunsaturated fatty acids
PHC	Primary Health Care
TLC	Therapeutic Lifestyle Changes
RCTs	Randomized control trials

SADHS	South African Demographic and Health Study
SANHANES	South African Nutrition and Health Examination Survey
SAHS	South African Hypertension Society
SEMDSA	Society for endocrinology, metabolism and diabetes of South Africa
SES	Socio-economic status
SMS	Short-message-service
SOC	Stage of change
SSISA	Sports Science Institute of South Africa
TB	Tuberculosis
UK	United Kingdom
WC	Waist circumference
WHO	World Health Organisation
YLL	Years of life lost

## **Chapter 1**

### **INTRODUCTION**

Around 20 years ago, South Africa experienced a large-scale political change by hosting its first democratic election. During this time, health-care policies were developed with the aim to prioritise the management of diseases and increase access to quality health care (Mayosi et al., 2009). Although the HIV/AIDS epidemic received a robust political and public health response, the country neglected to implement strategies and interventions for non-communicable diseases (NCDs) such as cardiovascular disease (CVD), diabetes mellitus (DM), chronic respiratory disease, cancer and mental illness (Mayosi et al., 2012; Levitt et al., 2011). Unfortunately, low- and middle-income countries such as South Africa are suffering the brunt of premature deaths from NCDs (WHO, 2013).

Underlying the above-mentioned NCDs are intermediate risk factors such as hyperglycaemia, hypertension, high cholesterol and obesity (WHO, 2013). Recently, the 2012 South African Nutrition and Health Survey (SANHANES) reported that these risk factors are following concerning trajectories (Shisana et al., 2013). For example, the SANHANES reported that half of women, and around quarter a of men in South Africa were classified overweight or obese (Shisana et al., 2013), which is an increase from the 1998 and 2003 Demographic and Health Surveys. These metabolic risk factors often arise from chronic exposure to modifiable risk factors such as an unhealthy diet, physical inactivity, smoking and excessive alcohol consumption, as well as non-modifiable risk factors such as increasing age, gender and genetic predisposition (WHO, 2013). In South Africa the mortality rates attributed to modifiable risk factors have been estimated as 3.2% for low vegetable and fruit intake, 3.3% for insufficient physical activity, 8.5% for smoking and 7.1% for excessive alcohol consumption (Groenewald et al., 2007). These diseases and risk factors particularly affect individuals with a low socio-economic status, who concurrently struggle to access quality healthcare and treatment (Di Cesare et al., 2013; Mayosi et al., 2009). It is also known that strong underlying environmental and social forces such as urbanisation, globalisation, industrialisation, health and nutrition transitions are driving the country's NCD burden (Abrahams et al, 2011; Cecchini et al., 2010).

With the current and projected burden of disease attributed to intermediate risk factors and NCDs, as well as their imminent threat to human health and economic productivity, it is imperative that South African initiate and prioritise strategies and interventions for prevention and treatment of NCDs and associated risk factors. This is challenging since the majority of research on prevention and control of NCDs is from high-income countries (Ebrahim et al., 2013; Heneghan et al., 2013). This is not ideal as the underlying risk factors for NCDs such as socio-economic status, access to food and agricultural factors can affect NCD burden in low- and middle-income countries differently to high income countries (Ebrahim et al., 2013;

Dobe, 2012). Nevertheless, South Africa has started investing in the prevention of NCDs, which is evident in the 2011 National Declaration on Prevention and Control of NCDs (Mayosi et al., 2012; Singh, 2011). The declaration pledges to reduce premature deaths from NCDs by 25%, reduce overweight and obesity prevalence by 10%, increase physical activity levels by 10%, and a decrease mean salt intake to <5g per day (Mayosi et al., 2012). The country has also shown additional commitment by implementing population-level legislation on tobacco, excessive alcohol consumption, food labelling and salt (Mayosi et al., 2012; Puoane et al., 2012). A national directorate for Chronic Diseases, Disability and Geriatrics Unit has been established (Bradshaw et al., 2011), while the Medical Research Council (MRC) for South Africa has produced a comprehensive technical report on NCDs in South Africa (Steyn et al., 2006). Furthermore, the country has updated its national food-based dietary guidelines (DOH, 2012), while recent surveillance and burden estimations on NCDs have been made available in the recent SANHANES report (Shisana et al., 2013). In order to achieve the above-mentioned targets, WHO 2008-2013 and WHO 2013-2020 Action Plans for the Global Strategy for the Prevention and Control of NCDs (WHO, 2009) and a national declaration recommends the following: the institution of political commitment, strong surveillance, realignment of health care, and primary focus on reducing preventable modifiable risk factors such as unhealthy diet, physical inactivity, excessive alcohol consumption and smoking (Singh, 2011).

There are two areas that still require significant investment to make it feasible to reach the targets for NCDs and obesity prevention. Firstly, the public health care services require significant investment of resources in order to provide optimal care for patients with NCDs. Secondly, a greater focus on individual and community interventions that could be implemented simultaneously with population-level interventions is required (Puoane et al., 2012; Bradshaw et al., 2011). Bradshaw et al. (2011) stated in their MRC report on NCDs: “an effective NCD policy has two aspects, namely, population-wide interventions and health care interventions”

It is important for governmental health care services to establish lifestyle programmes for obesity and NCDs in order to empower individuals to take responsibility for their health and improve treatment outcomes. In high-income countries, lifestyle interventions have proved to be successful in a variety of clinical settings and have achieved significant results in weight loss and NCD-related outcomes (Kirk et al., 2012; Steinsbekk et al., 2012; Taggart et al., 2012; Greaves et al., 2011; Venditti & Kramer 2012; Seagle et al., 2009). These approaches are either self-help (Latner, 2001), individual counselling (Grace 2011), or group-based programmes (Steinsbekk et al., 2012; Paul-Ebhohimhen & Avenell 2009) and

are often facilitated by dietitians and specialist nurses (Steinsbekk et al., 2012). However, the results of these programmes need to be interpreted with caution as the findings and intervention design may not be applicable within the context of South Africa's disease and risk factor burdens, public health care services and socio-demographic profile. For example, it should be borne in mind that cultural perceptions of adiposity and food preferences are vastly different among race groups in South Africa (Airhihenbuwa et al., 2013; Love et al., 2008), thus interventions would need to be culturally tailored in order to accommodate values, perceptions, expectations and beliefs (Airhihenbuwa et al., 2013; De-Graft Aikins et al., 2012). In addition to cultural and social aspects, it has been recommended that interventions include behavioural strategies that enhance self-efficacy, self-empowerment and promote behaviour change (Dobe, 2012; Baker et al., 2011).

At primary health care level, the usual care model for obese patients with a NCD/NCD risk factor involves medical management supervised by a medical doctor and if possible, a one-on-one session with a dietitian. Since the Western Cape PHC services are experiencing large patient loads (Parker et al., 2012; Goeiman et al., 2011) and dietetic services are limited at all levels of care (Goeiman et al., 2011), facility-based group programmes should be investigated as a possibility to increase patient treatment coverage. This approach has the potential to provide education to larger numbers of patients and be more resource-sparing than one-on-one counselling. At this point in time there is no research on the feasibility, including patient preference and resources, as well as potential success of implementing a group-based programme for patients with NCDs and obesity attending PHC facilities in South Africa.

## **AIMS AND OBJECTIVES**

The **primary aim** of this research was to compare the impact of a six-week facility-based therapeutic group (FBTG) programme with that of usual care on weight loss and reduction in BMI in obese patients with one or more risk factors for the development of NCDs or existing NCDs attending a district hospital in the Cape Metropole.

The **secondary aims** of this research were as follows:

- To compare the impact of the FBTG programme with that of usual care on intermediate and modifiable risk factors for NCDs in the target population.
- To characterise the total baseline sample, as well as to compare patients who choose the FBTG programme with patients who choose usual care.

The **objectives** of this research were as follows:

To determine and describe the following characteristics for the total sample at baseline (secondary outcome):

- Socio-demographic variables including age, gender, race, residential area, employment status, education level and income.
- Non-communicable disease (NCD) status including diabetes mellitus (DM) and cardiovascular disease (CVD).
- Medication prescription for DM, hypercholesterolemia and high blood pressure (HBP)
- Intermediate risk factors for NCD development including blood pressure (BP), glycosylated haemoglobin (HbA1c) and total cholesterol.
- Modifiable risk factors for NCD development including diet, physical activity, and smoking status.
- Anthropometric measurements including weight, body mass index (BMI) and waist circumference.
- Stage of change.
- Risk factor profile

To describe and compare the baseline characteristics between patients who chose the FBTG intervention and those who chose usual care (secondary outcome).

To implement the FBTG and usual care interventions, conduct follow-up assessment of primary and secondary outcome variables and perceived compliance in treatment completers and conduct the following analyses:

- Determine and compare the within-group changes over six months between the two treatment groups for weight and BMI (primary outcome).
- Compare baseline characteristics, weight and BMI between treatment completers (FBTG and usual care) and LTFU.
- Determine and compare the within-group changes over six months between the two treatment groups for the intermediate and modifiable risk factors (secondary outcome).
- Determine and compare the shifts in stage of change between the two treatment groups at six months (secondary outcome).
- Determine and compare perceived compliance with physical activity, dietary intake, behaviour and pharmacological recommendations between the two treatment groups at six months.

## **DEFINITION OF TERMS**

### **Treatment groups:**

- FBTG patients who chose to enter into a structured, six-week programme designed to address behavioural risk factors for NCDs such as diet and physical activity followed by a 20-week period of no contact before final follow-up assessment at six months.
- Usual care patients who chose to continue with their usual care that was defined as the current routine treatment provided to a patient with NCDs and/or risk factors for NCDs at False Bay Hospital, with final follow-up at six months. Usual care includes initial one-on-one consultations dietitian, with availability of further one-on-one follow-up appointments with the dietitian at the patients' discretion.

### **District Hospital:**

“The district hospital plays a pivotal role in supporting primary health care on the one hand and being a gateway to more specialist care on the other. The District Health System (DHS) has been adopted as the vehicle to deliver Comprehensive Primary Health Care Services in South Africa. District hospitals also form part of the district health system in the new policy. This means that services provided in district hospitals will be fully integrated with services provided in primary care.” (DOH, 2002)

## **OUTLINE OF CHAPTERS 2 TO 5 OF THIS DISSERTATION**

Chapter 2 provides a review of the literature on intermediate and modifiable risk factors specifically for diabetes mellitus (DM) and cardiovascular disease (CVD). The review also provides perspectives on the socio-ecological approach to intervention and behaviour change theory, and most importantly, essential programme components for lifestyle interventions are outlined and available research on group-based interventions are critiqued. The first article that covers one of the two secondary aims of this research is presented in Chapter 3 entitled “A profile of NCD risk factors as well as treatment preference in obese patients seeking lifestyle treatment at a district hospital in the Cape Metropole”. The second article covers the primary aim and the other secondary aims of this research is presented in Chapter 4 entitled “The impact of a group-based programme on the weight status and risk factors for NCD development in obese patients attending a district hospital in the Cape Metropole”. The final chapter, Chapter 5, presents an overview of the results reported in Chapters 3 and 4, final conclusions as well as recommendations. Chapters 3 and 4 are presented in a non-specific journal article format in order to prepare this research for

publication. It should be noted that there is unavoidable overlap between chapters in content and references.

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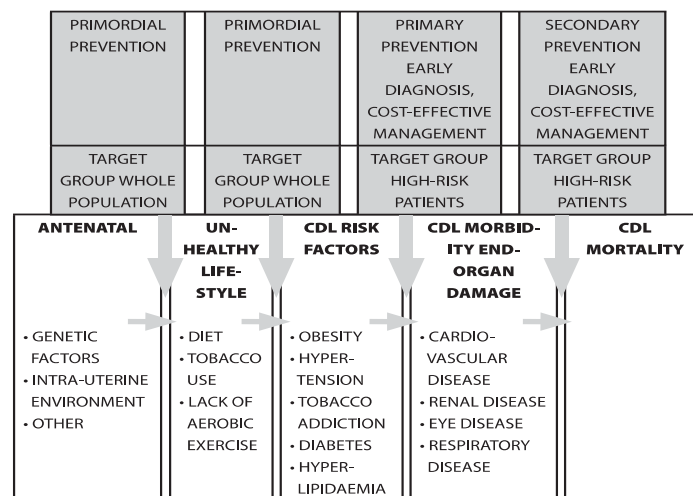
## **Chapter 2**

### **LITERATURE REVIEW**

## 2.1 Risk factors for NCDs

There are multifactorial determinants for NCDs that can be classified as non-modifiable, modifiable and intermediate. The non-modifiable risk factors can be described as innate factors that cannot be changed such as age, genetics, gender and race and can arise as early as during intra-uterine development (Puoane et al., 2012; Mayosi et al., 2009; Steyn, 2006a). Modifiable risk factors are those that can be reduced or treated, and include unhealthy diet, physical inactivity, smoking and excessive alcohol intake. Long-term exposure to these risk factors results in the development of intermediate risk factors such as obesity, HBP, high blood glucose and high cholesterol (Steyn, 2006a). Furthermore, risk factors for NCDs are moderated by social, economic, environmental and political influences and health transitions (Dobe, 2012; Popkin et al., 2012; Popkin, 2006).

Figure 1 provides an overview of the phases of NCD development and the appropriate interventions (Steyn, 2006a).



**Figure 1: Risk factors for NCD development (Steyn 2006a)**

*Abbreviation: CDL: chronic diseases of lifestyle*

### 2.1.1 Non-modifiable risk factors

#### **Age**

Aging and subsequent accumulation of risk factors over an individual's lifecourse can significantly increase risk for NCDs (Fulop et al., 2010). The biological processes of aging include chronic inflammation, oxidative stress, hormonal changes and an unfavourable body fat ratio (Fulop et al., 2010). These processes promote the development of atherosclerosis,

hypertension and dyslipidaemia that ultimately lead to the development of CVD (Perk et al., 2012). As expected, the presence of risk factors for NCDs such as high cholesterol, high blood glucose, high blood pressure and physical inactivity have been found to be more prevalent in older individuals in South Africa (Shisana et al., 2013).

The proportion of older individuals in South Africa is predicted to triple in the next decade (Mayosi et al., 2009). This epidemiological shift in age distribution can be attributed to improvements in medicine and management of infectious diseases that allows a larger number of individuals to live longer and thus incur the consequences of aging (Mayosi et al., 2009). This is an important consideration for South Africa as the increase in proportion of older adults will subsequently increase the number of people living with NCDs (Mayosi et al., 2009).

### **Genetics**

NCDs are generally viewed as polygenetic conditions and their development can be linked to a bidirectional interaction between genotype and environment (Senekal, 2012; Godfrey et al., 2010). Environmental risk factors can interact with any number of polymorphisms by increasing or decreasing the expression of genes that may increase the risk for NCDs (Loos, 2009). It has been estimated that genetic polymorphisms may explain between 40 to 70% of the variance for example in obesity and NCD prevalence (Loos, 2009).

The role of genetics in the development of NCDs in South Africa has not been thoroughly investigated (Molleutze & Levitt 2006). However, it is well known that certain high penetrance genetic polymorphisms can result in high cholesterol levels, irrespective of environmental influences (Senekal, 2012; Puoane et al., 2008). This condition is found in select South African populations and is referred to as familial hypercholesterolaemia (Senekal, 2012; Puoane et al., 2008).

There has been increased interest in the developmental origins of NCDs also known as 'foetal programming'. The theory behind 'foetal programming' explains that when genes are exposed to a nutrient-deficient intra-uterine environment, they may adapt and express differently in an environment of nutritional abundance, resulting in undesirable metabolic conditions (Godfrey et al., 2010; Levitt & Lambert, 2002). Therefore, low birth weight infants who become overweight in childhood or adulthood have a higher risk of NCDs because of the poor adaptation of their genes and organs during periods of overnutrition (Godfrey et al., 2010; Levitt & Lambert, 2002). Furthermore, long-term malnutrition in childhood (which

often manifests as stunting) followed by improvements in the nutritional environment can result in increases in adiposity (Puoane et al., 2008). This is concerning for a developing country such as South Africa, where a combination of nutrition transitions, high rates of maternal malnutrition, low birth weight infants, childhood stunting and obesity exist simultaneously (Levitt & Lambert 2002).

### ***Race***

There are indications that certain race groups are pre-disposed or more vulnerable to certain NCDs, and in some cases the differences are further stratified according to gender. However, the association between race and NCDs is often difficult to interpret since risk factors may be a reflection of socio-environmental determinants of NCDs rather than racial characteristics (Schutte et al., 2012; Stern et al., 2010; Bourne et al., 2002). For example, the migration of race groups from traditional living to westernised living often results in increased prevalence of NCDs in these individuals (Pollard, 2011; Stern et al., 2010).

In South Africa, differences in the prevalence of obesity, HBP, DM and CVD among racial groups have been reported (Hardy, 2013). Black African females have been found to have higher BMIs than mixed ancestry, Indian and white females (Shisana et al., 2013), which seems to be associated with decreased beta cell mass (Van der Merwe & Pepper 2006) and a higher degree of insulin resistance present in black African women (Hardy, 2013; Goedecke et al., 2009). There is also evidence that a greater proportion of black African women are experiencing early-onset chronic heart failure (Hardy, 2013). The South African Indian population appear to have the highest prevalence of DM compared to other race groups (Shisana et al., 2013; SEMDSA, 2012). For example, Indian groups have a 17.1% risk of developing DM compared to 6.2% risk in urban black Africans (SEMDSA, 2012). Furthermore, the recent SANHANES reported that mixed ancestry and Indian groups presented with significantly higher HbA1c levels compared to other race groups (Shisana et al., 2013). Conversely, white individuals appear to develop adult-onset DM together with high insulin levels rather than insulin deficiency (Van der Merwe & Pepper, 2006).

The prevalence of HBP also tends to differ among race groups. The 2012 SANHANES reported that black African and Indian groups presented with lower blood pressures than other white and mixed ancestry groups (Shisana et al., 2013). However, when gender is taken into consideration, HBP prevalence has been reported to be higher in black African and mixed ancestry women compared to white women (Hasumi & Jacobsen, 2012). Furthermore, the high prevalence of HBP observed among black Africans in other studies

has been associated with an inherent dysfunctional renal renin and sodium transportation (Seedat & Rayner, 2012; Van der Merwe & Pepper, 2006).

Dyslipidaemia seems to be largely prevalent in mixed ancestry, white and Indian groups (Shisana et al., 2013). Subsequently, CVD and cardiac events are more prominent in these groups (Puoane et al., 2008; Norman et al., 2007a). Black African population groups tend to present with more favourable atherosclerotic lipid profiles than other race groups (Sliwa et al., 2012; Norman et al., 2007a; Van der Merwe & Pepper 2006), however this scenario is changing since their exposure to unhealthy foods and physical inactivity is on the rise (Peer et al., 2013b; Sliwa et al., 2012). There is a high prevalence of familial hypercholesterolemia in the South African population that results in high levels of low-density lipoproteins and total cholesterol (Klug et al., 2012). White South African women also appear to have a greater prevalence of atherogenic lipid profiles compared to black African women, which has been attributed to racial differences in lipid metabolism (Goedecke et al., 2010). The prevalence of low HDL levels appear to be similar in all race groups (Shisana et al., 2013; Sliwa et al., 2012).

### **Gender**

There appears to be several differences in risk factors and NCD prevalence between male and females, with South African women experiencing a higher prevalence of collective risk factors for NCDs (Phaswana-Mafuya et al., 2013). Overweight and obesity rates are much higher in women compared to men (Shisana et al., 2013; Peer et al., 2013a; Malhotra et al., 2009; Van der Merwe & Pepper 2006) with increased disability-adjusted life years (DALYs) and mortality rates attributed to excess body weight being twice as high in women than in men (Joubert et al., 2007a). DM, early onset heart failure, hypertension and stroke appears to affect more women than men (Shisana et al., 2013; Hasumi & Jacobsen 2012; Norman et al., 2007b).

Hasumi and Jacobsen (2012) explained that differences in the prevalence of some NCDs and risk factors may also be attributed to higher number of diagnoses made in women since they tend to seek medical care more regularly than men.

## **2.1.2 Modifiable risk factors**

### ***Unhealthy diet and poor food choices***

There is sufficient evidence to show that an unhealthy diet is a major contributor to NCD development (Ezzati & Riboli 2013; Popkin, 2006). Moreover, an unhealthy diet is considered an equally independent causal risk factor for NCDs when compared to smoking, pollution and obesity (Lock et al., 2005).

A global and national shift in dietary patterns namely the nutrition transition, is largely responsible for the emergence of NCDs and obesity (Ezzati & Riboli 2013; Popkin, 2012; Abrahams et al., 2011; Voster et al., 2011; Popkin, 2006). The nutrition transition refers to a population's shift from a traditional diet that contains culturally available foods towards a 'westernised' diet that includes more refined foods high in energy, salt, and fat (especially saturated and trans fatty acids) due to increases in animal protein sources and unhealthy food preparation (Ezzati & Riboli 2013; Voster et al., 2011; Popkin, 2006). Furthermore, increases in sugar intake and reduced intake of fibre that are also characteristic of the transition, are due to increased consumption of added sugar and high-sugar beverages and decreased intake of legumes and fruit and vegetables respectively (Ezzati & Riboli 2013; Voster et al., 2011; Popkin, 2006). In addition to these changes in dietary patterns, populations in the nutrition transition consume larger portion sizes and more energy-dense convenience foods (Popkin, 2012; Popkin, 2006). Unfortunately, South Africa's nutrition transition is particularly progressive as it is being augmented by globalisation, economic development and insufficient interventions (Abrahams et al., 2011; Popkin, 2006).

Excessive intakes of added sugar and sugary food items are associated with obesity as they provide energy without adding nutrients or a feeling of satiety (Steyn & Temple, 2012; Lichtenstein et al., 2006). Furthermore, the excessive consumption of sucrose and high-fructose corn syrup (HFCS) from high-sugar beverages is increasingly linked to NCD development (Steyn & Temple, 2012). Refined carbohydrates appear to raise triglycerides and reduce HDL cholesterol (Siri-Tarino et al., 2010). However, HFCS is still not widely used in food and drink items in South Africa compared to developed countries. Nevertheless, sugar intake in South Africa has increased because of the greater availability and consumption of sugary beverages (Steyn & Temple, 2012), and has displaced healthier beverages such as milk and water (Popkin, 2006). These have been found that added sugar in the diet is much higher in urban populations (33%) compared to rural populations (3%) (Steyn & Temple, 2012).

It is known that the type of fat consumed can influence an individual's cholesterol profile and hence their risk of stroke and CVD (Smuts & Wolmarans et al., 2013; Riediger et al., 2009; Lichtenstein et al., 2006). Saturated fatty acids (in particular lauric, myristic and palmitic) and trans fatty acids (the hydrogenated form of vegetable oil commonly found in convenience foods and baked products) significantly increase total cholesterol and low-density lipoprotein (LDL) (Vannice, & Rasmussen, 2014). Although dietary cholesterol increases blood total cholesterol and LDL cholesterol, it is not an independent dietary contributor for high cholesterol (Aranceta & Perez-Rodrigo, 2012; Katcher et al., 2009). Polyunsaturated (specifically omega-3 fatty acids) and monounsaturated fats do not raise LDL cholesterol and therefore reduce the risk of CVD if they are eaten in moderation and replace a greater proportion of saturated and trans fat in the diet (Smuts & Wolmarans et al., 2013; Lichtenstein et al., 2006). Omega-3 fatty acids found in sardines, pilchards, mackerel and salmon, are necessary to provide anti-atherosclerotic effects (Mozaffarian et al. 2011; Aranceta & Perez-Rodrigo 2012; Steyn et al., 2008), yet are insufficient in the diet of most of the South African population (Steyn, 2006b). Data on fat intake in South African adults is fairly limited, yet studies have found that the majority of the population commonly consumes fat from animal sources such as milk and meat, oils high in polyunsaturated fatty acids, and obtains trans fatty acids from hard margarines, fast foods and baked products (Smuts & Wolmarans et al., 2013). It should be borne in mind that the quality of vegetable oil and spreads used in home preparation of foods and in a hydrogenated form in commercial foods appears to be largely dependent on cultural preference and socio-economic status (Hawkes et al., 2012; Steyn, 2006b).

A diet high in sodium chloride and low in potassium and calcium, has been acknowledged as a contributor to the development of high blood pressure (He et al., 2013; Frisoli et al., 2011; Dickinson et al., 2006) and ultimately stroke, left ventricular hypertrophy and kidney disease (Frisoli et al., 2011). It has been reported that South Africans consume an average of 8.1g salt per day, which is much higher than the recommended four to six grams per day (Bertram et al., 2012). Charlton et al., (2005) examined the dietary intake and urinary excretion of sodium, calcium and potassium among three different race groups namely black, white and mixed ancestry in South Africa. The self-reported intake of added salt was higher in the black African and mixed ancestry groups, with sodium intake being higher than the recommended intake in all groups and highest in participants with high blood pressure. Furthermore, potassium intake was below the recommended intake for the whole sample and this finding was attributed to a low intake of fruit and vegetables. Overall, bread appears to be the greatest dietary source of sodium intake in the South African population (Bertram et al., 2012). In addition, breakfast cereals, processed meat, baked products,

pizza, salted biscuits and soup powders are also large contributors of sodium intake (Charlton et al., 2005).

Unfortunately, South Africans are also consuming insufficient amounts of fruit and vegetables, which is a known risk factor for NCDs (Naude, 2013; Schneider et al., 2007b). Furthermore, low potassium intake corresponds with low fruit and vegetable consumption and is considered a significant contributor to high blood pressure (Houston, 2011). The mean fruit and vegetable intake has been reported to be 80.2g fruit and 120g vegetables per day, and combined intake is estimated at less than three portions per day (Schneider et al., 2007b). In particular, the intake of less than 5 portions of fruit and vegetables daily has been associated with reduced survival (Bellavia et al., 2013), DALYs (Schneider et al., 2007b), CVD and gastro-intestinal cancers (Naude, 2013; Schneider et al., 2007b).

### ***Physical inactivity***

It has been reported that inactive individuals have a two-fold greater risk of developing NCDs compared to sufficiently active individuals (Lambert & Kolbe-Alexander, 2006). This is because physically inactive individuals lack the protective effects of physical activity that include regulation of energy balance, and reduction of BP, cholesterol and glucose (Powell et al., 2011; Guthold et al., 2008; Kesaniemi et al., 2001). Physical activity can be categorised as occupational, recreational, formal and informal, and can be further defined by duration, intensity and dose-response (Powell et al., 2011). Joubert et al., (2007b) outlines the global comparative risk survey categories for physical activity as: inactive (little or no formal physical activity per week), insufficiently active (less than 150 minutes of moderate-intensity physical activity per week), and sufficiently active (greater than 150 minutes of moderate-intensity physical activity per week).

Leisure time sedentary behaviour can be explained as activities that require minimal physical movement and expend low amounts of energy, such as television viewing (Owen et al., 2010; Sisson et al., 2009). This type of activity can displace formal physical activity, and there is accumulating evidence for the association between leisure time sedentary behaviour ranging from one to four hours and features of metabolic syndrome, namely central adiposity, insulin resistance, high blood pressure and dyslipidaemia (Grondved & Hu, 2011; Owen et al., 2010; Sisson et al., 2009). Held et al., (2012) illustrated this association by using the global INTERHEART data to show that owning a car and a television significantly increased sedentary activity and subsequent risk for cardiac events, obesity, HBP and DM.

South Africa appears to have a high prevalence of physical inactivity. According to the World Wide Health Survey on physical inactivity by Guthold et al., (2008) the prevalence of physical inactivity in South Africa is 47.6% in women and 44.7% in men. The 2012 SANHANES reported around half of women and a third of men were classified as unfit, which is an indication of low engagement in physical activity (Shisana et al., 2013). Another cross-sectional study in South African adults older than 50 years (n=3840) reported that 60% of adults older than 50 years of age did not engage in any moderate intensity physical activity (Peltzer & Phaswana-Mafuya, 2012). Lambert and Kolbe-Alexander, (2006) posit that the combined prevalence of both physical inactivity and obesity in South Africa is likely to contribute to a high burden of NCDs and DALYs.

### ***Smoking***

It is well established that smoking damages the cardio-vascular system by promoting oxidative stress, thrombogenesis, vasoconstriction, inflammation, blood pressure, lipid oxidation and insulin resistance (Perk et al., 2012). Consequently, chronic exposure to these vascular effects result in atherosclerosis, DM, CVD, and stroke (Ezzati & Riboli, 2013; Perk et al., 2012). The effect of smoking on NCDs is dependent on both dose and duration of smoking (Ezzati & Riboli, 2013). The South African Dyslipidaemia Guidelines (2012) classifies smoking as a risk factor if a person is currently smoking or if a person has a smoking history equal to 10 pack years (20 cigarettes a day for 10 years) (Klug et al., 2012).

In South Africa, smoking prevalence varies by province, living area, race, gender, income and education attainment (Sitas et al., 2013; Shisana et al., 2012; Maritz & Mutemwa, 2012; Peer et al., 2009). According to the South African Demographic and Health Study (SADHS), smoking prevalence in men was reported as 42% and 35% in 1998 and 2003 respectively, while prevalence remained at 10 to 11% in women at both time points (Peer et al., 2009). Recently, it has been found that a greater proportion of males and individuals of mixed ancestry smoke (Shisana et al., 2013). Moreover, smoking prevalence is higher among urban residents and individuals with low education attainment (Peer et al., 2009).

### ***Excessive alcohol intake***

Excessive alcohol intake is detrimental to organs and tissues, and exacerbates risk factors and the progression of NCDs such as CVD and DM by increasing triglycerides, blood pressure, glucose, cardiomyopathy, blood clotting and vasospasm (Rehm et al., 2010). Furthermore, excessive alcohol intake increases non-nutritive energy intake and risk of weight gain (Yeomans, 2010).

Alcohol consumption and its effect on NCDs is dose-dependent and its relationship is often referred to as a J-shaped curve (Ronksley et al., 2011; Rehm et al., 2010). For example, individuals who abstain from alcohol do not acquire the protective benefits of moderate alcohol consumption (2.5 to 14.9 grams of alcohol or one to two drinks per day), however excessive quantities (>60g alcohol per day or >4 drinks per day) are detrimental to health (Ronksley et al., 2011; Rehm et al., 2010).

On a global scale, the drinking patterns of South Africans are considered excessive (Shisana et al, 2013; Schneider et al., 2007a). The 1998 SADHS reported that among individuals who drink, one third consume more than the recommended drinks per day (Schneider et al., 2007a). There is a greater prevalence of excessive alcohol intake in men compared to women (Peer et al., 2013a; Shisana et al., 2013).

### 2.1.3 Intermediate risk factors

Intermediate risk factors for NCDs include obesity, HBP, high blood glucose and high cholesterol and develop from above-mentioned modifiable and non-modifiable risk factors. Table 1 indicates the targets for control for the intermediate risk factors according to the 2012 Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines (SEMDSA, 2012) and 2011 South African Hypertension guidelines (SAHS) (Seedat & Rayner, 2012).

**Table 1 Targets for control for intermediate risk factors**

<b>Risk factor</b>	<b>Target for control</b>
<b>Weight</b>	*Body mass index 18.5 – 24.9
<b>Waist circumference</b>	*< 102cm in men * < 88cm in women
<b>Serum Cholesterol</b>	*Total cholesterol <4.5 mmol/l *LDL-C <2.5 *HDL-C >1.0 (men) >1.2 (women) *Triglyceride <1.7
<b>Blood pressure</b>	*SBP <130, DBP <85
<b>Serum Glucose</b>	**Fasting glucose 4.0 – 7.0 mmol/l **Target HbA <sub>1c</sub> < 7%

\*SAHS 2011, \*\*SEMDSA GUIDELINES 2012

### ***Obesity and large abdominal girth***

Obesity is defined as presenting with a body mass index (BMI)  $\geq 30\text{kg/m}^2$  and is clinically defined as excess body and visceral fat for height (WHO, 2011a; Friedman, 2009). On the basis of the laws of thermodynamics, obesity develops due to an energy imbalance through overconsumption of energy and insufficient energy expenditure, which results in excessive body fat deposition (Giskes et al., 2011; Friedman, 2009; Van der Merwe & Pepper, 2006). Besides the simple physiological cause of obesity, genetics, innate metabolism, unhealthy food and living environments are contributing to escalating obesity rates (Sharma & Padwal, 2010). These environments are also termed “obesogenic” as they increase the opportunity for individuals to consume energy-dense, unhealthy foods and beverages while reducing the need for physical activity because of mechanisation, improved transport and sedentary leisure time activities (Giskes et al., 2011).

Obesity is considered as both a mediator and an independent risk factor for NCDs (Prospective Studies Collaboration, 2009; Guh et al., 2009; Poirier et al., 2006). For example, obesity mediates insulin resistance, atherogenic dyslipidaemia, inflammation, oxidative stress, blood pressure and pancreatic dysfunction resulting in the development of diabetes and CVD. Morbidly obese individuals have a 20-fold increase in risk of developing DM (Marinou et al., 2010). Even though BMI cannot discern between lean tissue and adipose tissue, it is highly correlated with body fatness (Joubert et al., 2007a). Furthermore, obesity independently increases mortality by 30% for every  $5\text{kg/m}^2$  increase in BMI above  $25\text{kg/m}^2$  (Marinou et al., 2010) and obese individuals have a reduced median survival of 8 to 10 years (Prospective Studies Collaboration, 2009).

Abdominal adiposity, which is measured by waist circumference, is an independent risk factor for NCD-related morbidity and mortality (WHO, 2011a; Janiszewski et al., 2007). This is because abdominal adipose tissue is able to produce harmful inflammatory adipokines that reduce insulin sensitivity, increase the release of fatty acids into the hepatic portal vein and increase metabolic dysfunction (Marinou et al., 2010). In particular, insulin resistance that is associated with abdominal adiposity is considered a strong precursor for heart disease, diabetes, dyslipidaemia and hypertension (Marinou et al., 2010; Van der Merwe & Pepper 2006). For example, a 1cm increase in waist circumference has reported to be associated with a 2% increase in CVD events (Marinou et al., 2010), while excessive abdominal fat has been associated with a five-fold increase risk of DM (Janiszewski et al., 2007).

South Africa is experiencing an escalating incidence of obesity (Shisana et al., 2013). Since the SADHS (2003), obesity has increased most prominently in females from 27% to 39.2%, while the prevalence in males has increased from 8.8% to 10.6% (Shisana et al., 2013). Other smaller studies support the national prevalence. For example, a cross-sectional study in Khayelitsha reported obesity prevalence of 25.9 to 54.3% in women and 3.0 to 20.4% in men (Malhotra et al., 2009) while other studies among urban black Africans in Soweto (Tibazarwa et al., 2009), mixed ancestry individuals in Cape Town (Erasmus et al., 2012), and in an urban sample in black and mixed ancestry townships in Free State (Van Zyl et al., 2012) also found high proportions of obesity in their samples.

### ***Hypercholesterolaemia***

An atherogenic lipid profile is described as high blood concentrations of total cholesterol, LDL cholesterol and triglycerides, and low blood concentrations of HDL cholesterol (Perk et al., 2012; Lichtenstein et al., 2006). High HDL cholesterol is considered to be protective of heart disease as it increases excretion of LDL in the liver (Perk et al., 2012; Lichtenstein et al., 2006). Around 59% of ischemic heart disease and 29% of stroke has been attributed to high total cholesterol levels (Norman et al., 2007a).

Genetic predisposition, unhealthy diet, poor glycaemic control, insulin resistance, physical inactivity and obesity can also negatively influence lipid profiles (Siri-Tarino et al., 2010; Lichtenstein et al., 2006). In South Africa, one out of five males and one out of three females have high total and LDL-cholesterol (Shisana et al., 2013) while HDL-cholesterol is also sub-optimal in some of the South African population (Shisana et al., 2013; Sliwa et al., 2012).

### ***High blood pressure***

Chronic hypertension is considered a major contributor to NCD development and to disability-adjusted life years in South Africa (Seedat & Rayner, 2012). High blood pressure increases vascular damage, atherosclerosis and CVD (Dharmashankar & Widlansky, 2010; Lichtenstein et al., 2006). The associated inflammation and oxidative stress that accompanies HBP causes hardening of endovascular lining and narrowing of vessel walls (Dharmashankar & Widlansky, 2010; Sacks & Campos, 2010). Specific dietary determinants of hypertension include excessive alcohol, high saturated fat, high sodium intake and low potassium intake (Lichtenstein et al., 2006; Charlton et al., 2005), while obesity is considered a significant risk factor for HBP (Kotsis et al., 2010).

The prevalence of hypertension in South Africa has been reported in national surveys as 10.2% (Shisana et al., 2013), 14.8% (SADHS, 2003), 12.8% (SADHS, 1998), and 10% (Hasumi & Jacobsen, 2012). It has also been estimated that 42% of strokes and 50% of ischemic heart disease can be attributed to high blood pressure in South Africa (Norman et al., 2007b).

### ***Hyperglycaemia***

Hyperglycaemia is detrimental to both micro- and macro-vascular systems, tissues and organs, hence its association with NCD development (Nolan et al., 2011). Poor glycaemic control arises from initial insulin resistance and/or reduced functioning of the beta cells of the pancreas (SEMDSA, 2012; Nolan et al., 2011). A genetic predisposition, obesity, physical inactivity and aging can all contribute to developing hyperglycaemia and DM (Nolan et al., 2011).

The SANHANES reported that approximately 20% of the survey participants presented with impaired glucose homeostasis while 9.5% were confirmed with DM (Shisana et al., 2013). The rising prevalence of impaired glucose homeostasis and DM has been attributed to obesity rates and an increase in the country's aging population (Peer et al., 2012).

#### **2.1.4 Underlying environmental and socio-economic factors**

Many risk factors for NCDs arise from distal causes namely globalisation, urban living and low socio-economic status (Cecchini et al., 2010). The sections that follow illustrate how these underlying causes of NCDs can significantly affect an individual's ability to prevent and manage NCDs (Cecchini et al., 2010).

### ***Globalisation***

Globalisation is by definition "the increasing interconnectedness of countries and the openness of borders to ideas, people, commerce and financial capital" (Beaglehole & Yach, 2003). Globalisation has had profound impact on a variety of risk factors for NCDs that include dietary intake, physical activity, smoking and excessive alcohol consumption (Basch et al., 2013; Ebrahim et al., 2013).

Globalisation has negatively influenced dietary intake by increasing inter-country trade of cheaper subsidised agricultural produce and ingredients namely poor quality hydrogenated

oils, refined carbohydrates, high-fructose corn syrup and processed foods (Hawkes et al., 2012; Swinburn et al., 2011). It should be noted that the effect of globalisation on dietary intake is accompanied by a reduced dependence on local produce and traditional meals (Abrahams et al., 2012). Unfortunately, this has led to increases in dietary intake of sugar, salt, fat and alcohol at population-level (Swinburn et al., 2011; Puoane et al., 2008). Both the institution and marketing of global fast food and cool drink companies have increased to an extent that brands are recognised by all levels of society, in both low- and middle-income countries (Basch et al., 2013).

### ***Urban living***

The migration of rural populations to urban areas is a global phenomenon, and a large-scale problem in South Africa (Allender et al., 2011; Stern et al., 2010). According to the 2011 South African Census, over 60% of the country's population were living in urban environments (Stats SA, 2011). Urban environments are becoming synonymous with the term 'obesogenic' environment, since these living areas expose populations to unhealthy foods and built environments that discourage physical activity (Kirk et al., 2010; Puoane et al., 2008). It has been suggested that the number of years spent in an urban environment is relative to the incidence of NCDs (Malhotra et al., 2008; Bourne et al., 2002).

In particular, the rural-urban migration of black South Africans has increased their vulnerability to NCDs since they experience significant changes in diet and lifestyle (Stern et al., 2010; Bourne et al., 2002). Traditional dietary patterns and home-cooked meals are often replaced with a 'westernised' diet that includes convenience foods high in fat, salt and sugar and low in nutritive quality and fibre (Basch et al., 2013; Steyn et al., 2012; Pretorius & Sliwa 2011; Voster et al., 2011). Furthermore, low-income urban environments in South Africa typically accommodate more fast-food outlets (Feeley et al., 2011), unhealthy street foods (Steyn & Labadarios, 2011), sugar-sweetened beverages (Steyn & Temple, 2012), and informal alcohol outlets (Pretorius & Sliwa, 2011; Schneider et al., 2007a) compared to rural areas. This is because many communities born out of urbanisation are not conveniently situated to central business districts and supermarkets, therefore urban communities are compelled to supply convenience foods from informal shops (Steyn et al., 2012; Drewnowski, 2009; Bourne et al., 2002). Furthermore, high unemployment rates in these urban communities have encouraged informal vendors to sell low-cost, unhealthy foods to the community in order to generate income (Puoane et al., 2007).

Urban areas also deter physical activity, specifically occupational, transportational and leisure-time formal physical activity (Hallal et al., 2012). Mechanisation and technological advancements reduce the need for labour-intensive physical work that subsequently reduces occupational energy expenditure (Hallal et al., 2012; Held et al., 2012; Ershow, 2009). The use of motorised transport reduces the opportunity for transportational physical activity, while poor urban land-design limits 'walkability' and aesthetic recreational areas (Hallal et al., 2012; Held et al., 2012; Ershow, 2009; Diez Roux, 2003). In a South African context, the level of crime in urban environments can significantly dissuade participation in outdoor recreational physical activity (Shinew et al., 2013; Puoane et al., 2007).

In South Africa, there is considerable evidence to show the effect of urban living on the prevalence of NCDs and risk factors for NCDs (Shisana et al., 2013; Steyn et al., 2012; Van Zyl et al., 2012; Pretorius & Sliwa 2011; Stern et al., 2011; Mendez et al., 2005). More recently, the SANHANES report indicated a significantly higher prevalence of high cholesterol and high blood glucose in urban residents compared rural residents (Shisana et al., 2013). Other local studies, namely the Cardiovascular Risk in black South Africans (CRIBSA) study (Peer et al., 2013b), Transition, Health and Urbanisation (THUSA) study (Malan et al., 2008), and Heart of Soweto (HOS) study (Pretorius & Sliwa, 2011), have concluded that urban living is a major determinant of NCDs and risk factors for NCDs because of high exposure to stress, unhealthy foods and physical inactivity.

### ***Socio-economic status***

Socio-economic status (SES) is a collection of measures and strata of income, educational attainment, employment and occupation (Pampel et al., 2010). These measures are strongly inter-related, for example, having higher educational attainment increases the likelihood of greater employment and income opportunities (Braveman et al., 2011; Pampel et al., 2010). South Africa is considered a lower-middle-income country although the socio-economic inequality has shifted much of the population into poverty (Schneider et al., 2009), with large proportions of the population requiring social grants and being of low SES (Puoane et al., 2012).

Unhealthy behaviours such as an unhealthy diet, physical inactivity, smoking and excessive alcohol intake tend to cluster in lower SES population groups (Margolis, 2013; Pampel et al., 2010). Moreover, poor compliance with healthy behaviours and low levels of health-seeking behaviour also appear to be strongly related to low SES (Margolis, 2013; Pampel et al., 2010). These findings have been attributed to reduced perception of health risks, a lower

comprehension of health information and poor locus of control in individuals with a low SES (Margolis, 2013; Braveman et al, 2011; Pampel et al., 2010). In addition, lower SES groups may not be motivated by the prospect of longevity, therefore may have a low incentive to invest in preventative behaviours (Pampel et al., 2010).

Poor SES and social inequality affect dietary intake in various ways. Individuals living in deprived socio-economic conditions tend to consume foods with cheaper ingredients namely refined starches, vegetable oils, and low-nutrient, high calorie snacks (Drewnowski, 2009). Furthermore, fast foods and energy-dense foods are considered to be more palatable, satisfying and convenient (Temple and Steyn, 2011). It should be borne in mind that economically deprived individuals may prioritise food for hunger alleviation, rather than nutrient density or health benefits (Lawrence et al., 2009; Puoane et al., 2007). Thus, individuals who are experiencing poverty and food insecurity may struggle to adopt the South African food-based dietary guidelines (FBDGs) (Love et al., 2008).

The cost of healthy eating has been analysed in the United States (Drewnowski, 2009) and in South Africa (Pretorius & Sliwa, 2011; Temple & Steyn, 2011). Both studies concluded that the differential energy cost per megajoule for healthier food items was much higher than food containing predominantly fat and sugar (Drewnowski, 2009). In the South African study, the six most commonly consumed “healthier foods” were 10 to 60% more expensive when assessed per 100g weight. The study also concluded that a healthier diet could cost 69% more than the typical diet. However, Pretorius and Sliwa (2011) found that the cost of a healthy diet aligned with the South African FBDGs can be similar to usual unhealthy intake (Pretorius & Sliwa, 2011).

Many studies have reported an association between low SES and physical inactivity (Hallal et al., 2012; Held et al., 2012; Pampel et al., 2010; Ball et al., 2008). The association appears to be more apparent in women (Hallal et al., 2012; Ball et al., 2006) and could be attributed to long working hours, family and household responsibilities, as well as lack of aesthetic recreational space for women to participate in physical activity (Ball et al, 2006). A study in the United States reported that women with low SES have a strong preference for television viewing over physical activity during leisure time (Ball et al., 2006), and consider informal physical activity gained through occupational means as sufficient (Ball et al, 2006). On the other hand, a lack of education can prompt men and women into more labour-intensive jobs that would contribute to greater occupational energy expenditure (Roskam et al., 2010; Bourne et al., 2002).

Unfortunately, lower SES groups also experience more chronic psychosocial stress than higher SES groups (Braveman et al., 2011). It has been suggested that these circumstances can prompt individuals into using unhealthy coping mechanisms such as binge eating, smoking and excessive alcohol intake (Pampel et al., 2010).

It should be borne in mind that improvements in SES may not necessarily protect against obesity and NCDs (Roskam et al., 2010; Pampel et al., 2010). For example, increased prevalence of obesity, hypertension (Sliwa et al., 2012; Schneider et al. 2009) and physical inactivity (Shisana et al., 2013) have been associated with improved economic conditions in South Africa. This is because improvements in household economic status allows for the adoption of a more affluent lifestyle that for example could increase access to energy-dense foods (Roskam et al., 2010; Bourne et al. 2002) and cigarettes (Pampel et al., 2010).

The relationships between SES and NCDs in South Africa and sub-Saharan appear to differ among race groups. Steyn et al., (2005) measured the odds of having an acute myocardial infarction among educational attainment strata. The odds of acute myocardial infarction decreased with increasing education in Whites and mixed ancestry however, the findings appeared to be reversed in the black African population. The increasing odds of acute myocardial infarction in black African groups with increasing education was attributed to the high prevalence of hypertension and the adoption of a westernised way of eating and living as SES improved (Steyn et al., 2005).

### ***Socio-Cultural factors***

Socio-cultural factors appear to influence perceptions of body weight (Dorsey et al., 2009) and dietary intake (Kruger et al., 2005). For example there are misconceptions among black African-American groups in the United States, Africa and South Africa that obesity represents good health and high SES (Ziraba et al., 2009; Van der Merwe & Pepper 2006). As African countries are experiencing the double burden of NCDs and HIV/AIDS, weight loss is often viewed in a negative sense as a possible symptom of progressive HIV/AIDS (de-Graft Aikins et al., 2010; Puoane et al., 2008). This has been reflected in the results of the South African Health and Demographic Study (SADHS) that indicated that many black African participants incorrectly perceived their weight status to be healthy when they were in fact overweight or obese (Puoane et al., 2002). However, white women appear to acknowledge their true weight status and perceive obesity in a negative light (Senekal et al., 2003; Puoane et al., 2002). These differences may be explained by the adoption of

Westernised views on weight by white and urban cultures where 'thinness' is the ideal (Van der Merwe & Pepper 2006).

In the United States, socio-cultural factors strongly influence dietary intake and lifestyle, and probably similarly to South Africa women. The studies by Lawrence et al., (2009) and Noia et al., (2013) explain that socio-economic and historical oppression of minority groups have encouraged cultures to adjust their dietary practices in line with foods that were affordable, accessible and acceptable. Both South African and African-American black women seem to prefer to provide meals representative of their cultural and household taste preferences, which unfortunately can represent unhealthy cooking methods and/or food choices (Lawrence et al., 2009; Love et al., 2008).

## **2.2 Management of NCDs**

The management of NCDs involves weight management, healthy eating, increased physical activity and medication together with behavioural strategies that support these lifestyle modifications.

### **2.2.1 Weight management**

It is well established that modest weight loss of 5 to 10% reduces NCD risk factors namely high blood pressure (Frisoli et al., 2011; Poirier et al., 2006), high cholesterol (Wing et al., 2011; Poirier et al., 2006), high glucose (Evert et al., 2014; Wing et al., 2011; Dyson 2010; Bantle et al., 2008; Poirier et al., 2006), harmful inflammatory cytokines (Eckel et al., 2008), and improves cardio-vascular function (Dyson, 2010; Poirier et al., 2006).

The Academy of Nutrition and Dietetics, formerly known as the American Dietetic Association (ADA), recommends that the management of overweight and obesity is aligned with the nutrition care process that includes assessment, diagnosis, intervention, monitoring and evaluation (Seagle et al., 2009). Following assessment of BMI, central adiposity, medical history and diet, appropriate interventions for diet and physical activity should be applied to induce a negative energy balance and weight loss (Rao et al., 2011; Rowberg 2010; Seagle et al., 2009). It has been recommended that energy intake be reduced by 2100kJ to 4200kJ per day through reduced dietary intake and increased physical activity to induce approximately 0.5kg to 1kg weight loss per week (Seagle et al., 2009; Bantle et al., 2008; NHLBI, 1998).

The National Heart, Lung, and Blood (NHLB) Institute guidelines for the management of obesity recommend lifestyle modification in all overweight and obese patients, and recommend pharmacotherapy for patients with a BMI > 30 and surgery in patients with a BMI >40 (Eckel, 2008). Although these guidelines are evidence-based, it is unlikely that the management of obesity in primary health care (PHC) in South Africa could incorporate pharmacological and surgical options. Unfortunately, there are currently no South African guidelines for weight management in PHC.

## 2.2.2 Dietary recommendations

### *Dietary approaches for NCD management*

Dietary recommendations for NCD prevention and management involve total energy intake, macronutrient composition, and quantity of fat as well as fibre and salt intake. Recommendations for the Prudent, DASH, Mediterranean and carbohydrate-restricted diet for CVD and DM prevention and management are presented in Table 2.

**Table 2: Summary of macronutrient distributions, fibre and sodium recommendations and their health effects**

	Prudent diet/ TLC <sup>a</sup>	DASH <sup>b</sup>	Mediterranean <sup>c</sup> (Traditional Greece)	Carbohydrate-restricted diet <sup>d</sup>
<b>Energy</b>	2000	2000	2000	2000
<b>CHO (% of TE)</b>		58%	ND	10 – 60%
<b>Protein (% of TE)</b>	~15%	15%	ND	25-35%
<b>Total fat (% of TE)</b>	≤30%	27%	42.9%	39%
<b>Saturated (% of TF)</b>	<7 to 10%	6%	13%	
<b>Monounsaturated (%TF)</b>	~20%	13%	22.7%	17%
<b>Polyunsaturated (%TF)</b>		8%	6.9%	
<b>Fibre (g)</b>	20-30g	29g		
<b>Sodium (g)</b>	2g	1.5-2g	ND	
<b>Health effects</b>	↓weight, ↓LDL-C ↓TC, ↓TGs	↓weight, ↓SBP, ↓DBP, ↓TC, ↓LDL-C,	↓weight, ↓SBP, ↓DBP, ↑HDL, ↓BG, ↓insulin, ↓CRP	↓weight, ↓TGs, ↓SBP, ↓DBP, ↑HDL

Abbreviations: TE: total energy, TF: total fat, g: grams, LDL-C: low-density lipoprotein cholesterol, HDL-C, high-density lipoprotein cholesterol, TC: total cholesterol, TGs: triglycerides, SBP: systolic blood pressure, DBP: Diastolic blood pressure.

References: <sup>a</sup>Kelley et al., 2011, Hill et al., 2009, Sacks et al., 2009; <sup>b</sup>Mozaffarian et al., 2011; <sup>c</sup>Evert et al., 2014, Mozaffarian et al., 2011; <sup>d</sup>Wheeler et al., 2012, Hite et al., 2011

There is a general consensus that total energy intake should be reduced in overweight and obese individuals to promote weight loss. Recommendations regarding macronutrient composition does vary with some supporting reducing carbohydrate intake (Wheeler et al.,

2012; Hite et al., 2011). However, current evidence shows that manipulation of the macronutrient composition of the diet does not influence the amount of weight loss or improve NCD risk profile on an energy-restricted diet (Evert et al., 2014; Kirk et al. 2012; Sacks et al., 2009a; Laddu et al., 2011; Dyson 2010). It is evident from Table 2 that the prudent diet does not affect triglycerides and HDL cholesterol (Kelley et al., 2011; Wheeler et al., 2012), the DASH diet does not reduce triglycerides, while the Mediterranean and carbohydrate-restricted diet do not improve LDL-cholesterol yet improves HDL-cholesterol and insulin resistance (Wheeler et al., 2012). However, the focus should thus be on appropriate energy intake, avoiding extreme approaches to macronutrient content (e.g. carbohydrate intake less than < 35%), and improving the quality of food choices. Most importantly, a food-based approach that promotes a diet high in fruit, vegetables, fibre, unsaturated fat and limits refined carbohydrates and salt, is consistently recommended for long-term weight management and NCDs (Evert et al., 2014; Dyson, 2010; Bantle et al., 2008). In addition, food regulation, portion control, meal planning and self-monitoring should accompany dietary prescriptions (Evert et al., 2014; Collins, 2011; Seagle et al., 2009), as well as individualisation whereby diets are adjusted for disease status, metabolism, socio-economic status and cultural food preferences (Evert et al., 2014; Walker et al., 2010; Sacks et al., 2009a).

### ***Adaptation of the South African FBDG for NCDs and associated risk factors***

The South African FBDGs provide general recommendations for healthy eating (DOH 2012a). The guidelines are not disease-specific but can be adapted for NCD education as summarized below (Pretorius & Sliwa, 2012; Steyn, 2006b).

- “Eat plenty of fruit and vegetables everyday” (DOH, 2012a)

Sufficient daily intake of fruit and vegetables can provide a range of benefits and micronutrients, antioxidants, phytochemicals and fibre, which are important components of a cardio-protective diet (Naude, 2013; Boeing et al., 2012; Pretorius & Sliwa, 2012; Mozaffarian et al., 2011). Antioxidants such as flavonoids, vitamin C and beta-carotene are believed to reduce oxidative damage of the vascular system, reduce blood clotting and provide anti-inflammatory effects (Van Duyn & Pivonka, 2000). The potassium in fruit and vegetables increases vasodilatation of blood vessels thereby assisting with the reduction of BP (Houston, 2011). Fruit and vegetables can also assist with weight management if used to displace energy-dense foods (Boeing et al., 2012).

Various dietary guidelines have advised between 4 to 10 portions per day with one portion equivalent to medium-sized fruit (such as an apple), half a cup of cooked vegetables or one cup of raw vegetables. The South African FBDGs recommend 4 to 7 servings per day bearing in mind dietary patterns, socio-economic status and total energy intake of select groups (DOH, 2012). A higher intake of 8 to 10 servings of fruit and vegetables is recommended in the DASH diet for individuals with high blood pressure (Hill et al., 2009; Lichtenstein et al., 2006).

- “Eat dry beans, split peas, lentils and soya” (DOH, 2012a)

Regular consumption of legumes is beneficial as these foods are low in fat and are a good source of unrefined carbohydrates, protein, micronutrients, antioxidants and both soluble and insoluble fibre (Bouchenak & Lamri-Senhadji, 2013). In particular, phytochemicals such as isoflavonoids and tocopherols are highly concentrated in legumes and aid in reducing inflammation and oxidative stress (Bouchenak & Lamri-Senhadji, 2013). The high fibre content of legumes is associated with reductions in post-prandial glucose, BP, total and LDL-cholesterol, and reduction in risk of DM and CVD (Bouchenak & Lamri-Senhadji, 2013; Marinangeli & Jones 2012; Mozaffarian et al., 2011). These beneficial effects are owed to fibre’s ability to slow digestive transit time and reduce post-prandial glucose and insulin output (Bouchenak & Lamri-Senhadji, 2013; Mozaffarian et al., 2011; Messina, 1999). Soluble-fibre and phytosterols in particular, can reduce cholesterol absorption within the gastro-intestinal tract (Bouchenak & Lamri-Senhadji, 2013; Mozaffarian et al., 2011). Fibre can also increase satiety and reduce the energy-density of meals, which may assist with weight reduction (Bouchenak & Lamri-Senhadji, 2013; Marinangeli & Jones, 2012; Messina, 2002). A diet high in soya protein has been associated with reducing cholesterol, however this association may also be related to the displacement of animal protein and saturated fat with soya (Lichtenstein et al., 2006).

One serving of cooked legumes or 30g soya per day is recommended in the 2012 South African FBDGs. It is important to note that the recommendation for fibre intake is 14g/4200kJ per day (Evert et al., 2014), which can be achieved with the regular consumption of legumes and soya as half a cup of kidney beans or lentils provide 4.5g and 7.8g fibre respectively (Messina 1999).

- “Eat fats sparingly; choose vegetable oils rather than hard fats” (DOH, 2012a);

The amount and type of dietary fat are important considerations in NCD management (Vannice & Rasmussen 2014; Mozaffarian et al., 2011). Fat has a higher energy content per gram than carbohydrates and protein, thus restriction of fat intake is necessary to prevent

excess energy intake (Lichtenstein et al., 2006). Current recommendations for fat intake emphasise the consumption of sources rich in monounsaturated fatty acids (MUFA) and polyunsaturated fatty acids (PUFA) (especially omega-3 fatty acids), and accompanied with the reduction of saturated fat and trans fat (Evert et al., 2014; Aranceta & Perez-Rodrigo, 2012; Mozaffarian et al., 2011; Lichtenstein et al. 2006). Food products enriched with plant sterols have been shown to reduce total cholesterol and LDL-cholesterol by reducing cholesterol absorption and bile acid secretion (Dyson et al., 2011). Table 3 outlines the role of different fats and the recommended intake per total energy.

**Table 3: Food sources, therapeutic effects and recommendations of dietary fats and oils**

Fatty acids	Main dietary sources	Possible therapeutic effects	Recommended intake (% of TE)
<b>MUFA</b>	Nuts, olive oils, canola oil,	↓risk of heart disease and ischemic stroke <sup>b</sup> ↓TC <sup>c</sup> ↑HDL-C when MUFA replaces some CHO <sup>a,c</sup>	15 to 20% <sup>a</sup>
<b>PUFA: n-3</b>	Oily fish such as anchovies, salmon, mackerel, sardines, trout, herring and pilchards Oils: flaxseed, canola, soybean oil	anti-inflammatory <sup>a,b,c</sup> antiarrhythmic <sup>a,b,c</sup> ↓platelet aggregation <sup>a</sup> ↓TGs, ↓SBP <sup>b,c</sup> , ↓DBP <sup>b,c</sup> ↓risk of CVD events <sup>a,b,c</sup>	0.5 to 2% or 500mg/d (EPA + DHA) or 2 servings of oily fish per week
<b>PUFA: n-6</b>	Vegetable/seed oils	↓TC <sup>d</sup> ↓ CVD risk when replaces SFA <sup>d</sup> ↓ reduce risk of diabetes mellitus <sup>d</sup>	2.9 to 9%
<b>Plant sterols</b>	Soybean oil, nuts	anti-inflammatory <sup>d</sup> ↓TC, ↓LDL-C, reduce cholesterol synthesis <sup>e</sup>	2 to 2.5g <sup>e</sup>

Abbreviations: LA: linoleic acid; EPA: eicosapentaenoic acid; DHA: docosahexaenoic acid; ALA: alpha-linolenic acid. %E: %total energy intake. *Abbreviations:* LDL: low density lipoprotein, HDL: high-density lipoprotein; SBP: Systolic Blood Pressure (SBP); Diastolic Blood Pressure (DBP); HbA<sub>1c</sub>: Glycated Haemoglobin

References: <sup>a</sup>Vannice, & Rasmussen (2014); <sup>b</sup>Aranceta & Perez-Rodrigo 2012; <sup>c</sup>Mozaffarian et al., 2011; <sup>d</sup>FAO 2010; <sup>e</sup>Houston 2012

“Make starchy foods part of most meals” (DOH, 2012a).

The type and amount of starchy foods consumed in a diet are important considerations in the treatment of NCDs. Unrefined starchy foods are also labelled ‘wholegrains’ that indicates that the bran, germ and endosperm are still intact (Mozaffarian et al., 2011). Each of these components provide a varied amounts of fibre, micro-nutrients, anti-oxidants and phytochemicals. As mentioned above, sufficient fibre is necessary for glycaemic control, insulin response, cholesterol-lowering and energy balance (Evert et al., 2014; DOH, 2012a; Dyson et al. 2011; Mozaffarian et al., 2011), therefore should be consumed regularly.

The amount of starchy foods in the diet is dependent on the total energy prescription, and in patients with DM the focus is on aligning total carbohydrate intake with glycaemic control, medication, metabolic requirements and physical activity (Evert et al., 2014; Dyson et al., 2011). The American Diabetes Association (ADA) recommends that 45% of energy should come from carbohydrates (Evert et al., 2014), while SEMDSA and Diabetes United Kingdom (UK) recommend a range of 45% to 60% carbohydrates of total energy per day (Amod et al., 2012, Landau et al., 2012).

•“Use sugar and foods and drinks high in sugar sparingly” (DOH, 2012a)

Sweetened beverages, high-sugar snacks and added sugar should be limited within the diet in order to prevent and manage obesity, DM and possibly CVD (Temple & Steyn, 2013; Steyn & Temple, 2012). The 2003 Department of Health (DOH) guideline for sugar consumption was  $\leq 55\text{g}$  per day or 6% to 10% of total energy intake (Steyn et al., 2003). This is approximately double the recommendation by the American Heart Association for women (25g) and for men (37.5g) per day (Temple & Steyn, 2013). In a 2009 Position Statement from the American Heart Association, it was proposed that added sugar allowance in sedentary individuals should approximate nine teaspoons per 9240kJ per day for sedentary males, and three teaspoons per 6720kJ for sedentary females (Johnson et al., 2009). In individuals with DM, added sugar and foods and drinks containing sugar can be incorporated in small amounts as part of total carbohydrate intake bearing in mind total energy intake and medication (Evert et al., 2014; Bantle et al., 2008). Furthermore, the South African FBDG recommend between two teaspoons per 6500kJ, and six teaspoons per 8500kJ and 10500kJ. Both a review on sugar intake in South Africa (Temple & Steyn, 2013) and 2012 SEMDSA recommend an upper limit of 10% for added sugar intake (SEMDSA, 2012). In order to achieve these recommendations, non-nutritive sweeteners and low-energy sweeteners can be used to displace some energy and/or added sugar intake (Evert et al., 2014).

“Use salt and foods high in salt sparingly” (DOH, 2012a)

A reduction in dietary sodium is necessary to achieve optimal BP (Houston, 2011). This includes a reduction in added salt in addition to the reduction in sodium-containing seasonings, sauces, soup powders, canned vegetables, processed meat, salted fish, processed cheese and fast foods (DOH, 2012a; Seedat & Rayner, 2012). In South Africa, bread is considered to be the greatest contributor of sodium intake (Charlton et al., 2005). Fortunately population-wide, sodium-reducing interventions within the food industry was put in place in 2012 to restrict sodium content in a variety of foodstuffs (Puoane et al., 2012).

The recommendation for daily salt intake for South Africans with NCDs and risk factors for NCDs is 5g per day that equates to approximately 2500mg sodium per day (DOH, 2012a). It has been recommended that patients should be educated on low-sodium foods (<120mg per 100g serving), food labelling and salt-free flavourings (lemon juice, herbs and sodium-free spices) (Seedat & Rayner, 2011).

#### Alcohol intake and recommendations

The current South African FBDGs do not contain a guideline for alcohol intake. However, it is well-established that excessive alcohol consumption should be avoided for the prevention and management of NCDs (Parry et al., 2011), especially in patients with NCD-related complications such as neuropathy and hypertriglyceridemia (Bantle et al., 2008). At this point, evidence suggests that alcohol in moderation can be integrated into the usual diet since it is cardio-protective (Ronksley et al., 2011). Red wine contains the flavonoid, resveratrol, which has been associated with increased HDL-cholesterol, and reduced inflammation, blood thickening and atherogenesis (Yang et al., 2011). It should be borne in mind that the protective benefits of alcohol on CVD appear to be limited in overweight and obese individuals (Lobstein & Daube, 2012).

The recommendation for alcohol intake is two drinks per day for men and one drink per day for women (around 15-30g ethanol) (Evert et al., 2014; Seedat & Rayner, 2012; Bantle et al., 2008; Lichtenstein et al., 2006). Additional considerations for patients with DM include the restricted use of high-sugar beverages commonly served with alcohol, and alcohol should be taken with meals to avoid hypoglycaemia especially in insulin-dependent patients with DM (Bantle et al., 2008).

### **2.2.3 Physical activity**

Regular physical activity has beneficial effects on energy balance, weight maintenance, blood pressure, insulin, lipids and glucose (Fletcher et al., 2013; Laddu et al., 2011; Powell et al., 2011). In addition, moderate to vigorous physical activity contributes to improved cardiac stroke volume, glucose regulation, and reduced peripheral resistance, blood coagulation and inflammation (Powell et al., 2011). Regular physical activity can reduce HbA1c levels up to 0.65% (Dyson et al., 2011), and reduce SBP by 5 to 10mmHg points and DBP by 1 to 6mmHg (Semlitsch et al., 2013).

The protective effects of physical activity depend on the duration, frequency, and intensity thereof (Powell et al., 2011). Furthermore, a combination of resistance training and aerobic exercise is recommended for reducing NCD risk factors (Fletcher et al., 2013; Walker et al., 2010; WHO, 2011b; SEMDSA, 2012). Table 4 outlines the recommendations for physical activity from the WHO, AHA, SEMDSA & SAHS guidelines. Moderate to vigorous planned activity undertaken in leisure time may be more protective of cardiac events compared to occupational physical activity (Held et al., 2012). This finding was attributed to higher intensity of planned physical activity compared to unplanned, occupational physical activity (Held et al., 2012).

**Table 4: Guidelines for physical activity**

<b>NCD/risk factor</b>	<b>Organisation</b>	<b>Recommendation</b>
<b>General health</b>	WHO (2011b)	150 minutes moderate-intensity aerobic physical activity per week or 75 minutes of vigorous-intensity physical activity per week Plus muscle-strengthening activities on 2 or more days of the week
<b>General health + additional benefits</b>		300 minutes of moderate-intensity aerobic physical activity per week Plus muscle-strengthening activities on 2 or more days of the week
<b>Cardiovascular disease</b>	AHA (2013) <sup>a</sup>	≥5 days of the week for 30 to 60 minutes depending on exercise tolerance and weight Plus muscle-strengthening activities on 2-3 days of the week
<b>Diabetes</b>	SEMDSA (2012)	General: 150 minutes moderate-intensity aerobic physical activity per week or 75 minutes of vigorous-intensity -intensity physical activity per week Plus muscle-strengthening activities on 2-3 days of the week For weight management and DM: 225-420 minutes of moderate-physical activity
<b>Hypertension</b>	SAHS 2011 <sup>b</sup>	30 minutes per day on most days of week

Abbreviations: WHO: World Health Organisation, AHA: American Heart Association, SEMSDA, Society for Endocrinology, Metabolism & Diabetes of South Africa, SAHS: South African Hypertension society.

<sup>a</sup>Fletcher et al., 2013, <sup>b</sup>Seedat & Rayner, 2012

At this point, there does not appear to be specific guidelines for maximum number of hours that could be spent engaged in sedentary activity, as evidence is still emerging and intervention studies for reducing sedentary activity are insufficient to guide policies (Owen et al., 2010; Thorp et al., 2010). However, it has been recommended that 120 minutes of light activity should replace sedentary physical activity during leisure time each day (Owen et al., 2010).

## **2.2.4 Behaviour change strategies**

Modifiable risk factors are behaviour-orientated, therefore behaviour modification strategies should accompany conventional dietary and lifestyle education (Dobe, 2012; Spahn et al., 2010).

### ***Patient-centred care and motivational interviewing***

Patient-centred care requires the caregiver or counsellor to move away from curative, autocratic counselling to a more motivational approach that incorporates mutual decision-making and goal setting (Armstrong et al., 2011; Levitt et al., 2011). Motivational interviewing includes core principles that facilitate behaviour change in the individual such as use of empathy, enhancement of self-efficacy, use of problem-solving strategies and mutual collaboration (Young, 2010). The process also involves employing open-ended questions, affirmations of patient progress, and active listening (Spahn et al., 2010; Young, 2010). This collaboration assists with mutual decision-making between the health professional and patient, while autonomy is maintained so that individuals take ownership of their disease by developing self-management strategies (Armstrong et al., 2011; Mash and Allen, 2004).

The patient-centred approach has been found to be associated with behaviour change (Armstrong et al., 2011; Young, 2010; Funnell, 2010), however its implementation in busy health care facilities appears to be challenging. This notion was illustrated by research conducted by Mash and Allen (2004) on the feasibility of motivational interviewing among South African medical doctors working in PHC settings. The doctors were expected to implement various motivational interviewing techniques and rate the application of each of the tools. Assessing a patient's readiness to change, encouraging self-management and collaborating on mutual decisions were found to be extremely helpful. However, it was considered a time consuming method that would be difficult to standardise and maintain by medical doctors in busy PHC settings (Mash & Allen, 2004).

### ***Goal setting***

Goal setting is a consistent feature within behaviour change theories and models (Spahn et al., 2010) and may assist with behaviour change by increasing personal awareness, autonomy and self-management of disease (Bodenheimer & Handley, 2009). Goals should be negotiated between health professional and patient in order to establish autonomous plans of action for improvement in diet, physical activity, biochemical measures and also weight loss. In addition, goals should be realistic, specific and challenging to the individual

(Bodenheimer & Handley, 2009; Van Dorsten and Lindley, 2008). It should be borne in mind that the achievement of goals can depend on the level of self-efficacy and readiness for change (Battersby et al., 2010; Van Dorsten and Lindley, 2008). Thus it has been suggested that interventions should initiate goal setting at the beginning of an intervention in order to initiate personal awareness and motivation (Van Dorsten and Lindley, 2008). Thereafter, personal goals can be adjusted during the intervention period, and during maintenance or relapse phases (Crawford & Glover, 2012).

### ***Self-management, self-efficacy and problem-solving***

The self-management concept describes the level of a patient's participation and control of their disease process (Pulvirenti et al., 2011; Battersby et al., 2010). It also encompasses a variety of psychosocial skills, strategies and processes such as self-efficacy, self-empowerment (Battersby et al., 2010) and problem solving (Funnell, 2010). Since NCDs are chronic in nature, an individual's ability to self-manage is essential to improve and maintain health of patients and reduce dependence on healthcare providers (Pulvirenti et al., 2011).

Self-efficacy can be explained as an individual's belief that they are able to manage their condition and meet their personalised goals (Dobe, 2012; Spahn et al., 2012). Participants with high levels of self-efficacy have been shown to employ a greater number of self-management behaviours (Battersby et al., 2010). Self-efficacy promotes inner introspection, assertiveness and ownership over his/her chronic disease (Dobe, 2012; Pulvirenti et al., 2011).

Problem solving is another core self-management skill (Funnell, 2010; Spahn et al., 2010; Van Dorsten and Lindley, 2008). The process of problem-solving involves: (1) Identifying and pinpointing the problem, (2) identifying alternative ways of coping with the problem, (3) choosing one solution among those alternatives, (4) rehearsing the chosen alternative, (5) implementing the alternative, and (6) reviewing, revising plans, further rehearsing or developing skills (Van Dorsten & Lindley 2011; Fisher et al., 2005). Collaborative problem solving can assist participants with decision-making (Battersby et al., 2010), reduce barriers to change (Spahn et al., 2010), and reduce unhealthy habitual behaviours and increase coping skills for challenging environments (Fisher et al., 2005).

The provision of both health education and self-management techniques has been associated with improved outcomes for chronic conditions (Battersby et al., 2010). Bodenheimer and Handley (2009) stated that health professionals should be aware that their

purpose is not confined to reaching targets for control in patients with NCDs, but rather to increase the level of self-management. This has important implications for South Africa since there is a heavy burden of NCDs within a constrained health system (Levitt et al., 2011). Therefore, if patients increase their level of self-management, it may reduce the burden on PHC and improve patient outcomes.

### ***Self-monitoring***

Van Dorsten and Lindley (2008) described self-monitoring as one of the most important behaviour change components for weight loss. This is because the personal recording of weight, dietary intake and physical activity increases an individual's awareness of his/her progress and assists health professionals with providing appropriate feedback (Spahn et al., 2010; Van Dorsten & Lindley, 2008). It has been recommended that health professionals should encourage food and activity journals by patients and subsequently review the records to ensure compliance (Rowberg, 2010).

### ***Social support***

Social support is extremely important for individuals undergoing behaviour change and can be provided by family, friends and/or health professionals (Gallagher et al., 2013; Spahn et al., 2010). Stubbs et al., (2011) stated that "humans are intensely social animals and often find it far easier to solve specific problems in a social context provided they consider that their environment to be safe and secure". The use of peer support groups can assist with the transfer of knowledge, self-management and coping strategies (Funnell, 2009; WHO, 2008). Moreover, patients with the same disease are often able to provide empathy and understanding of the challenges involved in disease management (Funnell, 2009). Group-based or peer support groups feature more regularly in interventions for patients with DM as it has been recognised that patients with DM need support in addition to medical treatment (WHO, 2008). Social and peer groups should be considered for lifestyle interventions in South Africa since the approach can improve use of the health professional's time, promote self-management within larger groups, and allow for the inclusion of families and carers.

### ***Perspective on the challenges of behaviour change strategies***

Barriers that interfere with behaviour change include poor perception of health risks (Dobe, 2012), poor internal motivation (Teixeira et al., 2012), lack of knowledge, poor interpretation of educational messages (Wattana et al., 2007), low self-efficacy (Spahn et al., 2010), poor health literacy (Shillinger et al., 2002), lack of social support (Lawrence et al., 2009) and

poor faith in health professionals (Price et al., 2007). Poor goal setting techniques may also interfere with behaviour change. For example, an overestimation of weight loss goals may be counterintuitive since participants may become disappointed at the lack of progress and may withdraw prematurely from lifestyle programmes (Crawford & Glover, 2012).

### **2.2.5 Pharmacological intervention**

In this section of pharmacological approaches to NCDs and their associated intermediate risk factors, the use of anti-hypertensives, oral hypoglycaemics and insulin and statins will be discussed, however pharmacological treatment of weight loss will not be covered. Pharmacological interventions are extremely important for the management of NCDs (Abegunde, 2013) and it is fortunate the drugs required for heart disease and diabetes are reasonably affordable and provide good secondary prevention (Beaglehole et al., 2008). However, the success of pharmacological interventions is limited to the availability of medication, function of the health system and patient adherence (Abegunde, 2011). The most widely used drugs for NCDs and risk factors include anti-hypertensives, oral hypoglycaemics, insulin, and statins.

#### ***Anti-hypertensives***

The 2011 South African Hypertension Society guidelines (Seedat & Rayner, 2012) recommend that health professionals establish CVD risk before prescribing medication for high blood pressure by using an algorithm that considers the effects of genetic predisposition, age, abdominal girth, smoking, dyslipidaemia, and DM. This ensures that the patient receives the appropriate treatment at the appropriate time. Initially, anti-hypertensive drugs are prescribed when SBP/DBP is consistently higher than 140mmHg/90mmHg or greater than 140mmHg/80mmHg (Seedat & Rayner, 2012). Diuretics, angiotensin-converting enzyme inhibitors and calcium channel blockers are commonly used to treat HBP in South Africa (Seedat & Rayner, 2012). Angiotensin receptor blockers are the preferred anti-hypertensive treatment in patients with DM as they are less renal toxic (Seedat & Rayner, 2012).

#### ***Oral hypoglycaemics and insulin***

Insulin and oral hypoglycaemics are used for management of DM when lifestyle interventions are not sufficient in achieving glycaemic control (SEMDSA, 2012). One of the most widely used oral hypoglycaemics is metformin, which is commonly prescribed as first-

line therapy at time of diagnosis (SEMDSA, 2012). Metformin assists with glycaemic control by reducing hepatic production and gastrointestinal absorption of glucose, while increasing glucose and fatty acid uptake at cellular level (SEMDSA, 2012). Unfortunately, gastrointestinal symptoms are common but resolve in most patients over time. A second oral agent, sulphonylureas, is prescribed in order to increase insulin output from the pancreas (SEMDSA, 2012). Weight gain and hypoglycaemia are the two main side effects of sulphonylureas (SEMDSA, 2012). Insulin should be considered when oral agents have not achieved glycaemic control and HbA1c levels are >10%, or random glucose levels are continually greater than 16.7mmol/l (SEMDSA, 2012). Insulin can be prescribed in conjunction with oral agents and prescribed in long-acting and short-acting formulae. Patient education on the usage of insulin and the administration is vital to prevent complications such as hypoglycaemia (SEMDSA, 2012).

### ***Statins***

Statins are commonly prescribed as cholesterol-lowering agent in patients with high cholesterol, heart disease, or as a preventative measure in patients with DM, smokers and hypertensive participants (SEMDSA, 2012). Statins are associated with a reduction in cardiac events and stroke (Klug et al., 2012; Sadowitz et al., 2010). Statins inhibit the production of cholesterol in the liver and are particularly effective in reducing total cholesterol and LDL cholesterol (Sadowitz et al., 2010). Side-effects in some patients include muscle weakness and pain and is often the main cause for discontinuation of statins (Grundy, 2013).

### ***Adherence***

Adherence to medication for NCDs and risk factors for NCDs is pivotal for the success of secondary and tertiary management of NCDs (Abegunde, 2013). The most common reasons for poor compliance to medication have been reported as reduced motivation, forgetfulness, misinterpretation of scripts, side effects, long waiting times when collecting medication and medication shortages at public health facilities (Seedat & Rayner, 2012). Therefore, health care professionals should educate participants on their medication prescription and the importance of adherence (Abegunde, 2013).

### ***Western Cape Chronic Dispensing Unit***

The Western Cape Provincial Department of Health has implemented the Chronic Dispensing Unit (CDU), which is a successful endeavour to reduce waiting times and

pressure at hospital pharmacies that manage large numbers of patients with NCDs and other chronic conditions (Du Plessis, 2008). According to the CDU protocol, a general practitioner needs to assess the patient and classify the patient as “stable” before issuing a prescription for the CDU. The prescriptions are sent to an outsourced medication depot where they are packaged and sent back to the hospital or clinic. The pharmacists at the facilities are then able to issue the pre-packaged medicines directly to the patient in a short space of time. Therefore, patients are encouraged to reach satisfactory health in order to benefit from the CDU system. It was reported that waiting times were reduced from approximately four hours to less than 20 minutes using the CDU system (Du Plessis, 2008).

## **2.3 Intervention planning perspectives**

### **2.3.1 Socio-ecological approach to intervention**

The socio-ecological model refers to “people’s interactions with their physical and socio-cultural surroundings” (Fisher et al., 2005). The ‘ecological approach’ to NCD intervention aims to target individual, family, community, and policy (Slawson et al., 2013; Fisher et al., 2005). According to Slawson et al., (2013), interventions that target multiple behaviours and/or socio-ecological levels may have a ‘synergistic effect’ on decreasing NCD burden, and may thus result in larger impact on population health compared to interventions that address single behaviours in individuals (Slawson et al., 2013; Sarrafzdegen et al., 2006).

#### ***Individual level interventions***

Individual (intrapersonal) interventions target the personal beliefs, knowledge and self-efficacy of an individual (Slawson et al., 2013; Sacks et al., 2009b; Robinson, 2008). In a healthcare facility, this would involve focused, individual face-to-face consultations (Sacks et al., 2009b; Robinson, 2008), which is considered ideal to address personal challenges, and establish collaborative goal setting (Fisher et al., 2005). It also allows the health professional to adjust meal plans according to the patient’s condition, medication, personal food preferences and eating patterns (Fisher et al., 2005). On the other hand, Diez Roux (2003) maintains that intra-personal interventions for NCDs are mildly effective since environmental and community factors limit an individual’s ability to change poor lifestyle behaviours. This is because the health status of an individual is often strongly governed by political, legal, cultural and economic factors (Kumanyika et al., 2008; Lock et al., 2005; Diez Roux, 2003). It could be argued that one-on-one interventions are labour-intensive and inefficient since they focus on individual risk factors in isolation. Therefore, in order for interventions that target individual behavioural determinants to be truly effective, individual

dietary advice should be adjusted according to family food income (Temple and Steyn 2011) in the presence of community and policy interventions (Puoane et al., 2012).

### ***Interpersonal level interventions***

Interpersonal interventions focus on family and friends and their impact on behaviour change (Slawson et al., 2013; Robinson, 2008). The inclusion of family and friends in interventions is considered important since they are likely to influence lifestyle behaviours of the individual (Noia et al., 2013; Robinson, 2008). Furthermore, an increase in collaboration between family members and the individual may increase compliance (Robinson, 2008). For example, it is recommended that individuals responsible for food purchases and meal planning be included in interventions in order to support the necessary dietary changes in the homestead (Noia et al., 2013; Robinson, 2008). As women are often central figures in the provision of meals, interventions should focus on increasing their ability to adjust traditional cooking methods and make healthy food purchases (Noia et al., 2013; Robinson, 2008). It has also been shown that a family that enjoys partaking in physical activity is likely to provide a supportive interpersonal environment for individual behaviour change (Richards et al., 2008).

### ***Community interventions***

Community interventions target larger community groups and their respective social and cultural behaviours (Slawson et al., 2013; Robinson, 2008). These interventions may be implemented at institutions and organisation such as schools, workplace and neighbourhoods (Slawson et al., 2013). Including a community focus in NCD interventions is important since social and cultural influences affect the way community members view health, weight and lifestyle (Kumanyika et al., 2008). A key consideration for community-level interventions is to include community members in intervention planning (Draper et al., 2010; Fisher et al., 2005). For example, community members could be involved with urban planning and resource allocation to improve neighbourhood walkability and recreational space (Fisher et al., 2005). Community interventions may also collectively empower community members to improve dietary intake and physical activity levels (Draper et al., 2010; Richards et al., 2008).

Food choices can for example be improved by the introduction of healthy foods via community supermarkets (Robinson, 2008), schools and work canteens (Kumanyika et al., 2008). As far as physical activity is concerned, Sacks et al., (2009) and Sallis et al., (2006) suggest that schools, religious institutions and non-governmental community organisations

(NGOs) should advocate, initiate and accommodate physical activity interventions since they provide positive, familiar environments for community members (Noia et al., 2013; Robinson, 2008). Community participation in physical activity may also alleviate safety concerns in high crime areas (Richards et al., 2008).

The championing of health events and campaigns is also considered a positive community intervention (Sacks et al., 2009b; Robinson, 2008). For example the South African school-based HealthKick and Siyadlala interventions aimed at school-going children and all age groups respectively, have been implemented in communities to improve physical activity and health (Puoane et al., 2012). In addition, The *Community Health Intervention Programme* (CHIPs) intervention supported by Sports Science Institute of South Africa (SSISA) also promotes physical activity and healthy lifestyles in adults in low-income communities (SISSA 2012). The full impact of these interventions are not yet known, however their implementation is being monitored (Puoane et al., 2012).

### ***Policy level interventions***

Policy interventions are considered population-scale interventions and generally target underlying determinants of health and disease (Slawson et al., 2013; WHO, 2010; Sacks et al., 2009b; Robinson, 2008). These interventions should include a variety of governmental agencies that are directly or indirectly involved in improving the health of a population (Slawson et al., 2013), since the Health sector cannot be solely responsible for providing interventions for NCDs.

Food pricing interventions may have a significantly greater impact on NCD disease burden, than interventions that focus on the individual dietary intake (Cecchini et al., 2010). Legislation and policy adjustment for the food industry, trade, and agriculture sectors may provide large-scale reductions in the population's consumption of unhealthy foods (WHO, 2009). It has also been proposed that money gained from taxation of unhealthy foods could be used to subsidise fruit and vegetables (Temple & Steyn, 2011; Kumanyika et al., 2008). These interventions would require the integration of economic, agricultural and healthcare policies (Lock et al., 2005).

There is evidence that South Africa is implementing population-scale interventions for dietary intake (Puoane et al., 2012). The DOH issued a regulation on the reduction of salt in foods under section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act 972 (Act 54 of 1972) (DOH, 2012b). The act stipulates strict labelling laws and limits on sodium/100g that

include restrictions on specified food products such as bread, fat spreads, ready-to-eat savouries, processed sausages and cold meats (DOH, 2012b) while trans fatty acids will also be restricted in processed foodstuffs (Puoane et al., 2012).

The legislation, tax and price of alcohol and tobacco products has also been successfully implemented in South Africa (Puoane et al., 2012; Schneider et al., 2007a). Thus far, South Africa has introduced policies for the advertising and marketing of alcohol, while the Western Cape has introduced a liquor act that limits alcohol trading hours (Puoane et al., 2012). Interventions to reduce smoking rates include restrictions on advertising and marketing of tobacco products, increased taxes and introduction of 'smoke-free zones' in communal areas (Puoane et al., 2012; Groenewald et al., 2007). This intervention has had a positive impact on reducing smoking rates (Puoane et al., 2012; Groenewald et al., 2007). However, it should be borne in mind that increasing the price of cigarettes may increase the sale of imported illegal cigarettes (Groenewald et al., 2007). This practice together with illegal alcohol vendors is currently very common in low income communities. Thus, stricter community surveillance would need to accompany interventions for reducing alcohol and smoking (Groenewald et al., 2007).

As mentioned above, the involvement of other governmental policy-makers and ministries is pivotal for successful NCD intervention. The sports and education ministries should ensure that sports centres and recreational areas are built and maintained in all communities to ensure adequate aesthetic space for physical activity (Franzini et al., 2010; Sacks et al., 2009b; Sallis et al., 2006). The transport ministry should focus on the development of safe bicycle lanes and pedestrian sidewalks in order to encourage physical activity in order to increase transportational physical activity (Sallis et al., 2006), while the security ministry needs to ensure the safety of community members so that all populations can engage in activity without the fear of criminal activity (Franzini et al., 2010).

### **2.3.2 Behaviour change models theories**

There are several behavioural theories and models that can be considered when planning interventions for NCDs and obesity or can be to explain outcomes (Spahn et al., 2010). Table 5 provides a summary of behavioural theories and models commonly used in this respect, as well as relevant behaviour change strategies.

**Table 5: Behaviour change models and strategies**

Theory or model	Description	Behavioural strategies <sup>a, d</sup>
Transtheoretical Model <sup>a, b, c</sup>	Describes phases of behaviour change and can be used to indicate an individual's readiness to change health behaviours <sup>a, b, c, d, e</sup>	Stage of change <sup>a</sup> Goal setting <sup>a, d</sup> Motivational interviewing <sup>a, d</sup> Self-monitoring <sup>a</sup> Reinforcement <sup>a, d</sup> Peer support <sup>a</sup> Stimulus control <sup>a</sup> Prevention of relapse <sup>a, d</sup>
Cognitive Behavioural Theory	Describes an 'action-orientated' approach that aims to reduce negative or counterintuitive thoughts to improve behaviour <sup>a, b, c</sup>	Cognitive restructuring <sup>a</sup> Goal setting <sup>a</sup> Problem solving <sup>a</sup> Self-monitoring <sup>a</sup> Reinforcement <sup>a</sup> Peer support <sup>a</sup> Stress management <sup>a</sup> Stimulus control <sup>a</sup> Relapse prevention <sup>a</sup>
Health Belief Model	Measures concepts such as perception of risks of disease, challenges to behaviour change, as well as cues to action and self-efficacy <sup>b</sup> . The model also describes how 'behaviour reflects a person's participative interpretation of a situation' <sup>f</sup>	Problem-solving <sup>b</sup> Self-efficacy <sup>b</sup> Stimulates cue to action <sup>g</sup>

<sup>a</sup> Spahn et al., (2010); <sup>b</sup> Glanz & Bishop, (2010); <sup>c</sup> Salmela et al., (2009); <sup>d</sup> Young, (2010); <sup>e</sup> Sutton et al., (2003); <sup>f</sup> Price et al., (2007), <sup>g</sup> Carpenter, (2011)

### ***Transtheoretical Model***

The Transtheoretical Model is discussed in more detail as it is considered an important behavioural component in weight loss and NCD interventions. The principle behind the Transtheoretical Model is establishing the stage of change or readiness to change behaviour (Dobe, 2012; Glanz & Bishop 2010). The model can also be used to interpret patient outcomes or predict the likelihood of programme withdrawal since stage of change is indicative of personal motivation to change behaviour (Dobe 2012; Hickson et al., 2009; Chapman-Novakofski & Karduck, 2005).

Since behaviour change is considered a process and not an isolated event (Dobe, 2012; Glanz & Bishop, 2010; Salmela et al., 2009), it has been suggested that advice and

behavioural strategies be provided according to the patient's readiness to implement healthy behaviours (Glanz & Bishop, 2010; Salmela et al., 2009). This would involve screening for readiness to change prior to advising treatment by using a stages of change questionnaire to categorise a patient into either 'pre-contemplation', 'contemplation', 'preparation', 'action', 'maintenance', or 'relapse' stage (Salmela et al., 2009; Sutton et al., 2003). Individuals in the pre-contemplation stage present in a state of denial or may be unaware of the risks associated with poor lifestyle behaviours. These individuals are difficult to treat in an intervention setting since they do not have the intention to change their behaviour (Young, 2010; Salmela et al., 2009; Sutton et al., 2003). Individuals in the contemplation stage are not in denial about the state of their health, however are not in a position to make active decisions to change their unhealthy behaviours (Salmela et al., 2009; Sutton et al., 2003). Health professionals are discouraged from providing dictator-style advice when participants are resistant to change, but should rather use motivational interviewing and provide problem-solving strategies to move individuals towards preparation or action stage (Young, 2010). The preparation stage is considered a planning stage as individuals display intention to change. It is suggested that behavioural strategies such as goal setting and motivational interviewing should be applied in this stage (Young, 2010; Salmela et al., 2009). Individuals in the action stage are likely to commit to changing their lifestyles and implement dietary and physical activity recommendations. These individuals can therefore be targeted for more intensive lifestyle interventions (Young, 2010; Salmela et al., 2009; Sutton et al., 2003). Lastly, the maintenance stage and prevention of relapse requires frequent contact between individuals and health professionals in order to maintain behaviour change (Van Dorsten and Lindley, 2008).

There are some considerations in measuring stage of change. Sutton et al., (2003) noted that individuals categorised in action stage are often not truly compliant with their diet and exercise regimes, and therefore are often misclassified. To address these challenges, it was suggested that more specific questions should be designed for inclusion in the stage of change questionnaires. For example, instead of asking the patient to state their readiness to "consume a diet low in fat", be more specific in establishing their readiness to "drink skim milk" or "eat chicken without skin". It has been suggested that the development and application of more definitive stage of change questionnaires may improve the validity and interpretation of the questionnaires (Sutton et al., 2003).

## **2.4 Intervention structure**

### ***Delivery mode***

Health education for NCDs can be delivered through individual consultations (Grace, 2011), group education (Hoddinott et al., 2010) and more recently, through web-based programmes (Neve et al., 2010). Individual consultations for obesity can address individual risks (Grace, 2011), while group-based interventions provide social support and can address NCDs at intrapersonal and community level (Hoddinott et al., 2010).

There does not appear to be a marked difference in outcomes between group-based and individual interventions (Steinsbekk et al., 2012; Greaves et al., 2011; Hoddinott et al., 2010; Norris et al., 2002). Various studies have reported a variety of outcomes with some studies showing superior outcomes for individual education (Sperl-Hillen et al., 2011) and other studies and literature reviews showing superior outcomes using the group-based approach (Jolly et al., 2011; Khasteganan & Tsiami 2011; Jovanovic et al., 2009; Paul-Ebhohimhen & Avenell 2009). It could be argued that patient outcomes actually depend on intervention exposure regardless of delivery mode (Jolly et al., 2011). However, in the context of strained health systems in South Africa, group-based interventions and social support strategies may be more cost-effective.

### ***Socio-demographic considerations***

South Africa is a good example of socio-demographic diversity and there is large variation in language, culture, beliefs, and educational attainment among the population (Phaswana-Mafuya et al., 2013; Coovadia et al., 2009; Senekal et al., 2003). This diversity presents a challenge for interventionists when developing appropriate interventions (Noia et al., 2013; Phaswana-Mafuya et al., 2013; De-Graft Aikins et al., 2012; Coovadia et al., 2009; Senekal et al., 2003). For example, it is known that women and older patients participate more frequently in lifestyle interventions compared to younger individuals (Stubbs et al., 2011; Moroshko et al., 2011). Interventions for men and younger individuals may thus need to be tailored to improve participation. Furthermore, individuals with low education attainment may have difficulties with the comprehension of written and numerical nutrition education (Sacco et al., 2012; Lawrence et al., 2009). Visual aids, education material and language should thus be adjusted according to the socio-demographic profile of the programme participants (Noia et al., 2013; Fitzgibbon et al., 2011; Marchand et al. 2011; Shoneye et al., 2011; Puoane et al., 2007; Wang & Baydoun, 2007; Blixen et al., 2006). These patients should also be provided with 'tangible' dietary messages rather than education on the scientific benefits of healthy foods (Noia et al., 2013).

Most importantly, a lack of cultural tailoring within conventional lifestyle interventions has been highlighted in studies in Africa (De-Graft Aikins et al., 2012), the United Kingdom (Davidson et al., 2013) and the United States (Parker et al., 2010; Blixen et al., 2006). This lack of generalisability for certain cultural groups tends to result in sub-optimal patient outcomes and programme effectiveness (Airhihenbuwa et al., 2013; Lindberg et al., 2012). Therefore, a culture-centred approach has been recommended for health promotion of NCDs since it addresses the needs of the community and their perceptions of health and obesity (Airhihenbuwa et al., 2013). Gucciardi et al., (2007) posit that group-based programmes that includes patients with similar beliefs, language, attitudes and challenges may obtain superior outcomes. Parker et al., (2012) stated that language-appropriate health promotion and education would be particularly important to facilitate comprehension of health education (Parker et al., 2012). To facilitate alignment of an intervention within the cultural context, the target community in the intervention should be included in the planning process in order to gain insight into the needs and challenges of the attending participants (Davidson et al., 2013; Puoane et al., 2007).

However at this point in time, research on tailored interventions is insufficient to support evidence-based guidelines for lifestyle interventions for specific socio-demographic groups (Davidson et al., 2013; Osei-Assibey et al., 2012; Sperl-Hillen et al., 2011).

### ***Intervention dosage, duration and intensity***

Intervention 'dosage' or the amount of exposure to a programme, appears to be fundamental for improving patient outcomes. Dosage can include session attendance and duration of programme. Lifestyle interventions are usually divided up into a 'core' or treatment phase, and a maintenance phase. The core phase typically contains more intensive and frequent sessions, while post-intervention maintenance sessions usually occur less frequently (Venditti & Kramer, 2012).

There is a well-established relationship between intervention dosage and weight reduction (Gallagher et al., 2013; Toth-Capelli et al., 2013; Finkler et al., 2012; Venditti & Kramer 2012; Greaves et al., 2011; LeBlanc et al., 2011; Venditti et al., 2008). A meta-analysis of 17 studies reported that a programme participant experienced 0.26% percentage weight loss per session attended (Venditti & Kramer, 2012). Furthermore, participants with DM who attended all of the 16 prescribed sessions in an adapted diabetes prevention programme (DPP) intervention lost 6.7kg, compared to 1.6kg in those who attended less than 10 sessions (Samual-Hodge et al., 2009). The United States Preventative Services task force

found a similar association and reported that patients who attended 12 to 26 sessions experienced significantly more weight loss than those who attended less than 12 sessions (LeBlanc et al., 2011). Intervention dosage has also been correlated with biochemical outcomes. It has been suggested that HbA1c could be reduced by 0.04% for every hour of education received by a patient (Norris et al., 2002). Furthermore, Norris et al., (2002) estimated that an average of 23.6 hours of education would be necessary to reduce HbA1c by a clinically significant reduction of 1% (Norris et al., 2002).

However, Baker et al., (2011) suggests that more research is required to define the number of sessions required to significantly impact behaviour change during the core intervention (Baker et al., 2011). There are large variations in the levels of intervention dosage applied and advised, for example, a systematic review of lifestyle interventions reported a range of 1 to 80 sessions, with session duration varying from 15 to 150 minutes per session, and study periods ranging from 12 to 24 months (Greaves et al., 2011). Rowberg et al., (2010) advised that the core intervention should be conducted over 3 months, and provide 12 to 18 months of maintenance support, while Venditti and Kramer (2012) and Kirk et al., (2012) recommended that lifestyle programmes should be facilitated for a minimum of four and six months respectively. Steinsbekk et al. (2012) found that programmes that provided between 19 to 52 hours of education over six to 10 months experienced superior results than less intensive interventions. Lastly, the DPP provides 16 structured intervention sessions within the core programme (Whittemore, 2011). The Academy of Nutrition and Dietetics Evidence-based Nutrition Practice Guidelines for medical nutrition therapy for patients with DM recommend a minimum of three to four sessions (45 – 90 minutes) over three to six months (Evert et al., 2014). Although some recommendations for sessions during the intervention phase have been published, further research is still required to determine the level of contact during the maintenance period in order to prevent weight gain (Turk et al., 2009).

Poor attendance has been associated with poor inner motivation (Car et al., 2012; Byrne et al., 2012), low education attainment (Moroshko et al., 2011), transport difficulties, time limitations, financial limitations, forgetfulness, and long waiting times at facilities (Car et al., 2012). Despite these challenges, interventions should utilise methods to improve attendance since it is strongly associated with outcome. One proposed method is the use of short-message-service (SMS), which has been used in a variety of health care interventions to improve attendance and adherence in programmes for sexual health, infectious diseases, smoking cessation and chronic illness. A Cochrane review by Car et al. (2012) reported that participants who received SMS reminders were more likely to attend healthcare appointments. However, only four meta-analyses were included in the review and further

research required to justify its use in interventions for NCDs. It has also been reported that attendance rates can be improved by using peer-style education and contingency rewards (Stubbs et al., 2011).

### ***Programme facilitators***

It has been suggested that programme effectiveness and patient outcomes may be dependent on the skills of the programme facilitator (Jolly et al., 2011; Sperl-Hillen et al., 2011). Many types of educators have been used to facilitate lifestyle interventions for NCDs and obesity namely doctors, nurses, dietitians and lay counsellors (Greaves et al., 2011; Cardona-Morrell et al., 2010). Research suggests suitable training, skills and experience are imperative for convening behavioural programmes (Kirk et al., 2012; Steinsbekk et al., 2012; Greaves et al., 2011; Grace, 2011; Seagle et al., 2009). The level of training necessary to increase the skills of a programme facilitator has not been defined. However, the Diabetes Prevention Programme requires doctors, nurses and dietitians to complete a two-day training course on the programme protocol (Venditti & Kramer, 2012). Samuel-Hodge et al., (2012) conducted a comprehensive weight loss intervention for low income women and provided 26 hours of training for programme facilitators prior to implementation of the intervention.

A position statement for weight management by the Academy of Nutrition and Dietetics (Seagle et al., 2009) recommends that dietitians should be considered as key programme facilitators since they have comprehension of both dietary applications and behavioural strategies. It has been reported in a systematic review of group-based lifestyle programmes for DM that the use of a dietitian as the primary facilitator was associated with the greatest reduction in HbA1c (Steinsbekk et al., 2012). Dietitian-led personalized programmes appear to be very effective for weight management yet may be dependent on level of professional training (Grace, 2011; Digenio et al., 2009). Grace et al., (2011) argues that dietitians may not have sufficient training on specialised behavioural counselling skills and patient-centred care which is imperative for managing obese patients (Grace, 2011). Dietitians in Australia, Canada and the UK have also acknowledged that dietitians lack some behavioural counselling skills required to manage obesity (Grace, 2011). The findings by Paul-Ebhohimhen and Avenell (2009) following a systemic review of group-based programmes suggested that psychologist-led interventions provided superior results to programmes facilitated by dietitians, which tends to support this notion.

A study on patient preference for health educators in PHC in the Western Cape showed that the majority of participants, including those with preference for chronic clubs and support groups, preferred doctors and nurses for individual counseling and workshops (Parker et al., 2012). The least favoured educators were lay health educators or nutrition advisors. It should be noted that dietitians were not provided as an option since their services are not provided on a daily basis at most PHC facilities. The results are paradoxical since doctors and nurses have limited time to educate participants on managing their NCDs (Parker et al., 2012). A doctor who participated in the study stated that it is only possible to spend around five minutes on lifestyle education (Parker et al., 2012).

Peer counsellors within support group settings have potential to lead and advocate for culturally sensitive lifestyle groups within their communities. A peer is defined as a person who either has a chronic illness, or is a close relative of the patient (WHO, 2008). The peer-led support groups can be established informally and function without continuous health professional input (WHO, 2008). Peer counsellors with similar race and cultural backgrounds may optimise collaboration and the delivery of interventions for NCDs in South Africa (Puoane et al., 2007). Although research on use of peer counsellors lacks usability in low- and middle-income countries (WHO, 2008), the approach should be considered to extend interventions and health promotion in South Africa. This may be achieved by using the current HIV/AIDS adherence counsellors to address barriers to change and initiate motivational interviewing.

### ***Session content***

It has been recommended that the curricula designed for interventions for NCDs should address all modifiable risk factors for NCDs since these diseases have similar origins (Phaswana-Mafuya et al., 2013; Steyn & Levitt, 2006). The provision of both lifestyle modification and behavioural change strategies are considered key features for such interventions (Venditti & Kramer, 2012). A summary of the curricula developed and implemented for three published lifestyle programmes are shown in Table 6. All three curricula show evidence of inclusion of behavioural strategies, dietary education and advice on physical activity.

**Table 6: Session content and curricula in interventions**

	<b>Diabetes Prevention Programme<sup>a,b</sup></b>	<b>X-pert programme for patients with DM<sup>c</sup></b>	<b>Culturally tailored programme<sup>d</sup></b>
Description	Well-known evidence-based programme for prevention and control of DM that was developed in United States. The programme is based on research conducted by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease	The X-PERT programme was designed as a structured, group-based programme for patients with DM.	This is a culturally-tailored programme undertaken in Canada for Portuguese participants with DM who are considered to be ethnic minority.
Country of origin	United States of America	United Kingdom	Canada
Number of sessions	16 sessions over 24 weeks (1 hour per session)	6 weekly sessions (2 hours per session)	Two-day programme (15 hours)
Medical education	Not specified	Education on causes and complications of uncontrolled DM. Weight management discussed. Uses board game to increase participation.	Education on DM and medication, glucose monitoring and management of hypo- and hyper-glycaemia.
Dietary education	Emphasis on portion control, balanced meals and caloric intake. Uses plate model, food models, food labels, recipes and menus in sessions.	Emphasis on portion control (especially carbohydrates). Uses plate model, food models and food labels in sessions.	Emphasis on portion control, meal planning and caloric intake. Uses plate model and culturally-tailored food models and food labels.
Physical activity education	Education only	Education only	Education and 1 supervised session using resistance stretch bands.
Key behavioural strategy	Goal setting Self-monitoring Problem-solving Stimulus control Stress management Motivation	Goal setting Self monitoring Self empowerment	Problem-solving Cognitive reframing Stress management
Other activities		Supermarket tour to assist with purchasing and food labelling	Cooking demonstration using culturally appropriate ingredients and recipes.

<sup>a</sup>Kramer et al., (2009); <sup>b</sup>CDC, (2013); <sup>c</sup>Deakin et al., (2006); <sup>d</sup>Gucciardi et al., (2007)

### **Size of groups**

A systematic review by Steinsbekk et al., (2012) on group-based interventions for DM found that groups sizes ranged from five to 40 participants. It has been suggested that

interventions should aim for an average group size of 10 patients, since larger groups may reduce participation, collaborative teaching and individual attention (Rickheim et al., 2002). The determination of the optimal group size for increasing effectiveness of FBTG interventions needs further investigation.

### ***Concluding perspectives***

The review of the literature on planning interventions for NCDs, risk factors for NCDs and weight loss shows that they can be delivered through a variety of modalities as long as there is sufficient intervention dosage to support behaviour change. However, a definitive number of sessions and specifications for intervention duration (core and maintenance phases) is not clear and probably depends on intervention participants and available resources. Age, culture and educational attainment should be taken into account when planning interventions and programme curricula, since these socio-demographic variables are likely to influence participation in lifestyle programmes. Lifestyle programmes can also be facilitated by a variety of health professionals and lay counsellors, however it is probable that programme facilitators need to be trained prior to commencing intensive interventions. Furthermore, programme facilitators should have skills to implement behaviour change strategies that are pivotal in lifestyle programmes.

## **2.5 Critical overview of group-based intervention studies for NCDs and risk factors for NCDs**

The aim of this section is to critically comment on published group-based interventions for NCDs or risk factors for NCDs (Table 7) that applied a group-based approach and outlined programme components of interest such as change in weight, intervention dosage and session content. Fifteen intervention studies and two systematic reviews with one meta-analysis could be traced and were included for these purposes. The duration of these studies ranged from four to thirty months, however the focus of this discussion is on the core intervention phase that ranged from three months to twelve months. Three of the studies summarized in Table 11 (Adolfsson et al., 2007; Deakin et al., 2006; Wattana et al., 2006) were also included in the systematic review by Steinsbekk et al., (2012).

### ***Settings***

All studies took place in high-income countries (USA, Canada, Sweden, Finland, United Kingdom and Australia) except for one RCT that was undertaken at a community hospital in Eastern Thailand. No suitable studies could be traced that were conducted in developing

countries or African countries. This scenario is unfortunate since the available literature cannot be generalised for a South African population because of the differences in disease burdens, healthcare and socio-economic strata that are likely to be different from the high-income countries listed above. Nevertheless, the studies can provide perspectives on intervention planning (intervention dosage, weight loss and attendance), and their results, discussion and limitations will provide some insight in an area that is significantly under-researched in developing countries.

### ***Study designs***

Most studies were RCTs, with the exception of five studies that employed a non-controlled intervention design without a comparative group (Andersson et al., 2008; Hollis et al., 2008; Vadheim et al., 2010; Absetz et al., 2007; Chan et al., 2007). Both systematic reviews included RCTs only (Steinsbekk et al., 2012; Gallagher et al., 2013) while the meta-analysis by Steinsbekk et al., (2012) highlighted important associations between group-based interventions and several outcomes such as change in weight, HbA1c and self-efficacy. The use of RCTs may only explain what can be achieved in controlled academic settings in selective groups of the population. Therefore, a similar argument can be made about the generalisability of these studies, and consideration should be given to their interpretation for group-based interventions in 'real-world' settings such as primary health care in South Africa. However, RCTs are able to significantly reduce bias in a sample by reducing self-selection of participants.

### ***Sample size and patient characteristics***

The number of adult participants per study ranged from 87 to 1685, while the systematic reviews included 2833 (Steinsbekk et al., 2012) and 1428 (Gallagher et al., 2013) participants. Eleven of the 17 studies provided interventions for participants with risk factors for DM or for participants with established DM (Absetz et al., 2007; Adolfsson et al., 2007; Chan et al., 2006; Deakin et al., 2006; Gucciardi et al., 2007; Moore et al., 2011; Rickheim et al., 2002; Vadheim et al., 2010; Wattana et al., 2007; Wolf et al., 2004; Steinsbekk et al., 2012). Other studies included participants with obesity (Ash et al., 2006), obesity and intermediate risk factors (Andersson et al., 2008; Heshka et al., 2000), obesity with CVD and/or DM (Gallagher et al., 2013), and overweight with HBP (Appel et al., 2003).

The BMI cut-off for entry in these group-based studies ranged from 18.5kg/m<sup>2</sup> to 45kg/m<sup>2</sup>. Very few studies provided interventions for specific race groups. All studies included both women and men however all studies except for one (Deakin et al., 2006) reported a higher

proportion of female participants at baseline. Hollis et al., (2008) reported that there were a similar number of Caucasian and African-Americans among women, but found a higher proportion of Caucasians among men.

Only two studies discussed the effect of having a small sample size (Adolfsson et al., 2007; Wattana et al., 2007) since a small sample is less powered to detect true differences between intervention groups and therefore the results have to be interpreted with caution. Most studies found no significant differences in baseline characteristics between group-based and control participants. However one RCT reported that intervention participants were more likely to be married or co-inhabit compared with participants in the control group (Adolfsson et al., 2007). This is an important consideration since intervention groups with dissimilar characteristics offer the opportunity for confounding and subsequently biased results. It should also be noted that there were often a higher proportion of women in the intervention studies.

### ***Intervention period***

Most studies were divided up into a core intervention phase (more intensive group-based sessions), and a maintenance phase that included follow-up sessions that were either individual or group-based. The lowest number of core group sessions offered were four sessions over six months by Rickheim et al., (2002) and Wattana et al., (2006). Two studies provided five core sessions either over an eight-week period with one follow up session (Absetz et al., 2007), or on a weekly basis (Adolfsson et al., 2007). Four intervention studies provided six core sessions either over six weeks (Ash et al., 2006; Deakin et al., 2006), six months (Moore et al., 2011) or an unspecified period (Wolf et al., 2004). In addition, Ash et al., (2006) provided a further two follow up sessions over a 12-month period.

The more intensive interventions provided either 14 to 25 sessions (Hollis et al., 2008), 18 sessions (Appel et al., 2003), or up to 26 visits over six months (Heshka et al., 2000). Two studies delivered their interventions in shorter durations over three consecutive days (Gucciardi et al., 2007) and two weeks (Andersson et al., 2008). The latter intervention also included 14 follow up visits over a two-year maintenance period (Andersson et al., 2008).

In the meta-analysis by Steinsbekk et al., (2012), results were stratified in 0-5 sessions, 6-10 sessions, and 11 or more sessions over one to twelve months. Gallagher et al., (2013) reported that most studies in their review offered weekly sessions over 3-6 months and

provided follow up maintenance sessions over 3-6 months. Chan et al., (2007) did not describe the number of sessions delivered during their intervention.

Many studies stated that their intervention period may have been inadequate (Adolfsson et al., 2007; Gucciardi et al., 2007; Moore et al., 2011; Rickheim et al., 2002). Unfortunately, an intervention of short duration may result in insufficient intervention dosage, and there is concern about whether the outcomes achieved in the core intervention can be maintained over a longer period of time.

Based on the review of the studies, interventions should offer a minimum of six to 10 core sessions in order to provide sufficient intervention dosage required to improve outcomes, and include several sessions in the maintenance phase in order to prevent relapse. However, in a South African PHC setting, the number of sessions provided and the duration of the intervention will largely depend on resources including time, available staff and funding.

#### ***Facilitators and intervention team***

Nine interventions included dietitians as part of their multi-disciplinary team. Four interventions included physiotherapists who provided assessments and/or education on physical activity (Absetz et al. 2007; Andersson et al. 2008; Ash et al., 2006; Gucciardi et al. 2007). Two studies included psychologists (Gucciardi et al., 2007; Vadheim et al., 2010), while other studies included trained behavioural counsellors and peer counsellors (Appel et al., 2003; Chan et al., 2007; Heshka et al., 2000; Hollis et al., 2008; Moore et al., 2011). Only one study included a pharmacist who provided education on medication adherence (Gucciardi et al., 2007), while another study used a physician and specialist nurse to deliver education (Adolfsson et al., 2007). The systematic reviews reported that dietitians, specialist nurses, exercise specialists and peer educators were commonly used to facilitate the interventions (Gallagher et al., 2013; Steinsbekk et al., 2012). Only one study investigated a commercial programme (Weight Watchers), which was convened by the programme's mentors (Heshka et al., 2000).

Many of the intervention studies provided comprehensive training for the facilitators prior to the intervention. Both Absetz et al., (2007) and Adolfsson et al., (2007) provided a two-day training for their facilitators, while Moore et al., (2011) provided a 3-day training workshop for their facilitators. Other studies only indicated that facilitators were provided with training

prior to commencing the intervention (Ash et al., 2006; Hollis et al., 2008; Rickheim et al., 2002; Vadheim et al., 2010).

It is clear that these interventions aimed to ensure that facilitators were providing consistent education and their facilitation and education approaches were aligned with the intervention's protocol. Thus, it could be theorised that facilitators who receive additional training may provide more effective facilitation. Furthermore, it is not clear whether certain types of health professionals or the number of facilitators influence programme effectiveness. Gucciardi et al., (2007) explained that facilitators who were culturally similar may provide superior facilitation. Steinsbekk et al., (2012) reported that the largest improvement in HbA1c was observed in two studies that used a dietitian as the primary educator. However, dietitians can only provide 'advice-only' when it comes to physical activity therefore the incorporation of the other health professionals such as physiotherapists could assist with providing more effective physical activity education through supervised sessions. On the other hand, dietitians are able to comprehensively address diet compared to other types of facilitators. Even though different facilitators have a range of abilities to offer lifestyle programmes, it would be fairly important to utilise a facilitator that is committed to the programme and provides both education and support for programme participants.

### **Attendance**

In general, all the studies reported that more than half of intervention participants attended all the group sessions offered by the intervention programme. Some studies provided detail on attendance rates for example 69% of participants attended all five intervention sessions (Adolfsson et al., 2007); 54% (Rickheim et al., 2002) and 57% (Absetz et al. 2007) of participants attended all six intervention sessions; 78% (Wolf et al., 2004) and 82% (Deakin et al., 2006) of participants attended four or more out of six intervention sessions offered. In the study by Appel et al., (2003), 78% attended 15 out of 18 intervention sessions while Hollis et al., (2008) reported that 61% of their participants attended 16 out of 20 sessions (Hollis et al., 2008). Two studies reported attendance rates by number of sessions, for example Heshka et al., (2000) reported an average of 21 weekly weight watchers sessions over six months, while Vadheim et al., (2010) reported that an average of 14 out of 16 sessions were attended.

It is also evident from these studies that session attendance appears to be a strong predictor of weight loss. For example, participants who attended an average of 14 sessions in two different studies achieved between 5.8kg to 7.5kg weight loss over four to six months (Hollis

et al., 2008; Vadheim et al., 2010) compared to 0.3kg loss over four months (Deakin et al., 2006) and 2.6kg loss over six months (Moore et al., 2011) in interventions offering up to six sessions.

Heshka et al., (2000) provided participants with weekly Weight Watchers vouchers and it could be speculated that the results and attendance rates may have been different if participants were expected to pay for the sessions. Furthermore, interventions in 'real world' settings are unlikely to offer contingency rewards. Alternately, it would be more critical for interventions to investigate the causes of poor attendance in order to aid future planning. This would be especially important if patients were not attending sessions because of reasons related to the intervention design. Unfortunately, poor attendance that relates to the individual such as time commitments are difficult to resolve.

### ***Programme curricula***

The session components were largely heterogeneous. Two studies provided a detailed curricula (Gucciardi et al., 2007; Deakin et al., 2006) while the majority provided brief outlines of their dietary education. Most studies provided education on changing eating habits, plate proportions, portion control, meal planning and including a variety of foods. Two studies based their dietary interventions on the DASH guidelines (Appel et al., 2003; Hollis et al., 2008), while two other studies followed the Diabetes Prevention Programme curriculum (Table 6, Section 2.4) (Absetz et al. 2007; Vadheim et al., 2010). The systematic review by Gallagher et al., (2013) reported that most dietary education focused on the prudent diet while two studies with a CVD focus specifically prescribed the Mediterranean diet or DASH diet. Healthy cooking demonstrations were included in two studies (Andersson et al., 2008; Gucciardi et al., 2007) while one study provided a shopping tour to improve the interpretation of food labels (Deakin et al., 2006).

Two studies provided culturally tailored interventions for specific ethnic groups (Chan et al., 2007; Gucciardi et al., 2007). One of the studies focused on Portuguese-speaking adults in Canada (Gucciardi et al., 2007) and another on indigenous Australians (Chan et al., 2007). Both interventions placed emphasis on providing culturally sensitive education such as healthy preparation of traditional meals and language-specific educational materials. These studies also used facilitators with similar backgrounds and languages to the programme participants. The intervention by Wattana et al., (2007) was set in rural Thailand thus only included Thai individuals and provided education in their native language.

Even though some studies included non-Caucasians, there was no indication that the curricula had been adapted to include culturally acceptable education (Appel et al., 2003; Heshka et al., 2000; Hollis et al., 2008; Moore et al., 2011; Vadheim et al., 2010; Wolf et al., 2004). For example, the study by Vadheim et al., (2010) was conducted on rural, native American Indians and applied the Diabetes Prevention Programme curricula yet did not specify how it was adjusted for this intervention group. The meta-analysis by Gallagher et al., (2013) only included one sub-group targeted at African-Americans, while Steinsbekk et al., (2013) included two studies specifying non-Caucasian participants, but did not elaborate on the racial profiles and cultural approach of these studies.

The most important objective of a programme curriculum is that it is tailored to the attending participants. Gucciardi et al., (2007) explained that curricula that incorporate the participants' culture, language, norms, attitudes and beliefs are more likely to be adopted and applied. A second consideration should be given to the translation of scientific medical and nutrition education into tangible messages and practical sessions in the participants preferred language. Cooking demonstrations that educate participants on healthy meal preparations and use of healthy ingredients in line with traditional eating preferences are more tangible than 'advice only' approaches. Scientific theory, counting calories and food labelling should be reserved for participants with a basic understanding of numeracy. Programme participants with low educational attainment may benefit from simple nutrition education messages that focus on improving the quality of diet and visual aids such as the plate model to educate participants on portion control (Gucciardi et al., 2007).

### ***Anthropometric goals and outcomes***

Many studies used a goal-based approach for weight loss for example >5-7% (Absetz et al., 2007), 5-10% (Andersson et al., 2008); or >5% over 12 months (Wolf et al. 2004), 7% over 16 weeks (Vadheim et al., 2010), 6.8kg (Appel et al., 2003) or 4kg weight loss over six months (Hollis et al., 2008). One study recommended that patients aim to achieve 0.5 to 1kg weight loss per week (Ash et al., 2006). These reported weight loss goals are all in line with current weight loss recommendations (see Section 2.2.1 on recommendations for weight management).

The majority of studies compared weight loss achieved by the intervention groups over the intervention period, however two studies did not report on anthropometric changes (Gucciardi et al., 2007; Wattana et al., 2006). Six studies reported a significantly greater weight loss in the group-based participants compared to control participants over four to six

months (Moore et al., 2011; Deakin et al., 2006; Elmer et al. 2006; Appel et al. 2003; Heshka et al., 2000) and at 12 months (Wolf et al., 2004). Furthermore, two of the above-mentioned studies also reported that the control group participants gained weight over the intervention period (Deakin et al., 2006; Wolf et al., 2004). Three of the studies that used non-controlled intervention design reported significant within-group changes in weight loss over the intervention period (Andersson et al. 2008; Hollis et al., 2008; Vadheim et al., 2010). One study reported that significant weight change over the intervention period was only evident in men (Absetz et al., 2007). In contrast, three studies reported no significant differences in anthropometric measures between intervention groups (Adolfsson et al., 2007; Ash et al., 2006; Rickheim et al., 2002), or weight change within the a non-controlled intervention study (Chan et al., 2007). Furthermore, in the systematic review and meta-analysis of seven studies, it was also reported that BMI and weight reduction was greater in group-based participants but the overall result was not significantly different (Steinsbekk et al., 2012).

It is thus difficult to make conclusive remarks on the effectiveness of group-based programmes to reduce weight, since studies differed in duration, methodology, intervention dosage, outcomes and programme design. The non-significant findings reported by some studies may be explained by their study limitations such as a small sample size (Adolfsson et al. 2007), high rate of lost to follow up (Rickheim et al., 2002), and insufficient contact time (Adolfsson et al., 2007, Rickheim et al. 2002). Chan et al., (2007) attributed the lack of progress to the timing of the implementation of their intervention, which coincided with the holiday period when patients may have been less adherent to lifestyle recommendations.

It should be noted that weight loss also appears to be greater in interventions that were undertaken without control groups. The reported weight losses of -5.0kg, -5.8kg, -7.5kg, and -11.1kg over four to six months (Andersson et al., 2008; Hollis et al., 2008; Vadheim et al., 2010; Chan et al., 2007) were achieved in these single studies while RCTs reported weight losses of -0.3kg, -2.6kg, -2.8kg, -4.9kg; 5.0kg & -5.8kg over four to six months (Appel et al., 2003; Ash et al., 2006; Deakin et al., 2006; Rickheim et al., 2002).

The majority of studies did not report on changes in waist circumference. This is unfortunate since it has been recommended that BMI be reported together with waist circumference since central obesity is an independent risk factor for morbidity and mortality (WHO 2011a). Two of the studies that measured waist circumference found a significant reduction in waist circumference in intervention participants without significant reductions in weight (Absetz et al., 2007; Chan et al., 2007).

### ***Biochemical and clinical outcomes***

In the studies that included participants with DM, HbA1c was often used as a primary outcome measure for glycaemic control. Four studies found that there were no significant improvements in glycaemic control (Absetz et al., 2007; Adolfsson et al., 2007; Deakin et al., 2006; Wolf et al., 2004), while four studies found significant changes to HbA1c over the intervention period (Rickheim et al., 2002; Gucciardi et al., 2007; Moore et al., 2011; Wattana et al., 2007). One study reported that participants who attended four group-based intervention sessions experienced a significantly greater reduction in HbA1c, 2.5% over six months compared to the reduction of 1.7% experienced by participants who received four individual counselling sessions (Rickheim et al., 2002). Furthermore, the meta-analysis that included 1827 group-based intervention participants reported a 0.44% reduction in HbA1c over six months that was significantly greater than the change experienced by control patients (Steinsbekk et al., 2012). One study found a significant increase in HbA1c (by 0.3%) among group-based participants and the finding was attributed to unhealthy dietary patterns that resumed over the holiday season during the intervention period (Chan et al., 2007).

Four studies found that group-based interventions had no impact on blood lipids (Absetz et al. 2007; Chan et al., 2007; Deakin et al., 2006; Wolf et al., 2004), while two studies reported significant reductions in blood lipids at six months (Wattana et al., 2007) and 14 months (Deakin et al., 2006). Furthermore, five studies found that a group-based intervention had a positive effect on BP (Moore et al., 2011; Absetz et al., 2007; Chan et al., 2007; Wattana et al., 2007; Appel et al., 2003).

Only some of the studies found that group-based interventions were more beneficial in reducing HbA1c and BP compared to control groups (Steinsbekk et al., 2012; Rickheim et al., 2002; Gucciardi et al., 2007; Moore et al., 2011; Wattana et al., 2007). However, it should be borne in mind that biochemical changes can be difficult to interpret as they are affected by medication prescription and adherence, and most importantly the synergistic effects of weight loss, healthy eating and physical activity.

### ***Dietary outcomes***

Only five studies reported on definitive dietary changes during the intervention periods. Appel et al., (2003) conducted the most comprehensive dietary analysis. Twenty-four hour recalls were used to determine changes in fruit, vegetable, dairy, alcohol, sodium and protein intake at six months. These authors reported that significantly more fruit and

vegetable portions were consumed by the participants in the group-based intervention with DASH guidelines ( $7.8 \pm 3.2$  portions per day) compared to those in the control 'advice only' group ( $4.9 \pm 2.7$  portions per day). Furthermore, total fat and saturated fat decreased significantly in the group-based intervention from 33.3g to 23.8g and 11.0g to 7.7g respectively. Positive improvements were also seen in dairy, alcohol and sodium intake in the intervention group (Appel et al., 2003). Deakin et al., (2006) reported that group-based participants had a significantly greater increase in fruit and vegetable intake from 2.8 to 5.2 portions per day compared to the increase of 2.9 to 3.1 portions in the control group over the intervention period (Deakin et al., 2006).

One study described improvements in dietary intake by the attainment of dietary goals (Absetz et al., 2007). Forty-eight percent of participants achieved the goal of eating less than 30% fat from total energy while increasing fibre intake to 15g per 4200kJ. The changes were significant when compared to a Diabetes Prevention Programme reference group (Absetz et al., 2007). In another study, a personal rating of 'adherence to diet' namely intake of high fibre foods, high fat foods, and high sugar foods was used as a dietary measure (Gucciardi et al., 2007). There were significant improvements in diet adherence scores in the group-based intervention compared to the control group (Gucciardi et al., 2007). Lastly, one study described change in eating patterns using a questionnaire that measured 'the frequency with which they made particular choices' (Moore et al., 2011). Scores significantly improved in the group-based intervention compared to the control group (Moore et al., 2011).

From the limited information on dietary interventions, it is evident that group-based interventions that provide more intensive dietary education seem to be superior to control groups that receive 'advice only'. When interpreting dietary information, it should be borne in mind that the reliability and validity of self-reported dietary intake may be limited, especially in obese participants. It is well established that study participants may underestimate or overestimate their actual intake, while improvements in knowledge gained in the intervention sessions may be used by patients to report optimal intake rather than actual consumption. However, although subjective, dietary assessments that are associated with patient outcomes such as change in weight or biochemical measures should be measured in interventions.

### ***Physical activity outcomes***

Different measures were used for describing change in physical activity across interventions (Table 11). These included fitness tests (Appel et al. 2003, Andersson et al., 2007), self-reported estimation of weekly physical activity (Appel et al., 2003), knowledge and self-efficacy gained on physical activity (Adolfsson et al., (2007) and physical activity questionnaires such as the International Physical Activity Questionnaire (IPAQ) (Ash et al., 2006). Gallagher et al., (2013) reported that five out of eight RCTs included in the systematic review used physical activity diaries to measure self-reported physical activity. Four studies reported change in self-reported physical activity in minutes per day or week (Hollis et al., 2008; Moore et al., 2011; Rickheim et al., 2002; Vadheim et al., 2010). Wattana et al., (2006) did not measure physical activity, however documented whether participants were employed in labour-intensive jobs. Two studies used questionnaires to measure frequency of physical activity, however did not report the results (Deakin et al., 2006; Gucciardi et al., 2007). Another three studies did not measure changes in physical activity over the intervention period (Chan et al., 2007; Heshka et al., 2000; Wolf et al., 2004).

Both Appel et al., (2003) and Ash et al., (2006) showed a slight, non-significant improvement in fitness in the intensive intervention group, although there was no difference in the reported physical activity between groups (Appel et al., 2003). Similarly, another study observed that group-based participants engaged in more physical activities per week of longer duration over the intervention period yet the change in physical activity was not significant within and between groups (Rickheim et al., 2002).

Both Absetz et al., (2007) and Deakin et al., (2006) reported that participants engaged in significantly more moderate to high intensity activity per day on average, however did not report the average duration per day. Moore et al., (2011) reported that participants were engaging in significantly more informal (e.g. household chores) and formal (moderate to vigorous activity) activity during the intervention period (Moore et al., 2011). Gallagher et al., (2013) did not report on changes in physical activity, however the study did find that interventions that included physical activity as a significant component (in addition to diet) experienced superior weight loss results compared interventions that only focused on diet. This was attributed to participants achieving a greater negative energy balance when applying both diet and physical activity in the intervention (Gallagher et al., 2013).

Two studies reported physical activity at the end of the intervention, however did not report on change over the intervention period as this was not measured at baseline. Firstly, Hollis

et al., (2008) found that intervention participants engaged in an average of 117 minutes of moderate to vigorous physical activity per week at the end of the intervention (Hollis et al., 2008) while the participants in the study by Vadheim et al., (2010) achieved  $248 \pm 167$  minutes per week with 65% of participants meeting the goal of 150 minutes per week over the intervention period (Vadheim et al., 2010).

The studies employed a variety of methods to measure and explain changes in physical activity. The IPAQ is a validated tool to measure physical activity, however it was reported by Ash et al., (2006) that physical activity can be over reported using this tool. Similarly to dietary intake assessments, self-reported records of physical activity are subjective and are considered less valid and reliable than other measures, such as fitness tests. Further research should also review whether the impact of supervised physical activity sessions is greater than 'advice only'. Nevertheless, physical activity is a vital component of NCD management and should be included in interventions.

### ***Behavioural outcomes***

Many of the behavioural components used in the studies were based on behavioural models namely Social Cognitive Model (Absetz et al., 2007; Ash et al., 2006; Hollis et al., 2008), Empowerment Model (Deakin et al., 2006), Theory of Planned Behaviour Model (Gucciardi et al., 2007), Transtheoretical Model (Hollis et al. 2008; Moore et al., 2011; Rickheim et al., 2002), Adult Learning Model (Rickheim et al., 2002), Public Health Nursing Model (Rickheim et al., 2002) and Health Belief Model (Rickheim et al., 2002). Some studies did not mention a specific model, yet used various behaviour change strategies such as self-efficacy, problem solving and goal setting (Appel et al., 2003; Chan et al., 2007; Vadheim et al., 2010). One study employed an empowerment framework over the intervention period and found a slight non-significant increase in self-efficacy in the group-based intervention participants compared to the control participants (Adolfsson et al., 2007). Two studies (Ash et al., 2006; Moore et al., 2011) and one systematic review (Steinsbekk et al., 2012) measured self-efficacy and found significant improvements in the group-based intervention participants. Even though Wattana et al., (2006) did not measure changes in self-efficacy, the authors hypothesized that the change in glycaemic control could be due to increases in self-efficacy (Wattana et al., 2006). Another study showed that improvements in psychosocial adjustment, goal setting and readiness for change significantly improved outcomes in group-based intervention participants (Deakin et al., 2006). Another study reported a positive linear relationship between dietary adherence and the scores measured for intentions, attitudes and deliberate behaviour (Gucciardi et al., 2007). The majority of

studies encouraged self-monitoring by promoting the use of food and physical activity diaries. Wolf et al., (2004) did not apply any behavioural models and theories in their intervention.

Thus, the studies that employed behaviour models or strategies all indicated that these are beneficial in supporting and achieving various outcomes. Behavioural models and strategies appear to be important components for weight loss and/or NCD interventions because they increase a patient's ability to achieve personal goals, monitor weight and glucose levels, and increase their adherence to lifestyle changes.

### ***Lost to follow up (LTFU)***

Thirteen studies reported LTFU rates that ranged between 6-56%, but only two described the reasons for LTFU. Rickheim et al., (2002) reported that the most commonly cited reasons for LTFU were moving out of area, work commitments, time limitations, and contentment with progress. In the second study, time, poor health, and being allocated to a less preferred study group were the most common reasons for LTFU (Wolf et al., 2004).

A few studies also found associations between patient characteristics and LTFU. It was reported that participants LTFU were more likely to be single (unmarried or not living with a partner) (Absetz et al., 2007), younger, more obese, female (Ash et al., 2006; Heshka et al., 2000), or had low-income status and smoked (Heshka et al., 2000).

### ***Concluding remarks***

Therapeutic programmes are often complex in nature and offer participants a variety of behaviour changing techniques and advice. It is likely that a synergetic effect of intervention components namely the facilitator, session content, intervention focus, participant dynamics, and intervention environment contribute to patient outcomes and programme effectiveness. It would also be a valuable endeavour to calculate the costs of individual versus group-based interventions as well as human resource costs such as time in order to establish cost-effectiveness. For example, one study argued that a group-based programme would be able to reach a larger audience at a lower cost per session (Ash et al., 2006). The researchers used their own intervention and explained that if a dietitian facilitated six group-based programmes per year (10-12 participants per group, 60-72 per year), it would cost \$106.00 to \$117.00 (R1060 to R1170) per session compared to \$253 to \$415 (R2529 to R4148) for individualised dietetic sessions for 25 people per year (Ash et al., 2006).

Other important measures are predictors of drop out and weight loss. Only one study reported on the predictors of weight loss (Hollis et al., 2008). The strongest predictors for weight loss were a higher baseline BMI, increased submission of food diaries, increased physical activity levels and a higher attendance at intervention sessions (Hollis et al., 2008). Attendance rates was also supported by the systematic review by Gallagher et al., (2013) that stated that frequent and sustained contact with the intervention team was strongly associated with weight loss.

Steinsbekk et al., (2012) summarised the findings of their comprehensive systematic review of group-based interventions for participants with DM as follows: “Based on current evidence, there are indications that interventions delivered by a single educator, delivered in less than ten months, with more than 12 hours and between 6 and 10 sessions give the best results, but more research is needed to confirm this.” Overall, the results showed that group-based interventions could be delivered in a variety of settings by trained facilitators to improve clinical, lifestyle, anthropometric and behavioural outcomes and in some cases, achieve greater incomes than standard or individual care. Further research on the group-based approach is needed in South Africa since the current literature supports the use of a group-based approach in homogenous population groups in middle- to high-income settings.



Sample Inclusion criteria	Design and length of study	Location of and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
2.			<p><b>Control group</b></p> <p>Routine care</p> <p>Individual non-intensive counselling once a year</p>	<ul style="list-style-type: none"> <li>• Self-monitoring of glucose</li> <li>• Weight management</li> <li>• Portion and carbohydrate control</li> </ul> <p>Interactive with frequent group discussion</p>	<p><b>Limitations</b></p> <p>Small sample size and limited generalizability</p> <p>Short-term trial</p> <p><b>Recommendations</b></p> <p>More evidence is needed to prove that empowerment significantly improved glycaemic control and other clinical measures.</p>	
3.	<p><b>n=187</b></p> <p>19% men, 81% women</p> <p><b>Inclusion criteria</b></p> <p>Convenience sampling</p> <p>BMI&gt;30</p> <p>Adults &gt; 18 years</p>	<p>Longitudinal design</p> <p><b>Study length:</b></p> <p>2 years</p> <p>Initial results at 6 months</p>	<p>Outpatient Obesity clinic, Sweden</p> <p><b>Facilitators</b></p> <p>Physician</p> <p>Dietitian</p> <p>Physiotherapist</p> <p>Nurses</p> <p><b>Group-based intervention:</b></p> <p>1-2 weeks of intensive group counselling</p> <p>8-10 per group</p> <p>Gender-specific groups</p>	<p><b>Goals</b></p> <ul style="list-style-type: none"> <li>• Weight loss 5-10%</li> <li>• 1600-1800 kcal diet plan</li> <li>• 25-30% fat from TE (10% Saturated fat)</li> <li>• Increase fibre, fruit and vegetables</li> <li>• Reduce sugar and alcohol</li> </ul> <p><b>Components</b></p> <ul style="list-style-type: none"> <li>• Conventional dietary and PA advice with plate model</li> <li>• Theory and group discussion</li> <li>• Goal setting</li> <li>• Cooking demonstration</li> <li>• Changing habits</li> </ul>	<p>6 month results reported only</p> <p>17% LTFU at 6 months</p> <p><b>Attendance rates</b> NR</p> <p>Significant weight reduction at months:</p> <p>-5.0kg in women (p&lt;0.001)</p> <p>-11.1kg in men (p&lt;0.001)</p> <p>PA results not reported</p> <p>No dietary measures included</p> <p><b>Limitations</b></p> <p>No control group</p> <p><b>Recommendations</b></p> <p>Group programmes provide social support and positive necessary to facilitate behaviour change.</p> <p>Programme was most effective when sessions were regular</p>	Andersson et al. (2008)

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>4. n=801</p> <p><b>Randomisation of participants to one standard care group, and two treatment groups:</b></p> <p>(1) Advice-only (n=273, men 29%, women 63%)</p> <p>(2) Intervention format with general guidelines (n=268, men 35%, women 65%)</p> <p>(3) Intervention format with DASH guidelines (n=269, 43% men, 57% women)</p> <p><b>Inclusion criteria</b></p> <p>&gt; 25 years with pre- or stage 1 hypertension BMI 18.5 – 45.0</p>	<p>Collaborative RCT, multicentre, 3-arm</p> <p><b>Study length:</b> 18 months</p> <p>Initial results presented at 6 months</p>	USA	<p><b>Facilitators</b></p> <p>Dietitian</p> <p>Health educators trained on behavioural counselling</p> <p><b>Group-based intervention:</b></p> <p>(1) Advice-only received two individual sessions</p> <p>(2) Intervention format with general guidelines in 14 group sessions and 4 individual sessions</p> <p>(3) Intervention format with DASH guidelines in 14 group sessions and 4 individual sessions</p>	<p><b>Goals:</b></p> <ul style="list-style-type: none"> <li>6.8kg weight loss if BMI &gt; 25</li> <li>180 min PA/week</li> <li>Less than 2300mg dietary sodium per day</li> <li>1 alcoholic beverage per day for women and 2 drinks per day for men</li> <li>Saturated fat &lt; 7%, total fat &lt; 25% of total energy (group 3 only)</li> <li>2-3 portions low fat dairy (group 3 only)</li> <li>9-12 servings fruit and vegetables (group 3 only)</li> </ul> <p><b>Group 1 “advice only”</b></p> <p>Counselling on weight loss and reduced sodium diet</p> <p>Information pamphlets.</p> <p><b>Group 2 &amp; 3 intervention based on DASH goals:</b></p> <ul style="list-style-type: none"> <li>Food diaries</li> <li>Self-monitoring, problem-solving and reinforcement</li> </ul>	<p><b>Only results at 6 months presented:</b></p> <p>LTFU NR</p> <p>Attendance at 6 months:</p> <p>Group 1: 95%</p> <p>Group 2: 70% attended at least 15/18 sessions</p> <p>Group 3: 78% attended at least 15/18 sessions</p> <p>Change in weight (kg)</p> <p>Group 1: -1.1 (3.2)</p> <p>Group 2: -4.9 (5.5) (p&lt;0.001) (Versus group 1)</p> <p>Group 3: -5.8 (5.8) (p&lt;0.001) (Versus group 1)</p> <p>Change in SBP/DBP (mmHg)</p> <p>Group 1: -6.6 (9.2)/-3.8 (6.3)</p> <p>Group 2: -10.5 (10.1)/-5.5 (6.7) (p&lt;0.001)</p> <p>Group 3: -11.1 (9.9)/-6.4 (6.8) (p&lt;0.001)</p> <p>Fruit &amp; Vegetable intake</p> <p>Group 1: 0.5 (2.8)</p> <p>Group 2: 0.5 (2.6) (p&lt;0.79)</p> <p>Group 3: 3.0 (3.6) (p&lt;0.001)</p> <p><b>Limitations:</b></p> <p>Limited generalizability due to specific inclusion criteria</p> <p><b>Recommendations:</b></p> <p>Intensive intervention and maintenance necessary for public health to achieve significant weight and BP reduction</p>	Appel et al. (2003)

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>5. <b>n=176</b></p> <p><b>Randomisation of participants to:</b></p> <p>(1) group-based intervention (n=57, 33% men, 67% female),</p> <p>(2) individualised intervention (n=65, 25% men, 75% women)</p> <p>(3) control group receiving information only (n=54, men=22%, women 78%).</p> <p><b>Inclusion criteria</b></p> <p>Adults &gt; 18 years</p> <p>BMI &gt;27</p>	<p>RCT</p> <p><b>Study length:</b></p> <p>12 months</p> <p>Initial results at 6 months</p>	<p>Private and public outpatient depart</p> <p>Brisbane, Australia</p>	<p><b>Facilitators</b></p> <p>Dietitian</p> <p><b>Group-based intervention:</b></p> <p>(1) Nutrition booklet only (no advice)</p> <p>(2) 8 weekly individual contacts with dietitian</p> <p>(3) Intervention group format 6 group session and 1 follow up session. 10-12 participants per group</p> <p>Follow up at 3, 6 and 12 months.</p>	<p><b>Goals</b></p> <p>Weight loss 0.5-1.0kg per week</p> <p><b>Group session content</b></p> <ul style="list-style-type: none"> <li>• Social cognitive model</li> <li>• Tri-phasic design: knowledge, CBT and relapse prevention</li> <li>• Emphasis on empowerment and participation</li> <li>• Cognitive behaviour model</li> </ul>	<p><b>LTFU</b></p> <p>28% LTFU in group intervention</p> <p>17% LTFU in individualised intervention</p> <p>37% LTFU in written advice only</p> <p><b>Attendance rates NR</b></p> <p>Patient who dropped out tended to be younger and had higher BMIs</p> <p><b>Results presented at 6 months only</b></p> <p>Non-significant change in weight (kg) between groups:</p> <p>Nutrition booklet only: -1.0</p> <p>Individual one-to-one advice: -2.6</p> <p>Group intervention: -2.8</p> <p>Change in WC (cm) 0-6 months NS between groups?</p> <p>Nutrition booklet only: -4.6 (1.5)</p> <p>Individual one-to-one advice: -4.8 (1.1)</p> <p>Group intervention: -4.6 (1.5)</p> <p>PA changes reported, but not dietary measures.</p> <p><b>Limitations</b></p> <p>High rate of drop out especially in nutrition booklet only group</p> <p>Self-reporting of PA levels</p> <p><b>Recommendations</b></p> <p>Inclusion of self-efficacy advice prolongs intervention effect.</p> <p>Group intervention more cost-effective than individual dietetic sessions</p>	<p>Ash et al. (2006)</p>

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
6. <b>n=101</b> 23% men, 77% women <b>Inclusion criteria</b> Convenience sampling Indigenous Australians >20 years of age IFG, DM or BMI > 25	Prospective cohort, efficacy study <b>Study length:</b> 6 months	Urban setting Queensland, Australia	<b>Facilitators</b> Health workers Indigenous elders  <b>Group-based intervention:</b> Community based education programme Three groups (# per group NR) Session details NR	<b>Session content</b> Main emphasis on self-monitoring using glucometers and pedometers (Further details NR)	21% LTFU <b>Attendance:</b> NR <b>At 6 months. Change in:</b> BMI: -0.4 (-0.80 to 0.05), (p=0.090) WC: -3.1 (-0.7 to -5.4), (p=0.010) DBP: -4.6 (-1.2 to -8.0), (p=0.010) HbA1c: +0.31 (0.18-0.44), (p=<0.001) No significant change in no. of steps at six months (p=0.552)  <b>Limitations</b> No control group  <b>Recommendations:</b> Include control group in future studies to strengthen findings Future interventions should be more intensive	Chan et al. (2007)
7. <b>n=314</b> Randomisation of participants with DM to (1) group-based intervention (n=157, 50% men, 40% women) (2) control (n=157, 51% men, 49% women)  <b>Inclusion criteria</b> Adults with DM	RCT <b>Study length:</b> 14 months <b>Initial results:</b> 4 months	Primary health care facilities in UK	<b>Facilitators</b> Registered dietitian  <b>Facilitators</b> Three individual appointments: Dietitian (30 minutes), practice nurse (15 minutes) and GP (10mins)  <b>Group-based intervention:</b> Six 2-hour sessions 16 participants per group	<b>Goals</b> NR  <b>Session content:</b> <ul style="list-style-type: none"> <li>• Emphasis on self-efficacy</li> <li>• Problem solving and self-monitoring</li> <li>• Weight management</li> <li>• Portion and carbohydrate control</li> <li>• Empowerment model</li> <li>• Supermarket tour</li> <li>• Group discussion</li> </ul>	<b>Attendance:</b> 81.5% attended 4 or more group sessions At 4 months Intervention: -0.3kg Control: +0.1kg 14 months: Intervention: Significant weight loss -0.5kg (p<0.001) Significant WC reduction -4.0cm in women (p<0.001) -2cm WC reduction in men +2.4 portions fruit and vegetables per day Total sugar and sucrose significantly increased in FB TG	Deakin et al. (2006)

Sample Inclusion criteria	Design and length of study	Location of and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
			Follow up at 4 and 14 months Drop out considered if patient missed 2 sessions		<p><b>Control</b></p> <p>+1.1kg weight loss -1.0cm WC reduction in women -0cm WC reduction in men +0.2 portions fruit and vegetables per day</p> <p>Intervention group had greater yet non-significant reduction of HbA1c and total cholesterol. Knowledge, psychosocial variables and PA significantly higher than control group.</p> <p><b>Limitations</b> Volunteer bias</p> <p><b>Recommendation</b> Empowering participants plays a significant role in outcome.</p>	
<p>8. <b>n=87</b> Portuguese adult participants with DM randomly assigned to (1) Group intervention (n=41, 31% men, 69% women) (2) Control (n=46, 68% men, 32% women)</p> <p><b>Inclusion criteria</b> Portuguese-speaking adults with DM</p>	<p>RCT <b>Study length:</b> 3 months</p>	<p>Urban area, Toronto Canada</p>	<p><b>Facilitators</b> Diabetes educators (nurses and dietitians) Physiotherapist Pharmacist Psychologist</p> <p><b>Group-based intervention:</b> Three consecutive weekdays 5-8 participants per group</p> <p><b>Control</b> received individual counselling only: 3 one-to-one sessions</p>	<p>More of an educational focus than clinical focus</p> <p><b>Session content</b></p> <ul style="list-style-type: none"> <li>• Large focus on cultural factors</li> <li>• Visual teaching aids used more than written aids</li> <li>• Family members encourage to attend</li> <li>• Culturally tailored dietary advice, cooking demonstrations and recipes</li> <li>• Problem solving &amp; cognitive reframing</li> <li>• Goal setting</li> </ul>	<p><b>LTFU</b> 29% LTFU in intervention group 22% LTFU in control group Non-completers more likely to be unemployed</p> <p><b>Anthropometrical changes</b> NR Intervention participants significantly improved on psychosocial and dietary variables compared to advice only group Significant improvement in HbA1c at 3 months (p&lt;0.01) Self-reported nutrition adherence was not associated with improvement in HbA1c Theory of planned behaviour used in intervention group</p>	

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
				<p><b>Goals</b></p> <ul style="list-style-type: none"> <li>Nutrition advice with emphasis on portion control, consistency, □ Total energy and fat</li> <li>Theory of planned behaviour model</li> </ul>	<p><b>Limitations</b></p> <p>Small study sample Short-term observation time (3 months) Per-protocol used (excluded drop outs)</p> <p><b>Recommendations</b></p> <p>Programmes that delivered education that was language and culturally sensitive environment were considered highly effective in changing eating behaviour. Larger, long-term RCTs are need to prove whether group interventions are significantly more effective than one-to-one counselling</p>	Gucciardi et al. (2007)
<p>9. <b>n=342</b></p> <p>Randomisation of participants:</p> <p>(1) Group intervention: (n=172, 18% men, 82% women)</p> <p>(2) Control (n=170, 13% men, 87% women)</p> <p><b>Inclusion criteria</b></p> <p>BMI 27-40</p> <p>Adults 18-65 years</p>	<p>Multicentre RCT</p> <p><b>Study length:</b> 2 years</p> <p>Initial results at 12 months</p>	<p>Six academic research centres in USA</p>	<p><b>Facilitators</b></p> <p>Previous weight watchers graduates</p> <p><b>Group-based intervention:</b></p> <p>Commercial programme: Free vouchers to attend weekly Weight watchers meetings</p> <p>Control group: self-held with two 20-minutes individual consultations with the dietitian.</p>	<p><b>Goals</b></p> <p>NR</p> <p><b>Group session content:</b></p> <ul style="list-style-type: none"> <li>Weekly weigh-in's</li> <li>Meal plans and PA plans</li> <li>Cognitive restructuring</li> </ul>	<p><b>LTFU:</b></p> <p>Intervention: 17.5%</p> <p>Control: 19.0%</p> <p><b>Attendance:</b></p> <p>At 6 months: 21 group sessions</p> <p>Significant correlation between attendance and weight loss</p> <p><b>Group-based intervention:</b></p> <p>At 6 months. Significant change in:</p> <p>Weight: -4.8kg, (p&lt;0.001)</p> <p>BMI: -1.7kg/m<sup>2</sup> (p&lt;0.001)</p> <p>WC: -4.3cm</p> <p><b>Control:</b></p> <p>At 6 months. Change in:</p> <p>Weight: -1.4kg</p> <p>BMI: -0.5kg/m<sup>2</sup> (p&lt;0.001)</p> <p>WC: -0.7cm</p> <p>Differences in weight, BMI and WC change between groups were all significant</p>	Heshka et al. (2000).

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
					<p><b>Predictors of drop out:</b> Younger, higher BMI, lower income and smokers</p> <p><b>Limitations</b> Self selection bias Limited generalizability</p> <p><b>Recommendation</b> Intensive commercial weight loss programme was more effective than self-help approach</p>	
<p>10. <b>n=1685</b> 41% men, 59% women <b>Inclusion criteria</b> Adults &gt;25 BMI 25-45 Hypertension or dyslipidaemia</p>	<p>Phase I Multicentre non-randomized intervention <b>Study length:</b> 30 months  Initial results presented at 6 months</p>	USA	<p><b>Facilitators</b> Nutrition counsellors Behavioural counsellors  <b>Group-based Intervention</b> 20 group sessions 18-25 participants per group Sessions were participatory</p>	<p><b>Goals</b></p> <ul style="list-style-type: none"> <li>• Lose &gt;4kg over 6 months to qualify for phase II</li> <li>• Reduce total energy by 500kcal daily</li> <li>• 180 minutes of PA/week</li> <li>• DASH guidelines for fruit, vegetable, sodium and alcohol</li> </ul> <p><b>Facilitators</b></p> <ul style="list-style-type: none"> <li>• Food and PA records</li> <li>• Reduce portion sizes and follow healthy eating guidelines</li> <li>• Goal setting</li> <li>• Social cognitive theory and SOC model</li> <li>• Group-based problem-solving</li> <li>• Physical activity and food demonstrations</li> </ul>	<p>8% <b>LTFU</b></p> <p><b>Attendance</b> Mean 14/20 sessions attended 61% attended 16 or more sessions over 6 months Non-African American attended more sessions than other African Americans <b>Change in weight (kg) 0-6 months:</b> -5.8kg weight loss 69% achieved ≥4kg loss Mean PA 117 minutes per week 2.9 portions of fruit and vegetable daily</p> <p><b>Predictors of weight loss:</b> Higher baseline weight, higher attendance at group sessions, increased submission of food diaries, higher self-reported exercise.</p> <p><b>Limitations</b> No control group Self-reported PA and diet adherence</p> <p><b>Recommendations</b> Attendance and food and activity records should be standard in interventions as they promote weight loss</p>	Hollis et al. (2008)

Sample Inclusion criteria	Design and length of study	Location of and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>11. <b>n=307 men 41%, women 59%</b></p> <p>Randomisation to (1) Group intervention (n=208) (2) Control (n=99)</p> <p><b>Inclusion criteria</b></p> <p>IFG or 1 risk factor for DM</p> <p>Adults &gt; 55 years old or &gt;45 years and obese or &gt; 35 years with high risk for DM</p>	<p>RCT</p> <p>Study length: 6 months</p>	<p>2 Urban areas and one rural area in Victoria, Australia</p>	<p><b>Facilitators</b></p> <p>Trained facilitators</p> <p><b>Group-based intervention:</b></p> <p>Lifestyle intervention</p> <p>Size of groups NR</p> <p>Six sessions over 6 months</p> <p><b>Control group:</b></p> <p>Received standard medical care</p>	<p><b>Goals</b></p> <p>Not specified</p> <p>Improve psychosocial, diet and PA</p> <p><b>Components</b></p> <ul style="list-style-type: none"> <li>SOC model, self-efficacy scale and knowledge scale used for assessment</li> <li>Advice on diet, exercise, goal setting and behaviour change</li> </ul> <p><b>Control group:</b> Received standard medical care through GPs(Additional details not reported)</p>	<p>12% LTFU in intervention group</p> <p>8% LTFU in control group</p> <p>Reasons for declining intervention: time, location and depression</p> <p><b>Attendance</b> rate NR</p> <p>Significant weight difference at 6 months (P&lt;0.001):</p> <p>Intervention: -2.6kg</p> <p>Control: -0.8</p> <p>Between group results were significant for weight difference, WC difference, FBG, lipids, BP, knowledge, motivation, mood, diet and PA levels.</p> <p>No improvement nor deterioration in control group</p> <p>Participants who declined intervention had higher weights and WC</p> <p><b>Limitations</b></p> <p>Short-term study period unable to assess long-term success</p> <p>Selection bias</p> <p><b>Recommendations</b></p> <p>Educational and supportive group programmes should be used more often as they improve weight loss and clinical outcome compared to standard GP care</p> <p>Further studies required to address non-participation in interventions</p>	<p>Moore et al. (2011)</p>

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>12. <b>n=170</b></p> <p>Randomly assigned to:</p> <p>(1) Group intervention (n=87, 36% men, 64% women)</p> <p>(2) individual education (n=83, 32% men, 68% women )</p> <p><b>Inclusion criteria</b></p> <p>Have DM</p> <p>Aged 30-80 years</p>	<p>RCT</p> <p><b>Study length:</b></p> <p>6 months</p>	<p>USA</p>	<p><b>Facilitators</b></p> <p>Registered dietitian</p> <p>Diabetes specialist nurse</p> <p><b>Group-based intervention:</b></p> <p>Four sessions over 6 months</p> <p>Four to eight participants per group</p> <p>Control group and intervention group received equal number of sessions</p>	<p><b>Goals</b></p> <p>Personal, individualised goals for PA and diet</p> <p><b>Session content</b></p> <ul style="list-style-type: none"> <li>Based on a National DM programme and sequential curriculum</li> <li>Group dynamics</li> <li>Carbohydrate counting</li> <li>Portion control</li> <li>Self-monitoring and problem solving</li> <li>Healthy eating</li> <li>Models used for programme design: Adult Learning Model, Public Health Nursing Model, Health Belief Model, Transtheoretical Model</li> <li>Food and glucose diaries</li> </ul> <p><b>Control group:</b></p> <p>Individual education with dietitian and specialist nurse (details not specified)</p>	<p>50% <b>LTFU</b> in intervention at 6 months</p> <p>41% LTFU in control at 6 months</p> <p><b>Attendance</b> declined over time. 54% attended all 6 sessions</p> <p>Further investigation revealed participants who dropped out cited work and family commitments, or did not require further intervention.</p> <p>No significant weight differences at 6 months between groups (p=0.16)</p> <p>Group: -2.6kg</p> <p>Individual: -4.7kg</p> <p>No significant differences between groups</p> <p>Significant improvements weight and psychosocial variables within groups (not between groups).</p> <p>No dietary measures included</p> <p><b>Limitations</b></p> <p>Homogenous population</p> <p>High drop out rate</p> <p>Short-term follow up</p> <p><b>Recommendations</b></p> <p>Either individual or group interventions delivered in 4 structured sessions can be used to effectively improve weight and psychosocial outcomes in participants with DM</p> <p>Group sizes should not exceed 8 per group</p> <p>Reason for drop out should be assessed</p>	<p>Rickheim et al. (2002)</p>

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>13. <b>n=101</b></p> <p>12% men, 88% women</p> <p><b>Inclusion criteria</b></p> <p>Convenience sampling</p> <p>Adults &gt; 18 years old</p> <p>BMI &gt; 25kg/m<sup>2</sup></p> <p>One or more risk factor for DM/CVD</p>	<p>Longitudinal pre-test and post-test study</p> <p><b>Study length:</b> 4 months</p> <p>Limited details on follow up reviews</p>	<p>Rural setting Montana, USA</p>	<p><b>Facilitators</b></p> <p>Dietitian</p> <p>Certified Diabetes counsellor</p> <p>Psychologist</p> <p><b>Group-based intervention:</b></p> <p>6 weekly sessions (60 minutes)</p> <p>6 maintenance sessions (one sessions every 6 months)</p> <p>Maintenance phase NR</p> <p>25-35 participants per group</p>	<p><b>Goals:</b></p> <p>7% weight loss during core programme</p> <p>Reach ≥ 150 minutes PA/week</p> <p><b>Session content</b></p> <p>Reduce total energy and fat</p> <ul style="list-style-type: none"> <li>• Reduce Nutrient-density</li> <li>• Reduce Physical activity</li> <li>• Problem solving and stress management</li> <li>• Goal setting</li> <li>• Supervised PA twice a week</li> <li>• Food and PA diaries</li> </ul>	<p>17% <b>LTFU</b> at 16 weeks</p> <p>Mean <b>attendance:</b> 14.4 ± 1.6 out of 16 sessions</p> <p>65% of participants reached ≥ 150 min PA/week</p> <p>73% lost &gt;5% body weight</p> <p>52% lost &gt;7% body weight</p> <p>Mean difference: - 7.5±4.1kg</p> <p>Changes in dietary intake not reported</p> <p>No biochemical measurements taken at 4 months</p> <p><b>Limitation:</b></p> <p>No control group</p> <p>Self-reported diet and PA assessments</p> <p><b>Recommendations:</b></p> <p>Programme viewed feasible and effective</p>	<p>Vadheim et al. (2010)</p>
<p>14. <b>n=147</b></p> <p><b>Participants with DM randomly assigned to:</b></p> <p><b>(1) intervention group (n=75, 20% men, 80% women)</b></p> <p><b>(2) usual care (n=72, 28% men, 72% women)</b></p> <p><b>Inclusion criteria</b></p> <p>Adults &gt; 35 years</p>	<p>RCT</p> <p><b>Study length:</b> 6 months</p>	<p>Community hospitals, Eastern Thailand</p>	<p><b>Facilitators</b></p> <p>Nurse</p> <p><b>Group-based intervention:</b></p> <p>One 2hr education session</p> <p>Four group discussion session</p> <p>Plus two additional individual sessions</p>	<p><b>Goals</b></p> <p>Improve HbA1c, CHD risk score and QOL (Specific details not reported)</p> <p><b>Session content</b></p> <ul style="list-style-type: none"> <li>• Emphasis on self-management; goal setting, self-monitoring and problem-solving</li> <li>• Meals planning</li> <li>• PA</li> <li>• Medication adherence</li> <li>• Stress reduction</li> </ul>	<p>6% <b>LTFU</b> at 6 months</p> <p>Weight difference over 6 months NR</p> <p>Significant improvements in HbA1c, CHD risk score (reduced lipids, BP and QOL in intervention group)</p> <p>Dietary measures not reported</p> <p><b>Limitation</b></p> <p>Lack of generalizability</p> <p>Small sample size</p> <p><b>Recommendations</b></p> <p>Interventions that encourage self-efficacy are associated with reduced HbA1c and CHD risk and should be part of regular care</p>	<p>Wattana et al. (2006)</p>

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>15. <b>n=147</b></p> <p><b>Randomisation of participants to one standard care group (n=71, 38% men, 68% women), and treatment group (n=73, 42% men, 58% women)</b></p> <p><b>Inclusion criteria</b></p> <p>BMI &gt; 27 with DM</p> <p>Adults &gt; 20 years</p>	<p>RCT</p> <p><b>Study length:</b></p> <p>12 months</p> <p>Some results presented at 6 months</p>	<p>Virginia, USA</p>	<p><b>Facilitators</b></p> <p>Registered Dietitian</p> <p><b>Group-based intervention:</b></p> <p>Twelve-month lifestyle intervention</p> <p>6 small group sessions</p> <p>6 individual sessions</p> <p>Telephonic follow up</p> <p>Measurement follow up 4, 6, 8, 12 months</p> <p><b>Control group:</b></p> <p>Received education material only</p>	<p><b>Standard care</b></p> <p>Counselling on weight loss</p> <p>Information pamphlets</p> <p><b>Intervention goals</b></p> <ul style="list-style-type: none"> <li>• 5% weight loss, and WC reduction</li> <li>• Reduction in HbA1c, lipids, medication</li> <li>• Improved quality of life</li> </ul> <p><b>Session content</b></p> <ul style="list-style-type: none"> <li>• Goal setting</li> <li>• Other goals based on ADA guidelines for weight management and DM (Details NR reported in article)</li> <li>• Further details not reported</li> </ul>	<p>16% <b>LTFU</b> at 6 months</p> <p><b>Attendance</b> at group sessions: 78% attended 4 or more sessions</p> <p>Change in weight (kg) at 4 months (actual weights NR)</p> <p>Difference between groups (p&lt;0.001)</p> <p>Change in weight (kg) at 6 months (actual weights NR)</p> <p>Difference between groups (p&lt;0.001)</p> <p>Change in weight (kg) at 8 months</p> <p>Difference between groups -5.0kg (95% CI -7.2;-2.9) (p&lt;0.001)</p> <p>Change in weight (kg) at 12 months:</p> <p>Intervention: 20% achieved ≥5% weight loss</p> <p>-2.4kg (95% CI -4.1;-0.6),</p> <p>WC: -5.5cm (95% CI -7.4;-3.6),</p> <p><b>Usual care</b></p> <p>14% achieved ≥5% weight loss</p> <p>+0.6kg (-1.0;+2.2)</p> <p>WC: -1.4cm (95% CI -3.1;+0.4),</p> <p>Reduced reliance on medication by intervention group and had improved quality of life</p> <p>Attendance not associated with outcomes</p> <p>HbA1c and lipids not significantly difference at 12 months</p> <p>Dietary changes not reported</p> <p><b>Limitations</b></p> <p>Weight loss more difficult in DM participants and reduced effect size. Lack of generalizability for use in other populations. Poor implementation of physical activity intervention.</p> <p><b>Recommendation:</b> Dietitian-run intervention programme for weight loss is cost-effective, feasible and moderately effective. Frequent contact with RD improved outcomes in initial 8 months.</p>	<p>Wolf et al. (2004)</p>

Sample Inclusion criteria	Design and length of study	Location and setting	Intervention facilitators and group description	Key components of interventions	Results	Reference
<p>16. n=2833 (40% men, 60% women)</p> <p><b>Inclusion criteria</b> Adults with DM</p>	<p>Systematic review and meta-analysis of 21 RCTs published between 2003 - 2008</p>	<p>Developed countries</p>	<p>Compares group-based self-management education versus standard or usual care or no intervention</p>	<ul style="list-style-type: none"> <li>Goals</li> <li>Clinical</li> <li>Lifestyle</li> <li>Psychosocial</li> <li>Anthropometric</li> </ul>	<p><b>LFTU:</b> Studies included if they had &lt; 10% drop out</p> <p>For 3 heterogeneous studies (n=433), intervention group lost 2.08kg (NS)</p> <p>For 7 studies (n=1159), BMI at 6 months (-0.21kg/m<sup>2</sup>) (NS)</p> <p>Group interventions resulted in significant improvements in glycaemic control, knowledge and self-efficacy.</p> <p>Large association between number of hours/sessions of education and outcome.</p> <p>Trend towards multi-disciplinary team and improved outcomes</p> <p>HbA1c improved most significantly when dietitian was single educator</p> <p><b>Limitations</b></p> <p>All studies conducted in developed countries in participants with DM therefore lack usability in developing countries and other NCDs</p>	<p>Steinsbekk et al. (2012)</p>
<p>17. n=1428 (39% men, 61% women)</p> <p><b>Inclusion criteria</b> Adults with NCDs and/or risk factors for NCDs</p>	<p>Systematic review and meta-analysis of 8 RCTs published between 1997 – 2010 of up to 12-month duration</p>		<p>Group-based multi-component interventions</p>	<p>Dietary interventions</p> <p>Supervised or structured physical activity programmes</p> <p>Behavioural strategies: goal setting, self-monitoring and stress management</p>	<p>Mean weight loss stratified over intervention duration:</p> <p>3-4 months: range -2.0-4.0kg</p> <p>5-6 months: 1.3 – 8.2kg</p> <p>Group interventions resulted in modest weight loss (significance differences between group and controls not reported)</p> <p>Large association between number of hours/sessions of education and outcome.</p> <p>Peer support considered as an important component</p> <p><b>Limitations</b></p> <p>Detailed data was missing on in some studies</p> <p>Most studies conducted in United States</p> <p>Cost-effectiveness was not calculated</p>	<p>Gallagher et al., (2013)</p>

*Abbreviations:* RCT: randomised control trial; DPS: Diabetes Prevention Study; DPP: Diabetes Prevention Programme; NR: Not reported; NS: Not significant; LTFU: Lost to follow up; BMI: Body Mass Index; WC: Waist circumference; PA: Physical activity.

<sup>a</sup>DPS reference group: Tuomilehto, J., Lindström, J., Eriksson, J. G., Valle, T. T., Hämäläinen, H., Ilanne-Parikka, P., Keinänen-Kiukaanniemi, S., et al., (2001) Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *New England Journal of Medicine*, 344(18), 1343-1350.

## **2.6 Global, national and provincial strategies for secondary and tertiary NCD prevention**

Secondary prevention aims to reduce the extent of NCD disability, morbidity and mortality attributed to poor management of NCDs (de-Graft Aikins et al., 2010; Marchand et al., 2011), while tertiary interventions targets populations with the disease with the aim to delay NCD-related complications (Marchand et al., 2011). Since NCDs and their risk factors are already present in epidemic proportions in many countries, secondary and tertiary prevention are urgent and should be prioritised on global, national and local levels. A lack of secondary interventions denies the right of patients with NCDs and risk factors to sufficient knowledge, and ultimately reduces their own ability to manage their condition (de-Graft Aikins et al., 2010). The following sections outline both proposed and established global, national and provincial strategies for secondary and tertiary prevention of NCDs.

### ***The global strategy***

Maher et al., (2009) proposed that the global response to the NCD epidemic should be viewed as “cost of action” versus the “cost of inaction”. ‘Inaction’ is likely to result in large losses of human productivity and life (Wagner & Brath, 2012). Fortunately, global interest in NCD prevention is gaining momentum, and the Millennium Development Goals (MDGs) and WHO guidelines have been established for primary, secondary and tertiary prevention of NCDs. For example, one MDG is to reduce premature deaths attributed to DM, CVD, cancer, stroke and lung diseases by 2% per year (Beaglehole et al 2011; Maher et al., 2009). The WHO 2008-2013 and 2013-2020 action plans serve as a guide for global and national policy-makers outlining specific strategies for prevention and management of NCDs (WHO; 2013; WHO, 2009). The WHO global strategy has three main objectives for the priority planning for NCDs: 1) to improve surveillance of NCDs and their risk factors throughout the socio-ecological model, 2) to reduce exposures to determinants on a population and individual level, and 3) to improve prevention strategies for individuals suffering from NCDs (WHO, 2009).

### ***National strategy***

Despite the large amounts of epidemiological research on the burden of NCDs in South Africa, research and interventions for secondary prevention such as lifestyle programmes have been minimal (Mayosi et al., 2009). Furthermore, South Africa cannot rely on limited evidence-based research from other developing countries or studies undertaken in high-

income countries since their socio-economic and environmental causes of NCDs may be different (Heneghan et al., 2013).

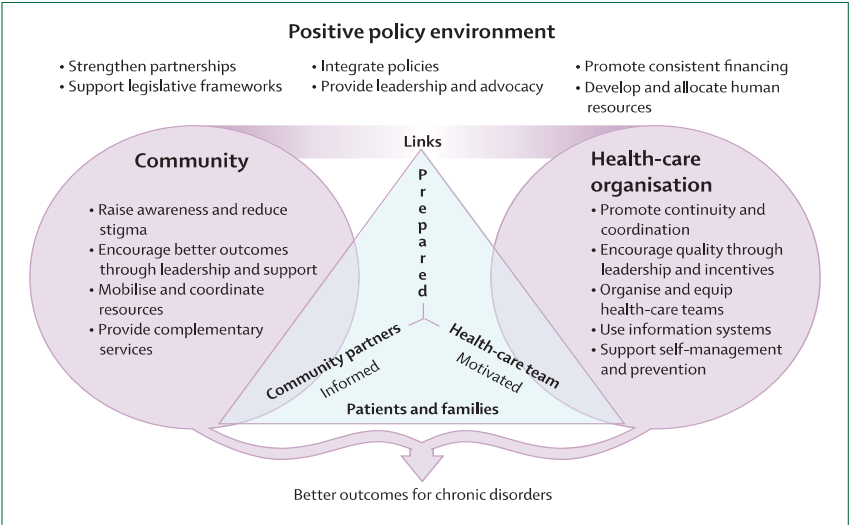
Beaglehole et al. (2011) proposed that the following is essential for national level planning of NCD management: commitment from national government to mobilise resources and set national targets for NCD prevention; prevention strategies for modifiable risk factors should be rolled out on all socio-ecological levels and stages of lifecourse; treatment for NCDs and their risk factors should be enhanced in the health sector; global collaboration and funding for NCD programmes should be provided to low income countries. Lastly, surveillance, monitoring and feedback should become instilled within the national action plan in order to evaluate the effectiveness of the national strategies and monitor disease burden (Beaglehole et al., 2011).

South Africa's response to NCDs appears to be in the developmental stages and there is some evidence of national planning (Singh, 2011; Mayosi et al., 2009) as outlined by Beaglehole et al., (2011). Mayosi et al., (2012) reported that a national plan for NCD management in the health sector is underway, and governmental commitment to both new and existing policies has been strengthened with the objective to concurrently reduce inequalities of the South African health system. This is evident from the declaration on the Prevention and Control of NCDs, that was defined at the United Nations summit on NCDs in 2011 (Mayosi et al., 2012), as well as a DOH framework that focuses on inter-sectorial action for interventions for modifiable risk factors of NCDs, namely excessive alcohol, smoking, unhealthy diet and physical inactivity (Singh, 2011). Both the declaration and DOH framework are aligned with the WHO 2008-2013 action plan that promotes national advocacy and policy changes for agriculture, trade, taxation and food production sectors, as well as collaboration with social development and environmental departments (WHO, 2009). The recent SANHANES report has significantly contributed to NCD burden surveillance (Shisana et al., 2013), while national targets for NCD reduction have been developed (Box 1).

- Reduce premature mortality from NCDs by 25%
- Reduce prevalence of obesity and overweight by 10%
- Reduce prevalence of hypertension by 20% through lifestyle modification
- Reduce smoking by 20%
- Reduce per head consumption of alcohol by 20%
- Reduce mean salt intake to less than 5g/day
- Increase prevalence of physical activity by 10%

**Box 1: 2020 South African targets for prevention and control of NCDs (Mayosi et al., 2012)**

It has been suggested by Levitt et al. (2011) that governmental health care services that manage large numbers of patients with NCDs, should be aligned with the WHO Chronic Care Model (Levitt et al., 2011) (Figure 2). This model recommends that chronic care be based on positive policy development, that is required to drive healthcare objectives and link government ministries with communities.

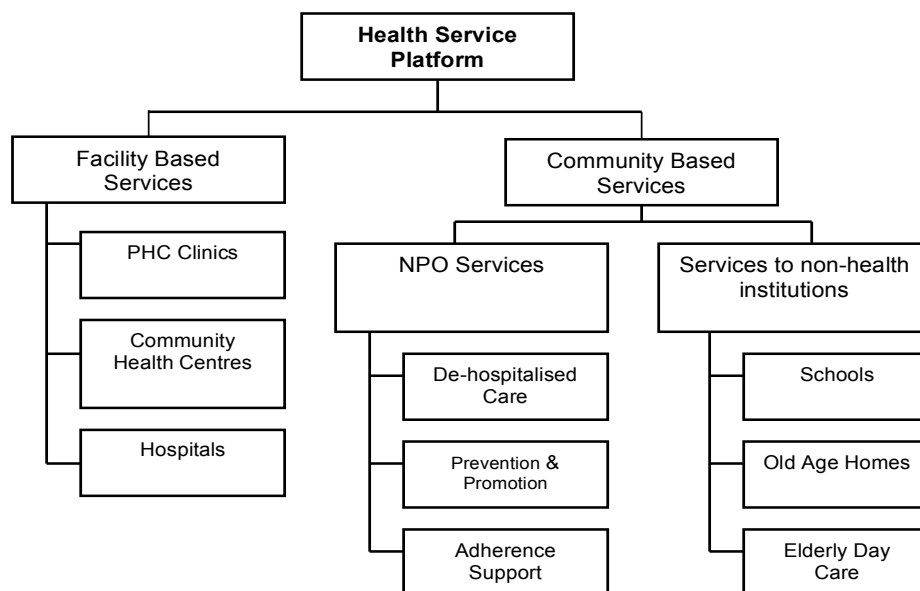


**Figure 2: WHO Innovative care for chronic diseases framework (Beaglehole et al., 2008)**

PHC is predicted to play the strongest role in the management of the NCDs (Levitt et al., 2011; WHO, 2010; Mayosi et al., 2009). This is because PHC is considered as the primary place where patients seek medical care for NCDs (Parker et al., 2012; Levitt et al., 2011). Therefore, improvement in NCD management and continuity of care will require regular screening practices, strong hospital referral systems, NCD surveillance registers, behavioural programmes targeting lifestyle, improved medication dispensing, and possibly the use of HIV/AIDs adherence counsellors to support patients with NCDs (Levitt et al., 2011).

Levitt et al., (2011) suggested that the South African government should approach the NCD policy development and interventions with similar vigour to that of the HIV/AIDS intervention. Primarily, a similar political response is needed to ensure adequate funding for the roll out of NCD interventions for human resources, chronic medications, and screening and diagnostic tools (Levitt et al., 2011; Maher et al., 2009). Since both NCDs and HIV/AIDS are chronic in nature, it has been proposed that resources be shared within South Africa's health system since there are similarities in their objectives such as increasing adherence to medication, positive lifestyle choices, and continuity of care (Levitt et al., 2011).

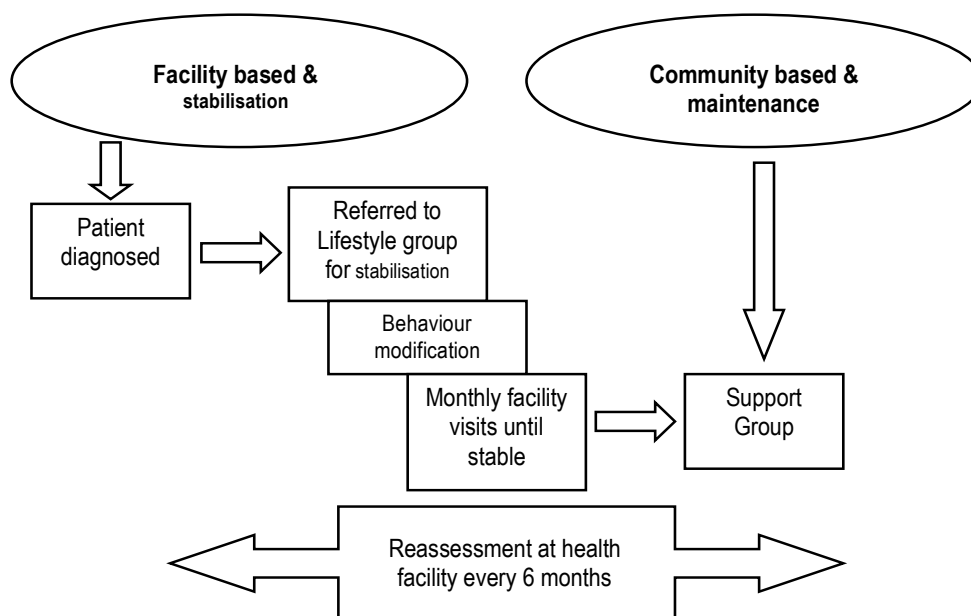
In the Western Cape, a provincial task team developed a chronic disease management framework and policy for NCDs that outlines health service priorities and guidelines for implementation of interventions (DOH, 2009). It was proposed within the framework that collaboration between health care facilities and the community would be necessary to upscale NCD care (DOH, 2009). Figure 3 shows the layout of the Western Cape health service platform and illustrates how the delivery of NCD care would need to expand across healthcare facilities and communities. In 2009, Western Cape Provincial DOH listed 42 community health centres, 240 fixed clinics and 162 mobile clinics as providers for services for NCDs.



**Figure 3: Western Cape Health Service platform**

This policy also included a Chronic Disease Management model (Figure 4) that illustrates how a group-based lifestyle programme for NCDs could be implemented at facility and

community level (DOH, 2009). The health facilities would be responsible for providing a therapeutic education programme targeting behaviour and modifiable risk factors for NCDs, whereas community services would ensure continuity of care, monitoring and support of patients. Furthermore, the model is aligned with the WHO's Chronic Care model (Figure 3) proposed by both Levitt et al., (2011) and Beaglehole et al., (2008). The therapeutic education programme would involve a six-week facility-based therapeutic group (FBTG) programme facilitated by an interdisciplinary team including medical doctors, clinical nurses, pharmacists, dietitians, physiotherapists and health promoters that could provide risk assessments, screening and health education. Specific education tools and resources were also developed, for example, a Chronic Disease Management flip chart for behavioural counselling and stationary for documentation of patient progress (DOH, 2009).



**Figure 4: Chronic Disease Management Model (DOH 2009)**

The implementation of the model has been found to be challenging as a result of lack of investment in NCDs within the health sector and lack of “responsible and dedicated” staff members at health care facilities needed to implement and monitor the policy and FBTGs (Personal communication, Mrs Unita Van Vuuren: Deputy Director for Chronic Disease Management in the Western Cape). A recent publication on Health Promotion activities for NCDs in 30 Western Cape PHC facilities highlighted a variety of challenges, such as lack of screening equipment such as scales, stadiometers, measuring tapes, glucometers and glucose strips, and large BP cuffs as well as inappropriate methods of health promotion (Parker et al., 2012).

## **2.7 NCD interventions in South Africa**

### **2.7.1 Overview**

As mentioned in section 2.6 under *National strategy*, studies measuring the feasibility and effectiveness of lifestyle programmes are lacking in South Africa. In a Cochrane review on global NCD-related research activities, Heneghan et al. (2013) showed that the majority of literature on NCD interventions has been conducted in high income countries. While South Africa is faring considerably better than the rest of the African continent, it is still significantly less than what has been achieved in developed countries (Heneghan et al., 2013). This is paradoxical, since it has been reported that the burden of NCDs is likely to be two to three times higher in developing countries (Mayosi et al., 2009). Table 8 outlines population-, community- and individual-level interventions that have targeted NCDs or risk factors for NCDs in South Africa. Since population level interventions have been discussed under section 2.3 and 2.6, further detail on community and individual-level interventions by Price et al., (2007), Puoane et al., (2007), Van Zyl & Rheeder (2004), Mash et al., (2012), and SISSA (2013) are presented in the section that follows.

**Table 7: Interventions for NCDs in South Africa**

<b>Risk factor</b>	<b>Population-scale interventions</b>	<b>Community and small-scale intervention</b>
Physical activity	HealthKick (WC schools), Moving matters (GP, EC schools) <sup>a</sup>	CHIPs (SISSA) <sup>b</sup> , Siyadladla (WC communities) <sup>a</sup> Draper et al., (2010): Intervention in Urban settlement
Unhealthy eating	Legislation for salt and trans fatty acids <sup>a</sup> Food labeling <sup>a, c</sup>	HealthKick (WC schools) <sup>a</sup>
Smoking	Legislation: 'smoke-free zones' <sup>a, c</sup> Taxation <sup>a, c, d</sup>	Physical & nurse counseling <sup>d</sup>
Alcohol	Legislation: marketing, advertising & retail <sup>c, d</sup>	
Obesity	Food labelling <sup>a</sup>	
Diabetes		Mash et al., (2012): Intervention in Cape Town (results pending) Price et al., (2007): Health programme in rural setting in KZN Van Zyl & Rheeder (2004): physician led-programme
CVD & HPT	Policies for salt, trans fatty acids and smoking <sup>a</sup> Food labeling <sup>a</sup>	
NCDs (general)	Policies for salt, trans fatty acids and smoking <sup>a</sup> Food labeling <sup>a</sup>	Puoane et al., (2007): CHWs and community

Abbreviations: WC: Western Cape, GP: Gauteng Province, EC: Eastern Cape, SISSA:., Sports Science Institute of South Africa, CHWs: Community Health Workers

<sup>a</sup>Puoane et al., (2012); <sup>b</sup>SISSA: <http://www.ssis.com/pages/social-investment/chips/>; <sup>c</sup>Mayosi et al., (2012);

<sup>d</sup>Cecchini et al., (2010).

### 2.7.2 Perspectives on small-scale interventions for NCDs in South Africa

Price et al., (2007) explored and described the feasibility of a patient-centred programme for black African patients with diabetes in rural Kwazulu-Natal. The focus of the intervention was to improve self-efficacy and describe barriers to self-management in 1000 individuals who were exposed to the lifestyle intervention. Anthropometric, biochemical and lifestyle measures were not reported. The programme was voluntary and facilitated by a local registered nurse. The overall results showed that self-efficacy could be enhanced if there was collaborative engagement with community members and positive, culturally sensitive programme components were provided (Price et al., 2007).

Puoane et al., (2007) described a community-based intervention facilitated by trained lay health promoters in Khayelitsha in the Western Cape. The intervention assessed the effectiveness of a health club, *Masiphakame Ngempilo Yethu!* (Let's stand up for our health!) in 25 intervention participants and compared dietary intake (frequency of fruit, vegetables and red meat, and cooking methods) and physical activity (minutes per day) with 29 control patients. The health club included weekly sessions on weight loss, diet and activity over a six-month period. The study found modest increases in the knowledge of NCDs and risk factors as well as a modest difference in food preparation techniques. However, there were no significant differences in anthropometric measures, physical activity, and the consumption of fruit and vegetables between groups. This finding was attributed to prevailing socio-economic and environmental factors that possibly limited individual change (Puoane et al., 2007).

The physician-led programme by Van Zyl and Rheeder (2004) used a quasi-experimental design to compare two public health tertiary care facilities providing care for patients with DM. The intervention clinic (n=141) applied SEMDSA principles and guidelines in a structured approach that provided individual consultations from medical doctors and nurses that focused on general medical care for DM. In addition, each patient was referred to a dietitian for dietary assessment and advice. The control clinic (n=159) continued with usual care practices where decisions on tests and follow up appointments were made independently (non-structured approach). This approach did not include additional specialist appointments for foot care, nutrition and pharmaceutical adherence counselling. The results showed that the structured approach and increase in patient contacts improved HbA1c and general quality of care provided to these patients. However, there was no statistical difference in HbA1c levels between groups. The study highlighted that the four to five annual visits were insufficient to provide optimal care and well below the eight to fifteen visits

provided in United States clinics (Van Zyl & Rheeder, 2004). The study by Van Zyl and Rheeder et al., (2004) attributed their findings to providing structured sessions and increased quality of care, which is currently not provided in usual care.

The study by Mash et al. (2012) is of interest since it may provide evidence for group-based interventions in PHC and is aligned with the objective of our research. The results of the intervention are not available at this point in time, however the authors have outlined their protocol and objectives. The group-based intervention is targeted at individuals with DM (n=720) who will receive four group sessions by a health promoter in community health centres, and will be compared to usual care (n=850). Usual care was described as patients who received 'ad hoc' health talks and possible individual counselling from health care professionals at their health facility. The study will measure changes in anthropometry (weight loss and waist circumference), biochemistry (HbA1c and total cholesterol), blood pressure, quality of life and behavioural variables such as self-management and locus of control. The authors have also indicated that should the group-based approach be proven to be effective in improving patient outcomes, it should be implemented throughout the Western Cape (Mash et al., 2012). It would be of utmost importance to review the challenges and limitations of this study in order to prepare future interventions.

CHIPs is another intervention supporting primary and secondary prevention of NCDs in lower income areas in Cape Town (SSISA, 2013). It is supported and maintained by the Sports Science Institute of South Africa (SSISA) with the aim to increase physical activity and provide general education on maintaining a healthy lifestyle. An evaluation of the CHIPs programme is not available (SSISA, 2013). A study by Draper et al. (2010) conducted a qualitative study on the impact of physical activity intervention (based on CHIPs) in both school learners and adults in a low income community in rural Limpopo. The study found that the adult participant's knowledge and empowerment increased with the intervention, and could be implemented in other areas in South Africa (Draper et al., 2010).

Even though lifestyle interventions in South Africa are limited, the studies outlined above do provide some perspective. Price et al. (2007) reported that there were numerous barriers to self-care, including poor perception of health, low levels of confidence, poor access to transport, and lack of culturally sensitive education material for DM (Price et al., 2007) that ultimately reduced the potential for behaviour change. Other issues included negative perceptions of western medicine, poor literacy and low income (Price et al., 2007). Puoane et al., (2007) attributed the low rates of behaviour change experienced among their study

participants to the prevailing environmental and socio-economic factors that reduce an individual's ability to make changes to their lifestyle. The situational analysis of the community itself showed environmental factors namely poverty, lack of knowledge, and access to cigarettes, alcohol and unhealthy foods, were the main contributors to the risk factors for NCDs (Puoane et al., 2007). Draper et al., (2010) expressed similar sentiments and explained that social problems, family commitments and transport difficulties affected participation rates in their physical activity intervention (Draper et al., 2010). However, the investigators affirmed that community involvement was instrumental in conducting the physical activity intervention in low-income settings. Van Zyl and Rheeder (2004) highlighted the importance of structured and more regular sessions that are more likely to sufficiently address all patients' needs, and are superior to usual care. Therefore, it would be important to identify and address the above-mentioned challenges since these appear to reduce personal behaviour change and reduce the effectiveness of intervention.

### **2.7.3 NCD interventions in South Africa: the way forward**

FBTGs proposed by the Western Cape DOH may be an approach that requires further exploration. Group-based interventions may be more cost-effective and resource sparing, and can address socio-ecological challenges within a group setting, however barriers to behaviour change and environmental factors could hinder these efforts. Nevertheless, three systematic reviews have reported that FB TGs can improve a variety of outcomes compared to individual interventions (Gallagher et al., 2013; Steinsbekk et al., 2012; Paul-Ebhohimhen & Avenell 2009). In addition, group-based interventions provide intra-support systems, a sense of belonging and increase inner motivation that could propel behaviour change (Hoddinott et al., 2010; Van der Ven 2003). The group-based setting has also been promoted for individuals with mental illnesses such as depression and anxiety, which are fairly common in participants living with chronic conditions (Van der Ven, 2003).

It would be important for South Africa's interventionists to investigate both the efficacy and effectiveness of group-based lifestyle interventions in order to adequately guide NCD policy. This is because efficacy studies or randomised controlled trials aim to prove that an intervention or treatment is superior or equal to other interventions and are usually based on a specific group of individuals with specific characteristics, in a controlled environment (Streiner & Norman, 2009). On the other hand, effectiveness studies may be more appropriate since they aim to describe whether or not the intervention or treatment was successfully applied within reality (Streiner & Norman, 2009). These studies include so-

called 'real world' patients and the results are considered 'more generalisable' since the intervention was applied within a typical environment and can provide evidence for the feasibility (Marchand et al., 2011). Perhaps effectiveness studies are more important in South African at this stage since they take into account the broader challenges and diversity of populations. Even though efficacy seeks to add validity to the intervention results, effectiveness studies would be able to provide suggestions for public health dissemination (Glasgow et al., 2003). An future intervention could be conducted in a variety of race groups, and set within the constraints of the public health services.

In summary, there is a lack of both local, and international research on lifestyle programmes for NCDs in developing countries, who ironically are experiencing high disease burdens from NCDs. While population-level interventions are evident and being strengthened in South Africa (Puoane et al., 2012), evidence of structured lifestyle programmes in PHC centres for individuals and community members need investigation. This is because many South Africans may be motivated to lose weight and/or could potentially self-manage their disease yet require support and therapeutic education. Therefore, both population-level and individual-level interventions should be implemented in South Africa simultaneously, while the research focus should move towards interventions that target the individual and communities.

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## **Chapter 3**

### **ARTICLE 1**

#### **NONCOMMUNICABLE DISEASE RISK FACTORS AND TREATMENT PREFERENCE IN OBESE PATIENTS SEEKING LIFESTYLE TREATMENT AT A DISTRICT HOSPITAL IN THE CAPE METROPOLE**

## INTRODUCTION

Non-communicable diseases (NCDs) such as type 2 diabetes mellitus (DM) and cardiovascular disease (CVD) are among the leading causes of premature morbidity and mortality in South Africa (Mayosi et al., 2009). In the Western Cape, CVD and DM are included in the top 10 causes of premature death, while CVD, DM, respiratory illness and cancer collectively contribute to the majority of deaths in the population over 40 years of age (Groenewald et al., 2012).

The causes of NCDs are multifactorial and arise from any combination of underlying, modifiable, non-modifiable and intermediate risk factors. Underlying socio-economic, cultural, political, and environmental determinants including population aging, globalisation, urbanisation and the accompanied nutrition transition have contributed to the increase of NCDs in many developing countries including South Africa (Van Zyl et al., 2012; Abrahams et al., 2011; Stern et al., 2010; Mayosi et al., 2009; Puoane et al., 2008). Furthermore, the presence of NCDs and multiple risk factors have been found to be higher in population groups with low income and low educational attainment in both low-middle income (Hosseinpoor et al., 2012; Rosengren et al., 2009) and high-income countries (Margolis, 2013; Shankar et al., 2010). It has also been reported that individuals living in urban environments such as informal settlements in Cape Town (Peer et al., 2013; Puoane et al., 2006) as well as urban areas in North-West province (Schutte et al., 2012), Soweto (Tibazarwa et al., 2009) and Free State (Van Zyl et al., 2012) have a high prevalence of modifiable or behavioural risk factors such as unhealthy diet, physical inactivity, smoking and excessive alcohol intake. Together with the presence of non-modifiable risk factors such as age, genetic predisposition, gender and race, intermediate risk factors such as obesity, high blood pressure, high blood glucose and cholesterol develop over time (Ezzati & Riboli 2013). The country's increasing prevalence of obesity is of particular concern since it exacerbates the other intermediate risk factors and NCDs resulting in a greater risk for disability and mortality (Whitlock et al., 2009). Of note is that the 2003 South African Demographic and Health Survey (SADHS 2003) reported that 27.4% of women and 8.8% of men were obese, while the 2012 South African National Health and Nutrition Examination Survey (SANHANES) reported that 39.2% of women and 10.6% of men were classified as obese (Shisana et al., 2013). The prevalence of overweight and obesity in the Western Cape province has been estimated as 57.1% in women and 38.4% in men (highest across all provinces) (Chopra et al, 2007).

It has been acknowledged that South Africa's political and health sector response to these escalating risks and burdens has been inadequate (Mayosi et al., 2012; Puoane et al., 2012). This may be partly due to the evolution of the country's health system to rely on a curative model for managing infectious diseases (Levitt et al., 2011). It is also evident that isolated approaches such as targeting single risk factors are considered ineffective since modifiable and intermediate risk factors tend to cluster in individuals (Shankar et al., 2010; Jiménez-García et al., 2011; Drieskens et al., 2010). In order to address the situation, primary health care (PHC) and district health services have recently undergone restructuring to improve standards of care, accommodate the growing population and manage escalating disease burden (Chopra et al., 2009). Furthermore, substantial improvements have been made in NCD surveillance (Shisana et al., 2013; Mayosi et al., 2009), medication distribution (Du Plessis 2008) and policy development (Puoane et al., 2012; DOH, 2009). However, health promotion, behavioural counselling services and continuity of care for patients with obesity and NCDs in Western Cape PHC facilities are probably insufficient to address modifiable risk factors such as unhealthy diet and physical inactivity (Parker et al., 2012). For example, a patient requiring dietary counselling and support for obesity and/or NCDs may attend a 'once-off' individual appointment with a dietitian and attend follow up appointments on an infrequent basis due to the limited number of dietetic clinics at PHC facilities. Unfortunately this scenario is unlikely to change given the current ratio of Western Cape residents to dietitians (66000 to 1), and as Goeiman et al., (2011) stated "the demand for [nutrition] services in the Western Cape continues to exceed the extent to which services can be provided by the available resources". Furthermore, it has been reported that 13 338 patients with diabetes and 23 395 with hypertension visit governmental PHC facilities every month (Parker et al., 2012), and these patients would require regular lifestyle counselling in addition to their medical treatment.

Fortunately, the Western Cape Provincial Department of Health (DOH) policy for management of NCDs supports the need for sufficient therapeutic education and has proposed the initiation of a six week, group-based intervention at governmental PHC facilities for patients with NCDs to address modifiable risk factors, behaviour change and adherence (DOH 2009). As a result, it is not clear whether patients would choose to participate in this type of intervention. Evidence from current literature in developed countries (Brown & Gould 2011; Wilson et al., 2010), Africa (de-Graft Aikins et al., 2012) and South Africa (Ibanez-Gonzalez & Norris 2013; Van der Hoeven et al., 2012) suggests that patients' preference for a specific type of treatment is largely dependent on the socio-demographics of the patient such as their age and cultural perceptions, health status, access to quality healthcare and practical difficulties.

Therefore, the aims of this paper are firstly, to present a comprehensive profile of treatment seeking obese patients with NCDs and/or NCD risk factors at a district hospital and secondly, to compare patients who chose the dietitian-led group-based programme with patients who chose to continue with individual consultations (referred to as usual care).

## **METHODS**

### **Study design**

This paper is based on the cross-sectional baseline data of a six month lifestyle intervention study with a quasi-experimental design where patients could choose to participate in either a six-week facility-based therapeutic group (FBTG) programme or continue with usual care received at a government PHC facility. Usual care is considered as the continuation of one-on-one consultations with the dietitian, attended at the patient's discretion.

### **Study population and recruitment**

The study population were obese patients attending False Bay Hospital who required management of NCDs and/or risk factors for NCDs. False Bay Hospital is a district government hospital situated in the southern sub-district of Cape Town, South Africa that provides medical care for patients without medical health insurance. However, a small minority of patients who have private medical aid is also treated at False Bay Hospital. Patients attending False Bay Hospital feed in from the following suburbs: Ocean view (predominantly mixed ancestry community), Masipumele (predominantly black African community), Fish Hoek (predominantly white community), Simons Town (predominantly mixed ancestry and white community), and Muizenberg (mixed ancestry, black African and white community). Masipumele contains both formal and informal housing, while the other residential areas consist of formal housing.

After routine appointments with the medical doctor, all eligible patients were referred to the hospital dietitian for an individual consultation and possible recruitment. Eligible patients were required to be older than 18 years and have a BMI  $\geq 30\text{kg/m}^2$ , with one or more intermediate risk factors such as raised blood pressure ( $>130/80\text{mmHg}$ ), raised HbA1c ( $>7\%$ ), raised total cholesterol ( $>4.5\text{mmol/l}$ ), and/or one or more existing NCD such as DM or heart disease. A basic understanding of the English language was also necessary as the programme was conducted in English. Patients were excluded if they were pregnant or lactating, had any form of organ failure, severe psychiatric disorder or physical restrictions. A description of the FBTG was provided during the initial recruitment consultation and eligible patients were given the option to choose entrance into the FBTG intervention or to continue with their usual care.

The sample size estimation was based on the mean weight loss of  $2.8 \pm 4.0$  kg (group-based patients) and  $1.0 \pm 2.9$  kg (control) over six months as reported in an intervention by Ash et al., (2006). At least 60 patients in each group would be required to achieve 80% power at a 5% significance level. However, if a weight difference of  $3 \text{ kg} \pm 5$  together with an 80% power and 5% significance level, as reported in a study of low income women by Samuel-Hodge et al., (2009) is considered, a sample of 44 participants would be required in each treatment group (total  $n=88$ ). Therefore, a sample size of 44 to 60 patients would be considered sufficient to detect between group differences in weight change over six months. As attrition rates in weight loss interventions have reported to be high (Moroshko et al., 2011), oversampling is warranted. Thus, during April 2010 and June 2011, 96 intervention patients and 97 usual care patients ( $n=193$ ) were entered into the study.

### **Permission and ethical considerations**

Permission to conduct the research was obtained from the Department of Health (DOH) and the medical superintendent of False Bay Hospital. Ethical approval was granted from the University of Cape Town (UCT) Faculty of Health Science Human Research Ethics committee (Ref: 18/2010). Patients were only entered into the study if they provided written consent (Addendum A) after receiving a verbal and written explanation of the study procedures and expectations.

### **Measures**

An interviewer administered questionnaire (Addendum 1), developed for the purpose of this study, as well as the hospital database CLINICOM and patients' folders were used to obtain information on socio-demographic variables, weight loss goal, disease status, medication prescriptions, biochemical measures, BP, smoking status, physical activity levels, dietary intake and stage of change. During the initial recruitment consultation the hospital dietitian interviewed the patient to complete the questionnaire and conducted the necessary anthropometric measurements.

### ***Socio-demographic assessments***

The socio-demographic characteristics collected verbally using the interviewer administered questionnaire included employment status and the number of years of formal education (successful years of schooling, diplomas and certificates). As many patients may not have completed secondary school, but may have completed other qualifications, the total number of formal years of education were calculated and reported instead of the categorisation of

education attainment into primary, secondary and tertiary levels. Information on race (mixed ancestry, black African, white and Asian), gender (male and female), date of birth, family income and residential address of patients, were transferred directly from CLINICOM to the data spread sheet. Family income was classified using the Western Cape provincial categories: H0 for R0.00 or government pension, H1 for R0.00 – R4166.66, H2 for R4166.67 – R8333.33, H3 for > R8333.34, and P for private medical aid.

All patients were also asked to define their six-month weight loss goal and usual care patients were asked to provide a reason for declining the six-week FBTG intervention, using open-ended questions.

### ***Anthropometric measurements***

Anthropometric measurements were conducted according to the World Health Organisation (WHO) guidelines (WHO, 2008) and included weight, height and waist circumference using a calibrated scale, stadiometer and non-stretchable measuring tape respectively. All measurements were recorded to the nearest 0.1kg or 0.1cm on the provincial chronic disease monitoring form in the patient's folder (Addendum 2). Weight and height were measured in light clothing and without shoes. The height of the patients was obtained by placing their heels together and their back, scapulae and buttocks in contact with the vertical plain of the stadiometer. The patient's head was set in Frankfort plane and hair/head coverings were adjusted in order to ensure accuracy. Body Mass Index (BMI) was calculated as weight in kilograms (kg) divided by height in meters squared and categorised according to the WHO classification for BMI (WHO, 2006) namely 30 – 34.9kg/m<sup>2</sup> as obese class I, 35 – 39.9 kg/m<sup>2</sup> as obese class II, and  $\geq$  40kg/m<sup>2</sup> as obese class III or morbidly obese.

Waist circumference was measured midway between the last palpable rib and the top of the hip-bone, after normal expiration using a non-stretchable tape measure (WHO, 2008). The waist circumference measurement was categorised according to the WHO classification as an increased risk for the development of metabolic syndrome and NCDs if >102cm in men and >88cm in women (WHO, 2011a).

### ***Biochemical and clinical measures***

Fasting blood samples and BP measurements were collected by nursing staff in the outpatients department. Missing values were issued for patients who did not attend their scheduled appointment for biochemical and clinical assessments. The blood samples were

analysed by the National Health Laboratory Service (NHLS) for glycated haemoglobin (HbA1c) and total cholesterol. HbA1c was only analysed for patients with Type II DM. An automated sphygmomanometer was used to measure the BP of each patient when in a seated position with the cuff above the elbow. The diagnosis of hypercholesterolaemia and high blood pressure was confirmed by the medical doctors using the International Classification of Disease codes (ICD-10) (BHF, 2007) and was recorded in the patient's folder.

### ***Disease status, medication usage and smoking***

Information on disease status as well as medication usage was recorded from the medication prescription chart in the patient's folder. The diagnosis of DM and CVD was also confirmed using the ICD-10 codes (BHF, 2007) and was recorded by the medical doctor in the patients' folder. Smoking status was obtained verbally in terms of current smoking status and the number of 'pack years'. Pack years were calculated as the number of years an individual has smoked one packet of cigarettes per day (Klug et al., 2012). For example, if a patient smoked two packets of cigarettes per day for 20 years, he/she would be classified to have 40 'pack years', or if a patient smoked half a packet a day for ten years, he/she would be classified to have five 'pack years'.

### ***Formal physical and leisure time sedentary activity assessment***

The amount of time spent on formal physical activity was recorded as a self-reported estimation of planned, moderate- to high-intensity physical activity on the interviewer questionnaire. Patients were initially asked whether or not they participated in formal physical activity. The number and duration of physical activity sessions per week from weekly or monthly accounts were used to calculate the number of minutes of physical activity per week. Patients were further categorised as inactive (no physical activity), insufficiently active (some physical activity) and sufficiently active ( $\geq 150$  minutes per week) according to the physical activity categories outlined by Joubert et al. (2007). The number of minutes per day spent watching television was recorded and used as a reflection of leisure time sedentary activity.

### ***Dietary intake assessment***

The aim of the dietary assessment was to determine the number of standard portions consumed per day from indicator food groups. For these purposes, a semi-quantified food frequency questionnaire (FFQ) (Addendum 1) consisting of 54 food items was developed

from which 10 indicator food groups were derived (Table 3.1). The food list was developed by an expert panel of registered dietitians using existing FFQ questionnaires that were used to assess dietary intake in patients with DM in Cape Town with a socio-economic status (SES) similar to our study population (Stone, 2010; Seme, 2013). The standard portion sizes included for each food item were based on the exchange lists (UCT, 2010) or the food based dietary guidelines for South Africa (DOH, 2012). The plate model was used to illustrate standard portion sizes to patients. The frequency of intake of the standard portion of each food item was recorded as the number of times the food was consumed per day, week or month. The number of standard portions consumed per day for each food item was calculated by dividing the number of times the patient consumed the standard portion by one if consumed daily, by seven if consumed weekly, and by 28 if consumed monthly. The unit of analysis thus was the number of times a standard portion size of a particular food item was consumed daily. The daily number of standard portions consumed for each food item was then used to calculate the daily number of standard portions consumed from each of the 10 indicator food groups. Patients were additionally asked how many formal meals and snacks they consumed on a daily basis.

**Table 3.1 Indicator food groups derived from 54-item FFQ questionnaire**

<b>Indicator food group</b>	<b>Items included (standard portion size)</b>
<b>Fruit and vegetables</b>	Fresh fruit (1 tennis ball size); starchy vegetables (1/2 cup); cooked vegetables (1/2 cup), salad (1 cup)
<b>High fat foods</b>	Fried potato chips (1 potato); red meat (90g portion); organ meat (90g portion); fried fish (90g portion); fried chicken (90g portion); chicken with the skin (90g portion); pies (1 unit); sausage rolls (1 unit); samosas (1 portion); vetkoek (1 vetkoek); polony (2 slices); eggs (1); cheese (30g); full cream milk (125ml); take-aways (1 meal)
<b>Fats</b>	Brick margarine (1 tsp); butter (1 tsp); lite margarine (1 tsp); oil (1 tsp); olive/canola oil (1 tsp); mayonnaise (1 tsp); peanut butter (1 tsp)
<b>Energy dense snacks</b>	Baked goods (1 piece of cake, biscuits); crisps (1 packet); sweets (1 unit); chocolates
<b>High fibre foods</b>	Brown bread (1 slice); whole wheat/low GI bread (1 slice); legumes (1/2 cup); high fibre cereals (1/2 cup)
<b>Refined CHO foods</b>	White bread (1 slice); maize porridge (1/2 cup); sugar (1 tsp); jam (1 tsp); syrup (1 tsp)
<b>Added sugar</b>	White or brown cane sugar added to food or drink (1 tsp)
<b>High-sugar beverages</b>	Fruit juice (125ml); sugar-containing carbonated drinks (250ml); cordials (250ml)
<b>Healthier, lower fat choices</b>	Lean red meat (90g); poultry without skin/being fried (90g); tinned fish (90g or ½ tin); poached/boiled eggs (1); low fat and fat free dairy (125ml); lite margarine (1 tsp); low fat mayonnaise (1 tsp)
<b>Alcohol</b>	One unit: Beer (340ml) or tot of spirits (30ml) or wine (125ml)

*Abbreviations:* CHO: carbohydrate

### ***NCD risk factor profile***

The risk factor profile calculations described by Van Zyl et al., (2012) were adapted to calculate the total number of risk factors for NCDs for each patient by adding the presence of high blood pressure, high cholesterol, current smoking, physical activity less than 150 minutes per week (WHO, 2011b), leisure time sedentary activity more than 120 minutes per day (Grontved & Hu, 2011), and fruit and vegetable intake <5 portions per day (WHO, 2004). A minimum of 0 indicated no risk factors present while a maximum of six could be obtained if all risk factors were present.

### ***Stage of change***

To determine the patient's readiness to increase their intake of healthy foods, an adapted version of the 12-item Readiness for Change questionnaire (RCQ) was used (Addendum 1). The original RCQ was developed to determine the stage of change (SOC) in individuals with excessive alcohol intake (Rollnick et al., 1992). This was adapted by Senekal et al. (unpublished) for the purposes of their research to reflect readiness to consume healthy foods by members of a South African medical scheme. The adapted RCQ aimed to categorise patients in a pre-contemplation, contemplation or action stage. The adapted questionnaire consists of nine statements from which three relate to each stage of change category. The response categories and scoring included -2 "Strongly disagree", -1 "Disagree", 0 "Unsure", +1 "Agree", or +2 "Strongly agree". These scores were added together to calculate a score between -6 to +6 for each stage. The highest of the three scores indicates the stage of change the patient is in. When the scores for two categories were equal, the patient would be classified as being in the higher stage of the two stages (Heather et al. 1993).

The stage of change categories were interpreted as follows: patients in pre-contemplation stage do not demonstrate any intent to change their behaviour; patients in contemplative stage are aware of their problems and present with some inclination to change their behaviour, but are not committed to making active changes; and patients in action stage are in a highly motivated position where they are able to actively change their behaviour, or are already engaging in healthy behaviours (Young, 2010).

### **Statistical methods**

Data was entered into a Microsoft Excel (2007) spread sheet on a daily basis and was checked and cleaned prior to analysis in STATA 11.0 (Statacorp Lp, 2009). The numerical

variables were checked for normality by exploratory analysis using box and whisker plots and Shapiro-Wilk tests.

The descriptive analysis involved the calculation of proportions for categorical data as well as means and standard deviations for numerical data. Independent t-tests (normal data) and rank-sum tests (non-normal data) were used to assess for differences between the two treatment groups (patients who chose the FBTG intervention versus those who chose usual care) for age, education, biochemical measures, BP, pack years for smoking, weight, height, BMI, waist circumference, weight loss goal, physical activity, dietary intake and risk factor scores. Pearson Chi-squared or Fisher's exact tests (if expected frequencies were less than five) were used to compare the two treatment groups for gender, race, residential area, employment status, income status, smoking status, disease status, medication usage and categories for BMI, waist circumference and stage of change.

All results with a p-value  $<0.05$  were described as statistically significant.

## RESULTS

### ***Socio-demographic characteristics***

The majority of patients who entered the study were female of mixed ancestry, who were approximately 50 years old and had a formal education of approximately 10 years (Table 3.2). Most patients indicated that they received a family income between R0.00 and R4166.66 and just over half of the total sample was employed at the time of the assessment. The majority of patients were from the residential areas of Ocean View and Fish Hoek.

There were no significant differences between patients who chose the FBTG intervention versus usual care (referred to treatment groups) for age, gender, race, employment status, education and income. Fewer patients from Masipumele (a residential area that consists of mainly black African individuals) and more patients from Muizenberg chose the FBTG intervention. Patients who chose the FBTG intervention tended to have a higher education level, while black African patients tended to choose usual care over the FBTG intervention. The reasons indicated by usual care patients for declining entrance into the FBTG included: work commitments (n=37; 38.1%), preference for individual consultations (n=14; 14.4%), transport problems (n=9; 9.3%), family commitments (n=5, 5.2%), medical problems (n=2; 2.1%), demotivation (n=1; 1.0%), out of area (n=1; 1.0%) and time limitations (n=1; 1.0%). Twenty-seven patients (27.8%) did not communicate a clear reason for declining the FBTG intervention.

### ***Disease status, biochemical values, medication usage and smoking***

DM was more prevalent than heart disease among the total sample (Table 3.3). Less than 10% of the sample had both DM and heart disease. Less than half the sample presented without NCDs, however the majority of patients presented with intermediate risk factors for NCDs such as HBP and high cholesterol. The numbers of patients with NCDs, HBP and high cholesterol were similar between the treatment groups.

The mean HbA1c for the total sample was classified as poor glycaemic control (SEMDSA, 2012), while mean total cholesterol, SBP and DBP were all classified as high (Seedat & Rayner, 2012). Usual care patients had significantly poorer glycaemic control than FBTG intervention patients. Total cholesterol and BP did not differ significantly between the two treatment groups.

**Table 3.2 Socio-demographic information for the total sample and by treatment groups**

	Total sample (n=193)	FBTG Intervention (n=96)		Usual care (n=97)		p-value
		n	Value	n	Value	
<b>Age in years, mean (SD)</b>	50.4 (12.9)	96	50.3 (13.2)	97	50.4 (12.8)	0.940 <sup>a</sup>
<b>Gender (column %)</b>						
Female	77.7	76	79.2	74	76.3	0.631 <sup>b</sup>
Male	22.3	20	20.8	23	23.7	
<b>Race (column %)</b>						
Mixed ancestry	49.2	52	54.2	43	44.3	0.072 <sup>b</sup>
Black	24.9	17	17.7	31	31.0	
White/Asian	25.9	27	28.1	23	23.7	
<b>Residential area (column %)</b>						
Ocean view	28.0	28	29.2	26	26.8	0.045 <sup>b</sup>
Masipumele	16.1	10	10.4	21	21.7	
Fish Hoek	27.5	23	23.0	30	30.9	
Simons Town	7.8	11	11.5	4	4.1	
Muizenberg	20.7	24	25.0	16	16.5	
<b>Currently employed (% yes)</b>	54.4	48	50.0	57	58.8	0.222 <sup>b</sup>
<b>Formal education, mean (SD) (years)</b>	10.1 (2.7)	95	10.5 (2.8)	96	9.7 (2.6)	0.050 <sup>c</sup>
<b>Family income/month<sup>d</sup>, (column %)</b>	<b>(%)</b>		<b>(%)</b>		<b>(%)</b>	
H0: ( R0.00/gov pension)	19.1	17	17.7	20	20.6	0.671 <sup>b</sup>
H1: (R0.00 – R4166.66 )	61.1	60	62.5	58	59.8	
H2: ( R4166.67 – R8333.33)	12.4	14	14.6	10	10.3	
H3: ( > R8333.34 )	4.7	4	4.2	5	5.2	
Private (Medical aid)	2.6	1	1.0	4	4.1	

Abbreviations: SD: standard deviation

<sup>a</sup> Independent t-test (normally distributed data), <sup>b</sup> Chi squared test, <sup>c</sup> Wilcoxon rank-sum test (non-normally distributed data),

<sup>d</sup> H0, H1, H2, H3, government classification for monthly income at time of assessment

Note: % "Yes" reported, balance recorded as "No"

The majority of patients with DM were using oral hypoglycaemics, followed by a combination of insulin and oral hypoglycaemic tablets. Very few patients with DM used insulin therapy alone. Almost half of the patients with high cholesterol and most of the patients with HBP were taking cholesterol-lowering and anti-hypertensive medication respectively. There were no significant differences in medication usage between the two treatment groups. Over half the sample had never smoked, while about one in six patients were currently smoking at the time of assessment. The total sample had a mean pack years of close to 25 years. The proportion of current smokers was significantly higher among usual care patients compared

to FBTG patients. There was no difference in the number of pack years between the two treatment groups.

**Table 3.3 Disease status, intermediate risk factors\*, BP\*, medication and smoking in total sample and by treatment groups**

	Total sample (193)		FBTG Intervention (n=96)		Usual care (n=97)		p-value
	n	Value	n	Value	n	Value	
<b>NCDs (column %)</b>							
No NCDs	93	40.4	46	48.0	47	47.4	0.457 <sup>a</sup>
One (Diabetes or CHD)	85	51.8	44	45.8	41	42.3	
Two (Diabetes & CHD)	15	7.8	5	5.2	10	10.3	
<b>Diabetes (% yes)</b>	81	41.5	36	37.5	45	46.4	0.268 <sup>a</sup>
<b>Heart disease (% yes)</b>	35	18.1	18	18.8	17	17.5	0.825 <sup>a</sup>
<b>Intermediate risk factors</b>							
High cholestol (% yes)	121	69.5	57	65.5	64	73.6	0.249 <sup>a</sup>
HBP (% yes)	161	83.4	78	81.3	83	85.6	0.420 <sup>a</sup>
<b>Biochemical measures and BP, mean (SD)</b>							
HbA1c (%)	65	9.1 (2.0)	31	8.4 (1.5)	34	9.7 (2.3)	0.008 <sup>b</sup>
Total cholesterol (mmol/l)	166	5.4 (1.2)	83	5.4 (1.2)	83	5.5 (1.6)	0.827 <sup>c</sup>
Systolic BP (mmHg)	189	145.6 (21.0)	95	142.8 (20.6)	94	148.3 (21.2)	0.127 <sup>c</sup>
Dystolic BP (mmHg)	189	84.5 (12.0)	95	83.6 (11.7)	94	85.5 (12.3)	0.279 <sup>b</sup>
<b>Medication</b>							
<b>Diabetes (column %)</b>							
No (diet controlled)	0	0	0		0		NA
Using oral medication only	55	67.9	21	58.3	34	75.6	0.263 <sup>d</sup>
Using insulin only	3	3.7	2	5.6	1	2.2	
Using insulin & oral medication	23	28.4	13	36.1	10	22.2	
<b>High cholesterol (% yes)</b>	58	49.1	23	44.2	35	53.0	0.342 <sup>a</sup>
<b>High BP (% yes)</b>	150	93.1	70	89.8	80	96.4	0.087 <sup>a</sup>
<b>Smoking status (column %)</b>							
Never smoked	133	58.6	58	60.4	55	56.7	0.028 <sup>a</sup>
Current smoker	31	16.1	9	9.4	22	22.7	
Previous smoker	49	25.4	29	30.2	20	20.6	
Smoking (pack years), mean (SD)	80	23.6 (20.6)	38	20.6 (18.7)	42	26.4 (22.1)	0.213 <sup>c</sup>

*Abbreviations:* NCDs: non-communicable diseases; SD: standard deviation; BP: blood pressure; HbA1c: Glycated haemoglobin

<sup>a</sup> Chi squared test, <sup>b</sup> Independent t-test (normally distributed data), <sup>c</sup> Wilcoxon rank-sum test (non-normally distributed data),

<sup>d</sup> Fishers exact test

\*Note: % "Yes" reported, balance recorded as "No". Information taken from patients prescription chart and based on ICD-10 coding for diagnosis. N varies due to missing values if patients did not attend their appointment for biochemical or BP measurements, or if blood test not conducted.

## Anthropometry

Weight status and other anthropometric measurements are presented in Table 3.4. The mean BMI of the total sample was in the obese class II category (WHO, 2006). The distribution of BMI among the three obese BMI categories was similar between the two treatment groups. There were no differences between the two treatment groups for weight, height, BMI and BMI categories.

The mean waist circumference of the total sample was in the increased risk range for the development of metabolic syndrome and NCDs (WHO, 2011a). Both men and women presented with waist circumferences above the recommended cut offs of >102cm in men and >88cm in women (WHO, 2011a). Furthermore, the waist circumferences of the majority of men and women were greater than the recommended cut offs. There were no differences in waist circumference between treatment groups. FBTG intervention patients tended to have a higher weight loss goal than usual care patients.

**Table 3.4 Anthropometric measures for total sample and by treatment groups**

	Total sample (193)		FBTG Intervention (n=96)		Usual care (n=97)		p-value
	n	Value	n	Value	n	Value	
<b>Weight (kg), mean (SD)</b>	193	102.4 (18.6)	96	101.9 (17.4)	97	103.0 (19.7)	0.863 <sup>a</sup>
<b>Height (metres), mean (SD)</b>	193	1.6 (0.1)	96	1.6 (0.1)	97	1.6 (0.1)	0.292 <sup>a</sup>
<b>Weight classification</b>							
<b>BMI (kg/m<sup>2</sup>), mean (SD)</b>	193	39.3 (7.3)	96	38.9 (6.8)	97	39.8 (7.8)	0.591 <sup>a</sup>
<b>BMI categories (column %)</b>		(%)		(%)		(%)	
<b>30 – 34kg/m<sup>2</sup> (Obese Class I)</b>	65	33.7	32	33.33	33	34.02	0.562 <sup>b</sup>
<b>35-39kg/m<sup>2</sup> (Obese Class II)</b>	56	29.0	31	32.29	25	25.77	
<b>&gt;40kg/m<sup>2</sup> (Obese Class III)</b>	72	37.3	33	34.38	39	40.21	
<b>Waist circumference (WC)</b>							
<b>Women, mean (SD)</b>	147	117.3 (12.6)	76	115.3 (12.1)	71	119.4 (12.8)	0.050 <sup>c</sup>
<b>Men, mean (SD)</b>	42	115.8 (9.0)	20	117.4 (9.9)	22	114.3 (8.0)	0.384 <sup>b</sup>
<b>WC categories</b>		(%)		(%)		(%)	
<b>Females &gt; 88cm (% yes)</b>	155	98.6	75	98.7	70	98.6	0.961 <sup>b</sup>
<b>Males &gt; 102cm (% yes)</b>	44	100.0	20	100.0	22	100.0	
<b>Weight-loss goal</b>							
<b>Weight (kg), mean (SD)</b>	189	12.7 (7.3)	95	13.6 (7.1)	94	11.8 (7.5)	0.076 <sup>a</sup>

*Abbreviations:* kg: kilograms; SD: standard deviation; BMI: body mass index; WC: waist circumference; cm: centimetres

<sup>a</sup> Wilcoxon rank-sum test (non-normal data), <sup>b</sup> Chi squared test, <sup>c</sup> Independent t-test (normally distributed data)

\*Note: % "Yes" reported, balance recorded as "No". N varies due to missing values.

Waist circumference cut offs: >102cm in men and >88cm in women (WHO, 2011a)

### **Formal physical activity and leisure time sedentary activity**

About one in seven patients in the total sample engaged in formal physical activity (Table 3.5), with time spent engaging in formal physical activity being less than half an hour per week. Time spent watching television amounted to more than two hours per day. There were no differences between the two treatment groups for these measures.

**Table 3.5 Physical activity and leisure time sedentary activity for total sample and by treatment groups**

	Total sample (193)		FBTG Intervention (n=96)		Usual care (n=97)		p-value
	n	Value	n	Value	n	Value	
<b>Participates in formal physical activity, (% yes)</b>	27	14.1	13	13.8	14	14.4	1.000 <sup>a</sup>
<b>Formal physical activity (min/week), mean (SD)</b>	191	20.7 (77.3)	94	26.1 (99.3)	97	15.5 (47.0)	0.993 <sup>b</sup>
<b>Leisure time sedentary activity (min/day), mean (SD)</b>	189	136.6 (106.0)	92	130.9 (104.8)	97	141.0 (107.3)	0.286 <sup>b</sup>

*Abbreviations:* Min: Minutes; SD: standard deviation

<sup>a</sup>Chi squared test, <sup>b</sup>Wilcoxon rank-sum test (non-normally data)

\*Note: % "Yes" reported, balance recorded as "No". N varies due to missing values.

### **Dietary intake**

The daily number of standard portions consumed from indicator food groups is indicated in Table 3.6. Data for the total sample showed that the intake of high fat foods and energy-dense foods combined was about four standard portions per day. Approximately five teaspoons of added sugar, more than a glass of high-sugar beverage and approximately 10 std. refined carbohydrate portions were consumed each day. However, only three standard high fibre food portions, two combined standard fruit and vegetable portions and nearly three standard portions of low fat food choices were consumed each day. Alcohol intake was approximately half a unit per day in the total sample. On average, meals were consumed regularly, while only one snack was consumed between meals on a daily basis.

Usual care patients ate significantly less snacks and more refined carbohydrates than FBTG intervention patients. Furthermore, usual care patients tended to have a higher intake of added sugar and high-sugar beverages, and a lower intake of fruit and vegetables compared to the FBTG patients. There were no other differences in intake between the two treatment groups for the other indicator food groups.

**Table 3.6 Daily frequency of indicator food groups for the total sample and by treatment groups**

	Total sample (193)		FBTG Intervention (n=96)		Usual care (n=97)		p-value
	n	Value	n	Value	n	Value	
<b>Indicator food groups<sup>*</sup>, mean (SD)</b>							
Fruit & vegetables	187	2.2 (1.5)	93	2.5 (1.8)	94	1.9 (1.2)	0.065 <sup>a</sup>
Fruit	187	1.3 (1.3)	93	1.6 (1.5)	94	1.1 (1.0)	0.095 <sup>a</sup>
Vegetables	187	0.9 (0.5)	93	0.9 (0.5)	94	0.8 (0.5)	0.127 <sup>a</sup>
High fat foods	187	2.3 (1.7)	93	2.1 (1.4)	94	2.5 (1.8)	0.874 <sup>a</sup>
Fats	187	4.6 (2.6)	93	4.6 (2.6)	94	4.7 (2.5)	0.454 <sup>a</sup>
Energy-dense snacks	187	1.5 (2.0)	93	1.5 (1.8)	94	1.4 (2.2)	0.271 <sup>a</sup>
High-fibre foods	187	3.1 (2.8)	93	3.3 (2.8)	94	2.9 (2.9)	0.225 <sup>a</sup>
Refined carbohydrate foods	187	10.6 (10.2)	93	9.4 (7.8)	94	12.4 (12.3)	0.030 <sup>a</sup>
Added sugar	187	5.1 (8.5)	93	4.0 (5.8)	94	6.2 (10.5)	0.089 <sup>a</sup>
High-sugar beverages	187	1.3 (2.3)	93	1.1 (2.4)	94	1.5 (2.3)	0.070 <sup>a</sup>
Alcohol	187	0.4 (3.0)	93	0.6 (4.6)	94	0.1 (0.5)	0.167 <sup>a</sup>
Healthy choices	187	2.4 (2.0)	93	2.6 (2.0)	94	2.3 (2.1)	0.183 <sup>a</sup>
<b>Meals and Snacks, mean (SD)</b>							
No. of meals per day	187	2.6 (0.6)	93	2.6 (0.6)	94	2.5 (0.6)	0.712 <sup>a</sup>
No. of snacks per day	187	1.2 (1.2)	93	1.4 (1.3)	94	1.0 (1.1)	0.009 <sup>a</sup>

Abbreviations: FFQ: food frequency questionnaire; SD: standard deviation

<sup>a</sup> Wilcoxon rank-sum test used for non-normally distributed data.

Note: See table 3.1 for description of indicator food groups and addendum 1 for FFQ. N varies due to missing values.

### ***NCD risk factor profile***

The mean number of risk factors present was almost four out of a maximum of six (Table 3.7). The three highest ranked risk factors for NCDs were low physical activity levels, low fruit and vegetable intake and high blood pressure.

Low fruit and vegetable intake differed between the two treatment groups with significantly less usual care patients meeting the goal of five or more fruit and vegetable portions per day. Significantly more usual care patients were smoking at the time of assessment. Overall, usual care patients had a significantly higher number of NCD risk factors than FBTG intervention patients.

**Table 3.7 Risk factors profile\* for total sample and by treatment group**

Risk factor (ranked)	Rank	Total sample (193)		FBTG Intervention (n=96)		Usual care (n=97)		p-value
		n	% yes	n	% yes	n	% yes	
< 150 minutes physical activity per week	1	183	95.8	89	94.7	94	96.9	0.493 <sup>a</sup>
Less than 5 fruit & vegetables daily	2	173	92.5	82	88.2	91	96.8	0.025 <sup>b</sup>
High blood pressure	3	161	83.4	78	81.3	83	85.6	0.420 <sup>b</sup>
High cholesterol	4	121	69.5	57	65.5	64	73.6	0.249 <sup>b</sup>
> 2 hours TV viewing	5	102	54.0	47	51.1	55	56.7	0.439 <sup>b</sup>
Currently smoking	6	31	16.1	9	9.4	22	22.7	0.012 <sup>b</sup>
<b>Total risk factors, mean (SD)</b>		193	4.0 (1.1)	96	3.8 (1.1)	97	4.2 (1.1)	0.008 <sup>c</sup>

Abbreviations: M: mean; SD: standard deviation, TV: television

<sup>a</sup> Fisher exact test for comparison of FB TG intervention and usual care group patients

<sup>b</sup> Chi squared test for comparison of FB TG intervention and usual care patients

<sup>c</sup> Wilcoxon rank-sum test used for non-normally distributed data

\*Note: These risk factors are in addition to obesity in all patients and large waist circumference in majority of patients defined for the purposes of this research

### Stage of change

The majority of patients (68.8%) in the total sample were in the contemplative stage (Table 3.8). There were no significant differences between the two treatment groups although there was a trend for the FB TG intervention patients to be more likely to be in the action phase.

**Table 3.8 Stage of change for total sample and by treatment group**

Stages of change <sup>a</sup>	Total sample (193)		FB TG Intervention (n=96)		Usual care (n=97)		p-value
	n	%	n	%	n	%	
Pre-contemplative stage	3	1.6	2	2.1	1	1.0	0.326 <sup>b</sup>
Contemplative stage	130	68.8	60	63.8	70	73.7	
Action stage	56	29.6	32	34.1	24	25.3	

<sup>a</sup> See Addendum 1 for stage of change questionnaire

<sup>b</sup> Fisher exact test for comparison of FB TG intervention and usual care group patients

Note: See Addendum 1 for stage of change assessment questionnaire. N varies due to missing values.

## DISCUSSION

The findings of this study may provide health professionals and public health policy-makers with insight into planning interventions for obesity and NCDs at PHC facilities by providing a profile of treatment-seeking patients, as well as those who chose a FBTG type intervention versus those who chose usual care. Of note is that research on patient characteristics associated with their preferences for lifestyle interventions in both developed and developing countries, is inconclusive which could be explained by the complexity of psychosocial, biological, ethnic and environmental influences that affect health-related perceptions and decision-making (Borradaile et al., 2012; De-Graft Aikins et al., 2012; Brown & Gould 2011; Moroshko et al., 2011).

Despite obesity and NCDs affecting both men and women in the Western Cape (Chopra et al., 2007), the majority of our total sample were women. This finding is not uncommon in lifestyle intervention studies and it has been suggested that women seek treatment for obesity and general health problems more often than men (Pagoto et al., 2012; van der Hoeven et al., 2012; Gray et al., 2009; Gregory et al., 2008; Hankey et al., 2002). A recent study in the North West province reported that men did not actively participate in their health and wellbeing when compared to women (van der Hoeven et al., 2012). Moreover, evidence from developed countries shows that men appear to prefer individualised treatment for health problems and a physical activity focus, over group-based weight loss programmes (Stubbs et al., 2011; Poobalan et al., 2010; Gray et al., 2009). In contrast, our results indicated that there were no differences in the proportion of men and women who chose the group-based versus the usual care interventions.

The differences in representation of race groups in lifestyle interventions have been highlighted in two recent systematic reviews on multi-ethnic lifestyle interventions in developed countries (Davidson et al., 2013; Fitzgibbon et al., 2012) as well as descriptive studies in the United States (Shavers et al., 2002; Fontaine et al., 2000). The studies all found low recruitment rates of black African-American patients into health research and lifestyle programmes. It is thus interesting to note that the race profile of the total sample also reflects that a low percentage of black African patients volunteered to participate in our study. Furthermore, there was a non-significant trend for black African patients to choose usual care over the FBTG intervention. It is possible that these trends could be explained by the findings that South African Black females perceived adiposity as a reflection of well-being and wealth (Van der Merwe & Pepper, 2006, Kruger et al., 2005), while weight loss is perceived as an indication of illness and poverty (Puoane et al., 2008). It is also possible

that black African patients in our study may have perceived that the FBTG intervention lacked cultural tailoring and therefore may have been less willing to participate. While there is limited literature on this issue, it has been reported that African-American females from the United States felt that many of the current weight loss and lifestyle programmes were not tailored to their personal challenges and cultural preferences (Davidson et al., 2013; Noia et al., 2013; Fortaine et al., 2000). For example, Noia et al., (2013) pointed out that factors such as traditional cooking, food choices and socio-economic issues such as limited finances have influenced the eating and lifestyle behaviours of African-Americans over centuries (Noia et al., 2013). It is also interesting to note that there were fewer patients from Masipumele (area with both informal and formal housing) who opted for the FBTG intervention. It would be important to investigate whether there were any barriers or preferences for interventions among this group of patients.

The importance of education in health outcomes is embedded in the statement by Shankar et al., (2010) that exposure to education over an individual's life course is likely to affect an individual's response to health problems in adult life. In our study, the usual care patients who declined the more intensive FBTG intervention tended to have lower education attainment. This possible association is supported by the findings by LaRowe et al., (2009) that low education attainment was associated with reduced treatment-seeking behavior. Gee et al., (2012) also showed that low education attainment and low SES were two of the most common characteristics in hypertensive patients (n=6142) with low desire to change. Similarly, Bish et al., (2005) reported that low education attainment was strongly associated with reduced efforts to lose weight and change behaviour. These associations may be explained by the lower levels of health literacy (Noia et al., 2013), risk perception (Margolis 2013; Braveman et al, 2011; Pampel et al., 2010), and locus of control (Margolis 2013; Braveman et al, 2011; Pampel et al., 2010) that are commonly observed in individuals with low educational attainment. It has also been suggested that because individuals with lower SES may be less motivated by longevity, they may be less encouraged to practice preventative lifestyle behaviours (Pampel et al., 2010). Therefore, it may be possible that better educational status may increase the likelihood of a treatment seeking patients at a primary health care facility to opt for a more intensive intervention.

Investigation into the income of patients revealed that the total sample had an average household income of up to R4167.00 per month (annual income of up to R50 004.00), which is less than the average annual income of R78 157.00 to R143 460.00 in the Western Cape as reported in the 2011 Census (StatsSA 2011). Even though some hospital patients may under-report their income to hospital administration in order to qualify for lower hospital rates

(informal discussion at hospital management meetings), our findings indicate that this sample is representative of a low-income group. Thus we could speculate that some of the usual care patients from low-income households did not want to commit to the FBTG programme, as they may have preferred to prioritise their money for living expenses over the cost of weekly transport to the hospital. Current literature suggests that participation in lifestyle interventions could be improved by implementing programmes within the community at places of worship or school halls as this would reduce travelling costs and provide a familiar environment for patients (Noia et al., 2013). The fact that healthy eating is generally more expensive (Temple & Steyn, 2011), may have also deterred patients from selecting the FBTG intervention. However, as income was similar across the two treatment groups, it should be considered as a potential barrier for any treatment seeking patient attending a PHC facility for either usual care or more intensive lifestyle interventions.

Even though half of the total sample was employed at the time of recruitment and there were no differences in employment status between treatment groups, usual care patients cited work commitments as the main reason for declining the FBTG intervention. This is unfortunate, since economically active South Africans with risk factors for NCDs and NCDs, are at risk of premature morbidity and mortality and should be prioritised to receive interventions in order to preserve their health and well-being. Since facilities are unlikely to accommodate FBTGs or dietetic clinics after-hours, worksite interventions should be considered. The applicability for worksite interventions in South Africa is still under debate (Norris & Pettifor, 2009), but it would provide a worthy platform for secondary prevention of NCDs, in addition to interventions delivered in PHC facilities. One could also speculate that unemployed or part-time employed individuals would be more likely to enter and complete a six-week FBTG programme. However, financial constraints associated with unemployment may preclude them from doing so.

The need for individualised treatment appears to be an important factor for patients seeking treatment for obesity (Parker et al., 2012; Burke et al., 2008). This may explain why the preference for individual consultations was the second most cited reason after work commitments for declining participation in the FBTG intervention. This finding is supported by Parker et al., (2012) who conducted a study on the health promotion activities for NCDs in Western Cape PHC facilities. The authors found that the majority of patients interviewed opted for individual counselling as their ideal method for therapeutic education. A descriptive study on patient experiences with weight loss programmes in the United States showed that many participants favour self-help over group weight loss programmes as it allows for greater flexibility, particularly in dietary intake and physical activity (Burke et al.,

2008). On the other hand, patients appear to choose group-based weight loss programmes for professional guidance and peer support (Parker et al., 2012; Burke et al., 2008). Despite these varied preferences for weight loss treatment, frequent individual counselling for all patients with NCDs and/or obesity will be a challenge for health professionals working in PHC.

It is concerning that over a third of patients recruited into the study were classified as morbidly obese (BMI > 40kg/m<sup>2</sup>) and nearly all patients presented with waist circumferences in the undesirable range. It is known that central adiposity exacerbates insulin resistance, dyslipidaemia, and hyperglycaemia (WHO, 2011a). Therefore weight loss is warranted as a primary intervention for patients in this sample, and frequent contacts with dietitians would be necessary to support behaviour change. As there were no differences in anthropometric measures between the FBTG and usual care patients, weight status is probably not associated with treatment choice.

The average six-month weight loss goal reported by treatment seeking patients was 13.6kg (0.6kg per week) in FBTG intervention patients and 11.8kg (0.5kg per week) in usual care patients. The general recommendation for weight loss is 0.5kg to 1kg per week (Seagle et al., 2009), which translates into a 12 to 24kg loss over a six-month period. Even though FBTG patients' weight loss goal tended to be higher than that of usual care patients, both could be considered to be reasonable targets. The higher weight loss goals of the FBTG intervention patients may be a reflection of a higher personal motivation for change (Crawford & Glover 2012; Linde et al., 2004). However, overestimation of weight goals has also been associated with programme withdrawal as patients who experience poor progress may lose motivation to continue with lifestyle changes (Grave et al., 2005; Foster et al., 2001). Factors that motivate patient's to lose weight are not fully understood (Van Wormer et al., 2010; Annunziato & Lowe 2007; O'brien et al., 2007), but studies have suggested that strong motives to improve health (Brown & Gould 2011; Annunziato & Lowe 2007; O'Brien et al., 2007; Hankey et al., 2002), improve physical appearance (Brown & Gould 2011; O'Brien et al., 2007; Annunziato & Lowe 2007) and associated underlying psycho-social issues (Annunziato & Lowe 2007; O'Brien et al., 2007; Foster et al., 2001), appear to be common factors.

Mean glucose, BP and cholesterol levels were all within undesirable ranges. Factors such as poor compliance with treatment, age, weight status, unhealthy diet and physical inactivity may explain this finding. Long-term glycaemic control in patients with DM was particularly poor in usual care patients. In comparison to 2012 SANHANES in participants aged 55 to

64 years old, our sample had a higher prevalence of DM (12.7% and 19% self-reported in SANHANES male and female population respectively), heart disease (6.1% and 9.5% self-reported in SANHANES male and female population respectively), high cholesterol (13.2% and 11.1% self-reported in SANHANES male and female population respectively), and high blood pressure (30.9% and 46.5% self-reported in SANHANES male and female population respectively). However, this finding is expected since the study recruited patients with NCDs or at high risk of NCDs.

The majority of patients with high blood pressure and all patients with diabetes received pharmacological intervention at the time of the study, however only half of the patients who had high cholesterol were on statins. The likely explanation is that medical doctors applied risk stratification and would thus firstly prescribe lifestyle advice to patients who had high cholesterol but were not at very high risk for CVD. However, even though healthy diet and regular exercise can be prescribed to reduce cholesterol to an acceptable level without pharmacological intervention (Klug et al., 2012), it is known that lifestyle advice is limited in PHC settings (Parker et al., 2012). Thus it would be a concern that many patients remain without adequate pharmacological intervention for high cholesterol, which if left untreated could contribute to CVD. Overall, the presence of poorly controlled intermediate risk factors in this sample is concerning and these patients should be primed for secondary intervention in order to prevent further complications and the development of NCDs in those without DM and CVD. Lifestyle interventions should be strengthened and made available to patients who may not require pharmacological intervention, or would prefer to decrease dependence on their medication.

In addition to the above-mentioned risk factors and NCDs, around 16% of the total sample were smokers. There were significantly more current smokers among usual care patients compared to FBTG patients. It could be argued that smokers may have a general lack of motivation to change a variety of lifestyle behaviours and hence declined the FBTG intervention. Alternatively, it could be speculated that patients who actively enter into a lifestyle programme may already be actively engaged in a healthy lifestyle. These possibilities are supported by some studies that suggest that unhealthy lifestyle behaviours tend to cluster in individuals (Shankar et al., 2010; Jimenez-Garcia et al., 2011; Drieskens et al., 2010) while treatment-seekers tend to employ a variety of healthy lifestyle practices (LaRowe et al., 2009). In their study on the prevalence of obesity in smokers enrolled in a cessation program, LaRowe et al., (2009) found that patients who were actively trying to stop smoking, also reported engaging in more healthy behaviours and had a healthier profile than patients who did not want to stop smoking (LaRowe et al., 2009). Furthermore, a large

cross-sectional study in Spanish patients with DM by Jimenez-Garcia et al. (2011) showed that patients who presented with multiple unhealthy behaviours such as smoking, high alcohol intake, physical inactivity and poor diet were more likely to be non-adherent to lifestyle guidelines and have fewer contacts with health professionals.

One of the most concerning findings among patients in this study was the low level of self-reported physical activity, which was equally poor in both treatment groups. The proportion of the sample who were physically inactive was 86%, which is much higher than the national prevalence of inactivity for men (44.7%) and women (47.6%) (Guthold et al., 2008). It is also higher than the prevalence of 66.5% found in a study of urban dwellers in the Free State (Van Zyl et al., 2012). Furthermore, the reported 21 minutes per week of physical activity in the total sample is much lower than the 150 (for general health) to 300 minutes per week recommended by the WHO for adults aged 18 to 64 years old to reduce risks of NCDs (WHO 2011b). The causes of low physical activity were not measured in this sample, although other research has indicated that socio-environmental factors such as poor neighbourhood safety, lack of recreational space, and lack of exposure to physical activity education over an individual's lifetime are the primary causes (Phaswana-Mafuya et al., 2013).

Time spent watching television (TV) is often used to gauge the level of low energy expenditure or sedentary activity (Grontved & Hu 2011; Sisson et al., 2009). Excessive TV viewing is considered an unhealthy behaviour as it is known to displace formal moderate physical activity and promote the consumption of unhealthy snacks and beverages (Grontved & Hu 2011; Sisson et al., 2009). Two to four or more hours per day of TV viewing has been strongly associated with increased incidence and mortality from DM and CVD (Sisson et al., 2009; Grontved & Hu 2011). It is thus concerning that patients in both treatment groups reported a mean of over two hours of television watching per day, which was not inclusive of other sedentary activities such as using the computer or listening to the radio. It would be strongly advised that interventions include education on the risks of sedentary activity and consumption of unhealthy snacking. It is also important to bear in mind that patients' total energy expenditure may be further reduced due to mechanisation, which reduces labour intensive applications for work, travel, household tasks and food preparation (Hallal et al., 2012).

This study also demonstrated that the dietary intake reflects the 'Western' eating patterns that have been associated with an increased risk of developing NCDs (Ezzati & Riboli 2013; Popkin et al., 2012). The patients in this study reside in urban communities where there is

access to a variety of fast food restaurants and informal vendors that typically sell foods that are energy-dense and high in fat, salt, sugar and refined carbohydrates. This is reflected by our findings that indicated that the combined average of 8.4 standard portions of high fat and energy-dense food items, over one glass of high-sugar beverages and approximately five teaspoons of added sugar are typically consumed by this sample per day. Furthermore, refined carbohydrates were consumed more regularly than high fibre foods. Alcohol intake that amounted to approximately half a unit per day was not considered excessive in either treatment group, which is a positive finding since it has been associated with increased risk for HBP (Schneider et al., 2007a). However, it is possible that some patients may have underreported alcohol intake, which has been a limitation in estimating alcohol intake in other South African studies on reporting on alcohol consumption (Peltzer et al., 2011; Suliman et al., 2010).

In this study, fruit and vegetable intake was 2.2 standard portions per day, which is similar to findings by Schneider et al., (2007b) who reported that South Africans consume less than three portions of fruit and vegetables per day. Intake in both studies fall short of the recommendations made by the dietary approaches to stop hypertension (DASH) that promotes eight to 10 portions of fruit and vegetables per 8400kcal (Lichtenstein et al., 2006) as well as the 2012 South African food-based dietary guidelines that promote a minimum of five portions per day (Naude 2013). Unfortunately, low fruit and vegetable intake is strongly associated with reduced survival (Bellavia et al., 2013), as well as poor socio-economic status (Darmon & Drewnowski 2008), which may be one of the reasons why our sample consumed inadequate amounts of fruit and vegetables. Therefore, it is likely that population-wide strategies would be necessary to increase fruit and vegetable intake in the South African population. Patients in this sample were also making approximately three standard portions of low fat food choices per day, which was indicative of choosing “lite” or low fat choices over energy-dense, high fat or frying foods. It is known that healthy food choices are affected by their cost and access as well as cultural acceptance, knowledge and perceived control over healthy food choices (Temple & Steyn 2011; Lawrence et al., 2009; Love et al., 2008). It could thus be argued that health education may not be sufficient to change purchasing and eating behaviours if the cost of healthy foods continues to be unfavourable, while cheap, unhealthy foods are readily accessible in urban communities undergoing nutrition transition.

Patients who chose the FBTG intervention consumed more snacks and less refined carbohydrates and tended to have a lower intake of sugar, high-sugar drinks and a higher intake of fruit and vegetables. These trends may be an indication that these patients may

already have been practicing some healthy habits, which is reflective of being in 'action' stage. There were no significant differences between the two treatment groups for stages of change, but there was a trend for FBTG patients to be more likely to be in the action stage. The majority of the total sample were in contemplative stage that indicates that they were not actively changing unhealthy food choices (Young 2010; Sutton et al., 2003). Thus, the effectiveness of individual dietary counselling or the FBTG intervention may be limited in these patients since the success of lifestyle programs depend on commitment and motivation to change.

Finally, the top three risk factors in each treatment group were physical inactivity, low fruit and vegetable intake, and high blood pressure. It is important to note that the combined effect of these three risk factors have been reported to account for over 30% of the burden of NCDs and around half of the mortality rate attributed to NCDs (Strong et al., 2005). Our findings are similar to those found in a cross-sectional study of urban dwellers in the Free State that ranked physical activity, high BMI, hypertension, smoking and high cholesterol in descending order as the primary risk factors for NCDs present in their study sample (Van Zyl et al., 2012).

The findings of this research need to be considered bearing in mind the limitations of using self-reported data on dietary intake, physical activity and other lifestyle factors. A strength is that data on biochemical and clinical measures and disease status was obtained from patient files and the hospital database and thus not self-reported.

## CONCLUSION

The socio-demographic and health profile of this urbanised sample of obese patients with NCDs (DM or CVD) or risk factors for NCDs shows that patients were representative of a middle-aged, low-income group that are mostly female of mixed ancestry. Most patients resided in Ocean View, Muizenburg and Fish Hoek. The most prevalent NCD among this sample was DM followed by CVD, while the majority of patients suffered from hypertension and over two thirds had high cholesterol. This study also revealed that despite the fact that the majority of patients receive pharmacological treatment for HBP and DM, most have high glucose, BP and cholesterol levels. Furthermore, the patients are engaged in a variety of modifiable risk factors such as smoking, unhealthy eating patterns and physical inactivity.

Patients who chose the FBTG intervention and those who chose usual care were similar with respect to age, gender distributions, employment status, income, weight loss goals, proportions of DM and CVD, weight, BMI, waist circumference, BP, cholesterol, medication usage, daily physical activity participation and activity levels, amount of time spent watching television, most indicator food groups and stage of change. Usual care patients had lower educational attainment than FBTG patients. Furthermore, usual care patients also had a higher NCD risk profile than FBTG patients since they presented with a significantly higher smoking prevalence, poorer glycaemic control, higher intake of refined carbohydrates, lower intake of fruit and vegetables, and a tendency for a higher intake of added sugar and high-sugar beverages. There was also a trend for FBTG patients to be more likely to be in action phase. It could be argued that usual care patients were less motivated to change their lifestyle and therefore chose to remain with the less invasive usual care. Alternatively, some of the usual care patients could be motivated to change their lifestyle but preferred individualised care.

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## **Chapter 4**

### **ARTICLE 2**

**A facility-based therapeutic group programme versus usual care for weight loss in obese patients attending a district hospital in the Cape Metropole**

## INTRODUCTION

Non-communicable diseases (NCDs) are becoming the greatest threat to human health and economic potential worldwide (Beaglehole et al., 2011). In developing countries such as South Africa, the burden of NCDs namely diabetes mellitus (DM), cardiovascular diseases (CVD), stroke and cancer are believed to be two to three times higher than in developed countries (Mayosi et al., 2009). There is uncertainty as to whether South Africa is prepared for the resource-demanding chronic care required to manage both the current and impending proportions of the population suffering from NCDs (Levitt et al., 2011).

Obesity is considered a potent risk factor for NCDs, and has been recognised as both a global health challenge (Popkin et al., 2012) and an emerging problem in Africa (Kruger et al., 2011; Ziraba et al., 2009). The current prevalence of obesity and overweight in South Africa is considerably high and is contributing to the disease burden in both high and low socio-economic groups (Shisana et al., 2013; Van der Merwe & Pepper, 2006). The risk factor profile in urbanised South African groups with obesity or NCDs can be attributed to unhealthy 'western' eating patterns (Abrahams et al., 2011), physical inactivity (Guthold et al., 2008), smoking (Sitas et al., 2013; Groenewald et al., 2007) and excessive alcohol consumption (Shisana et al., 2013). Fortunately, these common modifiable risk factors have been nominated to receive urgent intervention in South Africa (Singh, 2011). Although, guidelines for the management of DM (SEMDSA, 2012), hypertension (Seedat et al., 2011), food and labelling laws (Puoane et al., 2012), tobacco control policies (Puoane et al., 2012) and strategic planning for NCDs (Singh, 2011) are available, updated evidence-based guidelines for multi-level management of obesity and NCDs within public health services are still lacking. It should be borne in mind that the initiation of a robust response to NCDs may be hindered due to the demand on the country's health system and resources required to manage HIV/AIDS and Tuberculosis disease burdens (Levitt et al., 2011).

While the argument for population-scale interventions for obesity and NCDs seem to be gaining favour (Cecchini et al., 2010), the lack of small-scale lifestyle interventions leave much of the population without the incentive to take responsibility for their own health (Teixeira et al., 2012). Since patients with NCDs (who are without private medical insurance) usually seek medical treatment at government primary health care (PHC) facilities in South Africa, Levitt et al., (2011) suggested that screening and lifestyle interventions should be implemented at this level (Levitt et al., 2011). In developed countries, structured lifestyle interventions for obesity and NCDs are widely accessible and have proved to be successful

in a variety of settings and delivery modes (Kirk et al., 2012; Steinsbekk et al., 2012; Taggart et al., 2012; Greaves et al., 2011; Venditti & Kramer 2012; Seagle et al., 2009).

There are many factors to consider when designing a lifestyle intervention. Interventionists can use delivery modes such as self-help (Latner 2001), one-on-one consultations or group-based interventions (Steinsbekk et al., 2012; Paul-Ebhohimhen & Avenell 2009). Furthermore, the intervention may have a single- or multi-focus on diet, physical activity, psychological and behavioural components (Kirk et al., 2012). An important consideration is the amount of contact time between patient and programme as contact time appears to be a consistently significant predictor of improved outcomes (Gallagher et al., 2013; Toth-Capelli et al., 2012; Finkler et al., 2012; Venditti & Kramer 2012; Greaves et al., 2011; Le Blanc et al., 2011). However, current practice in PHC is for dietitians to provide once-off, one-on-one counselling sessions for weight or NCD management since dietetic services are often stretched across several clinics and community health centres. This practice can be considered an inefficient exercise, as patients with obesity and NCDs require numerous contacts and reinforcement with health professionals in order to understand and apply diet and lifestyle recommendations (Venditti & Kramer 2012; Gallagher et al., 2012; Greaves et al., 2011; Rowberg et al., 2010).

It needs to be noted that resource-limited PHC facilities in the Cape Metropole are expected to provide services for 13 338 patients with diabetes and 23 395 patients with hypertension every month (Parker et al., 2012). With these points in mind, it is vital that lifestyle interventions are developed to be cost-effective and resource sparing. Group-based programmes may offer a partial solution since the mode of delivery allows for a greater number of patients to receive therapeutic education and possibly may accommodate more frequent contact. Moreover, group programmes also allow intervention at a higher level of the socio-ecological model by including family and community members. At this point, it appears that group-based interventions have been receiving more attention (Kirk et al., 2012; Steinsbekk et al., 2012; Moore et al., 2011; Hoddinott et al., 2010; Paul-Ebhohimhen & Avenell 2009), however the studies and meta-analyses have used predominately randomised control trials in developed countries and lack generalisability for the 'real-world' settings such as PHC facilities in the Cape Metropole.

In South Africa, there have been very few interventions for adults with NCDs. These include a physician-led structured programme for patients with DM (Van Zyl & Rheeder 2004), a tailored programme for black rural patients with DM (Price et al., 2007), a nurse-led program that focused on screening and medical management of DM (Katz et al., 2009), a physical activity intervention for adults in Limpopo (Draper et al., 2010), and an intervention

programme for NCDs in an urban settlement (Puoane et al., 2007). A group-based multi-component intervention for patients with DM in Cape Town is currently underway (Mash et al., 2012) and is likely to offer significant insight in lifestyle programmes at community level. Although these programmes for patients with DM (van Zyl & Rheeder 2004; Price et al., 2007; Katz et al., 2009) and physical activity (Draper et al., 2010) were found to be effective within their settings, they did not employ a multi-focus approach (diet, physical activity and behavioural strategies) that is required to make a long-term, clinically significant impact on patient outcomes. It was also noted that the success of the physical activity programme (Draper et al., 2010) and the community intervention for patients with NCDs (Puoane et al., 2007) were limited by prevailing social and environmental factors. In addition, all programmes may not have provided adequate intervention exposure that is required to improve health outcomes.

Even though evidence for lifestyle interventions in PHC is limited, there are other developments that indicate the DOH's commitment to the prevention and control of NCDs. For instance, the DOH is in the process of developing national strategies for NCDs (Mayosi et al., 2012; Singh, 2011) and a Western Cape Chronic Disease Management (CDM) task team has developed guidelines and a model for a group-based NCD intervention at both facility and community level (DOH, 2009 unpublished). The model suggests that a PHC facility should provide a six-week facility-based therapeutic group (FBTG) programme, with provision of community support groups thereafter. To date, the proposed FB TG programme has been piloted in the Cape Metropole and rural areas, but the reporting of the efficacy and effectiveness thereof is not available (DOH, 2009). Therefore, False Bay Hospital, which is a PHC district hospital in the Southern sub-district of the Western Cape, undertook to facilitate and measure the effectiveness of the FB TG programme. The primary purpose of this paper is to measure the impact of the dietitian-led FB TG intervention in obese patients with NCDs or risk factors for NCDs, attending False Bay Hospital. The study aims to provide insight into lifestyle interventions in PHC setting that would be helpful for the DOH to consider in the planning of national strategies for NCDs.

## **METHODS AND MATERIALS**

### **Study design**

A quasi-experimental study design was used to compare the outcomes of the lifestyle intervention group (the FBTG) with patients who received usual care at a government PHC facility over a six month intervention period. The random assignment of patients was not possible as a result of limited throughput of eligible patients within the time frame of the study. Patients who agreed to participate were allocated to their treatment of choice.

### **Study Population and recruitment**

The study population were obese patients attending False Bay Hospital, who required management of NCDs and/or risk factors for NCDs. The district government hospital provides medical care for patients without health insurance. However, a small number of patients have private medical aid. Patients attending False Bay Hospital feed in from the following suburbs: Ocean view (predominantly mixed ancestry community), Masipumele (predominantly black African community), Fish Hoek (predominantly white community), Simons Town (predominantly mixed ancestry and white community), and Muizenberg (mixed ancestry, black African and white community). Masipumele contains both formal and informal housing, while the other residential areas consist of formal housing.

The recruitment of outpatients by the hospital dietitian (primary investigator) was conducted during an initial consultation after routine referral for dietary advice from the medical doctor. To be included in the study, patients were required to be older than 18 years and have a body mass index (BMI)  $\geq 30\text{kg/m}^2$  with one or more intermediate risk factors for NCDs such as raised blood pressure ( $>130/80\text{mmHg}$ ), raised HbA1c ( $>7\%$ ), raised total cholesterol ( $>4.5\text{mmol/l}$ ), and/or one or more existing NCD namely DM or heart disease. A basic understanding of the English language was also necessary as the program was conducted in English. Patients were excluded if they could not commit to all the FBTG sessions, were pregnant or lactating, or had any form of organ failure, severe psychiatric disorder or were physically restricted.

During the initial consultation with the hospital dietitian, the option of the FBTG or usual care intervention was presented to patients who met the study's inclusion and exclusion criteria. Once patients decided on their preferred group, additional details of the study were presented and signed consent was obtained. Patients who chose the FBTG intervention

were provided with additional information on dates and details of the six-session FBTG programme and were grouped according to their living area in order to prepare their entrance into community support groups thereafter.

The sample size estimation was based on the mean weight loss of  $2.8 \pm 4.0$ kg (group-based patients) and  $1.0 \pm 2.9$ kg (control) over six months as reported in an intervention by Ash et al., (2006). At least 60 patients in each group would be required to achieve 80% power at a 5% significance level. However, if a weight difference of 3kg (SD 5) together with an 80% power and 5% significance level, as reported in a study of low income women by Samuel-Hodge et al., (2009) is considered, a sample of 44 participants would be required in each group (total  $n=88$ ). Therefore, a sample size of 44 to 60 patients would be considered sufficient to detect between group differences in weight change over six months. As attrition rates in weight loss interventions have been reported to be high (Moroshko et al., 2011), oversampling is warranted. Thus, during April 2010 and June 2011, 96 intervention patients and 97 usual care patients ( $n=193$ ) were entered into the study.

### **Permission and ethical considerations**

Permission to conduct the research was obtained from the Department of Health (DOH) and the medical superintendent of False Bay Hospital. Ethical approval was granted from the University of Cape Town (UCT) Faculty of Health Sciences, Human Research Ethics committee (Ref: 18/2010). Patients were only entered into the study if they provided their written consent (Addenda A) after receiving a verbal and written explanation of the study procedures and expectations. Participation in the study posed no additional risks to patients since the procedures were within the Western Cape Chronic Disease Management Policy. No adverse problems arose during the intervention period and patients were given the right to withdraw from the study at any time.

### ***Intervention design and procedures***

Table 4.1 provides a summary of the protocol and data collection points for all study patients from baseline to six months. Irrespective of their assigned group, all patients received the same routine medical assessments with the medical doctors, and initial dietetic consultation and dietary counselling with the hospital dietitian at baseline. The initial consultation with the dietitian involved a description of the intervention and the study procedures, consent and baseline assessments (Addendum A). Thereafter, the dietitian provided a 30-minute consultation on diet and lifestyle. The dietary advice was based on the patient's diet history

and focused on portion control and improving the quality of the diet using the South African Food-Based Dietary Guidelines (DOH, 2012) and the plate model (USDA, 2011).

**Table 4.1 Protocol for study patients from baseline to six months**

<b>Week</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>26</b>
<b>FBTG Program roll out</b>								
Group program		x	x	x	x	x	x	
Psycho-social counselling		x	x	x				x
Group diet education		x	x	x	x	x		
Individual diet education	x x							
Group exercise education				x	x			
Group pharmacist education						x		
Group maintenance counselling							x	
<b>Data collection</b>								
Socio-demographic details	x x							
Weight and waist circumference	x x	x	x	x	x	x	x	x x
Waist	x x	x	x	x	x	x	x	x x
BP	x x	x	x	x	x	x	x	x x
*HbA1c & Total cholesterol	x x							x x
Perceived compliance <sup>a</sup>			x	x	x	x	x	x x
Stage of change <sup>a</sup>	x x						x	x x
FFQ <sup>a</sup>	x x							x x
Exercise assessment <sup>a</sup>	x x						x	x x
Leisure time assessment <sup>a, b</sup>	x x							
Smoking assessment <sup>a, b</sup>	x x							

*Abbreviations:* FBTG: Facility based therapeutic group; BP: Blood pressure; HbA1c: Glycated Haemoglobin; FFQ: Food frequency questionnaire;

<sup>a</sup>See Addendum 1 for questionnaire, <sup>b</sup>Leisure time and smoking assessment not conducted at six months.

Note: XX indicates that both the FBTG intervention and usual care patients received the assessment or intervention

The six-session FBTG intervention was based on the Western Cape NCD model of care (Addendum C) and was designed to be participatory. According to the model of care, the FBTG intervention should be facilitated by a multi-disciplinary team over six weekly visits, and should be followed by monthly community-based support groups until the follow up assessment at six months. For the purposes of this study, the FBTG programme was coordinated by the hospital dietitian and the six sessions were free of charge. The FBTG sessions were facilitated by a multi-disciplinary team consisting of a dietitian, medical doctor, pharmacist, physiotherapist and nurse. Prior to commencement of the FBTG, the dietitian prepared the six-session curriculum that included education on goal setting, healthy eating, physical activity, behaviour change and adherence, and advice on weight and behaviour maintenance (Table 4.2). A FBTG session ran for a minimum of 60 minutes to a maximum

of 90 minutes, which allowed for  $\pm 30$  minutes of theory and  $\pm 30$  minutes for group discussion or practical tasks. On the day of the session, each patient received a short message service (SMS) to remind them of their scheduled FBTG session. The weekly sessions were held on a weekday afternoon from 2pm to about 3.30pm as the physiotherapist room was available at this time. This time was also convenient for patients who worked part-time.

Dietary education was provided in most sessions (see Table 4.1) by the hospital dietitian using the latest version of the South African Food-Based Dietary Guidelines (Love et al., 2008). The guidelines were tailored for NCD prevention and management with specific emphasis on portion control as well as reduction in fat, sugar and unhealthy convenience foods (Table 4.2). The “5-a-day” guideline for fruit and vegetable intake was also promoted. Three dietary tools were issued to patients during the FBTG that included a dietary list showing healthy and unhealthy foods choices, a flexible meal plan that allowed patients to build their meals using portion-specific foods and an example of a  $\pm 6300$ kJ healthy eating plan.

A flipchart for NCDs, which was developed by psychologists, holistic practitioners and life coaches, was used to address barriers for behaviour change during the FBTG intervention (DOH, 2009). The flip chart addressed issues such as poor goal setting, denial, victim and addictive behaviour, and was used to encourage patients to discuss individual, social and environmental issues that could reduce their ability to change.

The physiotherapist provided two 45-minute sessions on the importance of physical activity. The initial session focused on breathing, pulse rate, fitness and the risks and benefits of exercising with certain NCDs and risk factors such as hypertension and hyperglycaemia. The second session involved a practical session whereby patients were expected to engage in low-level physical activity according to their ability.

During the fifth FBTG session, the pharmacist provided a short talk on medication adherence and details of the chronic dispensing unit (CDU). The CDU service is used for chronic but stable patients who are encouraged to achieve stability in order to benefit from the shorter waiting times at the pharmacy (Du Plessis 2008). The session was also used as an opportunity for patients to ask questions about their prescriptions and discuss their personal tolerance of medications.

The final session of the FBTG focused on the importance of community support groups and maintenance of healthy behaviours and weight loss. The session was either delivered by a registered nurse who had previously worked with diabetic support groups or by a support group coordinator from the local non-governmental organisation (NGO) for the False Bay area. Despite the formal referral of FBTG intervention patients to the community-based NGO and verbal encouragement of patients to attend monthly support groups, the initiation and facilitation of these groups did not occur.

All participants were scheduled for an individual follow-up consultation with the dietitian six months after baseline assessments took place. Follow-up assessments and dietary counselling were done during this consultation. There were no scheduled follow ups for FBTG patients from the end of the six-week FBTG to six-month follow-up assessment.

**Table 4.2 Curriculum for FBTG sessions**

<b>First session</b>
Goal setting module
Introduction of clients and staff. Patients are given an overview of program
Patients set individualized goals with the assistance of dietitian <sup>a</sup>
Nutrition education session: FBDG <sup>b</sup> : Enjoy a variety of foods, Eat plenty of fruit & vegetables
<b>Second session</b>
Relaxation and breathing
Understand, manage and control of NCDs and symptoms
Health risk factors e.g. why are you smoking, not exercising, eating habits <sup>a</sup>
Assist patients to come to terms with current behaviour and to make better decisions to address the challenges
Issue of meal plans according to energy requirements & assessments
Nutrition education session: FBDG <sup>b</sup> : Make starchy foods the basis of most meals, Use less Salt, Use fats sparingly
<b>Third session</b>
Understanding life, diseases and dealing with health challenges <sup>a</sup>
Managing life's challenges and environments <sup>a</sup>
Nutrition education session: FBDG <sup>b</sup> : Use food and drinks containing sugar sparingly and not between meals, drink lots of clean
Education session: Pharmacist: medication adherence counselling
<b>Fourth session</b>
Reframing your perspective on your health <sup>a</sup> , Problem solving and changing habits <sup>a</sup>
Education session: Physiotherapist: FBDG <sup>b</sup> : Be active! Appropriate Exercise for your CDL & Injury prevention
Nutrition education session: FBDG <sup>b</sup> : Eat dry beans, peas, lentils and soya regularly, Chicken, fish, meat, milk or eggs can be
<b>Fifth session</b>
Making permanent lifestyle changes
How to make changes permanent and the importance of self monitoring
Nutrition education session: Summary of FBDG <sup>b</sup> & exercise goals
<b>Sixth session</b>
The importance of patient driven support groups for the management of NCDs and maintenance of weight loss.
<i>Abbreviations:</i> FBDG: Food Based Dietary Guideline; NCDs: Non-communicable diseases; NGO: Non-governmental organisation

<sup>a</sup> The provincial flip Chart for cognitive behaviour therapy was used during this education session, <sup>b</sup>The provincial FBDG Flip Chart: A Guide to Healthy Eating was used during this education session

### ***Usual care***

Usual care was defined as the current routine treatment provided to a patient with NCDs and/or risk factors for NCDs at False Bay Hospital. This includes initial one-on-one consultations with the medical doctor and dietitian. Follow-up appointments are usually scheduled with the medical doctor every six months, while patients attend appointments with the dietitian at their discretion and availability.

### **Measures**

An interviewer administered questionnaire (Addendum 1) developed for the purposes of this study, as well as the hospital database CLINICOM and patients' folders were used to obtain information on socio-demographic variables, weight loss goal, disease status, biochemical measures, BP, smoking status, physical activity levels, dietary intake, stage of change and perceived compliance. During the initial recruitment consultation the hospital dietitian interviewed the patient to complete the questionnaire, and conducted the necessary anthropometric measurements on each patient.

### ***Socio-demographic assessments, weight loss goal and reasons for declining the FBTG intervention***

The socio-demographic characteristics that were collected verbally using the interviewer administered questionnaire included employment status and the number of years of formal education (successful years of schooling, diplomas and certificates). As many patients may not have completed secondary school, but may have completed additional qualifications, the total number of formal years of education were calculated and reported instead of the categorisation of education attainment into primary, secondary and tertiary levels. Information on the race (mixed ancestry, black African, white and asian), gender (male and female), date of birth, family income and residential address of patients, were transferred directly from CLINICOM to the data spread sheet. Family income was classified using the Western Cape provincial categories: H0 for R0.00 or government pension, H1 for R0.00 – R4166.66, H2 for R4166.67 – R8333.33, H3 for > R8333.34, and P for Private medical aid.

All patients were also asked to define their six-month weight loss goal and usual care patients were asked to provide a reason for declining the six-week FBTG intervention using open-ended questions.

### ***Disease status and smoking***

Information on disease status was recorded from the medication prescription chart in the patient's folder. The diagnosis of DM and CVD was confirmed by the medical doctors using the International Classification of Disease codes (ICD-10) (BHF, 2007) and was recorded in the patient's folder. Smoking status was obtained verbally in terms of current smoking status and the number of 'pack years'. Pack years were calculated as the number of years an individual has smoked one packet of cigarettes per day (Klug et al., 2012). For example, if a patient smoked two packets of cigarettes per day for 20 years, he/she would be classified to have 40 'pack years', or if a patient smoked half a packet a day for ten years, he/she would be classified to have five 'pack years'.

### ***Attendance and lost to follow up***

Attendance records for all study patients were recorded on a daily basis. Reasons for non-attendance at dietetic appointments or FBTG intervention sessions were collected by telephonic interview. Patients were considered lost to follow up (LTFU) and non-completers if they did not attend their scheduled six-month assessment at the end of the intervention period. Patients with data for both baseline and six-month collection points were defined as complete cases.

### ***Anthropometric measurements***

Anthropometric data was collected at baseline, throughout the FBTG and at six months on the provincial chronic diseases monitoring form that was kept in the patient's folder (Addendum 2). Measurements were conducted according to the WHO (2008) guidelines and included weight, height and waist circumference using a calibrated electronic scale, stadiometer and non-stretchable measuring tape respectively. All measurements were recorded to the nearest 0.1kg and 0.1cm where applicable. Weight and height were measured in light clothing and without shoes. The height of the patients was obtained by placing their heels together and their back, scapulae and buttocks in contact with the vertical plain of the stadiometer. The patient's head was set in Frankfort plane and hair/head coverings were adjusted in order to ensure accuracy. BMI was calculated as weight in kilograms (kg) divided by the height squared (in meters) and categorised according to the WHO classification for BMI (WHO, 2006) namely 30 – 34.9kg/m<sup>2</sup> as Obese Class I, 35– 39.9 kg/m<sup>2</sup> as Obese Class II, and  $\geq 40$ kg/m<sup>2</sup> as Obese Class III.

Waist circumference was measured midway between the last palpable rib and the top of the hip-bone, after normal expiration using a non-stretchable tape measure (WHO 2008). The

waist circumference measurement was categorised according to the WHO classification as an increased risk for the development of metabolic syndrome and NCDs if >102cm in men and >88cm in women (WHO, 2011a).

### ***Biochemical and clinical measures***

Fasting blood samples and BP measurements were collected by nursing staff in the outpatients department. Missing values were issued for patients who did not attend their scheduled appointment for biochemical and clinical assessments. The blood samples were analysed by the National Health Laboratory Service (NHLS) for glycated haemoglobin (HbA1c) and total cholesterol. HbA1c was only analysed for patients with Type II DM. An automated sphygmomanometer was used to measure the BP of each patient when in a seated position with the cuff above the elbow. The diagnosis of hypercholesterolaemia and high blood pressure was confirmed by the medical doctors using the ICD-10 codes (BHF, 2007) and was recorded in the patient's folder.

### ***Formal physical and leisure time sedentary activity assessment***

The amount of time spent on formal physical activity was recorded as a self-reported estimation of planned, moderate- to high-intensity physical activity on the interviewer questionnaire. Patients were initially asked whether or not they participated in formal physical activity. The number and duration of physical activity sessions per week from weekly or monthly accounts were used to calculate the number of minutes of physical activity per week. Patients were further categorised as inactive (no engagement in physical activity), insufficiently active (some physical activity) and sufficiently active ( $\geq 150$  minutes per week) according to the physical activity categories outlined by Joubert et al., (2007). The number of minutes per day spent watching television was recorded and used as a reflection of leisure time sedentary activity.

### ***Dietary intake assessment***

The aim of the dietary assessment was to determine the number of standard portions consumed per day from indicator food groups. For these purposes, a semi-quantified food frequency questionnaire (FFQ) (Addendum 1) consisting of 54 food items was developed from which 10 indicator food groups were derived (Table 4.3). The food list was developed by an expert panel of registered dietitians using existing FFQ questionnaires that were used to assess dietary intake in patients with DM in Cape Town with a socio-economic status (SES) similar to our study population (Stone, 2010; Seme, 2013). The standard portion

sizes included for each food item were based on the exchange lists (UCT 2010) or the food based dietary guidelines for South Africa (DOH, 2012). The plate model was used to illustrate standard portion sizes to patients. The frequency of intake of the standard portion of each food item was recorded as the number of times the food was consumed per day, week or month. The number of standard portions consumed per day for each food item was calculated by dividing the number of times the patient consumed the standard portion by one if consumed daily, by seven if consumed weekly, and by 28 if consumed monthly. The unit of analysis thus was the number of times a standard portion size of a particular food item was consumed daily. The daily number of standard portions consumed for each food item was then used to calculate the daily number of standard portions consumed from each of the 10 indicator food groups. Patients were additionally asked how many formal meals and snacks they consumed on a daily basis.

**Table 4.3 Indicator food groups derived from 54-item FFQ questionnaire**

<b>Indicator food group</b>	<b>Items included (standard portion size)</b>
<b>Fruit and vegetables</b>	Fresh fruit (1 tennis ball size); starchy vegetables (1/2 cup); cooked vegetables (1/2 cup), salad (1 cup)
<b>High fat foods</b>	Fried potato chips (1 potato); red meat (90g portion); organ meat (90g portion); fried fish (90g portion); fried chicken (90g portion); chicken with the skin (90g portion); pies (1 unit); sausage rolls (1 unit); samosas (1 portion); vetkoek (1 vetkoek); polony (2 slices); eggs (1); cheese (30g); full cream milk (125ml); take-aways (1 meal)
<b>Fats</b>	Brick margarine (1 tsp); butter (1 tsp); lite margarine (1 tsp); oil (1 tsp); olive/canola oil (1 tsp); mayonnaise (1 tsp); peanut butter (1 tsp)
<b>Energy dense snacks</b>	Baked goods (1 piece of cake, biscuits); crisps (1 packet); sweets (1 unit); chocolates
<b>High fibre foods</b>	Brown bread (1 slice); whole wheat/low GI bread (1 slice); legumes (1/2 cup); high fibre cereals (1/2 cup)
<b>Refined CHO foods</b>	White bread (1 slice); maize porridge (1/2 cup); sugar (1 tsp); jam (1 tsp); syrup (1 tsp)
<b>Added sugar</b>	White or brown cane sugar added to food or drink (1 tsp)
<b>High-sugar beverages</b>	Fruit juice (125ml); sugar-containing carbonated drinks (250ml); cordials (250ml)
<b>Healthier, lower fat choices</b>	Lean red meat (90g); poultry without skin/being fried (90g); tinned fish (90g or 1/2 tin); poached/boiled eggs (1); low fat and fat free dairy (125ml); lite margarine (1 tsp); low fat mayonnaise (1 tsp)
<b>Alcohol</b>	One unit: Beer (340ml) or tot of spirits (30ml) or wine (125ml)

*Abbreviations:* CHO: carbohydrate

### ***Stage of change***

To determine the patient's readiness to increase their intake of healthy foods, an adapted version of the 12-item Readiness for Change questionnaire (RCQ) was used (Addendum 1). The original RCQ was developed to determine the stage of change (SOC) in individuals with excessive alcohol intake (Rollnick et al., 1992). This was adapted by Senekal et al. (unpublished) for the purposes of their research to reflect the readiness to consume healthy foods by members of a South African medical scheme. The adapted RCQ aimed to categorise patients in a pre-contemplation, contemplation or action stage. The adapted questionnaire consists of nine statements from which three relate to each stage of change category. The response categories and scoring included -2 "Strongly disagree", -1 "Disagree", 0 "Unsure", +1 "Agree", or +2 "Strongly agree". These scores were added together to calculate a score between -6 to +6 for each stage. The highest of the three scores indicates the stage of change the patient is in. When the scores for two categories were equal, the patient would be classified as being in the higher stage of the two stages (Heather et al. 1993).

The stage of change categories were interpreted as follows: patients in pre-contemplation stage do not demonstrate any intent to change their behaviour; patients in contemplative stage are aware of their problems and present with some inclination to change their behaviour, but are not committed to making active changes; and patients in action stage are in a highly motivated position where they are able to actively change their behaviour, or are already engaging in healthy behaviours (Young, 2010).

### ***Perceived compliance***

An adapted version of the questionnaire developed by Harbron (2011) was used to assess the patient's perceived compliance to the main treatment components namely diet, physical activity, behaviour change and medication adherence during the FBTG and at six months. For each of these treatment components, patients were asked to score themselves out of ten, with zero indicating perceived complete non-compliance and a score of 10 indicating perceived full compliance. Perceived compliance scores were collected at week 2, 3, 4, 5 and 6 in FBTG intervention patients, as well as at six-months in both treatment groups. The mean perceived compliance scores for diet, physical activity, behaviour change and medication adherence were calculated for each component at the end of the six-week FBTG. In addition, a combined score of all four components were calculated at the end of FBTG, and at six months in both intervention groups.

## **Statistical methods**

The primary outcomes of the study were changes in weight and BMI at six months. Secondary outcomes included change in waist circumference, total cholesterol, HbA1c, BP, dietary intake, physical activity, and stage of change. Data was entered into a Microsoft Excel (2007) spread sheet on a day-to-day basis where it was checked and cleaned prior to analysis in STATA 11.0 (Statacorp Lp, 2009). The numerical variables were checked for normality by exploratory analysis using box and whisker plots and Shapiro Wilk tests.

The descriptive analysis involved the calculation of means and standards deviations for numerical data as well as proportions for categorical data. To compare the treatment groups (full baseline sample and completers) at baseline, independent t-tests (normal numerical data) and rank-sum tests (non-normal numerical data) were used for age, education, pack years for smoking, weight, height, BMI, waist circumference, weight loss goal, biochemical levels, BP, physical activity per week, dietary intake and perceived compliance scores. Pearson Chi-squared or Fishers exact tests (if expected frequencies were less than five) were used to compare categorical variables including gender, race, residential area, employment status, income status, presence of NCDs and intermediate risk factors, smoking status, participation in physical activity and levels of physical activity, as well as stage of change. Baseline differences between treatment groups for the total sample were considered as possible confounders. The above-mentioned statistical tests were also used to compare baseline numerical and categorical variables between completers with patients LTFU for age, gender, race, living area, employment, education, family income, weight and BMI (Table 4.5)

To compare treatment groups at the conclusion of the intervention (six months), independent t-tests (normal data) and rank-sum tests (non-normal data) were used for weight, BMI, waist circumference, biochemical levels, BP, physical activity per week, dietary intake and perceived compliance scores. Wilcoxon signed-rank tests were used to assess change over the intervention period within each treatment group for weight, BMI, waist circumferences, biochemical levels, BP, physical activity per week, and dietary intake. The change within treatment groups for all the mentioned variables were compared between treatment groups using independent t-tests (normal data) and rank-sum tests (non-normal data). Pearson Chi-squared or Fishers exact tests were used to compare treatment groups for the following categorical variables: percentage weight loss, participation in physical activity and levels of physical activity, and stage of change at six months. Baseline data for completers only were considered for these analyses.

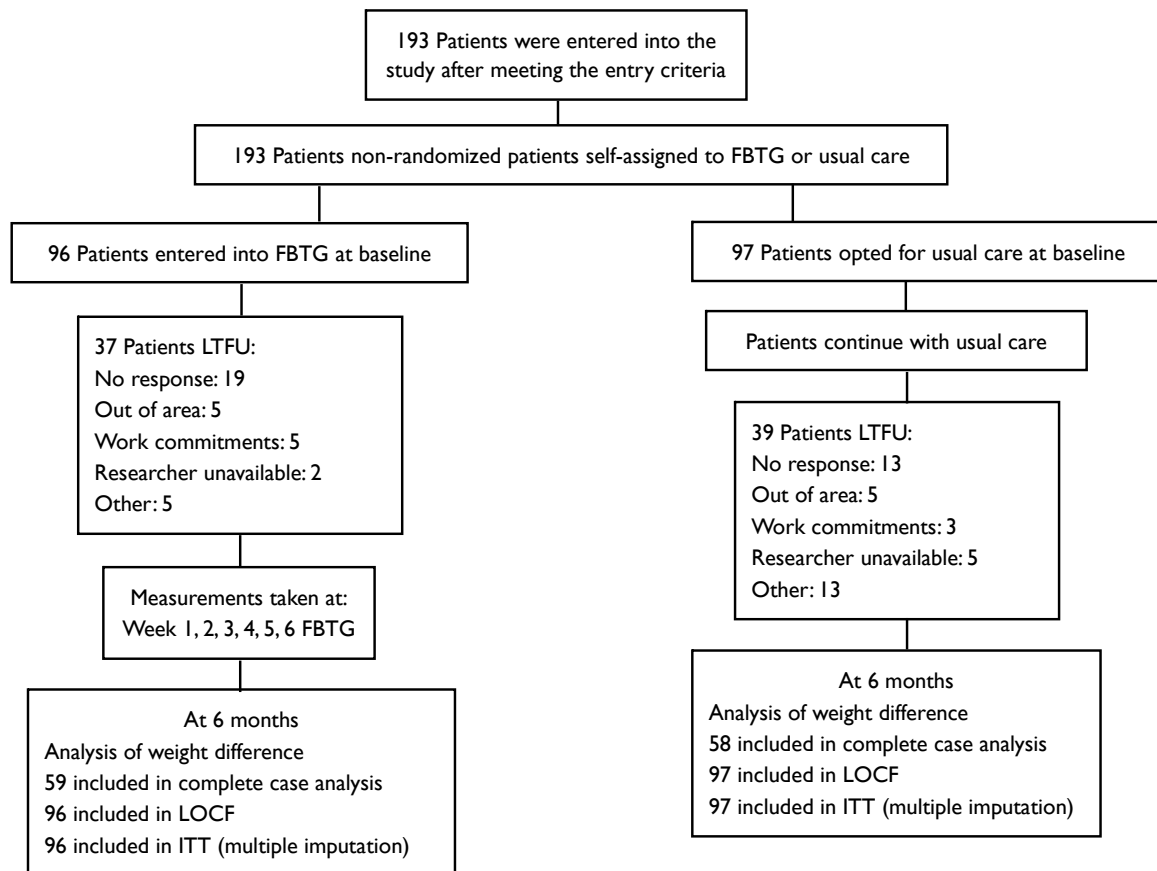
To assess the impact of the intervention on the primary outcome variables (weight and BMI), three methods of data management were used to account for the missing values in accordance with the recommendations made by Altman (2009). Firstly, the analysis of complete cases included only patients who attended their final six-month assessment and hence 'completed' the study, also known as per protocol analysis. Secondly, ITT analysis was applied using imputation by last observation carried forward (LOCF). LOCF was conducted by carrying the last recorded weight and BMI within the intervention period over to the six-month data collection point to include all recruited patients in the analyses. Thirdly, another form of ITT, namely multiple imputation, was applied using the STATA multiple imputation command that predicts the likelihood of the weight and BMI outcomes at six months of patient LTFU using a set of independent variables (Elobeid et al., 2009). The multiple imputation command for our analysis incorporated treatment group, age, race, gender, education and employment as the independent variables. ITT analysis was conducted irrespective of the number of sessions attended by FBTG patients and number of follow up appointments made by usual care patients.

It should be noted that there are caveats within each ITT approach. The analysis of weight change in completers can increase the likelihood of bias, since the characteristics of completers may differ from non-completers (Altman, 2009). A reduced sample size also reduces the study's ability to detect differences between groups and the ITT approach can over- or underestimate weight change in either group. Multiple bias and validity concerns can arise using the LOCF method since the imputed weights do not necessarily reflect the weight the patient would have achieved if they had completed the study. Bearing in mind these limitations, Altman (2009) recommends the use of all three approaches in order to gain an objective interpretation of results.

In order to account for differences found among baseline socio-demographic variables (Table 4.4), the change in weight and BMI over six months in the primary outcome analysis was stratified by living area (Ocean View, Masipumele, Fish Hoek, Simons Town and Muizenburg) and education level (below and above 10 years of formal education) (Table 4.8). As there were no differences between treatment groups for weight change stratified by living area, these results were not presented in a table in the results section. Education was stratified by calculating the median education of the sample, and subsequently both intervention groups were stratified into less than 10 years of education and more than 10 years of education. Weight loss over six months was compared between and within groups, for both educational strata and reported in the results section. All results with a p-value of <0.05 were described as statistically significant.

## RESULTS

Figure 4.1 illustrates the flow of patients through the study, patients lost to follow up (LTFU) and statistical analysis used to account for missing values.



**Figure 4.1 Flow of patients through study from baseline to six months**

**Abbreviations:** FBTG: facility-based therapeutic group; LTFU: lost to follow up; LOCF: Last observation carried forward; ITT: intention-to-treat

There were no significant differences between treatment groups for age, gender, race, employment status, education and income for the full baseline sample (Table 4.4). Black patients tended to choose usual care over the FBTG intervention. There was a significantly lower proportion of patients from Masipumele who accepted the invitation for the FBTG intervention. Patients who accepted the invitation into the FBTG intervention tended to have a higher education level ( $p=0.050$ ). The numbers of patients with NCDs, HBP and high cholesterol were similar between treatment groups. Over half of the sample in both groups had never smoked, and the proportion of current smokers was significantly higher among usual care patients compared to FBTG patients. There was no difference in the number of pack years between groups (Table 4.4).

**Table 4.4 Socio-demographic, disease status, intermediate risk factors and smoking by treatment groups**

	FBTG Intervention (n=96)		Usual care (n=97)		p-value
	n	Value	n	Value	
<b>Age in years</b> , mean (SD)	96	50.3 (13.2)	97	50.4 (12.8)	0.940 <sup>a</sup>
<b>Gender</b> (column %)					
Female	76	79.2	74	76.3	0.631 <sup>b</sup>
Male	20	20.8	23	23.7	
<b>Race</b> (column %)					
Mixed ancestry	52	54.2	43	44.3	0.072 <sup>b</sup>
Black African	17	17.7	31	31.0	
White/Asian	27	28.1	23	23.7	
<b>Residential area</b> (column %)					
Ocean view	28	29.2	26	26.8	0.045 <sup>b</sup>
Masipumele	10	10.4	21	21.7	
Fish Hoek	23	23.0	30	30.9	
Simons Town	11	11.5	4	4.1	
Muizenberg	24	25.0	16	16.5	
<b>Currently employed</b> (% yes)	48	50.0	57	58.8	0.222 <sup>b</sup>
<b>Formal education</b> mean (SD)	95	10.5 (2.8)	96	9.7 (2.6)	0.050 <sup>c</sup>
<b>Family income/month</b> <sup>*</sup> (column %)					
H0: ( R0.00/gov pension)	17	17.7	20	20.6	0.671 <sup>b</sup>
H1: (R0.00 – R4166.66 )	60	62.5	58	59.8	
H2: ( R4166.67 – R8333.33)	14	14.6	10	10.3	
H3: ( > R8333.34	4	4.2	5	5.2	
Private (Medical aid)	1	1.0	4	4.1	
<b>NCDs, biochemical and BP measures</b>					
Diabetes (% yes)	36	37.5	45	46.4	0.268 <sup>b</sup>
Heart disease (% yes)	18	18.8	17	17.5	0.825 <sup>b</sup>
High blood pressure (% yes)	78	81.3	83	85.6	0.420 <sup>b</sup>
High cholestol (% yes)	57	65.5	64	73.6	0.249 <sup>b</sup>
<b>Smoking status</b> (column %)					
Never smoked	58	60.4	55	56.7	0.028 <sup>b</sup>
Current smoker	9	9.4	22	22.7	
Previous smoker	29	30.2	20	20.6	
Smoking (pack years) mean (SD)	38	20.6 (18.7)	42	26.4 (22.1)	0.213 <sup>c</sup>

*Abbreviations:* SD: standard deviation; NCD: non-communicable diseases; BP: blood pressure

<sup>a</sup>Independent t-test (normally distributed data), <sup>b</sup>Chi squared test, <sup>c</sup>Wilcoxin rank-sum test (non-normally distributed data)

\*Note: H0, H1, H2, H3, government classification for monthly income at time of assessment

Individual appointments with the dietitian (inclusive of initial and six-month follow assessments) over the intervention period totalled 1.8±0.9 appointments in FBTG patients

and  $1.6 \pm 0.5$  in usual care patients. There was no difference in attendance between groups ( $p=0.9372$ ). FBTG patients attended an average of  $3.7 \pm 1.7$  FBTG sessions.

A total of 76 patients (38.5% of FBTG group and 40.2% of usual care group) did not attend their final six-month follow-up appointment and thus were LTFU (Table 4.5). Patients that were LTFU were significantly more educated and tended to be younger than completers. There were no other statistically significant differences between completers and those LTFU.

**Table 4.5 Comparison of baseline demographic variables between completers and patients LTFU**

	Completers (n=117)		LTFU (n=76)		p-value
	n	Value	n	Value	
<b>Age (years), mean (SD)</b>	117	51.8 (12.5)	76	48.1 (13.3)	0.053 <sup>a</sup>
<b>Gender (column %)</b>					
Female	87	74.4	63	82.9	0.164 <sup>b</sup>
Male	30	25.6	33	17.1	
<b>Race (column %)</b>					
Mixed ancestry	58	49.6	37	48.7	0.484 <sup>b</sup>
Black	26	22.2	22	29.0	
White/Asian	33	28.2	17	22.3	
<b>Living area (column %)</b>					
Ocean view	32	27.3	22	29.0	0.444 <sup>d</sup>
Masipumele	16	13.7	15	19.7	
Fish Hoek	37	31.7	16	21.1	
Simons Town	10	8.6	5	6.6	
Muizenberg & beyond	22	18.8	18	23.7	
<b>Currently employed (% yes)</b>	62	53.0	43	56.6	0.625 <sup>b</sup>
<b>Education (years), mean (SD)</b>	116	9.7 (3.1)	75	10.7 (1.8)	0.015 <sup>c</sup>
<b>Family income/month* (column %)</b>					
H0: ( R0.00/government pension)	24	20.5	13	17.1	0.451 <sup>d</sup>
H1: (R0.00 – R4166.66 )	74	63.3	44	57.9	
H2: ( R4166.67 – R8333.33)	11	9.4	13	17.1	
H3: ( > R8333.34)	6	5.1	3	3.9	
Private (medical aid rates)	2	1.7	3	4.0	
<b>Weight (kg)</b>					
Baseline mean (SD)	117	101.6 (18.0)	76	103.7 (19.4)	0.455 <sup>c</sup>
<b>BMI (kg/m<sup>2</sup>)</b>					
Baseline mean (SD)	117	38.7 (6.8)	76	40.2 (7.9)	0.221 <sup>c</sup>

*Abbreviations:* LTFU: Lost to follow up; M: mean; SD: standard deviation; BMI: body mass index

<sup>a</sup>Independent t-test (normally distributed data), <sup>b</sup>Chi squared test, <sup>c</sup>Wilcoxin rank-sum (non-normally distributed data), <sup>d</sup>Fisher exact test

\*Note: H0, H1, H2, H3, government classification for monthly income at time of assessment

Table 4.6 lists the documented reasons given by patients for not attending the final assessment. The highest proportion of patients LTFU was recorded as 'no response/non-attendance'. This reason indicates that patients were absent on the day of their scheduled six-month appointment with the dietitian without providing a detailed reason, or could not be reached via telephone, despite attempts to contact them. The other reasons for not attending the final six-month appointment included being out of the area, work commitments, unavailability of the principle investigator and medical problems. Transport problems, time limitations, family commitments and a single death accounted for the rest of the patients LTFU.

**Table 4.6 Reasons for non-attendance at six-month assessment by treatment group**

	FBTG intervention LTFU (n=37)		Usual care LTFU (n=39)	
	n	%	n	%
<b>No response/ non-attendance at six-month assessment</b>	20	54.1	18	46.2
<b>Out of area at time of follow/moved away</b>	5	13.5	5	12.8
<b>Work commitments</b>	5	13.5	3	7.7
<b>Principle investigator unavailable</b>	2	5.4	5	12.8
<b>Medical admission/problem</b>	3	8.1	3	7.7
<b>Other<sup>a</sup></b>	2	5.4	5	12.8

<sup>a</sup> Other reason include: Transport problems (n=3), Time limitations (n=2), Family commitments (n=1), Deceased (n=1)

Baseline and six month weight, BMI, % weight loss and relevant comparisons are presented in Table 4.7. There were no significant differences between the two treatment groups for weight and BMI at baseline and at six months. FBTG patients experienced a significant within-group reduction in weight and BMI over six months, while there tended to be a non-significant reduction in weight and BMI in usual care patients. The weight loss/gain range among FBTG patients was larger than that for usual care patients. The mean % weight loss for both treatment groups was below 5% and tended to be lower in the usual care group. There was no significant difference between treatment groups for percentage weight loss categories and weight gain was evident in both treatment groups. In the FBTG intervention, there was no significant difference ( $p=0.087$ ) in weight loss experienced at six weeks ( $-2.0\pm 2.4\text{kg}$ ) and six months ( $-2.9\pm 5.2\text{kg}$ ). The mean number of sessions attended by patients in the FBTG intervention was  $3.7\pm 1.7$ . The FBTG patients who attended only one group session ( $n=14$ ) gained a mean of  $0.7\pm 5.0\text{kg}$  while patients who attended all six sessions ( $n=16$ ) lost  $4.1\pm 7.0\text{kg}$  over the six months intervention period.

**Table 4.7 Baseline and 6 month follow up height, weight, BMI (primary outcomes) and related variables – change within and comparisons between treatment groups**

Variable	FBTG Intervention		Usual care		p-value
	n	Value	n	Value	
<b>Height (metres)</b>					
Full sample mean (SD)	96	1.62 (0.08)	97	1.61 (0.09)	0.292 <sup>a</sup>
Completers mean (SD)	59	1.62 (0.08)	58	1.62 (0.09)	0.992 <sup>a</sup>
<b>Weight (kg)</b>					
<b>Baseline</b>					
Full sample* mean (SD)	96	101.9 (17.4)	97	103.0 (19.7)	0.863 <sup>b</sup>
Completers** mean (SD)	59	100.4 (16.8)	58	102.8 (19.3)	0.540 <sup>b</sup>
<b>6 months</b>					
Completers mean (SD)	59	97.5 (15.4)	58	101.7 (20.1)	0.304 <sup>b</sup>
Change within groups** mean (SD)	59	-2.9(5.2)	58	-1.2(3.7)	0.041 <sup>b</sup>
Change within groups, p-value**		<0.001 <sup>c</sup>		0.070 <sup>c</sup>	
<b>BMI (kg/m<sup>2</sup>)</b>					
<b>Baseline</b>					
Full sample* mean (SD)	96	38.9 (6.8)	97	39.8 (7.8)	0.591 <sup>b</sup>
Completers** mean (SD)	59	38.3 (6.6)	58	39.2 (7.1)	0.556 <sup>b</sup>
<b>6 months</b>					
Completers** mean (SD)	59	37.2 (6.0)	58	38.7 (7.3)	0.278 <sup>b</sup>
Change within groups** mean (SD)	59	-1.1 (2.0)	58	-0.5 (1.5)	0.043 <sup>b</sup>
Change within groups, p-value**		<0.001 <sup>c</sup>		0.070 <sup>c</sup>	
Change in weight range (kg)	59	-24.0;+9.4	58	-10; +5.8	
<b>% Weight loss mean (SD)</b>	59	2.6 (4.8)	58	1.6 (3.9)	0.061 <sup>b</sup>
<b>% Weight loss category (column %)</b>					
Weight loss > 5% (%)	14	23.7	10	17.2	0.255 <sup>d</sup>
Weight loss 0.1 – 4.9%	29	49.1	24	41.4	
Weight gain	16	27.2	24	41.4	
<b>Baseline weight-loss goal</b>	95	13.6 (7.1)	94	11.8 (7.5)	0.076 <sup>a</sup>

*Abbreviations:* M: mean; SD: standard deviation; BMI: body mass index

<sup>a</sup>Independent t-test applied (normally distributed data), <sup>b</sup>Wilcoxin rank-sum test (non-normally distributed data), <sup>c</sup>Wilcoxin sign-rank (non-normally distributed paired data), <sup>d</sup>Chi squared test

\*Relevant to intention to treat analysis (see Table 4.8), \*\*Relevant to by per protocol analysis (see Table 4.8)

Note: Variance in n due to missing values either at baseline assessment or six-month follow up

Results of the impact analyses for weight loss according to three statistical methods are presented in Table 4.8. The results of the per protocol, LOCF and multiple imputation analyses confirm that FBTG patients achieved significantly greater reductions in weight and BMI over six months compared to usual care patients. Stratification by education level showed that there was no significant difference in weight loss between the two treatment

groups in patients with less than 10 years of education. However, among patients with 10 or more years of education, FBTG patients lost significantly more weight than usual care patients. There was no difference in waist circumference between treatment groups at baseline (Table 4.9). The mean waist circumference in women and men was greater than the recommended cut offs of >102cm in men and >88cm in women (WHO, 2011a). However, at six months mean waist circumference was significantly lower in FBTG patients compared to usual care patients. FBTG patients experienced a significant within-group reduction in waist circumference over the intervention period, which was significantly greater than the non-significant reduction experienced by usual care patients. In the FBTG intervention, there was no significant difference ( $p=0.157$ ) in waist circumference loss experienced at six weeks ( $-2.9\pm 3.0\text{cm}$ ) and six months ( $-3.7\pm 5.2\text{kg}$ ).

Patients in the usual care group had significantly higher HbA1c levels at baseline compared to the FBTG patients, however there was no difference in HbA1c levels between groups at six months (Table 4.9). The usual care patients experienced a significant within-group reduction in HbA1c over six months, which was significantly higher than the non-significant reduction experienced by the FBTG patients. There were no significant differences between treatment groups for total cholesterol at baseline, at six months and change over six months. However, both groups experienced within-group reductions in cholesterol over the intervention period, which was significant for usual care patients and tended to be significant for FBTG patients.

At baseline, FBTG patients had a significantly lower SBP than usual care patients, however there were no differences in DBP between treatment groups (Table 4.9). At six months, FBTG patients had a significantly lower SBP and DBP compared to usual care patients. FBTG patients also experienced significant within-group reductions in both SBP and DBP over six months, while usual care patients achieved a significant reduction in DBP only. However, the mean within-group reductions in SBP and DBP over six months did not differ significantly between treatment groups.

**Table 4.8 Comparison of the impact of the two treatments on the weight and BMI (primary outcomes) in patients using three different statistical methods**

	Complete case analysis (n=117)			ITT: LOCF (n=193)			ITT: Multiple imputation (n=193)		
	Intervention (n=59)	Usual care (n=58)	p-value	Intervention (n=96)	Usual care (n=97)	p-value	Intervention (n=96)	Usual care (n=97)	p-value
<b>Weight (kg)</b>									
Mean change (SD)	-2.9 (5.2)	-1.2 (3.7)	0.041 <sup>a</sup>	-2.2 (4.5)	-1.0 (3.3)	0.011 <sup>a</sup>	-2.8 (4.9)	+0.2 (9.7)	0.002 <sup>a</sup>
<b>BMI (kg/m<sup>2</sup>)</b>									
Mean change (SD)	-1.1 (2.0)	-0.5 (1.5)	0.043 <sup>a</sup>	-0.9 (1.7)	-0.4 (1.3)	0.011 <sup>a</sup>	-1.1 (4.9)	+0.1 (4.0)	0.002 <sup>a</sup>
<b>Weight difference stratified by education*</b>									
<b>Education &lt; 10 years</b>									
Weight (kg) change mean (SD)	-2.3 (4.0) n=22	-1.9 (3.7)** n=23	0.955 <sup>a</sup>	-2.5 (3.8) n=26	-1.8 (3.8) n=34	0.550	-2.9 (4.4) n=26	-1.2 (10.3) n=34	0.325 <sup>a</sup>
<b>Education ≥10 years</b>									
Weight (kg) change mean (SD)	-3.2 (5.8)** n=37 p=0.678 <sup>a</sup>	-0.9 (3.6) n=34 p=0.139 <sup>a</sup>	0.010 <sup>a</sup>	-2.1 (4.7) n=69 p=0.448 <sup>a</sup>	-0.7 (2.8) n=62 p=0.081 <sup>a</sup>	0.007	-2.7 (5.2) n=69 p=0.838 <sup>a</sup>	+0.9 n=62 p=0.174 <sup>a</sup>	0.003 <sup>a</sup>

Abbreviations: ITT: Intention-to-treat; LOCF: last observation carried forward; M: mean; SD: standard deviation; BMI: body mass index

<sup>a</sup>Wilcoxin rank-sum test used for non-normally distributed data.

\*Note: Education tended to be different between the treatment groups at baseline, and thus impact analysis was also conducted stratified by years of education

**Table 4.9 Baseline and six month WC, biochemical and clinical measures – changes within and comparison between treatment groups (completers)**

	FBTG Intervention		Usual care		p-value
	n	Value	n	Value	
<b>Waist circumference (cm)</b>					
Baseline completers mean (SD), women	45	115.2 (12.1)	42	118.7 (13.4)	0.120
Baseline completers mean (SD), men	14	117.9 (10.0)	16	115.9 (8.7)	0.568
6-month mean	59	112.0 (11.6)	57	117.3 (13.1)	0.013 <sup>a</sup>
*Change within groups mean (SD)	59	-3.7 (5.2)	57	-0.6 (4.6)	<0.001 <sup>a</sup>
Change within groups, p-value		<0.001		0.423	
<b>**HbA1c (%), mean (SD)</b>					
Baseline completers mean (SD)	25	8.2 (1.2)	28	9.9 (2.4)	0.005 <sup>b</sup>
6 month					
Completers mean (SD)	20	8.5 (1.6)	28	8.2 (1.6)	0.450 <sup>a</sup>
Change within groups mean (SD)	20	-0.1 (1.3)	28	-1.6 (2.1)	0.034 <sup>a</sup>
Change within groups, p-value		0.933 <sup>c</sup>		<0.001 <sup>c</sup>	0.681 <sup>a</sup>
<b>Total cholesterol (mmol/l)</b>					
Baseline Completers mean (SD)	54	5.4 (1.3)	53	5.5 (1.1)	0.680 <sup>b</sup>
6 month					
Completers mean (SD)	44	5.2 (1.16)	44	5.1 (0.9)	0.816 <sup>b</sup>
Change within groups mean (SD)	41	-0.4 (1.3)	40	-0.5 (1.1)	0.828 <sup>b</sup>
Change within groups, p-value		0.071 <sup>c</sup>		0.012 <sup>c</sup>	
<b>Systolic blood pressure (mmHg)</b>					
Baseline Completers mean (SD)	58	142.2 (20.9)	57	151.6 (21.1)	0.017 <sup>b</sup>
6 month					
Completers mean (SD)	55	136.5 (17.7)	54	146.4 (21.4)	0.006 <sup>a</sup>
Change within groups mean (SD)	55	-6.3 (22.0)	54	-5.5 (21.3)	0.838 <sup>a</sup>
Change within groups, p-value		0.047 <sup>c</sup>		0.063 <sup>c</sup>	
<b>Diastolic blood pressure (mmHg), mean (SD)</b>					
Baseline completers mean (SD)	58	82.5 (10.5)	57	85.7 (12.1)	0.133 <sup>b</sup>
6 month					
Completers mean (SD)	59	78.1 (10.7)	64	82.7 (12.6)	0.033 <sup>b</sup>
Change within groups mean (SD)	58	-5.3 (13.6)	64	-3.5 (14.9)	0.473 <sup>b</sup>
Change within groups, p-value		0.004 <sup>c</sup>		0.036 <sup>c</sup>	

Abbreviations: M: mean; SD: standard deviation; HbA1c: Glycated haemoglobin;

<sup>a</sup> Wilcoxin rank-sum test (non-normally distributed data), <sup>b</sup> Independent t-test applied (normally distributed data), <sup>c</sup> Wilcoxin signed-rank test (non-normally distributed paired data)

\*ANCOVA applied to adjust for baseline values, \*\*Measured patients with DM only

Note: Variance in n due to missing values either at baseline assessment or six-month follow up

Waist circumference cut offs: >102cm in men and >88cm in women (WHO, 2011a)

There was no significant difference between treatment groups at baseline for time spent per week engaging in physical activity (Table 4.10). However, at six months FBTG patients

spent significantly more time per week engaging in physical activity. The FBTG patients experienced a significant within-group increase in time spent per week engaging in physical activity over six months, which was significantly more than the non-significant change experienced by the usual care patients. The majority of patients in both treatment groups were not participating in formal physical activity and were classified as inactive at baseline. However, a significantly greater proportion of FBTG patients indicated that they were participating in formal physical activity at six months ( $p=0.008$ ). Furthermore, significantly more FBTG patients met the recommended target of >150 minutes of formal physical activity per week compared to usual care patients by the end of the intervention period ( $p=0.009$ ).

#### 4.10 Baseline and six month physical activity levels - changes within and comparison between treatment groups (completers)

	FBTG Intervention		Usual care		p-value
	n	Value	n	Value	
Physical activity (minutes/week)					
Baseline completers mean (SD)	58	3.5 (8.9)	58	2.2 (6.8)	0.520 <sup>a</sup>
6 month					
Completers mean (SD)	59	55.0 (89.0)	58	14.0 (46.6)	0.003 <sup>a</sup>
Change within groups mean (SD)	59	+32.3 (99.0)	58	-1.0 (37.6)	0.015 <sup>a</sup>
Change within groups, p-value		0.007 <sup>b</sup>		0.986 <sup>b</sup>	
<b>Participating in physical activity</b>					
Baseline Completers mean (% yes)	10	17.2	8	13.8	0.608 <sup>c</sup>
6 months (% yes)	22	37.3	9	15.5	0.008 <sup>c</sup>
<b>Physical activity level<sup>f</sup></b>					
Inactive completers at baseline (% yes)	48	82.8	50	86.2	
Insufficiently active at baseline (% yes)	6	10.3	7	12.1	
> 150 minutes per week at baseline (% yes)	4	6.9	1	1.7	0.515 <sup>d</sup>
Inactive at 6 months (% yes)	37	62.7	49	84.5	
Insufficiently active at 6 months (% yes)	13	22.0	8	13.8	
> 150 minutes per week at 6 months (% yes)	9	15.3	1	1.72	0.009 <sup>d</sup>

<sup>a</sup> Wilcoxin rank-sum test (non-normally distributed data), <sup>b</sup> Wilcoxin signed-rank test (non-normally distributed paired data), <sup>c</sup> Chi squared test, <sup>d</sup> Fisher exact test

\*Note: Inactive (no physical activity), insufficiently active (>0 to <150 minutes) and sufficiently active ( $\geq 150$  minutes per week) according to the physical activity categories outlined by Joubert et al., (2007). N varies due to missing values either at baseline assessment or six-month follow up. Variance in n due to missing values either at baseline assessment or six-month follow up

The intake of standard portions per day of indicator food groups at baseline and six months, as well as the changes over six months are presented in Table 4.12. At baseline, usual care patients had a significantly higher intake of refined carbohydrates compared to FBTG patients. There were no other significant differences at baseline. At six months, FBTG

patients had a significantly higher intake of vegetables, and consumed significantly, less refined carbohydrates and added sugar compared to usual care patients. Over the six months intervention period, usual care patients significantly increased their intake of fruit, fruit and vegetables combined, low fat foods and significantly reduced their intake of energy-dense snacks, refined carbohydrates and added sugar. FBTG patients significantly increased their intake of vegetables and significantly reduced their intake of high fat foods, fats, energy-dense snacks, refined carbohydrates and added sugar over the intervention period. However, the mean within-group changes in these indicator food groups did not differ significantly between the treatment groups.

There was no significant difference in the number of meals consumed at baseline between the treatment groups (Table 4.12). By six months, both treatment groups presented with a significant within-group increase in the number of meals consumed per day, but these changes were not significantly different between the two treatment groups. There were no significant differences between the treatment groups for number of snacks consumed at baseline, at six months and within-group change over six months. However, the FBTG experienced a significant within-group reduction in the number of snacks consumed each day.

**Table 4.11 Baseline and six month intake from indicator food groups - changes within and comparison between treatment groups (completers)**

	FBTG Intervention		Usual care		p-value
	n	Value	n	Value	
<b>Fruit &amp; vegetables (portions per day)</b>					
Baseline mean(SD)	56	2.6 (1.8)	56	1.8 (1.1)	0.074 <sup>a</sup>
6 months mean(SD)	53	2.8 (1.6)	56	2.6 (1.6)	0.456 <sup>a</sup>
Change over 6 months mean(SD)	51	+0.3 (2.1)	55	+0.7 (1.5)	0.569 <sup>a</sup>
Change within group p-value	51	p=0.197 <sup>b</sup>	55	p=0.006 <sup>b</sup>	
<b>Fruit (portions per day)</b>					
Baseline mean(SD)	56	1.7 (1.6)	56	1.1 (0.8)	0.065 <sup>a</sup>
6 months mean(SD)	53	1.7 (1.4)	56	1.7 (1.2)	0.890 <sup>a</sup>
Change over 6 months mean(SD)	51	+0.0 (1.8)	55	+0.6 (1.2)	0.198 <sup>a</sup>
Change within group p-value	51	p=0.563 <sup>b</sup>	55	p=0.002 <sup>b</sup>	
<b>Vegetables (portions per day)</b>					
Baseline mean(SD)	56	0.9 (0.5)	56	0.8 (0.6)	0.345 <sup>a</sup>
6 months mean(SD)	53	1.1 (0.4)	56	0.9 (0.6)	0.008 <sup>a</sup>
Change over 6 months mean(SD)	51	+0.3 (0.6)	55	+0.1 (0.6)	0.182 <sup>a</sup>
Change within group p-value	51	p=0.003 <sup>b</sup>	55	p=0.065 <sup>b</sup>	
<b>High fat foods (portions per day)</b>					
Baseline mean(SD)	56	1.9 (1.1)	56	2.2 (1.9)	0.986 <sup>a</sup>
6 months mean(SD)	53	1.4 (1.3)	56	1.8 (1.8)	0.349 <sup>a</sup>
Change over 6 months mean(SD)	51	-0.4 (1.2)	55	-0.4 (2.1)	0.904 <sup>a</sup>
Change within group p-value	51	p=0.013 <sup>b</sup>	55	p=0.082 <sup>b</sup>	
<b>Fats (portions per day)</b>					
Baseline mean(SD)	56	4.4 (2.5)	94	4.8 (2.8)	0.420 <sup>a</sup>
6 months mean(SD)	53	3.7 (2.6)	56	4.0 (1.8)	0.287 <sup>a</sup>
Change over 6 months mean(SD)	51	-0.8 (2.4)	55	-0.7 (2.7)	0.892 <sup>a</sup>
Change within group p-value	51	p=0.029 <sup>b</sup>	55	p=0.050 <sup>b</sup>	
<b>Energy dense snacks (portions per day)</b>					
Baseline mean(SD)	56	1.5 (1.9)	56	1.4 (2.4)	0.169 <sup>a</sup>
6 months mean(SD)	53	0.8 (1.0)	56	0.8 (1.8)	0.136 <sup>a</sup>
Change over 6 months mean(SD)	51	-0.9 (2.0)	55	-0.6 (2.5)	0.373 <sup>a</sup>
Change within group p-value	51	p=0.003 <sup>b</sup>	55	p=0.007 <sup>b</sup>	
<b>High fibre foods (portions per day)</b>					
Baseline mean(SD)	56	3.5 (2.9)	56	2.9 (3.2)	0.151 <sup>a</sup>
6 months mean(SD)	53	3.1 (2.2)	56	3.4 (2.8)	0.875 <sup>a</sup>
Change over 6 months mean(SD)	51	-0.7 (1.5)	55	-0.5 (2.1)	0.640 <sup>a</sup>
Change within group p-value	51	0.274 <sup>b</sup>	55	p=0.156 <sup>b</sup>	

Abbreviations: FFQ: food frequency questionnaire; M: mean; SD: standard deviation

<sup>a</sup> Wilcoxin rank-sum test (non-normally distributed data), <sup>b</sup> Wilcoxin signed-rank test (non-normally distributed paired data)

**Table 4.11 continued**

	FBTG Intervention		Usual care		p-value
	n	Value	n	Value	
<b>Refined CHO foods (portions per day)</b>					
Baseline mean(SD)	56	8.3 (7.1)	56	12.7 (13.7)	0.006 <sup>a</sup>
6 months mean(SD)	53	4.5 (3.3)	56	7.8 (6.8)	0.008 <sup>a</sup>
Change over 6 months mean(SD)	52	-4.1 (7.1)	56	-5.3 (11.8)	0.573 <sup>a</sup>
Change within group p-value	52	p=0.000 <sup>b</sup>	56	p>0.001 <sup>b</sup>	
<b>Added sugar (teaspoons per day)</b>					
Baseline mean(SD)	56	3.6 (5.2)	56	6.6 (12.2)	0.058 <sup>a</sup>
6 months mean(SD)	53	1.3 (2.2)	56	3.3 (4.8)	0.006 <sup>a</sup>
Change over 6 months mean(SD)	51	-2.3 (4.9)	55	-3.5 (11.1)	0.825 <sup>a</sup>
Change within group p-value	51	p=0.004 <sup>b</sup>	55	p=0.002 <sup>b</sup>	
<b>High-sugar beverages (portions per day)</b>					
Baseline mean(SD)	56	1.1 (1.9)	56	1.1 (2.1)	0.790 <sup>a</sup>
6 months mean(SD)	54	0.7 (1.3)	56	0.9 (1.6)	0.857 <sup>a</sup>
Change over 6 months mean(SD)	53	-0.4 (2.0)	55	-0.2 (1.9)	0.841 <sup>a</sup>
Change within group, p-value	53	p=0.127 <sup>b</sup>	55	p=0.073 <sup>b</sup>	
<b>Alcohol (units per day)</b>					
Baseline mean(SD)	56	0.2 (0.8)	94	0.1 (0.5)	0.407 <sup>a</sup>
6 months mean(SD)	53	0.2 (0.6)	56	0.1 (0.3)	0.489 <sup>a</sup>
Change over 6 months mean(SD)	52	-0.0 (0.3)	55	-0.0 (0.2)	0.441 <sup>a</sup>
Change within group, p-value	52	p=0.382 <sup>b</sup>	55	p=0.833 <sup>b</sup>	
<b>Low fat choices (portions per day)</b>					
Baseline mean(SD)	56	2.6 (1.9)	94	2.4 (2.2)	0.299 <sup>a</sup>
6 months mean(SD)	54	3.0 (2.0)	58	2.7(1.91)	0.604 <sup>a</sup>
Change over 6 months mean(SD)	53	+0.3 (2.5)	55	+0.5 (2.7)	0.492 <sup>a</sup>
Change within group, p-value	53	p=0.201 <sup>b</sup>	55	p=0.037 <sup>b</sup>	
<b>No. of meals per day</b>					
Baseline mean(SD)	56	2.6 (1.9)	94	2.5 (0.6)	0.750 <sup>a</sup>
6 months mean(SD)	53	2.7 (0.5)	56	2.7 (0.5)	0.725 <sup>a</sup>
Change over 6 months mean(SD)	51	0.2 (0.6)	55	0.2 (0.7)	0.975 <sup>a</sup>
Change within group, p-value	51	p=0.010 <sup>b</sup>	55	p=0.002 <sup>b</sup>	
<b>No. of snacks per day</b>					
Baseline mean(SD)	56	1.4 (1.2)	94	1.1 (1.1)	0.148 <sup>a</sup>
6 months mean(SD)	53	0.9 (1.0)	56	0.8 (0.8)	0.652 <sup>a</sup>
Change over 6 months mean(SD)	51	-0.5 (1.5)	55	-0.2 (1.4)	0.447 <sup>a</sup>
Change within group, p-value	51	p=0.044 <sup>b</sup>	55	p=0.226 <sup>b</sup>	

Abbreviations: FFQ: food frequency questionnaire; M: mean; SD: standard deviation, CHO: carbohydrate

<sup>a</sup> Wilcoxin rank-sum test (non-normally distributed data), <sup>b</sup> Wilcoxin signed-rank test (non-normally distributed paired data)

Note: N varies due to missing values either at baseline assessment or six-month follow up

There was no significant difference in stage of change between groups at baseline (Table 4.12). By six months, significantly more FBTG patients were in the action stage and less were in the contemplation stage compared to usual care patients.

**Table 4.12 Baseline and 6 month stage of change\* between treatment groups (completers)**

	FBTG Intervention		Usual care		p-value
	n	%	n	%	
<b>Stage of change</b>					
<b>Pre-contemplation stage</b>					
Baseline (% yes)	0	0.0	1	1.8	
6 months (% yes)	0	0.0	0	0.0	
<b>Contemplation stage</b>					
Baseline (% yes)	40	69.0	38	66.7	
6 months (%yes)	14	25.5	28	50.9	
<b>Action stage</b>					
Baseline (%yes)	18	31.0	18	31.6	0.920 <sup>a</sup>
6 months (%yes)	41	74.5	27	49.1	0.010 <sup>b</sup>

<sup>a</sup> Fishers exact test, <sup>b</sup> Chi squared test

\*Note: See Addendum 1 for stage of change questionnaires

N varies due to missing values either at baseline assessment or six-month follow up

Perceived compliance scores for diet, exercise and medication did not differ between groups at six months (Table 4.13). However, perceived compliance to behavioural aspects was significantly higher for FBTG than usual care patients over the intervention period. The lowest self-reported perceived compliance scores were for diet and exercise in both treatment groups. Both groups reported that their adherence to medication was very good over the intervention period.

**Table 4.13 Perceived compliance scores\* for total sample and by treatment group**

Perceived compliance score at six months	FBTG Intervention		Usual care		p-value
	n	Score out of 10	n	Score out of 10	
Diet, mean (SD)	53	6.2 (3.4)	54	5.8 (1.6)	0.222 <sup>a</sup>
Exercise, mean (SD)	53	5.1 (2.2)	54	4.9 (2.0)	0.531 <sup>a</sup>
Behaviour change, mean (SD)	53	7.4 (1.9)	53	6.3 (2.0)	0.004 <sup>b</sup>
Medication, mean (SD)	53	9.1 (1.4)	53	9.1 (1.4)	0.946 <sup>b</sup>
Total perceived compliance score, mean (SD)	53	27.9 (4.2)	53	26.0 (4.8)	0.065 <sup>a</sup>

*Abbreviations:* SD: standard deviation

<sup>a</sup> Independent t-tests applied, <sup>b</sup> Wilcoxin rank-sum test used for non-normally distributed data

\*Note: See Addendum 1 for perceived compliance questionnaire

N varies due to missing values either at baseline assessment or six-month follow up

Perceived compliance to diet, physical activity, behaviour change and medication was not significantly different in FBTG patients between the end of the six-week programme (intensive phase) and six-month follow-up (Table 4.14).

**Table 4.14 Perceived compliance scores at six-week FBTG intervention**

Mean compliance score	Week 2 n=72	Week 3 n=59	Week 4 n=51	Week 5 n=41	Week 6 n=43	Average FBTG <sup>b</sup>	6 months n=58 <sup>c</sup>	Difference between b and c (p-value)
Diet, mean (SD)	6.4 (1.5)	6.3 (1.9)	6.6 (1.8)	7.2 (1.6)	7.3 (1.6)	6.6 (1.4)	6.2 (1.8)	p=0.107 <sup>a</sup>
Physical activity, mean (SD)	5.0 (2.1)	5.0 (2.0)	5.6 (2.1)	5.4 (2.1)	5.9 (2.1)	5.2 (1.7)	5.1 (2.2)	p=0.350 <sup>a</sup>
Behaviour change, mean (SD)	7.8 (1.6)	7.4 (1.8)	8.0 (1.6)	7.7 (1.9)	8.5 (1.4)	7.8 (2.0)	7.4 (1.9)	p=0.245 <sup>a</sup>
Medication usage, mean (SD)	9.3 (1.5)	9.2 (1.5)	9.5 (1.4)	9.6 (1.3)	9.6 (1.3)	9.4 (1.4)	9.1 (1.4)	p=0.453 <sup>a</sup>

*Abbreviations:* M: mean; SD: standard deviation

<sup>a</sup> Wilcoxin signed-rank test for paired data, <sup>b</sup> Average perceived compliance score weeks 2 to 6, <sup>c</sup> Perceived compliance score at six months

Note: See Addendum 1 for perceived compliance questionnaires

## DISCUSSION

The results of this study show that patients who received a dietitian-led FBTG intervention at a district government hospital experienced greater weight losses (primary outcome) and improvements in several secondary outcomes compared to patients who received usual care. Although the mean weight reduction of 2.9kg (BMI  $-1.1\text{kg}/\text{m}^2$ ) in the FBTG over the six-month intervention period may be considered modest, it is within the range of  $-1.3$  to  $-8.2\text{kg}$  reported in a systematic review on interventions for NCDs of approximately six-month duration (Gallagher et al., 2013). Furthermore, it is slightly more than the  $-2.08\text{kg}$  reported in a meta-analysis of weight loss interventions for patients with DM (Steinsbekk et al., 2012), slightly less than the  $-3.5\text{kg}$  found in a meta-analysis of behavioural weight loss programmes for obese minority ethnic groups (Seo & Sa, 2008) and the  $-3.7\text{kg}$  in a weight loss intervention for low income women (Samuel-Hodge et al., 2009).

The FBTG experienced a 2.6% mean weight loss over six months with 23.7% of patients achieving  $\geq 5\%$  weight loss that is recommended to induce clinical meaningful reductions in intermediate risk factors for NCDs, and NCDs such as DM and CVD (Wing et al., 2011). The mean percentage weight loss achieved in our study was considerably less than the 8.5% (Anderson et al., 2004) and 5% to 9% (Franz et al., 2007) reported in meta-analyses for weight loss interventions of six months duration. However, it is important to note that the outcomes reported in some of the above-mentioned efficacy trials are likely to be greater than the results achieved in our study, since most studies employed a more intensive intervention approach. For example, the DPP provides 16 therapeutic education sessions over a six-month period (Kramer et al., 2009). Furthermore, in a review on lifestyle programme components, it has been recommended that regular sessions should be provided for at least four to six months by trained facilitators in order to induce  $>5\%$  weight loss (Venditti & Kramer 2012). Thus it is important to note that the DPP's provision of sessions is over twice as many as our FBTG, while the recommended duration for lifestyle interventions is three times longer than our six-week programme. Our findings also appear to support regular programme exposure since it was observed that FBTG patients that attended all six sessions lost approximately 4kg, compared to patients who attended one session who experienced a small increase in weight.

It has been acknowledged that the majority of weight loss occurs in the most intensive phase of an intervention (Kirk et al, 2012; Franz et al, 2007). Typically, weight loss of 0.5 to 1.0kg per week is recommended during the intensive phase of interventions and requires an

energy deficit of 500kcal (2090kJ) to 1000kcal (4185kJ) per day (Laddu et al., 2011; Seagle et al., 2009). In our study, FBTG patients achieved an average of 0.5kg weight loss per week (2.7kg over six weeks) during the six week intensive FBTG phase and were able to maintain this loss over the period between the end of the FBTG programme and six month follow up. This is a positive outcome since patients can revert back to their original weight in the absence of support and reinforcement (Turk et al., 2009). However, the finding may also be interpreted as a lack of progress during the period, which could be reflected by the non-significant decreases in perceived compliance scores for diet, physical activity, and behaviour change. Therefore, it could be speculated that the motivation of FBTG patients to continue losing weight and maintain full compliance may have weakened because of the absence of frequent contact and support. It has been widely recommended in the literature that maintaining contact and support post-intervention for at least 12 months is necessary to prevent weight regain and sustain behaviour change (Kirk et al., 2012; Venditti & Kramer 2012; Turk et al., 2009; Tangney et al., 2005).

It should also be noted that the roll out of community-based support groups (as per NCD model of care in addendum 3) did not take place. This was despite formal referral of all patients who attended the FBTG intervention treatment to the non-governmental organisation (NGO) that was nominated to provide this support over the 18 weeks before the six month follow-up assessments. The reasons for the unsuccessful roll out of the community-based support group are not clear. We posit that had this component been in place, the impact of the FBTG intervention may have been greater. Investigation of barriers that contributed to this situation is thus recommended in future research.

The large range of weight losses experienced in the FBTG is a matter of concern. The range of a reduction of 24.0kg to an increase of 9.3kg could indicate a significant variation in response among patients attending the FBTG intervention. It is known that individual weight loss depends on many factors such as initial BMI, weight loss history, age, the level and intensity of lifestyle counselling, energy deficits, length of the intervention (Finkler et al., 2012) and readiness for change (Sutton et al., 2003). Although it was beyond the scope of this research to investigate the predictors of weight loss, further research is warranted to improve the interpretation of these findings.

There were equal numbers of patients from the two treatment groups who did not complete the study and the LTFU of 39% is within the range of 10 to 80% reported in other weight loss intervention studies (Moroshko et al., 2011). However, it is still a concern for study investigators when a large number of patients drop out of a study since it may reduce the validity of the results and increase the challenge of managing missing data. At this point, the

available literature from developed countries indicates that the causes of LTFU in weight loss interventions can be related to the individual, the intervention received, psychosocial variables, or practical difficulties (Moroshko et al., 2011). Although the reasons for LTFU could not be obtained in around half of our sample, being out of area, work commitments and lack of availability of the principle investigator, were some of the practical difficulties experienced in this study. Furthermore, our analysis of complete cases versus those LTFU did indicate that patients who were more educated and tended to be younger were more likely to be LTFU. The finding on age is supported by many studies (Moroshko et al., 2011; Groeneveld et al., 2009; Bautista-Castaño et al., 2004; Heshka et al., 2003; Honas et al., 2003), however the higher education levels in non-completers is in contrast to what has previously been reported (Moroshko et al., 2011). It could be speculated that more educated patients in this sample felt they had the ability to manage their own diet and apply lifestyle changes, or had found the level of the FBTG intervention too basic. It is also worth considering that the socio-demographic characteristics of South African patients may affect attrition rates differently to those experienced in developed countries.

There appears to be a lack of standardised guidelines for the management of missing data in experimental studies, as well as guidance on the appropriate use of ITT analysis (Elobeid et al., 2009). In a survey of weight loss RCTs by Elobeid et al., (2009), the majority of studies employed per protocol analyses (complete cases only) or LOCF. The problem with these two methods is the strong likelihood of bias when reporting results for patients who were adherent to the study protocol (per protocol analysis), and reporting imputed data based on assumption (LOCF) (Elobeid et al., 2009; Altman 2009). Both Altman (2009) and Elobeid et al., (2009) recommend that complete case analysis and LOCF be reported with more sophisticated methods of ITT such as mixed models and multiple imputation. Thus, the conclusion made is strengthened if all three ITT results provide the same outcome. While our study did not employ a RCT design, the experimental nature and large number of patients LTFU still warranted ITT analyses. The weight difference in the complete cases, imputation with LOCF, and software generated multiple imputation all showed that intervention patients were able to significantly reduce weight and BMI compared to usual care patients.

It is also important to note that our findings show that education level may moderate the impact of the FBTG intervention, with weight loss significantly higher in the FBTG when comparing those with education  $\geq 10$  years. However, for patients with less than 10 years education there was no difference in weight loss between FBTG and usual care patients. We speculate that a higher education level may have improved engagement in the FBTG

intervention and self-application of therapeutic education. Thus the FBTG intervention may only result in better weight loss outcomes than usual care in those with a higher level of education.

The significant difference in weight loss between the treatment groups is reflected in the significantly higher reduction in waist circumference in the FBTG compared to the usual care group (-3.7cm versus -0.6cm respectively). The reductions experienced by FBTG patients are comparable with the 2.5cm (Moore et al., 2011), 3.1cm (Chan et al., 2007) and 4.6cm (Ash et al., 2006) reductions in waist circumferences found in other interventions of similar duration. A reduction in central adiposity may result in lower risk of metabolic problems and NCDs such as DM and CVD (WHO 2011a). However, as the mean waist circumference of both treatment groups (112cm in FBTG and 117cm in usual care) was still above the recommended cut off of <88cm for women and <102cm for men (WHO, 2011a) after the intervention period, this finding may have little clinical significance.

In this study, the mean weight loss goals over the intervention period for FBTG and usual care patients were 13.6kg and 11.8kg respectively, and can be interpreted as approximately 0.5kg per week in both groups. Despite being in line with the recommended weight loss per week (Seagle et al., 2009), many patients seemed to have overestimated their ability to achieve these goals. Evidence suggests that an overestimation of weight loss goals may either increase self-determination, or alternatively may be counterintuitive by causing disappointment and withdrawal from interventions as patients perceive this as a lack of progress (Crawford & Glover 2012; Elfhag & Rössner, 2005). In our study, goal setting was addressed in the FBTG, however deeper consultation with patients may be needed to address realistic weight outcomes that are aligned with patient's motives to lose weight, in order to prevent possible programme withdrawal or personal dissatisfaction with progress.

Usual care patients had poorer glycaemic control at baseline compared to FBTG patients, however were able to significantly reduce HbA1c and cholesterol over the intervention period. Despite the significant weight loss, reduction in waist circumference girth and increases in physical activity, FBTG patients did not experience a significant change in either biochemical measure. However, it should be noted that the biochemical results from our research must be interpreted with caution since only two thirds of the HbA1c results and half of the cholesterol results in both groups could be obtained at six months. Therefore, the small sample size at six months may limit the ability to detect true changes over the intervention period. The collection of biochemical data was challenging in the PHC setting as patients were reluctant to make additional visits to the hospital for their fasting HbA1c or

cholesterol measurements. It could also be argued that the differences in compliance with pharmacological treatment may explain the findings for HbA1c and total cholesterol. However, this is not supported by the results for perceived compliance with pharmacological treatment, which was around 9 out of 10 for both groups.

Blood pressure measurements were easier to acquire therefore a greater number of measures were available for analysis. The lack of significant difference in improvement in BP between treatment groups is also not in line with expectations, as both weight loss and increased physical activity are known to reduce BP (Frisoli et al., 2011). Frisoli et al., (2011) reported that weight loss induces a -2mmHg/-1mmHg in BP for every kilogram lost, physical activity induces -5mmHg in BP if sufficiently active, and sodium restriction can induce a -4 to -7mmHg reduction in BP. The fact that weight loss was less than the 5%, which is associated with clinical benefits, may also explain the lack of difference in effect in BP.

Patients in this sample were encouraged to engage in physical activity for the reduction in risk factors for NCDs, to assist with management of established NCDs and to create an energy deficit for weight loss. Physical activity was also promoted as a method to reduce central adiposity since combined diet and physical activity are considered more effective for reducing waist adiposity than a single lifestyle change (Laddu et al., 2011). Our results indicate that the FBTG intervention was effective in increasing the physical activity levels of FBTG patients from 26.1 to 55.0 minutes per week over the intervention period, while no changes were evident in the usual care group. This difference is not reflected in the perceived compliance score for physical activity that was approximately 5 out of 10 for both groups. Although the FBTG intervention were able to nearly double their weekly physical activity levels and increase their participation in formal physical activity over the intervention period, these results are still well below the recommended 150 minutes per week for adults aged 18-64 years (WHO 2011b). Approximately 15.3% of FBTG patients and 1.72% of usual care patients were able to reach this level of physical activity over the intervention period. In addition, our sample was considerably less active at baseline and 6 months when compared to the national prevalence of physical inactivity for men (36%) and women (27%) who are sufficiently active (Kolbe-Alexander et al., 2012). It should also be borne in mind that even higher physical activity levels (300 minutes per week) are required to prevent weight gain and acquire additional health benefits (WHO 2011b; Seagle et al., 2009). The most recent SEMDSA guidelines for obese patients with diabetes also advocate 225-420 minutes of moderate-intensity physical activity per week in order to facilitate weight loss in overweight patients (SEMDSA 2012). Overall, it appears that a large dose of physical activity is required to elicit an energy deficit, increase metabolism and promote weight loss

(Gourlan et al., 2011; Laddu et al., 2011), yet patients have difficulties reaching the recommended targets.

It is possible that the improvements observed in FBTG patients were a direct result of the physiotherapist's involvement in the six-week FBTG intervention together with the additional motivation and behavioural strategies provided throughout the programme. The two sessions by the physiotherapist were designed to be practical and specific exercises were encouraged in patients with NCDs. Since intervention dosage is strongly associated with weight loss, it is probable that a higher dosage of physical activity education or supervised intervention is required to assist patients with increasing their weekly physical activity to a minimum of 150 minutes per week. In a meta-analysis of physical activity interventions for obese individuals by Gourlan et al., (2011), it was reported that 37 sessions was strongly associated with increased physical activity levels. This level of input is far beyond what could possibly be achieved in our FBTG intervention or at a PHC facility, however it does shed light on the need to define the number of sessions required to produce clinically meaningful increases in physical activity. Furthermore, it has also been indicated that 'advice only' interventions for physical activity do not seem to be adequate when compared to structured and prescribed physical activity (Umpierre et al., 2011; Dombrowski et al., 2010). It should also be borne in mind that underlying causes of low levels of physical activity in urban communities namely crime, lack of green recreational space and reduction in occupational and transport-related physical activity (Peltzer & Phaswana-Mafuya 2012) may have discouraged study patients from participating in regular activity. Nevertheless, the dosage and type of advice on physical activity provided during the FBTG far exceeds the advice that patients usually receive during one-to-one consultations with dietitians, medical doctors or other health professionals at PHC level.

The study also demonstrated that food choices made by patients seem to be in line with dietary patterns commonly seen in South African urban groups (Stern et al., 2010). Usual care patients improved their intake of fruit, fruit and vegetables combined and low fat foods, while reducing energy-dense snacks, refined carbohydrates and added sugar. FBTG patients increased their consumption of vegetables and decreased refined carbohydrates, added sugar, high fat foods, fats and energy-dense snacks intake over six months. Overall, both groups seemed to have benefitted from exposure to the interventions in terms of improvement in food choices. This could be attributed to the improvements in knowledge and self-efficacy gained through either intervention. The dietary results were also reflected by the similar scores reported for perceived compliance to diet by both groups at six months. However, it is interesting to note that these perceived compliance scores for diet was only

approximately 6 out of 10 in both groups at the end of the intervention period. Furthermore, FBTG patients had a significantly higher perceived compliance score for diet at six weeks compared to six months. These results indicate that FBTG patients were probably more compliant to diet during the intensive phase than the period between the FBTG programme and six month follow up.

Despite the modest differences between groups for the within-group dietary changes, several interesting observations were made. At six months, the FBTG patients were consuming significantly less sugar per day (approximately one teaspoon) compared to usual care patients who consumed approximately three teaspoons per day. This finding excludes sugar intake from sucrose, fructose and glucose found in high sugar beverages, sugar-containing snacks and spreads. Furthermore, the FBTG patients were consuming approximately 175ml high-sugar drinks daily, while usual care patients consumed approximately 225ml per day. The amount of added sugar and high-sugar beverages consumed by South African adults has not yet been established. However our results are in line with the United States population who consume an average of 170ml of sugar-sweetened beverages per day (Bleich et al., 2009). Unfortunately, this dietary habit is associated with increased risk of DM, metabolic syndrome and heart disease, specifically when one to two high-sugar beverages are consumed per day (Steyn & Temple 2012).

An improvement in fruit and vegetable intake over the intervention period was evident in both groups. As the usual care group significantly increased their fruit intake and the FBTG significantly increased their vegetable intake, both groups reached similar levels of intake of fruit and vegetables combined at six months. Usual care and FBTG patients reported consuming an average of 2.6 and 2.8 portions of fruit and vegetables per day respectively at six months. This intake is comparable to the available evidence on daily fruit and vegetable intake in South Africans (Schneider et al., 2007), yet is well below the 5 to 9-a-day that is recommended by various international and national organisations such as the World Health Organisation (WHO 2004), American Heart Association (AHA) (Lichtenstein et al., 2006), SAHS (Seedat et al., 2011) and the food-based dietary guidelines for South Africa (DOH 2012).

It can be argued that some of the food-based dietary guidelines may have been difficult to implement by some patients. This point is supported by the conclusions made by Love et al., (2008) that showed that some South African population groups consider fruit and vegetables as the most costly items to include regularly in a healthy diet. Moreover, Temple & Steyn (2011) estimated that an additional R1090.00 per month would be required to cover

the costs of healthier food items for a family of five. This amount is probably not achievable for the majority of patients in this sample who relied on a family income less than R4166.66 per month. Another possible reason for poor dietary choices that was also highlighted by Love et al., (2008), is that cultural and personal preferences for high fat and high salt foods often displace fruit and vegetables. Therefore, it is a challenge for health professionals to advise patients to consume healthier, more costly, and less palatable foods over possibly less expensive, preferred foods. With these difficulties in mind, perhaps the primary focus for dietary interventions for low-income obese patients with NCDs should remain on reducing unhealthy foods and engage in healthy eating behaviours that do not incur additional cost such as removing excess fat from animal protein, reducing added sugar to a minimum and reducing portion sizes. For example, the usual care group was consuming an average of 1.5 servings (1 serving = 250ml) of high-sugar beverages per day at baseline. The cost of a 330ml bottle soft drink is approximately R8.00 (pricecheck.co.za). Informal communities often sell large bags of fruit (5-10 portions) and reasonable priced vegetables for R5.00 to R10.00 per bag. Therefore, advising patients to reduce their high-sugar beverages, energy-dense snack consumption, cigarettes and alcohol may allow for a greater contribution to healthier food items such as fruit, vegetables and legumes. These practical examples were emphasised and reinforced in the dietary advice delivered by the dietitian in FBTG sessions since there was ample time to do so. Yet, the effect of individual and intervention-based dietary advice may remain impractical if South African governmental departments do not intensify population-scale interventions that reduce cost of healthy foods.

The majority of patients in both groups were in 'contemplation stage' at baseline, indicating that they may not have been ready to commit to actively changing their diet and increasing their physical activity. It was evident that at six months, a greater number of FBTG patients were in the action stage, while less usual care patients seemed to have moved to the action stage. Furthermore, the fact that the perceived compliance score for behaviour change was significantly higher in FBTG than in the usual care group, supports this possibility. It could thus be argued that the FBTG intervention contributed towards increasing patients' readiness for change to actively improve their lifestyle. It has been suggested that additional psychological or behavioural interventions may be necessary in resistant patients, especially prior to intensive lifestyle interventions (Rao et al., 2011; Hickson et al., 2009). Young (2011) argues that 'no person is completely without motivation' and it is important to apply techniques such as motivational interviewing within a supportive and empathetic environment to allow patients to shift forward through the stages of change. Many of the motivational interviewing strategies such as open-ended questions, reflective listening, and

affirmations were employed in the FBTG session discussions, however these are unlikely to be applied in busy PHC settings by doctors and dietitians during one-on-one consultations. Despite the comments by Young (2010), the experience gained in this study and in studies by Hickson et al., (2009) and Huisman et al., (2009) suggest that the time and resources used for more intensive interventions such as FBTG interventions should be prioritised for patients who are ready to change, whereas patients with low goal ownership and low motivation to change should first receive additional behavioural interventions. This may also reduce rates of drop out of poorly motivated patients who enter into lifestyle interventions, yet are not ready to change lifestyle practices. Because behavioural components namely problem-solving, autonomous goal setting, and peer support are essential for improving and interpreting patient outcomes (Baker et al., 2011; LeBlanc 2011; Glanz & Bishop 2010; Spahn et al., 2010), they should be firmly incorporated into intervention designs.

We acknowledge the limitations of our study such as the use of a convenience sample and the non-randomisation of patients, since this approach can contribute to systematic bias as those who volunteered for the FBTG program were possibly more motivated, which could have overestimated the effect of the intervention. A second limitation is the number of patients LTFU, which reduced the sample size and subsequently the power of the study to reliably detect differences between the FBTG intervention and usual care patients at six months. A third limitation is that not all cholesterol and HBA1c measures were collected at six months therefore the sample size was less than expected. Finally, the information obtained on self-reported dietary intake, physical activity, and behavioural measures should be interpreted with caution. This was a particular matter of concern in the measurement of dietary intake as it is possible that patients provided a subjective report that is more representative of 'ideal' intake, rather than actual intake.

## CONCLUSION

This study was able to show that a group-based lifestyle programme implemented at a PHC hospital is superior to the current usual care for obese patients with NCDs or risk factors for NCDs. Patients who attended the FBTG intervention showed significant improvements in weight, BMI, waist circumference, blood pressure, physical activity, and behavioural components such as an increase in readiness for change and perceived compliance to behaviour change. Usual care patients also experienced non-significant reductions in weight, waist circumference, yet a greater proportion gained weight over the intervention compared to the FBTG. Usual care patients also experienced reductions in HbA1c, cholesterol and BP. Both groups made improvements in food choices, however the perceived compliance scores for diet remained around 6 out of 10 over the intervention period.

It appears that patients may require considerably more input and therapeutic education than currently perceived. This is because our FBTG patients only attended around four sessions out of a possible six, which may have been insufficient to induce clinically meaningful changes in weight, waist circumference, biochemical measures, diet, physical activity, behaviour change and compliance.

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## **Chapter 5**

### **OVERVIEW, FINAL CONCLUSIONS AND RECOMMENDATIONS**

## OVERVIEW OF FINDINGS

South Africa is at a critical stage in its economic development, but the burden from non-communicable diseases (NCDs) and obesity are set to immobilise a large proportion of the working-aged population (Bradshaw et al., 2011; Levitt et al., 2011; Mayosi et al., 2009). Even though the HIV/AIDS epidemic is ranked the number one cause of premature death in South Africa, NCDs are predicted to supersede its position in the coming decades (Levitt et al., 2011). Both international (WHO, 2013; WHO, 2009) and national policy-makers (Singh, 2011; Mayosi et al., 2009) have called for urgent prioritisation of NCDs. In South Africa, it has been suggested that the considerable attention and robust interventions used to manage the HIV/AIDS epidemics should be applied similarly to NCDs (Levitt et al., 2011).

Therapeutic health education targeted at the individual or intrapersonal level is fundamental in increasing a patient's ability to manage their NCD or weight problem (Slawson et al., 2013; Teixeira et al., 20). Even though large numbers of patients seek care for NCDs and obesity at PHC facilities, at this point there are no studies that have evaluated the impact of lifestyle interventions on patient outcomes at this level of care. This situation prompted our research to firstly explore the characteristics of a baseline sample of patients who sought treatment for obesity, NCDs and/or NCD risk factors at our PHC hospital, and then compare those who chose the dietitian-led facility-based therapeutic group (FBTG) programme with those who chose to continue with usual care. The treatments investigated in this study were the provision of 30 minutes of dietary counselling for both treatment groups at baseline, and thereafter, FBTG patients were provided with six group-based sessions that provided education on diet and physical activity together with behavioural strategies such as goal setting and problem-solving. The FBTG also referred patients to community based support groups (as per NCD model of care in addendum 3), however it should be noted that the roll out of these groups did not take place. The impact of the FBTG intervention on weight and BMI (primary outcomes) and several secondary outcomes were measured and compared between treatment groups. This research aimed to provide DOH and public health interventionists with a deeper understanding of the potential of lifestyle interventions undertaken in busy PHC settings.

In our baseline sample, three out of four patients were female and mostly of mixed ancestry, around 50 years of age with an education level of approximately 10 years and a family income of between R0.00 and R4166.66. Approximately 50% of the sample were employed, and most resided in Ocean View (predominantly mixed ancestry) and Fish Hoek

(predominantly white). There were no differences between treatment groups for age, gender, employment status, and income. However, there were significantly more patients from Masipumele who chose usual care, and there was a trend for patients with higher educational attainment to choose the FBTG intervention. At initial recruitment, the majority of usual care patients indicated that they couldn't attend the six-week intervention due to work commitments. Other reasons included preference for individual consultations and practical difficulties such as transport problems and family obligations. The socio-demographic differences observed between treatment groups are important to note since interventions that are personalised for specific gender, education, income, age or cultural factors, may increase recruitment, participation, programme satisfaction and most importantly improve patient outcomes (Brown & Gould 2011). Furthermore, it is possible that by placing an individual in their preferred treatment, for example, self-help, individual counselling, a group-based programme or a worksite programme, attrition rates could be reduced.

Diabetes Mellitus (DM), high blood pressure and high cholesterol were more prevalent than heart disease. Patients with DM had an elevated HbA1c of 9.1% at baseline, while the majority of the sample presented with raised cholesterol (5.4 mmol/l) and high blood pressure (146/85mmHg). This was despite evidence that pharmacological treatment of patients with DM and high blood pressure was in place. However, only half of those with high cholesterol were receiving medication. There were no differences between treatment groups in the full baseline sample for DM, heart disease, high cholesterol and high blood pressure, as well as the medication prescriptions for these NCDs and intermediate risk factors. At baseline, FBTG completers presented with a significantly lower systolic blood pressure (SBP) than usual care completers. Over the intervention period, usual care completers were able to significantly reduce their HbA1c levels, cholesterol and diastolic blood pressure (DBP). FBTG patients experienced a significant reduction in SBP and DBP only. The within-group change for HbA1c was significantly greater in usual care patients compared to FBTG patients. There were no statistically significant differences in changes in biochemical measures and BP between treatment groups over the intervention period. The interpretation of the biochemical results was challenging as a direct result of the considerable number of missing values at six months. The greater within-group changes in usual care patients were not expected bearing in mind the lack of weight loss and low physical activity levels observed over the intervention period. It is speculated that differences in pharmacological treatment may have contributed to these findings. Overall, the multi-component design of the FBTG made it difficult to identify which programme

components significantly contributed towards the changes in these biochemical and clinical variables.

The mean BMI ( $39.3\text{kg/m}^2$ ) of the full baseline sample placed the patients in the obese class II category. Among completers, there were no differences between treatments for weight, height, BMI and waist circumference at baseline. Weight change over six months was significantly greater in FBTG patients when compared to usual care patients in the per protocol (FBTG:  $-2.9\text{kg}\pm 5.2$ , usual care  $-1.2\text{kg}\pm 3.7$ ), ITT using last observation brought forward (FBTG:  $-2.2\pm 4.5$ , usual care  $-1.0\pm 3.3$ ) and ITT using multiple imputation (FBTG:  $-2.8\pm 4.9$ , usual care  $+0.2\text{kg}\pm 9.7$ ) analyses. Percentage weight loss was 2.6% in FBTG patients and 1.6% in usual care patients, with a greater number of the usual care patients gaining weight over the intervention period. FBTG patients who attended all six sessions lost 4.1kg compared to 0.7kg gained in patients who attended one programme session. There was also a large range in weight loss/gain observed among FBTG patients (+9kg to -24kg). FBTG patients with education  $\geq 10$  years lost significantly more weight than usual care patients at the same education level. Waist circumference reduced by -3.7cm in FBTG patients, which was significantly greater than the -0.6cm achieved in usual care patients.

It is important to note that despite the weight loss achieved by FBTG patients, most patients did not reach the 5% weight loss that is necessary to produce clinically relevant reductions in NCD risk (Seagle et al., 2009). Furthermore, nearly all patients remained above undesirable cut offs for BMI and waist circumference. It could be speculated that patients in both treatment groups may have required significantly more intervention exposure and support during and after their initial intervention to achieve at least 5% weight loss. This notion is supported by the fact that FBTG patients who attended all six sessions experienced a greater reduction in weight than those who attended one session only. There is also ample published evidence that supports the association between intervention exposure and weight loss. (Gallagher et al., 2013; Venditti & Kramer 2012; Greaves et al., 2011; Le Blanc et al., 2011). Lastly, it is possible that education moderates the impact of the FBTG, with higher educated patients responding better to more intensive interventions than to usual care. The fact that both treatment groups set realistic weight loss goals at baseline is encouraging. However, as indicated above, weight loss in both treatment groups was considerably less than what was aimed for.

Only 14% of the full baseline sample participated in formal physical activity, which amounted to approximately 20 minutes per week. The total sample spent over two hours per day

watching television, which is an indication of leisure time sedentary activity. By the end of the intervention period, FBTG patients significantly increased their physical activity by 32.3 minutes per week, with significantly more patients participating in formal physical activity (37.3%) compared to usual care patients (15.5%), who experienced a small reduction in weekly physical activity (-1.0 minutes per week). Furthermore, FBTG patients were significantly more likely to meet the target for engaging in 150 minutes physical activity when compared to usual care patients. The inclusion of the physiotherapist-led sessions in the FBTG possibly increased the patients' physical activity related self-efficacy, which is necessary to support regular engagement in physical activity (Ashford et al., 2010). The higher level of physical activity achieved by FBTG patients most probably contributed to the negative energy balance in patients who lost significant amounts of weight over the intervention period.

The full baseline sample displayed unhealthy eating patterns such as low fruit and vegetable intake, and the daily consumption of high fat foods, energy-dense snacks and refined carbohydrates. Furthermore, over one glass of high-sugar beverage and approximately five teaspoons of sugar were consumed each day. Patients also consumed approximately three meals per day and one snacks, which is aligned with Department of Health's guidelines for healthy eating information for consumers (DOH 2012). FBTG patients consumed significantly less refined carbohydrates and significantly more snacks than usual care patients at baseline in the total group and significantly less refined carbohydrates at baseline when considering completers only. Over the intervention period, usual care patients achieved significant within-group increases in fruit, fruit and vegetables, and low fat choices together with significant reductions in energy-dense foods, refined carbohydrates, added sugar with a trend for decreasing fats and high sugar beverages. FBTG patients significantly increased vegetable intake, while reducing high fat foods, fats, energy-dense foods, refined carbohydrates, and added sugar. The within-group changes in all indicator food groups did not differ significantly between treatment groups at six months. However, FBTG patients consumed significantly more vegetables and less refined carbohydrates and added sugar at six months. It should be noted that our dietary intake assessment tool was not validated and may not have been sensitive enough to discern true dietary intake and differences between treatment groups. However, it could be argued that inherent errors in the dietary assessment tool would have been the same at baseline and at six months and that the documented changes in dietary intake reflect true modifications in the patients diets. When considering the dietary findings, it needs to be borne in mind that intervention was delivered to a low income group, thus despite more intensive dietary advice provided to the

FBTG, the patients may not have been able to implement all the recommended food-based dietary guidelines.

The majority of patients in the full baseline sample were in the contemplation phase prior to receiving treatment, with the remainder being in action stage. By six months, FBTC completers were significantly more likely to be in the action stage than usual care completers. The proportion of FBTC patients in the action stage increased from 31% at baseline to 75% at six months, while 32% of usual care patients were in action stage at baseline and 49% at six months. It could be argued that including patients in an intensive lifestyle programme who are in pre-contemplation or contemplation stage of change may only result in attrition, and subsequently inefficient use of dietetic clinic time or FBTC resources. Alternatively, the prominent shift of FBTC patients from contemplation stage to action stage over the intervention period shows that the intervention could contribute to increasing readiness for change. Although not validated, the stage of change tool employed in this study was useful in measuring shifts in stage of change in our treatment groups. The possibility of using the tool for screening patients prior to choosing treatment for weight loss should be investigated.

Perceived compliance measured during the FBTC and at the end of the intervention, showed that both treatment groups rated their compliance to diet and physical activity as average (approximately 5 to 6 out of 10), their compliance to behavioural aspects as above average (approximately 7 out of 10), and compliance to medication prescriptions as very high (approximately 9 out of 10). The average mean perceived compliance scores for FBTC patients were similar throughout the intervention period. It is concerning that patients in both treatment groups felt that they did not comply well with the dietary and physical activity components of their treatment, while compliance with pharmacological management was perceived to be very good. This finding is in line with the reported propensity for patients to be more compliant with pharmacological than lifestyle interventions (Mafutha & Wright 2013; Chung et al., 2008).

Approximately 1 in 5 patients in the full baseline sample were smoking at the time of recruitment, with current and previous smokers presenting with nearly 25 pack years. Significantly more usual care patients were smoking at baseline compared to FBTC patients. In the risk profile analysis, it was found that the three highest ranked risk factors for the full baseline sample were engaging in less than 150 minutes of formal physical activity per week (95.8% of sample), consuming less than five fruit and vegetables per day (92.5% of sample),

and having high blood pressure (83.4% of sample). Overall, patients in the full baseline sample had an average of four out of six risk factors (modifiable and intermediate) in addition to obesity and large abdominal girth. Usual care patients appeared to have a poorer risk profile at baseline, as they presented with significantly poorer glycaemic control, higher smoking prevalence, and were significantly less likely to meet the goal of 150 minutes of physical activity per week and consumption of five fruit and vegetables daily.

The outcomes of this research need to be interpreted within the context of the following limitations:

- Allocation to treatment group was not randomized. However, the study design did allow investigation of characteristics of treatment-seeking patients attending a government PHC facility, as well as characteristics of those who chose a particular treatment in the 'real-world' setting.
- Self-reported data for socio-demographic details, smoking, dietary intake, physical activity, stage of change and perceived compliance should be interpreted with caution, bearing in mind that patients may not recall correctly, misinterpret questions and report information that is aligned with socially accepted norms, rather than true information.
- Incomplete data for biochemical measures, including HbA1c or cholesterol reduced the sample size and power to detect differences between treatment groups.
- Both the dietary intake and stage of change assessment questionnaires were not validated for the target population. However, it could be argued that inherent errors in the assessment tools for dietary intake and stage of change would have been the same at baseline and at six-months and that the documented changes in these variables reflect true modifications in the patients diets and stage of change.
- Approximately 40% of patients were LTFU, which reduced the sample size and possibly the power to detect differences between treatment groups. We, however, posit that the fact that all three types of analyses used to compare weight loss between the treatment groups (by protocol, ITT imputation with last weight carried forward, ITT using multiple imputation) showed a significant difference, supports the validity of the findings. It also needs to be noted that there were no significant differences between completers and those LTFU at baseline, with the exception of education, which was considered in the analysis of primary outcomes.

## **FINAL CONCLUSIONS**

Overall it can be concluded that the multi-component FBTG intervention was more effective than usual care in inducing weight loss (primary outcome) and waist circumference reduction. It was also more effective in improving physical activity levels and stage of change, which may have contributed to the weight loss outcome. Both treatments were effective in improving blood pressure and some food choices. The usual care treatment was more effective in reducing HbA1c, bearing in mind possible bias as a result of missing data. There are indications that the higher intervention dosage within the FBTG may have resulted in greater weight loss.

## **RECOMMENDATIONS**

The following recommendations are made based on the outcomes of this research:

1. We recommend that usual care (the provision of dietary advice to patients on a one-to-one basis in PHC facilities) be continued in light of the findings that it may result in improved food choices, biochemical measures and blood pressure. We suggest that more regular one-on-one sessions than what is currently provided in PHC facilities may result in greater effects, including weight loss.
2. Although confirmation of the outcomes of this research in a randomized trial would be ideal, we recommend that the FBTG programme be considered for implementation in PHC facilities bearing in mind the following considerations:
  - Patient willingness to receive treatment
  - Patient preference for treatment
  - Level of education (target patients with  $\geq 10$  years of education)
  - Stage of change (target patients in contemplation and action stage)
  - Availability of a skilled group facilitator and necessary facility resources
  - Exposure to appropriate intervention dosage
3. We recommend that barriers to successful roll out of NGO facilitated community-based support groups be investigated and addressed as such support may result in greater weight loss and long term maintenance.

4. We recommend that the possibility of using the stage of change questionnaire as a screening tool in a treatment algorithm be investigated.
  
5. It is finally recommend that the DOH and The National and Provincial Integrated Nutrition Programme (INP) collaborate to develop evidence-based guidelines for managing obese patients and patients with NCDs in PHC. In addition, an algorithm should be designed to better direct patient and health professionals towards the most appropriate intervention, while outlining the process for the implementation of FBTGs and/or weight management clinics within PHC.

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## ADDENDA

**ADDENDUM A: PARTICIPANT INFORMATION AND INFORMED CONSENT FORM (usual care):**

**TITLE: The impact of the LIFE program on the weight status and risk factors for NCD development in obese patients attending a district hospital in the Cape Metropole.**

**Researcher: Contact Details**

Kathryn Manning  
Registered Dietician  
False Bay Hospital

Tel (W): 021 782 1121 ext 166  
Fax (W): 021 782 2306

Dear \_\_\_\_\_

You are invited to take part in a study for research.

In South Africa, there are many people who have weight problems, and diseases such as diabetes, high blood pressure, and heart disease. These diseases can be treated by changing eating habits, increasing exercise, and taking medication. We want to see whether False Bay Hospital is able to help you achieve this. We would like to obtain your permission to use your details.

The details that we would like to take from your folder are the following:

- Weight, height, waist measurements and blood pressure.
- Any blood tests relating to your disease such as HbA1c and cholesterol.
- Your monthly income, living area (not address), age, gender, nationality, ethnic origin and diagnosis.

What would be expected of you:

- To give permission to take the information listed above from your folder.
- To attend your usual doctors' appointments and have your routine bloods taken.
- To tell us about your medications, food intake, exercise habits, smoking status and education level.

**Please note that your name, surname and folder no. will not be used in the study as your medical details will be identified with a random code. Your details will be confidential.**

**Other important details:**

- The research has been approved by the Medical Superintendent at False Bay Hospital, Department of Health, and the Ethics Committee of the University of Cape Town. These people and departments feel there is no risk to you or the hospital should you participate in this study.
- You are welcome to withdraw from the study at any time, and will not be questioned.

For queries or complaints, please contact either Kathryn Manning (dietitian) or False Bay Hospital's Medical Superintendent Dr Rob Martell on 021 782 1121 or Prof Marc Blockman of the UCT Research Ethics Committee on 021 4066492.

**Based on the above, please sign and complete the section below if you are willing to allow the researcher to use your details:**

I (your name & surname) _____, have read the information provided in this document, and I understand what is required. I agree that my details can be used for research purposes. This decision was made of my own free will, and I was not forced to take part in this study.	
Your signature _____	Signature of a witness _____
Date _____	Date _____

**ADDENDUM A: PARTICIPANT INFORMATION AND INFORMED CONSENT FORM: (FBTG patients)**

**TITLE: The impact of the LIFE program on the weight status and risk factors for NCD development in obese patients attending a district hospital in the Cape Metropole.**

**Researcher: Contact Details**

Kathryn Manning  
Registered Dietician  
False Bay Hospital

Tel (W): 021 782 1121 ext 166  
Fax (W): 021 782 2306

Dear \_\_\_\_\_

You are invited to take part in a study for research.

In South Africa, there are many people who have weight problems, and diseases such as diabetes, high blood pressure, and heart disease. These diseases can be treated by changing eating habits, increasing exercise, and taking medication.

A program named Lifestyle Intervention for Empowerment (LIFE) program was developed to help patients to better manage their diseases and improve their health. We want to test the program to see if it does help patients to achieve this. We would like to obtain your permission to use your details obtained from the LIFE Program for research purposes.

The details that we would like to take from your folder are the following:

- Weight, height, waist measurements and blood pressure.
- Any blood tests relating to your disease such as HbA1c and cholesterol.
- Your monthly income, living area (not address), age, gender, nationality, ethnic origin and diagnosis.

What would be expected of you:

- To give permission to take the information listed above from your folder.
- To attend each LIFE program session at False Bay Hospital. Each session will run for 2 hours every week for six weeks. Then we would like you to attend a monthly support group session in your community.
- To attend your doctors' appointments and have your routine bloods taken.
- To tell us about your medications, food intake, exercise habits, smoking status and education level.

**Please note that your name, surname and folder no. will not be used in the study as your medical details will be identified with a random code. Your details will be confidential.**

**Other important details:**

- The Program is free of charge.
- The research has been approved by the Medical Superintendent at False Bay Hospital, Department of Health, and the Ethics Committee of the University of Cape Town. These people and departments feel there is no risk to you or the hospital should you enrol in the LIFE program.
- You are welcome to withdraw from the study at any time, and will not be questioned.

For queries or complaints, please contact either Kathryn Manning (dietitian) or False Bay Hospital's Medical Superintendent Dr Rob Martell on 021 782 1121 or Prof Marc Blockman of the UCT Research Ethics Committee on 021 4066492.

**Based on the above, please sign and complete the section below if you are willing to allow the researcher to use your details:**

I (your name & surname) \_\_\_\_\_, have read the information provided in this document, and understand what is required. I agree that my details can be used for research purposes. This decision was made of my own free will, and I was not forced to take part in the LIFE program.

Your signature \_\_\_\_\_

Signature of a witness \_\_\_\_\_

Date \_\_\_\_\_

Date \_\_\_\_\_

## ADDENDUM A: Assessment questionnaires

Assessment questionnaires		Folder #:				
<input type="checkbox"/> Intervention group <input type="checkbox"/> Control group		Date: __ / __ /20__.				
<b>1. Food Frequency Questionnaire:</b> <input type="checkbox"/> baseline <input type="checkbox"/> six month follow up						
No.	Food Item	Portion description	How often do you eat the following foods?			
			Never	Daily	Weekly	Monthly
1.	3 meals per day					
2.	2 meals per day					
3.	1 meal per day					
4.	In between snacks 1-3 per day					
5.	Bread, white	1 slice				
6.	Bread, brown	1 slice				
7.	Bread, whole-wheat/seeded	1 slice				
8.	Cereal, high fibre	½ cup				
9.	Cereal, low fibre	½ cup				
10	Boiled Rice, pap, pasta, samp, potato	½ cup				
11	Potato, fried (chips)	1 potato				
12	Starchy vegetables	½ cup				
13	Other vegetables	½ cup				
14	Fruit, whole	1				
15	Legumes	½ cup				
16	Red meat, high fat	90g				
17	Red meat, medium fat	90g				
18	Red meat, lean	90g				
19	Chicken, with skin	90g				
20	Chicken, fried	90g				
21	Chicken/turkey/ostrich, no skin	90g				
22	Fish, fried	90g				
23	Fish, fresh	90g				
24	Fish, tinned	90g				
25	Organ meats	90g				
26	Processed meat	2 slices				
27	Eggs, fried	1				
28	Eggs, boiled/poached	1				
29	Cheese	30g				
30	Milk products <input type="checkbox"/> full fat	125ml				
31	Milk products <input type="checkbox"/> low fat	125ml				

32	Milk products <input type="checkbox"/> fat free	125ml				
33	Margarine <input type="checkbox"/> hard/butter/ghee	1 tsp				
34	Margarine <input type="checkbox"/> lite	1 tsp				
35	Butter	1 tsp				
36	Oil	1 tsp				
37	Mayonnaise <input type="checkbox"/> full fat	1 tsp				
38	Mayonnaise <input type="checkbox"/> low fat	1 tsp				
39	Peanuts/peanut butter	1 tsp				
40	Take aways	1 unit				
41	Baked goods	1 unit				
42	Crisps	1 packet				
43	Stock cubes, soup powder, salty flavourings	1 TBS/ 1 stock cube				
44	Sugar, white or brown sugar	1 tsp				
45	Sweets (boiled/jelly)	1				
46	Jam/syrup/honey	1 tsp				
47	Chocolate	250ml				
48	Water	250ml				
49	Cool drinks <input type="checkbox"/> normal	250ml				
50	Cool drinks <input type="checkbox"/> sugar-free	250ml				
51	Juice (squash)	250ml				
52	Juice (100%)	125ml				
53	Alcohol (1 beer, 1 tot, 1 125ml wine)	1 unit				
54	Tea/Coffee	1 cup				

## **2. Weight goals**

Do you want to lose weight?	Yes/no
How much weight would you like to lose over 6 months?	

## **3. Smoking status**

Do you smoke?	Yes/ no
Pack years (1 pack of cigarettes over how many years)	

## **4. Physical activity assessment**

Exercise type	Formal/informal	Frequency				Duration
		Never	Daily	Weekly	Monthly	
No. of minutes/day spent watching TV:						

### 5. Education level & employment status

	Level				
	<u>1.No education</u>	<u>2.Primary education</u>	<u>3.Secondary education</u>	<u>4.Tertiary education</u>	<u>5.Diploma/certificate</u>
<u>Level Completed</u>					
<u>No. of years of formal education:</u>					
<u>Currently employed</u>				<u>Yes/ no</u>	

### 6. Perceived compliance

1) To what extent do you feel you have followed the diet guidelines over the past week?

Not at all      0%       100%

2) To what extent do you feel you have increased your physical activity over the past week?

Not at all      0%       100%

3) To what extent do you feel you have worked on changing your mindset and habits over the past week?

Not at all      0%       100%

4) To what extent do you feel you have taken your medication correctly over the past week?

Not at all      0%       100%

### 7. Stage of change assessment

	Strongly agree	Agree	Unsure	Disagree	Strongly Disagree
I do not worry about what I eat (PC)					
I am trying to eat more healthy foods than I used to (A)					
I enjoy eating unhealthy foods, but eat too much of them at times (C)					
Eating more healthy foods would be pointless for me (PC)					
I recently started to eat more healthy foods (A)					
My intake of unhealthy foods is a problem sometimes					
There is no need to think about changing what I eat (PC)					
Sometimes I think that I should eat more healthy foods (C)					
Anyone can talk about wanting to eat more healthy foods, but I am actually doing something about it (A)					

**8. Drop out assessment/decline:**

Please provide reason for not completing the program/not attending 6-month follow up:



### Addendum C: DOH Model of care for management of NCDs

