PERCEIVED BARRIERS TO LIFESTYLE MODIFICATION, MOTIVATION, KNOWLEDGE AND SERVICE NEEDS OF DIABETIC ADULTS AND THEIR HEALTH CARE PROVIDERS IN CHENNAI, TAMIL NADU, INDIA

BY

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ABSTRACT

Introduction: Over 415 million people worldwide live with diabetes mellitus, of which 50% live in five countries: China, India, the United States of America, Brazil and Indonesia. The number of people with diabetes is predicted to rise to 552 million by 2030 and may affect up to 79.4 million individuals in India. Diabetes mellitus is a chronic, non-communicable disease resulting in increased blood glucose levels. Poor control of diabetes leads to the development of complications that affect quality of life and health, and may even lead to death. Diabetics face many barriers such as time constraints, lack of knowledge, fear or depression, lack of self-motivation and lack of support from family and medical personnel. Barriers faced by health care providers (HCPs) are inadequate knowledge on treatment and management of diabetes, focusing on acute management rather than the preventive care, delay in clinical response to poor control and competing care demands. Given the fact that a large percentage of the world's diabetics live in India, more research is needed to investigate the barriers that diabetics and their HCPs face in this unique region.

Aim: This study aimed to evaluate the barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their HCPs in Chennai, Tamil Nadu, India.

Location: The study was conducted in Apollo Specialty Hospital, Vanagaram, Chennai, India.

Objectives:

(i) To identify the barriers to lifestyle modification as perceived by South Indian Type 2 diabetic adults.

(ii) To identify the barriers to motivation, knowledge and service needs as perceived by South Indian Type 2 diabetic adults.

(iii) To identify the challenges as perceived by HCPs in providing education, motivation and services to their diabetic patients.

Method: A sample of 50 male and female adults with type 2 diabetes from a private specialty hospital in Chennai were randomly selected to participate in this study. Participants had to be

type 2 diabetic, aged between 18 to 70 years; diagnosed for more than one year; with not more than two other co-morbidities, excluding pre-renal or renal failure; latest glycosylated haemoglobin (HbA_{1c}) available and previously been seen by a dietician. For HCPs (n=25) comprising of nurses, doctors and dieticians, the inclusion criteria were that they had to have been practicing for more than a year. Separate questionnaires were developed for the diabetic patients and for the HCPs. The patient questionnaires were conducted in an interview format and in the language (English or Tamil), preferred by the patients. The HCPs completed the questionnaires on their own.

Results: The diabetic patients in this study ranged in age between 41 to 68 years and had a mean body mass index (BMI) of 26.8 kg/m^2. The mean HbA_{1c} was 8.05% and most patients had hypertension alone, as a comorbidity. In general, patients felt that they had no barriers to glucose monitoring, although 28% indicated that being busy with family was a barrier. Common barriers to exercise were being busy with work or family (72%) as well as fear and pain (44%). The most common barriers to healthy eating were eating away from home (52%; n=26), cost or expense of healthy foods (52%; n=26) and taste of food (46%; n=23). Extrinsic motivation significantly influenced the decision to take medication ($p=0.001$), check blood glucose levels ($p=0.001$) and keep health care appointments ($p<0.05$). Exercise was the only habit this sample followed regularly due to intrinsic motivation ($p=0.030$). Significantly, 82% of patients indicated that they understood their disease condition ($p<0.05$), whilst a significant small number reported that they would benefit from a workshop that provided knowledge and skills to help manage their diabetes ($p=0.001$). Most patients had confidence in treatment and advice obtained from health care providers ($p=0.001$), and their own skills and knowledge to prepare healthy meals ($p<0.05$). Most patients understood their disease condition and complications ($p<0.05$). A higher income ($p=0.031$) and consuming a mixed diet ($p<0.05$) was associated with higher HbA_{1c} levels amongst patients. A significant positive correlation was found between BMI and HbA_{1c}, as well as between BMI and income. Patients following a vegetarian diet were found to have a lower HbA_{1c}. Health care providers (HCPs) felt that they had sufficient skills for lifestyle counselling ($p=0.001$), but also reported that their biggest barrier to counselling was time constraints ($p=0.026$). Health care providers indicated that patients found following an eating plan the most difficult to maintain (88%), followed by

exercise (48%). Health care providers all agreed that patients should be assigned responsibility for self-care ($p<0.05$), even though healthcare providers indicated that important barriers to lifestyle changes were unwillingness to change ($p<0.05$), insufficient knowledge on complications ($p=0.008$) and lack of support from co-workers or bosses ($p=0.005$). There was a significant positive correlation between the experience level of the healthcare providers and the frequency with which they motivated and supported lifestyle changes (rho = 0.547, $p=0.005$) and how confident they were that they had the knowledge or skills needed to teach their patients (rho =0.406, $p=0.004$). The experience level of the HCPs and the frequency with which they referred patients to other team members (rho = 0.767, $p<0.05$) and how confident they were that they had the skills for lifestyle counselling (rho = 0.577, $p=0.003$), were also significantly positively correlated.

Conclusion: For patients, being busy with family, work or other tasks was a common barrier to glucose monitoring and exercise, while a diet plan was not commonly used to control blood glucose levels. Overall, patients were satisfied with the services provided by their HCPs and were keen to participate in online medical support from health care providers. According to HCPs, patients found following an eating plan and exercise the most difficult to adhere to, while glucose monitoring and taking medication were the least difficult to adhere to. All healthcare providers agreed that patients should be assigned responsibility of self-care. According to HCPs, unwillingness to change, insufficient knowledge on complications and lack of support from co-workers or bosses, were the most important barriers to lifestyle counselling. Time constraints also prevented HCPs from counselling their patients adequately. In general, the more experienced HCPs were more likely to motivate and support lifestyle changes, more confident in their knowledge or skills and more likely to refer patients to other health care team members. It is evident that this sample need to place greater emphasis on dietary management of diabetes. They could benefit from regular information updates on how to effectively manage their diabetes.

PREFACE

The dissertation was written between June 2015 and November 2017 using data collected from Chennai, India, under the supervision of Dr Kirthee Pillay.

Signed:  Date: 29/11/2017

Sharona Stalin (Candidate)

As supervisor of the candidate, I agree to the submission of this dissertation.

Signed: _____ Date: _____

Dr Kirthee Pillay (Supervisor)

DECLARATION

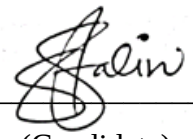
I, Sharona Stalin, declare that:

1. The entirety of the work contained in this dissertation is my original work, except where otherwise stated.

2. This dissertation, or any part of it, has not been submitted for any degree or examination at any other university.

3. Where other sources have been used they have not been copied and have been properly acknowledged.

4. This dissertation does not contain text, graphics or tables copied and pasted from the internet, unless specifically acknowledged, and the source being detailed in the dissertation and in the relevant reference section.

Signed:  Date: 29/11/2017

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LIST OF ABBREVIATIONS

ADA	American diabetes association
BMI	Body mass index
CBT	Cognitive behavioural therapy
CKD	Chronic kidney disease
CURES	Chennai Urban Rural Epidemiology Study
CVD	Cardiovascular disease
DAWN	Diabetes Attitudes, Wishes and Needs
DFU	Diabetic foot ulcer
DME	Diabetic macular oedema
DM	Diabetes mellitus
DN	Diabetic nephropathy
DPN	Diabetic peripheral neuropathy
DR	Diabetic retinopathy
DSME	Diabetes self-management education
DSMS	Diabetes self-management support
EASD	European Association for the Study of Diabetes
FBG	Full blood glucose
FFA	Free fatty acid
GFR	Glomerular filtration rate
GI	Glycaemic index
HbA_{1c}	Glycosylated haemoglobin
HCPs	Health care providers
HD	Healthy diet
HDL-C	High-density lipoprotein cholesterol
HPA	Healthy physical activity
HTN	Hypertension
ICMR	Indian Council of Medical Research
ICMR-INDIAB	Indian Council of Medical Research-India Diabetes
IDDM	Insulin dependent diabetes mellitus

IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
LDL-C	Low-density lipoprotein cholesterol
MNT	Medical nutrition therapy
NABH	National Accreditation Board of Hospitals
NFHS	National Family Health Survey
NIDDM	Non-insulin dependent diabetes mellitus
PAD	Peripheral arterial disease
PHC	Primary Health Centres
PPBG	Post prandial blood glucose
PwC	PricewaterhouseCoopers
QOL	Quality of life
RSSDI	Indian Research Society for the Study of Diabetes in India
SITE	Screening India's Twin Epidemic
SMBG	Self-monitored blood glucose
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
UK	United Kingdom
USA	United States of America
USD	United States Dollar
WHO	World Health Organization
WHR	Waist to Hip Ratio

CHAPTER 1: INTRODUCTION, THE PROBLEM AND ITS SETTING

1.1 Importance of the study

According to the International Diabetes Federation (IDF), 415 million people were living with diabetes mellitus (DM) worldwide in 2015 [International Diabetes Federation (IDF) Diabetes Atlas 2015, p13] and this is expected to rise to 552 million by 2030 (Whiting, Guariguata, Weil & Shaw 2011). Diabetes mellitus accounted for approximately 5 million deaths (aged 20 to79 years) worldwide in 2015, of which 46.6% were under the age of sixty years (IDF Diabetes Atlas 2015, p57). The World Health Organization (WHO) predicts that diabetes will be the seventh leading cause of death worldwide by 2035 (Mathers & Loncar 2006). Fifty percent of adults with diabetes in 2014 lived in five countries: China, India, the United States of America (USA), Brazil and Indonesia. These countries also accounted for one half of the world's adult population in 2014 [NCD Risk Factor Collaboration (NCD-RisC 2016)]. It is predicted that by 2030, DM may affect up to 79.4 million individuals in India, 42.3 million in China and 30.3 million in the USA (Whiting *et al* 2011; Wild, Roglic, Green, Sicree & King 2004).

Between 1980 and 2014, the worldwide age-standardised adult diabetes prevalence increased from 4.3% to 9.0% in men and from 5.0% to 7.9% in women (NCD-RisC 2016). Currently, the greatest number of people with diabetes worldwide fall into the 40 to 59 year old age group, and this is predicted to remain so in 2030, although there will be nearly as many people with diabetes in the 60 to79 year old age-group (Whiting *et al* 2011). Globally, about 174.8 million people were estimated to have undiagnosed DM in 2013 (Beagley, Guariguata, Weil & Motala 2014).

Diabetes mellitus is a chronic, non-communicable disease resulting in increased blood glucose levels. In diabetes, there is a deficiency of insulin secretion by the pancreas or ineffectiveness of secreted insulin, which can be inherited or acquired (IDF Diabetes Atlas 2015, p12). The two main forms of diabetes are type 1 diabetes mellitus (T1DM) or insulin dependent diabetes mellitus (IDDM) and type 2 diabetes mellitus (T2DM) or non-insulin dependent diabetes mellitus (NIDDM). Type 1 diabetes mellitus is caused by an autoimmune reaction, in which the body's defence system attacks the insulin-producing beta cells in the pancreas. As a result, the body can no longer produce the insulin it needs. The reason for this is not fully understood.

The disease can affect people of any age; however, onset usually occurs in children or young adults. People with this form of diabetes require insulin daily in order to control blood glucose levels. Without insulin, a person with T1DM will die (IDF Diabetes Atlas 2015, p12). Type 2 diabetes is the most common type of diabetes. It usually occurs in adults, but is increasingly seen in children and adolescents. In T2DM, the body is able to produce insulin but becomes resistant, so that the insulin is ineffective. Over time, insulin levels may subsequently become insufficient. Both insulin resistance and deficiency lead to high blood glucose levels (IDF Diabetes Atlas 2015, p23). In the case of individuals with raised blood glucose levels, that are not high enough for a diagnosis, a diagnosis of impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) may be made (IDF Diabetes Atlas 2015, p26).

Type 2 diabetes mellitus is often undiagnosed and studies to assess the number of newly occurring cases are complicated, resulting in insufficient data on true incidence (WHO 2016b). The general management of diabetes involves the education of patients. This is based on assessed needs and includes the following: disease process, treatment option, nutritional plan, exercise plan, knowledge of diabetes medicine prescribed, blood glucose monitoring, knowledge of acute and chronic complications, psychosocial issues and individual strategies to promote health (Funnell, Brown, Childs, Haas, Hosey, Jensen, Maryniuk, Peyrot, Piette, Reader, Siminerio, Weinger & Weiss 2011). National guidelines and standards of care for diabetes are now available in many countries worldwide. Despite this, the management of patients with diabetes in practice remains suboptimal in most countries (Venkataraman, Kannan & Mohan 2009).

Medical nutrition therapy is a cornerstone of diabetes management and involves the calculation of a diet based on ideal body weight, yielding a kilojoule (kilocalorie) requirement. The diet should include 55% to 60% of energy from carbohydrates, 20-25% of energy from fat (of which no more than 10% should be saturated fatty acids), 10%-15% of energy from protein, as well as fibre [Indian Council of Medical Research (ICMR) 2005]. Portion control in the management of diet and daily exercise also play very important roles in maintaining ideal body weight (Nyenwe, Jerkins, Umpierrez & Kitabchi 2011). Medical treatment to treat

hyperglycaemia include oral hypoglycaemic agents (T2DM) or insulin (T1DM) (Nyenwe *et al* 2011).

Approximately 69.1 million from India were found to have diabetes in 2015, second only to China (IDF Diabetes Atlas 2015, p17). According to the ICMR a lower proportion of the Indian population was affected in the Northern India States (Chandigarh 0.12 million and Jharkhand 0.96 million), as compared to Maharashtra (North India) (9.2 million) and Tamil Nadu (South India) (4.8 million) (Anjana, Ali, Pradeepa, Deepa, Datta, Unnikrishnan, Rema & Mohan 2011). Similarly, the National Urban Survey, conducted across the metropolitan cities of India showed that 11.7% were affected in Kolkata (Eastern India) and 6.1% in Kashmir Valley (Northern India) (Zargar, Khan, Masoodi, Laway, Wani, Bashir & Dar 2000). In New Delhi (Northern India), approximately 11.6% were affected with 9.3% in West India (Mumbai), 13.5% in Chennai (South India), 16.6% in Hyderabad (South India) and 12.4% in Bangalore (South India) (Ramachandran, Snehalatha, Kapur, Vijay, Mohan, Das, Rao, Yajnik, Prasanna & Nair 2001). Population-based studies in the city of Chennai in South India over the last two decades have shown an increase in the prevalence of diabetes from 8.3% in 1989, to 18.6 % in 2006 (Mohan, Sandeep, Deepa, Shah & Varghese 2007).

As evidence suggests, the prevalence of diabetes is swiftly increasing, especially in urban India. This increase can be attributed to the predictable risk factors of urbanisation, unhealthy eating habits, decrease in physical activity, inherent genetic attributes and differences in body composition **(**Anjana *et al* 2011). The Asian-Indian phenotype[1] and lifestyle changes associated with urbanisation and sedentary lifestyles, have contributed to the rise in diabetes in India (Mohan *et al* 2007). Diabetes control in India is not ideal with a mean glycosylated haemoglobin (HbA_{1c}) of 9.0%, which is at least 2.0% higher than that suggested by international bodies (Joshi 2015). In an Indian study conducted in 2004, between 50-60% of diabetics did not achieve the glycaemic target for HbA_{1c} (Rao, Bhatnagar & Murphy 2011). Comparatively, in the United Kingdom (UK), the prevalence of inadequate glycaemic control

[1] Asian Indians have a small body size with thinner limbs, which is suggestive of a smaller muscle mass. They are centrally obese, with a higher waist-to-hip ratio and higher subscapular-to-triceps skinfold ratio; hereby termed thin-fat Indian.

(HbA_{1c} of >7%) was 76% (Fox, Gerber, Bolinder, Chen & Kumar 2006) and 50% in the USA (Resnick, Bardsley, Foster & Ratner 2006).

Poor control of diabetes leads to the development of complications that affect the quality of life, health and may even lead to death. During the course of diabetes the heart, blood vessels, eyes, kidneys and nerves are damaged and there is an increased risk for heart disease and stroke. Owing to this damage a reduction in blood flow combined with nerve damage (neuropathy) in the feet increases the risk for foot ulcers, infection and eventually the need for limb amputation. Diabetic retinopathy is an important cause of blindness and occurs because of long-term accumulated damage to the small blood vessels in the retina (WHO 2016b).

In India, neuropathy is the most common complication (24.6%) followed by cardiovascular complications (23.6 %), renal complications (21.1%), retinopathy (16.6%) and foot ulcers (5.5%) (Ramachandran *et al* 2001). These results compare closely with results from the South Indian population (Kaveeshwar & Cornwall 2014). Poor glycaemic control, which has been observed in the Indian diabetic population (Unnikrishnan, Rema, Pradeep, Deepa, Shanthirani, Deepa & Mohan 2007), is responsible for the micro and macrovascular changes that are seen in diabetes. In India, a considerable percentage of patients are unaware of the diabetes condition (25%), risk factors (obesity and physical inactivity) and secondary complications of diabetes (60%) (Mohan, Raj, Shanthirani, Datta, Unwin, Kapur & Mohan 2005). Further, almost half of the patients are unaware that good glycaemic control would help to avoid complications related to diabetes (Mehrotra, Bajaj, Kumar & Singh 2000). A study by Mehrotra *et al* (2000), conducted in India, found that only 7.6% of patients were aware of HbA_{1c} testing for the diagnosis of diabetes, in the year 2000 (Mehrotra *et al* 2000) and 21.7% in the year 2006 (Nagpal & Bhartia 2006). Only 10.3% of patients reported receiving diabetes self-management education (Nagpal & Bhartia 2006) and 20-30% reported not being up-dated on new information and developments on diabetes (Wangnoo, Maji, Das, Rao, Moses, Sethi, Unnikrishnan, Kalra, Balaji, Bantwal, Kesavadev, Jain & Dharmalingam 2013).

In traditional societies like India, socio-cultural factors play an important role in determining patient attitude to diabetes and its management (Osman & Curzio 2012). The therapeutic

modalities should consider the socio-cultural sensitivities of patients (fasting and other religious requirements), which affect their ability to adhere to treatment recommendations (Pathan, Sahay, Zargar, Raza, Khan, Ganie, Siddiqui, Amin, Ishtiaq & Kalraet 2012). A large number of physicians practising in India find themselves unable to base their treatment decisions on western guidelines, which do not cater to uniquely Indian concerns, including the social and cultural concerns (Hasan, Zodpey & Saraf 2012). Another study from Kuwait showed that doctors, nurses and dieticians needed to understand more about the social and cultural habits of their patients, and consider the expected barriers to adherence to lifestyle changes when giving advice (Serour, Alqhenaei, Al-Saqabi, Mustafa & Ben-Nakhi 2007).

Sachdeva, Khalique, Ansari, Khan, Mishra & Sharma (2015), described the need for a multidisciplinary team with culturally apt interventions to manage diabetes. In the same study, many patients responded that doctors had advised them to change their diet; however, they felt this was difficult to do due to religious or cultural factors (Sachdeva *et al* 2015). It is also important for health care providers (HCPs) to realise that there is no lone model of diabetes care that fits all ethnic communities or all people within a community. A patient's level of ethnic affiliation and acculturation should also be assessed before counselling (Tripp-Reimer, Choi, Skemp Kelley & Enslein 2001).

Besides the social and cultural concerns, there are many other barriers to the effective management of diabetes in India. A study in Chennai, South India, by Kapur, Kapur, Ramachandran, Mohan, Aravind, Badgandi & Srishyla (2007), showed that some diabetics found that HCPs did not provide individualised dietary advice and self-management training. Family support was lacking and the long duration of the disease often broke the patient's resolve. A study by Jayakumar (1997) conducted in Kerala, South India showed that common diet sheets, physicians lack of knowledge and advice given on the first visit only and only if blood sugar was not controlled, were insufficient to ensure lifestyle changes in diabetics (Jayakumar 1997). A study in Bangladesh reported that patients' poor attendance at clinics was the strongest reason for non-adherence to lifestyle modification in diabetics (Mumu, Saleh, Ara, Afnan & Ali 2014).

Studies conducted in other countries have reported similar findings. A Jamaican study found that inadequate knowledge, low perception of risk and weak motivational factors were barriers to lifestyle changes and glycaemic control among diabetics. The study further demonstrated that the ’s primary source of information was their physician, thus indicating a change to a collaborative approach (Wint, Duff, McFarlane-Anderson, O’ Connor, Bailey & Wright-Pascoe 2006). In Hawaii, employed diabetics felt that there was a lack of understanding and support from family members and co-workers. The study moreover explained that a barrier related to co-ordinated services existed, where participants frequently discussed the need for a collaborative approach to health care (Fukunaga, Uehara & Tom 2011).

The Diabetes Attitudes, Wishes and Needs (DAWN) (2005) study found that psychosocial problems were common among diabetic patients worldwide, and that only 20% of Indian diabetics were compliant with dietary advice (Peyrot, Rubin, Lauritzen, Snoek, Matthews & Skovlund 2005). The subsequent DAWN-2 study (2013) showed that distress was reported in 40% of family members in India; although the largest proportion of family members (59.5%) were more willing to be involved in care (Holt & Kalra 2013).

Exercise is known to help control blood sugar levels in diabetics (Adams 2013; Moreira, Simões, Moraes, Motta, Campbell & Simões 2012); however, many diabetics cite a lack of time (Fukunaga *et al* 2011) as the main reason for not exercising. It has been reported that exercise is beneficial in decreasing body fat and improving lean mass in patients with type 2 DM (Sigal, Kenny, Boulé, Wells, Prud'homme, Fortier, Reid, Tulloch, Coyle, Phillips, Jennings & Jaffey 2007; Boule´, Haddad, Kenny, Wells & Sigal 2001). According to The Joint Position Statement of the American College of Sports Medicine and the American Diabetes Association (ADA) (2010), both aerobic and resistance training improve insulin action, blood glucose control, fat oxidation and storage in muscle (Colberg, Sigal, Fernhall, Regensteiner, Blissmer, Rubin, Chasan-Taber, Albright & Braun 2010).

The DAWN-2 study conducted in 17 countries reported that 19.2% of people with diabetes reported experiencing discrimination, intolerance and lack of support from their community (Nicolucci, Kovacs Burns, Holt, Comaschi, Hermanns, Ishii, Kokoszka, Pouwer, Skovlund,

Stuckey, Tarkun, Vallis, Wens & Peyrot 2013). Additionally, 21.5% of family members believed that people with diabetes experienced discrimination because of their diabetes (Kovacs Burns, Nicolucci, Holt, Willaing, Hermanns, Kalra, Wens, Pouwer, Skovlund & Peyrot & DAWN-2 Study Group 2013). Likewise, 32.8% of health-care professionals felt that discrimination was an issue (Holt, Nicolucci, Kovacs Burns, Escalante, Forbes, Hermanns, Kalra, Massi-Benedetti, Mayorov, Menéndez-Torre, Munro, Skovlund, Tarkun, Wens & Peyrot 2013). The Indian diabetic faces above average rates of discrimination, with the rates only higher in Turkey (Holt & Kalra 2013). Experiencing discrimination because of diabetes is associated with diabetes-related distress for people with diabetes and is therefore an area of concern (Holt & Kalra 2013).

In addition to countless physical complications, diabetes adversely affects the emotional health and wellbeing of those with the condition. Clinical depression rates among those with diabetes are estimated to be between 10% and 30% (Li, Ford, Strine & Mokdad 2008; Anderson, Freedland, Clouse & Lustman 2001). A meta-analysis conducted by Anderson *et al* (2001) showed that the presence of diabetes doubles the odds of co-morbid depression. Diabetics are required to make significant lifestyle changes and self-management behaviours that impose a significant burden on the patient, and may lead to depression (De Groot, Golden & Wagner 2016).

According to HCPs, reasons for suboptimal glycaemic control include patients' resistance to lifestyle change and starting insulin, noncompliance and psychosocial issues. Health care providers cited the lack of time to deal with these complex patients and their multiple issues as a key reason for prolonged suboptimal control (LeBlanc, Rosales, Kachroo, Mukherjee, Funk, Schneider & Nichols 2014). Health care provider's inadequate knowledge on treatment and management of diabetes, focusing on acute management rather than preventive care, delayed clinical response to poor control and competing care demands are a few of the physician-related barriers to diabetes control in India (Venkataraman *et al* 2009).

Experts in diabetes education suggest that the greatest challenge to improving outcomes for people with T2DM is more effective multi-component behaviour change strategies (Norris,

Zhang, Avenell, Gregg, Bowman, Serdula, Brown, Schmid & Lau 2004). "Typical" approaches include scare tactics, advice-giving, badgering, and other highly directive styles that are not conducive to behaviour change (Moran, Bekker & Latchford 2008). In contrast, approaches that include patient empowerment, education, psychosocial understanding and, more recently, brief behaviour change counselling, have shown promising results (Dellasega, Gabbay, Durdock & Martinez-King 2010). A study in Israel reported that well informed and motivated diabetic patients were more successful in obtaining and maintaining good control of their risk factors, resulting in reduced cardiovascular risk and slower progression of microvascular disease (Rachmani, Slavacheski, Berla, Frommer-Shapira & Ravid 2005).

Consequently, knowledge and motivation to make changes play a vital role in the treatment of diabetes. Expanding on the former, motivation is described as two conflicting needs. Firstly, clear information that propels that person to take action or secondly, the person making their own choices (Borra, Kelly, Tuttle & Neville 2001). Centis, Trento, Dei Cas, Pontiroli, De Feo, Bruno, Sasdelli, Arturi, Strollo, Kreutzenberg, Invitti, Di Bonito, Di Mauro, Pugliese, Molteni & Marchesini (2014), in Italy, using the transtheoretical model showed that the phase of change and motivation to embrace a healthier diet and intensify their physical activity, remains problematic in a large percentage of individuals with T2DM. This was irrespective of age and co-morbidities (Centis *et al* 2014). These phases are described as pre-contemplation (not ready), contemplation (getting ready), preparation (ready), action and maintenance (Prochaska, DiClemente & Norcross 1992). A study conducted in the Netherlands showed that diabetic subjects receiving lifestyle-counselling interventions (based on the transtheoretical model), supported the gap between motivation and action (Vermunt, Milder, Wielaard, Baan, Schelfhout, Westert & van Oers 2013).

Although optimal management of diabetes is central to diabetes care, there are many barriers faced by diabetic patients on a daily basis. These barriers range from time constraints, lack of knowledge, fear or depression, lack of self-motivation and lack of support from family and medical personnel. Given the fact that such a large percentage of the world's diabetics live in India, more research is needed to investigate the barriers that Indian diabetics face. Therefore,

this study aimed to evaluate the barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their health care providers in Chennai, Tamil Nadu, India.

1.2 Aim of the study

This study aimed to evaluate the barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their health care providers in Chennai, Tamil Nadu, India.

1.3 Research objectives

The objectives of this study were:

1.3.1 To identify the barriers to lifestyle modification as perceived by South Indian type 2 diabetic adults.

1.3.2 To identify the barriers to motivation, knowledge and service needs as perceived by South Indian type 2 diabetic adults.

1.3.3 To identify the challenges as perceived by HCPs in providing education, motivation and services to their diabetic patients.

1.4 Hypotheses

The following hypotheses were tested:

1.4.1 The perceived barriers to lifestyle modification include time constraints, lack of motivation, lack of skills development, emotional wellbeing and lack of support from HCPs and family.

1.4.2 The perceived barriers to motivation, knowledge and service needs include lack of skills development, proper counselling, follow-up with HCPs and emotional wellbeing.

1.4.3 The perceived barriers to knowledge include a lack of in depth counselling, written information, understandable explanation on risks and complications of disease, lack of follow-up with HCPs and a lack of holistic care, where all team members are involved.

1.4.4 The perceived barriers to services provided include time constraints, lack of manpower, lack of a team approach, lack of knowledge and counselling skills.

1.5 Study parameters

1.5.1 For the purpose of this study, only the general in-patient department (Wards A, D, G) at Apollo Specialty Hospital, Vanagaram was used as a study site.

1.5.2 Only adults with T2DM between the ages of 18 to 70 years and with not more than two co-morbidities were included in the study.

1.5.3 In addition to the criteria mentioned in 1.5.2, only patients who were Tamil or English speaking and who lived in Chennai, were included in the study.

1.5.4 Renal diabetics were excluded from the study, as these patients require specialised management, which is different for patients with T2DM without renal involvement.

1.5.5 The collection of data was conducted between the months of January 2017 and March 2017.

1.5.6 The diagnosis of diabetes at Apollo Hospitals is as per WHO recommendations for diagnostic criteria for diabetes mellitus, which is fasting glucose of >7mmol/l or 126mg/dL.

1.6 Study assumptions

The following assumptions were made:

1.6.1 All patients understood either English or Tamil, the languages in which the questionnaires were formulated.

1.6.2 All participants, including both the patients and the HCPs, answered the questionnaire honestly.

1.7 Definition of terms

Adult - "one who is fully developed and matured and who has attained the intellectual capacity and the emotional and psychological stability of a mature person; a human male or female after a specific age (as 18 or 21)" (Anderson, Keith, Novack & Elliot 2002, p48).

Barrier - "something non-physical that obstructs or separates, such as barriers to communication or compliance" (Anderson *et al* 2002, p182).

Diabetes mellitus - "diabetes is a group of metabolic diseases characterised by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. The chronic

hyperglycaemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels" (ADA 2003).

Health care providers - "any individual, institution, or agency that provides health services to health care consumers" (Anderson *et al* 2002, p784).

Knowledge - "facts, information and skills acquired through experience or education; it can also be regarded as the theoretical or practical understanding of a subject" (Stevenson 2010, p 671).

Motivation - "the processes that accounts for an individual's intensity, direction and persistence of effort toward attaining a goal" (Lambrou, Kontodimopoulos & Niakas 2010).

Perception- "a conscious recognition and interpretation of sensory stimuli that serve as a basis for understanding, learning and knowing or for motivating a particular action or reaction" (Anderson *et al* 2002, p1310).

1.8 Summary

Globally, the prevalence of diabetes has reached pandemic proportions. The prevalence of type 2 diabetes in adults living in India, particularly South India, has become alarming. Despite the developments in pharmaceutical and diagnostic therapy, healthcare and advances in the array of guidelines available, the control of diabetes worldwide, including India, remains suboptimal. Inadequate management of diabetes leads to serious consequences for the individual with diabetes and the increasing costs for the wider health economy. Barriers to effective diabetes management include both patient- and health care provider-related issues. Patient-related barriers include time constraints, lack of knowledge, weak motivational factors, lack of family and medical support. Health care provider-barriers include sub-optimal knowledge of guidelines, constraints of time and facilities and attitudinal issues. Health care providers are not always aware of the most effective interventions and tend to spend more time on acute management rather than chronic care. The complexity of T2DM as a disease and the multiple interventions required, make HCPs wary of treating T2DM. This is especially since disease prognosis remains unpredictable in spite of aggressive management. Although, various studies have been done worldwide and within Chennai to address the barriers to lifestyle, none have covered the perceptions of the HCPs and the barriers to motivation. Considering this, there is a need to investigate the barriers to change from the perspective of the patient and

HCPs, this study aimed to evaluate the barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their health care providers in Chennai, Tamil Nadu, India. It is hoped that the results from this study would identify and improve the understanding of these barriers and recommend ways of better managing and assisting the diabetic patient.

CHAPTER 2: LITERATURE REVIEW

This chapter reviews the definition and types of diabetes mellitus as well as diagnosis, risk factors, complications and co-morbidities. Management and the barriers faced by diabetics in lifestyle modification, support, motivation and acquiring adequate, appropriate knowledge are also reviewed. The difficulties faced by Indian diabetics in a developing country and the change from disease treatment to patient treatment are also covered.

2.1 Definition and types of diabetes mellitus

Diabetes mellitus is a chronic, non-communicable disease resulting in increased blood glucose levels. In diabetes, there is deficient insulin secretion by the pancreas or ineffectiveness of secreted insulin which can be inherited or acquired (IDF Diabetes Atlas 2015, p12). There are several forms of diabetes, such as:

a. Type 1 diabetes mellitus or insulin dependent diabetes mellitus (IDDM) is caused by an autoimmune reaction, in which the body's defence system attacks the insulin-producing beta cells in the pancreas. As a result, the body can no longer produce the insulin it needs. The reason for this is not fully understood and the disease can affect people of any age. However, onset usually occurs in children or young adults. People with this form of diabetes require insulin daily in order to control blood glucose levels. Without insulin, a person with type 1 diabetes mellitus will die (IDF Diabetes Atlas 2015, p12).

b. Type 2 diabetes mellitus or non-insulin dependent diabetes mellitus (NIDDM) (other specific types include damage to the pancreas by specific causes such as toxins and infections). Type 2 diabetes is the most common type of diabetes. It usually occurs in adults, but is increasingly seen in children and adolescents. In T2DM, the body is able to produce insulin but becomes resistant and the insulin is ineffective. Over time, insulin levels may subsequently become insufficient. Both insulin resistance and deficiency lead to high blood glucose levels (IDF Diabetes Atlas 2015, p23). In the case of individuals with raised blood glucose levels that are not high enough for a diagnosis, a diagnosis of IGT or IFG may be made (IDF Diabetes Atlas 2015, p26).

c. Impaired glucose tolerance (blood glucose $\geq$ 11.1mmol/l after 2 hr of 75g of glucose intake) and impaired fasting glucose (blood glucose 6.1 to 6.9 mmol/l) (Kumar, Goel, Jain, Khanna & Chaudhary 2013).

d. Gestational diabetes mellitus (GDM) occurs only during pregnancy. It can lead to serious health risks for both the mother and child. Gestational diabetes mellitus is associated with an increased risk of both mother and child developing T2DM later in life (IDF Diabetes Atlas 2015, p26).

2.2 Diagnosis of diabetes mellitus

The WHO recommendations for diagnostic criteria for diabetes mellitus and intermediate hyperglycaemia is shown in Table 2.1 (WHO 2006).

Table 2.1: WHO recommendations for diagnostic criteria for diabetes mellitus and intermediate hyperglycaemia (WHO 2006)

Diabetes	
Fasting plasma glucose	≥7.0mmol/l (126mg/dl)
2–h plasma glucose*	**or** ≥11.1mmol/l (200mg/dl)
Impaired Glucose Tolerance (IGT)	
Fasting plasma glucose	<7.0mmol/l (126mg/dl)
2–h plasma glucose*	**and** ≥7.8 and <11.1mmol/l (140mg/dl and 200mg/dl)
Impaired Fasting Glucose (IFG)	
Fasting plasma glucose	6.1 to 6.9mmol/l (110mg/dl to 125mg/dl)
2–h plasma glucose*	**and (if measured)** <7.8mmol/l (140mg/dl)

* Venous plasma glucose 2–h after ingestion of 75g oral glucose load

* If 2–h plasma glucose is not measured, status is uncertain as diabetes or IGT cannot be excluded

The WHO (2006) further recommends that the following be used as diagnostic tests:

a. Venous plasma glucose should be the standard method for measuring and reporting. However, in recognition of the widespread use of capillary sampling, especially in under-resourced countries, conversion values for capillary plasma glucose are provided for post-load glucose values. Fasting values for venous and capillary plasma glucose are identical.

b. Glucose should be measured immediately after collection by near patient testing, or if a blood sample is collected, plasma should be immediately separated or the sample should be

collected into a container with glycolytic inhibitors and placed on ice-water until separated, prior to analysis (WHO 2006).

Glycosylated haemoglobin (HbA_{1c}) reflects the average blood glucose concentration over the previous few weeks, rather than the blood glucose concentration at that moment (reflected by the fasting and 2-hour blood glucose measurements mentioned earlier) (WHO 2011, p6). The use of the HbA_{1c} test for monitoring blood glucose levels was the result of reports from major outcomes studies including, the Diabetes Control and Complications Trial Research Group, the UK Prospective Diabetes Study, Action to Control Cardiovascular Risk in Diabetes Study Group, Action in Diabetes and Vascular Disease, Preterax and Diamicron Modified Release Controlled Evaluation and Veterans Affairs Diabetes Trial (IDF Clinical Guidelines Task Force 2012). With the HbA_{1c}, health care providers can observe the patient's blood glucose control to determine risk of complications. Further to this, the HbA_{1c} test should only be mandatory where it is affordable and or available (IDF Clinical Guidelines Task Force 2012).

2.3 Risk factors for diabetes mellitus

Aside from the common risk factors, such as urbanisation, industrialisation, globalisation and aging, other factors place Indians more at risk of diabetes mellitus than other race groups. It has been suggested that the higher percentage of body fat to lean body mass, central obesity, obesity, intra-uterine period and rapid growth gain in infanthood, including genetic factors, increases the risk (Tandon & Raizada 2014).

2.3.1 Genetic predisposition

Mohan *et al* (2007) examined a few studies that showed that Asian Indians (a citizen of Asian descent with ancestors in India) were at increased risk of developing T2DM, compared to other ethnic groups (Mohan *et al* 2007). Reasons for this remain unclear, although the "Asian Indian phenotype" is considered to be a major contributing factor to the increased risk of diabetes (Deepa, Farooq, Deepa, Manjula & Mohan 2006; Joshi 2003). According to the "Asian Indian phenotype", Asian Indians have a small body size, which has been termed thin-fat Indian. Asian Indians have thinner limbs, which is suggestive of a smaller muscle mass. However,

despite their thinness, they are centrally obese, with a higher waist-to-hip ratio (WHR) and higher subscapular-to-triceps skinfold ratio, than their British counterparts (Joshi 2015).

Asian Indians have a higher waist to hip ratio than other race groups; even though their body mass index (BMI) is lower (Mohan *et al* 2007). This implies that they have greater abdominal obesity. It has also been shown that the Indian Asian has more abdominal and visceral fat for any given BMI (Raji, Seely, Arky & Simonson 2001). However, a later study conducted by Szuszkiewicz-Garcia, Li, Grundy, Abate & Chandalia (2012), noted that Asian Indian women did not have significant differences in visceral and abdominal fat, compared to Caucasian women (Szuszkiewicz-Garcia *et al* 2012). Another study showed that for any given amount of body fat, Asian Indian men had increased insulin resistance (Chandalia, Abate, Garg, Stray-Gundersen & Grundy 1999).

The "thin-fat Indian baby" as observed by Yajnik, Fall, Coyaji, Hirve, Rao & Barker (2003) and Yajnik, Lubree, Rege, Naik, Deshpande, Deshpande, Joglekar & Yudkin (2002), suggests that Indian neonates are born smaller but are relatively fatter compared to Caucasian babies (Yajnik *et al* 2003;Yajnik *et al* 2002). Further to this, Krishnaveni, Hill, Veena, Leary, Saperia, Chachyamma, Karat & Fall (2005), showed that the "thin-fat phenotype" in neonates continues in childhood and could be the initial cause of the diabetogenic adult phenotype. According to the "thin-fat phenotype", Indian babies are lighter, with small abdominal and arm circumferences, but show relative sparing of subscapular skinfold thickness. This phenotype is described as muscle-thin but adipose ('thin-fat') body composition (Krishnaveni *et al* 2005). This suggests that Asian Indians are more prone to diabetes and metabolic abnormalities (Krishnaveni *et al* 2005).

While some genes seem to confer increased susceptibility to diabetes in Asian Indians (Abate, Chandalia, Satija, Adams-Huet, Grundy, Sandeep, Radha, Deepa & Mohan 2005; Vimaleswaran, Radha, Ghosh, Majumder, Deepa, Babu, Rao & Mohan 2005), some protective genes in Europeans do not appear to protect Indians (Radha, Vimaleswaran, Babu, Abate, Chandalia, Sathija, Grundy, Ghosh, Majumder, Deepa, Rao & Mohan 2006).

2.3.2 Lifestyle

2.3.2.1 Fast food culture

It is useful to understand how diets have changed across the low- and medium-income world to converge on what is often termed the "Western diet." This is broadly defined by high intake of refined carbohydrates, added sugars, fats and animal-source foods (Popkin, Adair & Ng 2012). Fast foods and snack foods are generally high in fat and commonly contain trans-fatty acids, both of which contribute to insulin resistance (Odegaard & Pereira 2006). Data available from low- and middle-income countries document this trend in all urban areas and increasingly in rural areas. Diets rich in legumes, vegetables, and grains are disappearing in all regions and countries worldwide. Some major global developments in technology have been behind this shift (Popkin *et al* 2012).

Popkin *et al* (2012) also observed that refined oils have become more abundant and affordable over the past decades. Shetty (2002), observed that city dwellers in India appeared to consume a higher percentage of energy from fat (32%), as compared to rural areas (17%) (Shetty 2002). Colles, Singh, Kohli & Mithal (2013) found an inconsistency between the level of education and socio-economic advantage related to healthy eating food choices. Colles *et al* (2013) found that younger people purchased fast or take away foods more frequently, mostly due to taste, as a determinant of their food choice. This suggests that the younger generation are eating more processed, high fat and sugary foods (Colles *et al* 2013).

2.3.2.2 Sedentary lifestyle

Exercise has been shown to be beneficial in decreasing body fat and improving lean mass in patients with T2DM (Sigal *et al* 2007; Boule´ *et al* 2001). Exercise also plays a major role in the prevention and control of insulin resistance, T2DM and diabetes-related health complications. Both aerobic and resistance training can improve insulin action as well as the management of blood glucose levels, lipids, high blood pressure, cardiovascular risk and quality of life (Sanz, Gautier & Hanaire 2010; Roumen, Corpeleijn, Feskens, Mensink, Saris & Blaak 2008; Sigal *et al* 2007; Simmons, Harding, Jakes, Welch, Wareham & Griffin 2006; Boule´ *et al* 2001; Pan, Li, Hu, Wang, Yang, An, Hu, Lin, Xiao, Cao, Liu, Jiang, Jiang, Wang,

Zheng, Zhang, Bennett & Howard 1997). Regular training with varying types of exercise should be undertaken regularly to have continued benefits (Colberg *et al* 2010).

According to The Joint Position Statement of the American College of Sports Medicine and the American Diabetes Association (2010), both aerobic and resistance training improve insulin action, blood glucose control, fat oxidation and storage in muscle. Resistance exercise also enhances skeletal muscle mass (Colberg *et al* 2010). Further to this, the paper states that achieving the recommended levels of physical activity may help to achieve weight loss. However, up to 60 minutes of exercise on a daily basis may be required when relying on exercise alone, for weight loss (Colberg *et al* 2010).

Van Dijk, Tummers, Stehouwer, Hartgens & van Loon (2012), showed that frequent short spells of exercise were equally effective in improving glycaemic control as less frequent exercise spells, of longer duration. Hereby, the total amount of exercise accomplished seems to be of greater importance with respect to glycaemic control (Van Dijk *et al* 2012). It has been noted that quality of life (QOL) and depression rates are also related to physical activity. The Joint Position Statement of The American College of Sports Medicine and the American Diabetes Association (2010), mentions that increased physical activity and physical fitness can reduce symptoms of depression and improve health-related QOL in those with T2DM (Colberg *et al* 2010).

Colberg *et al* (2010) suggests that people with T2DM should do moderate to vigorous aerobic exercise for at least 150 minutes/week over a period of at least three days during the week, with no more than two consecutive days between bouts of aerobic activity (Colberg *et al* 2010). In addition to aerobic training, type 2 diabetics should also undertake moderate to vigorous resistance training at least 2-3 days/week (Colberg *et al* 2010). The Position Statement from Exercise and Sport Science Australia recommends that individuals with T2DM should accrue a minimum of 210 minutes of moderate intensity or 125 minutes of vigorous intensity exercise each week, using a combination of both aerobic and resistance training (Hordern, Dunstan, Prins, Baker, Singh & Coombes 2012). If possible, the total amount of exercise should consist of some aerobic and some resistance training. However, if only one type can be done, then

either type alone will also be effective. In older adults with multiple chronic diseases, the risks associated with exercise are considered less than those of inactivity. As a result, exercise training should be an essential component of any treatment plan for all patients at risk of or with T2DM (Hordern *et al* 2012).

2.4 Complications and co-morbidities of diabetes mellitus

2.4.1 Complications of diabetes mellitus

Because the average gap between onset and detection of diabetes is between 4 to 7 years, the degenerative changes secondary to aging and prolonged hyperglycaemia can damage tissues, leading to microvascular and macrovascular complications (Harris, Klein, Welborn & Knuiman 1992). The macrovascular complications include coronary artery disease, peripheral arterial disease and stroke. The microvascular complications include retinopathy, diabetic nephropathy and peripheral neuropathy (Kulshrestha, Seth, Tripathi, Seth & Kumar 2015).

2.4.1.1 Cardiovascular disease

According to the WHO, cardiovascular diseases (CVDs) are a group of disorders of the heart and blood vessels. It includes coronary heart disease (disease of the blood vessels supplying the heart muscle), cerebrovascular disease (disease of the blood vessels supplying the brain), peripheral arterial disease (disease of blood vessels supplying the arms and leg), rheumatic heart disease (damage to the heart muscle and heart valves from rheumatic fever, caused by streptococcal bacteria), congenital heart disease (malformations of heart structure existing at birth), deep vein thrombosis and pulmonary embolism (blood clots in the leg veins, which can dislodge and move to the heart and lungs) (WHO 2017b).

In Chennai, the Chennai Urban Rural Epidemiology Study (CURES) (2006) reported the prevalence of coronary artery disease to be 21.4% [Mohan, Deepa, Rani, Premalatha & Chennai Urban Population Study (CUPS No.5) 2001]. According to the A1chieve study, 23.6 % of Indian diabetics had cardiovascular complications (Mohan, Shah & Saboo 2013). The Indian Council of Medical Research India Diabetes Study (ICMR-INDIAB) (2014), reported that of the four regions of Tamil Nadu, Maharashtra, Jharkand and Chandigarh, Tamil Nadu (South India) had the highest cholesterol to high-density lipoprotein cholesterol (HDL-C) ratio,

mean cholesterol and low-density lipoprotein cholesterol (LDL-C) levels (Joshi, Anjana, Deepa, Pradeepa, Bhansali, Dhandania, Joshi, Unnikrishnan, Nirmal, Subashini, Madhu, Rao, Das, Kaur, Shukla & Mohan 2014).

Corroborating the Asian Indian phenotype (increased plasma insulin levels, insulin resistance, increased waist circumference, excess visceral fat and low adiponectin levels), Deepa *et al* (2006), showed a high prevalence of low HDL-C levels in Indian type 2 diabetics (Deepa, Sandeep & Mohan 2006, p145). A study conducted in South India by Velmurugan, Deepa, Ravikumar, Lawrence, Anshoo, Senthilvelmurugan, Enas & Mohan (2003), using 587 type 2 diabetics at a Chennai hospital with a mean age of 55 ± 10 years, showed that lipoprotein (a) had a strong association with intimal medial thickness of carotid arteries in type 2 diabetic subjects (Velmurugan *et al* 2003). According to Yadav, Tiwari & Dhanaraj (2008), the prevalence of macrovascular disease was higher in Asians, compared to Europeans (Yadav *et al* 2008). Further to this, Asian patients were found to have more macro and microvascular complications at diagnosis of diabetes, compared to European patients. In addition, the history of ischemic disease was more prevalent in Asians and Americans compared to Europeans (Yadav *et al* 2008).

Sasisekhar, Alekhya, Jagadeesh & Sudha (2012) showed that 28.18% of their South Indian study group had cardiovascular disease, which made it the second most common cause of deaths in one district in Andra Pradesh, India (Sasisekhar *et al* 2012). This study showed similar rates of cardiovascular disease as in the CURES from 2006. The authors attributed this to several contributory factors like coronary atherosclerosis, chronic hyperglycaemia, glycosylation of myocardial proteins and microvascular disease, which are intrinsically associated with diabetes mellitus (Sasisekhar *et al* 2012; Mohan *et al* 2001).

2.4.1.2 Retinopathy

Diabetic retinopathy (DR) and diabetic macular oedema (DME) are common microvascular complications affecting the eye, in diabetic patients. These complications could lead to a sudden and incapacitating impact on visual acuity, eventually causing blindness. In advanced stages of DR, there is growth of abnormal retinal blood vessels, secondary to ischemia. These

blood vessels grow in an attempt to supply oxygenated blood to the hypoxic retina. At any time during the progression of DR, patients with diabetes can also develop DME, which involves retinal thickening in the macular area. Diabetic macular oedema occurs after breakdown of the blood-retinal barrier because of leakage of dilated hyperpermeable capillaries and micro aneurysms (Ciulla, Amador & Zinman 2003).

Diabetic retinopathy is a major cause of vision loss in patients with diabetes. The longer patients have diabetes, the higher the prevalence of DR. The Chennai Urban Rural Epidemiology Study (CURES) reported that the prevalence of DR in the urban diabetic Chennai population was 17.6% (Rema, Premkumar, Anitha, Deepa, Pradeepa & Mohan 2005). In 2012, the prevalence of DR in 35 studies across the USA, Australia, Europe and Asia was 34.6% [Yau, Rogers, Kawasaki, Lamoureux, Kowalski, Bek, Chen, Dekker, Fletcher, Grauslund, Haffner, Hamman, Ikram, Kayama, Klein, Klein, Krishnaiah, Mayurasakorn, O'Hare, Orchard, Porta, Rema, Roy, Sharma, Shaw, Taylor, Tielsch, Varma, Wang, Wang, West, Xu, Yasuda, Zhang, Mitchell, Wong & the Meta-Analysis for Eye Disease (META-EYE) Study Group 2012]. The prevalence of DR in the urban diabetic Chennai population was still lower than worldwide rates.

2.4.1.3 Microvascular disease

a. Neuropathy

A group of nerve disorders known as diabetic neuropathies occurs as a result of constant high blood sugar levels. Patients are unable to perceive sensations like heat, cold and pain in extremities because of nerve damage. Due to the lack of these sensations, the patient may not be aware of a sore or an ulcer in the foot. Along with delayed or non-healing of ulcers due to diabetes, many patients lose their limbs (D'Souza, Kulkarni, Bhaskaran, Ahmed, Naimish, Prakash, Tabreez, Dahiya, Thapar, Mithra, Kumar, Holla, Darshan & Kumar 2015). One of the most chronic and debilitating complication of diabetes is diabetic peripheral neuropathy (DPN) (Bansal, Gudala, Muthyala, Esam, Nayakallu & Bhansali 2014). A challenge with the development of DPN is that the changes are subtle and occur as people age. As a result, the signs of nerve damage are missed or ignored and are blamed on aging (D'Souza *et al* 2015).

Bansal *et al* (2014) reported that 29.2% of North Indian type 2 diabetic patients had DPN (Bansal *et al* 2014). This is similar to CURES, which found the prevalence of diabetic neuropathy to be 26.1% amongst diabetic subjects in Chennai (Pradeepa, Rema, Vignesh, Deepa, Deepa & Mohan 2008). However, a study with 1401 type 2 diabetics in Chennai found a prevalence of diabetic neuropathy of 19.8% (Rani, Raman, Rachapalli, Pal, Kulothungan & Sharma 2010). Foot infection is a common complication and a leading cause of hospital admission among diabetic patients in India (Viswanathan & Kumpatla 2009). Recurrence of foot infection is commonly seen and is mainly due to the presence of neuropathy and peripheral vascular disease (Vijay, Narasimham, Seena, Snehalatha & Ramachandran 2000). Approximately 40 to 72% of lower extremity amputations related to diabetes were found in 31 centre across India (Viswanathan & Kumpatla 2009). Morbach, Lutale, Viswanathan, Möllenberg, Ochs, Rajashekar, Ramachandran & Abbas (2004), found that although peripheral vascular disease (PVD) was more common in Germany than Tanzania and Chennai; the amputation rate was higher among Indians, due to progressive infection (Tanzania vs. Germany vs. India: 12% vs. 48% vs. 13%, respectively) (Morbach *et al* 2004).

b. Foot ulcers

Patients with diabetes are prone to developing diabetic foot ulcer (DFU). Diabetic foot ulcer is a common complication of DM with an increasing trend over the past few decades (Yazdanpanah, Nasiri & Adarvishi 2015). Several risk factors for diabetic foot ulcers have been identified. These include peripheral neuropathy, vascular disease, limited joint mobility, foot deformities, abnormal foot pressures, minor trauma, a history of ulceration or amputation, and impaired visual acuity. Diabetic neuropathy, peripheral vascular disease, foot deformity and previous diabetic foot ulceration or lower extremity amputation and being diagnosed with DM for more than 10 years, are additional risk factors. A previous diagnosis of acute myocardial infarction and stroke, interdigital mycosis and calluses, gender (male), older patients and high BMI are also known risk factors. Co-morbidities such as retinopathy, elevated HbA_{1C}, high plantar pressure, infections, inappropriate foot self-care habits and peripheral arterial disease also increase risk for developing DFU (Yazdanpanah *et al* 2015; Bortoletto, de Andrade, Matsuo, Haddad, González & Silva 2014; Waaijman, de Haart, Arts, Wever, Verlouw & Nollet 2014; Monteiro-Soares, Boyko, Ribeiro, Ribeiro & Dinis-Ribeiro

2012; Frykberg, Zgonis, Armstrong, Driver, Giurini, Kravitz, Landsman, Lavery, Moore, Schuberth, Wukich, Andersen & Vanore 2006).

Foot ulceration in patients with diabetic peripheral neuropathy can be caused by foot deformities and gait instability, due to increased plantar pressure (Fernando, Crowther, Pappas, Lazzarini, Cunningham, Sangla, Buttner & Golledge 2014; Bacarin, Sacco & Hennig 2009). According to Viswanathan & Kumpatla (2009), a foot ulcer can also develop due to a combination of peripheral vascular disease, peripheral neuropathy, infection and poor foot care (Viswanathan & Kumpatla 2009). Many foot complications associated with diabetes in rural India are neuropathic and infective, rather than vascular in origin, as in developed countries (Aleem 2003). A multicentre study covering 31 centres across India with 1985 type 2 diabetic subjects, showed that a total of 1295 (65%) patients had undergone amputations, both major and minor. The prevalence of neuropathy was high (82%) and 35% had peripheral vascular disease (Viswanathan & Kumpatla 2009). In the A1chieve study (2013), conducted on 20 000 type 2 Indian diabetics, the reported prevalence of foot ulcers was 5.1% (Mohan *et al* 2013).

2.4.1.4 Nephropathy

Diabetic nephropathy (DN) or diabetic kidney disease is a syndrome characterised by the presence of extreme quantities of urine albumin excretion, diabetic glomerular lesions and loss of glomerular filtration rate (GFR) in diabetics (Lim 2014). The pathophysiological mechanisms of diabetic nephropathy are not completely understood. It may be due to the glycosylation of circulating and intrarenal proteins, hypertension, and abnormal intrarenal haemodynamics (Evans & Capell 2000). Poor metabolic control is critical in the cause of diabetic nephropathy. Nephropathy is uncommon in patients with glycosylated haemoglobin (HbA_{1c}) consistently less than 7.58% (Evans & Capell 2000).

Diabetic nephropathy can be diagnosed early by elevated urine albumin and monitoring the decline of the GFR. However, not all patients with chronic kidney disease have elevated urine albumin at the onset. Therefore, both the blood and urine should be screened (Hahr & Molitch 2015). Chronic kidney disease (CKD) is increasing among Indian patients, as shown in a narrative review by Sequira, Prabhu, Mayya, Nagaraju, Devi, Nayak & George (2016). This

increased prevalence is largely due to diabetes and hypertension (Sequira *et al* 2016). The CURES (2005) study reported that the prevalence of microalbuminuria and nephropathy was 26.9% and 2.2%, respectively (Unnikrishnan *et al* 2007). The prevalence of renal complications amongst Indian diabetics in the A1chieve study was 21.1% (Mohan *et al* 2013).

2.4.2 Co-morbidities

2.4.2.1 Hypertension

Over one billion people are estimated to have hypertension, worldwide (Chobanian, Bakris, Black, Cushman, Green, Izzo, Jones, Materson, Oparil, Wright, Roccella, the National Heart, Lung and Blood Institute Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure & the National High Blood Pressure Education Program Coordinating Committee 2003). The high prevalence of hypertension (HTN) makes it a significant factor for mortality and morbidity (Mohan *et al* 2013). A strong link has been found between changing lifestyle factors and an increase in both diabetes and hypertension (Mohan *et al* 2013).

Diabetes and hypertension coexist in 40%-60% of patients with T2DM in the USA, making hypertension a common co-morbid condition in diabetics (Arauz-Pacheco, Parrott & Raskin 2002; Sowers, Epstein & Frohlich 2001). As both diabetes and hypertension affect the same target organs, people with co-existing DM and HTN are at increased risk of developing atherosclerosis, retinopathy, renal failure, non-traumatic amputations and CVD (Stamler, Vaccaro, Neaton & Wentworth 1993). The Systolic Hypertension in the Elderly Program and the Systolic Hypertension in Europe Study found that those with coexisting DM had an approximate doubling in cardiovascular morbidity and mortality (Tuomilehto, Rastenyte, Birkenhäger, Thijs, Antikainen, Bulpitt, Fletcher, Forette, Goldhaber, Palatini, Sarti & Fagard 1999; Curb, Pressel, Cutler, Savage, Applegate, Black, Camel, Davis, Frost, Gonzalez, Guthrie, Oberman, Rutan & Stamler 1996).

In India, about 50% of diabetic individuals have HTN (Mohan *et al* 2013). The Screening India's Twin Epidemic (SITE) cross-sectional study conducted in 10 Indian states established

that diabetes and hypertension were coexistent in 20.6% of patients. This shows an extensive strain of the rise of DM and HTN in India (Joshi, Vadivale, Dalal & Das 2011).

2.4.2.2 Dyslipidaemia

Dyslipidaemia is defined as elevated total or LDL-C levels or low levels of HDL-C (Fodor 2011). It is the key independent modifiable risk factor for CVD (Haffner 1999; Grundy 1997). The Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) study (2015), showed the presence of abnormalities in at least one lipid parameter in 76.9% of the general population in Tamil Nadu; translating into 35.9 million individuals. In the same study, Tamil Nadu also had the highest cholesterol to HDL-C ratio (42.3%) (Pradeepa, Anjana, Joshi, Bhansali, Deepa, Joshi, Dhandania, Madhu, Rao, Geetha, Subashini, Unnikrishnan, Shukla, Kaur, Mohan & Das 2015). Further to this, HDL-C levels were the most common lipid abnormality, thus illustrating the Asian Indian phenotype (Joshi *et al* 2014). A meta-analysis of randomised controlled trials showed that effective treatment of dyslipidaemia reduces morbidity and mortality (Costa, Borges, David & Carneiro 2006).

2.4.2.3 Obesity

Obesity is defined as a condition of abnormal or excessive fat accumulation in adipose tissue, to the extent that health is impaired. The amount of excess fat and its distribution in the body, either around the waist and trunk (abdominal, central or android obesity) or peripherally around the body (gynoid obesity), have important health implications (Ofei 2005). Although under nutrition was well-known to exist in India, it is now overweight and obesity that are being reported more frequently. Excess body fat, abdominal adiposity, increased subcutaneous and intra-abdominal fat and deposition of fat in ectopic sites (such as liver, muscle, and others), are common among Indians. Obesity is a known predictor for the extensively prevalent metabolic syndrome and T2DM in India (Kalra & Unnikrishnan 2012).

The ICMR-INDIAB (2015) reported on the prevalence of obesity (generalised and abdominal) in urban and rural states of India. The highest prevalence of both types of obesity (generalised obesity and abdominal obesity) was found in Chandigarh, followed by Tamil Nadu (South India), Maharashtra and Jharkhand (Pradeepa *et al* 2015). The CURES conducted in Chennai,

Tamil Nadu reported age-standardised prevalence of generalised obesity to be 45.9%, while that of abdominal obesity was 46.6% (Deepa *et al* 2006).

The prevalence of obesity in India is on the rise due to an increased energy intake. This is due to increased purchasing power and availability of high fat, energy-dense foods, along with a reduction in energy expenditure from urbanisation and mechanisation (Misra & Shrivastava 2013; Misra, Sharma, Gulati, Joshi, Sharma, Ghafoorunissa, Ibrahim, Joshi, Laxmaiah, Kurpad, Raj, Mohan, Chandalia, Krishnaswamy, Boindala, Gopalan, Bhattiprolu, Modi, Vikram, Makkar, Mathur, Dey, Vasudevan, Gupta, Puri, Joshi, Khanna, Mathur, Krishnaswamy, Madan, Karmarkar, Seth, Passi, Chadha, Bhardwaj & National Dietary Guidelines Consensus Group 2011). Along with the increase in overweight and obesity, the escalation in metabolic syndrome and T2DM in India has reached epidemic proportions (Gulati & Misra 2014). The ICMR-INDIAB (2015) study found that the increase in obesity prevalence was not restricted to urban areas, but was also noted in rural areas of India. This suggests a further rise in obesity prevalence due to urbanisation (Pradeepa *et al* 2015).

2.5 Management of diabetes mellitus

Medical therapy, physical activity, medical nutrition therapy, psychological and social therapy and self-management form part of the management of diabetes mellitus. This is discussed further in this section.

2.5.1 Medical therapy

Historically, the management of high blood sugar levels (hyperglycaemia) has been the focus of treatment for T2DM. Research and therapy has also focused on other corresponding features, such as dyslipidaemia, hypertension, hypercoagulability, obesity and insulin resistance (Nathan, Buse, Davidson, Ferrannini, Holman, Sherwin & Zinman 2009). The ADA Position Statement (2011) goal of lowering HbA_{1c} to below or around 7%, has been shown to reduce microvascular and neuropathic complications associated with diabetes. If implemented soon after the diagnosis of diabetes, it is associated with a long-term reduction in macrovascular disease. Therefore, a reasonable HbA_{1c} goal for many non-pregnant diabetic adults is 7% (ADA 2011). This goal was reconfirmed in the ADA Position Statement of 2017

(ADA 2017). Recommended targets for effective diabetic control in adults are shown in Table 2.2 (Kumar *et al* 2013).

Table 2.2: Recommended targets for effective diabetic control in adults (after Kumar *et al* 2013)

Parameter	**Target level**
Glycosylated haemoglobin (HbA_{1c})	< 7%
Triglyceride level (fasting)	< 150 mg/dL (1.69 mmol/l)
High density lipoprotein cholesterol	> 40 mg/dL (1.04 mmol/l) (in males) > 50 mg/dL (1.30 mmol/l) (in females)
Low density lipoprotein cholesterol	< 100 mg/dL (2.59 mmol/l) (individuals without overt cardiovascular disease) < 70 mg/dL (1.81 mmol/l) (individuals with overt cardiovascular disease)
Body mass index	<25 kg/m^2
Systolic blood pressure	< 130 mmHg (or below the 90^{th} percentile for age, sex, and height, whichever is lower)
Diastolic blood pressure	< 80 mmHg (or below the 90^{th} percentile for age, sex, and height, whichever is lower)

Pharmacological treatment and blood glucose monitoring, as part of medical therapy, is discussed next.

2.5.1.1 Pharmacological treatment

The use of metformin, a biguanide (a group of anti-diabetic drugs that lowers blood sugar) as first-line therapy in T2DM was supported by findings from a large meta-analysis (Palmer, Mavridis, Nicolucci, Johnson, Tonelli, Craig, Maggo, Gray, De Berardis, Ruospo, Natale, Saglimbene, Badve, Cho, Nadeau-Fredette, Burke, Faruque, Lloyd, Ahmad, Liu, Tiv, Wiebe & Strippoli 2016). The ADA Position Statement (2017) suggests the following treatment algorithm for type 2 diabetes mellitus: in patients with metformin contraindications or intolerance, an initial drug from other classes (sulfonylurea, thiazolidinedione, DPP-4 Inhibitor, SGLT2 inhibitor, GLP-1 receptor agonist), should be considered. If HbA_{1c} is > 9%,

(75 mmol/ml), dual combination therapy (combining drugs) should be considered to achieve the target HbA_{1c} level quicker (ADA 2017).

When these combination methods are ineffective and hyperglycaemia is severe, insulin should be considered as part of any combination regimen. Severe hyperglycaemia is seen when symptoms of any catabolic features (weight loss and ketosis) are present. Thereafter, combination insulin injectable therapy should be considered when blood glucose is >300 mg/dL (16.7 mmol/L) or HbA_{1c} is >10%, or if the patient has symptoms of hyperglycaemia (i.e., polyuria or polydipsia) (ADA 2017).

2.5.1.2 Blood glucose monitoring

Blood glucose monitoring has developed from doubtful methods like urine testing to colorimetric blood glucose strips. Later, glucose sensors and manually calibrated glucometers were used. In the present modern era, auto-calibrated accurate glucometers with biosensors for self-monitored blood glucose (SMBG) are available. Estimation of HbA_{1c} remains the gold standard for glucose monitoring (Khadilkar, Bandgar, Shivane, Lila & Shah 2013). Glycosylated haemoglobin reflects average blood glucose levels over approximately three months and has a strong predictive value for diabetes complications (ADA 2017). The frequency of HbA_{1c} testing should depend on the clinical situation, the treatment regimen and the clinician's judgment. The use of point-of-care HbA_{1c} testing may provide an opportunity for more timely treatment changes during encounters between patients and HCPs. Patients with T2DM with stable glycaemia well within target, may only require HbA_{1c} testing twice a year (ADA 2017).

Two studies from the Indian subcontinent have shown racial and ethnic differences in HbA_{1c} levels. Kumar, Bhansali, Ravikiran, Bhansali, Dutta, Thakur, Sachdeva, Bhadada & Walia (2010), in a regional study from North India, showed that use of the ADA cut-offs for HbA_{1c} in the Indian population, resulted in 38% of the patients being underdiagnosed for diabetes. Kumar *et al* (2010) proposed an HbA_{1c} cut-off of 6.1% for the Indian population, which was also validated in a similar study from South India (Mohan, Vijayachandrika, Gokulakrishnan, Anjana, Ganesan, Weber & Narayan 2010).

Self-monitoring of blood glucose (SMBG) is the easiest and the most widely used method of short-term glucose monitoring, worldwide. Finger stick glucose testing using a glucometer is the prototype of SMBG. These points of care devices have transformed the concept of glucose monitoring at home (Khadilkar *et al* 2013). However, there is contradictory evidence on the clinical benefits of SMBG for patients with T2DM, who are not on insulin therapy. Positive effects include decreased hospital admissions and morbidity (Burge 2001). Negative results include no improvement in glycaemic control because the glycaemic control is not constant (Farmer, Wade, French, Simon, Yudkin, Gray, Craven, Goyde, Holman, Mant, Kinmonth, Neil & DiGEM Trial Group 2009). A nocebo effect has also been described by a few studies, which showed that SMBG in patients with T2DM resulted in increased anxiety and depression (Fisher, Polonsky, Parkin, Jelsovsky, Amstutz & Wagner 2011). There is also uncertainty about the optimal frequency and timing of self-monitoring (Hawkins 2010).

Although SMBG is an important monitoring tool to help patients reach their ideal HbA_{1c} levels, a Chennai-based study found that there was inadequate training and knowledge of SBMG in 75.8% of patients (Krishnan & Thirunavukkarasu 2016). In India, health systems have not been able to effectively manage diabetes and this is reflected in the number of people with diabetes (50-60%), who do not achieve the glycaemic target of $HbA_{1c} < 7\%$ (Wangnoo *et al* 2013).

2.5.2 Physical activity

Aerobic exercise is defined as any physical exercise that requires additional effort by the heart and lungs to meet the skeletal muscles increased demand for oxygen. Aerobic exercise increases the breathing rate and ultimately raises the heart and lung efficiency. Prolonged aerobic exercise (at least 20 minutes three times per week) is recommended for the maintenance of a healthy cardiovascular system. Examples of aerobic exercise include running, jogging, swimming and vigorous dancing or cycling (Anderson *et al* 2002, p50).

The ADA Position Statement on Physical Activity and Diabetes (2004) describes the effect of exercise on insulin. According to this position statement, during the course of physical activity, whole-body oxygen consumption may increase by as much as 20-fold and larger escalations may occur in the working muscles. As a result, skeletal muscles use its own stores of glycogen

and triglycerides as well as free fatty acids (FFAs) derived from the breakdown of adipose tissue triglycerides and glucose released from the liver, to meet its energy needs under these circumstances (ADA 2004).

In type 1 diabetics, an unnecessary release of counter insulin hormones during physical activity may escalate already high levels of glucose and ketone bodies, and may cause diabetic ketoacidosis. Consequently, insulin increases due to exogenous insulin administration can diminish or even thwart the raised deployment of glucose and other substrates caused by physical activity, and hypoglycaemia may occur. Similarly, these fears exist in patients with type 2 diabetes on insulin or sulfonylurea therapy. Generally, hypoglycaemia during physical activity tends to be less problematic in this group. Undeniably, physical activity may improve insulin sensitivity and reduce blood glucose levels into the normal range for type 2 diabetics (ADA 2004).

According to the American College of Sports Medicine and the American Diabetes Association, persons with type 2 diabetes should undertake at least 150 minutes/week (2.5 hours/week) of moderate to vigorous aerobic exercise, spread out during at least three days during the week, with no more than two consecutive days between bouts of aerobic activity (Colberg *et al* 2010). Van Dijk *et al* (2012) concluded that a short 30-minute session of moderate-intensity endurance-type exercise substantially reduces the prevalence of hyperglycaemia, throughout the subsequent day in type 2 diabetic patients. Hereby, frequent short spells of exercise are equally effective in improving glycaemic control as less frequent exercise spells of a longer duration. Therefore, the total amount of work done seems to be of key importance with respect to glycaemic control (Van Dijk *et al* 2012).

Evidence from 12 randomised control tests using 864 patients, suggests that yoga can significantly decrease full blood glucose (FBG), post prandial blood glucose (PPBG), HbA_{1c}, total cholesterol (TC) and LDL-C levels and increase HDL-C levels (Cui, Yan, Yan, Pan, Le & Guo 2017). In the Indian subcontinent, 1292 subjects with diagnosed T2DM and pre-diabetes were recruited from different states of India (Karnataka, Maharashtra, Gujarat, Rajasthan, and Tamil Nadu), for a yoga-based lifestyle intervention, introduced through 10-

day non-residential camps. A statistically significant decrease in baseline values for FBG, PPBG, HbA_{1c}, TC and LDL-C levels and post intervention assessments (first day and tenth day respectively), and increased HDL-C were noted (Cui *et al* 2017). According to Colberg *et al* (2010), both aerobic and resistance training improve insulin action, at least acutely, and can assist with the management of blood glucose levels, lipids, blood pressure, cardiovascular disease risk, mortality and quality of life; however, exercise must be undertaken regularly to have continued benefits (Colberg *et al* 2010).

2.5.3 Medical nutrition therapy

For persons with diabetes, the most perplexing part of the treatment plan is determining what to eat. Most medical nutrition therapy guidelines prescribe to the ADA position; that is there is no "one-size-fits-all" eating pattern for people with diabetes. The ADA and European Association for the Study of Diabetes (EASD) also recognise the vital role of nutrition therapy in overall diabetes management. It is recommended that each person with diabetes should practice self-management and be engaged in education and treatment planning with the health care provider. It is also suggested that a personalised eating plan be developed along with encouraging the consumption of healthy foods that are consistent with the prevailing population-wide dietary recommendations. The eating plan should also be in line with an individual's preferences and culture (Inzucchi, Bergenstal, Buse, Diamant, Ferrannini, Nauck, Peters, Tsapas, Wender & Matthews 2012).

The ADA Position Statement (2017) states that, "all individuals with diabetes should receive individualized medical nutrition therapy (MNT), preferably provided by a registered dietician who is knowledgeable and skilled in providing diabetes-specific MNT." Medical nutrition therapy delivered by a registered dietician is associated with HbA_{1c} decreases of 0.5–2% for people with type 2 diabetes (Coppell, Kataoka, Williams, Chisholm, Vorgers & Mann 2010; Wolf, Conaway, Crowther, Hazen, Nadler, Oneida & Bovbjerg 2004; Ziemer, Berkowitz, Panayioto, El-Kebbi, Musey, Anderson, Wanko, Fowke, Brazier, Dunbar, Slocum, Bacha, Gallina, Cook & Phillips 2003; King, Peacock & Donnelly 1999).

Nutrition therapy guidelines for adult diabetics from the ADA (2017) is shown in Table 2.3. It outlines the quantity and frequency of the intake of all macronutrients, sodium, supplementation and sugar. Table 2.4 shows the dietary guidelines for diabetes from the ICMR (2005) and Table 2.5 shows diabetic dietary guidelines from the National Dietary Guidelines Consensus Group in India (Misra *et al* 2011).

Table 2.3 American Diabetes Association Position Statement on the nutrition therapy guidelines (given as daily) for adults with diabetes (ADA 2017)

Energy	Carbohydrates	Protein	Fat	Sodium	Supplementation	Sugar
1,200-1,500 kcal/day for women; 1,500-1,800 kcal/day for men. Adjusted for the individual's baseline body weight. Further to this, many obese individuals with type 2 diabetes would benefit from weight loss of 5% due to better glycaemic control, lipids and blood pressure. Sustained weight loss of >7% is optimal.	Replace refined carbohydrates and added sugars with whole grains, legumes, vegetables, and fruits. The consumption of sugar sweetened beverages and processed "low-fat" or "non-fat" food products with high amounts of refined grains and added sugars should be strongly discouraged. The modified plate method (which uses measuring cups to assist with portion measurement) may be an effective alternative, although carbohydrate counting is preferred for insulin dependent diabetics.	Daily protein intake also has no strong evidence to suggest a specified amount, hereby should be individualised to the diabetics co-morbidities and lipid profiles.	The type of fats consumed is more important than total amount of fat when looking at metabolic goals and CVD risk. There is insufficient evidence to prescribe omega-3 fatty acids, as studies have not shown benefits concerning glycaemic control or prevention of CVD.	Sodium intake should be as for the general population. People with diabetes should limit their sodium consumption to 2,300 mg/day. Sodium intake recommendations should take into account palatability, availability, affordability, and the difficulty of achieving low-sodium recommendations in a nutritionally adequate diet.	No clear evidence of benefit from herbal or non-herbal (i.e., vitamin or mineral) supplementation for people with diabetes, without underlying deficiencies. Supplement with vitamin B12 for Metformin-treated patients after periodic testing.	For people who are accustomed to sugar sweetened products, non-nutritive sweeteners have the potential to reduce overall calorie and carbohydrate intake and may be preferred to sugar when consumed in moderation.

Table 2.4 Dietary guidelines for diabetes from the Indian Council of Medical Research (2005)

Energy	**Carbohydrates**	**Protein**	**Fat**	**Fibre**	**Sodium**	**Fruit**
The calorie requirements for a diabetic person depends on physical activity and nutritional status as in a normal individual, unless there is glycosuria. Individuals with >120% of ideal weight is considered overweight and <90% of ideal weight is underweight. The caloric intake of a person with diabetes should be altered gradually, preferably not more than 500 Kcal per day.	Carbohydrate (55-60% of total calorie requirement). • Avoid sugar, honey, jaggery (a sweetener made from the sap present in the flower buds of the coconut palm tree) and sweets. • Restrict processed, refined food like maida-based products (refined white flour). • Main source should be cereals, mixed coarse grains, whole pulses, salads and soybeans. • Roots and tubers should be used sparingly.	10-15% of total calorie requirement. Protein from vegetable sources, low fat milk and milk products, fish and lean meats are preferable.	20-25% of total calorie requirement • Saturated fat should be < 7% of total calorie intake (including ghee and butter). • Rest should be from MUFA and PUFA. • n6/n3 ratio = 5:10 • Trans-fatty acids (hydrogenated vegetable oils) should be avoided. • Dietary cholesterol intake should be minimal and should not exceed 300 mg per day. • Use more than one type of edible oil. • Oils containing linoleic acid (n-6) only, such as ground nut, sesame, cotton seed, rice bran, and safflower should be used along with oils containing alpha linolenic acid (n-3) such as soyabean, mustard and canola.	Traditionally, the Indian diet is rich in fibre. Fibre rich foods include whole grains (*ragi*, *jowhar*, barley and oats) whole pulses, soybean, green leafy vegetables and fenugreek seeds.	Up to 6g/day is permitted. Restrict pickles, papad, chutney and salty processed foods.	Whole fruits are recommended in moderatrion (1-2 servings), however, very sweet fruits and fruit juices should be avoided. **Alcohol** Alcohol intake is best avoided and if used it should be in moderation. It may exacerbate neuropathy, dyslipidemia, obesity and may worsen the control of diabetes.

Table 2.5 Diabetic dietary guidelines from the National Dietary Guidelines Consensus Group in India (Misra *et al* 2011)

Carbohydrates	**Low Glycaemic Index (GI) Foods**	**Fruits and vegetables**	**Fibre**	**Sugar**
The daily carbohydrate intake should be approximately 50-60% of the total calorie intake. For example, in 1,800 and 2,000 calorie diets, the carbohydrate intake for a sedentary to moderately active individual should be 225-270 g/day and 250-300 g/day, respectively. The primary source of complex carbohydrates in the diet should be cereals (whole wheat, brown rice), millets (pearl millet [*bajra*], finger millet [*ragi*], great millet [*Jowar*]), pulses (red gram [*tur dal*], green gram [*sabut moong*]), and legumes (soya, horse gram [*kulthi*]). Complex carbohydrates should be preferred over refined carbohydrates and its products (e.g. wholegrain bread over white [maida] bread).	Low GI foods (e.g. oats [*jai*], unpolished rice, parboiled rice, whole pulses, beans [*fali*], and legumes [*sabutanaz]* and some whole fruits [like guava, apple]), should be preferred. High GI foods (refined flour, root vegetables such as yam [*sooran/shakarkand*], potato, tapioca [a type of *shakarkand]*, colocasia [*arbi*]), should be consumed in moderation.	A minimum of four or five servings per day of fruits and vegetables is recommended (i.e., approximately 400-500 g/day including three vegetable and two fruit portions [e.g. 100 g of raw vegetables (e.g. cauliflower, brinjal) (20-30 Kcal); 100 g of fruit e.g. one apple (59 Kcal]). Fruits should be eaten whole, preferably with the skin, whenever feasible, instead of fruit juices.	The total dietary fibre in the daily diet should be 25-40 g/day (e.g. 100 g of apple [1 small apple] gives 1.0 g of fibre; 100 g of whole-wheat flour gives 1.9 g of fibre). Whole grains, cereals, pulses, vegetables, and fruits contain high dietary fibre.	Avoid simple sugars like crystalline sugar, sugarcane juice, sweetened carbonated beverages, fruit juices, and sugar syrups.

2.5.4 Psychological and social therapy

Thomas Willis, who claimed that diabetes was caused by "extreme sorrow", first noted the importance of emotional issues in diabetes over 300 years ago, in 1674. It has been emphasised that there is more to diabetes than just glucose control, and emotions play an important role in diabetes (Kalra, Sridhar, Balhara, Sahay, Bantwal, Baruah, John, Unnikrishnan, Madhu, Verma, Sreedevi, Shukla & Kumar 2013). Both type 1 and type 2 diabetes mellitus are emotionally and cognitively demanding diseases that place patients at risk for a variety of psychological conditions. The burden of depression and other psychological conditions has increased globally and there is an acute need to better understand and intervene on the interplay between psychological conditions and diabetes (De Groot *et al* 2016).

Depression and diabetes may be associated with behavioural or biological pathways. Adverse health behaviours linked with depression, such as a sedentary lifestyle, poor diet, smoking and non-adherence to treatment recommendations and self-care may influence diabetes and its complications. Biological pathways include hormonal abnormalities, alterations in glucose transport function and increased immuno-inflammatory activation (Kalra *et al* 2013). In the cross-sectional DAWN study conducted in 2004 in over 13 countries, researchers found that psychosocial problems were common among diabetic patients globally (Peyrot *et al* 2005). In the DAWN-2 study the number of Indian participants with depression was below average, while the number with high diabetes distress was higher than average. Indian diabetics scored third highest on the WHO-5 psychological well being scale, after Mexico and Denmark (Holt & Kalra 2013).

Interestingly, even though India has 69.2 million diabetics, diabetic Indian family members have the lowest prevalence of likely depression and third best pyschological well-being. This could be because India has the largest proportion of family members (59.5%) willing to be more involved in diabetes care and second highest (57.5%) willing to be involved in helping people with diabetes deal with their feelings about diabetes (Nicolucci *et al* 2013). Indian diabetic psychosocial problems differ greatly from those encountered in western culture. A few of the important factors that effects diabetes management, in India, include economic and cultural factors as well as traditional medicine (Kalra *et al* 2013).

2.5.5 Self-management

According to the ADA Position Statement on diabetes management (2017), lifestyle management is an essential aspect of diabetes care and includes diabetes self-management education (DSME), diabetes self-management support (DSMS), nutrition therapy, physical activity, smoking cessation counselling and psychosocial care. Patients, health and home care providers should focus together on how to optimise lifestyle from the time of the first medical assessment and throughout all the ensuing medical evaluations and follow-ups, to improve diabetes care (ADA 2017). Funnel *et al* (2011) describes DSME as the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. This process incorporates the needs, goals and life experiences of the person with diabetes and is guided by evidence-based standards (Funnel *et al* 2011)

A systematic review of the literature from 1980 to 2001, found eight publications that tested the effects of modification of provider-patient interaction and provider consulting style on patient diabetes self-care and diabetes outcomes, in general practice or hospital outpatient settings. The review found that patient behaviour focused interventions showed good efficacy and efficiency and improved patient self-care and diabetes outcomes. Patient-centred was more difficult to sustain, required intensive support and was not very effective in improving patient self-care and health outcomes, when executed alone (Van Dam, van der Horst, van den Borne, Ryckman & Crebolder 2003).

Despite the advances in diabetes management, the self-management activities of diabetes remain intricate, with difficulties experienced in incorporating treatment recommendations into the current lifestyles of diabetics (Odegard & Capoccia 2007). According to Kadirvelu, Sadasivan & Shu Hui Ng (2012), the empowerment approach to diabetes care recognises the patient as the source of control. This means that the patient has the responsibility for decision-making and action in their day-to-day management of the condition. This would call for a change in the management approach from a physician-centred model to a proactive patient-centred model, as shown in Figure 2.1. This implies that patients need to adopt behaviours that help them engage in the process of actively self-managing their diabetes (Kadirvelu *et al* 2012).

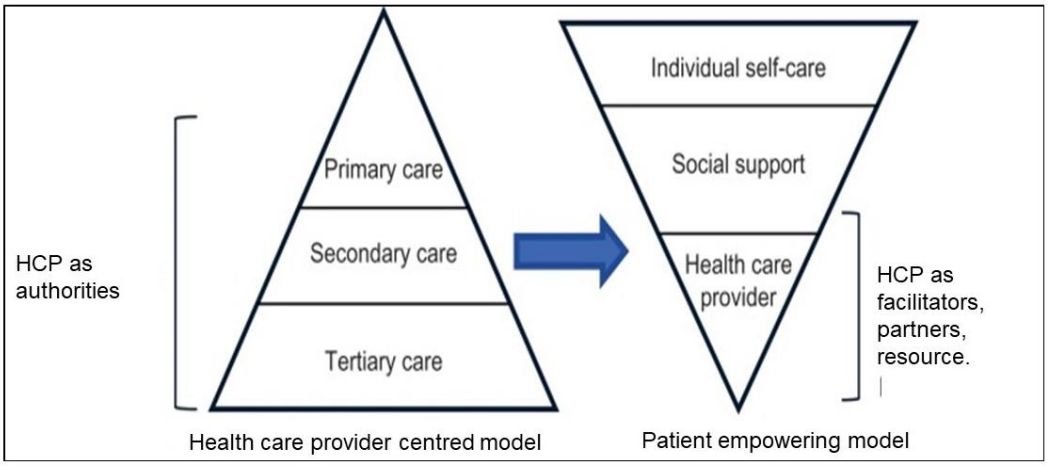

Figure 2.1: Shift in the model of management of diabetes (adapted from Kadirvelu *et al* 2012)

Comparatively, T2DM entails significant self-management components as opposed to other chronic illnesses. This includes activities and behaviours, such as measuring blood-glucose levels, taking multiple medications at appropriate times, recognising and responding to symptoms, managing acute episodes, maintaining an optimal diet, physical activity, weight management, smoking cessation, managing psychological responses to illness and managing relations with significant others (Clark, Becker, Janz, Lorig, Rakowski & Anderson 1991). Although these activities are typically undertaken in cooperation with a health care provider, self-management is more than just strict adherence to a prescribed behavioural regimen. It involves a high level of control on the part of the patient, some self-sufficiency with respect to adjusting the regimen as necessary and deliberate decision-making and problem-solving (Kadirvelu *et al* 2012).

2.6 Barriers to lifestyle changes

2.6.1 Time constriants

Self-management of chronic diseases has become the responsibility of the patient (Feste & Anderson 1995). It is stressed that the most important choices affecting the health of a person are made by that person, not by health professionals (Glasgow & Anderson 1999). Therefore, the use of ones time in managing the disease would seem paramount.

A review article by Yuncken (2014), found that both practitioners and patients alike cited inadequate time for appointments and assessments, as one of the barriers to lifestyle changes (Yuncken 2014). In a study conducted in Portland, USA, LeBlanc *et al* (2014), found that the most common care setting issue was a lack of provider time to care for complex patients (LeBlanc *et al* 2014). Kapur *et al* (2008), reported that 30% of physicians found time for one on one discussions with patients and the maximum time spent on one patient was only ten minutes (Kapur *et al* 2008).

AlQuaiz & Tayel (2009) showed that a lack of time was reported by more than two thirds (67.6%) of the study group, as a barrier to following a healthy diet. Further to this, age was inversely associated with a lack of time, wherein the younger age group reported a lack of time, more frequently (AlQuaiz & Tayel 2009). A lack of time was the most frequently (24%) mentioned barrier to adherence to a healthy diet in a European study (Lappalainen, Saba, Holm, Mykkanen, Gibney & Moles 1997).

In a study conducted in over 27 centres in the USA, 50% of the 1076 patients mentioned that the most common barrier to physical activity was time management (Venditti, Wylie-Rosett, Delahanty, Mele, Hoskin & Edelstein 2014). In a study conducted in Hawaii, participants acknowledged limited time as a barrier to diabetes management. Participants mostly reported time limitations and balancing family and work responsibilities as their barriers to lifestyle changes. Patients also indicated that they had limited time to exercise (Fukunaga *et al* 2011).

Currently, there seems to be no other studies in India exploring the effect of time contraints on patients, however, it is assumed that this would also be a barrier as it affects diabetics globally.

2.6.2 Lack of counselling or information

Diabetics generally have a poor knowledge of diabetes care and there is usually no consistency in the way information is delivered to them (Wint *et al* 2006). Patients' lack of knowledge about diabetes can hinder their ability to manage their disease. Several studies have investigated the awareness levels of diabetes among both patients and HCPs. The CURES study in urban Chennai, Tamil Nadu reported that nearly 25% of the population was unaware of diabetes, and only 22.2% of the population and 41% of known diabetic subjects felt that diabetes could be prevented (Mohan *et al* 2005). Futher to this, the knowledge of risk factors of diabetes was even lower, with only 11.9% of study subjects reporting obesity and physical

inactivity as risk factors; 23% knew that diabetes could lead to foot problems; and only 5.8% knew it could cause a heart attack (Mohan *et al* 2005). Another population-based study in Chennai, Tamil Nadu reported that only 41% of adult Indians over 20 years old were aware of the risks associated with diabetes and almost all diabetic patients (92.3%) sought the help of a general practitioner for treatment, instead of a diabetic specialist (Murugesan, Snehalatha, Shobhana, Roglic & Ramachandran 2007).

In Jamaica, a lack of education was one of the factors contributing to poor control of DM (Wilks, Sargeant, Gulliford, Reid & Forrester 2001). Another study in Jamaica found that the main source of information was the physician (62.4%) and knowledge scores were inversely associated with age, but positively associated with time since diagnosis. Forty seven percent of patients did not know the meaning of the word "diabetes" and 18% believed that diabetes was curable. Seventy one percent (94 out of 133 patients) reported the need for more education (Wint *et al* 2006). A case-control study in Italy found that patients who did not receive any form of educational intervention, had a fourfold increased risk of developing complications, analysed by multivariate logistic regression analysis (Nicolucci, Cavaliere, Scorpiglione, Carinci, Capani, Tognoni & Benedetti 1996). Patient education is a fundamental prerequisite for diabetes self-management (Assal, Jacquemet & Morel 1997; Anderson, Funnell, Butler, Arnold, Fitzgerald & Feste 1995). It is important that both physicians and diabetes educators provide unequivocal and consistent information, with a view to modifying patient perceptions, attitudes and behaviour (Van den Arend, Stolk, Krans, Grobbee & Schrijvers 2000).

2.6.3 Lack of support from family, work and health care workers

For many diabetics, the day-to-day management of their condition can be overwhelming (Clark 2008). Studies have shown that subjects diagnosed with diabetes experience psychosocial challenges that can have significant effects on their lives (Peyrot & Rubin 1997). While social support is mostly a positive resource, clinicians need to be aware of potential negative effects that may inhibit self-care behaviour and undermine self-management goals (Gallant 2007). In most instances, support from family and friends is freely given, but there is a tendency for this to be provided principally during the acute stages of a disease, i.e., when the disease is initially diagnosed, when there is poor progression of diabetes, or when the person is terminally ill.

However, this tends to reduce when the disease continues over an extended period. A qualitative study indicated that patients may feel criticised, nagged or guilty about receiving help from family members (Carter-Edwards, Skelly, Cagle & Appel 2004). Poorly executed family support, where they do not undertake illness-care tasks on the patient's behalf, can lead to worse patient outcomes (Franks, Stephens, Rook, Franklin, Keteyian & Artinian 2006; Beanlands, Horsburgh, Fox, Howe, Locking-Cusolito, Pare & Thrasher 2005). Family barriers to self-care could particularly affect younger, more functional patients, who are often trying to juggle multiple active family roles themselves (e.g. parent, child, and spouse) (Samuel-Hodge, Headen, Skelly, Ingram, Keyserling, Jackson, Ammerman & Elasy 2000).

The DAWN study investigated the quality-of-life, psychological well-being, likelihood of depression and diabetes distress in family members living with people with diabetes. The study found that 6.9-13.6% of family members reported a "poor" or "very poor" quality-of-life, while 8.0-16.2% reported a WHO-5 score of ≤ 28, indicative of likely depression. Indian family members had the lowest prevalence of likely depression and scored third best in terms of psychological well-being (Kovacs Burns *et al* 2013).

An evaluation of social support in 249 diabetics with a disease duration of around five years, found that more than 60% of spouses of patients believed that the disease could be managed effectively. However, 65% of spouses felt that the problem of diabetes was minor and required minimal support. More than 60% of children felt that their parents were normal (Sridhar & Madhu 2002). Family members, peers and HCPs are important sources of interpersonal influence that can either increase or decrease the commitment to, and engagement in health promoting behaviour (Pender 2001, pp 59-78).

2.6.4. Lack of motivation

Motivation can be defined as the processes that accounts for an individual's intensity, direction and persistence of effort toward attaining a goal (Robbins 1996, p210). According to Borra *et al* (2001), consumers are motivated by two potentially conflicting needs, clear information that propels them to take action and for the power to make their own choices. In most cases motivation stems from a need which must be fulfilled, and this in turn leads to a specific

behaviour. Fulfilment of needs results in some type of reward, which can be either intrinsic or extrinsic. The former is derived from within the individual, e.g. taking pride and feeling good about accomplishing a goal, whereas the latter relates to rewards given by another person (Buchbinder & Shanks 2007, pp 49-71).

The trans-theoretical model of Prochaska, Redding & Evers (2002, pp 1102-1114), provides a cognitive measure of motivation to change. This model integrates key constructs into a comprehensive theory of change that can be applied to a variety of behaviours, populations and settings. It consists of a five-option forced-choice question, with response options reflecting five dimensions: (a) pre-contemplation, (b) contemplation; (c) preparation (d) action; (e) maintenance (Prochaska *et al* 2002). Centis *et al* (2014), studied 1353 Italian outpatients with T2DM attending 14 tertiary centres. Patients completed a validated questionnaire, consisting of two corresponding sets of instruments to define the stage of change for healthy diet (HD) and healthy physical activity (HPA), respectively (Centis *et al* 2014). The stage of change favouring progress to healthier behaviours was more common with regard to HD than to HPA, with higher scores in action and maintenance. Differences were observed in relation to gender (males scored higher in maintenance than females in both HD and HPA), age (younger were more willing to change or take action) and duration of disease (longer duration of disease was less likely to change their diet or physical activity). Further to this, resistance to change toward HD was associated with a higher BMI, while resistance to improve HPA increased with BMI and decreased with education level (Centis *et al* 2014).

Wint *et al* (2006) found that even though many subjects were aware of the complications of DM, few were motivated to make lifestyle changes by the perceived risk or by the actual experience of complications. However, some were motivated by a desire to follow their doctors' orders (Wint *et al* 2006). This study found weak motivational factors in diabetics (Wint *et al* 2006). In the study by Fukunaga *et al* (2011), participants mentioned that they needed social and motivational support, such as frequent support groups or a diabetes "buddy" (Fukunaga *et al* 2011).

The Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers Control Program study in India, showed that even among patients whose HbA_{1c} values were measured, 53% were not given glycaemic targets. The study also reported the relaxation of targets as the duration of diabetes increased (Sharma, Seshiah, Sahay, Das, Rao, Shah, Akhtar & Shetty 2012). The majority of doctors recognised difficulty in long-term maintenance of HbA_{1c} targets. This may be one of the contributing factors to the lack of motivation to achieve good glycaemic control by diabetic patients (Joshi 2015).

Interestingly, Tripp-Reimer *et al* (2001) reported that issues of motivational strategies were also significant. The use of spiritual and gospel songs as motivation for exercise had positive results in African-Americans with diabetes (Tripp-Reimer *et al* 2001). Kalra *et al* (2017) have suggested the following national recommendations for India:

a) Physicians should receive formal training in interventions involving motivational interviewing.
b) Patients should be motivated to initiate or intensify insulin using motivational approaches.
c) Long-term motivational therapy with suitable follow-up is needed with cognitive behavioural therapy (CBT), to improve HbA_{1c} levels in poorly controlled patients (Kalra *et al* 2017).

2.6.5 Emotional wellbeing

"Emotional well-being encompasses how you feel about yourself, your ability to successfully manage your feelings as you deal with life's challenges and the quality of your relationships" (Federal Occupational Health Agency 2017). Emotional balance can contribute greatly to overall mental and physical health (Federal Occupational Health Agency 2017). The DAWN-2 study, which surveyed adults with diabetes, adult family members and HCPs, showed that diabetes remained a major physical and psychological burden for many individuals with diabetes, in all 17 countries surveyed (Holt & Kalra 2013). Poor emotional well-being is a good predictor of depression, which affects one-third of patients with T2DM (Krieger, Zimmermann, Huffziger, Ubl, Diener, Kuehner & Grosse Holtforth 2014; Roy & Lloyd 2012; De Wit, Pouwer, Gemke, Delemarre-van de Waal & Snoek 2007). Diabetes has been found to

have a negative impact on all domains (areas or fields) 5.1.1investigated, including emotional well-being (46.2%) (Holt & Kalra 2013).

Many health-care professionals felt that people with diabetes needed to improve various self-management activities, such as dealing with emotions associated with diabetes (63.2%) (Holt *et al* 2013). Family members reported that diabetes had a significant negative impact on emotional well-being (44.6%) (Kovacs Burns *et al* 2013). Lower scores for emotional well-being were found in Dutch diabetic patients that were female, unemployed or incapacitated, with high levels of education, using antidepressants or with macrovascular complications or diabetic peripheral neuropathy (Hendriks, van Soldt, van Vugt, Groenier, Roelofsen, Maas, Bilo, Kleefstra & van Hateren 2017). There was a positive, non-clinically relevant relationship between physical activity and emotional well-being in both men and women (Hendriks *et al* 2017). In another study in the USA, factors like patient's emotional well-being were associated with adherence to diabetes medication (Rubin 2005). In some countries, up to a third of health-care professionals received no formal training in diabetes. Training was mainly deficient in the psychological aspects, as only 20% of patients had training in this area, while 58% wanted more training in this area (Holt & Kalra 2013). Psychological support is essential to establish emotional well-being in diabetics. It should be assessed and provided from the onset of diagnosis, rather than later (Sridhar 2012, pp 20-36).

2.7 Challenges faced by the diabetic living in India

2.7.1 Urbanisation

According to Goryakin, Rocco & Suhrcke (2017) urbanisation is the process of the population shifting from rural to urban areas within countries (Goryakin *et al* 2017). Rapid urbanisation, which is altering the physical and social habitat of cities, is considered as one of the most important global health issues of the twenty-first century (WHO/UN-HABITAT 2010, p8). Results gathered from 173 countries over 28 years, specify that urbanisation appears to have contributed to an increase in average BMI and cholesterol levels. People living in the least urbanised countries are also expected to have an up to 2.3kg/m^2 lower BMI than those in the most urbanised ones. Moreover, the least urbanised countries are expected to have a lower prevalence of diabetes among women. This association is also much stronger in the low and

middle-income countries, and is likely to be mediated by energy intake-related variables, such as calorie and fat supply per capita (Goryakin *et al* 2017).

The projected increase in diabetes prevalence to 10.1% in 2035 in the South East Asia region is a consequence of ongoing large-scale urbanisation and increasing life expectancy (Whiting *et al* 2011). In India, the proportion of the population aged over 50 years is expected to increase from 27% to 35% between 2013 and 2035 (IDF Diabetes Atlas 2014). The increasing prevalence of diabetes in South East Asia can be attributed to a multitude of interrelated factors, including rapid industrialisation and urbanisation and the ensuing changes in lifestyle factors (Ramachandran & Snehalatha 2010; Chan, Malik, Jia, Kadowaki, Yajnik, Yoon & Hu 2009). The Asian Indian phenotype and lifestyle changes associated with urbanisation and sedentary lifestyles have contributed to the rise of diabetes in India (Mohan *et al* 2007). Pradeepa & Mohan (2017) reported that rapid socioeconomic transition with urbanisation and industrialisation are the main causes for the global diabetes epidemic (Pradeepa & Mohan 2017). Misra, Pandey, Devi, Sharma, Vikram & Khanna (2001), reported that migration from rural areas to urban slums in metropolitan cities in India have contributed to obesity, glucose intolerance and dyslipidaemia (Misra *et al* 2001).

Epidemiological studies conducted in India, showed that not only was the prevalence of diabetes high in urban India, but was also increasing (Ramachandran *et al* 2001; Ramachandran, Snehalatha, Latha, Vijay, Viswanathan 1997; Ramachandran, Snehalatha, Dharmaraj & Viswanathan 1992). Urbanisation has brought several changes in the lifestyles of people living in urban areas in India and it is associated with a greater prevalence of diabetes and coronary risk factors (Yadav & Krishnan 2008; Gupta, Rastogi, Sarna & Sharma 2007). Chowdhary & Lasker (2002) found that the prevalence of central obesity in North India increased with the level of urbanisation in both men and women, by 8.7% and 34.5%, respectively (Yadav & Krishnan 2008).

2.7.2 Food habits (traditional vs. western)

Dietary habits and practices are influenced by culture and religion as well as economic conditions. Oil and sugar are considered an integral part of the daily diet in Indian families.

Religion is a key aspect of culture that often decides food habits and patterns. Culturally determined dietary practices involve the identification of foods, methods of food preparation, condiment selection, timing and frequency of meals and the ritual, social, and symbolic use of foods (Sachdeva *et al* 2015). For example, a meat-based diet is not acceptable in Hindu communities and Hindus and Muslims often practice fasting. India is a country with several religious festivals. Fasting for Hindus includes not consuming non-vegetarian foods and following a lacto-vegetarian diet. When Muslims fast, it involves not eating or drinking anything from sunrise to sunset. Sweets and high fat foods are significant components of these festivals and ceremonies. Foods, especially, sweets are shared as gifts with relatives and friends during ceremonies (Sachdeva *et al* 2015).

In recent years, there has been a marked increase in the rates of obesity in countries including India. This has been attributed to unhealthy lifestyle practices associated with the introduction of western-style fast foods that are higher in fat and refined carbohydrates (Yadav *et al* 2008; Popkin 2001). Indians have become more affluent, urbanised, and mechanised during the previous decade. A busy lifestyle and the easy availability of convenience food have led to irregular meals and frequent snacking on energy-dense fast foods. Fast foods refer to energy-dense foods prepared and sold commercially by roadside vendors and food outlets, prepared either by deep-frying or with preheated or precooked ingredients. These foods typically have low nutritional value and preparation time, including ready-to-use gravies and soups, packaged salty snacks, ready-made cookies and commercial fast foods, rather than traditional home-cooked food (Misra, Khurana, Isharwal & Bhardwaj 2009). Furthermore, consumption of animal foods, sweetened carbonated drinks, sugar and sweeteners have also increased (Table 2.6).

Table 2.6: Secular trends of nutrient consumption in India (Misra *et al* 2011)
(All variables expressed in the unit calories/capita/day)

	Average values (calories/capita/day)		
Product	**1979-1981**	**1989-1991**	**1999-2001**
Total animal product	120	163	196
• Animal fat	23	28	47
• Eggs	3	5	6
• Seafood	5	7	8
• Meat	16	20	22
• Milk-excluding butter	71	102	111
Total vegetable product	1963	2202	2296
Alcoholic beverages	5	8	11
Cereals	1368	1508	1470
Fruits	31	34	51
Oil crops	25	37	43
Pulses	120	133	109
Rice (milled)	670	779	751
Starchy roots	41	40	49
Sugar and sweeteners	193	221	247
Sugar crops	8	9	11
Vegetable oils	127	158	239
Vegetable	32	35	45
Wheat	390	461	493
Grand total	2083	2365	2492

There have been major increases in the production of beef, pork, dairy products, eggs, and poultry across low-and middle-income countries (Du, Mroz, Zhai & Popkin 2004; Popkin & Du 2003). Most of the global increases in animal-source foods have been in low- and middle-income countries. For example, India has had a major increase in the consumption of dairy products and China in pork and eggs (Popkin *et al* 2012).

Vaz, Yusuf Bharathi, Kurpad & Swaminathan (2008), reported that besides rural-urban differences in dietary patterns in India, there have been improvements in socioeconomic status (Vaz *et al* 2008). These include an increased intake of legumes, vegetables, milk and in the case of non-vegetarians, foods of animal origin. Other changes include substitution of coarse grain with the more prestigious and often highly polished cereals such as rice. There has also been a reduction in the overall cereal intake, although this continues to be high by western

standards. A progressive increase in the intake of edible fat, sugar and sweets and overall energy, has led to an increase in obesity (Vaz *et al* 2008).

The challenge for India, as in other countries, is to counteract the inevitable degenerative phase of the nutrition transition. Efforts are needed to improve nutritional knowledge and practice among health professionals, as well as the public. In order to facilitate healthy nutritional practices there is a need for initiatives that link enhanced agricultural produce to effective food storage, and delivery systems that ensure a more equitable distribution of healthy food at affordable prices (Vaz *et al* 2008).

2.7.3 Physical activity

Physical activity in any domain (recreation, transportation, household chores, and/or occupation) is beneficial for health and recommended by the WHO (WHO 2016a). Although India has traditionally been associated with under nutrition; overweight, obesity, and their consequences are now becoming increasingly common. Indians exhibit unique features of obesity with excess body fat, abdominal adiposity, increased subcutaneous and intra-abdominal fat and deposition of fat in ectopic sites (such as liver, muscle, and others). Obesity is a major driver for the widely prevalent metabolic syndrome and T2DM. Although this phenomenon is a global one, India is unique in that it has to grapple with both over- and under-nutrition at the same time (Kalra & Unnikrishnan 2012).

The prevalence of overweight and obesity are more than three times higher in urban areas, compared to rural areas. This may be due to reduced levels of physical activity in the urban areas. According to the National Family Health Survey (NFHS), overweight and obesity are both higher for women than men across the city of Chennai, state of Tamil Nadu and nationally [National Family Health Survey (NFHS-4) 2016b]. A higher prevalence of obesity seen in the urban areas in developing countries including India is associated with the change from rural to urban lifestyles, causing decreased levels of physical activity and increased energy intake (Ramachandran & Snehalatha 2010).

Physical inactivity has been shown to explain, at least in part, the diabetes epidemic (Mohan, Gokulakrishnan, Deepa, Shanthirani & Datta 2005). A study to determine the prevalence of overweight, obesity, under-nutrition, and physical activity status in five urban Indian cities (Moradabad, Trivandrum, Calcutta, Nagpur and Bombay), found that obesity, overweight, central obesity and sedentary behaviour coexisted with under-nutrition and have become a public health problem in all five cities (Singh & Pella 2007). The prevalence of obesity and sedentary behaviour was significantly greater in Trivandrum, Calcutta and Bombay, compared with Moradabad and Nagpur. Sedentary behaviour was significantly associated with obesity compared with non-obese subjects in both sexes, which may be due to greater economic development in metropolitan cities (Singh & Pella 2007). In Chennai, India, urban participants were found to lead a predominantly sedentary lifestyle (75% of the participants were physically inactive) (Mohan, Radhika, Sathya, Tamil, Ganesan & Sudha 2009).

With an increasing number of diabetes deaths worldwide since 1990, (Global Burden of Disease 2013, Mortality and Causes of Death Collaborators 2015), greater attention and investments in interventions to promote physical activity in the public is required. More studies using a detailed quantification of total physical activity will help to find a more precise estimate for different levels of physical activity (Kyu, Bachman, Alexander, Mumford, Afshin, Estep, Veerman, Delwiche, Iannarone, Moyer, Cercy, Vos, Murray & Forouzanfar 2016)

2.7.4 Social and socio-economic factors

Social factors currently play a small role in the treatment plan for diabetes. Nonetheless, social factors have an important role in acceptance, adherence to treatment and overall outcome of diabetes management. Moreover, social bonds, especially family bonds, are known to influence outcomes of diabetes management, which holds the key to avoiding negative progression of the disease (Chesla, Fisher, Mullan, Skaff, Gardiner, Chun & Kanter 2004). The practical and emotional strains arising out of this affect diabetes management and family beliefs. Hereby, improving family support is required to help improve patient morale. However, unresolved family conflicts about diabetes are associated with more depressive symptoms and lower quality of life (Wen, Parchman & Shepherd 2004).

The influence of social class or socioeconomic status on the incidence and management of diabetes is observed globally, as well as in India. In India, the prevalence of diabetes is reportedly higher in the highest socioeconomic groups and dwindles with decreasing socioeconomic status (Safraj, Anish, Vijayakumar, Kutty & Soman 2012). While diabetes was once considered a disease of affluence, in the last decade its prevalence rates in the middle and lower income groups in India have shown a trend toward convergence (Deepa, Anjana, Manjula, Narayan & Mohan 2011). Families with higher average family income and education profile are known to spend more on diabetes care (Kumar, Nagpal & Bhartia 2008).

In the poorest countries, people with diabetes and their families bear almost the whole cost of medical care. In India, individuals with limited financial resources continue to spend a major proportion of their income on diabetes management (Ramachandran, Shobhana, Snehalatha, Augustine, Murugesan, Viswanathan, Kapur & Williams 2007). In India, 25% of the population live under the poverty line, 41.6% of the population live under 1.25 USD (united states dollar) a day and the economic burden of diabetes has a major impact on diabetes care (Ramachandran *et al* 2007). The direct medical cost to identify one subject with glucose intolerance is 115 USD (Ramachandran *et al* 2007). The cost of insulin amounts to 350 USD per year, while medication for non-insulin-requiring patients costs about 70 USD per year (Ramachandran 2007). Out-of-pocket expenditure for hospital treatment for diabetes in India claims 17% of the annual household expenditure in poor households. The majority of these expenses are financed through borrowing (Rao *et al* 2011). Out-of-pocket expenditure constitutes about 62% of all health expenses, a major drawback in a country like India, where a large segment of the population is poor (World Bank Data 2016). Poor households can spend up to 25% of their annual household income on diabetes care (IDF Clinical Guidelines Task Force 2012).

2.7.5 Cultural factors and literacy levels

Health behaviours are guided by continuous interactions of intrapersonal factors with the cultural environment (Samuel-Hodge *et al* 2000). Widespread cultural practices and attitudes that impede appropriate health-related behaviour make diabetes management in India challenging. The low rate of literacy contributes to poor diabetes care. Lower levels of literacy

in the country are associated with lower awareness of diabetes and its complications (Mehrotra *et al* 2000) and are reported to be significantly associated with higher HbA_{1c} levels (Nagpal & Bhartia 2006). Another example where cultural practices affect diabetes management is the relative difference in diabetes control between genders. It has been reported that there is significantly lesser awareness of diabetes and poorer rates of compliance to therapy among housewives (Lahiri, Haldar, Chowdhury, Sarkar, Bhadury & Datta 2011). This study reported that all patients who were non-complaint due to financial constraints were women. This is despite the fact that women are known to have a higher rate of diabetes prevalence compared to men (Lahiri *et al* 2011). This shows the effect of the low literacy rates of women as compared to men in India, because of the culure in India of women not being as important to educte as men. Hereby this leads women to not having good paying jobs and ultimately cannot pay for their own medical treatment. Also, due to the fact the women do not work or earn very little, the burden falls to the male of the family which leads to resources being depleted. In India, it is reported that cost-effective focus for overall diabetes care is placed on the nuclear family as a unit (Sridhar 2007), which occupies 60% of the total household units [National Family Health Survey (NFHS-3) 2007] with a mean number of 4.8 persons per house (rural areas - 4.9 persons, urban areas - 4.6 persons) (NFHS-3 2007). Therefore low literacy due to cultural effects directly influences cost of medical care in a family.

2.7.6 Religion

It is important for health care providers to acknowledge and consider cultural differences in the form of language, educational backgrounds, religion, health attributions, beliefs and practices toward illness (Vaughn, Jacquez & Baker 2009). Because of the vast diversity of cultural and religious health attributions, beliefs and practices, it is important to prioritise such factors in diabetes care and education (Vaughn *et al* 2009). In chronic conditions like diabetes, religious or spiritual beliefs become increasingly important; firstly, because they provide social and emotional support and, secondly, because they aid in coping with the stress of the disease (Wangnoo *et al* 2013).

Hindus observe fasting and go on a strenuous pilgrimage like Amarnathji, which is a difficult pilgrimage Hindus take to a shrine near Amarnath, India, which houses an ice Shiva Lingam.

The shrine is located in a cave at 3,888m and is only accessible by foot. This is undertaken as part of their religious traditions during various times of the year (Ganie, Koul, Razv, Laway & Zargar 2012). Jains (those who follow the ancient Indian religion of Jainism), have varying fasts, one of which is not eating from dusk to dawn, irrespective of the duration of this period (Julka, Sachan, Bajaj, Sahay, Chawla, Agrawal, Saboo, Unnikrishnan, Baruah, Parmar & Kalra 2017). The National Family Health Survey (NFHS-3) (2007), reported that Christians are more likely than any other religious group to eat chicken, meat, fish or eggs at least once a week. Jains and Sikhs (those who follow the religion of Sikhism, founded in Northern India), rarely eat chicken, meat, fish or eggs, but they are more likely than any other religious group, to consume milk or curd. Jains are also more likely than any other religious group to eat fruit at least once a week (NFHS-3 2007).

People with diabetes are advised to follow their physician's advice in observing fasts or going on pilgrimages, to avoid any glycaemic emergencies (Ganie *et al* 2012). People with diabetes, who wish to fast, have been stratified based on the severity of disease, and specific rules and recommendations have been issued (Jaleel, Raza, Fathima & Jaleel 2011). People with diabetes who are categorised in the "observe fasting" group are further advised to follow the recommended strategies to ensure safety before, during and after the month of Ramadan (month of fasting for Muslims) (Jaleel *et al* 2011).

2.7.7 Indian women and diabetes

Women are often viewed as the custodian of family values and culture. This responsibility to maintain cultural practices and pass them on to younger generations can make it difficult for women with diabetes to make lifestyle changes, leading to poor health outcomes (Black 2002). Approximately three quarters of women in Indore City, India found it difficult to follow care advice by doctors and self-medication was very common among women (Sushama & Nandita 2012; Black 2002). As mentioned earlier, the prevalence of overweight and obesity is higher among women than men in India, including the city of Chennai, state of Tamil Nadu (NHS-4 2016b).

Gender discrimination toward healthcare, including diabetes, is observed worldwide. In India, higher outpatient attendance for T1DM is recorded for men than for women (<30 years age) (Kalra, Kalra & Kumar 2009a). Interestingly, half of these young women who are at a marriageable age often stop their follow-up visits at clinics due to perceived social stigma, often leading to medical consequences, including diabetic ketoacidosis (Kalra *et al* 2009a). Women also show poorer compliance to therapy due to greater economic dependence on family members (Lahiri *et al* 2011). Differences in functional limitations between adults with and without diabetes are more evident in women than they are in men, due to their strong association with biological and behavioural factors (Chiu & Wray 2011).

In India, parents usually get their daughters married without disclosing that they have diabetes. This eventually leads to grave consequences. Another aspect of gender discrimination in diabetes care comes from the role of parents in the management of children with T1DM, where mothers often share a disproportionate burden of diabetes care in the child. If fathers do not share the responsibility, they feel out of touch with the complexities of management. Therefore, it is important to ensure distribution of responsibility between the parents (Sridhar 1996). On the dietary side, mean consumption values for cereals, pulses and legumes, dairy products, tubers, fruit and vegetables (this includes fruit, leafy vegetables, other vegetables and roots), meat and poultry, visible fats and oils and sugars were significantly higher in Indian men than women, whereas eggs were higher in women (Radhika *et al* 2009). This suggests that women may have higher risk for poor dietary intake and possible nutrient deficiencies.

2.8 Change from disease treatment to patient treatment

Patient-centred care has become a recognised part of medical practice. Client-centred (patient-centered) care has become popular through institutes like the Picker Institute and Institute of Medicine (Kalra *et al* 2013). Recent guidelines on the managing of diabetes care have additionally reinforced the need for patient-centeredness, using the term "patient-centered approach" in their terminology (Inzucchi *et al* 2012). This is defined as an approach to "providing care that is respectful of and responsive to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions" (Inzucchi *et al* 2012). With this approach, health care providers need to familiarise themselves with patient's needs and

ideas, as well as providing recognition and encouragement, in keeping with the individual patient's perspective. Prueksaritanond, Tubtimtes, Asavanich & Tiewtranon (2004) found that a patient-centred approach had a favourable effect on improving the health status of type 2 diabetics in terms of biological (glycaemic control) and behavioural indicators (eating, exercise, compliance and symptoms of diabetes). Specialists also saw the need for and significance of therapeutic patient education, through a patient-centred approach in diabetes management (Kalra, Baruah, Ganapathy, Ganie, Sahay & Unnikrishnan 2009b).

2.8.1 Challenges of shifting to holistic care

Successful diabetes management has remained elusive, even with a wide variety of therapeutic options now accessible to clinical practitioners (Peyrot *et al* 2005). A purely pharmacological approach to successfully managing diabetes is insufficient. Factors beyond pharmacological interventions, which focus on patient's need, resources, values and strategies are needed. Therefore, employing approaches such as motivational interviewing, cognitive behaviour therapy and behaviour change counselling may help to change patient behaviour (Kalra *et al* 2009b).

Lifestyle changes represent the first step in management and a team approach is often necessary. Even patients with good glucose control should have access to formal diabetes education, to train them in the use of technical aids and increase their knowledge of the disease. Diabetics should be accompanied through the different stages of disease acceptance, which form the basis for current and future treatment adherence (Assal *et al* 1997). In India, there is a wide disparity in the healthcare facilities available in rural and urban areas, due to the unbalanced healthcare system. Institutions run by the state (where medical care is free or offered at subsidised rates), private institutions (where patients have to pay for services) and a large number of medical practitioners, share healthcare delivery. People do not have any restrictions in utilising any of the available medical facilities and they can access any level of care, depending on their economic feasibility, proximity and knowledge about the facility. Individuals, who can afford it, are able to attend the private centres for their diabetes care (Ramachandran 2007).

Although India has several institutions offering high quality healthcare, these facilities are limited in their ability to maintain healthcare standards because of poor maintenance and state of infrastructure in many parts of the country. Most public health facilities are disorganised, inadequately managed, staffed, and have badly maintained medical equipment. The number of public health facilities is also inadequate. For example, India needs 74,150 community health centres per million people, but has less than half that number. In addition, at least 11 Indian states do not have laboratories for testing drugs and more than half of the existing laboratories are not properly equipped or staffed (Viswanathan & Rao 2013).

The principal responsibility for public health funding lies with the state governments, which provide approximately 80% of public funding. The central government contributes another 15%, mostly through national health programs [PricewaterhouseCoopers (PwC) 2007, p5]. With a 22% shortage of primary health centres (PHCs) and a 32% shortage of community health centres (CHCs), it is estimated that 50% of beneficiaries travel more than 100 km to access quality care (PwC 2017). India has only 1.1 beds per 1,000 people, compared to the world average of 2.7 and 70% of India's healthcare infrastructure is in the top 20 cities (PwC 2017).

As a way forward, many hospitals are obtaining National Accreditation Board of Hospitals (NABH) accreditation to improve the quality and standards of care. So far, 157 hospitals achieved this in 2016, many of which are in the private sector (PWC 2017). Problems such as lack of appropriate infrastructure and health personnel, poor updating of knowledge about diabetes among general practitioners, poor access to diabetes drugs and healthcare facilities, economic disparities in the healthcare system and the socioeconomic burden on the patient are the main obstacles in diabetes care (Viswanathan & Rao 2013).

Effective management of diabetes offers only part of the solution for the problem of diabetes. This means that other aspects of care, important from the perspective of diabetes control, may be difficult to provide within the health system itself. Aspects related to diet and the amount of physical activity undertaken is influenced by interplay of various sectoral policies and forces. In India, several rural areas still face the problem of under nutrition and are unable to access better food products. Restrictive dietary advice for diabetic patients in such areas

becomes difficult, which means that national or state policies for food procurement, pricing and marketing have to be implemented to ensure sustained availability of inexpensive and accessible dietary substitutes (Viswanathan & Rao 2013).

It has been shown that various factors like inadequate knowledge of guidelines, primary focus on acute management rather than the preventive care, competing care demands, delayed clinical response to poor control, time constraints, inadequate resources and attitudinal issues are some of the physician-related issues in diabetes control in India (Venkataraman *et al* 2009). Therefore, the health system in India has to strengthen the standard of diabetes care at all levels, along with nationally accepted management protocols and regulatory frameworks, which can help to tackle this challenge (Viswanathan & Rao 2013).

2.8.2 Shift to personal care of patients

Several authors have demonstrated that support from health care practitioners is integral to people learning how to self-manage diabetes (Gleeson-Kreig 2008; Rosland, Kieffer, Israel, Cofield, Palmisano, Sinco, Spencer & Heisler 2008; Tang, Brown, Funnell & Anderson 2008). For instance, a survey in the USA found that more than 40% of participants identified their physician as having provided the greatest social support in managing their diabetes (Tang *et al* 2008). A central theme for social support is empowerment, which refers to providing people with chronic disease and their caregivers, with the maximum amount of control over their own lives. This can enhance subjective quality of life for persons with chronic disease (Rosenfield 1992).

Health care practitioners can promote self-management in their diabetic patients by carrying out patient-centred activities. For patients who rely primarily on their physician for support, effective patient-physician communication may be particularly important, with evidence to show that patients practiced better self-management when their providers had superior communication skills (Heisler, Bouknight, Hayward, Smith & Kerr 2002). Health care professionals need to pay attention to various aspects like style and content of verbal interaction, verifying patient understanding, determining perceptions of key messages, and

other strategies in fostering behaviour change (Gensichen, Von Korff, Rutter, Seelig, Ludman, Lin, Ciechanowski, Young, Wagner & Katon 2009).

To ensure that patients recognise the importance of self-management and become fully engaged in it, there should be negotiation of goals to help HCPs and patients achieve a balance between accepting medical care and desiring to live a normal life. Interestingly, Indian HCPs strongly felt that diabetes should be given higher priority (78.6%); this proportion was higher than that for any other country (Holt & Kalra 2013). It has been suggested that every patient should have a specifically designed, individualised group-based support, since each person may present with a unique set of needs, risks and limitations (Oftedal, Karlsen & Bru 2010). Such a personalised strategy is based on the premise that different patients with chronic disease may respond to similar treatments in different ways. If all patients were to be treated using a broad-brush approach, this would be at the expense of disregarding their individual sociocultural differences and characteristics. This has enormous potential to add value to the management of patients with chronic disease by providing targeted treatments, improving quality of life and being more cost-effective (Oftedal *et al* 2010).

Major members of the health care team, including nurses, pharmacists, dieticians, and behavioural specialists such as psychologists, should preferably work together for the complete assessment of each diabetic patient, on an individual basis. Hereby, with this, start the most appropriate therapy to accomplish the best health care aim. Therefore, HCPs have to consider a patient-centred approach to effect positive health-behaviour change and to establish a co-operative relationship with the diabetic patient (Kadirvelu *et al* 2012). A system of collaborative care should be instituted, where patients are motivated to be able to carry out optimal self-care. This implies co-management care, where a care plan includes goals developed through negotiation and agreement among patients, health care providers, family, carers and other supports. Health care providers also provide ongoing support to work towards optimal patient self-care behaviours in time. The prerequisites of this empowerment approach are cooperation and respect, where patients are fully responsible for self-management of their diabetes and in control of decision-making, with an adult-to-adult relationship between health care practitioners and patients (Kadirvelu *et al* 2012).

2.8.3 Frequency of follow-up

While DSME is necessary, it is not sufficient for patients to sustain a lifetime of diabetes self-care (Piette & Glasgow 2001, pp 207-251). Initial improvements in metabolic and other outcomes usually diminish after six months (Norris, Lau, Smith, Schmid & Engelgau 2002). To sustain the level of self-management needed to effectively manage diabetes, most patients need ongoing diabetes DSMS. Diabetes self-management support is defined as activities that assist the individual with diabetes to implement and sustain the ongoing behaviours needed to manage their illness. The type of support provided can include behavioural, educational, psychosocial or clinical (Anderson, Funnell, Nowankwo, Gillard, Oh & Fitzgerald 2005; Funnell, Nwankwo, Gillard, Anderson & Tang 2005; Tang, Gillard, Funnell, Nwankwo, Parker, Spurlock & Anderson 2005; Glazier, Bajcar, Kennie & Willson 2006). Aggressive interventions and vigilant follow-up should be pursued for those considered at very high risk (e.g. those with HbA_{1C} > 7%) (Zhang, Gregg, Williamson, Barker, Thomas, Bullard, Imperatore, Williams & Albright 2010). Diabetic patients who were monitored by a nurse case manager, under the direction of a family physician, or an endocrinologist, had improved glycaemic control within 12 months (Aubert, Herman, Waters, Moore, Sutton, Peterson, Bailey & Koplan 1998) and improved blood pressure, cholesterol and glycaemic control at one year (Ishani, Greer, Taylor, Kubes, Cole, Atwood, Clothier & Ercan-Fang 2011).

Guidelines for the management of type 2 diabetes mellitus in the Indian context have also now been developed through a joint consultation by the ICMR and WHO in 2005 (ICMR 2005) (Table 2.7). Services for diabetes management can be used for service delivery at various levels. Follow-up is recommended at primary health care, community health and district hospital levels (Venkataraman *et al* 2009).

Table 2.7: Services for diabetes management (adapted fromVenkataraman *et al* 2009)

Activity	Community	Sub-centre	PHC	CHC	District Hospital
Health education	√	√	√	√	√
Identification of those at high risk		√	√	√	√
Blood sugar testing			√	√	√
Treatment initiation			√	√	√
Management on insulin				√	√
Screening for complications				√	√
Follow-up for compliance			√	√	√
Management of complications					√

Viswanathan & Rao (2013) reported that the treatment of diabetes and its complications is a major challenge in India owing to several issues, including sociocultural factors, lack of appropriate facilities for diabetes care, an inadequate health system, poor monitoring and follow-up of patients, and problems in implementing effective management and educational strategies (Viswanathan & Rao 2013). The ICMR suggests that HbA_{1c} be checked every 3 to 6 months and a clinical examination be completed on every visit to the physician, minimally every 3 months (ICMR 2005).

The Indian Research Society for the Study of Diabetes in India (RSSDI) suggests that diabetics should have access to a dietician or nutritionist or other health-care professionals trained in the principles of nutrition, at or around the time of diagnosis. An initial consultation with follow-up sessions as required, individually or in groups, should be provided (RSSDI 2015). Further to this, staff are required to develop theoretically based, patient-centred, ongoing follow-up education programs for diabetics (RSSDI 2015). Access to specialist care and structured follow-up systems including recall for annual assessment are essential, as is the need to address the transition from empowered self-care to dependency and hospitalisation (RSSDI 2015).

Frequency of monitoring for selected parameters in patients with diabetes is given in Table 2.8 (Kumar *et al* 2013).

Table 2.8: The frequency of monitoring for selected parameters in patients with diabetes (Kumar *et al* 2013)

Parameter	**Frequency of monitoring/screening**
Body weight and height and calculated body mass index (BMI)	At least twice a year.
Blood pressure	At least twice a year.
Glycosylated haemoglobin (HbA_{1c})	At least twice a year (in patients who have stable glycaemic control), quarterly (in patients who are not meeting glycaemic goals or whose therapy is changed).
Lipid profile	Annually (especially in adults).
Urine albumin	Annually (in type 1 DM patients with diabetes duration of $\geq$ 5 years, and in all type 2 DM patients).
Serum creatinine	At initial examination (in adults and children with type 1 DM).

Parameter		Frequency of monitoring/screening
Fundoscopy and visual acuity		At initial examination (in adults and children ≥ 10 years with type 1 diabetes) thereafter, annually, or more frequently (if retinopathy is progressing), first trimester or even earlier (in women with pre-existing diabetes who become pregnant or planning pregnancy). Close follow-up (throughout pregnancy and for one year post-partum).
Neuropathy	Screening for digital symmetric polyneuropathy	At diagnosis of type 2 DM, and five years after diagnosis of type 1 DM, thereafter at least annually.
	Electrophysiological testing	If clinical features are atypical.
	Screening for signs and symptoms of cardiovascular autonomic neuropathy	At diagnosis of type 2 DM, and five years after diagnosis of type 1 DM.
Comprehensive foot examination		Annually.
Peripheral arterial disease (PAD)		As and when required by the clinician.

2.8.4 Use of social media

Patients are increasingly looking to the internet for information about medical conditions or treatment (Fox 2009). One survey indicated that patients searched the internet more frequently than they communicated with their doctors about health care questions (Elkin 2008). With over 400 million registered users worldwide, Facebook is an important online meeting place for social networking (Greene, Choudhry, Kilabuk & Shrank 2010). Many sites for disease-specific groups have arisen on Facebook, representing important sources of information, support and engagement for patients with chronic diseases (Greene *et al* 2010). Facebook holds great potential for promoting health as it is one of the largest social networking sites in the world. Zhang, He & Sang (2013), analysed 1352 messages posted to an active Facebook diabetes group to identify the characteristics of the group. The results revealed that the group was international in nature and users overcame language barriers to communicate with people with similar conditions. Users' interactions were structured around information, emotion, and community building. They exchanged medical and lifestyle information and highly valued their peers' personal experiences, opinions and advice. They also demonstrated a positive

attitude toward the reality of living with diabetes and generously provided encouragement and affirmation to one another (Zhang *et al* 2013). Facebook provides a forum for reporting personal experiences, asking questions and receiving direct feedback for people living with diabetes. However, promotional activity and personal data collection are also common, with no accountability or checks for authenticity (Greene *et al* 2010).

mHealth is defined by the WHO (WHO Library Cataloguing-in-Publication Data 2011, p6), as follows: "mHealth is a component of eHealth. To date, no standardized definition of mHealth has been established. The Global Observatory for eHealth (GOe) defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices. mHealth involves the use and capitalisation on a mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications including general packet radio service (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS) and Bluetooth technology." mHealth interventions offer the potential to overcome many of the traditional barriers by offering convenience and care in a natural environment and minimising the barriers of distance, time and cost. For the clinician, mHealth interventions offer the ability to evaluate a prescribed course of action, monitor adverse events and identify areas for improvement (Hamine, Gerth-Guyette, Faulx, Green & Ginsburg 2015; De Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car & Atun 2012).

Mobile phones (i.e., mobile phones with advanced computing and internet access) and tablet computers (i.e., general-purpose computers contained in a single panel and usually operated through a touch screen) have become the most popular and widespread types of mobile devices (European Commission 2015). In India, 61.8 % of women in urban areas and 36.9% of women in rural areas own mobile phones (NFHS-4 2016a) and close to 66% of British adults claim to own a mobile phone (Ofcom 2015a) and over half own a tablet (Ofcom 2015b). In the United States, a report by the Pew Research Center found that 64% of all adults now own a mobile phone (Smith & Page 2015) and 34% of American adults own a tablet computer (Zickuhr

2013). This suggests that mobile phones are widely used and social media may have a more important role to play in managing diabetes.

Evidence indicates that there is the potential for applications (apps) to be used in improving symptom management through self-management interventions. The use of applications in mHealth have the potential to improve health outcomes among those living with chronic diseases through enhanced symptom control (Whitehead & Seaton 2016). Petrovski, Zivkovic & Stratrova (2015) conducted a study to evaluate results from social media (Skype and Facebook) and CareLink software as tools to improve diabetes control in patients with type 1 diabetes, using insulin pumps with glucose sensors for one year. Petrovski *et al* (2015) found that social media allowed patients to gain diabetes knowledge and information and interact in their daily insulin adjustments. Moreover, it could help patients cope better with their daily life (Petrovski *et al* 2015).

The world is experiencing an extraordinary phenomenon: the exponential growth of mobile communications not only in developed countries but also in the developing world, where such technology is bypassing conventional telephony systems and allowing people to communicate across vast geographical distances, which until now, were inaccessible. The International Telecommunications Union (ITU) estimates that by the end of 2010, 77% of the world's population had a subscription to a mobile phone and over 85% were covered by a mobile phone network (Geneva International Telecommunications Union 2010).

If implemented strategically and systematically, mHealth can revolutionise health outcomes, providing virtually anyone with a mobile phone, with medical expertise and knowledge in real-time. This is a benefit, particularly to those marginalised or living in remote areas, who would otherwise not have access to this information or care (WHO Library Cataloguing-in-Publication Data 2011, p77).

2.9 Conclusion

Diabetes management remains a challenge for developed and developing countries alike. The implementation of evidence-based guidelines and restructuring of clinical care organisation

has yielded gains in some countries. In India, as in other countries, the health system has traditionally been designed to cater for acute illness and maternal and child health concerns. The need for long-term care for non-communicable diseases is a relatively new health concern, and personnel and infrastructure are not yet geared to face this task. Consequently, many health systems are exploring different models of care and advocating approaches that place more emphasis on a patient-centred approach. It is evident that social support has much unrealised potential as both an effective and cost-effective means to manage the epidemic of T2DM. While health practitioners need to be aware of the barriers to social support, it is clear that the way forward is a collaborative model involving health care providers, patients, and their social support network. To empower patients to easily access and adapt this information in their everyday life, certified paramedical staff for diabetes education are needed. The central role of families in creating the immediate context of patient care in India must also be recognised in diabetes education. India will also need to plan for the care of the sizeable number of people with diabetes, in order to prevent and decrease morbidity due to complications. A health system strengthening approach with standards of care at all levels, nationally accepted management protocols and regulatory framework can help in tackling this challenge.

CHAPTER 3: METHODOLOGY

This chapter describes the methods used in this study. It outlines the background information on the study site, study design, materials and methods, pilot study, data quality control, reduction of bias, statistical analysis and ethical considerations.

3.1 Background information on the study site

This study was conducted at the in-patient units at a private hospital; Apollo Specialist Hospital, Vanagaram in Chennai, Tamil Nadu, India (Figure 3.1 & Figure 3.2). Apollo Speciality Hospitals, Vanagaram, is the 50th hospital in the Apollo network. It is equipped with the latest technology and is staffed with expert doctors and patient care personnel. It is situated in Vanagaram, a suburb of Chennai, Tamil Nadu. Apollo Speciality Hospital is a 260 bedded facility, spread over almost 135000 square feet. It aims to provide tertiary care in several key specialties with special emphasis on cardiology and cardiothoracic surgery, orthopaedics and trauma (Apollo Hospitals Southern Region 2017). This site was chosen as it reflects the typical Indian diabetic population residing in Chennai.

Figure 3.1 Apollo Speciality Hospital, Vanagaram, Chennai, India

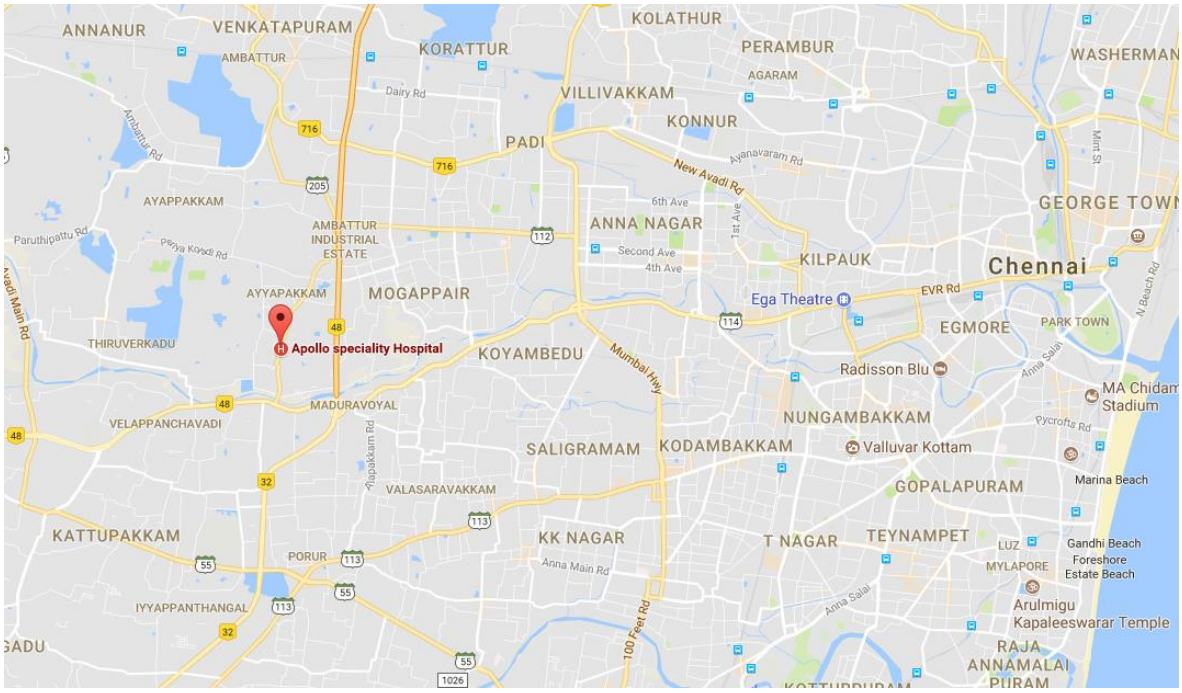

Figure 3.2: Location of Apollo Speciality Hospital, Vanagaram, Chennai, Tamil Nadu

India, with a population of 1.2 billion people, is the second most populous country in the world (Pradeepa *et al* 2015). India lies to the north of the equator between 6º 44’ and 35º 30’ north latitude and 68º 7’ and 97º25’ east longitude. India’s coastline measures 7517 km in length. Of this distance, 5423 km belongs to peninsular India and 2094 km to the Andaman, Nicobar, and Lakshadweep island chains. The Indian climate is strongly influenced by the Himalayas and the Thar Desert. Four major climatic groupings are predominant in India: tropical wet, tropical dry, subtropical humid and montane (this climate means that the higher the elevation the colder it becomes). Dense forests are common at moderate elevations; but, as the elevation increases, the climate becomes harsher, and the plant community transitions to grasslands (Joshi 2015).

The country consists of twenty-nine states, of which Tamil Nadu is one. Tamil Nadu is located in the Southeast area of India and has 32 districts in total. The state has a population of 72 147 030 as per Census 2011 and covers an area of 130058 square kilometres. There are 1033 females for every 1000 males in Tamil Nadu (NFHS-4 2016b). The percentage of literate

women is 79.4% compared to 89.1% men (NFHS-4 2016b). The infant mortality rate is 21 per 1000 live births as compared to the country's rate of 41 per 1000 live births (NFHS-4 2016a).

The capital of Tamil Nadu is Chennai, with an area of 178 square kilometres and a population of 4 646 732 (4.64 million in Census 2011) (8.6 million estimated by 2017). The gender ratio is 989 females per 1000 males with a literacy ratio of 90.2% (male 93.7%; female 86.6%) (Government of Tamil Nadu 2017). According to the Planning Commission's (Government of India) 2013 report, the state line of poverty for Tamil Nadu was 937 Indian Rupees (14 USD) monthly per capita, and 11.2% (8.2 million) people live below this poverty line (Government of India, Press Information Bureau 2013).

In Tamil Nadu, 23.8 % of children under 5 years of age were underweight. Adult females and males with a BMI of less than 18kg/m^2 were 14.6% and 12.4%, respectively (NFHS-4 2016b). Nationally, 35.7% of children under the age of 5 years were underweight and adult females and males with a BMI of less than 18 kg/m^2 were 22.9% and 20.2%, respectively (NFHS-4 2016a). In Tamil Nadu, 30% of women (15 to 49 years) were overweight or obese (BMI $\geq$ 25.0 kg/m^2) while 28.2% of men (15 to 49 years) were overweight or obese (NFHS-4 2016b). According to the same survey in Tamil Nadu, 3.9 % of women (between 15 to 49 years) had high blood sugar levels (> 9 mmol/l), while 5.6% of males of the same age group had high blood sugar levels (NFHS-4 2016b). According to the ICMR, 18.6% of people in Chennai, capital of Tamil Nadu were diabetic in 2006 (Mohan *et al* 2007) and 4.8 million were diabetic in Tamil Nadu (South India) in 2011 (Anjana *et al* 2011). Approximately 0.5% of women (15 to 49 years) and 1.2% of men (15 to 49 years) had very high blood pressure (systolic >160mm/Hg and diastolic >110mm/Hg) (NFHS-4 2016b).
Figure 3.3 shows the location of Chennai in relation to the state of Tamil Nadu.

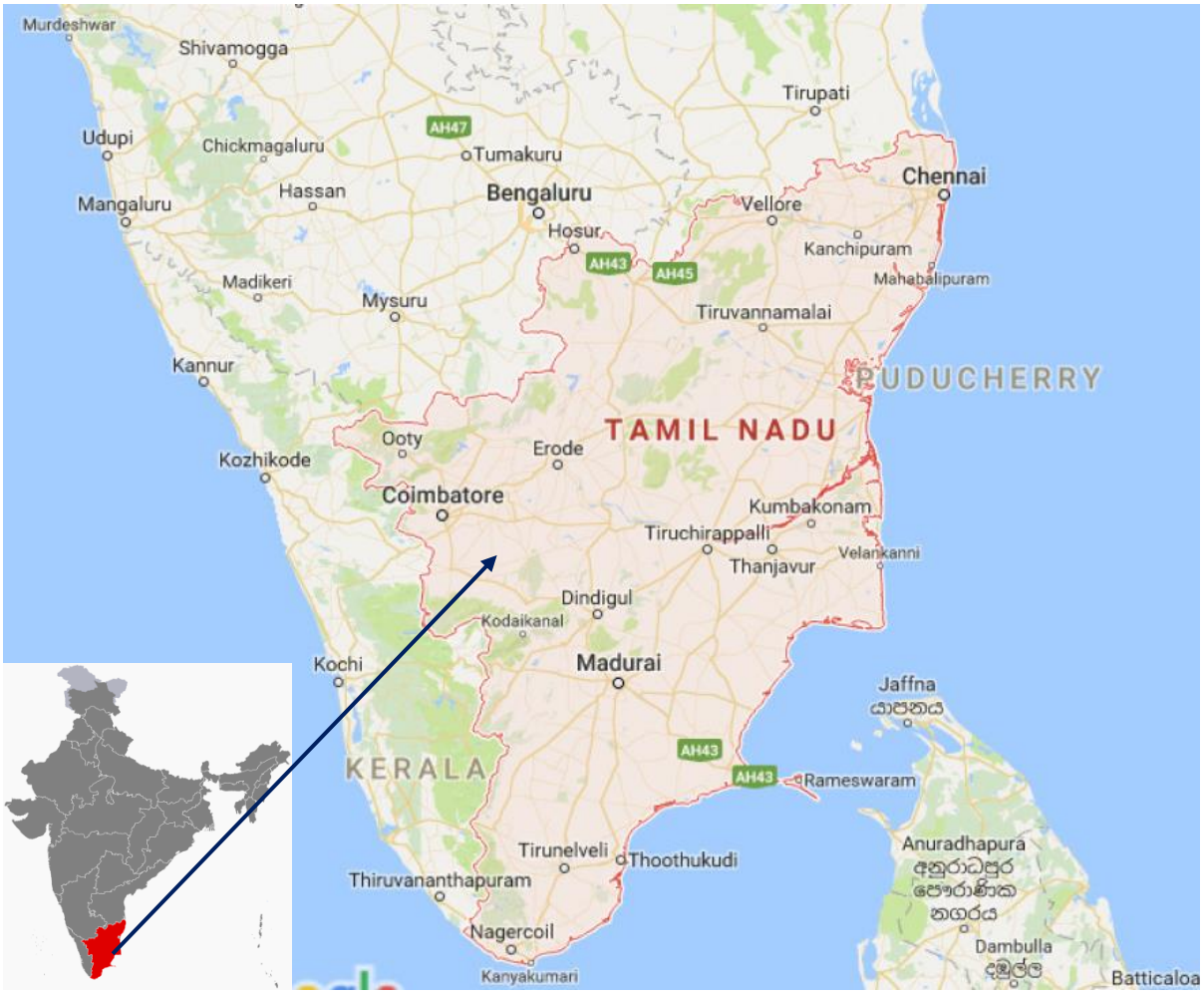

Figure 3.3: Map showing Tamil Nadu, India

3.2 Study design

This was a cross-sectional, observational study conducted using questionnaires with closed-ended and open-ended questions. Cross-sectional studies measure both exposure and outcome in the present and at the same point in time (Margetts & Nelson 2001, p5). A cross- sectional survey is a type of observational or descriptive study where the researcher has no control over the exposure of interest (Margetts & Nelson 2001, p369). In observational studies, the investigator may be able to exploit “natural experiments” where exposure is restricted in some groups in the community, compared to other groups (Margetts & Nelson 2001, p5).

3.3 Study population and sample selection

3.3.1 Study population

This study was conducted on in-patients of Apollo Speciality Hospital, Vanagaram. The medical, general and surgical in-patient wards with diabetic adult patients were used. Type 2 diabetic adults between 18 to 70 years old; with no more than two co-morbidities; diagnosed for at least one year and previously seen by a dietitian were invited to participate in the study. The health care providers used had one year or more of experience. All subjects were of Indian origin living in Chennai, Tamil Nadu. Type 2 diabetes was chosen for this study, as this condition is more prevalent and problematic in this community than other types of diabetes. T2DM adults were chosen as receiving ethical approval for them to partake in a study is more likely in private institutions.

3.3.2 Sample selection

Systemic sampling was used in this study. "Systemic sampling is a version of simple random sampling which avoids the need for a sampling frame at the outset, and so simplifies the randomization procedure. Like simple random sampling, it ensures the same sampling fraction for each sampling unit, but in practice only the first unit sampled is randomly selected." (Margetts & Nelson 2001, p66). The renal, cardiac and intensive care units were excluded as per inclusion criteria for subjects. The outpatient department was excluded as per request of the hospital administration due to this department being a high "traffic" area and to avoid patients becoming impatient and irritable. Patients with renal failure or co-morbidity were not included. The maximum sample size allowed in the study was 50, as stipulated by the hospital management. The health care providers sample size was limited to 25, as specified by the hospital management.

Inpatients medical records were checked for above criteria (3.3.1) and those meeting them were asked to participate in the study.

3.4 Study materials and methods

3.4.1 Questionnaires

Two questionnaires were developed for use in this study. One was developed to be answered by Type 2 diabetic patients in English (Appendix A). This questionnaire was translated into

Tamil (vernacular language in Chennai) (Appendix B), for those who wished to answer in Tamil. The other questionnaire was designed to be answered by HCPs (Appendix C). The patient questionnaire was designed to be answered through an interview with the researcher, while the health care professionals' questionnaire was self-administered. The patient questionnaire was developed with input from the research supervisor and Consultant Diabetologists. The researcher also developed the questionnaire by drawing on experience gained from working in a Chennai private hospital. The questionnaire was validated (face validity and content validity) by three Consultant Diabetologists, not involved in development of the questionnaire.

3.4.1.1 Patient questionnaire

The patient questionnaire was divided into the following five sections: demographic characteristics of the patient, barriers to lifestyle modification, motivation, service needs and knowledge of the diabetic patient. The barriers to lifestyle modification section was further subdivided to include the specific lifestyle changes and their barriers; such as eating habits and nutritional medical care. The researcher conducted all interviews with the patients that agreed to participate.

3.4.1.2 Health provider questionnaire

The health provider questionnaire was divided into the following three sections: demographic characteristics of the healthcare professional, medical care and motivation and barriers in counselling. The health care providers completed the questionnaire on their own.

3.5 Data collection

Patients who met the inclusion criteria in the various in-patient wards were invited to participate in the study. The researcher explained the aims and objectives of the study. The researcher explained the informed consent form (Appendix D) to patients who were willing to participate in the study. After consent was obtained, a time was set up to interview the patient according to the patient's convenience. The interviews were conducted by the researcher at the patient's bedside with at least one family member present during the interview, in line with a requirement from the NABH. In general, most of the interviews were conducted in the private

rooms of the patients or in six-bedded general wards. The bilingual researcher conducted all interviews in the language (English or Tamil) preferred by the patient. The HCPs with over one year of experience were randomly selected and invited to participate. Once they agreed to participate, they signed the consent forms. The HCPs completed the questionnaire in their own time and returned them to the researcher

3.6 Pilot study

A pilot study was conducted in the general in-patient department of Apollo Speciality Hospitals, Vanagaram. This site was chosen as it reflects the typical Indian diabetic population residing in Chennai. Five adult diabetic patients who met the inclusion criteria participated in the study. The unique hospital identification number of the pilot study patients were kept with the researcher for the main study, so as not to use the same patients in the main study. The inclusion criteria were type 2 diabetics, diagnosed for at least one year; aged between 18 to 70 years; no more than two co-morbidities, excluding renal complications; latest HbA_{1c} available and had seen a dietician previously. The researcher went through medical records of the inpatients and those who fulfilled the above criteria were included. The researcher explained the study to the patients who met the inclusion criteria. Those who agreed to participate were interviewed according to their convenience. Three healthcare providers who met the inclusion criteria agreed to participate in the study. The inclusion criterion was that the healthcare provider should have been practising for more than one year. The objectives of the pilot study were to assess whether the wording in the questionnaire was clear and unambiguous, to determine the appropriateness and usefulness of all questions and to identify any repeated or futile questions. The pilot study also aimed to approximate the time taken to complete the questionnaire.

3.7 Reduction of bias

In order to reduce bias, the researcher ensured that there was no discussion between patients while the interview was being conducted. Further to this, no two patients from the same 6-bedded ward were interviewed during the same duration of stay in hospital. Although family members were present, patients answered the questions on their own. Patients were encouraged to be honest when completing the questionnaire and were assured that their responses would

remain anonymous and confidential. The researcher ensured that patients only participated once, as the patient's unique hospital identification number was noted for the researcher to crosscheck before recruiting patients. The researcher requested the HCPs not to discuss their answers with other health care providers and to keep all information disclosed confidential.

3.8 Data quality control

The researcher captured the data, which was crosschecked for possible errors. Responses were coded and the codes were entered onto the Microsoft Excel spreadsheet. Questionnaires were numbered for cross reference purposes. Errors were corrected before statistical analysis was conducted.

3.9 Statistical analysis

Data was captured onto Microsoft Excel spread-sheets and transferred to a statistical package, Statistical Package for Social Sciences (SPSS 22). The data was analysed by a statistician, using appropriate statistical techniques such as descriptive statistics, chi-square goodness-of-fit test, Spearman's/Pearson correlation, one sample t-test, Binomial test, Kruskal Wallis test and independent samples t-test. A p-value of <0.05 was regarded as being statistically significant.

3.10 Ethical considerations

Ethical approval was obtained from the University of KwaZulu-Natal, Humanities and Social Science Ethics Committee (HSS/0101/016M) (Appendix E). Apollo Hospitals: Institutional Ethics Committee-Clinical Studies issued a supporting letter for the research to be conducted (Appendix F). Each participant was required to read and sign a consent form before participating in the study (Appendix D).

CHAPTER 4: RESULTS

This chapter presents the study results.

4.1 Results of patient-orientated questionnaire

4.1.1 Demographic characteristics

Demographic characteristics of the patients is shown in Table 4.1.

Table 4.1: Demographic characteristics of patients (n=50)

Characteristic	**n (%)***
Gender	
Male	27 (54)
Female	23 (46)
Age (years)	
41-45	5 (10)
46-50	9 (18)
51–55	15 (30)
56-60	9 (18)
61-65	5 (10)
66-70	7 (14)
Highest level of education	
Primary	6 (12)
Secondary	12 (24)
Tertiary	13 (26)
Post Graduate	19 (38)
Access to domestic help	
Yes	27 (54)
No	23 (46)

***** Percentage of total sample (n=50)

The majority of patients were over 51 years of age (72%; n=36). The male to female ratio was approximately 1.2. Mean age was 55 years old. Sixty-four percent (n=32) of the patients had completed tertiary education, while 38% (n=19) had postgraduate degrees. Just over half (54%; n=27) of the patients had access to domestic help.

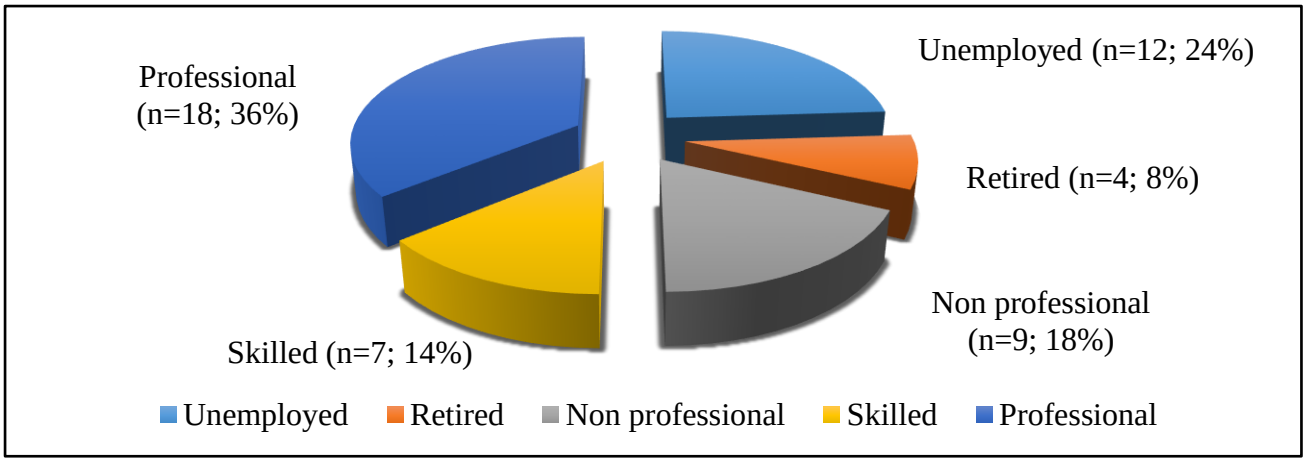

Figure 4.1: Occupation of patients

More than a third of the patients were professionals (n=18), 14% (n=7) were skilled labourers and 18% (n=9) were non-professionals. Twenty-four percent (n=12) were unemployed while 8% (n=4) were retired (Figure 4.1).

4.1.2 Socio-economic characteristics

Eight two percent (n=41) of the patients earned more than 35 000 Indian Rupees per month (538 USD) and of this 48% (n=24), earned more than 45 000 Indian Rupees per month (692 USD) (Figure 4.2)

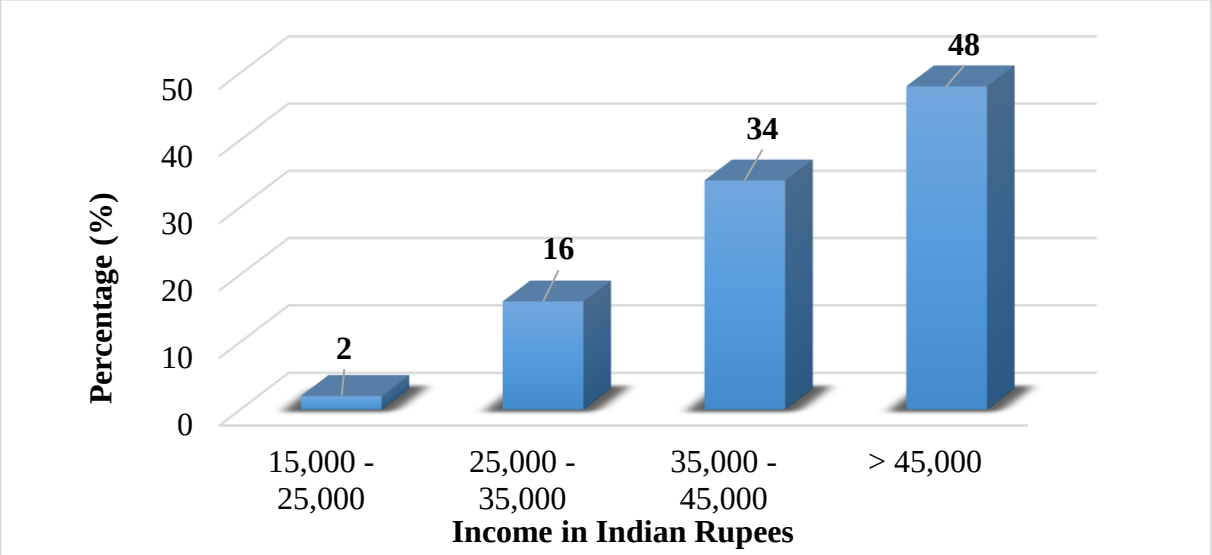

Figure 4.2: Monthly income earned by patients

4.1.3 Household characteristics

Twenty-six percent of the patients (n=13) had four people living in the household, which was also the highest number of people in a household. More than 60% of the patients (n=31) did not have any senior citizens (> 60 years) living in the household, while 38% (n=19) reported no children in the household (Table 4.2).

Table 4.2: Household characteristics

People in household	Number n (%)*	Number of senior citizens n (%)*	Number of children n (%)*
0	0 (0)	31 (62)	19 (38)
1	1 (2)	9 (18)	5 (10)
2	12 (24)	10 (20)	15 (30)
3	8 (16)	0 (0)	8 (16)
4	13 (26)	0 (0)	3 (6)
5	9 (18)	0 (0)	0 (0)
5	4 (8)	0 (0)	0 (0)
7	2 (4)	0 (0)	0 (0)
8	1 (2)	0 (0)	0 (0)

* Percentage of total sample (n=50)

4.1.4 Anthropometric characteristics

The mean weight for this sample was 72.8 kg (SD±12.62) and the mean height was 1.64 m (SD±0.085). Table 4.3 and Figure 4.3 shows the BMI ranges of patients.

Table 4.3: Body mass index of patients (WHO classification 2017a)

BMI range (kg/m^2)	Classification	n (%)*
18.5 or less	Underweight	0 (0)
18.5-24.9	Normal	18 (36)
25.0-29.9	Overweight	23 (46)
30.0-34.9	Obese, Class I	9 (18)

* Percentage of total sample (n=50)

Forty six percent of patients fell within the BMI range of 25-29.9 kg/m^2 (overweight) as compared to 18% (n=9) with a BMI of 30.0-34.9 kg/m^2 (obese, class I) and 36% (n=18) within the normal BMI range of 18.5-24.9 kg/m^2 (Figure 4.3).

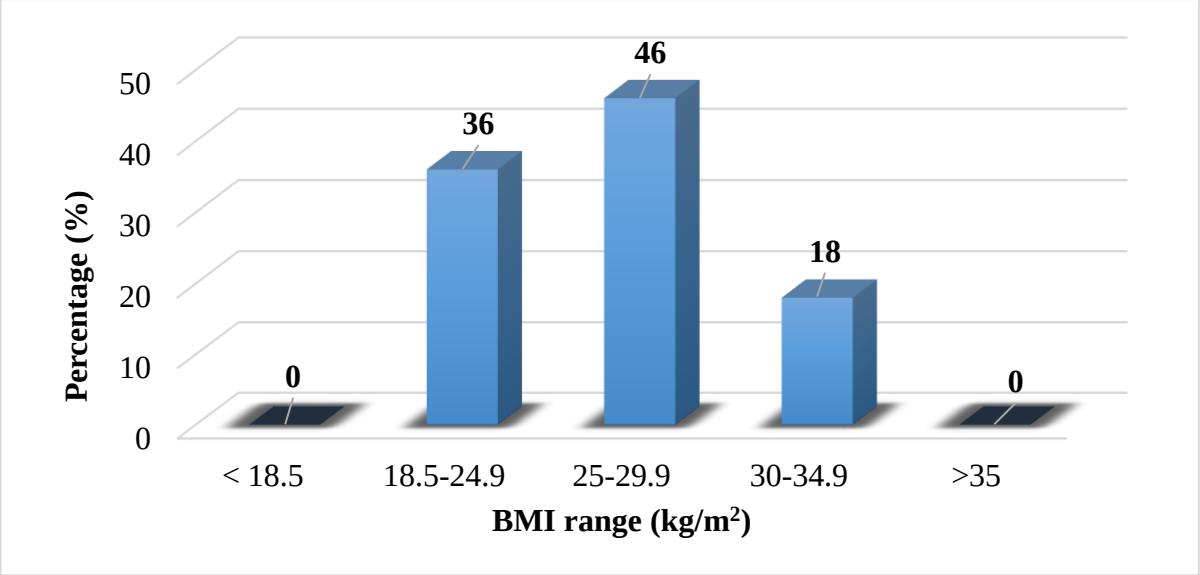

Figure 4.3: Body mass index ranges of patients

4.1.5 Diabetes duration and co-morbidities

The duration for which the patients had been diagnosed with diabetes is shown in Table 4.4.

Table 4.4: Duration of diabetes amongst patients

Years	n (%)*
1-3 years	12 (24)
4-6 years	13 (26)
7-9 years	5 (10)
10-12 years	13 (26)
13-15 years	3 (6)
16- 18 years	2 (4)
19- 21 years	2 (4)
>21 years	0 (0)

* Percentage of total sample (n=50)

The minimum duration of diabetes in this study group was two years and the maximum was 20 years, with a mean of 7.94 years (SD ± 4.917). Co-morbidities of patients are presented in Table 4.5.

Table 4.5: Co-morbidities of patients

Co-morbidities	**n (%)***
Cardiac	6 (12)
Dyslipidaemia	2 (4)
Dyslipidaemia, Hypothyroidism	1 (2)
Hypertension	14 (28)
Hypertension, Arthritis	1 (2)
Hypertension, Arthritis, Diabetic foot ulcer	1 (2)
Hypertension, Cardiac	2 (4)
Hypertension, Dyslipidaemia	6 (12)
Hypertension, diabetic foot ulcer	1 (2)
Hypertension, Hypothyroidism	4 (8)
Hypertension, Hypothyroidism, Cardiac	1 (2)
Hypertension, Hypothyroidism, Tuberculosis (treated)	1 (2)
Hypertension, Obesity, Early cardiac	2 (4)
Hyperthyroidism, Lower respiratory tract infection	3 (6)
None	5(12)

* Percentage of total sample (n=50)

The most common co-morbidity was hypertension (on its own) (28%; n=14) while hypertension in combination with other co-morbidities was reported by 38 % (n=19). Eighteen percent (n=9) reported cardiac co-morbidities.

4.1.6 Glycosylated haemoglobin values

The lowest HbA_{1c} value in this study group was 6.1% and the maximum was 12.1%, with a mean of 8.05% (SD ± 1.42) (Table 4.6 and Figure 4.4).

Table 4.6: Glycosylated haemoglobin (HbA_{1c}) values of patients

HbA_{1c}	**n (%)***
6.0-6.4%	3 (6)
6.5-6.9%	9 (18)
7.0-7.4%	14 (28)
7.5-7.9%	2 (4)
8.0-8.4%	6 (12)
8.5-8.9%	6 (12)
9.0-9.4%	3 (6)
9.5-9.9%	0 (0)
10.0-10.4%	1(2)
10.5-11%	5 (10)
>11%	1 (2)

* Percentage of total sample (n=50)

According to the ADA (2017), the recommendation for HbA_{1c} is < 7%. Twenty-four percent of the patients (n=12) were in line with this recommendation. Ten percent (n=5) of the patients had an HbA_{1c} value of 10.5-11.0%.

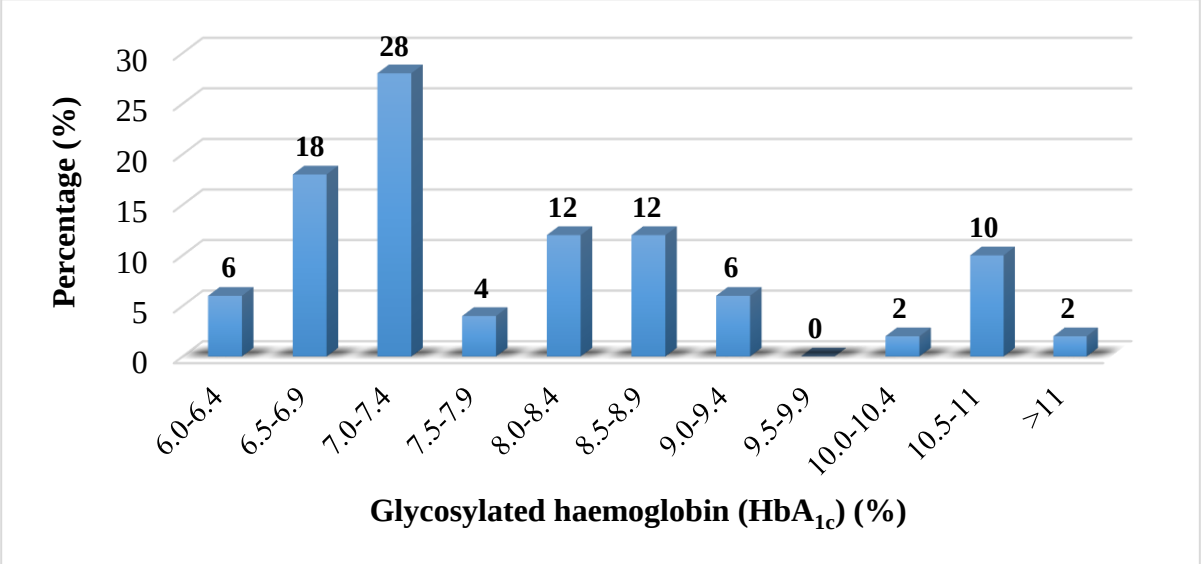

Figure 4.4: Glycosylated haemoglobin (HbA_{1c}) values of patients

4.1.7 Diet followed and meal preparation

The type of diets consumed by patients is shown in Figure 4.5

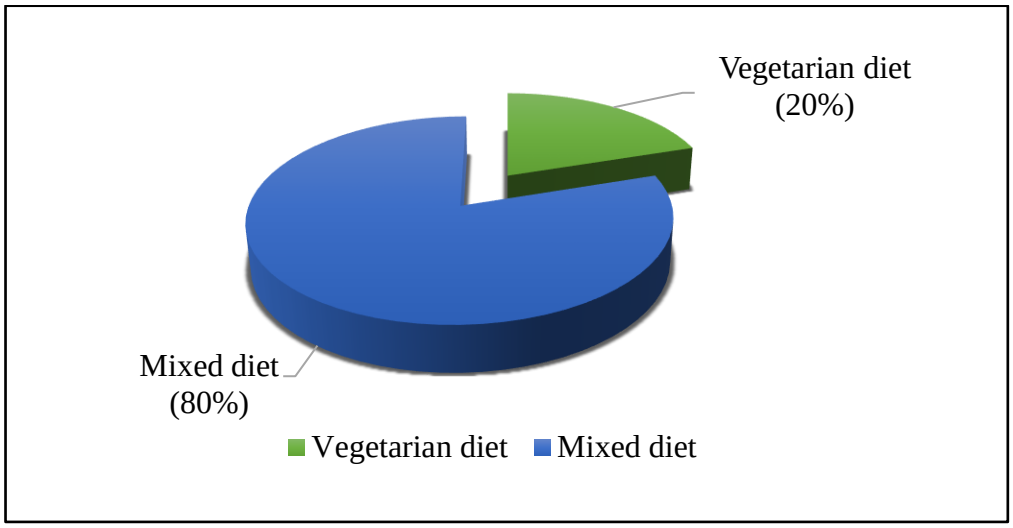

Figure 4.5: Types of diets consumed by patients

A mixed diet (including meat and vegetables) was followed by 80% (n=40) of the patients, while 20% (n=10) followed a vegetarian diet (specifically lacto-vegetarian diet). About half of the patients (n=25) reported that their wives were responsible for preparing their meals, while 42% (n=21) prepared their own meals and 4% (n=2) had meals prepared by their mother and daughter (Figure 4.6).

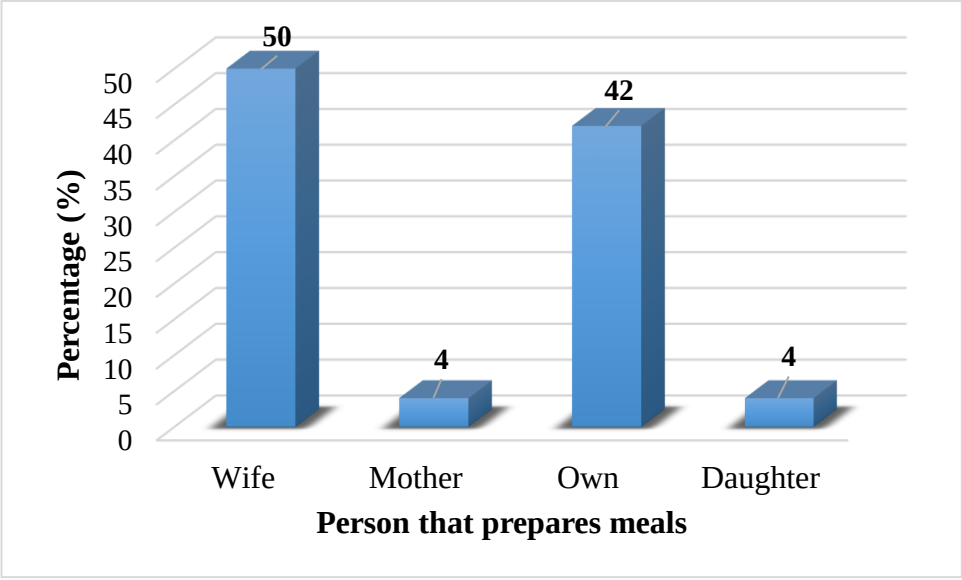

Figure 4.6: Person that prepares meals

4.1.8 Blood glucose monitoring

Just more than half of the patients (n=26) reported that they had a working glucometer to test blood glucose levels, while 48% (n=24) did not have a glucometer (Figure 4.7).

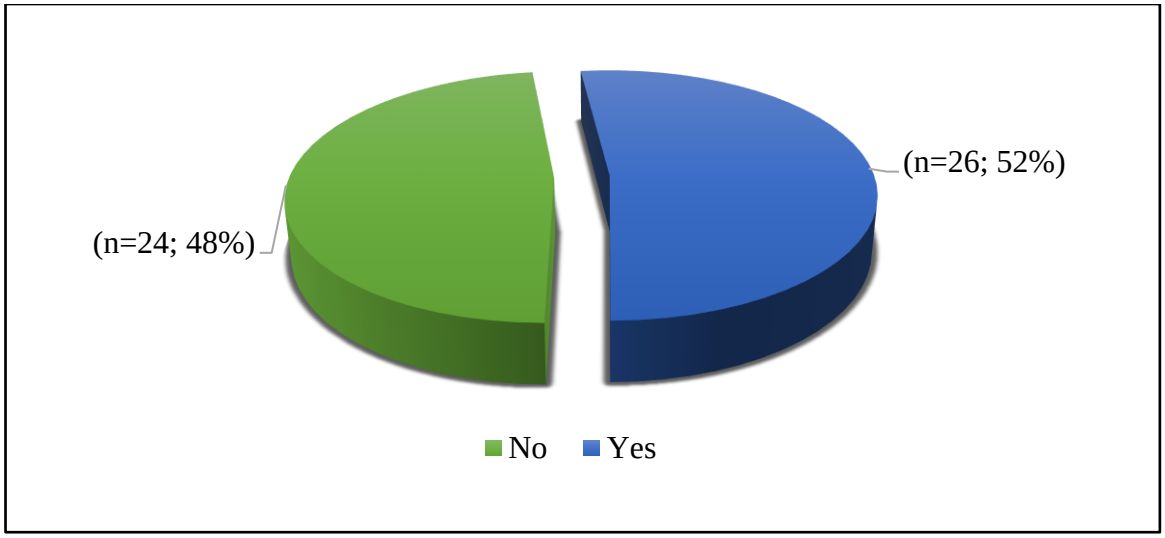

Figure 4.7: Patients who had a working glucometer

The frequency with which patients tested their blood glucose levels is shown in Figure 4.8.

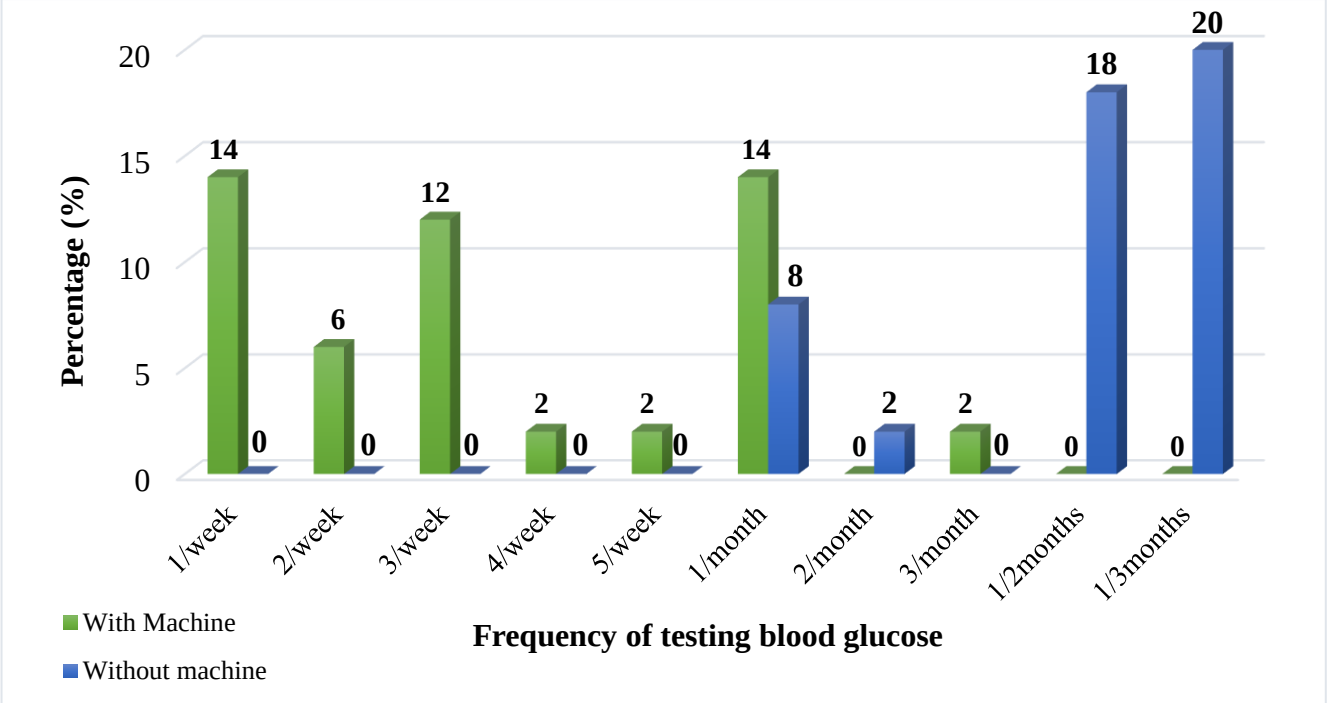

Figure 4.8: Frequency with which patients with and without glucometers tested their blood glucose levels

Patients who had glucometers tested their blood glucose more frequently than those who did not have a glucometer; however, this was not statistically significant. Patients with machines monitored their blood glucose from once a week to once a month. Patients were more likely to monitor their blood glucose more frequently, if they had a working glucometer in their homes. Patients without glucometers tested their blood glucose at the local hospital or local laboratory (Figure 4.9).

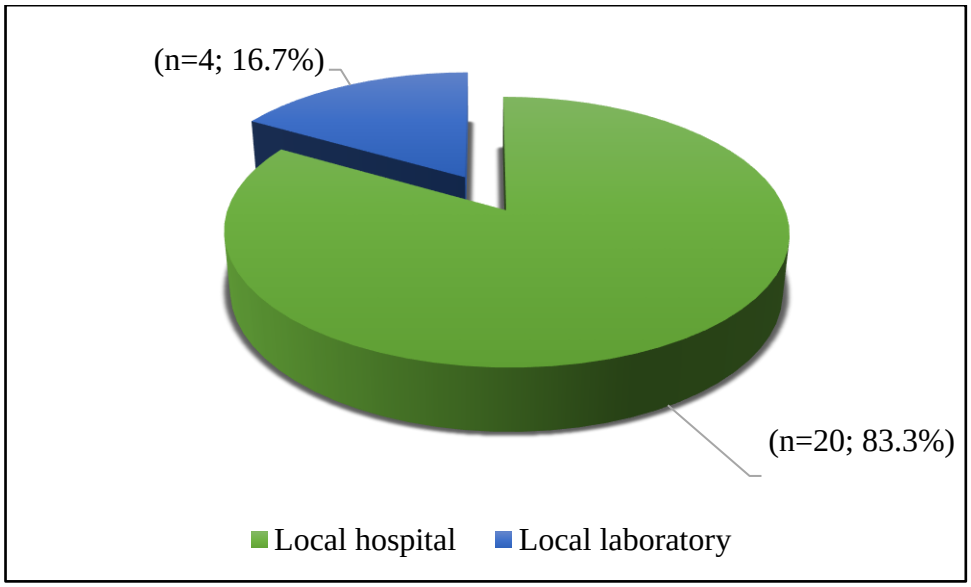

Figure 4.9: Medical facilities where patients without glucometers tested their blood glucose levels

Possible barriers to blood glucose monitoring is shown in Table 4.7.

Table 4.7: Possible barriers to blood glucose monitoring by patients

Barrier	Never n (%)*	Rarely n (%)*	Sometimes n (%)*	Often n (%)*	Always n (%)*	No response n (%)*
Feeling depressed, angry, stressed or bored	47(94)	2(4)	0 (0)	0 (0)	0 (0)	1(2)
Afraid to prick myself	50 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Family and friends are not supportive	50 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
When away from home (vacation, business trips, at relatives)	45 (90)	0 (0)	5 (10)	0 (0)	0 (0)	0 (0)
My daily routine (walking, to bed, eat, work etc.) changes	34 (68)	1 (2)	6 (12)	9 (18)	0 (0)	0 (0)
Frustrated with lack of results (e.g. no weight loss, high blood sugar levels)	43 (86)	2 (4)	4 (8)	1(2)	0 (0)	0 (0)
Family, work, or other tasks keep me too busy	29 (58)	1 (2)	6 (12)	14 (28)	0 (0)	0 (0)

* Percentage of total sample (n=50)

A significant number of patients felt that feeling depressed, angry, stressed or bored [χ^2 (2) = 82.840, p< 0.05], being away from home [χ^2 (2) = 32.000, p< 0.05], frustration [χ^2 (2) = 99.600, p< 0.05], being busy with work or family [χ^2 (2) = 35.920, p<0.05] and their routine or schedule changes [χ^2 (2) = 51.920, p<0.05] were "never" barriers to glucose monitoring. Family, work or other tasks keep me too busy was cited as often being a barrier to glucose monitoring for 28% (n=14) of the patients, while 18% (n=9) cited their daily routine changes as often being a barrier to glucose monitoring.

4.1.9 Physical activity

The number of hours spent per week on each exercise type is shown in Table 4.8

Table 4.8: Duration of physical activity reported by patients per week

	Never n (%)*	**<30min** n (%)*	**30-60 min** n (%)*	**1-3hrs** n (%)*	**>3hrs** n (%)*
Stretching or strengthening exercises (i.e. yoga)	41 (82)	0 (0)	3 (6)	5 (10)	1 (2)
Walking	6 (12)	0 (0)	3 (6)	24 (48)	17 (34)
Swimming or water exercise	49 (98)	0 (0)	0 (0)	1 (2)	0 (0)
Bicycling (including stationary, exercise bikes)	48 (96)	0 (0)	2 (4)	0 (0)	0 (0)
Aerobic exercise (i.e. Rowing, Obitrek)	50 (100)	0 (0)	0 (0)	0 (0)	0 (0)
Other aerobic exercise (e.g. Zumba)	50 (100)	0 (0)	0 (0)	0 (0)	0 (0)

* Percentage of total sample (n=50)

A significant number (82%; n=41) did not do yoga as their form of physical activity [χ^2 (2) = 87.280, p< 0.05]. A significant number indicated that they walked as a form of exercise for 1-3 hours weekly (48%; n=24) or more than 3 hours weekly, respectively (34%; n=17) [χ^2 (2) = 22.800, p<0.05]. The majority of the patients (98%; n=49) never engaged in any swimming or water exercises [χ^2 (2) = 46.080, p< 0.05] and never did any bicycle exercises (96%; n=48) [χ^2 (2) = 42.320, p<0.05].

Possible barriers to physical activity are shown in Table 4.9.

Table 4.9: Possible barriers to physical activity

Barriers	**Never** n (%)*	**Rarely** n (%)*	**Sometimes** n (%)*	**Often** n (%)*	**Always** n (%)*	**No response** n (%)*
Feeling depressed, angry, stressed or bored	42 (84)	0 (0)	8 (16)	0 (0)	0 (0)	0 (0)
Exercise and physical activity cause pain and discomfort for me	17 (34)	11 (22)	18 (36)	4 (8)	0 (0)	0 (0)
Family and friends are not supportive	48 (96)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)
When away from home (vacation, business trips, at relatives)	47 (94)	0 (0)	3 (6)	0 (0)	0 (0)	0 (0)
My daily routine (walking, to bed, eat, work etc.) changes	30 (60)	2 (4)	11 (22)	2 (4)	5 (10)	0 (0)
Frustrated with lack of results (e.g. No weight loss, high blood sugar level)	44 (88)	3 (6)	3 (6)	0 (0)	0 (0)	0 (0)
Family, work, or other tasks keep me to busy	26 (52)	2 (4)	6 (12)	16 (32)	0 (0)	0 (0)

* Percentage of total sample (n=50)

A significant number of patients felt that feeling depressed, angry, stressed or bored [χ^2 (2) = 23.120, p<0.05], being away from home [χ^2 (2) = 38.720, p<0.05], frustration [, χ^2 (2) = 67.240, p<0.05], their routine or schedule changes [χ^2 (2) = 55.400, p<0.05] and support from family [χ^2 (2) = 88.360, p<0.05] were "never" barriers to physical activity.

Family, work or other tasks keep me too busy was cited as often being a barrier to physical activity for 32% (n=16) of the patients, while 8% (n=4) cited fear or pain from exercise as often being a barrier to physical activity.

4.1.10 Eating habits and nutritional medical care

The manner in which patients chose to control their blood glucose through dietary management is shown in Table 4.10.

Table 4.10: Dietary methods used to control blood glucose

	Never n (%)*	**Rarely** n (%)*	**Sometimes** n (%)*	**Often** n (%)*	**Always** n (%)*
Watch calories in foods, to decide what you eat	30 (60)	5 (10)	6 (12)	5 (10	4 (8)
Leave a meal or snack out, to reduce calories or fat	27 (54)	1 (2)	11 (22)	5 (10)	6 (12)
Eat small portion sizes to reduce the calories or fat	24 (48)	2 (4)	11 (22)	11 (22)	2 (4)
Use low calorie, lite, reduced fat or fat-free products	34 (68)	3 (6)	10 (20)	3 (6)	0 (0)
Use sugar free or reduced sugar products	20 (40)	1 (2)	7 (14)	14 (28)	8 (16)
Not eat foods you like because they were too high in fat, sugar or calories	9 (18)	0 (0)	10 (20)	14 (28)	17 (34)
Use a written diet or meal plan to know what to eat	41 (82)	2 (4)	4 (8)	3 (6)	0 (0)

* Percentage of total sample (n=50)

A significant number of patients reported that they did not watch calories in foods [χ^2 (2) = 50.200, $p<0.05$], leave out a meal or snack to reduce calories [χ^2 (2) = 41.200, $p<0.05$], eat small portion sizes to reduce calories in foods [χ^2 (2) = 32.600, $p<0.05$], choose low calorie, 'lite', reduced fat or fat-free products [χ^2 (2) = 51.920, $p<0.05$] or use a written diet or meal plan to know what to eat [χ^2 (2) = 86.800, $p<0.05$], to control their blood glucose levels. Use of sugar free or reduced sugar products was always used to control blood glucose by 16% (n=8) of the patients, while 28% (n=14) of patients cited that they often did not eat foods they liked because they were too high in fat, sugar or calories.

Ninety percent of the patients (n=45) were able to purchase fresh vegetables and fruits regularly. Only 10% (n=5) could not purchase fresh fruit and vegetables regularly ($p<0.05$) (Figure 4.10). Seventy-four percent of patients (n=37) were able to eat fruits and vegetable daily, whereas 26% (n=13) could not ($p=0.001$) (Figure 4.11).

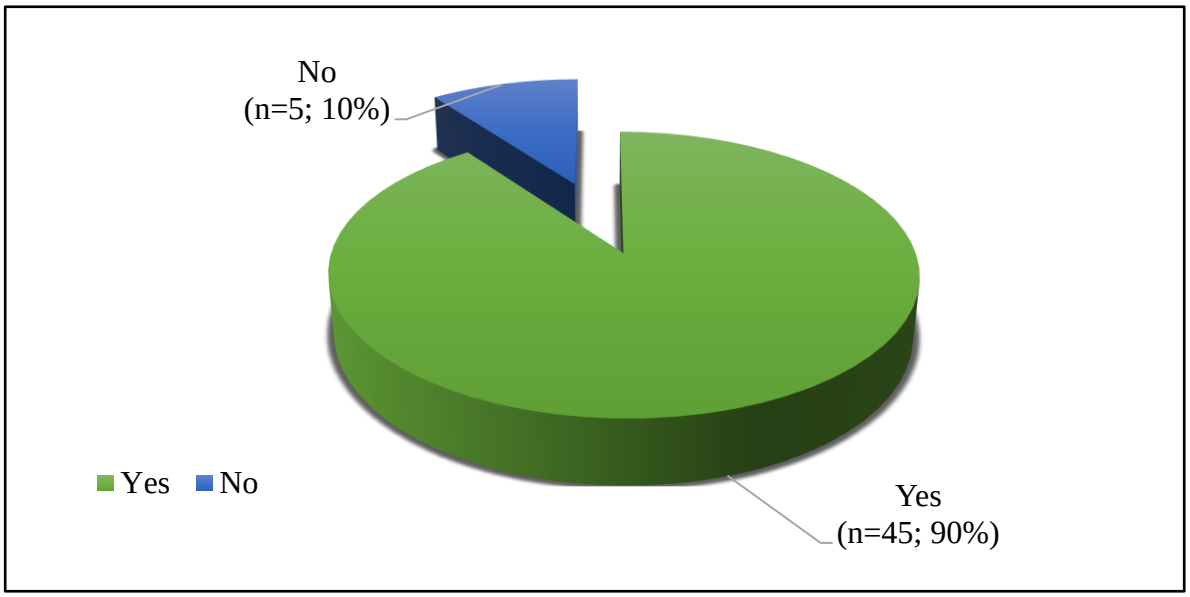

Figure 4.10: Patients able to purchase fruits and vegetables regularly

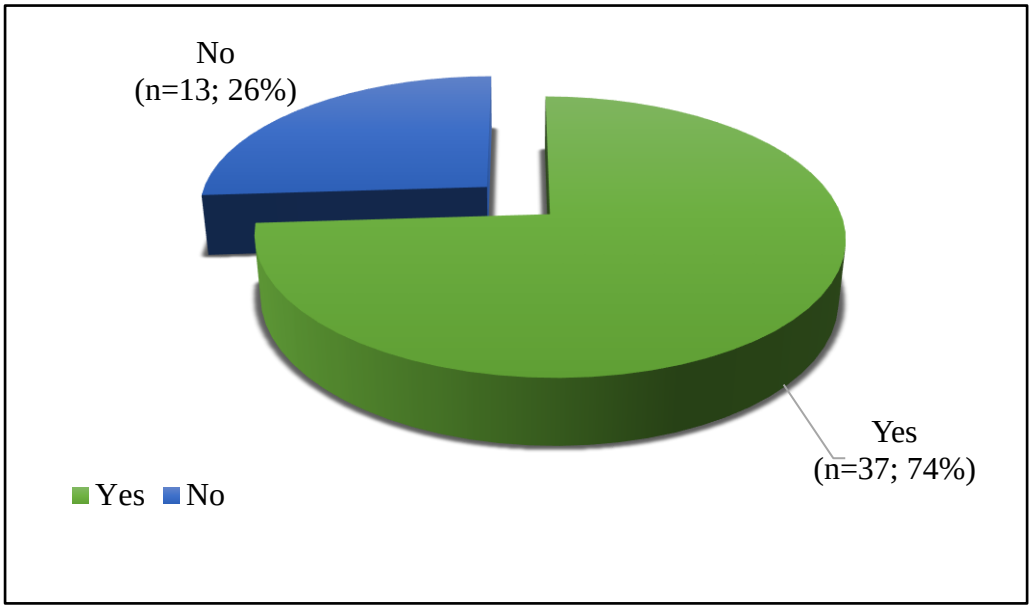

Figure 4.11: Patients that ate fruits and vegetables daily

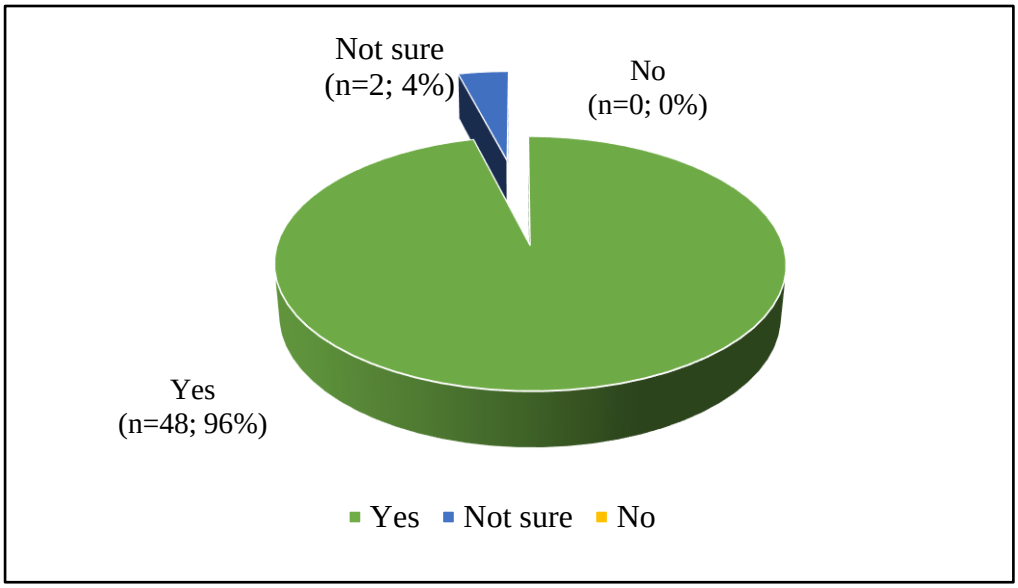

Figure 4.12: Percentage of patients educated on a healthy diet

Ninety-six percent (n=48) of the patients agreed that a healthy diet was explained to them while 4 % (n=2) were not sure ($p < 0.05$) (Figure 4.12).

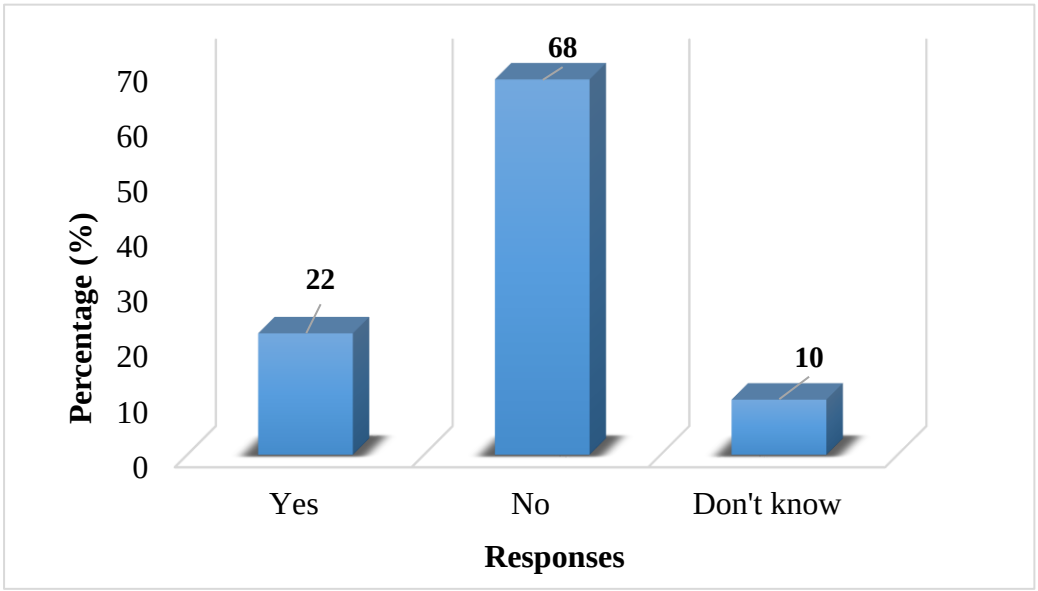

Figure 4.13: Patients that followed a diet plan to control their blood glucose levels

A significant number (68%; n=34) reported that they did not follow a diet plan to control their blood glucose levels [χ^2 (2) = 28.120, $p<0.05$], while 22% (n=11) did follow a diet plan (Figure 4.13).

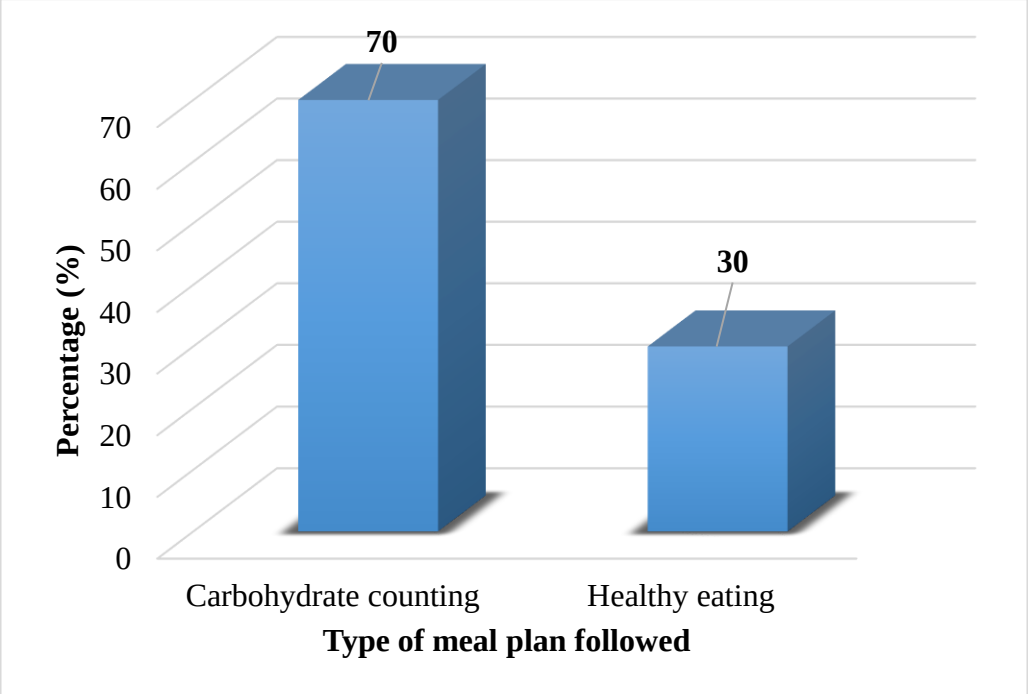

Figure 4.14: Type of meal plan followed

Seventy percent of the patients (n=7), followed a meal plan that involved carbohydrate counting while 30% (n=3) followed a meal plan based on healthy eating (Figure 4.14).

Possible barriers to following healthy eating and nutritional medical care are shown in Table 4.11.

Table 4.11: Possible barriers to following healthy eating and nutritional medical care

Barriers	Never n (%)*	Rarely n (%)*	Sometimes n (%)*	Often n (%)*	Always n (%)*
Eating unhealthy when feeling bored, angry, depressed or stressed	41 (82)	3(6)	6 (12)	0 (0)	0 (0)
Eating excessively because of food cravings, hunger or snacking	28 (56)	13 (26)	9 (18)	0 (0)	0 (0)
Eating unhealthy due to temptations from family or friends that are not supportive	30 (60)	12 (24)	8 (16)	0 (0)	0 (0)
Eating unhealthy when eating away from home (e.g. fast food, restaurants, and relatives)	10 (20)	14 (28)	18 (36)	8 (16)	0 (0)
Eating unhealthy due to lack of results (e.g. no weight loss, high blood sugars)	44 (88)	4 (8)	2 (4)	0 (0)	0 (0)
Eating unhealthy because you are too busy with family, work, or other responsibilities	26 (52)	6 (12)	10 (20)	8 (16)	0 (0)
Eating the same as rest of family, due to taste or convenience	21 (42)	6 (12)	14 (28)	3 (6)	6 (12)
Healthy foods are difficult to prepare	19 (38)	0(0)	23 (46)	8 (16)	0 (0)
Healthy foods are too expensive	22 (44)	2 (4)	24 (48)	2 (4)	0 (0)

* Percentage of total sample (n=50)

Eating unhealthily when feeling bored, angry, depressed or stressed [χ^2 (2) = 53.560, p<0.05], having food cravings, hunger or snacking [χ^2 (2)=12.040, p=0.002], lack of family support [χ^2 (2) = 16.480, p<0.05], lack of results [χ^2 (2)=67.360, p<0.05], being busy with family, work or other responsibilities [χ^2 (2)=20.080, p<0.05], eating the same as the rest of the family due to taste or convenience [χ^2 (2)=21.800, p<0.05] were statistically significantly 'never' a barrier to following healthy eating.

A significant number of patients (46%; n=23) indicated that lack of skills was 'sometimes' a barrier to following healthy eating habits and 48% (n=24) stated that cost or expense of food was 'sometimes' a barrier to following healthy eating habits.

4.1.11 Medication and medical care

All patients answered 'yes' to the question of whether their doctor prescribed medication for their diabetes.

The possible barriers faced by patients concerning medication and medical care are shown in Table 4.12.

Table 4.12: Possible barriers to medication and medical care

Barriers	Never n (%)*	Rarely n (%)*	Sometimes n (%)*	Often n (%)*	Always n (%)*
Feeling stressed, depressed, angry or bored	47 (94)	2 (4)	0 (0)	0 (0)	1 (2)
The medicine has bad side effects	47 (94)	1 (2)	0 (0)	0 (0)	2 (4)
Family or friends are not supportive	50 (100)	0 (0)	0 (0)	0 (0)	0 (0)
When away from home (e.g. vacation, business trips)	50 (100)	0 (0)	0 (0)	0 (0)	0 (0)
My daily agenda (waking, bedtime, eat, work, etc.) changes	49 (98)	0 (0)	1 (2)	0 (0)	0 (0)
Due to lack of results (e.g. high blood sugars)	49 (98)	0 (0)	1 (2)	0 (0)	0 (0)
Being too busy with family, work, or other tasks	48 (96)	0 (0)	1 (2)	0 (0)	0 (0)
The medication is too expensive	47 (94)	3 (6)	0 (0)	0 (0)	0 (0)
Use of alternate medicine/treatment like Siddha medicine, Ayurvedic or Acupuncture	45 (90)	0 (0)	0 (0)	1 (2)	4 (8)

* Percentage of total sample (n=50)

A significant number of patients reported that feeling bored, angry, depressed or stressed [χ^2 (2) = 82.840, p<0.05], having fear or pain [χ^2 (2) = 82.840, p<0.05], changes in schedules or daily routine [χ^2 (2)=46.080, p<0.05], lack of results [χ^2 (2) = 46.080, p<0.05], being busy with family, work or other tasks [χ^2 (2)=42.320, p<0.05], cost of medication [χ^2 (2)=38.720, p< 0.05] or use of alternate treatment [χ^2 (2)=82.840, p<0.05], were never barriers to medical treatment.

4.1.12 Motivation of patients

Table 4.13 and Figure 4.15 shows which type of motivation (intrinsic/internal factors or (extrinsic/external factors) influenced patients to change behaviours.

Table 4.13: Motivation of patients

	Intrinsic motivation n (%)*	Extrinsic motivation n (%)*	No motivation n (%)*
I follow my medication regimen regularly because …	13 (26)	37 (74)	0 (0)
I check my blood sugar levels because …	13 (26)	37 (74)	0 (0)
I follow my eating plan because …	18 (36)	20 (40)	12 (24)
I exercise regularly (4 – 5 times/ week for 20-30min) because …	25 (50)	15 (30)	10 (20)
I keep my health care provider (doctor, dietician, diabetic educator, etc.) appointments because …	8 (16)	42 (84)	0 (0)

* Percentage of total sample (n=50)

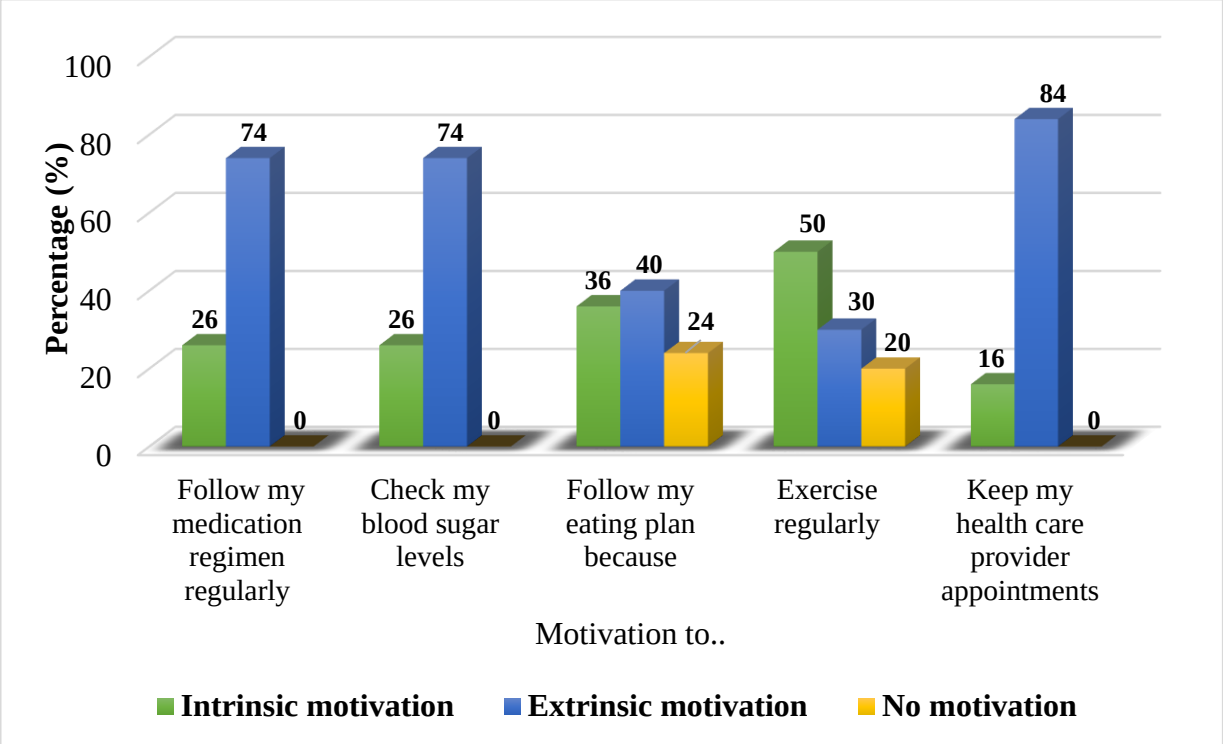

Figure 4.15: Types of motivation that influenced diabetic patients

A significant of number of patients indicated they were motivated by extrinsic factors to follow their medicine regimen [χ^2 (2)=11.520, p=0.001], to check their blood glucose levels [χ^2 (2) = 11.520, p=0.001] and keep appointments with their health care provider [χ^2 (2)=23.120, p< 0.05]. A significant number of patients reported that intrinsic factors was their main motivation to exercise regularly [χ^2 (2)=7.000, p=0.030].

Although the following observations were not significant, they are interesting to note; patients with intrinsic motivation to follow a diet plan (36%) were not obese with only half these patients being overweight. Similarly, people with no motivation (24%, n=12) to change their diet, had a BMI over 25kg/m^2 with only one patient being of normal weight. Of the extrinsically motivated patient (40%; n=20), five (25%) had a BMI of over 30 kg/m^2, with the rest being overweight (50%; n=10) or normal weight (25%; n=5).

The possible barriers to motivation are shown in Figure 4.16.

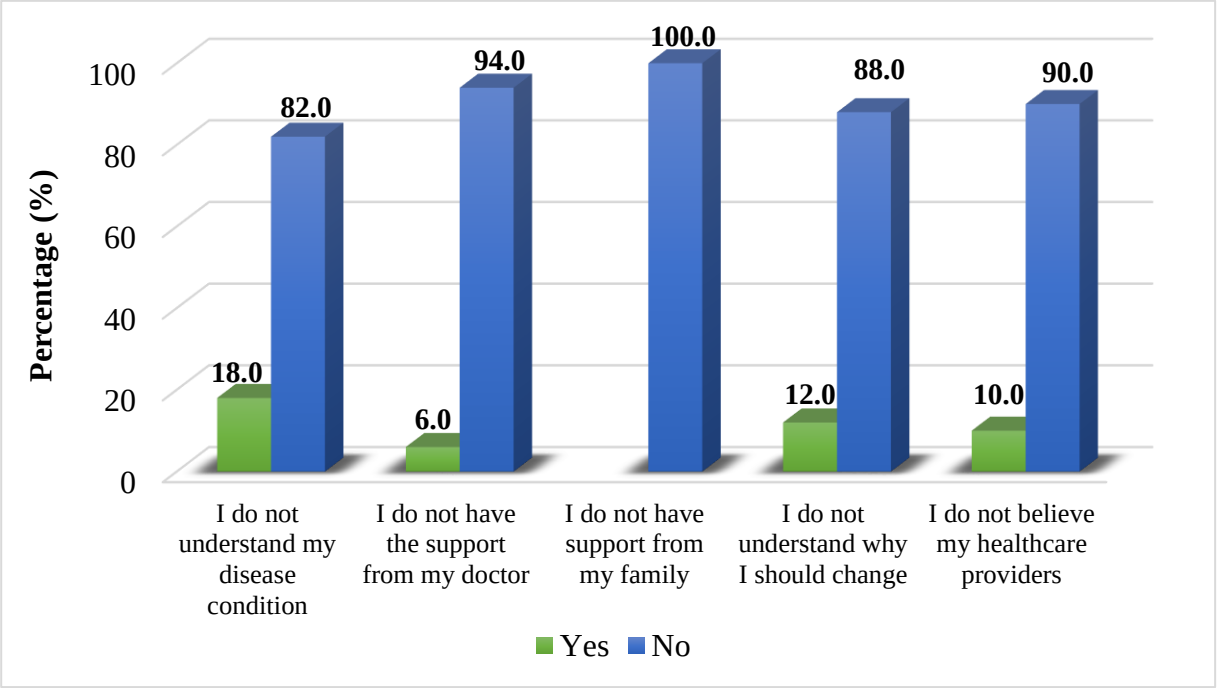

Figure 4.16: Possible barriers to motivation

A significant number of patients (82%; n=41) indicated that they understood their disease condition and (88%; n=44) understood why they needed to change their lifestyle ($p<0.05$). The majority of patients indicated that they had support from their doctor (94%; n=47), while all patients (100%; n=50) had support from family ($p<0.05$). Ninety percent (n=45) reported that they believed their healthcare providers ($p<0.05$).

4.1.13 Service needs of patients

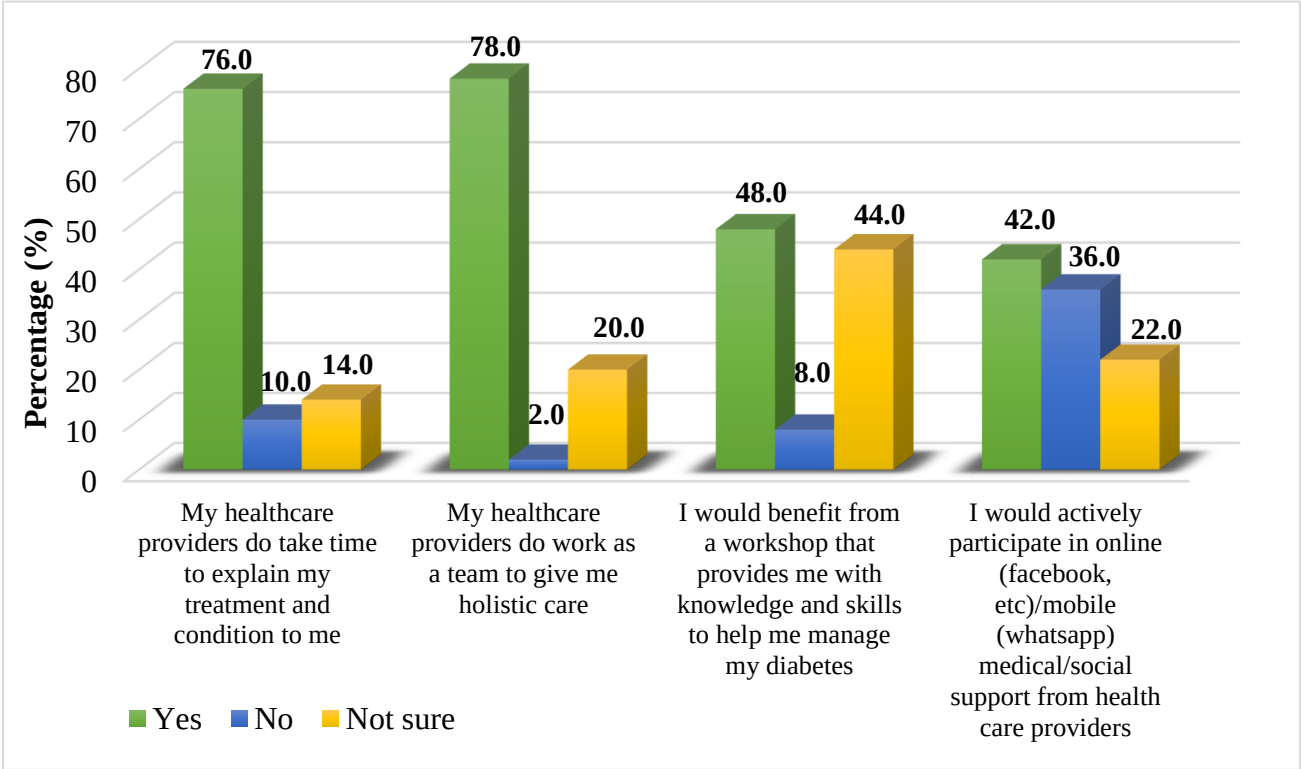

Figure 4.17: Service needs of patients

A significant number of patients reported that their healthcare providers took the time to explain their treatment and condition to them [χ^2 (2) = 41,080, $p<0.05$] and that their healthcare providers worked as team to give them holistic care [χ^2 (2) = 47,320, $p<0.05$]. A small, however, significant number of patients indicated that they would benefit from a workshop that provided knowledge and skills to help them manage their diabetes [χ^2 (2) = 14,560, $p=0.001$]. Although not significant, 42% (n=21) patients were willing to actively participate in online (Facebook, etc.)/mobile (WhatsApp) medical/social support from health care providers.

4.1.14 Knowledge and understanding of diabetes

A significant number of patients indicated that their caregiver or themselves had the knowledge to provide healthy meals for their diabetes [χ^2 (2) =13,520, p<0.05], that experts did not change their treatment or advice too often [χ^2 (2) =13,960, p=0.001] and that they understood their disease symptoms, risks and complications [χ^2 (2) =31,000, p<0.05] (Figure 4.18).

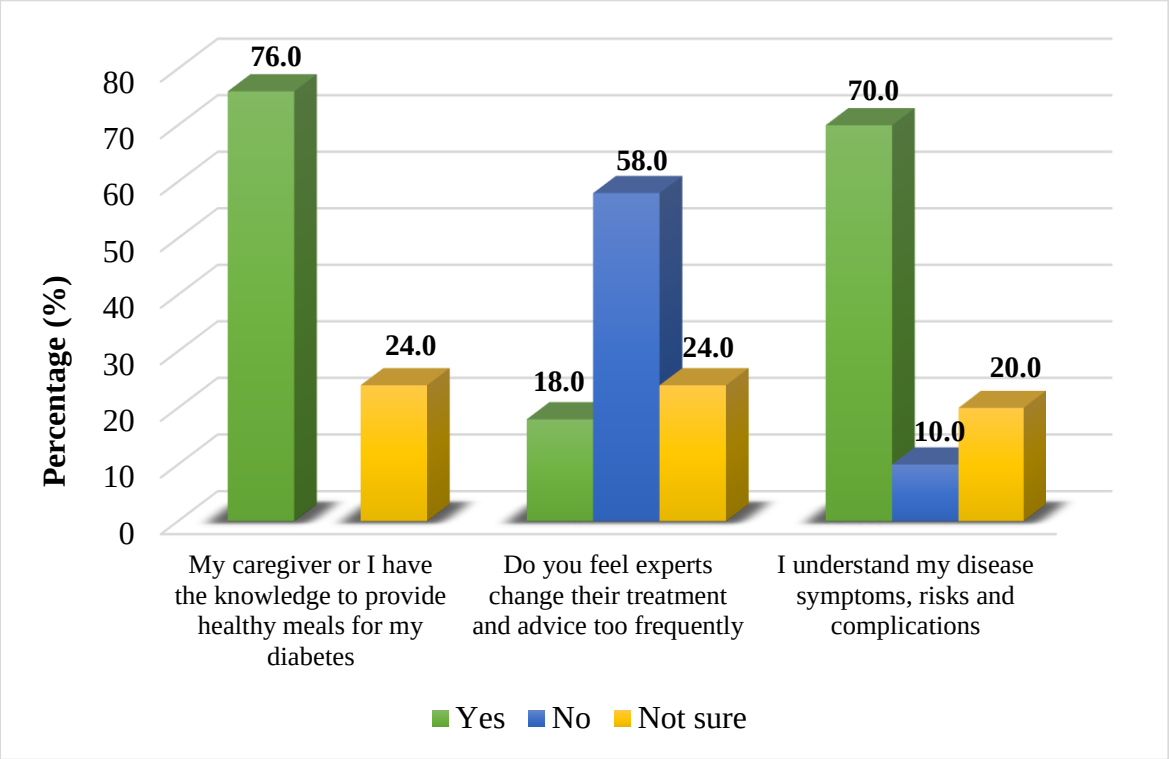

Figure 4.18: Knowledge and understanding of diabetes

4.1.15 Other significant findings

a) There was a significant positive correlation between income and HbA_{1c} (rho = 0.306; p=0.031). This implies that higher income was associated with higher HbA_{1c} values.

b) There was a significant difference in the HbA_{1c} score for those who followed a vegetarian or mixed diet [t (33.605) = -4.079, p=<0.05]. Those following a mixed diet (M=8.300) had a higher HbA_{1c} score than those who followed a vegetarian diet (M=7.040). Although this was observed for this sample, it cannot be reflected onto the general diabetic population. In addition, even though there was a significant finding between HbA_{1c} and type of diet, it

cannot be inferred that a vegetarian diet improves blood glucose control, due to the small sample.

c) There was a significant positive correlation between HbA_{1c} and BMI (rho = 0.679; p <0.05). This finding should be interpreted with caution, as there are other co-morbidities or factors that could influence HbA_{1c}.

4.2 Health care provider-orientated questionnaire

4.2.1 Demographic characteristics

The demographic characteristics of HCPs are described in Table 4.14.

Table 4.14: Demographic characteristics of health care providers

Characteristic	**n (%)***
Gender	
Male	11 (44)
Female	14 (56)
Age	
21-30 years	11 (44)
31-40 years	7 (28)
41–50 years	5 (20)
51-60 years	2 (8)
Occupation	
Consultant	4 (16)
Snr Doctor	2 (8)
Jnr Doctor	4 (16)
Snr Nurse	6 (24)
Diabetic Specialist	7 (28)
Jnr Nurse	2 (8)
Years of experience	
1-5	9 (36)
6- 0	4 (16)
11-15	5 (20)
16-25	5 (20)
> 25	2 (8)

* Percentage of total sample (n=25)

Of the HCPs, 44% (n=11) were males and 56% were females (n=14). Health care providers ranged in age from 21 years to 53 years (mean=34.4 years; SD±9.57). The years of experience ranged from 1 to 29 years (mean=11.48 years; SD±8.98).

Figure 4.19 shows the occupation of the different healthcare providers that participated in the study.

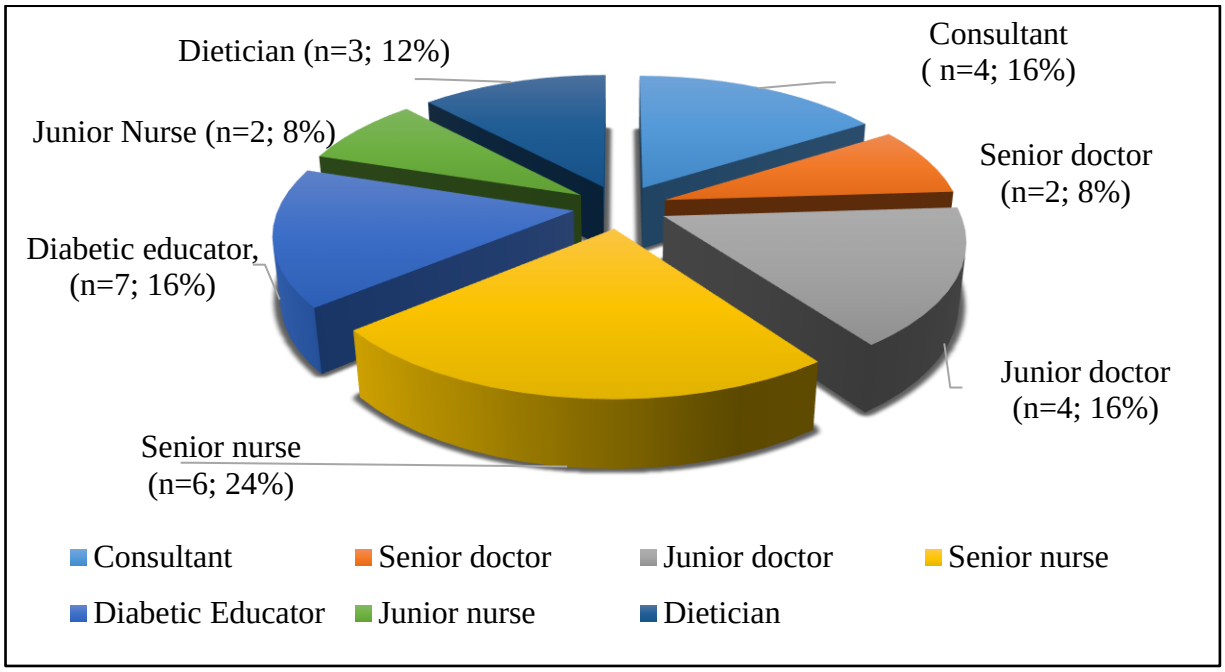

Figure 4.19: Occupation of health care providers

4.2.2 Medical care provided by healthcare providers

The responses on medical care provided by health care providers are shown in Table 4.15.

Table 4.15: Medical care provided by health care providers

	Never n (%)*	**1 x a year n(%)***	**2 x a year n (%)***	**Quarterly n (%)***	**Monthly n (%)***
How often do you see your diabetic patient?	0 (0)	2 (8)	0 (0)	4 (16)	19 (76)
	Never	**Rarely**	**Sometimes**	**Often**	**Always**
Diabetic patients follow their medicine regimen	0 (0)	0 (0)	2 (8)	19 (76)	4 (16)
Do your patients ask you what their medication is for?	0 (0)	0 (0)	10 (40)	15 (60)	0 (0)
Do patients ask you to clear their doubts regarding their condition?	0 (0)	0 (0)	11 (44)	14 (56)	0 (0)
My task is to motivate and support the patient in his/her lifestyle change	0 (0)	2 (8)	12 (48)	7 (28)	4 (16)
My task is to give information on lifestyle related risks	0 (0)	7(28)	8 (32)	4 (16)	6 (24)
How often do you refer your patient to other team members, such as the dietician, physiotherapist, diabetic educator, podiatrist, psychologist and optician?	0 (0)	1(4)	6 (24)	12 (48)	6 (24)
How often are there inter-disciplinary meetings to discuss care of your patients or share new knowledge on treatment?	10 (40)	3 (12)	6 (24)	6 (24)	0 (0)
To the best of your knowledge, do your patients:	**Do not know**	**None**	**Some**	**Most**	**All**
Follow a blood glucose monitoring schedule?	4 (16)	0(0)	14 (56)	7 (28)	0 (0)
Exercise regularly?	13 (52)	0 (0)	12 (48)	0 (0)	0 (0)
Complain of hypoglycaemia episodes?	4 (16)	0 (0)	21 (84)	0 (0)	0 (0)
Complain of hyperglycaemia episodes	3 (12)	0 (0)	10 (40)	12 (48)	0 (0)
Ask you about exercise?	16 (64)	0	7 (28)	2 (8)	0 (0)
	Totally Disagree	**Partially Disagree**	**In Between**	**Partially Agree**	**Totally Agree**
Do you have sufficient skills for lifestyle counselling?	0 (0)	4(16)	5 (20)	8 (32)	8 (32)

* Percentage of total sample (n=25)

A significant number of HCPs indicated that diabetic patients 'often' followed their medicine regime [χ^2 (2)=20.720, p<0.05]; that they (health care providers) 'sometimes' felt it was their task to motivate patients [χ^2(2)=9.080, p=0.028] and that they 'often' referred to other team members [χ^2(2)=9.720, p=0.021]. Health care providers reported that they saw their patients monthly [χ^2(2)= 20.720, p< 0.05]; whilst they stated that 'some' patients monitored their blood glucose at home [χ^2 (2)=6.320, p=0.042], complained about hypoglycaemia [χ^2(2)=11.560, p =0.001] and exercised regularly [χ^2(2)=12.080, p=0.002]. There was a significant agreement (M = 3.80, SD ± 1.080) that health care providers had sufficient skills for lifestyle counselling [t(24)=3.703, p=0.001].

Healthcare provider most referred to were dietitians (60%, n =15), diabetic educators (36%, n=9).

4.2.3 Motivation and barriers to counselling

The areas of lifestyle change that patients found difficult to adhere to, are shown in Figure 4.20.

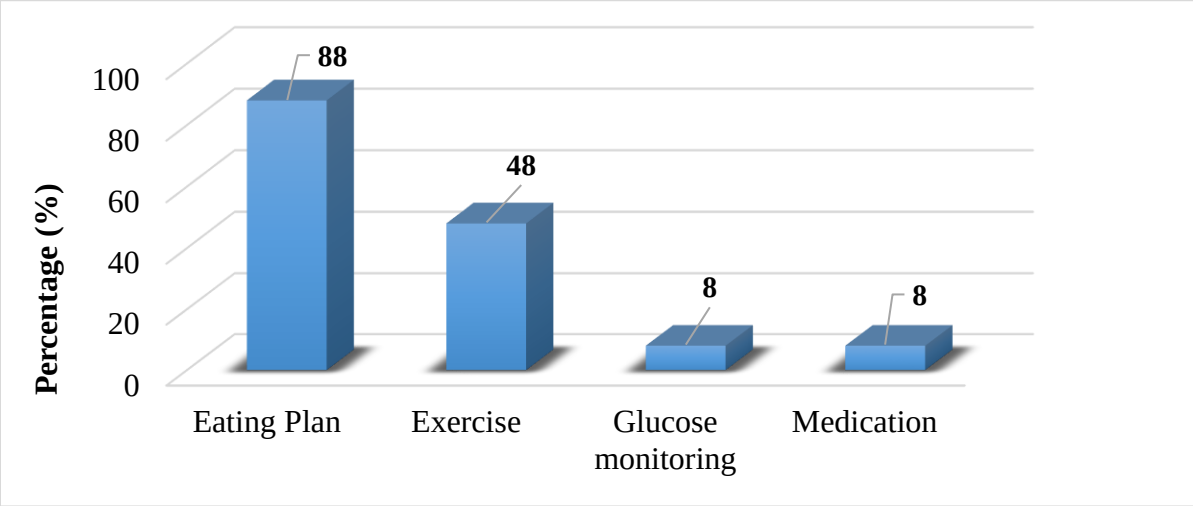

Figure 4.20: Areas of lifestyle change that patients found difficult to adhere to

Health care providers reported that patients found following an eating plan (88%) the most difficult to adhere to, followed by exercise (48%). Glucose monitoring and taking of medication was least difficult to maintain.

Patients complained that they had a lack of support from various groups of people (Figure 4.21).

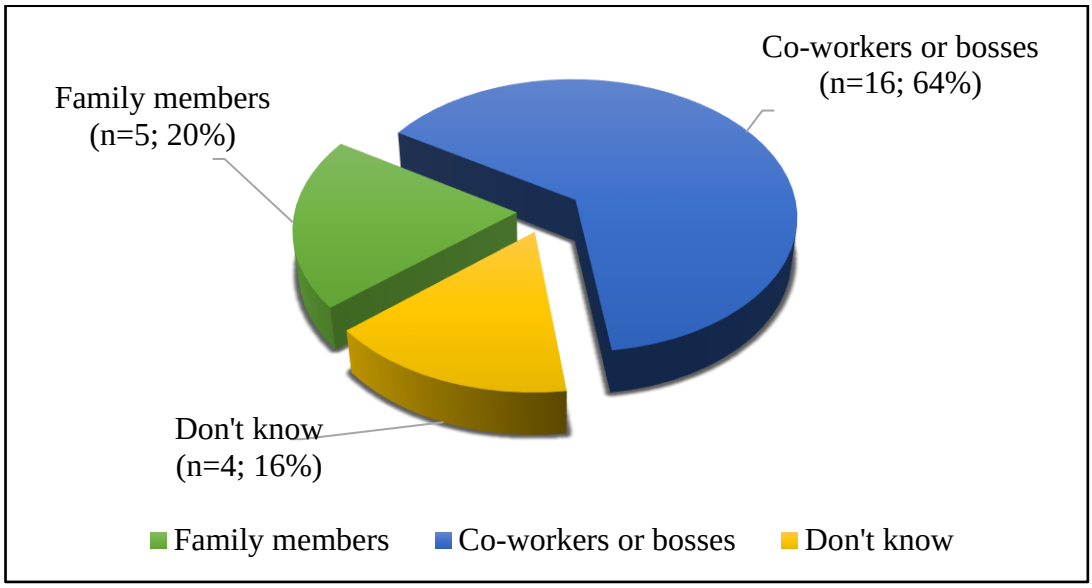

Figure 4.21: Groups of people patients complained that they had a lack of support from

Sixty-four percent (n=16) of HCPs reported that patients had a lack of support from co-workers or bosses, while 20% (n=5) reported a lack of support from family members.

Barriers to motivation and lifestyle counselling according to HCPs are shown in Table 4.16.

Table 4.16: Barriers to motivation and lifestyle counselling according to health care providers

	Totally disagree n (%)*	**Partially disagree n (%)***	**In between n (%)***	**Partially agree n (%)***	**Totally agree n (%)***
An important barrier to treatment is patient's unwillingness to change their lifestyle	0 (0)	0 (0)	3 (12)	19 (76)	3 (12)
Insufficient knowledge on complications of diabetes is a vital barrier in patient's treatment	0 (0)	0 (0)	18 (72)	6 (24)	1 (4)
Patients should be assigned responsibility of self-care	0 (0)	0 (0)	0 (0)	0 (0)	25 (100)
	Never	**Rarely**	**Sometimes**	**Often**	**Always**
Do your patients complain of depression and frustration due to their disease condition?	0 (0)	2 (8)	13 (52)	10 (40)	0 (0)
Do you find that time constraints are the problem for counselling your patients?	0 (0)	0 (0)	11 (44)	12 (48)	2 (8)
Do you feel that you are equipped with the knowledge or skills to teach your patients?	0 (0)	0 (0)	10 (40)	12 (48)	3 (12)
Would you actively participate in diabetes workshops, if organised by your hospital?	0 (0)	0 (0)	13 (52)	6 (24)	6 (24)

* Percentage of total sample (n=25)

All HCPs agreed that patients should be assigned responsibility of self-care ($p < 0.05$). Healthcare providers indicated that important barriers to lifestyle counselling were

unwillingness to change [t (24)=10.000, p<0.05], insufficient knowledge on complications [t (24) = 2.874, p=0.008] and lack of support from co-workers or bosses [χ^2 (2)=10.640, p<0.05]. A significant number of patients indicated to health care providers that they 'sometimes' and 'often' felt depressed and frustrated [χ^2 (2)=7.760, p=0.021] with their disease condition. Healthcare providers indicated that they 'sometimes' and 'often' [χ^2 (2)=7.280, p=0.026] felt that time constraints prevented them from counselling their patients adequately.

4.2.4 Other significant findings

a. There was a significant positive correlation between the experience level of the HCPs and the frequency with which they motivated and supported lifestyle changes (rho = 0.547, p = 0.005). The more experience a healthcare provider had, the more likely they were to motivate and support lifestyle changes.
b. There was a significant positive correlation between experience of healthcare providers and how confident they were that they had the knowledge or skills needed, to teach their patients (rho = 0.406, p = 0.004). The more experience a healthcare provider had, the more confident they were that they had the knowledge or skills needed to teach their patients.
c. There was a strong significant positive correlation between the experience of healthcare providers and the frequency with which they referred patients to other team members (rho = 0.767, p < 0.0005). The more experience a healthcare provider had, the more likely they were to refer their patients to other team members.
d. There was a significant positive correlation between experience of healthcare providers and how confident they were that they had the skills for lifestyle counselling (rho = 0.577, p = 0.003). The more experience a healthcare provider had, the more confident they were, that they had the skills needed to counsel patients on lifestyle changes.

4.3 Summary of findings

The diabetic patients in this study ranged in age from 41 to 68 years, with a mean weight, height and BMI of 72 kg, 1.64 m and 26.8 kg/m^2, respectively. The ratio of male to female was 1.2. Most patients had hypertension alone as a comorbidity and the mean HbA_{1c} was 8.05%. Most patients consumed a mixed diet (80%) and 42% of patients prepared their own meals. Fifty four percent of patients had domestic help, 48% had an income greater than 45 000 Indian

Rupees (692 USD) per month, and 38% held postgraduate degrees. Patients reported no significant barriers to glucose monitoring, although 28% indicated that being busy with family was a barrier. Most patients (88%; n=44) did some amount of walking weekly, with 34% completing more than 3 hours per week, whilst yoga was the next most common exercise (18%). Common barriers to exercise were fear and pain (44%) and being busy with work or family (72%). Most patients avoided foods high in fat, sugar or calories (82%; n=41), used sugar free or reduced sugar products (58%; n=29) and ate small portion sizes to reduce their calorie intake (52%; n=26). The most common barriers to not eating healthily were eating away from home (52%; n=26), cost or expense of healthy foods (52%; n=26) and taste of food (46%; n=23). Extrinsic motivation significantly influenced the decision to follow medication ($p=0.001$), check blood glucose levels ($p=0.001$) and keep health care appointments ($p<0.0005$). Exercise was the only habit this population followed regularly due to intrinsic motivation ($p=0.030$). Significantly, 82% of patients indicated that they understood their disease condition ($p<0.0005$), whilst a significant small number reported that they would benefit from a workshop that provided knowledge and skills to help manage diabetes ($p=0.001$). Most patients had confidence in treatment and advice obtained from health care providers ($p=.001$) and their own skills and knowledge to prepare healthy meals ($p<0.0005$). Most patients understood their disease condition and complications ($p<0.0005$). A higher income ($p=0.031$) and consuming a mixed diet ($p<0.0005$) was associated with higher HbA_{1c} levels amongst patients. Health care providers felt that they had sufficient skills for lifestyle counselling ($p=0.001$), but also reported that their biggest barrier to counselling was time constraints ($p=0.026$). Health care providers indicated that patients found following an eating plan (88%) the most difficult to maintain, followed by exercise (48%). Healthcare providers all agreed that patients should be assigned responsibility for self-care ($p<0.0005$), even though healthcare providers indicated that important barriers to lifestyle changes were unwillingness to change ($p <0.0005$), insufficient knowledge on complications ($p =.008$) and lack of support from co-workers or bosses ($p=0.005$).

CHAPTER 5: DISCUSSION

This study aimed to evaluate the barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their health care providers in Chennai, Tamil Nadu, India. This chapter discusses the results presented in Chapter 4.

5.1 Patient-orientated questionnaire

5.1.1 Demographic characteristics

All study participants were of Indian origin and living in Tamil Nadu, India. The sample interviewed at Apollo Speciality Hospital in Vanagaram represents Chennai's middle to higher socio-economic group. Although, there were patients from poorer backgrounds, they were able to receive treatment from a private hospital, due to medical aid benefits from their employers. The sample comprised of 50 patients with 54% male (n=27) and 46% female (n=23), with a male to female ratio of 1.2. This is similar to the Tamil Nadu sex ratio of 1.02 for urban areas (NFHS-4 2016b) and with the sex ratio from the CURES dietary profile of diabetics in Chennai of 0.82 (Radhika *et al* 2010). The minimum age was 41 years and maximum was 68 years with a mean of 55 years (SD±7.18). This is consistent with findings from Kapur *et al* (2008), which reported a mean age of 53 years (SD±10.2) and Ramachandran *et al* (2007) (mean=56.2 years and SD±10.5). Sixty-four percent (n=32) of the patients had completed tertiary education, with 38% (n=19) being postgraduate degree holders. Kapur *et al* (2008) (Chennai) reported that 48% (n=154) of their subjects had a college education. The possible reason for the current study population having a higher education level, could be that this study is more recent. In the current study, 64% of the diabetics had completed tertiary education. This was higher than findings from Kapur *et al* (2008) and Ramachandran *et al* (2007) who both reported that 45% of diabetics had a college or tertiary education. This could be a reflection of the strides India has made in higher education over the last decade. The results of this study are on par with the statistics from the state survey which indicated that 58.6% of women had 10 or more years of schooling in urban areas of Tamil Nadu (NFHS-4 2016b), increasing from 31.8% in 2005.

5.1.2 Socio-economic characteristics

A high percentage (82%) of people in this sample earned more than 35 000 Indian Rupees per month (538 USD); this was much higher than that observed by Ramachandran *et al* (2007) of approximately 8 300 Indian Rupees per month (128 USD) for urban families. This is possibly

due to inflation and the improvement of the economy in India. The facility used in this study was a private specialist hospital, so it is expected that the patients using the facility would earn a higher salary. According to Kumar *et al* (2008), families with a higher average family income and education profile are known to spend more on diabetes care. This trend was observed in the current study, as those earning a higher salary had opted to use a private hospital, instead of a government hospital.

All 12 (24%) unemployed patients were women and were housewives. Of the 12, 8% (n=4) had tertiary education and a monthly household income of greater than 35 000 Indian Rupees (538 USD); except for one patient who was a widow living on her own, being supported by her son. Interestingly, this patient was one out of three other senior citizens in this category who were unemployed, but had domestic help. This further reflects the social-economic wellness of the Indian middle class families in this sample. Thirty six percent of patients (n=18) were professionals, all of whom earned more than 45 000 Indian Rupees (692 USD) per month. This amount was more than double that reported by Ramachandran *et al* (2007). This is consistent with the original premise that diabetes was a disease of the wealthy, which may show how India's fast progressing economy has led to an increase in chronic diseases of lifestyle, such as diabetes. This is likely due to the rapid introduction of western fast foods, higher in fat and refined carbohydrates, into the Indian diet (Yadav *et al* 2008a; Popkin 2001) and sedentary lifestyles (Kalra & Unnikrishnan 2012; Mohan *et al* 2009).

5.1.3 Household characteristics

The percentage of people that lived in a nuclear family was 62%, as compared to Kapur *et al* (2008) who found that 59% of diabetics lived in a nuclear family. This finding seems to be representative of the 'modern' middle-class India, as the country was traditionally known to have more joint families than nuclear (a couple and their dependent children, regarded as a basic social unit) families. Fifty four percent of households had domestic help in this sample, again indicating an increase in the socio-economic status of middle-class India. In this sample, 50% (n=25) of the patient's wives did the cooking, 42% (n=21) of patients cooked for themselves or their daughters or mothers cooked for them (4% respectively). Colles *et al* (2013) observed a similar trend, as 57% of patient's wives did the cooking. Interestingly, no

male patient cooked for himself in this sample, which is indicative of Indian culture and gender roles that exist within this community. In the Indian community, women are still expected to do the cooking, even if they have careers.

5.1.4 Anthropometric characteristics

The mean weight of this sample was 72.8 kg (SD±12.62) and the mean height was 1.64 m (SD±0.085). Mohan *et al* (2013), who reported a mean weight of 69.1 kg (SD±10.2), noted similar findings. In the current study, 46% were overweight, as compared to 40.8% (in Chennai), reported by Ramachandran, Mary, Yamuna, Murugesan & Snehalatha (2008). This increase over an eight year period could be due to continuing urbanisation and change of eating habits from traditional to western (fast foods). The mean BMI reported in this study was 26.8 kg/m^2 (SD±3.098), which was similar to the mean BMI of 26.3 kg/m^2 (SD±3.7), observed in the A1chieve study (Mohan *et al* 2013). Body mass index was positively associated with HbA_{1c} in this sample. A similar positive correlation was found in Najran, Saudi Arabia (Babikr, Alshahrani, Hamid, Abdelraheem & Shalayel 2016). This suggests that achieving and maintaining a normal body weight may improve glucose control. However, no other Indian studies have reported this positive correlation.

5.1.5 Diabetes duration and co-morbidities

The most common co-morbidity was HTN (64%, n=32), while 12% (n=6) reported cardiac co-morbidities. This was consistent with Mohan *et al* (2013) who reported that 50% of diabetic individuals had HTN. The mean duration of diabetes in the current study was 7.94 years (SD ± 4.917), while Kapur *et al* (2007) reported, a mean duration of 8.9 years (SD ± 6.5) and Ramachandran *et al* (2007) reported 10.4 years (SD ± 7.1). This difference could possibly be due to the difference in study population and sample size.

5.1.6 Glycosylated haemoglobin values

The mean HbA_{1c} in this study sample was 8.05% (SD ± 1.42). Colles *et al* (2013) observed similar results of 8.2% ± 1.7. The current study did not find any significant relationship between duration of diabetes and HbA_{1c}. However, the A1chieve study (Mohan *et al* 2013) did report that blood glucose control (mean HbA_{1c} = 9.2%) was worse in patients with a longer

duration of diabetes (9.9 ± 5.5 years). In this study, the small sample size could explain the lack of significant findings between blood glucose control and diabetes duration. There was a positive association between HbA_{1c} and income, with a higher HbA_{1c} reported in patients with higher income. This was in contrast to studies conducted in the Netherlands and Sweden, which found that patients with lower HbA1c at diagnosis had a higher income (Elissen, Hertroijs, Schaper, Bosma, Dagnelie, Henry, van der Kallen, Koster, Schram, Stehouwer, Schouten, Berendschot & Ruwaard 2017; Martinell, Pingel, Hallqvist, Dorkhan, Groop, Rosengren, Storm & Stålhammar 2017). This could possibly be because India is an emerging economy while the Netherlands and Sweden have more established economies. People living in India are only now attaining jobs, lifestyles and income that western countries have experienced for decades. This trend may change in a few years in India, as it did in the west.

5.1.7 Diet followed and meal preparation

Twenty percent (n=10) of patients were lacto-vegetarians while 80% followed a mixed diet. Contrastingly, in New Delhi, India, Apollo Specialist Hospital reported that 60.1% of their subjects were vegetarian (Colles *et al* 2013). In the current study, those following a mixed diet had higher HbA_{1c} scores than those who followed a vegetarian diet. However, this observation cannot be applied to the diabetes community in general, as the sample size was too small. Yokoyama, Barnard, Levin & Watanabe (2015) in their meta-analysis found that a vegetarian diet significantly reduced HbA_{1c} by 0.4 percentage points in patients with T2DM. Kahleova & Pelikanova (2015) found that vegetarian diets were healthy, nutritionally adequate, effective for weight and glycaemic control and likely to reduce diabetes complications. It has also been found that the Indian lacto-vegetarian diet had beneficial effects on diabetes incidence, irrespective of high body weight and sedentary lifestyle (Praharaj, Goenka, Dixit, Gupta, Kar & Negi 2017).

5.1.8 Blood glucose monitoring

Fifty-two percent (n=26) of patients had glucometers and tested their blood glucose more frequently than those who did not have a glucometer; however, this was not statistically significant. This was consistent with Krishanan & Thirunavukkarasu (2016), who reported that 59.4% (n=91) of their subjects had glucometers. Patients were more likely to monitor their

blood glucose more frequently if they had a functioning glucometer in their home. There is some evidence on the use of glucometers for SMBG levels. Positive effects include decreased hospital admissions and morbidity (Burge 2001), while negative results included no improvement in glycaemic control, as there was no consistency with glycaemic control (Farmer *et al* 2009). A detrimental effect has also been shown (Fisher *et al* 2011), where SMBG in patients led to increased anxiety and depression.

The most common barriers to blood glucose monitoring was being too busy or changes in daily routine. Pain or fear was not significant as none reported this as a barrier, which was in contrast to the findings of Burge (2001), where 26% of patients indicated that finger pain was a main barrier to regular blood glucose monitoring (Chudyk, Shapiro, Russell-Minda & Petrella 2011; Burge 2001). According to Chudyk *et al* (2011), subjects felt that blood glucose monitoring was time-consuming. This was in line with the current study as 28% (n=14) reported that they were too busy to test their blood glucose levels. The fact that pain was not cited as a barrier in the current study could be because pain associated with finger pricking has decreased, due to the advancement from self-pricking lancets to automated pricking lancets. Further to this, none of the patients in the present study was on insulin, which may require finger pricking at least three times a day.

5.1.9 Physical activity

The most common form of exercise done by patients was walking, with most walking for more than one to three hours a week. This is in line with the American College of Sports Medicine and the ADA (Colberg *et al* 2010), which states that type 2 diabetics should do moderate to vigorous aerobic exercise for at least 150 minutes/week, over a period of at least three days during the week. Thirty-six percent (n=16) of patients from this study indicated that being busy with family work or other tasks, was a barrier to exercise. This was consistent with findings from Fukunaga *et al* (2011), who reported that most of their Hawaiian subjects mentioned that time limitations and balancing family and work responsibilities were barriers to exercise (Fukunaga *et al* 2011).

5.1.10 Eating habits and nutritional medical care

Even though all patients were seen by a dietician and had diet plans, 82% (n=41) did not follow a written diet plan. Only eight patients (16%) indicated that they controlled their blood glucose levels by using sugar free or reduced sugar products. Twenty-eight percent of patients did not eat food they liked often because they were unhealthy foods. This is in line with findings of Kapur *et al* (2008), who reported that 34% (n=115) of diabetic subjects did not follow a diet. Seventy-four percent of patients ate fruits and vegetables daily, even though 90% of the sample were able to purchase fruits and vegetables regularly. None out of the 13 patients that did not eat vegetables daily lived in an area in Chennai where fruits and vegetables were not available daily. The remaining four appeared to have lifestyles that were too busy to eat healthily or were living alone in the city. In the CURES study (2010), 90.9% of subjects had a very low consumption of fruit and vegetables (Radhika *et al* 2010). Colles e*t al* (2013) observed that 62.8% of their subjects ate less than four fruits and vegetables daily. The current study did not indicate the number of portions of fruit and vegetables eaten daily, as compared to Colles *et al* (2013). However, there seems to have been an improvement in fruit and vegetable consumption in the current study, compared to Rajasekharan, Kulkarni, Unnikrishnan, Kumar, Holla & Thapar (2015), which reported that 26.2% (76 out of 290) of participants consumed fruits/vegetables on all days of the week. This could be due to the fact that the facility used was a private-public partnership district hospital or the socio-economic status of their subjects, since it was reported that 55% of subjects were of a lower socio-economic status and only 44% were from middle to upper socio-economic backgrounds (Mangalore, India) (Rajasekharan *et al* 2015).

In the current study, 68% (n=34) did not follow a diet plan to control their blood glucose, whilst 22% (n=11) did follow a diet plan. Kapur *et al* (2008) also found similar results in that only 28% followed their diet for the full duration to control their blood glucose. Kapur *et al* (2008) indicated that younger males with a higher socioeconomic status and the less health conscious, were least likely to follow diets. In the current study, none of the aforementioned demographic or socioeconomic characteristics were applicable.

In the current study, the most cited barriers to eating healthily were lack of skills (46%) and cost or expense of food (48%). Fukunaga *et al* (2011) also reported that the most common

barrier to healthy eating was the cost of healthy foods. It is interesting to note that cost was cited as a barrier in the current study, even though the sample had a middle to high income. The possible reasons for this is that in India and especially in Chennai, organic foods have made a huge impact on the market. Many diabetic patients feel that healthy eating should include organic produce; however, organic foods are expensive. Further to this, cold pressed oils and A2 milk (milk from a specific breed of cow in Tamil Nadu, considered healthy) are readily available, but expensive, especially for larger families.

In the current study, patients sometimes or often complained of a lack of skills to deal with lifestyle changes, because of the lack of practical advice given by HCPs. Although not asked in the questionnaire, a spouse of one of the study participants mentioned that her husband worked night shifts and no one had advised them on how to manage his diet around this. Another patient felt she did not to know how to cook healthier meals, such as using less oil when cooking. Kapur *et al* (2008) found that subjects given advice by healthcare providers regarding healthy options, cooking methods and practical tips to deal with day-to-day lifestyle issues, were more likely to follow a diet plan.

5.1.11 Medication and medical care

In this study, the diabetic patients did not report any significant barriers to taking medication. Family support and regular reminders to take medication by their family could explain this finding. It has been reported that the Indian diabetic has far more family support compared to their western counterparts (Sridhar & Madhu 2002). Ten percent (n=5) of patients used Ayurvedic/Siddha powders (traditional Indian herbal therapies) in combination with their allopathic medication to treat their diabetes and co-morbidities. Kalra *et al* (2013) reported that some patients (14%) still utilised the traditional forms of medicine due to cost, effectiveness and availability. Health care providers should be sensitive and aware of the beliefs of patients and provide practical and comprehensive advice to patients who want to use traditional forms of medicine.

5.1.12 Motivation of patients

In this study, external (extrinsic) motives compelled patients to take their medication, check blood glucose levels and keep appointments with HCPs, whereas internal (intrinsic) cues helped patients to exercise. There was no significant motivation for maintaining or not maintaining healthy eating, although 40% (n=20) and 36% (n=18) indicated extrinsic and intrinsic motivation, respectively. Wint *et al* (2006) found that some were motivated by a desire to follow their doctors' orders (extrinsic motivation).

In this study, the most common barrier to motivation itself, was that patients did not understand their disease condition (18 %), did not know why they needed to change (12%), did not believe their healthcare providers (10%) and had a lack of support from their doctors (6%). Centis *et al* (2014) reported that resistance to change towards a healthy diet was associated with a higher BMI. A similar finding was noted in the current study as patients with intrinsic motivation to follow a diet plan (36%) were either a normal weight or overweight, according to BMI, with none obese. Patients with no motivation were all either overweight or obese. This suggests that diabetic patients who are intrinsically motivated to follow a diet are less likely to be overweight or obese. Internal cues to change may also be more beneficial in maintaining lifestyle changes.

5.1.13 Service needs of patients

This sample was satisfied with the care provide to them by HCPs and felt that they worked as a team to provide them with holistic care. This was in contrast to the findings of Wint *et al* (2006), where patients relied mainly on physicians as their primary source of information. The differences found in this study could be due to this study being more recent and that the facility used, Apollo Speciality Hospital, was accredited by the NABH in India, which emphasises teamwork and the holistic care of patients.

Interestingly a small, however, significant number of patients indicated that they would benefit from a workshop that provided knowledge and skills to help them manage their diabetes. This is promising for health care providers, as healthcare providers could use these workshops to provide more detailed, practical counselling to patients without the worry of time constraints. Some patients were willing to actively participate in online medical/social support from HCPs such as Facebook and WhatsApp. This is also encouraging for HCPs as they could instantly be

in touch with patients to provide support and the latest information on management of their disease. In addition, more patients, even in rural areas could be assisted sooner instead of later, by the instant messaging available with mobile social applications.

5.1.14 Knowledge and understanding of diabetes

Seventy-six percent of patients reported that they or their caregivers had the knowledge to provide healthy meals and 70% understood their disease symptoms, risks and complications. This is indicative of the change in counselling skills and knowledge acquired by healthcare providers over the past decade. This was consistent with Sridhar & Madhu (2002), who reported that more than 85% (n=193) of spouses had good knowledge about the disease. However, in the study by Wint *et al* (2006), 80% of subjects reported inadequate knowledge as a barrier to change, while the CURES study also found similar low rates of knowledge (Mohan *et al* 2005). Dinesh, Kulkarni & Gangadhar (2016), observed that those subjects that visited private medical facilities for their treatment were more knowledgeable than those who visited government facilities.

5.2 Health care provider-orientated questionnaire

5.2.1 Demographic characteristics

The mean age of the healthcare professionals in this study was 34.4 years, while the mean years of experience was 11.5 years. This could be due to the high turnover of doctors, as many young HCPs move on from this hospital after they have gained sufficient training and experience. Many nurses move on after a 2-year period to the Middle East while other healthcare providers venture into private practice or return to their hometown hospitals. This is a trend for most of the hospitals in India with only the highest paid consultants remaining in these hospitals.

5.2.2 Medical care provided by health care providers

Seventy-six percent of HCPs in the current study indicated that patients often followed their medicine regime. However, LeBlanc *et al* (2014) found that poor adherence to the medication regime was one of the main barriers to glycaemic control. Some healthcare providers (84%) reported that patients complained about hypoglycaemia (p=0.001); whereas in the DAWN-2 study, 61.3% of patients worried about the risk of hypoglycaemic events (Holt & Kalra 2013).

Hypoglycaemia is a worrying aspect for the patient and their families due the associated symptoms and complications. This was also noted in the current study and in the DAWN-2 study (Holt & Kalra 2013).

Accumulatively, 92% of HCPs reported that it was their task to motivate patients. Similarly, 98% of physicians and 100% of nurses felt it was their task to motivate patients from a study in Finland (Jallinoja, Absetz, Kuronen, Nissinen, Talja, Uutela & Patja 2007). This study group reported that 48% of healthcare providers would refer to other healthcare providers often. The most likely healthcare providers were dieticians (60%, n=15), followed by diabetic educators (36%). This is in keeping with the recommendation by RSSDI (2015) that all diabetics should have access to a dietician or a health care professional educated in nutrition. As in this study, at NABH accredited facilities, all diabetics are seen by dieticians on every admission and documented.

In the current study, healthcare providers (64%) felt that they had sufficient skills for lifestyle counselling (p=0.001). However, in the DAWN-2 study, 56% and 50.1% of healthcare providers felt that they needed more education on effective communication and motivation and self-management education to support long-term behaviour change, respectively (Holt *et al* 2013).This study compares better to DAWN-2, possibly due to that the present healthcare providers were already educated on the above.

5.2.3 Motivation and barriers to counselling

Health care providers reported that patients found following an eating plan (88%) the most difficult to adhere to, followed by exercise (48%). The DAWN-2 study found similar trends with Indian HCPs feeling that eating healthy (93.2%) and physical exercise (94.6%) needed more self-management from patients (Holt & Kalra 2013). In the current study, glucose monitoring and taking of medication was least difficult to maintain, whilst in the DAWN-2 study, 58.4% and 54.5% of HCPs felt that subjects needed more self-management in taking medications and testing blood sugar levels, respectively (Holt & Kalra 2013). In the current study, 64% (n=16) of HCPs reported that patients had a lack of support from co-workers or

bosses. Fukunaga *et al* (2011) similarly reported that subjects had a lack of understanding and support from co-workers. Discrimination in India was higher compared to the world average (27.2% vs. 17.6%) (Holt & Kalra 2013), which is a concern since discrimination due to diabetes is linked with diabetes-related distress for diabetics (Holt & Kalra 2013).

In the current study, all healthcare providers agreed that patients should be assigned responsibility of self-care ($p<0.05$). The DAWN-2 study reported a similar finding, where HCPs agreed that diabetes self-management was suboptimal and needed improving. However, there may be differences between healthcare professionals and diabetics in their perceptions of how to encourage self-management. The DAWN-2 study noted that HCPs felt that patients needed to improve various self-management activities, including eating healthy, being physically active, dealing with emotions associated with diabetes, testing blood glucose and taking medications as recommended. However, HCPs seemed to want to shift complete care onto patients, instead of being involved with their patients to help them lead a full and active life, to encourage and console them and help them understand the consequences of not meeting treatment goals (Holt & Kalra 2013). Healthcare providers who participated in this study indicated that the important barrier to lifestyle adaptions were unwillingness to change ($p<0.05$) , and less so for insufficient knowledge on complications ($p=0.008$). Fukunaga *et al* (2011), Kapur *et al* (2008), Jallinoja *et al* (2007) and Wint *et al* (2006) reported similar findings. Therefore, approaches such as motivational interviewing, cognitive behaviour therapy and behaviour change counselling (Kalra *et al* 2009b), should be adopted by HCPs and all health institutions, private or public.

Fifty-two percent and 40% of health care providers in the current study indicated that patients ‘sometimes’ and ‘often’ felt depressed and frustrated with their disease condition, respectively. Holt *et al* (2013), Fukunaga *et al* (2011) and Wint *et al* (2006) reported similar findings, where HCPs reported that patients complained about being depressed about their disease condition. Health care professionals recognised the need for resources to provide more person-centred diabetes care with over half requesting availability of psychological support and care (63%) (DAWN-2) (Holt & Kalra 2013). Although the finding was not significant, the HCPs in this

study reported that they would participate in workshops on diabetes management, with 48% indicating that they would often and always participate.

Health care providers in the current study reported that time constraints was an obstacle to counselling their patients adequately ($p=0.026$). This was also reported by Yuncken (2014), where practitioners had insufficient time to adequately assess patients with diabetes. Kapur *et al* (2008), reported that only 30% of physicians found time for one on one discussions with patients and the maximum time spent on one patient, was only ten minutes (Kapur *et al* 2008). In the current study, the more experience a healthcare provider had, the more likely they were to motivate and support lifestyle changes among patients. However, Jallinoja *et al* (2007), found that nurses with less experience felt they had sufficient skills to counsel patients, compared to their older counterparts. The researcher postulated that this could be due to the change of curriculum at nursing colleges (Jallinoja *et al* 2007). The reason for this finding in the current study could be the same (48% felt they were equipped with the knowledge or skills to teach their patients), since it was a more recent study and in-house and college training has improved in India, especially in NABH accredited facilities. The more experience a healthcare provider had, the more likely they were to refer their patients to other team members ($p<0.05$). However, no other studies reported the same. It is likely that the more experienced HCPs had experienced the benefit of teamwork in successfully managing the diabetic patient.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

This chapter presents the conclusions, study limitations and recommendations.

The objectives of this study were:

- To identify the barriers to lifestyle modification as perceived by South Indian diabetic adults.
- To identify the barriers to motivation, knowledge and service needs as perceived by South Indian diabetic adults.
- To identify the challenges as perceived by HCPs in providing education, motivation and services to their diabetic patients.

6.1. Conclusion

For the diabetic patients in this study, being busy with family, work or other tasks was a common barrier to glucose monitoring and exercise, while a diet plan was not commonly used to control blood glucose levels. Many patients did not follow the diets prescribed by their dieticians, possibly due to lack of preparation skills or cost of healthy foods. Barriers to medications and medical treatment were boredom, depression, stress, fear of pain, changes in routines, being busy and cost of medication. Having a glucometer meant that patients were more likely to test their blood glucose levels more frequently. Walking was a popular exercise among the sample, while water and bicycle exercises were not popular. There was evidence of both overweight and poor glycaemic control in the sample, suggesting that more focused interventions are needed to control weight and improve glycaemic control. Overall, patients were satisfied with the services provided by their HCPs, however, patients were keen to make use of online medical/social support from health care providers. It is evident that this sample need to place greater emphasis on dietary management of diabetes and that they could benefit from regular information updates on how to effectively manage their diabetes. Health care providers should consider individualising dietary education and giving guidelines that are more practical to deal with day-to-day lifestyle issues. In order to encourage the diabetic to make lifestyle changes, there needs to be an improvement in knowledge on complications and improved support from co-workers and bosses. Health care providers cited time constraints as a barrier to counselling their patients adequately. In general, the more experienced HCPs were more likely to motivate and support lifestyle changes, more confident in their knowledge or

skills and more likely to refer patients to other health care team members. External cues for motivation was common in this sample, with the only internal motivation cue being for exercise. The most common barriers to motivation were not understanding their disease condition and not knowing why they needed to change. All healthcare providers agreed that patients should be assigned the full responsibility of self-care, which showed their lack in understanding of the concept of self-care management and their roles as HCPs in it; which is to still actively guide, support and encourage their patients.

6.2 Study limitations

6.2.1 The sample size was small and systemically sampled which prevents generalised conclusions from being made.

6.2.2 The study relied on the honesty of the patients. However, it is possible that some patients were not completely honest in their reporting.

6.2.3 Since the study population were inpatients and seen during the course of their admission, there could have been changes to their medical treatment or counselling by the time of discharge. Hereby, they could possibly have had fewer or more barriers to lifestyle changes by discharge.

6.2.4 As this study was conducted in a private hospital, the findings are limited to diabetic patients treated privately and type 2 diabetics on medication.

6.3 Recommendations

6.3.1 As a developing country, India has a shortage of medical doctors and allied medical staff to treat its huge population; hereby quality counselling of diabetic patients is limited. To overcome this, lifestyle counsellors should be trained to offer the necessary counselling to diabetic patients and their family members. This would also benefit a resource-constrained country such as India, where there is a shortage of diabetic healthcare providers.

6.3.2 The nutritional curriculum at medical colleges should be restructured to include more traditionally/culturally acceptable dietary advice. Further to this, South India is unique in its climate, people and landscapes as compared to other western cities. Moreover, given the individualised needs of diabetics, the use of a “one-size fits all” concept in dietary management is limiting and needs to be reconsidered.

6.3.3 Social support from family and co-workers has an unrealised potential as both an effective and cost-effective method for self-management of T2DM. Educating family and co-workers on diabetes and how to support their diabetic family member or co-worker, may also improve the overall management of diabetes.

6.3.4 Future studies should include patients treated in public hospitals, to determine if the barriers to lifestyle modification, motivation, knowledge and service needs differ for diabetic patients treated in a public hospital.

6.3.5 Health care providers should consider the use of on-line support systems to provide medical and social support to diabetics, given the widespread availability and use of mobile phones.

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APPENDIX A: PATIENT-ORIENTATED DIABETES QUESTIONNAIRE IN ENGLISH

OFFICIAL USE:

DIABETES QUESTIONNAIRE (Patient Orientated)

(To be filled in by a professional health care provider, interviewing a patient)

Section A: DEMOGRAPHIC

1. GENDER: Male / Female
2. AGE (years): _____ 3. Height (cm): _____
4. WEIGHT (kg): _____ 5. BMI (kg/m^2): _____
6. INCOME (per month):

<Rs15,000	Rs 15,000 – 25,000	Rs 25,000 – 35,0000	Rs35,000 -45,000	>Rs 45,000

7. NO. OF PERSONS IN HOUSEHOLD: _____
10. NO. OF CHILDREN IN HOUSEHOLD: _____
11. NO.OF SENIOR CITIZENS IN HOUSEHOLD: _____ 12. DOMESTIC HELP: Yes/No
13. HIGHEST EDUCATION: _____
14. OCCUPATION: _____
15. CO-MORBIDITIES:_____
16. Last HbA1c: _____
17. Vegetarian or Mixed : _____
18. Who does the cooking at home: _____

Section B: LIFESTYLE MODIFICATION

A) Blood Glucose Monitoring

1. Do you have a working machine to monitor your blood sugar? **Yes/No**
2. How often in a week do you test your blood glucose level? _____
3. If you do not have a machine, how do you test your blood glucose levels? _____

Possible Barriers

4. During the past 3 months, how often has each of the following caused a problem in testing blood glucose?

	Never	Rarely	Sometimes	Often	Always	Key
a. Feeling depressed, angry, stressed or bored						E
b. I am afraid to prick myself.						P
c. Family and friends are not supportive.						S
d. When away from home (vacation, business trips, at relatives)						H
e. My daily routine (walking, to bed, eat, work etc) changes.						C
f. Frustrated with lack of results (eg. No weight loss, high BSL)						F
g. Family, work, or other tasks keep me to busy.						B

B) Physical Activity

KEY: Emotional (E), Fear/Pain (P), Support (S), Holidays (H), Schedule Changes(C), Frustration (F), Busy with work or family (B), Other treatment (O).
KEY FOR EATING HABITS: Emotional (E), Food cravings (C), Family support (F), Eating away from home (R), Lack or results (L), Busy(B), Taste (T), Lack of skills (S), Cost/Expense (X)
KEY FOR MOTION: Intrinsic motivation (IM) (a-d), Extrinsic motivation (EM) (e-f & h-i), No motivation (g, j,k)

1. During the past week, even if it was not a usual week for you, how much time in total did you spend on each of the following?

	None	<30min	30-60 min	1-3hrs	>3hrs
a. Stretching or strengthening exercises (ie. Yoga)					
b. Walking for exercise					
c. Swimming or water exercise					
d. Bicycling (including stationary, exercise bikes)					
e. Aerobic exercise (ie. Rowing, Obitrek)					
f. Other aerobic exercise (eg. Zumba)					

Possible Barriers

During the past 3 months, how often did each of the following affect you?

	Never	Rarely	Sometimes	Often	Always	KEY
a. Feeling depressed, angry, stressed or bored.						E
b. Exercise and physical activity cause pain and discomfort for me.						P
c. Family and friends are not supportive.						S
d. When away from home (vacation, business trips, at relatives)						H
e. My daily routine (walk, sleep, eat, work, etc) changes.						C
f. Frustrated with lack of results (eg. weight loss, high BSL)						F
g. Family, work, or other tasks keep me to busy.						B

C) Eating habits and nutritional medical care

	Never	Rarely	Sometimes	Often	Always
1. During the past 3 months, how often did you:					
a. Watch calories in foods, to decide what you eat?					
b. Leave a meal or snack out, to reduce calories or fat?					
c. Eat small portion sizes, to reduce the calories or fat?					
d. Use low calorie, lite, reduced fat or fat-free products?					
e. Use sugar free or reduced sugar products?					
f. Not eat foods you like because they were too high in fat, sugar, or calories?					
g. Use a written diet or meal plan to know what to eat?					

2. Are you able to buy fresh fruit and vegetables? **Yes/No/Not Sure**
3. Do you eat fresh fruit and vegetables daily? **Yes/No/Not Sure**
4. Has healthy eating been explained to you? **Yes/No/Not Sure**

5. Answer the following questions on how you control your blood glucose using food.
   A. Are you trying to follow a diet plan to better control your blood glucose?

KEY: Emotional (E), Fear/Pain (P), Support (S), Holidays (H), Schedule Changes(C), Frustration (F), Busy with work or family (B), Other treatment (O).
KEY FOR EATING HABITS: Emotional (E), Food cravings (C), Family support (F), Eating away from home (R), Lack or results (L), Busy(B), Taste (T), Lack of skills (S), Cost/Expense (X)
KEY FOR MOTION: Intrinsic motivation (IM) (a-d), Extrinsic motivation (EM) (e-f & h-i), No motivation (g, j,k)

i. Yes, I have a plan that I follow
ii. No, I am not following a plan but I know how food affects my blood sugar.
iii. No, do not know how food affects my blood sugar.

B. If you are following a meal plan, what kind of plan are you using?

i. I do not use a diet plan
ii. Carbohydrate counting
iii. Food exchange system
iv. Healthy foods
v. Food guide pyramid
vi. Fat gram counting
vii. Ayurvedic/Siddha system
viii. Low GI system
ix. Other. Specify: _____

Possible Barriers

6. Answer the below statements thinking about how they affect your eating habits.

	Never	Rarely	Sometimes	Often	Always	Key
a. Eating unhealthy when feeling bored, angry, depressed or stressed.						E
b. Eating excessively because of food cravings, hunger or snacking.						C
c. Eating unhealthy due to temptations from family or friends that are not supportive.						F
d. Eating unhealthy when eating away from home (e.g., fast food, restaurants, and relatives).						R
e. Eating unhealthy due to lack of results (e.g.no weight loss, high blood sugars).						L
f. Eating unhealthy because you are too busy with family, work, or other responsibilities.						B
g. Eating the same as rest of family, due to taste or convenience.						T
h. Healthy foods are difficult to prepare?						S
i. Healthy foods are too expensive?						X

D) Medication and Medical Care

1. Has your doctor prescribed medication for your diabetes?

a. Yes b. No

Possible barriers

2. During the past 3 months, has the following caused a problem in taking your medication?

KEY: Emotional (E), Fear/Pain (P), Support (S), Holidays (H), Schedule Changes(C), Frustration (F), Busy with work or family (B), Other treatment (O).
KEY FOR EATING HABITS: Emotional (E), Food cravings (C), Family support (F), Eating away from home (R), Lack or results (L), Busy(B), Taste (T), Lack of skills (S), Cost/Expense (X)
KEY FOR MOTION: Intrinsic motivation (IM) (a-d), Extrinsic motivation (EM) (e-f & h-i), No motivation (g, j,k)

	Never	Rarely	Sometimes	Often	Always	KEY
a. Feeling stressed, depressed, angry, or bored.						E
b. The medicine has bad side effects.						P
c. Family or friends are not supportive.						S
d. When away from home (e.g. vacation, business trips,).						R
e. My daily agenda (waking, bedtime, eat, work, etc.) changes.						C
f. Due to lack of results (e.g, high blood sugars).						L
g. Being too busy with family, work, or other tasks.						B
h. The medication is too expensive.						X
i. Do you take alternate medicine/treatment like Siddha medicine or Ayurvedic, Acupuncture etc?						O

j. If so, please state which: _____

Section C: MOTIVATION

In the questions below mark the statements that best describe your feelings.

1. I follow my medication regimen regularly because:

a. I want to keep healthy	e. I am following the doctor's orders	h. I have support from my family and friends
b. Understand the risks of DM	f. I feel compelled to	i. I have experienced the complications of diabetes
c. I do not want to die	g. I don't think this is important	j. I do not follow the regimen
d. I want to live		

If j. selected, state reason: _____

2. I check my blood sugar levels because:

a. I want to keep healthy	e. I am following the doctor's orders	h. I have support from my family and friends
b. Understand the risks of DM	f. I feel compelled to	i. I have experienced the complications of diabetes
c. I do not want to die	g. I don't think this is important	j. I do not follow the regimen
d. I want to live		

If j. selected, state reason: _____

3. I follow my eating plan because:

a. I want to keep healthy	e. I am following the doctor's/dietician's orders	h. I have support from my family and friends
b. Understand the risks of DM	f. I feel compelled to	i. I have experienced the complications of diabetes
c. I do not want to die	g. I don't think this is important.	j. I do not follow the regimen
d. I want to live		

If j. selected, state reason: _____

4. I exercise regularly (4 – 5 times/ week for 20-30min) because:

KEY: Emotional (E), Fear/Pain (P), Support (S), Holidays (H), Schedule Changes(C), Frustration (F), Busy with work or family (B), Other treatment (O).
KEY FOR EATING HABITS: Emotional (E), Food cravings (C), Family support (F), Eating away from home (R), Lack or results (L), Busy(B), Taste (T), Lack of skills (S), Cost/Expense (X)
KEY FOR MOTION: Intrinsic motivation (IM) (a-d), Extrinsic motivation (EM) (e-f & h-i), No motivation (g, j,k)

a. I want to keep healthy	e. I am following the doctor's orders	i. I have support from my family and friends
b. Understand the risks of DM	f. I feel compelled to	j. I have experienced the complications of diabetes
c. I do not want to die	g. I don't think this is important.	k. I do not follow the regimen
d. I want to live	h. I exercise less than this	

If k. selected, state reason: _____

5. I keep my health care provider (doctor, dietician, diabetic educator, etc) appointments because:

a. I want to keep healthy	e. I am following the doctor's orders	h. I have support from my family and friends
b. Understand the risks of DM	f. I feel compelled to	i. I have experienced the complications of diabetes
c. I do not want to die	g. I don't think this is important.	j. I do not follow the regimen
d. I want to live		

If j. selected, state reason:_____

Possible barriers

1. I do not understand my disease condition. Y/N (knowledge)
2. I do not have the support from my doctor. Y/N (medical support)
3. I do not have support from my family. Y/N (family support)
4. I do not understand why I should change. Y/N (knowledge)
5. I do not believe my healthcare providers. Y/N (mistrust)

Section D: Service Needs

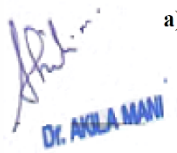
Please answer the following questions.

1. My healthcare providers do take time to explain my treatment and condition to me. **a) No, b) Yes, c) Not sure**
2. My healthcare providers do work as a team to give me holistic care. **a) No, b) Yes, c) Not sure**
3. I would benefit from a workshop that provides me with knowledge and skills to help me manage my diabetes: **a) No, b) Yes, c) Not sure**
4. I would actively participate in online (facebook, etc)/mobile (whatsapp) medical/social support from health care providers. **a) No, b) Yes, c) Not sure**

Section E: Knowledge

Please answer the following questions.

1. My caregiver or I have the knowledge to provide healthy meals for my diabetes. **a) No, b) Yes, c) Not sure**
2. Do you feel experts change their treatment and advice too frequently? **a) No, b) Yes, c) Not sure**
3. I understand my disease symptoms, risks and complications. **a) No, b) Yes, c) Not sure**



KEY: Emotional (E), Fear/Pain (P), Support (S), Holidays (H), Schedule Changes(C), Frustration (F), Busy with work or family (B), Other treatment (O).
KEY FOR EATING HABITS: Emotional (E), Food cravings (C), Family support (F), Eating away from home (R), Lack or results (L), Busy(B), Taste (T), Lack of skills (S), Cost/Expense (X)
KEY FOR MOTION: Intrinsic motivation (IM) (a-d), Extrinsic motivation (EM) (e-f & h-i), No motivation (g, j,k)

APPENDIX B: PATIENT-ORIENTATED DIABETES QUESTIONNAIRE IN TAMIL

OFFICIAL USE:

Nīriḻivu viṇāppaṭṭiyal (nōyāḷikaḷ cārntatu)

(Oru nōyāḷiyaip pēṭṭiyeṭuttu, oru toḻilmuṟai ārōkkiyap parāmarippu aḷippavarāl nirappappaṭavēṇṭum)

Pirivu A: Iṉappuḷḷiyiyal

1. Pāliṉam: Āṇ / peṇ
2. Vayatu (āṇṭukaḷ): _____ 3. Uyaram(cemī): _____
4. Eṭai (kilō): _____ 5. BMI (kg/m^2): _____
6. Varumāṉam (pirati mātam)):

<Rū.15,000	Rū. 15,000 – 25,000	Rū 25,000 – 35,0000	Rū 35,000 -45,000	>Rū 45,000

7. Kuṭumpa naparkaḷiṉ eṇṇikkai: _____
10. Kuṭumpattiṉ kuḻantaikaḷ eṇṇikkai: _____
11. Kuṭumpattiṉ mūtta kuṭimakkaḷ eṇṇikkai:_____
12. Uḷḷūr utavi: Ām/illai
13. Uyar kalvi:_____
14. Toḻil:_____
15. Iṇai nōykaḷ_____
16. Kaṭanta HbA1c:

_____

17. Caivamā allatu kalavaiyā: _____
18. Vīṭṭil yār camaikkiṟārkaḷ: _____

Pirivu B: Iratta kuḻukkōs kaṭṭuppāṭu/ paricōtaṉai

1. Uṅkaḷ irattac carkkaraiyai kaṇkāṇippataṟkāṉa oru vēlai ceyyum meṣiṉ uṅkaḷiṭam irukkiṟatā? Ām/illai
2. Nīṅkaḷ carkkarai aḷavukaḷai paricōtikkum nāṭkaḷil, carācariyāka ettaṉai muṟai nīṅkaḷ cōtippīrkaḷ? _____

3. Kaṭanta 3 mātaṅkaḷil, piṉvaruvaṉa ovvoṉṟum iratta kuḷukkōsai paricōtippatil piraccaṉai ēṟpaṭuttiṉa?

	Oru pōtumillai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
a. Tāḻ maṉanilaiyil, kōpamāka, maṉa'aḻuttamāka, allatu veṟuppāka uṇarvatu.					
b. Eṉṉai nāṉē kuttikkoḷḷa añcukiṟēṉ.					
c. Kuṭumpattiṉarum naṇparkaḷum ātaravāka illai.					
d.Vīṭṭiliruntu veḷiyē iruppatu (viṭumuṟai, viyāpāra payaṇaṅkaḷ, uṟaviṉarkaḷiṭattil)					
e.Eṉatu tiṉacari vaḻakkamāṉa paṇi (naṭappatu, paṭukkaikku celvatu, vēlai mutaliyaṉa) māṟṟaṅkaḷ.					
f. Muṭivukaḷ illāmaiyāl veṟuppaṭaikiṟēṉ (ekā. Eṭai iḻappillai, atika BSL)					
g. Kuṭumpam, vēlai maṟṟum piṟa vēlaikaḷ eṉṉai eppōtum mum'muramāka vaittirukkiṉṟaṉa.					

Pirivu C: Uṭal naṭavaṭikkai

1. Kaṭanta vārattil, atu uṅkaḷukku oru vaḻakkamāṉa vāramāka illaiyeṉṟālum, piṉvaruvaṉavaṟṟil evvaḷavu nērattai mottattil celavaḻittārkaḷ?

	Ētumillai	<30 Nimiṭam	30-60 Nimiṭam	1-3Maṇinēram	>3Maṇinēram
a. Nīṭṭal maṟṟum valuvākkum payiṟci (atāvatu, yōkā)					
b. Payiṟcikkāka naṭappatu					
c. Nīccal allatu nīr payiṟci					
d. Caikkiḷ ōṭṭutal (nilaiyāka, payiṟci paikkukaḷ					
e. Ērōpik payiṟci (atāvatu, paṭakōṭṭutal, ōpiṭrēk)					
f. Pira eropik payirci (e Ka, Jumpa)					

1. Kaṭanta 3 mātaṅkaḷ, piṉvaruvaṉa ovvoṉṟum evvaḷavu aṭikkaṭi uṅkaḷai pātikkiṟatu?

	Oru pōtu millai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
a. Maṉavētaṉaiyāka, kōpamāka, maṉa'aḻuttamāka allatu veṟuppāka uṇartal.					
b. Uṭaṟpayiṟci maṟṟum uṭal cārnta naṭavaṭikkaikaḷ valiyaiyum aceḷakariyattaiyum eṉakku uṇṭākkukiṉṟaṉa.					
c. Kuṭumpam maṟṟum naṇaparkaḷ ātaravāka illai.					
d. Vīṭṭiṟku veḷiyē irukkum pōtu (e.Kā., Viṭumuṟai, viyāpāra payaṇaṅkaḷ).					
e. Eṉatu tiṉacari nikaḻcci niral (naṭappatu, paṭukkainēram, cāppiṭuvatu, vēlai, mutaliyaṉa) māṟukiṟatu.					
f. Muṭivukaḷ illāmaik kāraṇamāka maṉavētaṉai yaṭaikiṟīrkaḷ (e.Kā., Eṭai iḻappillai, atika BSL)					
g. Kuṭumpam, vēlai allatu piṟa vēlaikaḷ eṉṉai mikavum mum'muramāka vaittirukkiṟatu.					

Pirivu D: Cāppiṭum tiṭṭam maṟṟum maruttu ūṭṭacattup parāmarippu

1. Kaṭanta 3 mātaṅkaḷil evvaḷavu aṭikkaṭi nīṅkaḷ:	Oru pōtumillai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
a. Nīṅkaḷ eṉṉa cāppiṭukiṟīrkaḷ eṉpatai muṭivu ceyvataṟkāka kalōrikaḷai kavaṉittu irukkiṟīrkaḷ?					
b. Kalōcarikaḷ allatu koḻuppiṉaik kuṟaippataṟkāka cāppāṭu allatu ciṟṟuṇṭiyai viṭṭirukkiṟīrkaḷ?					
c. Kalōrikaḷ allatu koḻuppiṉai kuṟaippataṟkāka ciṟu ciṟu aḷavukaḷil cāppiṭukiṟīrkaḷ?					
d. Kuṟainta kalōri, lēcāṉa, kuṟaikkappaṭṭa allatu koḻupparṟa tayārippukaḷai payaṉpaṭuttukiṟīrkaḷ?					
e. Cukar ḥprī allatu kuṟaikkappaṭṭa carkkarait tayārippukaḷaip payaṉpaṭuttukiṟīrkaḷ?					
f. Koḻuppu, carkkarai allatu kalōrikaḷ atikamāka iruppataṉ kāraṇamāka nīṅkaḷ virumpum uṇavai cāppiṭuvatillai?					
g. Eṉṉa cāppiṭuvatu eṉpatai aṟintu koḷvataṟkāka oru eḻuttuppūrvamāṉa uṇavukkaṭṭuppāṭu allatu cāppāṭut tiṭṭattai payaṉpaṭuttukiṟīrkaḷ?					
2. Uṇavaip payaṉpaṭutti evvāṟu uṅkaḷ iratta carkkaraiyai evvāṟu kaṭṭupaṭuttuvatu eṉpataṉ mītāṉa piṉvarum kēḷvikaḷukku patilaḷikkavum.					

A. Uṅkaḷ iratta kuḻukkōsai cirappāka kaṭṭuppaṭuttuvataṟkāka oru uṇavukkaṭṭuppāṭṭaip piṇparra nīṅkaḷ muyaṟcikkiṟīṟkaḷā?
   i. Ām, nāṉ piṇparrum oru tiṭṭam eṉakku irukkiṟatu.
   ii. Illai, nāṉ oru tiṭṭattaip piṇparravillai āṉāl eṉatu iratta carkkaraiyai uṇavu evvāṟu pātikkum eṉpatai nāṉ aṟintirukkiṟēṉ.
   iii. Illai, eṉatu iratta carkkaraiyai uṇavu evvāṟu pātikkum eṉpatai nāṉ aṟintirukkavillai.

B. Oru cāppāṭṭut tiṭṭattai nīṅkaḷ piṇparriṇāl, nīṅkaḷ eṉṉa vakaiyāṉat tiṭṭattaip payaṉpaṭuttukiṟīṟkaḷ?
   i. Nāṉ oru uṇavukkaṭṭuppāṭṭut tiṭṭattai payaṉpaṭuttavillai
   ii. Kārpōhaiṭrēṭ kaṇakkiṭutal
   iii. Uṇavu parimārra amaippu
   iv. Ārōkkiyamāṉa uṇavukaḷ
   v. Uṇavu vaḻikāṭṭu piramīṭu
   vi. Koḻuppu kirām kaṇakkiṭutal
   vii. Āyurvēta/ citta amaippu
   viii. Kuṟainta GI amaippu
   ix. Marravai, kuṟippiṭavum:

   _____

3. Kīḻuḷḷa kūṟṟukaḷ uṅkaḷ cāppiṭum paḻakkaṅkaḷai evvāṟu pātikkiṉṟaṉa eṉpatu paṟṟi cintittu avarriṟku patilaḷikkavum.

	Oru pōtumillai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
a. Veṟuppāka, kōpamāka, maṇavētaṇaiyāka allatu maṇa'aḻuttamāka uṇarumpōtu ārōkkiyamillāmal cāppiṭukiṟīṟkaḷ					
b. Uṇavukkāṇa aṭaṅkāta ācai, paci allatu cirruṇṭi uṇpatiṉ kāraṇamāka atikamāka cāppiṭukiṟīṟkaḷ					
c. Ātaravāka illāta kuṭumpattiṉar allatu naṇaparkaḷiṭamiruntāṇa tūṇṭutaliṉāl ārōkkiyamillāmal cāppiṭukiṟīṟkaḷ.					
d. Vīṭṭiṟku veḷiyē irukkumpōtu (e.Kā., Viraivu uṇavu, uṇavakaṅkaḷ marrum uṟaviṇarkaḷ) ārōkkiyamillāmal cāppiṭukiṟīṟkaḷ.					
e. Muṭivukaḷ illātataṉ kāraṇamāka ārōkkiyamillāmal cāppiṭukiṟīṟkaḷ. (E.Kā., Eṭai iḻappu illai, uyar irattac carkkaraikaḷ).					

	Oru pōtumillai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
f. Kuṭumpam, vēlai allatu piṟa poṟuppukaḷ kāraṇamāka ārōkkiyamillāmal cāppiṭukiṟīrkaḷ.					
g. Cuvai allatu ceḷakariyam kāraṇamāka, kuṭumpattiluḷḷa marṟavarkaḷ pōl cāppiṭukiṟīrkaḷ.					
h. Uṅkaḷ cāppiṭum tiṭṭam parṟi evvaḷavu aṭikkaṭi vicārikkiṟīrkaḷ?					
i. Uṅkaḷ uṇavuttiṭm parṟi teḷivāṇa eḷuttuppūrva takavalkaḷai evvaḷavu aṭikkaṭi peṟukiṟīrkaḷ?					
j. Uṅkaḷāl putiya paḻaṅkaḷ marṟum kāykaṟikaḷai tiṇacari vāṅka iyalukiṟatā?					

Pirivu E: Maruntu marṟum maruttuvap parāmarippu

1. Uṅkaḷ maruttuvar uṅkaḷ nīriḻiviṟku maruntu parinturaittirukkiṟārā?
   a. Ām b. Illai
2. Kaṭanta **3** mātaṅkaḷil, uṅkaḷ maruntai eṭuttukkoḷvatil piṇvaruvaṇap piraccaṇai ērpaṭuttiyuḷḷaṇavā?

	Oru pōtumillai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
a. Maṇa'aḷuttamāka, maṇavētaṇaiyāka, kōpamāka allatu veṟuppāka uṇarkiṟīrkaḷ.					
b. Maruntukku pakkaviḷaivukaḷ uḷḷaṇa.					
c. Kuṭumpattiṇar allatu naṇparkaḷ ātaravāka illai.					
d. Vīṭṭiṟku veḷiyē irukkum pōtu (e.Kā,Viṭumuṟai, viyāpāra, payaṇaṅkaḷ).					
e. Eṇatu tiṇacari nikaḻcci niral (naṭappatu, paṭukkainēram, cāppiṭuvatu, vēlai, mutaliyaṇa) māṟukiṟatu.					
f. Muṭivukaḷ illāmaik kāraṇamāka (e.Kā., Uyar irattac carkkarai).					
g. Kuṭumpam, vēlai allatu piṟa vēlaikaḷil mikavum mum'maramāka iruppatu.					
h. Maruntu vilai atikamāṇatu.					
i. Uṅkaḷ marunatukaḷ etaṟkāṇavai enṟu evvaḷavu aṭikkaṭi nīṅkaḷ aṟivīrkaḷ?					
j. Uṅkaḷ maruntukaḷ parṟi evvaḷavu aṭikka uṅkaḷ maruttuvaraik kēṭpīrkaḷ					
k. Uṅkaḷ cikiccaip parṟi nīṅkaḷ kēḷvikaḷ kēṭpīrkaḷā?					
l. Nīṅkaḷ citta allatu āyurvēta maruntu, akkupañcar mutalāṇa māṟṟu maruntukaḷ/cikiccai eṭuttukkoḷkiṟīrkaḷā?					

m. Appaṭiyāṉāl, tayavu ceytu etu eṉṟu terivikkavum:ஆம்/இல்லை_____

Pirivu F: Uṇarvu cārnta maṟṟum camūka nalaṉ

	Oru pōtu millai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum
1. Uṅkaḷ ārōkkiyap piraccaṉaikaḷāl maṉavētaṉaiyil irukkiṟīrkaḷā?					
2. Uṅkaḷ etirkālam kuṟittu accappaṭukiṟīrkaḷā?					
3. Uṅkaḷ ārōkkiyap piraccaṉaikaḷ kuṟittu viraktiyaṭaintirukkiṟīrkaḷā?					
4. Uṅkaḷ uṭalnalam uṅkaḷ poḻutupōkkukaḷ allatu kēḷikkai naṭavaṭikkaikaḷai pātittuḷḷatā?					
5. Uṅkaḷ uṭalnalam uṅkaḷ vīṭṭuppaṇikaḷai taṭai ceykiṟatā?					

6. Uṅkaḷ uṭalnalam uṅkaḷiṉ taṟkālika vēlaikaḷ maṟṟum ṣāppiṅkiṟku iṭaiyūṟu ceykiṟatā?
7. Uṅkaḷ nīriḻiviṟkāṉa perumpālāṉa ātaravai eṅkē aṟikiṟīrkaḷ?

a. Kuṭumpam b. Caka paṇiyāḷarkaḷ c. Ārōkkiya parāmarippu vaḻaṅkuṉarkaḷ d. Ātaravuk kuḻu	e. Camūka valaiyamaippu (mopail allatu PC) f. Ētumillai **g.** Maṟṟavai

Pirivu G: Ūkkuvippu

Kīḻuḷḷa kēḷvikaḷil uṅkaḷiṉ uṇarvukaḷai ciṟappāka vivarikkum vākkiyaṅkaḷai kuṟikkavum.

1. Nāṉ eṉatu maruttuva cikiccaiyai vaḻakkamāka piṇparṟukiṟēṉ ēṉeṉṟāl:

a. Nāṉ ārōkkiyamāka irukka virumpukiṟēṉ b. DMṉ iṭarkaḷai purintukoḷkiṟēṉ c. Nāṉ iṟakka virumpavillai d. Nāṉ vāḻa virumpukiṟēṉ	e. Eṉatu maruttuvariṉ uttaravukaḷai nāṉ piṇparṟukiṟēṉ f. Nāṉ varpuṟuttappaṭuvatāka uṇarkiṟēṉ g. Itu mukkiyam eṉṟu nāṉ niṉaikkavillai	h. Eṉatu kuṭumpattiṉar maṟṟum naṇparkaḷiṉ ātaravu eṉakkirukkiṟatu i. Nīriḻiviṉ cikkalkaḷai nāṉ aṉupavittirukki ṟēṉ j. Nāṉ cikiccaiyai piṇparṟavillai

2. Nāṉ eṉatu iratta carkkarai aḷavukaḷai cōtittēṉ ēṉeṉṟāl:

a. Nāṉ ārōkkiyamāka irukka virumpukiṟēṉ b. DMṉ iṭarkaḷai purintukoḷkiṟēṉ c. Nāṉ iṟakka virumpavillai d. Nāṉ vāḻa virumpukiṟēṉ	e. Eṉatu maruttuvariṉ uttaravukaḷai nāṉ piṉparṟukiṟēṉ f. Nāṉ varpuṟuttappaṭuvatāka uṇarkiṟēṉ g. Itu mukkiyam eṉṟu nāṉ niṉaikkavillai	h. Eṉatu kuṭumpattiṉar marṟum naṇparkaḷiṉ ātaravu eṉakkirukkiṟatu i. Nīriḻiviṉ cikkalkaḷai nāṉ aṉupavittirukki ṟēṉ j. Nāṉ cikiccaiyai piṉparṟavillai

3. Nāṉ eṉatu cāppiṭum tiṭṭattaip piṉparṟukiṟēṉ ēṉeṉṟāl:

a. Nāṉ ārōkkiyamāka irukka virumpukiṟēṉ b. DMṉ iṭarkaḷai purintukoḷkiṟēṉ c. Nāṉ iṟakka virumpavillai d. Nāṉ vāḻa virumpukiṟēṉ	e. Eṉatu maruttuvariṉ uttaravukaḷai nāṉ piṉparṟukiṟēṉ f. Nāṉ varpuṟuttappaṭuvatāka uṇarkiṟēṉ g. Itu mukkiyam eṉṟu nāṉ niṉaikkavillai	g. Eṉatu kuṭumpattiṉar marṟum naṇparkaḷiṉ ātaravu eṉakkirukkiṟatu h. Nīriḻiviṉ cikkalkaḷai nāṉ aṉupavittirukki ṟēṉ i. Nāṉ cikiccaiyai piṉparṟavillai

4. Nāṉ vaḻakkamāka uṭaṟpayiṟci ceykiṟēṉ (4 – 5 muṟaikaḷ/ vārattiṟku 20 – 30 nimiṭaṅkaḷ) ēṉeṉṟāl:

a. Nāṉ ārōkkiyamāka irukka virumpukiṟēṉ b. DMṉ iṭarkaḷai purintukoḷkiṟēṉ c. Nāṉ iṟakka virumpavillai d. Nāṉ vāḻa virumpukiṟēṉ	e. Eṉatu maruttuvariṉ uttaravukaḷai nāṉ piṉparṟukiṟēṉ f. Nāṉ varpuṟuttappaṭuvatāka uṇarkiṟēṉ g. Itu mukkiyam eṉṟu nāṉ niṉaikkavillai	h. Eṉatu kuṭumpattiṉar marṟum naṇparkaḷiṉ ātaravu eṉakkirukkiṟatu i. Nīriḻiviṉ cikkalkaḷai nāṉ aṉupavittirukki ṟēṉ j. Nāṉ cikiccaiyai piṉparṟavillai

5. Eṉatu ārōkkiya parāmarippu vaḻaṅkuṉar (maruttuvar, nīriḻiviyalāḷar, nīriḻivuk kalviyāḷar, mutalāṉōr) uṭaṉ cantipputtiṭṭaṅkaḷukku celkiṟēṉ, ēṉeṉṟāl:

a. Nāṉ ārōkkiyamāka irukka virumpukiṟēṉ b. DMṉ iṭarkaḷai purintukoḷkiṟēṉ c. Nāṉ iṟakka virumpavillai d. Nāṉ vāḻa virumpukiṟēṉ	e. Eṉatu maruttuvariṉ uttaravukaḷai nāṉ piṉparṟukiṟēṉ f. Nāṉ varpuṟuttappaṭuvatāka uṇarkiṟēṉ g. Itu mukkiyam eṉṟu nāṉ niṉaikkavillai	h. Eṉatu kuṭumpattiṉar marṟum naṇparkaḷiṉ ātaravu eṉakkirukkiṟatu i. Nīriḻiviṉ cikkalkaḷai nāṉ aṉupavittirukki ṟēṉ j. Nāṉ cikiccaiyai piṉparṟavillai

Pirivu H: Kalvi/ kavuṉcaliṅ tēvaikaḷ

Tayavu ceytu piṉvarum kēḷvikaḷukku patilaḷikkavum

Murṟilum maṟukkiṟēṉ	Pakuti maṟuk kiṟēṉ	Maṟukkavum illai ēṟkavumillai	Pakuti ēṟkiṟēṉ	Murṟilum ēṟkiṟēṉ.

1. Eṉatu ārōkkiyap parāmarippaḷippavar eṉakku viḷakkuvataṟku nēram eṭuttuk koḷkiṟār. .
2. Eṉatu ārōkkiyap parāmarippaḷippavar eṉatu nalaṉ kuṟittu akkaṟai eṭuttuk koḷkiṟār.
3. Eṉatu ārōkkiyap parāmarippu aḷippavarkaḷ eṉakku muḻumaiyāṉa parāmarippu aḷippataṟkāka kuḻuvākap paṇiyāṟṟukiṉṟaṉar
4. Nīriḻiviṟkāṉa cikkalkaḷ:
   a) nuraiyīral ceyaliḻappu;
   b) itayam marṟum ciṟunīraka nōy;
   c) ētumillai;
   D) teriyātu
5. Iratta kuḻukkōs kaṇkāṇippiṉ mukkiyattuvattai nāṉ purintukoḷkiṟēṉ **a) illai b) ām c) uṟutiyāt teriyātu**
6. Ārōkkiyamāka cāppiṭuvatu eṉpataṉ poruḷ:
   a) vaṟutta uṇavukaḷaika cāppiṭavatu, atikappaṭiyāka civappiṟaicci marṟum carkkarai cāppiṭuvatu.
   b) kuṟainta koḻuppu, niṟaiya kāykaṟikaḷ, tiṉacari 1 – 2 aṉumatikappaṭṭap paḻaṅkaḷ, kuṟainta kārpōhaiṭrēṭkaḷ;
   c) mēluḷḷa ētumillai,
   d) teriyātu
7. Eṉatu nīriḻiviṟkāṉa ūṭṭacattumikka cāppāṭṭiṉai tayār ceyvataṟkāṉa tiṟaṉ eṉakkirukkiṟatu. **a) illai b) ām c) uṟutiyākat teriyātu**
8. Eṉatu nīriḻiviṉai nirvakippataṟku utavuvataṟkāka aṟivu marṟam tiṟaṉkaḷai eṉakku vaḻaṅkum oru payiṟci vakuppu eṉakkup palaṉaḷikkum
   a) illai, b) ām, c) uṟutiyākat teriyātu
9. Nāṉ ceyaltiṟamāka āṉlaiṉ (Facebook, mutaliyaṉa), mopail (whatsapp) ārōkkiya parāmarippu aḷippavarkaḷiṭamiruntāṉa maruttuvam/camūka ātaravil nērmaṟaiyāka paṅkēṟpēṉ.

Oru pōtumillai	Aritāka	Cila nēraṅkaḷil	Aṭikkaṭi	Eppōtum

Uṅkaḷ nērattiṟkum poṟumaikkum mikka naṉṟi!

APPENDIX C: HEALTH CARE PROVIDERS-ORIENTATED DIABETES QUESTIONNAIRE

OFFICIAL USE:

DIABETES QUESTIONNAIRE (Health Care Provider Orientated)

(To be filled in by a professional health care provider)

Section A: DEMOGRAPHIC

1. GENDER: Male / Female
2. AGE: _____
3. OCCUPATION: _____
4. YEARS OF EXPERIENCE: _____

Section B: MEDICAL CARE

Please tick which is applicable to your practice.

1. Diabetic patients follow their medicine regimen.

Never	Rarely	Sometimes	Often	Always

2. How often do you see your diabetic patient?

Never	1 x yr	2 x yr	Quarterly	Monthly

3. Do your patients ask you what their medication is for?

Never	Rarely	Sometimes	Often	Always

4. Do patients ask you to clear their doubts regarding their condition?

5. My task is to motivate and support the patient in his/her lifestyle change.

6. My task is to give information on lifestyle related risks.

7. To the best of your knowledge, do your patients:
   A. Follow a blood glucose monitoring schedule?
   B. Exercise regularly?
   C. Complain of hypoglycaemia episodes?
   D. Complain of hyperglycaemia episodes?
   E. Ask you about exercise?

Do not know	None	Some	Most	All

8. How often do you refer your patient to other team members, such as the dietician, physiotherapist, diabetic educator, podiatrist, psychologist and optician?

Never	Rarely	Sometimes	Often	Always

9. Which discipline are you most likely to refer to? _____

10. How often are there inter-disciplinary meetings to discuss care of your patients or share new knowledge on treatment?

Never	Rarely	Sometimes	Often	Always

11. Do you have sufficient skills for lifestyle counselling?

Totally Disagree	Partially Disagree	In Between	Partially Agree	Totally Agree

Section C: MOTIVATION & BARRIERS IN COUNSELLING

1. In your opinion, which is the hardest thing for a diabetic to follow; eating plan, blood glucose monitoring, taking their medication, exercise, none or all of the above?

   _____

2. An important barrier to treatment is patient's unwillingness to change their lifestyle.

Totally Disagree	Partially Disagree	In Between	Partially Agree	Totally Agree

3. Insufficient knowledge on complications of diabetes is a vital barrier in patient's treatment.

4. Patients should be assigned responsibility of self care.

5. Which group of people do patients complain that they have lack of support from?
   a. Family members?
   b. Co-workers or bosses?

6. Do you patients complain of depression and frustration due to their disease condition?

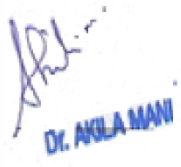
Never	Rarely	Sometimes	Often	Always

7. Do you find that time constraints are the problem for counselling your patients?

8. Do you feel that you are equipped with the knowledge or skills to teach your patients?

9. Would you actively participate in Diabetes workshops, if organised by your hospital?

Thank you for your time and patience!



APPENDIX D: INFORMED CONSENT DOCUMENT

INFORMED CONSENT DOCUMENT

Part A: STUDY PARTICIPANT INFORMATION SHEET

STUDY TITLE: ***Perceived Barriers to Lifestyle Modification, Motivation, Knowledge and Service Needs of Diabetic Adults and their Health Care Providers in Chennai, Tamil Nadu***

INSTRUCTIONS:

1. Please read and understand the information given below.
2. While reading the document and during the course of the study, you are free to ask any study related question. Your question will be answered and required study related clarification will also be provided.
3. LAR (Legally Acceptable Representatives) is a person who is legally allowed to take care of the study participant, signs this informed consent on behalf of the study participant and allow him/her to be a part of this clinical study.
4. A signed Xerox copy of this document will be provided to you.

INTRODUCTION

Background:

1. **What is the Purpose of the study?**

   The aim of this study is to assess perceived barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their health care providers in Chennai, Tamil Nadu.The research aims at knowing the challenges faced by the diabetic community and to find a way forward on helping them achieve a good quality of life.

2. **Who can take part in the study?**

   The people selected to participate in this study will include type 2 diabetics from the age 18 to 70 years; diagnosed for more than a 1 year; with not more than two other co-morbidities excluding pre-renal or renal failure or cancer; latest glycated hemoglobin (HbA1c) available and have previously been seen by a dietician.

   The health care providers will comprise of at least 25 nurses, doctors and dieticians that have been practicing for more than a year. There will be separate questionnaires for the diabetic patients and for the health care provider to complete.

3. **Duration of Your participation?**

Your participation in this study is only required for 1 hour as to complete the questionnaire.

4. **Total no of study participants:**

   The total number of participants is estimated to be 50 and the health care providers will comprise of at least 25 nurses, doctors and dieticians.

5. **Possible benefits of taking part in this study:**

   The investigator of the study will hope to gain a better understanding of what are the barriers to lifestyle changes of diabetics in Chennai. These results will be shared with other health care professionals and diabetic patients in the hope of creating a holistic approach to diabetic care. In doing so, this could help decrease and or delay the number of complications experienced by diabetics and hereby improving their quality of life.

6. **Possible disadvantage or risks of taking part in this study:**

   There is no possible risk involved in this study.

STUDY PROCEDURE:

Once ethics approval has been obtained from Apollo hospitals and the University of KwaZulu Natal, a pilot study will be conducted.

A pilot study will be first completed to test the validity of the questionnaire using three different trained interviewers and 5 diabetic subjects and 2 health care providers. The questionnaire will be carried out on a face to face basis and in the language preferred by the subject, either English or Tamil.

Once the questionnaire has been validated, the main study will commence. The study questionnaires will be conducted by the principal investigator.

Hereafter, data collected will be sent to the statistician and results extrapolated. The study along with a thesis will be submitted to the University for examining.

If the university finds the thesis and study satisfactory, results and a discussion will be published and will be available from the university.

Further to this, significant results will be available at the hospital in a pamphlet form for any interested parties. Participants will get the results via email or postal mail, in this pamphlet format.

COLLECTION OF DATA:

The collection of data is in the form of a questionnaire which will be filled in by the principal researcher whilst interviewing the participants.

CONFIDENTIALITY OF RECORDS:

All participants personal details will be kept confidential and some of these details will be published; such as your demographic information (age, sex, socio-economic status etc.). Please be assured that this information is anonymous and will not carry your medical number, address or name.

SIGNING OF THE CONSENT FORM

The consent form needs to be signed so that the principal investigator may carry out the interview with the participant's approval and understanding of the study.

RIGHTS DURING THE STUDY

The participant has the right to refuse the completion of the questionnaire or decline to answer any questions.

Any data collected from your medical files will be will be used for purposes of this research only.

Data will be stored in secure storage and destroyed after 5 years.

You have a choice to participate, not participate or stop participating in the research. You will not be penalized for taking such an action.

Your involvement is purely for academic purposes only, and there are no financial benefits involved.

QUESTIONS:

The participants may ask any relevant questions to the principal investigator during the interview. The principal investigator will not answer any questions related to the participant's current condition or medical treatment plan. These queries should be asked from your attending physician.

Part B: CONSENT TO ACT AS A PARTICIPANT IN THE STUDY

Study Title: ***Perceived Barriers to Lifestyle Modification, Motivation, Knowledge and Service Needs of Diabetic Adults and their Health Care Providers in Chennai, Tamil Nadu***

Name of Patient		Patient Initials			

Age (years)		Screening No.			

(Participant initials / signature / left thumb impression)

1. I confirm that I have read and understood the information sheet for the above observation study and have had the opportunity to ask questions

ii) I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected and without giving any reason

iii) I understand that the ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or Published.

iv) I understand that my identity will not be disclosed in any information released to any third parties or published.

v) I agree not to restrict the use of any data or results resulting from this research study provided such a use is only for scientific purpose(s)

vi) I agree to take part in the above data study.

_____ _____

Signature of Participant Date

(If the participant is illiterate then left thumb impression)

_____ _____

Signature of Legally Acceptable Representative Date

Relation to participant (LAR)

_____ _____

Signature of Witness Date

(If LAR is illiterate please provide witness signature)

SHARONA STALIN, RD(SA) _____ _____

Name of Investigator / Designee Signature Date

APPENDIX E: ETHICS APPROVAL FROM THE UNIVERSITY OF KWAZULU-NATAL

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

15 August 2016

Mrs Sharona Stalin 942491024
School of Agricultural, Earth and Environmental Sciences
Pietermaritzburg Campus

Dear Mrs Stalin

Protocol reference number: HSS/0101/016M
Project Title: Perceived barriers to lifestyle modification, motivation, knowledge and service needs of diabetic adults and their health care providers in Chennai, Tamil Nadu

Full Approval – Expedited Application

In response to your application received 28 January 2016, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol has been granted **FULL APPROVAL.**

Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment /modification prior to its implementation. In case you have further queries, please quote the above reference number.

PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 5 years.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully

.....
Dr Shenuka Singh (Chair)
Humanities & Social Sciences Research Ethics Committee

/pm

Cc Supervisor: Dr Kirthee Pillay
Cc Academic Leader Research: Professor Onisimo Mutanga
Cc School Administrator: Ms Marsha Manjoo

Humanities & Social Sciences Research Ethics Committee
Dr Shenuka Singh (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Telephone: +27 (0) 31 **260 3587/8350/4557 Facsimile:** +27 (0) 31 260 4609 **Email:** ximbap@ukzn.ac.za / snymanm@ukzn.ac.za / mohunp@ukzn.ac.za
Website: www.ukzn.ac.za

APPENDIX F: ETHICS APPROVAL FROM APOLLO HOSPITAL ETHICS COMMITTEE

Institutional Ethics Committee - Clinical Studies

Reg.No.: ECR/37/Inst/TN/2013

Apollo HOSPITALS TOUCHING LIVES

To
Ms. Sharona Stalin
Principal Investigator,
University of South Africa

29 June 2016

Ref: Protocol Title: Perceived Barriers to Lifestyle Modification, Motivation, Knowledge and Service Needs of Diabetic Adults and their Health Care Providers in Chennai, Tamil Nadu

Sub: Your letter dated 13 Jun 2016 for approval of the above referenced study and its related document.

Dear Ms. Sharona,
The Institutional Ethics Committee-Clinical Studies, Apollo Hospitals, Chennai reviewed and discussed the documents submitted by you related to the conduct of the above-referenced study at its meeting held on 21st June 2016 -

The following documents were reviewed:

1. Study Proposal, Including proposed recruitment plan(Signed & Dated)
2. Participant information sheet
3. Informed consent form
4. Proposed Questionnaire (patient and health care provider)
5. Current CV (Signed & Dated)
6. Approval letter from Apollo Speciality Hospital, Vanagaram
7. Approval letter from Diabetologists (Apollo Speciality Hospital, Vanagaram
8. Admission letter from University of Kwazulu Natal, South Africa

The following Institutional Ethics Committee – Clinical Studies members were present at the meeting held on 21st June 2016 at 3:30 pm at Apollo Research & Innovations , Conference Hall, Room No: 19, 2nd Floor, Krishnadeep Chambers, (Apollo Hospitals, Annex No: 1), Wallace Garden, Chennai -600006 –

Name	Gender	Designation	Affiliation	Position in the committee
Dr. Rema Menon	F	Blood bank officer	Apollo Hospitals, Chennai	Member Secretary
Dr. Pradeep Kumar	M	Pharmacologist	Apollo Hospitals, Chennai	Member (Pharmacologist)
Ms.Maimoona Badsha	F	Lawyer	Independent legal Practitioner, Chennai	Member (Lawyer)
Mrs.Malathy Chandrasekhar	F	Home based teacher	Freelance	Member (Layperson)
Dr. K.Sathyamurthi	M	Asst. Professor	Madras School of Social work, Chennai	Member (Social Scientist)

Apollo Hospitals Enterprise Limited,
21, Greams Lane, Off Greams Road, Chennai - 600 006, Tamilnadu, India. T : +91-44 2829 5045 / 6641 Fax : 91-44-2829 4449
E-mail : ecapollochennai@gmail.com

Institutional Ethics Committee - Clinical Studies

Reg.No.: ECR/37/Inst/TN/2013

Apollo HOSPITALS
TOUCHING LIVES

After due ethical and scientific consideration, the Institutional Ethics Committee – Clinical Studies has approved the conduct of the study.

The study is approved to be conducted by you in the presented form. Please note that the date of initiation of the study, the date of first patient participation and the date of last visit of the last patient should be informed to the Institutional Ethics Committee – Clinical Studies.

The Institutional Ethics Committee – Clinical Studies should be informed about the progress of the study on a yearly basis, any serious adverse events occurring in the course of the study, any changes in the protocol and patient information/informed consent, and a copy of the final study report should be provided. Please note that this approval will be valid for one year and re-approval can be requested subsequently to continue the study.

The Institutional Ethics Committee- Clinical Studies is constituted and works as per ICH-GCP, ICMR and revised Schedule Y guidelines.

Yours Sincerely,

Rema Menon

Date 1/7/16
Place: Chennai

Dr. Rema Menon,
Member Secretary,
Institutional Ethics Committee – Clinical Studies,
Apollo Hospitals, Chennai
Tamil Nadu, India

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE CLINICAL STUDIES
APOLLO HOSPITALS, AHEL
CHENNAI, TAMILNADU.

Apollo Hospitals Enterprise Limited,
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