EFFECT OF EDUCATIONAL INTERVENTION ON HEALTH PERCEPTION AND METABOLIC CONTROL OF DIABETES MELLITUS ON DIABETIC PATIENTS

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1. INTRODUCTION

The word "diabetes" is borrowed from the Greek word meaning "a siphon." In 2nd-century A.D Greek physician, Aretus the Cappadocian, named the condition "diabetes." He explained that patients with it had polyuria and "passed water like a siphon". Diabetes mellitus is broadly described as chronic, systematic diseases characterized by abnormalities in the metabolism of carbohydrate, protein, fats and insulin, abnormalities in structure and function of blood vessels and nerves **(American Diabetic Association, 2007).**

Prevalence and Mortality Risk of Diabetes

Diabetes is a Non Communicable disease which is becoming a major Public Health concern and researches over the past decade highlight that developing countries will bear the burden of this Epidemic in the 21st century. Currently, more than 70% of the people with diabetes live in low – and middle income countries. An estimated 285 million people, corresponding to 6.45 of the world's adult population, will live with diabetes in 2010. The number is expected to grow to 438 million by 2030. (**World Health Organisation, 2008**)

IDF Diabetes Atlas, 2009 reported that roughly 80% of the people with diabetes are in developing countries, of which India and China share the largest contribution. It is estimated that the total number of people with diabetes in 2010 to be around 50.8 million in India, rising to 87.0 million by 2030.The majority of people with diabetes in developing countries are in the 45 to 64 year age range. In contrast to this **t**he majority of people with diabetes in developed countries are more than 64 years of age and it is estimated that by 2030, this number will rise more than 48 million in developed countries.

National Diabetes Statistics, 2010 reported that in USA (2007), Diabetes was the seventh leading cause of death according to information based on U.S. death statics.
The risk for death among people with diabetes is about twice that of people of similar age but without diabetes. **WHO (2008**) projects implemented globally suggested that deaths caused by these health problems will increase by 17% over the next decade, with the greatest increase in low- and middle – income countries, mainly in the African (27%) and Eastern Mediterranean (25%) regions. The SEA Region is projected to have the highest number of deaths due to diabetes of all the regions in 2010.
United States Department of Health and Human Services (US DHHS)(2004), Centers for Disease Control and Prevention, National Center for Health Statistics Compressed Mortality File 1999-2008 reported that Diabetes Death Rate per 100,000 in USA is 21.8. It is evident that

the developing countries will bear the burden of this epidemic in 21st century. The greatest relative increase has occurred in eastern crescent sub Africa and India. It is assumed that the absolute increase in the number of people with diabetes will be in India. The number of death attribute to diabetes in 2010 shows a 5.5% increase over the estimate for the year 2007. Hence from this it can be concluded that diabetes has emerged as one of the world biggest health problem and its prevalence increasing at an alarming rate.

Risk Factor for Type 2 Diabetes

Mokdad et al reported in **2003** that besides diet composition, higher daily energy intake, related to consumption of saturated fats and refined carbohydrates, predisposes to obesity and type 2 diabetes. For each kg of weight gain it has been calculated that the risk for diabetes increases by about 4.5 percent. Diets high in monounsaturated fatty acids or low in fat and high in carbohydrate result in improvements in glucose tolerance in comparison to diets high in saturated fat. Diets enriched with monounsaturated fat may also reduce insulin resistance (**Parillo et al, 1992)**.

On comparing diabetic and non diabetic subjects, diabetic subjects have an increased risk of coronary heart disease with higher intakes of dietary cholesterol (**Hu et al, 2000**). In a study on 32 patients with advanced coronary heart disease, 4 weeks of a low glycaemia index diet improved their glucose tolerance and insulin sensitivity in comparison to a high glycaemia index diet. The same group reported that a diet with low glycemic index also improved adiposity insulin sensitivity in women at risk for coronary heart disease in comparison to high glycemic index diet. **(Frost et al, 1996).**

In patients with type 2 diabetes, the insulin resistance syndrome continues to gain support as an important risk factor for premature coronary disease, particularly with concomitant hypertension, hyperinsulinemia, central obesity, and the overlap of metabolic abnormalities of hypertriglyceridemia, low HDL, altered LDL, and elevated FFA. Most studies show that these patients have a low level of fitness in comparison to control patients. Regular physical activity has consistently shown to be effective in reducing levels of triglyceride particularly VLDL **(ADA, 2004)**

Number of researches reported that reducing the prevalence of smoking should be on the list of public health priorities for the prevention of type 2 diabetes in Asian countries.(**Yasuaki et al, 2010).**Chronic smokers have a higher risk to be insulin resistant and exhibit several aspects of the insulin resistance syndrome, and develop type 2 diabetes mellitus (DM2)(**Willi et al 2007,**

Carlsson et al 2004, Eliasson 2003,Facchini 1992).**Greenway** in **2004** suggested that Medications (ACE Inhibitors) help prevent kidney failure in most diabetics who don't smoke. Medications may not help tobacco users with diabetes. Several studies report that smokers are 50% more likely than non-smokers to get diabetes. People with diabetes who smoke have a higher death rate than people with diabetes who don't smoke.

Tobacco use by diabetics can block the tiny blood vessels in the eyes; they are at chance of getting gum disease and may suffer tooth loss. Those who smoke are more likely to get nerve damage in all parts of the body. This causes numbness and sometimes pain. They also have poor blood flow in their feet and legs. Tobacco use can make foot ulcers, foot infections and blood vessel disease in the legs**.** Tobacco raises blood sugar levels, making it harder to control diabetes. Hence diabetics have a high risk of heart disease. (**Chrousos, 1998**)

Stress has been shown to have a role in the cause of diabetes and certainly in the management of the diseases. There may be cortical mediated intra abdominal fat deposition, modulated by chronic stress , leading to metabolic syndrome several researches have shown that stressful life events may be associated with visceral adiposity and type 2 diabetes mellitus. In the management of type 2 diabetes mellitus, compliance depends on personality traits and health cultural beliefs. Diabetes specific psychological instruments for quality of life, wellbeing and treatment satisfaction could prove useful in clinical practice (**Bjorntorp et al, 2000**).

Complications Due to Diabetes

Diabetes contributes to nearly 200,000 deaths annually, and is the leading cause of kidney failure, blindness, leg and foot amputations. Persons with diabetes are between two and four times more likely to have heart disease, and five times more likely to have a stroke than non-diabetics (**Bellenir & Dresser, 1995**).

Research over the past decade has found that many diabetes-related complications once thought to be inevitable can be prevented with strict glycaemia control. The **Diabetes Control and Complications Trial (DCCT, 1993)** demonstrated that by keeping blood glucose levels as close to normal, micro vascular complications such as retinopathy, neuropathy, and nephropathy can be averted. Patients with insulin dependent Diabetes Mellitus (IDDM) who already showed early vascular complications were able to slow the progression of their complications with tight glycaemia control.

Diabetes mellitus is an endocrinological disorder affecting each and every cell of the body thereby bringing about alteration in the metabolism of proteins, carbohydrates and lipids.These metabolism alteration lead to the development of secondary complications resulting in the thickening of the basement membrane thereby affecting all the organs, finally leading to the multiple organ failure. Hence, understanding of the disease from various angels becomes quite important in the prevention or in the management of this disorder (**Uliyar, 1998**)

Economic Burden Due to Diabetes

Diabetes has long lasting adverse effects on a nation's health and economy, especially for developing countries. Healthcare expenditures on diabetes are expected to account for 11.6% of the total healthcare expenditure in the world in 2010. The estimated global healthcare expenditures to treat and prevent diabetes and its complications are expected to be at least 376 billion U. S. dollars in 2010.By 2030 this number is projected to exceed some US dollar 490 billion.(**Ramachandran et al 2010)**

Global expenditures on diabetes will be at least ID 418 billion in 2010, and at least ID 561 billion in 2030. An estimated average of ID 878 per person will be spent on diabetes in 2010 globally. Besides excess healthcare expenditure, diabetes also imposes large economic burden in the form of lost productivity and foregone economic growth. The largest economic burden is the monetary value associated with disability and loss of life as a result of the disease itself and its related complications **(International Diabetes Federation, 2009)**

The World Health Organisation (WHO) predicted net losses in national income from diabetes and cardiovascular disease of ID 555.7 billion in Brazil and ID 2.5 billion in Tanzania (2005 ID), between 2005 and 2015.Inspite of the large amount of people with diabetes in the SEA Region, spending on healthcare for diabetes is expected to be only USD 3.1 billion for the region, accounting for less than 1 % of the global total expenditures **(IDF, 2009).**

Grover et al in **2005** carried out a study on the cost of ambulatory care of diabetes mellitus (a study from north India). This study revealed that the total treatment cost was 7254.07 rupees, for the six months period in which the direct treatment cost was slightly more than two third (68.4%) of the total treatment cost and the indirect cost was much less (28.76 %) then total treatment cost. the total cost of care of diabetes was estimated at 14517.42 rupees per person annually according to this study. This study principally revealed that diabetes is an expensive illness to treat even in developing countries like India.

Rayappa et al in **1999** carried out a study on economic cost of diabetes care: the Bangalore urban district diabetes study. In this study the findings are revealed the cost of diabetes care in high and comparable to in cost in other countries. It revealed that direct and indirect costs of diabetes care for patients undergoing treatment that involved hospitalization was approximately US$850 per patient per year, of this direct costs account for US$ 399 per patient per year. **Ramchandradran** carried out a study in **2007** on socio economic burden of diabetes in India. Its results showed that the annual estimated cost could be rupees 90,200 million for diabetes health care.

Diabetes Self Management Education

The concept of diabetes education is not new; Diabetes Education has been viewed by experts as an essential part of diabetes care. Dr. Elliott P.Joslin, one of the pioneers of diabetes education and creator of the renown Joslin Diabetes Clinic in Boston, Massachusetts, stated that "The diabetic who knows the most lives the longest" **(Krall, 1985). Clement (1995)** defined Diabetes self-management education as a "process of providing the person with diabetes with the knowledge and skills needed to perform self-care, manage crises, and make lifestyle changes required to successfully manage this disease." (Krall, 1985)

Factors such as the patient's beliefs, attitudes, medical treatment, medical history, psycho-social support, and environment may also influence the fact that whether a person with diabetes is willing or able to make the necessary behavioural changes to improve metabolic control (Glasgow, Hampson, Strycker, & Ruggiero,1997; Herman & Dasbach, 1994; Anderson, Fitzgerald, & Oh, 1993; Rubin & Peyrot, 1993;Beeney & Dunn, 1990; Haire-Joshu, 1988; Ary, Toobert, Wilson, & Glasgow, 1986; Schafer, McCaul, & Glasgow, 1986; Alogna, 1980; Cerkoney & Hart, 1980).

Study conducted by **Miller et al** in **1978**, found that after implementing a comprehensive diabetes self-management training program, the rate of acute complications requiring hospitalization was reduced. This dramatic reduction in complications was estimated to save three million dollars in healthcare costs. Studies have shown that structured diabetes self-management education programs have been successful at improving metabolic control (**Peyrot & Rubin, 1994; Glasgow,Toobert, & Hampton, 1992; Garrard, Mullen, Joynes, McNeil, & Etzwiler,1990;Mazzuca, et al.,1986**). Reductions in the number of hospitalizations, ketoacidosis episodes, and amputations have been attributed to comprehensive diabetic education programs (**Mulhauser, et al., 1993; Miller & Goldstein, 1978).**

Peyrot and Rubin (1994) found that patients who improved their diabetes self-care behaviours improved their glycemic control. Educational programs that identify demographic variables, ethnic background, formal education level, diabetes health beliefs, barriers to participation, and other factors in diabetes self-management are more effective than ones just applying a didactic approach (Rubin, Peyrot, and Saudek, 1993; Peyrot and Rubin, 1988; Ingersoll, Orr, Herold, and Golden, 1986; Skyler, Seigler, and Reeves, 1982).

The use of The Health Belief Model which incorporates self- efficacy has been useful in explaining why some persons with diabetes are able to improve their metabolic control post-intervention and others are not (Wdowik, Kendall, and Harris, 1997; Pham, Forton, and Thibaudeau, 1996; Harris, Linn, Skyler, and Sandifer, 1987; Harris, et al., 1982; Cerkoney and Hart, 1980; Alogna, 1980; Becker, Maiman, Kirscht, Haefner, and Drachman, 1977). The Health Belief Model theorizes that for persons to modify their behaviour, perception that the benefits are greater than the perceived disadvantages is very essential**.** The Health Belief Model is especially useful for explaining how the patient's attitudes can influence self-care behaviours, and ultimately, metabolic outcomes.

Wooldridge, et al. (1992) found that HgbA1c improved significantly from pre- to post-education in a subgroup of patients who also improved health beliefs; however, they were unable to associate these improvements with self reported adherence or HgbA1c directly. Participants in practice of self care skills such as insulin administration, glucose monitoring, meal planning and getting actively involved in planning goals and strategies to overcome barriers to self care, should pay attention to selection of appropriate hypoglycaemic drug also as it is essential part of diabetes management

Many researchers have indicated the importance of self monitoring of blood glucose concentration for prevention of complications in patients with diabetes, it is recommended as a technique for improving control of blood glucose concentrations **(Evans et al, 1999; Diabetes Care, 1987). Stratton et al, 2000** reported**,** Blood-glucose control is critical for managing diabetes and preventing diabetes-related complications such as cardiovascular disease, retinopathy, nephropathy, and neuropathy.

A clear relationship between control of hyperglycemia and reduction of diabetes morbidity and mortality with type 2 diabetes strengthened the evidence for aggressive glycemic control in all diabetes populations. Intensive diabetes management has relied heavily on blood glucose

monitoring. Persons with diabetes who regularly monitor their blood glucose levels and work closely with their healthcare providers have fewer diabetes complications Diabetes care requires a high degree of self -care. Persons with diabetes are often asked to make major lifestyle changes such as practicing glucose self-monitoring, maintaining reasonable body weight, adjusting meal composition, size, and timing, following a medication regimen and performing other preventive practices as well as behavioural changes such as modifying food intake and exercise **(Robiner and Keel, 1997).**

Brown in **1999** suggested that Diabetes Self Management Education (DSME) has consistently been shown to improve health outcomes. Patients with diabetes who don't receive self-management training are four times more likely to develop a major complication of their diabetes. A cross sectional study by **Mc.Elanay et al, 2000**, conducted to examine whether the patients who reported of receiving education have increased diabetes knowledge, and how this has impacted on the control of diabetes, reported that diabetes education and increased patient participation in their disease management led to increased in diabetes knowledge and its metabolic control.

A study on education programme regarding awareness of using glucometer machine was done at M.V Diabetes Speciality Centre on 224 diabetic patients, which included 110 review patients (who have attended the education programme) and 114 new patients (visiting the centre for the first time). The study revealed that awareness of glucometer was significantly higher among those who attended the education programme (review patients) in comparison to new patients (89.1% vs. 61.4 %). Review patient (28.2%) and new patient (17.5%) were using glucometers to monitor their glycemic control. According to a study by **Hampton et al in1998**, it was inferred that attendance at the education sessions improved patient's knowledge about diabetes and led to a reduced dependence on oral hypoglycaemic therapy. A reduction in HbA1c was achieved and a reduction in weight was also attained as a result of the education programme.

A study conducted by **Garcia et al, 1996**, established an educational model for elderly patients with diabetes mellitus and the effects were studied in 148 diabetic patients aged above 60 years who participated in 60 monthly scheduled interactive meetings over a 5-year period. Empowering patients with skills, perceptions and ability to cope with diabetes and metabolic control was emphasized, rather than clinical aspects. Comparison between pre-program and 5 years post program demonstrated improvement in the HbA1c levels and a reduction in body weight and anti-diabetic medications was observed. There were less diabetes related conditions requiring emergency services and hospital admissions. To demonstrate the advantages of

behaviour modifying education on the metabolic profile of the type 2 diabetes mellitus patients, an experimental study was done by **Pivaral et al in 2000**. The experimental group consisted of 25 type 2 diabetic patients and the control group consisted of 24 patients. The education carried out was a behaviour modification module. Baseline measurements and subsequent monthly measurements of serum glucose, total cholesterol, and triglycerides were carried out for 9 months after the intervention. A reduction in serum glucose, total cholesterol and triglycerides was observed in the experimental group who received behaviour modifying education, whereas in the control group there was not much difference. Thus introduction of an education programme was found to have a positive effect on the metabolic control of patients. The cost of their pharmacological treatment was collected, 6 months before participation in the educational program, on entry into the program and at 4, 8, and 12 months after the initiation of the program. All parameters measured had improved significantly in the duration of one year. At 12 months, the decrease in pharmacotherapy required for control of diabetes, hypertension, and hyperlipidemia represented a 62% decrease in the annual cost of treatment.

The results of study conducted in Netherlands by **Van den Arend et al** in **2000**, indicated that primary care programs which integrated education into structured care were able to improve both the type 2 diabetic patient's knowledge about the disease and their self care behaviour. These improvements persisted even after the completion of the programs as highlighted by the follow up done after 12 month.

A number of studies regarding Diabetes Self Management Education have also been conducted in India also and have given positive results. In the cross-sectional study conducted at Chandigarh by **Kaur et al (1998)** on 60 diabetic individuals from whom 48 subjects knew that sweets and fatty foods should be avoided but only 18.3% were avoiding them, monitoring of blood sugar was poor (46.7%), oral anti diabetic drug compliance rate was 62.9% and none of the patients on insulin injections knew about self therapy. In the study conducted on 150 diabetic residents of Pondicherry by **Gopalan et al, 1991** it was observed that most of the patients were aware of the need for dietary care or medication, but only 50% modified their diet. Among them 97% used anti diabetic agents, some were using them wrongly and only 10.6% of the subjects tested their urine, although 71% were aware of the need. None of the patients had any formal education regarding diabetes and only 34% consulted the physician regularly. The results of these studies showed a large gap between knowledge and action.

2. SIGNIFICANCE OF STUDY

People with diabetes who want to live their lives without limits will need to know a lot about their illness. Epidemiologic data indicate that large numbers of patients do not receive the proper care or education necessary to develop self management abilities. A step-wise approach to diabetes self-care management is essential to improve the glycemic control of diabetics. A

further goal of diabetes education is to help patients develop coping skills to overcome their attitudinal and emotional barriers associated with diabetes management. The various aspects of Diabetes Self Care Education include medical nutrition therapy which encompasses regular glucose monitoring, proper dietary regime as well as proper medication Hence Diabetic education for self care not only enhance care and reduce the burden of complication but also indirectly reduce the overall economic costs of diabetes **(Kapur, 2001**).

The value of patient education is evident from researches demonstrating that patients who never received diabetes education showed a striking fourfold increased risk of a major complication. The basic objectives in the handling of type-2 diabetes mellitus patients are reaching normal metabolic control and preventing complications. This necessitates the introduction of an educational intervention project that links theory with practice through a communicative educational behaviour-modifying strategy. The expected outcomes would go beyond knowledge and glycemic control to include prevention of diabetes, improved quality of life and delaying of complications. Thus the beneficial results of diabetes educational model, reinforces the value of patient education as an essential part of diabetes care and suggests that an educational approach promoting healthy lifestyle habits and patient empowerment is an effective strategy with a potential to decrease the development of complications related to diabetes as well as the socio economic costs of the disease. Hence keeping in mind the above motioned fact the present study was planned with following

OBJECTIVES:

- To assess knowledge and perception of subjects regarding Diabetes.
- To develop an educational module for conducting diabetes intervention.
- To assess the effect of educational intervention on health perception and metabolic control of diabetes on diabetics.
- To assess the effect of educational intervention on the cost of pharmacological treatment.

Research Design

Area Selection (Urban Area of Jaipur City)

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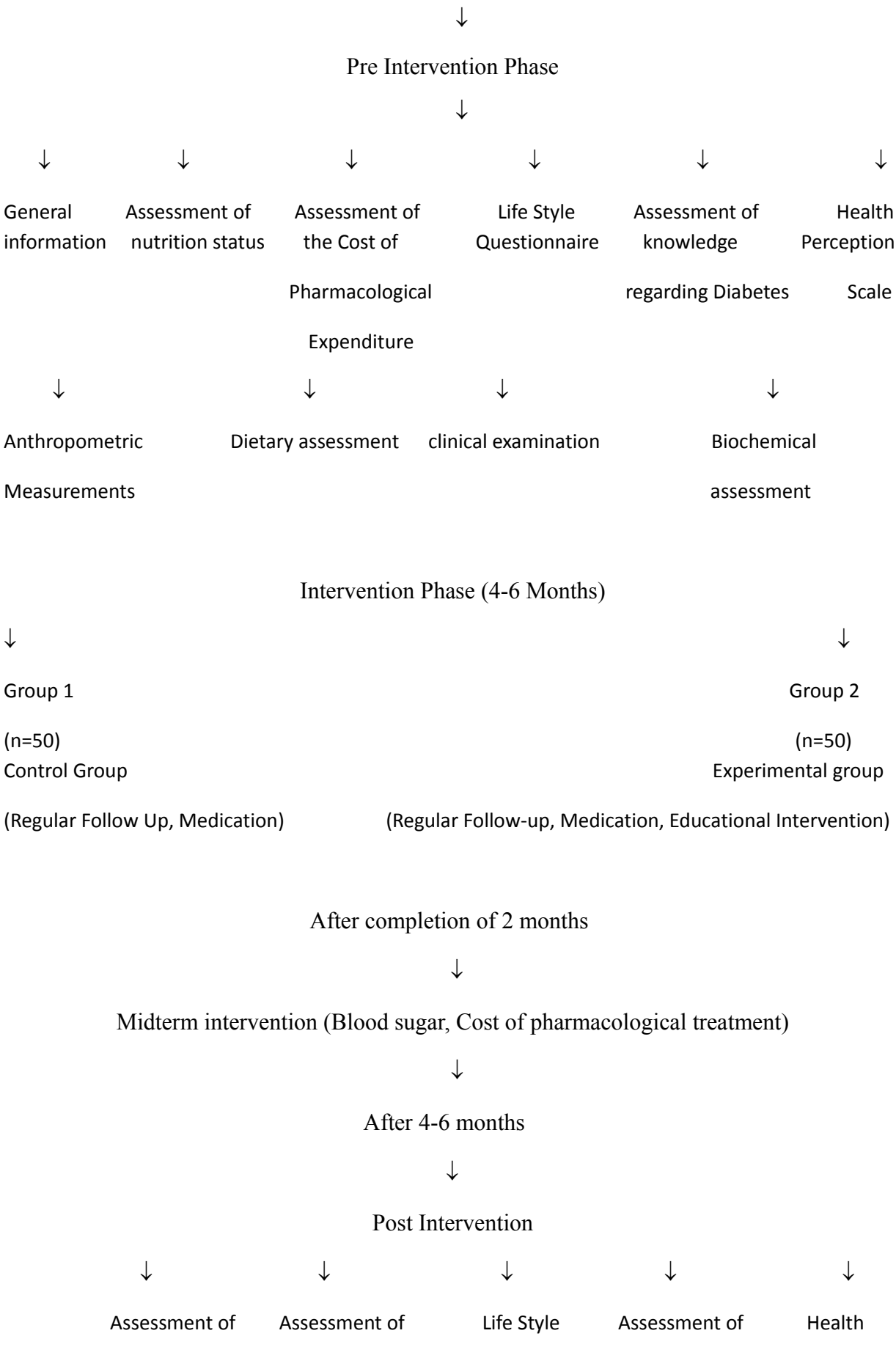
Sample Selection (n=100)


Pre Intervention Phase
General information
Assessment of nutrition status
Assessment of the Cost of Pharmacological Expenditure
Life Style Questionnaire
Assessment of knowledge regarding Diabetes
Health Perception Scale
Anthropometric Measurements
Dietary assessment
clinical examination
Biochemical assessment
Intervention Phase (4-6 Months)
Group 1
(n=50)
Control Group
(Regular Follow Up, Medication)
Group 2
(n=50)
Experimental group
(Regular Follow-up, Medication, Educational Intervention)
After completion of 2 months
Midterm intervention (Blood sugar, Cost of pharmacological treatment)
After 4-6 months
Post Intervention
Assessment of
Assessment of
Life Style
Assessment of
Health

nutrition status	the Cost of Pharmacological Expenditure	Questionnaire	knowledge regarding Diabetes	Perception Scale

3. METHODOLOGY

This chapter of study is mainly concerned with the methodological aspects pertaining to the present investigation. The design of the study refers to the logical manner in which units of study will be assessed and analyzed for the purpose of the drawing conclusions.

The study will be conduct in 3 phases that are:-

~~3.1~~ PHASE I- Pre Intervention (Baseline Study)

- Locale of the study
- Sample selection
- General information
- Assessment of nutrition status
    1. Anthropometry measurement
    2. Dietary assessment
    3. Clinical examination of symptoms related to diabetes
    4. Biochemical assessment
- Assessment of the cost of pharmacological expenditure
- Lifestyle Questionnaire
- Assessment of Knowledge Regarding Diabetes
- Health Perception Scale

3.2. PHASE II- Educational Intervention regarding Diabetes and its Management

3.3 **PHASE III- Mid Term Intervention**

- Blood sugar
- Assessment of the cost of pharmacological expenditure

3.4 **PHASE IV- Post Intervention**

- Assessment of Nutritional Status
- Assessment of the cost of pharmacological expenditure
- Lifestyle Questionnaire
- Assessment of Knowledge Regarding Diabetes
- Health Perception Scale

3.1 PHASE I- Pre Intervention

Locale of the study-

The study will be done in Jaipur City; Jaipur is one of the finest planned cities of India, located in the semi-desert lands of Rajasthan. Current Population of Jaipur in 2011 is 66, 63,971 and Population Density per Sq. Km is 598. The urban areas of the city will be surveyed finally areas will be shortlisted depending on their easy approachability and connectivity and availability of clinic of Doctors working as Diabeteologist and are ready to cooperate in present study.

Sample selection-

The subjects will be approached with the help of doctors whom they visit regularly, for this at least 3-4 clinics will be identified. we will be approaching the subjects through eminent doctors who are working in the field of diabetes from last 10-15 years, for this list of doctors will be prepared, they will be contacted, project objective will be explained to them and those who will be ready to cooperate, will be selected. The sample size of study will be approximately 100, the selection criteria of the subjects in the present study will include following points:-

- The age should be ≥ 45 years
- Overweight –Body Mass Index (BMI) ≥ 23kg/m²
- The subject should be free from any chronic diseases
- Duration of onset of diabetes should be between 2-5 years.
- Individual with central obesity-waist hip ratio: men.>90 cm, women, >80 cm.
- Previously identified Impaired Fasting Glucose (IFG) or Impaired Glucose Tolerance (IGT)
- Hypertension > 140/90 mmHg
- The subjects and their family should give consent ,and they should be willing to cooperate

Initially group meetings will be held in order to develop good rapport with the subjects

Finally all those subjects who will meet the criteria and will give consent for the study will be listed and randomly divided into two categories GROUP I it will be the Control group who will receive medication and regular follow up and GROUP II will be the Experimental Group besides medication this group will be participating in the intervention programme of diabetes management.

General information

In the baseline study general information of the subjects will be collected using a pre coded and pre tested interview schedule. Information will be collected related to sex, Date of Birth, Age, marital status, occupational status etc

Anthropometric Measurement

Nutritional Anthropometry is measurement of human body at various ages and levels of nutritional status. **(Bamji et al., 2003)**

Body Weight: It is the simplest reproducible anthropometric measurement for the evaluation of the nutritional status. It involves the body mass and is a composite of all body constituents like water, minerals, fat, protein, bone etc. **(Bamji et al, 2003)**

Technique- Bathroom weighing balance will be used as it is simple, portable, accurate and in expensive. The balance will be standardized by known mass from time to time .The subject will be asked to stand on the centre of the bathroom scale without touching anything else looking straight ahead. They will be instructed to remove their shoes and weight will be measured with minimum possible clothing. Measurements will be taking twice to avoid errors **(Jelliffe, 1996)**

Height – Height of an individual is made up of the sum of four component legs, spine, pelvis and skull Height is a predictor of long term malnutrition. **(Bamji et al, 2003)**

Technique-

A measuring inflexible tape known as heightometer will be use for measuring height. It will be hanged at 2 m high, vertically on a smooth wall perpendicular to the ground. Care will be take to see that the floor is even and not rough .The subject will be asked to remove their shoes and stand up as straight as possible on the flat floor ,with feet together and with heels apart ,buttocks, shoulders, and back of head touching the scale upright .The legs should be straight and shoulders relaxed. The head of the subject should be in positioned in such a way that the subject is looking straight forward and is comfortably erect , with lower orbit in the same horizontal plane as the external auditor meatus. The arms should be hung by the sides in a natural manner.

Body Mass Index-

After the cessation of linear growth Body Mass Index that is weight divide by height meter square provides a reasonable identification of nutritional status. It can be used as indicator of health risks. The ratio of weight (in kg)/height(mt.sq.) is referred to as body mass index.BMI provides a reliable indicator for most people and is used to screen for weight categories that may leads to health problem (annexure 1)

Waist-to-Height ratio-

The **Waist-to-Height ratio** (**WHtR**) of a person is defined as the person's waist circumference, divided by the person's height. The WHtR is a measure of the distribution of body fat. It is the best way to predict a person's risk of serious health problems such as diabetes, high blood pressure and heart disease. The simple measurement (waist divided by height) is equally fair to tall and short people. "Keeping your waist circumference to less than half your height can help increase life expectancy for every person in the world," said Ashwell, as reported in the Telegraph. (Annexure 2)

Waist –to –Hip ratio-

This step is the determination of body shape. Body shape has been found to be important when predicting a person's risk of cardiovascular diseases and metabolic conditions. Abdominal fat is an important risk marker for cardiovascular diseases and type 2 diabetes .The waist-to –hip ratio (WHR) can be used to classify people as either pear or apple shaped .people with a pear shaped body have a low WHR and are at a lower risk of cardiovascular complications, compared to people with an apple shaped body (Table and figure in Annexure 3)

Dietary assessment method-

Assessment of dietary intake will be done by 24 hour dietary recall and Food frequency questionnaire. In 24 hour dietary recall method the subject will be asked to recall all foods and drink taken in the previous 24 hours. This is method of oral questionnaire a set of 'standardised cups' will be used, the cups are used mainly to aid the respondent recall the quantities prepared

and fed to the individuals members. In Food frequency questionnaire method the subject given a list of different food item to indicate his or her intake (frequency and quantity) per week and per month .It is a in expensive, more representative and easy to use method and helps in quantitative assessment of diet.

Clinical examinations

A careful clinical history of symptoms is the best guide to assessing appropriate treatment. Thirst, polyuria, weight loss, fatigue are the most frequently reported symptoms; full physical examination is required to check the presence or absence of complications associated with diabetes. Skin changes like acanthosis nigricans (Hyper pigmentation in skin fold regions, such as of the neck, groin, and under the arms) is seen in cases of insulin resistance in some patients with type 2diabetes. Some patients observe that they have "dry mouth", polyuria especially nocturia, is a major symptoms of diabetes.

Biochemical assessment

The primary goal of therapy with type 2 diabetes is to achieve and maintain normal blood glucose and lipid level. Certain laboratory data are needed for diagnosis of type 2 diabetes these are Glycosylated haemoglobin levels (HbA1c), fasting and post prandial Blood sugar estimation and lipid profile.

Glycosylated haemoglobin levels (HbA1c) – The HbA1cis a measure of the average blood glucose (both high and low blood glucose levels) over a 3 month period of time and is used to measure the degree of glucose control. The haemoglobin molecule which is part of the red blood cell circulates throughout the bloodstream for about 90 days. As the glucose in the blood circulates, it attaches to the haemoglobin molecule. If there is a large amount of blood glucose circulating in the blood during that period of time the HbA1c will be high, if there is the normal amount of glucose in the blood, the HbA1c will be normal, HbA1c is reported as a percent. (Figure in Annexure 4)

Blood Sugar Estimation:

Fasting blood sugar (FBS) measures blood glucose after you have not eaten for at least 8 hours. It is often the first test done to check for pre diabetes and diabetes. Two**-hour postprandial blood sugar** measures blood glucose exactly 2 hours after you start eating a meal. (Annexure 5)

Procedure:

Fasting Blood Sugar: NBM (nil by mouth) for at least 8 hours before blood sample is taken**.** **2- Hour Postprandial blood sugar:** The subject should start eating a meal exactly 2 hours before the blood sample taken**. Cut offs for blood sugar:** 70-99 milligrams per decilitre (fasting), 70-145 mg/dl (postprandial).

Lipid profile – Lipid profile is the collective term given to the estimation of, typically, Total cholesterol, High-density lipoprotein cholesterol, Low-density lipoprotein cholesterol and Triglycerides. The American Diabetes Association (ADA) recommends that people with diabetes who have lipid levels that need correction should have a lipid profile taken at least annually.

Life style questionnaire: Assessment of the life style of the subjects will be done by using a well structured questionnaire. The onset as well as severity of diabetes is influenced by life style of an individual. The life style questionnaire will include questions related to behavioural measurement (smoking, drinking alcohol, tobacco consumption, etc.). Physical activity and diet of an individual. All these aspects vary from person to person and influence the health condition to great extent.

Assessment of knowledge regarding diabetes: The existing knowledge of the subjects regarding diabetes will be done with the help of a well designed and pre tested questionnaire.

Health Perception Scale: The health Perception Scale will be based on Health Belief Model used for determining patient's perception regarding diabetes. The 'health belief model' (HBM) is used to explain the reason for the adoption of healthy behaviours or acceptance of preventive health practices. The HBM is spelled out in terms of four constructs representing the perceived threat and net benefits: perceived susceptibility, perceived severity, perceived benefits, and perceived barriers. The HBM has been used to predict the population's use of health care services. Studies have shown that cost barriers are the most important factors in making a decision to change. This means that if a change costs too much either in money or time and energy, people with diabetes are less likely to implement it.

PHASE 2- Intervention – The Group II that is the Experimental Group will be involved in educational programme for diabetic intervention and will be exposed to a well structured training for period of 4-6 months. The training will be done according to below mentioned sessions.

3.2.1. Session1- PathoPhysiology and Diagnosis of Diabetes

Initially meetings will be organized with the patients and project objectives explain to them, counselling, consultation will be done to establish rapport with them. Finally patients will be made to understand the relationship between glucose, insulin and their role in glucose homoeostasis. Overview of the metabolic disorders of glucose metabolism and their diagnosis will be given.

Technique:

During this session a group of 5-10 subjects will be taken at a time and all the objectives will be presented in front of them, minute aspects associated with diabetes essential for them will be explained with the help of IEC approaches for this we will be using power point presentation, posters, charts, leaflets and pamphlets. Some materials will be distributed to them which they can go through. Finally discussion will be done with them, in order to analyse their retention power.

3.2.2. Session -2- Self Management

Self management is the corner stone of overall diabetes care, diabetes is a chronic diseases that requires decisions regarding food intake, exercise, and medication as well as regular glucose monitoring in order to manage blood glucose levels

Technique:

Initially barriers to self care will be identified individually for example Lifestyle barriers, Cultural or religious practices, Lack of knowledge and skills etc. Monitoring of blood sugar levels will be done and subjects will be given knowledge regarding:

Blood glucose targets:-

Targets should set individually for each person and in this IDF global guideline can be used as guideline (Annexure 6)

Monitoring Glucose targets:

This will be done by self monitoring of blood glucose (SMBG) and laboratory examination.

1. Regular monitoring of glucose using glucose monitoring skills is essential.
2. Glycosylated Haemoglobin Test, It is a laboratory test which will be used for measuring blood glucose control.

Blood glucose diary:

A diary is one of the keys to self management. We will encourage patient to record all blood glucose reading, not just those 'in target'. Subject will be encouraged to add comments to their diaries, regarding unusual activities. Comment such as, ate more at dinner, and walked for 30 minutes are helpful in correlating blood glucose results to specific activities.

Frequency of blood glucose testing:

People should test as often as they need to obtain enough data to self manage their diabetes. Testing frequency may need to be increased when blood glucose levels are out of range, during illness or when activities vary from the usual routine.

3.2.3. Session -3 Knowledge Regarding Nutrition

In this session we will tell the patient about the Medical Nutrition Therapy (MNT), it is the term used to describe the nutrition approach to treat diabetes and promote healthy eating habit the subjects will be provided with a framework for the development of a nutrition management plan tailored to the individual with diabetes. Nutrition management will be based on an individual nutritional assessment, the attainment of glycaemic goals or targets and the prevention or delay of the onset of diabetes-related complications

Technique:-

Nutrition care process consists of the following elements that are:-

I. Nutrition assessment – it is the initial step in developing an individualized nutrition education and meal plan we will collect all the information regarding patients from the medical records and analysis of data

- Height
- weight
- BMI
- Waist- to –hip ratio

II. Nutrition diagnosis- once the nutritional assessment has been completed ,we have enough information to determine the nutritional status and needs of the person with diabetes example of nutrition diagnosis are :

- Inadequate carbohydrate intake
- Over-sized portion sizes
- Poor timing of meals and medication

III. Nutrition intervention – This step involves the planning and implementation of Educational activities and counselling needed to modify the person's nutritional eating habits or behaviours. We will discuss in this session about 5 commonly used meal planning methods.

A. Food pyramid –The food pyramid is a visual that helps explain the kinds and the amounts of food that should be eaten. The base of the pyramid consists of the foods that should be eaten more frequently. As one goes up the side of the pyramid, the person should eat fewer serving of the foods indicated, eating the least amounts of the foods at the top of the pyramid. The foods at the top of the pyramid tend to be calorie dense and should be eaten sparingly (Annexure 7)

B. Plate method – It is a useful tool for people who have recently been diagnosed with diabetes and are just learning how to manage their meal plan or who just want a simple plan to follow. it is ideal for people who have difficulty dealing with numbers, learn by visualizing and eat out frequently. (Annexure 8)

C. Estimating portion sizes with hands – It is difficult sometimes to measure foods and know exactly the quantity of food that is being consumed .people can use their hands to estimate the correct portion size of food that they should eat. (Annexure 9)

D. Signal system-It is a useful aid to educate large numbers of people. The signal system is based on a traffic light concept. Food can move from the green to the red zone depending on the method of processing and cooking.

- RED ZONE-_These foods are rich in fat and in refined carbohydrate/sugars; they have a high glycaemic index or are low in fibre .they should be eaten in very limited quantities.
- YELLOW ZONE- These foods should be eaten in moderation since they may have a high glycaemic index, are low in fibre content, or have moderate amounts of fat.

- GREEN ZONE- These foods are healthy choices because they have a low glycaemic index are high in fibre, and low in fat. However foods in green zone should still only be eaten in recommended amounts. (Annexure 10)

E. Carbohydrate counting – Carbohydrate should account for 55-60% of the total calories taken on a daily basis; carbohydrate counting is becoming a more widely used meal planning approach for people with diabetes. Level 1 – One serving of carbohydrates approx 15 gm of carbohydrates i.e. 1/3 cup rice or 1 small chapatti will be worked out with the person according to their nutritional needs and life style. Level 2- People build on skills they have developed in level 1. They learn to look for pattern in their blood glucose levels, analysing if the blood glucose pattern is in response to the carbohydrate intake. This will require frequent blood glucose monitoring. Level 3- people who are interested in intensively managing their diabetes, are taking multiple daily injection of insulin should progress to level 3.blood glucose needs to be checked regularly. Insulin doses before meal and snakes are based on a predetermined carbohydrate to insulin ratio.

We will also discuss benefits of fibre (Annexure 11), Common source of different fats (Annexure-12), Frequency of eating out and consumption of alcohol in this session

Eating out – Eating out is a challenge for people with diabetes. However, eating out should be enjoyable and people can learn how to make healthy choices at any restaurant. Tips to be considered include , Become a 'fat detective': look for high fat foods, Understand portion size and when portion sizes are generous, ask for extra food to be shared or made ready to be taken away.

Alcohol and diabetes: - Recommendations for this involve, for men-two drinks per day or less and for women –one drink per day or less (Annexure 13)

3.2.4. Session -4- Benefits of Physical Activity

Regular physical activity or exercise has been found to provide physiology and psychological benefits that can improve blood glucose control, overall health and quality of health. We will evaluate person before prescribing an exercise regimen .exercise prescription will be developed around the person's goal for activity, their exercise history, diabetes history including control and complication, medical history, orthopaedic conditions, cardiovascular status and motivation/psychological issues.

Technique

The physical activity questionnaire will be used to assess the fitness of the person before beginning an exercise programme, and will be given to every person before an exercise regimen is initiated. An exercise prescription will be developed around the person's goal for activity, their exercise history, diabetes history including control and complication, medical history, orthopaedic condition, cardiovascular status and motivation/psychosocial issues. Household chores, yard work, recreational activities, and activities at work will be included and worked into the plan. Exercise prescription will include, Warm –up period, Period of intense exercise, Cool down period, Plan to increase intensity or duration of activity over time and Specific number of times a week and minutes of activity each day (Annexure 14).We will also discuss the patient about the yoga and its benefits, some yoga asana that are known to benefit the person with diabetes are following Suryanamaskar, Tadasan, Ardhmatsyendrasan, Shavasan etc.

3.2.5. Session -5 Knowledge Regarding Hypoglycaemia and Short Term Complication- In this session we will discuss hypoglycaemia, how it can be prevented, the sign and symptoms and appropriate treatment. It is essential for people with diabetes to know the cause, sign and symptoms, treatment and prevention strategies to minimise the risk of developing these complication.

Technique

General group discussion, PowerPoint presentation, posters, charts, leaflets will be used to disseminate the knowledge to the subject regarding the topic, and session will be organized for small-small groups so that one to one interaction can take place. Symptom related to the hypoglycaemia and hyperglycemia will be explained to them and treatment plan will be issued to them.

Cost of pharmacological treatment – Data regarding the cost incurred on pharmacological treatment of the subjects will be collected for 4 months prior to the participation in the educational intervention programme and during midterm intervention and post intervention.

Midterm intervention: - It will be done after two months of completion of intervention phase. In this, we will be performing blood sugar and assess the cost of pharmacological expenditure for both control and experimental group will be collected.

PHASE 3- Post Intervention

After completion of intervention phase (4-6 month) the impact of Educational Intervention regarding diabetes and its management will be analysed. For this purpose questionnaire related to life style, Health Perception Scale, and assessment of knowledge regarding diabetes**.** Both the control and experiment group will be filled again in order to compare their result and see the impact of educational intervention. Assessment of nutritional status will also be performed again for both the groups and results will be compared under following heads:-Anthropometry measurement, Dietary assessment, Clinical examination, Biochemical assessment and money spent on pharmacological treatment.

Statistical analysis: - The entire data will be finally tabulated and statistically analysed using appropriate statically tests:-frequency, chi square test, Mean and standard deviation, test etc.

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Annexure

Annexure 1

Annexure 2

Annexure 3.

Waist –to –hip ratio(cut offs for Asian)

Male	Female	Health risk based on WHR
0.95 or below	0.80 or below	Low risk
0.96-1.0	0.81-0.85	Moderate risk
1.0+	0.85+	High risk

Source-http://www.dietandfitnesstoday.com/waist-to-hip-ratio.php

Annexure 4

Annexure 5

Annexure 6

Condition	2 hour glucose	Fasting glucose	HbA_{1c}
	mmol/l(mg/dl)	mmol/l(mg/dl)	%
Normal	<7.8 (<140)	<6.1 (<110)	<6.0
Impaired fasting glycaemia	<7.8 (<140)	≥ 6.1(≥110) & <7.0(<126)	6.0-6.4
Impaired glucose tolerance	≥7.8 (≥140)	<7.0 (<126)	6.0-6.4
Diabetes mellitus	≥11.1 (≥200)	≥7.0 (≥126)	≥6.5

Target blood glucose levels

	HbA1c	Pre meal	2 hours post meal
IDF global guideline for type 2 diabetes	<6.5%	<110 mg/dl	<145 mg/dl
Target for most people with diabetes	<7%	90-130 mg/dl	<180 mg/dl

Source-IDF, 2005; ADA 2007

Annexure 7. Food Pyramid

Annexure 8 Plate method

Annexure 9

Annexure 10 Healthy and unhealthy food choices while planning a diet for people with diabetes.

Food groups	Green zone	Yellow zone	Red zone
Rice	Steamed rice	Pulao	Fried rice/biryani
Bread	Whole wheat bread	White bread	Cakes
Noodles	Steamed noodles		Deep fried noodles
Indian breads	Chapatti	Plain naan	Butter naan/ puri
Potatoes	Baked potatoes		French fries
Vegetables	Steamed vegetables	Sautéed vegetable	Deep fried vegetables
Salad	Green salad		Salad with mayonnaise
Sauce	Tomato based		Cream based
Fish	Steamed fish	Fish curry	Fried fish
Chicken	Grilled chicken	Pan fried	Butter chicken
Fruits	Apple, orange, peach ,guava	Unsweetened fruit juice	Sweetened fruit juice

Adapted from IDF slides –curriculum module 3-5: nutrition therapy

Annexure 11 Classification of foods that are high and low in fibre

Food groups	High fibre foods	Low fibre foods
Cereals	Whole cereals like whole wheat dalia ,whole wheat flour, brown bread	Refined cereals like rice ,white bread, suji, maida and its product,noodeles,macaroni
Pulses	Whole dal and dal with husk	Washed/dehusked dal
Meat ,fish ,poultry		Eggs, chicken ,fish
Vegetables	Peas ,beans lotus stem etc	Potato, yam
Fruits	Apple,cherries,pear ,peaches, plums ,guava	Fruit juices, squashes
Fats		Fats,oils,ghee,butter

Annexure 12

Common source of different fats

Fats	Sources
Saturated	Red meats ,butter ,cheese, margarine ,ghee, whole milk, cream
Polyunsaturated	Safflower oil, sunflower oil, corn oil
Monounsaturated	Olive oil, canola oil, ground nut oil, mustard oil, sesame oil
Trans fats	Baked product ,biscuits, cakes

Annexure 13

Below mentioned table can be used as a guide for selection of drink

Type of drink	Measure	Calories(average)
Whisky, gin, rum, vodka	30 ml	90 calories
Beer	650 ml	400 calories

Sweet wines	100 ml	130 calories
Dry wines	100 ml	90 calories

Annexure 14

.Exercise prescription –walking programme

Week	Warm Up	Target Zone Exercising*	Cool Down Time	Total Time
Week 1				
Session A	Walk normally 5 minutes	Then walk briskly 5 minutes	Then walk normally 5 minutes	15 minutes
Session B	Repeat above pattern			
Session C	Repeat above pattern			
Continue with at least three exercise sessions during each week of the program. If you find a particular week's pattern tiring, repeat it before going on to the next pattern. You do not have to complete the walking program in 12 weeks.				
Week 2	Walk 5 minutes	Walk briskly 7 minutes	Walk 5 minutes	17 minutes
Week 3	Walk 5 minutes	Walk briskly 9 minutes	Walk 5 minutes	19 minutes
Week 4	Walk 5 minutes	Walk briskly 11 minutes	Walk 5 minutes	21 minutes
Week 5	Walk 5 minutes	Walk briskly 13 minutes	Walk 5 minutes	23 minutes
Week 6	Walk 5 minutes	Walk briskly 15 minutes	Walk 5 minutes	25 minutes

Week 7	Walk 5 minutes	Walk briskly 18 minutes	Walk 5 minutes	28 minutes
Week 8	Walk 5 minutes	Walk briskly 20 minutes	Walk 5 minutes	30 minutes
Week 9	Walk 5 minutes	Walk briskly 23 minutes	Walk 5 minutes	33 minutes
Week 10	Walk 5 minutes	Walk briskly 26 minutes	Walk 5 minutes	36 minutes
Week 11	Walk 5 minutes	Walk briskly 28 minutes	Walk 5 minutes	38 minutes
Week 12	Walk 5 minutes	Walk briskly 30 minutes	Walk 5 minutes	40 minutes

Source- exercise and your heart, lung and blood institute/American Heart Association, NIH Publication no.93-1677, august1993