A STUDY TO ASSESS THE EFFECTIVENESS OF FENUGREEK SEED POWDER IN CONTROL OF BLOOD SUGAR LEVEL AMONG TYPE II DIABETES MELLITUS CLIENTS ATTENDING DIABETIC OUT PATIENT DEPARTMENT IN GOVERNMENT RAJAJI HOSPITAL, MADURAI.

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CERTIFICATE

This to certify that this dissertation titled, "A STUDY TO ASSESS THE EFFECTIVENESS OF FENUGREEK SEED POWDER IN CONTROL OF BLOOD SUGAR LEVEL AMONG TYPE II DIABETES MELLITUS CLIENTS ATTENDING DIABETIC OUT PATIENT DEPARTMENT IN GOVERNMENT RAJAJI HOSPITAL, MADURAI" is a bonafide work done by Ms. J. Poornima Mary Rodriguez, College of Nursing, Madurai Medical College, Madurai – 20, submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the university rules and regulations towards the award of degree of Master of Science in Nursing Branch IV Community Health Nursing under our guidance and supervision during the academic period from 2010 – 2011.

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ABSTRACT

Introduction: Diabetes Mellitus is a dreadful disease affecting majority of population worldwide. The estimated diabetes prevalence for 2010 worldwide is 285 million people corresponding to 6.4% of the world's adult population. The study was done to identify the effectiveness of fenugreek seed powder in control of blood sugar level among Type II Diabetes Mellitus clients attending diabetic outpatient department in Government Rajaji Hospital, Madurai. The main objective was to compare the pre and post blood sugar level in relation to intake of fenugreek seed powder among clients in experimental and control group. Methodology: The research design was pretest posttest design, by using simple random sampling technique, 60 type II Diabetes Mellitus clients. 30 in experimental group and 30 in control group were selected. 5 gram of Fenugreek Seed Powder was administered in early morning before breakfast for clients in experimental group for 30 days. The conceptual frame work was based on modified model of Wiedenbach's helping Art of clinical nursing theory. **Results:** The findings of the study showed that there was a significant (P<0.001) reduction in blood sugar level after administering fenugreek seed powder in experimental group. **Discussion:** It was identified that Fenugreek Seed Powder was effective in reducing blood sugar level. Fenugreek is cost effective, improves the general well being of client, prevents them from developing complications and reduces the dosage of drugs.

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CHAPTER - I

Introduction

"Many Little Things done by Many Little People in Many Little Places can change the Face of Earth"

Diabetes Mellitus means in Greek, "passing through honey". It is a disease which affects almost every organ of the body and is aptly titled the silent killer.

Diabetes is a long term disease with variable clinical manifestations and progressions chronic hyperglycemia, from whatever cause, leads to a number of complications like cardiovascular, renal, neurological, ocular and others such as intercurrent infections. (Park 2009)

The estimated diabetes prevalence for 2010 worldwide is 285 million people corresponding to 6.4% of the world's adult population. By 2030, the number of people with diabetes is estimated to have risen to 438 million. Far the highest increases in prevalence will happen in developing countries and this only confirms that diabetes is a disease associated with poverty. The major burden of the disease is borne by the low and middle income countries and it disproportionately affects the lower socio-economic groups, the disadvantaged and the minorities in the richer countries.

The estimates for both 2010 and 2030 showed little gender difference in the number of people with diabetes. 2010 statistics reported that there are expected to be one million more women than men with diabetes. However, this difference is expected to increase to six million by 2030.

(International Diabetic Federation-2010)

Diabetes is going to have a tremendous adverse effect of health and economy of our nation so it is essential to implement measures to treat the diabetes and decrease the incidence of Diabetic complications.

1.1 Need for the study:

Type II diabetes mellitus is a growing problem worldwide. India has the highest rate of diabetes in the world and Indians are particularly known to be at risk of developing the disease.

As per the diabetic statistics 2010, include the fact that there is one person in the world dying of diabetes every 10 seconds. Also there will be 2 new diabetic cases in the world being identified every 10 seconds.

Two major concerns are that much of this increase in diabetes will occur in developing countries, due to population growth, ageing, unhealthy sicks, obesity and sedentary life styles and there is a growing incidence of Type II diabetes – which accounts for about 90% of all cases at a younger age.

(CD Rajiv Gupta 2008)

Eye and Kidney disease are more common in India because of poorer diabetic control and late diagnosis of disease by which time complications such as eye and kidney disease have already developed.

(Rahul Potluri, 2007)

There are 6 million new diabetes sufferers in the world each year. Diabetes is now the fourth biggest cause of death worldwide. One million amputations each year are caused by Diabetes. Diabetes raises the sufferer's risk of developing a cardiovascular disease by two to four times.

It is estimated that diabetes accounts for 5% to 10% of nation's health budgets.

Economic Burden to Nation:

Due to its chronic nature, the severity of its complications and the means required to control them, diabetes is a costly disease, not only for affected individuals and their families, but also for the health systems.

Studies in India estimates that, for a low income Indian family with an adult with diabetes as much as 25% family income may be devoted to diabetes care. (Shaban Tharkar -2008)

Death and Disability

The International Diabetes federation (2010) estimates that the equivalent of an additional 23 million year of life are lost each year to the disability and reduced quality of life caused by diabetes complications.

In a recent study, Indians are susceptible to major complications related to diabetes like coronary artery disease, neuropathy, nephropathy and retinopathy. Prevalence of the complications are higher in low socio economic groups due to lack of good control of glycaemia and hypertension also due to behavioral factors.

There is an urgent need to implement preventive measures to reduce the high morbidity and mortality and to reduce the cost burden to patients and to the society.

(A Ram Chandra, 2009)

Global medical care expenditure for Diabetes

The International Federation reported that Diabetes threatens the health and economic prosperity of people in low and middle income countries. It also predicted that diabetes would cost the world economy at least \$376 billion in 2010, or 11.6 per of the total world health care expenditure. It was identified that by 2030, this number is projected to exceed \$490 billion. More than 80 per cent of spending on diabetes is in the world's richest countries and not in the poorer countries, where over 70 per cent

of people with diabetes live. India currently spends \$2.8 billion or one per cent of the global total expenditure. Diabetes will impose a huge economic burden on India and other countries. Apart form losing billions in lost productivity, India will also be spending \$2.8 billion annually on diabetes control measures by 2011. There are estimated to be 285 million diabetes cases. Diabetes, along with cardiovascular disease, cancer and chronic respiratory diseases, accounts for 60 percent of all deaths worldwide.

Diabetes imposes a large economic burden on the individual, national healthcare system and economy. Diabetes often goes undiagnosed in many people because they have only minor symptoms especially in the initial stages. (Ram Murthy 2010)

90% of diabetic complications can be prevented by appropriate control of diet and weight. Fenugreek is a remedy much used to regulate the glucose levels in diabetes. It has been mentioned in Indian, Chinese and Unani Medical Scriptures.

Current research is focused on claims that fenugreek is effective in treating Type II Diabetes Mellitus. 4 – Hydroxy-isoleucine which is a type of amino acid derived from fenugreek which has been found to increase the secretion of insulin from dormant islets of langerhans cells. It also reduces resistance to insulin and maintains glucose levels in the body.

Fenugreek is also very effective in keeping the Low Density Lipoprotein level low and raises the High Density Lipoprotein level in diabetes which helps in preventing complications associated with diabetes. Fenugreek also contains a number of antioxidants which protect the body from the damage of free radicals. (Lucy Tashman, 2009)

As per the diabetic statistics, the prevalence of diabetes and complications are high, and in order to improve the quality of life of diabetic clients, the investigator is motivated to study the effectiveness of fenugreek seed powder in control of blood sugar level among Diabetes Mellitus clients.

Recent studies revealed that on administration of fenugreek seed powder for a period of three weeks significantly improved the performance of Type II diabetic patients in the glucose tolerance test. This effect was found to be sustained and lasting with no undesirable side effects. Within the duration of this study there were no new incidences of heart problems such as angina and myocardial infection and no increase in blood pressure, indicating that fenugreek may be helpful in preventing the secondary complications of diabetes such as hyperlipidemia and atherosclerosis.

1.2 Statement of the Problem:

A study to assess the effectiveness of fenugreek seed powder in control of blood sugar level among Type II Diabetes Mellitus clients attending Diabetic Out Patient Department in Government Rajaji Hospital, Madurai.

1.3 Objectives:

- ❖ To compare the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group.
- ❖ To compare the pre and post Blood Sugar Level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental and control group.
- ❖ To associate the selected demographic variables and post intervention response of fenugreek seed powder in blood sugar level among Type II Diabetes Mellitus clients in experimental group.

1.4 Hypothesis:

- There will be a significant difference in pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group.
- There will be a significant difference in the pre and post blood sugar level
 in relation to intake of fenugreek seed powder among Type II Diabetes
 Mellitus clients in experimental and control group.
- There will be a significant association between the selected demographic variables and post intervention response of fenugreek seed powder in blood sugar level among Type II Diabetes Mellitus clients in experimental group.

1.5 Operational Definition:

Effectiveness:

It is the outcome of fenugreek seed powder in reducing blood sugar among Type II Diabetes Mellitus clients.

Fenugreek seed:

Fenugreek is an annual dicotyledonous plant belonging to the subfamily Papilionaceae, family Leguminaceae (the Fabaceae) with trifoliate leaves, branched stems, white flowers, roots bearing nodules and golden yellow seeds which are hard, yellowish brown and angular with a side of about 3mm.

Fenugreek seed powder:

It refers to 5 gm of fenugreek seed dried and powdered.

Type II Diabetes mellitus:

It is characterized by inappropriate insulin production and is also related to increased resistance to insulin at cell level.

1.6 Assumption:

- Type II Diabetes Mellitus clients will be willing to participate in the study
- ❖ Tool prepared for the study would be sufficient for collecting information regarding effectiveness of intake of fenugreek seed powder in maintaining normal blood sugar level
- Intake of fenugreek seed powder will have significant reduction in blood sugar level among Type II Diabetes Mellitus clients.

1.7 Delimitation:

The clients are selected only from Diabetic out Patient Department of Government Rajaji Hospital, Madurai.

CHAPTER II

Review of Literature

A synthesis of existing published writings that describes what is known or has been studied regarding the particular research question/purpose. (Carol L. Macnee, 2004)

2.1 Review of Research Studies are presented under 3 headings:

- I. Studies related to Fenugreek Seeds,
- II Studies related to Fenugreek Seed powder and diabetes mellitus
- III Studies related to diabetes mellitus on selected variables.

I. STUDIES RELATED TO FENUGREEK SEED

According to Abu Saleh M. Moosa, (2006) studied the effects of fenugreek serum lipid profile in hypercholesteremic Type II diabetic clients, on administration of 25 gm of fenugreek seed powder orally twice daily for 3 weeks and 6 weeks .The findings revealed that there was significant (P<0.001) reduction of serum total cholesterol, triacylglyceride and LDL-cholesterol in hypercholesteremic group. The study concluded that fenugreek seed powder would be considered as effective agent for lipid lowering purposes.

According to <u>Pandian RS</u>, <u>Anuradha CV</u>, <u>Viswanathan P</u>. (2002) the gastroprotective effect of fenugreek seeds were studied, on the basis of the effect of fenugreek seeds compared to omeprazole. The aqueous extract and a gel fraction isolated from the seeds showed significant ulcer protective effects. The cytoprotective effect of the seeds was due to the anti-secretory action but also due to the effects on mucosal glycoproteins. The fenugreek seeds prevented the rise in lipid peroxidation induced by ethanol presumably by enhancing antioxidant potential of the gastric mucosa thereby lowering mucosal injury</u>. Histological studies revealed that the

soluble gel fraction derived from the seeds was more effective than omeprazole in preventing lesion formation. These observations show that fenugreek seeds possess antiulcer potential.

According to M. Prasanna (2000) the hypolipidemic effect of fenugreek in hypercholesterolemia clients were studied. The Fenugreek seeds (FG) were powdered and was used for the study. The clients were divided into 3 groups of 6 each as follows: Group I received placebo 50 gm (rice powder and Bengal gram powder in equal measures) Group II -placebo 25 gm and Fenugreek 25 gm and Group III - Fenugreek 50 gm. Clients were directed to take each 50 gm pack orally before lunch and dinner every day for 20days. Blood samples were collected after overnight fasting on 0, 10th and 20th days during test period and estimated for lipid profile. There were no significant changes in lipid profile of group I clients. In groups II and III serum cholesterol, triglycerides and VLDL levels were significantly decreased when compared to group I. The study proved that Fenugreek powder given orally before food at 25gm and 50 gm twice a day have hypolipidemic effect.

According to Swafford S, Berens B. (2000) studied effect of fenugreek on breast milk production. The Objective is to assess the effect of fenugreek on breast milk production in exclusively breast-pumping women. Ten women kept diaries of their breast milk production for two weeks. The first week established baseline milk production. During the second week three capsules of fenugreek seed were taken three times daily. Average daily pump volumes for week 1 and week 2 were compared. These values were statistically analyzed using the Wilcoxon signed rank test. The average daily milk volume for week 1 was 207 ml compared to 464 for week 2. This increase was statistically significant (P=0.004). The use of fenugreek significantly increased volume of breast milk produced.

II. STUDIES RELATED TO FENUGREEK SEED POWDER AND DIABETES MELLITUS

According to Hiba A Bawadi (2009), Trigonella foenum-groecum has been reported to be beneficial for treating Type II Diabetes Mellitus. The study was conducted to investigate the postprandial hypoglycemic effect of fenugreek seeds on clients with Type II Diabetes Mellitus. Pretest - posttest control group design was used to test the hypothesis that fenugreek may have a hypoglycemic effect on blood sugar. One hundred sixty-six Type II Diabetes Mellitus clients were assigned into Fenugreek 0 (control group placebo drink), fenugreek 2.5 gm and fenugreek 5gm. The participants were instructed to drink the extract and chew the seeds. Postprandial plasma glucose level was measured before and 2 hours after the administration of the treatment. The clients in fenugreek 5gm group showed the greatest decrease postprandial glucose with a pretest-posttest difference of 41±6.1 mg/dl. Two hour plasma glucose dropped. Fenugreek seeds appear to have significant hypoglycemic activity in Type II Diabetes Mellitus clients.

According to Analava Mitra, D Bhattacharya, (2009) the present study was done to see the effects of different doses of fenugreek in Type II diabetes mellitus clients. Eighty (80) clients were chosen from a random rural population suffering from Type II diabetes mellitus with dyslipidaemia. Fenugreek seed powder in the diet in doses of 25 g, 50 g, 75 g and 100 g/day, were consumed by the clients in powdered form mixed with water as a drink. It was observed that reduction in blood sugar maintained a direct relationship with do of fenugreek given up to 75 g/day.

Nahas. R. (2009) observed on complementary and alternative medicine for the treatment of Type II diabetes mellitus. 50 clients added 25 g of defatted seed powder

to 1 meal for 15 days. The results reported that a decrease in fasting and post prandial blood sugar level.

According to Gupta & Gupta R.Lal B (2007) a study was done to evaluate the effects of Trigonella foenum-graecum (fenugreek) seeds on Type II diabetes mellitus. Twenty five newly diagnosed clients with Type II diabetes (fasting glucose < 200 mg/dl) were randomly divided into two groups. Group I (n 12) received 1 gm/day hydro alcoholic extract of fenugreek seeds and Group II (n=13) received usual care (dietary control, exercise) and placebo capsules for two months In group 1 as compared to group 2 at the end of two months, fasting blood glucose and post prandial. Serum triglyceride decreased and HDL cholesterol increased significantly in group 1 as compared to group 2 (p< 0.05). The study included that adjunct use of fenugreek seeds have significant reduction in Blood sugar level in Type II diabetes mellitus clients. There is also a favorable effect on hypertriglyceridemia.

According to Gupta A (2007), 25 Type II diabetic clients N=12 (fenugreek group) N=13 (Placebo group) were given the dose of 1 g/day hydro alcoholic extract of fenugreek seeds for 2 months. The results showed that the Fenugreek significantly reduced both fasting and postprandial blood glucose levels.

According to Bardia (2001) the Subjects were 20 Type II diabetes mellitus clients 2.5 g fenugreek seed twice daily for 30 days; the result showed that the fenugreek significantly reduced both fasting and postprandial blood glucose levels.

According to R. D. Sharma Ph.D (2001) the hypoglycemic effect of Fenugreek seed powder (Trigonella foenum graecum) was studied in 60 Type II diabetes mellitus clients. A prescribed diet with and without Fenugreek seed powder was given to clients for 7 days of a control period and for 24 weeks of the experimental period. During the experimental period twenty five grams of Fenugreek seed powder divided

into two equal doses was added to the diet and served during lunch and dinner. Diet containing Fenugreek seed powder lowered fasting blood glucose levels and improved glucose tolerance. Insulin levels were also diminished. Twenty four hour urinary sugar excretion was reduced significantly (p < 0.001). Glycosylated hemoglobin measured at the end of the 8th week of Fenugreek seed powder administration was reduced significantly (p <0.001). This shows that feeding Fenugreek seed powder is beneficial to diabetic subjects.

According to Raghuram TC (2001) 10 Type II diabetes mellitus clients (Aged between 38-54 yrs) were given the dose of 25g powdered fenugreek seed divided in to two equal doses for 15 days. The result showed that the mean plasma glucose levels were significantly reduced. Area under the curve (AUC) reduced. Increase in glucose metabolic clearance rate was significant.

Sharma and Raghuram (2001) in an RCT, studied the effects of a diet enriched with fenugreek seeds on Type II diabetes mellitus clients at the National Institute of Nutrition Researchition, Hyderabad, India, using a randomized, crossover design in two trials. The first group consisted of 15 clients randomized to receive a fenugreek enriched diet either during the first 10 days of the trial or during the second 10 days. These clients (33 percent female, ages 32 to 60) had diabetes from 2 months to 16 years. The second group consisted of five Type II diabetes mellitus clients (ages 35 to 58) who were also randomized to receive a fenugreek-enriched diet for either the first or second 20 days of the trial. The researchers concluded that the addition of 100 g of fenugreek seeds to the daily diet of Type II diabetes mellitus clients could be effective supportive therapy in the prevention and management of long-term complications of diabetes.

III. STUDIES RELATED TO DIABETES AND DEMOGRAPHIC VARIABLES

According to Rostam Golmohammadi and Bahrami Abdulrabman (2006), the study aimed to identify the relation between occupation stress and the development of Type II diabetes mellitus. We selected 123 employees among 3229 people that diagnosed as Type II diabetes mellitus as subject group and also 150 people, that has normal blood glucose as control group. First questionnaire was used to report characteristics of each subject and second questionnaire has 55 questions about work condition, job environment and personal feeling. This research suggested that occupational stress is related to the development of Type II diabetes mellitus and stress related to interpersonal relationship, physical demands and lack of job interest.

According to EstaChio and Schrier, (2005) the study aimed to identify the association between diabetic complications and exercise capacity in non insulin dependent diabetes mellitus clients. It has been demonstrated previously in Type2 Diabetes Mellitus clients that several risk factors (i.e., obesity, smoking, hypertension, and African-American race) are associated with an impaired exercise capacity. We studied 265 male and 154 female NIDDM clients who underwent graded exercise testing with expired gas analyses to determine the possible influences of diabetic neuropathy, nephropathy, and retinopathy on exercise capacity. The results were obtained controlling for age, sex, length of diagnosed diabetes, hypertension, race, and BMI. Thus the findings in this large Type II Diabetes Mellitus population without a history of coronary artery disease indicate a potential pathogenic relationship between micro vascular disease and exercise capacity.

According to Morikawa Y (2005) to investigate the relation between occupation and the development of Type II Diabetes Mellitus, we undertook a 10-year follow-up survey of male employees of a zipper and aluminum sash factory in Japan. Of 1,218 employees we followed 1,087 subjects. We classified the subjects into five

occupations: managers, technical workers, clerical workers, workers in transport, and laborers. The age-adjusted incidence of the workers in transport was the highest and that in laborers was the lowest. We used a multiple logistic analysis for adjustment with baseline characteristics such as age, BMI, fasting plasma glucose, and family history of diabetes mellitus. Adjusted relative risk of the workers in transport compared with the laborers was significantly high (3.95). Our work suggests that occupation is related to the development of Type II Diabetes Mellitus.

According to the Sotetsu study (2005), the study aimed to identify the relationship between weight change in your adulthood and the risk of Type II Diabetes Mellitus, the objective is to investigate the independent effect of weight change in young adulthood on the risk of prevalent Type II diabetes mellitus among middle-aged Japanese men, a case-control study was carried out in 895 male employees aged> or = 30 years of a railway company located in the vicinity of Tokyo. Adjusted odds ratios were calculated for prevalent diabetes in each category of weight change (obtained from subjects' medical records) in young adulthood and adulthood. Adjustment for current age, initial BMI, and weight change in each age stratum was performed by the Mantel-Haenszel method or multiple logistic regression analysis, it was identified that the weight change between 20 years of age at maxim weight was not associated with the risk of Type II diabetes mellitus. Weight gain between 20 and 25 years of age was significantly and positively associated with the risk of Type II Diabetes Mellitus.

According to Baba, Kuroda N (2005), the influence of age on diabetic autonomic neuropathy was studied. In the present study autonomic neuropathy was assessed by cardiac beat-to-beat variation during deep breathing (BBV) and pupil area prior to photic stimulus (Al). In the studies on BBV a total of 440 subjects (11-82)

years in age) were divided into three groups: those with duration of diabetes of less than 5 years and without obvious diabetic complications; those with duration of diabetes of longer than 5 years and with diabetic complications; and non-diabetic, healthy subjects. The relationship between BBV and age was examined in each group. In the studies on Al a total of 101 subjects (22-75 years in age) were investigated in the same way. The results were as follows: (1) The autonomic nerve function of young diabetics corresponds to that of old non-diabetics in terms of cardiac beat-to-beat variation and pupil area prior to photic stimulus; (2) in young diabetics duration of diabetes and the complications influence the autonomic nerve function; (3) autonomic nerve function is related to age. Age is more influential than duration of diabetes and diabetic complications, especially in the older subjects.

2.2 Conceptual Frame work

The conceptual frame work for research study presents the measure on which the purpose of the proposed study is based. The framework provides the perspective from which the investigator views the problem.

The study is based on the concept that administration of 5 gm Fenugreek Seed Powder to clients with Type II Diabetes Mellitus will control blood sugar level. The investigator adopted the Wiedenbach's helping Art of clinical Nursing Theory (1964) as a base for developing the conceptual frame work. Ernestin wiedenbach proposes helping art of clinical nursing theory in 1964 for nursing, which describes a desired situation and way to attain it. It directs action towards the explicit goal. This theory has three factors:

- Central Purpose
- Prescription
- Realities

Central Purpose:

It refers to what the nurse wants to accomplish. It is the overall goal towards which a nurse strives.

Prescription:

It refers to plan of care for a patient. It will specify the nature of action that will fulfill the nurse's central purpose

Realities:

It refers to the physical, physiological, emotional and spiritual factors that come in to play in situation involving nursing action. The five realities identified by Wiedenbach's are agent, recipient, goal, means and framework.

The conceptualization of nursing practice according to this theory consists of three steps as follows:

Step 1: Identifying the need for help

Step 2: Ministering the needed help

Step 3: Validating that the need for help was met.

Step 1: Identifying the need for help

This step involves determining the need for help. The Type II diabetes mellitus clients were identified based on demographic variables (Age, Sex, Education, occupation, family Income, family history, diet pattern, exercises, drug compliance, sleep pattern, body mass index) inclusive and exclusive criteria, simple random sampling technique was used to assign the clients in experimental and control group

Step 2: Ministering the needed help

5 gm of Fenugreek Seed Powder was given to experimental group

Agent → investigator

Recipient → Type II Diabetes Mellitus clients

Goal \rightarrow a. To reduce blood sugar level

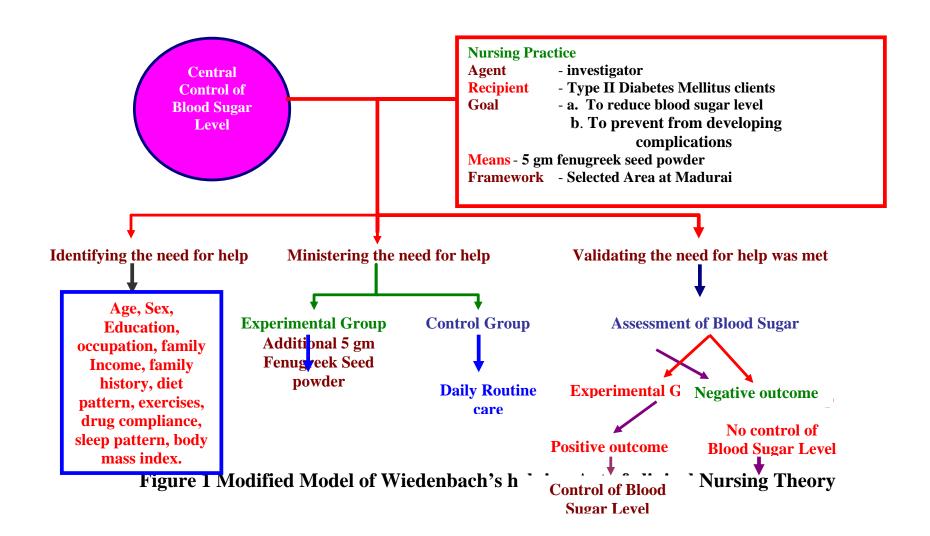
b. To prevent from developing complications.

Means → 5 gm Fenugreek Seed Powder

Frame work → Selected Area at Madurai

Step 3: Validating that need for help was met.

It is accomplished by means of post assessment of Blood sugar level. It is followed by analysis of the findings.



CHAPTER - III

Methodology

This chapter includes research approach, research design, variables, setting of the study, population, sample and sample size, sampling technique, developing of tool, content validity, Pilot study, data collection procedure, plan for data analyses and ethical consideration.

3.1 Research Approach:

The research approach used for this study is quantitative approach.

3.2 Research Design:

The overall plan for addressing a research question, including specifications for enhancing the study's integrity is referred to as Research Design.

The Pretest-Post test (before after) design.

RE 0_1 x 0_2

RC 0_3 - 0_4

 $R \rightarrow Randomization$

E → Experimental Group

 $C \rightarrow Control Group$

 $X \rightarrow Intervention$

O \rightarrow Observation

3.3 Research Variables

Variables included in the study are

Dependent Variable → Level of Blood sugar

Independent Variable → Fenugreek Seed Powder

Demographic Variables → Age, Sex, Education, occupation, income, family history, diet pattern, Non-vegetarian food intake, green leafy vegetables intake, roots and tubers intake, intake of sweets, intake of coffee/tea, exercise, checking blood glucose level, drug compliance, sleep pattern, Body mass Index

3.4 Setting of the study:

The setting was selected based on the feasibility of conducting the study, availability of sampling and proximity of setting to the investigator.

Main Study:

The main study was conducted among client's attending Diabetic out Patient Department in Government Rajaji Hospital, Madurai.

Pilot Study:

Pilot Study was also conducted in same setting with small sample size.

3.5 Population

Target Population:

The entire population in which the researcher is interested and to which he or she would like to generalize the results of a study. The study population comprises of all type II Diabetes Mellitus clients.

Accessible Population:

The population of people available for a particular study.

The Diabetes Mellitus clients those who are attending diabetic Out Patient Department in Government Rajaji Hospital, Madurai.

3.6 Sample:

A subset of a population, selected to participate in a study.

Main study - 60 diabetic clients

Pilot Study - 10 diabetic clients.

3.7 Criteria for sample selection

Inclusion criteria:

- Individuals who are taking oral hypoglycemic drugs Metformin 500 mg. and Glypenclamide 5 mg.
- Clients whose random blood sugar level is above 200 mg/dl.
- Clients aged between 31-60 years
- Both genders are included in this study.
- Clients with Type II diabetes mellitus within 5 year duration.

Exclusion Criteria:

- * Those with insulin dependent diabetes mellitus
- ❖ Those with gestational diabetes mellitus and Juvenile diabetes mellitus
- Those taking anti coagulants and antihypertensive drugs.
- Those with cardiovascular, Renal and neurological problems.
- Those with history of alcoholism and smoking
- Those who are not willing to participate in study

3.8 Sampling Technique:

Simple Random Sampling

In this technique the samples are selected at random from the sampling frame. By using this technique 60 Type II Diabetes Mellitus clients were selected, 30 in experimental group and 30 in control group.

3.9 Development and Description of Tool:

The tool used in this study was an interview/observation schedule on blood sugar for Type 2 diabetes Mellitus clients.

Section A: Demographic data of Type 2 diabetes Mellitus clients

Section B: Observation schedule on blood sugar.

3.10 Validity of the tool:

Content validity refers to the degree to which an instrument measures what is supposed to measure.

The data collection tool was submitted to 7 experts to obtain their content validity. Among them 5 were from nursing, two from medicine.

Based on their recommendation, few items were modified. The tool was first drafted in English and then translated into Tamil language. Validity was established by retranslating the tool to English.

3.11 Reliability of the tool:

The reliability of the tool was established by inter rater reliability method. The obtained reliability coefficient was high (r=0.99)

3.12 Pilot Study:

The pilot study was conducted in Diabetic out Patient Department of Government Rajaji Hospital, Madurai by obtaining prior permission from authorities. The pilot study was conducted in October 21 to October 28, 2011, 10 clients were selected as samples. Background factors were collected by interview method. The feasibility of study was established. Those participants were excluded from the main study.

3.13 Data Collection procedure:

The present study was conducted in Diabetic out Patient Department of Government Rajaji Hospital, Madurai. The data were collected for four weeks. Prior permission was sought and obtained from authorities.

Group of Type II diabetes Mellitus clients were selected. By using simple random sampling method the clients were selected, 30 in experimental and 30 in control group. The objectives and purpose of study was explained and confidentiality was maintained. Informed consent was obtained. Background data were collected using interview method. Pretest fasting and postprandial blood sugar level was checked in both experimental and control group. In experimental group 5 gm of fenugreek seed powder was given for 30 days. Regularity of the intake of fenugreek seed powder was ascertained by the investigator personally.

Post test was conducted for both groups after one month of intervention.

3.14 Plan for Data Analysis:

Data analysis was done according to the objectives both descriptive and inferential statistics. Analysis was done using SPSS version 16.

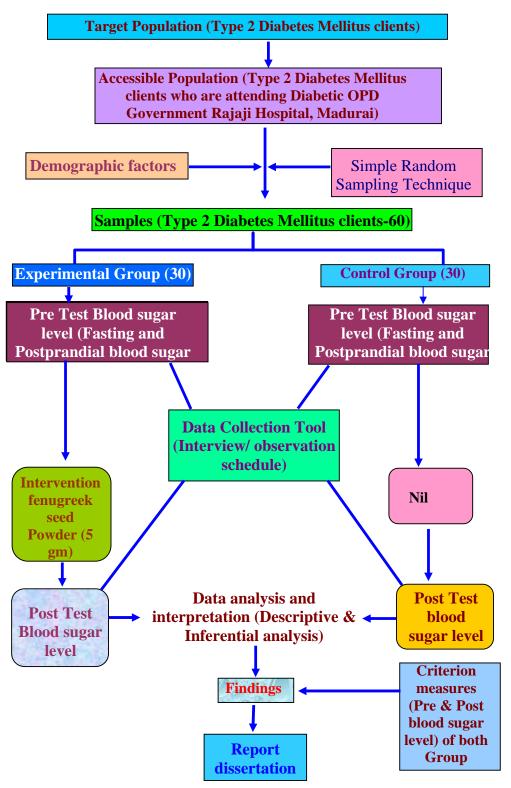
Analysis of demographic data was done by frequency and percentage. Paired 't' test to determine the difference between the pre intervention and post intervention score in terms of effectiveness of fenugreek seed powder. Chi square to determine the association between the selected demographic variables and post interventional score.

3.15 Ethical consideration:

The study objectives, intervention, and data collection procedures were approved by the research and ethical committee of the institution. Main study was conducted after obtaining permission.

Informed consent was obtained from Type II Diabetes Mellitus clients. The freedom was given to the client to leave the study at his/her will without assigning any reason. No routine care was altered or withheld.

FIGURE 2
Schematic Representation of Research Design



CHAPTER IV

Data Analysis and Interpretation

A process that pulls information together or examines connections between pieces of information to make a clearer picture of all of the information collected. (Carol L Macnee, 2004)

Objectives of the study:

- To compare the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group.
- To compare the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group and control group.
- To associate the selected demographic variables and post intervention response of fenugreek seed powder on blood sugar level among Type II Diabetes Mellitus clients in experimental group.

Organization of Data

SECTION A: Distribution of the subjects according to the demographic profile.

SECTION B: Comparison between pre and post blood glucose level in experimental group.

SECTION C: Comparison between pre and post blood glucose level in control group.

SECTION D: Comparison between experimental and control group blood glucose levels.

SECTION E: Association between selected demographic variables.

Section A

 $\label{eq:Table-1} \mbox{DISTRIBUTION OF THE SUBJECTS ACCORDING TO THE THEIR}$ $\mbox{DEMOGRAPHIC PROFILE:}$

S.No	Characteristics	Experime	ntal group	Control Group	
	Cnaracteristics	Frequency	Percentage	Frequency	Percentage
1	Age				
	a) 31-40 years	1	3.3	1	3.3
	b) 41-50 years	13	43.3	22	73.3
	c) 51-60 years	16	53.3	7	23.3
2	Sex	1.5	50	1.5	50
	a) Male	15	50	15	50
	b) Female	15	50	15	50
3	Educational status				
	a) Primary	23	76.7	20	66.7
	schooling	23	70.7	20	00.7
	b) High schooling	7	23.3	7	23.3
	c) Higher secondary	0	0	2	6.7
	d) Degree	0	0	1	3.3
4	Occupation				
	a) Sedentary worker	1	3.3	1	3.3
	b) Moderate worker	25	83.3	15	50.0
	c) Heavy worker	4	13.3	14	46.7
5	Family income per				
	year				
	a) Below poverty	19	63.3	15	50.0
	line				
	b) Above poverty	11	36.7	15	50.0
	line	11	30.7	13	30.0
6	Familial history			2	6.7
	a) Father	5	16.7	2	0.7
	b) Mother	1	3.3	5	16.7
	c) Paternal grand	4	13.3	6	20.0
	parent	4	13.3	0	20.0
	d) Maternal grant	2	6.7	2	6.7
	parent	2	0.7	<u> </u>	0.7
	e) Not applicable	18	60.0	15	50.0
7	Diet	17	56.7	6	20.0
	a) Vegetarian	1 /	30.7	U	20.0
	b) Non vegetarian	13	43.3	24	80.0
8	Non vegetarian	2	6.7	1	3.3

S.No	Characteristics	Experime	ntal group	Control Group	
	Characteristics	Frequency	Percentage	Frequency	Percentage
	food pattern				
	b) Twice in a week				
	c) Once in a week	5	16.7	13	43.3
	d) Never	23	76.7	16	53.3
9	Greens food				
	pattern	5	16.7	0	0
	b) Twice in a week				
	c) Once in a week	18	60.0	22	73.3
	d) Never	7	23.3	8	26.7
10	Roots and tubers			1	2.2
	a) Fully restricted	5	16.7	1	3.3
	b) Sometimes I eat	25	83.3	29	96.7
11	Sweet intake	5	16.7	3	10.0
	a) Fully restricted	3	16.7	3	10.0
	b) Sometimes I eat	25	83.3	27	90.0
12	Tea / coffee intake			20	96.7
	a) Two or less	30	100.0	29	90.7
	b) More than two	0	0	1	3.3
13	Exercises	8	26.7	6	20.0
	a) Regular	0	20.7	O	20.0
	b) Irregular	22	73.3	24	80.0
14	Blood glucose				
	status				
	b) Once in three	30	100.0	30	100.0
	month				
15	Drug compliance				
	a) Yes	30	100.0	30	100.0
16	Sleep pattern	24	80.0	22	73.3
	b) 8 hours	24	80.0	22	75.5
	c) More than 8	6	20.0	8	26.7
	hours	U	20.0	U	20.7
17	Body Mass Index	17	56.7	10	33.3
	b) 18.50- 24.99	1/	50.7	10	33.3
	c) 25- 25.99	7	23.3	15	50.0
	d) >30	6	20.0	5	16.7

The above table 1 presents the demographic profile of experimental and control group. In experimental group 1 (3.3%) was in age group between 31-40 years, 13 (43.3%) were in age group between 41-50 years, 16 (53.3%) were in age group between 51-60 years. By gender 15 (50%) were males, 15 (50%) were females. On the basis of educational status 23 (76.7%) have studied up to primary school, 7 (23.3%) have studied up to high school. By considering their occupation 1 (3.3%) was sedentary worker, 25 (83.3%) were moderate workers, 4 (13.3%) were heavy workers. On interviewing the family income 19 (63.3%) were below poverty line, 11 (36.7%) were above poverty line. On the basis of family history 5 (16.7%) have the history of diabetes mellitus from father, 1 (3.3%) from mother and, 4(13.3%) from paternal grand parent, 2 (6.7%) from maternal grand parent and 18(60%) were not from the above mentioned. The diet pattern shows that 17 (56.7%) were vegetarian, 13 (43.3%) were non vegetarian. On interviewing the non vegetarian food intake 2 (6.7%) consume twice in a week, 5 (16.7%) consumes once in a week, 23 (76.7%) have stopped consuming non vegetarian. As per the green leafy vegetables intake 5 (16.7%) consume twice in a week, 18 (60%) consumes once in a week, 7 (23.3%) never consume. On the basis of roots and tubers intake 5 (16.7%) have full restriction, 25 (83.3%) sometimes consume. By interviewing the sweets intake 5 (16.7%) had full restriction, 25(83.3%) sometimes consume. On the basis of tea/coffee intake per day 30 (100%) consumes two times a day. On the basis of exercise 8 (26.7%) were doing regularly, 22 (73.3%) were irregular in doing exercise. 30 (100%) were checking their blood glucose once in three months. 30 (100%) had drug compliance. As per the sleep pattern 24 (80%) had 8 hours sleep, 6 (20%) more than 8 hours sleep per day. On calculating the body mass index 17 (56.7%) belong to 18.50 – 24.99, 7 (23.3%) belong to 25 - 25.99, 6 (20%) belong to less than 30.

In control group 1 (3.3%) was in age group between 31-40 years, 22 (73.3%) were in age group between 41-50 years, 7 (23.3%) were in age group between 51-60 years. 15(50%) were males and 15(50%) were females. On the basis of educational status 20(66.7%) have studied up to primary school, 7(23.3%) have studied up to high school, 2(6.7%) were higher secondary, 1(3.3%) is a degree holder. By considering their occupation 1 (3.3%) was sedentary workers, 15 (50%) were moderate workers, 14 (46.7%) were heavy workers. As per the family income 15 (50%) were below poverty line, 15 (50%) were above poverty line. On considering the details of family history of diabetes mellitus 2 (6.7%) had the history from father, 5 (16.7%) from mother and, 6 (20%) from paternal grand parent, 2 (6.7%) from maternal grand parent and 15 (50%) were not from the above mentioned. the diet pattern shows that 6 (20%) were vegetarian, 24 (80%) were non vegetarian. On interviewing the non vegetarian food intake 1 (3.3%) consume twice in a week, 13 (43.7%) consumes once in a week, 16 (53.3%) were never consumed. As per the green leafy vegetables intake 22 (73.3%) consumes once in a week, 8 (26.7%) have stopped consuming non vegetarian.. On the basis of roots and tubers intake 1(3.3%) had full restriction, 29 (96.7%) sometime consumes. By interviewing the sweets intake 3 (10%) have full restriction, 27 (90%) sometime consumes. On the basis of tea/coffee intake per day 29 (96.7%) consumes two times a day, and 1 (3.3%) consumes more than two times. On the basis of exercise 6 (20%) were doing regularly, 24 (80%) were irregular in doing exercise. 30 (100%) were checking their blood glucose once in three months. 30 (100%) had drug compliance. As per the sleep pattern 22 (73.3%) had 8 hours sleep per day, 8 (26.7%) more than 8 hours sleep per day. On calculating the body mass index 10 (33.3%) belong to 18.50 – 24.99, 15 (50%) belong to 25 - 25.99, 5 (16.7%) belong to less than 30.

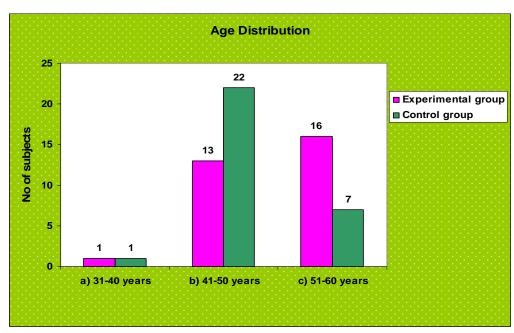


Figure – 3 shows the distribution of subjects in experimental and control group according to their age.

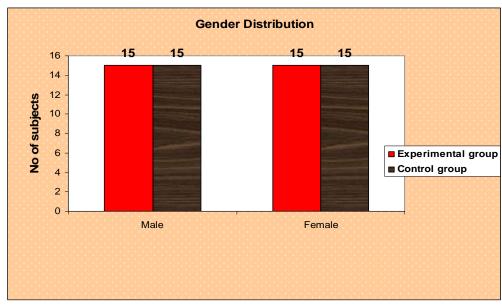


Figure 4 shows the distribution of subject in experimental and control group according to gender.

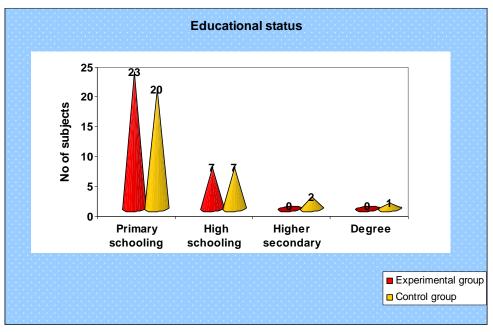


Figure – 5 shows the distribution of subjects in experimental and control group according to their educational back ground.

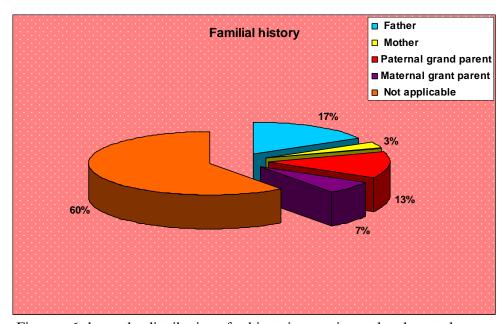


Figure – 6 shows the distribution of subjects in experimental and control group according to their familial history of diabetes mellitus.

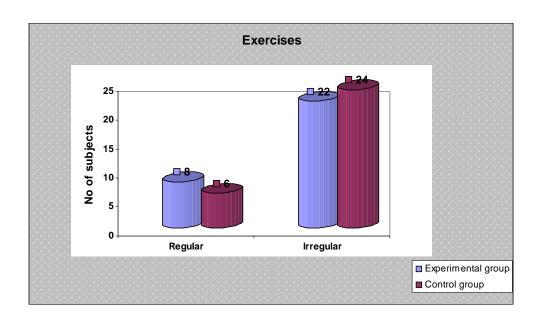


Figure – 7 shows the distribution of subjects in experimental and control group according to exercises.

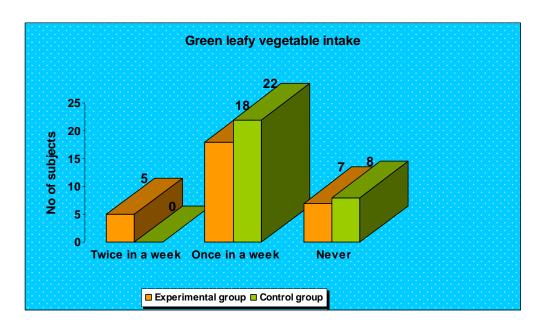


Figure – 8 shows the distribution of subjects in experimental and control group according to their green leafy vegetables intake.

Table - 2

Comparison between pre and post blood sugar level in experimental group

Section B

S.No	Test	N	Mean	S.D	"t" test value (paired)
1	Before intervention fasting blood glucose level	30	124.83	1.487	19.029*
	After intervention fasting blood glucose level	30	110.30	3.687	
2	Before intervention postprandial blood glucose level	30	257.33	6.391	14.931*
	After intervention postprandial blood glucose level	30	174.93	29.518	

* - Significant at 0.001 level

The above table -2 elicits that the obtained "t" values were 19.029, 14.931. The findings implies that there is a significant difference between fasting and postprandial blood sugar level before and after intervention. The mean score of fasting and postprandial blood sugar level 124.83, 110.30, 257.33, 174.93 respectively from pre intervention to post intervention depicts the effectiveness of the intervention as the mean score decreased.

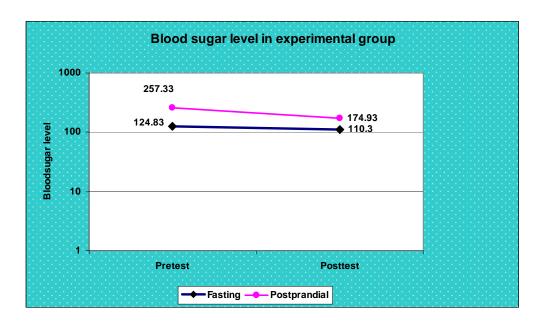


Figure – 9 shows the comparison of blood sugar level in experimental group.

Section C

Table - 3

Comparison between pre and post blood sugar level in control group

S.No	Test	N	Mean	S.D	"t" test value (paired)
1	Before one month fasting				
	blood glucose level	30	121.70	2.628	11.288*
	After one month fasting				
	blood glucose level	30	115.17	4.654	
2	Before one month				
	postprandial blood glucose level	30	256.66	7.696	
	After one month				7.165*
	postprandial blood	30	240.45	12.690	
	glucose level				

* - Significant at 0.001 level

The above table -3 elicits that the obtained "t" values were 11.288, 7.165. The findings implies that there is a significant difference between fasting and postprandial blood sugar level before and after one month during the study period. The mean score of fasting and postprandial blood sugar level 121.70, 115.17,256.66, 240.45 respectively for one month.

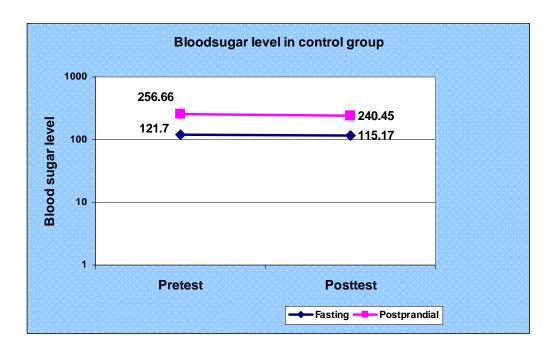


Figure – 10 shows the comparison of blood sugar level in control group.

Section D

Table - 4

Comparison between experimental and control group blood sugar levels

S.No	Test	N	Mean	S.D	"t" test value
1	Experimental Group after intervention fasting blood glucose level	30	110.30	3.687	4.474*
	Control Group after one month fasting blood glucose level	30	115.17	4.654	
2	Experimental Group after intervention postprandial blood glucose level	30	174.93	29.518	9.960*
	Control Group after one month postprandial blood glucose level	30	240.45	12.690	, , , , , , , , , , , , , , , , , , ,

* - Significant at 0.001 level

The above table -4 elicits that the obtained "t" values were 4.474, 9.960. The finding implies that there is a significant difference between fasting and postprandial blood sugar level between experimental and control group. The mean score of fasting and postprandial blood sugar level in experimental and control group are 110.30, 115.17, 174.93, 240.45 respectively which depicts the effectiveness of the intervention in experimental group comparing to control group.

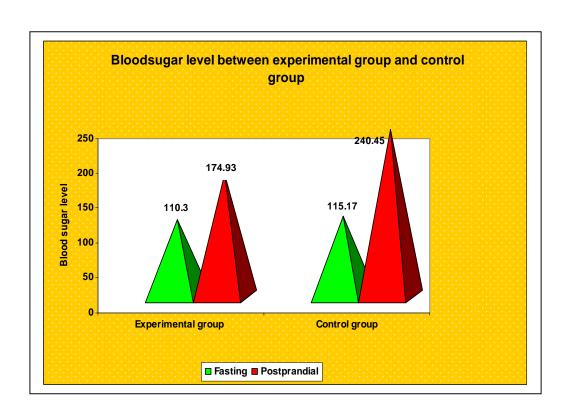


Figure -11 shows the comparison of blood sugar level in experimental group and control group.

Section E

 $Table-5 \label{eq:table-5}$ Association between diet and fenugreek response

	Positive response	Negative response	Total
Vegetarian	16	1	17
Non vegetarian	10	3	13
	26	4	30

$$\chi^2 = 1.88$$

$$P = 3.84$$

In above table calculated value is less than hypothetical value. Therefore it is concluded that, there is no significant difference between diet and blood sugar level.

 $Table-6 \label{eq:table-6}$ Association between green leafy vegetable intake and fenugreek response

Positive	Negative	Total
response	response	Total

Twice in a week	3	2	5
Once in a week	17	1	18
Never	6	1	7
	26	4	30

$$\chi^2 = 4.072$$

$$P = 5.99$$

In above table calculated value is less than hypothetical value. Therefore it is concluded that, there is no significant difference between green leafy vegetable intake and blood sugar level.

Table-7 Association between exercise and fenugreek response

	Positive response	Negative response	Total
Regular	7	1	8
Irregular	19	3	22

26	4	30

$$\chi^2 \qquad = \ 0.004$$

$$P = 3.84$$

In above table calculated value is less than hypothetical value. Therefore it is concluded that, there is no significant difference between exercise and blood sugar level.

Table-8 Association between sleep and fenugreek response

	Positive response	Negative response	Total
8 hour	22	2	24
More than 8 hours	4	2	6
	26	4	30

$$\chi^2 = 2.59$$

P = 3.84

In above table calculated value is less than hypothetical value. Therefore it is concluded that, there is no significant difference between sleep and blood sugar level.

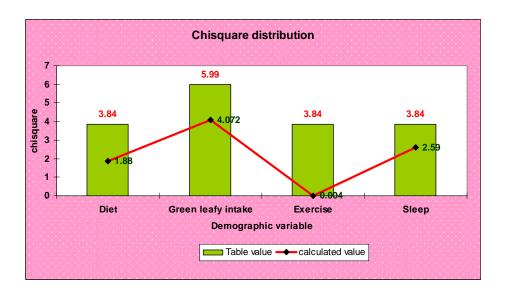


Figure – 12 shows the chi square distribution of selected demographic variables.

CHAPTER V

RESULTS AND DISCUSSION

Diabetes is a disease which needs lifelong treatment. Left untreated or improperly treated, it shortens life considerably or debases its quality substantially. They can be largely avoided by taking simple precautions and proper control of the disease which would certainly make it possible to lead a normal, active and healthy life.

To minimize the diabetic complications and to improve the quality of life of diabetic clients this experimental study was done. The purpose of the study was to evaluate the effectiveness of fenugreek seed powder in control of blood sugar level among Type II Diabetes Mellitus clients.

To maintain homogeneity the clients are selected from Diabetic out Patient Department of Government Rajaji Hospital, Madurai.

Most of Type II Diabetes Mellitus clients in experimental group 16(53.3%) were in age group between 51-60 years and in control group 22(73.3%) were in age group between 41-50 years. By gender 15(50%) were males, 15(50%) were females in experimental and control group. on the basis of educational status 23(76.7%) in experimental group and 20(66.7%) in control group have studied up to primary school .By considering their 25(83.3%) in experimental group and 15(50%) in control group were moderate workers. On interviewing the family income 19(63.3%) in experimental group and 15(50%) in control group were below poverty line. On the basis of family history 18(60%) in experimental group and 15(50%) in control group have no history of Type II Diabetes Mellitus.

The diet pattern shows that 17(56.7 %) in experimental group were vegetarian 24(80%) in control group were non vegetarian. On interviewing the non vegetarian

food intake 23(76.7%) in experimental group and 16(53.3%) in control group have stopped consuming non vegetarian. As per the green leafy vegetables intake 18(60%) in experimental group and 22(73.3%) in control group consumes once in a week. On the basis of roots and tubers intake 25(83.3%) in experimental group and 29(96.7%) in control group sometimes consume. By interviewing the sweets intake, 25(83.3%) in experimental group and 27(90%) in control group sometimes consume. On the basis of tea/coffee intake per day 30(100%) in experimental group and 29(96.7%) in control group consumes two times a day. On the basis of exercise 22(73.3%) in experimental group and 24(80%) in control group were irregular in doing exercise. 30(100%) in experimental group and control group were checking their blood glucose once in three months. 30(100%) in experimental and control group had drug compliance. As per the sleep pattern 24(80%) in experimental group and 22(73.3%) in control group had 8 hours sleep. On calculating the body mass index 17(56.7%) belong to 18.50 – 24.99in experimental group and 15(50%) belong to 25 - 25.99 in control group.

Findings based on hypothesis

 There will be a significant difference in pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group.

On comparing the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group. The obtained "t" values were 19.029, 14.931 which is significant at .001 levels. The findings implies that there is a significant difference between fasting and postprandial blood glucose level before and after intervention .The mean score of fasting and postprandial blood glucose level 124.83, 110.30, 257.33, 174.93

respectively from pre intervention to post intervention depicts the effectiveness of the intervention as the mean score decreased. This proves that the hypothesis is accepted.

❖ There will be a significant difference in the pre and post Blood Sugar Level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental and control group.

On comparing the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group and control group the obtained "t" values were 4.474, 9.960 which is significant at .001 levels. The finding implies that there is a significant difference between fasting and postprandial blood glucose level between experimental and control group. The mean score of fasting and postprandial blood glucose level in experimental and control group are 110.30, 115.17, 174.93, 240.45 respectively which depicts the effectiveness of the intervention in experimental group comparing to control group. This proves that the hypothesis is accepted.

 There will be a significant association between the selected demographic variables and post intervention response of fenugreek seed powder on blood sugar level among Type II Diabetes Mellitus clients in experimental group.

There is no significant association between the selected demographic variables and post intervention response of fenugreek seed powder on blood sugar level among Type II Diabetes Mellitus clients in experimental group. This proves that the hypothesis is rejected.

The study was supported by Hiba A Bawadi (2009), conducted a study to assess the postprandial hypoglycemic effect of fenugreek seeds on clients with Type II Diabetes Mellitus. The objective of the study was to identify the hypoglycemic effect of fenugreek seed powder. The design used for the study was Pretest - Posttest

control group design. One hundred sixty-six type 2 Diabetes Mellitus clients were divided into three groups Group one Fenugreek 0 (control group placebo drink), group two fenugreek 2.5 gm and group three fenugreek 5gm. Postprandial plasma glucose level was measured before and 2 hours after the administration of the treatment. The clients in group three fenugreek 5gm showed the greatest decrease postprandial glucose with a pretest-posttest difference (D) of 41±6.1 mg/dl. The study concluded that there was a decrease in two hour plasma glucose level. Therefore fenugreek seeds appear to have significant hypoglycemic activity in Type II Diabetes Mellitus clients.

CHAPTER - VI

Summary, Conclusion, Implications,

Recommendations, Limitations.

6.1 Summary of the study

The main aim of the study was to reduce the blood sugar level among the Type II diabetes mellitus clients attending Diabetic Out Patient Department, Government Rajaji Hospital, Madurai.

The Objectives of the study were:

- To compare the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II diabetes mellitus clients in experimental group.
- To compare the pre and post Blood Sugar Level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental and control group
- To associate the demographic variables and post intervention response of fenugreek seed powder on blood sugar level among Type II diabetes mellitus clients in experimental group.

The study attempted to examine the following research hypothesis.

- There will be a significant difference in pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus clients in experimental group.
- There will be a significant difference in the pre and post Blood Sugar
 Level in relation to intake of fenugreek seed powder among Type II
 Diabetes Mellitus clients in experimental and control group.
- 3. There will be a significant association between the selected demographic variables and post intervention response of fenugreek seed powder in blood sugar level among Type II Diabetes Mellitus clients in experimental group.

Literature review was done for the present study and presented in following headings.

- 1. Studies related to fenugreek seed
- 2. Studies related to fenugreek seed powder and diabetes mellitus
- 3. Studies related to diabetes mellitus on selected variables.

The investigator had developed a conceptual frame work based on modified Model of Wiedenbach's helping Art of clinical Nursing Theory.

The clients were selected from Diabetic Out Patient Department, Government Rajaji Hospital, Madurai.

The present study design was Pre test Post test design. By using simple random sampling technique 60 Type II diabetes Mellitus clients, 30 in experimental group and 30 in control group were selected.

The tool developed and used for data collection was structured interview and observation schedule. The content validity of the tool was obtained from 5 nursing experts and 2 medicine experts. The tool was reliable and feasible. The reliability of the tool was established by inter rater reliability method. The obtained reliability coefficient was high (r=0.99). First data was collected from experimental group and then followed by control group. Pre test fasting and post prandial blood sugar was measured in experimental and control group before intervention. 5 gm of fenugreek seed powder was given to experimental group for 30 days.

Pilot study was conducted in Diabetic out Patient Department of Government Rajaji Hospital, Madurai by obtaining prior permission from authorities. The pilot study was conducted in October 21 to October 28, 2011, 10 clients were selected as samples. Background factors were collected by interview method. The feasibility of

study was established and preceded to main study. Those participants were excluded from the main study. Gathered data was analyzed using SPSS Version 16.

6.2 Major Findings of the study:

- Most of Type II Diabetes Mellitus clients in experimental group 16 (53.3%)
 were in age group between 51-60 years and in control group 22 (73.3%) were
 in age group between 41-50 years.
- By gender 15 (50%) were males, 15 (50%) were females in experimental and control group.
- On the basis of educational status 23 (76.7%) in experimental group and 20 (66.7%) in control group have studied up to primary school.
- By considering their occupation 25 (83.3%) in experimental group and 15 (50%) in control group were moderate workers.
- On interviewing the family income 19 (63.3%) in experimental group and 15 (50%) in control group were below poverty line.
- On the basis of family history 18 (60%) in experimental group and 15(50%) in control group have no history of Type II Diabetes Mellitus.
- The diet pattern shows that 17 (56.7 %) in experimental group were vegetarian, 24 (80%) in control group were non vegetarian.
- On interviewing the non vegetarian food intake 23 (76.7%) in experimental group and 16 (53.3%) in control group have stopped consuming non vegetarian.
- As per the green leafy vegetables intake 18 (60%) in experimental group and 22 (73.3%) in control group consumes once in a week.
- On the basis of roots and tubers intake 25 (83.3%) in experimental group and 29 (96.7%) in control group sometimes consume.

- By interviewing the sweets intake, 25 (83.3%) in experimental group and 27 (90%) in control group sometimes consume.
- On the basis of tea/coffee intake per day 30 (100%) in experimental group and 29 (96.7%) in control group consumes two times a day.
- On the basis of exercise 22 (73.3%) in experimental group and 24 (80%) in control group were irregular in doing exercise.
- 30 (100%) in experimental group and control group were checking their blood glucose once in three months. 30 (100%) in experimental and control group had drug compliance.
- As per the sleep pattern 24 (80%) in experimental group and 22 (73.3%) in control group had 8 hours sleep.
- On calculating the body mass index 17 (56.7%) belong to 18.50 24.99 in experimental group and 15 (50%) belong to 25 25.99 in control group.
- On comparing the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type II Diabetes Mellitus patients in experimental group the obtained "t" values were 19.029, 14.931 which is significant at .001 levels. The findings imply that there is a significant difference between fasting and postprandial blood glucose level before and after intervention.
- On comparing the pre and post blood sugar level in relation to intake of fenugreek seed powder among Type 2 Diabetes Mellitus patients in experimental and control group the obtained "t" values were 4.474, 9.960 which is significant at .001 level The finding implies that there is a significant difference between fasting and postprandial blood glucose level between

experimental and control group which depicts the effectiveness of the intervention in experimental group comparing to control group

- The mean score of fasting and postprandial blood glucose level in experimental and control group are 110.30, 174.93, 115.17, 240.45 respectively which depicts the effectiveness of the intervention in experimental group comparing to control group.
- There is no significant association between the selected demographic variables and post intervention response of fenugreek seed powder on blood sugar level among Type II Diabetes Mellitus clients in experimental group.

6.3 Conclusion:

The study proves that fenugreek seed powder is effective in controlling blood sugar level among Type II Diabetes Mellitus clients and prevents them from developing complications.

6.4 Implications:

The implications of this study can be seen in areas of nursing practice, nursing education, nursing administration and nursing research.

Implications for nursing Practice:

- Nurses have a vital role in improving the quality of life of Type II diabetes
 mellitus clients. The incidence and prevalence of diabetes mellitus and its
 complications are reaching its peak every year. Since then, there is an urgent
 necessity to take preventive measures to reduce the burden of diabetes
 mellitus.
- It's a well known fact that life style modifications including weight loss,
 increased physical activity and dietary changes can prevent or delay the onset

- of diabetes. Inclusion of fenugreek seed powder is part of dietary modifications to reduce the incidence of diabetic complications.
- The nursing personnel should take initiative in conducting awareness programmes, educational programmes, mass media campaigns on prevention of diabetes mellitus and its complications and also educate to public on an inclusion of fenugreek seed powder in diet which is cost effective, reduces the need for increasing the dose of drugs and increases the general well being among diabetic clients.

Implications for nursing education

- As Nurse-educators, we must strengthen the concept of non-pharmacological methods for management of diabetes mellitus.
- Nursing education should emphasize more on preparing the nurses to impart current changes in health information and to update the knowledge in all fields.
- This can be achieved by equipping the nursing curriculum with knowledge regarding various health information.

Implications for nursing administration:

- Nurse as administrator should take initiation in formulating policies for short and long term health teaching.
- To improve the knowledge of nursing personnel, nurse administrator must assume the responsibility of organizing, staff development programme, in service programme for nurses and prevailing health situation in country and on remedies to overcome.
- They should also motivate nurses to participate in awareness programmes on reducing the incidence of diabetes mellitus complications.

 It is also necessary to impart knowledge about non pharmacological methods of diabetic management.

Implications for Nursing Research

- The nursing profession always believes in evidence based practice, to hike the
 quality of nursing care not only in hospital settings but also in primary care
 settings.
- Nurse should conduct periodic review of research findings and disseminate the findings through conferences, seminars and publication in professional, national and international journals an in the World Wide Web.
- It's all in the hands of nursing personnel to involve in research activities and to come out with successful remedies to reduce the emerging disease burden.

6.5 Recommendations

The study recommends the following for further research

- ❖ The study can be replicated with larger samples for better generalization.
- ❖ Comparative studies can be conducted between various alternate modalities
- ❖ The study can be conducted in different settings with similar facilitator

6.6 Limitations

- 1. The duration of study period is only for one month.
- 2. Since the sample size is only 60, generalization should be done with caution.

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LETTER SEEKING PERMISSION TO CONDUCT THE STUDY

From

J. Poornima Mary, M.Sc., (Nursing) II Year Student College of Nursing, Madurai Medical College, Madurai-20.

To

Dr. Arthur Joseph Asirvatham, MD., D.DIAB. Professor of Diabetology, Chief Diabetologist, Government Rajaji Hospital, Madurai Medical College, Madurai.

Through

The Principal, College of Nursing, Madurai Medical College, Madurai-20

Respected Sir,

Sub: Request for permission on Research study in Diabetic Outpatient Department in Government Rajaji Hospital, Madurai-20

This is to bring to your kind perusal that I am doing M.Sc., (Nursing) II Year in Madurai Medical College. As a part and partial fulfillment of the M.Sc., (Nursing) programme, I have to do research study, in which my topic is "A study to assess the effectiveness of fenugreek seed powder to control blood sugar level among the Type II diabetes mellitus clients attending diabetic out patient department in Government Rajaji Hospital, Madurai-20".

Hence I request you to kindly permit me for this research study in Diabetic out patient department, Government Rajaji Hospital, Madurai.

Thanking you,

Place: Madurai Yours sincerely,

Date:

(J. POORNIMA MARY)

LEITER SEEKING PERMISSION FOR CONTENT VALIDITY FOR TOOL

From

J. Poornima Mary M.Sc(N) II Year College Of Nursing Madurai Medical College Madurai-20.

To

Respected Madam/Sir,

Sub: Requesting opinion and suggestion of experts for content validity of tool for assessing effectiveness of Fenugreek Seed Powder in controlling Blood Sugar level among Type II diabetes mellitus clients.

.

I am J. Poornima Mary final year master degree nursing student in College Of Nursing, Madurai Medical College, Madurai in partial fulfillment of master degree in nursing, I have selected the topic for the dissertation to submit to the Dr. M.G.R. Medical University, Chennai. I request you to kindly validate the tool and give your expert opinion for necessary modification and I would be very grateful if you could refine the problem statement and the objectives.

Thanking you.

Place: Yours sincerely

Date:

(J. POORNIMA MARY)

Enclosure:

Statement of the problem Objectives Research tool

- 1. Demographic Profile
- 2. Assessment of Blood sugar level

CONTENT VALIDITY CERTIFICATE

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the tool developed for data collection by Mrs. J. Poornima Mary, on thesis entitled, "A STUDY TO ASSESS THE EFFECTIVENESS OF FENUGREEK SEED POWDER TO CONTROL BLOOD SUGAR LEVEL AMONG THE TYPE II DIABETES MELLITUS CLIENTS ATTENDING DIABETIC OUT PATIENT DEPARTMENT IN GOVERNMENT RAJAJI HOSPITAL, MADURAI-20" is relevant valid and fulfill the study objectives.

Date:	Signature.

Seal

LIST OF EXPERTS FOR CONTENT VALIDITY

1. Dr. Arthur Joseph Asirvatham, M.D., D.DIAB.

	Professor of Diabetology,
	Chief Diabetologist,
	Government Rajaji Hospital,
	Madurai.
2.	Dr.Joy Patricia, MD
	Reader, Institute of Community Medicine,
	Madurai Medical College, Madurai.
3.	Mr.John Sam Arun Prabhu, M.Sc(N), M.Sc(Psy), PGDHM
	HOD, Community Health Nursing,
	CSI JCON, Pasumalai.
4.	Mrs. Sorubarani, M.Sc(N)
	Reader in Community Health Nursing
	Matha College of nursing
	Manamadurai.
5.	Dr.Sylvia, M.Sc(N) PhD(N)
	HOD, Community Health Nursing
	Ultra College of nursing
	Madurai.
6.	Mrs.Murugalakshmi, M.Sc(N)
	Lecturer
	Ultra College of nursing
	Madurai.

PROCEDURE

- 1. 60 Type II diabetes mellitus clients were selected.
- 2. 30 clients in experimental group and 30 clients in control group.
- 3. Informed consent was obtained from each participant.
- 4. Fasting and Postprandial blood sugar level was assessed for experimental and control group before intervention.
- 5. 5 gm of fenugreek seed powder was given to clients in experimental group for 30 days.
- 6. Fasting and postprandial blood sugar level was assessed for experimental and control group after intervention.

AUTHORIZATION AND CONSENT FORM

I have been explained by Mrs. J. Poornima Mary, regarding her dissertation "A STUDY TO ASSESS THE EFFECTIVENESS OF FENUGREEK SEED POWDER TO CONTROL BLOOD SUGAR LEVEL AMONG THE TYPE II DIABETES MELLITUS CLIENTS ATTENDING DIABETIC OUT PATIENT DEPARTMENT IN GOVERNMENT RAJAJI HOSPITAL, MADURAI-20". I am willing to participate in the study.

Date:	Signature of the Client

QUESTIONNAIRE ON TYPE II DIABETES MELLITUS CLIENTS

SECTION I – DEMOGRAPHIC VARIABLES

- 1. Age
 - 31-40 years
 - 41-50 years
 - 51-60 years
- 2. Sex
 - Male
 - Female
- 3. Educational status
 - Primary school
 - High school
 - Higher secondary
 - Degree
- 4. Occupation
 - · Sedentary worker
 - Moderate worker
 - Heavy worker
- 5. Family income per year
 - Below poverty line(<24,000)
 - Above poverty line(24,000 and above)
- 6. Family history of diabetes mellitus
 - Father
 - Mother
 - Paternal grand parent
 - Maternal grand parent
 - Not applicable
- 7. Diet
 - Vegetarian
 - Non vegetarian
- 8. How often do you take non vegetarian food?
 - Daily
 - Twice in a week
 - Once in a week
 - Never

- 9. How often do you include green leafy vegetables in your diet?
 Daily
 Twice in a week
 - Twice in a week
 - Once in a week
 - Never
- 10. How strict are you restricting roots and tubers intake
 - Fully restricted
 - Sometimes I eat
 - I take as I like
- 11. How strict are you restricting sweets intake
 - Fully restricted
 - Sometimes I eat
 - I take as I like
- 12. How many serving of tea /coffee (without sugar) do you have per day
 - Two or less
 - More than two
 - Not applicable
- 13. Exercises
 - Regular
 - Irregular
- 14. How often do you check your blood glucose status
 - Once in a month
 - Once in 3 month
 - Once in 6 month
 - Only when needed
- 15. .How regular are you in taking medication
 - Regular
 - Irregular
- 16. State the hours of sleep per day
 - >8 hours
 - 8 hours
 - <8 hours
- 17. Body Mass Index
 - <18.50
 - 18.50-24.99
 - 25-25.99
 - >30

SECTION II

Blood sugar level

S.NO	BLOOD SUGAR	BEFORE INTERVENTION	AFTER INTERVENTION
1	FASTING		
2	POST PRANDIAL		