# EFFECTIVENESS OF TULSI LEAVES POWDER UPON BLOOD GLUCOSE

# **LEVEL IN DIABETIC PATIENTS**

BY

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A DISSERTATION SUBMITTED TO THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

APRIL 2013

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# DECLARATION

I hereby declare that the present dissertation entitled "Effectiveness Of Tulsi Leaves Powder Upon Blood Glucose Level In Diabetic Patients" is the outcome of the original research work undertaken and carried out by me under the guidance of Dr.Latha Venkatesan, M.Sc.,(N)., M.Phil.,(N)., Ph.D.,(N), Principal And Professor in Maternity Nursing and Mrs. Shobana.G, M.Sc., (N), Professor, Head of the department in Community Health Nursing, Apollo College of Nursing, Chennai. I also declare that the material of this has not been formed in any way, the basis for the award of any degree or diploma in this university or any other universities.

M.Sc (N) - II Year

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#### **SYNOPSIS**

A Quasi Experimental Study to Assess the Effectiveness of Tulsi Leaves (Ocimum Sanctum) Powder Upon Blood Glucose Level in Diabetic Patients at Selected Wards of Thiruverkadu Township, Chennai.

# **Objectives of the study**

- 1. To assess the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients
- To determine the effectiveness of tulsi leaves powder upon blood glucose level by comparing the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.
- 3. To determine the level of satisfaction regarding tulsi leaves powder administration among experimental group of diabetic patients.
- 4. To find out the association between the selected demographic variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.
- 5. To find out the association between the selected clinical variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.

A quasi experimental design was adopted for this study. Purposive sampling technique was used to select 30 in control group from keelayanambakkam and 30 in experimental group from 14<sup>th</sup> ward of Thiruverkadu Township. The blood glucose assessment chart and rating scale for level of satisfaction on administration of tulsi

leaves powder were the tools used to collect data, after establishing validity and reliability. The main data collection was done after determining the feasibility and practicability through pilot study.

The diabetic patients were identified through door to door enumeration. The blood glucose level was checked for both control and experimental group before and after administration of tulsi leaves powder. Tulsi leaves were freshly plucked from the plants, washed, dried under the shadow and powdered in a mixer. 2.5g of this powder is mixed with 10ml of plain water and was administered every day orally on empty stomach for four weeks and their level of satisfaction on tulsi leaves powder was assessed. The data was tabulated and analyzed by using descriptive and inferential statistics.

#### **Major Findings of the Study**

- Significant percentage of diabetic patients were in age group between 41 to 50 (43.3%, 33.4%), female (53.4.7%,46.6%), Hindus (50%, 53.4%), had High school education (30%, 33.4%), occupation as home makers (53.4%, 46.7%), and majority were married (90%, 93.2%), with monthly income between 5001 to 10,000 (66.7%, 76.6%), nonvegetarians (100%, 100%), non smokers (66.6%, 80%) and non alcoholics (70%, 76.6%) in control and experimental group respectively.
- Most of the diabetic patients had no family history of diabetes (56.6%, 73.4%), not on diabetic diet (40%, 66.6%), with height 156 to 160 cm (46.6, 70%), significant percentage of the diabetic patients had been suffering from diabetes mellitus for a duration between 1 to 2 yrs (36.6%, 53.4%), with BMI between 22.6 to 29.9 (50%,

50%), had body weight between 51-60 kg (46.6%, 43.4.7%), and majority of the patients was on oral hypoglycemic agents (100%, 100%), absence of comorbidities (63.4%, 73.4%), not performing regular exercise (66.6%, 73.4%) and not on other alternative or complementary therapy (100%, 100%).

- Majority of the diabetic patients in the control and experimental group had mild level of fasting blood glucose (86.67%, 90%) and most of them had moderate level of postprandial blood glucose (73.4%, 80%) before tulsi leaves powder administration. But there was a significant difference in the experimental group, as all the diabetic patients had mild level of fasting blood glucose (100%) and majority of them had mild level of postprandial blood glucose (93.3%) after tulsi leaves powder administration. Whereas in control group most of the diabetic patients had mild level of fasting blood glucose (83.3%) and moderate level of postprandial blood glucose (83.3%) in the post assessment. This could be attributed to the effectiveness of tulsi leaves powder administration.
- In control group there was no significant difference in the mean and standard deviation of fasting blood glucose (M=164.7, 169.9 & SD=11.77, 11.24) and postprandial blood glucose (M=231.7, 244.1 & SD=25.40, 23.24) before and after tulsi leaves powder administration. Whereas experimental group showed a significant difference (p<0.001) in the mean and standard deviation of fasting blood glucose (M=169.4, 117 & SD=7.90, 3.91) and postprandial blood glucose (M=239.8, 166.8 & SD=24.34, 19.93) before and after administration of tulsi leaves powder and it can be attributed to the effectiveness of tulsi leaves powder administration. Hence the null hypothesis Ho<sub>1</sub> was rejected.

- All of the diabetic patients in the experimental group were highly satisfied (100%) with regard to researcher, with regard to the method of tulsi leaves powder administration (100%), with regard to the effectiveness of tulsi leaves powder administration (100%) respectively. And most of the diabetic patients were highly satisfied with the nature of tulsi leaves powder (96.67%)
- There was a significant association between the selected demographic variables of age ( $\chi^2 = 7.45$ , df= 2), (p<0.05) and fasting blood glucose levels of diabetic patients before in pre test in control group, but there was no significant association with other demographic variables. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age.
- There was a significant association between the selected demographic variables of age ( $\chi^2 = 6.039$ , df= 2), (p<0.05) years and post prandial blood glucose levels, occupational status ( $\chi^2 = 6.868$ , df= 2), (p<0.05) and post prandial blood glucose levels of diabetic patients in post test in control group and experimental group, but the association with other demographic variables were not significant. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age in years and occupational status.
- There was a significant association between the selected clinical variables of height  $(\chi^2 = 7.339, df = 2)$ , (p<0.05) and post prandial blood glucose levels of diabetic patients in pre test and post test in control group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to height.
- > There was a significant association between the selected clinical variable duration of known period of diabetes ( $\chi^2 = 7.92$ , df= 2), (p<0.05) and post prandial blood glucose levels of diabetic patients after administration of tulsi leaves powder in

experimental group, but there was no significant association with other clinical variables. Hence the null hypothesis  $Ho_3$  was rejected with regard to duration of known period of diabetes.

# Recommendations

The researcher recommends the following studies in the field of nursing research

- > The same study could be conducted on larger samples for better generalization.
- The same study could be conducted for patients with impaired blood glucose levels.
- > The study could be replicated in different settings.
- A study could be conducted to assess the level of knowledge among nurses regarding the administration of tulsi leaves powder for the management of the patients with type 2 diabetes mellitus.
- > A similar study can be conducted with other traditional and herbal medicines.

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# **CHAPTER I**

# **INTRODUCTION**

## **Background of the Study**

# "The groundwork of all happiness is health."

# - Leigh Hunt

Diabetes mellitus is a chronic lifelong disease one has to live with. Currently, more than 70% of people with diabetes live in low and middle income countries. Diabetes is one of the major causes of premature illness and death worldwide. Without timely diagnosis and adequate treatment, complications and morbidity from diabetes rise exponentially.

Diabetes is an "Iceberg" disease. Although there is increase in both prevalence and incidence of Non-insulin dependent diabetes globally, it have been especially dramatic in newly industrialized countries and in developing countries. Currently the number of cases of diabetes worldwide is estimated to be around 230 million. Among these the greatest number of cases is being reported in India and china 36 million and 24 million respectively (International Diabetes Federation)

New figures for diabetes prevalence in India indicate that the epidemic is progressing rapidly across the nation, reaching a total of 62.4 million persons with diabetes in 2011. India, the world's second most populous country, now has more than 50 million people with type 2 diabetes than any other nation (Jared Diamond, 2011) The largest age group currently affected by diabetes is between 40-59 years. By 2030 this "record" is expected to move to the 60-79 age group with some 196 million cases. Non-communicable diseases including diabetes account for 60% of all deaths worldwide.

The financial burden borne by people with diabetes and their families as a result of their disease depends on their economic status and the insurance policies. In the poorest countries, people with diabetes and their families bear almost the whole cost of the medical care they can afford.

Type 2 diabetes can be managed with healthy eating, regular exercise, oral medications and alternative therapies. Tulsi (Ocimum sanctum) a sacred plant has its medicinal properties known for thousand years to various civilizations of the world. Tulsi acts as anti diabetic, antimicrobial, hepatoprotective, anti-inflammatory, anti-carcinogenic, radio-protective, immunomodulatory, neuro-protective, cardio-protective, mosquito repellent etc.,

Tulsi is a herb native to India and is regarded as one of the most important plants used in Ayurvedic medicine. It has a pleasant aroma. Although it is native to India, it is now widely grown throughout the world. The plant is hairy with multiple branches and small, tender leaves. The leaves and stems are used medicinally. This herb has been used for centuries in India for cooking, healing, and in worship rituals. Today, with the rise of diabetes in India, many diabetics there (and some elsewhere) are turning to holy basil to treat this life-altering disease. As the incidence of diabetes has grown in India, more people began to take tulsi because of its spiritual importance and its traditional reputation in Indian Ayurvedic medicine. In this case, traditional medicine proved to be right. The tulsi plant contains essential oils and produces caryophyllene, eugenol, and methyl eugenol. These oils are thought to improve pancreatic function by stimulating insulin production.

# Need for the study

According to the World Diabetes Atlas, India is projected to have around 51 million people with diabetes. It is estimated that there are currently 285 million people with diabetes worldwide and this number is set to increase to 438 million by the year 2030. There is also consensus that the South Asia region will include three of the top ten countries in the world (India, Pakistan and Bangladesh) in terms of the estimated absolute numbers of people with diabetes. (Anjana, et al. 2009)

Diabetes is a disease with rising prevalence worldwide. Every fifth patient visiting a consulting physician is a diabetic and every seventh patient visiting the family physician is diabetic. Every fifth person who suffers from diabetes in the world today is an Indian.

According to The Hindu daily, the prevalence of diabetes in TamilNadu is 4.8 million and prediabetes is 3.9 million people. (Diabetologia, 2011)

The prevalence of diabetes for all age-groups worldwide was estimated to be 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. The urban population in developing countries

is projected to double between 2000 and 2030. The most important demographic change to diabetes prevalence across the world appears to be the increase in the proportion of people above 65 years of age.

Because of the local availability of herbs, treatment according to the traditional system of medicine is often cheaper (Girti et al, 1997). The herb tulsi (Ocimum Sanctum) belongs to Labiatae family and is available in plenty in India. The leaves of the plant are considered to be very holy and often form a consistent part of the Hindu spiritual rituals. Janabai et al (1987) reported that tulsi had hypoglycemic effect. Controlled studies carried out in India as well as in many other countries have revealed that a Tulsi (Ocimum Sanctum) intake offers protection against diabetes which is related to nutritionally induce metabolic over load (Wynder et al, 1992). Hence, this study was carried out to assess the effectiveness of tulsi (OcimumSanctum) on blood sugar level.

There are different modalities of treatment for Diabetes Mellitus. Among them, in India alternative medicine plays an important role, eg: Ayurveda, Homeopathy etc. In Ayurveda herbal extracts from plant roots, leaves, flowers etc are commonly used as a mode of treatment. The role of Ayurveda in control of diabetes is under exploration. As such, tulsi is considered to be the most important herb in Ayurvedic healing. Ayurvedic practitioners swear by tulsi as a cure-all for many different illnesses. It is said to place the entire body back in healthy balance, both physically and spiritually.

With these projected increase in the diabetic population in future, South-East Asian countries will become the most challenged region in the World and will bear the maximum global burden of the diseases in the initial decades of the 21<sup>st</sup> century. The prevention and control of the diabetes pandemic and its complications is a major public challenge, but there is hope for the future. The progress of research in all fields of diabetes therapeutics from diabetes treatment to continuous glucose monitoring systems to novel insulin delivery system has been spectacular.

Indeed the number of cases, the options and strategies currently available to treat and prevent its complications is impressive. It remains to be seen if we are able to practically implement these therapeutic strategies so that we ameliorate the enormous health burden and financial burden associated with diabetes. Most of the studies reveal and say about the treatment of complications but very few studies say about management of diabetes mellitus. Looking in to the severity of the disease and beneficial effects of this herbal plant in managing diabetes, present study is planned.

The above facts triggered the investigator to do an experimental study to assess the effectiveness of tulsi leaves powder upon blood glucose level.

#### Statement of the problem

A Quasi Experimental Study to Assess the Effectiveness of Tulsi Leaves (Ocimum Sanctum) Powder Upon Blood Glucose Level in Diabetic Patients at Selected Wards of Thiruverkadu Township, Chennai.

# **Objectives of the study**

1. To assess the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients

- To determine the effectiveness of tulsi leaves powder upon blood glucose level by comparing the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.
- 3. To determine the level of satisfaction regarding tulsi leaves powder administration among experimental group of diabetic patients.
- 4. To find out the association between the selected demographic variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.
- 5. To find out the association between the selected clinical variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.

# **Operational Definitions**

# Effectiveness

In this study it refers to the outcome of tulsi leaves powder administration with regard to reduction in fasting and post prandial blood glucose level in experimental group of diabetic patients. The effectiveness was measured by comparing the mean scores of blood glucose level in control and experimental group of diabetic patients.

#### **Tulsi leaves powder**

In this study it refers to Tulsi leaves freshly plucked from the plants, washed, dried under the shadow and powdered in a mixer. 2.5g of this powder is mixed with 10ml of plain water and was administered every day orally on empty stomach for four weeks.

# **Diabetic patients**

In this study it refers to Patients who were diagnosed as type 2 diabetes by a qualified physician, having fasting blood glucose level above 110 mg/ dl and post prandial blood glucose above 140mg/dl and on oral hypoglycemic agents.

# Blood glucose level

In this study it refers to the fasting and post prandial blood glucose level in the capillaries of diabetic patients as measured by the researcher using glucometer.

# Satisfaction

In this study it refers to feeling of gratification attained by diabetic patients with tulsi leaves powder administration using satisfaction rating scale.

# **Null Hypotheses**

- **Ho**<sub>1</sub>: There will be no significant difference in the blood glucose level before and after administration of tulsi leaves powder among the control and experimental group of diabetic patients
- **Ho<sub>2</sub>:** There will be no significant association between selected demographic variables and blood glucose level before and after administration of tulsi leaves powder among the control and experimental group of diabetic patients
- **Ho<sub>3</sub>:** There will be no significant association between selected clinical variables and blood glucose level before and after administration of tulsi leaves powder among control and experimental group of diabetic patients.

# Assumptions

The study assumes that:

- Diabetes is a manageable disease when treated properly
- > Type 2 diabetes is seen only in adults
- > Tulsi plant is available plenty in India
- Tulsi leaves has its medicinal properties

# **Delimitations**

The study will be delimited to

- > Diabetic patients who are residing in Thiruverkadu
- > The period of data collection is only 4 weeks
- > The study is limited to type 2 diabetic patients.

# **Conceptual Framework**

The conceptual framework deals with the inter-related concepts that are assembled together in some rational schemes by virtue of their relevance to a common theme (Polit and Beck, 2010).

Conceptual framework of present study is based on "Sister Callista Roy's Adaptation Model". According to Sister Callista Roy: Nursing is defined as a practicecentered discipline geared towards persons and their responses to stimuli and adaptation to the environment. This model is based on the concepts of input, throughput and output.

# Input

Input refers to administration of tulsi leaves powder for type 2 diabetic patients in experimental group to reduce the blood glucose levels.

# **External stimuli**

Sedentary life style, diet and alcohol.

# Internal stimuli

Age, sex, genetic factors and obesity.

# Process

Process includes the coping mechanism. That is mainly two types, regulators and cognators.

# Regulators

Regulators are the subsystem of coping mechanism which responds automatically through neural, chemical and endocrine process.

# Cognators

Cognators are the subsystem of coping mechanism which responds through complex process of perception and information processing, learning, judgment and emotion.

# Effectors

The regulator and cognator mechanisms work within the four adaptive modes are effectors of physiological function, self concept, and role function and inter dependence.

# **Physiological functioning**

These are the ways of dealing with regard to diabetes mellitus. It includes diabetic diet, exercise and alternative or complimentary therapy.

# Self concept

It is a composite of beliefs and feeling. It refers to the client's level of satisfaction regarding consumption of tulsi leaves powder.

# **Role function**

Role function is how the diabetic patients perform their roles in the family, society and at the workplace.

# Interdependence

It is the interdependent role between the researcher and diabetic patients in maintaining blood glucose levels.

# Output

Output can be categorized into adaptive or maladaptive responses. In adaptive response the client will maintain blood glucose levels within normal limits. In maladaptive response the client's blood glucose levels will not be maintained within normal limits. These responses provide feedback for the system.

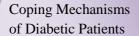
Stimuli For Diabetic Patients

# **External Stimuli**

Sedentary life style, diet, alcohol.

#### **Internal Stimuli**

Age, sex, genetic factors and obesity



# Cognator

Patients understand the importance of consuming tulsi leaves powder to maintain blood glucose levels within normal limits.

# Regulators

Changes in the symptoms of high blood glucose levels

# **Physiological** functioning

It includes diabetic diet, exercise and alternative/complement ary therapy.

# Self concept

Level of satisfaction of patients regarding consumption of tulsi leaves powder.

## **Role function**

Client's role in the family, society and at work place.

# **Inter dependence**

Interdependent role between the researcher and the client.

Stimuli within the client's adaptive zone

# Stimuli above the client's adaptive zone

# **Adaptive Responses**

client will maintain blood glucose levels within normal limits

> Ineffective adaptive responses

client's blood glucose levels will not be maintained within normal limits

Fig. 1 Conceptual Framework Based on Modified Sister Callista Roy's Adaptation Model

# **Projected Outcome**

The outcome of the study was reduction in the fasting and postprandial blood glucose level of diabetic patients in the experimental group after tulsi leaves powder administration.

# Summary

This chapter has dealt with the background, need for the study, statement of the problem, objectives, operational definitions, assumptions, null hypotheses, delimitations and conceptual framework.

# **Organization of the Report**

Further aspects of the study are presented in the following five chapters

- **In Chapter II** : Review of literature.
- In Chapter III : Research methodology- which includes research approach, design, setting, population, sample and sampling techniques, tool description, content validity and reliability of tools, pilot study, data collection procedure and plan for data analysis.
- **In Chapter IV** : Analysis and interpretation of data.
- In Chapter V : Discussion.
- **In Chapter VI** : Summary, conclusion, implications and recommendations.

#### **CHAPTER II**

# **REVIEW OF LITERATURE**

A literature review involves the systematic identification, location, scrutiny and summary of writers' materials that contain information on a research problem (Polit and Beck, 2010).

The task of reviewing literature involves the identification, selection, critical analysis and reporting of existing information on the topic of interest. Review of literature is an essential component for a worthwhile study in any field of knowledge. It helps the researcher to gain information on what has been done previously and to gain deeper insight into the research problem. It also helps to plan and conduct the study in a systematic way.

This chapter deals with a review of published and unpublished research studies and from related material. For the present study the review helped the researcher to develop an insight into the problem area. This helped the researcher in building the foundation of the study.

# The review of literature related to the present study is organized under the following headings

- Studies related to Diabetes mellitus
- Studies related to non pharmacological measures to reduce blood glucose level
- Studies related to effects of tulsi leaves
- Studies related to tulsi leaves and blood glucose level

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# **Studies Related To Diabetes Mellitus**

A study was conducted to evaluate the effect of combined therapy using acupressure therapy, hypnotherapy, and transcendental meditation (TM) on the blood sugar (BS) level in comparison with placebo in type 2 diabetic patients. We used "convenience sampling" for selection of patients with type 2 diabetes; 20 patients were recruited. For collection of data, an identical quasi-experimental design called "nonequivalent control group" was used. Therapy sessions each lasting 60-90 min were carried out on 10 successive days. Pre-tests, post-tests, and follow-up tests were conducted. Mean BS level in the post-tests and follow-up tests for the experimental group was reduced significantly in comparison with the pre-tests whereas in the placebo group no changes were observed. Combined therapy including acupressure therapy, hypnotherapy, and TM reduced BS of type 2 diabetic patients and was more effective than placebo therapy on this parameter. Bay R. (2011)

Rebecca et al (2009) conducted a double-blind, placebo controlled, randomized trial. Sixty incident type 2 diabetic subjects (aged 35–60 years) were recruited from St. Johns Medical College Hospital, Bangalore, India. The subjects were randomly assigned into the placebo or experimental group and were provided with 1 g alcoholic extract of the herb for 90 days. Anthropometric, biochemical, dietary, and physical activity assessment were carried out at baseline and were repeated at days 45 and 90 of the study. All subjects were provided with standard dietary and physical activity advice for blood sugar control. There was a significant decrease in the fasting, postprandial blood glucose and A1C of the experimental group compared with that of the placebo group. The fasting and postprandial blood glucose levels of the experimental group at

day 90 significantly decreased, by 16 and 18%, respectively. There were no significant changes observed in the serum lipid levels.

A study to determine whether type 2 diabetes can be prevented by interventions that affect the lifestyles of subjects at high risk for the disease is not known was conducted by Tuomilehto (2007). Samples were randomly assigned 522 middle-aged, overweight subjects (172 men and 350 women; mean age, 55 years; mean body-mass index 31) with impaired glucose tolerance to either the intervention group or the control group. sEach subject in the intervention group received individualized counseling aimed at reducing weight, total intake of fat, and intake of saturated fat and increasing intake of fiber and physical activity. Analysis of the data indicated Type 2 diabetes can be prevented by changes in the lifestyles of high-risk subjects.

A cross sectional study was conducted in Turkey to determine the level of knowledge of patients on diabetes mellitus among 524 rural adults with the age over 30 years by a knowledge questionnaire. The results showed that mean Diabetic knowledge score was  $30.2\pm3.46$ . The result indicated that the participants' knowledge on diabetes mellitus was lower. Gunav et al. (2006)

Roberto et al.(2005) carried out a study in Argentina by a team of researchers from a Not-For-Profit Organization called 'Don Roberto Fernandez Vina Foundation' (San Nicolas- Buenos Aires, Argentina) demonstrated that stem cells implanted into type 2 diabetespatients, in direct form into the pancreas, improve the production of Endogenous Insulin, increase the levels of "C Peptide", decrease blood glucose levels and glycated hemoglobin levels faster than other treatments. 84% of the patients that had received the autologuous bone marrow cells could also abandon the drugs that stimulate insulin production or the insulin that they had been receiving previously.

Major dietary patterns were studied for the ability to predict type 2 diabetes mellitus in a cohort of 4,304 Finnish men and women aged 40–69 years and free of diabetes at baseline in 1967–1972. A total of 383 incident cases of type 2 diabetes occurred during a 23-year follow-up. Two major dietary patterns were identified. The pattern labeled "prudent" was characterized by higher consumption of fruits and vegetables, and the pattern labeled "conservative" was characterized by consumption of butter, potatoes, and whole milk. The relative risks (adjusted for nondietary confounders) between the extreme quartiles of the pattern scores were 0.72 (95% confidence interval: 0.53, 0.97;  $p_{trend} = 0.03$ ) for the prudent pattern and 1.49 (95% confidence interval: 1.11, 2.00;  $p_{trend} = 0.01$ ) for the conservative pattern. It appears conceivable that the risk of developing type 2 diabetes can be reduced by changing dietary patterns. Montonen et al. (2004)

## Studies Related to Non Pharmacological Measures to Reduce Blood Glucose Level

A systematic review was conducted to critically evaluate the data from clinical trials examining the efficacy of mind-body therapies as supportive care modalities for management of the metabolic syndrome. Three clinical trials addressing the use of mind-body therapies for management of the metabolic syndrome were identified. Findings from the studies reviewed support the potential clinical effectiveness of mind-body practices in improving indices of the metabolic syndrome. Anderson JG (2011).

El-Sayed MI (2011) investigated antidiabetic activity of purslane seeds on type-2 diabetic subjects and to provide scientific basis for the clinical use of Portulaca oleracea (PO). A thirty subject with type-2 diabetes divided into two groups, to receive 5 g of PO seeds twice daily while in the second group, their participants receive 1,500 mg of metformin/day. Blood samples from participants before and after treatment were taken. The results demonstrated that PO seeds possessed notable hypoglycaemic, hypolipidaemic and insulin resistance reducer effects; possibly due to its contents of polyunsaturated fatty acids, flavonoids, and polysaccharides.

Fabian et al.(2011) Interviewed a total of 200 patients (59% men and 41% women) with type 1 (16%) or type 2 diabetes (84%) using a standardized, validated questionnaire; the results from 198 respondents were analyzed. A third of type 1 and type 2 diabetics (women > men; p < 0.01) reported current use of biologically-based CAM supplements, and intake was significantly (r = 0.203; p < 0.05) correlated to the degree of health awareness/interest in self-care in type 2 diabetics. The use of nutritional supplements (vitamins/multivitamins and minerals), herbal medicine, and cinnamon was reported most frequently. Prevention (36%) and improved well-being/quality of life (13%) but not the positive modulation of diabetes management (4%) were given as main motivations. Eighty-three percent of type 1 diabetics (women > men; p < 0.05) and 70% of type 2 diabetics already knew about the postulated positive effect of cinnamon on blood glucose. Up to 85% reported a willingness or a probable willingness to test the effect of cinnamon on blood glucose. Among patients with type 2 diabetes the subjectively felt disease burden was found to have a significant (r = 0.235; p < 0.01) impact on the willingness to use cinnamon preparations for better diabetes management.

Ingle et al. (2011) conducted a study to observe the effectiveness of acupuncture therapy in type 2 diabetes mellitus patients. In this study 20 patients were selected. All the patients were punctured by using acupuncture needle with electric stimulation (Accu Stimulator Apparatus), by DD wave, and the needles were retained for 20-30 minutes. The treatment was given for 3 months time period. At the end of study period it was observed that acupuncture having overall good impact in most of the parameters. A significant decrease were observed in patients after acupuncture therapy. This study was suggesting that acupuncture therapy was effective in improving glycemic control, reducing HbA1c, lipid profile and may helpful for reducing the complications in Indian patients with type 2 diabetes mellitus.

A 4-week, multicenter, randomized, double-blind, active-control trial. Patients were randomized into 4 groups to receive bitter melon 500 mg/day, 1,000 mg/day, and 2,000 mg/day or metformin 1,000 mg/day. All patients were followed for 4 weeks. There was a significant decline in fructosamine at week 4 of the metformin group (-16.8; 95% CI, -31.2, -2.4 µmol/L) and the bitter melon 2,000 mg/day group (-10.2; 95% CI, -19.1, -1.3 µmol/L). Bitter melon 500 and 1,000 mg/day did not significantly decrease fructosamine levels (-3.5; 95% CI -11.7, 4.6 and -10.3; 95% CI -22.7, 2.2 µmol/L, respectively). Bitter melon had a modest hypoglycemic effect and significantly reduced fructosamine levels from baseline among patients with type 2 diabetes who received 2,000 mg/day. However, the hypoglycemic effect of bitter melon was less than metformin 1,000 mg/day. Ingkaninan K et al (2011)

Mary (2011) Conducted an experimental study for four week. Type 2 diabetic patients were randomized into study and control group. The study group were

administered with 50 ml of cinnamon extract orally before breakfast. The fasting and postprandial blood glucose were checked before and after administration of cinnamon extract. In control group there was no significant difference in the mean and standard deviation of fasting blood glucose (M=173.23, 175.43 & SD=10.424, 10.190) and postprandial blood glucose (M=257.43, 264.63 & SD=28.426, 27.532) before and after cinnamon extract administration. Whereas experimental group showed a significant difference (p<0.001) in the mean and standard deviation of fasting blood glucose (M=170.40, 122.77 & SD=7.295, 7.253) and postprandial blood glucose (M=252.10, 167.10 & SD=26.519, 8.130) before and after administration of cinnamon extract and it can be attributed to the effectiveness of cinnamon extract administration.

In a qualitative study, 13 adults with or at risk for type 2 diabetes described their experiences with yoga and their beliefs regarding maintenance of yoga practice over time. Semistructured interviews occurred 16 to 20 months after completion of an 8week yoga-based clinical trial. Themes of readiness for continuing yoga, environmental support for yoga, and integrating yoga emerged through data analysis. Findings indicate that yoga is appealing to some individuals with diabetes, but maintaining yoga practice over time is a challenge. Diabetes educators may be able to support maintenance by discussing specific strategies with individuals who express interest in yoga practice. Alexander et al (2010).

In a clinical trial study, 24 type 2 diabetic patients were placed on 10 grams/day powdered fenugreek seeds mixed with yoghurt or soaked in hot water for 8 weeks. The differences observed in food records, BMI and serum variables were analyzed using paired-t-test and t-student and P<or=0.05 was considered as significant. After exclusion of 6 cases for changing in medication or personal problems, the results of 18 patients (11 consumed fenugreek in hot water and 7 in yoghurt) were studied. Findings showed that FBS, TG and VLDL-C decreased significantly (25 %, 30 % and 30.6 % respectively) after taking fenugreek seed soaked in hot water whereas there were no significantly changes in lab parameters in cases consumed it mixed with yoghurt. BMI, Energy, Carbohydrate, Protein and fat intake remained unchanged during study. This study shows that fenugreek seeds can be used as an adjuvant in the control of type 2 diabetes mellitus in the form of soaked in hot water. Kassain et al. (2009).

The researcher has undertaken a randomized study to find out the glycemic response of coffee sweetened with aqueous extract of stevia leaf as a natural sweetener among 90 patients. Sugar was replaced with stevia leaves. The result showed that the glycemic index registered by coffee with sugar and coffee with stevia extract were 69.29 and 63.29 respectively. Kocchar (2008).

Nazni et al. (2005) conducted an interventional study to assess the impact of flaxseed based therapeutic food on selected type 2 diabetic patients. Totally 50 type 2 diabetic subjects were selected for supplementation and divided into 2 groups of 25 subjects each. Experimental group (n=25) was supplemented with 5gms of flaxseed incorporated bread for a period of 90days as evening snack. The result showed that the administration of 5 % level processed flaxseed powder in the form of bread caused statistically significant reduction in the blood glucose levels and blood lipids levels. The mean values decrease from 224.3 to 167.5 for total cholestrol, 162.4 to 140.8 for blood glucose and 209 to 189 for post prandial blood glucose.

Gloria et al. (2003) conducted a total of 108 trials examining 36 herbs (single or in combination) and 9 vitamin/mineral supplements, involving 4,565 patients with diabetes or impaired glucose tolerance, met the inclusion criteria and were analyzed. There were 58 controlled clinical trials involving individuals with diabetes or impaired glucose tolerance (42 randomized and 16 nonrandomized trials). Most studies involved patients with type 2 diabetes. Heterogeneity and the small number of studies per supplement precluded formal meta-analyses. Of these 58 trials, the direction of the evidence for improved glucose control was positive in 76% (44 of 58). Very few adverse effects were reported.

# **Studies Related To Effects of Tulsi Leaves**

Shankar et al. (2011) Conducted a double-blinded randomized controlled trial for immunomodulatory effects of Tulsi (Ocimum sanctum Linn.) leaf extract on healthy volunteers. Results showed that consumption of Tulsi leaf on empty stomach increases immunity and alcoholic extract of Tulsi modulates immunity.

Shankar mondal et al. (2009) reviewed the medicinal properties of tulsi leaves, to sum up different aspects of scientific studies on this medicinal plant. Scientific evidences are available on various medicinal aspects i.e. antimicrobial, adaptogenic, antidiabetic, hepato-protective, anti-inflammatory, anti-carcinogenic, radioprotective, immunomodulatory, neuro-protective, cardio-protective, mosquito repellent *etc*. to name a few.

The incidence of diabetes is increasing all over the world affecting more than 246 million people. Ninety non insulin dependent male diabetic subjects in the age

group of 40-60 years were selected from PAU, Ludhiana to study the effect of supplementation of tulsi and neem leaves on the signs and symptoms anthropometric parameters and blood pressure of the diabetic subjects. General information of the subjects was recorded by interview schedule. After one month control period ninety subjects were divided into three groups of 30 each. Group I was given tulsi leaf powder, group II was given neem leaf powder and group III given mixture of both leaf powder in the form of capsules. Daily dosage of four capsules i.e. 2 g powder (Lunch and dinner) was given and supplementation was carried out for a period of 3 months. The most common symptoms of diabetes observed in diabetic patients were polydypsia, polyurea, polyphagia and tiredness. Some other symptoms were sweating, burning feet, itching and headache. Significant reduction in all the diabetic symptoms was observed in all the three groups but maximum reduction was seen in group III patient who were given mixture of tulsi and neem leaf powder. Significant percent reduction in the symptoms like polydypsia (35, 33, 40), polyphagia (21, 35, 40) and headache (27, 38, 40) was observed in group I, II and III respectively. It can be concluded from the study that tulsi and neem leaves are helpful in reducing the diabetic symptoms and blood pressure of the subjects. Non significant improvement in the anthropometric parameters of the subjects was observed after supplementation of tulsi and neem leaves powder of the patients. Therefore these leaves should be regularly consumed by the diabetic patients to get relief from the diabetic symptoms. Singh et al (2009)

# Studies Related To Tulsi Leaves and Blood Glucose Level

Mitra A. (2007) conducted a study with 120 patients whose Fasting Blood Sugar values is below 180mg/dl and without any complications of diabetes, and free from

other diseases, are screened out of 2607 cases from hospitals at and around Kharagpur by random selection (lottery), divided into two groups of 60 patients each (lottery). The experimental group receives the composite of composite of Tulsi (Ocimum Sanctum) leaves, Amla (Emblica Officinalis), Bitter Gourd (Momordica Charantia), Gurmur (Gymnema sylvestre) leaves and Jamun (Syzygium Cumini) fruit and its seed the above substances mixed with Soybean sattu and used as a breakfast item for three months. The parameters like fasting blood sugar and lipid profile values for both experimental and control groups are measured at monthly intervals and compared statistically. Insulin resistance pictures are calculated. Normal distribution method is used to analyse the data. The composite in this study causes beneficial changes in the blood bio-chemic parameters with reduction of Insulin resistance in the patients.

In a clinical trial on 27 non insulin dependent diabetes mellitus patients, it was observed that supplementation of tulsi powder along with hypoglycaemic drugs for one month could significantly decrease the blood glucose, glycosylated proteins, total amino acids, uronic acid, triglycerides, low density lipoprotein (LDL) and very low density lipoprotein (VLDL), compared to control group on similar hypoglycaemic drugs. However, there was no significant change in high density lipoprotein (HDL) level. Rai et al (1997)

Agarwal et al (1996) conducted a randomized placebo-controlled, single blind trail of tulsi leaves in patients with non insulin-dependent diabetes mellitus. It was observed that taking dried tulsi leaves powder made from 2.5g fresh leaves per day orally on empty stomach could reduce the fasting glucose level upto 21mg/dl and post prandial blood glucose by 15.8 mg/dl.

Controlled studies carried out in India as well as in many other countries have revealed that a Tulasi (Ocimum Sanctum) intake offers protection against diabetes which is related to nutritionally induce metabolic over load (Wynder et al, 1992).

# **Summary**

The chapter dealt with the review of literature. The literature presented here was extracted from 13 primary and 10 secondary sources. It also enabled the researcher to design the study to develop the tool, plan for data collection procedure and analysis of the data.

# **CHAPTER III**

# **RESEARCH METHODOLOGY**

The methodology of the research study is defined as the way the client information is gathered in order to answer the research question or analyze the research problem.

The present study was conducted to assess the effectiveness of tulsi leaves powder upon blood glucose level of diabetic patients. This chapter deals with the methodology adopted by the researcher for the study. It includes research approach, research design, sample and sampling technique, development of data collection instruments, method of data collection, pilot study and plan for data analysis. On the whole it gives the general process for gathering and processing research data.

# **Research Approach**

Research approach is the most significant part of any research. The appropriate choice of the research approach depends on the purpose of the research study which is undertaken. According to Polit and Beck (2010) experimental research is an extremely applied form of research and involves finding out how a program, practice or policy is working. In this study, as the researcher wanted to assess the effectiveness of tulsi leaves powder upon blood glucose level of diabetic patients, the experimental approach was chosen to conduct this study.

## **Research Design**

A research design incorporates the most important methodological design that a researcher works in conducting a research study (Polit and Beck, 2010).

A quasi experimental research with non equivalent control group pre-test and post-test design was adopted for conducting this study. It fulfills the criteria such as manipulation and control.

The research design is represented diagrammatically as follows.

01	-	02
01	X	02

Х	-	Administration of tulsi leaves powder
01	-	Assessment of blood glucose level before administration
O2	-	Assessment of blood glucose level after administration

# Variables

An abstract concept that can be measured in a study is called a variable. Variables are characteristics that vary among the subject being studied.

#### **Independent variable**

The independent variable of the study was administration of tulsi leaves powder.

# Intervention

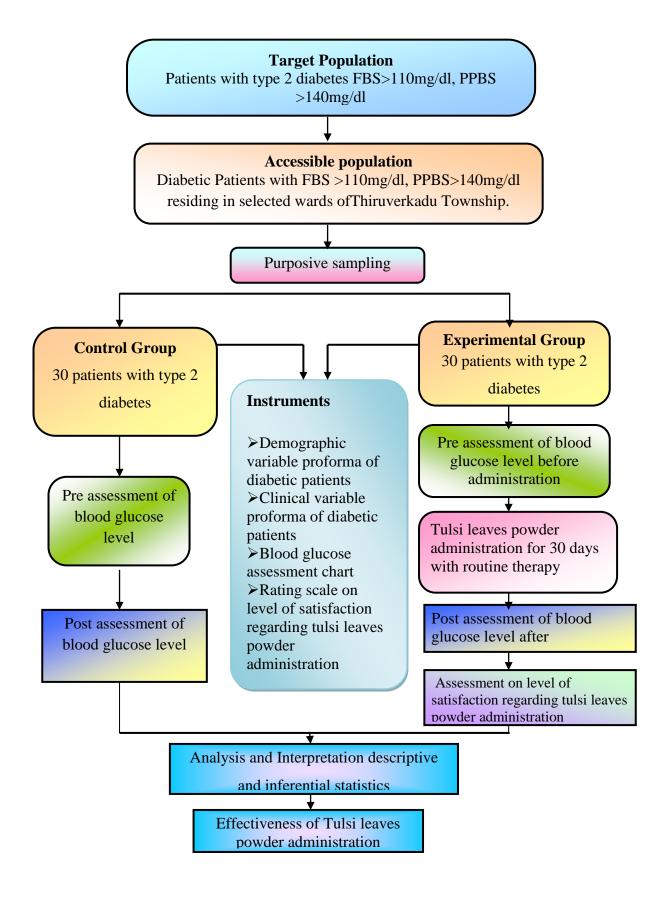
Tulsi leaves was plucked freshly from the plants, dried under the shadow and powdered in mixer. 2.5g of this powder is mixed with 10ml of plain water and administered every day orally on empty stomach for four weeks.

# Dependent variable

It was blood glucose level of diabetic patients before and after administration of tulsi leaves powder.

# Attribute variable

It includes the demographic and the clinical variables which has influence on the fasting and post prandial blood glucose level of diabetic patients.



**Fig.2 Schematic Representation of Research Design** 

# **Research Settings**

According to polit and hungler (2008) research setting is defined as the physical location in which the data collection take place in the study.

The study was conducted at selected wards of Thiruverkadu Township, Chennai. In this diabetic patients who residing in 14<sup>th</sup> ward was taken as experimental group and patients in Keelayanambakkam village was taken as control group. Thiruverkadu area belongs to Thiruvallur district, Ambatur Taluk. The village has all medical facilities like private clinic, sub center hospital and Apollo rural health center also cater service to all minor problems of the people in this village.

# **Population**

Population is an aggregate or totality of all the subjects that possess a set of specifications. The entire set of individuals having some common characteristics. (Polit and Beck, 2010)

# **Target Population**

Refers to entire population in which the researcher is interested and to which he/she would like to generalize the results of a study. In this study the target population comprises of patients with type 2 diabetes mellitus having fasting blood glucose level above 110mg/dl and post prandial blood glucose above 140mg/dl.

### **Accessible Population**

The accessible population is the list of population that the researcher finds in the area. The accessible population in this study was the diabetic patients with type-2 diabetes having fasting blood glucose level above 110mg/dl and post prandial blood glucose above 140mg/dl who residing in Thiruverkadu, Chennai.

# Sample

Sample consists of subset of the units that comprises the population (Polit and Beck, 2010). A sample of 60 patients with type 2 diabetes mellitus were selected for the study from Thiruverkadu Township, out of which 30 patients from 14<sup>th</sup> ward were purposively assigned to the experimental group and 30 patients from 5<sup>th</sup> ward to the control group.

# **Sampling Technique**

It was stated by Polit and Beck (2010) that sampling referred to the process of selecting a portion of the population to represent the entire population. A purposive sampling technique was used for the present study.

# **Sampling Criteria**

#### **Inclusion criteria**

- Patients with type 2 diabetes
- Diabetic patients with age above 40 years
- Diabetic patients with fasting and post prandial blood glucose above 110 mg/dl and 140 mg/dl respectively.

- Diabetic patients on oral hypoglycemic agents.
- Diabetic patients who are willing to participate

# **Exclusion criteria**

The study excludes

- Diabetic patients with complications
- > Diabetic patients who are not willing to consume tulsi leaves powder

# **Selection and Development of Study Instruments**

As the study aimed to evaluate the effectiveness of tulsi leaves powder upon blood glucose level, the data collection instruments were developed through an extensive review of literature in consultation with the opinion of experts and with the opinion of faculty members. The instruments used in this study were demographic variables Proforma, clinical variable proforma, blood glucose assessment chart and rating scale on level of satisfaction regarding tulsi leaves powder administration.

# Demographic variable proforma of diabetic patients

Demographic variable proforma include age, gender, religion, education, marital status, income, occupation, diet, habit of smoking and alcoholism. The researcher collected the data by interviewing the patient.

# Clinical variable proforma of diabetic patients

Clinical variable proforma includes duration of diabetes, family history of diabetes, whether on diabetic medications, on diabetic diet, weight in kilogram, height, body mass index, presence of other comorbidities, about exercise and whether on any other alternative or complementary therapy. The researcher collected the data by interviewing the patient.

## Blood glucose assessment chart

This was used to assess the fasting and post prandial blood glucose levels before and after tulsi leaves powder administration, tested by Easy care glucometer.

The blood glucose levels were categorized as:

# Fasting blood glucose level

Scoring	Interpretation
111-180 mg/dl	Mild elevation
181-250 mg/dl	Moderate elevation
>251 mg/dl	Severe elevation

# Post prandial blood glucose level

Scoring	Interpretation		
141-200 mg/dl	Mild elevation		
201-260 mg/dl	Moderate elevation		
>261 mg/dl	Severe elevation		

# Rating scale on level of satisfaction regarding tulsi leaves powder administration

This rating scale consists of 10 statements on satisfaction of patients regarding tulsi leaves powder administration upon blood glucose level. The response extended from highly satisfied, satisfied, dissatisfied, highly dissatisfied.

Score	Interpretation		
>76	Highly satisfied		
51-75%	Satisfied		
26-50%	Dissatisfied		
< 25%	Highly dissatisfied		

#### **Psychometric Properties of the Instruments**

# Validity

The content validity refers to the degree to which the item on an instrument adequately represents the universe of the content (Polit and Beck 2010). The content validity of the tool was obtained by getting opinion from seven experts. The validation has suggested some specific modifications. The modifications and suggestions of experts were incorporated in the final preparation of the tool.

# Reliability

Reliability refers to the accuracy and consistency of measuring tool (Polit and Beck, 2010).

## 1. Blood glucose assessment chart

The reliability of the instrument (glucometer) was determined by inter rater reliability technique and the 'r' value was found to be 0.85 which shows positive correlation indicates that instrument is highly reliable.

# 2. Rating scale on level of satisfaction regarding tulsi leaves powder administration

The satisfaction scale was tested using split half method and the reliability was found to be 0.90, indicating that the tool is highly reliable.

#### **Pilot Study**

Polit and Beck (2010) states that pilot study is a miniature of some parts of the actual study in which the instruments are administered to the subjects drawn from the same population. It is a small scale version or trial run done in preparation for the major study. The purpose is to find out the feasibility and practicability of the study design.

The pilot study was conducted on 6 Samples selected from Rajankuppam village as Experimental group and 6 samples were selected from keelayanambakkam as control group. Rapport was established with patients. The subjects were chosen by purposive sampling 6 in control group and 6 in experimental group. Fasting and postprandial blood glucose level was assessed for both the control and experimental group. Tulsi leaves powder was administered for the experimental group once a day in empty stomach for 7 days. At the end of the 7<sup>th</sup> day fasting and postprandial blood glucose were assessed for both control and experimental group. Level of satisfaction was assessed through rating scale only in experimental group. The pilot study revealed that the present study was feasible to conduct.

## **Protection of Human Rights**

Permission was obtained from the Ethical Committee, Apollo Hospitals, Chennai and from chairman, Thiruverkadu Township to conduct the study. Consent was obtained from the study participants and confidentiality was maintained throughout the study.

#### **Data Collection Procedure**

The data collection is the gathering of information needed to address a research problem. The data collection was done for a period of four weeks from 25<sup>th</sup> June to 22<sup>nd</sup> July 2012. The researcher introduced herself and obtained consent from the subjects to participate in the study. An assurance was given regarding confidentiality while the actual data was collected. Researcher collected the data from diabetic patients in the selected villages.

The present study was conducted in 14<sup>th</sup> ward and 5<sup>th</sup> ward of Thiruverkadu Township, Chennai. The diabetic patients were identified by screening. Sixty patients were purposively selected as the study participants , 30 patients as control group in 5<sup>th</sup> ward and 30 patients were selected for experimental group in 14<sup>th</sup> ward of Thiruverkadu Township. The study was primarily concerned to assess the effectiveness of tulsi leaves powder upon blood glucose level of diabetic patients in the selected wards.

The baseline data of demographic variable and clinical variable were collected before the intervention in both control and experimental group. The level of fasting and post prandial blood glucose level were assessed on 0 and 28<sup>th</sup> day for control group and 0, 9<sup>th</sup>, 18<sup>th</sup> and 28<sup>th</sup> day of the intervention for experimental group. Tulsi leaves powder was prepared by plucking fresh leaves from the plants, dried under the shadow and powdered in mixer. 2.5g of this powder was mixed with 10ml of plain water and administered every day orally on empty stomach for four weeks. The diabetic patients in the control group were not receiving any intervention. The level of satisfaction on tulsi

leaves powder administration was assessed in the experimental group by using rating scale.

#### **Problems Faced During Data Collection**

The problems faced during the process of this study were,

- Some diabetic patients not willing to participate
- Some patients expressed that the duration is longer

# **Plan for Data Analysis**

Data analysis is the systematic organization and synthesis of research data and testing of null hypothesis by using the obtained data (Polit and Beck, 2010). Analysis and interpretation of data were carried out with descriptive statistics such as frequency, percentage, mean and standard deviation and inferential statistics such as independent 't' test and chi-square test.

# **Summary**

This chapter has dealt with the selection of research approach, research design, setting, population, sample, sampling technique, sampling criteria, selection and development of study instruments, validity and reliability of study instruments, pilot study, data collection procedure and plan for data analysis. The following chapter deals with analysis and interpretation of data using descriptive and inferential statistics

#### **CHAPTER IV**

# ANALYSIS AND INTERPRETATION

Data analysis is conducted to reduce, organize and give meaning to the data. The results obtained from data analyses require interpretation to be meaningful. Interpretation of data involves examining the results from data analysis, forming conclusions, considering the implications for nursing, exploring the significance of the findings and suggesting further studies (Polit and Beck, 2010).

The data was collected from 60 patients with type-2 diabetes mellitus, 30 in the control group and 30 in the experimental group to assess the effectiveness of tulsi leaves powder upon blood glucose level. The data were analysed according to the objectives and hypotheses of the study. Analysis of the data was compiled after all the data was transferred to the master coding sheet. The data were analyzed, tabulated and interpreted using appropriate descriptive and inferential statistics.

# **Organization of Findings**

- Frequency and percentage distribution of demographic variables in control and experimental group of diabetic patients.
- Frequency and percentage distribution of clinical variables in control and experimental group of diabetic patients.
- Frequency and percentage distribution of fasting and post prandial blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder.

- Comparison of mean and standard deviation of blood glucose levels of diabetic patients between control and experimental group before and after administration of tulsi leaves powder.
- Frequency and percentage distribution of level of satisfaction in experimental group after administration of tulsi leaves power.
- Association between selected demographic variables and fasting blood glucose levels of diabetic patients in control group before and after administration of tulsi leaves powder.
- Association between selected demographic variables and post prandial blood glucose levels of diabetic patients in control group before and after administration of tulsi leaves powder.
- Association between selected demographic variables and fasting blood glucose levels of diabetic patients in experimental group before and after administration of tulsi leaves powder.
- Association between selected demographic variables and post prandial blood glucose levels of diabetic patients in experimental group before and after administration of tulsi leaves powder.
- Association between the selected clinical variables and fasting blood glucose levels of diabetic patients in control group before and after administration of tulsi leaves powder.
- Association between the selected clinical variables and post prandial blood glucose levels of diabetic patients in control group before and after administration of tulsi leaves powder.

- Association between the selected clinical variables and fasting blood glucose levels of diabetic patients in experimental group before and after administration of tulsi leaves powder.
- Association between the selected clinical variables and post prandial blood glucose levels of diabetic patients in experimental group before and after administration of tulsi leaves powder.

Frequency and Percentage Distribution of Demographic Variables in Control and Experimental Group of Diabetic Patients.

Demographic variables	<b>Control Group</b>		Experimer	_
	n=30		n=	
	n	Р	n	р
Age in years				
31-40	1	3.3	4	13.3
41-50	13	43.3	10	33.4
51-60	10	33.4	12	40
61-70	6	20	4	13.3
Education				
No formal education	-	-	4	13.3
Primary Education	10	33.4	8	26.6
High school education	9	30	10	33.4
Graduate and above	1	3.2	1	3.4
Income per month				
2501 to 5000	4	13.3	1	3.4
5001 to 10,000	20	66.7	23	76.6
>10,000	6	20	6	20
Occupation Status				
Employed	13	43.3	14	46.7
Home maker	16	53.4	14	46.7
Retired	1	3.3	2	6.6

Dietary pattern				
Vegetarian	-	-	-	-
Non-vegetarian	30	100	30	100

Table 1 shows that significant percentage of diabetic patients were in age group between 41 to 50 (43.3%, 33.4%), females (53.4.7%, 46.6%), belonging to Hindu religion (50%, 53.4%), had High school education (30%, 33.4%), occupation as home maker (53.4%, 46.7%), majority of them were married (90%, 93.2%), with monthly income between 5001 to 10,000 (66.7%, 76.6%), non smokers (66.6%, 80%) and non alcoholic (70%, 76.6%) and most of them were nonvegetarians (100%,100%), in control and experimental group respectively.

**Fig 3** indicates that significant percentage of the diabetic patients in the control group and in the experimental group were females (53.4%, 46.6%).

**Fig 4** denotes that significant percentage of the diabetic patients both in control and experimental group belong to Hindu religion (50%, 53.4%).

**Fig 5** notifies that most of the diabetic patients both in control and experimental group had no habit of smoking (66.6%, 80%).

**Fig 6** indicates that most of the diabetic patients in the control group and most of them in the experimental group were non- alcoholics (70%, 76.6%).

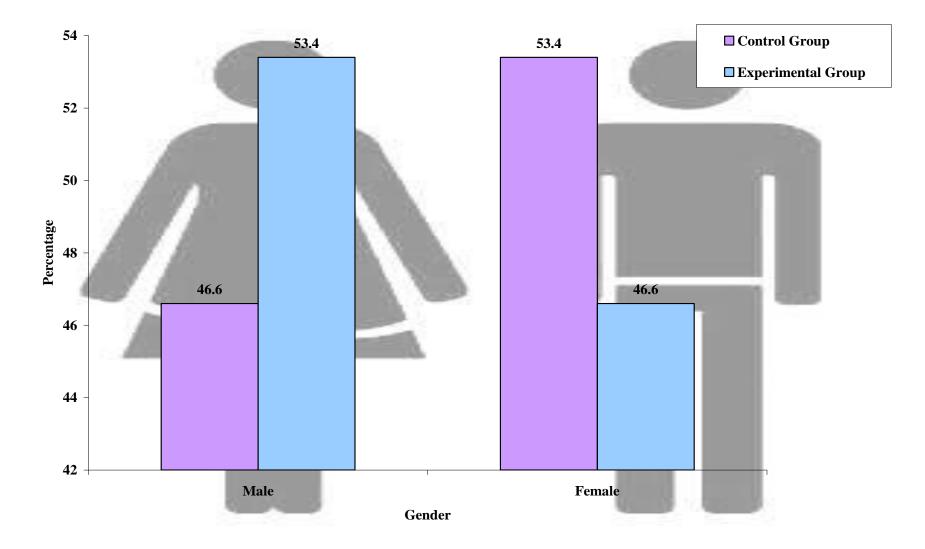


Fig. 3 Percentage Distribution of Gender in Diabetic Patients

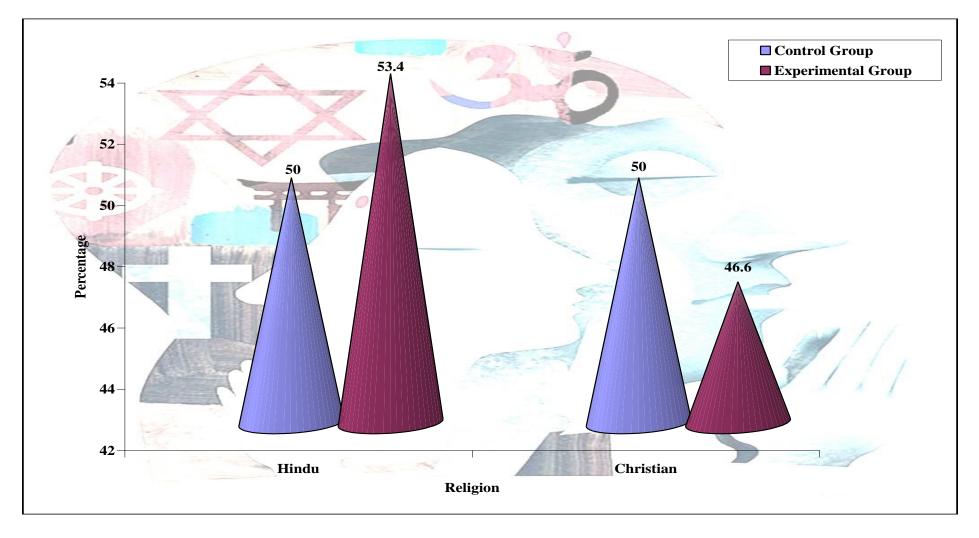


Fig. 4 Percentage Distribution of Religion in Diabetic Patients

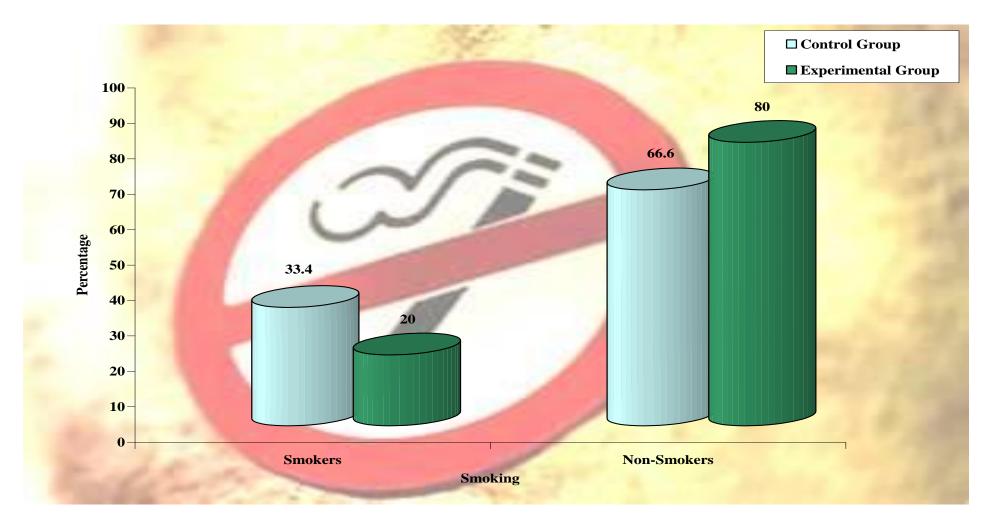


Fig. 5 Percentage Distribution of Habit of smoking in Diabetic Patients

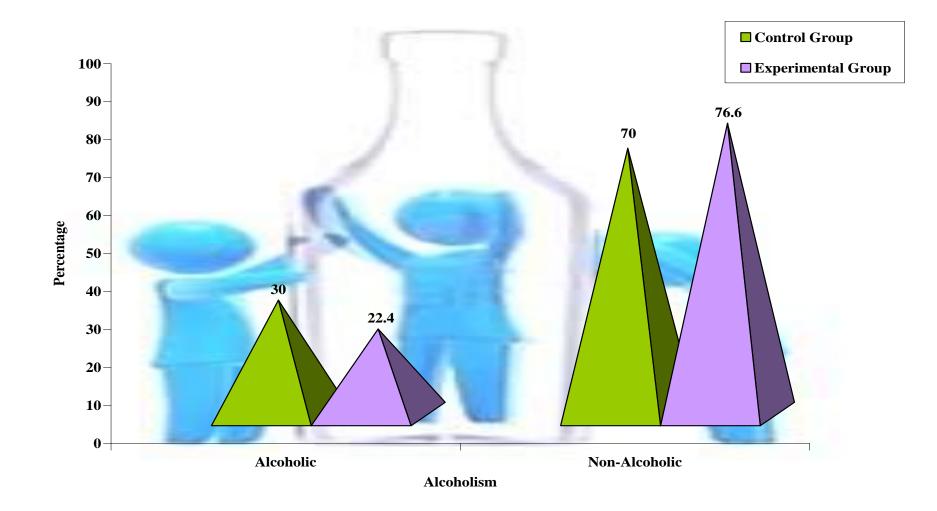


Fig. 6 Percentage Distribution of Habit of alcoholism in Diabetic Patients

Frequency and Percentage Distribution of Clinical Variables in Control and Experimental Group of Diabetic Patients.

Clinical variables	Control Group		Experimental Group	
	:	n=30		n=30
	Ν	р	n	Р
Duration of known period of diabetes				
<1 year	1	3.4	-	-
1-2years	11	36.6	16	53.4
3-5 years	12	40	12	40
> 5years	6	20	2	3.4
Family history of diabetes				
Present	13	43.4	8	26.6
Absent	17	56.6	22	73.4
Whether on hypoglycaemic agents				
Yes	30	100	30	100
No	-	-	-	-
Whether on diabetic diet				
Yes	18	60	10	33.4
No	12	40	20	66.6

Weight in Kg				
31 – 40	-	-	-	-
41 - 50	9	30	10	33.4
51 - 60	14	46.6	13	43.4
> 61kg	7	23.4	7	23.2
Height in Cms				
146 – 150	1	3.4	-	-
151 – 155	12	40	9	30
156 – 160	14	46.6	21	70
>160	3	1	-	-
BMI				
Less than 18.4	4	13.4	1	3.3
18.5 – 22.5	8	26.6	13	43.4
22.6 - 29.9	15	50	15	50
More than 30	3	10	1	3.3
Whether on any other alternative /				
complementary therapy				
Yes	-	-	-	-
No	30	100	30	100

Table 2 shows that significant number of the diabetic patients has been suffering from diabetes mellitus for a duration between 1 to 2 yrs (36.6%, 53.4%), had body weight between 51-60 kg (46.6%, 43.4.7%), had no family history of diabetes (56.6%, 73.4%), on oral hypoglycemic agents (100%, 100%), not on diabetic diet (40%, 66.6%),

with height 156 to 160 cm (46.6, 70%), with BMI between 22.6 to 29.9 (50%, 50%), and majority of them had absence of comorbidities (63.4%, 73.4%), not performing regular exercise (66.6%, 73.4%) and almost all of them were not on other alternative or complementary therapy (100%, 100%).

**Fig 7** indicates that significant percentage of the diabetic patients in the control and experimental group had no co morbidities (63.4%, 73.4%).

**Fig 8** states that significant percentage of the diabetic patients in the control group and most of them in the experimental group were not performing regular exercise (66.6%, 73.4%).

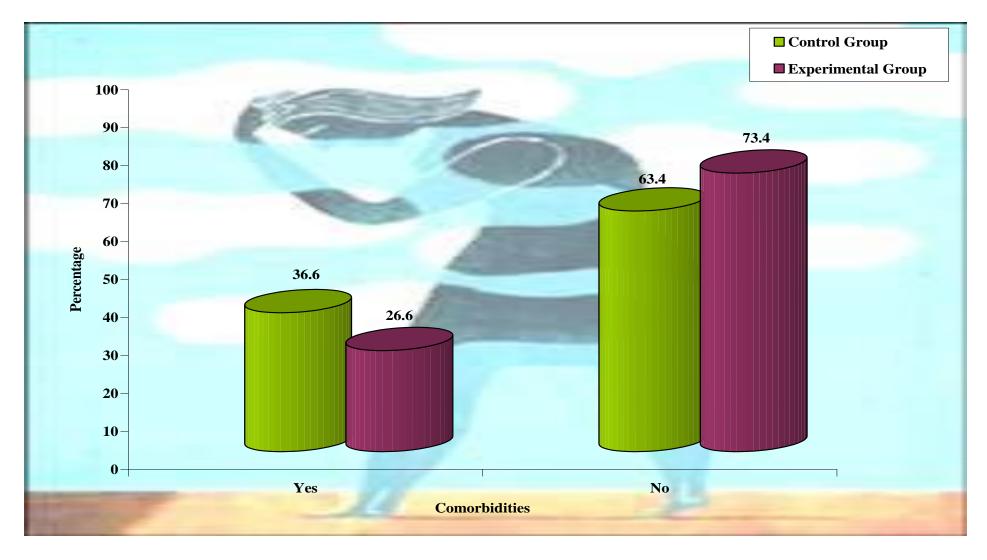


Fig. 7 Percentage Distribution of presence of diabetic patients Regarding co morbidities

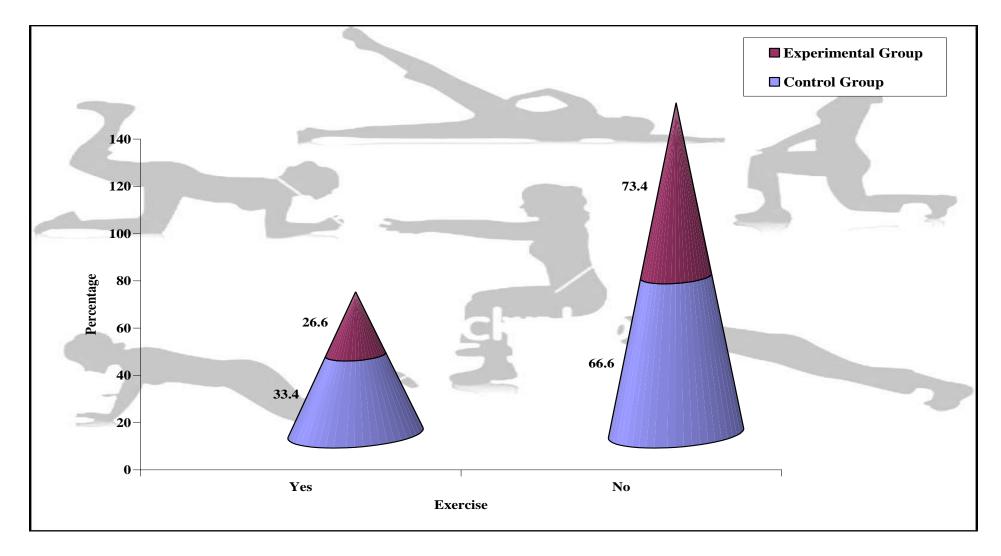


Fig. 8 Percentage Distribution of diabetic patients Regarding Regular exercise

Frequency and Percentage Distribution of Fasting and Post Prandial Blood Glucose Levels of Diabetic Patients in Control and Experimental Group Before and After Administration of Tulsi leaves powder.

Blood glucose levels	<b>Control Group</b>		Experimental Group	
	(n=30)		( <b>n</b> =	:30)
	n p		n	Р
Zero day of the intervention				
Fasting Blood Glucose				
Mild	26	86.67	27	90
Moderate	4	13.33	3	10
Severe	-	-	-	
Post prandial blood glucose				
Mild	2	6.6	-	-
Moderate	22	73.4	24	80
Severe	6	20	6	20
9 <sup>th</sup> day of the intervention				
Fasting blood glucose				
Mild	-	-	30	100
Moderate	-	-	-	-
Severe	-	-	-	-

Post prandial blood glucose				
Mild	-	-	8	26.66
Moderate	-	-	19	63.34
Severe	-	-	3	10
18 <sup>th</sup> day of the intervention				
Fasting blood glucose				
Mild	-	-	30	100
Moderate	-	-	-	-
Severe	-	-	-	-
Post prandial blood glucose				
Mild	-	-	19	63.34
Moderate	-	-	11	36.66
Severe	-	-	-	-
28 <sup>th</sup> day of the intervention				
Fasting blood glucose				
Mild	25	83.33	30	100
Moderate	5	16.67	-	-
Severe	-	-	-	-
Post prandial blood glucose				
Mild	-	-	28	93.33
Moderate	25	83.3	2	6.67
Severe	5	16.67	-	-

The data presented in Table 3 indicate that majority of the diabetic patients in the control and experimental group had mild level of fasting blood glucose (86.67%, 90%) and most of them had moderate level of postprandial blood glucose(73.4%, 80%) before tulsi leaves powder administration. Whereas in control group most of the diabetic patients had mild level of fasting blood glucose (83.33%) and moderate level of postprandial blood glucose (83.33%) and moderate level of postprandial blood glucose (83.33%). But there was a significant difference in the experimental group, all the diabetic patients had mild level of fasting blood glucose (100%) and majority of them had mild level of postprandial blood glucose (93.3%) after tulsi leaves powder administration. This could be attributed to the effectiveness of tulsi leaves powder administration.

Comparison of Mean and Standard Deviation of Blood Glucose Levels of Diabetic patients Between Control and Experimental Group before and after administration of Tulsi leaves powder.

Blood Glucose level	Control Group		<b>Experimental Group</b>		ʻt'
	(n=30)		( <b>n=30</b> )		Value
	М	SD	Μ	SD	
Fasting blood glucose					
0 day	164.7	11.77	169.4	7.90	1.958
28 <sup>th</sup> day	169.9	11.24	114	3.91	26.20
Post prandial blood glucose					
0 day	231.7	25.40	239.8	24.34	1.359
28 <sup>th</sup> day	244.1	23.24	166.8	19.93	14.89

Data from table 4 shows that, In control group the mean and standard deviation of fasting blood glucose in control group is (M=164.7, 169.9 & SD=11.77, 11.24) and postprandial blood glucose is (M=231.7, 244.1 & SD=25.40,23.24) before and after tulsi leaves powder administration which is not statistically significant (p>0.05), Whereas in experimental group mean and standard deviation of fasting blood glucose (M=169.4, 114 & SD=7.90, 3.91) and postprandial blood glucose (M=239.8, 166.8 & SD=24.34, 19.93) before and after administration of tulsi leaves powder is statistically significant (p<0.001) and it can be attributed to the effectiveness of tulsi leaves powder administration. Hence the null hypothesis Ho1 was rejected before and after administration of tulsi leaves powder.

Frequency and Percentage Distribution of Level of Satisfaction in Experimental Group of diabetic patients after Administration of Tulsi leaves powder.

Domains	Highly		Satisfied		Dissatisfied		Highly	
With regard to:	satisfied						dissat	tisfied
	n	р	n	р	n	р	n	Р
The researcher	30	100	-	-	-	-	-	-
The Nature of tulsi leaves	29	96.67	1	3.33	-	-	-	-
powder								
The Method of tulsi leaves	30	100			-	-	-	-
powder administration								
The Effectiveness of tulsi	30	100	-	-	-	-	-	-
leaves powder administration								

The table 5 depicts that, all of the diabetic patients in the experimental group were highly satisfied (100%) with regard to researcher, the method of tulsi leaves powder administration (100%) and the effectiveness of tulsi leaves powder administration (100%) respectively. Most of the patients were highly satisfied with the nature of tulsi leaves powder (96.67%).

Association between Selected Demographic Variables and Fasting Blood Glucose Levels of Diabetic Patients in Control Group Before and After Administration of Tulsi leaves powder.

Demographic variables	Pre Assessment		$\chi^2$	Post A	$\chi^2$	
	Mild	Moderate	value	Mild	Moderate	value
	n	Ν		n	n	
Age in years						
41-50	12	2	7.45	12	2	3.207
51-60	9	1	(df=2)	9	1	(df=3)
61-70	4	2		4	2	
Gender						
Male	11	3	1.429	10	4	2.912
Female	14	2	(df=1)	15	1	(df=1)
Religion						
Hindu	13	2	0.24	13	2	0.24
Muslim	-	-	(df=1)	-	-	(df=1)
Christian	12	3		12	3	
Education						
No formal education	-	-	1.052	-	-	1.052
Primary Education	8	2	(df=3)	8	2	(df=3)
High school	7	2		7	2	
Higher secondary	9	1		9	1	
Graduate and above	1	-		1	-	

Marital Status						
Married	22	5	0.666	22	5	0.666
Unmarried	-	-	(df=1)	-	-	(df=1)
Widower	3	-		3	-	
Income per month						
2501 to 5000	2	2	6.407	3	1	2.043
5001 to 10,000	19	1	(df=3)	18	2	(df=3)
>10,000	4	2		4	2	
Occupation Status						
Employed	11	2	4.615	10	3	5.039
Home maker	14	2	(df=2)	15	1	(df=2)
Retired	0	1		0	1	
Habit of smoking						
Yes	8	2	0.15	8	2	0.15
No	17	3	(df=1)	17	3	(df=1)
Habit of alcoholism						
Non-alcoholic	17	4	1.288	17	4	1.288
Alcoholic	8	1	(df=3)	8	1	(df=3)

\*\*p<0.05

It could be notified from table 6 that there was a significant association between the selected demographic variables of age in years and fasting blood glucose levels of diabetic patients in pretest in control group, but the association with other demographic variables were not significant. Hence the null hypothesis  $Ho_2$  was rejected with regard to age in years.

Association between Selected Demographic Variables and Post Prandial Blood Glucose Levels of Diabetic Patients in Control Group Before and After Administration of tulsi leaves powder.

Demographic variables	Pre A	ssessment		$\chi^2$	Post A	Assessment	$\chi^2$
	Mild	Moderate	Severe	value	Mild	Moderate	value
	n	n	Ν		n	n	
Age in years							
31-40	0	1	0	5.427	-	-	6.039
41-50	1	11	1	(df=6)	13	1	(df=2)
51-60	0	6	4		6	4	
61-70	1	4	1		6	0	
Gender							
Male	1	10	3	0.033	11	3	0.021
Female	1	12	3	(df=2)	14	2	(df=1)
Religion							
Hindu	1	11	3	0	12	3	0.016
Muslim	-	-	-	(df=6)	-	-	(df=3)
Christian	1	11	3		13	2	
Others	-	-	-		-	-	
Education							
No formal education	-	-	-	2.75	-	-	0.525
Primary Education	1	8	1	(df=8)	9	1	(df=4)
High school	1	5	3		7	2	
Higher secondary school	0	8	2		9	2	
Graduate and above	-	1	-		-	-	

Marital Status							
Married	1	20	6	0.075	22	5	0.66
Widower	1	2	-	(df=2)	3	-	(df=2)
Income per month							
2501 to 5000	-	4	-	1.153	4	-	0.923
5001 to 10,000	2	12	6	(df=4)	15	5	(df=4)
>10,000	0	6	0		6	-	
Occupation Status							
Employed	0	10	3	0.135	10	3	6.868
Home maker	2	12	3	(df=2)	15	2	(df=2)
Habit of smoking							
Yes	1	8	1	1.58	9	1	0.48
No	1	13	6	(df=2)	16	4	(df=2)
Habit of alcoholism							
Non-alcoholic	1	14	6	3.34	17	4	1.288
Alcoholic	1	8	-	(df=2)	5	-	(df=2)

\*\*p<0.05

It could be noticed from table 7 that there was a significant association between the selected demographic variables of age in years and post prandial blood glucose levels, occupational status and post prandial blood glucose levels of diabetic patients in post test in control group, but the association with other demographic variables were not significant. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age in years and occupational status.

Association between Selected Demographic Variables and Fasting Blood Glucose Levels of Diabetic Patients in Experimental Group Before and After Administration of tulsi leaves powder.

Demographic	В	efore	$\chi^2$	After	$\chi^2$
variables	admin	istration	value	administration	value
	Mild	Moderate		Mild	
	n	n		n	
Age in years					
31-40	3	1	1.48	4	
41-50	9	1	(df=3)	10	
51-60	11	1		12	
61-70	4	0		4	
Gender					
Male	14	2	0.238	16	
Female	13	1	(df=1)	14	
Religion					
Hindu	15	1	0.535	16	
Muslim	-	-	(df=3)	-	
Christian	12	2		14	
Others	0	0		-	

Education					
No formal education	3	1	0.535	4	
Primary Education	8	0	(df=4)	8	
High school	8	2		10	
education					
Higher secondary	7	0		7	
school education					
Graduate and above	1	0		1	
Marital Status					
Married	25	3	0.238	28	
Widow	1	0	(df=3)	1	
Widower	1	0		1	
Income per month					
2501 to 5000	1	-	0.114	1	
5001 to 10,000	20	3	(df=2)	23	
>10,000	6	-		6	
Occupation Status					
Unemployed	-	-	0.535	-	
Employed	12	2	(df=3)	14	
Home maker	13	1		14	
Retired	2	0		2	

Habit of smoking					
Yes	4	2	4.537	6	
No	23	1	(df=1)	24	
Habit of alcoholism					
Non-alcoholic	22	1		23	
Alcoholic	5	2		7	

It could be depicted from table 8 that there was significant association between the selected demographic variable of habit of smoking and fasting blood glucose levels of diabetic patients before administration of tulsi leaves powder in experimental group. Hence the null hypothesis  $Ho_2$  was rejected with regard to habit of smoking.

Association between Selected Demographic Variables and Post Prandial Blood Glucose Levels of Diabetic Patients in Experimental Group Before and After Administration of tulsi leaves powder.

Demographic	Before		$\chi^2$	After		χ <sup>2</sup>
variables	administration		value	administration		value
	Moderate	Severe		Mild	Moderate	
	n	n		n	n	
Age in years						
31-40	3	1	15.409	3	1	2.75
41-50	7	3	(df=3)	9	1	(df=3)
51-60	11	1		12	-	
61-70	3	1		4	-	
Gender						
Male	12	4	0.535	15	1	0.003
Female	12	2	(df=1)	13	1	(df=1)
Religion						
Hindu	12	4	0.535	16	-	2.44
Muslim	-	-	(df=2)	-	-	(df=2)
Christian	12	2		12	2	

Education						
No formal education	3	1	1.36	4	-	4.593
Primary Education	7	1	(df=4)	8	-	(df=4)
High school	7	3		8	2	
Higher secondary	6	1		7	-	
school						
Graduate and above	1	-		1	-	
Marital Status						
Married	23	5	1.205	26	2	0.076
Widow	1	-	(df=2)	1	-	(df=2)
Widower	-	1		1	-	
Income per month						
5001 to 10,000	19	5	(df=1)	22	2	(df=1)
>10,000	5	1		6	-	
Occupation Status						
Employed	11	3	0.030	13	1	0.009
Home maker	12	2	(df=2)	13	1	(df=2)
Retired	1	1		2	-	
Habit of smoking						
Yes	4	2	0.833	6	-	0.535
No	20	4	(df=1)	22	2	(df=1)

Habit of alcoholism						
Non-alcoholic	19	4	0.419	21	2	0.652
Alcoholic	5	2	(df=3)	7	-	(df=3)

\*\*\*p<.01

It could be revealed from table 9 that there was a significant association between the selected demographic variables of age and post prandial blood glucose levels of diabetic patients before administration of tulsi leaves powder in experimental group, but there was no significant association with other demographic variables. Hence the null hypothesis  $Ho_2$  was rejected with regard to age.

Association between the Selected Clinical Variables and Fasting Blood Glucose Levels of Diabetic Patients in Control Group Before and After Administration of tulsi leaves powder.

Clinical variables	Pre Assessment		$\chi^2$	Post A	$\chi^2$	
	Mild	Moderate	value	Mild	Moderate	value
	n	n		n	n	
Duration of known						
period of diabetes						
1-2years	10	2	2.006	10	2	0.678
3-5 years	11	1	(df=2)	11	1	(df=2)
> 5years	4	2		4	2	
Family history of						
diabetes						
Present	11	2	0.027	10	3	0.678
Absent	14	3	(df=1)	15	2	(df=1)
Whether on						
diabetic diet						
Yes	14	4	1	16	2	1
No	11	1	(df=1)	9	3	(df=1)

Weight in Kg						
41 - 50	8	1	4.91	8	1	4.91
51 - 60	13	1	(df=2)	13	1	(df=2)
> 61kg	4	3		4	3	
Height in Cms						
151 – 155	9	4	7.339	9	4	7.339
156 - 160	13	1	(df=2)	13	1	(df=2)
>160	3	-		3	-	
BMI						
Less than 18.4	3	1	7.323	3	1	2.523
18.5 – 22.5	8	-	(df=3)	8	-	(df=3)
22.6 - 29.9	13	2		12	3	
More than 30	1	2		2	1	
Regular exercise						
Yes	7	3	1.92	7	3	1.92
No	18	11	(df=1)	18	11	(df=1)

\*p<0.05

It could be identified from table 10 that there was a significant association between the selected clinical variables of height and post prandial blood glucose levels of diabetic patients in pre test and post test in control group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to height.

Association between Selected clinical Variables and Post Prandial Blood Glucose Levels of Diabetic Patients in Control Group Before and After Administration of tulsi leaves powder.

Demographic	Pre A	Assessment		$\chi^2$	Post A	Assessment	$\chi^2$
variables	Mild	Moderate	Severe	value	Mild	Moderate	value
	n	n	Ν		n	n	
Duration of known							
period of diabetes							
<1 year	-	-	-	6.164	-	-	6.531
1-2years	1	8	2	(df=6)	9	3	(df=2)
3-5 years	-	10	2		11	1	
> 5years	1	4	1		5	1	
Family history of							
diabetes							
Present	1	9	3	0.678	10	3	0.678
Absent	1	13	3	(df=1)	15	2	(df=1)
Whether on diabetic							
diet							
Yes	-	16	2	6.25	16	2	1
No	2	6	4	(df=1)	9	3	(df=1)
Weight in Kg							
41 – 50	1	6	2	1.077	7	2	0.28
51 - 60	1	10	3	(df=2)	12	2	(df=2)
> 61kg	-	6	1		6	1	

Height in Cms							
146 – 150	-	1	-	1.351	1	-	0.844
151 – 155	1	8	3	(df=6)	10	2	(df=3)
156 – 160	1	11	2		12	2	
>160	0	2	1		2	1	
BMI							
Less than 18.4	-	3	1	8.623	3	1	1.324
18.5 – 22.5	1	6	1	(df=6)	7	1	(df=3)
22.6 - 29.9	-	12	3		15	12	
More than 30	1	1	1		3	-	
Presence of							
Comorbidities							
Yes	1	8	2	0.19	9	2	0.028
No	1	14	4	(df=1)	16	3	(df=1)
Whether on regular							
exercise							
Yes	1	7	2	0.276	9	1	0.48
No	1	15	4	(df=1)	16	4	(df=1)

\*p<0.05

It could be identified from table 11 that there was no significant association between the selected clinical variables in the fasting blood glucose levels of diabetic patients before and after administration of tulsi leaves powder in control group. Hence the null hypothesis  $Ho_3$  was retained.

Association between the Selected Clinical Variables and Fasting Blood Glucose Levels of Diabetic Patients in Experimental Group Before and After Administration of tulsi leaves powder.

Clinical variables	]	Before	After				
	administration		$\chi^2$	administration	$\chi^2$		
	Mild Moderate		value	Mild	value		
	n	n		n			
Duration of known							
period of diabetes							
<1 year	-	-	3.836	-			
1-2years	15	1	(df=3)	16			
3-5 years	11	1		12			
> 5years	1	1		2			
Family history of							
diabetes							
Present	8	-	1.212	8			
Absent	19	3	(df=1)	22			
Whether on							
diabetic diet							
Yes	10	-	1.66	10			
No	17	3	(df=1)	20			

Weight in Kg					
41 - 50	8	2	3.785	10	
51 - 60	12	1	(df=2)	13	
> 61kg	7	0		7	
Height in Cms					
151 – 155	8	1	0.017	9	
156 - 160	19	2	(df=1)	21	
BMI					
Less than 18.4	1	-	3.809	1	
18.5 – 22.5	10	3	(df=3)	13	
22.6 - 29.9	15	-		15	
More than 30	1	-		1	
Comorbidities					
Yes	8	-	1.212	8	
No	19	3	(df=1)	22	
Whether on					
regular exercise					
Yes	7	1	0.075	8	
No	20	2	(df=1)	22	

Table 12 denotes that there was no significant association between the selected clinical variables in the fasting blood glucose levels of diabetic patients before and after administration of tulsi leaves powder in experimental group. Hence the null hypothesis  $Ho_3$  was retained.

Association between the Selected Clinical Variables and Post Prandial Blood Glucose Levels of Diabetic Patients in Experimental Group Before and After Administration of tulsi leaves powder.

Clinical variables	Before		$\chi^2$	After		$\chi^2$
	administration		value	administration		value
	Moderate	Severe		Mild	Moderate	
	n	n		n	n	
Duration of known						
period of diabetes						
1-2years	13	3	1.097	16	-	7.92
3-5 years	10	2	(df=2)	11	1	(df=2)
> 5years	1	1		1	1	
Family history of						
diabetes						
Present	7	1	0.383	7	1	0.596
Absent	17	5	(df=1)	21	1	(df=1)
Whether on diabetic						
diet						
Yes	9	1	0.937	9	1	0.267
No	15	5	(df=1)	19	1	(df=1)

Weight in Kg						
31 - 40	-	-	0.478	-	-	1.741
41 - 50	8	2	(df=3)	9	1	(df=3)
51 - 60	11	2		13	-	
> 61kg	5	2		6	1	
Height in Cms						
151 – 155	8	1	0.634	8	1	0.408
156 – 160	16	5	(df=2)	20	1	(df=2)
>160	-	-		-	-	
BMI						
Less than 18.4	1	-	0.57	1	-	15.01
18.5 – 22.5	10	3	(df=3)	13	-	(df=3)
22.6 - 29.9	12	3		13	2	
More than 30	1	-		1	0	
Comorbidities						
Yes	6	2	0.170	7	1	0.596
No	18	4	(df=1)	21	1	(df=1)
Whether on regular						
exercise						
Yes	5	8	2.088	7	1	0.596
No	19	22	(df=1)	21	1	(df=1)
D <0.05***						

P<0.05\*\*\*

It could be inferred from table 13 that there was a significant association between the selected clinical variable that is duration of known period of diabetes and post prandial blood glucose levels of diabetic patients after administration of tulsi leaves powder in experimental group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to duration of known period of diabetes.

### Summary

This chapter has dealt with analysis and interpretation of data obtained by the researcher. The analysis of the results showed that the fasting and post prandial blood glucose level of the diabetic patients was reduced in the experimental group after administration of tulsi leaves powder. The difference was found to be statistically significant at p<0.001 level. This implied that tulsi leaves powder has an effect on reducing blood glucose levels among type 2 diabetic patients.

### **CHAPTER V**

## DISCUSSION

Data relevant to the research findings were presented in chapter IV. Discussion of these results and their implications are presented in two sections: an investigation of the data regarding the research hypotheses is followed by presentation of implications for further research.

#### Statement of the problem

A Quasi Experimental Study to Assess the Effectiveness of Tulsi Leaves (Ocimum Sanctum) Powder Upon Blood Glucose Level in Diabetic Patients at Selected Wards Of Thiruverkadu Township, Chennai.

# **Objectives of the study**

- 1. To assess the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients
- To determine the effectiveness of tulsi leaves powder upon blood glucose level by comparing the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.
- 3. To determine the level of satisfaction regarding tulsi leaves powder administration among experimental group of diabetic patients.
- 4. To find out the association between the selected demographic variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.

5. To find out the association between the selected clinical variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.

A quasi experimental design was adopted for this study. Purposive sampling technique was used to select 30 in control group from keelayanambakkam and 30 in experimental group from 14<sup>th</sup> ward of Thiruverkadu Township. The blood glucose assessment chart and rating scale for level of satisfaction on administration of tulsi leaves powder were the tools used to collect data, after establishing validity and reliability. The main data collection was done after determining the feasibility and practicability through pilot study.

The diabetic patients were identified by door to door enumeration. The blood glucose level was checked for both control and experimental group before and after administration of tulsi leaves powder. Tulsi leaves were freshly plucked from the plants, washed, dried under the shadow and powdered in a mixer. 2.5g of this powder is mixed with 10 ml of plain water and was administered every day orally on empty stomach for four weeks and their level of satisfaction on tulsi leaves powder was assessed. The data was tabulated and analyzed by using descriptive and inferential statistics.

# The discussion is presented under the following headings

- Demographic variables of diabetic patients
- Clinical variables of diabetic patients

- Frequency and percentage distribution of fasting and post prandial blood glucose levels of diabetic patients in the control and experimental group before and after administration of tulsi leaves powder.
- Comparison of mean and standard deviation of blood glucose levels of diabetic patients between control and experimental group before and after administration of tulsi leaves powder.
- Level of satisfaction in experimental group of diabetic patients regarding tulsi leaves powder administration.
- Association between the selected demographic variables and fasting blood glucose level of diabetic patients in control and experimental group before and after administration of tulsi leaves powder.
- Association between the selected demographic variables and post prandial blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder.
- Association between the selected clinical variables and fasting blood glucose levels of diabetic patients before and after administration of tulsi leaves powder in control and experimental group.
- Association between the selected clinical variables and post prandial blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder.

# Demographic variables of diabetic patients

Significant percentage of diabetic patients were in age group between 41 to 50 (43.3%, 33.4%), female(53.4.7%, 46.6%), belonging to Hindu religion (50%, 53.4%),

had High school education (30%, 33.4%), occupation as home maker (53.4%, 46.7%), and majority were married (90%, 93.2%), with monthly income between 5001 to 10,000 (66.7%, 76.6%), nonvegetarian (100%, 100%), non smokers (66.6%, 80%) and non alcoholic (70%, 76.6%) in control and experimental group respectively.

Patients with diabetes mellitus were influenced by some of the variables. It was found that the diabetic patients were above the age of 45 years, which is in congruence with the report of American diabetes association (2004), according to which diabetes is common among people aged above 45 years. This finding was supported with the research conducted by Chaparro et al. (2008) that as the age of the person increases, the risk of diabetes also increases. It helps the nurses to concentrate more on this age group to reduce the morbidity and mortality related to increase in the blood sugar levels.

#### **Clinical variables of diabetic patients**

Most of the diabetic patients had no family history of diabetes (56.6%, 73.4%), not on diabetic diet (40%, 66.6%), with height 156 to 160 cm (46.6, 70%), significant percentage of the diabetic patients had been suffering from diabetes mellitus for a duration between 1 to 2 yrs (36.6%, 53.4%), with BMI between 22.6 to 29.9 (50%, 50%), had body weight between 51-60 kg (46.6%, 43.4.7%), and majority of the patients was on oral hypoglycemic agents (100%, 100%), no comorbidities (63.4%, 73.4%), not performing regular exercise (66.6%, 73.4%) and not on other alternative or complementary therapy (100%, 100%).

Significant number of patients had their height between 156-160cms. This was supported by Janghorbani et al. (2008) in their study which represents a more severe metabolic disturbance in a tall person than a shorter one. Most of the study participants had no co-morbidities. This might be because they were diagnosed early and were on regular treatment which might have eliminated the development of other co-morbidities. Most of the participants were not performing exercise which might have predisposed them to diabetes mellitus due to decreased utilization of glucose in the cells. This was supported by a study done by John et al. (2000) which revealed that lack of physical exercise leads to obesity and insulin resistance, which is responsible for type 2 diabetes.

# Fasting and post prandial blood glucose levels of diabetic patients in the control and experimental group before and after administration of tulsi leaves powder

Majority of the diabetic patients in the control and experimental group had mild level of fasting blood glucose (86.67%, 90%) and most of them had moderate level of postprandial blood glucose (73.4%, 80%) before tulsi leaves powder administration. After administration of tulsi leaves powder there was a significant difference in the experimental group, that all the diabetic patients had mild level of fasting blood glucose (100%) and majority of them had mild level of postprandial blood glucose (93.3%). Whereas in control group most of the diabetic patients had mild level of fasting blood glucose (83.3%) and moderate level of postprandial blood glucose (83.3%). This could be attributed to the effectiveness of tulsi leaves powder administration.

The above findings were supported by a study conducted by Agarwal et.al. (1996) which concluded that intake of dried tulsi leaves powder made from 2.5g fresh leaves per day orally on empty stomach could reduce the fasting glucose level upto 21mg/dl and post prandial blood glucose by 15.8 mg/dl.

Thus the researcher concluded that the mild level of blood glucose level can be brought to normal if appropriate measures are taken. Hence all the nurses can be empowered to get trained in alternative therapies and consecutively practice the same.

# Comparison of mean and standard deviation of blood glucose levels of diabetic patients between control and experimental group before and after administration of tulsi leaves powder

In control group there was no significant difference in the mean and standard deviation of fasting blood glucose (M=164.7, 169.9 & SD=11.77, 11.24) and postprandial blood glucose (M=231.7, 244.1 & SD=25.40, 23.24) before and after tulsi leaves powder administration. Whereas experimental group showed a significant difference (p<0.001) in the mean and standard deviation of fasting blood glucose (M=169.4, 117 & SD=7.90, 3.91) and postprandial blood glucose (M=239.8, 166.8 & SD=24.34, 19.93) before and after administration of tulsi leaves powder and it can be attributed to the effectiveness of tulsi leaves powder administration. Hence the null hypothesis Ho<sub>1</sub> was rejected.

This shows that tulsi leaves contains hypoglycemic effect which stimulates the blood glucose level. So, it is a very cost effective way of offsetting health problem related to glucose or insulin imbalances.

# Level of satisfaction in experimental group of diabetic patients regarding tulsi leaves powder administration

All of the diabetic patients in the experimental group were highly satisfied (100%) with regard to the researcher, the method of tulsi leaves powder administration (100%), the effectiveness of tulsi leaves powder administration (100%) respectively. And most of the diabetic patients were highly satisfied with the nature of tulsi leaves powder (96.67%).

These findings indicated that the administration of tulsi leaves powder is effective in reducing the blood glucose level, since it is easy to administer and cost effective. Tulsi as a friendly herb is used both internally and externally. It is a part of livelihood for every Indians. This attribute to the satisfaction of diabetic patients. Consumption of tulsi leaves may not pose problem for ritual Indians. Hence the community health nurse can administer tulsi leaves powder to the patients with type 2 diabetes mellitus.

Association between selected demographic variables and fasting blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder

There was a significant association between the selected demographic variables of age ( $\chi^2 = 7.45$ , df= 2), (p<0.05) and fasting blood glucose levels in the pre assessment of control group of diabetic patients, but there is no significant association with other demographic variables. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age.

This inferred that risk of incidence of diabetes increases with age. Hence life style modification and education on risk assessment has to begin in the older adult age group itself.

This finding was supported with the research conducted by Chaparro et al. (2008) which infer as the age of the person increases, the risk of diabetes also increases.

Association between selected demographic variables and post prandial blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder

There was a significant association between the selected demographic variables of age ( $\chi^2 = 6.039$ , df= 2), (p<0.05) occupational status ( $\chi^2 = 6.868$ , df= 2), (p<0.05) and post prandial blood glucose levels in control and experimental group of diabetic patients in the post test, but the association with other demographic variables were not significant. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age in years and occupational status.

This finding was supported by Kouvonen (2008) which showed that unemployment increases the risk of premature mortality by 63 percent.

There was a significant association between the selected demographic variables of age ( $\chi^2 = 15.409$ , df= 3), (p<0.001) and post prandial blood glucose levels of diabetic patients before administration of tulsi leaves powder in experimental group, but there was no significant association with other demographic variables. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age.

This inferred that risk of incidence of diabetes increases with age. Hence the community health nurse can be a diabetes case manager by concentrating on the older adults and elderly age group, conducting diabetic screening camps to detect the condition at the earliest. The nurse also holds the responsibility of identifying and educating the mass about the risk factors both modifiable and non modifiable.

Association between the selected clinical variables and fasting blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder

There was a significant association between the selected clinical variables of height ( $\chi^2 = 7.339$ , df= 2), (p<0.05) and post prandial blood glucose levels of diabetic patients in pre test and post test in control group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to height.

This was supported by Janghorbani et al. (2008) represent a more severe metabolic disturbance in a tall person than a shorter one.

# Association between the selected clinical variables and post prandial blood glucose levels of diabetic patients in control and experimental group before and after administration of tulsi leaves powder

There was a significant association between the selected clinical variable duration of known period of diabetes ( $\chi^2 = 7.92$ , df= 2), (p<0.05) and post prandial blood glucose levels of diabetic patients after administration of tulsi leaves powder in experimental group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to duration of known period of diabetes.

As duration increases the perception of seriousness of severity increases and tends to follow the therapeutic regimen strictly.

# Summary

This chapter has dealt with the objectives of the study, major findings of the demographic and clinical variables, comparison of fasting and postprandial blood glucose level of diabetic patients before and after administration of tulsi leaves powder in control and experimental group, association between selected demographic variables and clinical variables with the fasting and postprandial blood glucose of diabetic patients in both the groups and the level of satisfaction regarding tulsi leaves powder administration.

## **CHAPTER VI**

# SUMMARY, CONCLUSION, NURSING IMPLICATIONS AND RECOMMENDATIONS

The impact of the research project lies in reporting the findings. This is the most creative and demanding part of the study. This chapter gives a brief account of the present study, suggestions of the study and nursing implications. The present study was intended to analyze the effectiveness of tulsi leaves powder upon blood glucose level in diabetic patients.

#### Summary

### **Statement of the Problem**

A Quasi Experimental Study to Assess the Effectiveness of Tulsi Leaves (Ocimum Sanctum) Powder Upon Blood Glucose Level in Diabetic Patients at Selected Wards Of Thiruverkadu Township, Chennai.

## **Objectives of the Study**

- 1. To assess the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients
- 2. To determine the effectiveness of tulsi leaves powder upon blood glucose level by comparing the blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.

- 3. To determine the level of satisfaction regarding tulsi leaves powder administration among experimental group of diabetic patients.
- 4. To find out the association between the selected demographic variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.
- 5. To find out the association between the selected clinical variables and blood glucose level before and after administration of tulsi leaves powder in control and experimental group of diabetic patients.

### Null Hypotheses

- **Ho**<sub>1</sub>: There will be no significant difference in the blood glucose level before and after administration of tulsi leaves powder among the control and experimental group of diabetic patients
- **Ho<sub>2</sub>:** There will be no significant association between selected demographic variables and blood glucose level before and after administration of tulsi leaves powder among the control and experimental group of diabetic patients
- **Ho<sub>3</sub>:** There will be no significant association between selected clinical variables and blood glucose level before and after administration of tulsi leaves powder among control and experimental group of diabetic patients.

The conceptual frame work was based on Modified Sister Callista Roy's Adaptation model which was modified for the present study, and extensive review of literature and guidance by expert formed the foundation of development of the research tool. A quasi experimental design was adopted for this study. Purposive sampling technique was used to select 30 in control group from keelayanambakkam and 30 in experimental group from 14<sup>th</sup> ward of Thiruverkadu Township. The blood glucose assessment chart and rating scale for level of satisfaction on administration of tulsi leaves extract were the tools used to collect data, after establishing validity and reliability. The main data collection was done after determining the feasibility and practicability through pilot study.

The diabetic patients were identified by door to door enumeration. The blood glucose level was checked for both control and experimental group before and after administration of tulsi leaves powder. Tulsi leaves were freshly plucked from the plants, washed, dried under the shadow and powdered in a mixer. 2.5g of this powder is mixed with 10ml of plain water and was administered every day orally on empty stomach for four weeks and their level of satisfaction on tulsi leaves powder was assessed. The data was tabulated and analyzed by using descriptive and inferential statistics.

# Major Findings of the Study

Significant percentage of diabetic patients were in age group between 41 to 50 (43.3%, 33.4%), females (53.4.7%, 46.6%), Hindus (50%, 53.4%), had High school education (30%, 33.4%), occupation as home makers (53.4%, 46.7%), and majority were married (90%, 93.2%), with monthly income between 5001 to 10,000 (66.7%, 76.6%), nonvegetarians (100%,100%), non smokers (66.6%, 80%) and non alcoholics (70%, 76.6%) in control and experimental group respectively.

- Most of the diabetic patients had no family history of diabetes (56.6%, 73.4%), not on diabetic diet (40%, 66.6%), with height 156 to 160 cm (46.6, 70%), significant percentage of the diabetic patients had been suffering from diabetes mellitus for a duration between 1 to 2 yrs (36.6%, 53.4%), with BMI between 22.6 to 29.9 (50%, 50%), had body weight between 51-60 kg (46.6%, 43.4.7%), and majority of the patients was on oral hypoglycemic agents (100%, 100%), absence of comorbidities (63.4%, 73.4%), not performing regular exercise (66.6%, 73.4%) and not on other alternative or complementary therapy (100%, 100%).
- Majority of the diabetic patients in the control and experimental group had mild level of fasting blood glucose (86.67%, 90%) and most of them had moderate level of postprandial blood glucose (73.4%, 80%) before tulsi leaves powder administration. But there was a significant difference in the experimental group, as all the diabetic patients had mild level of fasting blood glucose (100%) and majority of them had mild level of postprandial blood glucose (93.3%) after tulsi leaves powder administration. Whereas in control group most of the diabetic patients had mild level of fasting blood glucose (83.3%) and moderate level of postprandial blood glucose (83.3%) in the post assessment. This could be attributed to the effectiveness of tulsi leaves powder administration.
- In control group there was no significant difference in the mean and standard deviation of fasting blood glucose (M=164.7, 169.9 & SD=11.77, 11.24) and postprandial blood glucose (M=231.7, 244.1 & SD=25.40, 23.24) before and after tulsi leaves powder administration. Whereas experimental group showed a significant difference (p<0.001) in the mean and standard deviation of fasting blood glucose (M=169.4, 117 & SD=7.90, 3.91) and postprandial blood glucose</p>

(M=239.8, 166.8 & SD=24.34, 19.93) before and after administration of tulsi leaves powder and it can be attributed to the effectiveness of tulsi leaves powder administration. Hence the null hypothesis Ho<sub>1</sub> was rejected.

- All the diabetic patients in the experimental group were highly satisfied (100%) with regard to researcher, with regard to the method of tulsi leaves powder administration (100%), with regard to the effectiveness of tulsi leaves powder administration (100%) respectively. And most of the diabetic patients were highly satisfied with the nature of tulsi leaves powder (96.67%)
- There was a significant association between the selected demographic variables of age ( $\chi^2 = 7.45$ , df= 2), (p<0.05) and fasting blood glucose levels of diabetic patients before in pretest in control group, but there was no significant association with other demographic variables. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age.
- There was a significant association between the selected demographic variables of age ( $\chi^2 = 6.039$ , df= 2), (p<0.05) years and post prandial blood glucose levels, occupational status ( $\chi^2 = 6.868$ , df= 2), (p<0.05) and post prandial blood glucose levels of diabetic patients in post test in control group and experimental group, but the association with other demographic variables were not significant. Hence the null hypothesis Ho<sub>2</sub> was rejected with regard to age in years and occupational status.
- There was a significant association between the selected clinical variables of height  $(\chi^2 = 7.339, df = 2)$ , (p<0.05) and post prandial blood glucose levels of diabetic patients in pre test and post test in control group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to height.

There was a significant association between the selected clinical variable duration of known period of diabetes ( $\chi^2 = 7.92$ , df= 2), (p<0.05) and post prandial blood glucose levels of diabetic patients after administration of tulsi leaves powder in experimental group, but there was no significant association with other clinical variables. Hence the null hypothesis Ho<sub>3</sub> was rejected with regard to duration of known period of diabetes.

#### Conclusion

There is a wide variety of complementary and alternative therapies which helps in reduction of blood glucose level. One of which is the tulsi leaves powder having anti diabetic property in it. It can be incorporated into the conventional care and practice. And the researcher too felt the result in her present study, concluded that tulsi leaves powder was effective in reducing the fasting and post prandial blood glucose level. Hence the complementary therapy is becoming more even integrated into the existing conventional care and is having both direct and indirect effect in general health care provision.

### Implications

The researcher has derived from the study, the following implications which are of vital concern in the field of nursing practice, nursing education, nursing administration and nursing research.

# **Nursing practice**

The community health nurse have a vital role in the health education of patients about various healthy habits. The nurse should educate the patients to take tulsi leaves powder along with oral hypoglycemic agents to control type 2 diabetes mellitus. We need evidence based practice in managing patients with diabetes mellitus. So, the nurse can be a part of it. Also, the nurse as a team leader, can plan and co-ordinate the activities for the patients, so that the incidence of diabetes mellitus can be reduced. Nurses have to give due importance to patients with diabetes mellitus and chronic conditions associated with it, so that early screening need to be done to prevent the complications, and nutritional supplementation such as tulsi leaves powder can be given to reduce the diabetes mellitus. Health care provider can also re-evaluate the traditional practices.

With emerging health care trends nurses must also know about the nutritional supplements, its benefits and its availability. This helps the clinical nurses to use and recommend cinnamon extract to control type 2 diabetes mellitus which in turn prevents major diseases like cardiovascular disease, neuropathy, nephropathy etc... We need to encourage the nurses to conduct health camp for the adults and elderly to detect their problems at the earliest.

### **Nursing education**

The nurse educators should suitably involve the concepts of AYUSH in the medical and nursing profession. Nurses should have knowledge about the factors, which enhance and reduce the blood glucose level. Nurses can be educated about the locally available tulsi leaves which have a hypoglycemic effect.

Integration of theory and practice is a vital need and it is important in nursing education. Complementary alternative medicine has been included in the curriculum of nursing education. But it is least practiced in the hospital and family care. Hence the nurse educator can lay emphasis on the complementary alternative medicine for diabetes mellitus and its relation to client's recovery.

With changing health trends, nursing education must lay emphasis on nutritional therapy such as tulsi leaves powder administration in reducing diabetes mellitus. Nursing educators should emphasize on various nutritional supplements and its health promoting properties.

# Nursing administration

In today's technological advances and the ever growing challenges of the health care needs, the administrator have the highest responsibility in proving the nurses with substantive continuing education opportunities in the alternative therapy. This will enable the nurses to update their knowledge, acquire special skills in managing the patients with type 2 diabetes mellitus and demonstrate high quality care.

Nurse administrator should take initiative and periodically organize continuing nursing education programmes for the nurses on control of blood glucose by using natural home remedies. These programmes can be conducted for the nursing personnel both in the hospital and community settings with media assistance in order to help them gain adequate knowledge regarding non pharmacological ways of reducing the incidence of diabetes mellitus. Nurse administrator should take adequate steps with the growing bodies in formulating policies and protocols in providing patient education and plans for man power, money, material, methods and time to conduct successful and useful patient education programmes. Nurse administrator should provide opportunity for the nurses to attend the various training programmes.

### Nursing research

As a result of growing demand, there is a heightened urgency to expand the evidence base to support the use of tulsi leaves powder. There is a need for extensive and intensive research in this area to generate more specific data base and to identify the benefits of the therapies and provide much needed information for the consumers and providers. It opens a big avenue for research on innovative, alternative methods to reduce the diabetes mellitus. Further researches need to be conducted to help the diabetic patients to come out of their health problems. The professional and student nurses can conduct further studies on the impact of various alternative methods for treating the patients with diabetes mellitus, so as to generate more scientific base on which new strategies for reducing the risk of complications are developed.

Nurses at different levels of hierarchy need to conduct ongoing researches in this area. Novice nurses and nursing students can also be encouraged for further research studies on the effectiveness of tulsi leaves powder in controlling the type 2 diabetes mellitus. Dissemination of the findings can be done through conference, seminar, publication in professional, national, international journals and World Wide Web. More research needs to be conducted with the use of locally available resources in reducing the type 2 diabetes mellitus. More theories can be generated based on the research findings.

### Recommendations

The researcher recommends the following studies in the field of nursing research

- > The same study could be conducted on larger samples for better generalization.
- The same study could be conducted for patients with impaired blood glucose levels.
- > The study could be replicated in different settings.
- A study could be conducted to assess the level of knowledge among nurses regarding the administration of tulsi leaves powder for the management of the patients with type 2 diabetes mellitus.
- > A similar study can be conducted with other traditional and herbal medicines.

### Limitations

- > The study findings cannot be generalized due to small sample size.
- Random sampling was not possible due to practical difficulties.
- True experimental research could not be conducted as there are chances of contamination effects.

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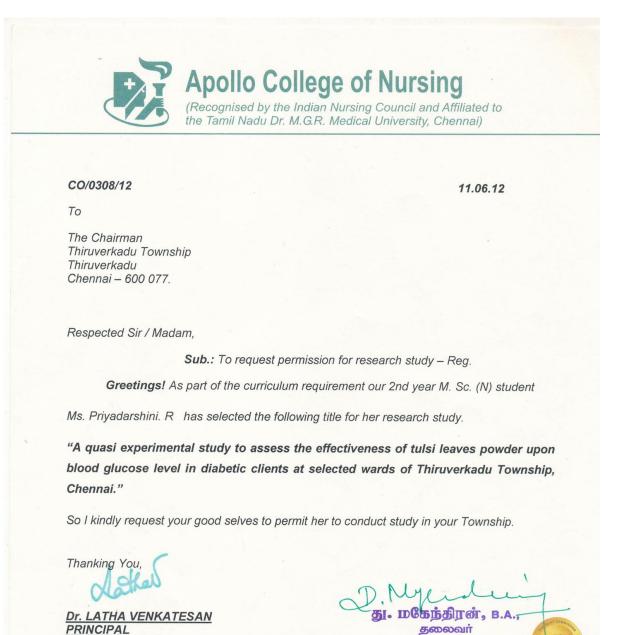
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### **APPENDIX I**

### LETTER SEEKING PERMISSION TO CONDUCT THE STUDY FROM THE

### AUTHORITATIVE PERSON IN COMMUNITY AREA



IS/ISO 9001:2000

Vanagaram to Ambattur Main Road, Ayanambakkam, Chennai - 600 095. Ph. : 044 - 2653 4387 Tele fax : 044 - 2653 4923 / 044- 2653 4386

தீருவேற்காடு நகராட்சி, சென்னை-600 077.

### **APPENDIX II**

### ETHICAL COMMITTEE CLEARANCE LETTER

# **Ethics Committee**

#### To,

Ms. Priyadarshini, 2<sup>nd</sup> year M.sc (Nursing), Department of Community Health Nursing, Apollo College of Nursing, Chennai.

Ref: A quasi experimental study to assess the Effectiveness of Tulasi leaves powder upon blood glucose levels in diabetic patients at selected wards of Thiruverkadu, Chennai.

Sub: Approval of the above referenced project and its related documents.

Dear Ms. Priyadarshini,

Ethics Committee-Apollo Hospitals has received the following document submitted by you related to the conduct of the above-referenced study.

- Project proposal.
- Participant consent form.

The Ethics Committee-Apollo Hospitals reviewed and discussed the study proposal documents submitted by you related to the conduct of the above referenced study at its meeting held on 29<sup>th</sup> August 2012.

The following Ethics Committee Members were present at the meeting held on 29<sup>th</sup> August 2012.

Name	Profession	Position in the committee
Mr. S. S. Narayanan	Ethicist	Chairman
Dr. Rema Menon	Clinician	Member Secretary
Dr. Radha Rajagopalan	Clinician	EC-Member
Dr. Krishnakumar	Clinician	EC-Member
Dr. Vijaya Kumar	Clinician	EC-Member
Dr. Clive Fernandes	Consultant Clinical Pharmacologist	Basic Medical Scientist
Dr. Nalini Roa	Social Worker	EC-Member
Ms. N. Suseela	Retired English Teacher	Layperson

Apollo Hospitals Enterprise Limited

21, Greams Lane, Off Greams Road, Chennai - 600 006 Tel : 91 - 44 - 2829 3333 Extn : 6008, 91 - 44 - 2829 5465 Extn : 6639 Fax : 91 - 44 - 2829 4449 E - Mail : ecapollochennai@gmail.com



30<sup>th</sup> August 2012



# **Ethics** Committee

Ms. Maimoona Badsha	Lawyer	Lawyer
Dr. Paul Dilipkumar	Clinician	EC-Member
Dr. V. Balaji	Clinician	EC-Member
Dr. M. A. Raja	Consultant Medical Oncologist	EC-Member

After due ethical and scientific consideration, the Ethics Committee has approved the above presentation submitted by you.

The EC review and approval of the report is only to meet their academic requirement and will not amount to any approval of their conclusions / recommendations as conclusive, deserving adoption and implementation, in any form, in any healthcare institution.

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

With Regards,

Kews Keno

Dr. Rema Menon, Ethics Committee-Member Secretary, Apollo Hospitals; Chennai, Tamil Nadu, India. Dr. REMA MENON MEMBER SECRETARY ETHICS COMMITTEE, APOLLO HOSPITALS APOLLO HOSPITALS ENTERPRISE LIMITED CHENNAI-600 008, TAMH\_NADU

Date:

Apollo Hospitals Enterprise Limited 21, Greams Lane, Off Greams Road, Chennai - 600 006 Tel : 91 - 44 - 2829 3333 Extn : 6008, 91 - 44 - 2829 5465 Extn : 6639 Fax : 91 - 44 - 2829 4449 E - Mail : ecapollochennai@gmail.com

## **APPENDIX III**

## PLAGIARISM ORIGINALITY REPORT

DI	agiarism Dotacto	r - Originality Poport		
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	Document Words Count: 14903			
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Plagiarism Detection Chart: Referenced (0.00%) Linked (0.00%) Plagiarism (1.00%) Original (99.00%)				
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Referenced 0% / Linked 0%				
		Original - 99% / 1% - Plagiarism		

### **APPENDIX IV**

### LETTER REQUESTING OPINIONS AND SUGGESTIONS OF EXPERTS FOR

### ESTABLISHING CONTENT VALIDITY OF RESEARCH TOOL

From R.Priyadarshini, M.Sc., (Nursing) Second Year, Apollo College of Nursing, Chennai - 600095.

To Forwarded Through: Dr. Latha Venkatesan, Principal, Apollo College of Nursing.

# Sub: Requesting for opinions and suggestions of experts for establishing content validity for Research tool.

Respected Madam,

I am a postgraduate student of the Apollo College of Nursing. I have selected the below mentioned topic for research project to be submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai as a partial fulfilment of Masters of Nursing Degree.

### TITLE OF THE TOPIC:

A quasi experimental study to assess the Effectiveness of Tulsi leaves powder upon Blood Glucose Level in Diabetic Patients at Selected wards of Thiruverkadu Township, Chennai.

With regards may I kindly request you to validate my tool for its appropriateness and relevance. I am enclosing the Background, Need for the study, Statement of the problem, Objectives of the study, Demographic Variable Proforma, clinical Variable Proforma, Observational check list, and Rating Scale on Level of Satisfaction of patients regarding the administration of tulsi leaves powder on diabetes mellitus for your reference. I would be highly obliged and remain thankful for your great help if you could validate and send it as soon as possible.

### Thanking you,

Yours sincerely, (R.Priyadarshini)

### **APPENDIX V**

### LIST OF EXPERTS FOR CONTENT VALIDITY OF THE TOOL

1. Dr. Latha Venkatesan, M.Sc., (N), M.Phil., (N), Ph.D., (N)

Principal, Apollo College of Nursing, Chennai – 95.

### 2. Dr.S. Venkatraman, M.D., (Diabetologist)

Senior Consultant, Apollo main Hospitals, Chennai – 10.

### **3. Prof. Mrs. Lizy Sonia.A, M.Sc (N)., Ph.D., (N)** Vice Principal, Apollo College of Nursing,

Chennai – 95.

**4. Mrs. Shobana.G, M.Sc (N).** Professor, Apollo College of Nursing, Chennai – 95.

### **5. Mrs.Sasikala.D, M.Sc (N).** Reader, Apollo college of nursing,

Chennai-95.

### 6. Mrs. Jaslina Gnanarani. J, M.Sc (N)., Ph.D., (N) Reader,

Apollo College of Nursing, Chennai – 95.

### 7. Mrs. Shenbahavalli.V, M.Sc (N).,

Lecturer, Apollo College of Nursing, Chennai – 95.

### **APPENDIX VI**

### CONTENT VALIDITY CERTIFICATE

I hereby certify that I have validated the research tool of Ms. R.Priyadarshini M.Sc.(Nursing) student who is undertaking research study . "A quasi experimental Study to assess the Effectiveness of Tulsi leaves powder upon Blood Glucose Level in Diabetic Patients at Selected wards of Thiruverkadu Township, Chennai."

•

Signature of Expert

### **APPENDIX VII**

### **RESEARCH PARTICIPANTS CONSENT FORM**

Dear participant,

I am R. Priyadarshini, M.Sc Nursing Student of Apollo College of Nursing, Chennai. As a part of my study, I have selected a research project on 'A quasi experimental Study to assess the Effectiveness of tulsi leaves powder upon Blood Glucose Level of Diabetic Patients in Selected wards of Thiruverkadu Township', Chennai.

I hereby seek your consent and cooperation to participate in the study. Please be frank and honest in your response. The information collected will be kept confidential and anonymity will be maintained.

Signature of the Researcher

I ....., hereby give my consent to participate in the study.

Signature of the Participant

### ஆராய்ச்சியில் பங்கு பெருபவருக்ககான ஒப்புதல் படிவம்

அன்பார்ந்த பங்கேற்பாளர்களே,

நான் அப்போலோ செவிலியா் கல்லூாியில் முதுகலை பயிற்சி பெரும் மாணவி. என்னுடைய பயிற்சியின் ஒரு பகுதியாக துளசி பொடி மூலமாக ரத்தத்தில் சா்க்கரை அளவுப் பற்றி அறிய ஆராய்ச்சி செய்கிறேன். இந்த ஆராய்ச்சியில் நீங்கள் பங்கு பெற, உங்களுடைய ஒப்புதல் மற்றும் ஒத்துழைப்பையும் வேண்டுகிறேன். உங்களுடைய குறிப்புகள் இரகசியமாக வைக்கப்படும், மற்றும் உங்களுடைய பெயா் வேறு எங்கும் வெளியிடப்பட மாட்டாது.

ஆராய்ச்சியாளரின் கையொப்பம்.

.....என்கிற நான், இந்த

ஆராய்ச்சியில் பங்கு பெற ஒப்புதல் அளிக்கிறேன்.

பங்கு பெறுவோரின் கையொப்பம்

### **APPENDIX VIII**

## CERTIFICATE FOR ENGLISH EDITING

### TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation " A quasi experimental study to assess the effectiveness of tulsi leaves powder (ocimum Sanctum) upon blood glucose levels in diabetic clients at selected wards of Thiruverkadu Township, Chennai by Ms. R. Priyadarshini, II year Msc (N), Apollo College of Nursing was edited for English language appropriateness by

V. USHA

Signature

V. USHA Prof. of English Nanak College Chennal - 600 042.

### **APPENDIX IX**

### CERTIFICATE FOR TAMIL EDITING

### TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation "A quasi experimental study to assess the effectiveness of tulsi leaves powder (ocimum Sanctum) upon blood glucose levels in diabetic clients at selected wards of Thiruverkadu Township, Chennai by Ms. R. Priyadarshini, II year Msc (N), Apollo College of Nursing was edited for Tamil language appropriateness by Dr. M.MURTH

Signature

Dr. M. MURTHI Asst. Professor & Head Department of Tamil Guru Nanak College, Chennal-600 042.

### **APPENDIX X**

### **DEMOGRAPHIC VARIABLE PROFORMA**

**Purpose:** This proforma is used by the researcher to collect information on demographic variables such as age, gender, religion, education, marital status, income, occupation, diet, habit of smoking and alcoholism.

**Instruction:** Please answer the following questions. This information will be filled by the researcher. Please be frank and free in answering these questions. The collected information will be kept confidential and anonymity maintained.

Sample no:

### 1. Age in years

1.1 31 to 40 1.2 41 to 50

1.3 51 to 60

1.4 61 to 70

### 2. Gender

2.1 Male

2.2 Female

### 3. Religion

- 3.1 Hindu
- 3.2 Muslim
- 3.3 Christian

3.4 Others



### 4. Education

4.1 No formal education
-------------------------

- 4.2 Primary education
- 4.3 High school education
- 4.4 Higher secondary school education
- 4.5 Graduate and above

### 5. Marital status

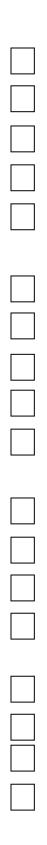
- 5.1 Married
- 5.2 Unmarried
- 5.3 Divorced
- 5.4 Widow
- 5.5 Widower

### 6. Income per month

- 6.1 < 2500
- 6.2 2501 to 5000
- 6.3 5001 to 10,000
- 6.4 > 10,000

### 7. Occupation status

- 7.1 Unemployed
- 7.2 Employed
- 7.3 Home maker
- 7.4 Retired



## 8. Dietary pattern

8.1 Vegetarian

8.2 Non-vegetarian

## 9. Habit of smoking

9.1 Yes

9.2 No

### 10. Habit of alcoholism

- 10.1 Non alcoholic
- 10.2 Alcoholic

## மாறுபட்டக் குறிப்புகளை அறியும் மாதிரிப்படிவம்

### நோக்கம்

மாதிரிப்படிவம் மாறுபட்டக் குறிப்புகளான வயது இந்த பால், , கல்வித்தகுதி, திருமண நிலை , குடும்ப வருமானம் தொழில், , உணவுகக்கட்டுப்பாடு, புகை பிடிக்கும் பழக்கம் , மற்றும் மது அருந்தும் பழக்கம் பற்றிய தவல்களை ஆராய ஆய்வாளர் பயன்படுத்தியது.

### அறிவுரை

பேட்டிக் காண்பவர் தன்னை அறிமுகம் செய்து கொண்ட ஆய்விற்கான நோக்கத்தை விளக்குவார் . பேட்டிக் காண்பவர் கேள்விகளை கவனமாக க் கேட்டு பெறப்படும் பதில்களை சரியான கட்டத்தில் 🗸 செய்வார் . இங்கு சேகரிக்கப்படும் தகவல்கள் பாதுகாக்கப்படும் மற்றும் ஆய்விற்காக மட்டுமே பயன்படுத்தப்படும்.

மாதிரி எண்:

1. வயது (ஆண்டுகளில்)	
1.1 31 - 40	
1.2 41 - 50	
1.3 51 - 60	
1.4 61 - 70	
2. பால்	
2.1 ஆண்	

2.2 பெண்

3. மதம்	
3.1 <b>இந்து</b>	
3.2 இஸ்லாமியர்	
3.3 கிறித்தவர்	
3.4 மற்றவர்	
4. கல்வித்தகுதி	
4.1 படிப்பறிவில்லாதவர்	
4.2 ஆரம்பக் கல்வி	
4.3 <b>உயர்நிலை</b>	
4.4 மேல்நிலைக் கல்வி	
4.5 பட்டப் படிப்பு	
5. <b>திருமண நிலை</b>	
5.1 திருமணமானவர்	
5.2 திருமணமாகதவர்	
5.3 கணவனை இழந்தவர்	

5.4 மனைவியை இழந்தவர்

### 6. **மாத வருமானம்**

6.1 < 2500

6.2 2501 - 5000

6.3 5001 - 10,000

6.4 >10,000

## 7. **தொழில்**

7.1 வேலை இல்லாதவர் 7.2 பணி செய்பவர் 7.3 இல்லத்தரசி

7.4 ஓய்வு பெற்றவர்

## 8. **உணவு முறை**

8.1 **சைவ**ம்

8.2 அசைவம்

## 9. புகை பிடிக்கும் பழக்கம்

- 9.1 புகை பிடிப்பவர்
- 9.2 புகை பிடிக்காதவர்

### 10. மது அருந்தும் பழக்கம்

- 10.1 மது அருந்துபவர்
- 10.2**மது அருந்தாதவ**ர்

# 



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### **APPENDIX XI**

### **CLINICAL VARIABLE PROFORMA**

**Purpose:** This proforma is used by the researcher to identify the clinical variables such as duration of diabetes, family history of diabetes, whether on diabetic medications, on diabetic diet, weight in kilogram, height, body mass index, presence of other comorbidities and about exercise.

**Instructions:** Please answer the following questions. This information will be filled by the researcher. Please be frank and free in answering these questions. The collected information will be kept confidential and anonymity maintained.

Sample no:

### 1. Duration of known period of diabetes

- 1.1 < 1 year</li>
   1.2 1 to 2 years
- 1.3 3 to 5 years
- 1.4 > 5 years

### 2. Family history of diabetes

- 2.1 Present
- 2.2 Absent

If yes specify ------

### 3. Whether on oral hypoglycaemic agents

3.1 Yes

3.2 No





Г		7

### 4. Whether on diabetic diet

4.1 Yes

4.2 No

### 5. Weight in kilograms

5.1 31 to 40

5.2 41 to 50

5.3 51 to 60

5.4 >70

### 6. Height in centimetre

6.1 146 to 150

6.2 151 to 155

6.3 156 to 160

6.4 >160

### 7. Body mass index

7.1 < 18.4

7.2 18.5 to 22.9

7.3 23 to 29.9

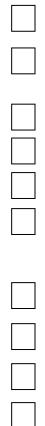
7.4 >30

### 8. Presence of other comorbidities

8.1 Yes

8.2 No

If yes specify	
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Γ		

## 9. Whether on regular exercise

9.1 Yes

9.2 No

## **10.** Whether on any other alternative or complementary therapy

- 10.1 Yes
- 10.2 No

## மருத்துவம் சார்ந்த சர்க்கரை நோயாளிகள் பற்றிய மாறுபட்டக் குறிப்புகளை அறியும் மாதிரிப்படிவம்

### நோக்கம்

இந்த மாதிரிப் படிவம் சர்க்கரை நோயாளிகளின் மருத்துவம் சார்ந்த சர்க்கரை நோயின் கால அளவு , குடும்பத்தில் சர்க்கரை நோய் , உணவுக்கட்டுப்பாடு, உடல் எடை , உயரம், உடல் பருமன் குறிப்பு , மற்ற நோய்கள், உடற் பயிற்சி மற்றும் வேறு எந்த மாற்று அல்லது ஈடு சிகிச்சை பற்றி அறிய பயன்படுத்தப் பட்டது.

### அறிவுரை

பேட்டிக் காண்பவர் தன்னை அறிமுகம் செய்து கொண்டு ஆய்விற்கான நோக்கத்தை விளக்குவார் . பேட்டிக் காண்பவர் கேள்விகளை கவனமாக க் கேட்டு பெறப்படும் பதில்களை சரியான கட்டத்தில் (🗸) செய்வார் . இங்கு சேகரிக்கப்படும் தகவல்கள் பாதுகாக்கப்படும் மற்றும் ஆய்விற்காக மட்டுமே பயன்படுத்தப்படும்

\_\_\_\_\_

1. சர்க்கரை நோய் இருப்பது அறிந்த கால அளவு

1.1	< 3	1 ஆ	ன்	ቡႻ	ள்
<b>T</b> . <b>T</b>	· ·	- 07		0.0	

1.2 1 -2 ஆண்டுகள்

1.3 3 – 5 **ஆண்டுக**ள்

1.4 > 5 ஆண்டுகள்

### 2. குடும்பத்தில் சர்க்கரை நோய் இருந்ததற்கான வரலாறு

2.1	Ø	ருந்	ஒது
-----	---	------	-----

2.2 இல்லை

இருந்தது	எனில்	குறிப்பிடவும்	۱
עפפישיא	01001100		

3.வாய் வழி இரத்த சர்க்கரை அளவை கட்டுப்படுத்தும் மாத்திரை

எடுத்துக்கொள்பவரா?

3.1 ஆம்

3.2 இல்லை

### 4. சர்க்கரை நோய்க்கான உணவுக்கட்டுபாட்டில் உள்ளீர்களா?

4.1 ஆம்

4.2 இல்லை

5. எடை (கிலோ)

5.1 145 - 150

5.2 151 - 155

5.3 156 - 160

5.4 >160

### 6. **உயரம் (செ.மீ)**

- 6.1 145 150
- 6.2 151 155
- 6.3 156 160

6.4 >160

### 7. உடல் பருமன் குறிப்பு

- 7.1 >18.4 7.2 18.5 – 22.9
- 7.3 23 29.9

7.4 >30

## 8. மற்ற நோய்கள உள்ளது

8.1 ஆம்

8.2 இல்லை

ஆம் எனில் குறிப்பிடவும் .....



## 9. **உடற்பயிற்சி**

- 9.1 **ஆம்**
- 9.2 இல்லை

## 10. வேறு எந்த மாற்று அல்லது ஈடு சிகிச்சையில் உள்ளீர்களா?

- 10.1 **ஆம்**
- 10.2 **இல்லை**

### **APPENDIX XII**

### **BLOOD GLUCOSE ASSESSMENT CHART**

### Purpose

This assessment chart is used to record the fasting and postprandial blood glucose before and after tulsi leaves powder administration.

### Instructions

The researcher documents the blood glucose levels after checking with the

glucometer.

Variable	CONTROL GROUP			EXPERIMENTAL GROUP				
	0 (	day	28 <sup>th</sup>	day	0 day	9 <sup>th</sup> day	18 <sup>th</sup> day	28 <sup>th</sup> day
Fasting blood glucose (mg/dl)								
Post Prandial blood glucose (mg/dl)								

### Fasting blood glucose level

Score	Interpretation
111-180 mg/dl	Mild elevation
181-250 mg/dl	Moderate elevation
>251mg/dl	Severe elevation
Post prandial blood glucose level Score	Interpretation
141-200 mg/dl	Mild elevation
201-260 mg/dl	Moderate elevation

S.NO	CONTENT	ITEMS	TOTAL	PERCENTAGE %
1	Questions related to the	1,2,3	3	25
	researcher			
2	Questions related to	7,8,9	3	25
	nature of tulsi leaves			
	powder			
3	Questions related to	4,5,6	3	25
	method of tulsi leaves			
	powder administration			
4	Questions related to	10,11,12	3	25
	effectiveness of tulsi			
	leaves powder			
	administration			
		Total	12	100 %

### **BLUE PRINT FOR LEVEL OF SATISFACTION**

### **APPENDIX XIV**

# RATING SCALE ON SATISFACTION REGARDING ADMINISTRATION OF TULSI LEAVES POWDER

### Purpose

This rating scale is used to determine the level of satisfaction of the participants regarding the administration of tulsi leaves powder and this is assessed by the researcher on the  $30^{\text{th}}$  day of data collection.

### Instruction

There are 10 items given below. Each item has 4 options – highly satisfied, satisfied, dissatisfied and highly dissatisfied. Describe your satisfaction regarding the administration of tulsi leaves powder. Please be frank and free. The responses will be kept confidential.

		Highly	Satisfied	Dissatisfied	Highly
S.NO.	ITEMS	satisfied			Dissatisfied
5.NU.		4	3	2	1
1	Explanation				
	regarding tulsi				
	leaves powder				
	administration				
2	Approach of the				
	researcher				
3	Time spent by the				
	researcher				
4	Duration of tulsi				
	leaves powder				
	administration				

5	Frequency of tulsi		
	leaves powder		
	administration		
6	Amount of tulsi		
	leaves powder		
	2.5gms/day		
7	Taste of tulsi		
	leaves powder		
8	Preparation of		
	tulsi leaves		
	powder		
9	Availability of		
	tulsi leaves		
10	Outcome of		
	blood glucose		
	level after		
	consuming tulsi		
	leaves powder		
11	Cost effectiveness		
12	No side effects		

## Scoring key:-

Highly satisfied	-	4
Satisfied	_	3
Dissatisfied	_	2
Highly dissatisfie	ed-	1

The total score is converted into percentage graded as given below:

Scoring	Interpretation
>76	Highly satisfied
51-75%	Satisfied
26-50%	Dissatisfied
< 25%	Highly dissatisfied

## இணைப்பு துளசி பொடியைக் கொடுத்ததன் மூலம் ஏற்பட்ட திருப்திக்கான அளவுகோல்

### நோக்கம்

இரண்டாம் வகை நீரிழிவு நோயாளிகளுக்கு துளசி பொடியைக் கொடுத்ததன் மூலம் ஏற்பட்ட திருப்தியை அளப்பதற்காக இந்த அளவு கோல் வடிவமைக்கப்பட்டு 31ம் நாளன்று ஆய்வாளரால் கணக்கிடப்பட்டது.

### அறிவுரை

இந்த அளவுகோலில் 12 வகைகள் உள்ளன .தயவு கூர்ந்து இவற்றைப் படித்து உங்களின் பதில்களை சுதந்திரமாகவும் தயக்கமின்றியும் அளியுங்கள் பதில்கள் இரகசியமாக வைக்கப்படும் .பதில்கள் அதிகத் திருப்தியிலிருந்து அதிகத் திருப்தியின்மை என்கின்ற எல்லைக்குள் அடங்கும் .உங்கள் பதில்களுக்கு நேராக செல்லவும் .

வ எ. ண்	வகைகள்	அதிகத் திருப்தி	திருப்தி	திருப்தியின் மை	அதிகத் திருப்தியி ன்மை
0001					
1.	துளசி பொடி				
	கொடுப்பதுப்பற்றி				
	ஆய்வாளர்				
	விவரித்தது				
2.	ஆய்வாளரின்				
	அணுகுமுறை				
3.	ஆய்வாளர்				
	செலவழித்த நேரம்				
	துளசிப்பொடி				
4	கொடுக்கப்பட்டக்				
	கால அளவு				
	துளசிப்பொடி				
5.	கொடுக்கப்பட்டக்				
	கால இடைவெளி				
6.	துளசிப்பொடியின்				

	அளவு		
7.	துளசிப்பொடியின் ருசி		
8.	துளசிப்பொடி		
	தயாரிக்கும் முறை		
9.	துளசி இலை		
	கிடைக்கக்கூடிய		
	தன்மை		
	இரத்த குளுகோஸ்		
10.	அளவைக்		
	குறைக்கும் தன்மை		
11.	செலவு		
12.	பக்க விளைவுகள்		
	இல்லை		

## மதிப்பெண் வழிகாட்டி

அதிகத்திருப்தி	-	4
திருப்தி	-	3
திருப்தியின்மை	-	2
அதிகத் திருப்தியின்மை	-	1

மொத்த மதிப்பெண்கள் கீழ்க்கண்ட முறையில் சதவிகிதத்திற்கு மாற்றப்பட்டுள்ளது

## மதிப்பீடு

 76-100%
 அதிகத்திருப்தி

 51-75%
 திருப்தி

 26-50%
 திருப்தியின்மை

 <25%</td>
 அதிகத் திருப்தியின்மை

### PENDIX XV

### **DATA CODE SHEET**

### **AG-Age in years** 1. 31 to 40 2.41 to 50 3.51 to 60 4.61 to 70 **GE-Gender** 1. Male 2. Female **RE-Religion** 1. Hindu 2. Muslim 3. Christian 4. Others **ED-Education** 1. No formal education 2. Primary education 3. High school education 4. Higher secondary school education 5. Graduate and above **MS-Marital status** 1. Married 2. Unmarried 3. Divorced 4. Widow 5. Widower **MI-Income per month** 1.< 25002. 2501 to 5000 3. 5001 to 10,000 4. > 10,000 **OS-Occupation status** 1. Unemployed 2. Employed 3. Home maker 4. Retired **DP-** Dietary pattern 1. Vegetarian 2. Non-vegetarian **HOS-Habit of smoking** 1. Yes 2. No **HOA-Habit of alcoholism** 1. Non – alcoholic 2. Alcoholic

DKPD-Duration of known period of diabetes 1. < 1 year 2.1 to 2 years 3.3 to 5 years 4.5 years **FH-Family history of diabetes** 1. Present 2. Absent HGD-Whether on oral hypoglycaemic agents 1. Yes 2. No Whether on diabetic diet 1. Yes 2. No WT-Weight in kilograms 1. 31 to 40 2.41 to 50 3.51 to 60 4.>70**HT-Height in centimetre** 1.146 to 150 2.151 to 155 3.156 to 160 4. > 160**BMI-Body mass index** 1. < 18.42. 18.5 to 22.9 3. 23 to 29.9 4.>30**CM-Presence of other comorbidities** 1. Yes 2. No **EX-Whether on regular exercise** 1. Yes 2. No ACT-Whether on alternative or complementary therapy 1. Yes 2. No

### APPENDIX XVI

### MASTER CODE SHEET - CONTROL GROUP

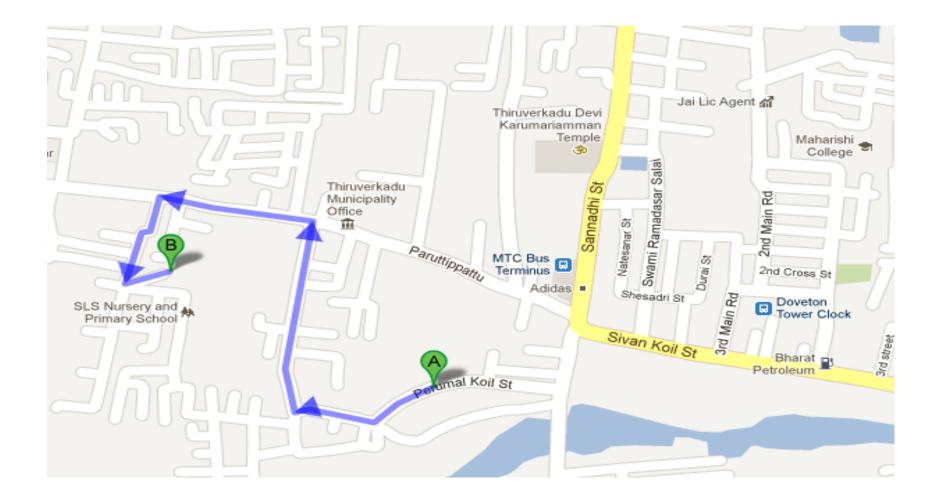
S.			т	)FMO	GRAI	ЭШС	VADI	ABLE						CUN	ICAL VA	DIAR	IF				BLO	OD GLU	JCOSE	
NO			1	JENIO	GRAI	me	VAND	ADLE						CLIN		ANIAD					PRE	TEST	POS	T TEST
	AG	GE	RE	ED	MS	MI	OS	DP	HOS	HOA	DKPD	FH	HGD	DD	WT	НТ	BMI	СМ	EX	ACT	FB GL	PP BGL	FB GL	PP BGL
1	2	1	1	2	1	2	2	2	1	2	2	1	1	1	2	2	1	1	1	2	176	224	173	223
2	2	1	1	2	1	2	2	2	1	1	2	1	1	1	2	2	1	2	1	2	188	232	189	239
3	3	2	1	4	1	3	3	2	2	1	3	2	1	2	3	4	3	2	2	2	171	276	174	269
4	2	2	3	4	1	3	3	2	2	1	3	1	1	2	3	2	3	2	2	2	156	248	155	242
5	4	2	3	3	1	3	3	2	2	1	4	1	1	2	3	3	2	2	2	2	159	258	159	260
6	3	2	3	2	1	3	3	2	2	1	1	1	1	2	3	2	2	1	2	2	168	301	164	292
7	2	1	1	2	1	3	2	2	1	2	3	2	1	2	3	4	1	2	1	2	150	252	153	256
8	1	2	1	5	1	2	3	2	2	1	2	2	1	1	4	2	4	1	2	2	185	250	184	256
9	2	1	1	4	1	3	2	2	2	1	2	2	1	1	4	3	3	2	1	2	165	290	167	295
10	2	2	3	4	1	4	3	2	2	1	2	2	1	1	3	3	2	1	2	2	171	244	171	244
11	3	1	3	4	1	4	2	2	2	1	3	2	1	1	4	3	3	1	2	2	174	210	172	216
12	3	1	3	3	1	3	2	2	1	2	2	1	1	2	2	2	1	1	2	2	159	275	154	270
13	4	1	1	4	1	3	4	2	1	2	4	2	1	1	4	3	3	2	2	2	185	220	181	216
14	2	2	1	4	1	3	3	2	2	1	3	2	1	2	3	3	2	2	2	2	176	258	173	270
15	4	2	3	3	5	3	3	2	2	1	4	2	1	2	2	2	2	2	1	2	143	198	140	216
16	2	1	1	3	1	3	2	2	1	2	3	2	1	1	2	3	2	2	2	2	152	208	152	246
17	2	2	3	2	5	2	3	2	2	1	2	2	1	1	3	3	3	1	1	2	173	256	176	196
18	2	1	3	2	1	3	2	2	2	1	2	1	1	2	4	2	3	2	2	2	179	250	182	206
19	3	1	3	3	1	4	2	2	2	1	3	1	1	1	4	2	4	1	1	2	187	246	182	260
20	4	2	1	3	1	4	3	2	2	1	4	2	1	2	3	1	3	2	1	2	196	262	186	256
21	3	2	3	2	1	3	3	2	2	1	3	2	1	1	2	2	3	2	1	2	173	238	173	236
22	3	1	1	2	1	4	2	2	1	2	2	2	1	2	2	3	3	1	2	2	176	252	174	258
23	3	1	3	2	1	3	2	2	1	2	3	2	1	1	3	3	3	2	2	2	164	222	160	239
24	2	1	1	2	1	3	2	2	1	2	2	1	1	2	3	3	4	1	2	2	158	192	170	256
25	2	2	1	3	5	3	3	2	2	1	3	2	1	1	4	4	3	2	2	2	170	233	170	204
26	4	2	1	4	1	4	3	2	2	1	4	1	1	1	3	2	3	2	2	2	171	246	176	232
27	2	2	3	4	1	3	3	2	1	2	3	1	1	1	3	2	2	1	2	2	174	230	178	238
28	3	2	3	4	1	3	3	2	2	1	2	2	1	1	2	3	2	2	2	2	178	258	178	239
29	4	2	1	3	1	3	3	2	2	1	4	1	1	1	3	3	3	2	1	2	168	232	163	230
30	3	1	1	3	1	3	2	2	2	1	3	1	1	1	2	3	3	2	2	2	175	281	170	259

### MASTER CODE SHEET - EXPERIMENTAL GROUP

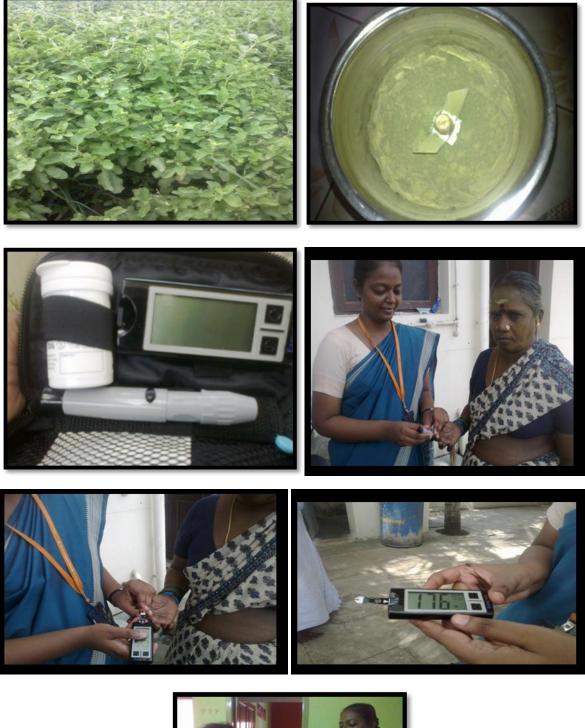
														BLOOD GLUCOSE									L	EV.	EL (	OF S	AT	ISFA	CTIO	N								
	DF	EMO	GRA	PHI		ARJ	[AB]	LE				CL	INIC	CAL	VA	RIA	BLE	2										1	2	3	4	5	6	7	89	10	11	12
																				0	D 4 37	oth	DAY	10th	DAY	aoth	DAY											
									H	D		1						0	DAY	91	JAY	18	DAY	28	DAY	-												
								н		K		н				В			Α		РР		PP		РР		PP										'	
S.		G	R	E N	и м	0	D		-	Р	F	G	D	V	VН	Μ	С	Е	С	FB	BG	FB	BG	FB	BG	FB	BG										'	
NO	AG	Е	E	DS	5 I	S	Р	S		D	Н	D	D	Т	T	Ι	Μ	Х	Т	GL	L	GL	L	GL	L	GL	L											
1	3	1	1	3 1	3	2	2	1	2	2	1	1	1	2	3	2	1	1	2	170	240	150	226	140	204	122	162	3	4	4	3	4	3	4	4 4	4	4	4
2	2	-	0	4 1	3	2	2	1	2	2	1	1	2	2	3	2	1	1	2	176	-	155	209	134	186	114	151	4	4	4	3	4	4	4	4 4	4	4	4
3	2	1	3 4	4 1	4	2	2	2	1	3	2	1	1	3	3	3	2	1	2	172	212	160	192	143	170	123	146	4	4	3	3	4	4	4	4 4	4	4	4
4	3		3 3	2 1	3	3	2	2	1	3	2	1	1	4	2	3	2	2	2	162	221	148	198	124	173	113	152	4		3	4	4	3	-	4 4	4	4	4
5	4		3	1 1	2	3	2	2	1	3	2	1	2	4	2	3	2	2	2	167	237	140	206	126	189	114	162	3		4	4	4	4	4	3 4	3	4	3
6	3	2		2 1	3	3	2	2	1	2	2	1	2	4	3	3	2	2	2	180	231	165	202	142	180	120	160	4	-	4	4	4	4	-	4 4	4	4	4
7	3	1	1 :	3 1	3	2	2	1	2	2	2	1	2	3	3	2	2	1	2	186	289	163	262	140	230	122	196	4	-	4	4	4	-		4 4	4	4	4
8	2	2	1	1 1	3	3	2	2	1	2	1	1	2	3	2	2	2	1	2	163	260	142	238	126	202	111	181	4	-	4	4	4	4	4	4 4	4	4	4
9	3	_	-	3 1	3	3	2	2	1	3	2	1	2	3	2	3	2	2	2	170	240	155	216	121	162	116	141	4	4	4	4	4	4	4	4 4	4	4	4
10	3	2		2 1	3	3	2	2	1	3	2	1	1	3	3	3	2	2	2	162	212	140	189	133	170	114	150	3		4	4	4	· ·	-	4 4	3	3	3
11	4	1		4 5	-	4	2	2	2	2	2	1	2	3	3	3	2	2	2	160	210	151	192	130	173	118	148	3		4	4	4	•		3 4	4	4	4
12	2	1	-	4 1	4	2	2	1	2	2	2	1	2	2	3	2	2	2	2	171	288	148	252	124	230	113	196	4	-		4	4		-	4 4	4	4	4
13 14	3	1		$   \begin{array}{c c}     2 & 1 \\     5 & 1   \end{array} $	3	2	2	2	1	2	2	1	2	3	3	3	2	2	2	1/0	241	145 130	223 232	123 120	201 206	118 116	182 179	4	-	4	4	4	-	<u>.</u>		4	4	4
14	3	2		$\frac{5}{2}$ 1	3	3	2	2	1	3	2	1	2	2	3	2	1	2	$\frac{2}{2}$	164	250	130	232	120	180	116	1/9	4	4	4	4	4	4	3	$\frac{4}{4}$	4	4	4
15	2			$\frac{2}{3}$ 1	3	2	2	2	1	2	2	1	2	4	3	3	2	2 1	$\frac{2}{2}$	169	225	140	201	125	256	112	220	4	4	4	4	4	4	4	$\begin{array}{c c} 4 & 4 \\ 4 & 4 \\ \end{array}$	4	4	4
17	2	-	0 .	$\frac{3}{3}$ 1	3	2	2	2	1	2	2	1	2	4	2	3	2	1	2	152	236	130	207	121	186	113	163	4	4	4	4	4	4	4	4 4	4	4	4
17	1	-	0 .	$\frac{3}{3}$ 1	3	2	$\frac{2}{2}$	2	1	2	2	1	1	4	2	4	1	2	2	163	230	143	207	1121	198	120	105	4	4	4	4	4	4	4	$\frac{4}{4}$	4	4	4
19	1	_	0 .	$\frac{3}{3}$ 1	3	3	2	2	1	4	2	1	2	2	2	3	1	2	2	169	278	145	263	131	236	120	202	4		4	4	4	4	4	$\frac{4}{4}$ 4	4	4	4
20	2		3	1 1	3	3	2	2	1	3	2	1	2	3	2	2	2	2	2	182	256	160	236	142	202	123	179	4		4	4	4	3	<u> </u>	3 3	-	4	4
20	4	1	-	3 1	3	3	2	2	1	2	2	1	2	2	2	3	2	2	2	171	214	152	196	136	174	118	143	4	-	4	3	4	4	-	4 4	4	4	4
22	3	1	-	2 1	3	2	2	1	2	3	2	1	2	2	3	2	2	2	2	176		160	197	130	175	121	159	4	-	4	4	4	3	4	3 4	4	4	4
23	1	1	3	3 1	3	2	2	1	2	4	2	1	2	2	3	2	2	2	2	188	220	160	201	142	180	126	156	3	4	3	4	4	4	4	4 4	4	4	4
24	2	1	-	3 1	4	2	2	2	1	3	1	1	1	3	3	2	2	2	2	160	240	145	223	126	196	113	175	4	4	4	4	4	4	4	4 4	3	4	4
25	2	2	1	1 1	3	3	2	2	1	3	2	1	2	3	3	3	2	1	2	176	265	153	242	129	220	117	196	4	4	4	4	4	4	4	4 4	4	4	4
26	2	1	3 4	4 1	4	2	2	2	1	2	1	1	1	3	3	3	2	2	2	171	225	160	203	136	180	120	154	4	4	4	3	4	4	4	4 4	3	4	4
27	3	2	3 1	2 4	. 3	3	2	2	1	2	2	1	1	3	3	3	2	2	2	168	219	141	195	121	175	116	150	3	4	3	4	4	3	3	4 4	4	4	4
28	3	2	1 4	4 1	4	2	2	2	1	2	1	1	2	2	3	2	2	2	2	164	208	149	182	123	160	115	144	4	4	4	4	4	4	4	4 4	4	4	4
29	3	1	3 4	1 1	4	2	2	2	1	2	2	1	2	2	3	2	1	2	2	160	240	140	229	120	198	118	156	4	4	4	4	4	4	4	4 4	4	4	4
30	4	1	1	2 1	3	4	2	2	1	2	2	1	2	2	3	2	1	2	2	172	269	136	240	116	206	114	177	4	4	4	4	4	4	4	4 4	4	4	4

### **APPENDIX XVII**

## AREA MAP



## APPENDIX XVIII PHOTOGRAPH DURING DATA COLLECTION





xlviii