

**IMPACT OF HERBS BASED LIFESTYLE INTERVENTION
REGIME ON SEXUAL DYSFUNCTION AND BLOOD
GLUCOSE LEVELS OF DIABETIC MALE ADULTS:
A RANDOMIZED CONTROLLED TRIAL**

A
Thesis
Submitted to



For the award of
DOCTOR OF PHILOSOPHY (Ph.D.)
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NUTRITION AND DIETETICS
By
Sukhjindar Singh Ghotra
(Registration Number - 41400157)

Supervised By
Dr. Nancy Sahni

Co-Supervised by
Dr. Vikas Kumar

**LOVELY FACULTY OF FOOD TECH AND SCIENCE
LOVELY PROFESSIONAL UNIVERSITY
PUNJAB
2018**

DECLARATION

I hereby declare that the work presented in the Thesis entitled “**Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults: A randomized controlled trial**” is my own and original. The work has been carried out by me at Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh and Department of Food Technology and Nutrition, School of Agriculture, Lovely Profession University (LPU), Phagwara, Punjab, India under the guidance of Supervisor **Dr. Nancy Sahni**, Dietician, Department of Dietetics, PGIMER, Chandigarh and Co-supervisor **Dr. Vikas Kumar**, Assistant Professor, Department of Food Technology and Nutrition, School of Agriculture, LPU, Phagwara, Punjab, India, for the award of the degree of Doctor of Philosophy (Ph.D.) in Nutrition and Dietetics.

Date:

Place: (SUKHJINDAR SINGH GHOTRA)
(Registration No. : 41400157)

I certified that the above statement made by the student is correct to the best of my knowledge and belief.

The Ph.D. Viva-Voice Examination of Sukhjindar Singh Ghotra has been held on

Date:

Place:

Supervisor: Dr. Nancy Sahni
Dietician, PGIMER, Chandigarh

Date:

Place:

Co- Supervisor: Dr. Vikas Kumar
Assistant Professor,
Dept. of Food Tech and Nutrition, LPU

Signature of External Examiner

CERTIFICATE



This is to certify that **Sukhjinder Singh Ghotra** (Registration No. 41400157) has personally completed thesis entitled “**Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults: A randomized controlled trial**” under our guidance and supervision. To the best of our knowledge, the present work is the result of his original investigation and study. No part of thesis has ever been submitted for any other purpose at any University.

The thesis report is appropriate for the submission and the partial fulfilment of the conditions for the evaluation leading to the award of Doctor of Philosophy (Ph.D.) in Nutrition and Dietetics.

Supervisor:

Dr. Nancy Sahni

Dietician, Department of Dietetics,
PGIMER, Chandigarh

Co-Supervisor:

Dr. Vikas Kumar

Assistant Professor
Food Technology and Nutrition
LPU, Punjab

(Committee members)

Dr. Sanjay K. Bhadada

Professor

**Department of Endocrinology
PGIMER, Chandigarh**

Dr. Amarjeet Singh

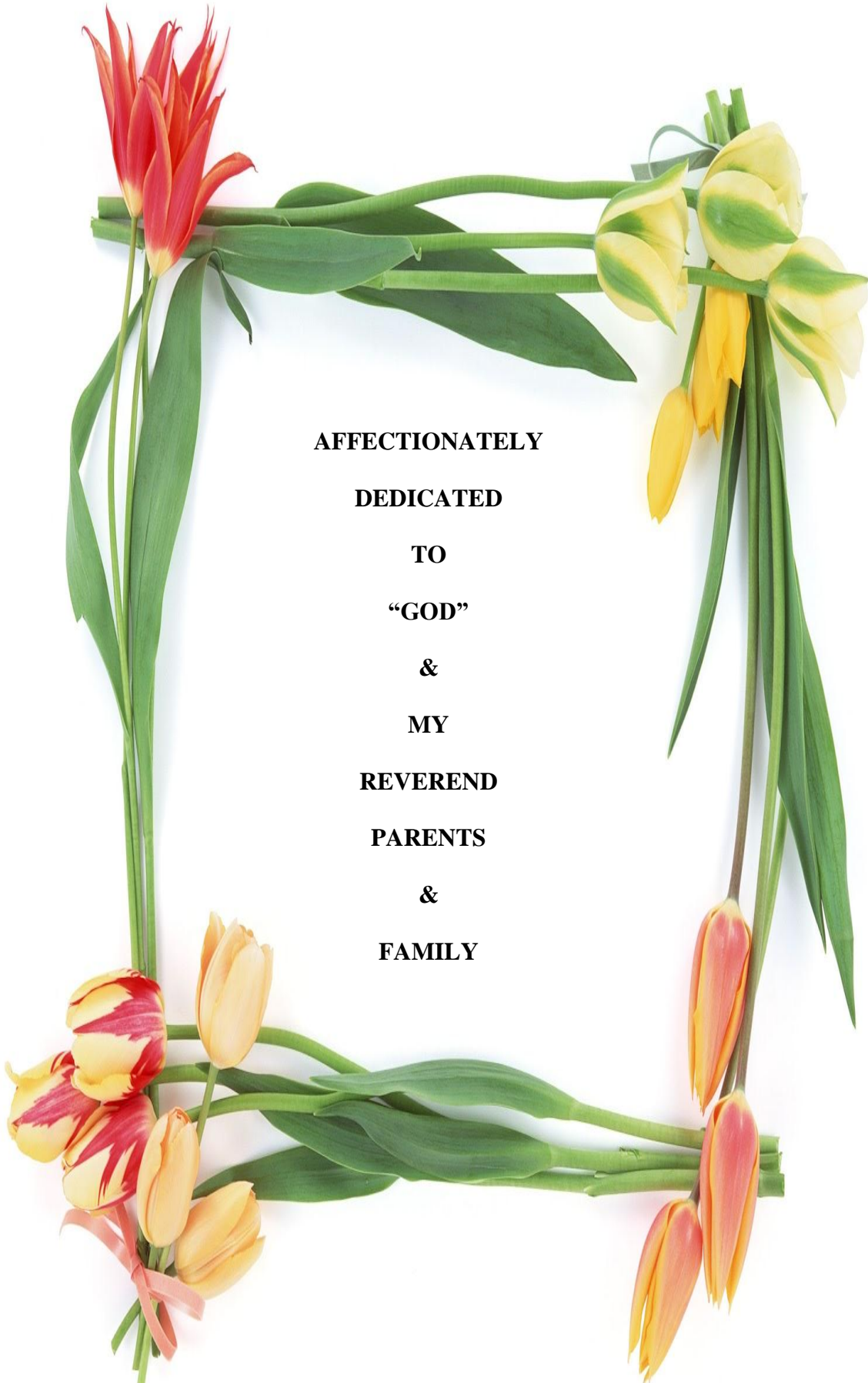
Professor

**Dept. of Community Medicine
PGIMER, Chandigarh**

Dr. A. K. Mandal

Professor and Head

**Department of Urology
PGIMER, Chandigarh**



**AFFECTIONATELY
DEDICATED
TO
“GOD”
&
MY
REVEREND
PARENTS
&
FAMILY**

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Date:

Place:

SUKHJINDAR SINGH GHOTRA

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ABSTRACT

Diabetes mellitus has become an epidemic problem worldwide, derange the healthcare system and have increased burden on healthcare system. Many studies show that high rate of urbanization and its effect on people's dietary habits, physical inactivity leads to an increasing prevalence of Type 2 diabetes mellitus and consequently sexual dysfunction. The progression and poor blood glucose control are also more among south Asians when compared to European populations.

Diabetes mellitus is a chronic disorder in which body does not use insulin properly or produce less insulin in the body. It is characterized by metabolic malfunction of carbohydrates, protein and fat in the body. Body cells do not use glucose, which result in increased glucose level in the blood. Diabetes mellitus patient's number is increasing and has become a major source of mortality and morbidity all over the world. There were over 72 million cases of diabetes in India in year 2017 recorded. Now 387 Million people are living with Type 2 diabetes mellitus in the world. Sexual dysfunction, in which a male is not able to make sexual relation (intercourse) as he wishes to do is also increasing in the society. According to National Health and Social Life Survey 2016 reports 31 per cent of Indian male population have sexual dysfunction. What is more alarming is that sexual dysfunction in diabetic patients is more than 50 per cent or three fold increased risk than normal person. There are not many studies done in India for prevalence of sexual dysfunction.

There are many treatments available both allopathic and Ayurvedic for managing diabetes mellitus but rarely a research has been done in combination with sexual dysfunction especially in Ayurvedic medicine. In recent years, the use of complementary and alternative medicines has become increasingly popular. Sexual dysfunction patients often seek alternatives, since many are reticent to express their sexual problems to doctor or are not satisfied with current treatment. These alternative medications may be more safe and free from side effects unlike chemical drugs. The present study attempts to identify innovations in the Indian herbal drug sector by analysing the potential of herbal impact on diabetic and sexual dysfunction adult patients.

Keeping this aim in mind, this study was done to analyse the prevalence of sexual dysfunction amongst diabetic population with reference to their nutritional status, treatment seeking behavior for sexual dysfunction as well as to study the effect of herbal powder supplements (*Gymnema sylvestre*, *Momordica charantia*, *Azadirachta indica*, *Citrullus colocynthis*, *Berberis aristata*, *Tribulus terrestris*, *Asphaltum* and *Withania somnifera*) and life style modification on blood glucose levels and IIEF (International Index of Erectile Function) score. Herbal powder formulation, standardisation as well as analysis for its purity was done form drug testing laboratory before starting the trial.

Two hundred eighty two patients with diabetes who met the diagnostic criteria of study enrolment were enrolled for the study. These were divided into two groups on the basis of IIEF score. One group with the sexual dysfunction and one without sexual dysfunction [less than <50 termed as sexually dysfunctioned and more than >50 termed as not sexually dysfunctioned] and excluded from the intervention part of the study. Out of total 282 patients who had IIEF score less than 50, 222 enrolled for randomized controlled trial (RCT) for intervention .Sixty patients who had IIEF score more than 50 were excluded from the study. The nutritional status of diabetic patients was directly proportional to the blood glucose levels and inversely proportional to sexual dysfunction. The study data showed that normal nutritional status patients have better control over blood glucose levels and IIEF score. The study data also highlighted prevalence rate of sexual dysfunction in our population (Type 2 adult male diabetic patients). It was 78.7 per cent. Only 11 per cent patients were taking any treatment for sexual dysfunction.

Among 222 patients further seventeen patients did not full fill intervention inclusion criteria (other medical problems) so were excluded from the study. There were total 205 adult male Type 2 diabetic patients with sexual dysfunction for RCT intervention study. We have enrolled total 100 patients for intervention study by block randomization 50 in each groups A and B. Group A were intervened with herbal supplement and exercise and dietary counselling and group B patients were intervened with placebo, exercise schedule and dietary counselling. The method used for present investigation was questionnaire cum interview method for intervention study. Everyday herbal powder supplementation was given to participants in two

divided doses. At the end of three months intervention after drop outs; total 67 patients were left; 41 in group A and 26 were in group B.

Highly significant reduction in fasting, postprandial and HbA1c levels was recorded in group A patients at the end of three months at the rate of 32.3 per cent in fasting blood glucose, 33.7 per cent in postprandial blood glucose level, 18.5 per cent in HbA1c level. Significant increases 11.13 per cent in IIEF score. Whereas the reduction of blood glucose levels and increase in IIEF score were non-significant in group B patients.

From the above study it may be concluded that this herbal powder supplementation can help in decreasing blood glucose levels and may increase IIEF score of diabetic patients. To conclude, this herbal powder has great potential for utilization and can be used as an adjunct therapy for treating diabetes mellitus and sexual dysfunction in diabetic adult male patients.

CHAPTER 1

INTRODUCTION

The world nowadays faces an epidemic of non-communicable diseases largely due to changing lifestyle, which will exceed communicable disease in developing and developed countries (WHO 2014). Diabetes is one of the most common non-communicable diseases in the world. Misra et al, (2011) reported that prevalence of diabetes is higher in rural population of India at a rate of 2.02 per 1000 people per year and 3.3 per 1000 per year in men when compared to women (0.88 per 1000 per year). According to International Diabetes Federation, 2013 report the number of diagnosed diabetic patients in India were 67 million and 35 million undiagnosed patients whereas, there were over 72 million cases of diabetes in India in year 2017 (International Diabetes Federation) recorded. Now 387 Million people are living with Type 2 diabetes mellitus in the world.

Diabetes mellitus is a chronic disorder in which body cannot use insulin properly or produces less insulin in the body. It is characterized by metabolic malfunction of carbohydrates, protein and fat in the body. Body cells do not use glucose, resulting in increased glucose level in the blood (Rizvi and Mishra, 2013). About 85-95 per cent of diabetes is Type 2 (Badran and Laher, 2012). Diabetes mellitus is becoming a pandemic problem worldwide and has been associated with sexual dysfunction in men as one of the complication of diabetes. A combination of these two problems is very common in the community. According to National Health and Social Life Survey 2016 reports 31 per cent of Indian male population have sexual dysfunctions. Sexual dysfunction in diabetic patients is more than 50 per cent or three fold increased risk than normal person. Sexual dysfunction is a problem in which a person is not able to make sexual relation (intercourse) as he wishes to do.

This field requires attention as it is mostly neglected by the health professionals. There are not many studies done in India for sexual dysfunctions in diabetic patients. These problems are influenced by psychosocial factors, physical inactivity, modern eating pattern, obesity, smoking, alcohol etc. and associated with impaired quality of life. There are lots of allopathic medicines e.g. OHA, insulin for diabetes. Blue pill commonly known as Viagra to treat sexual dysfunction is available

in the market. But these medicines can treat only upto an extent but cannot cure. There are numbers of side effects as well reported with these medicines. In recent years, the use of complementary and alternative medicines has become increasingly popular. Sexual dysfunction patients often seek alternatives, since many are reluctant to express their sexual problems to doctor or are not satisfied with current treatment. There is an international search for alternative oral hypoglycemic which are effective but having least or no toxicity especially for Type 2 diabetes mellitus cases.

One of the sources looked for is natural products such as herbal and relatively safer mineral sources. A number of plants and their extracts have been tried. Herbal medications tend to be safer and free from side effects unlike chemical drugs. Herbal drugs are gaining worldwide prominence due to their distinct advantages. The present study attempts to identify innovations in the Indian herbal drug sector by analysing the potential of herbal impact on diabetic and sexual dysfunction adult patients. The most vital need in India now is the prevention of diabetes in the society. Screening for diabetes or higher blood glucose level and for glucose intolerance is necessary for the people, even in younger age people below 30 years of age (Ramachandran and Snehalatha, 2009). There is lack of awareness or knowledge about diabetes care in diabetic patients as well as general public. Approximately 25 per cent of Indian population is unaware of diabetes and 41 per cent of diabetic patients knew that diabetes could be prevented (Poudel and Adhikari, 2013).

There are many therapies in use to treat diabetes and sexual dysfunction, but there are many limitations due to their side effects such as liver toxicity and failure of medicine effect (Dey et al, 2002). Alternative and affordable approaches are needed to manage the diabetes and sexual problems for the patients in developing countries. Therefore, herbs and other dietary supplements are being used as supplementary and alternative medicine to treat diabetes and sexual dysfunction. According to World Health Organization, many herbs are suitable source as primary health care for more than 80 per cent Asian population (Tabish, 2008). Herbal products are those in which there is use of any plant's parts like seeds, roots, leaves, bark or flowers is used for medicinal purposes. Scientific validation of several Indian plant has proved the efficacy of plants in reducing blood glucose levels (Dwivedi and Daspaal, 2013).

Despite all the advancement in medical science, medicinal plant are still an inevitable source of medicine preparation having a protective and curative effect. Many species are having significance medicine value and numerous are commonly used to treat and control specific ailments and diseases (Scartezzini and Sproni, 2002).

This study is aimed to explore the possibility of effect of herbs based lifestyle intervention has a potential to provide a beneficial impact on various sexual dysfunction (problems) and helps to maintain the blood glucose levels of diabetic male adults. The present study also attempted to intervene new combination of various herbs which are not available in the market to treat diabetes and sexual dysfunction. A lot of work has been already carried out for the natural therapy to treat diabetes and sexual problems using different herbs, but he use of these all herbs *Gymnema sylvestre* , *Momordica charantia* , *Azadirachta Indica* , *Citrullus colocynthis* , *Berberis aristata*, *Tribulus terrestris* , *Asphaltum* and *Withania somnifera* in a specific amount combination is still unexplored for treatment for diabetes and sexual dysfunction. Therefore to full fill this research gap present study is done.

All the eight herbs have been mentioned in classical Ayurvedic literature as potent anti-diabetic drug and also have aphrodisiac properties. There has been a number of clinical and experimental studies on the efficacy of each individual and or in combination (different) of these herbs as potent oral hypoglycemic or anti diabetic drug and aphrodisiac quality. The medicinal effect of these herbs may be due to presence of active compounds such as 1. *Gymnema sylvestre* has active compound Gymnemic acid - it prevent the absorption of excess glucose. 2. *Momordica charantia* have two components. Charantin a steroidal saponin agent with insulin like properties and Momordicin an alkaloid possesses hypoglycemic properties. 3. *Azadirachta indica* have active compounds Azadirachtin, Quercetin and Nimbidin. 4. *Citrullus colocynthis* have active compounds myristic, palmitic. 5. *Berberis aristata* has active compound berberine. It is alkaloids. 6. *Tribulus terrestris* has active compounds harmane and norharmene (alkaloids) 7. *Asphaltum* has active compound fulvic acid. 8. *Withania somnifera* has active compounds withanine, somnie and wihtaferine. These herbs act like hypoglycemic effect and aphrodisiac quality.

Herbs and allopathic medicines lack scientific and clinical data proving their efficacy and safety. Keeping this in mind, the present study was planned to record the effect of herbal intervention on Type 2 adult diabetic patients' as well on sexual dysfunction. This study trial might help in improving clinical outcomes for the same and be used as an important component of therapeutic intervention in near future. In this study also analyse the prevalence of sexual dysfunction amongst diabetic patients with reference to their nutritional status, treatment seeking behaviour for sexual dysfunction. Herbal powder formulation, standardisation as well as analysis for its purity was done from drug testing laboratory before starting the intervention trial study. FTIR analysis was also done in laboratory of Lovely Professional University for these herbal powder. Intervention study of herbal powder trial done in Endocrinology OPDs at PGIMER, Chandigarh.

CHAPTER 2

TERMINOLOGY

%	=	Per cent
±SD	=	Standard Deviation
ADA	=	American Diabetes Association
ANOVA	=	Analysis of variance
API	=	Active Pharmaceutical Ingredient
ASU	=	Ayurvedic Siddha Unani
AYUSH	=	Ayurvedic, Yoga and Naturopathy, Unani, Siddha and Homeopathy
BD	=	Twice a Day
BGL	=	Blood Glucose Level
BMI	=	Body Mass Index
CC	=	Calf circumference
CHO	=	Carbohydrate
CR	=	Counselling Room
CSSD	=	Central Sterile Services Department
CTRI	=	Clinical Trials Registry-India
DCCT	=	Diabetes Control and Complications Trial
DCGI	=	Drug Controller General of India
DM	=	Diabetes Mellitus
DPP	=	Diabetes Prevention Program
ED	=	Erectile dysfunction,
EF	=	Erectile Function
et al	=	And other
FAO	=	Food and Agriculture Organization
FBG	=	Fasting Blood Glucose Level

FFQ	=	Food Frequency Questionnaire
FPG	=	Fasting Plasma Glucose
FPO	=	Fruit Products Order (Law 1955)
FSSAI	=	Food Safety and Standards Authority of India
FTIR	=	Fourier Transform Infrared Spectroscopy
gm.	=	Gram
GOD-POD	=	Glucose oxidase peroxidase
HbA1c	=	Glycated haemoglobin
HOD	=	Head of Department
HPLC	=	High performance liquid chromatography
ICMR	=	Indian Council of Medical Research
IDDM	=	Insulin dependent diabetes mellitus
IIEF	=	International Index of Erectile Function
IS	=	Intercourse satisfaction
kcal	=	Kilocalories
Kg	=	Kilogram
LOD	=	Loss on drying
MAC	=	Mid arm circumference
MNA	=	Mini Nutritional Assessment
NFHS	=	National Family Health Survey
NGSP	=	National Glycohemoglobin Standardization program
NHSL	=	National Health and Social Life Survey
NIDDM	=	Non-Insulin dependent diabetes mellitus
NIN	=	National Institute of Nutrition
NNMB	=	National Nutrition Monitoring Bureau
OAD	=	Oral anti-diabetics
OF	=	Orgasmic Function
OGTT	=	Oral Glucose Tolerance Test

OHA	=	Oral Hypoglycemic Agent
OPD	=	Out Patient Department
OS	=	Overall satisfaction
PE	=	Premature Ejaculation
PGIMER	=	Postgraduate Institute of Medical Education and Research
PICF	=	Patient Informed Consent Form
PICO	=	Participants Intervention Comparator Outcome
PPBG	=	Postprandial Blood Glucose Level
RCT	=	Randomized Controlled Trial
SD	=	Sexual Desire / Sexual Dysfunction,
SGA	=	Subjective Global Assessment
SPSS	=	Statistical Package for Social Sciences
T1DM	=	Type 1 diabetes mellitus
T2DM	=	Type 2 diabetes mellitus
WHO	=	World Health Organisation

CHAPTER 3

REVIEW OF LITERATURE

A study of compatible literature is an essential step to get a good knowledge of what has been done with regard to the problem under study. Accordingly, review of the literature done through available journals, books, magazines, articles, research papers and literature which is relevant to the study are presented in this chapter.

The literature in the present study “Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels on diabetic male adults: A randomized controlled trial” have been reviewed as follows:

- 3.1 Prevalence of diabetes mellitus
- 3.2 Prevalence of sexual dysfunction
- 3.3 Introduction of diabetes mellitus
- 3.4 Introduction of sexual dysfunction
- 3.5 Treatment of diabetes mellitus
- 3.6 Treatment of sexual dysfunction
- 3.7 Sexual dysfunction and diabetes
- 3.8 Herbs and its hypoglycemic and aphrodisiac effect
- 3.9 Assessment of nutritional status in Type 2 adult male diabetic patients
- 3.10 Other factor and its relation with diabetes mellitus and sexual dysfunction

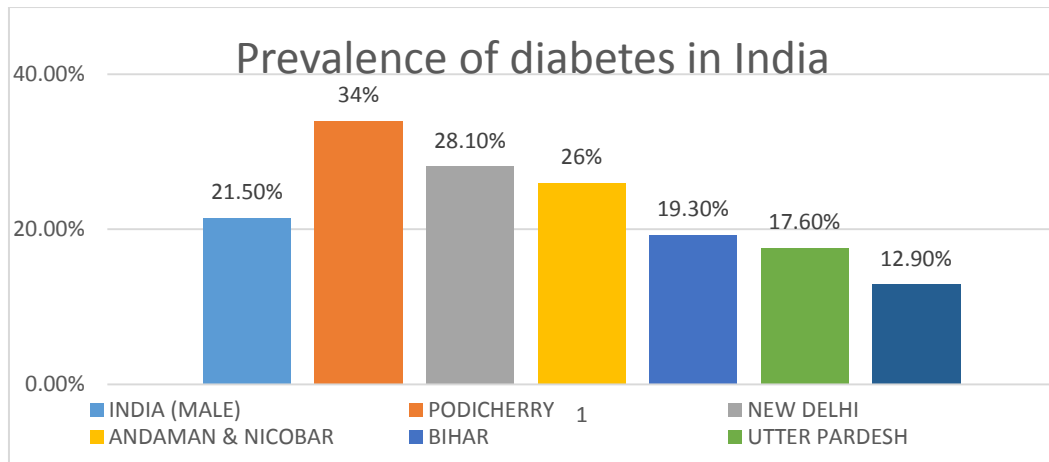
It also focuses on the effect of changeable, various herbal intervention, dietary modification and other lifestyle elements on hypoglycemic effect and sexual disorder in the diabetic male adult population.

3.1. Prevalence of diabetes mellitus

Nowadays, diabetes is furiously spreading disease in whole world. The number of diabetic patients are expeditiously increasing in every area of the universe. Countries are struggling to fight the disease. As stated by (Sarah et al., 2004), the diabetic mellitus cases are increasing due to increase in population, changes in dietary and lifestyle schedules as well as due to obesity, reduced activities and unhealthy behaviours routines. Urbanization and aging is also a big factor to enhance diabetes mellitus (WHO 1994). Due to increase in diabetic population, India has been declared as the diabetic capital of the world (India times, June 2017). Indian population have higher age related prevalence of diabetes mellitus, when compared with other population of diabetes of world (Ali et al, 2010).

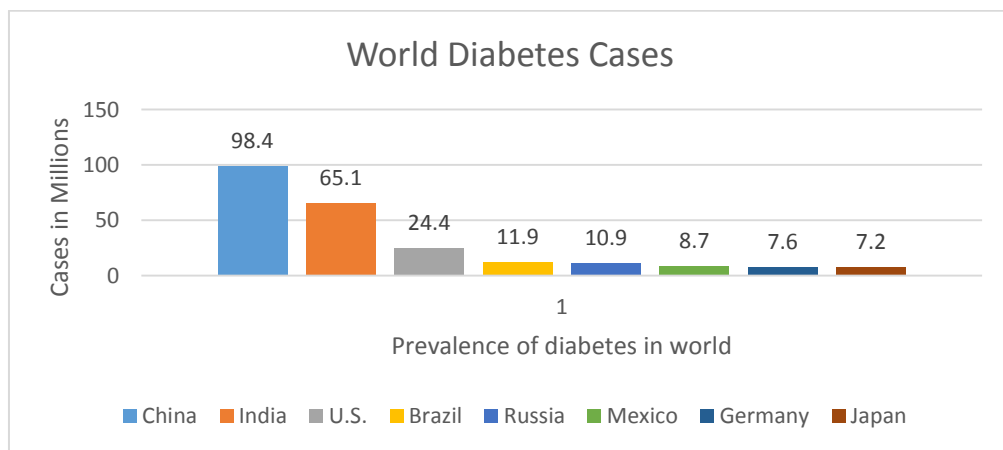
Indian states prevalence of diabetes in adult men was 21.5 per cent and ranged from a high of 34 per cent in Pondicherry followed by 28 per cent in New Delhi and lowest in Madhya Pradesh 12.9 per cent shown in figure 1 (National Nutrition Monitoring Bureau report, 2017). The prevalence of diabetes was highest in the age group of 60-70 years and lowest in age group of 18-30 years age. According to International Diabetes Federation, 2013 report the number of diagnosed diabetic patients in India were 67 million and 35 million undiagnosed patients whereas, there were over 72 million cases of diabetes in India in year 2017 (International Diabetes Federation) recorded. In India, recent study done by Anjana et al, (2011) stated that the prevalence of diabetes in 4 state of the country, 5.3 per cent in Jharkhand, 8.4 per cent in Maharashtra, 10.4 per cent in Tamil Nadu and 13.6 per cent in Chandigarh. According to Chandigarh have highest per centage of prevalence of diabetic cases may be due to higher income group (Anjana et al, 2011).

Inspite of availability of many different types of treatments the numbers of diabetes patients are increasing all over the world. (International Diabetes Federation, 2013). At present 387 Million people are living with Type 2 diabetes mellitus in the world however, its prevalence about 8.3 per cent. Among them 46.3 per cent people is still undiagnosed (Diabetes Self-care foundation, 2015). It is predicted that, shown in figure 3 by the year 2035, almost 600 million of us may be living with diabetes. According to Unwin et al, (2013) study report prevalence of diabetes mellitus patients in adults were between the ages of (20-79) years was 8.31 per cent (Unwin et al, 2013). Whereas, according to International Diabetes Federation there were approximately 382 million people with diabetes in the year 2014.



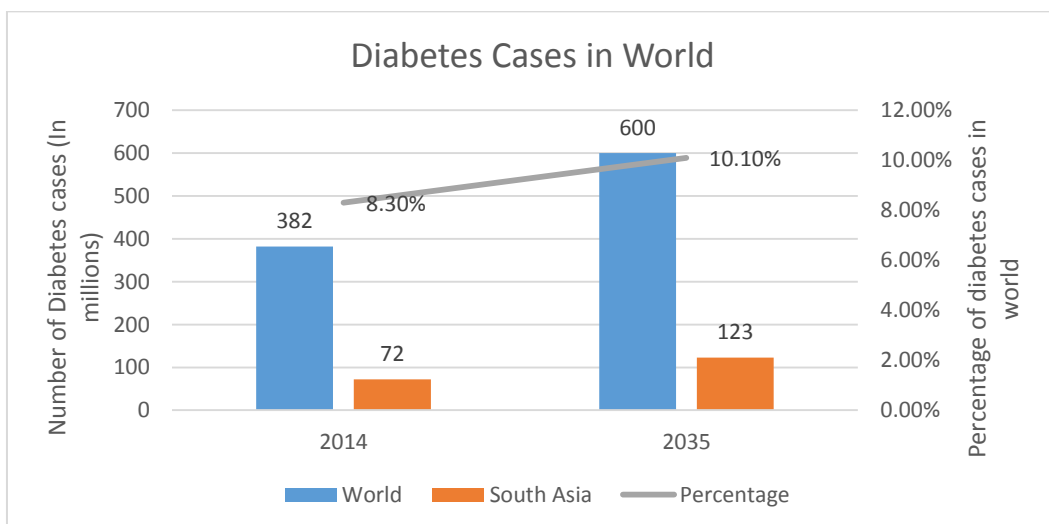
(National Nutrition Monitoring Bureau (NNMB) report, 2017)

Figure 1. Prevalence of diabetes in India (adult male)



(International Diabetes Federation, 2013)

Figure 2. Prevalence of diabetes in World



(Unwin et al, 2013; International Diabetes Federation, 2013; Ramachandran et al, 2014)

Figure 3. Prevalence of diabetes in World in 2014 and 2035 (predicted)

The prevalence rate of diabetic cases in world as shown in figure 2 is lowest in Japan and highest in China with 7.2 million and 98.4 million respectively. While in other countries it is 65.1 million in India on second number in world, 24.4 million in U.S., 11.9 million in Brazil, 10.9 million in Russia, 8.7 million in Mexico and 7.6 million in Germany persons affected by diabetes (International Diabetes Foundation, 2013). Diabetes is the World's 3rd most populous country. First most populous country with diabetics is china with 1.3 billion population. Second most populous country is India with 1.2 billion population. Third most populous country is 'DIABETES' with 387 million population. Fourth most populous country is USA with 321 million population (Diabetes Self-care foundation, 2015).

Diabetes occurring in young age vacillate the most invaluable and productive years of life. One in two people with diabetes are unaware of its existence. There is an expected 70 per cent diabetic patient increase in developing countries and about 20 per cent increase in diabetic patients in developed countries (International Diabetes Foundation, 2009). The overall predicted increase in diabetic person from 2010 to 2030 is 54 per cent with annual growth of 2.2 per cent. 36 per cent of these global increase of 154 million people with diabetes is estimated to occur in China and India only (Shaw et al, 2010). In developing countries, the majority of people with diabetes are in the age group of 45- 65 years of age and in developed countries, the majority of people with diabetes are in the age group of above 65 years (Chinyere et al, 2010).

3.2 Prevalence of sexual dysfunction

Like diabetes mellitus sexual dysfunction in male is also increasing in the society. Sex is a part and parcel for relationship adults of all ages. Diabetic people are more prone to sexual disorders. Sexual dysfunctions are caused due to many reason such as environment, nutritionally imbalanced diet (Saxena et al, 2012). Interference with reproductive life, self-esteem, quality of life, problem with partners, poor self-image and increase in stress, making sexual dysfunction a big problem of life (Consensus 1993; Heidelbaugh 2010).

Most of the public remain tacit about their sexual dysfunctions. Men's reaction to sexual problem includes shame and denial. Hence it's hard to get exact figure of people with sexual dysfunction. Study says about 64 per cent patients never disclose their sexual problems even with their doctors (Muse impotence report).

In developing countries it is a neglected aspect of life. Most of physicians do not question about patients sexual dysfunction (De et al, 2002; Saxena et al, 2012). According to NHSL, 2016 (National Health and Social Life Survey) the prevalence of sexual problems in India was 31 per cent.

According to McCulloch study, the prevalence ranges from 35 to 70 per cent in the world. United Nations estimated the 52 per cent of men at age range of 40-70 years have sexual problems (ED) (McCulloch et al, 1980; Hakim and Goldstein 1996; Klein et al, 1996; Chew et al, 2000; Fedele et al, 2000). Sexual dysfunction in diabetic patients is more than 50 per cent or three fold increased risk than normal person (Feldman et al, 1994; De et al, 2002, Heidelbaugh 2010; Maiorino et al, 2014; Kamenov 2015). There were 152 million people with sexual problem in the year 1995. It is projected to increase two-fold by the year 2025 to approx. 322 million men in the worldwide (Ayta et al, 1999).

Table 1. Prevalence of sexual dysfunction

S. No.	Methods	Results	References
1.	Prevalence of SD (ED)	30 per cent Ed in men age 40-70 years	De et al, 2002
2.	Prevalence of SD (ED)	Found ED among men with diabetes 45.8 per cent and without diabetes men showed 24.1 per cent (nearly double)	Bacon et al, 2003
3.	N= 1460, study for prevalence of severe and mild- moderate erectile dysfunction. Self-reporting technique used.	Result- severe=34 per cent and Mild-moderate= 24 per cent. Severe ED was mainly related to severity of diabetes. By tree growing technique 6 classes characterized by prevalence of severity of ED of between 19 per cent to 65 per cent.	De et al, 2003
4.	Prevalence of SD (ED)	Found 36 per cent of ED in diabetic patients	Fedele, 2005

5.	Prevalence of ED N=1947, Interview and questionnaire method.	Prevalence of ED was 35 per cent. Low education and psychosocial problems were associated to ED	Martins et al, 2010
6.	Prevalence of SD (ED)	186 male (age 19-100) diabetic patients, Prevalence of SD: ED 68.8 per cent, Show more prevalence of SD in DM	Owiti et al, 2012
7.	Prevalence of SD N=152 Type 2 diabetes patients. Cross sectional survey done.	Among them 69 per cent of men classified with some degree of sexual dysfunction. SD associated with higher age, clinical depression and diabetes related complication.	Rutte et al, 2015

(SD- Sexual dysfunction, ED- Erectile dysfunction, DM- Diabetes Mellitus)

3.3 Introduction of diabetes mellitus

According to WHO, 2011, the diabetes mellitus is a chronic ailment which occur due to malfunction of pancreas. Usually it occur when body do not use insulin properly present in the body or generate less insulin. It is featured by metabolic malfunction primarily carbohydrates metabolism, protein and fat in the body. Body cells does not utilize glucose, result in increased level of glucose in the blood (hyperglycemia) (Rizvi and Mishra 2013).

The higher level of blood glucose leads to damage of blood vessels, more over it causes eye disease, heart disease, autonomic neuropathy and the major detrimental consequence of it is sexual dysfunction. Other symptoms observed are Polyuria, Polydipsia (constant feeling of thirst), polyphagia (constant feeling of hunger), loss of weight, lack of energy, paraesthesia (tickling) and Delay in wound healing.

There are mainly three kinds of diabetes mellitus (WHO, 2011). Type 1 (Insulin dependent diabetes mellitus, IDDM) mostly occurs in children. Type 2 Diabetes Mellitus (Non-insulin dependent diabetes mellitus, NIDDM) and gestational diabetes mellitus. Type 2 diabetes mainly found in adults and obese people. Approx. 90-95 per cent of diabetic population have Type-2 diabetes (Patel et al, 2012). The 3rd type of diabetes is gestational diabetes which develops during pregnancy.

The cause of increasing diabetes includes overeating, hereditary factor, physical inactivity, smoking, stress and tension in daily life. It can be diagnosed by doing blood test for fasting blood glucose test, postprandial blood glucose test, HbA1c, oral glucose tolerance test and urinary sugar test.

3.4 Introduction of sexual dysfunction

Sexual dysfunction is a problem in which a person is not able to make sexual relation (intercourse) as he wishes to do.

Sexual dysfunction include following problem:

- Erectile dysfunction (ED)
- Premature ejaculation (PE)
- Lack of interest or diminished sexual desire

Sexual dysfunction have primary and secondary reasons. Primary reasons are rare and can be associated with low androgen levels, genetic defects and severe psycho-pathology. Secondary reason is more common, results from something else such as diabetes, arteriosclerosis, neurological disorders, psychological issues, prolonged stress. Blood pressure medications and antidepressants may also lead to sexual dysfunction, especially in the elderly.

3.4.1 Erectile Dysfunction (ED)

Erectile dysfunction is a situation in which a person is unable to achieve or maintain an erection sufficient for satisfactory sexual performance.

3.4.2 Premature Ejaculation (PE)

Premature ejaculation is a situation in which a man do not reach to its peak and gets early release of sperm without getting satisfactory sexual performance. A man cannot have control over ejaculation upto a sufficient period during intercourse to satisfy the partner. It is a temporary problem and every man may suffer from it at one time or the other. Premature ejaculation is a common problem and mainly young men are affected more. It affects millions of men around the world.

3.4.3 Lack of interest in sex

Lack of interest in sex also known as lack of libido. It is defined as the term use to describe a situation in which a person do not pay any interest in sexual activity. Risk factors involving in increasing the chance of developing sexual dysfunction are Patients may have poor blood glucose control, Smoking habits (Johannes et al, 2000), alcohol abuse, obesity (Esposito et al, 2008), sedentary lifestyle, heart disease, high blood pressure, Illicit drug use (e.g. cocaine, methamphetamine), nervous problems such as Alzheimer disease, Parkinson disease, fits etc., Psychological conditions (e.g. anxiety, depression, marital relationship problem, stress etc.), misuse of the sexual organ for a long period, high cholesterol is connected with high risk of sexual dysfunctions (Feldman et al, 1994; Heidelbaugh, 2010; Lue et al, 2017). Sexual dysfunction is also related to age, Body mass index, tenure of diabetes mellitus and its consequences (Enzlin et al, 2003). Sedentary lifestyle is a potent factor for sexual dysfunction (Kostis et al. 2005; Heidelbaugh, 2010). Obesity nearly double the peril of sexual dysfunction (Bacon et al, 2003).

There is no preferable first line diagnostic criteria for sexual dysfunction. Patient's history and physical check-ups are enough to make diagnoses of sexual problem (Heidelbaugh, 2010). The diagnosis is based on the patient's self-report in conjunction with a clinical evaluation. Validated sexual questionnaires, such as the International Index of Erectile Function (IIFL) may be helpful tool in the evaluation of erectile function (Rosen et al, 1997; Cappelleri et al, 1999).

3.5 Treatment of diabetes mellitus

Treatment option for diabetes mellitus (Type 1) is only Insulin regime. These are insulin pumps and insulin pens. Type 2 diabetes mellitus now are managing by many ways such as OHA (oral hypoglycemic agents) and insulin. Nowadays markets are flooded with anti-diabetic drugs. Many Ayurvedic and herbal formulas are also available in the market. Different traditional medicine from valuable plants are also ways in ancient time to treat diabetes. These herbal drugs were safe and have hypoglycemic effect. In Ayurvedic system of medicine various herbal or combo

herbal formula using popularly and effectively in the treatment of diabetes mellitus. Herbal supplement with diet and life style change and exercise are highly effective to control diabetes and its symptoms and having no or very little complications or side effect (Li et al, 2004). While allopathic medicine has no certainty that how long the drug will affect and how to avoid the complication and side effects. Annual failure was 3-30 per cent. The OHA failure is an inability to achieve satisfactory response including the biochemical parameter even after highest permissible dose. No surety that how long the drug will respond and how to avoid the complications or treat complications.

3.6 Treatment of sexual dysfunction

There are numbers of ways through which sexual dysfunction can be treated. Medication like oral pills that improves blood flow to the penis includes sildenafil (Viagra), tadalafil (Cialis), hormone replacement, injections, vacuum pump, surgery and psychotherapy. These medicine can treat sexual dysfunction, but may have potentially serious side effects in some men (Saxena et al, 2012; Lue et al, 2017).

Natural aphrodisiac are preferred to treat sexual dysfunctions. Many herbs are being used for their aphrodisiac properties. While allopathic medicine commonly known as Viagra might give relief but for temporary. It also have documented side effect in many men. In spite of various treatment of pharmacological agents and different treatment choices, patients continues to look for a natural alternatives or herbal remedies to regain his sexual vigor.

3.7 Sexual dysfunction and diabetes

Sexual dysfunction is more common in diabetic patients (De et al, 2002) because poorly controlled diabetes ruins the blood vessels and nervous system (Enzlin et al, 2003). The etiology of sexual dysfunction of patients with diabetes may be due to risk of vascular and neurological complications, endocrine or hormonal, medication use and psychological problems or in combinations of these problems (de and Goldstein, 1988; Thomas and LoPiccolo, 1994; Webster, 1994; Close and Ryder,

1995; Veves et al, 1995). The developing process of sexual dysfunction is slow and progressive. Hence it can be further slowed down and can be treated if reported well in time. If actual tissue damage then it is impossible to get it reversed.

3.8 Herbs and its hypoglycemic and aphrodisiac effect

Herbal medicine is widely used as treatment of diabetes mellitus and sexual dysfunction worldwide. Herbs are esteemed source of medicine throughout the human history. Today also they are widely used throughout the world. Herbal plant or its extract can be used directly or indirectly for treatment of diabetes mellitus and sexual dysfunction (Calabrese and Baldwin, 2001; Ransford et al, 2010). About 30 per cent preparation of allopathic medicine are plant based (Shinwari and Khan, 1998). Some pharmaceutical drug preparation shown in table below:

Table 2. Some pharmaceutical drug preparation from herbal plant

Synthetic Drugs	Function	Plant Botanical name (Family)
Aesculetin	Anti-dysentery	<i>Frazinus rhynchophylla</i> (Oleaceae)
Artemisinin	Antimalarial	<i>Artemisia annua</i> (Asteraceae)
Quinine	Antimalarial	<i>Cinchona ledgeriana</i> (Rubiaceae)
Morphine	Analgesic	<i>Papaver somniferum</i> (Papaveraceae)
Reserpine	Anti-hypertensive	<i>Rauwolfia serpentina</i> (Rauvolfioideae)
Sennosides	Laxative	<i>Cassia angustifolia</i> (fabaceae)
Vincristine	Anticancer	<i>Cantharthus rosues</i> (Periwinkle)
Xanthotoxin	Leukoderma; vitiligo	<i>Ammi majus</i> (Apiaceae)

(Oreagba et al, 2011)

Due to the availability of chemical analysis methods in the early 19th century, scientists started to extract and modify active compounds from the herbals, resulting in transition from raw herbs to synthetic pharmaceuticals. This is when the use of herbal medicines started to decline. Synthetic pharmaceuticals, however, are found

out to be relatively more expensive and produce numerous undesirable side-effects despite their strong pharmacological action. Thus people nowadays are shifting back to herbal drugs, which are originated from the nature and claim to be safer. These herbal plants have some dose of active compounds which produce physiological actions in the human being, which gives medicinal values to it (Zaidi, 1998). Some of the important bioactive compounds found in medicinal plants are alkaloids, glycosides, resins, gums, mucilages etc. All these plants are rich source of phytochemicals (Rizvi and Mishra, 2013).

India has a varied climate thus rich in medicinal plants, but unfortunately not much systematic attempt or researches has been made to work and utilize natural resources of the country. Nature has provided us a rich storehouse of herbal remedies to cure all ailments of mankind. Even as traditional source of medicines continuing to play a pivotal role in the field of diabetes. Although the allopathic medicine have a great achievement in the control of blood glucose level, it is greatly accepted in the world to treat diabetes. There are many allopathic medicine existing in the market like OHA and Insulin for diabetes and blue pills (Viagra) for sexual problems. Still risk exists due to its several side effects. Therefore, it is need of an hour to think from the Ayurvedic point of view for a better management of diabetes mellitus and sexual dysfunction (Patel et al, 2012).

There are 90 per cent of developing countries population which uses plants or its products to treat many primary health care problems (WHO, 2002). The WHO has listed 21,000 plants, which are used for medicinal purposes around the world. Among these, 2500 species of plants are found in India (Modak et al, 2007) and about 800 plants have been reported to show antidiabetic effects. A wide collection of plant-based active bioactive compounds have been established which proved their role in the treatment of diabetes and sexual problems (Patil et al, 2011). Herbal drugs are gaining worldwide prominence due to their distinct advantage. There are many herbal formulation or its combination available in the market for their hypoglycemic and aphrodisiac properties such as diabetcon, bittergourd powder, diacare, diabetcure to treat diabetes and mood up, gold night, pivagra, Shilajit plus and sparant used to treat

sexual dysfunction (Appendix-I). (Aphrodisiac-substance which stimulate the sexual desire)

The most common effective antidiabetic and aphrodisiac medicinal plants are used e.g. ghrita kumara (*Aloe vera*), neem (*Azadirachta indica*), Kohar Thumba (*Citrullus colocynthis*), gurmar (*Gymnema sylvestre*), karela (*Momordica charantia*), tulsi (*Ocimum sanctum*), bisasar (*Pterocarpus marsupium*), jamun (*Syzygium cumini*), methi (*Trigonella foenum-graecum*), *Tribulus terrestris*, *Yohimbe*, *Ginkgo biloba*, *Ginseng*, Tongkat Ali, Maca, Horny Goat Weed, Coleus, Rhodiola Rosea, Clove, Asparagus Roots, and others. Although they are generally safe and free of side effects (unlike chemical drugs).

The present study also attempt to intervene new combination of various herbs which are not available in the market to treat diabetes and sexual dysfunction. A lot of work has been already carried out for the natural therapy to treat diabetes and sexual problems using different herbs, but he use of these all herbs *Gymnema sylvestre*, *Momordica charantia*, *Azadirachta indica*, *Citrullus colocynthis*, *Berberis aristata*, *Tribulus terrestris*, *Asphaltum* and *Withania somnifera* in a specific amount combination is still unexplored for treatment for diabetes and sexual dysfunction. Therefore to full fill this research gap present study is done.

The following herbs is used to check the impact of herbal intervention for sexual dysfunction and blood glucose levels in Type 2 diabetic male adult's patients.

1. *Gymnema sylvestre* (Gurmar)

Chemical constitutes Gymnemic acid other calcium oxalate, anthraquinone compound, tartaric acid, cellulose. It used to treat diabetes. Its properties is to increase the beta cell in pancreas. Which help in control blood glucose level. *Gymnema* removes sugar from pancreas, restore pancreas function. It also repairs damaged pancreatic tissues. It resist the glucose binding sites hence not allow to glucose to accumulate in the blood (Baskaran et al, 1990; Shanmugasundaram et al, 1990; Bone 2002; Paliwal, 2009; Singh et al, 2010; Rizvi and Mishra, 2013; Syedy and Nama, 2014) (Plate 1).

2. *Momordica charantia* (Karela)

Momordica charantia also known as Karela or bitter gourd. It commonly used to treat diabetes mellitus. It help to decrease blood glucose level and also glucose in urine. Bitter gourd has lectin (Charantin and Momordicin) hypoglycemic agent which work as insulin. It also helps to reduce the blood and urine glucose levels (Harinantenaina et al, 2006; Kumar et al, 2010; Joseph and Jini, 2013; Rizvi and Mishra, 2013; Efird et al, 2014; Yin et al, 2014) (Plate 2).

3. *Azadirachta indica* (Neem)

Neem Leaves control blood sugar and acts as blood purifier. Neem maintains the proper functioning of liver. The ingredients of neem help to stimulate the inactive pancreatic cells to generate insulin when the glucose level is increased in the blood (Conrick, 2001; Kochhar et al, 2009; Singh et al, 2010) (Plate 3).

4. *Citrullus colocynthis* (Tumba)

Tumba management of diabetes mellitus as its saponin glycoside has a hypoglycemic property thus helpful in reducing the blood glucose level (Nmila et al, 2000; Gurudeeban et al, 2010) (Plate 4).

5. *Berberis aristata* (Rasont)

Berberis contain alkaloids like berberine and plamitine. Rasont helps to cure liver function, which increases the bile secretion. It also promote and regenerate the function of β -cells. It is used as anti-diabetic agent (Musumeci et al, 2003; Razzaq et al, 2011; Potdar et al, 2012; Dong et al, 2012) (Plate 5).

6. *Tribulus terrestris* (Gokhru kaanta)

Tribulus terrestris also known as gokhru kanta used as aphrodisiac and also act as anti-diabetic agent. Gokhru kanta is used to enhance testosterone production which helps in muscle building (Pokrywka et al, 2014). It has saponins and protodioscin compounds which used to increase the sexual potency of male. Relaxing and aphrodisiac effect obtained may be due to increase in the release of nitric oxide from

the endothelium and nerve endings (Frotan and Acharya, 1984; Adimoelja and Adaikan, 1997; Amin et al, 2006; Hussain et al, 2009; Do et al, 2013; Chhatre et al, 2014) (Plate 6).

7. Asphaltum (Shilajit)

Shilajit have aphrodisiac properties. It is used to increase sexual power and stamina in human. It is an organo-mineral preparation which is highly used since ancient times to treat many sexual problems. Shilajit have revitalizing properties which increases the sexual desire and strengthens the muscles. Shilajit also have anti diabetic properties (Tripathi et al, 1996; Agarwal et al, 2007; Wilson et al, 2011; Mishra et al, 2012; Patel et al, 2012; Saxena et al, 2012). Shilajit is effective in controlling the blood glucose level due to presence of fulvic acid (Modak et al, 2007) (Plate 7).

8. *Withania somnifera* (Ashwagandha)

It's also called Indian Ginseng. Active compound present in it are withanine, somnie and withaferine. It is widely used to treat sexual dysfunction and infertility problems. Its roots help to increase testosterone and other sexual hormone of men. It is excellent aphrodisiac agent. It also helps to cure various sexual problems such as erectile dysfunction and premature ejaculation (Mamidi and Thakar 2011; Ambiye et al, 2013). It is used to enhance libido. Ashwagandha has long been used as a remedy for diabetes in Ayurvedic medicine (Singh et al, 2010; Singh et al, 2011; Verma and Kumar, 2011; Thakur et al, 2015) (Plate 8).

All the eight herbs have been mentioned in classical Ayurvedic literature as potent anti-diabetic drug and also have aphrodisiac properties. There has been a number of clinical and experimental studies on the efficacy of each individual and or in combination (different) of these herbs as potent oral hypoglycemic or anti diabetic drug and aphrodisiac quality.



Plate 1. *Gymnema sylvestre* (Leave)



Plate 2. *Momordica charantia* (Fruit)



Plate 3. *Azadirachta indica* (Leaves)



Plate 4. *Citrullus colocynthis* (Fruit)



Plate 5. *Berberis aristata* (Root extract)



Plate 6. *Tribulus terrestris* (Fruit)



Plate 7. Asphaltum (Latex)



Plate 8. *Withania somnifera* (Root)

Plates 1-8 different herbs utilized for the herbal formulation

Table 3. Health benefits of some herbs

Herbs	Methods	Remarks	References
Independent herb effect			
<i>Gymnema sylvestre</i>	Use leaf extract to reduce blood glucose levels in 27 Type 1 diabetic patients (400 mg/day for 18 months). Non-randomized, two parallel groups. Non-randomized	Significant decrease in FBG and HbA1c. Reduce insulin requirements.	Shanmugasundaram et al, 1990
	<i>Gymnema sylvestre</i> extract for 18-20 months to Type 2 Diabetic patients (400mg/day). 2 parallel groups. 47 T2D all on OHA. Non-randomized.	Reduced FBG and HbA1c. Drug dosage decrease (OHA)	Baskaran et al, 1990
	400 mg twice a day to diabetic patients for three months	FBG (11 per cent), PPBG (13 per cent) and HbA1c (0.6-0.8 per cent decreased).	Joffe and Freed, 2001
	Gurmar leaf powder 6gram/day to 20 newly diagnosed Type 2 diabetic patients for 4 weeks. (40-60 Years)	FBG (1%) and PPBG (1%) level decrease.	Paliwal et al, 2009
	<i>Gymnema sylvestre</i> extract 1gm/day for 2 months to Type 2 diabetic patients	Significant decreases in FBG and PPBG. Increase in insulin and C-peptide levels.	Romaiyan et al, 2010
	M. charantia fried fruit given to 9 T2D patients (0.23kg/day for 8-11 weeks)	Decreased in HbA1c.	Leatherdale et al, 1981
	<i>Mormordica charantia</i> juice (fruit) given to 18 Type 2 diabetic patients (newly diagnosed) maturity onset diabetic patients.	Significantly improve in glucose tolerance in patients and decreased PPG.	Welhinda et al, 1986

	Non-randomized, short term trial.		
Momordica charantia	M. Charantia seeds to 6 T1D and 14 Type 2 diabetic patients given.	Significantly reduced in postprandial blood glucose level in both type of patients.	Grover and Gupta, 1990
	Aqueous extract to 7 cases and dried powder to 5 cases, once a day or three times a day for 3 weeks period.	By M. Charanita extract reduce 54 per cent and powder 25 per cent mean blood glucose levels. In extract cases HbA1c reduced from 8.37 to 6.1 per cent	Sirvastava et al, 1993
	Extract of <i>Momordica charantia</i> fruit given to 100 cases with T2D patients	86 among 100 shows remarkable reduction in FBG and PPBG levels.	Ahmed et al, 1999
	Compare effect of M. charantia juice 55ml/day for 5 months and rosiglitazone(OHA) to 25 T2D patients	M. charantia was more effective for diabetes and less complication than rosiglitazone.	Malik et al, 2009
	Powder of fresh unripe bitter gourd	Reduce fasting blood glucose by 48 per cent.	Verdi et al, 2010
	Berberine (Berberis aristata)	Compare effect of berberine or metformin to 0.5gm 3 times a day for 3 month given to 36 T2D patients.	Both have similar effect. Significant decrease in HbA1c 9.5 per cent to 7.5 per cent, FBG 10.6 to 6.9mmol/L, PPBG 19.8 to 11.1 mmol/L.
Extracts of B. aristata roots in diabetic rats		Show reduction in hyperglycemia.	Mittal et al, 2012
Tribulus	30 male with erectile dysfunction and 15 diabetic patients with erectile dysfunction and Tribulus terrestris extract given for 3 weeks three times a day in 250	Sexual drive enhance by 60 per cent in diabetic and non-diabetic patients with erectile dysfunction. Significant increase in	Adimoelja and Adaikan 1997

<i>terrestris</i>	mg doses.	DHEA-S (a hormone for spermatozoa) levels in diabetic and non diabetic subjects after treatment.	
	750mg/day of <i>T. terrestris</i> in 3 doses for 3 months	Significant difference in level of testosterone and IIEF-5.	Roaiah et al, 2016
<i>Citrullus colocynthis</i>	300mg <i>Citrullus</i> /day to 44 T2D patients for 2 months	Sig. decrease FBG and HbA1c	Fallah et al, 2006
	<i>C. colocynthis</i> fruit capsule 100mg three time a day given to 50 T2D patients for 2months.RCT	Significant decrease in HbA1c and FBG level	Huseini et al, 2009
Poly herbs effects			
<i>Azadirachta indica</i> and <i>Ocimum sanctum</i>	T2D patients (40-60 years) leaf powder 2gm daily 4 capsule 2times a day for 3 months. 3 groups study.one only <i>A. indica</i> , 2 nd only <i>O. sanctum</i> and 3 rd mix given	Significant reduction in diabetic symptoms, maximum in 3 rd group.	Kochhar et al, 2009
Poly herbal preparation	78 men 25-50 years age 2 capsule twice daily for 12 weeks. RCT, Single blind study	IIEF score improve significantly. Mean IIEF ↑ from 16.08(2.87) to 25.08 (4.56) in intervention group	Shah et al, 2012
Herbo-mineral compound vs. Shankhapusphi	Group A-34 patients, 3gm/day three doses before meal for 8weeks Group B-Shankhapusphi 1.5gm/day three dose for 8 weeks +herbo mineral compound.	Group A Significantly reduce diabetes symptoms, 4.05 per cent FBS, 9.95 per cent PPBG. Group B- symptom better relief, 18.04 per cent FBG, 27.75 per cent PPBG reduction recorded.	Patel et al, 2012

From the ancient times, various traditional medicine value plants have been used to treat diabetes. Some of them were clinically proven by various medicinal systems like Ayurveda and Chinese medicines. Many herbs have multiple benefits and with no side effect. These herbal drugs were used to decrease the blood glucose levels (Li et al, 2004). Presently these herbal product are receiving more attention because these are safe for human use. Markets are flooded with anti-diabetic medicine. With these study reference, we do our research study to develop new aphrodisiac-antidiabetic poly herbal formulations.

Herbs gives best results if taken with diet restriction and with proper exercise. There are many trials on alternative therapy going on throughout the world. Herbal drugs are gaining prominence worldwide due to their distinct advantages. These herbs also act as anti-diabetic drug. These helps in decreasing the blood glucose level by reducing the rapid absorption of end products of starch to glucose. It is one of the great advantages of traditional plant (Mehta, 1982). In Ayurveda single or multiple herbs (polyherbal) are used for treatment. Practitioners of traditional medicine believe that when combining the multiple herbs in a particular ration, it will give a better therapeutic effect, increase efficacy and reduce adverse effects or toxicity (Vickers et al, 2001).

The medicinal effect of these herbs may be due to presence of active compounds such as 1. *Gymnema sylvestre* has active compound Gymnemic acid - it prevent the absorption of excess glucose. It is steroids. 2. *Momordica charantia* have two components. Charantin a steroidal saponin agent with insulin like properties and Momordicin an alkaloid possess hypoglycemic properties. 3. *Azadirachta indica* have active compounds Azadirachtin, Quercetin and Nimbidin. 4. *Citrullus colocynthis* have active compounds myristic, palmitic. 5. *Berberis aristata* has active compound berberine. It is alkaloids. 6. *Tribulus terrestris* have active compounds harmene and norharmene (alkaloids) 7. *Asphaltum* has active compound fulvic acid. 8. *Withania somnifera* have active compounds withanine, somnie and wihtaferine.

Tulsi has hypoglycemic effect. Study showed that *Ocimum sanctum* anti-hyperglycaemic effect is due to its antioxidant properties (Tewari et al, 2012). Study shows that *Trigonella foenum-graecum* seeds have hypoglycemic effect if used daily 25-50 gm. can help in treatment of diabetes mellitus (Gupta and Verma, 2015). Many researchers' shows that many traditional medicinal plants have been selected to use for its hypoglycemic activities and cost effective and affordable in compare to modern

allopathic treatment of diabetes (Abhar and Schaalán, 2014). *Gymnema sylvestre* extract one gram per day given for two months to Type 2 diabetic patients and significance decrease in fasting and postprandial blood glucose level observed. It also increase in insulin and C-peptide levels (Romainyan et al, 2010). In study done by *Momordica charantia* powder of fresh unripe bitter gourd was given to diabetic patients and 48 per cent reduction in fasting blood glucose observed (Verdi et al., 2010).

Study done by Yin et al, (2008) compared the effect of *Berberine aristata* or metformin to 0.5 gram three times a day for three months given to 36 Type 2 diabetic patients and significant decrease in HbA1c 9.5 per cent to 7.5 per cent, fasting blood glucose level 10.6 mmol/L to 6.9 mmol/L and postprandial blood glucose level 19.8 mmol/L to 11.1 mmol/L seen (Yin et al., 2008). *Tribulus terrestris* 750 mg per day was given for three months to sexual dysfunction patients and significant difference in level of testosterone and International Index of Erectile Function (IIEF) was noted (Roaişh et al, 2015). A study done on *Citrullus colocynthis* fruit capsule 100 mg three times a day given to 50 Type 2 diabetic patients for two months and significant decrease in HbA1c and fasting blood glucose level was recorded (Huseini et al, 2009).

3.9 Assessment of nutritional status in Type 2 adult male diabetic patients

Appropriate assessment of nutritional status is essential in order to implement effective and timely nutritional intervention. Since no single parameter consistently meets the criteria; therefore an assessment of nutritional status should be undertaken.

3.9.1 Anthropometric markers

Anthropometric assessment may aim to assess body size and or body composition (Gibson, 2005). Anthropometric measures are easy to administer, inexpensive and are able to be monitored overtime. Simple anthropometric measurement such as height, weight, body mass index (BMI) should regularly be measured in patients with diabetes mellitus. The body mass index (BMI) is very useful for assessment of nutritional status.

3.9.2 Dietary intake assessment

Assessment of dietary intake by participant method shown in table 3.5 is less cumbersome than biological methods. There is a wide variability in the quality of the data depending upon the context and method of survey. These are eating habits of the

subjects, the nature of the diets and also the specific nutrient under study (Rockett and Colditz, 1997). Dietary history method is one of the oldest approaches for assessing individual diets but today it is used less frequently (Mensink et al, 2001). The food frequency questionnaire (FFQ) is a tool to measure most often used in epidemiological research to measure food intake. Different food groups with their eating frequency questionnaire asked in the survey.

3.9.3 The 24-hour recall method

It is widely used to provide information on foods consumed by the individual over the previous 24 hours (Bingham et al, 1995). The quantities consumed are retrieved in the course of an interview that may last from 20-30 minutes or more. It is used for assessing average intake of a larger population (Gibson, 2005).

Table 4. Dietary intake methods

S. No	Method	Details	Consideration for use	Reference
1.	Food-frequency questionnaire	A food list incorporating specific food groups and their frequency of consumption over a given time period.	Useful for epidemiology studies of the relation between nutrient intake and disease not useful for individual intake	Bingham et al, 1995
2.	Diet history	An open ended interview recalling usual intake over a specified period (frequency and quantity)	Useful in clinical practice, can be a time effective method to assess habitual intake when implemented correctly.	Gibson, 2005
3.	24-hour recall	An interview asking subjects to recall their dietary intake during the 24 hours prior to the interview or the previous day.	Useful for assessing average intake of a large population.	Gibson, 2005

3.10 Other factor and its relation with diabetes mellitus and sexual dysfunction

There are many factors which have relation with diabetes mellitus and sexual dysfunction described here such as malnutrition, obesity, smoking habits, and alcohol consumption. Malnutrition is defined as a state in which a deficiency, excess or imbalance of energy, protein and other nutrients causes adverse effects on body form, function and clinical outcome. While malnutrition is caused by poor nutritional intake, laboratory or anthropometric measurements are generally used to define it clinically. There are many tools which can be used to check the nutritional status of the patients. These are Mini Nutritional Assessment (MNA), Subjective Global Assessment (SGA) subject, etc. Even with the recent development of simple screening tools, systematic evaluation of nutrition assessment is still neglected (Omran and Morley, 2000).

Nutrition and metabolic de arrangements (Carbohydrates, Protein and fat) are only the problem in diabetes mellitus. It plays a major role in affecting clinical outcomes. Diabetic person has to consume low refined carbohydrates and should use complex carbohydrates. Dietary factors is a major factor, but largely it ignored by conventional medicine. It ignite the problems as men with diet high in refined sugar, caffeine experience more sexual problems. Intervention aimed at changing diet must consider to use proper foods. Nutritional education or counselling has traditionally focused on what changes should be made, and behavioural psychology has emphasized how to make the changes (Brownell and Cohen, 1995).

Modified diet help to prevent many problem like obesity, diabetes and also prevent sexual dysfunctions (Ghadiri and Gorji, 2004). A Finnish diabetes prevention study stated that low intake of total and saturated fat and diet increase in fibre can help to prevent the diabetes. In diabetes prevention program, dietary modification goals were to reduce the fat and energy intake by the peroson. In a spanish mediterranean diet study, in which high intake of vegetables, fruits, legumes, nuts and whole grains showed a decrease in incidence of diabetes (Schwarz et al, 2012)

Low intake of simple carbohydrates for daibetic patients imprves their insulin sensitivity and improve blood glucose levels. A meta analysis study showed that low intake of refined carbohydrates and low glycemix index were associated with low risk of developing Type 2 diabetes (Larsen et al, 2010). Solomon et al, (2010) stated that

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low glycemic index food intake combined with physical exercise can delay the onset of Type 2 diabetes (Solomon et al, 2010). Islam, (2011) study state that many vegetables contains abundance of anthocyanins, amino acid, mineral, vitamins, polyphenolics and antioxidants which are associated with protection form many disease such as diabetes mellitus, hypertension and cancer (Islam, 2011).

Diet has very important factor to control the diabetes. Many studies shows that the risk of diabetes can be increased or decreased by diet. The dietary factor such as refined cereal, sugar, sweet beverages, soft drinks, red and processed meat can increase the chance of diabetes and in opposition whole cereal, vegetables, nuts, complex carbohydrates can help in control the diabetes (Landaeta et al, 2013).

Exercise maintain effects person's general health and wellbeing. It also protects us from many diseases like obesity, diabetes, cardiovascular disease, hypertension, psychological stress and sexual dysfunction. Yamanouchi, (2002) and others the effect of walking before and after breakfast on blood Glucose levels in patients with Type1 diabetes treated with intensive insulin therapy. They examined the effect of walking at different timing on carbohydrate metabolism in patients with Type1 diabetes. Six subject's non-obese patients treated with intensive insulin therapy. The area under blood glucose response curve was significantly lower only in the AM when compared with that in the control. Concluded that these results might suggest that walking after meals improves glycemic control in patients with Type1 diabetes being treated with intensive insulin therapy consisting of the basal-Bolus (NPH-human regular) insulin regimen.

Kirwan et al, (2009) done a study on effect of seven days training programme insulin sensitivity in Type 2 diabetes mellitus. Fourteen obese with Type 2 diabetes, aged 62-64 for seven days. The training consisted of 30 min of cycling and 30 min of treadmill walking at approximately 70 per cent of maximal aerobic capacity daily for seven days. The result showed that one week of vigorous exercise training can induce significant improvements in insulin action in Type 2 diabetes. Kriska, (2003) stated that physical activity plays an important role in Type 2 diabetes prevention. 150 min weekly of moderate intensity physical activity (brisk walking). Irregular dietary habits significantly increase the risk of development of Type 2 diabetes. Proper dietary and regular exercise help to control sexual dysfunctions (Derby et al, 2000). Change in

lifestyle, mainly focussing on regular physical activity with healthy diet, are effective and safe ways to reduce cardiovascular diseases and premature mortality in all age groups; this will also prevent and treat sexual dysfunctions (Esposito et al, 2008).

Many studies shown that one-third of obese men with sexual dysfunction can regain their sexual activity after 2 years of adopting healthy health behaviours, mainly including a Mediterranean-style diet associated, regular exercise and reducing weight (Esposito and Giugliano, 2005; Esposito et al, 2010). Obesity is account for 80-85 per cent of the risk of developing Type 2 diabetes. Now latest research suggests that obese people are upto 80 times more likely to outcrop Type 2 diabetes mellitus (Syedy and Nama, 2014). Overweight and obesity may increase the risk of erectile dysfunction (ED) by 30–90 per cent as compared to normal weight subjects (Esposito et al, 2008).

Lack of exercise, poor dietary habits and smoking were significantly associated with increased risk of diabetes, even after adjustment of body weight. Most of the Type 2 diabetic cases can be prevented by adoption of healthier life style practices. Regular physical activity can help in reduce risk of Type 2 diabetes and even cardiovascular disease (Phielix and Mensink, 2008). Pilacinski et al, (2014) stated that, diet and alcohol consumption are related to the development of obesity, which can leads to diabetes. Bener et al, (2013) observed that only 21 per cent of diabetic patients do daily physical activities. A diabetic person should take more care about his body weight and food habit, regular exercise can also improve the utilization of the blood glucose through different tissue in the body which can reduces the symptoms of diabetes (Singh, 2011). There are many type of exercise which a person can do such as walking (brisk), running, cycling, swimming etc. walking is the most popular chocie of physical activity. Has been shown to reduce the risk of Type 2 diabetes by 60 per cent when a perosn walk for 150 minute per week (Wu et al, 2014).

Smoking and alcohol: alcohol and smoking cause more problem of sexual dysfunction (Kahn, 1995). Smoking can have effect on Type 2 diabetes, like insufficient physical activity, unhealthy dietary practices and alcohol consumption (Agardh, 2008). Alcohol consumption has risk of develop diabetes mellitus. Alcohol consumption increase the blood glucose levels and may cause ketoacidosis. Moderate to high alcohol consumption had positive association with incidence of diabetes.

Generally public concept that alcohol consumption cause increase in blood glucose level and can deteriorates the condition. But a meta-analysis study showed that controlled intake of alcohol (one to two drinks per day) can decrease the risk of diabetes by 30 to 40 per cent when compared to constitutive drinkers (Koppes et al, 2005). A meta-analysis study stated that current smokers had a 45 per cent increased risk of developing diabetes when compared with non-smokers peoples. There was a dose-response relationship between the number of smoking and diabetic risk (Willi et al, 2007). Kumpatla et al, (2013) suggested that to control the diabetes burden in India, proper government interventions and combined endeavour from all the stakeholders form the society are required.

Table 5. Relation of dietary factor for sexual dysfunction

S. No	Study design and intervention	Conclusion	Reference
1.	One hundred patients with erectile dysfunction compared with 100 age matched without erectile dysfunction men. A scale indicating the degree of adherence to the Mediterranean diet used.	It show that dietary factors may be important in the development of ED: adoption of healthy diets would hopefully help preventing ED.	Esposito et al, (2008)
2.	High fruit and vegetable, nuts, whole grains and fish but low in red and processed meal and refined grains is more represented in patients without erectile dysfunction.	The adoption of a Mediterranean diet may be associated with an improvement of erectile dysfunction. In Type 2 diabetic men with Mediterranean diet had lowest prevalence of sexual problem (ED).	Esposito et al, (2010)

CHAPTER- 4

RATIONALE, SCOPE AND AIM OF THE STUDY

4. RATIONALE AND SCOPE OF THE STUDY

These day diabetes and sexual dysfunction in male are very common in the society. There are many allopathic, homeopathic and Ayurvedic treatment available for the same. These rapid transitions are bringing previously unheard rates of diabetes; developing countries are facing a firestorm of ill health with inadequate resources to protect their population. Thus, it is necessary to increase awareness and importance of a healthful diet and physical activity, among population to combat this problem. Type 2 diabetes which forms almost 95 per cent of the total diabetes in India is largely a preventable disorder.

The study is of necessity because the condition of diabetes mellitus is a risk factor to developing sexual dysfunction. The present study also attempts to intervene new combination of various herbs which are not available in the market to treat diabetes and sexual dysfunctions. A lot of work has been already carried out for the natural therapy to treat diabetes and sexual dysfunction using different herbs. But the use of *Momordica charantia*, *Azadirachta indica*, *Gymnema sylvestre*, *Citrullus colocynthis*, *Berberis aristata*, *Tribulus terrestris*, *Asphaltum* and *Withania somnifera* herbs in combination is still unexplored for treatment of diabetes and sexual dysfunction. Most of the herbal combinations are used to treat diabetes or sexual dysfunction. But hardly any product is available which treat diabetes as well as beneficial to treat sexual dysfunction at the same time with one herbal supplement. Hence present study is done to fulfil this research gap.

All the eight herbs have been mentioned in classical Ayurvedic literature as potent anti-diabetic drugs. There has been a number of clinical and experimental studies on the efficacy of each individual and or combination (different) of these herbs as potent oral hypoglycemic anti-diabetic drugs. These are generally safe and without side effects (unlike chemical drugs)

The main aims of the study is to check the impact of herbal intervention, diet and therapeutic life modification in diabetic adult male patients to reduce blood glucose levels and sexual dysfunctions. This study is helpful in developing new formulation which help to in antidiabetic and aphrodisiac quality. The aim of the research is to improve the understanding of sexual health problems experienced by diabetic male adults. So if this intervention give an appropriate result then these generated data would help the management of diabetes mellitus and sexual dysfunction associated with diabetic adult male patients.

4.1 AIM OF THE STUDY

To explore the possibility of herbs based lifestyle intervention has a potential to have a beneficial impact on various sexual dysfunction (problems) and Blood glucose levels of diabetic male adults.

The other aim of the study was adequate control of hyperglycemia and glycosuria, prevention of complications of diabetes, disappearance of diabetic symptoms, maintance of appropriate of body weight and find and control sexual problems.

CHAPTER 5

OBJECTIVES OF THE STUDY

5. The present study was planned with the following objectives
1. To ascertain the prevalence and determinants of sexual dysfunction in male diabetic patients attending Endocrinology OPDs at PGIMER, Chandigarh.
 2. To identify the treatment seeking behavior of sexual dysfunctions in adult male diabetic patients.
 3. To assess the nutritional status of diabetic patients with sexual dysfunction.
 4. To formulate and analyze the nutritional and phytochemical potential of the herbs based regime for the intervention.
 5. To assess the impact of herbs based life style modification regime on the sexual dysfunction and blood glucose levels of diabetic male adults.

CHAPTER 6

MATERIALS AND RESEARCH METHODOLOGY

This chapter covers the detailed method and techniques used for conduct the intervention study entitled “**Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels on diabetic male adults: A randomized controlled trial**”. A mixed method are designed with combined qualitative inquiry, quantitative survey and intervention methods were also used. The research procedures have been distinctly described under the following headlines:

6.1 The 1st objective, “To ascertain the prevalence and determinants of sexual dysfunction in diabetic patients attending Endocrinology OPDs at PGIMER, Chandigarh.”

6.1.1 Study area: The study was carried out in new OPDs (Endocrinology) of PGIMER Chandigarh.

6.1.2 Study population: Diabetic adult male patients in reproductive age group visiting PGIMER, Chandigarh, Endocrinology OPDs.

6.1.3 Study duration: Twelve months

6.1.4 Research design: Quantitative, Interview based data collection,

6.1.5 Sample size: Using the case–control study formula the calculated sample size is 300. The sample size has been decided at $\alpha=0.05$ and power 80 per cent. This sample size was sufficient to outline the profile of diabetic patients with sexual dysfunction cases.

The sample size was determined according to (Fisher et al, 1991) formula:

The sample size for the population $> 10,000$. (As the study population more than $>10,000$)

The population were all the diabetic patients who attending the outpatient, Endocrinology OPD in New OPD, PGIMER, Chandigarh. Mostly patients were form north India such as Punjab, Haryana, Chandigarh, Himachal Pradesh and Utter Pradesh.

Formula -
$$n = \frac{Z^2 p q}{d^2}$$

Where, n= sample size (required)

Z= standard normal deviate at the required confidence level (usually set at 1.96 which correspond to 95 per cent confidence level)

p= proportion in the target population estimated to have a particular characteristics. 25 per cent (i.e. 0.25)

q= 1-p (proportion in the target population not having the particular characteristics) (1-0.25=0.75)

d= degree of accuracy required, usually set at 0.05 level (the level of statistical significance)

There are estimates available of the proportion in the target population assumed to have the characteristic of interest as noted by the prevalence rates in the various studies. Estimates of prevalence in regard to the study being done were deduced from the literature review. In studies the lowest prevalence was at 22 per cent and the highest at 35 per cent. This gave an average of 25.5 per cent. The Indian studies had prevalence's as; 31 per cent and 37 per cent. This gave an average of 24 per cent. To work out a single figure, an average of the two above, that is 27.25 per cent and rounded off to a whole figure as 25 per cent.

so, Z=1.96

p= 0.25

q = 0.75

d= 0.05

$$n = \frac{(1.96^2) (0.25) (0.75)}{0.05^2}$$

$$0.05^2$$

n= 288 (rounded-300)

6.1.6. Sampling method: Purposive sampling (Non-probability) was used in the study. This is because the patients who attended the diabetic clinic were not purely diabetic, as some of them have both diabetes and other problems. It is most common sampling technique in which group participants according to preselected criteria

relevant to a particular research question (Santha et al, 2015). Male and female both type of patients were attending the endocrinology OPDs. But the study deals only with married male diabetic patients. The researcher only sampled married males with diabetes of the age group 25-60 years. The sampling was done until the required sample size (300) was reached.

6.1.7 Age group. Age group of 25-60 years (Married Male)

6.1.8 Recruitment: Cases of diabetic male adults were selected for the study on the basis of below given inclusion and exclusion criteria

Inclusion criteria

- i) Aged between >25 <60 years
- ii) Married Male Diabetic Mellitus Patients (Type2).
- iii) Physician approval for selected patient.
- iv) Willingness to provide informed consent.
- v) Reproductive active male patients

Exclusion criteria

- i) Aged <25 >60 years.
- ii) Bedridden patients.
- iii) Patients due for any kind of surgery
- iv) Enrolled in other active intervention research studies.
- v) Patients not willing to participate in the study

6.1.9 Tools

6.1.9.1 A pre-tested interviewer- Administered questionnaire / Interview screening questionnaire / standard history form was used for data collection. (Appendix- II). Diabetic information questionnaire was also used (Appendix-III).

6.1.9.2 Sexual dysfunction- Self assessment questionnaire was used to check prevalence, determinants of sexual dysfunction and treatment seeking behaviour of sexual dysfunction in diabetic patients (Appendix-IV) Participant's life experience and life style of reproductive health questionnaire were also asked (Appendix-V).

6.1.9.3 International index of erectile function (IIEF-15) - IIEF questionnaire was used to detect sexual dysfunctions. The 15 question of International index of erectile function (IIEF) questionnaire is a validated, multi-dimensional, self-administered investigation that has been found useful in the clinical assessment of erectile dysfunction. It has total score 75 of questions. It evaluates several aspects of sexual function over five important domains: Erectile Function (EF), Sexual Desire (SD), Orgasmic Function (OF), Intercourse satisfaction (IS), and Overall satisfaction (OS) (Rosen et al., 1997; Cappelleri et al., 1999) (Appendix-VI).

6.1.9.4 Biochemical parameters- All the patients underwent the following tests, which are already being followed in the clinic as the clinic as a standard of care. This study does not involve any additional blood test. Test regarding blood glucose levels done.

- i) **Fasting blood glucose level (FBG)** GOD-POD procedure following to conduct fasting blood glucose level by ROCH analyzer.
- ii) **Postprandial blood glucose level (PPBG)** GOD-POD procedure following to conduct fasting blood glucose level by ROCH analyzer.
- iii) **HbA1c-** HbA1c test was done by HPLC-Ion exchange high performance liquid chromatography. HbA1c levels provide an estimate of plasma glucose levels during the preceding 3 months.

6.1.9.5 Physical activity questionnaire- For physical activity estimation questionnaire was used to assess the physical activity level of the person (Appendix-VII).

6.1.9.6 Anthropometrics parameters

All patients were measured for under mentioned body parameters by using standardises anthropometric techniques and instruments. Measure included-

- i) **Body weight** in (Kg)
- ii) **Height** in (cm)
- iii) **Mid-arm circumference (MAC)** in (cm)
- iv) **Calf circumference (CC)** in (cm)
- v) **Body mass index; BMI** = $\frac{\text{Body weight in Kg}}{\text{Height in metre}^2}$

Body weight amongst all subjects was measured with the help of portable weighting balance machine. Metallic anthropometer was used to measure height of study subjects upto the accuracy of 1 mm. Fibre glass measuring tape was used to measure mid arm circumference and calf circumference upto accuracy of 1mm.

Table 6. Classification of body mass index

Grading	BMI
Underweight	< 18.49
Normal	18.50 – 24.99
Overweight	25.00 – 29.99
Obesity	≥ 30.00

(National Family Health Survey (NFHS-4, 2015-16)

6.1.9.7 Nutritional intake assessment: Dietary history

- i) **24-hour recall-** The food dietary intake was taken for 24 hours by 24 hours recall method. The data was collected by face to face interviews. Patients were asked to recall and describe all food items eaten by him over the past 24 hours (Appendix-VIII).
- ii) **Calculation of nutrients-** Nutrients calculation done were energy, protein, fats and carbohydrates with the help of nutritive value tables (National Institute of Nutrition 2010 guidelines for Indian RDA, Hyderabad, India).
- iii) **Dietary Information-** In this section various questions related to dietary information / dietary habits of the individual are put forth (Appendix-IX).

Any successful method of diabetes treatment should aim to control the hyperglycemia and building up of the whole health level of the patient. Diet plays a vital role in such a treatment. The primary dietary consideration for a diabetic patient is that he takes a low calorie, low carbohydrates diet of high quality natural foods. Fruits, and vegetables, whole meal bread and dairy products form a good diet for the diabetic. The patient should avoid overeating and take five or six small meals a day rather than three big meal in one time.

6.1.9.8 ADA diagnostic criteria Normal, Diabetes, and pre-diabetes (Clinical practice recommendations 2010)

Type 2 Diabetes ADA Diagnosis Criteria:

The American Diabetes Association (ADA) criteria for the diagnosis of diabetes are any of the following:

- A hemoglobin A1c (HbA1c) level of 6.5 per cent or higher; the test should be performed in a laboratory using a method that is certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay, **or**
- A fasting plasma glucose (FPG) level of 126 mg/dL (7 mmol/L) or higher; fasting is defined as no caloric intake for at least 8 hours, **or**
- A 2-hour plasma glucose level of 200 mg/dL (11.1 mmol/L) or higher during a 75-g oral glucose tolerance test (OGTT), **or**
- A random plasma glucose of 200 mg/dL (11.1 mmol/L) or higher in a patient with classic symptoms of hyperglycemia (i.e., polyuria, polydipsia, polyphagia, weight loss) or hyperglycaemic crisis.

Table 7. Diagnostic criteria for normal, diabetes and pre diabetes (by ADA 2010)

S.No	Parameter	Normal	Diabetes	Pre-diabetes	Method
1.	Fasting Plasma Glucose (mg/dl)	< 100	≥ 126	100-125	No caloric intake for at least 8 hours
2.	2-h plasma glucose on OGTT (mg/dl)	< 140	≥ 200	140 – 199	WHO method: 75 g glucose load
3.	Random plasma glucose (mg/dl)	< 140	≥ 200	-	With classic symptoms of hyperglycemia or crisis
4.	HbA1c per cent	< 5.7	≥ 6.5	5.7 – 6.4	NGSP certified method standardized to the DCCT assay

6.1.10 Detailed research plan

1. The head of the Department (Endocrinology) was briefed about the study and permission taken for the study.
2. A counselling room (CR) was established in the concerned OPD of PGIMER with due permission from the Head of the Department.
3. Referral system to CR was established. All the concerned doctors in the OPD requested to refer the after initial work up and prescription to CR.
4. The eligible diabetic cases recruited from Endocrinology OPDs.
5. Investigator recruited the cases as per the inclusion and exclusion criteria till the representative sample was attained.
6. Investigator asked for the subjects' willingness to join the study and taken an informed written consent (Appendix-X).
7. Investigator documented the background information of the patients on a pretested, proforma e.g. socio-demographic profile, standardized history, Impact of diabetes on daily routine existing treatment regimes, dietary/nutritional regime prescribed and co-morbidities. Relevant information was also collected from the OPD cards and case sheets of the patients.

6.1.11 Ethical aspect Ethical permission was granted by Institutional Ethic Committee of PGIMER, Chandigarh (letter No. INT/IEC/2016/2005 dated: 29/04/2016) Ethical reapproved on 19/11/16 no. INT/IEC/ 2016/ 2558) (Appendix-XI).

6.2 The 2nd objective, "To identify the treatment seeking behaviour of sexual dysfunctions in adult male diabetic patients".

6.2.1 Study area same as 6.1.1

6.2.2 Study population same as 6.1.2

6.2.3 Study duration same as 6.1.3

6.2.4 Research design same as 6.1.4

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6.2.5 Sample size same as 6.1.5

6.2.6 Sampling method same as 6.1.6

6.2.7. Age group same as 6.1.7

6.2.8. Recruitment same as 6.1.8

6.2.9. Tools same as 6.1.9.1 – 6.1.9.8

6.2.9.9 Interview based questionnaire was used Schedule to identify the treatment seeking behaviour of sexual dysfunction cases in diabetic patients.

6.2.10. Detailed research plan same as 6.1.10 serial no 1. To 7

8. The treatment seeking behaviour of sexual dysfunctions in diabetic patients have documented.

6.2.11 Ethical aspect same as 6.1.11

6.3. The 3rd objective, “To assess the nutritional status of diabetic patients with sexual dysfunctions.”

6.3.1: Study area same as 6.1.1

6.3.2: Study population same as 6.1.2

6.3.3: Study duration same as 6.1.3

6.3.4: Research design Quantitative, Case-Control Study and Interview based data collection.

6.3.4.1 CASES– diabetic male aged between 21 and 65 years, who fit the diagnostic criteria for Sexual dysfunction were serve as cases.

6.3.4.2 CONTROL– Age (± 2 years) matched control male were studied. Diabetic male without any sexual dysfunction.

6.3.5 Sample size same as 6.1.5

6.3.6. Sampling method same as 6.1.6

6.3.7 Age group same as 6.1.7

6.3.8. Recruitment same as 6.1.8

6.3.9 Tools same as 6.1.9.1 to 6.1.9.8

6.3.9.9 Mini Nutrition Assessment (MNA) Questionnaire MNA was used to assess the nutrition status of patients. The MNA is non-invasive and validated questionnaire to evaluate nutritional status in adult diabetic male persons. By MNA without any laboratory data, nutritional status of the patients can be easily predicted with questions and anthropometric measurements. It has two parts. First part include 6 questionnaire. It classified into three group: 1° score < 7: malnourished, 2° score ≥ 8 and < 11: at risk of malnutrition, 3° score ≥ 12 : well-nourished, with a maximum of 14 points.

Another part: It classified into three group: classified in three groups: 1° score < 17: malnourished, 2° score ≥ 17 and < 24: at risk of malnutrition, 3° score ≥ 24 : well-nourished, with a maximum of 30 points. MNA-SF score equal or more than 12 excludes malnutrition and/ or malnutrition risk, which rendered further assessment unnecessary. MNF-SF score less than 12 indicates full MNA test. Total score more than 23 means normal nutritional status, 17-23 shows malnutrition risk and less than 17 indicates malnutrition.

The MNA is 19-item questionnaire comprising anthropometric measurements (BMI, mid-arm and calf circumference, and weight loss) combined with a questionnaire regarding dietary intake (number meals consumed, food and fluid intake), a global assessment (lifestyle, medication, mobility, presence of acute stress, and presence of dementia or depression) and a self-assessment (Vellas et al, 1999; Rubenstein et al, 2001; Gerber et al, 2003; Guigoz, 2006; Kaiser et al, 2009; Nestle Nutrition Institute, 2013). Mid-arm circumference (MAC) less than 21 cm and calf circumference (CC) less than 31 cm are related with malnutrition risk (Fattah Badr et al, 2014)

The mini nutritional assessment (MNA) tool (scale 0-14) (Garry and Vellas 1999) was developed for early detection of malnutrition and to permit early nutritional intervention when needed (Appendix-XII).

6.3.10 Detailed research plan same as 6.1.10

6.3.11 Ethical aspect same as 6.1.11

6.3.12 Study design

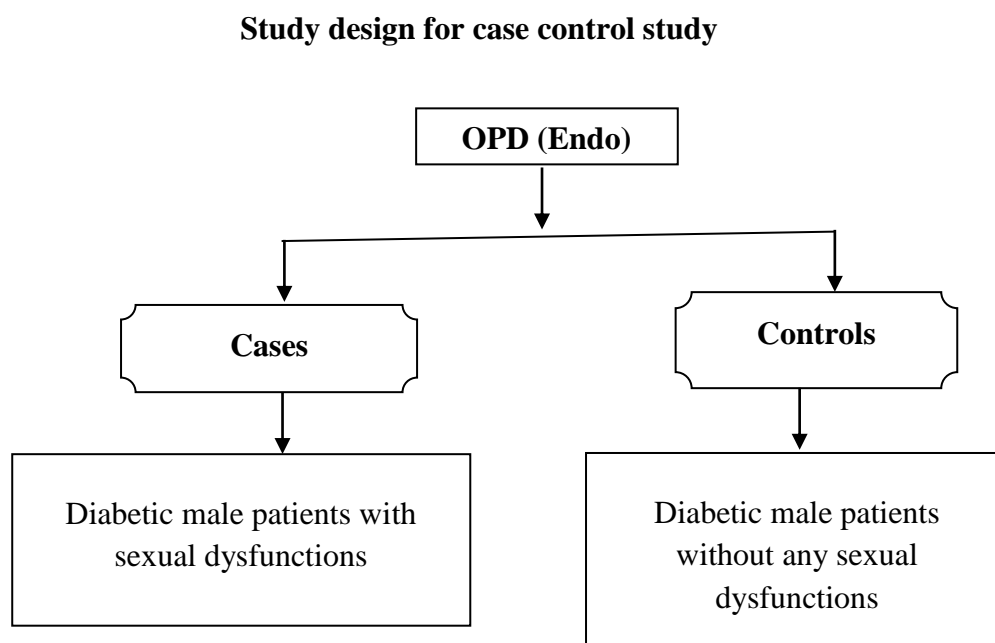


Figure 4. Study design for case-control study

6.4 The 4th objective, “To formulate and analyse the nutritional and phytochemical potential of the herbs based regime for the intervention.”

6.4.1 Research design Qualitative and Quantitative; content analysis

6.4.2 Formulation of herbs powder

This study started with five herbs (Table 8) to treat diabetic problem of diabetic patients.

Table 8. List of herbs for 1st trial

S. No	Ingredients (Botanical Names)	Common Names	Part used
1	<i>Gymnema sylvestre</i>	Gurmar	Leaf (dry)
2	<i>Momordica charantia</i>	Karela	Fruit (dry)
3	<i>Azadiracta indica</i>	Neem	Leaf (dry)
4	<i>Citrullus colocynthis</i>	Tumba	Fruit (dry)
5	<i>Berberis aristata</i>	Rasont	Root (extract)

As per the feedback of the patients, the combination of all the herbs resulted in improvement in sexual problem. But the result was not that much effective. Therefore a few other numbers of the herbs (Table 9) has been included in the herbal formulation for the better results.

Table 9. List of herbs for 2nd trial

S.No	Ingredients (Botanical Names)	Common Names	Part used
1	<i>Gymnema sylvestre</i>	Gurmar	Leaf
2	<i>Momordica charantia</i>	Karela	Fruit
3	<i>Azadiracta Indica</i>	Neem	Leaf
4	<i>Citrullus colocynthis</i>	Tumba	Fruit
5	<i>Berberis aristata</i>	Rasont	Root (Extract)
6	<i>Phoenix dactylifera</i>	Date	Fruit
7	<i>Tribulus terrestris</i>	Bhakra	Fruit
8	Asphaltum	Shilajit	Latex
9	<i>Withania somnifera</i>	Ashwagandha	Root
10	<i>Centratherum anthelminticum</i>	Kali jeeri	Seed
11	<i>Trigonella foenum-graecum</i>	Methi	Seed
12	<i>Trachyspermum ammi</i>	Ajwain	Fruit
13	<i>Zingiber officinal</i>	Sounth	Root
14	<i>Allium sativum</i>	Garlic	Bulbs
15	<i>Cinnamomum cassia</i>	Dalchinni	Root's skin

There were no good results with herbal combination. Some patients complained of stomach ache, so it was reduced to 8 herbs. Reapproval for ethics committee taken of this herbal combination.

Table 10. List of herbs for herbs powder formulation and analysis for intervention study.

S. No	Ingredients (Botanical Names)	Common Names	Part used	Quantity
1	<i>Gymnema sylvestre</i>	Gurmar	Leaf (dry)	50gm
2	<i>Momordica charantia</i>	Karela	Fruit (dry)	25gm
3	<i>Azadiracta indica</i>	Neem	Leaf (dry)	50 gm
4	<i>Citrullus colocynthis</i>	Tumba	Fruit (dry)	50 gm
5	<i>Berberisaristata</i>	Rasont	Root (extract)	50gm
6	<i>Tribulus terrestris</i>	Gokhru kaanta	Fruit (dry)	50 gm
7	Asphaltum	Shilajit	Latex	25gm
8	<i>Withania somnifera</i>	Ashwagandha	Root	50 gm

The Gurmar, Tumba, Rasont, Gokhru Kanata, Shilajit and Ashwagandha were collected from the market of Ambala City and neem leaf plucked from the tree, washed and dried. Karela whole fruit also purchased from local market (Ambala City) and dried. All herbs shredded manually and followed by drying in trays till constant weight. Thereafter, the dried husk of all herbs were ground into powder from using lab scale Wiley grinder followed by sieving using sieve shaker to get the uniform particle size (1mm) and used as a herbal powder for intervention supplement. Standardization has done (Quantity of each item). Source (FSSAI)/FPO approved product or label product, source of each item of herbs, same source has used for all the study duration. Storage life of herbs six months. Every month fresh herbal powder was prepared.

6.4.3 Analysis of herbal formulation

Content analysis method was used to assess the various herbs used to treat diabetic and sexual dysfunction in diabetic patients through government labs and references. It was included all herbs analysis of phytochemical substance found in herbs have analysed. Presence of any harmful substance or chemical, all adverse

effect was monitored and toxicity was analysed. This herbal powder was subjected to quantitative analysis of loss on drying, total ash value, acid insoluble ash, alcohol soluble ash and water soluble extract. Testing Report of herbs- for the testing purpose and quality assurance regarding raw material and final product samples were obtained from market and sent to government drug testing laboratory (A.S.U), Patiala, Punjab.

All the raw materials were tested as per the government guidelines in the laboratory. For the raw materials identification was checked as per the API, API atlas, quality standard of Indian medical plant and scientific Journal. For final product- as the sample is a combination of herbal formula (i.e. not from classical Ayurvedaic text books). Its testing was done depending upon the raw material provided for identification and used in final product by thin layer chromatography. Some analysis like L.O.D (loss on drying), total ash, acid insoluble ash, alcohol soluble extract and water soluble extract were done for purity and strength (Appendix-XIII). These herbal powder was first standardized as per standard procedures/ guidelines. Various physiochemical parameters viz. Loss on drying, Total Ash value. Acid Insoluble Ash value. Alcohol soluble Extract and water soluble extract values were determined accordingly.

For the qualitative analysis, the dried herbal powder of different herb e.g. *Gymnema sylvestre*, *Momordica charantia*, *Azadiracta indica*, *Citrullus colocynthis*, *Berberis aristata*, *Tribulus terrestris*, *Asphaltum* and *Withania somnifera* sample taken along with the final formulation were subjected to FTIR analysis (Shimadzu 8400 S FTIR spectrometer, equipped with KBr beam splitter) using approximately 5 mg of sample along with 5 mg KBr. FTIR spectrophotometer was operated at a special range of 4000–400 cm^{-1} spectral range with a maximum resolution of -0.85 cm^{-1} . The spectra so obtained for the respective samples were interpreted (result) as per the guidelines given by Stuart, 2004. The herbs analysis part FTIR was carried out in the Department of Food Technology and Nutrition, School of Agriculture, Lovely Professional University, Phagwara, Punjab.

6.5 The 5th objective, “To assess the impact of herbs based life style modification regime on the sexual dysfunction and blood glucose levels of diabetic male adults.

6.5.1 Study area same as 6.1.1

6.5.2 Study population same as 6.1.2 (Diabetic patients with sexual dysfunction. Their IIEF score <50 was checked. Then they was enrolled for intervention study.

6.5.3 Study duration Twelve months (Intervention for three months)

6.5.4 Research design Randomized Placebo-Controlled Trial (Two group RCT)

Definition of cases and control

CASES diabetic male aged between 25 and 60 years, who fit the diagnostic criteria for Sexual dysfunction was serve as cases and herbal intervention was given.

CONTROL Diabetic male adult patient’s age between 25 -60 years with sexual dysfunction but placebo intervention was given.

A total of 30 cases and 30 controls were selected.

6.5.5 Sample size- 60 (30 for each group)

Simply it can be 10 per cent the sample on each arm.

A sample size of 30 patients in each group for different diseases had been decided at alpha=0.05 and power 80 per cent.

Formula for sample size calculation for RCT (Randomized Controlled Trial)

A placebo controlled randomized trial proposes to assess the effectiveness of herbal powder to cure diabetic patients with sexual dysfunction. A previous study showed that proportion of subject cured by herbs is 80 per cent and clinically important difference of 20 per cent as compared to placebo is acceptable.

Level of significance =5 per cent, power =80 per cent, type of test= two sided

Formula= $n = [(z\alpha/2 + Z\beta)^2 * (p_1q_1 + p_2q_2)] / (P_1 - P_2)^2$ where $(q = 1 - p_1)$, $[(z\alpha/2 + Z\beta)^2 = C]$

Where, C=7.8 (for the power of 80 per cent and alpha=0.05)

N=sample size in one arm

$p_1=0.5, p_2=0.8, q=1-p$

N =sample size required in each group

P_1 = proportion of subject cured by drug $A=0.8$

P_2 = proportion of subject cured by placebo= 0.5

P_1-p_2 = clinically significant difference=0.3

$z_{\alpha/2}$ = this depends on level of significance, for 5 per cent this is 1.96

Z_{β} = this depends on power, for 80 per cent this is 0.20

Based on above formula the sample size for each group is 20.

To account for dropout and refused it was enhance to 30 per group.

6.5.6 Sampling method same as 6.1.6

6.5.7 Age group same as 6.1.7

6.5.8 Recruitment same as 6.1.8

6.5.9 Tools same as 6.1.9.1 to 6.1.9.3

6.5.9.4 Biochemical factors such as FBG, PPBG, and HbA1c levels in blood checked before starting the study and end of the study.

Serial number 6.5.9.5 to 6.5.9.8 same as 6.1.9.5 to 6.1.9.8

6.5.9.9 Performa was used to see the toxicity and any other adverse effect of herbal intervention also check patient's perception of improvement after herbal intervention (Appendix-XIV)

6.5.10 Detailed research plan:

1. The head of the department (Endocrinology) was briefed about the study and permission has taken up for the study.
2. A counselling room (CR) was established in the concerned OPD of PGIMER with due permission from the Head of the Department.
3. Referral system to CR was established. All the concerned doctors in the OPD has requested to refer the after initial work up and prescription to CR.

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A randomized controlled trial

4. The eligible diabetic cases was recruited from Endocrinology OPDs.
5. Investigator recruited the cases as per the inclusion and exclusion criteria till the representative sample is attained.
6. The study did not interfere with the existing medical/medicinal regimes prescribed by the concerned doctors.
7. Recruitment of the cases was done in the respective groups (Group 1 and 2) using block randomization method. Assignment of the subject to a particular group was done by the investigator based on the sequence generated for patient allocation /recruitment. There was single blinding.
8. Investigator asked for the subjects' willingness to join the study and taken an informed written consent (Appendix-X). Detailed information sheet also given to all patients regarding intervention study (Appendix-XV).
9. From the list thereafter the subjects were randomized into two groups and were offered the intervention as per the plan.
10. Expert opinion was taken from the Department of Endocrinology, Urology, Psychiatry, Biochemistry and Dietary Department of PGIMER, Chandigarh for finalizing the relevant components of the intervention.
11. Investigator documented the background information of the patients on a pretested, pilot tested proforma e.g. socio-demographic profile, standardized history, Impact of diabetes on daily routine existing treatment regimes, dietary/nutritional regime prescribed and co-morbidities. Relevant information was collected from the OPD cards and case sheets of the patients.
12. Some question were about personal and sexual history. Some of their question were very personal and may feel intrusive. So asked to please answer these question honestly.
13. Formulation of questionnaire was done to interview the respondents and to collect information. The questionnaire consists of list of questions which were prepared and in a systematic order to facilitate smooth communication and conversion for collection of data. The questionnaire was developed in simple language (In English and Hindi) in order to obtain appropriate information from the respondents.

6.5.11 Randomisation and blinding

Subject were randomized to receive herbal or placebo at a dose of 1 gm. twice daily for 12 weeks. The randomization sequence was generated manually by randomization table. Detail as given below. Patients were kept blinded to the random assignment. There were two group: Group A and Group B. Sample size for RCT was 60. Group A- sample size, n = 30 for Herbal powder intervention. Group B - sample size, n =30 for placebo intervention. Block randomization procedure follow to divide the patients into two groups. Diary was maintained for this purpose.

Block for randomization 6 in no

1. AABB
2. ABAB
3. BABA
4. ABBA
5. BAAB
6. BBAA

Random numbers selected from randomization table

Table 11. Randomization number table.

5	2	4	3	1	4
5	3	4	5	6	4
5	4	4	4	6	2
4	6	4	1	5	6
5	1	3	5	5	6
4	2	3	5	2	5

Herbs was supplied in form powder in packet with pudia each with 60 no for one month period. Keep diary for record of each patients. Patients were informed to record the herbs intake and note down any adverse event or suggestion.

Diet counselling- the group consisted of 50 male diabetic patients with sexual dysfunction given proper dietary counselling with standard diet charts according to their nutritional status. Specific diabetic diet chart were charted and handed over to the patients to be followed at home. Foods to be avoided or excluded were highlighted. The diet chart was thoroughly explained to the patients as well as the care taker. The patients were provided carbohydrates exchange (Appendix-XVI).

6.5.12 Ethical aspect

1. The trial was registered with CTRI (Clinical Trials Registry- India), National Institute of Medical Statistics (Indian Council of Medical Research) Government of India, CTRI No. CTRI/2017/02/007802. Registered on 07/02/2017 (Appendix-XVII)
2. Ethical permission was granted by Institutional Ethic Committee of PGIMER, Chandigarh (letter No. INT/IEC/2016/2005 dated: 29/04/2016) Ethical reapproved on 19/11/16 No. INT/IEC/ 2016/ 2558) (Appendix-XI).

All data was kept strictly confidential. A written consent was taken from study subjects after complete explanation about the research and the intervention to be given. Subjects were informed about complete procedure in a language they understand and assured that this herbs has not harmed them in any manner. The subjects were given full autonomy to participate or leave at any time during the study.

6.5.13 Hypothesis for research

Research question?

1. Is there any difference in blood glucose levels and International Index of Erectile Function (IIEF) Score (for sexual dysfunctions) on Type 2 adult male diabetic patient after intervention of herbal supplement?
2. Is there any difference in medicines and drugs (insulin) intake after the intervention of herbal supplement?

Hypothesis 1. The 'Null hypothesis' might be

- A. **Null hypothesis (Ho)** There is no significant difference in mean of blood glucose levels and IIEF Score.
- B. **Alternative hypothesis (H1)** There is a significant difference in mean of blood glucose levels and IIEF score. In adults diabetic patients. (Blood glucose levels= Fasting, Post meal and HbA1C)

Hypothesis 2. The 'Null hypothesis' might be

- A. **Null hypothesis (Ho)** There is no any significant difference in medicine and drug (insulin) intake after the intervention of herbal supplements.
- B. **Alternative hypothesis (H1)** There is a significant difference in medicine and drug (insulin) intake after the intervention of herbal supplements in adults diabetic patients.

Table 12 Research design RCT (PICO table)

The participants, intervention, comparator and outcome variable (PICO) are described in PICO *Table*

A summary of Population, Interventions, Comparators and Outcomes proposed to be considered in the study-			
(P) Population	(I) Intervention	(C) Comparator (Comparison intervention)	(O) Outcomes Variables (Measures)
Diabetic male patients aged 25-60 years with sexual dysfunctions.	<ol style="list-style-type: none"> 1. Herbal Intervention 2. Exercise 3. Diet Couselling 	<ol style="list-style-type: none"> 1. Placebo Intervention 2. Exercise 3. Diet Couselling 	<ol style="list-style-type: none"> 1. Anthropometric factors <ul style="list-style-type: none"> - Weight management (weight loss in case of obese) - BMI (Improvement) 2. Reproductive factors <ul style="list-style-type: none"> IIEF - 15 Score improvement (for sexual dysfunction) 3. Biochemical factors- (Improvement) <ul style="list-style-type: none"> - FBG - PPBG - HbA1c 4. Adherence degree or percent compliance with <ul style="list-style-type: none"> - 24 hour dietary recall - MNA Scoring - Exercise (45 minute brisk walk/ aerobic) - Herbal intake (Packet counting) - Medicine intake (any changes) - Insulin intake (any changes)

6.5.14 Cohort investigation and intervention regime

Pre and post study evaluation was done to evaluate the level of Adherence with intervention regime. Variables was investigated before and after the study. A Performa was developed to record the intervention impact thereof (Appendix-XIV). After randomization the subjects were distributed into 2 groups 1 (case) and group 2 (control). The subjects of group 1(Cases) intervention group received herbal intervention, exercise and counselling for diet and healthy lifestyle and group 2 (Control) received placebo, exercise and counselling for diet and healthy lifestyle. A diary was made for randomization and to record the intervention admission, and to note down there blood glucose level and impact thereof. These herbal supplement was given to the patients with their normal medicine/Insulin and we had seen the effect of these herbs on medicine, insulin requirement, blood glucose level, improvement in symptoms of diabetes and sexual dysfunction improvement. Duration of intervention was for three months. Doses of intervention was two doses (BD) before breakfast and before dinner.

Table 13. Contents of intervention package

S.No.	Contents	Intervention details
1.	Herbs	<p>These herbs were given in powder form. Each serving of powder have following herbs - <i>Gymnema sylvestre</i>, <i>Momordica charantia</i>, <i>Azadirachta indica</i>, <i>Citrullus colocynthis</i>, <i>Berberis aristata</i>, <i>Tribulus terrestris</i>, <i>Asphaltum</i> and <i>Withania somnifera</i>. The following herbs chosen for their ability in reducing blood sugar level and symptoms of sexual dysfunction in diabetic male adult patients. The dose amount was approximately 1gm. Herbal supplements were maintained for three months to properly effect on diabetic patients. PI him self-prepared the supplements. He provided supplement to the patents at interval of four weeks. He maintained a record of effect of given herbal supplements.</p> <p>PI made packets (Pudia) of herbal powder. The paper which were used for making packet, got sterile form CSSD Department (Central Sterile Services Department) of PGI, Chandigarh. This packet were kept in polythene bag (food grade).</p>
2.	Placebo	Curry leaves and moth dhal powder were used for placebo. Dose was same as herbal intervention. 1 gm. BD. 15 minute before breakfast and before dinner. For three months.
3.	Exercise	Exercise schedule were given which helped in lowering the blood sugar level and improve the symptoms of sexual dysfunction in diabetic male patients. Physical exercise routine = 40-45 minutes/day
4.	Diet counselling	Individualized diet counselling for diabetic diet was also done as per the need.

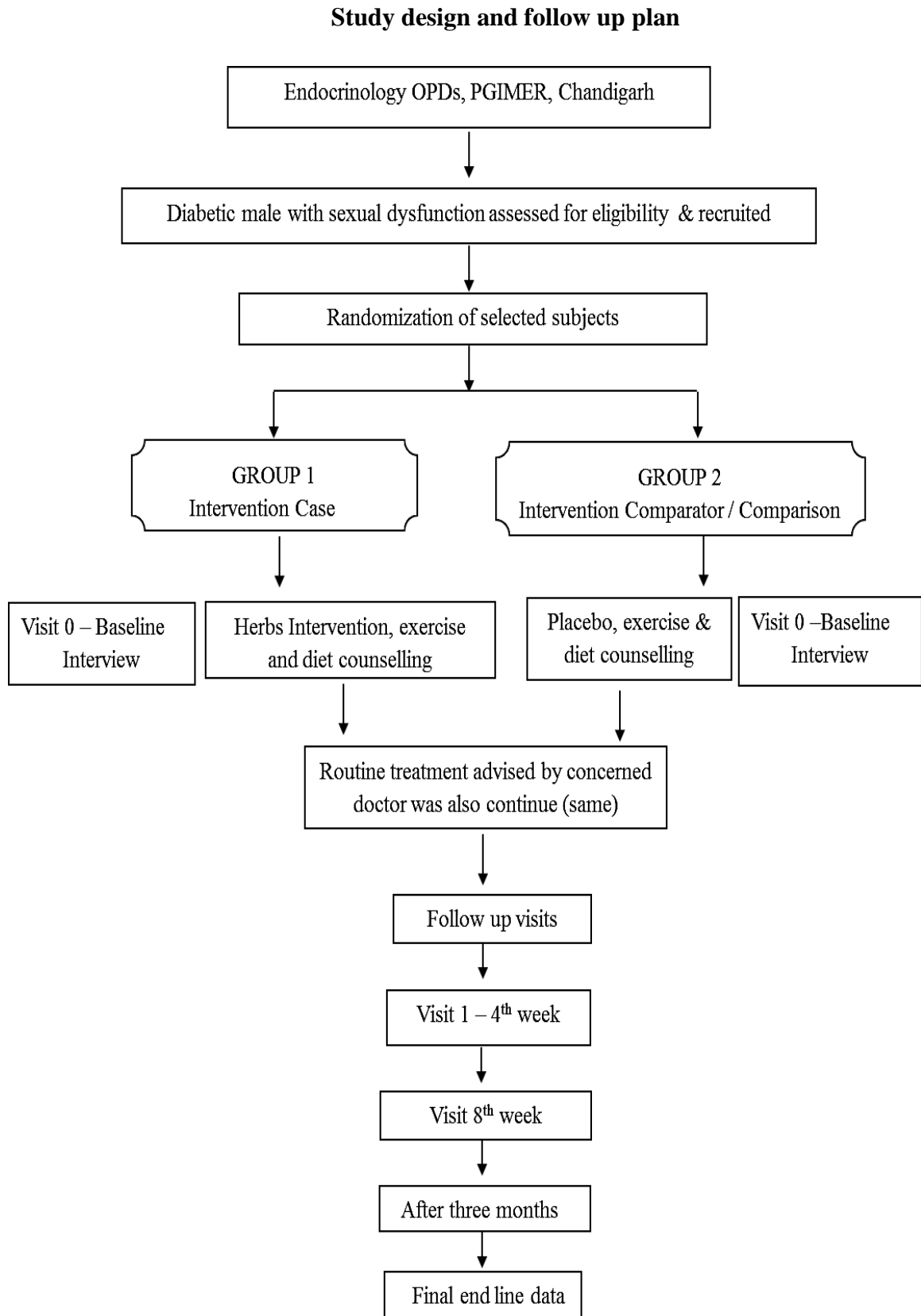


Figure 5. Study design and follow up plan for randomized controlled trial

6.6 STATISTICAL ANALYSIS

Statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc. Chicago, IL, Version 20.0 for windows). All quantitative variable were estimated using measures of central location i.e. mean and measure of dispersion i.e. standard deviation. Means were compared using student's t-test for two groups. For time related comparison Paired t-test was applied. For RCT study Independent t-test use. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using Chi square test. Pearson Correlations were calculated to see correlations for different variables. Analysis of variance (ANOVA) test was used to find out significant difference between means of experimental groups. All statistical tests were two sided and performed at a significance level of 0.05.

CHAPTER – 7

RESULTS AND DISCUSSION

The present study entitled “Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults: A randomized controlled trial” intervention part was carried out in the Department of Endocrinology, OPDs, Postgraduate Institute of Medical Education and Research, (PGI) Chandigarh and herbs analysis part was carried out in the Department of Food Technology and Nutrition, School of Agriculture, Lovely Professional University, Phagwara, Jalandhar, Punjab during the year 2015-2018. The results recorded in the different experiments with different objective have been described under the following heads.

7.1 To ascertain the prevalence and determinants of sexual dysfunction in male diabetic patients attending Endocrinology OPDs at PGIMER, Chandigarh.

7.1.1 Background information

Age wise distribution, education level, occupation, family income and physical activity level and its impact on blood glucose levels and IIEF score assessed.

7.1.2 Nutritional assessment

Body mass index and its impact on blood glucose level and IIEF score, Anthropometric measurements and Biochemical estimation assessed.

7.1.3 Dietary habits

Food habits, type of diet followed and type of milk consumption of patients and its impact on blood glucose level and IIEF score assessed.

7.1.4 Life style pattern

Smoking, alcohol consumption, duration of sleep and its impact on blood glucose levels and IIEF score assessed.

7.1.4 General Health status

General Health status, feeling of tiredness and their relation with their blood glucose levels and IIEF score assessed.

7.1.6 General Information

Age at time of marriage, age onset of diabetes and its relation with blood glucose level and IIEF score assessed. Diabetes related knowledge of the patients, Prevalence of symptoms of diabetes and Mean Nutrient intake of the respondents assessed.

7.1.7 Sexual dysfunction

Prevalence of sexual dysfunction in Type 2 adult male diabetic patients and its relation with blood glucose levels and IIEF score assessed.

Prevalence of sexual dysfunction according to age group category and type of sexual dysfunction assessed

7.2 To identify the treatment seeking behavior of sexual dysfunction in adult male diabetic patients.

Treatment seeking behavior of sexual dysfunction, Treatment detail for sexual dysfunction, Age of 1st sexual experience had, Feeling worried / depression because of sexual dysfunction, Reproductive health experience detail, Feedback regarding sexual experience, Sexual experience with other detail, General view regarding happiness with sexual life and Baseline characteristic of the study population with sexual dysfunction assessed.

7.3 To assess the nutritional status of diabetic patients with sexual dysfunction.

Mini Nutritional Assessment (MNA) status according to age group and Baseline characteristics according to MNA

7.4 To formulate and analyze the nutritional and phytochemical potential of the herbs based regime for the intervention.

FTIR analysis of herbs and Analysis of herbs from drug testing lab were done.

7.5 To assess the impact of herbs based life style modification regime on the sexual dysfunction and blood glucose levels of diabetic male adults.

7.5.1 Preface data of the selected patients for intervention study

Socio-economic status of the selected patients and follow-up detail assessed.

7.5.2 Impact of the three months intervention on biochemical parameters, IIEF scoring, anthropometric parameters of diabetic patients.

Biochemical profile before and after the intervention, IIEF score before and after the intervention and Anthropometric measurement before and after the intervention assessed.

7.5.3 Feedback response regarding effect of three months intervention on Type 2 adult male diabetic patients

7.1 The 1st objective, “To ascertain the prevalence and determinants of sexual dysfunction in diabetic patients attending Endocrinology OPDs at PGIMER, Chandigarh.

Total 300 patients adult male with Type 2 diabetes mellitus recruited for the study from Endocrinology OPD of PGIMER Chandigarh, a total 282 fulfilled the baseline requirement and filled the questionnaires (response rate was 94%). The sample size, response rate of the subjects of our study is in accordance with the study done by Fattah et al (2014).

7.1.1 Background information of the selected Type 2 adult male diabetic patients and their impact on blood glucose levels and IIEF score

The type of disease and its degree of severity and approach of health services is influenced by the demographic profile of the patients and area involved. The demographic profile like age, education level, occupation, physical activity pattern, and income level of total 282 Type 2 adult male diabetic patients were collected and correlation with blood glucose levels and International Index of Erectile Function (IIEF) accessed.

7.1.1.1 Age wise distribution of adult male diabetic (Type 2) patients and its impact on blood glucose levels and IIEF score

Table 14 and figure 6 shows that, among 282 patients, maximum respondents were from the age group 52-60 years i.e. 122 (43.3%), 98 (34.8%) from the age group 43-51years, 42 (14.9%) from 34-42 years the age group and 20 (7.1%) from the youngest age group 25-33 years. The diabetic patients were increasing in number with increase in their age.

Table 14. Age group wise distribution of respondents with mean blood glucose levels and IIEF score

Variables	Age-group	Number (%)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Age group of the respondents	25-33 Years	20 (7.1%)	183±56	249±63	9.6±2.4	49±8*
	34-42 Years	42 (14.9%)	167±51	239±66	8.8±2.1	43±11
	43-51 Years	98 (34.8%)	170±71	245±84	8.6±1.9*	42±11
	52-60 Years	122 (43.3%)	155±57	224±77	8.2±1.9*	36±13

(n=282) (* The mean difference is significant at the 0.05 level)

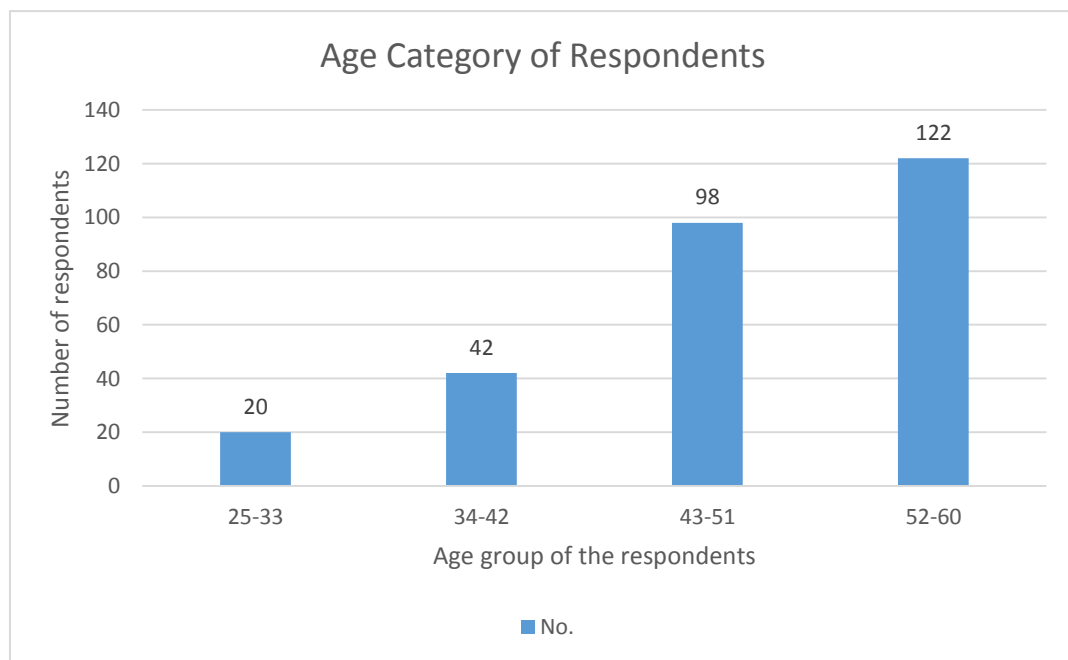


Figure 6 Age group of the Type 2 adult male diabetic patients

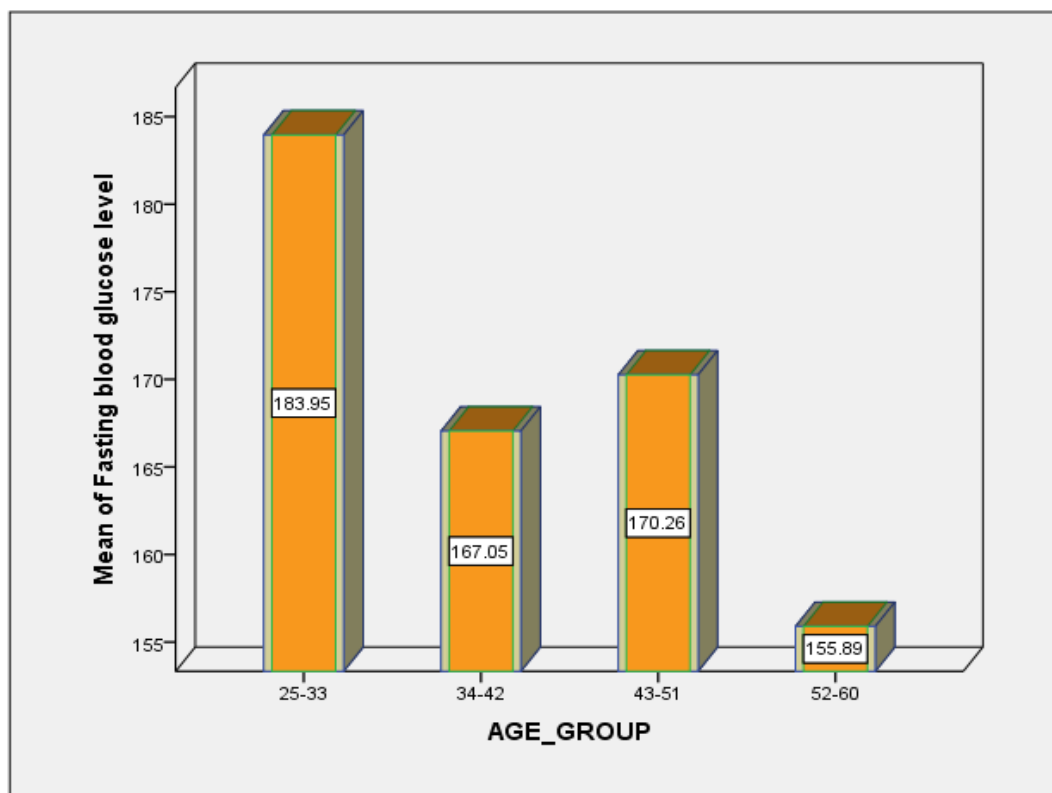


Figure 7. Mean blood glucose level of the respondents according to age group

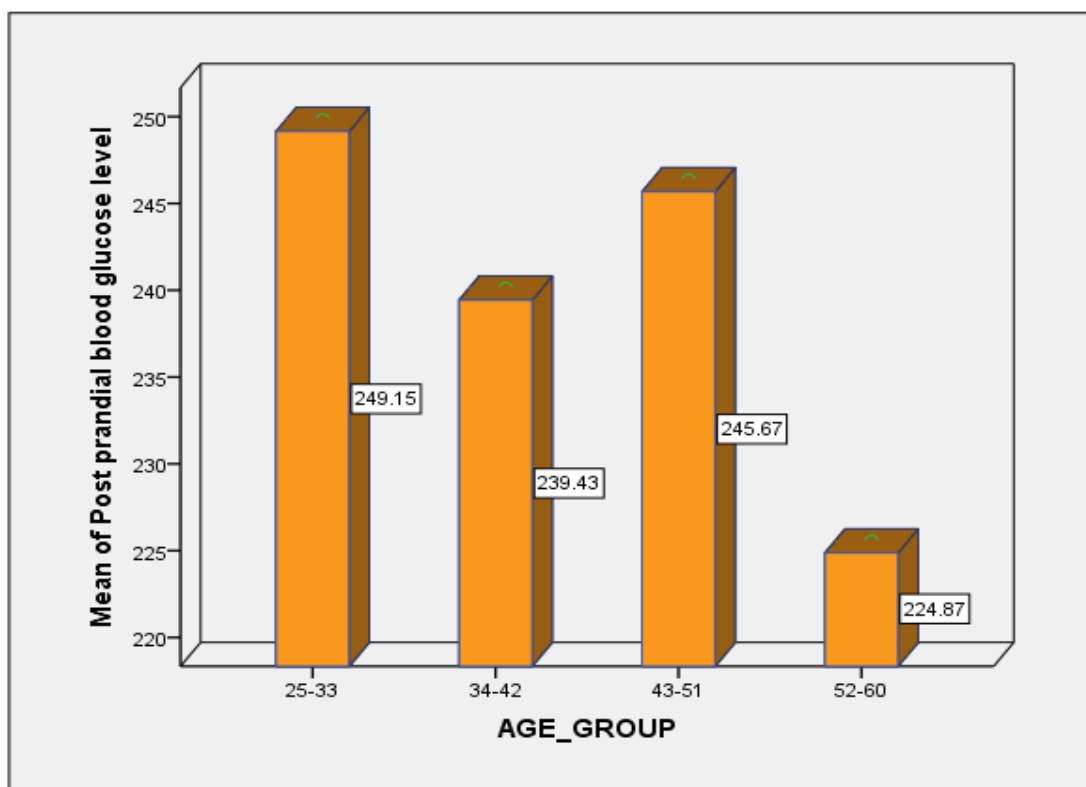


Figure 8. Mean postprandial blood glucose level of the respondents according to age group

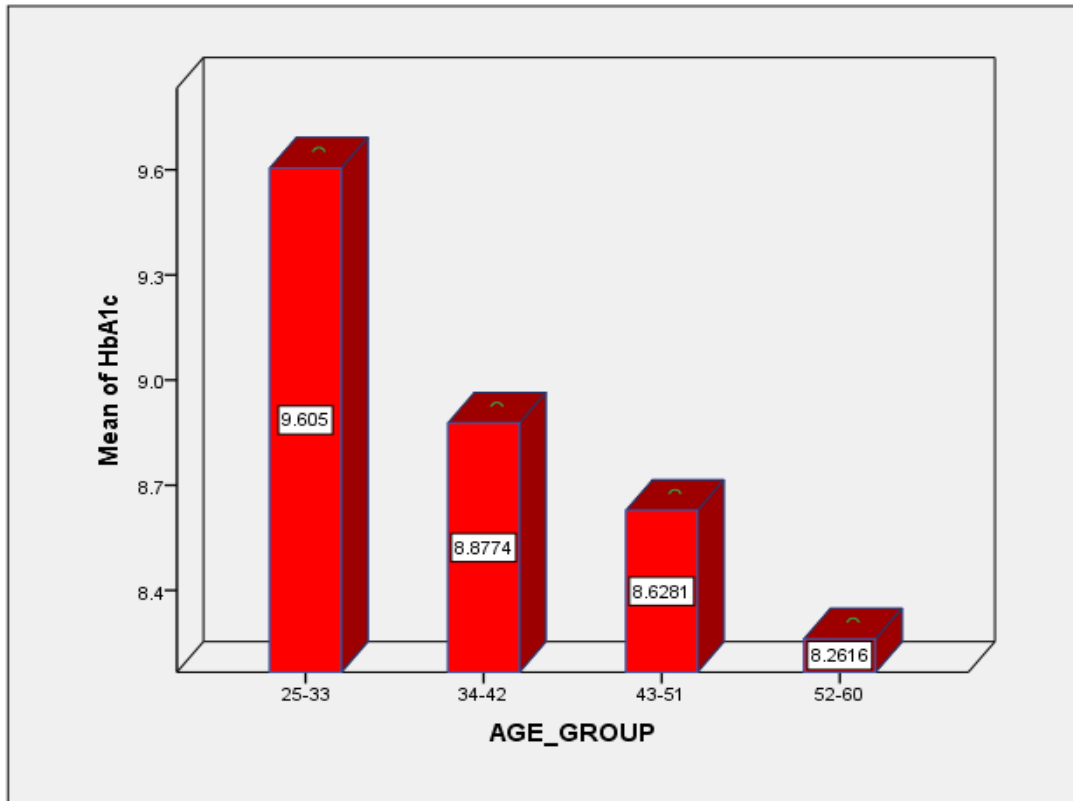


Figure 9. Mean HbA1c level of the respondents according to age group

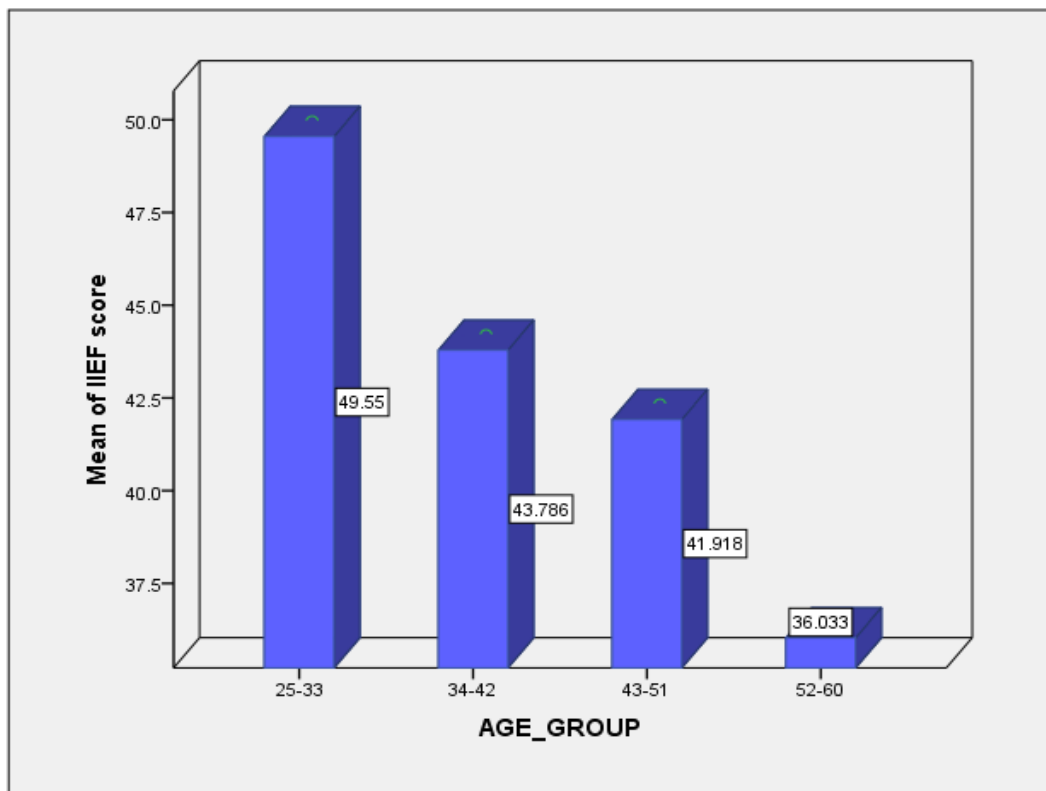


Figure 10. Mean IIEF score of the respondents according to age group

Table 14 and figure 7, 8, 9, 10 show, mean fasting blood glucose levels in age group 23-33 years, 34-42 years, 43-51 years and 52-60 years were 183 mg/dl, 167 mg/dl, 170 mg/dl and 155 mg/dl respectively. Mean postprandial blood glucose level were 249 mg/dl, 239 mg/dl, 245mg/dl and 224 mg/dl respectively. Mean HbA1c levels were 9.6 per cent, 8.8 per cent, 8.6 per cent and 8.2 per cent respectively. The mean international index of erectile function (IIEF) was 49, 43, 42 and 36 respectively.

HbA1c were significant lower in older (52-60 years) age groups and IIEF score were found to be significant higher in younger (25-33 years) age groups. While there was non-significant difference in mean fasting blood glucose level and postprandial blood glucose level of different age groups (Table 14). A similar study (Ramachandran et al, 1997) revealed that there is a significant increase in diabetics within the age group of 35-64 years. In another study done by (Likata et al, 2012) the mean age was 50.4 years and patients were increasing with increase in age.

National Institute for Health Care Excellence (2011) states that people ≥ 40 years have higher risk to develop Type 2 diabetes mellitus. Similar inference is in our study as number of diabetic patients increased as age increased. More diabetic patients were found in the age group 40 and above. The higher prevalence of diabetes in the younger age group and economically productive age imposes the burden on financial development of the nation. Experts say that diabetic adults leads to a significant burden to individual and national income losses by increased morbidity and mortality, decreased life expectancy and reduced quality of life (Mohan et al, 2013).

7.1.1.2 Education level and its impact on blood glucose levels and IIEF score

Education showed strong influence on blood glucose levels and sexual health of adult male diabetic patients (Type 2).

Table 15 shows the qualification of the respondents. Out of 282 respondents; 25.2 per cent (n=71) were Graduate and above, 12.1 per cent (n=34) were Intermediate (10+2), 30.5 per cent (n=86) were Matric (high school), 14.5 per cent (n=41) had education till Primary level and 6 per cent (n=17) Type 2 diabetic patients were illiterate. Table 15 and figure 11, 12, 13, 14 show the mean fasting blood glucose levels in graduate and above, Intermediate, Matric, Middle, Primary and

Illiterate group were 182 mg/dl, 156 mg/dl, 164 mg/dl 172 mg/dl, 173 mg/dl and 149 mg/dl respectively. Mean postprandial blood glucose level were 246 mg/dl, 233 mg/dl, 232 mg/dl, 245 mg/dl, 249 mg/dl and 218 mg/dl respectively. Mean HbA1c levels were 9.7 per cent, 8.2 per cent, 8.7 per cent, 8.6 per cent, 8.9 per cent and 8.1 per cent respectively. The mean international index of erectile function (IIEF) were 32, 33, 39, 40, 42 and 44 respectively.

HbA1c level has found to be significant lower and IIEF score was significant higher in educated (graduate and above) patients as compared to illiterate patients (Table 15).

Table 15. Education levels of the respondents with mean blood glucose levels and IIEF score

Variables	Education levels	Number (%)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Qualification	Illiterate	17 (6%)	182±61	246±69	9.7±2.0	32±9
	Primary	33 (11.7%)	156±73	233±97	8.2±1.7	33±10
	Middle	41 (14.5%)	164±61	232±76	8.7±2.4	39±13
	Matric	86 (30.5%)	172±68	245±77	8.6±1.9	40±13
	10+2	34 (12.1%)	173±59	249±87	8.9±2.3	42±10
	Graduate and Above	71 (25.2%)	149±49	218±64	8.1±1.7*	44±12*

(n=282) (* The mean difference is significant at the 0.05 level)

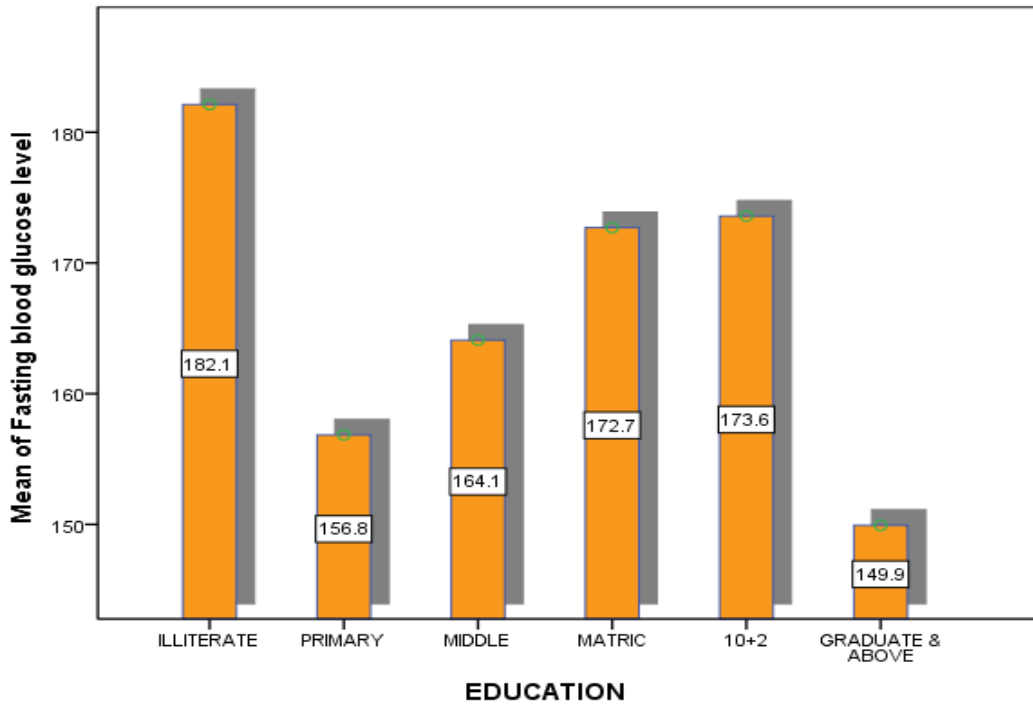


Figure 11. Mean fasting blood glucose level of the respondents according to education level

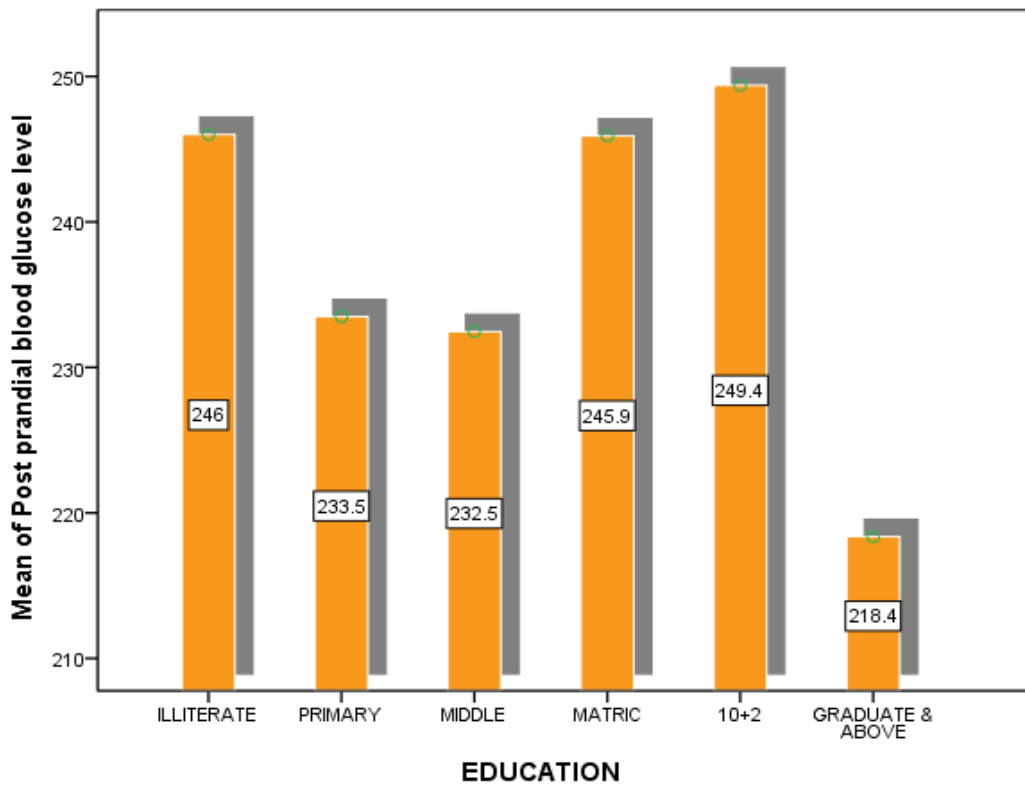


Figure 12. Mean postprandial blood glucose level of the respondents according to education level

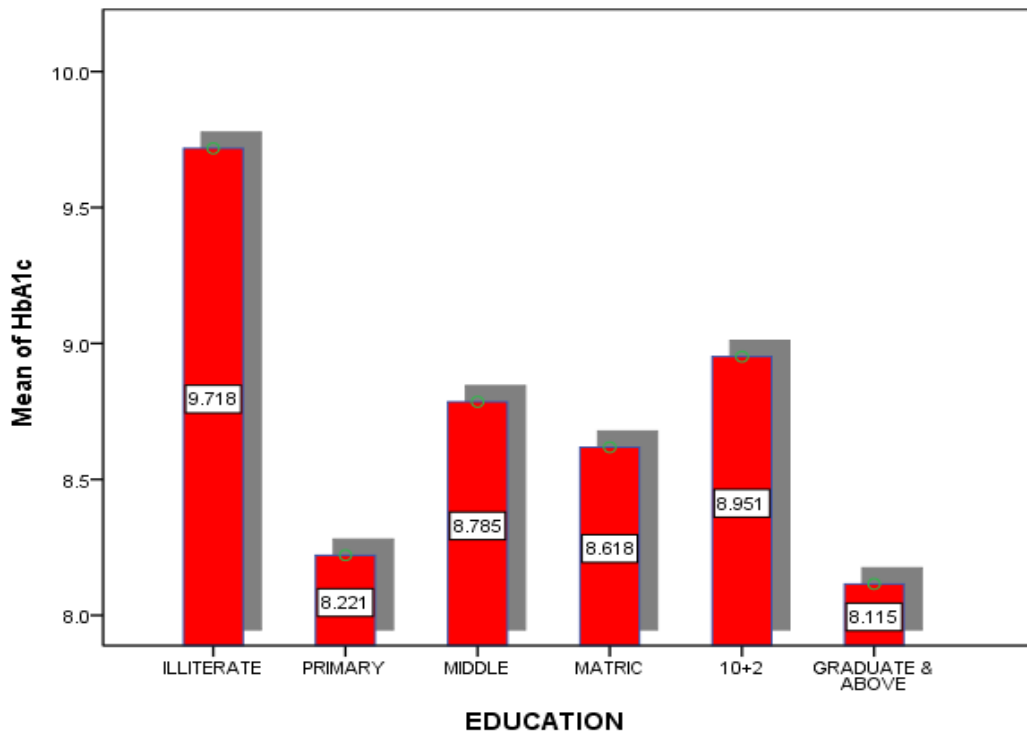


Figure 13. Mean HbA1c level of the respondents according to education level

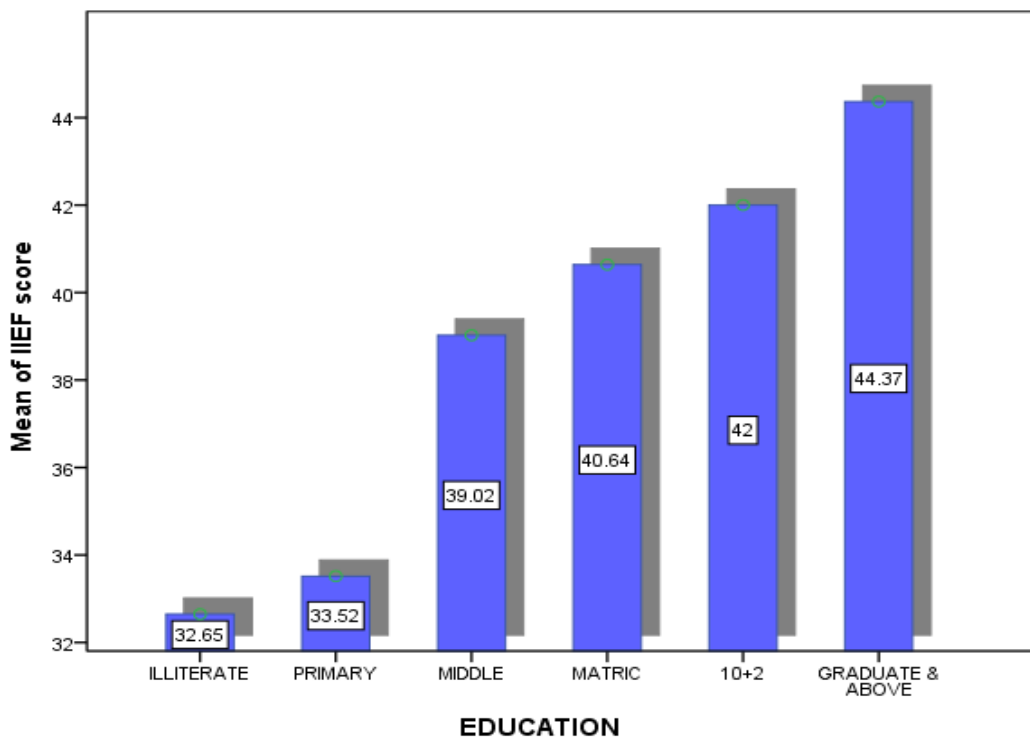


Figure 14. Mean IIEF score of the respondents according to education level

So it may be concluded that the higher the patients were educated, the better they had control over their blood glucose levels and lesser sexual problems. Education has strong influence on blood glucose level (Agardh et al, 2008). Herenda et al, (2007) state that total effect of passive and intensive education of patients with Type 2 diabetes resulted in improved metabolic control of the disease. In our study also there were good control over glycemic level in educated patients with significant difference as compared to illiterate patients.

7.1.1.3 Occupation levels and its impact on blood glucose levels and IIEF score

Does the type of occupation has impact on their health and blood glucose levels and sexual health?

From the table 16 the occupation level of the respondents were 91.5 per cent (n=258) are employed and 8.5 per cent (n=24) are unemployed or not involve in any type of work. Category of the employed respondents, out of 258 employed respondent maximum 43.02 per cent (n=111) are from Government service, 27.52 per cent (n=71) are doing private job, 22.87 per cent (n=59) doing Business and 6.59 per cent (n=17) do labourer job.

Table16. Occupation levels of the respondents and their mean blood glucose levels as well as IIEF score

Variables	Occupation	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Occupation of the respondents	Un-employed	24 (8.5%)	161±45	241±62	8.9±2.3	34±10
	Employed	258 (91.5%)	164±63	235±79	8.5±2.0	40±12*

(* The mean difference is significant at the 0.05 level)

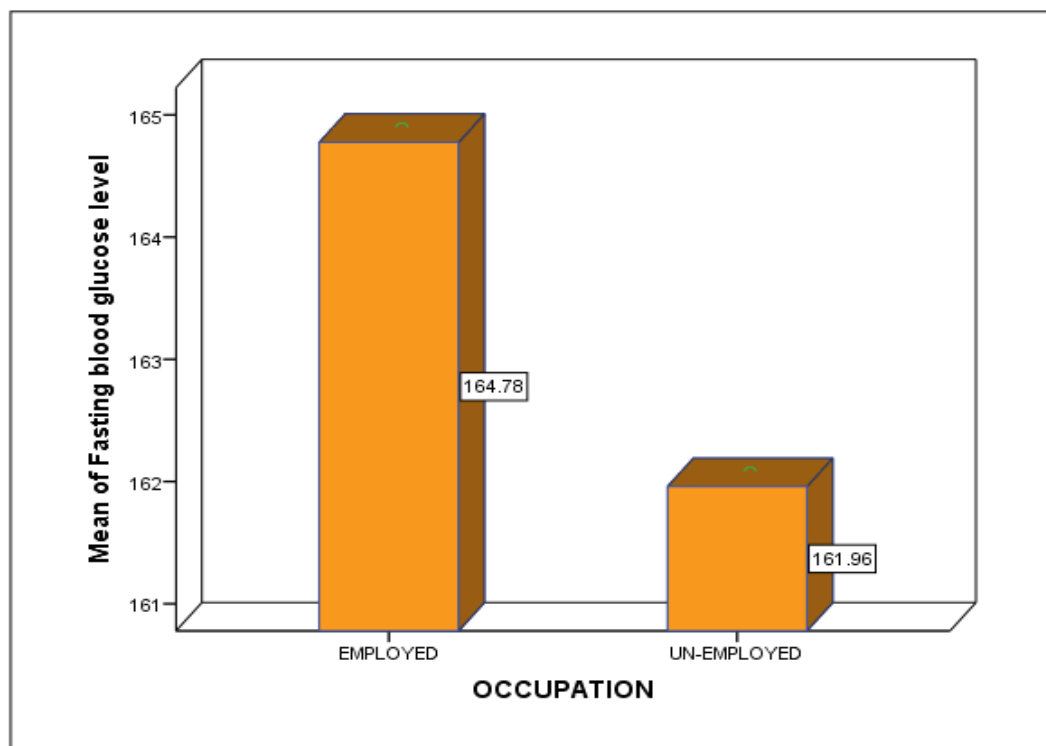


Figure 15. Mean fasting blood glucose level of the respondents according to occupation level

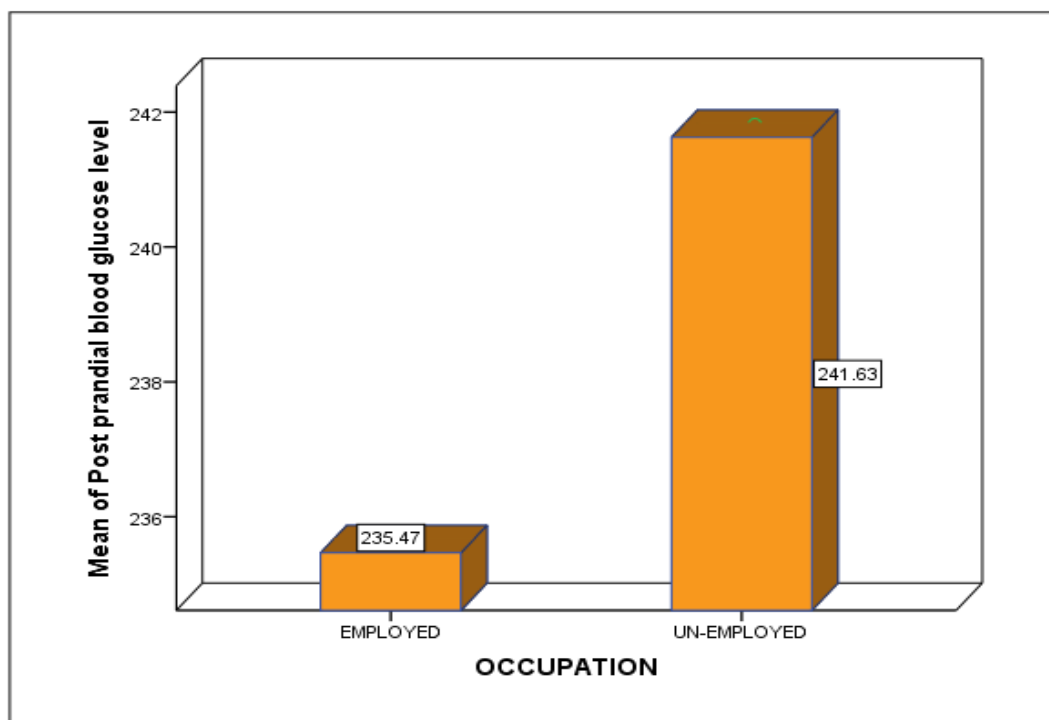


Figure 16. Mean postprandial blood glucose level of the respondents according to occupation Level

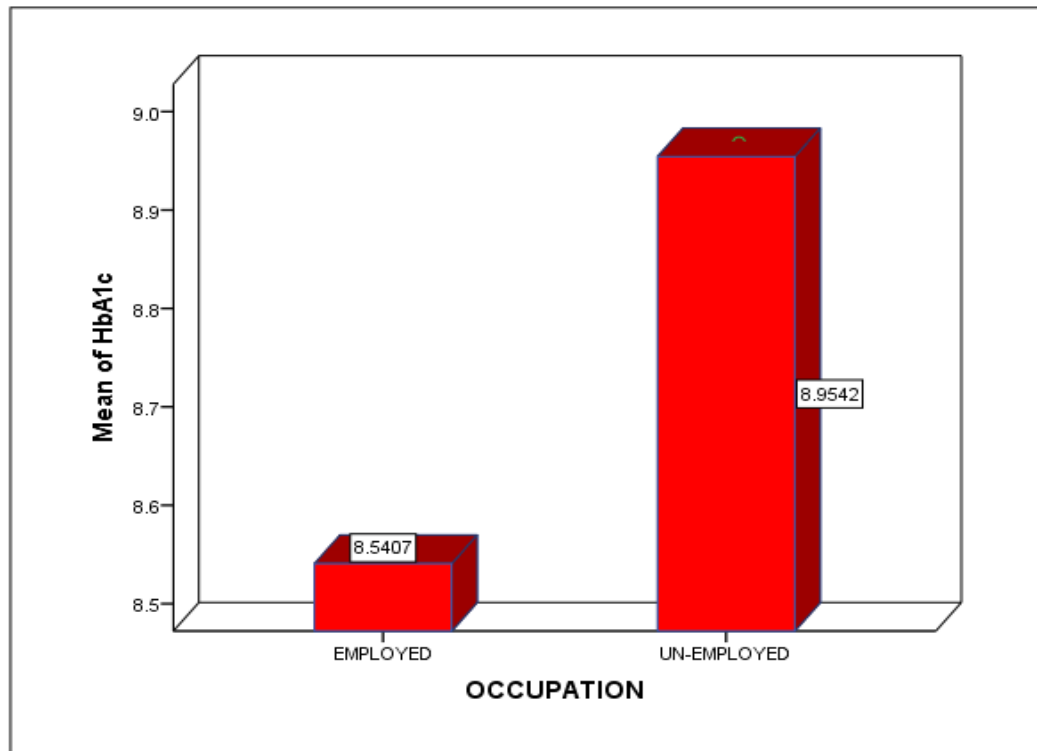


Figure 17. Mean HbA1c level of the respondents according to occupation level

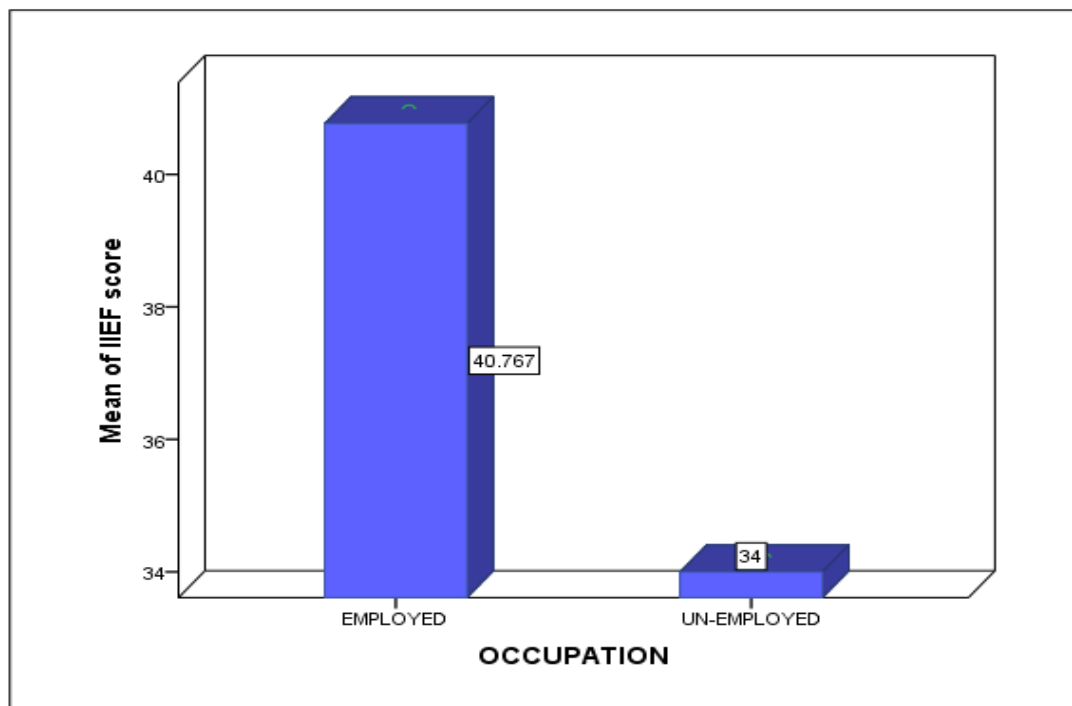


Figure 18. Mean IIEF score of the respondents according to occupation level

Table 16 and figure 15, 16, 17 18 shows the mean fasting blood glucose levels in unemployed and employed respondents were 161 mg/dl and 164 mg/dl respectively. Mean postprandial blood glucose level were 241 mg/dl and 235 mg/dl respectively. Mean HbA1c levels were 8.9 per cent and 8.5 per cent respectively. The mean international index of erectile function (IIEF) was 34 and 40 respectively.

The mean IIEF score was significant higher in employed respondents as compared to unemployed respondents. Whereas non-significant difference between fasting blood glucose level, postprandial blood glucose level and HbA1c level were found. It may be concluded that employed patients have better control over their sexual problems. On comparing this data with National nutrition monitoring bureau ICMR report, (2017) which shows that out of 32 per cent of the public who does service, 20.3 per cent do business and 18 per cent do labourer job. This data was similar with our findings. Rautio et al, (2017) stated that high exposure to unemployment may predispose to Type 2 diabetes and impaired glucose metabolism mostly in middle-aged individuals.

7.1.1.4 Family income (economic status) and its impact on blood glucose level and IIEF score.

Family income has strong influence on diabetes management by Type 2 adult male diabetic patients. Income status is a socio economic factor which has association with diabetes management.

Table 17. Family income levels of the respondents with mean blood glucose levels and IIEF score

Variables	Income (Rupee)	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Family Income level of the respondents	Low income group (< 25,000 Rupee)	174 (61.7%)	167±63	241±82	8.7±2.1	38±12
	Higher income group (>25000 Rupee)	108 (38.3%)	159±60	226±70	8.2±1.8*	42±11*

(* The mean difference is significant at the 0.05 level)

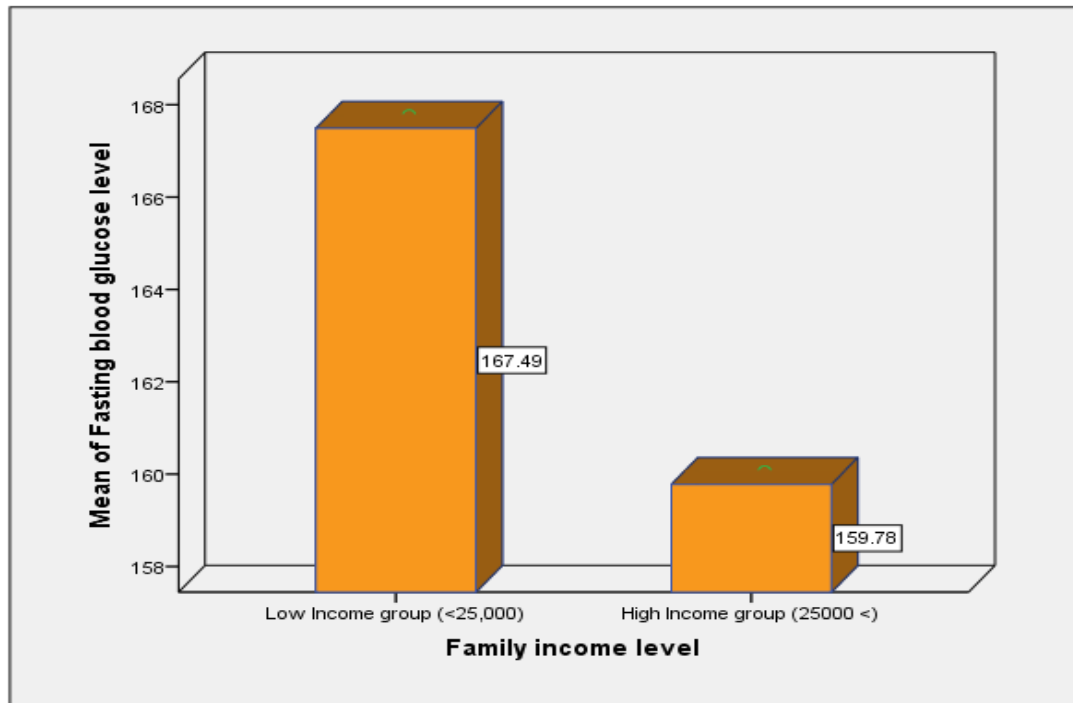


Figure 19. Mean Fasting blood glucose level of the respondents according to family income

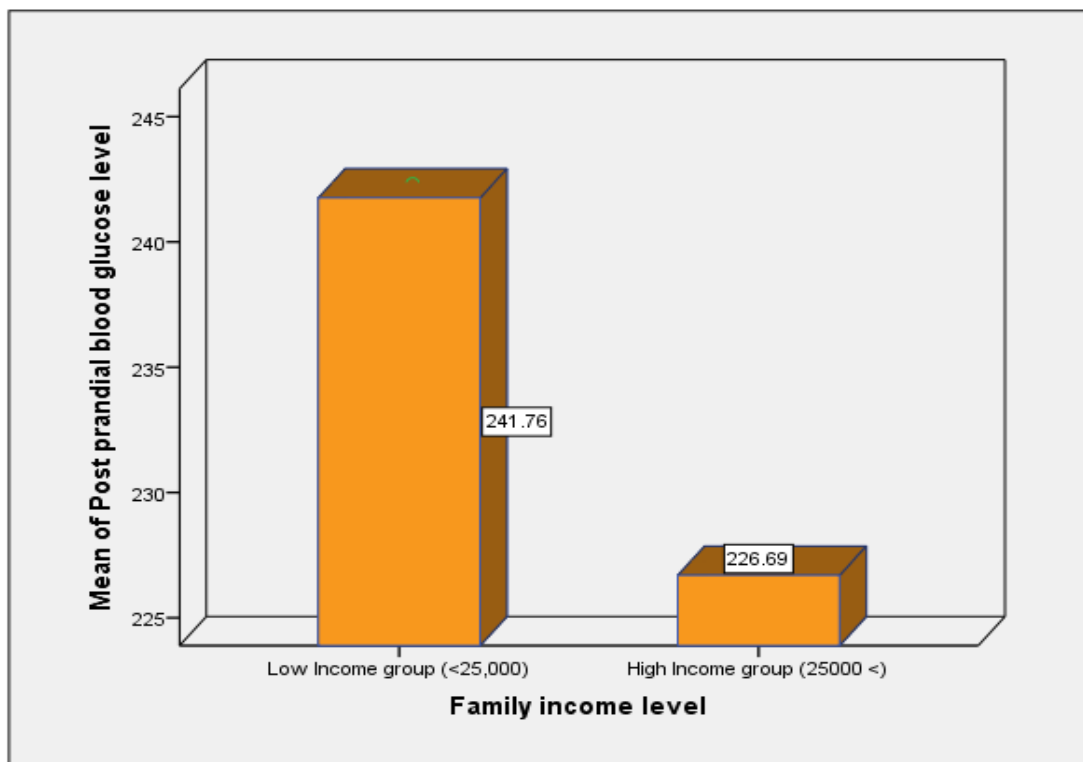


Figure 20. Mean postprandial blood glucose level of the respondents according to family income

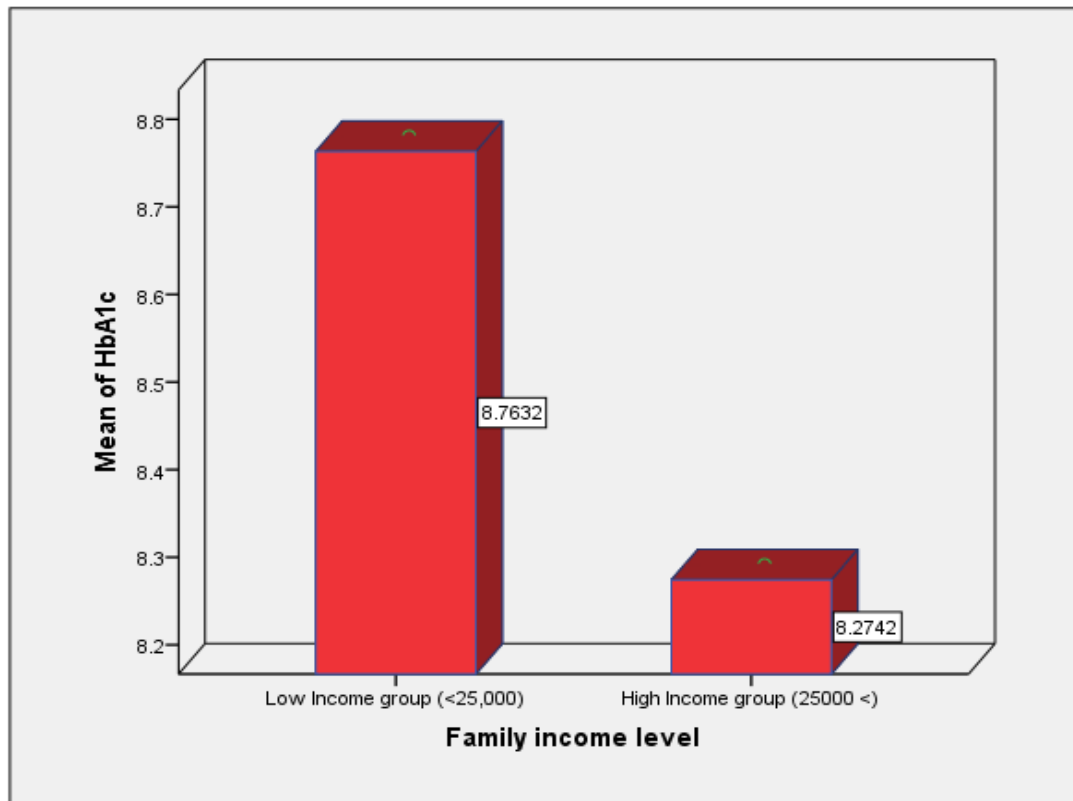


Figure 21. Mean HbA1c level of the respondents according to family income

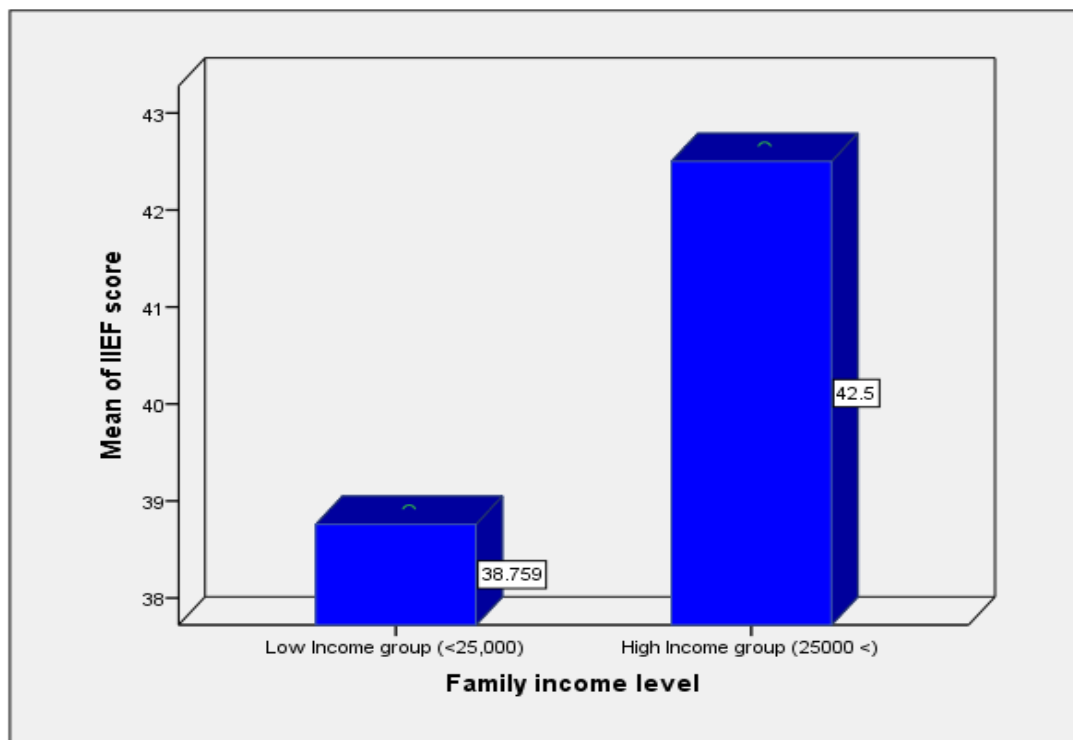


Figure 22. Mean IIEF score of the respondents according to family income

According to table 17 data show that the Income level of the respondents were, maximum respondent's 61.7 per cent (n=174) from low income group (< 25000 Rupee) and 38.3 per cent (n=108) from higher income group (> 25000 Rupee). Table 17 and figure 19, 20, 21, 22 shows the mean fasting blood glucose levels in low income family and higher income family group were 167 mg/dl and 159 mg/dl respectively. Mean postprandial blood glucose level were 241 mg/dl and 226 mg/dl respectively. Mean HbA1c levels were 8.7 per cent and 8.2 per cent respectively. The mean international index of erectile function (IIEF) were 38 and 42 respectively.

The mean HbA1c level was significantly lower and mean IIEF score was significantly higher in higher income group respondents as compared to low income group patients. It may be concluded that the patients with higher income have lower blood glucose levels (HbA1c) and higher IIEF score. Low income leads to low purchasing power. Patients may be unable to buy drug for their diabetic treatment. While patients with higher income have more money so they can have better control over their blood glucose levels and have lower sexual problems.

The average income of Indian men is Rupee 4941/- according to National nutrition monitoring bureau ICMR report, (2017). Socio economic status may influence access to quality of care, social support and availability of community resources. It may also influence knowledge (diabetic related), choice of treatment, exercise, dietary regimens and choice of medicine. Thus low income group may be associated with multiple risks. Espelt et al, (2011) stated that inverse association between Type 2 diabetic patients and socio economic status (Espelt et al, 2011). In our study also the income has an influence on diabetes management as stated by Corsi and Subramaiyan, (2012) that the income status was the strong socioeconomic factor associated with self-reported diabetes.

7.1.1.5 Physical activity level and its impact on blood glucose levels and IIEF score

Physical inactivity as an independent factor for the development of Type 2 diabetes. The availability of modernised transport facility and a shift in occupations combined with the television programmes has reduced the physical activity in all

groups of populations. Sedentary lifestyle increase mortality double the risk of diabetes, obesity and cardiovascular disease (Booth et al, 2012). Lack of exercise is one of the major factors to development of Type 2 diabetes mellitus. Distribution of selected Type 2 adult male diabetic patients according to their physical activity level given in Table 18.

Table 18. Physical activities levels of the respondents with mean blood glucose levels and IIEF score

Variables	Physical activity level	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Physical activity level of the respondents	Physically inactive	104 (36.9%)	177±67	250±83	8.6±2.0	38±13
	Physically active	178 (63.1%)	156±58*	227±73*	8.5±2.0	41±12

(n=282) (* The mean difference is significant at the 0.05 level)

The table 18 data shows that among 282 respondents’ 63.1 per cent (n=178) subject do physical activity and 36.9 per cent (n=104) were physically non active. Among active Type 2 diabetic male patients (n=178), majority of respondent 50 per cent (n=89) were moderate active while 43.26 per cent (n=77) light active and only 6.76 per cent (n=12) involved in vigorous or heavy activity. Table 18 and figure 23, 24, 25, 26 shows the mean fasting blood glucose levels in physically inactive and physically active respondents were 177 mg/dl and 156 mg/dl respectively. Mean postprandial blood glucose levels were 250 mg/dl and 227 mg/dl respectively. Mean HbA1c levels were 8.6 per cent and 8.5 per cent respectively. The mean international index of erectile function (IIEF) were 38 and 41 respectively.

The mean fasting blood glucose level and postprandial blood glucose level were significantly lower in physically active patients as compare to physically inactive patients. So, we may conclude that physically active patients have better control over their blood glucose levels. Physical active patients have higher IIEF score but with non-significant difference as compare to physically inactive patients.

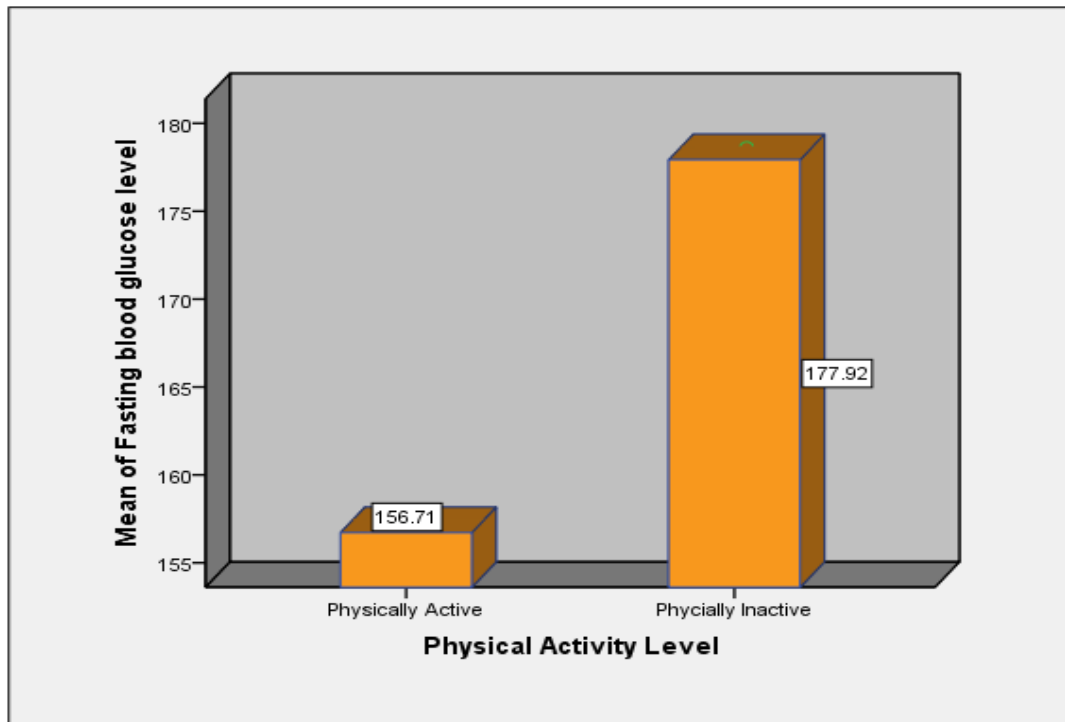


Figure 23. Mean fasting blood glucose level of the respondents according to physical activity level.

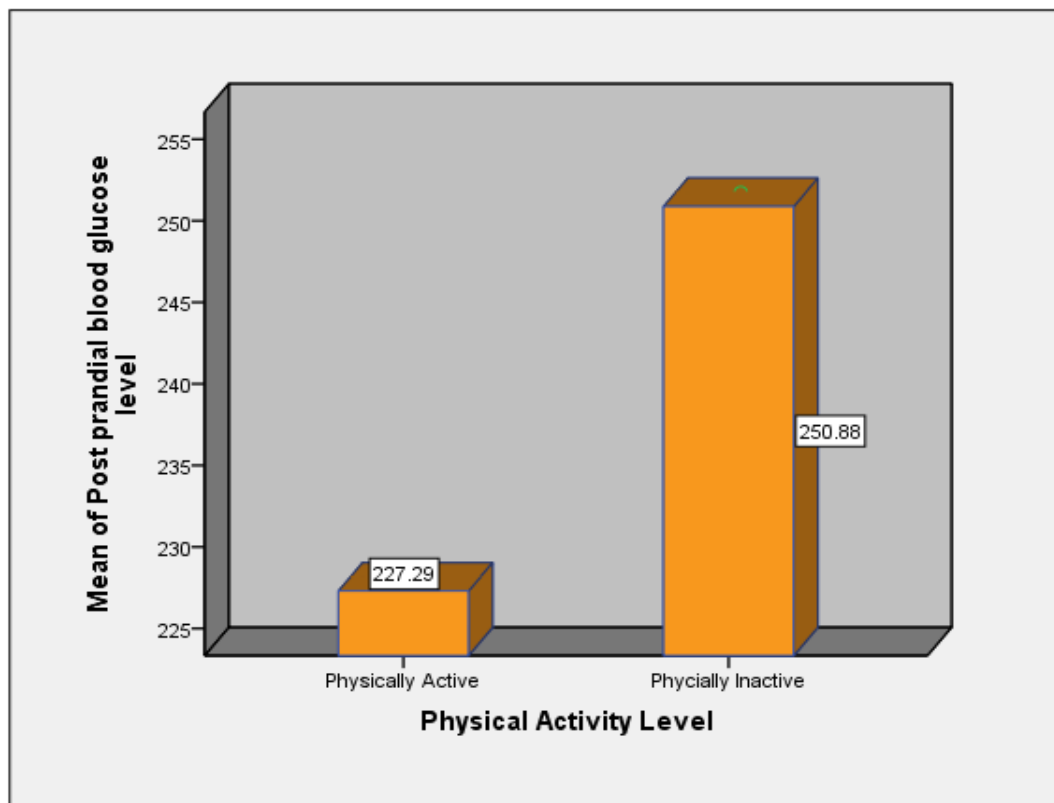


Figure 24. Mean postprandial blood glucose level of the respondents according to physical activity level.

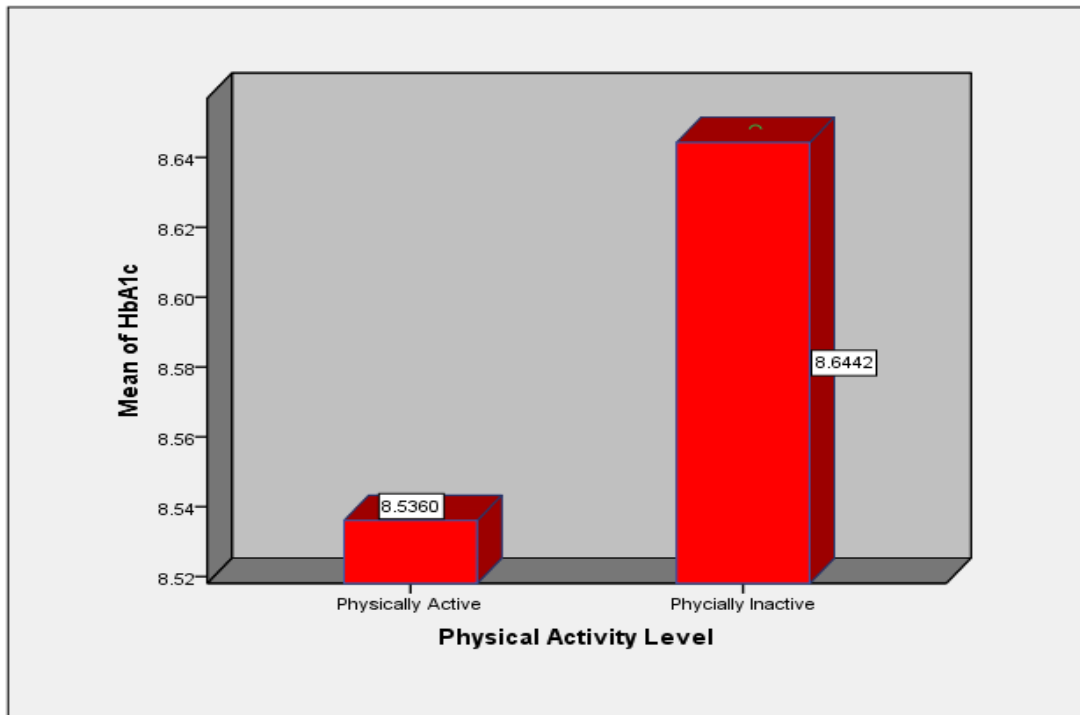


Figure 25. Mean HbA1c level of the respondents according to physical activity level

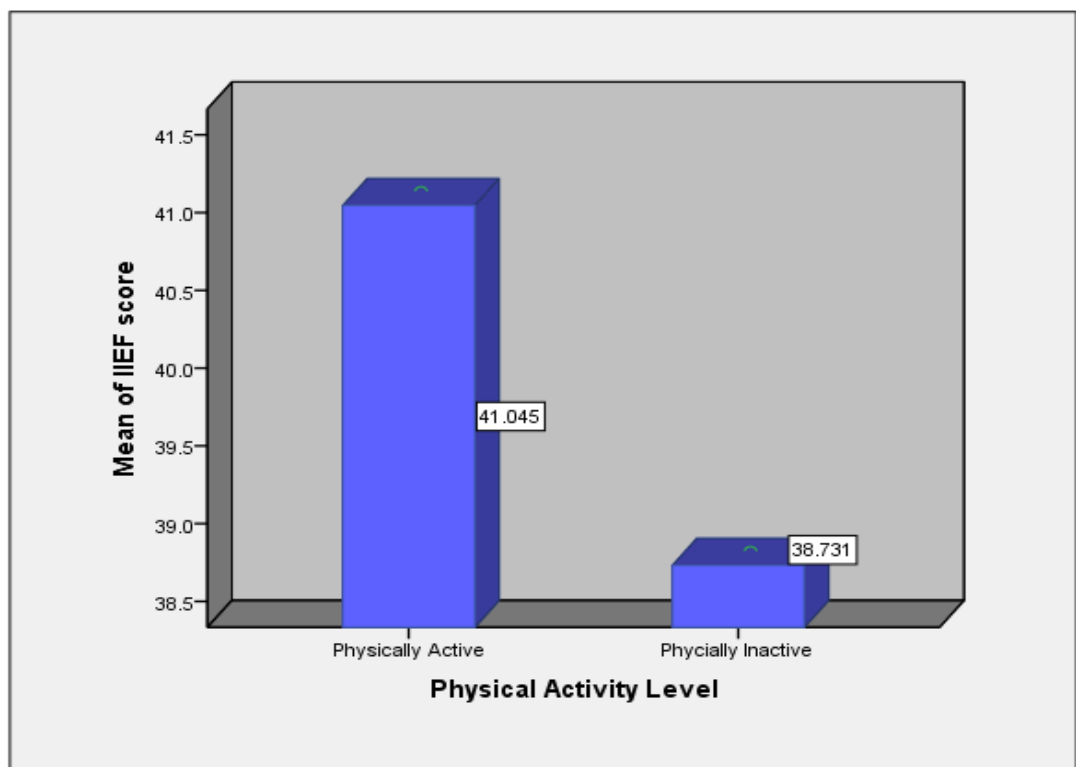


Figure 26. Mean IIEF score of the respondents according to physical activity level

Our results are in consonance with Zimmet and White, (1982); Taylor et al, (1984); Booth et al, (2012) and Bhushan et al, (2013) who concluded that physical inactivity and lack of exercise is an important risk factor for the development of NIDDM, which alters the interaction between insulin and receptors. Kukreja, (1992) reported that younger and lean individuals leading sedentary life have an equal chance of developing non- insulin dependent diabetes.

The most researched and valid reason for the same is the rapidly increasing economic status affected the cultural lifestyle during the last decades, pushing towards physical inactivity and sedentary behaviour which is a leading cause for the increasing rate of obesity which leads to higher prevalence of metabolic syndrome (Alokail et al, 2010). Madaan et al, (2014) also reported that modernization of life style had made the people more sedentary and inactive, which is one of the main factor for Type 2 diabetes. In our study also about 37 per cent Type 2 diabetic patients were non-active.

Physical activity is a defensive factor for the development of diabetes. Al-Kaabi et al, (2009) stated that not only physical activity, but leisure time activity is also an important factor for the development of Type 2 diabetes mellitus. Gill and Cooper, (2008) also reported that physical activity has a protective role in the development of Type 2 diabetes mellitus. An imbalance between physical activity and extra energy intake can lead to obesity, thus results in insulin resistance.

Data in national nutrition monitoring bureau report, 2017 (ICMR) shows that 23 per cent people only exercise. The physical activity ratio is higher (63.1%) in our study population. A study done by Anjana et al, (2014) reported that among 14227 participants studied, about 54 per cent were inactive while about 32 per cent were active and about 14 per cent were highly active. The region wise physical activity levels were as follows; Chandigarh have highest active level about 67 per cent, Tamil Nadu about 60 per cent, Maharashtra 55 per cent and Jharkhand has about 35 per cent. PGIMER Chandigarh also one of the study centres for this study. Our study has shown 63.1 per cent physically active level.

7.1.2 Nutritional assessment of the selected Type 2 adult male diabetic patients and their impact on blood glucose level and IIEF score

In this section, results computed for different anthropometric measurements taken on subjects have been discussed.

7.1.2.1 Body mass index (BMI) and its impact on blood glucose level and IIEF score

The body mass index level of the Type 2 adult male diabetic patients and its impact on blood glucose levels and IIEF score discussed here:

Table 19. Body mass index (BMI) of the respondents with mean blood glucose levels and IIEF score.

Variables	BMI levels	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
BMI category of the respondents	Under- weight (<18.4)	7 (2.5%)	178±35	215±64	11.1±2.3*	35±13
	Normal weight (18.50-24.99)	126 (44.7%)	168±65	246±80	8.7±2.1	39±12
	Over-weight (25.00-29.99)	114 (40.4%)	160±60	233±78	8.3±1.8	41±12
	Obese (≥30.00)	35 (12.4%)	158±60	212±66	8.3±1.9	42±11

(n=282) (* The mean difference is significant at the 0.05 level)

From table number 19, it is apparent that, out of (n=282) respondents 44.7 per cent (n=126); maximum have body mass index (BMI) within normal range. 55.3 per cent did not have BMI in normal range. Among these patients, 2.5 per cent (n=7) were underweight, 40.4 per cent (n=114) over-weight and 12.4 per cent (n=35) were obese category of BMI. Table 19 and figure 27, 28, 29, 30 shows the mean fasting blood glucose levels in under-weight, normal weight, over-weight and obese patients were 178 mg/dl, 168 mg/dl, 160 mg/dl and 158 mg/dl respectively. Mean postprandial blood glucose level were 215 mg/dl, 246 mg/dl, 233 mg/dl and 212 mg/dl respectively. Mean HbA1c levels were 11.1 per cent, 8.7 per cent, 8.3 per cent, and 8.3 per cent respectively. The mean international index of erectile function (IIEF) were 35, 39, 41 and 42 respectively.

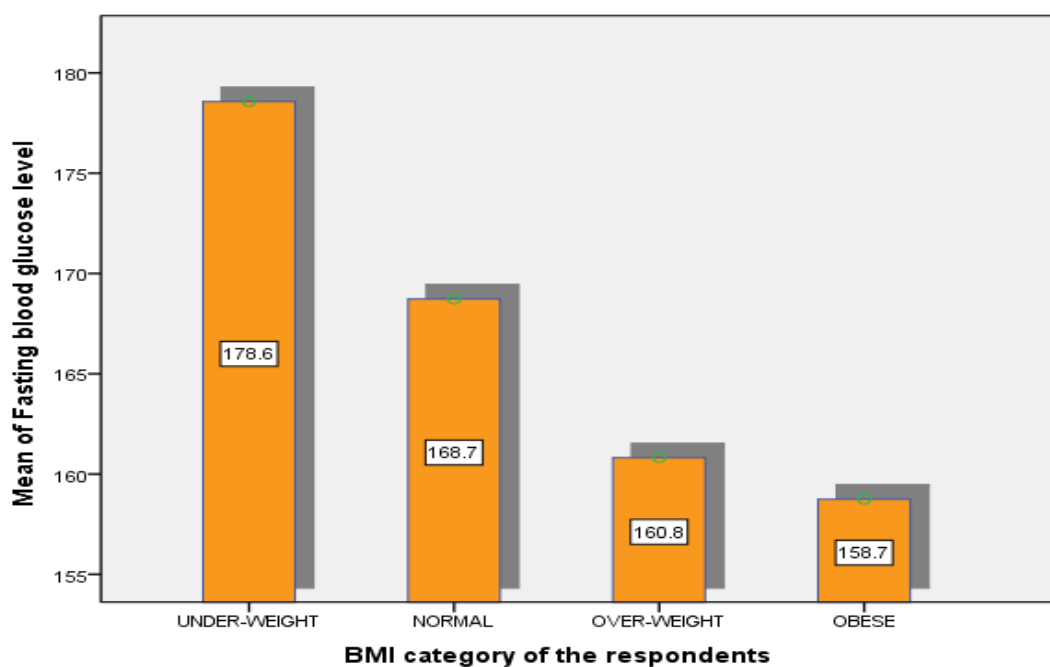


Figure 27. Mean Fasting blood glucose level of the respondents according to body mass index

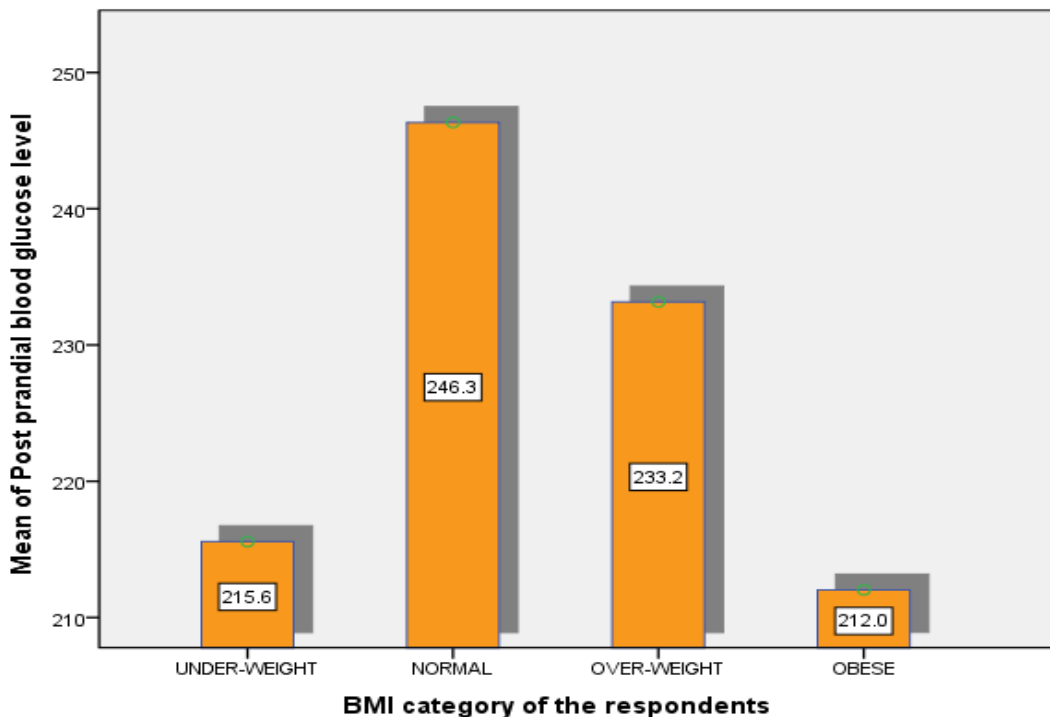


Figure 28. Mean postprandial blood glucose level of the respondents according to body mass index

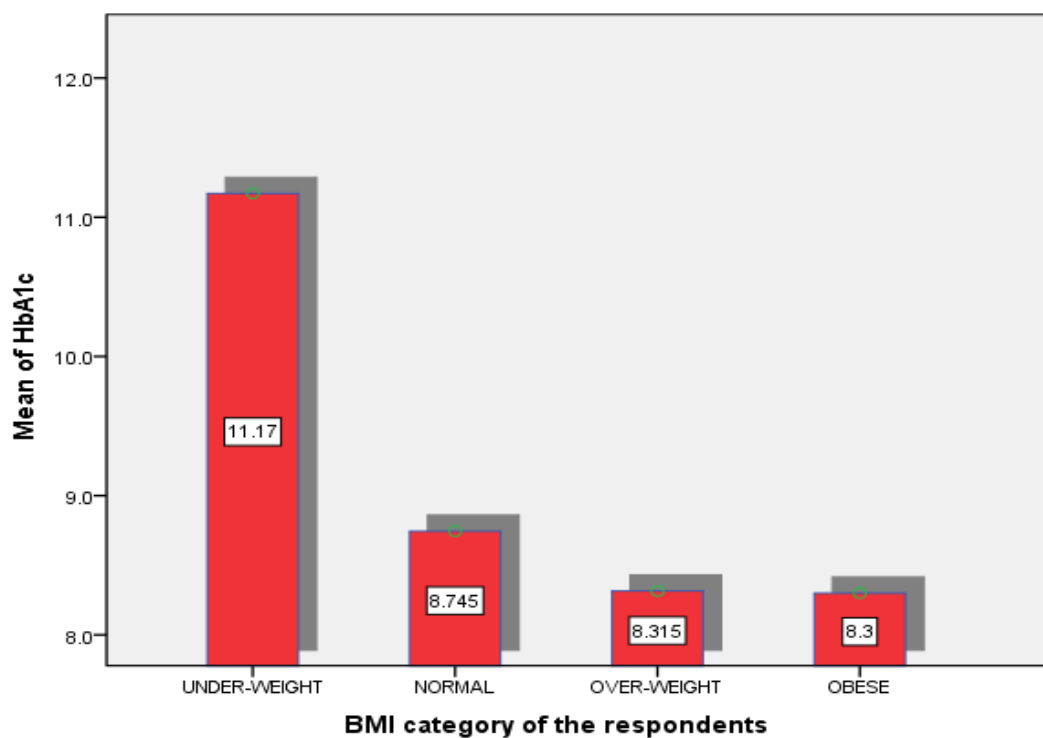


Figure 29. Mean HbA1c level of the respondents according to body mass index

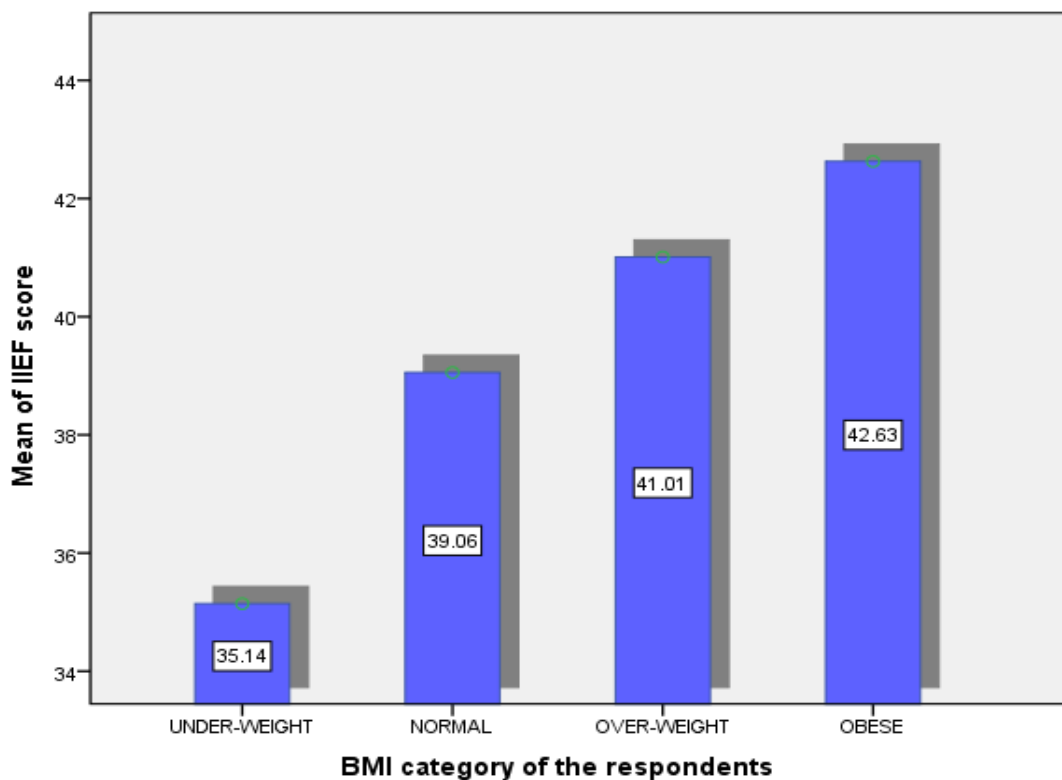


Figure 30. Mean IIEF score of the respondents according to body mass index

There was significant difference between mean HbA1c level of underweight patients and other BMI patients. On comparing this data of BMI with NFHS-4, 2015-2016 (National Family Health Survey); 20 per cent men were underweight, 19 per cent obese and 61 per cent within normal BMI range. Mean body mass index for men was found to be 21.8 kg/m². According to NFHS-4, 2015-2016, mean BMI in diabetic men was 19.9 kg/m² according to National Nutrition Monitoring Bearu (NNMB) urban nutrition report, (2017) by National Institute of Nutrition (Indian Council of Medical Research). It shows that our study population have more mean BMI level (26.64kg/m²).

Obesity is the key risk factor for diabetes. Despite of having lesser overweight and obesity rate, India has a higher prevalence of diabetes compared to western countries suggesting that diabetes may occur at a much less body mass index in Indian compared with Europeans (Rao et al, 2011). There has been a general acceptance that a Body Mass Index cut-off point lower than 25 kg/m² would increase the possibility of identifying diabetes or diabetes risk in Asians. So in Diabetes Prevention Program (DPP) BMI value of 22 kg/m² was chosen for Asians. American Diabetes Association (2014) state that there is evidence that lower BMI cut off value shows increased diabetes risk in some racial and ethnic groups.

7.1.2.2 Anthropometric measurements

In this section, results computed for different anthropometric measurements taken for (n=282) adult male Type 2 diabetic patients have been discussed. Mean± SD computed for height, body weight and body mass index are shown in table 20.

Table 20. Mean anthropometric measurement of the respondents.

Anthropometric Measurements	Mean ±SD	Reference value*
Height (cm)	167.26 ± 6.4	172.3
Weight (kg)	71.83±13.03	60
BMI (kg/m ²)	25.64±4.32	18.5-24.99 (Normal range)

*ICMR 2010

It is apparent from the table 20 data that the mean height of the respondents was 167.26±6.4 cm. which was below the reference value. The mean weight was 71.83±13.03 kg which was 18% above the standard reference weight as recommended by ICMR (2010). It is conformed that even modest changes in weight are associated to substantial increase in diabetes risk (National Institute for Health and Care Excellence, 2011). It is clear from the present study data that overweight was predominant among the recruited Type 2 adult male diabetic mellitus patients.

People with overweight are at a higher risk of developing Type 2 diabetes mellitus in comparison of normal weight individuals. Overweight ads pressure on the body’s ability to properly control blood glucose level using insulin and therefore makes it much more likely for one individual to develop Type 2 diabetes (Kelly, 2005).

The table 20 show that mean body mass index (BMI) was 25.64 ± 4.32 kg/m² of the Type 2 adult male diabetic patients, which shows that they were in pre obese category. A multi-ethnic cohort study identified that incident diabetes risk, adjusted for age, sex, socio demographic characteristics and BMI, was significantly higher for South Asians (20.8 per 1000), African (16.3 per 1000) and Chinese (9.3 per 1000) compared with non-Hispanic whites (9.5 per 1000) (Chiu et al, 2011).

7.1.2.3 Biochemical estimation

Biochemical parameters such as fasting blood glucose level, postprandial blood glucose level and glycosylated haemoglobin (HbA1c) of the recruited Type 2 adult male diabetic patients were discussed.

Table 21. Mean blood glucose levels of the respondents

Blood Glucose levels	Mean± SD	Desirable Level*
Fasting Blood Glucose level (mg/dl)	164.54±62.48	≥ 126
Postprandial Blood Glucose level (mg/dl)	235.99±78.07	≥ 200
HbA1c (%)	8.5±2.0	≥ 6.5

(n = 282) *NDEP 2011

It is observed from the table 21 that among 282 Type 2 adult male diabetic patients mean \pm SD fasting blood glucose level was 164.54 ± 62.48 mg/dl, postprandial blood glucose level was 235.99 ± 78.07 mg/dl, and HbA1c was 8.5 ± 2.0 per cent. When compared with desirable level of blood glucose, our study patients it showed higher fasting blood glucose level by 31 %, postprandial blood glucose level by 18% and HbA1c level by 31%.

Our study finding are is in accord with Madaan et al, (2014) study in which mean blood glucose level was 149 ± 19.51 mg/dl and postprandial blood glucose level was 259 ± 51.36 mg/dl. The HbA1c level of our study is on par with the Diabcare India, (2011) study in the mean HbA1c of 8.97 ± 2.2 per cent for more than 6000 diabetic patients in India and it shows the poor glycaemic control in India (Mohan et al, 2012). Our subjects showed a poor diabetic control despite of being on OHA or Insulin. The overall awareness, care, treatment and adequacy of control of diabetes in our sample were low.

7.1.3 Dietary habits of the respondents and its impact on blood glucose levels and IIEF score

Dietary habits is a modified risk factor that has been linked with increased risk of obesity, Type 2 diabetes and insulin resistance. The eating habits in the Indian culture are largely based on religion and Indian tradition. Hindu religion people mostly have vegetarian habits consume high vegetable diet with no beef or pork.

7.1.3.1 Food habit of the patients and its impact on blood glucose level and IIEF score

Food habits has an environmental risk factor in the onset and prevention of Type 2 diabetes. Food habit of the Type 2 adult male diabetic patients and its impact on blood glucose level and IIEF score was discussed.

The table number 22 data shows that among (n=282) respondents 42.9 per cent (n=121) were vegetarian and 57.1 per cent (n=161) were non-vegetarian.

Table 22. Food habit of the respondents with mean blood glucose levels and IIEF score

Variables	Food habit	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Food habit of the respondents	Vegetarian	121 (42.9%)	158±58	230±74	8.4±1.9	41±12
	Non-vegetarian	161 (57.1%)	168±65	240±80	8.6±2.1	39±12

(n=282)

Table 22 and figure 31, 32, 33, 34 shows the mean fasting blood glucose levels in vegetarian and non-vegetarian were 158 mg/dl and 168 mg/dl. Mean postprandial blood glucose level were 230 mg/dl and 240 mg/dl respectively. Mean HbA1c levels were 8.4 per cent and 8.6 per cent respectively. The mean international index of erectile function (IIEF) were 41 and 39 respectively.

The data shows vegetarian patients have low mean fasting, postprandial and HbA1c level and high IIEF score in compared to non-vegetarian patients but it was statistically non-significant.

Study done by Jenkin et al, (2003) revealed that there are many facets or components of a plant-based diet that might confer benefits on glycemia. Traditionally processed cereals and legumes have a low glycemic index, and whole-grain cereals appear to reduce the risk of developing diabetes.

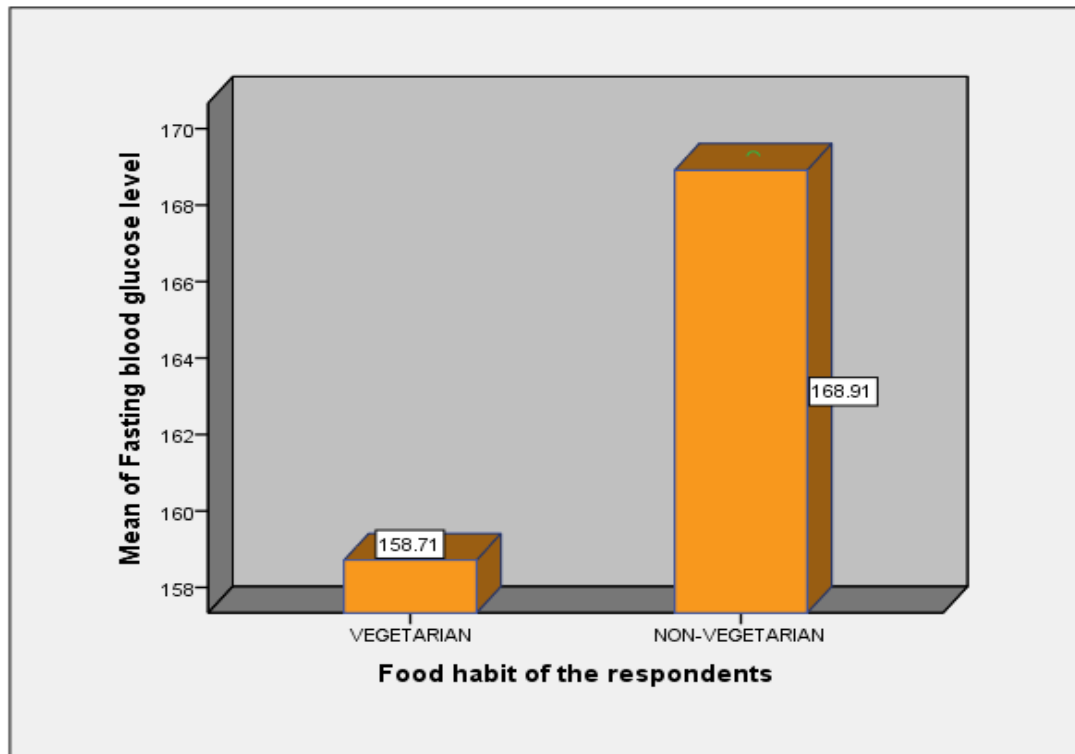


Figure 31. Mean Fasting blood glucose level of the respondents according to food habits

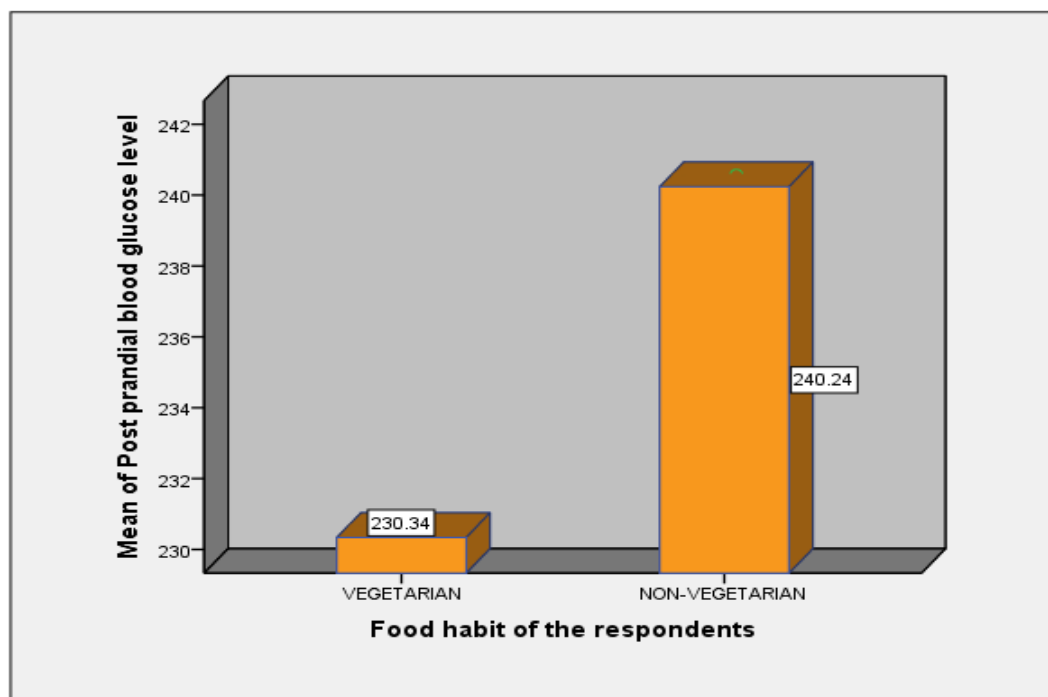


Figure 32. Mean postprandial blood glucose level of the respondents according to food habits

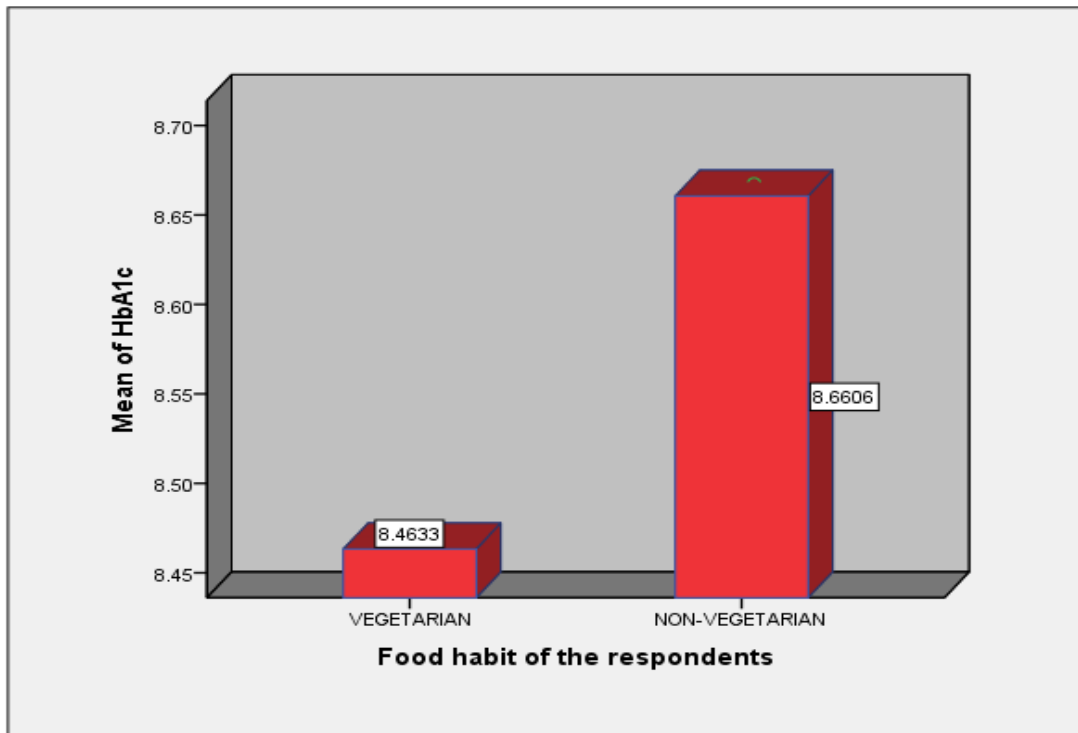


Figure 33. Mean HbA1c level of the respondents according to food habits

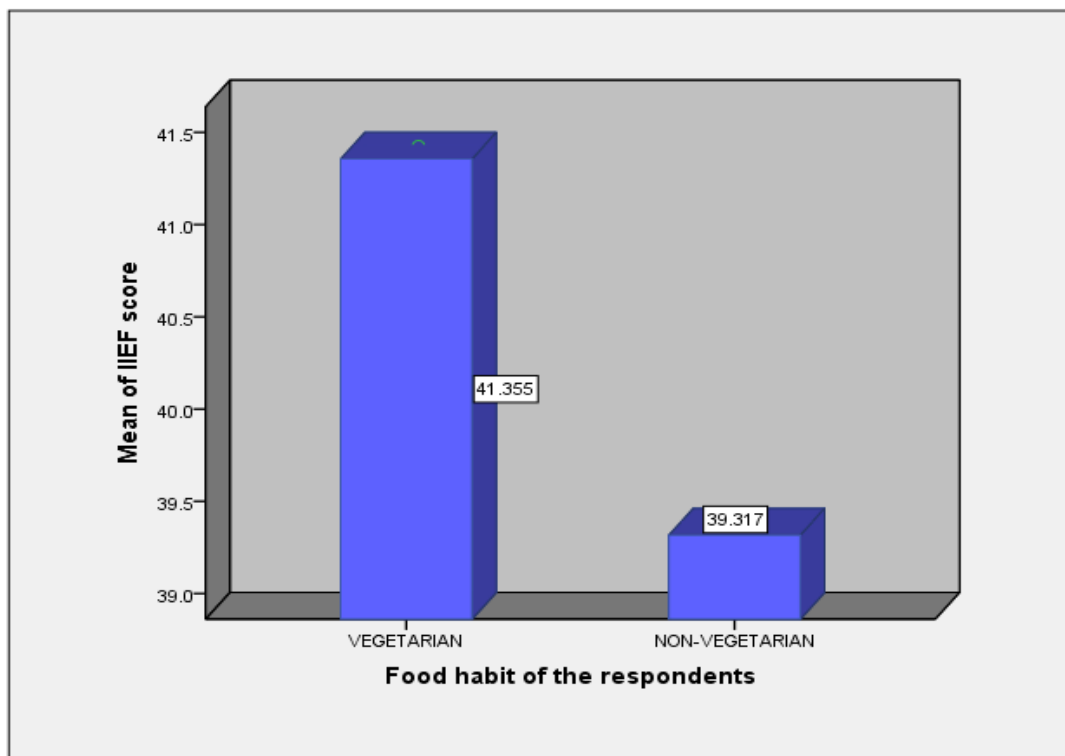


Figure 34. Mean IIEF score of the respondents according to food habits

Chiu et al, (2018) stated that consistent vegetarian diet was associated with 35% lower hazards (HR: 0.65, 95% CI: 0.46, 0.92), while converting from a non-vegetarian to a vegetarian pattern was associated with 53% lower hazards (HR: 0.47, 95% CI: 0.30, 0.71) for diabetes, comparing with non-vegetarian while adjusting for age, gender, education, physical activity, family history of diabetes, follow-up methods, use of lipid-lowering medications, and baseline BMI. Our study data also shows low blood glucose levels in vegetarian patients but with non-significant difference from non-vegetarian patients.

7.1.3.2 Type of diet followed by the respondents and its impact on blood glucose levels and IIEF score

Diet followed by Type 2 adult male diabetic patients has great impact on blood glucose levels and IIEF.

Table 23. Type of diet followed by the respondents with mean blood glucose levels and IIEF score

Variables	Type of diet	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Type of diet followed by the respondents	Diabetic diet	73 (25.9%)	150±56*	219±71*	8.4±2.0	42±12
	Normal diet	209 (74.1%)	169±53	241±79	8.6±2.0	39±12

(n=282) (* The mean difference is significant at the 0.05 level)

The table 23 data shows that among (n=282) Type 2 adult male diabetic patients 25.9 per cent (n=73) were following diabetic diet and 74.1 per cent (n=209) respondents were following normal diet pattern. Table 23 and figure 35, 36, 37, 38 shows the mean fasting blood glucose levels in diabetic diet patients and normal diet patients were 150 mg/dl and 169 mg/dl. Mean postprandial blood glucose level were 219 mg/dl and 241 mg/dl respectively. Mean HbA1c levels were 8.4 per cent and 8.6 per cent respectively. The mean international index of erectile function (IIEF) were 42 and 39 respectively.

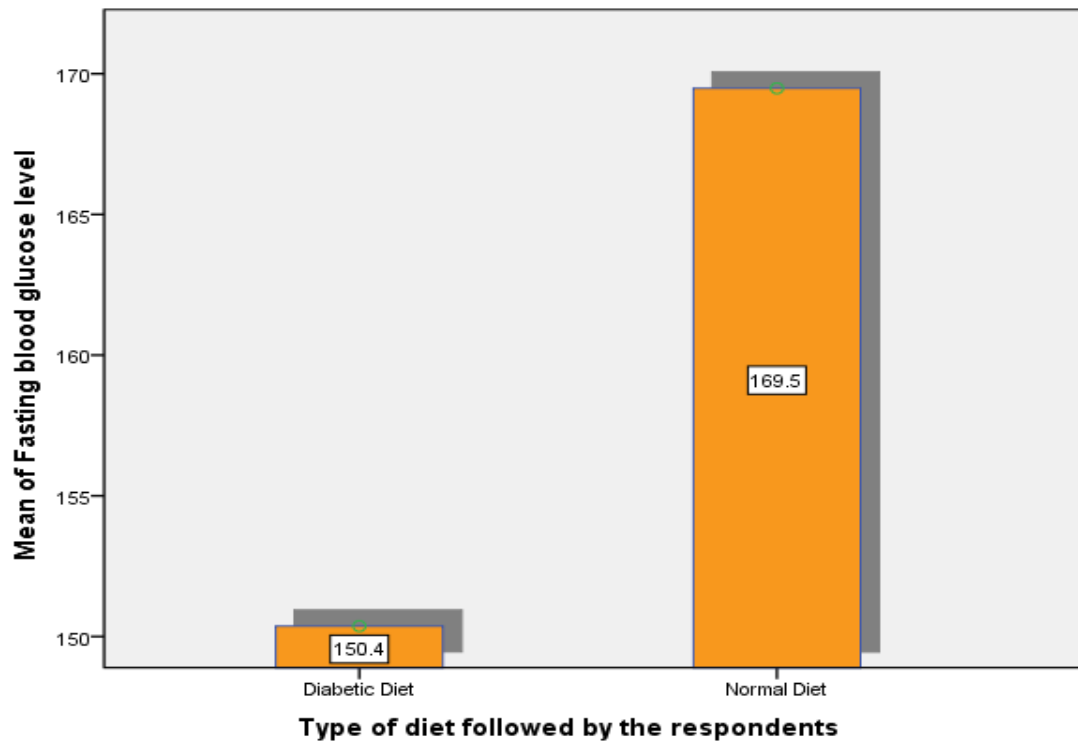


Figure 35. Mean fasting blood glucose level of the respondents according to type of diet followed

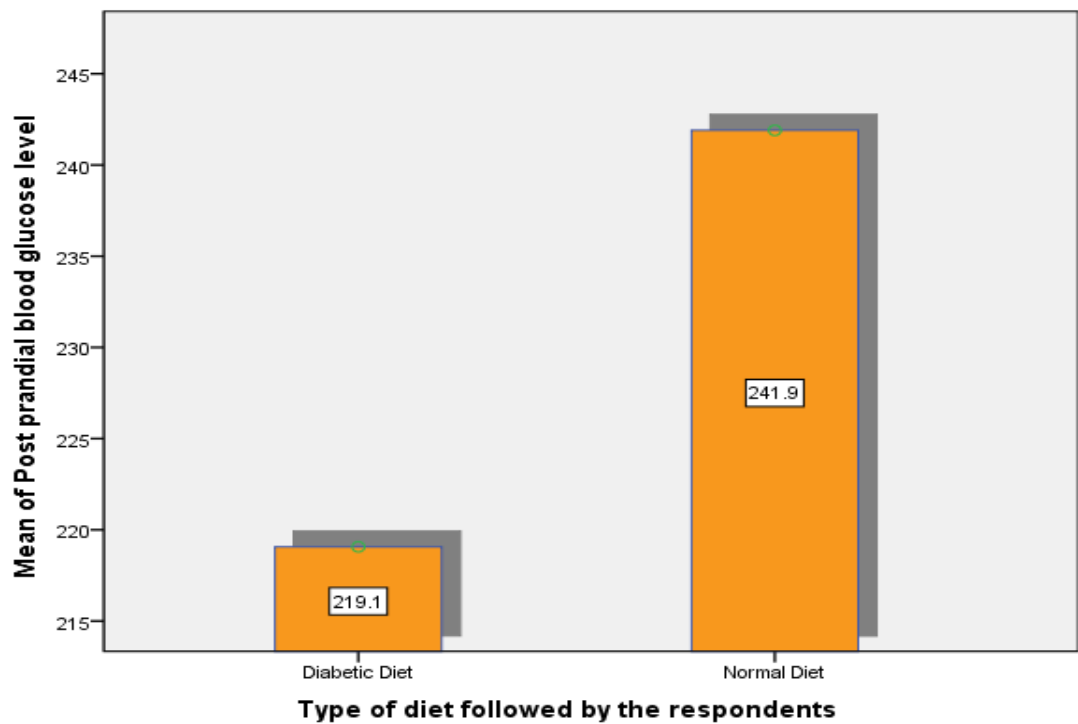


Figure 36. Mean postprandial blood glucose level of the respondents according to type of diet followed

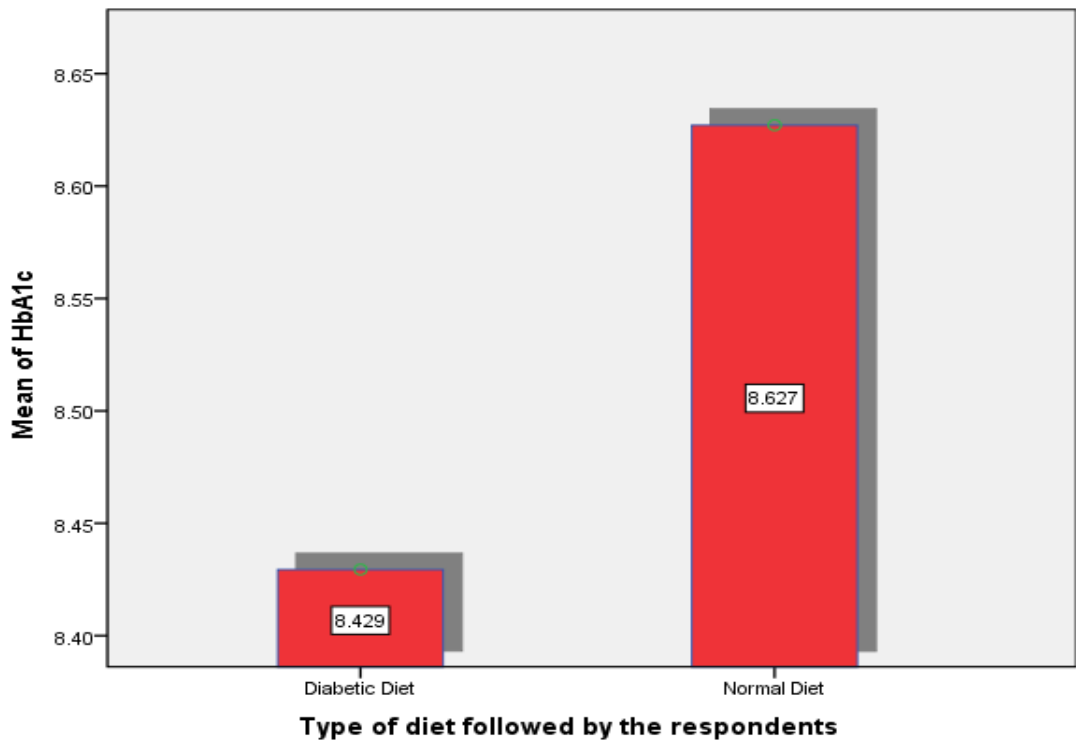


Figure 37. Mean HbA1c level of the respondents according to type of diet followed

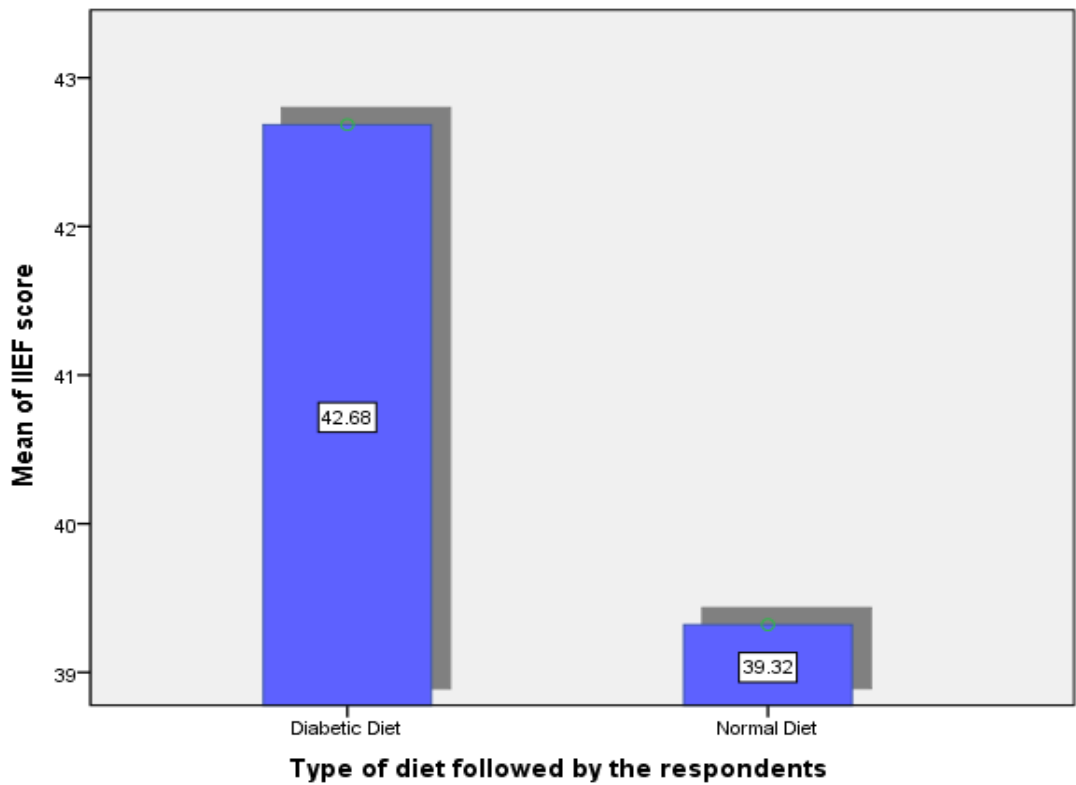


Figure 38. Mean IIEF score of the respondents according to type of diet followed

The mean fasting blood glucose level and mean postprandial blood glucose level in patients follow diabetic diet were significantly lower as compared to patient's follows normal diet pattern. While mean HbA1c level and mean IIEF score in patients following diabetic diet have non-significant difference as compared to patients on normal diet. So it may be concluded that Type 2 diabetic male patients on diabetic diet have better control over their blood glucose levels. While patients on normal diet pattern have poor blood glucose control.

Patel et al, (2012) study show that majority (73 %) western Indian Type 2 diabetic patients consuming diabetic diet as compared to our study sample only 25.9 per cent following diabetic diet.

7.1.3.3 Type of milk consumption by the respondents and its impact on blood glucose levels and IIEF score.

Dietary habits like type of milk consumption by Type 2 adult male diabetic patients and its impact on blood glucose level and IIEF.

Table 24.Type of milk consumption habit of the respondents with mean blood glucose levels and IIEF score.

Variables	Type of milk	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Type of Milk consumed by respondents	Whole Milk	222 (78.7%)	165±60	237±77	8.5±2.0	39±12
	Skimmed Milk	60 (21.3%)	161±68	230±81	8.6±2.0	42±12
	Tonned Milk	0**	-	-	-	-
	Skimmed Milk Powder	0**	-	-	-	-

(n=282) (**No consumption)

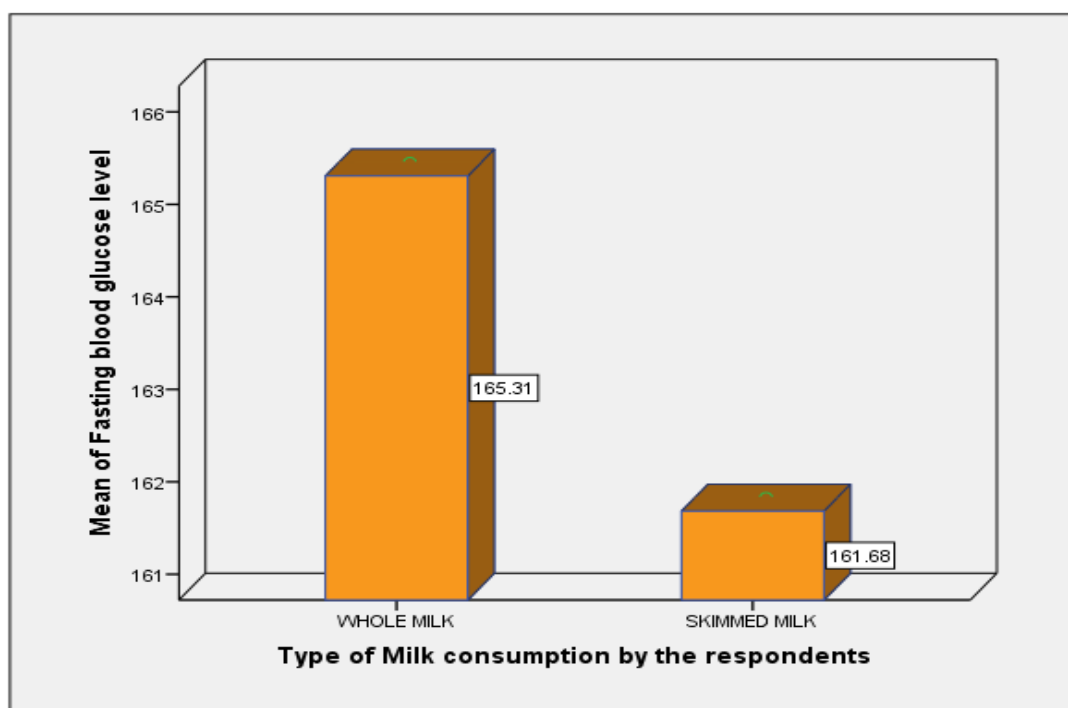


Figure 39. Mean fasting blood glucose level of the respondents according to type of milk consumption

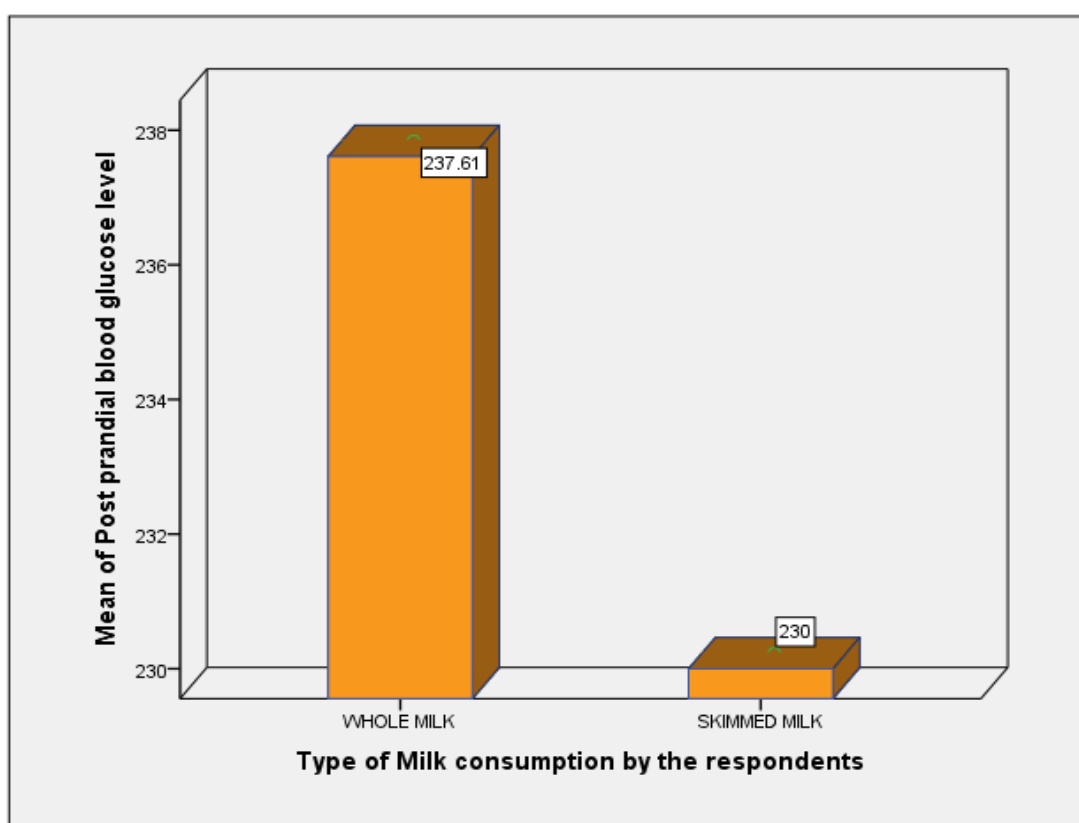


Figure 40. Mean postprandial blood glucose level of the respondents according to type of milk consumption.

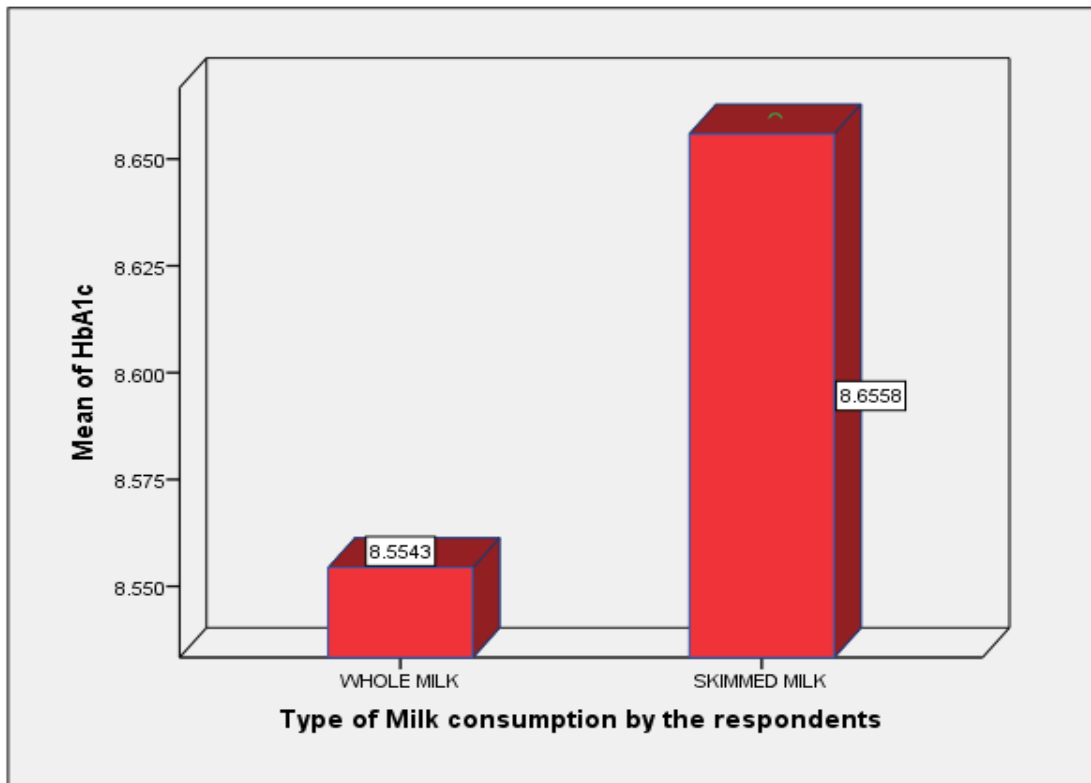


Figure 41. Mean HbA1c level of the respondents according to type of milk consumption

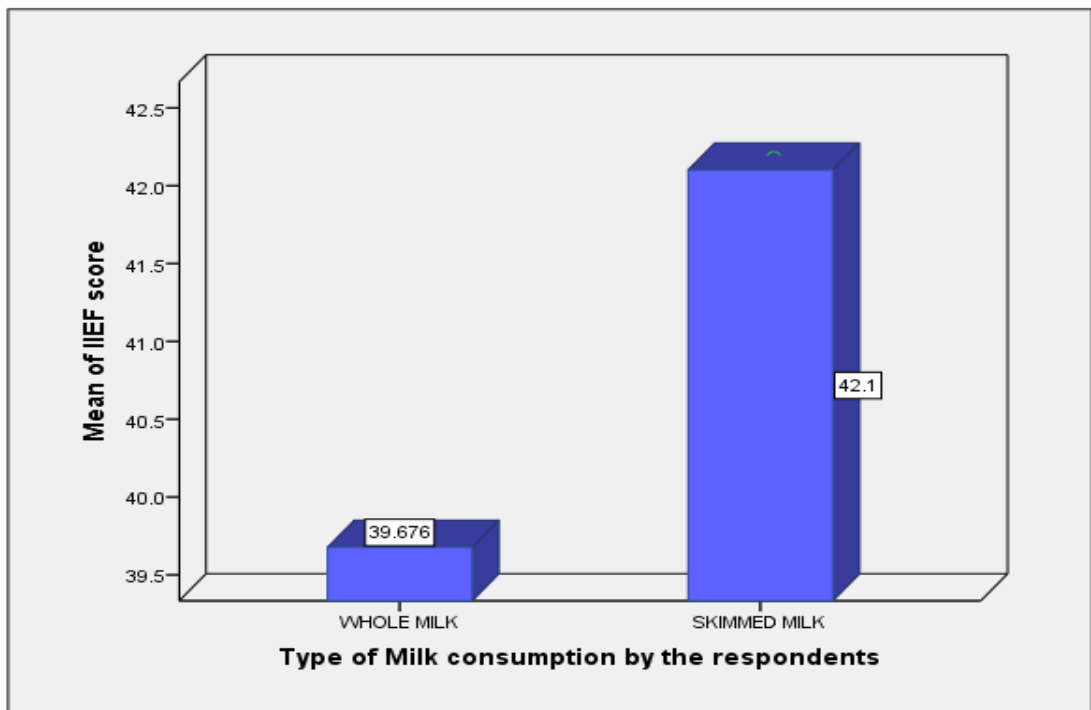


Figure 42. Mean IIEF score of the respondents according to type of milk consumption

The table 24 data shows that out of (n=282) respondents most of them 78.7 per cent (n=222) using whole milk in their daily diet and 21.3 per cent (n=60) subjects were using skimmed milk. No any respondents using toned milk or skimmed milk powder. Table 24 and figure 39, 40, 41, 42 shows the mean fasting blood glucose levels in patients using whole milk was 165 mg/dl and patients using skimmed milk was 161mg/dl. Mean postprandial blood glucose level were 237 mg/dl and 230 mg/dl respectively. Mean HbA1c levels were 8.5 per cent and 8.6 per cent respectively. The mean international index of erectile function (IIEF) were 39 and 42 respectively.

There were high mean fasting blood glucose level and postprandial blood glucose level in Type 2 diabetic adult male patients using whole milk as compare to patients using skimmed milk, but the difference were non-significant. While patients using skimmed have high HbA1c levels and low IIEF score as compare to patients using whole milk but figure were not statistically significant. A meta-analysis study done by Tian et al, (2017) state that whole milk and other milk or its product associated with lower risk of Type 2 diabetes and have beneficial effect on blood glucose levels. This study data show similar result as in our study, whole milk and skimmed milk does not show any significant difference on blood glucose levels and sexual dysfunctions.

7.1.4 Life style pattern

Life style pattern include smoking habits, alcohol consumption habits.

Life style modification can be very effective way to keep diabetes in control. Good blood glucose levels controls can slow the progression of long term complications. Multiple small changes can lead to improvements in diabetes control, including a decreased need for medication (Khan, 2012).

7.1.4.1 Smoking habit of the respondents and its impact on blood glucose levels and IIEF score

Smoking is an independent risk factor for Type 2 diabetes. A meta-analysis found that current smokers had a 45 per cent higher risk of developing diabetes when

compared with non-smokers (Willi et al, 2007). Smoking habits by the Type 2 adult male diabetic patients and its impact on their blood glucose level and IIEF score checked and discussed.

Table 25. Smoking habit of the respondents with mean blood glucose levels and IIEF score.

Variables	Options	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Smoking habits of the respondents	Yes	66 (23.4%)	165±62	234±75	8.46±1.9	38±13
	No	216 (76.6%)	164±62	236±79	8.60±2.0	40±12

(n=282)

The table 25 data represent that among (n=282) respondents, 23.4 per cent (n=66) do smoking, while 76.6 per cent (n=216) do not smoke. Table 25 and figure 43, 44, 45, 46 shows the mean fasting blood glucose levels in patients have smoking habits were 165 mg/dl while patients who did not smoke had fasting blood glucose at 164 mg/dl. Mean postprandial blood glucose level were 234 mg/dl and 236 mg/dl respectively. Mean HbA1c levels were 8.4 per cent and 8.6 per cent respectively. The mean international index of erectile function (IIEF) were 38 and 40 respectively.

There were non-significant difference in mean value of mean fasting blood glucose levels, postprandial blood glucose level, HbA1c and IIEF score in both the groups. When we compare this data with National Family Health Survey (NFHS-4), 2015-16; it is reported that 14 per cent Indian population smokes. In another survey report of NNMB urban nutrition, (2017) by National Institute of Nutrition (Indian Council of Medical Research, 16 per cent Indian people have smoking habits.

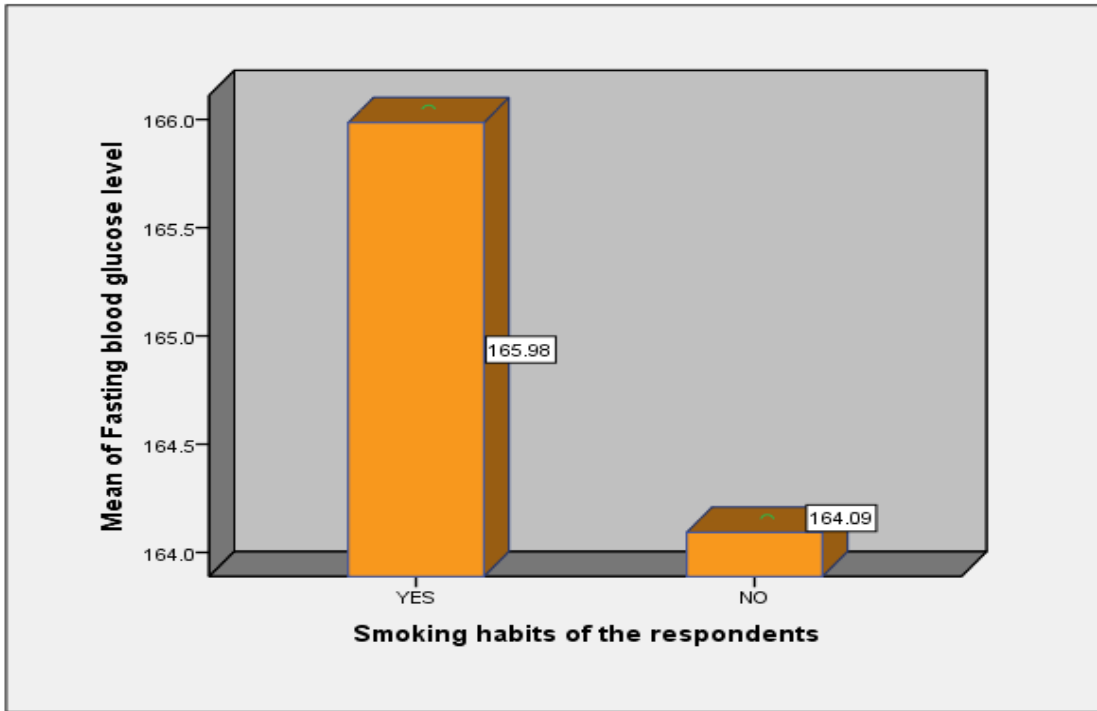


Figure 43. Mean fasting blood glucose level of the respondents according to smoking habit

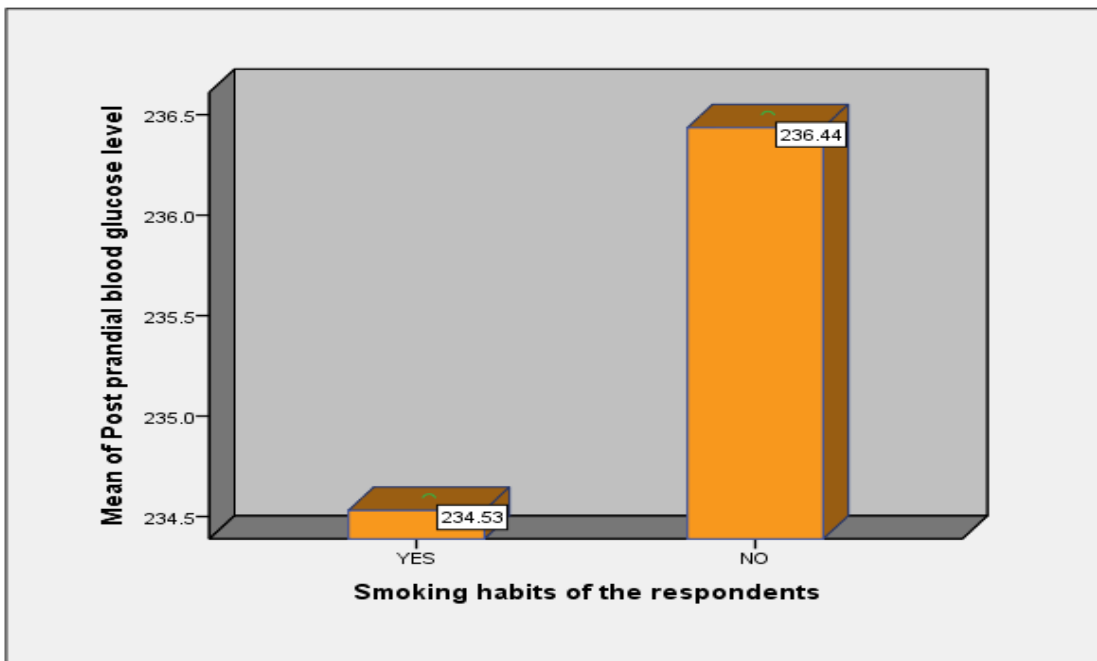


Figure 44. Mean postprandial blood glucose level of the respondents according to smoking habit

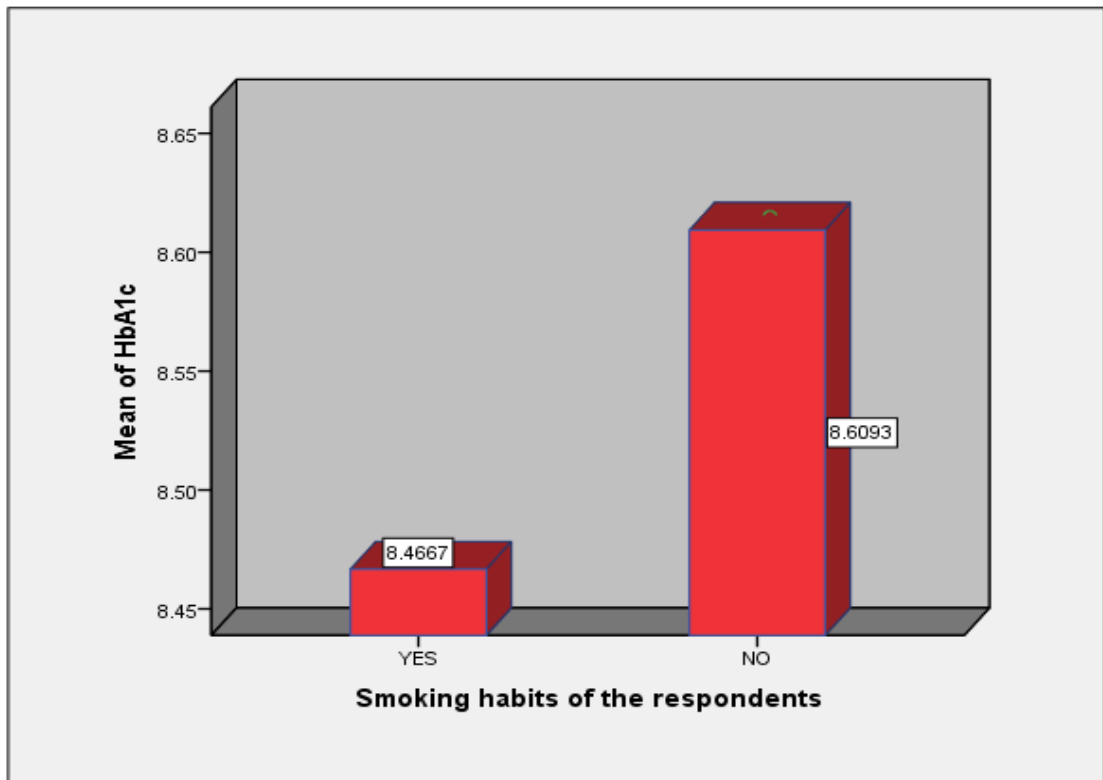


Figure 45. Mean HbA1c level of the respondents according to smoking habit

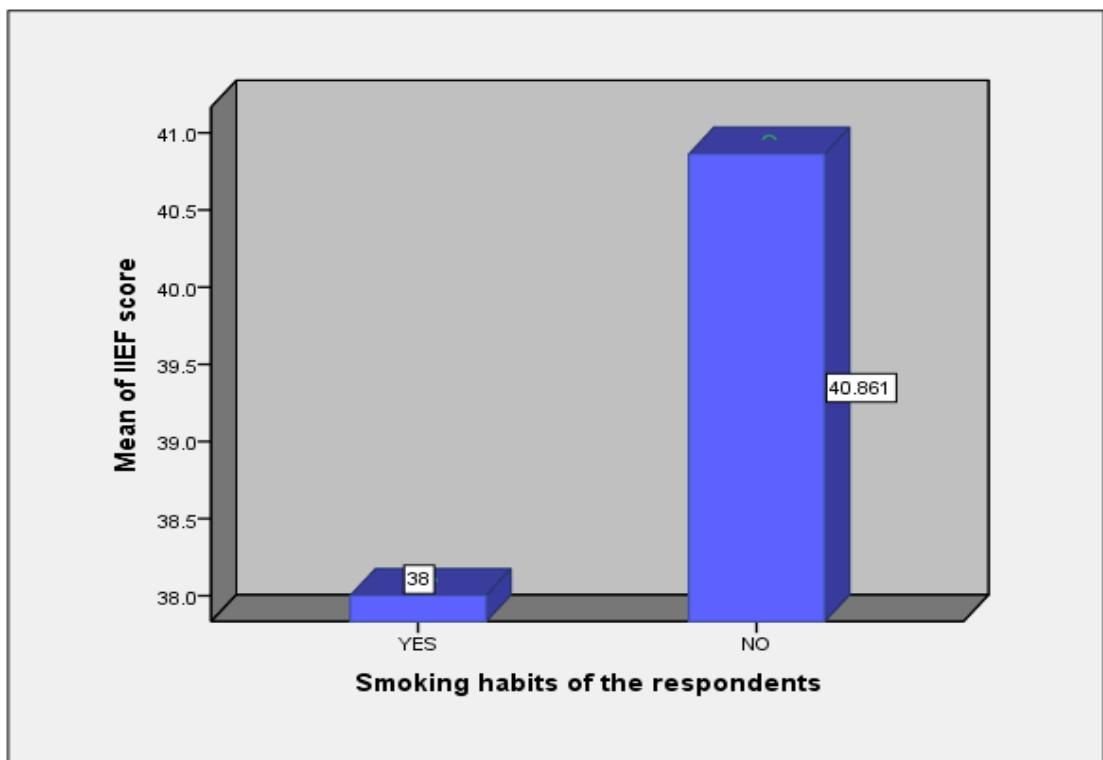


Figure 46. Mean IIEF score of the respondents according to smoking habit

Our sample population exhibited higher percentage of smokers. It was found to be 23.4 per cent smokers amongst diabetics and not population as a whole. Wakabayashi, (2014) reported that smokers have 30 - 40 per cent more risk of develop diabetes than non-smokers people. The risk of complications connected with tobacco use and diabetes in combination is nearly 14 times higher than risk of either smoking or diabetes alone (Haire and Thomas, 2005).

7.1.4.2 Alcohol consumption by the respondents and its impact on blood glucose levels and IIEF score

Alcohol consumption has great influence on diabetic patients' health and their blood glucose levels and sexual health. Alcohol consumption by Type 2 adult male diabetic patients and its impact on their blood glucose level and IIEF score discussed.

Table 26. Alcohol consumption by the respondents with mean blood glucose levels and IIEF score.

Variables	Options	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Alcohol consumption habits in the respondents	Yes	129 (45.7%)	171±67	248±83	8.7±2.0	39±11
	No	153 (54.3%)	158±56	225±72*	8.4±2.0	40±13

(* The mean difference is significant at the 0.05 level) (n=282)

Table no 26 data represents that among (n=282) respondents 45.7 per cent i.e. (n=129) patients were consuming alcohol, while 54.3 per cent (n=153) did not consume alcohol. Table 26 and figure 47, 48, 49, 50 shows the mean fasting blood glucose levels in patients consuming alcohol was 171 mg/dl while non-drinkers alcohol showed mean at 158 mg/dl. Mean postprandial blood glucose level were 248 mg/dl and 225 mg/dl respectively. Mean HbA1c levels were 8.7 per cent and 8.4 per cent respectively. The mean international index of erectile function (IIEF) were 39 and 40 respectively.

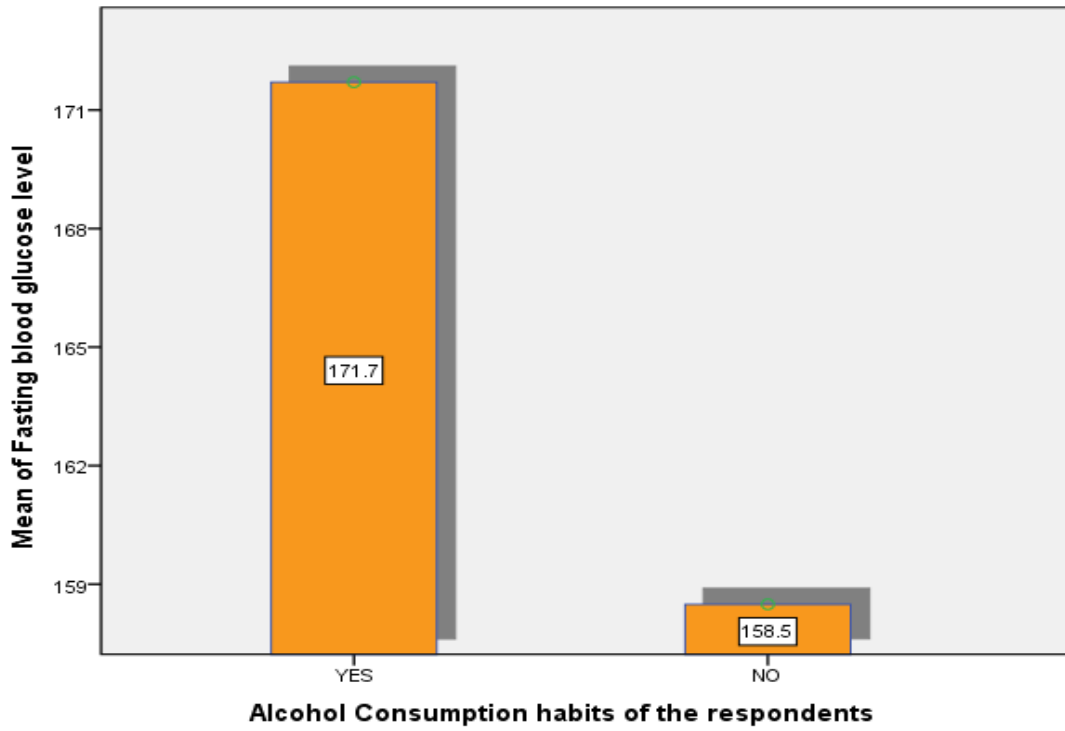


Figure 47. Mean fasting blood glucose level of the respondents according to alcohol consumption



Figure 48. Mean postprandial blood glucose level of the respondents according to alcohol consumption

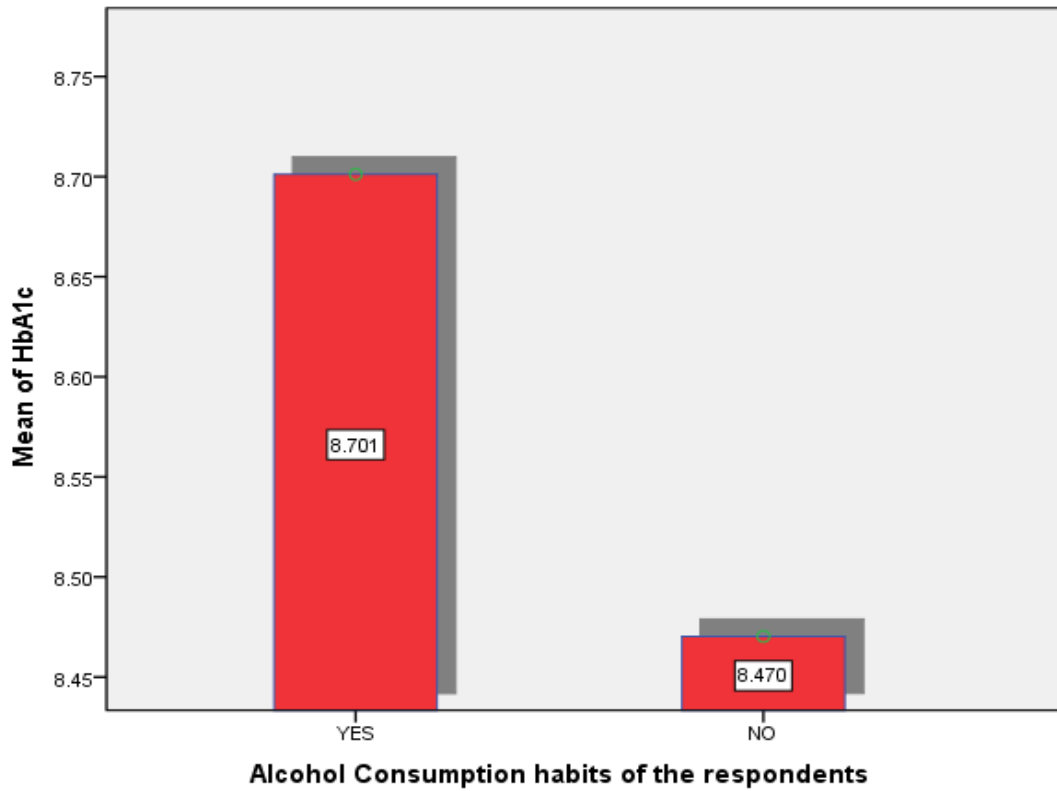


Figure 49. Mean HbA1c level of the respondents according to alcohol consumption

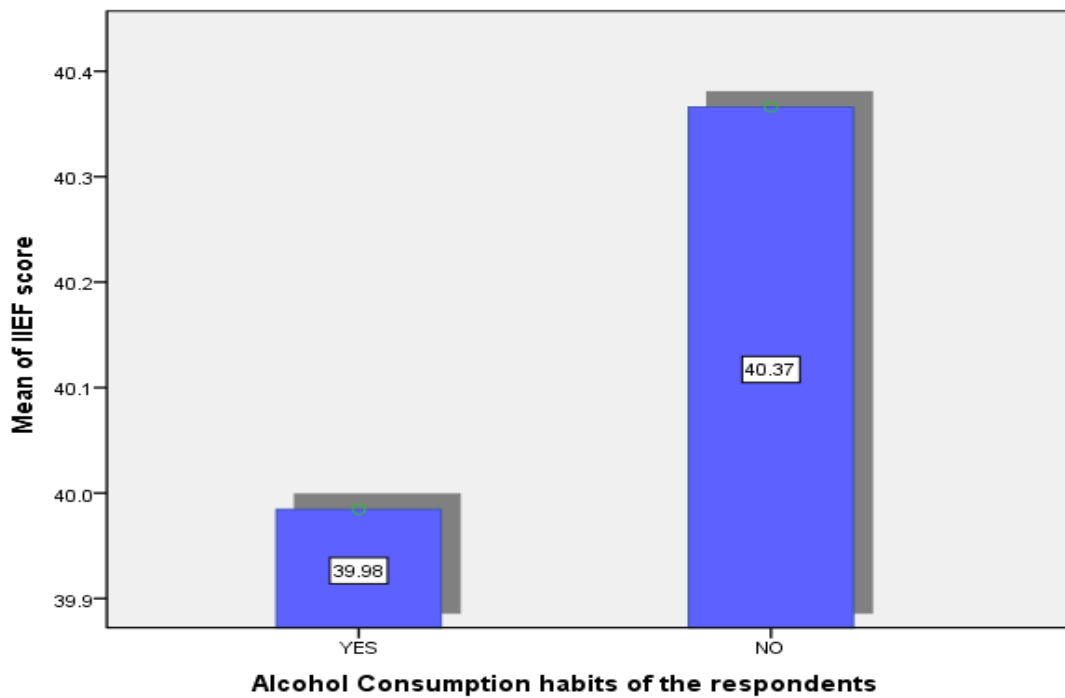


Figure 50. Mean IIEF score of the respondents according to alcohol consumption

The mean postprandial blood glucose levels of non-consuming alcohol patients was significantly lower as compared to alcohol consuming diabetic patients. While there were non-significant mean difference of fasting blood glucose, HbA1c and IIEF score in both the groups. It may concluded from the data that Type 2 adult male diabetic patients consuming alcohol may have significant effect on their blood glucose level.

Emanuele et al, (1998) stated that alcohol consumption can worsen blood glucose control and worsen diabetes-related complication. Alcohol consumption was at 29 per cent in India according to the National Family Health Survey (NFHS-4), 2015-16 while in our study subjects it was 45.7 per cent. In another survey report of National nutrition monitoring bureau (NNMB) urban nutrition report, (2017) 30 per cent Indian people consume alcohol.

7.1.4.3 Duration of sleep by the respondents and its relation to their blood glucose levels and IIEF score

Table 27. Duration of sleep by the respondents with mean blood glucose levels and IIEF score

Variables	Sleeping hours	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Duration of sleep by the respondents	4-6 hours	59 (20.9%)	171±59	245±76	8.87±2.3	40.5±11
	7-9 hours	217 (77%)	162±63	233±78	8.49±1.9	40.2±12
	10-12 hours	6 (2.1%)	183±56	254±61	8.41±1.4	34.0±11

(n=282)

Table 27 data shows that maximum respondents’ 77 per cent (n=217) respondent take 7-9 hours’ sleep, 20.9 per cent (n=59) have 4-6 hours’ sleep and 2.1 per cent (n=6) sleeps 10-12 hours. Table 27 and figure 51, 52, 53, 54 shows the mean fasting blood glucose levels in patients sleeping hours 4-6 hours, 7-9 hours and 10-12 hours were 171 mg/dl, 162 mg/dl and 183mg/dl. Mean postprandial blood glucose level were 245 mg/dl, 233 mg/dl and 254 mg/dl respectively. Mean HbA1c levels were 8.87 per cent, 8.49 per cent and 8.41 per cent respectively. The mean international index of erectile function (IIEF) were 40.5, 40.2 and 34.0 respectively.

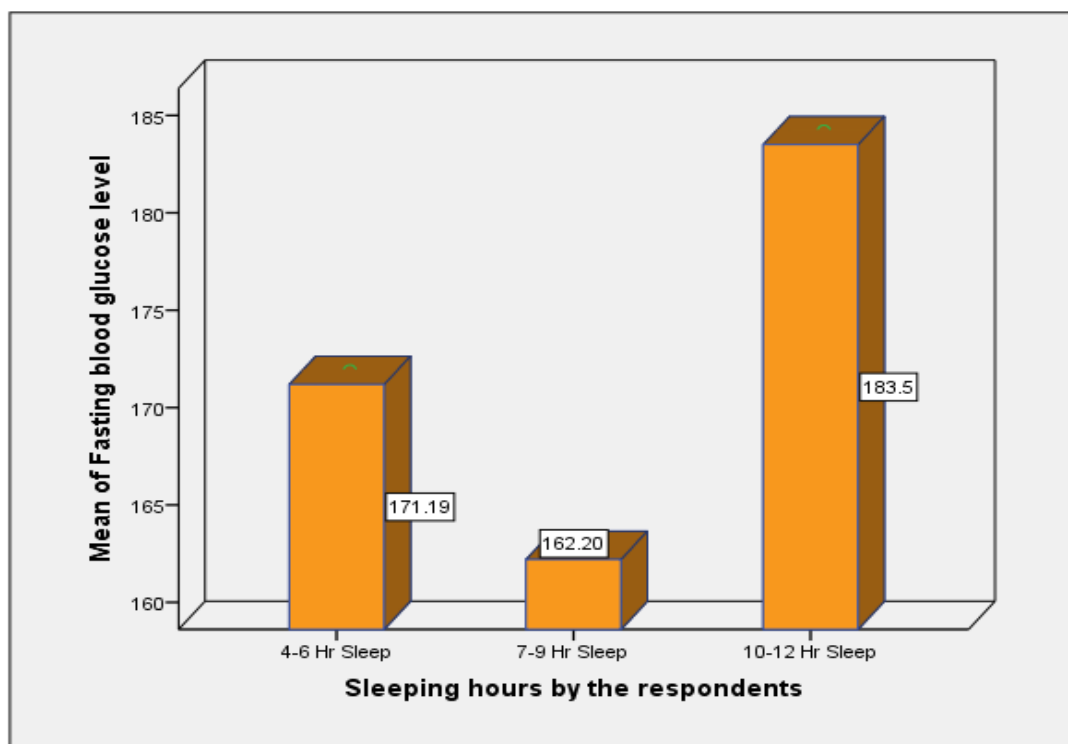


Figure 51. Mean fasting blood glucose level of the respondents according to sleeping hours

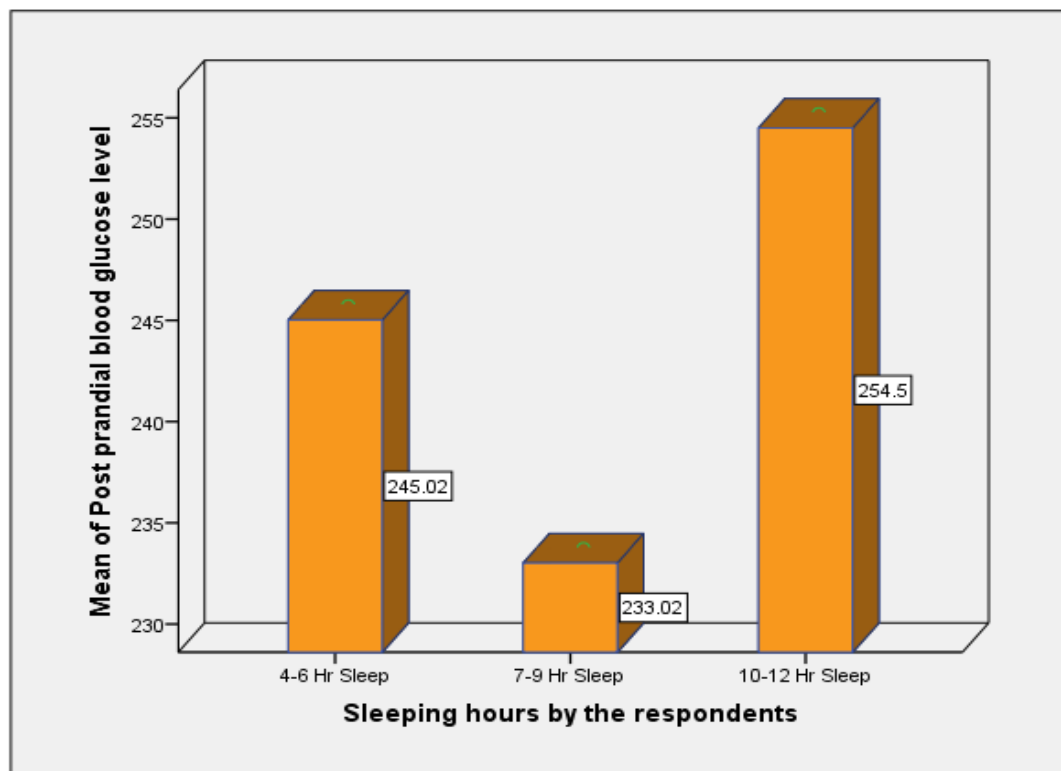


Figure 52. Mean postprandial blood glucose level of the respondents according to sleeping hours

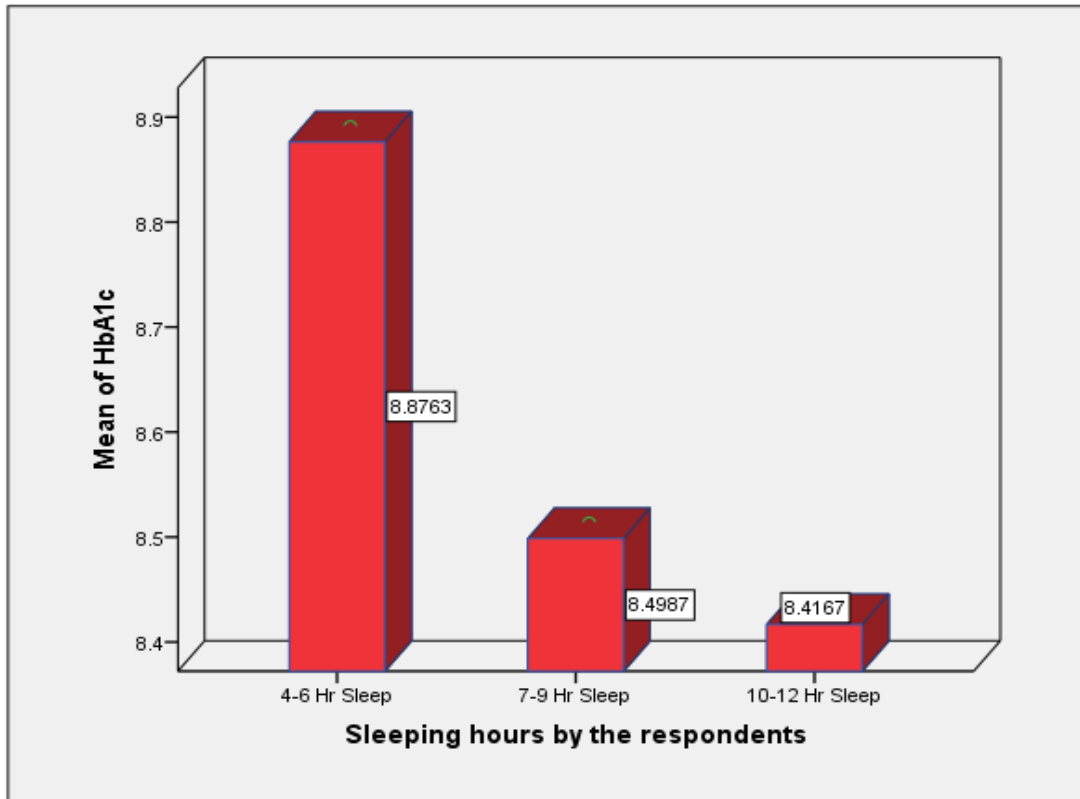


Figure 53. Mean HbA1c level of the respondents according to sleeping hours

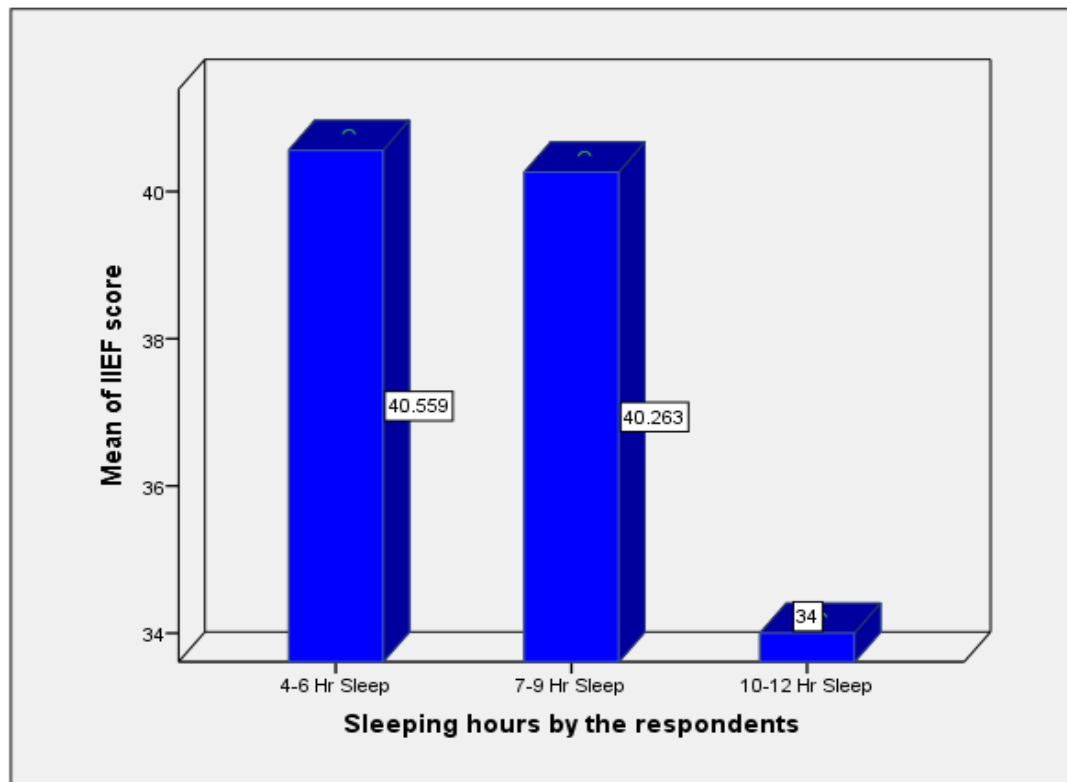


Figure 54. Mean IIEF score of the respondents according to sleeping hours

There were non-significant difference in mean value of fasting, postprandial blood glucose levels, HbA1c and IIEF score value in all the groups. Knutson, (2007) research reviewed that sleep loss (less hour sleep) can lead to impairments in glucose metabolism, Booth et al, (2012) and Gozashti et al, (2016) found that there is a linear correlation between sleep duration and glycemic control. Lin et al, (2016) state that short sleep duration was associated with a higher prevalence of diabetes and it was strong in young adults.

7.1.5 General Health status of the Type 2 adult male diabetic patients

Diabetes mellitus effect the general health status of Type 2 adult male diabetic patients is assessed and its impact on blood glucose levels and IIEF score is discussed.

7.1.5.1 General Health status of the respondents and its relation with their blood glucose levels and IIEF score

Table 28. General health status of the respondents with mean blood glucose levels and IIEF score.

Variables	Options	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
General health status of the respondents	Very good	18 (6.4%)	172±94	233±97	8.78±2.3	55±8*
	Good	206 (73%)	161±58	233±73	8.50±1.9	40±11*
	Fair	47 (16.7%)	174±67	244±93	8.76±2.4	35±13
	Poor	11 (3.9%)	167±58	244±66	8.71±1.6	28±10

(* The mean difference is significant at the 0.05 level) (n=282)

The table 28 shows the general health status of the respondents, maximum 73 per cent (n=206) were good health, 6.4 per cent (n=18) were very good health, 16.7 per cent (n=47) were fair health condition and 3.9 per cent (n=11) were poor health status.

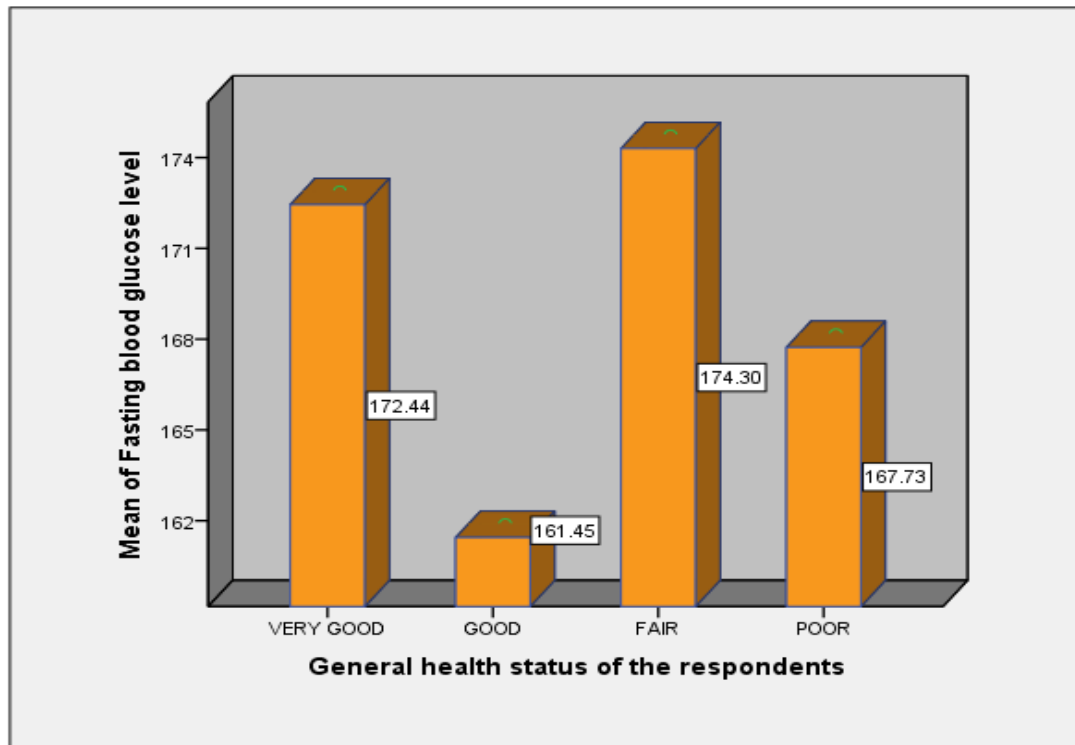


Figure 55. Mean fasting blood glucose level of the respondents according general health status

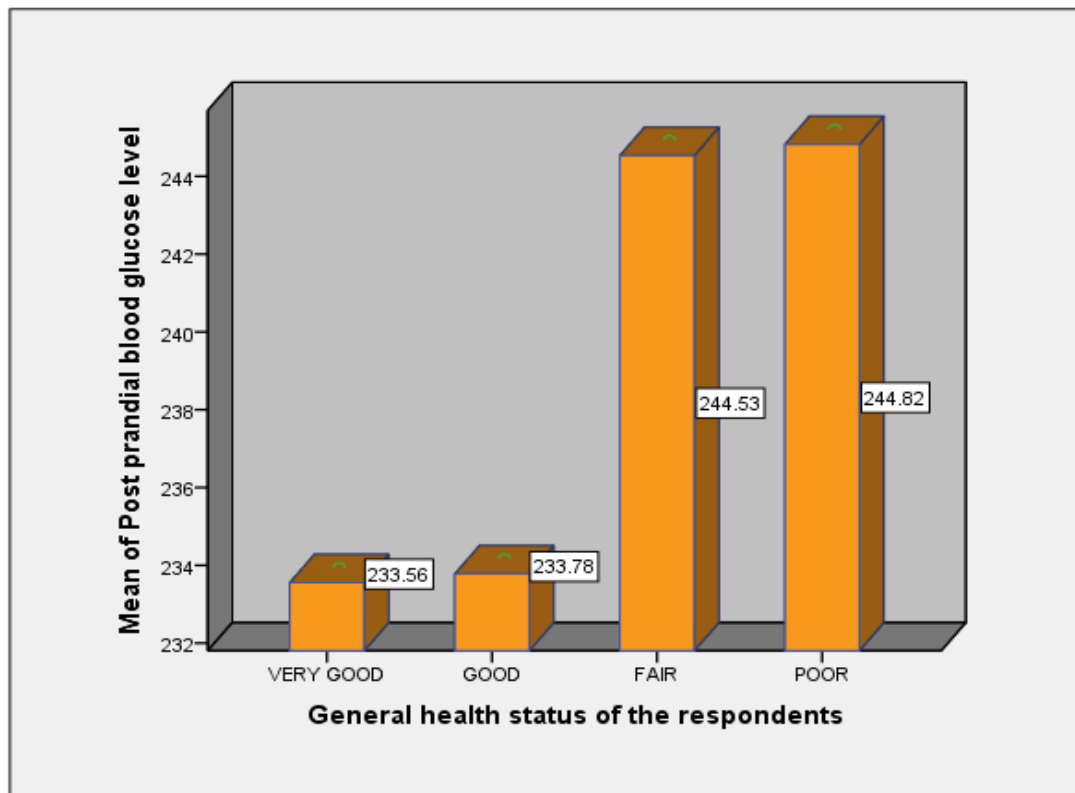


Figure 56. Mean postprandial blood glucose level of the respondents according general health status

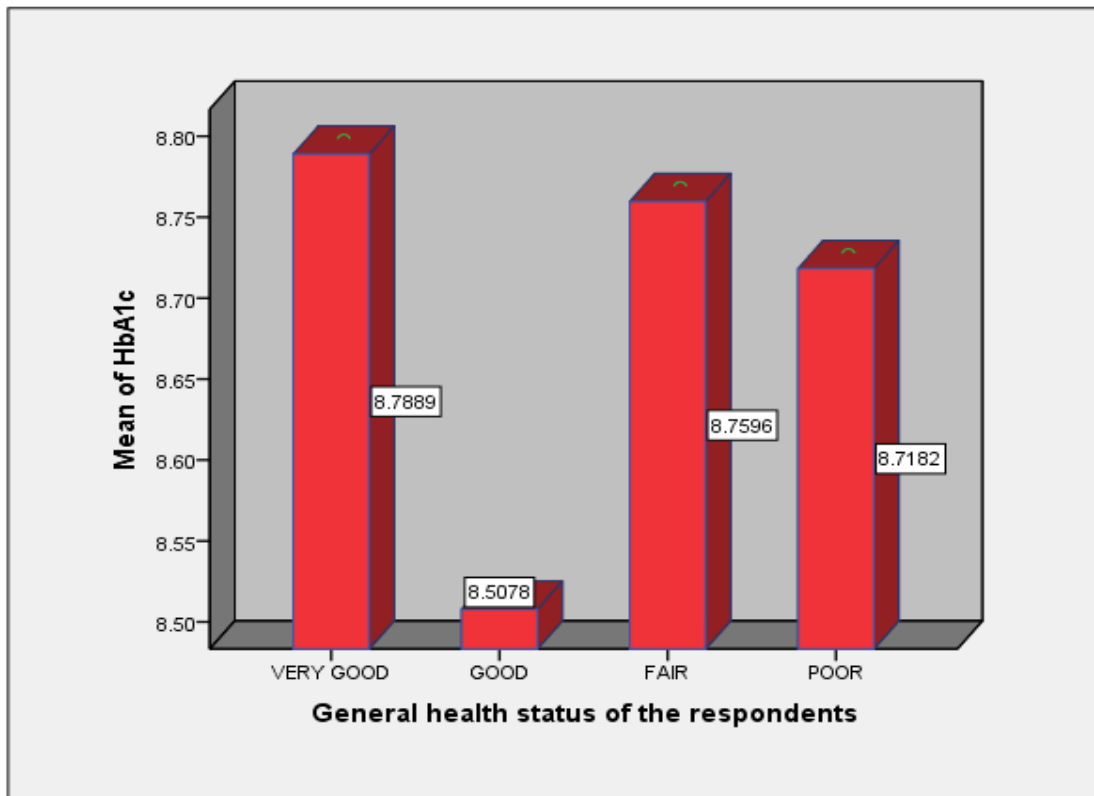


Figure 57. Mean HbA1c level of the respondents according general health status

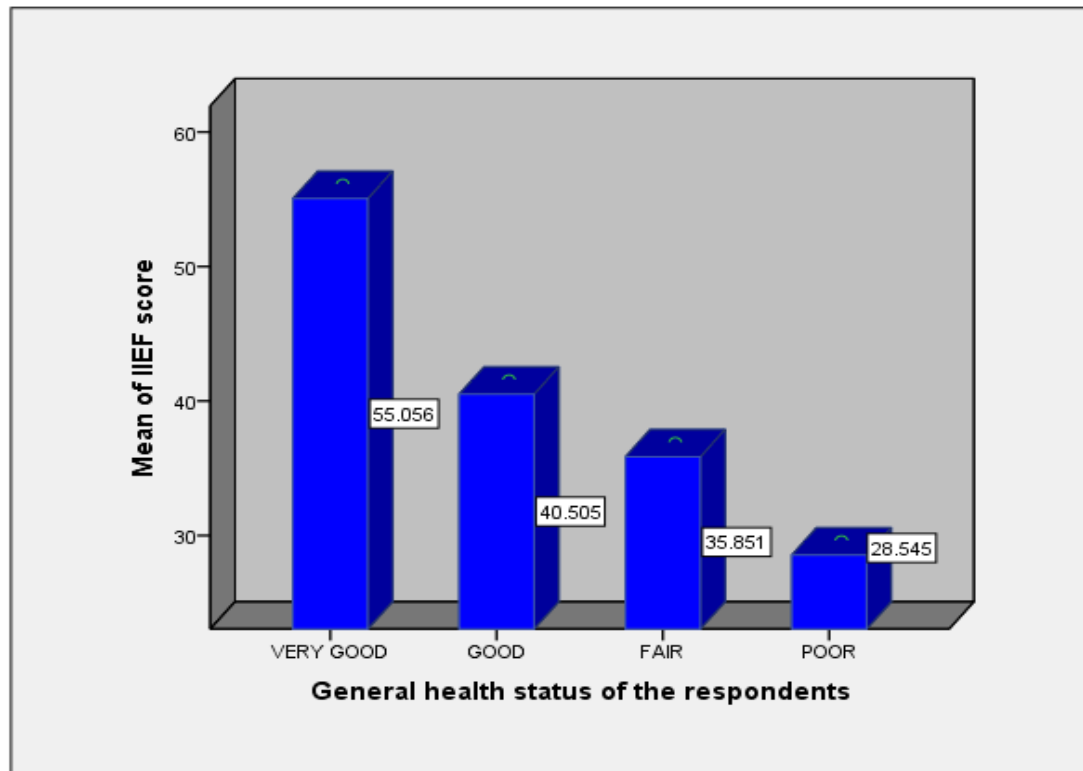


Figure 58. Mean IIEF score of the respondents according general health status

Table 28 and figure 55, 56, 57, 58 shows the mean fasting blood glucose levels in patient’s general health status very good, good, fair and poor were 172 mg/dl, 161 mg/dl, 174 mg/dl and 167 mg/dl. Mean postprandial blood glucose level were 233 mg/dl, 233 mg/dl, 244 mg/dl and 244 mg/dl respectively. Mean HbA1c levels were 8.78 per cent, 8.50 per cent, 8.76 per cent and 8.71 per cent respectively. The mean international index of erectile function (IIEF) were 55, 40, 35 and 28 respectively.

The mean of IIEF score was significantly higher in very good and good health status of the diabetic patients as compared to fair and poor health status patients. While non-significant difference in mean value of fasting, postprandial blood glucose level and HbA1c. So it may conclude that Type 2 diabetic male patient’s health status can effect on their IIEF score or on their sexual health. Harris, (2000) study the health care and health status and outcome for patients with Type 2 diabetes and found 42 per cent patients assessed their health status as fair or poor and conclude that health status and outcomes are unsatisfactory. Our studies shows about 20 per cent patients assessed their health status as fair and poor.

7.1.5.2 Feeling of tiredness by the Type 2 adult male diabetic patients and its impact on their blood glucose levels and IIEF score

Table 29. Feeling of tiredness by the respondents with mean blood glucose levels and IIEF score

Variables	Options	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Feeling of tiredness by the respondents	All of the Time	179 (63.5%)	167±60	239±74	8.82±2.1	35±11
	Some of the time	58 (20.6%)	167±67	240±89	8.11±1.6	47±10
	Hardly any time	25 (8.9%)	153±71	223±74	8.19±1.9	50±9*
	Never	20 (7.1%)	143±53	211±78	8.17±2.0	47±10

(* The mean difference is significant at the 0.05 level) (n=282)

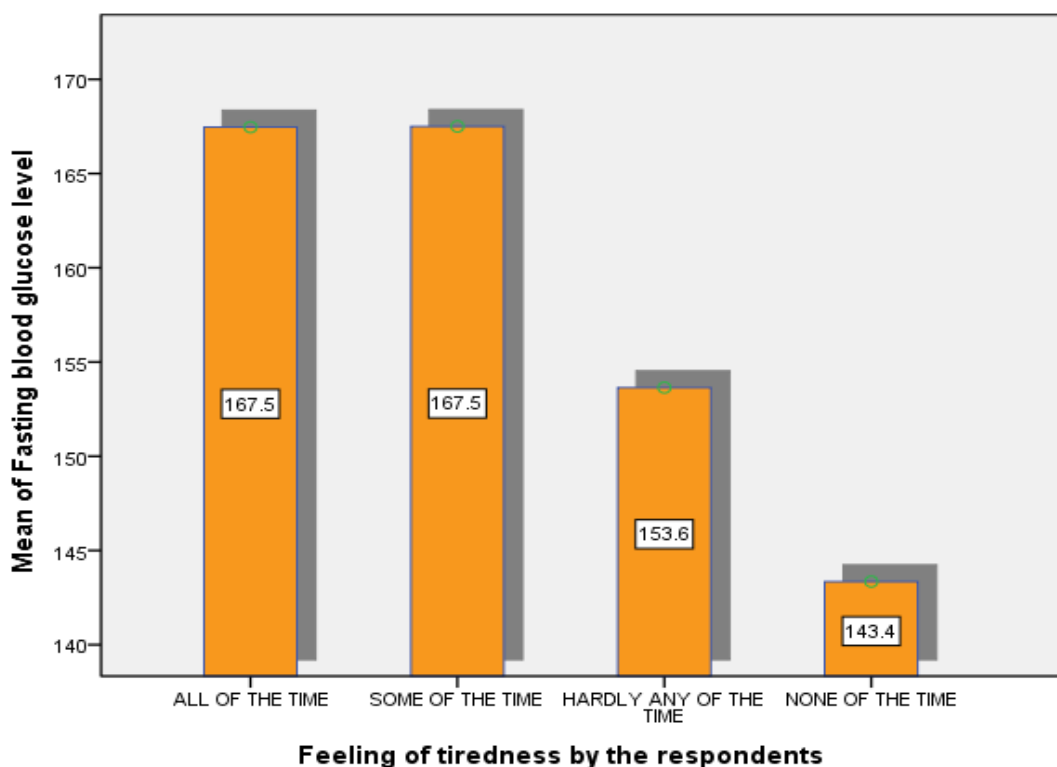


Figure 59. Mean fasting blood glucose level of the respondents according to feeling of tiredness

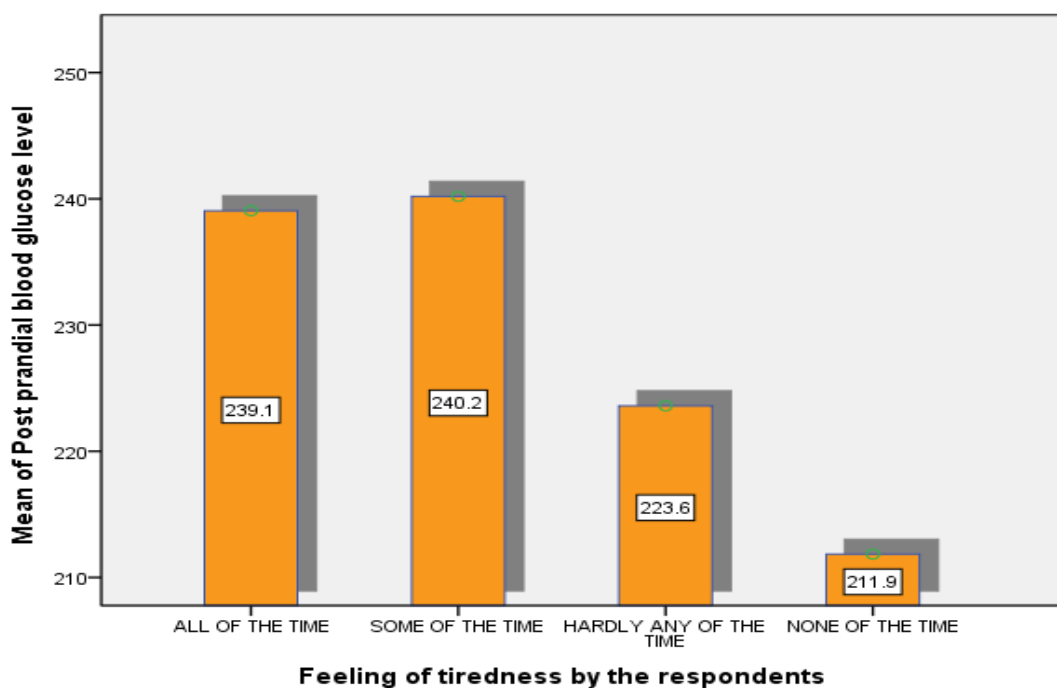


Figure 60. Mean postprandial blood glucose level of the respondents according to feeling of tiredness

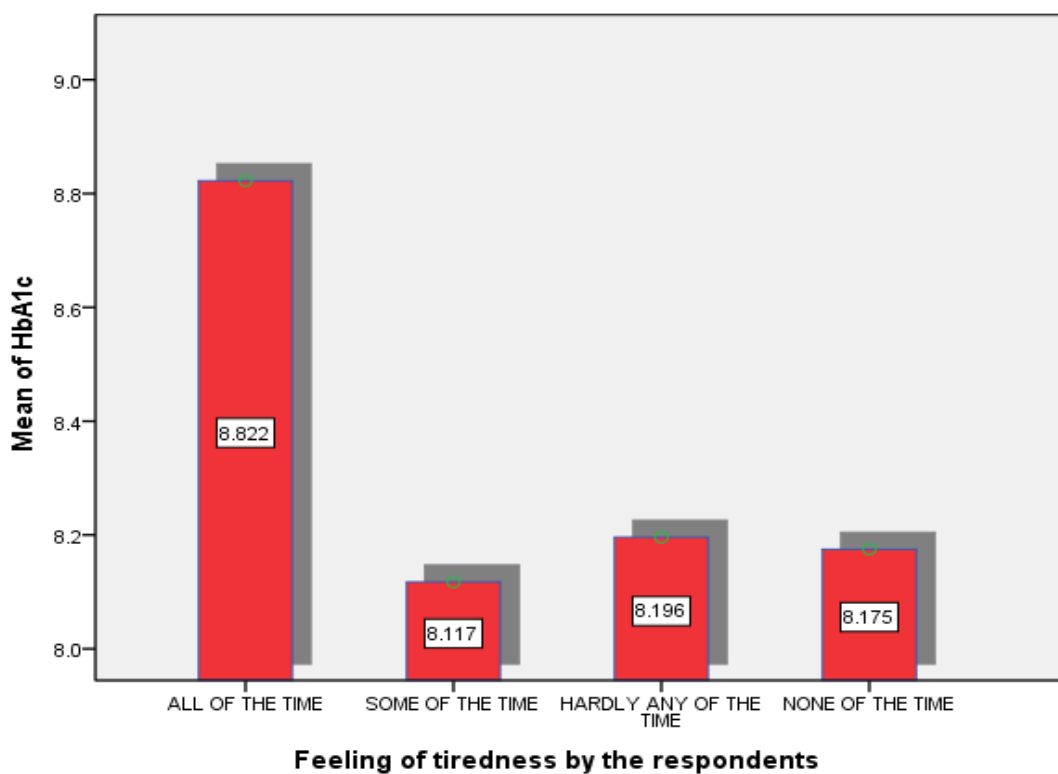


Figure 61. Mean HbA1c level of the respondents according to feeling of tiredness

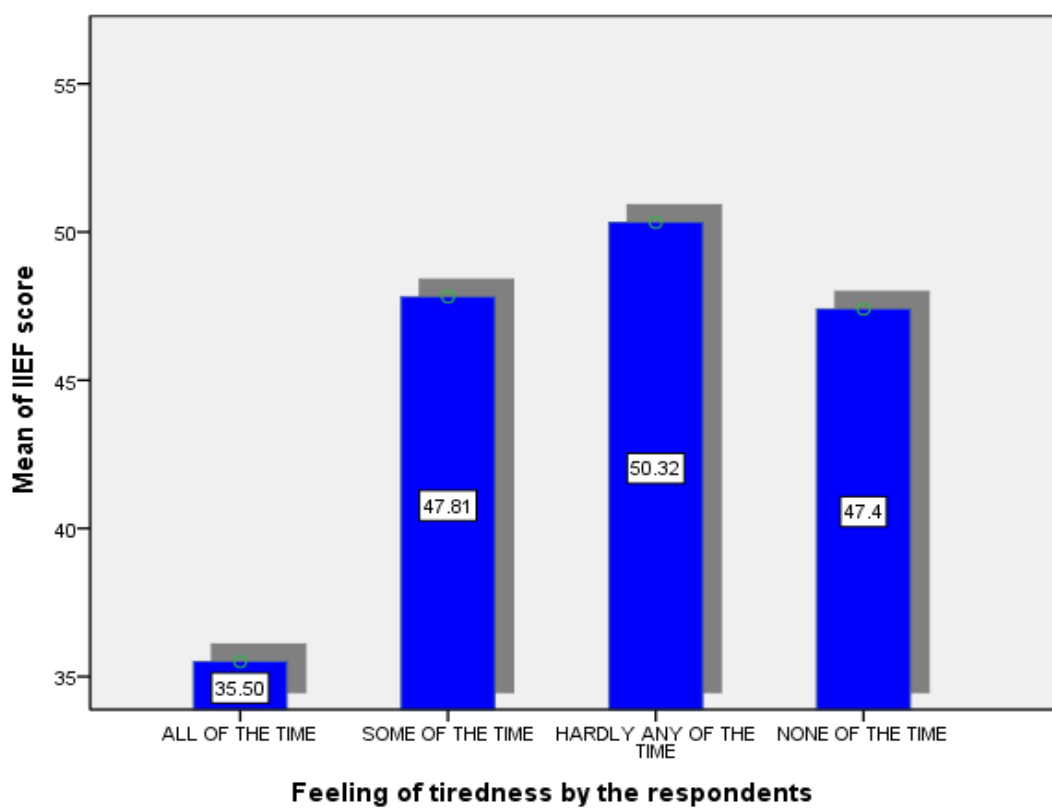


Figure 62. Mean IIEF score of the respondents according to feeling of tiredness

From the table 29 apparent that most of the respondents 63.5 per cent (n=179) feeling tired all of the time, 20.6 per cent (n=58) sometime feel tired, 8.9 per cent (n=25) patients feel tired hardly any of the time and 7.1 per cent (n=20) patients never feel tired. Table 29 and figure 59, 60, 61, 62 shows the mean fasting blood glucose levels in patient's feeling tiredness level all of the time, some of the time, hardly any time and never tired were 167 mg/dl, 167 mg/dl, 153 mg/dl and 143mg/dl. Mean postprandial blood glucose level were 239 mg/dl, 240 mg/dl, 223 mg/dl and 211 mg/dl respectively. Mean HbA1c levels were 8.82 per cent, 8.11 per cent, 8.19 per cent and 8.17 per cent respectively. The mean international index of erectile function (IIEF) were 35, 47, 50 and 47 respectively.

The IIEF score of hardly feel tired was significantly higher as compared to all time feel tiredness. While there were non-significant difference in mean fasting, postprandial blood glucose values and HbA1c in the groups. So it may conclude that Type 2 diabetic male patient's energy level/ feeling of tiredness effect on IIEF score or on their sexual health. Park et al, (2015) find that fatigue is indirectly related to glucose control, but only in patients who have elevated HbA1c levels and also stated that number and severity of diabetes symptoms were the strongest predictors of fatigue.

7.1.6 General Information of the Type 2 adult male diabetic patients

General information regarding diabetes mellitus such as blood glucose monitoring habits, event of hypoglycaemia, fluctuation in glucose level, medicine and drug detail discussed.

7.1.6.1 Age at time of marriage of the respondents and its impact on blood glucose level and IIEF score

The table 30 data shows that the marriage age of (n=282) subjects, maximum subject 48.9 per cent (n=138) got marriage at the age group of 21-25 years, then 27 per cent (n=86) at the age group 26-30 years, 5 per cent (n=14) subjects at the age group 31-35 years and 19.1 per cent (n=54) got married at under age before the minimum legal age of marriage of 21 years, 1.4 per cent (n=4) at age group 11-15

years and 17.7 per cent (n=50) at the age group 16-20 years. The mean marriage age was 23.87 ± 3.97 years.

Table 30. Age at marriage (Age group wise) of the respondents with mean blood glucose levels and IIEF score

Variables	Age at marriage	Number (%age)	Mean \pm SD FBG (mg/dl)	Mean \pm SD PPBG (mg/dl)	Mean \pm SD HbA1c (%)	Mean \pm SD IIEF
Age at marriage (Age group wise)	11-15 Years	4 (1.4%)	159 \pm 18	244 \pm 42	8.3 \pm 1.9	32 \pm 14
	16-20 Years	50 (17.7%)	164 \pm 71	242 \pm 85	8.2 \pm 2.2	37 \pm 11
	21-25 Years	138 (48.9%)	168 \pm 65	239 \pm 83	8.8 \pm 1.9	40 \pm 12
	26-30 Years	76 (27%)	159 \pm 53	226 \pm 64	8.3 \pm 2.0	42 \pm 12
	31-35 Years	14 (5%)	156 \pm 58	227 \pm 72	8.3 \pm 2.1	38 \pm 14

(* The mean difference is significant at the 0.05 level) (n=282)

According to National Family Health Survey (NFHS-4) 2015-2016 report of India the mean marriage age is 24.5 years which is similar with our study. NFHS-4 data show 26 per cent men marriage at age before the minimum legal age of marriage of 21 years while our study data show that 19 per cent respondents marriage before the legal marriage age.

The table 30 and figure 63, 64, 65, 66 shows that mean fasting blood glucose levels in different marriageable age groups 11-15 years, 16-20 years, 21-25 years, 26-30 years and 31-35 years were 159 mg/dl, 164 mg/dl, 168 mg/dl, 159 mg/dl and 156 mg/dl respectively. Mean postprandial blood glucose level were 244 mg/dl, 242 mg/dl, 239 mg/dl, 226 mg/dl and 227 mg/dl respectively.

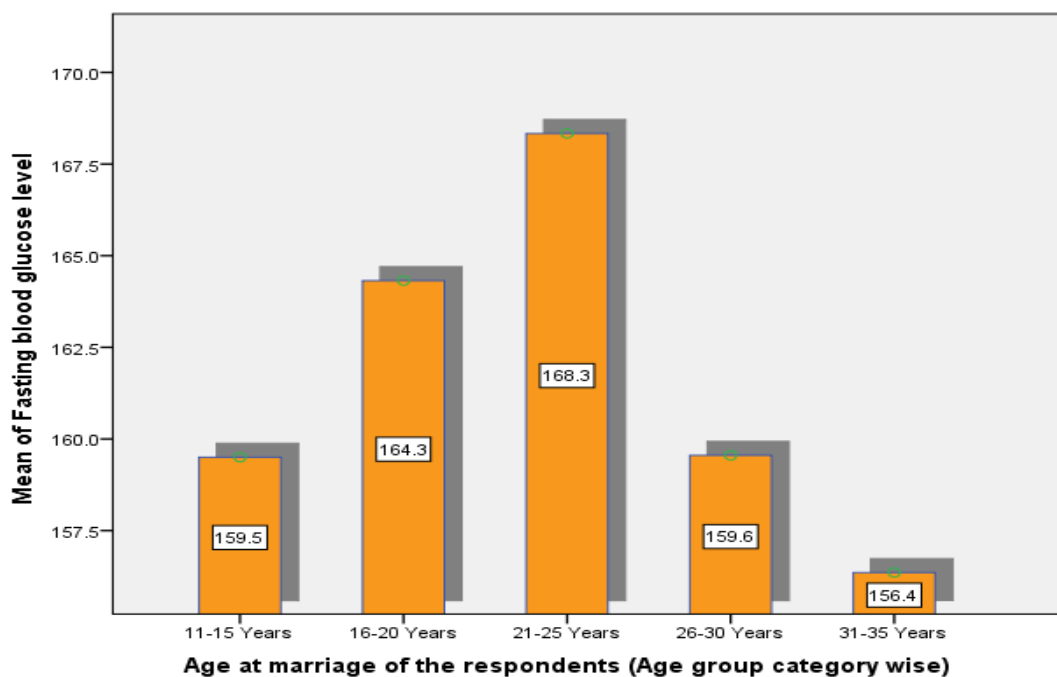


Figure 63. Mean fasting blood glucose level of the respondents according to age at marriage

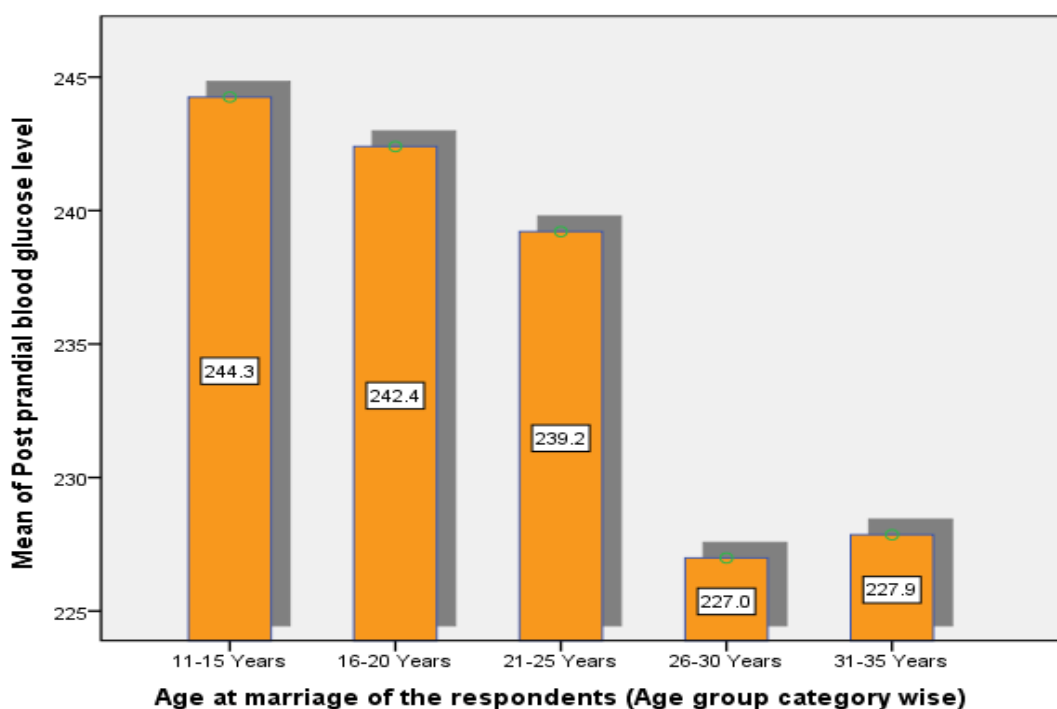


Figure 64. Mean postprandial blood glucose level of the respondents according to age at marriage

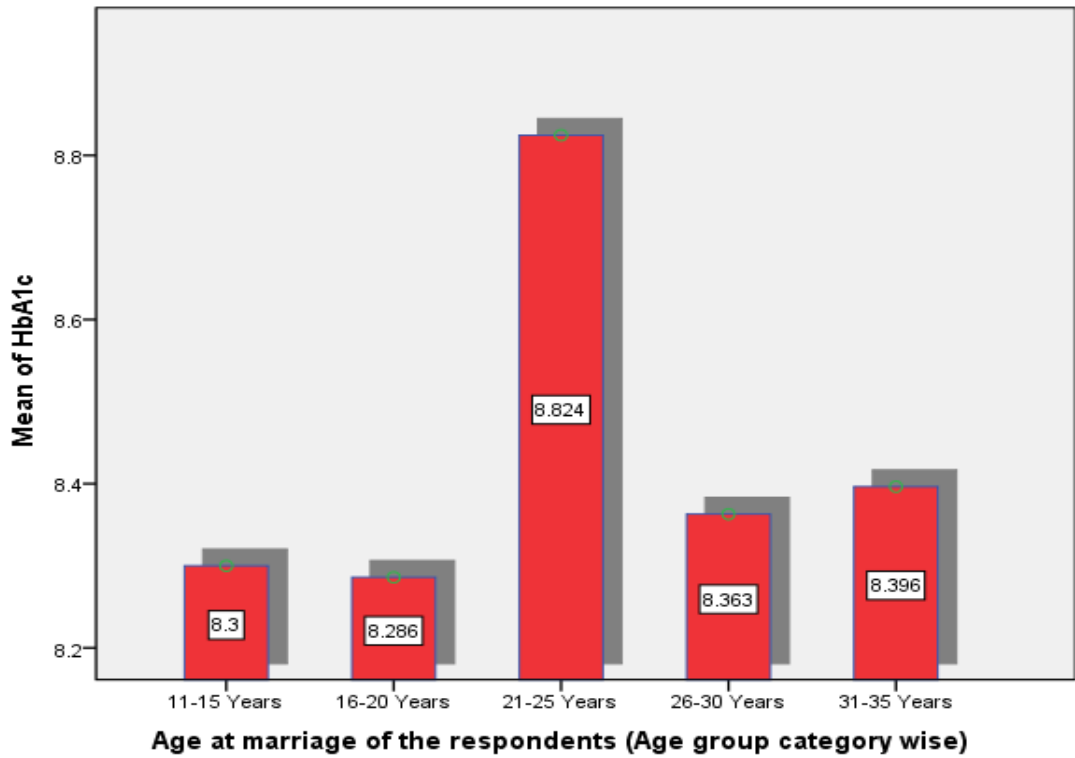


Figure 65. Mean HbA1c level of the respondents according to age at marriage

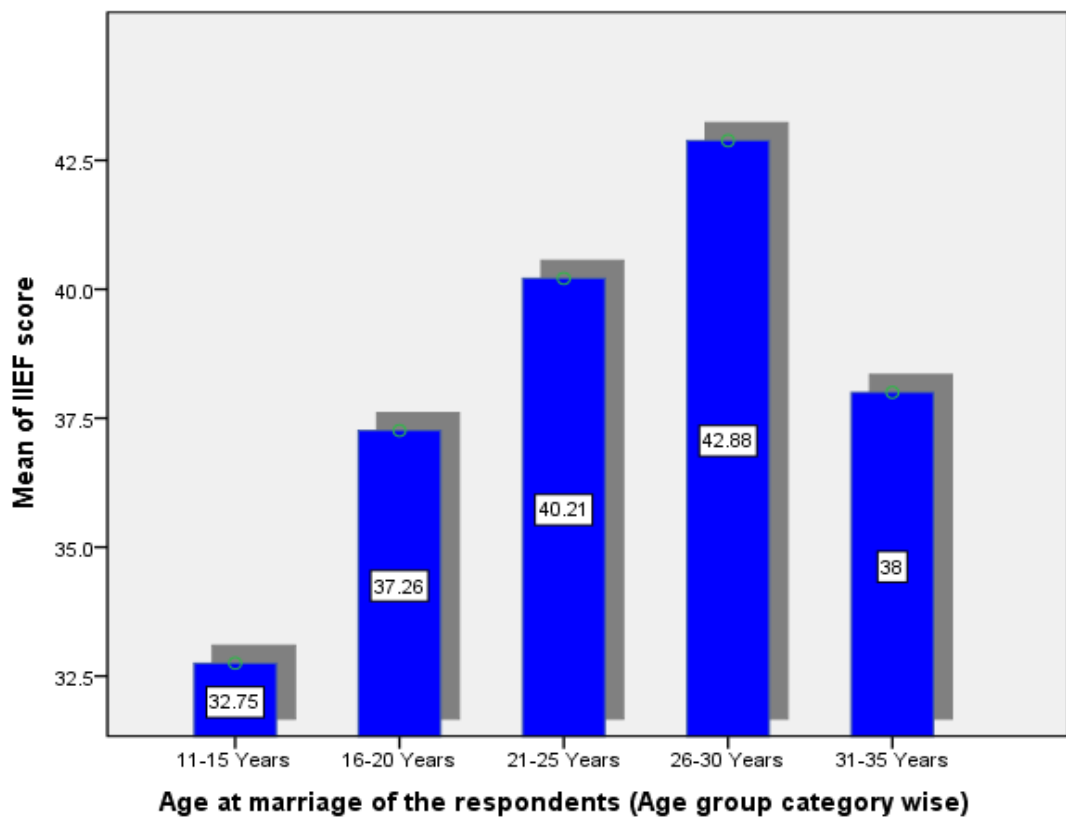


Figure 66. Mean IIEF score of the respondents according to age at marriage

Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults:

A randomized controlled trial

Mean HbA1c levels were 8.3 per cent, 8.2 per cent, 8.8 per cent, 8.3 per cent and 8.3 per cent respectively. The mean international index of erectile function (IIEF) were 32, 37, 40, 42 and 38 respectively. There were non-significant difference in mean of fasting, postprandial blood glucose, HbA1c level and IIEF score in the groups.

7.1.6.2 Age onset of diabetes (Age group wise) of the respondents and its impact on blood glucose levels and IIEF score

Table 31. Age onset of diabetes (Age group wise) of the respondents with mean blood glucose levels and IIEF score

Variables	Age onset of diabetes	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Age onset of Diabetes (Age group category wise) of the respondents	21-33 Years	50 (17.7%)	172±46	249±63	9.4±2.3	41±13
	34-42 Years	78 (27.7%)	166±57	245±74	8.5±1.8	40±12
	43-51 Years	108 (38.3%)	168±73	236±87	8.5±1.9	40±11
	52-60 Years	46 (16.3%)	144±53	204±67*	7.8±1.9*	37±14

(n=282) (* The mean difference is significant at the 0.05 level)

The table 31 shows that the age onset of diabetes mellitus among (n=282) subjects were, maximum subject 38.3 per cent (n=108) got diabetes in the age group of 43-51 years, then 27.7 per cent (n=78) from the age group 34-42 years, 17.7 per cent (n=50) subjects from the age group 21-33 years and 16.3 per cent (n=46) from the age group 52-60 years. The mean age onset of diabetes was 42.61±8.3 years.

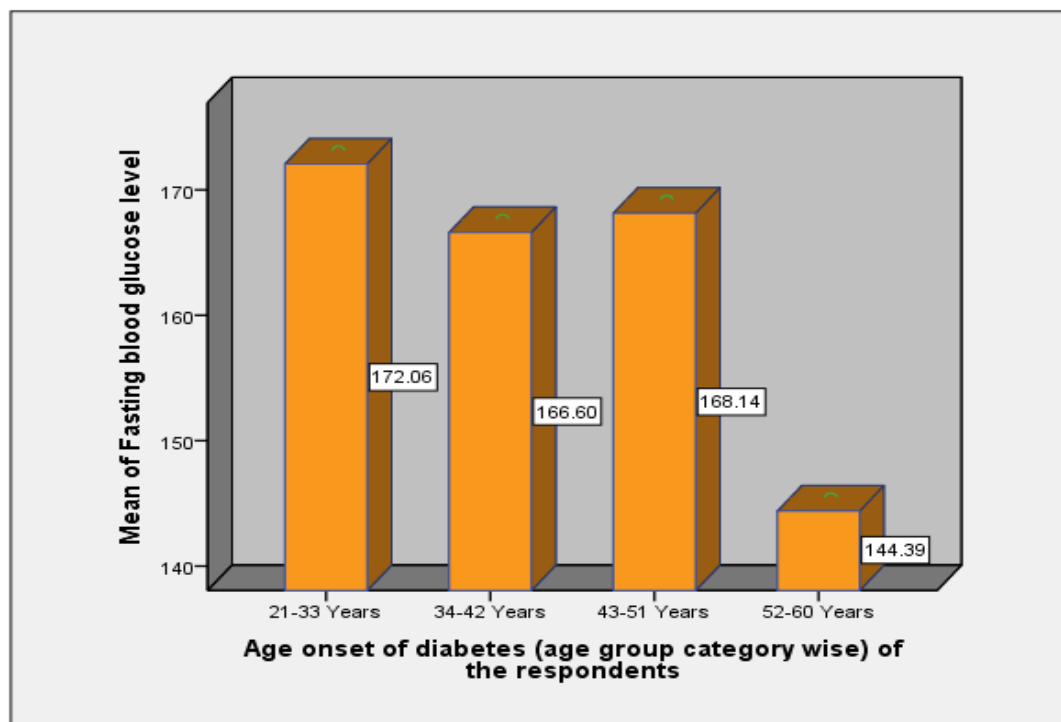


Figure 67. Mean fasting blood glucose level of the respondents according to age onset of diabetes

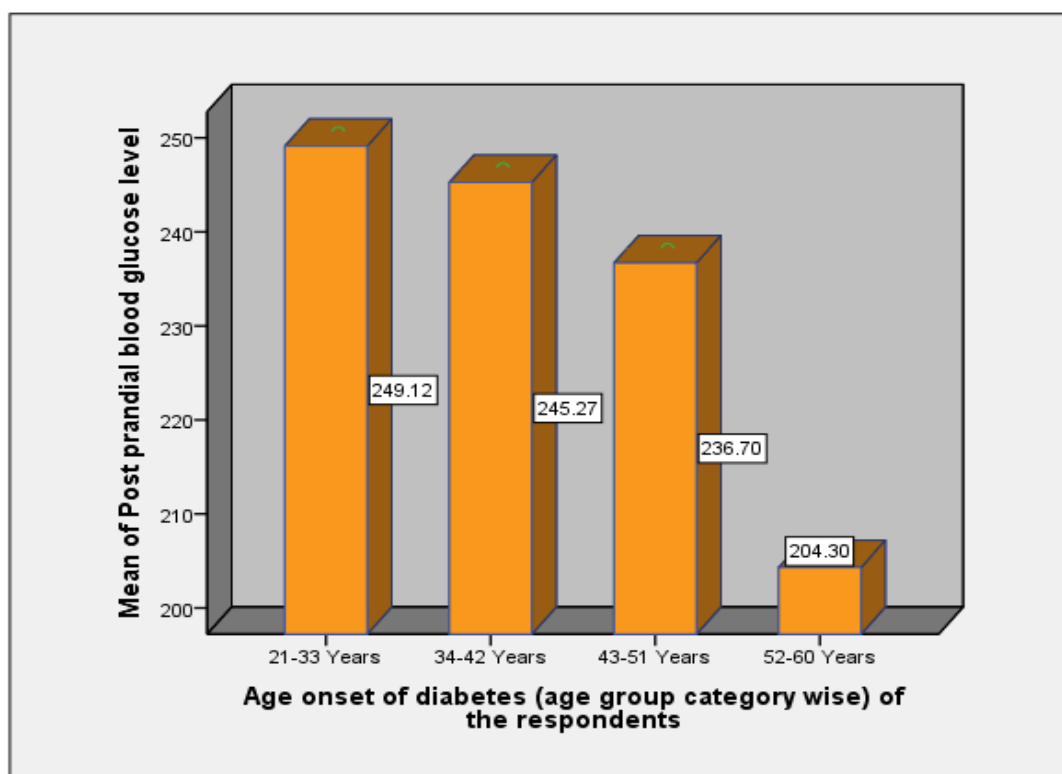


Figure 68. Mean postprandial blood glucose level of the respondents according to age onset of diabetes

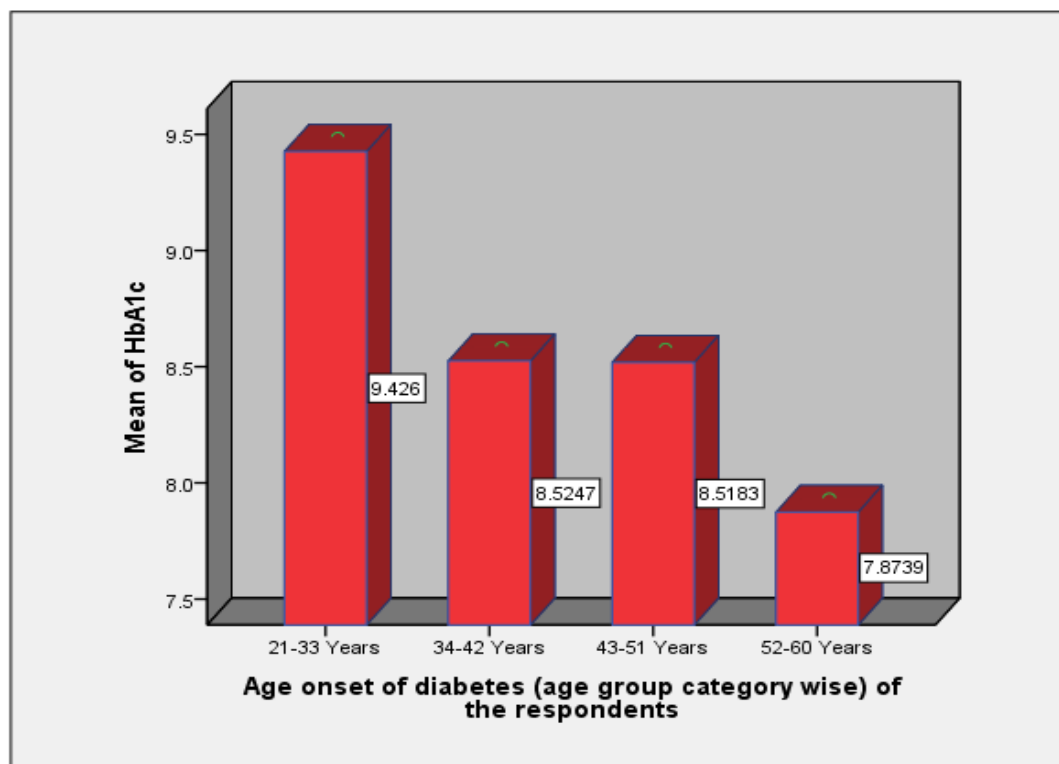


Figure 69. Mean HbA1c level of the respondents according to age onset of diabetes

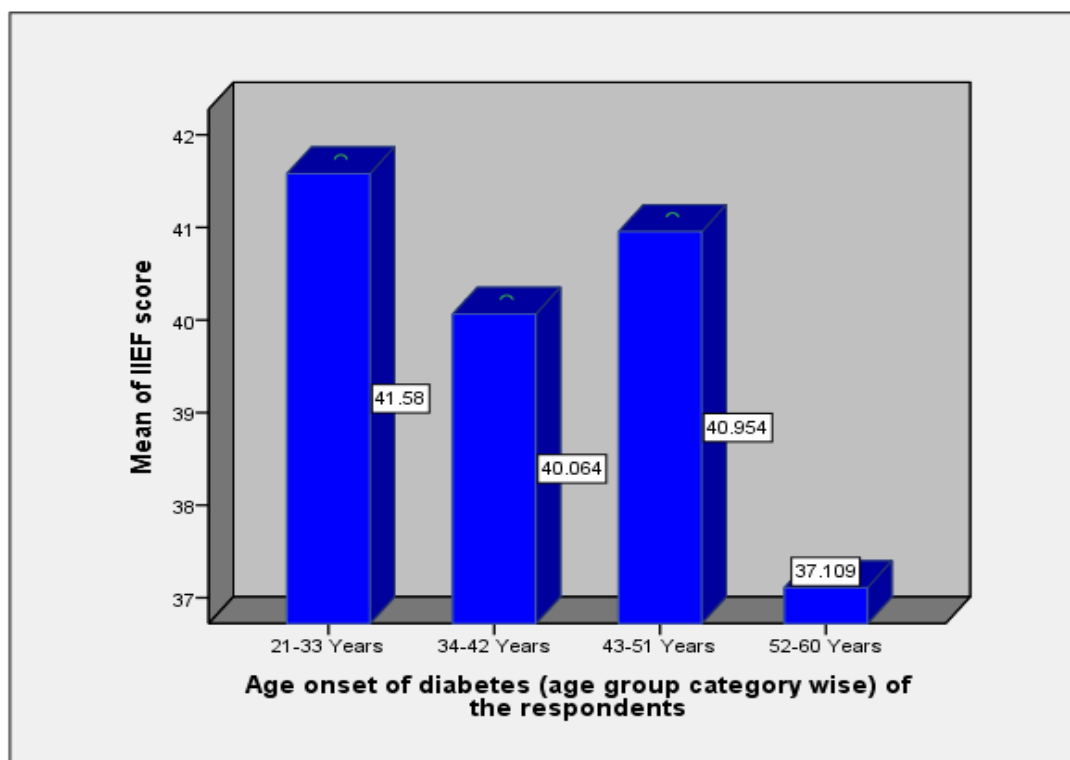


Figure 70. Mean IIEF score of the respondents according to age onset of diabetes

Table 31 and figure 67, 68, 69, 70 shows the mean fasting blood glucose levels in age onset of diabetes in different age group 21-33 years, 34-42 years, 43-51 years and 52-60 years were 172 mg/dl, 166 mg/dl, 168 mg/dl and 144 mg/dl respectively. Mean postprandial blood glucose level were 249 mg/dl, 245 mg/dl, 236 mg/dl and 204 mg/dl respectively. Mean HbA1c levels were 9.4 per cent, 8.5 per cent, 8.5 per cent, and 7.8 per cent respectively. The mean international index of erectile function (IIEF) were 41, 40, 40 and 37 respectively.

The mean postprandial blood glucose and HbA1c level of older age group (52-60) years patients were significantly lower as compared to younger age group (21-33) years. While non-significant difference in mean of fasting blood glucose level and IIEF score in all the groups. It may concluded from the data that the patients age onset of diabetes in older age have better control over their postprandial blood glucose and HbA1c levels. A study done by Al-Saeed et al, (2016) also gives similar result as our study revealed that the negative effect of diabetes on morbidity and mortality is greatest for those diagnosed at a young age compared with Type 2 diabetes mellitus of usual onset.

7.1.6.3 Diabetes related knowledge of the respondents

Table 32. Diabetes related knowledge of the respondents (Type 2 diabetic patients)

Variables	Number (%age)
Mean Age of onset of diabetes (Years)	42.61±8.3
Blood Glucose Monitored Regularly	180 (63.8%)
Ever had Hypoglycemia	34 (12.1%)
Glucose Fluctuation	62 (22%)
Medicine for Diabetes	260 (92.2%)
Regularity in Medicine intake	227 (80.5%)
Insulin intake	73 (25.9%)

The table 32 data shows that the mean age onset of diabetes was 42.61±8.3 years. Out of (n=282) respondent 63.8 per cent (n=180) were check their sugar levels regularly. Twelve per cent (n=34) respondent have experience of hypoglycaemia, 22 per cent (n=62) patients have fluctuation in their blood glucose level. Among (n=282) respondent maximum 92.2 per cent (n=260) take medicine to treat their diabetes mellitus and 80.5 per cent (n=227) take their medicine regularly. 25.9 per cent (n=73) patients take insulin along with OHA to treat diabetes. Study done by Patel et al, (2012) state that only 37 per cent subject self-monitor of blood glucose level. In our study sample it was 63.8 per cent.

7.1.6.4 Prevalence of symptoms of diabetes in patients (Type 2 adult male)

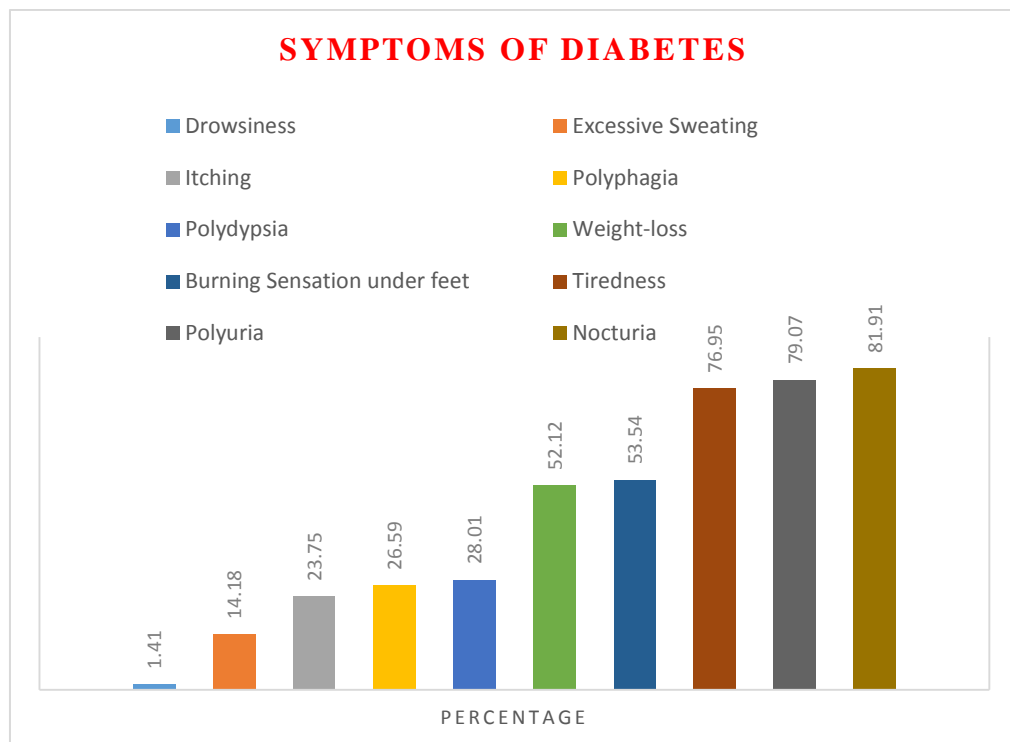


Figure 71. Prevalence of symptoms of diabetes mellitus in Type 2 adult male diabetic patients (n=282)

Figure 71 revealed that the most common symptom observed in the selected subjects (n=282) was Nocturia 81.91 per cent (n=231), Polyuria 79.07 per cent (n=223), Tiredness 76.95 per cent (n=217), followed by burning sensation under feet 53.54 per cent (n=151), weight loss during disease 52.12 per cent (n=147), Polydypsia 28.01 per cent (n=79), polyphagia 26.59 per cent (n=75), itching 26.59 per cent (n=67), excessive sweating 14.18 per cent (n=40) and least symptom drowsiness 1.41 per cent (n=4).

These were the symptoms present in the respondents while we collect data at baseline. All the respondents were on their regular treatment which they receiving in OPDs. These manifestations are due to constant hyperglycemia and hyper molar lesions due to sorbitol accumulation (Malone et al, 1984; Bareford et al, 1986; Hosojima, 2002). These symptoms were presents in our study population when they were on their regular treatment with OHA and insulin. It shows overall awareness and treatment and control over symptoms were low in our study sample.

7.1.6.5 Mean nutrient intake of the respondents

The table 33 revealed data about mean nutrient intake by the Type 2 adult male diabetic patients. The average daily energy intake of respondents were 1805 ± 327 kcal, daily protein intake was 62 ± 11 gm. The average mean carbohydrates intake was 252 ± 57 gram. The weight mean of the respondent was 71.83 ± 13.03 kg.

Table 33. Mean nutrient intake by the respondents

Nutrient	Mean \pm SD
Energy (kcal)	1805 ± 327
Protein (gm.)	62 ± 11
Carbohydrates (gm.)	252 ± 57
Weight (kg.)	71.83 ± 13.03

(n=282)

The normal energy requirement of the patients (25 kcal per kg body weight) 1795 kcal, which is very close to daily energy consumption. The normal protein allowance is 1 gm. /kg body weight. In our sample mean weight was 71.83 kg protein intake was 62 gm., so our sample mean protein consumption 0.87 gm. per kg body weight, which is about 14 per cent less than the normal daily intake of protein. Which was calculated.

Food balance data form the Food and Agriculture Organization (FAO) shows that the change in energy intake in Asian countries have been small but there have been large changes in consumption of animal product, sugar and fats. Joshi et al., (2012) revealed that the carbohydrates is the main source of energy in Indian diets, the percentage of total energy intake taken from carbohydrates has declined from 80.3 per cent in 1979 to 75.5 per cent in 2001. The quality of carbohydrates has also changed from the traditional high-fiber or complex carbohydrates to the low-fiber (refined) carbohydrates such as polished white rice, and refined flours. There is also an increase in the percentage of energy coming from dietary fats in 1979 at 8.9 per cent and in 2001 it shows at 13.9 per cent.

A study done by Joshi et al, (2014) shows that carbohydrates constitutes 64.1 per cent of total energy from diet in the Type 2 diabetes mellitus patients, which is higher the recommended level. Carbohydrates intake for diabetic patients as per Nation Institute of Nutrition is 50-60 per cent of total calorie from carbohydrates (preferably form complex carbohydrates). In our sample carbohydrates consumption is 12 per cent high. Kaur et al, (2009) study data shows that energy intake by Non-insulin dependent diabetic mellitus patients was adequate which is quite similar with our study findings.

7.1.7 Sexual dysfunction in the Type 2 adult male diabetic patients

7.1.7.1 Prevalence of sexual dysfunction in the respondents and its impact on blood glucose levels and IIEF score

Total (n=282) adult male Type 2 diabetic patients attending endocrinology OPDs of PGIMER, Chandigarh, assess for prevalence of sexual dysfunction.

Table 34. Prevalence of sexual dysfunction according to (self-reported) the respondents with mean blood glucose levels and IIEF score

Variables	Options	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Prevalence of sexual dysfunction (self-reported)	Yes	228 (80.9%)	167±61	238±78	8.5±1.9	36±11
	No	54 (19.1%)	153±65	223±76	8.5±2.2	55±4*

(* The mean difference is significant at the 0.05 level) (n=282)

Table 35. Prevalence of sexual dysfunction according to IIEF score in the respondents with mean blood glucose levels and IIEF score

Variables	Options	Number (%age)	Mean±SD FBG (mg/dl)	Mean±SD PPBG (mg/dl)	Mean±SD HbA1c (%)	Mean±SD IIEF
Prevalence of sexual dysfunction (With IIEF score)	Yes (IIEF <50)	222 (78.7%)	167±61	240±78	8.6±1.9	35±10
	No (IIEF >50)	60 (21.3%)	152±63	217±75*	8.4±2.2	56±3*

(* The mean difference is significant at the 0.05 level) (n=282)

Table 34 and 35 data shows about prevalence of sexual dysfunction in our study population (Type 2 adult male diabetic patients). We have checked the prevalence in two ways. First we asked respondents regarding presence of any sexual dysfunction (Self-reported). Secondly we filled International Index of Erectile function questionnaire (15 questions) and got the scores. (Total 75) we divided IIEF score <50 positive for sexual dysfunction and >50 negative for sexual dysfunction. Both the analytical methods gives about same values. Prevalence of sexual dysfunction analysis with IIEF score is discussed.

The table no 35 data shows that 78.7 per cent (n=222) patients have sexual dysfunction and 21.3 per cent (n=60) patients do not have any sexual dysfunction. Data show the prevalence of sexual dysfunction was 78.7 per cent in Type 2 adult male diabetic patients. Table 35 and figure 72, 73, 74, 75 shows the mean fasting blood glucose levels in patients with sexual dysfunction was 167 mg/dl and patients without any sexual dysfunction was 152 mg/dl. Mean postprandial blood glucose level were 240 mg/dl and 217 mg/dl respectively. Mean HbA1c levels were 8.6 per cent and 8.4 per cent respectively. The mean international index of erectile function (IIEF) were 35 and 56 respectively.

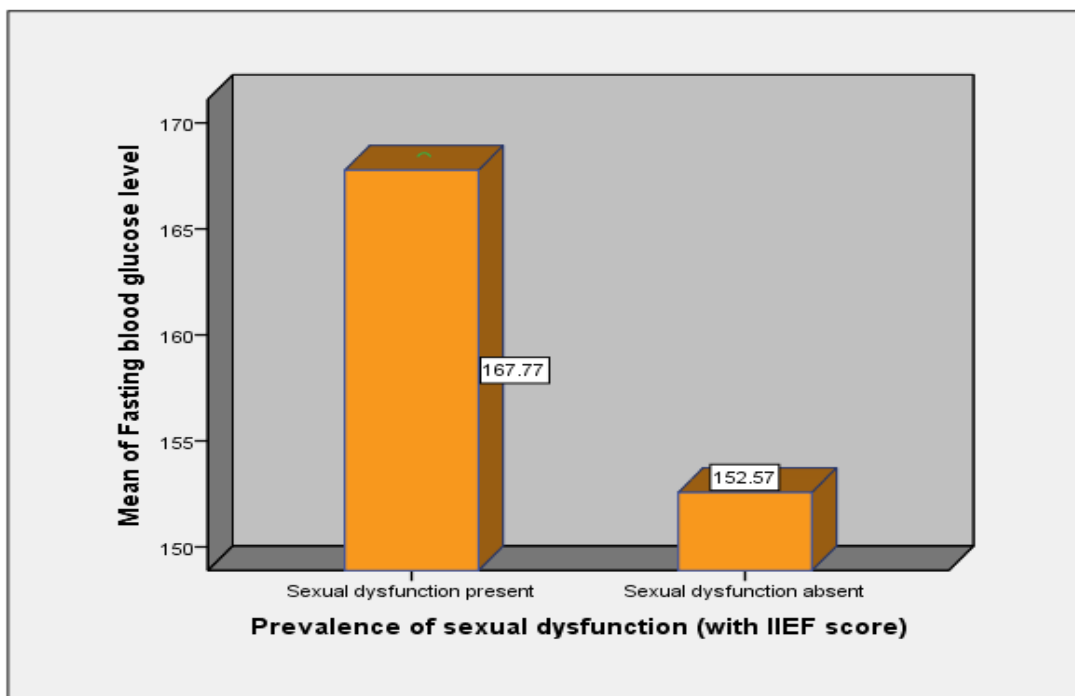


Figure 72. Mean fasting blood glucose level of the respondents according to prevalence of sexual dysfunction

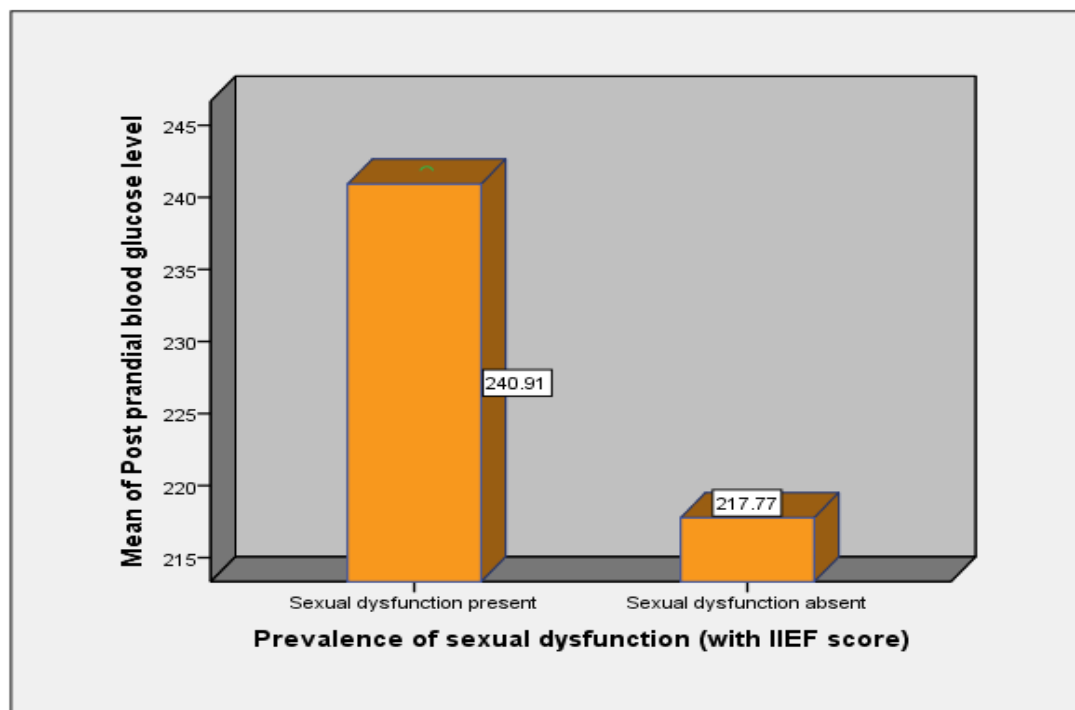


Figure 73. Mean postprandial blood glucose level of the respondents according to prevalence of sexual dysfunction

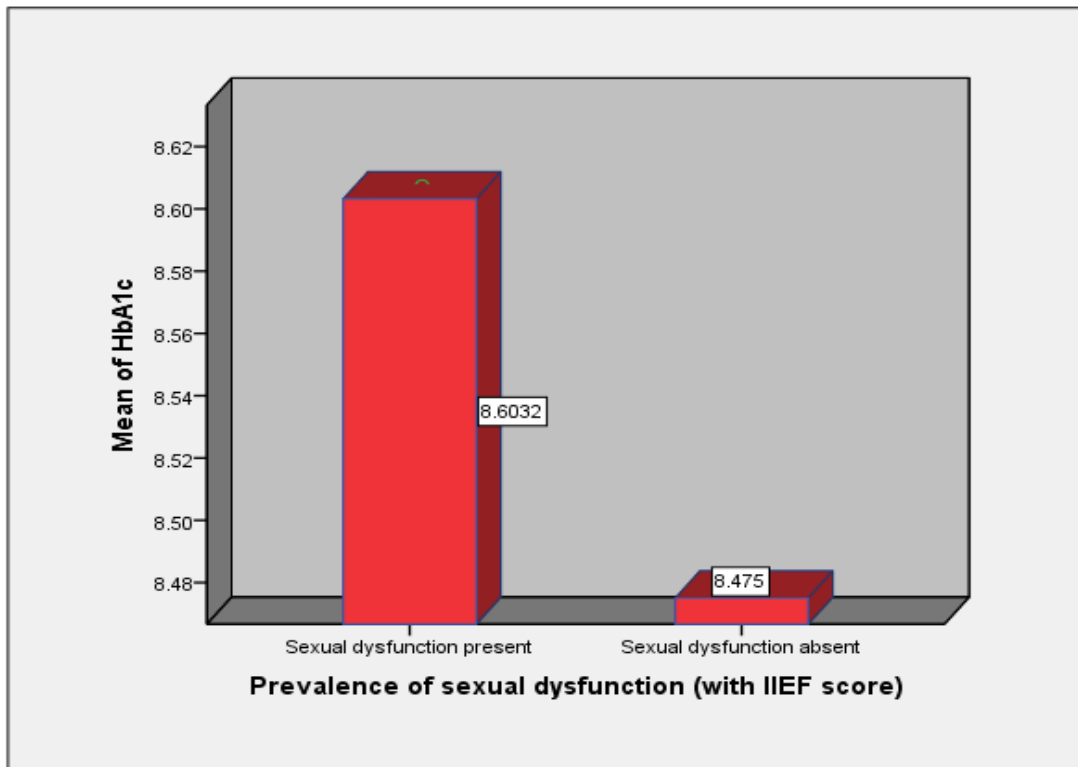


Figure 74. Mean HbA1c level of the respondents according to prevalence of sexual dysfunction

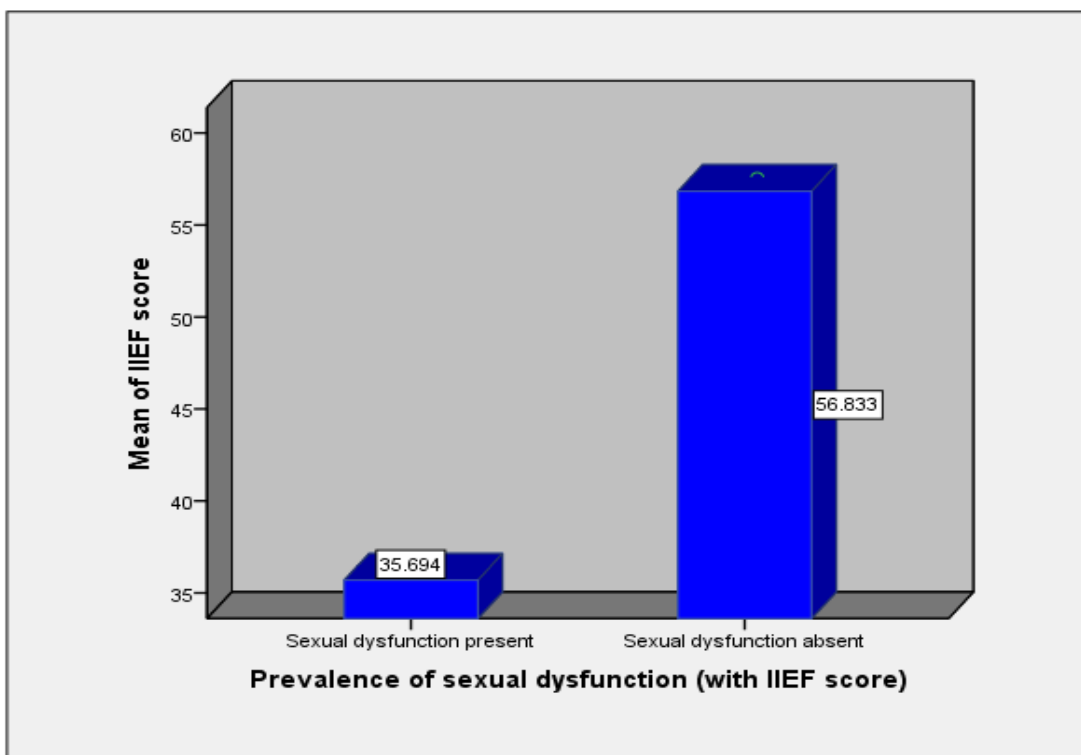


Figure 75. Mean IIEF score of the respondents according to prevalence of sexual dysfunction

The mean postprandial blood glucose level was significantly low and mean IIEF score was significantly high in patients without sexual dysfunction as compared to patients with sexual dysfunction. While there was non-significant difference between mean value of fasting blood glucose and HbA1c levels in both groups. So it may concluded from the data that the Type 2 adult male diabetic patients without sexual dysfunction have good control over their blood glucose levels and high IIEF score.

In another study for males, the average prevalence rate of sexual dysfunction was 74 per cent (Balde et al, 2006; McCulloch et al, 2009). Which is quite similar with our study. Study done by Ziaei et al, (2010) in Iran showed prevalence rate of sexual dysfunctions were 77 per cent in diabetic male patients, which is very close to our study. Likata et al, (2012) study shows 65.1 per cent prevalence rate of sexual dysfunction in diabetic male patients.

7.1.7.2 Prevalence of sexual dysfunction in Type 2 adult male diabetic patients according to age group category

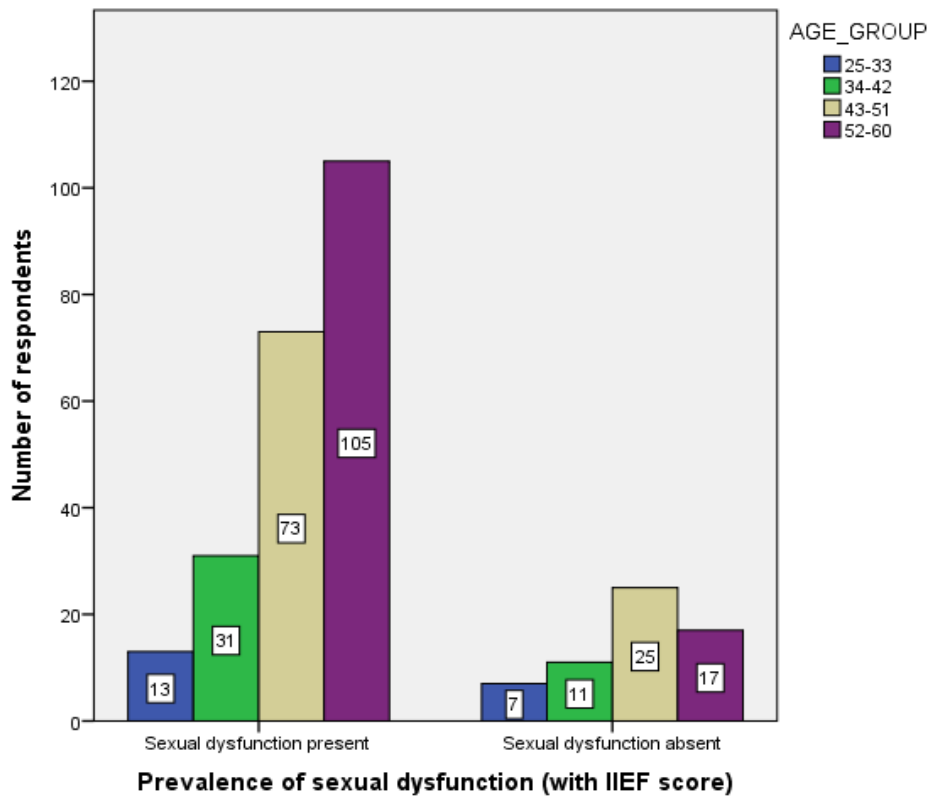


Figure 76. Prevalence of sexual dysfunction in respondents according to age group

Figure 76 shows that prevalence of sexual dysfunction in diabetic patients were increasing with increase in age group of the respondents. The maximum respondents were from the age group 52-60 years 37.2 per cent (n=105), 25.9 per cent (n=73) from the age group 43-51years, 11 per cent (n=31) from 34-42 years the age group and only 4.6 per cent (n=13) from the youngest age group 25-33 years.

7.1.7.3 Types of sexual dysfunction in the respondents

There are mainly three type of sexual dysfunction commonly found in male. Type of sexual dysfunction in Type 2 diabetic male adults in our study population were discussed.

Table 36. Types of sexual dysfunction in the respondents

Variables	Options	Number (%age)
Type of sexual dysfunction	Premature ejaculation (PE)	111 (48.64%)
	Erectile dysfunction (ED)	187 (82.01%)
	No interest in sex	67 (29.38%)
Number of sexual dysfunction subject have	Only one sexual dysfunction	129 (56.57%)
	Two sexual dysfunction	61 (26.75%)
	All three sexual dysfunction	38 (16.66%)

(n=222)

The table 36 data shows that the type of sexual dysfunction present in Type 2 adult diabetic patients were 48.64 per cent (n=111) patients have premature ejaculation, 82.01 per cent (n=187) have erectile dysfunction and 29.38 per cent (n=67) patients have no interest in sexual activity. 56.57 per cent (n=129) patients have only one sexual dysfunction, 26.75 per cent have two sexual dysfunctions and 16.66 per cent (n=38) have all three types of sexual dysfunctions.

It can be concluded from the table 36 data that Type 2 adult male diabetic patients have mainly three types of sexual dysfunction. Most of the patients have erectile dysfunction (82 per cent). Then premature ejaculation and last no interest in sex. Mostly 56.57 per cent patients have only one type of sexual dysfunction and 16 per cent patients have all three types of sexual dysfunctions.

The overall result of 1st objective that the reduced physical activity, attitude toward taking medicine, low level of overall education and aging are the factors which affect the respondents of our study. A combination of these factors possibly contributes to the low level of awareness, treatment and control of diabetes mellitus in our study population. Health seeking behavior and more of increased blood glucose level due to low control to health care system, not taking proper drug, no exercise or less active and diet management problem (not follow diabetic diet) and high consumption of carbohydrates.

7.2: The 2nd objective, “To identify the treatment seeking behavior of sexual dysfunctions in diabetic patients”, attending endocrinology OPDs of PGIMER, Chandigarh.

Total 282 patients assessed for treatment seeking behavior regarding sexual dysfunction.

7.2.1 Treatment seeking behavior of sexual dysfunction by the respondents

Sexual dysfunction is very common in diabetic adult male patients. The treatment seeking behaviour of sexual dysfunction by Type 2 adult male diabetic patients.

Table 37. Treatment seeking behavior of the respondents

S. No	Variables	Options	Number (%age)
1.	Notice time of sexual dysfunction	Past Year 1-2 Years 3-4 Years 5 Years or more Do Not Know	107 (37.9%) 53 (18.8%) 18 (6.4%) 40 (14.2%) 4 (1.4%)
2.	From where taking treatment	Private hospital/ clinic Government hospital	12 (4.3%) 4 (1.4%)
3.	Treatment preference	Allopathic Nutritional therapy and Ayush	15 (5.3%) 1 (0.4%)
4.	Mean time for sexual dysfunction (years)		1.6±1.3
5.	Taking any treatment		25 (10.96%)

(n=222)

The table 37 reveals that among (n=222) respondents, 37.9 per cent (n=107) notice sexual dysfunction within past one year, 18.8 per cent (n=53) notice past one to two years, 6.4 per cent (n=18) noticed past 3-4 years, 14.2 per cent (n=40) respondents have noticed sexual dysfunction five or more than 5 years and 1.4 per cent (n=4) do not know when they have sexual dysfunction. 4.3 per cent (n=12) respondents were getting treatment form private hospital or clinic and 1.4 per cent (n=4) getting treatment for sexual dysfunction from government hospitals. 5.3 per cent (n=15) respondent preferred allopathic medicines for treating sexual dysfunction followed by only one (0.4 per cent) who believed in Ayush and nutritional therapy of treatment for sexual dysfunction. Mean time for sexual dysfunction was 1.6±1.3 years. Only about 11 per cent (n=25) person taking treatment for their sexual dysfunction.

Patients related barriers like lack of awareness, poor motivation, shy nature, economic constants, denying risk, stress, fear, confusion, immediate benefits not seen, lack of family and social support, lack of trust in medical care providers, changing behavior and sustaining the changes are difficult which result in neglect the management of sexual dysfunction. This also reflects in present study that more than 90 per cent sexual dysfunction patients were not consultation with their physician. A study done by Rahman et al, (2011) state that erectile dysfunction among common in men, however sexual dysfunction is not a health condition that patients would commonly discuss with their doctors despite the fact that they are already seeing doctors for various other medical reasons.

7.2.2 Treatment details for sexual dysfunction by the respondents

Table 38. Treatment details for sexual dysfunction by the respondents

Variables	Options	Number (%age)
Dr. asked about sexual dysfunction	Yes	8 (3.61%)
	No	157 (70.72%)
	Not answered	57 (25.67%)
Tried Viagra, Levitra or Cialis medicine	Yes	58 (26.12%)
	No	164 (73.87%)
Sexual medicine (Viagra) work to your satisfaction	Yes	26 (44.83%)
	No	32 (55.17%)

(n=222)

Table 38 data represents that among (n=222) sexual dysfunction in diabetic patients, only 3.51 per cent (n=8) were asked by doctor about their sexual dysfunction. 70.72 per cent (n=157) were never asked by physician regarding their sexual dysfunction and 25.67 per cent (n=57) were not answered about this. 26.12 per cent (n=58) were tried medicine like Viagra, Levitra or Cialis for their sexual dysfunction and rest 73.87 per cent (n=164) never tried any medicine for their sexual dysfunction. Among 58 participants who tried sexual dysfunction medicine, 44.83 per cent (n=26) were got beneficial affect or medicine work according to their satisfaction and 55.17 per cent (n=32) were not happy with the result of medicine they tried for their sexual dysfunction.

7.2.3 Age of 1st sexual experience had by the respondents

Table 39 data shows age group of the respondents when they had their first experience of having sex. Subjects start their first experience of having sex at age group 11-15 years were 7.8 per cent (n=22), 34 per cent (n=96) had their 1st experience at age group 16-20 years, maximum respondents 41.5 per cent (n=117) had their first sexual experience at the age group 21-25 years, 15.2 per cent (n=43) had at the age group 26-30 years and only 1.4 per cent (n=4) had their first sexual experience at the age group 31-35 years. The mean age of first sexual experience was 21.62 ± 4 Years.

Table 39. Age of 1st sexual experience had by the respondents

Age-group	Number (%age)
11-15 Years	22 (7.8%)
16-20 Years	96 (34%)
21-25 Years	117 (41.5%)
26-30 Years	43 (15.2%)
31-35 Years	4 (1.4%)
Mean \pm SD age of 1 st Sex Exp. (Years)	26.62 \pm 4

(n=282)

According to national family health survey (NFHS-4) 2015-16 of India, age of 1st sexual intercourse by men (age 25-49 years) in India is at age 24.3 years, five years older than women. One per cent of men age 25-49 years had first sexual intercourse before age 15 and 7 per cent had sexual intercourse before age 18. By age 25 years, 55 per cent of men have had first sexual intercourse. The median age of first intercourse of 24.3 years. The median age at first sexual intercourse for men

was increased from 22.6 years in 2005-2006 to 24.3 years in 2015-2016 (Source- NFHS-4, 2015-2016 report).

7.2.4 Feeling of worried/ depression because of sexual dysfunction by Type 2 adult male diabetic patients

Table 40. Feeling of worried/ depression by respondents due to sexual dysfunction

S. No	Variables	Options	Number (%age)
1.	Worried/ depressed due to having sexual dysfunction	All of the time	86 (38.73%)
		Some of the time	49 (22.07%)
		Hardly any of the time	41 (18.46%)
		Not answer	46 (20.72%)
2.	Feel low self-esteem as result of having sexual dysfunction	All time	85 (38.28%)
		Some time	50 (22.53%)
		Hardly any time	42 (18.92%)
		Not answer	45 (20.27%)

(n=222)

Table 40 data show that the 38.73 per cent (n=86) respondents worried or depressed all the time due to having sexual dysfunction, 22.07 per cent (n=49) worried some of the time that they have sexual dysfunction and 18.46 per cent (n=41) hardly any of the time worried or depressed due to their sexual dysfunction. 20.72 per cent (n=46) not answer. Among (n=222) 38.28 per cent (n=85) diabetic patients feel all time low self-esteem as result of have sexual dysfunction, 22.53 per cent (n=50) some time, 18.92 per cent (n=42) hardly feel any time low self-esteem as result of have sexual dysfunction. 20.27 per cent (n=45) not answer.

7.2.5 Reproductive health experience detail of the respondents

Table 41. Reproductive health experience detail of the respondents

S. No.	Variables	Options	Number (%age)
1.	After how much time after having meal do sexual activity	Immediate after meal After one hour After two hour After three hour After four hour	4(1.4%) 68 (24.1%) 191 (67.7%) 14 (5%) 5 (1.8%)
2.	Any problem if have sex after immediate meal	Stomach upset Indigestion	24 (8.5%) 5 (1.8%)
3.	Time of sexual activity	Day Night Any time Not answer	2 (0.7%) 206 (73%) 73 (25.9%) 1 (0.4%)
4.	Time when you feel more enjoyable	Day Night Any time Do not know	4 (1.4%) 218 (77.3%) 57 (20.2%) 3 (1.1%)
5.	Special time when want to do sex	5-6 am 10-11 pm No	26 (9.2%) 49 (17.4%) 207 (73.4%)
6.	Feeling (enjoyment) when do sex using condom	More Less Not answer	10 (3.5%) 119 (42.2%) 153 (54.3%)
7.	Do you feel less enjoyment in sex after having children		64 (22.7%)
8.	Use condom		180 (63.8%)

(n=282)

The table 41 data represent about the reproductive health experience details of the respondents. First experience, after how much time having their dinner (meal) they had sex, Among (n=282) respondents 1.4 per cent (n=4) were do sex after immediate dinner, 24.1 per cent (n=68) do sex after one hour their meal, maximum respondents 67.7 per cent (n=191) do sexual activity after two hours of their dinner, 5 per cent (n=14) involve in sexual intercourse after three hours their meal and only 1.8 per cent (n=5) do sex after four hour of their meal.

2nd experience regarding, any problem they face if they do sex after immediate having their meal, 8.5 per cent (n=24) got stomach upset if they do sex after immediate taking meal and 1.8 per cent (n=5) had indigestion problem when they do sex after immediate having their meal. 3rd experience regarding time at what time they do sexual activity, maximum respondents 73 per cent (n=206) they do sex at night time, 0.7 per cent only two respondents do sex in day time, 25.9 per cent (n=73) respondents have sexual activity at any time day or night and 0.4 per cent one person did not answer.

4th experience regarding time at what time they feel more enjoyable to do sexual activity, maximum respondents 77 per cent (n=218) they like to do sex at night time only, 1.4 per cent four respondents like to do sex in day time, 20 per cent (n=57) respondents feel more enjoy to do sexual activity at any time day or night and 1.1 per cent three person do not know. 5th experience regarding any special time when respondents want to do sex or more urge to have sex, 9.2 per cent (n=26) like to have sex at 5 or 6 am (in the early morning) and 17.4 per cent (n=49) like to do sex or have more urge to do sex at 10 or 11 pm at night. Maximum 73.4 per cent (n=207) do not have any like or any specific time to do sex.

6th experience regarding feeling when they use condom during sex, 42.2 per cent (n=119) respondents said they have less feeling or less enjoy if they use condom and 3.5 per cent (n=10) said, they have more enjoy while they use condom. 54.3 per cent (n=153) do not answer. 7th experience regarding enjoy to have sex after having children, 22.7 per cent (n=64) respondents they have less enjoyment in having sex after they had baby. 8th experience regarding usage of condom, 63.8 per cent (n=180) use condom.

7.2.6 Feedback details regarding sexual experience by the respondents

In table 42 first variable regarding how often respondents had sex, maximum 68.8 per cent (n=194) respondents do sex monthly, 17.7 per cent (n=50) do weekly sexual activity, 11.7 per cent (n=33) do twice in a week and only 1.8 per cent (n=5) respondents do sexual activity daily. According to NFHS-4, 2015-2016 data 31 per cent Indian men age (15-49) years reported having sexual intercourse weekly. While in our study only 17 per cent do sexual activity weekly.

Table 42. Feedback details regarding sexual experience by the respondents

S.No.	Variables	Options	Number (%age)
1.	Frequency of sex	Daily Two time a week Weekly monthly	5 (1.8%) 33 (11.7%) 50 (17.7%) 194 (68.8%)
2.	Time period of sex	1-2 minute 3-4 minute 5-7 minute 8-10 minute 11-20 minute	148 (52.5%) 31 (11%) 46 (16.3%) 26 (9.2%) 31 (11%)
3.	Erect penile in early morning		58 (20.6%)
4.	Taking anything to increase sexual powder		50 (17.7%)
5.	Feel fear to have sex		12 (4.3%)
6.	Partner refusing to have sex		178 (63.1%)

(n=282)

Second variable regarding duration (time) to do sexual activity, most of the respondents 52.5 per cent (n=148) do sexual activity only for 1-2 minutes, 11 per cent (n=31) do sex for 3-4 minutes, 16.3 per cent (n=46) respondents take 5-7 minutes for do sexual activity, 9.2 per cent (n=26) subjects take 8-10 minutes time to do sex and 11 per cent (n=31) person do sex for 11-20 minutes.

Third variable regarding erect penile in early morning only 20.6 per cent (n=58) respondents had erect penile in the early morning time. Fourth variable

regarding use of an aphrodisiac / anything to increase their sexual powder, 17.7 per cent (n=50) respondents only use some aphrodisiac to increase their sexual power. Fifth variable regarding feel fear to have sex, 4.3 per cent (n=12) respondents only feel fear to have sexual activity. Sixth variable regarding refusal of partner to have sexual activity, 63.1 per cent (n=178) respondent's partner refuse to have sex or to do any sexual activity. Which is a matter of further investigate to find out the reason for the same?

7.2.7 Sexual experience with other by the respondents

Table 43 data show sexual experience with other than partner, maximum 66.3 per cent (n=187) do not involve to do sex with other than own partner, only 27 per cent (n=76) adhibit to have sex with other than own partner, 1.4 per cent (n=4) respondents not give any answer and 5.3 per cent (n=15) do not know or do not want to tell anything about sexual activity other than own partner.

Table 43. Sexual experience with other by the respondents

S. No.	Variables	Options	Number (%age)
1.	Sex with other than wife	Yes	76 (27%)
		No	187 (66.3%)
		Not answer	4 (1.4%)
		Do not know	15 (5.3%)
2.	Feel same pleasure with other partner	More	27 (9.6%)
		Less	2 (0.7%)
		Not answer	236 (83.7%)
		Do not know	17 (6%)
3.	Number of women you had sex	Only one	165 (58.5%)
		Two	49 (17.4%)
		Four	16 (5.7%)
		Five and more	25 (8.9%)
		Not answer	27 (9.6)
4.	Opinion about sex with other than partner	Good	8 (2.8%)
		Bad	229 (81.2%)
		Not answer	36 (12.8%)
		Do not know	9 (3.2%)

(n=282)

2nd variable regarding feeling of pleasure when having sex with other partner, 9.6 per cent (n=27) respondents were feel more pleasure when have sex with other partner, only 0.7 per cent (n=2) were feel less pleasure when have sex with other partners. 83.7 per cent (n=236) respondents were not answer this questions and 6 per cent (n=17) were response they don't know about this.

3rd variable regarding number of women respondents had sex with, maximum 58.5 per cent (n=165) had sex with only one women, 17.4 per cent (n=49) respondents had sex with two women, 5.7 per cent (n=16) had sexual relation with four women, 8.9 per cent (n=25) person had sex with five and more than five women and 9.6 per cent (n=27) not answer this question.

4th variable regarding opinion of the respondents regarding having sex with other than partners, maximum 81.2 per cent (n=229) respondents reply its bad to have sex with other than partners, 2.8 per cent (n=8) says it's good to have sexual relation with other than own partners, 12.8 per cent (n=36) not answers this questions and 3.2 per cent (n=9) respondents says they do not know about this.

In national family health survey 2015-2016 (NFHS-4) says 2 per cent of men reported having more than one sexual partner in past 12 months while our study show a high number about 32 per cent population have more than two partners.

7.2.8 General view regarding happiness with sexual life by the respondents

Table 44. General view regarding happiness with sexual life by the respondents

Variables	Options	Number (%age)
In general, happiness with sex life	Very happy	7 (2.5%)
	Pretty happy	97 (34.4%)
	Not happy	174 (61.7%)
	Do not know	4 (1.5%)

(n=282)

From table 44 revealed that among (n=282) respondents maximum 61.7 per cent (n=174) not happy with their sexual life, 34.4 per cent (n=97) were pretty happy with their sexual life, only 2.5 per cent (n=7) were very happy with their sexual life and 1.5 per cent (n=4) were do not know about their status of sexual life. The table data show most of the respondent were not happy with their sexual life.

7.2.9 Baseline characteristic of the study population with sexual dysfunction

Table 45 data show that the total (n=282) subject divided in two group on the basis of their IIEF score (15 questionnaire). The IIEF score > 50 do not have sexual dysfunction and < 50 IIEF score have sexual dysfunction. We compare the mean score of basic character of the respondents with sexual dysfunction and without sexual dysfunction. The result table show out of total (n=282) respondents 78.7 per cent (n=222) have sexual dysfunction and 21.3 per cent (n=60) don't have sexual dysfunction.

Table 45. Baseline characteristic of the respondents with sexual dysfunction

Variables	With sexual dysfunction	Without sexual dysfunction	Total
Numbers of Patients	222 (78.7%)	60 (21.3%)	282
Age (mean±SD) in Years (range 25-60 yrs.)	49.41±4.1*	45.40±8.7	48.56±8.1
BMI (Mean) kg/m ²	25.4±4.1	26.5±4.9	25.64±4.3
Weight (Kg)	71.06±12.3	74.67±15.0	71.83±13.0
Height (cm)	167.19±6.47	167.53±6.43	167.26±6.45
Energy (kcal)	1872±370	1787±313	1805±327
Protein (gm.)	61.17±11.37	63.59±13.2	61.69±11.8
Fat (gm.)	38.29±8.0	39.33±7.9	38.51±8.0
Carbohydrates (gm.)	248.65±54.25*	267.55±65.76	252.67±57.29

(* The mean difference is significant at the 0.05 level) (n=282)

This data show that on our study population of diabetic adult male have 78.7 per cent prevalence rate of sexual dysfunction. The age (mean±SD) difference in the both group was significantly difference with 49.41±4.1 years in respondents with sexual dysfunction and 45.40±8.7 years without sexual dysfunction. The BMI (mean±SD) of respondents with sexual dysfunction was 25.4±4.1 kg/m² and the respondents without sexual dysfunction with 26.5±4.9 kg/m² non-significantly difference. The height mean±SD of the patients was 167.26±6.45 cm, mean height of patients with sexual dysfunction was 167.19±6.47 cm and without sexual was 167.53±6.43 cm with non-significant p value. The weight mean±SD of the respondents was 71.83±13.0 kg, mean weight of patients with sexual dysfunction was 71.06±12.3 kg and without sexual dysfunction was 74.67±15.0 kg with non-significantly difference.

7.3 The 3rd objective, “To assess the nutritional status of diabetic patients with sexual dysfunction”, attending endocrinology OPDs of PGIMER, Chandigarh.

In this objective of study evaluate the nutritional status of diabetic patients and association between malnutrition, glucose levels and sexual dysfunction of diabetic patients were done. Malnourished patients may be more prone to higher level of glucose levels and sexual dysfunction. Total (n=282) respondents assess for the nutritional status in adults diabetic patients. Details as follows.

7.3.1 Mini nutritional assessment (MNA) status according to age group of the respondents

Total of (n=282) patients were included in the study. Our results did not show any patients under the ‘Malnourished’ category in MNA, therefore patients were categorized into “At risk of malnutrition’ and ‘Normal nutrition status’ groups.

Table 46. Mini nutritional assessment status according to age group of the respondents

Variables	At risk of Malnutrition	Normal Nutritional Status	Total
Numbers	114 (40.4%)	168 (59.6%)	282
Age (mean \pm SD) in years	47 \pm 8.4	49 \pm 7.9	48 \pm 8.1
25-33 Years	10 (8.8%)	10 (6.1%)	20 (7.1%)
34-42 Years	19 (16.7%)	23 (13.7%)	42 (14.9%)
43-51 Years	40 (35.1%)	58 (34.5%)	98 (34.8%)
52-60 Years	45 (39.5%)	77 (45.8%)	122 (43.3%)

(n=282)

From the table 46 data it revealed that, (n=114) 40.4 per cent subjects were 'At the risk of malnutrition' and (n=168) 59.6 per cent were at 'Normal nutritional status' with no significant difference between both the group ($p > 0.05$). The total sample mean \pm SD age in years was 48 \pm 8.1 years, ranged from 25-60 years old.

There was non-significant difference in age of both group of MNA, at risk of malnutrition mean age were 47 \pm 8.4 years and normal nutritional status mean age was 49 \pm 7.9 years. Most of studies show nutritional assessment of diabetic patients in old age by MNA (Vellas et al, 1999; Turnbull and Sinclair, 2002; Gerber et al, 2003; Saka et al, 2010; Sanz et al, 2013; Fattah et al, 2014; Liu et al, 2017). Table 46 and figure 77 shows the maximum respondents were from the age group 52-60 years n=122 (43.3%), 98 (34.8%) from the age group 43-51years, 42 (14.9%) from 34-42 years the age group and 20 (7.1%) from the youngest age group 25-33 years. Data shows patients were increasing with increase in age in both group.

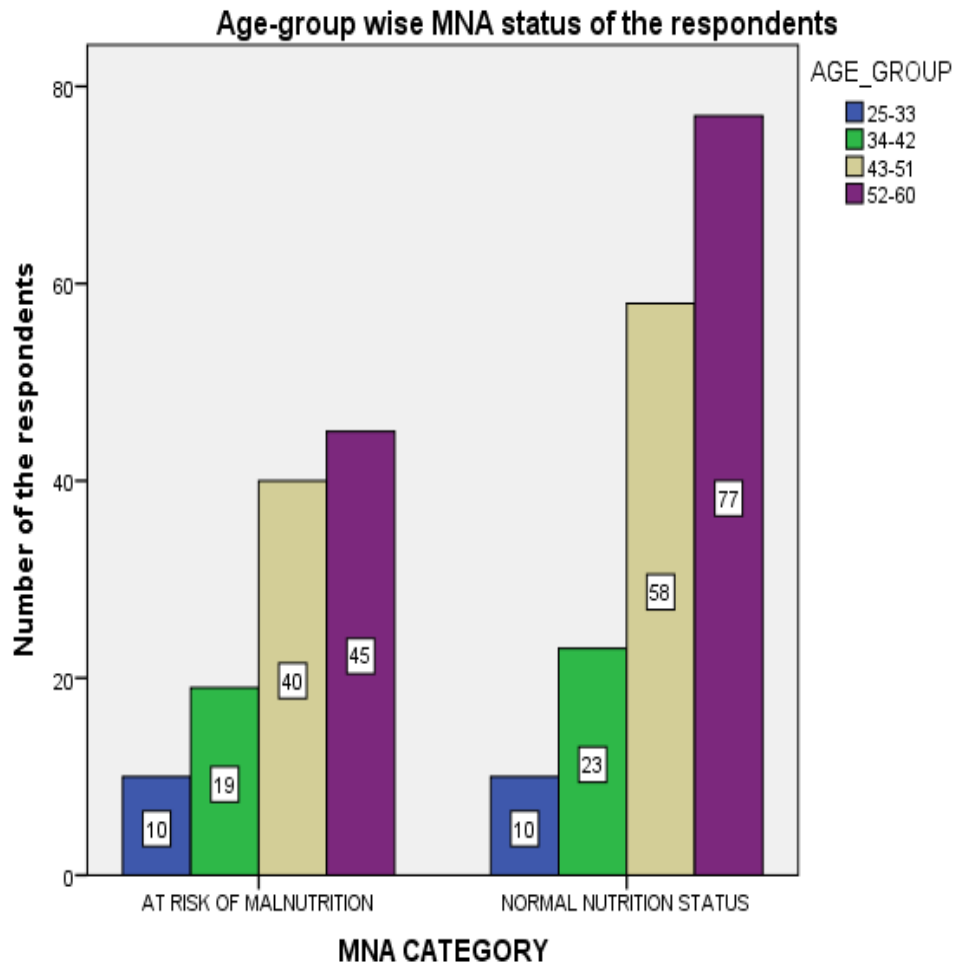


Figure 77. Mini nutritional assessment status of the respondents according to age group category.

Similar with other studies 44 per cent with poor nutritional status Pertoldi et al, (1996), Saka et al, (2010) and Shaikh et al, (2017) with about 62 per cent malnutrition. Liu et al, (2017) also did similar study with (n=302) elderly participant with MNA but in older patients (≥ 65) with Type 2 diabetes and 18.5 per cent malnourished, 33.1 per cent at risk of malnutrition and 48.3 per cent normal nutritional status patients, which is quite similar with our study. Gau et al, (2016) identified patients ‘At risk of malnutrition’ (70.5%) and ‘Malnourished’ (14.6%).

Prevalence of malnutrition and diabetes in north Indian population was similar with other study in Europe by Sanz et al, (2013) 40 per cent at risk of malnutrition where they have done mini nutritional assessment (MNA) for elderly diabetic patients. This data show that in Europe diabetic patients were at risk of malnutrition at

the mean age of 78 years (40%) while in our study in India mean age 48 years have (40%) at the risk of malnutrition. Similarly, in European studies most of case of diabetes were in the age group of 50-65 years.

In our study the mean age (48±8.1 years) and age range (25-60 years), was comparable to study done by Oyibo et al, (2001) and Shaikh et al, (2017) shown mean age of patients was 58 and 47 year, range of age 29-78 and 30-70 years respectively. The nutritional status worsens with age same in our study comparable with Sanz et al, (2013). The sample size and non-significant difference in age of both the group of our study is in accordance with the study done by Fattah et al, (2014).

7.3.2 Baseline characteristics of the respondents according to mini nutritional assessment (MNA)

Table 47. Baseline characteristics of the respondents according to mini nutritional assessment (MNA)

Variables	At risk of malnutrition	Normal nutritional status	Total	p value
Numbers	114 (40.4%)	168 (59.6%)	282	-
Fasting blood glucose (mean ±SD) (mg/dl)	176.9±68.9	156±56.3	164±62	(p < 0.05)*
Postprandial blood glucose level (mean ±SD) (mg/dl)	254±84.4	223.7±71.1	235±60	(p < 0.05)*
HbA1c (mean ±SD) (%)	9.0±2.3	8.2±1.7	8.5±2.0	(p < 0.05)*
IIEF (mean ±SD)	39.4±12.3	40.7±12.9	40.1±12.6	(p > 0.05)*
Body mass index (mean ±SD) kg/m ²	24.7±5.1	26.2±3.4	25.6±4.3	(p < 0.05)*
MNA (mean ±SD) (score 0-14 points)	10.29±1.0	13.38±0.7	12.13±1.7	(p < 0.05)*

(* The mean difference is significant at the 0.05 level) (n=282)

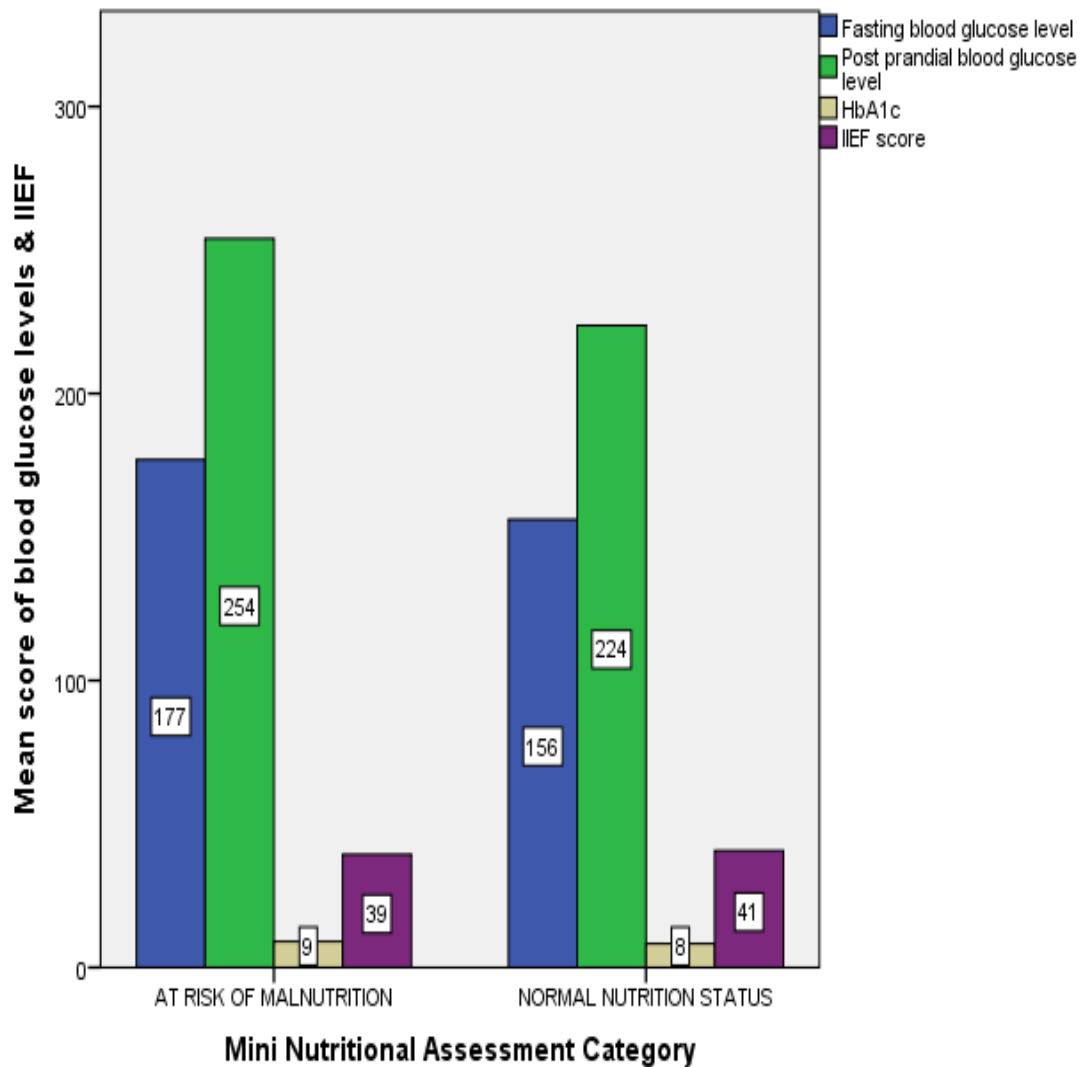


Figure 78. Blood glucose levels and IIEF score in MNA category of the respondents

The table 47 and figure 78 data show that the total mean \pm SD fasting blood glucose level, postprandial blood glucose level, HbA1c and international index of erectile function (IIEF) level were 164 ± 62 mg/dl, 235 ± 60 mg/dl, 8.5 ± 2 per cent and 40.1 ± 12.6 score respectively. When compared in both group of MNA, 'At risk of malnutrition' patients showed fasting blood glucose, postprandial blood glucose, HbA1c and IIEF score were 177 ± 69 mg/dl, 254 ± 84 mg/dl, 9.0 ± 2.3 per cent and 39.4 ± 12.3 score respectively. Patients with 'Normal nutritional status' levels showed 156 ± 56.3 mg/dl, 223.7 ± 71.1 mg/dl, 8.2 ± 1.7 per cent and IIEF score 40.7 ± 12.9 respectively. There were significant difference in mean value of fasting blood

glucose, postprandial blood glucose and HbA1c levels in both the groups. While non-significant difference in mean IIEF score of both the groups.

The total mean \pm SD body mass index (BMI) of the patients was 25.6 \pm 4.3 kg/m² in overweight range. 'At risk of malnutrition' had significantly lower BMI 24.7 \pm 5.1 when compared to 'Normal nutritional status' patients 26.2 \pm 3.4kg/m². The total MNA mean \pm SD score was 12.13 \pm 1.7, in 'At the risk of malnutrition' 10.29 \pm 1.0 and 13.38 \pm 0.7 in 'Normal nutritional status' patients which was significantly difference.

The main finding of this study was that nutritional status of diabetic patients of adult age group was directly proportional to the blood glucose levels and inversely proportional to sexual dysfunction. Our data shows 'Normal nutritional status' patients have better control over blood glucose levels and IIEF score. About 40 per cent diabetic patients with at risk of malnutrition with high blood glucose levels show that malnutrition is a health problem which can controlled by proper nutritional assessment and counselling.

The mean MNA score 12.13 (7-14) our study is similar with other study 12.23 of Turnbull et al, (2002) for diabetic patients. His score is non-significant while our study show highly significant in both group. MNA score correlated significantly with other parameters in our study resemble with other study of Turnbull and Sinclair, (2002) and Gerber et al, (2003). Like other study MNA was non-significant correlation with age (Gerber et al, 2003). The mean BMI in our study is similar with the finding of Agarwal et al, (2017); Saka et al, (2010) and Sanz et al, (2013), finding i.e. low BMI in at risk of malnutrition group is also similar with our finding.

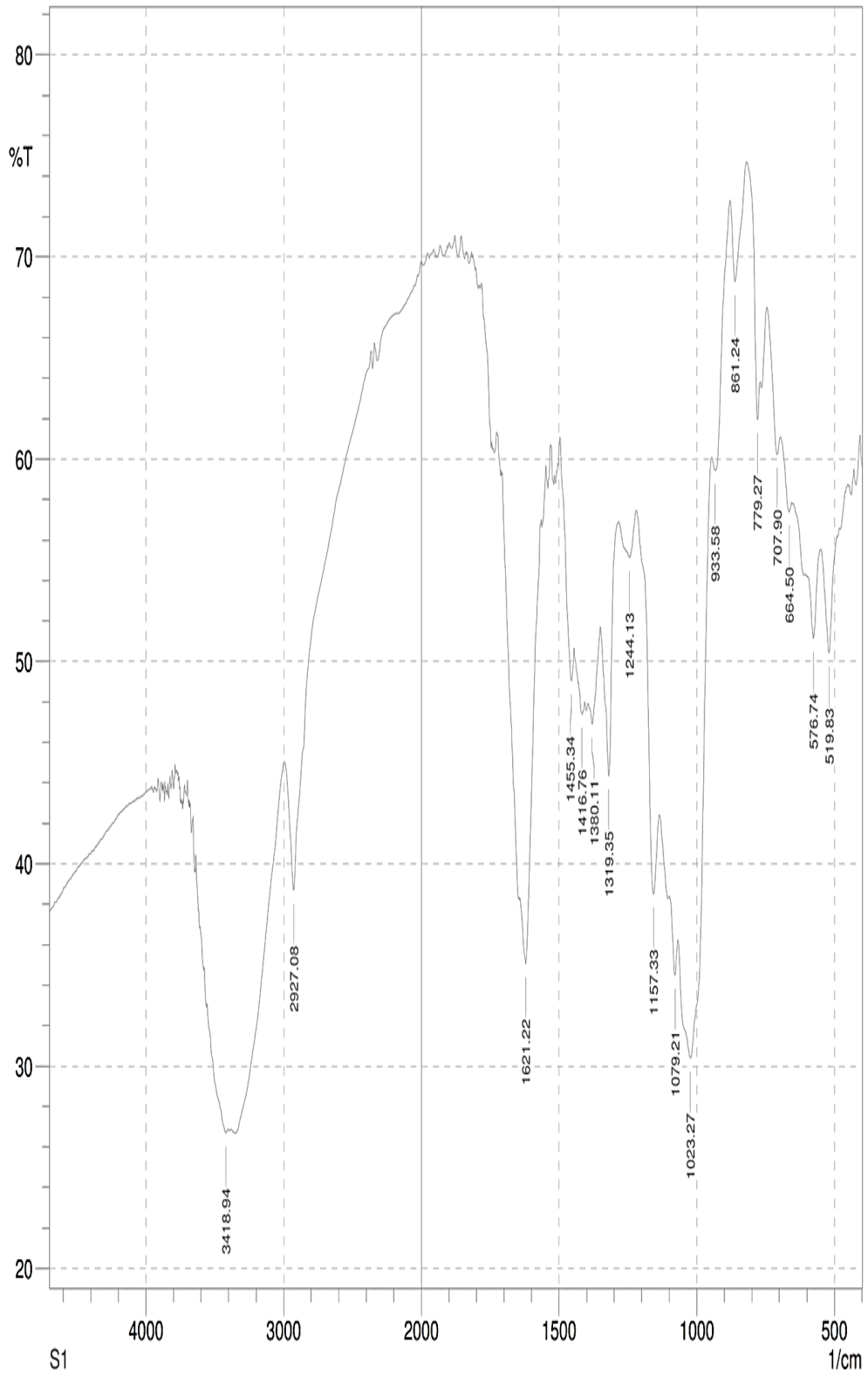
There were statistically significant difference between body mass index, fasting blood glucose, postprandial blood glucose level and HbA1c. These finding are in congruence with other studies (Panagiotakos et al, 2004; Bakari et al, 2006; Agrawall et al, 2017) The mean BMI found in our study was in the overweight range (Bakari et al, 2006) and higher in normal nutritional status subjects. Our findings are similar to other studies that also used the MNA as tool for evaluates the nutritional status of diabetic patients and HbA1c associated with MNA (Vischer et al, 2010). A study done by Shaikh et al, (2017) also shows similar output with (n=387) subjects, MNA done and mean age and blood glucose level similar with our results.

7.4 The 4th objective, “To formulate and analyze the nutritional and phytochemical potential of the herbs based regime for the intervention”.

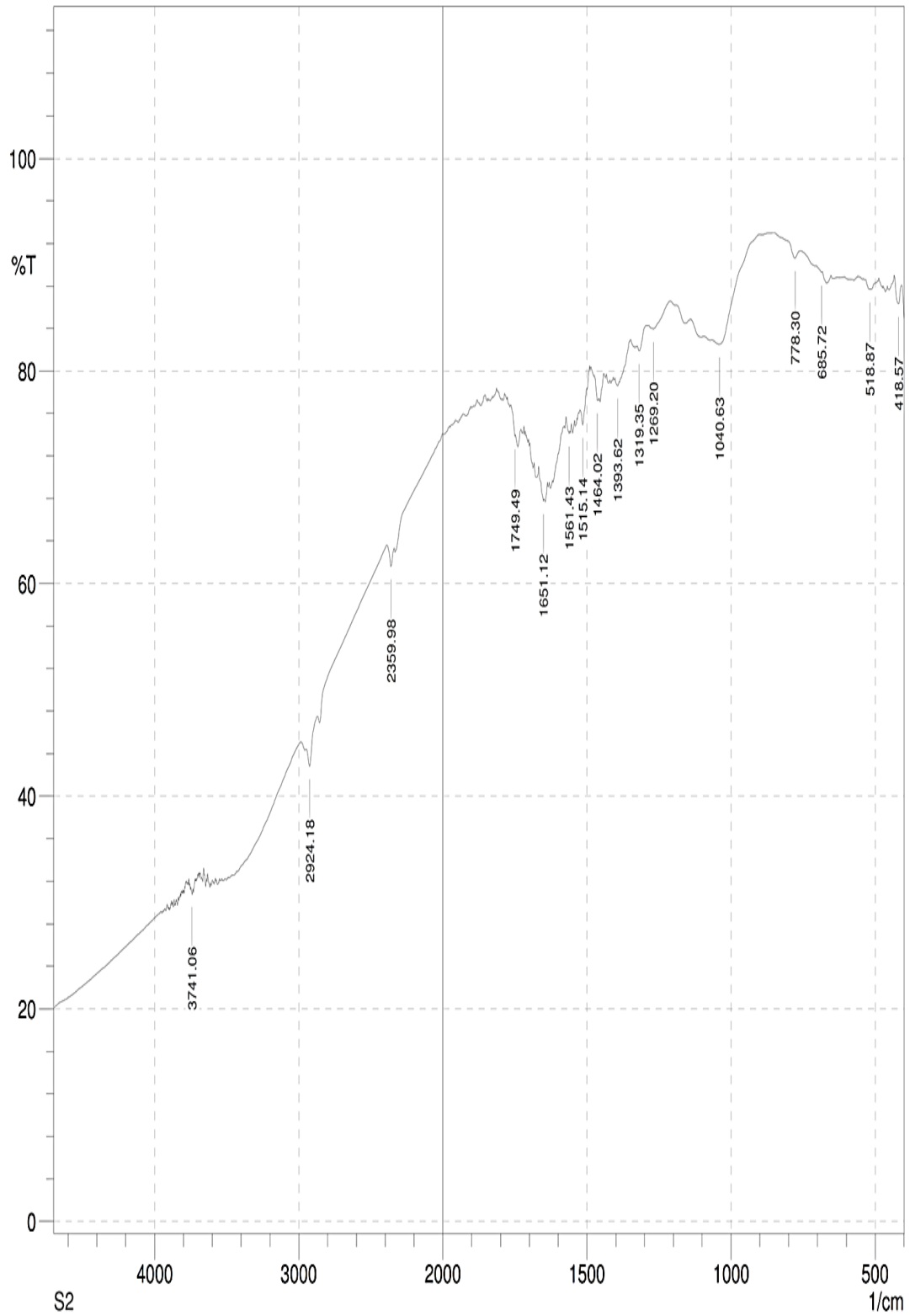
7.4.1 FTIR analysis of herbs

Fourier Transform Infrared Spectroscopy (FTIR) done for all the herbs and for final products. For the qualitative analysis; different herb samples *Gymnema sylvestre*, *Momordica charantia*, *Azadirachta indica*, *Citrullus colocynthis*, *Berberis aristata*, *Tribulus terrestris*, *Asphaltum* and *Withania somnifera* along with the final formulation were subjected to Fourier Transform Infrared Spectroscopy (FTIR) analysis (Shimadzu 8400S FTIR spectrometer, equipped with KBr beam splitter) using approximately 5 mg of each sample along with 5 mg KBr. FTIR spectrophotometer was operated at a spectral range of 4000–400 cm^{-1} with a maximum resolution of -0.85 cm^{-1} . The spectra so obtained for the respective samples were interpreted as per the guidelines given by Stuart, (2004).

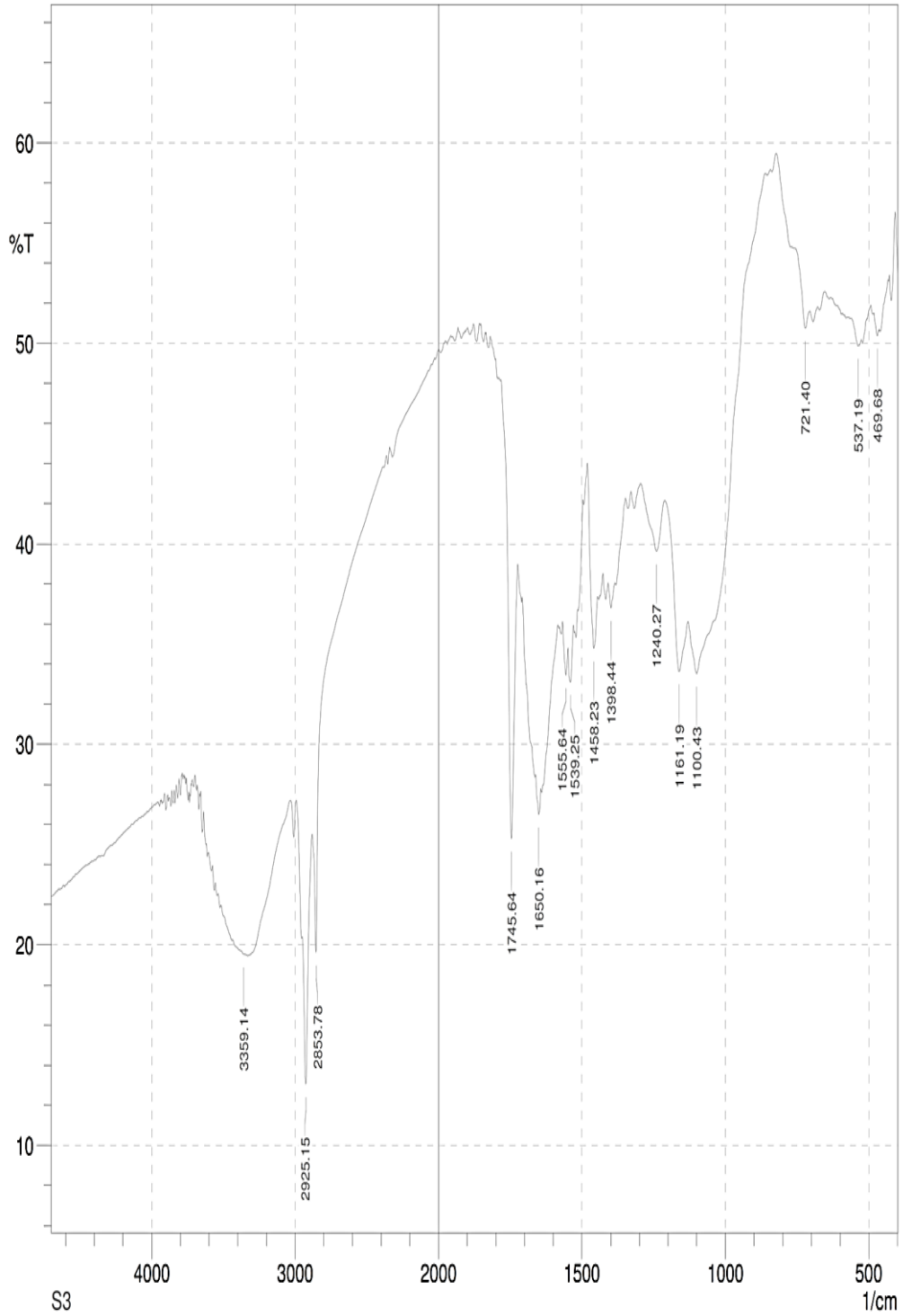
FTIR spectrometer is certainly one of the most important analytical techniques available today to virtually study physicochemical and conformational properties of any sample (Stuart, 2004). Infrared spectra of *Withania somnifera* (sample 1), *Gymnema sylvestre* (sample 2), *Citrullus colocynthis* (sample 3), *Momordica charantia* (sample 4), *Tribulus terrestris* (sample 5), *Azadirachta indica* (sample 7), *Asphaltum* (sample 8), *Berberis aristata* (sample 9) and Final Product (mixture of all herbs) (sample 6) were compared to check the qualitative effect of various herbs phytochemical potential by identifying the presence of major functional groups. The details of the peak indicated that all the sample showed peaks on the same wavelengths but a marked variation was observed in the intensities a significant effect on final product enhancement of the phytochemical of the all herbs.



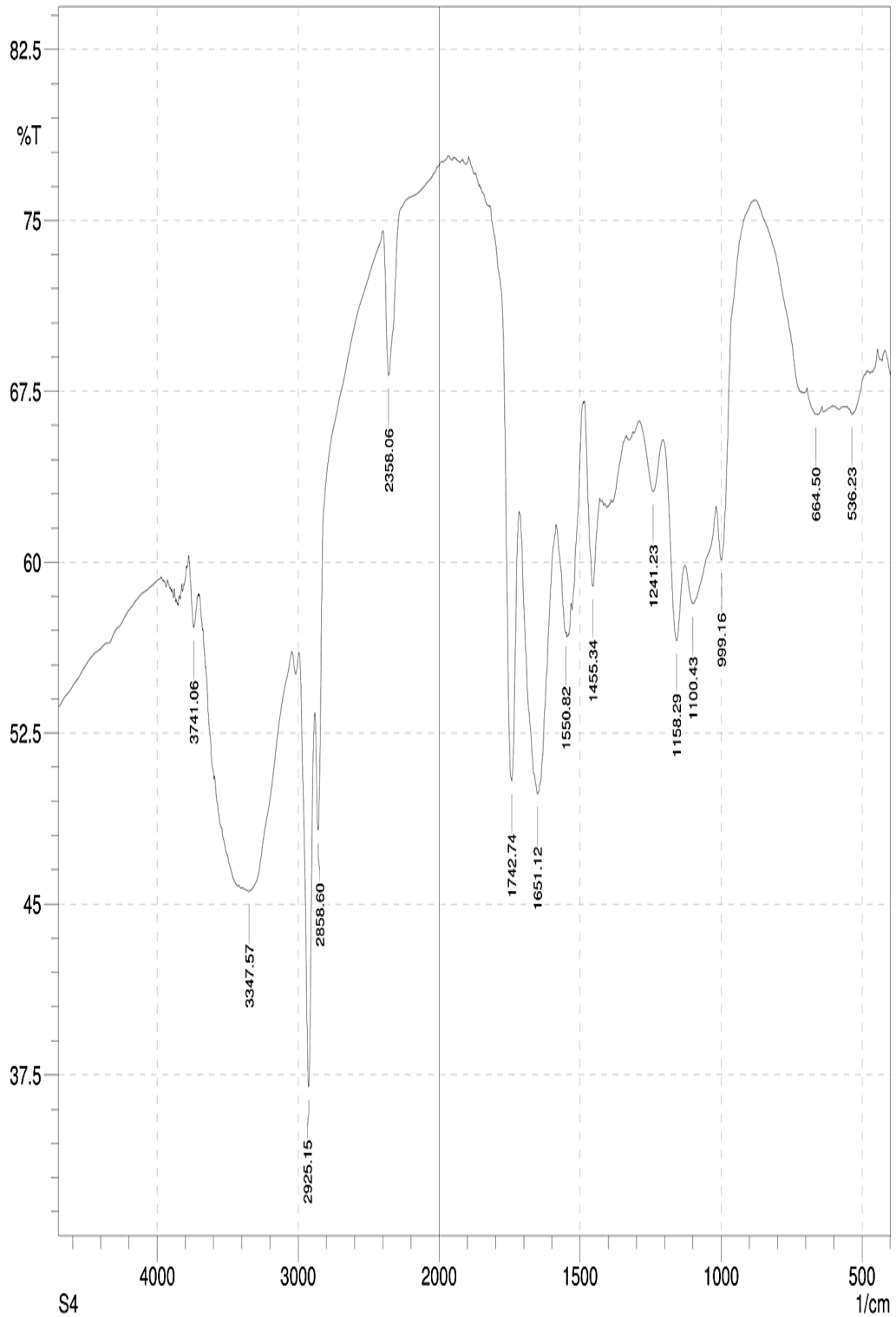
Sample 1



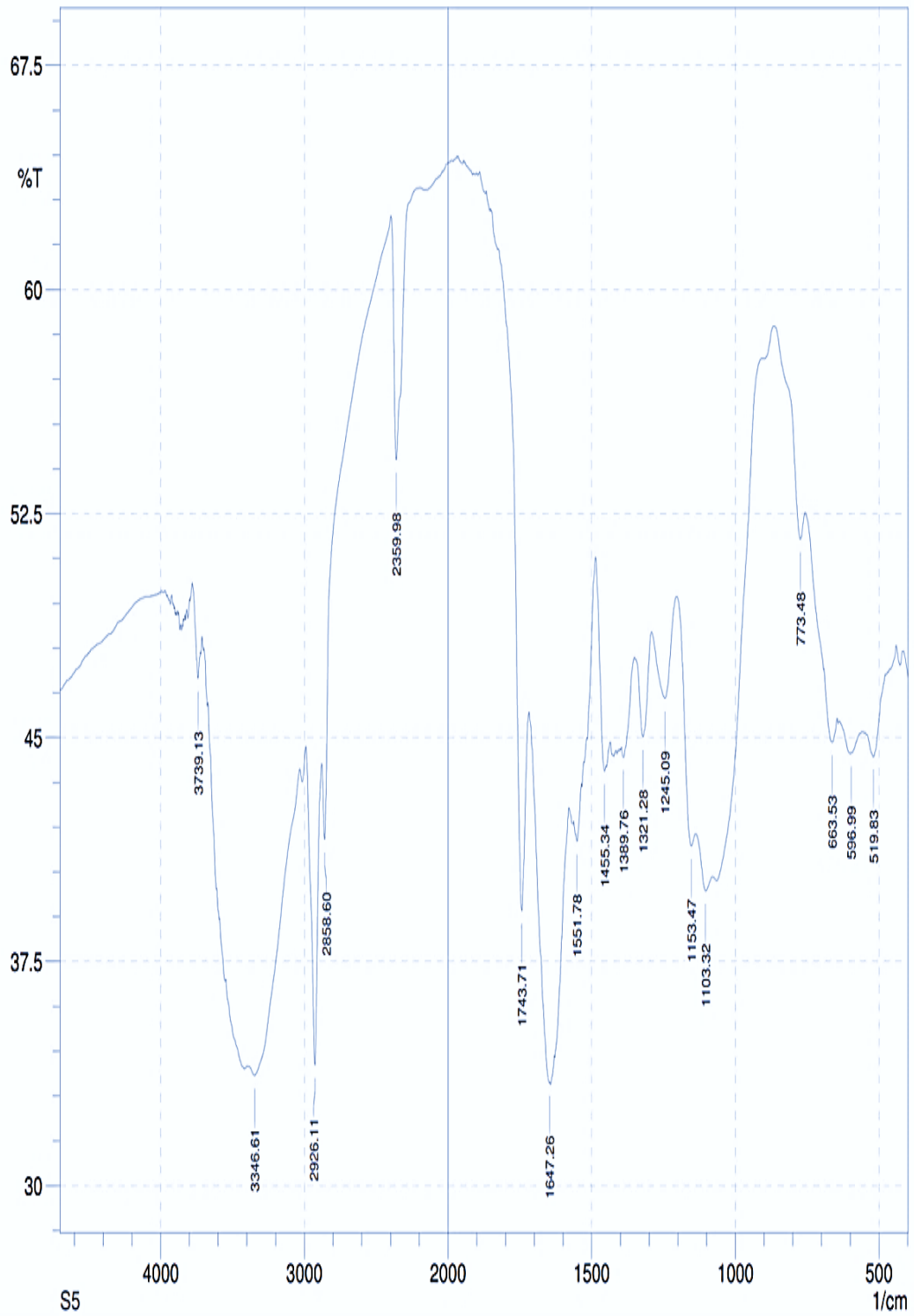
Sample 2



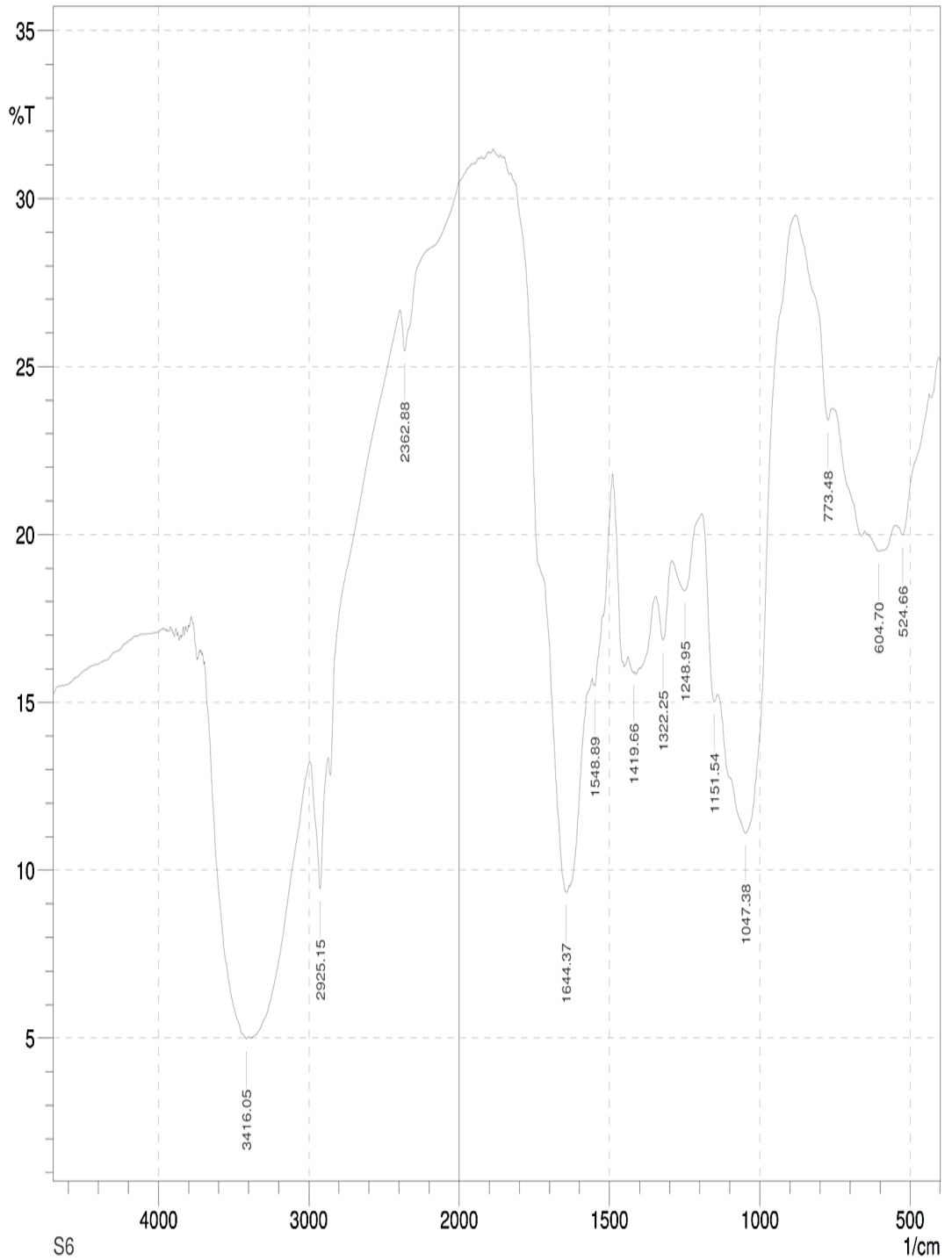
Sample 3



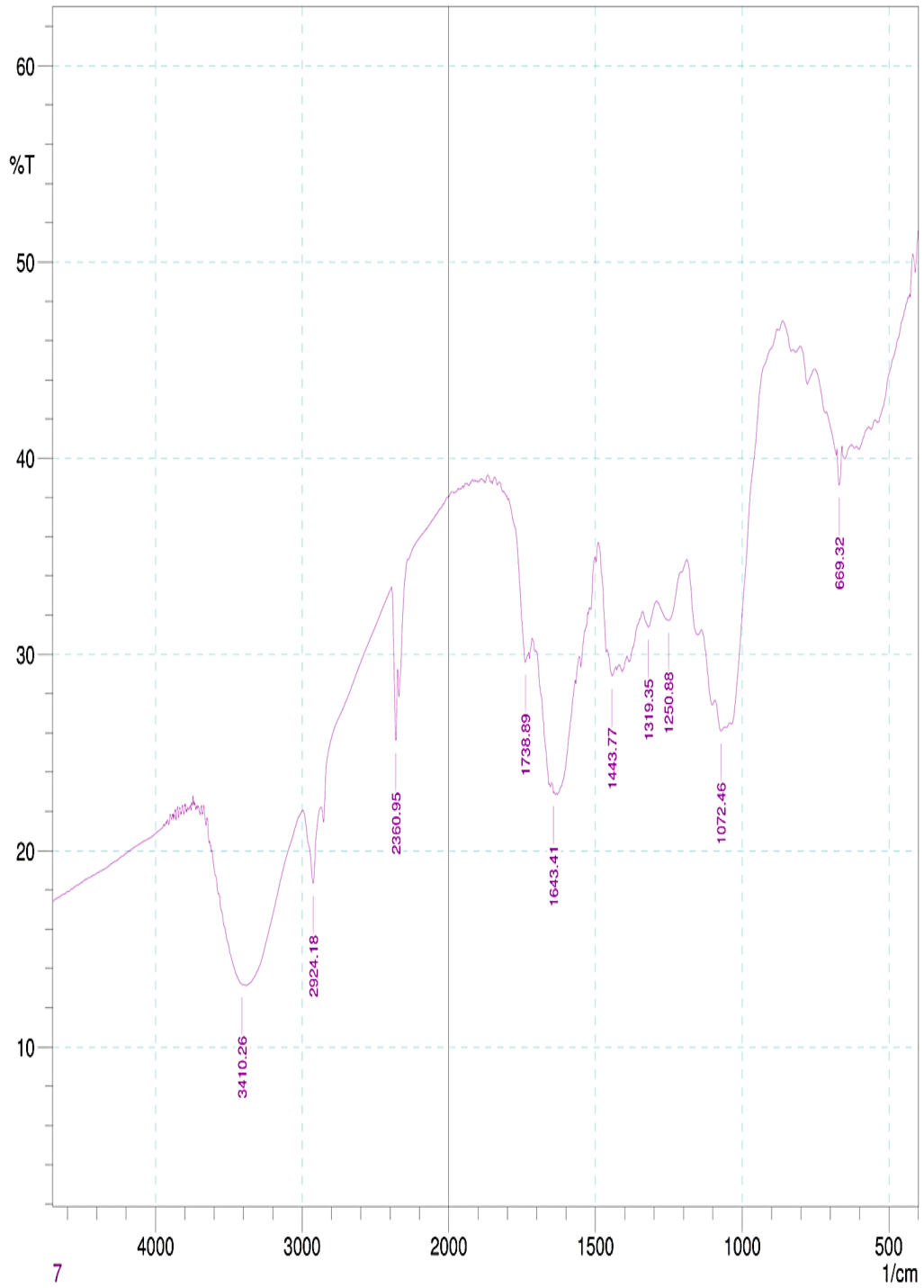
Sample 4



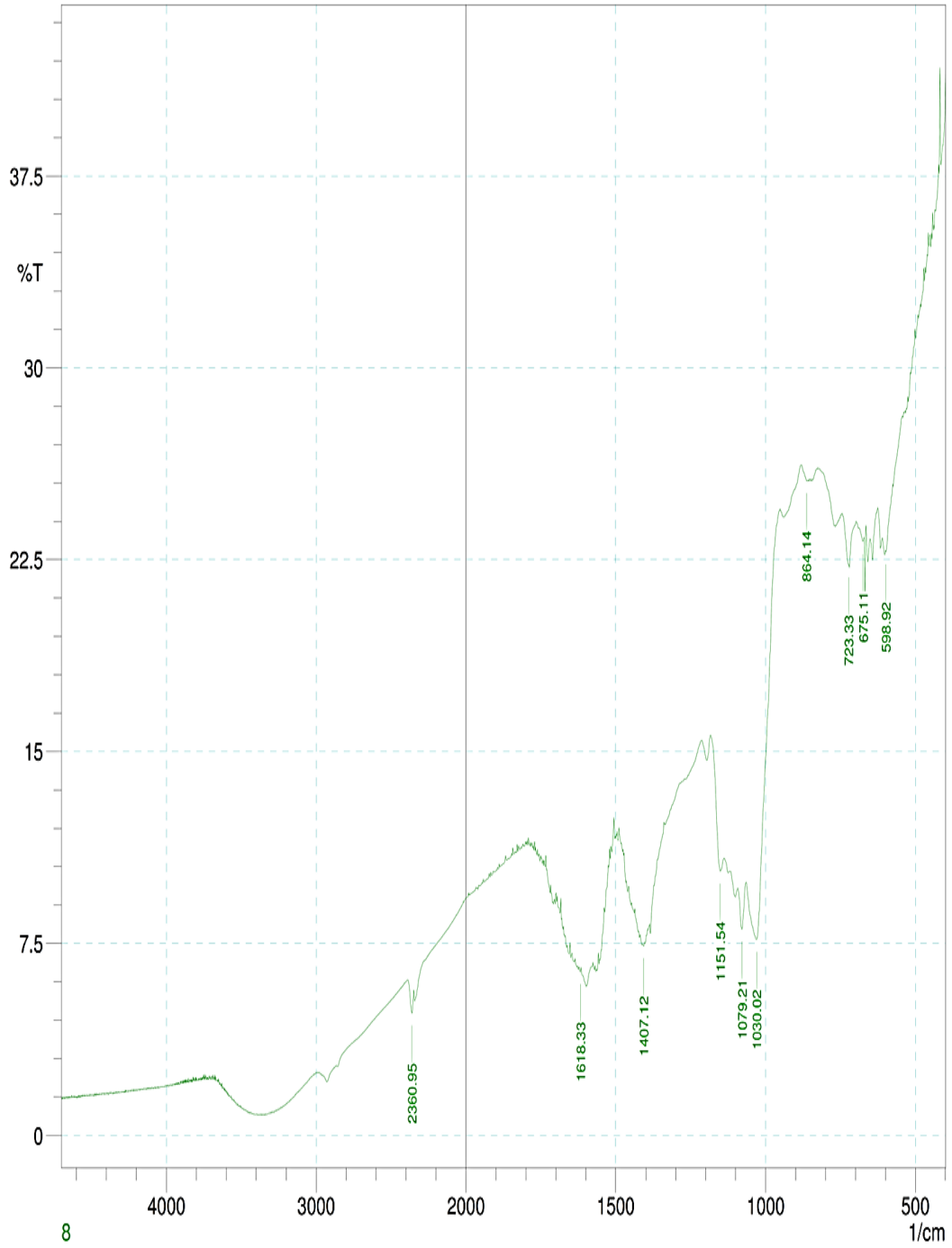
Sample 5



Sample 6

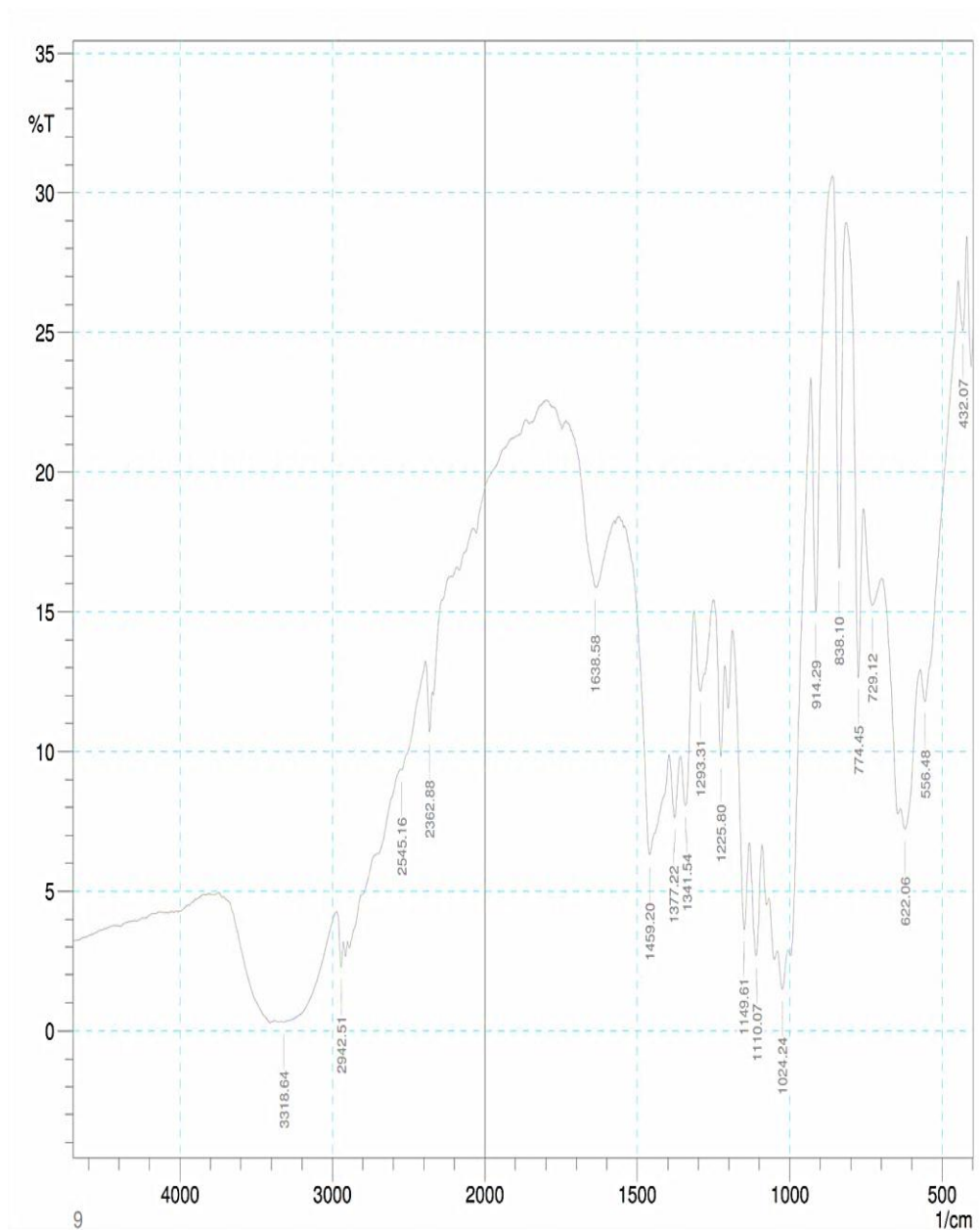


Sample 7



8

Sample 8



Sample 9

Figure 79. FTIR graphs for different samples 1-9 (herbs) showing peaks at different bands

(**Sample 1** *Withania somnifera*, **Sample 2** *Gymnema sylvestre*, **Sample 3** *Citrullus colocynthis*, **Sample 4** *Momordica charantia*, **Sample 5** *Tribulus terrestris*, **Sample 6** Final product, **Sample 7** *Azadirachta indica*, **Sample 8** Asphaltum, **Sample 9** *Berberis aristata*).

ASHWAGANDHA			NEEM			GHOKRU KANTA			KARELA			GURMAR		
Peak	Area	Compound	PEAK	AREA	COMPOUND	PEAK	AREA	COMPOUND	PEAK	AREA	COMPOUND	PEAK	AREA	COMPOUND
519.83	16.262	P=S stretching (Phosphorus compound)	669.32	7.028	C-H bending (Alkenes)	519.83	21.888	P=S stretching (Phosphorus compound)	536.23	1.874	P=S stretching (Phosphorus compound)	418.57	1.536	P-S stretching
576.74	12.647	P=S stretching (Phosphorus compound)	1072.46	19.41	C-O stretching (Alcohol & phenols)	596.99	10.438	P=S stretching (Phosphorus compound)	664.5	6.067	C-H bending (Alkenes)	518.87	0.86	P=S stretching (Phosphorus compound)
664.5	9.293	=C-H bending (Alkynes)	1250.88	40.924	hemicellulose, Pectin	663.53	15.507	=C-H bending (Alkenes)	999.16	21.591	C-H bending (Alkenes)	685.72	1.106	=C-H bending (Alkenes)
707.9	9.807	=C-H bending (Alkynes)	1319.35	23.415	Amide groups (amino acid)	773.48	27.606	=C-H bending (Alkenes)	1100.43	24.922	C-O stretching (Alcohol & phenols)	778.3	3.439	=C-H bending (Alkenes)
779.27	7.875	=C-H bending (Alkynes)	1443.77	14.361	Amide groups (amino acid)	1103.32	23.057	C-O stretching (Alcohol & phenols)	1158.29	17.28	cellulose	1040.63	9.707	cellulose
861.24	8.766	β -D-fructose, β -D-sucrose	1643.41	4.894	pectin, H-O-H stretching, Oxalic acid	1153.47	22.976	cellulose, C-O stretching	1241.23	16.145	hemicellulose	1269.2	4.46	pectin, amide group, amino acid
933.58	12.57	Carboxylic acid (C-O-H out-of-plane bending)	1738.89	21.968	hemicellulose	1245.09	28.264	hemicellulose	1455.34	11.328	amide group, amino acid, ascorbic acid	1319.35	2.647	amide group, amino acid
1023.27	52.38	Cellulose	2360.95	22.25	P-H stretching (Phosphorus acid)	1321.28	19.824	amide groups, amino acid	1550.82	8.335	amide group, amino acid, ascorbic acid	1393.62	1.495	amide group, amino acid
1079.21	13.622	Lysine	2924.18	87.907	fat & carbohydrates	1389.76	15.427	amide groups, amino acid	1651.12	33.041	pectin, oxalic acid, H-O-H bending	1464.02	1.543	amide group, amino acid, ascorbic acid, C-H bending
1157.33	26.861	Cellulose, C-O Stretching, Aliphatic C-O stretching	3410.26	131.523	O-H stretching (moisture)	1455.34	12.148	amide groups, amino acid, ascorbic acid	1742.74	20.151	hemicellulose	1515.14	2.722	lignin, amide group, amino acid, ascorbic acid
1244.13	16.276	Hemicellulose, C-O stretching, Aliphatic C-O stretching				1551.78	7.6	amide groups, amino acid, ascorbic acid	2358.06	46.062	P-H stretching (Phosphorus acid)	1561.43	1.712	amide group, amino acid, ascorbic acid
1319.35	19.681	Serine				1647.26	29.311	pectin, oxalic acid, H-O-H bending	2858.6	83.369	C-H stretching	1651.12	2.944	pectin, oxalic acid, H-O-H bending
1380.11	13.914	Leucine, Methyl symmetrical C-H bending				1743.71	31.411	C=O stretching	2925.15	37.097	fat & carbohydrates	1749.49	1.997	C=O stretching
1416.76	7.398	Glutamic acid				2359.98	43.936	P-H stretching (Phosphorus acid)	3347.57	91.97	O-H stretching (moisture)	2359.98	10.36	P-H stretching (Phosphorus acid)
1455.34	13.809	Valine				2858.6	122.201	C-H stretching	3741.06	8.995	O-H stretching	2924.18	27.309	fat & carbohydrates
1621.22	27.272	Pectin, Amide I, C=C stretching				2926.11	44.098	fat & carbohydrates				3741.06	4.402	O-H stretching
2927.08	169.833	Aldehyde C-H stretching, O-H stretching (fat & CHO)				3346.61	20.422	O-H stretching (moisture)						
3418.94	80.046	O-H stretching (moisture)				3739.13	14.673	O-H stretching						

THUMBA			RASOUNT			SHILAJIT			FINAL PRODUCT		
PEAK	AREA	COMPOUND	PEAK	AREA	COMPOUND	PEAK	AREA	COMPOUND	PEAK	AREA	COMPOUND
469.68	4.542	P-S stretching, S-S stretching (Sulfur compound)	432.07	16.297	P-S stretching	598.92	14.915	P=S stretching (Phosphorus compound)	524.66	71.058	P=S stretching (Phosphorus compound)
537.19	7.433	P=S stretching (Phosphorus compound)	556.48	94.857	P=S stretching (Phosphorus compound)	675.11	9.125	=C-H bending	604.7	31.941	C-H bending (Alkenes)
721.4	14.292	C-H bending	622.06	68.136	=C-H bending (Alkenes)	723.33	14.03	C-H bending	773.48	69.103	C-H bending (Alkenes)
1100.43	98.925	C-O stretching (Alcohol & phenols)	729.12	47.365	C-H bending, =C-H bending (Alkenes)	864.14	10.19	β -D-fructose, C-H bending	1047.38	200.243	cellulose
1161.19	34.86	cellulose, amide group, amino acid	774.45	39.861	=C-H bending (Alkenes)	1030.02	100.503	cellulose	1151.54	40.679	cellulose, amide group, amino acid
1240.27	32.725	hemicellulose, amide group, amino acid	838.1	27.611	a-D-glucose	1079.21	28.36	C-O stretching (Alcohol & phenols)	1248.95	71.84	hemicellulose, amide group, amino acid
1398.44	10.283	amide group, amino acid	914.29	44.474	a-D-glucose, β -D-glucose	1151.54	42.045	cellulose, amide group, amino acid	1322.25	39.067	amide group, amino acid
1458.23	15.172	amide group, amino acid, ascorbic acid	1024.24	59.53	cellulose	1407.12	8.704	amide group, amino acid, ascorbic acid, C-C stretching	1419.66	16.093	amide group, amino acid, ascorbic acid
1539.25	4.919	amide group, amino acid, ascorbic acid	1110.07	57.694	amide group, amino acid	1618.33	8.031	pectin, H-O-H bending	1548.89	9.284	amide group, amino acid, ascorbic acid
1555.64	8.506	amide group, amino acid, ascorbic acid	1149.61	62.147	cellulose, amide group, amino acid	2360.95	49.09	P-H stretching (Phosphorus acid)	1644.37	76.793	pectin, oxalic acid
1650.16	10.358	pectin, oxalic acid, H-O-H bending	1225.8	34.815	amide group, amino acid				2362.88	33.32	P-H stretching (Phosphorus acid)
1745.64	25.902	hemicellulose	1293.31	29.027	amide group, amino acid				2925.15	114.561	fat & carbohydrates, C-H stretching
2853.78	216.011	C-H stretching	1341.54	44.956	amide group, amino acid				3416.05	327.246	O-H stretching (moisture)
2925.15	49.983	fat & carbohydrates	1377.22	38.823	amide group, amino acid, C-H bending						
3359.14	14.332	O-H stretching (moisture)	1459.2	143.794	amide group, amino acid, ascorbic acid						
			1638.58	59.061	pectin, oxalic acid, H-O-H bending						
			2362.88	42.018	P-H stretching (Phosphorus acid)						
			2545.16	156.453	O-D stretching						
			2942.51	69.313	C-H stretching						
			3318.64	705.569	O-H stretching (moisture)						

Fourier-transform infrared spectroscopy is certainly one of the most important analytical techniques available today to virtually study the physicochemical and conformational properties of any sample of different state that may be liquids, solutions, pastes, powders, films, fiber, and gas (Stuart, 2004). FTIR determines the presence or absence of a particular functional group (Stuart, 2004). A comparison of Infrared spectra of different Herbs samples determined the structural similarities and differences between these samples. Figure 79 shows the FTIR spectra of 8 herbs and mixture. The spectrum shows absorbance at different peak such as 861, 933, 1023, 1079, 1244, 1319, 1380, 1416, 1455, 1621 2927, and 3418 cm^{-1} . The table 48 shows the peak and area of different herbs. The absorption band appearing at 856 cm^{-1} is attributed to the stretching of methyl β -D-glucopyranoside and β -D-sucrose (Stuart, 2004). The peak at 1049 cm^{-1} denoting the presence of C-O stretching indicates the presence of cellulose. The peak ranging between 1600-1100 cm^{-1} attributes to the presence of amide groups i.e., amide I and amide II showing the presence of different amino acid such as lysine, valine, phenylalanine and tyrosin (Stuart, 2004). The absorption band at 1647 cm^{-1} attributes to -C=O stretching of oxalic acid (Jung et al, 2005). Peaks for C-H bonds of fat and carbohydrate were observed in different herbs at the region of 2928 cm^{-1} and peak ranging between 3200-3600 cm^{-1} (3365 cm^{-1}) is attributed to O-H stretching of moisture content (Stuart, 2004). The area of peaks in final product increase, which show that the active compound present in all herbs available in final product.

7.4.2 Analysis of herbs from drug testing lab

These herbal powder was first standardized as per standard procedures/guidelines. Various physiochemical parameters viz. Loss on drying, Total Ash value. Acid Insoluble Ash value. Alcohol soluble Extract and water soluble extract values were determined accordingly. List of lab report attached as (Appendix- XIII). The following result were found when final product analysis done in Government Drug Testing Laboratory (A.S.U.-Ayurvedic Siddha Unani) Patiala.

Description of product	:	Light greenish brown powder.
L.O.D. (loss on drying)	:	4.7 per cent
Total Ash value	:	9.6 per cent
Acid Ash value	:	1.06 per cent
Alcohol Soluble Extract	:	19.92 per cent
Water Soluble Extract	:	30 per cent

Testing Report of herbs- for the testing purpose and quality assurance regarding raw material and final product samples were obtained from market and sent to government drug testing laboratory (A.S.U), Patiala, Punjab. The reports record after testing are attached as (Appendix – XIII) and details as per the report as follows- All the raw materials were tested as per the government guidelines in the laboratory. For the raw materials identification was checked as per the API, API atlas, quality standard of Indian medical plant and scientific Journal.

For final product as the sample is a combination of herbal formula (i.e. not from classical Ayurvedaic text books). Its testing was done depending upon the raw material provided for identification and used in final product by thin layer chromatography. Some analysis like L.O.D (loss on drying), total ash, acid insoluble ash, alcohol soluble extract and water soluble extract were done for purity and strength.

7.5 The 5th objective, “To assess the impact of herbs based life style modification regime on the sexual dysfunction and blood glucose levels of diabetic male adults” attending endocrinology OPDs of PGIMER, Chandigarh.

The present part of the study was conducted to realize the therapeutic potential of Herbal powder supplementation on the blood glucose levels and sexual dysfunction of Type 2 diabetic patients (NIDDM) subjects. The herbal powder was given to diabetic subjects for 3 months their pre and post blood glucose levels and IIEF score were assessed and the result have been presented and discussed. Total 282 respondents assess for sexual dysfunctions.

Total (n=300) eligible patients referred from endocrinology OPD. Out of there (n=18) patients were excluded (11 not interested, 4 unmarried and 3 spouse expired). Thus (n=282) patients were enrolled in the study. These patients analysis for presence of sexual dysfunction with IIEF (International Index of Erectile Function) tools. With IIEF score (<50) have sexual dysfunction and (>50) diabetic patients without sexual dysfunction. Out of (n=282), (n=222) diabetic patients have IIEF score <50 and (n=60) patients have >50 score. Then (n=17) patients not full fill including criteria for RCT so excluded from the study. We have (n=205) diabetic male patients with sexual dysfunction for RCT intervention study.

Patients were divided into two groups by block randomization, 50 patients were allocated to group A and 50 patients were allocated to group B. Figure 80 and 81 depicts the trial attrition. Finally 82 per cent (n=41) and 52 per cent (n=26) total 67 per cent (n=67) patients completed the study in group A and group B respectively. The response rate for intervention in study was 82 per cent for group A for herbal intervention and 52 per cent for group B placebo intervention and overall response rate was 67 per cent.

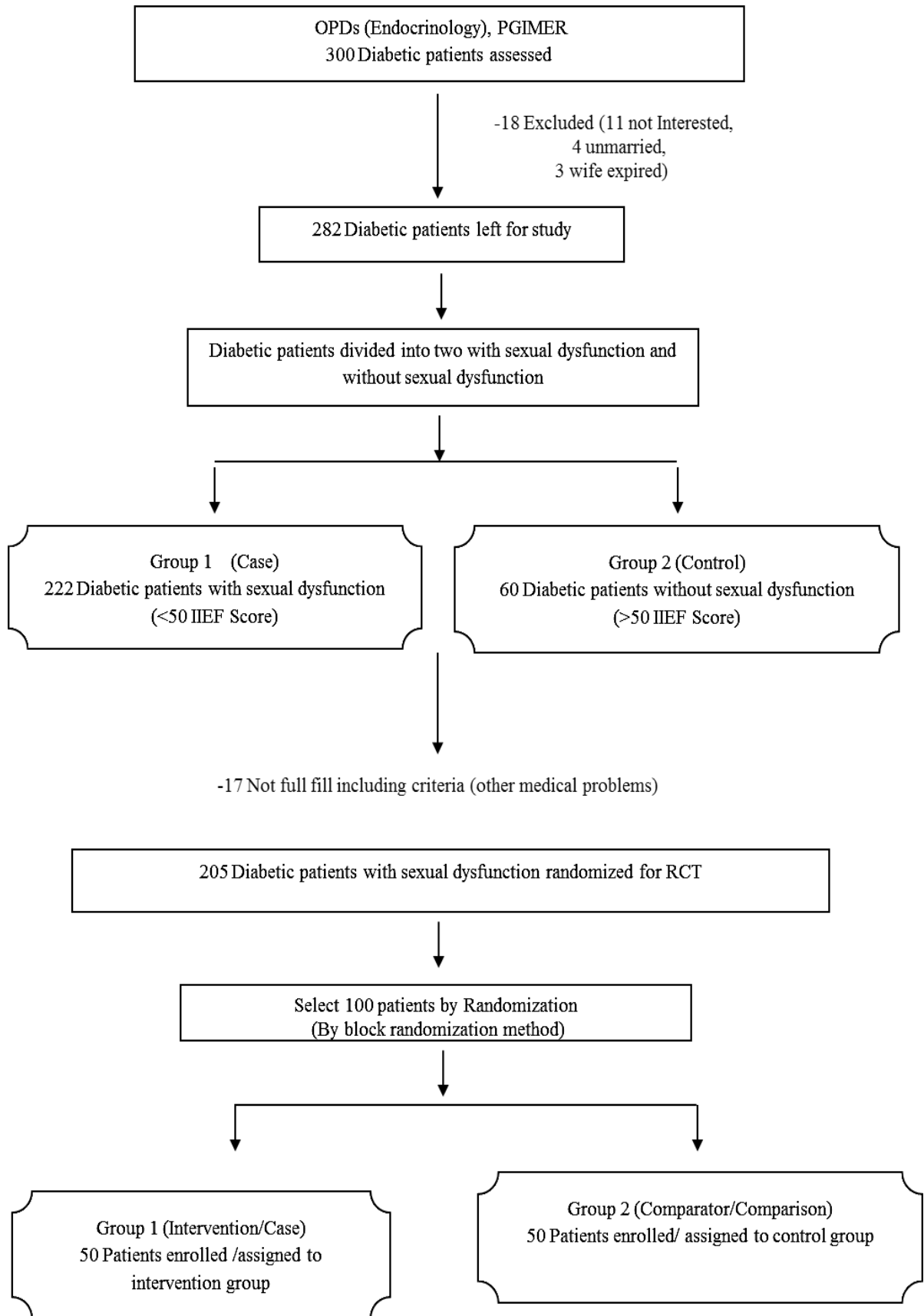


Figure 80. Trial attrition for the intervention study (RCT)-I

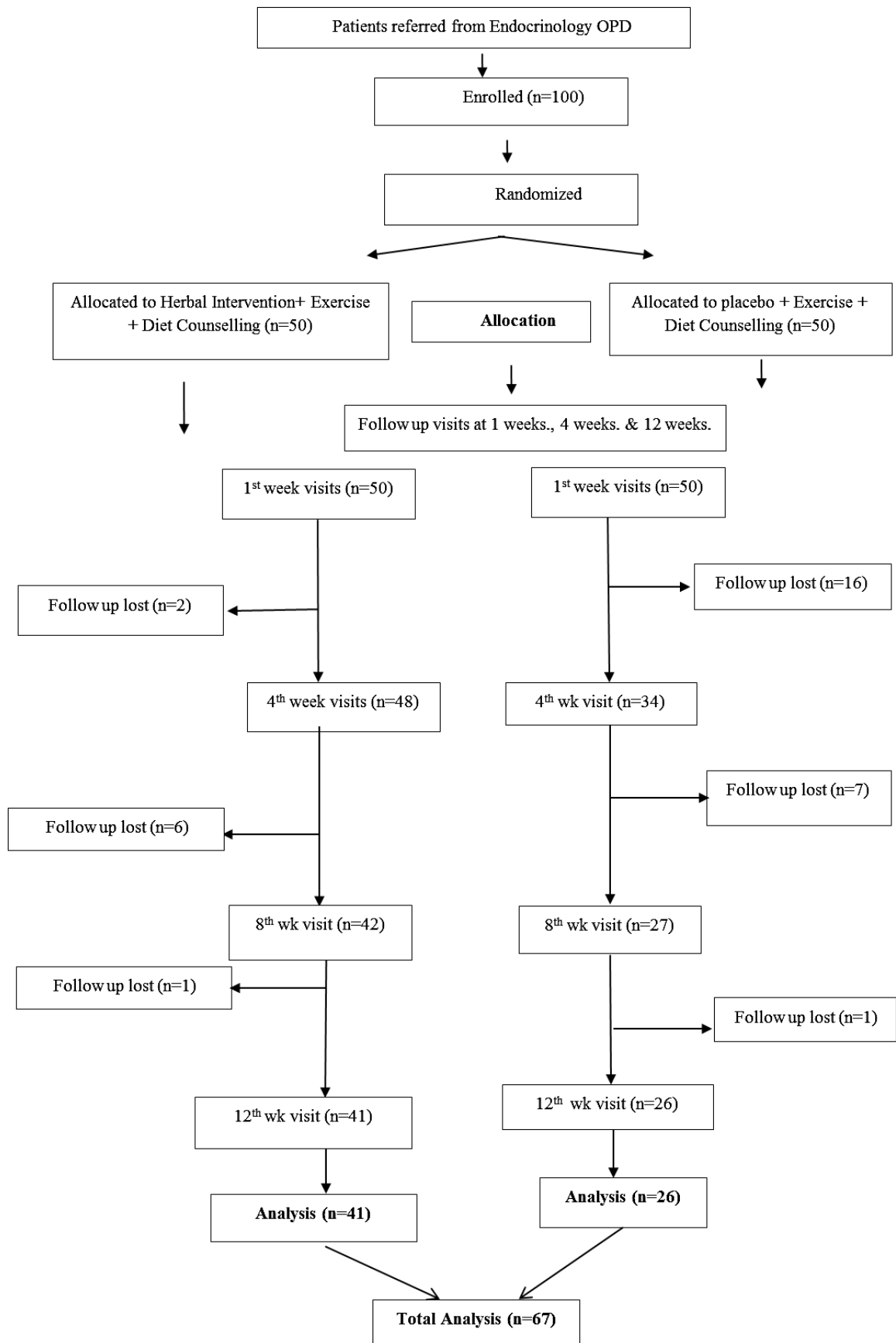


Figure 81. Study design and trial attrition for intervention study (RCT)-II

7.5.1 Preface data of the selected patients for intervention study

7.5.1.1 Socio – economics status of the selected patients

Socio economics status is a complex indicator of lifestyle, behavior, knowledge of health promotion and access to health services. The age, education level and physical activity of 67 Type 2 adult male diabetic patients recruited for clinical intervention trial is presented follow. Among that 41 were in group A (herbal intervention) and 26 in group B (placebo intervention).

Table 49. Socio economics background of the respondents of intervention group

variable	Options	Group A (n=41)	Group B (n=26)	p value
Age in Years Mean±SD (range 25-60 years)	Age in Years Mean±SD	50.05±8.24	47.50±6.45	(p > 0.05)
Age group (years)	25-33 years	4 (6.0%)	1 (1.5%)	(p > 0.05)
	34-42 years	4 (6.0%)	4 (6.0%)	
	43-51 years	12 (20.9%)	14 (20.9%)	
	52-60 years	21 (31.3%)	7 (10.4%)	
Education	Illiterate	4 (9.8%)	2(7.7%)	(p > 0.05)
	Primary	2(4.95)	2(7.7%)	
	Middle	6(14.65)	1(3.8%)	
	Matric	9(22%)	7(26.9%)	
	Hr. Secondary	7(17.1%)	4(15.4%)	
	Graduate and above	13(31.7%)	10(38.5%)	
Occupation Employed		36 (87.8%)	23 (88.4%)	(p > 0.05)
Occupation Un-employed		5 (12.2%)	3 (11.6%)	(p > 0.05)
Employed Category	Private Job	5 (13.8%)	3 (13%)	(p > 0.05)
	Business	6 (16.6%)	6 (26%)	
	Government Job	22 (61%)	13 (56.5%)	
	Labourer	3 (8.3%)	1 (4.3%)	

(n=67) Significance was considered at *0.05

From the table no 49 revealed that the mean age of the respondents in intervention group A was 50.05 ± 8.24 years and 47.50 ± 6.45 years placebo intervention group B with non-significant difference. The above table 49 data shows that in group A, maximum number of patients belonged to the age group of 52-60 years 21 (31.3%) followed by the age group 43-51 years 12 (20.9%) , 4 (6.0%) from the age group 25-33 years and 34-42 years. In group B, maximum number of patients belonged to the group of 43-51 years 14 (20.9%) followed by the age group 52-60 years 7 (10.4%), 4 (6.0%) from the age group 34-42 and only 1 (1.5%) from the age group 25-33 years.

Study done by Mohan and Pradeepa, (2009) stated that Type 2 diabetes has been become prevalent among younger age groups, which could have long lasting effects on the health of the nation and its economy. In present study also about 20 per cent patients form younger age group (25-42 years). Advanced age above 45 was associated with more than threefold increase in the risk of diabetes when compare to younger age groups. So as age increase number of diabetic patients also increases.

It was noted that qualification of the Type 2 adult male diabetic patients, out of 67 in group A, maximum 31.7 per cent (n=13) are Graduate and above, 17.1 per cent (n=7) are Intermediate, 22 per cent (n=9) are Matric (high school), 14.65 per cent (n=6) are Middle class, 4.9 per cent (n=2) are primary and 9.8 per cent (n=4) are illiterate subjects. In group B maximum 38.5 per cent (n=10) are Graduate and above, 15.4 per cent (n=4) are Intermediate, 26.9 per cent (n=7) are Matric (high school), 3.8 per cent (n=1) are Middle class and 7.7 per cent (n=2) are primary and illiterate subjects.

Occupation level of the respondents in group A was 87.8 per cent (n=36) are employed and 12.2 per cent (n=5) are unemployed or not involve in any type of work. In group B was 88.4 per cent (n=23) are employed and 11.6 per cent (n=3) are unemployed or not involve in any type of work. Category of the employed respondents, out of 59 employed in group A respondent maximum 61.1 per cent (n=22) are from Government service, 13.8 per cent (n=3) are doing private job, 16.6 per cent (n=6) doing Business and 8.3 per cent (n=3) do labourer job. In group B respondent maximum 56.5 per cent (n=13) are from Government service, 13 per cent (n=3) are doing private job, 26 per cent (n=6) doing Business and 4.3 per cent (n=1) do labourer job.

When this data compare with National nutrition monitoring bureau ICMR report, (2017) shows 32 per cent public do service, 20.3 per cent do business and 18 per cent do labourer job. This data was similar with our findings.

7.5.1.2 Follow-up detail of the selected patients

Table 50. Attendance at follow-up visit for intervention by the respondents.

Group A	Attendance	Group B	Attendance
Baseline 0 week	50 (100%)	Baseline 0 week	50 (100%)
2nd visit 4th week	48 (96%)	2nd visit 4th week	34 (68%)
3rd visit 8th week	42 (84%)	3rd visit 8th week	27 (54%)
4th visit 12th week	41 (82%)	4th visit 12th week	26 (52%)

(n=100)

Figure 50 depicts the trial attrition in patients with follow-up. Overall 100 patients enrolled in the intervention study in two groups A and B respectively. 9 (18%) patients from group A dropped out. 24 (48%) from group B dropped out. Overall dropout rate in the study was 33 per cent.

7.5.2 Impact of three months intervention on biochemical parameters, IIEF scoring, anthropometric parameters of diabetic patients.

After the baseline data was collected, all the patients were intervene for three month period intervention. To group A herbal powder, diet counselling and exercise schedule. To group B placebo powder, diet counselling and exercise schedule were given.

The following results pertain to the impact of the three months intervention on biochemical parameters, IIEF scoring, anthropometric parameters of diabetic patients.

7.5.2.1 Biochemical profile of the respondents before and after the intervention

Effect of supplementation of herbal powder on blood glucose levels between group A and B at 0 weeks (Baseline) and 12 weeks discussed as follow:

Group A (n = 41) and B (n= 26)

Results are expressed as mean±SD. Data was analyzed using student unpaired t test between intervention groups A vs. placebo intervention group B.

Table 51. Biochemical profile of the respondents before and after the intervention

Variables	Group	Time period		p value
		Baseline (1 week) Pre Intervention	12 week Post Intervention	
Fasting Blood Glucose(Mean) mg/dl	A	164.68±56.51	111.54±19.87	(p ≤0.001)*
	B	166.88±56.11	163.92±56.27	(p ≥0.001)
Postprandial (Mean) mg/dl	A	228.71±75.73	151.63±28.07	(p ≤ 0.001)*
	B	244.46±61.74	221.92±60.92	(p ≥0.001)
HbA1c (Mean) per cent	A	8.39±1.67	6.83±0.87	(p ≤ 0.001)*
	B	8.45±1.42	8.40±1.49	(p ≥0.001)

(*significance was considered at p ≤ 0.001 level) (n=67)

Fasting blood glucose level (FBG)

The table 51 data revealed that the mean±SD fasting blood glucose in group A diabetic patients was found to be 164.68±56.51 mg/dl at the baseline, which was reduce significantly (p ≤ 0.001) to 111.54±19.87 mg/dl after three months of herbal intervention. It shows 32.3 per cent reduction in fasting blood glucose level.

While group B show non-significant ($p \geq 0.001$) difference in mean \pm SD fasting blood glucose level before 166.88 \pm 56.11 mg/dl and 163.92 \pm 56.27 mg/dl after three month of placebo intervention. It show only 1.80 per cent reduction in fasting blood glucose level after intervention of three months.

It may be concluded from the results of the study that significant difference exists in fasting blood glucose between herbal intervention and placebo intervention groups. It was concluded that herbal intervention is better than placebo intervention in reducing fasting blood glucose level.

Postprandial blood glucose level (PPBG)

The mean \pm SD postprandial blood glucose level in group A was 228.71 \pm 75.73 mg/dl at the baseline, was reduce significantly to level 151.63 \pm 28.07mg/dl after three months herbal intervention. It shows 33.7 per cent reduction in postprandial blood glucose levels at baseline and end of the study period of three months.

In study group B the mean \pm SD postprandial blood glucose level was reduce to from 244.46 \pm 61.74 mg/dl to 221.92 \pm 60.92 mg/dl at non-significantly after the intervention of three months. It shows the reduction of 9.42 per cent after 12 weeks study period.

There is a significant difference between herbal intervention and placebo intervention group, which shows the effect of herbs on them. It was concluded that herbal intervention has significant improvement in the performance of postprandial blood glucose level of adult male diabetic patients. It was concluded that herbal intervention is better than placebo intervention in reducing postprandial blood glucose level.

HbA1c

The mean \pm SD of HbA1c level at baseline in group A of study population was 8.39 \pm 1.67 per cent, was significantly ($p \leq 0.001$) reduce to level 6.83 \pm 0.87 per cent after the intervention of herbal powder for three months. It shows 18.5 per cent reduction in HbA1c level after the period of three months.

The difference in mean of intervention group of herbal was found to be highly significant ($p \leq 0.001$) which confirms the herbal intervention is playing an important role in lowering glycosylated haemoglobin level.

In group B the mean \pm SD HbA1c level at baseline was 8.45 \pm 1.42 per cent reduce non-significantly ($p \geq 0.001$) to level 8.40 \pm 1.49 per cent. It shows 0.59 per cent reduction in before and after the intervention of placebo in group B for the period of three months. Hence there is a significant difference between experimental and control group, which shows the effect of herbs on them. It was concluded that herbs had significant improvement in the performance of HbA1c level of diabetic patients.

It may concluded from the results of the study that significant difference exists in HbA1c level between herbal intervention and placebo intervention group. It was concluded that herbal intervention group is better than placebo intervention group in reducing and controlling HbA1c level in Type 2 male adult diabetic patients.

7.5.2.2 IIEF score of the respondents before and after the intervention

Sexual dysfunction parameters

IIEF (International Index of Erectile Function)

From the table 52 data show that the mean \pm SD IIEF score in group A was 40.05 \pm 10.50 at baseline (before the study) and after the herbal intervention period of three month, it has increase to significantly score of 44.51 \pm 10.40. The data shows 11.13 per cent increase in IIEF score before and after the intervention period of three months.

Table 52. IIEF score of the respondents before and after the intervention

Variables	Group	Time period		p value
		Baseline (1 week) Pre Intervention	12 week Post Intervention	
IIEF Score (Mean)	A	40.05 \pm 10.50	44.51 \pm 10.40	($p \leq 0.001$)*
	B	40.77 \pm 8.37	40.77 \pm 8.28	($p \geq 0.001$)*

(* The mean difference is significant at the 0.001 level) (n=67)

In group B the mean \pm SD IIEF score at baseline was 40.77 \pm 8.37 score, it increase at non-significantly score at 40.77 \pm 8.28 after the intervention of placebo to group B for the period of three months. It shows 0 per cent increase in IIEF score after the intervention.

7.5.2.3 Anthropometric measurement of the respondents before and after the intervention

Anthropometric measurements parameters

i) Weight

From the table 53 data revealed that the mean \pm SD weight of the respondents of group A was 72.98 \pm 11.74 kg was reduced non-significantly ($p \geq 0.05$) to 72.61 \pm 10.87 kg after the intervention of herbs for three months by the impact of intervention. Impact of intervention in group A. it shows reduction of 0.5 per cent in mean weight of the subjects after the study period of three months.

In group B the mean \pm SD weight at baseline was 70.92 \pm 14.58kg was increase non-significantly ($p \geq 0.05$) to 71.69 \pm 16.84 kg. This data shows increase of 1.08 per cent in mean weight of the subject after the intervention of three months.

From the results, it was cleared depicted that the difference in body weight of intervention group before and after the study was only 0.5 per cent decrease in group A and 1.08 per cent increase in group B. The difference was statically analyzed and found to be non-significant in both the groups supplemented with herbs and placebo.

Table 53. Anthropometric measurement of the respondents before and after the intervention

Variables	Group	Time period		p value
		Baseline (1 week) Pre Intervention	12 week Post Intervention	
Weight of Person (Kg)	A	72.98 \pm 11.74	72.61 \pm 10.87	($p \geq 0.05$)*
	B	70.92 \pm 14.58	71.69 \pm 16.84	($p \geq 0.05$)*
BMI (Mean) kg/m ²	A	25.88 \pm 4.41	25.75 \pm 4.10	($p \geq 0.05$)*
	B	24.78 \pm 3.98	25.03 \pm 4.67	($p \geq 0.05$)*

(* The mean difference is significant at the 0.05 level) (n=67)

ii) Body mass index

The mean \pm SD BMI of patient of group A showed 0.5 per cent decrease in BMI level, 25.88 ± 4.4 kg/m² at the beginning and 25.75 kg/m² at the end of the three month of intervention. It show non-significant level of decrease.

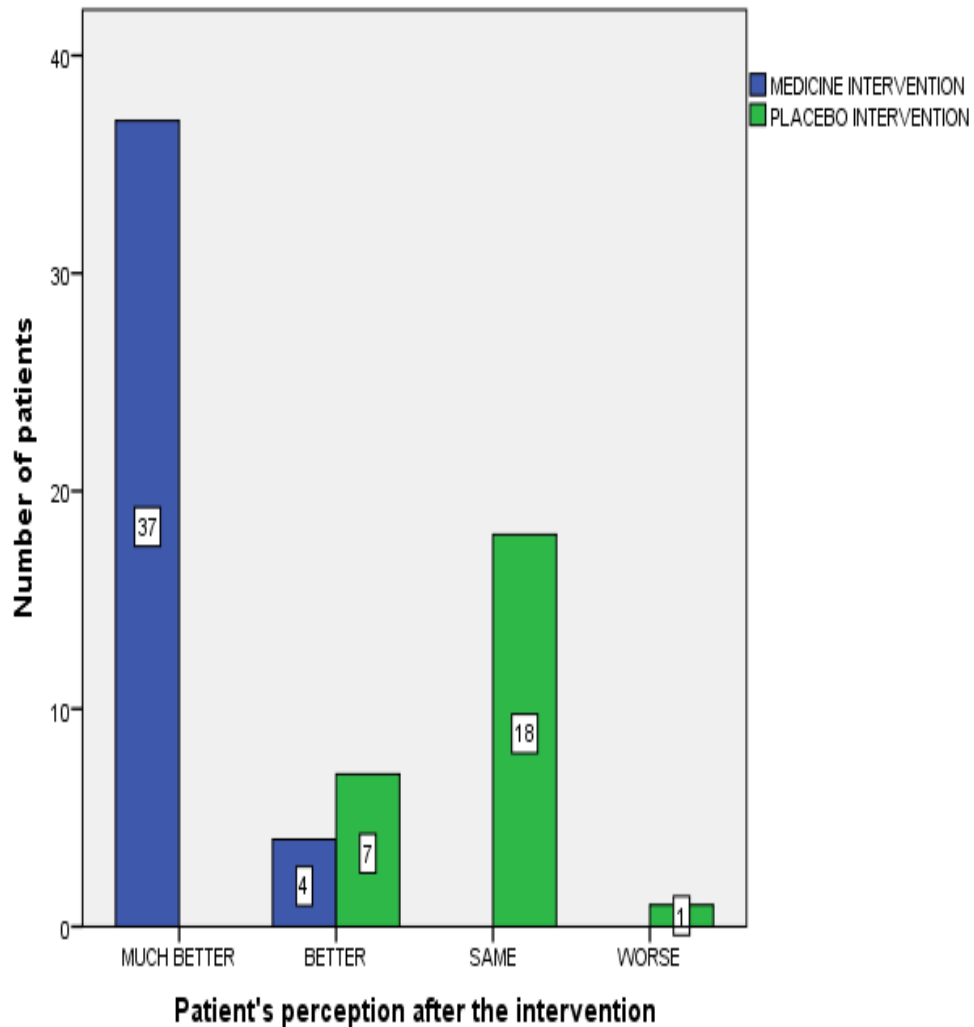
In group B the mean \pm SD BMI level before intervention was 24.78 ± 3.9 kg/m² increase non-significantly ($p \geq 0.05$) level $25.03\pm$ kg/m² after the placebo intervention for three months. It shows increment of 1.08 per cent in mean \pm SD BMI level after three months period. From the table 53 it was clear that the body mass index of intervention group (A and B) showed a non-significant at ($p \geq 0.05$) level difference.

In this study, the combination of eight herbs powder depicted a per cent reduction of 32.3 per cent fasting blood glucose levels (FBG), 33.7 per cent in postprandial blood glucose level (PPBG) and 18.5 per cent HbA1c after an intervention period of three months. In other similar study (Joffee, 2001) where only one herb, *Gymnema sylvestre* extract (400mg) was given twice a day to diabetic patients for three months'. FBG and PPBG level decreased by 11 and 13 per cent respectively. A 0.6 to 0.8 per cent decrease was observed in HbA1c. It shows combination of herbs has better effect on FBG, PPBG and HbA1c levels as compared to a single herb.

Our study results are comparable to some studies (Shanmugasundaram et al, 1990; Anuradha, 2001; Paliwal, 2009) as well, where administration of spirulina, Gurmar extract and Gurmar leaf powder was done in diabetic patients, for 60 days along with diet counselling. Significant reduction in the blood glucose levels (fasting, postprandial and random) in the experimental group was noticed. A study done by Gupta, 1990 administration of *M. charantia* seeds to six Type 1 diabetic and 14 Type 2 diabetic patients significantly decreased the PPBG level in both groups (Grover and Gupta, 1990). In a latest study Rahman 2009 compared effect of *M. charantia* and rosiglitazone, between 25 Type 2 diabetic patients fruit juice (*M.charantia*) 55ml/day for 5 months and found *M.charantia* was more effective in the management of diabetes and its complication than rosiglitazone.

7.5.3 Feedback response regarding effect of three months intervention on Type 2 adult male diabetic patients

7.5.3.1 Patient's perception of improvement and his satisfaction with the herbal therapy at the end of the intervention

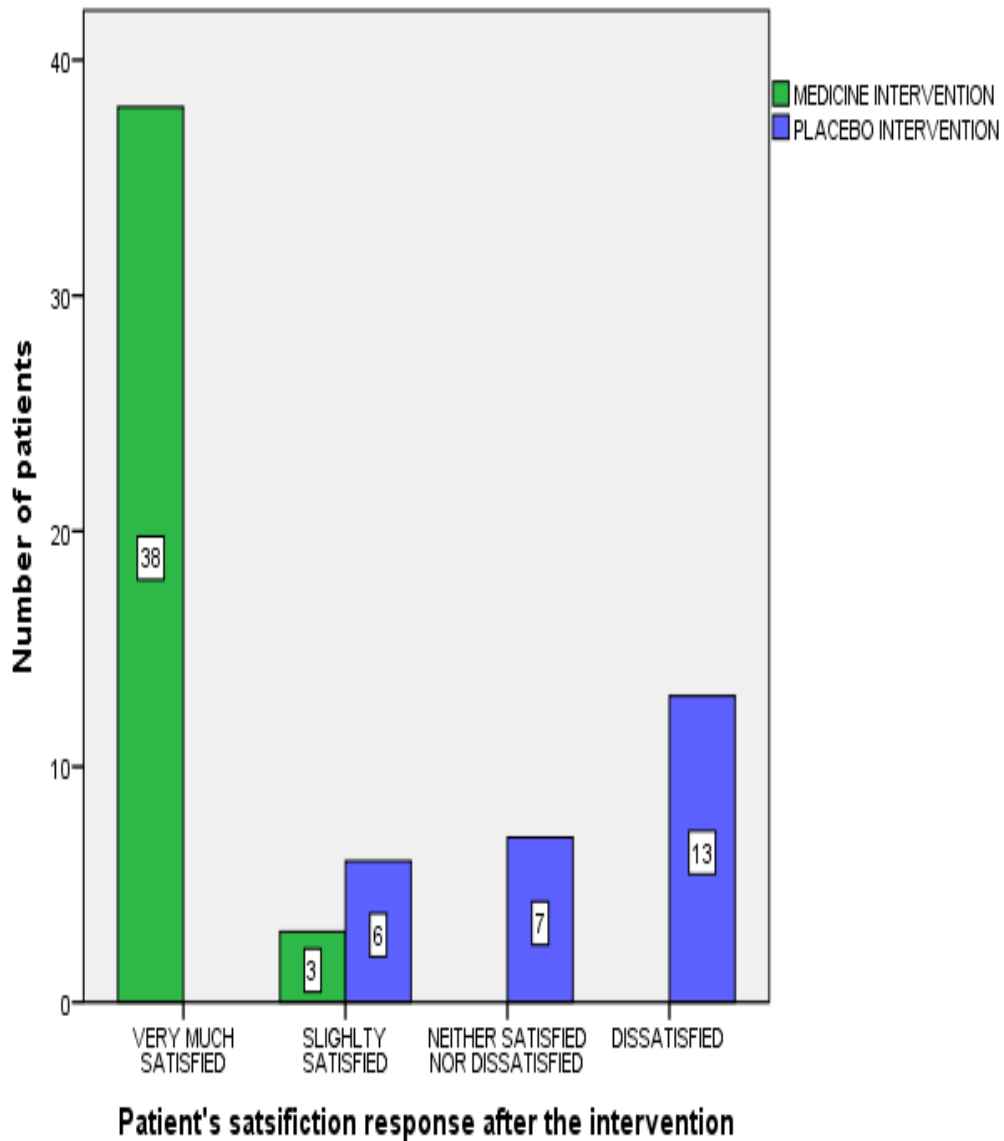


(n=67)

Figure 82. Patient's perception after the intervention period

The figure 82 show that in group A (herbal intervention) (n=41), response after herbal intervention was 90.24 per cent (n=37) feel much better, 9.75 per cent (n=4) feel better and in group B (placebo intervention) (n=26), 26.92 per cent (n=7) feel better, 69.23 per cent (n=18) feel same as before intervention no any improvement and 3.84 per cent (n=1) only condition more deteriorate.

7.5.3.2 Patient's satisfaction response after the intervention

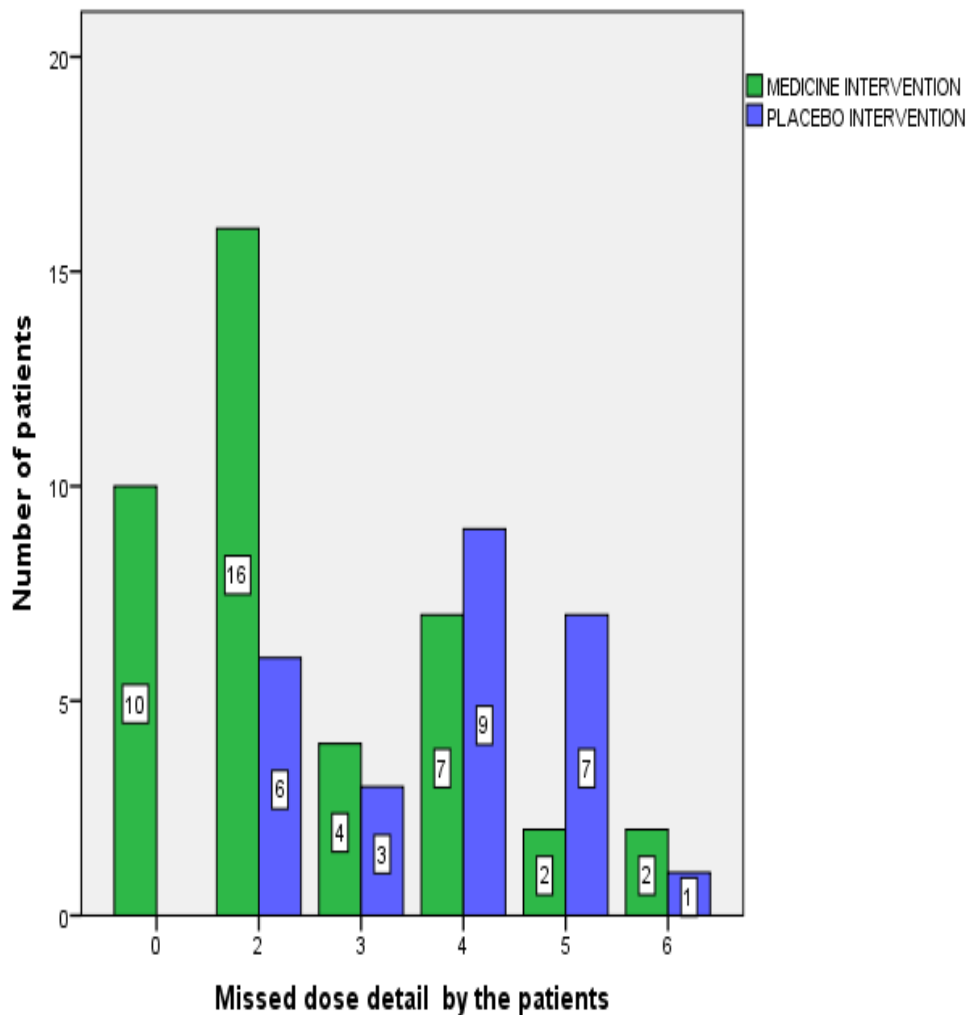


(n=67)

Figure 83. Patient's satisfaction response after the intervention

From figure 83 data revealed that in group A (herbal intervention) (n=41), response after herbal intervention was 92.68 per cent (n=38) very much satisfied, 7.31 per cent (n=3) slightly satisfied and in group B (placebo intervention) (n=26), 23.07 per cent (n=6) slightly satisfied, 26.92 per cent (n=7) neither satisfied nor dissatisfied and 50 per cent (n=13) dissatisfied from placebo intervention.

7.5.3.3 Missed dose details of the intervention(Herbs/Placebo)

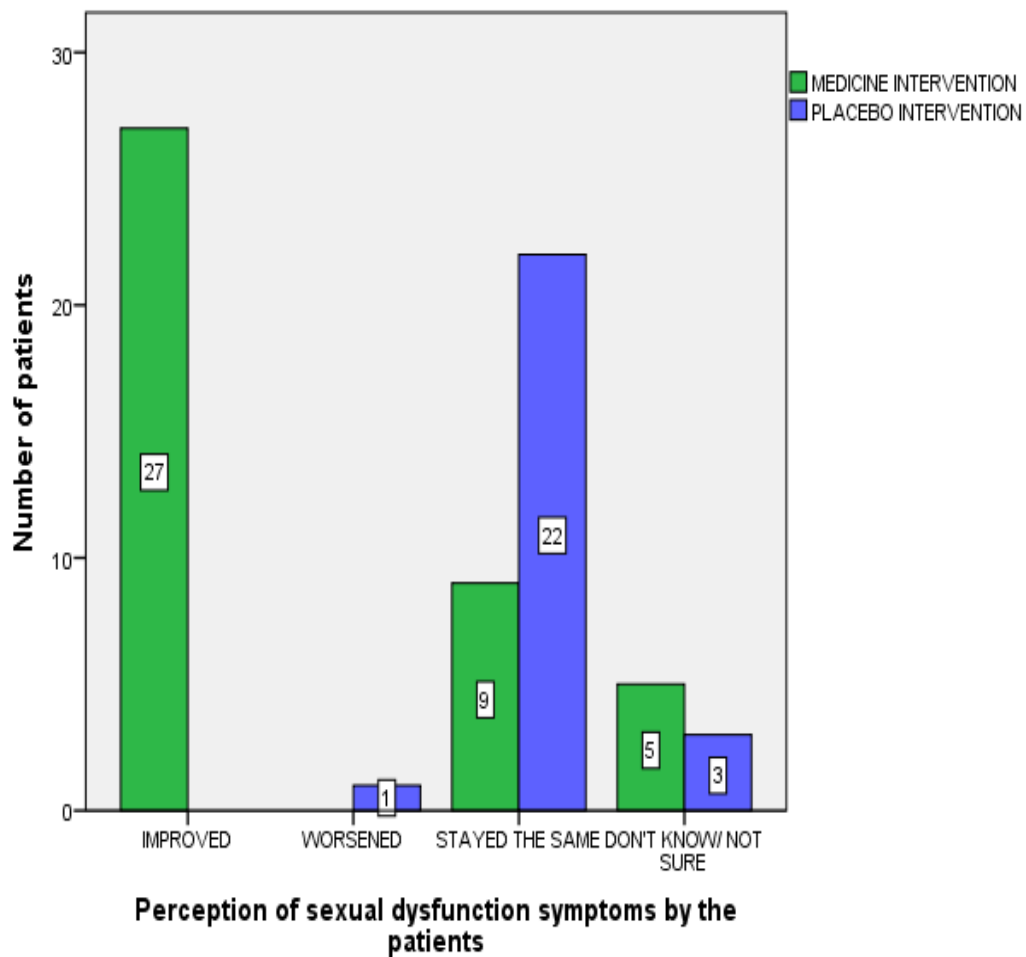


(n=67)

Figure 84. Missed dose details of the intervention by the patients

Figure 84 shows missed dose details of intervention supplement, in group A (herbal intervention) (n=41), was 24.39 per cent (n=10) not missed any dose took regular all dose of herbal powder, 39.02 per cent (n=16) missed two dose of herbal supplement, 9.75 per cent (n=4) missed three dose, 17.07 per cent (n=7) subjects missed five doses, 4.87 per cent (n=2) missed six doses and in group B (placebo intervention) n=26, no any person missed any dose, 23.07 per cent (n=6) miss two doses, 11.53 per cent (n=3) misses three doses, 34.61 per cent (n=9) missed four doses, 26.92 per cent (n=7) missed five doses and 3.84 per cent (n=1) missed six doses of placebo intervention.

7.5.3.4 Perception of sexual dysfunction symptoms after the intervention



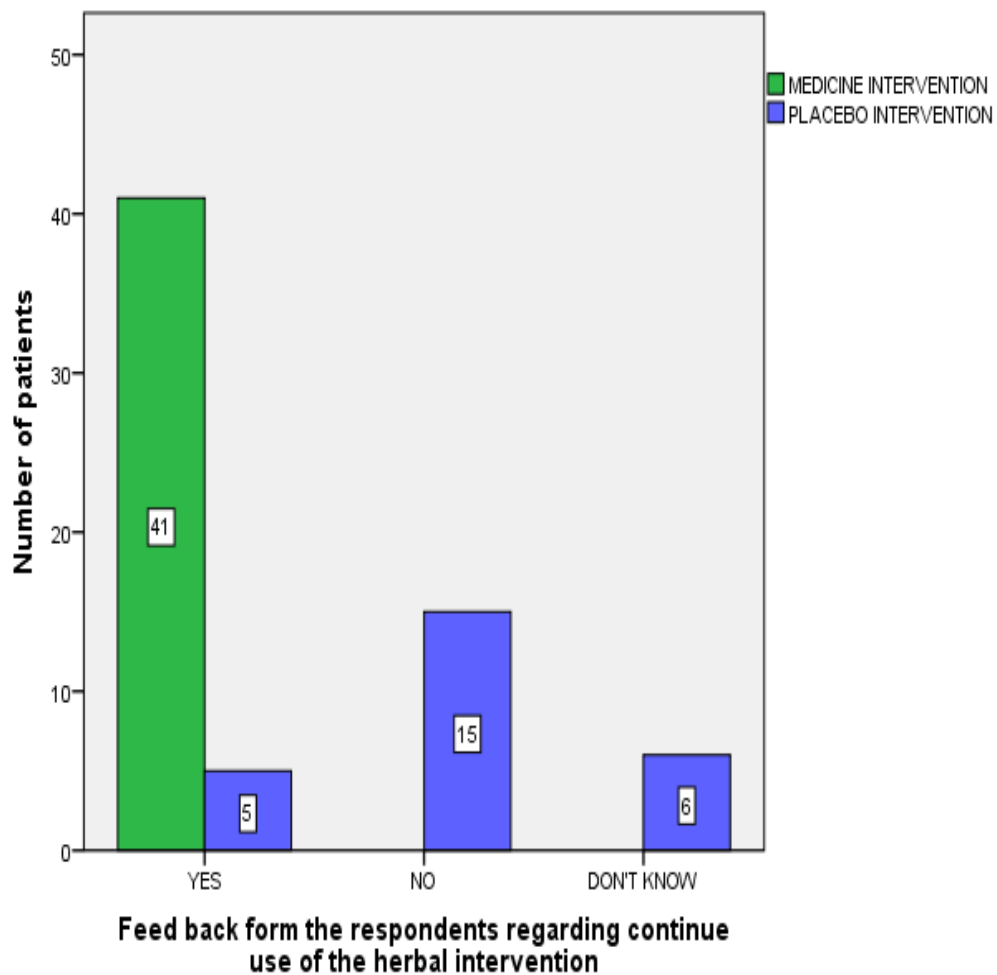
(n=67)

Figure 85. Perception of sexual dysfunction by the patients after the intervention

Figure 85 shows response about status of sexual dysfunction symptoms after three months interventions, in group A (herbal intervention) (n=41), 68.85 per cent (n=27) improved in their sexual dysfunction, 21.95 per cent (n=9) response same symptom as before and 12.19 per cent (n=5) don't know about their sexual symptoms.

In group B (placebo intervention) n=26, mostly 84.61 per cent (n=22) response that sexual symptoms remain same as before intervention, 3.84 per cent (n=1) symptom deteriorate and 11.5 per cent (n=3) don't know about their symptoms of sexual problem.

7.5.3.5 Feedback response for the patients regarding continue use of herbal supplement



(n=67)

Figure 86. Feedback response from the patients regarding continue use of the herbal intervention

Figure 86 shows response regarding continue use of this therapy (Herbal intervention) after three months interventions, in group A (herbal intervention) all 100 per cent (n=41) all were confident to continue the same therapy for long time.

While in group B (placebo intervention) n=26, only 19.23 per cent (n=5) were confident and want to continue the same therapy for long time, 57.69 per cent (n=15) don't want continue the same therapy for long time and 23.07 per cent (n=6) don't know about their status they want to continue or not for the same therapy for long time.

7.5.3.6 Response after the intervention from the respondents

Table 54. Response after the intervention from the respondents.

S. No.	Variables	Options	A (n=41)	B (n=26)
1.	Any side effect or any other health problem since start of this herbal treatment	Yes	0	0
		No	41(100%)	26 (100%)
2.	Physical active	Yes	41 (100%)	26 (100%)
3.	Follow diabetic diet	Yes	41 (100%)	26 100%)

(n=67)

From the table 54 data shows response regarding any side effect or any other health problem after three months interventions, in group A (herbal intervention) all 100 per cent (n=41) all were response do not any problem or any side effect of this herbal supplementation. While in group B (placebo intervention) also all 100 per cent (n=26) response they also don not have any problem or any side effect due to this intervention. All (n=47) respondents follow regular exercise and diet regime during this intervention period.

7.5.3.6 Insulin intake details of the respondents at baseline and after the intervention

Table 55. Mean insulin intake details of the respondents after the intervention

Variables	Group	Time period		p value
		Baseline (1 week) Pre Intervention	12 week Post Intervention	
Mean Insulin intake (unit)	A(n=11)	33.36±13.94	16.73±15.62	(p > 0.05)
	B (n=2)	24±0	29±1.4	(p > 0.05)

(* The mean difference is significant at the 0.05 level)

Table 55 data revealed response regarding mean insulin intake before and after the three months interventions period, in group A (herbal intervention) only (n=11)

Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults:

respondents using insulin to treat diabetes mellitus and they using mean insulin intake was 33.36 ± 13.94 units which reduce after 12 weeks 16.73 ± 15.62 units with non-significantly difference. While in group B (placebo intervention) only three subject using inulin and at baseline mean insulin intake was 24 ± 0 unit which after three months intervention increase to 29 ± 1.4 units.

7.5.3.7 Medicine and insulin intake effect details after the intervention period

Table 56 depicts regarding changes in medicine intake and insulin intake after three months interventions, in group A (herbal intervention) six person insulin intake reduce, three person stop insulin, and two person on same dose of insulin after the three months intervention period. There was significant difference in medicine intake reduction and insulin intake reduction as compared in herbal intervention and placebo intervention groups.

Table 56. Changes in medicine and insulin intake detail of the respondents after the intervention

Variables	Options	Group A	Group B	P value
Any Change in Insulin Intake A (n=11) B (n=3)	Reduce	6 (42.9%)	0	*(p < 0.05)
	Stop	3 (21.4%)	0	
	Increased	0	2 (14.3%)	
	Same	2 (14.3%)	1 (7.1%)	
Any Change in Medicine Intake A (n=37) B (n=26)	Reduce	7 (11.1%)	0	*(p < 0.05)
	Stop	7 (11.1%)	0	
	Increased	0	2 (3.2%)	
	Same	23 (36.5%)	24 (38.1%)	

(Significance p value was considered at *0.05)

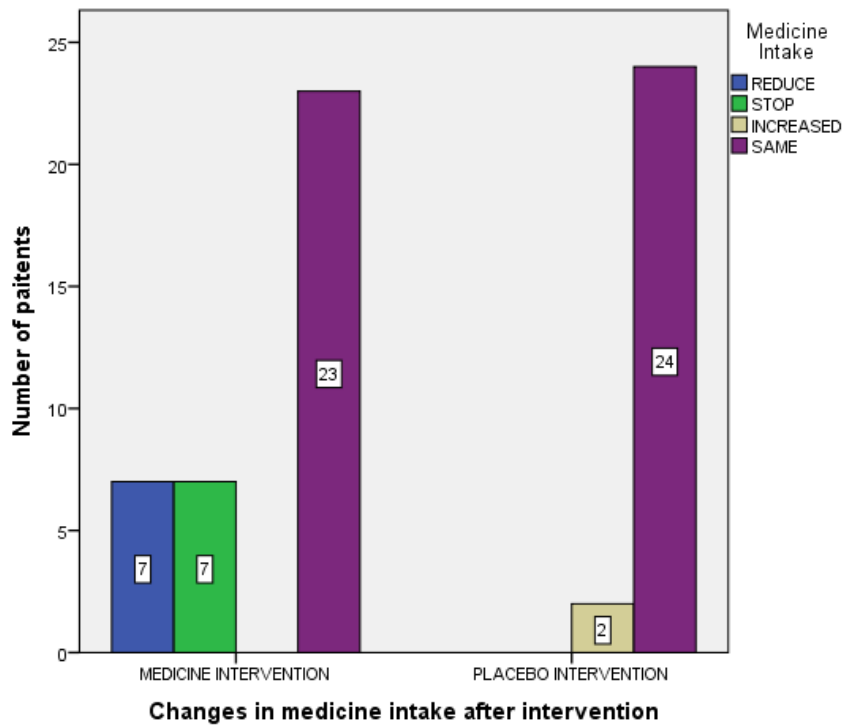


Figure 87. Change in medicine intake after the intervention by the patients

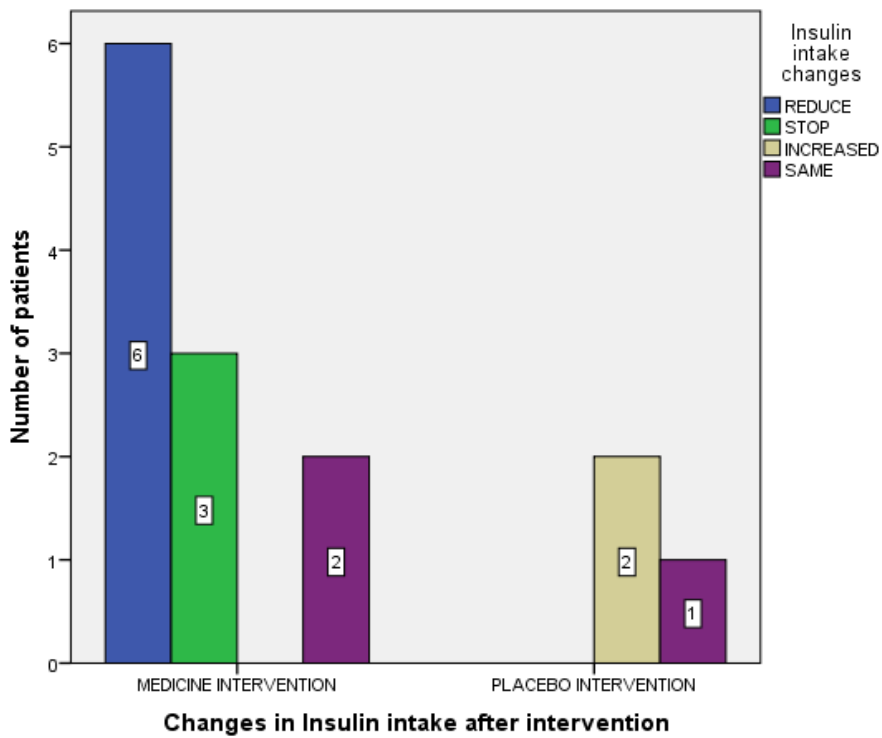


Figure 88. Change in insulin intake after the intervention by the patients

While in medicine intake seven person medicine intake reduce, seven person stop to intake their medicine for reduce blood glucose and (n=23) person were on same dose of medicine after the three month intervention periods. In group B placebo intervention two persons increase their insulin intake and one was on same dose of insulin. For medicine intake two person medicine dose increase and (n=24) person were remain on same dose of their medicine or OHA.

7.5.3.8 Symptoms improvement details after the intervention of the respondents

Table 57. Details of symptoms improvement of the respondents after intervention

Symptoms	Number	Option	Group A	Group B	p value
Nocturia	A (n=32)	Less	32 (59.3%)	3 (5.6%)	(p < 0.001)*
	B (n=22)	Same	0	19 (35.2%)	
Polyuria	A (n=28)	Less	28 (57.1%)	6 (12.2%)	(p < 0.001)*
	B (n=21)	Same	0	15 (30.6%)	
Tiredness	A (n=33)	Less	33 (62.3%)	2 (3.8%)	(p < 0.001)*
	B (n= 20)	More	0	1 (1.9%)	
		Same	0	17 (32.1%)	
Burning Sensation under feet	A (n=20)	Less	20 (74.1%)	2 (7.4%)	(p < 0.001)*
	B (n=7)	Same	0	5 (18.5%)	
Weight Loss	A (n=17)	Less	8 (26.7%)	4 (13.3%)	(p > 0.001)*
	B (n=13)	More	2 (6.1%)	1 (3.3%)	
		Same	7 (23.3%)	8 (26.7%)	
Itching	A (n=10)	Less	10 (71.4%)	3 (21.4%)	(p > 0.001)*
	B (n=4)	Same	0	1 (7.1%)	
Polydypsia	A (n=10)	Less	10 (43.5%)	11 (47.8%)	(p > 0.001)*
	B(n=13)	Same	0	2 (8.7%)	
Polyphagia	A (n=5)	Less	5 (41.7%)	6 (50%)	(p > 0.001)*
	B (n=7)	More	0	1 (8.3%)	
Excessive Sweating	A (n=7)	Less	7 (87.5%)	1 (12.5%)	(p > 0.001)*
	B (n=1)	Same	0	0	

(Significance p value was considered at *0.001)

Table 57 data shows the improvement in the symptoms of the patients after the interventions as follows:

Nocturia symptoms in group A symptoms after three months intervention period Nocturia symptoms reduce among all (n=32) subjects while in group B three subjects symptoms reduce and (n=19) subjects symptoms remain same. There was significant difference in nocturia symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Polyuria symptoms in group A all (n=28) subjects response their symptom of polyuria reduce and in group B (n=6) subjects response for reduce in symptoms and (n=15) reports same symptom as before the intervention. There was significant difference in polyuria symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Tiredness symptom in group A subjects report less in all (n=33) respondents while in group B two subjects report about reduce in tiredness symptoms, one said increase and (n=17) subject's symptoms remain same as before the intervention period. There was significant difference in tiredness symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Burning sensation under feet symptoms in group A all (n=20) subjects report reduce in symptoms and in group B (n=2) report about reduction in symptoms and (n=5) subjects symptoms remain same. There was significant difference in burning sensation under feet symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Weight loss in group A (n=8) subjects report less weight loss, (n=2) increase weight loss and seven report the weight remain same after the intervention period. In group B four subjects less weight loss, one more weight loss and (n=8) subject's weight remain the same as before the intervention period.

Itching in group A all (n=10) patients with this symptoms report that symptoms were less after the three months intervention period, in group B three patients says

symptoms were less and one said same symptoms as before the intervention period. There was non-significant difference in itching symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Polydypsia in group A all (n=10) subjects say their symptoms reduce after three months intervention and in group B (n=11) subjects symptoms reduce and (n=2) subjects symptoms remain same as before the intervention. There was non-significant difference in Polydypsia symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Polyphagia in group A all (n=5) subjects symptom reduce and in group B (n=6) subjects symptoms reduce and one's remain same as before the intervention. There was non-significant difference in polyphagia symptoms reduction in herbal intervention groups as compared to placebo intervention group.

Excessive sweating in group A all (n=7) subjects symptoms reduce and in group B only one subjects symptoms reduce after the intervention of three months.

CHAPTER 8

CONCLUSION, FUTURE SCOPE AND SUGGESTION

8.1 Conclusion

The present study on “Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults: A randomized controlled trial” was undertaken to explore the possibility if an herbs based lifestyle intervention has a potential to have a beneficial impact on various sexual dysfunction and blood glucose levels of diabetic male adults.

Data shows that more than 50 per cent of people whose have diabetes remain undiagnosed. About 20 to 30 per cent already has developed complications before them being diagnosed for diabetes. Conservative nature towards discussing sexual issues in Indian population is another factor which aggravates the problems. Most of the herbs which were used to prepare herbal intervention for diabetes and sexual dysfunction are commonly found in local Indian market.

One hundred Type 2 adult male diabetic patients were selected. The age ranged from 25-60 years. The selected subjects were randomly assigned by randomization table to two groups of fifty each; fifty with group A as herbal powder intervention group and fifty with group B placebo intervention group. Herbal formulation brought down highly significant reduction in fasting blood glucose level, postprandial blood glucose level and HbA1c level and statistically significant increase in IIEF score. This herbal supplement showed 32.3 per cent reduction in fasting blood glucose, 33.7 per cent reduction in postprandial blood glucose level, 18.5 per cent reduction in HbA1c level and 11.13 per cent increase in IIEF score; whereas placebo group showed non-significant changes in blood glucose levels and IIEF score after the intervention of three months.

This herbal supplement can be used as adjunct for treatment of diabetes mellitus and sexual dysfunction in diabetic adult male patients. Therefore, there is a great potential for utilization of this herbal powder. The other finding of the study is that a high prevalence of malnutrition among adult with diabetes was observed. Malnutrition was found to be related to blood glucose levels and HbA1c level and showed poor diabetic control. Patients with normal nutritional status analysed through

MNA showed better control over blood glucose as well as IIEF score. Forty per cent were categorized as 'at risk of malnutrition' and showed poor diabetic control. So, Periodic nutritional assessment of diabetic patients will help in better monitoring and therefore fair control over their blood glucose levels and sexual dysfunction. Improved quality of nutritional care services in terms of nutritional monitoring and diet counselling should be provided to prevent progression of diabetes and sexual dysfunction.

Adverse event and Side effect

There was not any adverse event or any side effect noted of these herbal intervention. This herbal powder was well tolerated during the study period.

8.2. Future scope

As result shows there can be a big scope of the developed herbal powder supplement to use as adjunct for treatment of diabetic mellitus patients with sexual dysfunction with the intervention of pharmaceutical industry.

8.3. Suggestion

Based on the results of the study following recommendations were drawn.

1. Another similar study on diabetic female patients regarding sexual satisfaction can be done.
2. Raising awareness through education camp among diabetic patients soon as soon possible to evade a remaining lifetime burdened diabetes.
3. Doctor and patient should consider sexual health to a part of normal health and TV add can be given to aware the public.
4. There should be special trained expert in sexual health/ sexologist to treat such problem in endocrinology OPDs.
5. The conservative nature towards sexual dysfunction barrier to be broken.
6. All adult men with diabetes should regularly screened for sexual dysfunction.

To managing your diabetes well includes healthy eating, regular exercise, and reducing stress, will benefit your entire body, not just your nether regions. “I think it’s very likely that a good sex life leads to better health,” says Lindau. “And better health leads to good sex.” By American Diabetes association 1701, (2015).

Discussion on Hypothesis

1. The first hypothesis framed that there any significant difference in blood glucose levels and IIEF score on Type 2 adult male diabetic patients after the intervention period of herbal supplement. The result of present study reveals that there was a significant change on biochemical parameter (blood glucose levels) and sexual dysfunction parameters (IIEF score) variables when compared to placebo group. Therefore the researcher’s hypothesis was accepted.
2. In the second hypothesis it was stated that there any difference in medicines and drugs (insulin) intake after the intervention of herbal supplements. The result of present study reveals that after the intervention period the intake of medicine and drugs (Insulin) was reduced in compare to placebo group. Hence the researcher hypothesis was accepted and null hypothesis was rejected.

CHAPTER 9

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CHAPTER 10

APPENDIX

APPENDIX-I

**Some Marketed Antidiabetic, Strength and Vitality Ploy herbal Formulations
(Market Survey):**

Name	Company	Ingredients
Diabecon	Himalaya	<i>Gymnema sylvestre, Pterocarpus marsupium, Glycyrrhiza glabra, Casearia esculenta, Syzygium cumini, Asparagus racemosus, Boerhavia diffusa, Sphaeranthus indicus. Tinospora cordifolia, Swertia chirata, Tribulus terrestris, Phyllanthus amarus, Gmelina arborea, Gossypium herbaceum, Berberis aristata, Aloe vera, Triphala, Commiphora wightii, Shilajeet, Momordica charantia, Piper nigrum, Ocimum sanctum, Abutilon indicum, Curcuma longa, Rumex maritimus.</i>
Diasulin	Tobbest Busindo	<i>Cassia auriculata, Coccinia indica, Cuccuma longa, Emblicia officinalis, Gymnema sylvestre, Momordica charantia, Scoparia dulcis, Syzygium cumini, Tinospora cordifolia, Trigonella foenum graecum.</i>
Bitter gourd powder	Garry and Sun natural remedies	<i>Momordica charantia</i>
Dia-care	Admark Herbals ltd	Sanjeevan Mool, himej, Jambu beej, kadu, namejav, Neem chal
Diabetes-Daily Care	Nature's Health Supply	Alpha Kipoic Acid, Cinnamon 4 per cent Extract, Chromax, Vanadium, Fenugreek 50 per cent extract, Gymnema sylvestre 25 per cent extract, Momordica charantia 7 per cent extract, Licorice Root 20 per cent extract
Gurmar Powder	Garry and Sun natural remedies	<i>Gymnema sylvestre</i>
Diabecure	Nature beaute sante	<i>Juglans regis, Berberis vulgaris, Erythrea centaurium, Millefolium, Taraxacum</i>
Diabeta	Ayurvedic cure	<i>Gymnema sylvestre, Vinca rosea, Curcuma longa, Azadirachta indica, Pterocarpus marsupium, Momordica charantia, Syzygium cumini, Acacia Arabica, Tinospora cordifolia, Zingiber officinale</i>
Syndrex	Plethico Laboretaries	Germinated Fenugreek seed extract
Madhumeh Amrit	D.P. Drugs	<i>Apium gravelens, Gentiana chiratita, Tinospora cordifolia, Azadirachta indica</i>
Amar Vati	D.P. Drugs	<i>Chlorophytum tuberosum, Withania somnifera, Bambusas arundinacea, Myristica fragrans</i>

Rizer	Vital Care	<i>Withania somnifera, Asparagus racemosus, Tribulus terrestris, Dioscorea bulbifera, Pueraria tuberosa, Eclipta alba, Tinospora cordifolia, Mucuna pruriens, Liquidamber oreintalis</i>
Diabac	Bacfo	<i>Gymneme sylvestre, Aegle marmelos, Asphaltum, Eugenia jambolana, Ficus bengalensis</i>
Dia Now	Richfield International Pvt ltd	<i>Syzygium cumini, Trigonella foenum graecum, Azadirachta indica, Emblica officinalis, Cassia auriculata, Zymnema sylvestre, Andrographis paniculata, Tribulus terrestris, Pterocarpus marsupium</i>
Diabegon	Dindayal Aushadhi	<i>Terminalia chebula, Terminalia bellirica, Emblica officinalis, Zingiber officinale, Piper longum, Piper nigrum, Gymnema sylvestre, Eugenia jambolana, Pterocarpus marsupium, Trigonella fenum-graecum, Curucma longa, Tinospora cordifolia, Momordica charantia, Asfetum punjabinum,</i>
Ashwgandha pak	Wilson Drugs and pharmaceutical(p) ltd	Ashwagandha, Dalchini, tejpatta, nagkesar elacichi, jaiphal, kesar, vanshlochan, mochras, long, gokhru,
Chuhara pak	Wilson Drugs and pharmaceutical(p) ltd	Chuhara, Pipli, Kali musli, Safed musli, Long, Jaiphal, Javitri, Tejpatter, Bala, Kesar,
Bio-Gymnema	Ayush Pharmaceutical and Mktg Pvt ltd	<i>Gymnema sylvestre, Pterocarpus marsuplum, Ocimum basillicum, Momorida charantia, Azadirachta indica, Vinca rosea, Salacia chinensis, Aegel marmelos, Trigonella foenum graecum, Syzygium cumini</i>
Sparant	Vital Care	<i>Mucuna pruriens, Withania somnifera, Tribulus terrestris, Ipomoea digitata, Asparagus adscendens, Shilajita, Myristica fragrans</i>
Rizer	Vital Care	<i>Withania somnifera, Asparagus racemosus, Tribulus terrestris, Dioscorea bulbifera, Pueraria tuberosa, Eclipta alba, Tinospora cordifolia, Mucuna pruriens, Liquidamber orientalis (Shilajit)</i>
Stresscom	Dabur	Ashwagadha roots
Empromin	Trio healthcare Pvt ltd	<i>Withania somnifera, Asparagus racesus, Ipomoea digitata, Eclipta alba, Glycyrrhiza glabra, Phyllanthus embica,</i>
Piyagra	Surjichem Herbs India	Laung, Jiaphal, Kuchla, Kali mirch, Konch beej, Akarkara, Setawar, Shilajit, Kesar, Bhasm
Shilajit Plus	Surjichem Herbs India	<i>Asphaltum Punjabinium, Triphala, Withania somnifera</i>
Gold Night	Surjichem Herbs India	<i>Caryophyllus aromaticus, Myristica fragrans, Crocus sativus, Withania somnifera, Pueraria tuberosa, Tribulus terrestris, Asparagus adscendens, Sida cardifolia, Mucuna pruriens, Mesua ferrea, Strychnos-nus-vomica, Piper nigrum, Asparagus racemosus, Acacia arabica, Asphaltum punjabinum</i>
Mood Up	Elee Care Pharmaceuticals	<i>Myristica fragrans, Crocus sativus linn moult, Asparagus adscendens roxb, Strychnos Nox vominca linn, Shilajit, Mucuna prurita hook, Asparagus racemosus willd, Withania somnifera linn</i>

Appendix II

Interviewer-Screening Questionnaire (ISQ)

STRICTLY CONFIDENTIAL
(For research purpose only)

Part 1 A: - Identification and Socio-demographic data

Q1.Sr. No. _____ Q2. Date _____ Q3.CRNo. _____

Q4. Name of person: _____

Q5. Age _____ (years) (25-60 yrs.)

Q6. Address/City: _____

Q7. Phone No.- _____ / _____

Q8. Education: (1=Illiterate, 2=Primary, 3=Middle, 4=Matric, 5=10+2, 6=Graduate and above)

Q9. Marital Status: (1=Unmarried 2=Married, 3=Divorcee 4=Separated)

Q10. Age at: Marriage _____ years

Q11. Occupation: (1= Employed 2 = Unemployed)

Q11 (a). If Employed (1==Private Job, 2=Business, 3=Govt Job , 4= Laborer, 5= others _____)

Q12. Righteousness: (1=Hindu, 2=Sikh, 3=Muslim, 4=Christian, 5=Others)

Q13. Type of family: 1=Nuclear, 2=Joint

Q14. Family income/ month: Rs. _____

Appendix III

Diabetes information questionnaire

- Q1. Age of onset of diabetes _____ Years
- Q2. Symptoms present for diabetes?
- | | | |
|----------------|---------------------------------|-----------------|
| 1. Polydypsia | 5. Itching | 9. Polyuria |
| 2. Polyphagia | 6. Tiredness | 10. Nocturia |
| 3. Drowsiness | 7. Excessive sweating | 11. Other _____ |
| 4. Weight Loss | 8. Burning sensation under feet | |
- Q3. Blood glucose monitored regularly? Yes= 1, No=2
- Q4. Ever had hypoglycemia? Yes = 1, No=2 If yes
- Q5. Ever glucose level fluctuate? Yes=1, No=2
- Q6. Do you take any medicines? Yes=1, No=2 If yes
- Q7. (A) Detail _____
- Q8. Do you take your medicines regularly? Yes=1, No=2
- Q9. Do you take insulin Yes=1, No=2 If yes
- Q10. (A) Detail _____

Bio chemical estimations

S.No	Blood test	Unit	Date	Last Reading
Q11.	Glucose (fasting)	mg/100 ml		
Q12.	Postprandial glucose (After 2 hrs.)	mg/100 ml		
Q13.	Before/ After meal RBG	mg/100 ml		
Q14.	Hb1Ac	%		

APPENDIX IV

Schedule to identify the treatment seeking behaviour of sexual dysfunction in diabetic male patients

- Q1. Do you have any sexual dysfunction? (Yes=1, No=2)
- Q2. Which problem you have? (Premature ejaculation=1, Erectile Dysfunction=2, Lack of interest in sexual activity=3)
- Q3. When notice this condition/Symptoms? (From year=1, 1-2 years =2, 3-4 years =3, ≥ 5 years =4, don't know=5)
- Q4. Presently taking any treatment for Sexual dysfunction?(Yes =1, No = 2)
- Q5. Time lag between onset of symptoms and consultation?
1. Same day
 2. 1-7 days
 3. 8-30 days
 4. One month or more, if more, write the number of months.....
- Q6. Onset of the problem was: (Gradual =1, Sudden=2)
- Q7 (A). If sudden, was it related in onset to? (Surgery=1, New medication=2, Life event=3, Penile injury=4)
- Q8. Provide details of agencies you have consulted for treatment in past include home remedies.

Sr. No.	Name of Agency	Time Lag	Treatment Given	Duration	Money Spent	Referred by	Effect

Q9. Since how long have you been taking the treatment? Specify

Q10. From where are you taking treatment for Sexual dysfunction?

1. Private clinic/hospital
2. Govt. Hospital/ PHC/ Dispensary
3. Private pharmacy
4. NGO clinic
5. Self-Medication
6. Others, Specify...

Q11. Which treatment do you prefer for Sexual Dysfunction?

1. Allopathic
2. AYUSH
3. Physiotherapy
4. Acupressure/ Acupuncture
5. Nutritional Therapy
6. Others, Specify

Q12. If No, why did not you take any treatment?

- | | | |
|-----------------------|---------------------|-------------------------------------|
| 1. Felt shy
Km | 4. No Time | 7. Too far away,
how much? |
| 2. Consider it normal | 5. No escort | 8. No transport |
| 3. Got better | 6. Not enough money | 9. Not took it seriously |

RISK FACTORS FOR SEXUAL DYSFUNCTION

- | | | |
|---|-------|------|
| Q13. Do you ride a bicycle regularly? | YES=1 | NO=2 |
| Q14. Have you ever smoked cigarettes regularly? | YES=1 | NO=2 |
| Q15. Have you ever had alcohol drinking? | YES=1 | NO=2 |
| Q16. Have you had prostate problem? | YES=1 | NO=2 |

APPENDIX V

Life experience, life style and of reproductive health

- Q1. Age when first time you experienced sexual intercourse? _____years
- Q2. Do you enjoy sound sleep? (Yes=1, No=2)
- Q3. How many hours do you sleep daily? _____
- Q4. At what time you get up _____
- Q5. After how much time (hour) taking dinner you going for sexual activity. _____
- Q6. If you ever do sex immediately having your meal any problem you faced such as stomach upset/ Indigestion? (1=stomach upset, 2= indigestion, 3=No problem, 4= any other _____)
- Q7. When you do sex? (1=day, 2= night, 3= any time, 4= NA, 5=don't know)
- Q8. What time you feel more enjoyable? (1=day, 2= night, 3= any time, 4= not answer 5= don't know)
- Q9. Any specific time when you want to have sex such as night 10 pm or 11 pm or early morning 5 am or 6 am. _____
- Q10. Some people in early morning have erect penile do you have same?
(Yes =1, No=2)
- Q11. Do you use any unlawful drugs? (1 = Yes, 2 = No, 3 = Do not know, 4 = N A)
- Q12 (A) If Yes, what drugs? (Weed=1, Heroin=2, Steroids=3, Other=4 _____)
- Q13. Do ever you take any medicine or anything special thing to increase sexual power? (1 = Yes, 2 = No, 3 = Do not know, 4 = Not answered)
- Q14. Of what sort of your penis upon achieving orgasm/ discharge?
1. Unable to achieve orgasm 3. Partial (equal to or less than half erect)
2. No erection at all 4. Partial (better than half erect)
5. Full erection
- Q15. How long you do sexual activity _____ (Time in minutes)
- Q16. Do you feel fear to have sex or in sexual relations?
(1 = Yes, 2 =No, 3 = Do not know, 4= N A)
- Q17. Are your partner refusing to have sex?
(1 =Yes, 2 =No, 3 =Do not know, 4=N A)
- Q18. How often you had sex? (Daily=1, Two time in week=2, Weekly=3, Monthly=4)
- Q19. Have sex other than spouse while married?
(1 = Yep, 2 = Nope, 3 = Do not know, 4 = Not answered)
- Q20. A if yes, feel same pleasure with other partner?
(1= More, 2=Less, 3 = Not known, 4= N A)

Q21 (B) or same problem (PE/ED) with other partner?

(1 = Yep, 2 = Nope, 3 = Do not know, 4 = Not answered)

Q22. Number of women intercourse done with during entire life?

(1=1, 2=2, 3=4, 4= 5 and more, 5 = Not known, 6 = Not answered)

Q23. In your opinion having sex with other than partner?

(1 = Good, 2 = Bad, 3 = Don't know, 4 = Not answered)

Q24. How many children do you have: _____

Q25. Have you had any difficulty fathering children? (Yes=1, No=2)

Q26. When you had your first baby after marriage?

1. After one year of marriage 3. After three year of marriage
2. After two year of marriage 4. After four year or more of marriage
5. No baby

Q27. Do you feel any problem or less enjoyment in sexual activity after having children? (Yes = 1, No = 2)

Q28. Do you use condom during sex? (1 = Yep, 2 = Nope, 3 = not known, 4 = N A)

Q29. Feel same enjoyment in sexual activity while using condom.

(1 = More, 2 = Less, 3 = don't know, 4 = Not answered)

Q30. How often attends Devine gatherings.

(1 = Daily, 2 = Weekly, 3 = Monthly, 4 = Never, 5= N A)

Q31. How often does you pray?

(1 = Daily, 2 = Weekly, 3 = Monthly, 4 = Never, 5 = Not answered)

Q32. Happiness of marriage?

(1 = Extreme happy, 2 = Pretty happy, 3 = No happy, 4= not known, 5 = NA)

Q33. Do you have any stress, anxiety or depression?

(1 = Yep, 2 = Nope, 3 = not known, 4 = N A)

Q34. In general, I am happy with my sex life.

(1=Extreme happy, 2 = Pretty happy, 3 = No happy, 4=not known, 5 = NA)

Q35. Want to participate in Study (Intervention). (Yes=1, No=2)

Q36. Willingness to provide informed consent and to visit hospital for follow up.

(Yes=1, No=2)

Q37. Any pre-existing condition (Kidney problem, liver dysfunction)

(Present=1, Not present=2)

Q38. Enrolled in other active intervention research studies? (Yes=1, No=2)

Q 39. Your overall general health status?

1=Fantastic, 2= Very good, 3=Good, 4=Fair, 5=Poor

APPENDIX VI

**INTERNATIONAL INDEX
OF ERECTILE FUNCTION
(IIEF)**

HOSPITAL NUMBER (IF KNOWN)

NAME

DATE OF BIRTH / / AGE

ADDRESS

.....

.....

Patient Questionnaire

TELEPHONE

These questions ask about the effects that your erection problems have had on your sex life over the last four weeks

only

Please check one box

- | | | |
|----|---|---|
| Q1 | How often were you able to get an erection during sexual activity? | 0 No sexual activity
1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always |
| Q2 | When you had erections with sexual stimulation, how often were your erections hard enough for penetration? | 0 No sexual activity
1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always |
| Q3 | When you attempted intercourse, how often were you able to penetrate (enter) your partner? | 0 Did not attempt intercourse
1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always |
| Q4 | During sexual intercourse, <u>how often</u> were you able to maintain your erection after you had penetrated (entered) your partner? | 0 Did not attempt intercourse
1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always |

- Q5 During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?
- Q6 How many times have you attempted sexual intercourse?
- Q7 When you attempted sexual intercourse, how often was it satisfactory for you?
- Q8 How much have you enjoyed sexual intercourse?
- Q9 When you had sexual stimulation or intercourse, how often did you ejaculate?
- Q10 When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?
- Q11 How often have you felt sexual desire?
- Q12 How would you rate your level of sexual desire?
- Q13 How satisfied have you been with your overall sex life?
- Q14 How satisfied have you been with your sexual relationship with your partner?
- Q15 How do you rate your confidence that you could get and keep an erection?
- 0 Did not attempt intercourse
1 Extremely difficult
2 Very difficult
3 Difficult
4 Slightly difficult
5 Not difficult
- 0 No attempts
1 One to two attempts
2 Three to four attempts
3 Five to six attempts
4 Seven to ten attempts
5 Eleven or more attempts
- 0 Did not attempt intercourse
1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always
- 0 No intercourse
1 No enjoyment at all
2 Not very enjoyable
3 Fairly enjoyable
4 Highly enjoyable
5 Very highly enjoyable
- 0 No sexual stimulation or intercourse
1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always
- 1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always
- 1 Almost never or never
2 A few times (less than half the time)
3 Sometimes (about half the time)
4 Most times (more than half the time)
5 Almost always or always
- 1 Very low or none at all
2 Low
3 Moderate
4 High
5 Very high
- 1 Very dissatisfied
2 Moderately dissatisfied
3 Equally satisfied & dissatisfied
4 Moderately satisfied
5 Very satisfied
- 1 Very dissatisfied
2 Moderately dissatisfied
3 Equally satisfied & dissatisfied
4 Moderately satisfied
5 Very satisfied
- 1 Very low
2 Low
3 Moderate
4 High
5 Very high

APPENDIX VII

Physical activity questionnaire.

How Physically Active Are You RAPA-I

- Q1. Do any physical activities? Yes = 1, No = 2
- Q2. What type of exercise you do? (1.Light=walking, stretching, 2.Moderate=fast walking, aerobics. 3. Vigorous=stair, jogging)
- Q3. Duration of exercise in a week? (1=daily, 2 = 3 time in a week, 3 = 5 time in a week)
- Q4. Time spend for exercise (minutes)? (1 = 15-20, 2 = 30, 3 = 40-45, 4 = 60)
- Q5. Duration of exercise daily? 1= once daily, 2 = twice daily

RAPA-II

- Q6. Do any exercise to increase muscle strength/ Gym? Yes = 1, No = 2
- Q7. Duration of gym in a week? (1=daily, 2 = 3 time in a week, 3 = 5 time in a week)
- Q8. Time spend in gym (minutes)? (1 = 15-20, 2 = 30, 3 = 40-45, 4 = 60)
- Q9. Duration of gym daily? (1= once daily, 2 = twice daily)

APPENDIX VIII

24 hours dietary recall questionnaire

DAILY SAMPLE MENU

ENERGY (kcal)	PROTIEN (gm)	FAT (gm)	CARBOHYDRATES (gm)

Early Morning:

(Timing)

Breakfast:

(Timing)

Mid-morning:

(Timing)

Lunch:

(Timing)

Evening:

(Timing)

Dinner:

(Timing)

Before retiring to Bed:

(Timing)

APPENDIX IX

General dietary habits questionnaire

- Q1. How would you describe your food habits? (Vegetarian = 1, Non vegetarian = 2)
- Q2. How many litres of oils /fats does your family consume in a month? Kgs or lits / Month_____
- Q3. Total no of family members? _____
- Q4. Which oil you consume for cooking at home? (1 = Refined oil,2 = Mustard oil, 3 = Desi ghee, 4 = Coconut oil, 5 = Olive oil, 6 = Dalda, 7 = Butter, 8 = mix oil)
- Q5. What type of milk do you regularly consume? (Whole milk =1, Skimmed Milk = 2, Toned milk = 3, Skimmed milk powder = 4)
- Q6. From where to get milk? (1=Milk Man, 2= Milk Plant packet, 3=Fresh from dairy)
- Q7. Do you routinely remove fat / skin from milk before using? (Yes = 1, No = 2)
- Q8. Consume tinned /canned food? (Yes =1, No = 2)
- Q9. Are you on any special diet? (Yes =1, No = 2)
- Q10 (A) If yes, what diets are you currently following (Diabetic diet = 1, Low fat diet =2)
- Q11. Do you add sugar or jaggery or any sweetener to tea/ coffee? (Yes =1, No = 2)
- Q12. Do you feel hungry or get cravings more than usual? (Yes =1, No = 2)
- Q13. What snack do you take when feeling hungry? _____
- Q14. Type of meal you have: (Homemade=1, Hotel=2, other specify =3)
- Q15. In comparison with other people of the same age, how does the patients consider his/her status? (0=not as good, 1=do not know, 2=as good, 3=better)

APPENDIX X

Participant's Informed Consent Form (PICF) (प्रतिभागी सूचित सहमति पत्र)

Study Title: "Impact of herbs based lifestyle intervention regime on Sexual Dysfunction and Blood Glucose level of diabetic male adults: A randomized controlled trial".

अध्ययन का शीर्षक" :मधुमेह व यौन रोग पर जड़ी बूटियों का प्रभाव पर आधारित जीवन शैली का प्रभाव मधुमेह वयस्कों में : एक यादृच्छिक नियंत्रित परीक्षण"

Name of Principal Investigator: Dt. Sukhjindar Singh Ghotra Tel. No. 7087009045, 9467677012

प्रधान अन्वेषक का नाम :Dt. सुखजिंदर सिंह घोतरा दूरभाष नं7087009045 , (9467677012

<p>1. I confirm that the contents of the participant information sheet dated _____ that was provided to me have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.</p> <p>(इस प्रतिभागी सूचना पत्र जो दिनांक _____ को मुझे प्रदान की गई थी, मैंने इसे सावधानी पूर्वक पढ़ लिया है / मुझे उस भाषा में विस्तार से समझा दिया गया है जो मुझे समझ में आती है और मैंने सभी तथ्यों को अच्छी तरह समझ लिया है/ मैं पुष्टि करता हूँ कि मुझे सवाल पूछने का अवसर दिया गया है।)</p>
<p>2. The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail.</p> <p>(अध्ययन का प्रकार और प्रयोजन तथा उसके संभावित खतरों / लाभ और अध्ययन पूरा होने की अनुमानित अवधि, और अध्ययन के अन्य प्रासंगिक जानकारी के उद्देश्य के बारे में विस्तार से मुझे समझा दिया गया है।)</p>
<p>3. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I am over 21 years of age. (मैं समझता हूँ कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं किसी भी कारण देने के बिना किसी भी समय वापस लेने के लिए, आज़ाद हूँ, और इस पर मेरी चिकित्सा देखभाल या कानूनी अधिकार पर कोई प्रभाव नहीं पड़ेगा। मेरी उम्र 21 साल से अधिक है।)</p>
<p>4. I understand that the person working, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.</p> <p>(मैं समझता हूँ कि जो व्यक्ति इस अध्ययन पर काम कर रहे हैं, आचार समिति और नियामक अधिकारियों को वर्तमान अध्ययन और किसी भी आगे अनुसंधान के लिये, मेरे स्वास्थ्य के रिकॉर्ड को देखने के लिए मेरी अनुमति की जरूरत</p>

<p>नहीं होगी, चाहे मैं परीक्षण से वापस ले लें। मैं इस का उपयोग करने के लिए सहमत हूँ। हालांकि, मैं समझता हूँ कि मेरी पहचान और जानकारी तीसरे पक्ष के लिए जारी या प्रकाशित नहीं किया जाएगा।)</p>
<p>5. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).</p> <p>(इस अध्ययन से उत्पन्न होने वाले डेटा या परिणाम का उपयोग करने के लिए सहमत हूँ इस तरह के एक प्रयोग केवल वैज्ञानिक उद्देश्य (ओं) के लिए है।)</p>
<p>6. I agree to take part in the above study. I hereby give my full, free and informed consent to the investigators to enrol me and initiate the study as per the protocol.</p> <p>(मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ। मैं इसके द्वारा मेरे दाखिला लेने और प्रोटोकॉल के अनुसार अध्ययन आरंभ करने के लिए जांचकर्ताओं को मेरी, पूर्ण स्वतंत्र और सूचित सहमति देता हूँ।)</p>

Signature / Left Thumb Impression of the Subject: _____ Date: ____/____/____

प्रतिभागी के हस्ताक्षर / अंगूठे का निशान : _____ दिनांक: ____/____/____)

Signatory's Name: _____ Phone No. _____

हस्ताक्षरकर्ता का नाम : _____ फोन नं . _____)

This is to certify that the above consent has been obtained in my presence.

) यह प्रमाणित किया जाता है कि उपरोक्त सहमति मेरी उपस्थिति में प्राप्त की गई है।(


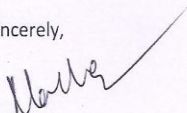
Signature of the Investigator: _____ Date: ____/____/____

) प्रधान अन्वेषक के हस्ताक्षर : _____ दिनांक : ____/____/____)

Study Investigator's Name: _____ Phone No. _____

APPENDIX XI

Ethical committee letter

Institutional Ethics Committee Postgraduate Institute of Medical Education and Research, Chandigarh	
	
Prof. D Behera <i>Chairman</i>	Prof. Nandita Kakkar <i>Convener</i>
Chairperson Prof. D Behera	No: INT/IEC/2016/2005 Date: 29/4/2016
Members Dr. Madhu Khullar Dr. Savita Kumari Dr. A Chakrabarti Dr. P Kumar Dr. R Minz Dr. Rashmi Bagga	Dr. Sukhjinder Singh Department of Dietetics Title: Impact of herbs based lifestyle intervention regime on sexual dysfunction of diabetic male adults : A randomized controlled Trial Reference No. NK/2766/study/87 Dear Dr. Sukhjinder Singh, The Institute Ethic Committee (Intramural) at their meeting held on 25.04.2016 has APPROVED your study protocol. It is understood that the study will be conducted strictly as per the submitted protocol. Any deviations from the approved protocol and study documents must be sent the ethic committee for re-approval. Any adverse reaction or condition noted during the study period should be reported to the ethic committee immediately. All future correspondence with respect to your project, please attach a photocopy of this letter. With kind regards, Yours sincerely,  (Nandita Kakkar) Convener Instt. Ethic Committee (Intramural)
Convener Prof. Nandita Kakkar	Copy To: - Education cell
Contact Office: +91 172 2755266 Ph: +91 172 2755141	

Office: Institutional Ethics Committee, Room No – 6006, sixth floor, Research Block B, PGIMER, Chandigarh.

Institutional Ethics Committee
Postgraduate Institute of Medical Education and Research, Chandigarh

Prof. D Behera
 Chairman

R Diet/906
 19.11.16



Prof. Madhu Khullar
 Acting Convener

No: INT/IEC/2016/2538

Date: 19-11-16

Chairperson

Prof. D Behera

Dr. Sukhjinder Singh
 Dept. of Dietetics,

Members

Dr. Savita Kumari

Title: Impact of herbs based lifestyle intervention regime on sexual dysfunction & blood glucose levels of diabetic male adults: A randomized controlled trial.

Dr. A Chakrabarti

Reference No: NK/2766/Study/87

Dr. P Kumar

Dear Dr. Sukhjinder Singh,

Dr. R Minz

The Institute Ethic Committee (Intramural) at their meeting held on 27.10.2016 has **APPROVED** your request for **modified study protocol**.

Dr. Rashmi Bagga

Convener

Prof. Madhu Khullar

It is also mention here that the previous protocol was already approved by the Institute Ethic Committee (Intramural), vide reference No. NK/2608/DM/3107, dated of meeting 25,04,2016.

Contact

Office:
 +91 172 2755266

It is understood that the study will be conducted strictly as per the submitted protocol. Any deviations from the approved protocol and study documents must be sent the Institute Ethic Committee for re-approval. Any adverse reaction or condition noted during the study period should be reported to the above said committee immediately.

All future correspondence with respect to your project, please attach a photocopy of this letter.

With kind regards,

Yours sincerely,

M Khullar

(Prof. D Behera)
 Chairman, Instt. Ethic Committee (Intramural)

Copy To:

Medical Education Cell, PGIMER, Chandigarh.

Office: Institutional Ethics Committee, Room No – 6006, sixth floor, Research Block B, PGIMER, Chandigarh.

Dr. Sukhjinder Singh - for information -
cc - in Research file

APPENDIX – XII

Mini Nutritional Assessment (MNA) questionnaire

Complete the screen by filling in the boxes with the appropriate numbers.

Add the numbers for the screen. If score is 11 or less, continue with the assessment to gain a Malnutrition Indicator Score.

Screening	
A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties? 0 = severe decrease in food intake 1 = moderate decrease in food intake 2 = no decrease in food intake	<input type="checkbox"/>
B Weight loss during the last 3 months 0 = weight loss greater than 3kg (6.6lbs) 1 = does not know 2 = weight loss between 1 and 3kg (2.2 and 6.6 lbs) 3 = no weight loss	<input type="checkbox"/>
C Mobility 0 = bed or chair bound 1 = able to get out of bed / chair but does not go out 2 = goes out	<input type="checkbox"/>
D Has suffered psychological stress or acute disease in the past 3 months? 0 = yes 2 = no	<input type="checkbox"/>
E Neuropsychological problems 0 = severe dementia or depression 1 = mild dementia 2 = no psychological problems	<input type="checkbox"/>
F Body Mass Index (BMI) = weight in kg / (height in m)² 0 = BMI less than 19 1 = BMI 19 to less than 21 2 = BMI 21 to less than 23 3 = BMI 23 or greater	<input type="checkbox"/>
Screening score (subtotal max. 14 points) 12-14 points: Normal nutritional status 8-11 points: At risk of malnutrition 0-7 points: Malnourished For a more in-depth assessment, continue with questions G-R	<input type="checkbox"/> <input type="checkbox"/>
Assessment	
G Lives independently (not in nursing home or hospital) 1 = yes 0 = no	<input type="checkbox"/>
H Takes more than 3 prescription drugs per day 0 = yes 1 = no	<input type="checkbox"/>
I Pressure sores or skin ulcers 0 = yes 1 = no	<input type="checkbox"/>
J How many full meals does the patient eat daily? 0 = 1 meal 1 = 2 meals 2 = 3 meals	<input type="checkbox"/>
K Selected consumption markers for protein intake <ul style="list-style-type: none"> • At least one serving of dairy products (milk, cheese, yoghurt) per day yes <input type="checkbox"/> no <input type="checkbox"/> • Two or more servings of legumes or eggs per week yes <input type="checkbox"/> no <input type="checkbox"/> • Meat, fish or poultry every day yes <input type="checkbox"/> no <input type="checkbox"/> 0.0 = if 0 or 1 yes 0.5 = if 2 yes 1.0 = if 3 yes	<input type="checkbox"/> <input type="checkbox"/>
L Consumes two or more servings of fruit or vegetables per day? 0 = no 1 = yes	<input type="checkbox"/>
M How much fluid (water, juice, coffee, tea, milk...) is consumed per day? 0.0 = less than 3 cups 0.5 = 3 to 5 cups 1.0 = more than 5 cups	<input type="checkbox"/> <input type="checkbox"/>
N Mode of feeding 0 = unable to eat without assistance 1 = self-fed with some difficulty 2 = self-fed without any problem	<input type="checkbox"/>
O Self view of nutritional status 0 = views self as being malnourished 1 = is uncertain of nutritional state 2 = views self as having no nutritional problem	<input type="checkbox"/>
P In comparison with other people of the same age, how does the patient consider his / her health status? 0.0 = not as good 0.5 = does not know 1.0 = as good 2.0 = better	<input type="checkbox"/> <input type="checkbox"/>
Q Mid-arm circumference (MAC) in cm 0.0 = MAC less than 21 0.5 = MAC 21 to 22 1.0 = MAC greater than 22	<input type="checkbox"/> <input type="checkbox"/>
R Calf circumference (CC) in cm 0 = CC less than 31 1 = CC 31 or greater	<input type="checkbox"/>
Assessment (max. 16 points)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Screening score	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Total Assessment (max. 30 points)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
References 1. Vellas B, Villars H, Abellan G, et al. Overview of the MNA® - Its History and Challenges. <i>J Nutr Health Aging</i> . 2008; 10:456-465. 2. Rubenstein LZ, Harker JO, Salva A, Guigoz Y, Vellas B. Screening for Undernutrition in Geriatric Practice: Developing the Short-Form Mini Nutritional Assessment (MNA-SF). <i>J Geront</i> . 2001; 56A: M368-377 3. Guigoz Y. The Mini-Nutritional Assessment (MNA®) Review of the Literature - What does it tell us? <i>J Nutr Health Aging</i> . 2006; 10:466-487.	
Malnutrition Indicator Score 24 to 30 points <input type="checkbox"/> Normal nutritional status 17 to 23.5 points <input type="checkbox"/> At risk of malnutrition Less than 17 points <input type="checkbox"/> Malnourished	

APPENDIX XIII

Lab reports of the herbs

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Final Product Powder

DTL Receipt No : 17/475

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil

Date of Receipt : 19/07/2017


Names of ingredients purporting to have been used in the preparation of the
sample : Gurmar, Karela, Neem, Kohar Tumbo, Rasunt,
Ashwagandha, Shilajit.

Description : Light greenish brown powder.

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification	Confirmed	By Thin Layer Chromatography
2.	L.O.D	4.7%	-----
3.	Total Ash Value	9.6%	-----
4.	Acid Insoluble Ash	1.06%	-----
5.	Alcohol Soluble Extract	19.92%	-----
6.	Water Soluble Extract	30%	-----

Date: 20/9/2017.


 Scientific Officer

/o

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Gurmar (Raw Material)

DTL Receipt No : 17/475

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Gurmar (Gymnema Sylvestre).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (As per API)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


 Scientific Officer

**Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)**

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Karela (Raw Material)

DTL Receipt No : 17/476

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil

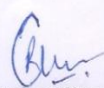
Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Karela (Momordica Charantia).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (As per API)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


 Scientific Officer

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Neem (Raw Material)

DTL Receipt No : 17/477

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Neem (Azadirachta Indica).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


 Scientific Officer

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Kohar Tumbo (Raw Material)

DTL Receipt No : 17/478

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Kohar Tumbo (Citrullus Colocynthis).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (As per API)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


 Scientific Officer

5

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Rasunt (Raw Material)

DTL Receipt No : 17/479

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Rasunt (Berberis Aristata).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (Quality Standard of Indian Medicinal Plant Vol - 3)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


 Scientific Officer

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Gokshru (Raw Material)

DTL Receipt No : 17/480

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Gokshru (Tribulus Terrestris).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (As per API)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


Scientific Officer

7

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Ashwagandha (Raw Material)

DTL Receipt No : 17/481

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Ashwagandha (Withania Somnifera).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (As per TLC Atlas for Ayurvedic Pharmacopoeia Drugs)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/9/2017.


 Scientific Officer

8

Government Drug Testing Laboratory (A.S.U) Patiala
(Food & Drug Administration, Punjab.)

Name & Address : Dr. Sukhjinder Singh, Assiatant Dietician, PGIMER,
Chandigarh.

Sample Name : Shilajit (Raw Material)

DTL Receipt No : 17/482

Batch No : Nil

Mfg Date : Nil

Expiry Date : Nil


Date of Receipt : 19/07/2017

Names of ingredients purporting to have been used in the preparation of the
sample : Shilajit (Asphaltum).

Results of Analysis

S.No.	Tests/Analysis Parameters	Results	Limits / Remarks
1.	Identification (Paper from Soil Bio. Biochem. Vol - 25, No - 3, pp 377-381, 1993, Printed in Great Britain)	Confirmed	By Thin Layer Chromatography
	-----	-----	-----
	-----	-----	-----

Date: 20/7/2017.


 Scientific Officer

ANNEXURE XIV

Patient's perception of improvement after herbal intervention

1. Date _____

2. CR No. _____

3. Serial No. _____

4. Name of person: _____

5. Have you taken the herbal medicine as per prescription?

1. = YES, 2 = NO

6. How do you feel after taking the HERBAL FORMULA

(1) Feel better (2) Good (3) Same (4) No affect (5) not known

7. Satisfaction with the herbal powder given to you.

(1) Much contented (2) Slightly contented (3) Neither pleased nor satisfied
(4) Dissatisfied (5) not known

8. Any missed dose of herbal powder? Details—

9. Do you feel that your symptoms of SEXUAL DYSFUNCTION

(1) Improved, (2) Worsened (3) same (4) Not sure

10. Have you experienced any side effects or other unwanted health problems since the

start of this herbal treatment?

1. = Yes, 2. = No If yes, what –details-

11. Do you feel confident to continue the therapy for long time

(1) Yes (2) No (3) not known

12. Do you changed your regular diet since the last meeting?

1. = Yes, 2= No. If Y/N explain?

13. Has your regular exercise regimen changed since the last meeting?

1. = Yes, 2= No. If Y/N explain?

14. Now Symptoms present for diabetes?

1. Polydipsia Less / More / Same 6. Tiredness Less / More / Same

2. Polyphagia Less / More / Same 7. Excessive sweating Less / More / Same

Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults:

A randomized controlled trial

3. Drowsiness Less / More / Same 8. Burning sensation under feet Less/
More/Same
4. Weight Loss Less / More / Same 9. Polyuria Less / More / Same
5. Itching Less / More / Same 10. Nocturia Less / More / Same

Bio chemical estimations

S.No.	Blood test	Unit	Date	Reading
15.	Glucose (fasting)	mg/100 ml		
16.	Postprandial glucose (After 2 hrs.)	mg/dl		
17.	Hb1Ac	%		

18. Weight of person _____ Kg
19. Allopathic medicine –any changes?
1. Medicine reduce 2. stop 3. Increased. Before _____ After _____
20. Insulin details / any changes?
1. Insulin reduced 2. Stop 3. Increased. Before _____ After _____

APPENDIX XV

Patient information sheet

Title of the study “Impact of herbs based lifestyle intervention regime on Sexual dysfunction and Blood glucose levels of diabetic male adults: A randomized controlled trial”

Dear Patients,

We liked to invite you to take part in this intervention study. You can withdraw from participate at any time from the study. It will not affect the treatment you receive at our Institute.

What is the purpose?

The aim of the study is to explore the potential herbs based lifestyle intervention on various sexual dysfunction (problem) and blood glucose levels of diabetic male adults. So that diabetic patients can use it.

Method of intervention study

After participation in the intervention study, you will undergo a detailed evaluation. A detailed history will be done. You will categorized in to two groups.

Duration of participation?

Expected duration of the subject participation is for three months.

Benefit by participating in the study?

By participating in the study you will be able to provide data on current status of your diabetes (blood glucose level) and prevalence of sexual dysfunction if you have any. We will use herbal powder to treat these problem. Which will make your blood glucose level normal and improve your sexual dysfunction.

You will get:-

1. We will give you herbal supplement (free of cost) to treat diabetes and sexual dysfunction.
2. We will give detail diet chart to control blood glucose level. (Diabetic diet chart)
3. We will tell you detail and benefit of exercise to which help to control blood glucose level.

Possible risks?

No significant risk. All common herbs will be used for intervention.

What will happen if you do not consent?

It is up to decide whether to participate in the study or not. Your involvement in this intervention study is totally voluntary and you can withdraw yourself any time. After withdraw yourself form study, it will not affect the treatment services you are eligible for. The study does not involve any expenditure on your part.

Will participation in this interventional study be kept confidential?

The detailed collected in this study will made anonymous and no information shared to any other person without your consent. Your detail will be kept confidential in the whole course of this study.

For other extra information

If you would like any further information, or have any further queries concerning the research study, you are encouraged to contact the research team.

Contact Information**Principal Investigator**

Dt. Sukhjindar Singh Ghotra

E-mail: sukhji05@gmail.com Mobile: 07087009045/ 09467677012

APPENDIX XVI

Diet Chart (Diabetic Diet)**Food allowed**

Cereal - Rice with vegetable (not daily), bajra, jowar, maize / Makki, bajra, jawar, Dalia, Suji as Upma (with vegetables)

Snacks:- Idlis, dosa, vadas, besan halwa (No sugar), cutlets, roasted corn, roasted channa, cheelas. dhokla (only cooked at home)

Desserts:- without sugar or no artificial sweetner (can use stevia leaves for make dish sweet) carrot, halwa, Freshly prepared kheer, custard, besan halwa,

Pulses- All legumes, beans, gram flour, black gram, etc. 60 gm (2 bowl) whole pulses like moong , masoor, chana dal can be taken in whole day

Milk and its products- Milk 500 ml Skimmed milk and its products i.e. curd, paneer, lassi

Vegetables- Seasonal and fresh vegetables like lauki/ghiya, tori, tinda leafy vegetable, karela etc. can be taken liberally.

Salad- kheera, kakri, tomato, muli, cabbage etc

Fruits- fruit intake as per plan and fruit like Apple, pineapple, guava, papaya can take. Fruits should be eaten as such. Fruit juices should be avoided.

Sugar and its products- sugar and its products should not include in any form in the diet.

Fat and oils- all kinds of fats and oils can use. Daily consumption of oils per day should be 20 to 30 ml or 3 – 4 tsp per day. Use different oils, (mustard oil+R/oil+desi ghee)

Dry fruits- All dried fruits can be taken. But due to sugar avoid raisin. Daily 6-8 almonds can use.

Liquids/beverages- Lemon water, plain soups, plain soda, buttermilk, fresh milk, fresh curd, fresh soups milk shake prepared at home, Plain tea/ coffee

Non veg- Egg white, chicken, fish, Freshly cooked meat, etc. can be taken grilled, roasted and boiled.

Seasonings – illaichi, dalchini, pudina, dhania, vinegar, garlic, tamarind, and **methi seed** etc whole/ground spices and condiments

Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults:

A randomized controlled trial

Fiber- fiber content should be high in the diet. All fresh and raw fruits and vegetables contain ample amount of fiber so it should be included in daily diet and should be eaten as such. Fruit juices should be avoided

Food avoided

Cereal- Rice (limited amount can use), maida, suji,

Processed cereals- Noodles. Pastas, white bread, pizzas, bread crumbs, soup sticks,

Snacks- Petty, burger, crackers, biscuits, namkeen mixture, cutlets

Pulses-try to avoid washed pulses. Use whole pulses

Milk and its products- Whole milk and its products like creams, khoya, processed cheese,

Vegetables- vegetables like shakarkandi, kachalu, potato.

Fruits- Fruits like banana, chickoo, grapes, Mango

Dry fruit- khajur, raisins, Moongfali/groundnut (in excess).

Sugar and its products (desserts)- sweet item such as sugar, shaker, guar, honey, glucose, ice-creams, cake, chocolates, pies, laddu , eclairs, milk cakes, jalebi, burfi,all sweets.

Fat and oils-

Liquids/ beverages- sharbats, spert, soups (commercial), Strong tea / coffee, all aerated drinks/cold drinks, alcohol

Tinned and canned foods:- Vegetables and fruits in packed form.

Meat- Seekh kabaab, tikke . Mutton, organ meat like kidney, liver, pork, red meat, egg yolk.

Miscillineous – Tinned/ canned juices, Ready to eat food products like soups, puries, pickles , table salt, junk and fast food like burger , pizza, potato chips and potato finger ,lays, kurkure etc, bakery products like cakes, pastries, market sweets, deep fried foods, papad , pakodas , puris. .

Other items- all fried foods such as samosa, golgappa, chat, papdi etc

Preparation of Missi Atta

Whole Wheat	–	5kg	Bajra	-	1 kg
Whole black gram	–	3kg	Soyabean daal	–	1kg
Barley/ Jowar	–	1kg	Methi seeds	-	100-150 gm
Til	-	200 gm	Ajwain	-	50 gm

Impact of herbs based lifestyle intervention regime on sexual dysfunction and blood glucose levels of diabetic male adults:

A randomized controlled trial

Instructions

1. Maintain your body weight.
2. Small meals at frequent intervals are advised i.e. 5-6 times per day.
3. Fasting and feasting should be avoided. Don't starve with hunger.
4. Every day 45 min to 1 hour brisk walk or any other exercise is compulsory.
5. Do not smoke and consume alcohol.
6. Consume at least 10-12 glasses of drinking water daily.

Your day's menu plan

Calories-

Proteins-

Early morning-	Nimbu pani	1	glass	(without	sugar)
	or Nimbu Chai	1	cup	(without	sugar)
Breakfast-	Milk	200	ml	(without	sugar)+
	Bread (whole wheat)	2			slice
	Paneer or egg	25 gm/1	boiled white part only	OR	
	Missi roti	1+	vegetable	1	bowl
	curd	150 gm			
Mid morning-	Fruit	1			
	Sprouted dal/chana/ vegetable poha/dalia	50 gm	25 gm	(1bowl)	
Lunch/dinner-	Salad	1			plate
	Missi roti/chapatti	3/2			
	Vegetable curry	1	to	2	bowl
	Dal	1			bowl
	Curd	150			gm
	Paneer/ Chicken	30 gm/100gm			
Evening tea-	Tea	150ml/	1 cup	(without	sugar)
	Biscuit (fibre)	2		OR	
	veg. Toast or Sandwich				2
	total oil to be use per day- 20ml				

Use of other foods in daily menu

Methi, Garlic, Alsi seeds, mustard seeds, curry leaves, karela and gond katira

Bran Biscuits – Britannia nutria choice/Marie gold/Diet bik

Oil of your choice – Rice bran oil/Olive oil/Canola oil/Saffola gold/ Ricella

VEGETABLE EXCHANGE	
Green leafy veg	500 g (spinach, cabbage etc)
Other vegetable	200 g (karela, ghia etc)
Root vegetable	160 g (onion, carrot etc)

MEAT EXCHANGE	
Egg white	1
Fish	90 g
Chicken	100 g
Meat	50g

FRUIT EXCHANGE (Any one fruit in a Day)	
Apple (large)	½ (80 g)
Apple (small)	1
Orange	1No. or (90 g)
Mosambi	1 No or (130 g)
Papaya	½ (125 g)
Pears	1 (100 g)
Guava	1 (100 g)
Jamun	6 to 7 (100 g)
Arhu	2 (100 g)
Alucha	4 to 5 (100 g)
Kharbujha	½ (200 g)
Jamun	6-7 Nos

MILK EXCHANGE	
Milk (cow)	1 cup (150 ml)
Milk (Buffalo)	½ cup (70 ml)
Milk (toned)	1 cup (150 ml)
Milk (Skimmed)	3.5 cup (350 ml)
Milk (double toned)	1.5 cup (200 ml)
Butter milk	2.5 cup (600 ml)

CEREAL EXCHANGE	
Chapatti	1(Flour-30gm)
Brown Bread	2 slices
Porridge (oats)	30gm
Cornflakes	25 gm dry

PULSES EXCHANGE	
Dal	30 gm
Paneer	50gm
Soyabean	25gm

APPENDIX XVII

CTRI registry

CTRI Number	CTRI/2017/02/007802 [Registered on: 07/02/2017] - Trial Registered Retrospectively	
Last Modified On	03/11/2017	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Other (Specify) [herbs]	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	"Effect of Herbs on diabetes and their sexual problems in diabetic male persons."	
Scientific Title of Study	"Impact of herbs based lifestyle Intervention regime on Sexual Dysfunction & Blood Glucose Level of diabetic male adults: A randomized controlled trial"	
Secondary IDs if Any	Secondary ID	Identifier
	INT/IEC/2016/2538 Dated: 19/11/2016	Protocol Number
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Sukhjinder Singh Ghotra
	Designation	Assistant Dietician
	Affiliation	PGIMER, Chandigarh
	Address	Department of Dietetics Nehru Hospital PGIMER Chandigarh 110-B Sainik Vihar Colony, Jandli Ambala Haryana Chandigarh CHANDIGARH 160012 India
	Phone	0172-2755662
	Fax	
	Email	sukhji05@gmail.com
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)
Name		Dr Nancy Sahni Guide
Designation		Dietitian
Affiliation		PGIMER, Chandigarh
Address		Department of Dietetics Nehru Hospital PGIMER Chandigarh Chandigarh CHANDIGARH 160012 India
Phone		0172-2758045
Fax		
Email		nsahni74@yahoo.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Sukhjinder Singh Ghotra
	Designation	Assistant Dietician
	Affiliation	PGIMER, Chandigarh
	Address	Department of Dietetics Nehru Hospital PGIMER Chandigarh 110-B Sainik Vihar Colony, Jandli Ambala Haryana Chandigarh CHANDIGARH 160012 India
	Phone	0172-2755662

	Fax	
	Email	sukhji05@gmail.com
Source of Monetary or Material Support	Source of Monetary or Material Support	
	> Sukhjinder Singh house No 110 B Sainik Vihar Colony Jandli Ambala	
Primary Sponsor	Primary Sponsor Details	
	Name	Sukhjinder Singh Ghotra
	Address	110-B Sainik Vihar Colony, Jandli Ambala Haryana
	Type of Sponsor	Other [Person, Self with help of family]
Details of Secondary Sponsor	Name	Address
	NIL	NIL
Countries of Recruitment	List of Countries	
	India	
Sites of Study	Name of Principal Investigator	Name of Site
	DrSanjay Kumar Bhadada	PGIMER Chandigarh
		Site Address
		PGIMER New OPD, Room no 4032 ENDOCRINOLOGY OPD 4TH FLOOR CHANDIGARH, 160012 Chandigarh CHANDIGARH
		Phone/Fax/Email
		7087009582 sukhji05@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status
	Institutional Ethics Committee PGIMER CHANDIGARH	Approved
		Date of Approval
		19/11/2016
		Is Independent Ethics Committee?
		No
Regulatory Clearance Status from DCGI	Status	Date
	Not Applicable	No Date Specified
Health Condition / Problems Studied	Health Type	Condition
	Patients	Diabetic adult patients 25-60 years age with sexual dysfunction problems.
Intervention / Comparator Agent	Type	Name
	Comparator Agent	curry leaves and moth dhal powder will be used in equal parts.
		Details
		Equal amount of both will have to used as placebo. Dose will be 1gm, for three months period, orally 15 minute before meal, BD dose
	Intervention	Herbal supplements of following herbs will be used for intervnetnion.
		Gurmar-50gm Karela-25gm Neem-50 gm Tumba-50gm Rasont-50gm Gokhru kanta-50gm Shilajit-25gm Ashwagandha-50gm stevia-5gm mixture of above said herbs will used as intervention. BD dose before 15 minutes breakfast and dinner, 1 gm dose have to be taken.
Inclusion Criteria	Inclusion Criteria	
	Age From	25.00 Year(s)
	Age To	60.00 Year(s)
	Gender	Male

	Details	1.Married Male Diabetic Mellitus Patients with sexual dysfunction problems (Type2). 2.Physician approval for selected patient. 3.Able to read 4.Have personal mobile phone/ Access to a telephone 5.Willingness to provide informed consent.
Exclusion Criteria	Exclusion Criteria	
	Details	1.Any preexisting condition / contraindications (abnormal creatinine levels, liver dysfunction) 2.Bedridden patients. 3.Patients due for operations. 4.Enrolled in other active intervention research studies.
Method of Generating Random Sequence	Random Number Table	
Method of Concealment	An Open list of random numbers	
Blinding/Masking	Participant Blinded	
Primary Outcome	Outcome	Timepoints
	1. invprovement in blood glucose value such as fasting post prandial & HbA1c. 2. Improvement in sexual dysfunction problems. 3. Improvement in BMI.	three months
Secondary Outcome	Outcome	Timepoints
	Improvement in general health of diabetic patients	three months
Target Sample Size	Total Sample Size=80 Sample Size from India=80	
Phase of Trial	Phase 2	
Date of First Enrollment (India)	23/08/2018	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=1 Months=0 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Completed	
Publication Details	"none yet"	
Brief Summary	Study ethical apprvl first taken on 29/4/18 and start piolet study. and after the findig reapprval taken on 19/11/18.	

APPENDIX XVIII
Key to master chart

Edu-Education	1=Illiterate 2=Primary 3=Middle 4=Matric 5=10+2 6=Graduate and above
Occupation	1=Employed 2=Unemployed
Occ_detail-Occupation details	1=Private Job 2=Business 3=Govt Job 4=Laborer 5=Other
Blood_mont-Blood glucose monitoring	1=Yes 2=No
Hypoglycemia	1=Yes 2=No
Glu_fluctuate-Glucose level fluctuate	1=Yes 2=No
Physical_activity	1=Yes 2=No
Food_habits	1=Vegetarian 2=Non-vegetarian
Milk_type	1=Whole milk 2=Skimmed milk 3=Toned milk 4=Skimmed milk powder
Special diet	1=Yes 2=No
Sex_problem-sexual dysfunction	1=Yes 2=No
Sex_dys_treat- sexual dysfunction treatment	1=Yes 2=No
Viag_try-Try Viagra or other	1=Yes 2=No
Viag_res-viagra result	1=Yes satisfied 2=No satisfied 3=Don't know

Smoking	1=Yes 2=No
Alcohol	1=Yes 2=No
Dep_sex_dys-worried/depression due to sexual dysfunction	1=All of the time 2=Some of the time 3=Hardly any of the time 4=Not answer
Tiredness	1=All of the time 2=Some of the time 3=Hardly any of the time 4=Never
Sex-when	1=Day 2=Night 3=Any time 4=Not answer 5=Don't know
More_enj_time-Time when more enjoy	1=Day 2=Night 3=Any time 4=Not answer 5=Don't know
Prtner_ref- partner refused to have sex	1=Yes 2=No 3=Don't Know 4=Not answer
Sex_ofst-how often had sex	1=daily 2=two time a week 3=weekly 4= monthly
Sex_other	1=Yes 2=No
Sex_oth_op-sex with other, your opinion	1=Good 2=Bad 3=Don't know 4=Not answered
Sex_less_enjoy-less enjoy in sex after children	1=Yes 2=No
Condom_use	1=Yes 2=No 3=Don't know 4=Not answer
Condom_enj	1=More 2=Less 3=Don't know 4=Not answered

Ge_health-general health status	1= Excellent 2=Very good 3=Good 4=Fair 5=Poor
Med_int-herbal medicine taken	1=Yes 2=No
Med_int_feel-feeling after taking herbal medicine	1=much better 2=better 3=same 4=worse
Med_int_satis-satisfied with herbal powder	1=Very much satisfied 2=Slightly satisfied 3=Neither satisfied nor dissatisfied 4=Dissatisfied
Sex_dys_sym-sexual dysfunction symptoms	1=Improved 2=Worsened 3=Stayed the same 4=Don't know
Med_int_side_eff-side effect of herbal powder	1=Yes 2=No
Med_int_cont-Continue herbal powder	1=Yes 2=No 3=Don't know
Diet_change	1=Yes 2=No
Exercise_change	1=Yes 2=No
Symptoms post all	1=Less 2=More 3=Same
Medicine_change	1=Reduce 2=Stop 3=Increase 4=Same
Insulin_change	1=Reduce 2=Stop 3=Increase 4=Same

S.No.	Age	Education	Marriage_age	Occupation	Occ_detail	Income	Age_onset_diab	Polydyspsia	Polyphagia	Drowsiness	Weight_loss	Itching	Tiredness	Sweating	Burn_un_feet	Polyuria	Nocturia	Blood_mont	Hypoglycemia	Gl_u_fluctuate	Fasting_glucose	Postpr_gluose	Fast_glu_post	Postpr_post	HbA1c	HbA1c_post	Physical_activity	Food_habit	Milk_type	Special_diet	Height	Weight	Weight_post	BMI	MNA_Score	Total_MNA_2	Energy (kcal)	Protein (gm)	Fat (gm)	CHO (gm)	Sex_problem	Premature_ej	Erectile_dys	Less_int-sex	Sex_dys_treat	Viaq_try	Viaq_res	Smoking				
1	53	3	17	1	3	40000	52	1													102	166	166	160	7.3		1	2	2	1	1.73	70	23.39	14	28.5	1523	45.8	23.1	214.4								1					
2	59	4	20	1	2	10000	54	1													275	126	325	160	9.6	6.7	1	1	1	2	1.69	80	77	28.01	14	28.5	1623	60.6	26.6	268	1	1	1	2	2	2	2	2				
3	44	5	26	1	2	20000	40				1										225	206	364	345	11.5	10.5	1	1	1	2	1.71	65	65	22.23	8	22.5	1560	56.2	28.1	232.4	1	1					2	2				
4	58	6	27	1	3	80000	52								1						109	95	165	145	7.1	6.9	1	1	1	2	1.73	87	87	29.07	12	27.5	1499	48.2	31.25	194.8	1	1	1				2	2	2			
5	58	4	17	1	3	45000	54				1				1						119	103	124	102	6.1	5.6	1	1	1	2	1.65	70	70	25.71	14	28.5	1813	63.6	34.46	279.3	1	1	1	1	2	2	2	2	2			
6	47	6	29	1	3	50000	40	1	1				1								150	282	240	340	7.5	10.6	1	2	1	2	1.66	71	72	25.77	14	28.5	1452	46.1	26.98	214.3	2						2	2	2			
7	55	6	28	1	3	70000	54				1										114	107	179	130	6.4	6	1	2	3	1	1.73	72	68	24.06	11	23.5	1627	57.4	38.88	209	2			1	2	2	2	2				
8	32	6	26	1	3	80000	31	1	1												254	124	272	145	7.8	6.4	2	1	1	2	1.75	88	83	28.73	14	28.5	2341	70.6	66.96	294.6	2						2	2	1			
9	30	4	24	1	5	80000	30				1										248		338		12.6		1	2	2	2	1.63	60		22.8	10	22.5	1672	52.2	33.36	233.5	1		1	1	2	2	2	2	2			
10	57	2	21	1	3	40000	54	1	1			1	1	1	1	1	1	2	2	2	123		175		7.5		1	2	1	1	1.61	77	77	29.71	9	18.5	1820	64.75	42.46	261.9	2			1	2	2	2	2	2			
11	52	3	23	1	3	35000	44									1	1	2	2	2	117		156		6.2		1	2	1	2	1.68	72		25.51	14	28.5	1991	66.1	44.2	312.8	2						2	2	1			
12	54	6	20	1	1	40000	51						1		1	1	1	2	2	2	100		140		5.8		2	2	1	2	1.65	79		29.02	14	27.5	1689	61	35.96	251.7	2			1	2	2	2	2	2			
13	42	6	27	2		8000	41	1	1												116	113	176	167	7.7	7.6	1	1	1	2	1.83	70	70	20.90	6	16.5	1723	57.7	44.16	241.1	1	1	1			1	2	2	2	2	2	
14	48	6	28	1	3	50000	44														130	150	160	170	6.4	7.4	2	2	2	2	1.64	60	61	22.31	13	27.5	1894	64.1	49.3	269.4	2	1					2	2	2	2	2	
15	45	3	31	1	1	8000	44	1	1								1	2	2	2	180		335		7.9		2	2	1	2	1.65	62		22.77	8	20.5	1677	53.5	42	208.4	2	1	1				1	1	2	2	2	
16	45	6	24	1	3	60000	37								1						104		154		6.7		1	2	1	2	1.75	72		23.51	12	25.5	1869	68.35	45.11	277.3	1		1	1	2	1	2	1	2	1		
17	55	4	26	1	2	40000	54	1								1	1	1	2	2	85	120	200	180	7.8	7.9	1	1	1	2	1.79	115	130	35.89	14	29.5	1607	52.4	43.59	232.3	2						2	2	2	2	2	
18	58	3	23	2		90000	53	1			1				1	1	1	2	2	2	162	126	207	168	10.5	7	1	1	1	2	1.71	80	80	27.36	14	29.5	2218	91.1	54.1	304.5	1	1	1	1	2	1	2	2	2	2		
19	47	4	28	1	2	20000	44	1			1	1	1			1	1	2	2	2	163	240	208	260	7.4	11.5	1	2	1	2	1.65	60	61	22.04	9	22.5	1998	65.2	37.06	297.8	1	1					2	2	2	2	2	
20	57	3	23	1	3	21000	45				1					1	1	1	2	2	170	142	230	190	8.5	7.7	1	2	1	1	1.72	77	77	26.03	14	28.5	2092	73.65	51.41	295.2	1	1	1	1	2	2	2	2	2			
21	57	4	29	1	3	30000	52									1	2	2	2	2	168		200		7.2		2	1	1	1	1.63	73		27.48	14	28.5	2074	81.95	39.65	330.9	1			1	2	2	1	2	2	2		
22	47	5	26	1	3	60000	44									1	1	1	2	2	133	105	173	140	8	6.1	1	1	1	2	1.7	79	76	27.34	14	28.5	2060	79.15	47.85	311.3	1	1				2	2	0	2	2		
23	59	1	19	1	4	6000	57	1								1	1	2	2	2	165	101	220	162	11.5	7.1	2	1	1	2	1.58	47	47	18.83	11	24	2034	62.4	33.2	284	1		1	1	1	2	2	0	1	2		
24	36	6	26	1	3	25000	35	1	1							1	1	2	2	2	242	238	328	312	12.1	11.8	2	2	1	2	1.77	105	109	33.52	14	27.5	1939	63.95	53.39	244.7	2						2	2	0	2	2	
25	57	6	28	1	3	83000	42				1										127	100	257	230	9.3	9	1	2	1	1	1.77	64	63	20.43	11	23.5	1583	40.7	34.7	179.5	2						2	2	0	2	2	
26	54	4	24	1	3	56000	52	1	1							1	1	2	2	2	187		281		9		2	2	1	1	1.67	86		30.84	11	25.5	1265	44.2	29.9	162.3	1				1	2	2	0	2	2		
27	48	2	28	1	2	25000	43									1	1	1	2	2	116		162		7		1	1	1	2	1.67	87		31.20	14	28.5	1845	64.55	34.85	260.7	1	1	1	1	2	2	0	1	2	2	2	
28	52	4	24	2	5	5000	42	1			1	1	1			1	1	1	2	1	215		355		9.6		1	2	1	1	1.75	63		20.57	9	21.5	1074	36.65	27.61	136.3	1	1	1	1	2	2	0	2	2			
29	36	6	22	1	3	45000	33	1	1							1	1	2	1	1	160		206		11.3		2	2	1	2	1.68	93		32.95	11	24.5	1507	56.15	36.65	193.1	1	1	1	1	1	2	0	2	2	2		
30	39	6	18	2	5	5000	30									1	1	2	1	155		325		10.8		1	1	1	2	1.68	67		23.74	11	22.5	1341	45.2	21.4	204.2	1	1	1	1	2	2	0	2	2	2			
31	42	4	22	1	3	40000	41				1										142		176		7.8		1	2	1	1	1.7	72		24.91	14	28.5	2038	67.1	36.44	324.3	2						2	0	1	2	2	2
32	60	6	25	1	5	10000	52	1								1	1	1	1	1	160		190		6.6		1	1	2	1	1.65	76		27.92	14	28.5	1315	46.8	26.25	189.8	1				1	2	2	0	2	2		
33	39	5	25	1	5	10000	31									1	1	2	1	200		308		8.6		1	2	1	2	1.63	65		24.46	14	27.5	1597	58.4	34.98	226.8	1	1	1	1	2	2	1	1	2	2	2		
34	40	3	14	1	4	5000	38	1	1							1	1	2	2	2	162		240		7.3		1	2	2	2	1.67	60		21.51	10	24.5	1795	57.6	32.4	250.8	1	1	1	1	2	2	0	2	2	2	2	
35	55	2	22	1	4	5000	54	1	1							1	1	1	1	1	94		96		6.6		2	1	1	2	1.72	60		20.28	12	25.5	1857	63.1	34.1	273	1				1	2	2	0	1	2	2	2
36	51	6	29	1	3	80000	48									1	1	1	2	2	121		148		6.7		1	1	2	2	1.72	94		31.77	14	27.5	2091	59.2	50.42	271.8	1	1					2	2	0	2	2	
37	48	4	22	1	3	15000	46				1					1	1	2	2	2	137		204		7																											

S.No.	Age	Education	Marriage_age	Occupation	Occ_detail	Income	Age_onset_diab	Polydyspsia	Polyphagia	Drowsiness	Weight_loss	Itching	Tiredness	Sweating	Burn_un_feet	Polyuria	Nocturia	Blood_mont	Hypoglycemia	Glu_fluctuate	Fasting_glucose	Postprp_glucose	Fast_glu_post	Postprp_post	HbA1c	HbA1c_post	Physical_activity	Food_habit	Milk_type	Special_diet	Height	Weight	Weight_post	BMI	MNA_Score	Total_MNA_2	Energy (kcal)	Protein (gm)	Fat (gm)	CHO (gm)	Sex_problem	Premature_ej	Erectile_dys	Less_int-sex	Sex_dys_treat	Viaq_try	Viaq_res	Smoking			
61	55	3	22	1	5	10000	30														132	188	250	189	9.1		1	2	1	1	1.63	65	24.46	14	28.5	1905	70.6	36.6	283	2											
62	29	3	23	1	2	15000	28															185	150	250	189	7.9	6.8	1	2	1	2	1.68	69	24.45	14	28.5	1776	66.2	41.5	228.4	1	1	1	1	2	2	2	2	2		
63	57	1	25	1	3	45000	50															112	201			7.2		1	1	2	1	2	1.6	60	23.44	14	24.5	1878	62.1	41.94	254.6	1	1	1	1	2	2	2	2	2	
64	45	3	18	1	1	6000	38															98	223			8.6		1	2	1	2	1.58	64	25.64	14	28.5	1918	72.1	36.2	296.2	1	1	1	1	2	2	2	2	1		
65	55	2	25	1	1	2000	45	1														135	193			10		2	2	1	2	1.58	70	28.04	14	27.5	1427	51.15	32.4	196.1	1	1	1	1	2	2	2	2	2		
66	50	6	29	1	3	50000	40															204	341			8.2		2	2	1	2	1.65	55	20.20	11	25.5	2023	74.05	46.15	291.6	1	1	1	1	2	1	1	1	1		
67	54	4	24	1	3	36000	39	1														143	250			6.8		1	1	1	2	1.67	72	25.82	9	22.5	1671	65.25	38.85	236.1	1	1	1	1	1	1	1	2	2		
68	39	5	25	1	5	50000	36															127	144			7.7		1	1	1	2	1.73	75	25.06	14	28.5	1810	63.35	33.65	258.3	1	1					2	2	2		
69	46	4	21	1	3	20000	44															102	160			9.8		2	2	2	2	1.8	68	20.99	12	25.5	2302	79.5	44.66	354.6	2						2	2	2		
70	39	6	31	1	1	10000	39	1	1													112	145			5.1		2	1	1	1	1.83	86	25.68	13	27.5	1571	54.95	31.45	214.3	2						2	2	2		
71	59	2	18	1	3	25000	58															360	475			9.8		1	2	1	2	1.54	58	24.46	14	27.5	1685	57.1	31.2	247.4	1	1	1				2	2	2		
72	47	6	33	1	1	8000	45															97	94	119	110	6.9	6.2	1	2	2	1	1.66	89	91	22.30	14	28.5	2000	72.15	38.75	296.3	2						2	2	1	
73	60	3	30	1	5	5000	54															232	340			10		2	2	1	2	1.66	57	20.69	8	20.5	1949	73.35	47.71	280.5	1	1	1	1	2	2	2	2	2		
74	40	5	26	1	3	35000	39	1														121	95	155	135	6.4	5.5	1	2	2	2	1.8	72	22.22	10	23.5	1600	62.8	49	186.3	2						2	2	2		
75	42	5	25	1	3	100000	31															167	283			7.8		2	2	1	2	1.7	80	27.68	12	26.5	1676	58.55	35.05	221.5	1			1	1	1	1	1	2		
76	56	4	14	2		10000	42															172	300			10		2	2	1	2	1.83	86	25.68	13	25.5	1645	54.6	27.4	245.8	1	1	1	1	2	2	0	2	2		
77	52	6	24	1	3	40000	48															153	216			8.3		1	2	1	2	1.73	90	30.07	8	21.5	1291	44.4	21.4	199.2	1	1	1	1	2	2	0	2	2		
78	47	5	27	1	3	40000	45															155	130	244	210	10.2	8.4	1	2	2	1	1.73	63	63	21.05	13	27.5	2287	73.15	46.75	336.5	1	1	1	1	2	2	1	1	2	
79	40	5	23	1	3	14000	28	1														125	155			7.8		1	2	2	2	1.7	71	24.57	10	24.5	1439	49.6	32.8	177.4	1	1	1				2	2	0	2	
80	45	2	24	1	3	20000	41															176	172			8		2	2	1	2	1.64	71	26.40	14	28.5	1409	46.2	28.3	188.2	1	1	1	1	2	2	2	2	1		
81	50	1	13	1	2	5000	49	1														171	158	240	190	9.8	9	2	2	2	2	1.58	64	64	25.64	10	23.5	1532	47.4	34.6	199.6	1	1	1	1	2	1	1	1	1	
89	56	4	24	1	3	40000	55															132	110	206	159	9.3	7	1	2	1	1	1.7	70	70	24.22	10	23.5	1760	59.3	49.46	192.8	2						2	0	1	
90	30	5	24	1	1	10000	30	1	1													281	125	305	180	10.2	7.9	2	1	1	2	1.7	75	75	25.95	11	25.5	1981	66.55	39.41	282.7	1	1					2	2	0	1
91	58	1	23	1	2	20000	43															245	100	250	150	9.8	7.6	2	1	1	2	1.52	94	88	40.69	14	28.5	1475	53.2	36.7	179.2	1	1	1	1	2	2	0	2	2	
92	52	2	30	1	5	2000	50															130	167			7.2		1	2	1	2	1.65	54	19.83	12	24.5	1490	54.7	24.8	244.6	1	1	1				2	2	0	1	
93	50	4	25	1	3	14000	48	1														91	213			7.3		1	1	1	1	1.71	76	25.99	14	28.5	2328	78.45	47.69	339.3	2						2	0	2		
94	52	4	20	1	3	55000	49															118	160			6.2		1	2	1	2	1.62	69	26.29	14	27.5	1402	48.95	31.65	175.1	2						2	0	1		
95	50	2	24	1	1	10000	45															200	250			8.6		1	2	1	2	1.68	70	24.80	14	28.5	1472	50.3	38.9	173.1	1	1	1				2	2	0	1	
96	47	4	21	1	5	6000	42															299	440			12.1		2	2	1	2	1.7	60	20.76	9	21.5	1735	64.05	33.65	257.3	1	1					2	2	0	2	
97	42	5	23	2		5000	41															300	95	351	150	10.1	6.4	2	1	1	1	1.62	70	70	26.67	14	27.5	996	40.4	25.7	130.1	1	1					2	2	0	2
98	33	4	23	1	4	10000	31															163	185			8.7		2	1	1	2	1.71	65	22.23	13	27.5	2012	77.25	41.55	300.9	1	1	1	1	1	1	1	1	2		
99	28	3	25	1	2	4000	12															206	110			7.2		1	2	1	1	1.7	49	16.96	11	22.5	2056	63.5	45.95	304	1	1	1	1	2	1	2	2	2		
100	45	4	24	1	2	5000	39															236	350			10.8		2	2	2	2	1.59	48	18.99	9	20.5	1611	52	29.18	236	2							2	0	2	
101	49	4	30	1	3	30000	41															118	296			7.6		1	2	1	1	1.7	67	23.18	14	28.5	2176	73.4	42.89	345.9	1	1	1	1	2	1	1	2	2		
102	51	4	22	1	3	65000	46															240	296			10.8		1	1	2	2	1.72	80	27.04	11	25.5	1771	59	48.88	208.8	1	1	1	1	2	2	0	2	2		
103	58	6	26	1	3	40000	37															68	140			6.4		1	1	1	2	1.67	60	21.51	10	22.5	1892	57.55	36.19	259.9	1	1	1				2	2	0	2	
104	43	6	26	1	3	36000	28	1	1													166	170			6.6		2	2	1	2	1.82	96	28.98	12	24.5	1716	64.9	44.16	224.6	1	1					2	1	2	2	
105	55	5	25	1	3	70000	50	1														319	424			12.7		1	2	1	2	1.68	95	33.66	11	24.5	1765	57.8	29.8	255.6	1	1					2	2	0	2	
106	54	4	22	2		10000																																													

S.No.	Age	Education	Marriage_age	Occupation	Occ_detail	Income	Age_onset_diab	Polydyspsia	Polyphagia	Drowsiness	Weight_loss	Itching	Tiredness	Sweating	Burn_un_feet	Polyuria	Nocturia	Blood_mont	Hypoglycemia	Glu_fluctuate	Fasting_glucose	Postprp_glucose	Fast_glu_post	Postprp_post	HbA1c	HbA1c_post	Physical_activity	Food_habit	Milk_type	Special_diet	Height	Weight	Weight_post	BMI	MNA_Score	Total_MNA_2	Energy_(kcal)	Protein_(gm)	Fat_(gm)	CHO_(gm)	Sex_problem	Premature_ej	Erectile_dys	Less_int-sex	Sex_dys_treat	Viag_try	Viag_res	Smoking			
128	45	6	28	1	3	50000	41									1	1	1	1	1	119		243		8.3		1	1	1	2	1.7	84		29.07	14	28.5	1911	61.85	47.47	248.8	1	1	1								
129	52	4	25	1	3	35000	28									1	1	1	1	1	161		307		9		1	2	1	1	1.74	80		26.42	14	28.5	1879	62.95	38.91	261.9	1	1	1								
130	48	3	29	1	2	55000	47	1								1	1	1	2	2	191		307		11.9		1	1	2	2	1.64	55		20.45	12	25.5	1318	43.3	34.82	172.6	2										
131	33	5	23	1	3	10000	29				1					1	1	1	2	2	127	122	264	196	6.7	6.6	1	1	1	1	1.62	73	73	27.82	14	28.5	1518	63	38	200.8	1	1									
132	54	6	27	1	3	140000	50									1	1	1	2	2	110		150		7.4		1	1	1	2	1.6	75		29.30	12	26.5	1478	47.05	45.47	163.1	2										
133	51	3	19	1	3	26000	50				1					1	1	1	1	1	125		222		7.3		1	1	1	1	1.67	58		20.80	12	25.5	2069	74.6	45.54	300.4	2										
134	50	3	20	1	4	4000	49	1			1					1	1	1	2	2	90		178		6.8		1	2	1	1	1.6	81		31.64	11	25.5	1612	65.2	41.7	207.2	1	1									
135	56	3	31	1	3	27000	55	1			1					1	1	1	2	2	120		180		6.1		2	2	1	2	1.65	72		26.45	13	26.5	1260	31.2	29.1	147.7	1										
136	45	6	29	1	2	100000	40				1					1	1	1	2	2	266		305		9.6		2	2	1	1	1.73	85		28.40	14	28.5	923	36.15	20.65	126	1	1									
137	45	4	19	1	5	15000	35				1					1	1	1	2	2	197		290		8.2		1	2	1	2	1.71	72		24.62	12	26.5	1861	65.25	43.05	255.1	1	1									
138	40	1	22	1	2	7000	39	1	1							1	1	1	2	2	72		145		12.2		2	2	1	2	1.63	51		19.20	9	22.5	1989	70.2	34.6	307.8	1										
139	53	6	25	1	3	80000	50									1	1	1	2	2	154		184		8.1		1	2	1	2	1.56	70		28.76	12	26.5	1818	64.65	39.35	243.9	2										
140	58	2	23	1	1	6000	33				1					1	1	1	2	2	141		351		12.1		1	2	1	2	1.63	50		18.82	10	22	2219	72.15	44.47	325.5	1	1									
141	50	1	25	1	2	5000	49	1			1					1	1	2	2	2	189		235		9.4		2	2	2	2	1.77	68		21.71	13	27.5	1220	38.6	26.1	149.2	1										
142	50	4	25	1	5	20000	45				1					1	1	2	2	2	195		255		10.4		1	1	1	2	1.86	85		24.57	11	24.5	1934	71.2	43.96	271	1	1	1								
143	43	4	19	1	2	10000	42	1	1		1					1	1	2	2	2	277		310		9.4		1	2	1	2	1.76	74		23.89	11	24.5	1247	40.2	25.06	212.6	2										
144	36	6	31	1	1	20000	30		1		1					1	1	2	2	2	158		260		10.9		1	2	1	2	1.69	66		23.11	14	28.5	2538	82.65	61.37	374.4	2										
145	50	4	20	1	2	10000	41				1					1	2	2	2	2	110		200		6.7		2	1	1	2	1.58	65		26.04	14	27.5	1430	52.9	36.2	164.4	1										
146	55	1	33	1	2	20000	43				1					1	1	1	2	2	132		165		7		1	2	2	2	1.73	60		20.05	12	25.5	1726	57.65	47.31	217.1	1	1	1								
147	42	5	23	1	3	50000	26	1	1		1					1	1	1	1	1	228	150	287	180	9.7	9.3	1	2	1	2	1.85	85	84	24.84	14	28.5	2168	70.8	33.2	331.6	1	1	1								
148	46	2	20	1	4	10000	42	1	1		1					1	1	2	2	2	134	99	242	135	6.4	6.2	1	2	1	2	1.74	70	70	23.12	9	22.5	943	31.6	20.6	120.9	1	1									
149	57	4	32	1	2	10000	49				1					1	1	1	2	2	267		288		12.1		1	1	1	1	1.66	97		35.20	11	25.5	1708	59.75	33.15	237.5	1										
150	57	5	26	1	2	10000	53				1					1					98		183		6.8		1	1	2	1	1.58	75		30.04	13	27.5	2400	81.65	57.45	340.1	2										
151	55	6	23	1	2	8000	50				1					1	1	1	2	2	108		164		9.8		1	1	1	1	1.6	76		39.04	14	28.5	1274	42.2	33.96	161	1	1	1								
152	30	6	27	1	3	45000	29									1	1	1	2	2	145		225		7.5		2	1	1	1	1.65	80		29.38	14	28.5	1729	52.1	43.72	242.6	2										
153	56	6	28	1	3	90000	39									1	1	1	1	1	167		198		9.2		2	1	2	1	1.66	65		23.59	14	28.5	1577	58.55	39.05	197.9	1										
154	53	6	25	1	3	50000	49				1					1	1	1	2	2	201	104	344	180	10.2	7.6	2	1	1	2	1.67	70	73	25.10	13	27.5	1822	60.65	45.85	221.1	1	1									
155	55	3	20	1	3	20000	53				1					1	1	1	2	2	126	106	144	136	6.7	6.2	2	1	1	2	1.63	70	70	26.35	14	28.5	2243	71.65	51.95	306.3	1	1	1								
156	57	4	28	1	3	55000	56	1	1		1					1	1	2	2	2	149		220		6.2		1	1	1	1	1.64	74		27.51	11	25.5	1913	71	43.2	251.6	2										
157	46	5	28	1	3	45000	41	1			1					1	1	1	1	2	123	98	187	168	8.5	7.91	1	1	1	1	1.67	60	60	21.50	10	24.5	2034	65.65	48.73	289	1	1	1								
158	52	2	23	2		5000	50									1	1	1	1	1	124		144		6.6		1	1	1	2	1.6	77		30.81	14	27.5	2229	77.2	63.22	263.5	1										
159	45	4	23	1	5	3000	42									1	2	2	2	238		411		8.4		1	1	1	2	1.72	80		27.04	14	28.5	1633	53.75	38.61	204.4	1	1	1									
160	51	6	22	1	3	70000	48									1	1	1	2	2	86		181		7		1	1	2	2	1.58	63		25.24	14	28.5	1777	59.35	38.41	241.1	1	1	1								
161	57	4	19	1	5	5000	35				1					1	1	1	2	2	191		255		7.5		1	2	1	2	1.71	66		22.57	12	26.5	1794	75.55	47.25	233.1	1										
162	52	6	22	1	3	75000	44	1			1					1	1	1	2	2	190		240		8.2		2	2	1	1	1.8	88		27.16	13	26.5	1752	59	38.36	249	1										
163	43	4	21	1	5	14000	42				1					1	1	1	2	2	101		164		7.1		1	1	1	2	1.68	81		28.70	14	28.5	2043	71.15	42.01	287.9	2										
164	49	5	21	1	2	30000	46				1					1	1	1	2	2	163		206		9.9		2	2	2	2	1.65	120		44.08	11	25.5	1550	46	36.9	196.2	1	1	1								
165	60	3	24	1	5	5000	50				1					1	1	1	1	1	185		240		9.5		2	2	1	2	1.68	75		26.57	11	24.5	1645	55.35	47.17	200.3	1										
166	49	2	25	1	2	10000																																													

S.No.	Age	Education	Marriage_age	Occupation	Occ_detail	Income	Age_onset_diab	Polydyspsia	Polyphagia	Drowsiness	Weight_loss	Itching	Tiredness	Sweating	Burn_un_feet	Polyuria	Nocturia	Blood_mont	Hypoglycemia	Glu_fluctuate	Fasting_glucose	Postprp_glucose	Fast_glu_post	Postprp_post	HbA1c	HbA1c_post	Physical_activity	Food_habit	Milk_type	Special_diet	Height	Weight	Weight_post	BMI	MNA_Score	Total_MNA_2	Energy_(kcal)	Protein_(gm)	Fat_(gm)	CHO_(gm)	Sex_problem	Premature_ej	Erectile_dys	Less_int-sex	Sex_dys_treat	Viaq_try	Viaq_res	Smoking
188	47	2	19	1	3	32000	45	1													263		340		7.7		2	2	1	2	1.6	65		25.39	11	24.5	1509	53.85	34.75	195.1	1	1	1		2	2	2	
189	40	2	25	1	3	25000	30	1	1	1	1	1	1	1	1	1	1	1	2	2	200		312		8.5		1	2	1	2	1.66	81		29.39	13	27.5	1489	54.9	28.9	214.2	1	1	1	1	1	1	2	
190	59	5	27	1	2	20000	53	1			1				1			1	2	2	140		180		6.9		1	2	1	2	1.76	82		26.47	13	27.5	1552	59	39.5	199.1	1	1	1	1	1	1	2	
191	48	3	23	1	3	40000	46					1			1	1	1	1	2	1	160		220		9		1	2	1	2	1.75	85		27.76	14	28.5	1551	52.3	32.6	210.6	1	1	1	2	1	1	2	
192	45	3	25	1	3	35000	43	1				1	1	1	1	1	1	1	2	2	268		375		7.5		1	1	1	2	1.78	90		28.41	14	28.5	2617	94.85	53.41	370.1	1	1	1	2	2	2	2	
193	49	4	28	1	1	3000	48				1	1	1			1	1	2	2	2	187	110	279	135	12	7.4	1	2	1	2	1.73	54	55	18.04	11	22.5	1674	57.15	34.93	227.7	1	1	1	2	2	2	2	
194	56	2	31	1	3	22000	55				1				1	1	1	1	2	1	91		223		11.9		1	1	1	2	1.64	58		21.56	11	22.5	2023	66.25	49.17	269.5	1	1	1	2	2	2	1	
195	39	4	18	1	5	3000	36				1	1	1			1	1	2	2	2	154		195		8		2	2	1	2	1.7	93		32.18	9	22.5	1986	69.7	42.35	272.9	1	1	1	2	2	2	1	
196	60	4	24	1	3	25000	54		1						1	1	1	1	2	1	76		146		6.6		2	2	1	2	1.67	72		25.82	13	26.5	1524	52.95	41.41	180.9	1	1	1	2	2	2	2	
197	60	6	27	1	3	30000	55											1	2	2	95		125		6.2		1	1	2	1	1.64	70		26.03	14	28.5	2324	79.35	49.47	343.5	2			2	2	2	2	
198	40	4	23	1	2	7000	39								1		1	2	2	2	138		327		10.1		2	2	2	2	1.61	76		29.32	14	27.5	2068	64.4	38.66	296	1	1	1	2	2	2	2	
199	50	2	29	1	4	3000	47					1	1	1	1	1	1	1	2	2	154		209		8.7		1	1	1	2	1.64	86		31.98	14	28.5	2055	66.2	35.36	314.2	1	1	1	2	2	2	2	
200	47	5	29	1	1	40000	46		1		1	1	1			1	1	1	2	2	285		320		11.7		1	2	1	2	1.65	60		22.04	12	26.5	1812	60.55	39.61	243.5	2			2	2	2	2	
201	58	4	25	1	3	30000	36				1	1	1			1	1	1	1	1	173		242		6.63		1	1	1	2	1.71	65		22.23	10	24.5	1635	57.65	39.11	221.7	1	1	1	2	2	2	2	
202	50	4	31	2	0	4000	40					1	1			1	1	1	2	2	263	164	308	224	8.6	8.9	2	2	1	1	1.67	60	65	21.51	13	26.5	1871	64.8	49.74	227.1	1	1	1	2	2	2	2	
203	38	6	24	1	2	8000	35						1			1	1	1	2	2	152		224		6.9		1	2	1	2	1.68	62		21.97	13	27.5	2015	64.95	43.47	283.9	1	1	1	2	2	2	2	
204	53	4	23	2		8000	41				1	1	1			1	1	1	2	2	110		271		6.8		1	2	1	2	1.62	60		22.86	10	23.5	2171	75.35	44.51	320.7	1	1	1	2	2	2	1	
205	52	1	24	1	5	10000	49						1			1	1	1	2	2	187		275		11.2		2	1	1	2	1.71	77		26.33	14	27.5	2193	75.05	46.11	309.9	1	1	1	2	2	2	2	
206	57	4	27	1	3	45000	43				1	1	1			1		1	2	2	154		234		12.9		1	1	1	1	1.69	61		21.36	12	26.5	1955	65.25	46.89	258.5	1	1	1	2	2	2	2	
207	32	6	25	1	3	30000	30				1			1		1	1	2	2	2	180				9.2		1	1	2	2	1.77	75		23.94	13	27.5	1890	63.95	36.25	258.5	1	1	1	2	2	2	2	
208	51	4	19	1	2	20000	36								1	1	1	1	2	2	247		314		9.1		1	2	1	2	1.7	75		25.95	12	26.5	1734	54.55	41.97	224	1	1	1	2	2	2	1	
209	55	4	21	1	3	38000	54				1				1	1	1	1	2	2	109	101	146	114	7.5	6.2	1	2	2	2	1.61	75	74	28.93	11	25.5	1862	60.95	38.51	261.1	1	1	1	2	2	2	2	
210	48	4	28	1	3	30000	44	1			1	1	1			1	1	2	2	2	290	270	340	295	7.9	7.2	1	1	1	2	1.72	71	70	24.00	11	25.5	1758	62.5	41.44	238.8	1	1	1	2	2	2	2	
211	38	5	23	1	1	10000	34									1	1	2	2	2	142		332		9.7		2	1	1	2	1.69	80		28.01	14	28.5	2885	96	39.8	463.6	2			2	2	2	2	
212	52	6	25	1	3	42000	51	1			1	1	1			1	1	2	2	2	141		185		6.4		1	1	1	1	1.69	90		31.51	11	24.5	2016	67.75	40.61	285.1	1	1	1	2	2	2	1	
213	51	4	24	1	3	36000	45					1	1			1	1	1	2	1	140		180		7.3		1	1	1	1	1.55	75		31.22	14	28.5	1498	48.3	36.36	205.7	1	1	1	2	2	2	2	
214	58	5	27	1	2	10000	41								1	1	1	1	1	1	115		140		6.7		1	1	1	2	1.67	70		25.10	14	28.5	1866	71.25	42.75	236.9	1	1	1	2	2	2	2	
215	30	5	27	1	1	25000	28				1			1		1	1	1	1	2	152		195		13.1		1	1	1	1	1.71	82		28.04	11	25.5	1737	67.75	46.75	199.3	1	1	1	1	2	2	2	
216	50	4	21	1	3	34000	49	1	1						1	1	1	1	2	2	105		195		6.9		1	1	1	2	1.64	60		22.31	13	27.5	1982	65.15	42.39	275.3	1	1	1	2	2	2	2	
217	32	1	22	1	2	5000	27	1			1	1	1	1	1	1	1	2	2	2	283	120	315	205	11.5	8.8	2	2	1	2	1.6	72	72	28.13	11	25.5	2157	69.8	35.86	335	1	1	1	2	2	2	2	
218	33	5	25	1	1	80000	32				1	1	1	1		1	1	2	2	2	220		344		13.6		1	2	1	2	1.64	67		24.91	11	25.5	1386	50.75	25.25	206.9	1	1	1	2	1	1	2	
219	47	4	21	1	5	30000	46				1			1	1	1	1	1	2	2	80		109		9.7		1	2	1	1	1.65	70		25.71	13	27.5	2062	81.6	43	306.3	2			2	2	2	2	
220	50	4	21	1	4	5000	46							1	1			2	2	2	360		410		11.5		1	1	1	1	1.74	85		28.08	14	28.5	1837	60.95	39.61	246	1	1	1	1	1	1	2	
221	58	2	19	1	5	2000	51		1		1				1	1	1	2	2	2	127		300		10.7		1	2	1	1	1.74	77		25.43	11	25.5	2083	70.15	39.91	303.5	1	1	1	1	1	1	2	
222	55	4	17	1	3	45000	50					1	1			1	1	1	2	2	84		114		8		1	1	1	1	1.76	74		23.89	14	28.5	1710	56.95	39.11	222.7	1	1	1	2	2	0	2	
223	54	2	30	2		15000	46				1				1	1	1	2	2	2	165		221		6.5		2	2	1	2	1.73	70		23.39	14	28.5	1914	64.15	40.11	264.3	1	1	1	2	1	2	2	
224	37	5	16	1	4	5000	36				1				1	1	1	2	2	2	145		195		6.5		1	2	1	2	1.65	55		20.20	8	20.5	1292	39.7	23.75	182.3	1	1	1	2	1	2	2	
225	52	3	18	2		5000	31				1	1	1	1	1	1	1	1	2	2	147		214		15.2		2	2	1	2	1.72	70		23.66	13													

S.No.	Age	Education	Marriage_age	Occupation	Occ_detail	Income	Age_onset_diab	Polydyspsia	Polyphagia	Drowsiness	Weight_loss	Itching	Tiredness	Sweating	Burn_un_feet	Polyuria	Nocturia	Blood_mont	Hypoglycemia	Glu_fluctuate	Fasting_glucose	Postpr_glucose	Fast_glu_post	Postpr_post	HbA1c	HbA1c_post	Physical_activity	Food_habit	Milk_type	Special_diet	Height	Weight	Weight_post	BMI	MNA_Score	Total_MNA_2	Energy (kcal)	Protein (gm)	Fat (gm)	CHO (gm)	Sex_problem	Premature_ej	Erectile_dys	Less_int-sex	Sex_dys_treat	Viag_try	Viag_res	Smoking	
248	32	4	26	1	1	7000	31	1			1	1	1	1	1	1	1	2	2	2	101		168		6		2	2	1	2	1.78	93		29.35	11	25.5	2190	73.8	31.1	352.2	1	1			1	2	2	2	
249	60	3	25	1	2	8000	53				1	1			1	1	1	1	2	2	148		205		7.6		2	1	2	2	1.61	71		27.39	13	27.5	1710	56.95	39.11	222.7	1	1			1	2	2	2	
250	36	6	26	1	5	6000	30	1	1		1					1	1	1	2	2	134	140	245	210	7.8	7.2	2	1	1	2	1.67	72	72	25.82	13	27.5	1977	69.3	45.86	256	1	1	1		2	2	2	2	
251	46	4	23	1	3	46000	43		1		1	1	1	1		1	1	1	2	1	218		260		9.4		1	2	1	2	1.72	75		25.35	11	25.5	2186	76.55	37.55	325.5	1	1			1	2	2	2	
252	58	4	21	1	5	3000	55	1	1		1	1	1	1	1	1	1	2	2	2	204		285		8.6		2	2	1	2	1.73	70		23.39	13	27.5	2049	71.75	35.85	302.3	1	1			1	2	2	2	
253	44	3	26	1	1	8000	43	1	1		1	1	1	1	1	1	1	2	2	2	149		277		8.8		2	2	1	2	1.75	80		26.12	11	24.5	2306	74.2	37.88	347.4	1	1			1	2	1	2	2
254	43	5	21	1	2	30000	35				1	1	1	1				1	2	2	150		157		9.3		1	1	1	2	1.7	75		25.95	14	28.5	1814	60.6	27.2	285	1	1			1	2	2	2	
255	43	4	32	1	1	9000	33				1	1	1	1	1	1	1	1	2	2	207		297		6.2		2	1	1	2	1.69	55		19.26	9	22	1823	56.3	41.72	254.6	1	1			1	2	2	2	
256	33	6	26	1	2	10000	32	1	1	1	1	1	1	1	1	1	1	2	2	2	192		240		8.3		1	1	1	2	1.63	60		22.58	9	23.5	1726	58.95	33.95	239.1	1	1			2	1	2	1	
257	60	2	18	1	3	10000	59	1	1		1	1	1	1	1	1	1	2	2	2	90		148		6.5		1	2	1	2	1.63	51		19.20	11	24	2117	72.75	38.13	313.3	1	1	1		1	2	2	1	
258	56	3	21	1	3	19000	55	1	1			1	1	1	1	1	1	2	2	2	160		200		8.7		1	2	2	2	1.62	49		18.67	11	23.5	1714	54.2	32.66	249.4	2				2	2	1		
259	54	2	24	1	2	6000	48				1	1	1	1	1	1	1	2	2	2	417		535		12.2		2	2	2	2	1.61	48		18.52	10	20	1745	63.6	46.38	205	1	1			1	2	2	2	
260	60	4	25	1	5	10000	50		1		1				1	1	1	1	2	2	255		297		8.3		1	1	1	1	1.77	76		24.26	11	25.5	1332	46.55	29.25	170.3	1	1			1	1	2	2	
261	59	3	24	1	2	5000	39					1	1	1	1	1	1	2	2	2	158		198		8.5		2	1	2	2	1.62	74		28.20	13	26.5	2092	69.05	50.41	292	1	1			1	2	1	2	2
262	40	6	22	1	2	35000	39				1	1	1	1	1	1	1	2	2	2	306		360		11.5		1	2	2	2	1.73	99		33.08	11	25.5	1367	47.75	30.45	172.7	1	1			1	1	2	2	
263	54	6	29	1	3	50000	32					1	1	1	1	1	1	1	2	2	142		170		6.7		1	2	1	2	1.7	75		25.95	14	28.5	2036	74.8	44.46	291.8	1	1			1	2	2	1	
264	59	4	29	1	3	21000	44	1	1		1	1	1	1	1	1	1	2	2	2	132		160		6.4		2	1	2	2	1.6	85		33.20	14	28.5	1947	63.95	41.19	272.9	1	1			1	2	2	1	
265	49	3	21	1	1	20000	41								1	1	1	1	2	2	148		265		6.7		2	2	2	2	1.62	55		20.96	12	26.5	1487	50.55	31.75	195.1	2				2	2	1		
266	54	4	29	1	3	45000	53	1	1	1	1	1	1	1	1	1	1	2	2	2	187		289		6.1		1	2	1	2	1.77	65		20.75	11	24.5	1849	61.8	28.4	287.4	1	1			1	2	2	1	
267	40	4	25	1	3	25000	38				1	1	1	1				1	2	2	141	140	179	160	7.75	6.9	1	1	1	1	1.63	70	73	26.35	13	27.5	1943	61.8	33.66	293.5	1	1			2	2	2	2	
268	53	4	27	1	1	12000	52		1		1					1	1	2	2	2	109		210		7.5		1	1	1	2	1.6	70		27.34	11	25.5	1981	66.55	39.41	282.7	2				2	2	2		
269	38	6	26	1	2	30000	37	1			1	1	1	1	1	1	1	2	2	2	190		235		8.1		1	1	1	2	1.69	120		42.02	11	25.5	1638	57.35	30.75	232.7	2				2	2	2		
270	44	2	39	1	1	4500	43	1			1	1	1	1				2	2	2	80		140		8.4		1	1	2	2	1.57	53		21.50	10	22.5	1606	56.15	32.65	216.7	1	1			1	2	2	2	
271	55	6	21	1	5	4000	53								1	1	1	1	2	2	130		169		7.4		1	2	1	1	1.63	85		31.99	14	28.5	1402	48.95	31.65	175.1	1	1			1	2	2	2	
272	46	2	20	1	4	8000	45	1			1	1	1	1	1	1	1	1	2	2	116		244		7.5		1	2	1	2	1.55	60		24.97	11	24.5	1252	45.95	26.65	170.1	1	1			1	2	2	2	
284	55	3	20	1	4	2000	45				1	1	1	1	1	1	1	1	2	2	224		321		6.3		2	2	1	2	1.76	68		21.95	13	24.5	1606	56.15	32.65	216.7	1	1	1		1	2	2	2	
285	54	3	22	1	3	60000	51				1	1	1	1	1	1	1	2	2	2	200		250		8.4		2	2	2	2	1.73	85		28.40	11	25.5	1587	59.3	35.68	214.4	1				1	2	2	2	
286	57	2	23	1	5	5000	53									1	1	1	1	2	2	122		167		6.7		1	2	1	2	1.78	76		23.99	14	28.5	1564	54.15	33.35	200.8	1	1			1	2	2	2
287	38	6	23	1	3	40000	37	1			1	1	1	1	1	1	1	2	2	1	153		270		10.6		1	1	1	2	1.64	72		26.77	11	24.5	948	28.3	22.2	116.9	1	1			1	2	2	2	
288	49	6	25	1	3	78000	41				1	1	1	1	1	1	1	1	2	2	160		226		8.4		1	1	1	2	1.72	68		22.99	13	26.5	1335	46.55	32.35	156.7	1	1			1	2	2	2	
289	52	4	21	1	4	2000	49	1	1		1				1	1	1	1	2	2	147		231		9.1		1	2	1	2	1.57	60		24.34	11	25.5	1379	51.05	24.95	225.1	1	1			1	2	2	1	
290	25	3	23	2	0	8000	24	1	1		1	1	1	1	1	1	1	1	1	1	152		185		14.7		1	1	1	1	1.56	42		17.26	8	18.5	2001	72.35	31.35	318.1	2				2	2	2		
291	43	6	25	1	3	40000	36					1				1	1	2	2	2	181		259		10.2		1	2	1	2	1.67	99		35.50	14	28.5	1708	54.5	37.92	252	1	1			2	2	2		
292	54	4	30	1	3	38000	50				1	1	1	1	1	1	1	1	2	2	145		185		8.58		1	1	1	2	1.75	88		28.73	13	26.5	2143	75.3	42.56	308.8	1	1			1	2	2	2	
293	49	4	30	1	3	40000	48	1			1	1	1	1				2	2	2	231	157	299	233	9	7.2	2	2	1	2	1.71	58	58	19.84	11	25.5	2168	71.75	40.01	323.5	1	1			1	2	2	1	
294	58	2	25	2	0	2000	45				1	1	1	1	1	1	1	1	2	2	185		210		8.6		1	2	1	2	1.66	72		26.13	13	27.5	1085	37.7	24.9	143.3	1	1			1	2	2	2	
295	60	2	23	1	4	3000	58	1			1	1	1	1	1	1	1	2	2	2	155		172		7.2		1	2	1	2	1.63	64		24.09	12	26.5	1299	45.7	27.1	184.8	1	1			1	2	2	2	
296	51	6</																																															

