ROLE OF NEUROBICS AND SANSKAR REMODELLING IN DIABETIC MANAGEMENT

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Declaration by Candidate

I hereby declare that this thesis entitled "Role of Neurobics and Sanskar Remodelling in Diabetic management is a bonafide and genuine research work carried out by me, under the guidance of Dr. P.A. Nikose, Professor, Department of Physiology.

I hereby solemnly affirm that the contents of this thesis have not been submitted earlier in candidature of any degree elsewhere. The university is permitted to have legal rights for subsequent uses.

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Certificate

This is to certify that the work embodied in this thesis for the degree of Doctor of philosophy (Physiology) of Datta Meghe Institute of Medical Sciences, (Deemed University),Nagpur, entitled " Role of Neurobics and Sanskar Remodelling in Diabetic management", was undertaken by Dr. Dalia Biswas and was carried out in the Department of Physiology, JNMC, Sawangi (Meghe),Wardha under my guidance and direct supervision to my satisfaction.

This thesis fulfills the basic ordinance governing the submission of thesis laid down by Datta Meghe Institute of Medical Sciences University, Nagpur.

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"ROLE OF NEUROBICS AND SANSKAR REMODELLING IN DIABETIC MANAGEMENT."

This is to certify that the work "Role of Neurobics and Sanskar Remodelling in Diabetic management" for the degree of Doctor of Philosophy (Physiology) of Datta Meghe Institute of Medical Science (Deemed University) Nagpur, 2012-2015 is undertaken by Dr. Dalia Biswas, Professor, Department of Physiology, Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha.

We have great pleasure in forwarding this thesis to Datta Meghe Institute of Medical Sciences (Deemed University), Nagpur.

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- Johann Gottfried Von Herder.

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LIST OF ABBREVIATIONS

AADE	-	American Association Diabetes Educators .
ADA	-	American Diabetes Association.
ADVANCE	-	Action in Diabetes and Vascular disease: PreterAx and Diamicro N MR Controlled Evaluation.
AHEAD	-	Action for Health in Diabetes.
ARR	-	Adjusted Rate Ratio.
BG	-	Blood Glucose.
BMI	-	Body Mass Index .
CONSORT	-	Consolidated Standards of Reporting Trials.
CT	-	Computed Tomography.
CUPS	-	The Chennai Urban Population Study
CURES	-	Chennai Rural Population Epidemiology Study.
CVD	-	Cardiovascular Disease.
DBP	-	Diastolic Blood Pressure.
DPP	-	Diabetes Prevention Program.
DPPOS	-	Diabetes Prevention Program Outcomes Study
DSME	-	Diabetes Self-Management Education.
EOS	-	Executive Opinion Survey.
EU	-	European Union.
FINDRISC	-	Finnish Diabetes Risk Score.
FPG	-	Fasting Plasma Glucose.
HRR	-	Hazard Rate Ratio.
HRs	-	Hazard Ratios.

IDRS	-	Indian Diabetes Risk Score.
IGT	-	Impaired Glucose Tolerance.
IMAGE	-	Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention.
IMT	-	Intimal Medial Thickness.
KAP	-	Knowledge, Attitude and Practice.
LSM	-	Life Style Modification.
LSMP	-	Lifestyle Modification Programmes.
MET	-	Metformin.
MetS	-	Metabolic Syndrome.
NCD	-	Non-Communicable Diseases.
NHANES	-	National Health and Nutrition Examination Surveys.
NIDDM	-	Non Insulin Dependent Diabetes Mellitus.
PPBG	-	Post Prandial Blood Glucose.
PVD	-	Peripheral Vascular Disease .
QALY	-	Quality Adjusted Life Years.
QOL	-	Quality of Life.
RM	-	Rajyoga Meditation.
RR	-	Relaxation Response.
RRR	-	Relative Rate Ratio.
SAT	-	Subcutaneous Adipose Tissue .
SBP	-	Systolic Blood Pressure.
SHIELD	-	Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes.
SRM	-	Sanskar Remodelling .

T2D	-	Type 2 Diabetes.
T2DM	-	Type 2 diabetes Mellitus.
VAT	-	Visceral adipose tissue .
WC	-	Waist Circumference.
WHO	-	The World Health Organization .
WHOQOL	-	World health organization Quality of Life assessment.
WHR	-	Waist/Height Ratio.

INTRODUCTION

Diabetes Mellitus is a metabolic disorder of multiple aetiologies characterized by chronic hyperglycemia with disturbance of carbohydrate, protein and fat metabolism resulting from defects of insulin secretion, insulin action or both.(1). 2011 National Diabetes factsheet released on 26th Jan 2011 estimates about 246 million diabetics worldwide in the year 2010 with prevalence rates of 11.3% among the adults of 20-65 age group(2)

Diabetes mellitus is one of the most common chronic diseases across the world and number of diabetic patients is on rise. According to the World Health Organization (WHO, 2006), diabetes mellitus affects at least 171 million people and causes 3.2 million deaths, six deaths every minute and 8700 deaths everyday. WHO estimates that in 2030 there will be an increase of 70% in the number of cases of diabetes in developed countries, and 42% in developing countries. Currently the overall direct health care costs of diabetes mellitus ranges from 2.5% to 15% of annual health care budgets of developed and developing countries. This is likely to affect 366 million people by 2030. In this report, WHO has also anticipated that number of people with diabetes will be more than double in 2030 as a consequence of population aging and urbanization. (WHO, 2006).(3)

According to WHO, in India alone, diabetes is expected to increase from 40 million in 2006 to 79.4 million by 2030.(4).

The first national study on the prevalence of type 2 diabetes in India was done between 1972 and 1975 by the Indian Council Medical Research (ICMR, New Delhi)(5).

The Chennai Urban Population Study (CUPS) and Chennai Rural Population Epidemiology Study (CURES) provided valuable data from India on the complications related to diabetes. The prevalence of coronary artery disease was 21.4 per cent among diabetic subjects compared to 9.1 per cent in subjects with normal glucose tolerance(6). The prevalence of CAD in IGT subjects were 14.9 per cent in the same study. It was also seen that the diabetic subjects had increased subclinical atherosclerosis as measured by intimal medial thickness (IMT) at every age point compared to subjects with normal glucose tolerance(7). A recent study showed that carotid intima medial thickness increased with worsening grades of glucose tolerance as well as with increase in the number of components of metabolic syndrome(8). The prevalence of peripheral vascular disease (PVD) was 6.3 per cent among diabetic subjects compared to 2.7 per cent in non-diabetic subjects(9), and these figures are lower than the prevalence reported in western populations(10). This is probably due to lower age at onset for diagnosis of type 2 diabetes in India.

Several studies on migrant Indians across the globe have shown that Asian Indians have an increased risk for developing type 2 diabetes (T2DM) and related metabolic abnormalities compared to other ethnic groups(11-13). Although the exact reasons are still not clear, certain unique clinical and biochemical characteristics of this ethnic group collectively called as the “Asian Indian phenotype” is considered to be one of the major factors contributing to the increased predilection towards diabetes(14,15). Despite having lower prevalence of obesity as defined by body mass index (BMI), Asian Indians tend to have greater waist circumference and waist to hip ratios(16) thus having a greater degree of central obesity. Again, Asian Indians have more total abdominal and visceral fat for any given BMI(17) and for any given body fat they have increased insulin resistance(18). Moreover, they have lower levels of the

protective adipokine adiponectin and have increased levels of adipose tissue metabolites(19). Another way to explain the diabetes epidemic in these and other ethnic groups like Africans and Asian Indians is through Neel's 'thrifty genotype' hypothesis(20). This hypothesis proposes that some genes are selected over previous millennia to allow survival in times of famine by efficiently storing all available energy during times of feast. However, these very genes lead to obesity and type 2 diabetes when exposed to a constant high energy diet.(21).

The onset of the disease in urban Indian adults is about a decade earlier than their western counterparts and the prevalence of type 2 diabetes mellitus constitutes about 85-95% of all the diabetes in developed countries accounting for an even higher percentage in developing countries (22). Now it is beyond doubt that India actually has the highest number of diabetics in the world and government of India has launched the national programe for control of diabetes mellitus, cardiovascular disease and stroke in January 2008.(3). All these diseases are under the category of non- communicable diseases(NCDs). As per WHO report diabetes mellitus stands 4th in order of non communicable diseases which has to be tackled in a warfooting worldwide.

Non-communicable diseases (NCDs) impose a large burden on human health worldwide. Currently, more than 60% of all deaths worldwide stem from NCDs. Moreover, what were once considered "diseases of affluence" have now encroached on developing countries. In 2008, roughly four out of five NCD deaths occurred in low- and middle-income countries (WHO, 2011a), up sharply from just under 40% in 1990 (Murray & Lopez, 1997). Moreover, NCDs are having an effect throughout the age distribution – already, one-quarter of all NCD-related deaths are among people below the age of 60 (WHO, 2011a). NCDs also account for 48% of the healthy life

years lost (Disability Adjusted Life Years–DALYs) worldwide (versus 40% for communicable diseases, maternal and perinatal conditions and nutritional deficiencies, and 1% for injuries) (WHO, 2005a). Adding urgency to the NCD debate is the likelihood that the number of people affected by NCDs will rise substantially in the coming decades. One reason is the interaction between two major demographic trends. World population is increasing, and although the rate of increase has slowed, UN projections indicate that there will be approximately 2 billion more people by 2050. In addition, the share of those aged 60 and older has begun to increase and is expected to grow very rapidly in the coming years. Since NCDs disproportionately affect this age group, the incidence of these diseases can be expected to accelerate in the future. Increasing prevalence of the key risk factors will also contribute to the urgency, particularly as globalization and urbanization take greater hold in the developing world. NCDs stem from a combination of modifiable and non-modifiable risk factors.(23).

Non-modifiable risk factors refer to characteristics that cannot be changed by an individual (or the environment) and include age, sex, and genetic make-up. Although they cannot be the primary targets of interventions, they remain important factors since they affect and partly determine the effectiveness of many prevention and treatment approaches. A country's age structure may convey important information on the most prevalent diseases, as may the population's racial/ethnic distribution.(24).

Modifiable risk factors refer to characteristics that societies or individuals can change to improve health outcomes. WHO typically refers to four major ones for NCDs: poor diet, physical inactivity, tobacco use, and harmful alcohol use (WHO,).The composition of human diets has changed considerably over time, with

globalization and urbanization making processed foods high in refined starch, sugar, salt and unhealthy fats cheaply and readily available and enticing to consumers – often more so than natural foods (Hawkes, 2006; Kennedy, Nantel, & Shetty, 2004; Lieberman, 2003; WHO, 2002). As a result, overweight and obesity, and associated health problems, are on the rise in the developing world (Cecchini, et al., 2010). Exacerbating matters has been a shift toward more sedentary lifestyles, which has accompanied economic growth, the shift from agricultural economies to service-based economies, and urbanization in the developing world. This spreading of the fast food culture, sedentary lifestyle and increase in bodyweight has led some to coin the emerging threat a "globesity" epidemic (Bifulco & Caruso, 2007; Deitel, 2002;Schwartz, 2005).(24). The pathway from modifiable risk factors to NCDs often operates through what are known as intermediate risk factors" – which include overweight/obesity, elevated blood glucose, high blood pressure and high cholesterol. Secondary prevention measures can tackle most of these risk factors, such as changes in diet or physical activity or the use of medicines to control blood pressure and cholesterol, oral agents or insulin to control blood sugar and pharmacological/surgical means to control obesity. Although intervening on intermediate risk factors may be more effective (and more cost-effective) than waiting until NCDs have fully developed, treating intermediate risk factors may, in turn, be less effective (and less cost-effective) than primary prevention measures or creating favorable social and policy environments to reduce vulnerability to developing disease (Brownell & Frieden, 2009; National Commission on Prevention Priorities, 2007; Satcher, 2006; Woolf, 2009). After all, even those with the will to engage in healthy practices may find it difficult to do so because they live or work in environments that restrict their ability to make healthy choices. For these reasons, the need to address social

determinants of NCDs was reiterated at the 64th World Health Assembly held in Geneva, Switzerland in May 2011 by WHO Member States in preparation for the UN High-Level Meeting in September 2011. Macro-level contextual factors include the built and social environment; political, economic and legal systems; the policy environment; culture; and education. Social determinants are often influenced by political systems, whose operation leads to important decisions about the resources dedicated to health in a given country. (24).

Non-communicable diseases have been established as a clear threat not only to human health, but also to development and economic growth. Claiming 63% of all deaths, these diseases are currently the world's main killer. Eighty percent of these deaths now occur in low- and middle-income countries. Half of those who die of chronic non-communicable diseases are in the prime of their productive years, and thus, the disability imposed and the lives lost are also endangering industry competitiveness across borders.(24). Mounting evidence highlights how millions of deaths can be averted and economic losses reduced by billions of dollars if added focus is put on prevention. A recent World Health Organization report underlines that population-based measures for reducing tobacco and harmful alcohol use, as well as unhealthy diet and physical inactivity, are estimated to cost US$ 2 billion per year for all low- and middle-income countries, which in fact translates to less than US$ 0.40 per person. The rise in the prevalence and significance of NCDs is the result of complex interaction between health, economic growth and development, and it is strongly associated with universal trends such as ageing of the global population, rapid unplanned urbanization and the globalization of unhealthy lifestyles. In addition to the tremendous demands that these diseases place on social welfare and health systems, they also cause decreased productivity in the workplace, prolonged disability

and diminished resources within families. The results are unequivocal: a unified front is needed to turn the tide on NCDs. Governments, but also civil society and the private sector must commit to the highest level of engagement in combatting these diseases and their rising economic burden. Global business leaders are acutely aware of the problems posed by NCDs. A survey of business executives from around the world, conducted by the World Economic Forum since 2009, identified NCDs as one of the leading threats to global economic growth. Therefore, it is also important for the private sector to have a strategic vision on how to fulfill its role as a key agent for change and how to facilitate the adoption of healthier lifestyles not only by consumers, but also by employees. If the challenges imposed on countries, communities and individuals by NCDs are to be met effectively this decade, they need to be addressed by a strong multistakeholder and cross-sectoral response, meaningful changes and adequate resources.(24,22).

As policy-makers search for ways to reduce poverty and income inequality, and to achieve sustainable income growth, they are being encouraged to focus on an emerging challenge to health, well-being and development: After all, 63% of all deaths worldwide currently stem from NCDs – chiefly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. These deaths are distributed widely among the world's population – from high income to low-income countries and from young to old (about one-quarter of all NCD deaths occur below the age of 60, amounting to approximately 9 million deaths per year). NCDs have a large impact, undercutting productivity and boosting healthcare outlays. Moreover, the number of people affected by NCDs is expected to rise substantially in the coming decades, reflecting an ageing and increasing global population.(25).

The World Economic Forum and the Harvard School of Public Health evaluated the economic burden of NCDs in 2010.

Five key messages emerge from their evaluation-

- First, NCDs already pose a substantial economic burden and this burden will evolve into a staggering one over the next two decades. For example, with respect to cardiovascular disease, chronic respiratory disease, cancer, diabetes and mental health, the macroeconomic simulations suggest a cumulative output loss of US$ 47 trillion over the next two decades.
- Second, although high-income countries currently bear the biggest economic burden of NCDs, the developing world, especially middle-income countries, is expected to assume an ever larger share as their economies and populations grow.
- Third, cardiovascular disease and mental health conditions are the dominant contributors to the global economic burden of NCDs.
- Fourth, NCDs are front and centre on business leaders' radar. The World Economic Forum's annual Executive Opinion survey (EOS), which feeds into its Global Competitiveness Report, shows that about half of all business leaders surveyed worry that at least one NCD will hurt their company's bottom line in the next five years, with similarly high levels of concern in low, middle- and high-income countries – especially in countries where the quality of healthcare or access to healthcare is perceived to be poor. These NCD-driven concerns are markedly higher than those reported for the communicable diseases of HIV/AIDS, malaria and tuberculosis.

- Fifth, the good news is that there appear to be numerous options available to prevent and control NCDs. For example, the WHO has identified a set of interventions they call “Best Buys”. There is also considerable scope for the design and implementation of programmes aimed at behaviour change among youth and adolescents, and more cost effective models of care – models that reduce the care-taking burden that falls on untrained family members. Further research on the benefits of such interventions in relation to their costs is much needed. (24).

From 1983 to 2008, there has been a seven-fold increase in diabetes world-wide, its most extreme form. Metabolic syndrome and it consequences including cardiovascular disease, cancer and dementia are emerging as the major driver of most chronic diseases of aging. Up to fifty percent of diabetics and nearly all pre-diabetic are undiagnosed. Current strategies of pharmacologic intervention have proven ineffective or harmful. Emerging research clarifies underlying causes of this pandemic of insulin resistance including our refined, nutrient poor, high glycemic load diet, sedentary lifestyle and chronic stress. Novel etiologic factors including environmental toxins, food sensitivities, hormonal dysregulation, gut microbiology, latent infections, nutrient deficiencies and abnormal gene expression provide important diagnostic considerations and avenues for therapeutic intervention. A whole systems approach based on functional medicine provides a methodology for a comprehensive approach to this life-threatening and economically crippling modern disease.(26).

The need to prevent type 2 diabetes was recognized as early as the 1920s , but surprisingly little was done to apply preventive measures against this disease in subsequent decades (2,3). One of the main problems was the lack of evidence based

on well-conducted studies. There were several clinical trials, but they were usually grossly underpowered, had flaws in design and conduct, and most used antidiabetes drugs as the intervention. Luckily, firm positive results from several randomized controlled trials using lifestyle intervention have become available during recent years. Also, several properly designed and conducted trials using antidiabetes drugs in individuals at high risk, i.e., with intermediate hyperglycemia, have reported favorable results (27). The bottom line is that these recent trials have unequivocally demonstrated that it is possible to reduce the rate of progression to type 2 diabetes in high-risk individuals with intermediate hyperglycemia.(28). Other studies have evaluated the possibility that a multifaceted treatment approach including a focus on lifestyle factors (i.e., diet and physical activity) would be more beneficial than a primary treatment focus on glycemia. A number of large-scale RCTs (i.e., Da Qing DPS, MALMO Feasibility Study, Finnish DPS, United States DPP, Indian DPP, SLIM, and Japanese DPS trials) have been performed in persons who are at risk for T2DM (overweight/obese, IGT and/or IFG) in order to evaluate lifestyle modification of diet and physical activity [29-33]. Findings indicated that the combined lifestyle intervention of dietary and physical activity relative to the education control or usual/standard- care condition produced greater risk reduction for progressing to T2DM. Meta-analysis indicated that over all of these studies, the risk of becoming T2DM was reduced by about 51% (range: 42%-67% reduction) by the combination intervention.(34). Similarly, the United States DPP and Look Ahead trials in T2DM at-risk individuals have reported substantial improvements in subclinical cardiometabolic markers for those treated with lifestyle interventions (35-40).

The Malmö study from Sweden used in creased physical exercise and weight loss as major intervention strategies to prevent and delay type 2 diabetes. Subjects

with im-paired glucose tolerance had less than half the risk of developing type 2 diabetes compared with those who chose not to take part in the exercise program during the 5 year follow up.(41). The Da Qing study compared diet, exercise, and diet plus exercise with a no-treatment control group and found that all three lifestyle approaches reduced the risk of developing diabetes by 31–46%. In this Chinese study, people with IGT were randomized by clinic into one of the four groups: exercise only, diet only, diet plus exercise, and a control group. The cumulative incidence of type 2 diabetes during 6 years was significantly lower in the three intervention groups compared with the control group (41% in the exercise group, 44% in the diet group, 46% in the diet plus exercise group, and 68% in the control group) and remained significant even after adjusting for differences in baseline BMI .(42) .The two major goals of the Diabetes Prevention Program (DPP) lifestyle intervention were a minimum of 7% weight loss/weight maintenance and a minimum of 150 min of physical activity similar in intensity to brisk walking. Both goals were hypothesized to be feasible, safe, and effective based on previous clinical trials in other countries (43–47). Since initiating the DPP in 1996, two randomized trials have been published that report , positive effects from lifestyle intervention (48,49). The Finnish Diabetes Prevention Study(DPS) was one of the first controlled, randomized studies to show that type 2 diabetes is preventable with lifestyle intervention (50). This study had 522 overweight subjects with IGT showed that a lifestyle intervention designed to produce weight loss improved dietary intake and physical activity and reduced the risk of diabetes by 58 %.(51). These results have been reproduced by the Diabetes Prevention Program (DPP), in which lifestyle intervention, with a similar 58% risk reduction, was superior to the metformin treatment (52). The lifestyle intervention used in the DPP was not designed to be used in community settings (53), whereas one

of the main objectives in the DPS was to test an intervention feasible in primary health care..(54). The Diabetes Prevention Program Outcomes Study (DPPOS) began after the Diabetes Prevention Program (DPP) in 1994. The study assessed patients at high risk of developing diabetes to determine if lifestyle modifications of improved diet and exercise along with on oral anti-diabetes medication would prevent the development of diabetes. After meeting its objectives, DPPOS was established to assess the long-term effects of these interventions.(55). Diabetes self-management education (DSME), the process of teaching people to manage their diabetes, has been considered an important part of the clinical management of diabetes since the 1930s.(56,57). DSME is a critical element of care for all people with diabetes and is necessary to prevent or delay the complications of diabetes.(58) . American Diabetes Association (ADA) recommends assessing self-management skills and knowledge of diabetes at least annually and providing or encouraging continuing education.(59). DSME is considered "the cornerstone of treatment for all people with diabetes" by the Task Force to Revise the National Standards for Diabetes Self-Management Education Programs, which is a group representing national public health and diabetes-related organizations. This need is also recognized in objective 5-1 of Healthy People 2010: (60), to increase to 60% (from the 1998 baseline of 40%) the proportion of persons with diabetes who receive formal diabetes education. The goals of DSME are to optimize metabolic control and quality of life and to prevent acute and chronic complications, while keeping costs acceptable.(61).

The increase in diabetes is a worldwide phenomenon, and has been on the agenda of the World Health Organization since the early 1990s. The increase of type 2 diabetes is also a major public health problem across the entire European Union (EU). Type 2 diabetes is increasing in prevalence, especially among working-age

populations, but also in children and adolescents. Even if the prevalence of obesity were to remain stable until 2030, which seems unlikely, it is anticipated that the number of people with diabetes will more than double (62,63). Clinical studies have shown that even individuals with a high risk for diabetes can significantly reduce that risk and delay the onset of type 2 diabetes by adopting a healthy, nutritionally balanced diet, increasing physical activity, and maintaining or reducing body weight (64-69). Translating this evidence into practice necessitates active development of efficient prevention strategies and programmes (70). To fulfil this need, action at a European level was taken by launching the IMAGE project to unify and improve the various prevention management concepts which currently exist across the European Union. Two international European funded Projects namely DE-PLAN (71) and IMAGE (72) have been addressing the implementation process. The strength of the IMAGE deliverables were the free availability and the chance to modify the content to meet local conditions(73) . The DE-PLAN initiative (Diabetes in Europe–Prevention Using Lifestyle, Physical Activity, and Nutritional Intervention) was designed to develop the evidence for diabetes prevention practice in 17 European countries (74). The European Union–supported IMAGE project went one step further, and it was established to collate the evidence in a systematic manner. (75-77).

IMAGE stands for "Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention" and it builds on the results of the EU public health research project DE-PLAN which relates to the efficient identification of individuals at high risk for type 2 diabetes in the community . The objectives of the IMAGE project were: to develop common evidence-based European guidelines for prevention of type 2 diabetes; to develop a European curriculum; and to launch an e-health training portal for the training of prevention managers (PM).

Furthermore, the project aimed to produce European standards for quality management of these interventions. These actions formed a unique Europe-wide evidence-based guidance system to systematically improve the prevention of type 2 diabetes in Europe.(78). The research evidence has inspired national and local authorities and health care providers all over the world to start programs and activities to prevent type 2 diabetes and its complications. Based on the experiences from the clinical trials, as well as from the "real world" implementation programs, the IMAGE Study Group collated information in a systematic manner. The IMAGE deliverables include a European evidence-based guideline for the prevention of type 2 diabetes, a toolkit for the prevention of type 2 diabetes in Europe, and the quality indicators for the prevention of type 2 diabetes in Europe. (79).

RCTs using lipid- and blood pressure-reduction interventions have consistently shown efficacy in decreasing cardiovascular morbidity and mortality and all-cause mortality in T2DM patients (80). Indeed, the STENO-2 trial employed a more multifactorial intervention approach combining glucose regulation, blood pressure control, aspirin use, and lipid-lowering agents (81). Despite achieving a moderate to insufficient blood glucose control (HbA1c ~7.9%) in the intensive group relative to the control group, in STENO-2, a significant decrement was observed in cardiovascular events (59%), cardiovascular-related mortality (57%), and all-cause mortality (46%). Thus, cardiometabolic risk factor treatment in T2DM appears to be critical to improve CVD morbidity and mortality (82). Nevertheless, despite the success of the STENO-2 multifactorial approach, mortality upon 13 years of follow-up remained very high (30% for intensive-therapy; 50% for conventional therapy). (83).

Type 2 diabetes can be delayed or prevented among people who have IGT with lifestyle interventions or medication, as shown by major clinical trials of diabetes prevention, but it is a completely different issue to translate this message derived from the lifestyle trials to clinical practice. (84).

The primary prevention is Diabetes education since Diabetes is a complex disease requiring the adoption of numerous skills and behaviors in order for the disease to be managed successfully. Diabetes education seeks to reach these goals by-

- providing knowledge and skill training;
- facilitating problem-solving;
- helping individuals identify barriers;
- motivating for lifestyle adaptation; and
- developing coping skills to achieve goals.(85).

Recent findings from cardiovascular prevention trials among patients with longstanding diabetes cast doubt on the benefits of very intensive treatment of glycaemia but do highlight the benefits of treatment early in the course of the disease. (86).

Better adherence to health behaviours results in a greater risk reduction, in a dose-dependent manner; and seven year follow-up data indicate that for individuals who succeed in making five modest lifestyle changes, the rate of progression to type 2 diabetes is reduced to almost zero. (87). Evidence suggests that weight loss and physical activity are the main drivers for diabetes prevention. However, a major challenge is how to implement these findings into “real world” healthcare systems. The resource intensive interventions used in clinical efficacy trials need to be translated into pragmatic, more affordable, programmes, that can be delivered not only in routine clinical practice but also that retain their effectiveness. (88).

Diabetes provides a prime example of this fundamental interaction of individual characteristics with the ecological or contextual factors. For example, Pima Indians living in the U.S. have the highest prevalence of type 2 diabetes of any population in the world, yet Pimas living traditional lifestyles in Mexico have relatively low levels of diabetes. Ample evidence links genetics to diabetes within the Pima population, but exposure to an obesogenic environment is critical to expression of this very strong genetic propensity.(89).

Despite advances in Diabetes management, many people with diabetes have less than optimal metabolic control and continue to suffer from preventable complications. The gap between optimal evidence-based medicine and actual practice can be great, dependent not only on the ability of the clinician to make changes in practice patterns but also on the central role of the patient in implementing optimal management plans in daily life.(90).

It is almost impossible to overestimate the impact of the DCCT on diabetes treatment and research. Seemingly overnight, large numbers of patients were expected to follow a demanding, intensive treatment regimen that previously had been recommended only for those who were most highly motivated and diligent in their diabetes self-management. Health care practitioners were also expected to know how to help patients achieve these lofty treatment goals. In addition to problems in implementing intensive treatment, questions arose concerning the effects of these regimens on quality of life (QOL) for patients. Intensive regimens also posed new dilemmas for health care practitioners and patients, not the least of which was the dramatic increase in risk for episodes of severe hypoglycemia when patients attempted to lower blood glucose (BG) levels. It quickly became clear that the greatest challenge to contemporary diabetes treatment was overcoming the many

psychobehavioral and social–environmental barriers to optimal self-management. Not surprisingly, the medical establishment turned to behavioral scientists for assistance, and new and stronger partnerships emerged between psychology and diabetes health.(91).

The growing recognition of the need to incorporate psychological perspectives into treatment and prevention efforts led to a 1999 NIH-sponsored conference on behavioral science and diabetes, which invited prominent researchers to summarize the status of the field and make recommendations for future directions of scientific pursuit (Marrero, Peyrot, & Garfield, 2001). As we enter the new century, the impact of behavioral medicine can be seen in almost every area of diabetes education and treatment, and the effort to integrate psychology into mainstream diabetes management shows no sign of diminishing.(91).

People should have the will to adhere to a programme, which should be easy. An ancient Indian saying is "Aahar,Baivhaar and Vichar is the key to healthy living. Relating to this age old dictum one has to practice **healthy eating** (their own diet depending upon environment culture and biodiversity), **healthy behaviour** which can be achieved by Sanskar Remodelling and **Positive thinking** which can be practiced by a technique called as Neurobics.

Neurobics are mental exercises, that can enhance the brain's performance, a scientific evidence to support this idea can be found in Keep Your Brain Alive, Workman Publishing.(92,93). The term neurobics was coined by late neurobiologist Lawrence Katz and Manning Rubin in their book KEEP YOUR BRAIN ALIVE to describe unique mental exercises designed to keep the brain alert.(94). The term was popularized by Lawrence Katz as early as 1999.(95). It is presumed that unusual sensory stimulation and activities like **non-routine actions and thoughts**, produce

more of such chemicals of the neurobiology system of body that encourage growth of new dendrites and neurons in the brain. Routine actions become so automatic to the individual that most of actions are done largely unconsciously. Such automated or unconscious actions require less activity in the brain, and exercise it less. With the help of neurobics exercises, it is claimed that one can stimulate the brain. Neurobics as developed by Dr. Lawrence C. Katz and Manning Rubin is based upon solid scientific evidence that novel activities and exercises using all our senses can enhance the production of growth factors that strengthen synapses and improve mental fitness including memory.(96).

Mental exercises/ Neurobics improves brain function and actually protects against cognitive decline, as does physical exercise. Neurobics can be considered as a part of Rajyoga meditation, as this meditation involves the process of creating positive thoughts.(97). All thoughts are energies, so neurobics can be included in energy medicine.

People with diabetes require multiple interventions to reach their glycemic goals. Energy therapies have been a useful aid in improving health and well-being. Energy is all around us, within us, interacting internally and externally. The influence of disease on body energy fields and the influence of body energy fields on disease are areas just being explored in medicine. Our medicine has typically focused on illness, whereas energetic healing focuses on the connection of mind, body, and spirit. Energy medicine may be useful as a complementary therapy and adjunct to standard medical approaches as diabetics require multiple interventions to reach their optimum glycemic goals.(98).

Sanskar is a Sanskrit word meaning “Habits” or “usual Behavior”. Repeated actions causes a habit. Nowadays , it has become a habit to think negatively. This has

become a usual behaviour or sanskar. This habit of negative thinking is changed to the habit of positive thinking by the practice of Rajyoga meditation. The already formed or modelled sanskar is re-modelled by this process and hence the process can be labelled as" Sanskar Re-modelling"(SRM).The different examples of positive thinking are-

"I can do it". "I will do what is right". "I have to be good to all". "I shall follow healthy eating program"' " I am active". "I take medicines at regular time". "I regularly monitor my Blood sugar levels", " I can solve my problems", "I am coping with my disease well".

These type of thinking has to be practiced assertively and has to be affirmed which will then lead to SRM. As one practices SRM, adoption of self –care behaviours become achieveable.

The 7 self-care behaviors are healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping. (99).

Connections among psychological variables, behavioral factors, coping, metabolic control, and quality of life(QOL) are appreciable and multidirectional. Interventions for which, well-controlled studies indicate benefits for quality of life and/or metabolic control includeing general self-management. Psychological, emotional, related behavioral factors,and quality of life are important in diabetes management, and are worthy of attention in their own right, and influence metabolic control. A range of interventions that achieve benefits in these areas provide a base for developing versatile programs to promote healthy coping.(60)

Because of the negative impact diabetes can have on both psychosocial and health status, more recent research has focused on QOL in people living with this illness. In fact, current research has viewed QOL as being just as important an

outcome variable as metabolic control and one which may be more important to patients than health status (Delamater, 2000; Rubin, 2000). (100).

The food pattern of people change from country to country and place to place depending upon their cultural and ethnic diversity. Therefore a fixed programme of fixed diet management cannot be applicable to all diabetics patients in all parts of the globe and at all time. Hence, modification should be based as per the region. Therefore fixing a fixed protocol for food may not help the patient to follow lifelong.. Different trials have shown the efficacy of balanced diet and adequate exercise in achieving glycemic goals. As the disease is multifactorial , these two interventions namely diet and exercise were not sufficient to tackle the problem satisfactorily. Hence. We wanted to test two new interventions namely Neurobics and SRM. Our hypothesis is that these two interventions can be of additive support in the management of diabetes.

AIM AND OBJECTIVES

Aim-

"To study the effect of Neurobics and Sanskar Re-modelling in Diabetics."

Objectives-

1. To find out the Body mass index (BMI) and waist circumference in study and control group.
2. To compare the systolic blood pressure (SBP) and diastolic blood pressure (DBP) among both the groups.
3. To find out the fasting blood sugar (FBS) and post prandial blood sugar (PPBS) in both the groups.
4. To analyze the 4 domains of WHO-QOL-Bref in both the groups.

REVIEW OF LITERATURE

An extensive review of published articles related to diabetes; prevalence, quality of life (QoL), prevention, diet and exercise were accessed from Web of Science, BMJ, BMC, Lancet, Diabetes care, etc. The literature review covered published materials from 1991 to 2014 focusing on diabetes prevention programs.

Review of Literature shall be done under the following heads-

1. Diabetes & Life style modification Programmes
2. Diabetes &Body mass Index
3. Diabetes &Blood pressure
4. Diabetes &Quality of Life
5. Diabetes & Neurobics
6. Diabetes & Sanskar Re-modellingg

1. Diabetes and Lifestyle modification-

1991-K. -F. Eriksson, and F. Lindgärde undertook a feasibility study titled " Prevention of Type 2 (non-insulin-dependent) diabetes mellitus by diet and physical exercise The 6-year Malmö feasibility study"

From a previously reported 5-year screening programme of 6,956, 47–49-year-old Malmö males, a series of 41 subjects with early-stage Type 2 (non-insulin-dependent) diabetes mellitus and 181 subjects with impaired glucose tolerance were selected for prospective study and to test the feasibility aspect of long-term intervention with an emphasis on life-style changes.

A 5-year protocol, including an initial 6-months (randomised) pilot study, consisting of dietary treatment and/or increase of physical activity or training with

annual check-ups, was completed by 90% of subjects. Body weight was reduced by 2.3–3.7% among participants, whereas values increased by 0.5–1.7% in non-intervened subjects with impaired glucose tolerance and in normal control subjects (p<0.0001); maximal oxygen uptake (ml · min^{-1} · kg^{-1}) was increased by 10–14% vs decreased by 5–9%, respectively (p<0.0001). Glucose tolerance was normalized in > 50% of subjects with impaired glucose tolerance, the accumulated incidence of diabetes was 10.6%, and more than 50% of the diabetic patients were in remission after a mean follow-up of 6 years. Blood pressure, lipids, and hyperinsulinaemia were reduced and early insulin responsiveness to glucose loading preserved. Improvement in glucose tolerance was correlated to weight reduction (r=0.19, p<0.02) and increased fitness (r=0.22, p<0.02). Treatment was safe, and mortality was low (in fact 33% lower than in the remainder of the cohort). They concluded that long-term intervention in the form of diet and physical exercise is feasible even on a large scale, and that substantial metabolic improvement can be achieved which may contribute to prevent or postpone manifest diabetes.(101).

1994-Diabetes Prevention Program Outcomes Study (DPPOS). The Diabetes Prevention Program Outcomes Study (DPPOS) began as the Diabetes Prevention Program (DPP) in 1994. The study assessed patients at high risk of developing diabetes to determine if lifestyle modifications of improved diet and exercise along with on oral anti-diabetes medication would prevent the development of diabetes. After meeting its objectives, DPPOS was established to assess the long-term effects of these interventions. One of the measures used in the study is the Quality of Well-Being Scale.(102).

1997 -Xiao-Ren Pan, Guang-Wei Li, Ying-Hua Hu, , et al reported a study on "the effects of Diet and Exercise in Preventing NIDDM in People With Impaired Glucose Tolerance": This study was called " the Da Qing IGT and Diabetes Study".

Individuals with impaired glucose tolerance (IGT) have a high risk of developing NIDDM. The purpose of this study was to determine whether diet and exercise interventions in those with IGT may delay the development of NIDDM, i.e., reduce the incidence of NIDDM, and thereby reduce the overall incidence of diabetic complications, such as cardiovascular, renal, and retinal disease, and the excess mortality attributable to these complications.

In 1986, 110,660 men and women from 33 health care clinics in the city of Da Qing, China, were screened for IGT and NIDDM.. Of these individuals, 577 were classified (using World Health Organization criteria) as having IGT. Subjects were randomized by clinic into a clinical trial, either to a control group or to one of three active treatment groups: diet only, exercise only, or diet plus exercise. Follow-up evaluation examinations were conducted at 2-year intervals over a 6-year period to identify subjects who developed NIDDM.. Cox's proportional hazard analysis was used to determine if the incidence of NIDDM varied by treatment assignment.

The cumulative incidence of diabetes at 6 years was 67.7% (95% CI, 59.8–75.2) in the control group compared with 43.8% (95% CI, 35.5–52.3) in the diet group, 41.1% (95% CI, 33.4–49.4) in the exercise group, and 46.0% (95% CI, 37.3–54.7) in the diet-plus-exercise group ($P < 0.05$). The relative decrease in rate of development of diabetes in the active treatment groups was similar when subjects were stratified as lean or overweight (BMI < or ≥ 25 kg/m^2). In a proportional hazards analysis adjusted for differences in baseline BMI and fasting glucose, the diet, exercise, and diet-plus-exercise interventions were associated with 31% ($P < 0.03$),

46% ($P < 0.0005$), and 42% ($P < 0.005$) reductions in risk of developing diabetes, respectively.

They concluded that diet and/or exercise interventions led to a significant decrease in the incidence of diabetes over a 6-year period among those with IGT. (103).

2001. Susan L. Norris,Michael M. Engelgau, andK.M. Venkat Narayan**,** did a systematic review of randomized controlled trials . Their work was titled as" Effectiveness of Self-Management Training in Type 2 Diabetes" Objective of the study was to systematically review the effectiveness of self-management training in type 2 diabetes**.**

Studies were original articles published between 1980 and 1999, reporting the results of randomized controlled trials of the effectiveness of self-management training in people with type 2 diabetes. Relevant data on study design, population demographics, interventions, outcomes, methodological quality, and external validity were tabulated. Interventions were categorized based on educational focus (information, lifestyle behaviors, mechanical skills, and coping skills), and outcomes were classified as knowledge, attitudes, and self-care skills; lifestyle behaviors, psychological outcomes, and quality of life; glycemic control; cardiovascular disease risk factors; and economic measures and health service utilization.

A total of 72 studies described in 84 articles were identified for this review. Positive effects of self-management training on knowledge, frequency and accuracy of self-monitoring of blood glucose, self-reported dietary habits, and glycemic control were demonstrated in studies with short follow-up (<6 months). Effects of interventions on lipids, physical activity, weight, and blood pressure were variable. With longer follow-up, interventions that used regular reinforcement throughout

follow-up were sometimes effective in improving glycemic control. Educational interventions that involved patient collaboration may be more effective than didactic interventions in improving glycemic control, weight, and lipid profiles. No studies demonstrated the effectiveness of self-management training on cardiovascular disease–related events or mortality; no economic analyses included indirect costs; few studies examined health-care utilization. Performance, selection, attrition, and detection bias were common in studies reviewed, and external generalizability was often limited.

They concluded that educational interventions that involved patient collaboration may be more effective than didactic interventions in improving glycemic control, weight, and lipid profiles.. They felt that further research is needed to assess the effectiveness of self-management interventions on sustained glycemic control, cardiovascular disease risk factors, and ultimately, microvascular and cardiovascular disease.(104).

2002- In this year the **Diabetes Prevention Program (DPP)** was reported. The Diabetes Prevention Program (DPP) was a 27-center randomized clinical trial to determine whether lifestyle intervention or pharmacological therapy (metformin) would prevent or delay the onset of diabetes in individuals with impaired glucose tolerance (IGT) who are at high risk for the disease.

The purpose of the present study was to provide a detailed description of the highly successful lifestyle intervention administered to 1,079 participants, which included 45% racial and ethnic minorities and resulted in a 58% reduction in the incidence rate of diabetes . The two major goals of the Diabetes Prevention Program (DPP) lifestyle intervention were a minimum of 7% weight loss/ weight maintenance and a minimum of 150 min of physical activity similar in intensity to brisk walking.

Both goals were hypothesized to be feasible, safe, and effective based on previous clinical trials. The methods used to achieve these lifestyle goals included the following key features: *1*) individual case managers or "lifestyle coaches;" *2*) frequent contact with participants; *3*) a structured, state-of-the-art, 16-session core-curriculum that taught behavioral self-management strategies for weight loss and physical activity; *4*) supervised physical activity sessions; *5*) a more flexible maintenance intervention, combining group and individual approaches, motivational campaigns, and "restarts;" *6*) individualization through a "toolbox" of adherence strategies; *7*) tailoring of materials and strategies to address ethnic diversity; and finally *8*) an extensive network of training, feedback, and clinical support.

Lifestyle intervention decreased the incidence of type 2 diabetes by 58% compared with 31% in the metformin-treated group, and information on adherence to these interventions has already been reported .(105).

2003 - Jaana Lindström, Anne Louheranta,Marjo Mannelin, et al conducted a 3 year Lifestyle intervention study on diet and physical activity which was named as **"**The Finnish Diabetes Prevention Study (DPS)".

The goal of the study was to describe the *1*) lifestyle intervention used in the Finnish Diabetes Prevention Study, *2*) short- and long-term changes in diet and exercise behavior, and *3*) effect of the intervention on glucose and lipid metabolism.

Their study included 522 middle-aged, overweight subjects with impaired glucose tolerance who were randomized to either a usual care control group or an intensive lifestyle intervention group. The control group received general dietary and exercise advice at baseline and had an annual physician's examination. The subjects in the intervention group received additional individualized dietary counseling from a nutritionist. They were also offered circuit-type resistance training sessions and

advised to increase overall physical activity. The intervention was the most intensive during the first year, followed by a maintenance period. The intervention goals were to reduce body weight, reduce dietary and saturated fat, and increase physical activity and dietary fiber.

The intervention group showed significantly greater improvement in each intervention goal. After 1 and 3 years, weight reductions were 4.5 and 3.5 kg in the intervention group and 1.0 and 0.9 kg in the control group, respectively. Measures of glycemia and lipemia improved more in the intervention group.

They concluded that the intensive lifestyle intervention produced long-term beneficial changes in diet, physical activity, and clinical and biochemical parameters and reduced diabetes risk. This type of intervention is a feasible option to prevent type 2 diabetes and they recommended that this type of intervention should be implemented in the primary health care system. (106).

2003 - Marco Mensink, Ellen E. Blaak, Eefje Corpeleijn, et al conducted a study titled"Lifestyle Intervention According to General Recommendations Improves Glucose Tolerance". Their study intended to know whether changing dietary and physical activity habits has the potential to postpone or prevent the development of type 2 diabetes.

They evaluated the impact of a 2-year combined diet and physical activity intervention program on glucose tolerance in Dutch subjects at increased risk for developing diabetes.

Subjects with glucose intolerance were randomly assigned to either the lifestyle intervention group (INT) or control group (CON). The INT received regular dietary advice and was stimulated to increase their physical activity. The CON

received a brief leaflet about healthy diet and increased physical activity. Primary outcome measure was the change in glucose tolerance.

In total, 88 subjects completed 2 years of intervention (40 subjects in the INT, 48 subjects in the CON, mean BMI 29.4 kg/m2). Subjects in the INT reduced their body weight, waist circumference, and (saturated) fat intake and improved their aerobic capacity. Two-hour plasma glucose concentration declined from 8.7 to 8.0 mM in the INT and rose from 8.6 to 9.4 mM in the CON (p _ 0.01). Subjects adherent to both the diet and exercise intervention showed the largest reduction in 2-hour glucose levels.

Their results showed that a lifestyle intervention program according to general recommendations improves glucose tolerance, even in a less obese and more physical active population. Furthermore, our results underscore the importance of combining diet and physical activity to improve glucose tolerance and insulin resistance.(107).

2005- Kazue Yamaoka, and Toshiro Tango did a meta-analysis of randomized controlled trials titled " Efficacy of Lifestyle Education to Prevent Type 2 Diabetes"'. The objective of the study was to evaluate the efficacy of lifestyle education for preventing type 2 diabetes in individuals at high risk by meta-analysis of randomized controlled trials, as assessed by incidence and a reduced level of plasma glucose 2 h after a 75-g oral glucose load (2-h plasma glucose).

Through an electronic search, 123 studies were identified. A literature search identified eight studies that met strict inclusion criterion of meta-analysis for 2-h plasma glucose and five studies for the incidence of diabetes. All were randomized controlled trials of 6 months with lifestyle education that included a dietary intervention. Subjects were adults diagnosed as being at high risk for type 2 diabetes. The difference in mean reduction of 2-h plasma glucose from baseline to the 1-year

follow-up and relative risk (RR) of the incidence of diabetes in the lifestyle education group versus the control group were assessed. Overall estimates were calculated using a random-effects model. Those estimates were confirmed by several models, and the possibility of selection bias was examined using a funnel plot.

It was found that the Lifestyle education intervention reduced 2-h plasma glucose by 0.84 mmol/l (95% CI 0.39 –1.29) compared with the control group. The 1-year incidence of diabetes was reduced by 50% (RR 0.55, 95% CI 0.44–0.69) compared with the control group. Results were stable and little changed if data were analyzed by subgroups or other statistical models. Funnel plots revealed no selection bias.

This study concluded that Lifestyle education was effective for reducing both 2-h plasma glucose and RR in high-risk individuals and may be a useful tool in preventing diabetes.(108).

In **2005**, Jeff Curtis, and Charlton Wilson conducted a study titled "Preventing Type 2 Diabetes Mellitus".. They presented the results of a systematic review of the literature examining the evidence for different strategies aimed at preventing type 2 diabetes in patients with these conditions. The strongest evidence supports an intensive lifestyle intervention designed to induce modest weight loss. The greatest degree of prevention, based on lesser quality evidence, may be imparted by bariatric surgery. Metformin and troglitazone have appreciable evidence in specific populations, and orlistat and acarbose have slightly less evidence among obese patients, for preventing diabetes. Ramipril, captopril, losartan, pravastatin, and estrogens show some very preliminary promise for preventing diabetes in patients treated for hypertension, hyperlipidemia, and menopause, but each needs a more rigorous evaluation. Type 2 diabetes is a serious, costly, and increasingly common

disease. Several conditions commonly seen in family medicine settings confer increased risk of developing diabetes. Among these conditions are impaired glucose tolerance, impaired fasting glucose, obesity, gestational diabetes, hypertension, hyperlipidemia.

They conducted a systematic review of the literature to identify research that addresses the prevention of type 2 diabetes. They searched MEDLINE, via PubMed, for reports in English of randomized, controlled trials in humans between January 1, 1965, and January 30, 2004, using the search terms "type 2 diabetes AND prevention," "NIDDM AND prevention," and "adult onset diabetes AND prevention." This search produced a total of 282 articles. We reviewed the titles and abstracts of each study. They also added 5 studies that did not appear in the search but were suggested by subject matter experts or identified during review of the articles. From the combination of these data sources, they identified 18 articles in which preventing type 2 diabetes was the objective. These articles were reviewed in full for confirmation of the primary research outcome, description of the target population and intervention, and identification of the relative and absolute risk reduction of the intervention **Amid all the attention given to the increasing incidence of type 2 diabetes, there is also ever-mounting evidence that the disease is preventable, even among those at highest risk. The preventive strategy with the best supporting evidence is an intensive lifestyle intervention, designed to produce modest weight loss.** Although on face value the success of the DPP and the DPS may tempt physicians to recommend healthy eating and regular exercise, using the specific intervention strategies as the basis for a discussion with patients, and to believe therefore that they have provided an evidence-based preventive intervention, it is important to realize that even the control groups in these studies received more

intervention than routine physician recommendations. The interventions were intensive, interdisciplinary, individualized programs aimed at inducing weight loss. Truly implementing a version of these interventions will require developing treatment teams with the ability to motivate patients to make changes in lifestyle patterns that have probably been present for decades.

The intervention that seems (based on lesser quality evidence) to have the greatest potential for preventing diabetes is bariatric surgery. However, this treatment is far more invasive than the lifestyle interventions, and the surgery requires lifestyle modifications that are probably more intensive. Because of its cost and invasiveness, bariatric surgery will probably never be the diabetes prevention strategy of choice for the majority of the at-risk population.

The medications with the strongest evidence supporting their ability to prevent diabetes are metformin and troglitazone. Of course, troglitazone is no longer available, and whether other thiazolidinediones will have similar benefits is yet to be seen. Orlistat and acarbose also show considerable promise. The other medications included in this review (ramipril, captopril, losartan, pravastatin, and estrogens) have been evaluated only in post hoc subgroup analyses. Therefore, they do not carry nearly the weight of evidence for preventing diabetes that metformin, orlistat, and acarbose do.

It is clear that there is much yet to learn about preventing type 2 diabetes. For example, does the combination of lifestyle intervention and medication have a greater effect than either alone? Does preventing diabetes by these strategies also prevent the micro- and macrovascular complications of diabetes, or does it merely prevent glucose elevation above diagnostic values? And can earlier intervention among patients with familial risk but no aberration in glucose homeostasis prevent diabetes

more effectively than intervention after other risk factors have become apparent? However, there is sufficient evidence that diabetes can be prevented using techniques and agents that are currently available. They concluded that the onus is now on physicians to implement this evidence to help patients improve their chances of leading lives free of this disease. (109).

2006 - Lindström J[1], Ilanne-Parikka P, Peltonen M, Aunola S, Eriksson JG, Hemiö K, Hämäläinen H, Härkönen P, Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Mannelin M undertook a study titled " Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study".

Their hypothesis for the study was that lifestyle interventions can prevent the deterioration of impaired glucose tolerance to manifest type 2 diabetes, at least as long as the intervention continues. In the extended follow-up of the Finnish Diabetes Prevention Study, They assessed the extent to which the originally-achieved lifestyle changes and risk reduction remained after discontinuation of active counselling.

Overweight, middle-aged men (n=172) and women (n=350) with impaired glucose tolerance were randomly assigned to intensive lifestyle intervention or control group. After a median of 4 years of active intervention period, participants who were still free of diabetes were further followed up for a median of 3 years, with median total follow-up of 7 years. Diabetes incidence, bodyweight, physical activity, and dietary intakes of fat, saturated fat, and fibre were measured.

During the total follow-up, the incidence of type 2 diabetes was 4.3 and 7.4 per 100 person-years in the intervention and control group, respectively (log-rank test p=0.0001), indicating 43% reduction in relative risk. The risk reduction was related to the success in achieving the intervention goals of weight loss, reduced intake of total

and saturated fat and increased intake of dietary fibre, and increased physical activity. They found that the beneficial lifestyle changes achieved by participants in the intervention group were maintained after the discontinuation of the intervention, and the corresponding incidence rates during the post-intervention follow-up were 4.6 and 7.2 (p=0.0401), indicating 36% reduction in relative risk.

They concluded that lifestyle intervention in people at high risk for type 2 diabetes resulted in sustained lifestyle changes and a reduction in diabetes incidence, which remained after the individual lifestyle counselling was stopped.(110).

2006- Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V; Indian Diabetes Prevention Programme (IDPP) undertook a study titled " Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1)".

Lifestyle modification helps in the primary prevention of diabetes in multiethnic American, Finnish and Chinese populations. With this background, in a prospective community-based study, they tested whether the progression to diabetes could be influenced by interventions in native Asian Indians with IGT who were younger, leaner and more insulin resistant than the above populations.

They randomised 531 (421 men and 110 women) subjects with IGT (mean age 45.9+/-5.7 years, BMI 25.8+/-3.5 kg/m(2)) into four groups. Group 1 was the control, Group 2 was given advice on lifestyle modification (LSM), Group 3 was treated with metformin (MET) and Group 4 was given LSM plus MET. The primary outcome measure was type 2 diabetes as diagnosed using World Health Organization criteria.

The median folljow-up period was 30 months, and the 3-year cumulative incidences of diabetes were 55.0%, 39.3%, 40.5% and 39.5% in Groups 1-4, respectively. The relative risk reduction was 28.5% with LSM (95% CI 20.5-37.3, p=0.018), 26.4% with MET (95% CI 19.1-35.1, p=0.029) and 28.2% with LSM + MET (95% CI 20.3-37.0, p=0.022), as compared with the control group. The number needed to treat to prevent one incident case of diabetes was 6.4 for LSM, 6.9 for MET and 6.5 for LSM + MET.

The result of their study was that the progression of IGT to diabetes is high in native Asian Indians. Both LSM and MET significantly reduced the incidence of diabetes in Asian Indians with IGT; there was no added benefit from combining them.(111).

In **2008**- Jaana Lindström, Markku Peltonen, Johan G. Eriksson, etal, conducted a study titled " Determinants for the Effectiveness of Lifestyle Intervention in the Finnish Diabetes Prevention Study"**.**

With the background that intensive lifestyle intervention significantly reduced diabetes incidence among the participants in the Finnish Diabetes Prevention Study, they investigated whether and to what extent risk factors for type 2 diabetes and other baseline characteristics of the study participants modified the effectiveness of the lifestyle intervention.

Overweight, middle-aged volunteers with impaired glucose tolerance were randomly assigned to intensive lifestyle intervention (n = 265) or to a control group (n = 257) for a median of 4 years. Diabetes status was ascertained annually with repeated oral glucose tolerance testing. Incidence rates of diabetes and hazard ratios (HRs) comparing the intervention group with the control group were calculated by sex and baseline tertiles of age, BMI, waist circumference, plasma glucose concentration at

fasting and 2 h after a glucose load, fasting serum insulin and insulin resistance index, and categories of composite baseline Finnish Diabetes Risk Score (FINDRISC). Interactions between the intervention assignment and baseline risk factors on diabetes risk were analyzed.

The intervention was most effective among the oldest individuals (HRs 0.77, 0.49, and 0.36 by increasing age tertiles, respectively; $P_{interaction}$ = 0.0130) and those with a high baseline FINDRISC (HRs 1.09, 0.84, 0.34, and 0.22 by increasing risk score category, respectively; $P_{interaction}$ = 0.0400). The effect of the intervention on diabetes risk was not modified by other baseline characteristics or risk factors.

They concludes that the the FINDRISC may be useful in identifying high-risk groups most likely to benefit from intensive lifestyle intervention to prevent type 2 diabetes. (112).

In **2008**- a study titled "The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing Diabetes Prevention Study: a 20-year follow-up study" was undertaken by Li G, Zhang P, Wang J, Gregg EW, Yang W, Gong Q, Li H, Li H, Jiang Y, An Y, Shuai Y, Zhang B, Zhang J, Thompson TJ, Gerzoff RB, Roglic G, Hu Y, and Bennett PH.

Intensive lifestyle interventions can reduce the incidence of type 2 diabetes in people with impaired glucose tolerance, but how long these benefits extend beyond the period of active intervention, and whether such interventions reduce the risk of cardiovascular disease (CVD) and mortality, is unclear. With this background they aimed to assess whether intensive lifestyle interventions have a long-term effect on the risk of diabetes, diabetes-related macrovascular and microvascular complications, and mortality.

In 1986, 577 adults with impaired glucose tolerance from 33 clinics in China were randomly assigned to either the control group or to one of three lifestyle intervention groups (diet, exercise, or diet plus exercise). Active intervention took place over 6 years until 1992. In 2006, study participants were followed-up to assess the long-term effect of the interventions. The primary outcomes were diabetes incidence, CVD incidence and mortality, and all-cause mortality.

Compared with control participants, those in the combined lifestyle intervention groups had a 51% lower incidence of diabetes (hazard rate ratio [HRR] 0.49; 95% CI 0.33-0.73) during the active intervention period and a 43% lower incidence (0.57; 0.41-0.81) over the 20 year period, controlled for age and clustering by clinic. The average annual incidence of diabetes was 7% for intervention participants versus 11% in control participants, with 20-year cumulative incidence of 80% in the intervention groups and 93% in the control group. Participants in the intervention group spent an average of 3.6 fewer years with diabetes than those in the control group. There was no significant difference between the intervention and control groups in the rate of first CVD events (HRR 0.98; 95% CI 0.71-1.37), CVD mortality (0.83; 0.48-1.40), and all-cause mortality (0.96; 0.65-1.41), but our study had limited statistical power to detect differences for these outcomes.

The outcome of their study was that group-based lifestyle interventions over 6 years can prevent or delay diabetes for up to 14 years after the active intervention. However, whether lifestyle intervention also leads to reduced CVD and mortality remains unclear.(113).

In **2009**- A study was conducted with a title namely "A Lifestyle Intervention Study in Patients with Diabetes or Impaired Glucose Tolerance: Translation of a Research Intervention into Practice" by Oksana A. Matvienko, and James D. Hoehns**,**

The objectives of this study were to translate a research-validated lifestyle modification curriculum of the Diabetes Prevention Program (DPP) into a community-based program delivered by trained graduate students on a university campus and determine whether this delivery approach is effective in lowering risk factors of type 2 diabetes in at-risk adults.

A convenience sample of 29 prediabetic or type 2 diabetic patients completed a 12-month behavior modification intervention to achieve and maintain at least 7% weight loss and become more active. Changes in weight, waist and hip circumferences, blood pressure, metabolic biomarkers, physical activity levels, and medication were assessed.

At 6 and 12 months, 39% and 56% of patients had lost ≥5% of their weight. The mean weight loss at 12 months was 6%. Significant improvements were noted in most other anthropometric measurements and diastolic BP (−4.1 mm Hg). Significant reductions in total cholesterol (−11.7%), LDL-C (−7.6%), and HDL-C (−6.5%) were observed by 6 months but not at 12 months. Fasting glucose (−12%), systolic BP (−8.4 mm Hg), and diastolic BP (−7.0 mm Hg) were significantly improved in a subgroup of participants with at least 5% weight loss. HbA1c levels were associated with percentage weight loss. Twenty-seven percent of participants on diabetes medication had their drug discontinued.

They concluded that weight-related findings of this study are comparable with those of the DPP. DPP curriculum implemented in a nonclinical setting can help some adults at-risk for or in early stages of diabetes improve anthropometric and certain metabolic outcomes. (114).

2011-Long-term effects of a randomised trial of a 6-year lifestyle intervention in impaired glucose tolerance on diabetes-related microvascular complications: the

China Da Qing Diabetes Prevention Outcome Study. This study was conducted by Gong Q[1], Gregg EW, Wang J, An Y, Zhang P, Yang W, Li H, Li H, Jiang Y, Shuai Y, Zhang B, Zhang J, Gerzoff RB, Roglic G, Hu Y, Li G, Bennett PH. In their study they determined the effects of 6 years of lifestyle intervention in persons with impaired glucose tolerance (IGT) on the development of retinopathy, nephropathy and neuropathy over a 20 year period.

In 1986, 577 adults with IGT from 33 clinics in Da Qing, China were randomly assigned by clinic to a control group or one of three lifestyle intervention groups (diet, exercise, and diet plus exercise). Active intervention was carried out from 1986 to 1992. In 2006 we conducted a 20 year follow-up study of the original participants to compare the incidence of microvascular complications in the combined intervention group vs the control group.

Follow-up information was obtained on 542 (94%) of the 577 original participants. The cumulative incidence of severe retinopathy was 9.2% in the combined intervention group and 16.2% in the control group ($p = 0.03$, log-rank test). After adjusting for clinic and age, the incidence of severe retinopathy was 47% lower in the intervention group than the control group (hazard rate ratio 0.53, 95% CI 0.29-0.99, $p = 0.048$). No significant differences were found in the incidence of severe nephropathy (hazard rate ratio 1.05, 95% CI 0.16-7.05, intervention vs control, $p = 0.96$) or in the prevalence of neuropathy (8.6% vs 9.1%, $p = 0.89$) among the 20 year survivors.

They concluded that lifestyle intervention for 6 years in IGT was associated with a 47% reduction in the incidence of severe, vision-threatening retinopathy over a 20 year interval, primarily due to the reduced incidence of diabetes in the intervention group. However, similar benefits were not seen for nephropathy or neuropathy.(115).

In **2011**, Mayur Patel, M. Patel,Yash M. Patel, and Suresh K. Rathi, conducted a study titled " A Hospital-based Observational Study of Type 2 Diabetic Subjects from Gujarat, India". The aim of this observational study was to describe the profile of subjects with type 2 diabetes mellitus from Gujarat, India. The study was performed with newly-diagnosed 622 type 2 diabetic subjects who attended the Department of Diabetology at the All India Institute of Diabetes and Research and Yash Diabetes Specialties Centre (Swasthya), Ahmedabad, during August 2006–January 2009. The subjects completed an interviewer-administered questionnaire. The questionnaire included variables, such as sociodemographic factors, presenting symptoms, risk profile (hypertension, obesity, dyslipidaemia, and glycaemic status), family history of diabetes, physical activity, and behavioural profile. Blood pressure, body mass index (BMI), glycosylated haemoglobin levels, and fasting lipid profile were measured. Descriptive and bivariate analyses were carried out using the SPSS software (version 11.5). In total, 622 type 2 diabetes mellitus (T2DM) cases with mean age of 47.7±10.9 years were studied. Of the 622 subjects, 384 (62%) were male. The majority (68%) of the T2DM subjects were obese, and 67% had a positive family history of diabetes. Renal dysfunctions and vision impairment were, respectively, found in 10% (n=62) and 9% (n=57) of the 622 T2DM subjects. The mean HbA1c level was 9.02±1.67%, and good glycaemic control (HbA1c level <7%) was achieved only in 7.4% of the T2DM subjects. Results of chi-square analysis showed that higher BMI ($\geq$25 kg/m^2) was significantly associated with hypertension among the T2DM subjects ($p<0.01$). There were significant differences ($p<0.05$) between male and female subjects with respect to mean age, BMI, waist and hip-circumference, and mean low-density lipoprotein (LDL) level. The results revealed that many factors, such as obesity, family history of diabetes, dyslipidaemia, uncontrolled glycaemic

status, sedentary lifestyles, and hypertension were prevalent among the T2DM subjects. The characterization of this risk profile will contribute to designing more effective and specific strategies for screening and controlling T2DM in Gujarat, India.(116).

In **2012**, a study titled "Efficacy of lifestyle interventions in reducing diabetes incidence in patients with impaired glucose tolerance: a systematic review of randomized controlled trials" was studied by Uzung Yoon, Lai Lai Kwok, and Athanasios Magkidis.

Their search showed that every year over 3.8 million people are dying of diabetes and its complications. Lifestyle intervention was suggested to have beneficial effects in preventing and reducing diabetes incidence. Especially interventions in patients with impaired glucose tolerance (IGT), who belong to a high risk group in developing diabetes, are supposed to be very effective. According to the evidence heirarchy, a 1a level of evidence is missing and therefore a systematic review verifying the efficacy of lifestyle intervention is needed.

The electronic database PubMed, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Health Technology Assessment database were searched. Main inclusion criteria were randomized controlled trials, impaired glucose tolerance, lifestyle intervention with control group and observation time >6 month. Outcome measures were all diabetes events, as defined by the authors of each study, all-cause mortality, diabetes mortality, and quality adjusted life years (QALY). Two independent reviewers abstracted the found studies by title, abstract and full-text analysis. Furthermore the reporting quality of each study was assessed by using the CONSORT criteria (Consolidated Standards of Reporting Trials) and the methodological quality by SIGN 50 instrument (Scottish

Intercollegiate Guidelines Network methodology checklist for randomized controlled trials). The primary outcome measure was diabetes incidence. Secondary outcome measures were overall mortality, disease-specific mortality, quality adjusted life years (QALY), and clinical parameters; body mass index (BMI), weight change, blood pressure, blood parameter, smoking, alcohol consumption.

Results of 7 trials which included 25 relevant publications were identified. Kappa Cohens for title-analysis were K=0.77, (CI=0.71-0.83), abstract-analysis K=0.81 (CI=0.64-0.92) and full-text analysis K=0.78 (CI=0.57- 0.98). Overall 5663 patients were analyzed with primary follow-up time: India (3 yr), Japan (4 yr), Sweden (5 yr), Da Qing (6 yr), SIM (3 yr), DPP (5 yr), DPS (4 yr) and drop-out rate ranges from 5% to 28%. Diabetes incidence ranges from 3% to 46% in the intervention group and 9.3% to 67.7% in the control group. The India study reported ARR= 16%, RRR= 29% (p=0.018), Japan: ARR= 6.3%, RRR= 65% (p<0.001), Sweden: ARR= 4%, RRR= 25% (p=not significant), Da Qing: ARR= 22%, RRR= 32% (p<0.05), SLIM: ARR= 20%, RRR= 53% (p=0.025), DPP: ARR= 15%, RRR= 58% (significant, no p value reported), and DPS: ARR=12%, RRR= 52% (significant, no p value reported). Mortality and morbidity were only analyzed in Da Qing study which showed no statistical differences (overall mortality: HRR 0.96, CI 0.65-1.41, CVD-mortality: HRR 0.83; CI 0.48-1.40, CVD event: HRR 0.98; CI 0.71-1.37).

Under consideration of heterogeneity in lifestyle interventions and follow up time of the included studies, this systematic review illustrated that lifestyle intervention can have a beneficial effect on the incidence of diabetes.(117).

In **2013 ,** a study titled "Preventing Type 2 Diabetes Mellitus: A Call for Personalized Intervention" was conducted by Harry Glauber, and Eddy Karnieli**,** They reviewed the many factors known to influence risk of developing DM2 and

summarized treatment trials demonstrating the possibility of preventing DM2. In parallel with the rising prevalence of obesity worldwide, especially in younger people, there has been a dramatic increase in recent decades in the incidence and prevalence of metabolic consequences of obesity, in particular prediabetes and type 2 diabetes mellitus (DM2). Although approximately one-third of US adults now meet one or more diagnostic criteria for prediabetes, only a minority of those so identified as being at risk for DM2 actually progress to diabetes, and some may regress to normal status. Given the uncertain prognosis of prediabetes, it is not clear who is most likely to benefit from lifestyle change or medication interventions that are known to reduce DM2 risk. Applying the concepts of personalized medicine and the potential of "big data" approaches to analysis of massive amounts of routinely gathered clinical and laboratory data from large populations, we call for the development of tools to more precisely estimate individual risk factors.(118).

In **2014**, the Diabetes Prevention Program Research Group conducted a study titled"10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study"

They investigated the persistence of the effects namely in the 2·8 years of the Diabetes Prevention Program (DPP) randomised clinical trial, diabetes incidence in high-risk adults was reduced by 58% with intensive lifestyle intervention and by 31% with metformin, compared with placebo , in the long term.

All active DPP participants were eligible for continued follow-up. 2766 of 3150 (88%) enrolled for a median additional follow-up of 5·7 years (IQR 5·5–5·8). 910 participants were from the lifestyle, 924 from the metformin, and 932 were from the original placebo groups. On the basis of the benefits from the intensive lifestyle intervention in the DPP, all three groups were offered group-implemented lifestyle

intervention. Metformin treatment was continued in the original metformin group (850 mg twice daily as tolerated), with participants unmasked to assignment, and the original lifestyle intervention group was offered additional lifestyle support. The primary outcome was development of diabetes according to American Diabetes Association criteria. Analysis was by intention-to-treat. This study was registered with ClinicalTrials.gov, number NCT00038727.

During the 10·0-year (IQR 9·0–10·5) follow-up since randomisation to DPP, the original lifestyle group lost, then partly regained weight. The modest weight loss with metformin was maintained. Diabetes incidence rates during the DPP were 4·8 cases per 100 person-years (95% CI 4·1–5·7) in the intensive lifestyle intervention group, 7·8 (6·8–8·8) in the metformin group, and 11·0 (9·8–12·3) in the placebo group. Diabetes incidence rates in this follow-up study were similar between treatment groups: 5·9 per 100 person-years (5·1–6·8) for lifestyle, 4·9 (4·2–5·7) for metformin, and 5·6 (4·8–6·5) for placebo. Diabetes incidence in the 10 years since DPP randomisation was reduced by 34% (24–42) in the lifestyle group and 18% (7–28) in the metformin group compared with placebo.

They found that during follow-up after DPP, incidences in the former placebo and metformin groups fell to equal those in the former lifestyle group, but the cumulative incidence of diabetes remained lowest in the lifestyle group. They concluded that prevention or delay of diabetes with lifestyle intervention or metformin can persist for at least 10 years.(119).

2. Diabetes and Body mass index-

In **2002**, Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM of the Diabetes Prevention Program Research Group

conducted a study titled "Reduction In The Incidence Of Type 2 Diabetes With Lifestyle Intervention or Metformin".

They hypothesized that modifying factors like elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle with a lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes.

They randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups.

The average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin.

They concluded that lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin.(120).

In **2003**,W K Grylls, J E McKenzie, C C Horwath and J I Mann undertook a study titled a**s** "Lifestyle factors associated with glycaemic control and body mass index in older adults with diabetes"

The aim of the study was to investigate the relations between lifestyle factors (diet and exercise), glycated haemoglobin (HbA_{1c}) and body mass index (BMI) in older adults with diabetes.

It was a community hospital-based cross-sectional study of 150 noninstitutionalized, ambulatory adults with diabetes, residing within New Zealand's Kapiti region.

Patients were recruited from all general practices; two diabetes clinics; local diabetes society and through advertisements in community newspapers. A total of 211 eligible people were identified, but 60 refused to participate and one withdrew. In all, 150 people completed the study (71% participation rate).

Nutrient intakes were calculated by a food-frequency questionnaire. Physical activity was assessed by interview using a validated questionnaire. Medical history and demographic data were obtained by interview or self-completed questionnaires; height, weight and HbA_{1c} were measured. Multivariate models using bootstrapping and stepwise linear regression were used to select factors associated with HbA_{1c} and BMI.

Each five-unit increase in energy from dietary saturated fat and five-unit increase in BMI were associated with 6% (95% confidence interval=2–10%; *P*=0.004) and 4% (0.3–7%; *P*=0.031) increases in HbA_{1c}, respectively. For females with moderate, compared with low overall activity, there was a 14% (7–20%; *P*=0.000) reduction in BMI while for males the reduction was only 5% (-1–11%; *P*=0.116). BMI decreased 5% (2–9%; *P*=0.004) with each 10-y increase in age, while

a five-unit increment in energy from dietary sucrose was associated with a 6% (1–11%; *P*=0.025) increase in BMI.

The study concluded stating that reducing dietary saturated fat and excess body weight may be a useful means of improving glycaemic control in older adults with diabetes. Increasing physical activity and reducing energy from dietary sucrose may assist weight control, the former particularly in women.(121).

In 2004, the WHO expert consultation group on Public Health in their report titled-" Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies" addressed the debate about interpretation of recommended body-mass index (BMI) cut-off points for determining overweight and obesity in Asian populations, and considered whether population-specific cut-off points for BMI are necessary. They reviewed scientific evidence that suggests that Asian populations have different associations between BMI, percentage of body fat, and health risks than do European populations. The consultation concluded that the proportion of Asian people with a high risk of type 2 diabetes and cardiovascular disease is substantial at BMIs lower than the existing WHO cut-off point for overweight (25 kg/m2). However, available data do not necessarily indicate a clear BMI cut-off point for all Asians for overweight or obesity. The cut-off point for observed risk varies from 22 kg/m2 to 25 kg/m2 in different Asian populations; for high risk it varies from 26 kg/m2 to 31 kg/m2. No attempt was made, therefore, to redefine cut-off points for each population separately. The consultation also agreed that the WHO BMI cut-off points should be retained as international classifications. The consultation identified further potential public health action points (23·0, 27·5, 32·5, and 37·5 kg/m2) along the continuum of BMI, and proposed methods by which

countries could make decisions about the definitions of increased risk for their population.(122).

In **2007**, a study titled-"The relationship of body mass index to diabetes mellitus, hypertension and dyslipidaemia: comparison of data from two national surveys" was conducted by H E Bays, R H Chapman, and S Grandy, the SHIELD Investigators' Group.

The objectives of this study were to explore the relation between body mass index (BMI) and prevalence of diabetes mellitus, hypertension and dyslipidaemia; examine BMI distributions among patients with these conditions; and compare results from two national surveys. The Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes (SHIELD) 2004 screening questionnaire (mailed survey) and the National Health and Nutrition Examination Surveys (NHANES) 1999–2002 (interview, clinical and laboratory data) were conducted in nationally representative samples ≥ 18 years old. Responses were received from 127,420 of 200,000 households (64%, representing 211,097 adults) for SHIELD, and 4257 participants for NHANES. Prevalence of diabetes mellitus, hypertension and dyslipidaemia was estimated within BMI categories, as was distribution of BMI levels among individuals with these diseases. Mean BMI was 27.8 kg/m^2 for SHIELD and 27.9 kg/m^2 for NHANES. Increased BMI was associated with increased prevalence of diabetes mellitus, hypertension and dyslipidaemia in both studies ($p < 0.001$). For each condition, more than 75% of patients had BMI ≥ 25 kg/m^2. Estimated prevalence of diabetes mellitus and hypertension was similar in both studies, while dyslipidaemia was substantially higher in NHANES than SHIELD. In both studies, prevalence of diabetes mellitus, hypertension and dyslipidaemia occurred across all ranges of BMI, but increased with higher BMI. However, not all

overweight or obese patients had these metabolic diseases and not all with these conditions were overweight or obese. Except for dyslipidaemia prevalence, SHIELD was comparable with NHANES. They concluded by stating that - consumer panel surveys may be an alternative method to collect data on the relationship of BMI and metabolic diseases.(123).

In the year **2008**, George A Bray, Kathleen A Jablonski, Wilfred Y Fujimoto, et al undertook a study titled "Relation of central adiposity and body mass index to the development of diabetes in the Diabetes Prevention Program".

They hypothesized that greater central adiposity is related to the risk of diabetes, and that central adiposity measured by computed tomography (CT) is a better predictor of the risk of diabetes than is body mass index (BMI), waist circumference (WC), waist/hip ratio (WHR), or waist/height ratio.

Visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT) were measured at the L2–3 and L4–5 disc spaces in 1106 of the 3234 participants in the Diabetes Prevention Program. Sex-specific proportional hazards models were used to evaluate the association between VAT and SAT at cuts, BMI, and other measures of central adiposity as predictors of the development of diabetes.

They found that men had more VAT than did women. White subjects had more VAT at both cuts than did other ethnic groups. The ratio of VAT to SAT was lowest in African Americans of both sexes. Among men in the placebo group, VAT at both cuts, WC, BMI, waist/height ratio, and WHR predicted diabetes (hazard ratio: 1.79–1.44 per 1 SD of variable). Among women in the lifestyle group, VAT at both cuts predicted diabetes as well as did BMI, and L2–3 was a significantly better predictor than was WC or WHR. SAT did not predict diabetes. None of the body fat measurements predicted diabetes in the metformin group.

They came to the conclusion that in the placebo and lifestyle groups, VAT at both cuts, WHR, and WC predicted diabetes. No measure predicted diabetes in the metformin group. CT provided no important advantage over these simple measures. SAT did not predict diabetes. (124).

In **2009**, Faculty of Medicine and Health Sciences undertook a study titled "Knowledge, Attitude and Practice (KAP) of Lifestyle Modification among Diabetic Patients at Tampin Tengah".

The background of their study was that more and more diabetic patients are developing complications due to suboptimal glycaemic control. Lifestyle modifications - diet modification, weight control and exercise - play an important role in management of patients with type-2 diabetes mellitus. These modifications are equally important as pharmacological measures in achieving optimum glycaemic control. The objective of this study was to study the knowledge, attitude and practice (KAP) of lifestyle modification among diabetic patients at Tampin Tengah. It was a analytical cross-sectional study which described the knowledge, attitude and practice of lifestyle modifications among diabetic patients living in Tampin Tengah. Sample population was selected through convenient sampling. A face-to-face interview was carried out for data collection. Information on respondents' socio-demographic background and their knowledge, attitude and practice on lifestyle modifications were collected using a self-devised questionnaire. Chi-square test was used in the analyses to determine the statistical association between variables. The total number of respondents interviewed in this study was 327. The mean age (range) of respondents was 56 (19-86) years old. Majority were Indians (43.1%) and female (54.7%). 55.7% of respondents received primary education level or less. With regard to the body mass index, most respondents (61.2%) have BMI of more than 25. This study revealed

69.1% of the respondents showed adequate knowledge, 92.7% of the respondents showed positive attitude and 81.3% of them had good practice. There was no significant statistical association between knowledge and attitude (p>0.05). However, there was significant statistical association between knowledge and practice for all aspects of lifestyle modifications (p<0.05), and also between attitude and practice for diet modification (p50.00) and exercise (p4.00).: The study concluded that majority of diabetic patients who participated in this study had adequate knowledge, positive attitude and good practice on all aspects of lifestyle modifications. However, there are still rooms for improvements as this study indicates that it is necessary to plan for interventions that are culturally competent, promotion of exercise of increased intensity, and education of family members.(125).

2011-"Predictability of body mass index for diabetes: Affected by the presence of metabolic syndrome?" This study was conducted by Farzad Hadaegh**,** Mohammadreza Bozorgmanesh**,** Maryam Safarkhani**,** Davood Khalil and Fereidoun Azizi: They prospectively examined the relative contributions and joint relationship of metabolic syndrome (MetS) and body mass index (BMI, $kg.m^{-2}$) which are established independent risk factors in the development of diabetes, with incident diabetes in a Middle Eastern cohort.

Participants of the ongoing Tehran lipid and glucose study were followed on a triennial basis. Among non-diabetic participants aged â‰¥ 20 years at baseline , those with at least one follow-up examination were included for the current study. Multivariate logistic regression models were used to estimate sex-specific adjusted odd ratios (ORs) and 95% confidence intervals (CIs) of baseline BMI-MetS categories (normal weight without MetS as reference group) for incident diabetes among 2186 men and 3064 women, aged â‰¥ 20 years, free of diabetes at baseline.

During follow up (median 6.5 years); there were 369 incident diabetes (147 in men). In women without MetS, the multivariate adjusted ORs (95% CIs) for overweight (BMI 25-30 kg/m2) and obese (BMIâ‰¥30) participants were 2.3 (1.2-4.3) and 2.2 (1.0-4.7), respectively. The corresponding ORs for men without MetS were 1.6 (0.9-2.9) and 3.6 (1.5-8.4) respectively. As compared to the normal-weight/without MetS, normal-weight women and men with MetS, had a multivariate-adjusted ORs for incident diabetes of 8.8 (3.7-21.2) and 3.1 (1.3-7.0), respectively. The corresponding ORs for overweight and obese women with MetS reached to 7.7 (4.0-14.9) and 12.6 (6.9-23.2) and for men reached to 3.4(2.0-5.8) and 5.7(3.9-9.9), respectively.

This study highlights the importance of screening for MetS in normal weight individuals. Obesity increases diabetes risk in the absence of MetS, underscores the need for more stringent criteria to define healthy metabolic state among obese individuals. Weight reduction measures, thus, should be encouraged in conjunction with achieving metabolic targets not addressed by current definition of MetS, both in every day encounter and public health setting. (126).

2011-In the journal of Diabetes Care**,**Globalization of Diabetes, Frank B. Hu,, published a study titled “The role of diet, lifestyle, and genes”.

This is a review study which states that Type 2 diabetes is a global public health crisis that threatens the economies of all nations, particularly developing countries. Fueled by rapid urbanization, nutrition transition, and increasingly sedentary lifestyles, the epidemic has grown in parallel with the worldwide rise in obesity. Asia's large population and rapid economic development have made it an epicenter of the epidemi. Asian populations tend to develop diabetes at younger ages and lower BMI levels than Caucasians. Several factors contribute to accelerated

diabetes epidemic in Asians, including the "normal-weight metabolically obese" phenotype; high prevalence of smoking and heavy alcohol use; high intake of refined carbohydrates (e.g., white rice); and dramatically decreased physical activity levels. Poor nutrition in utero and in early life combined with overnutrition in later life may also play a role in Asia's diabetes epidemic. Recent advances in genome-wide association studies have contributed substantially to our understanding of diabetes pathophysiology, but currently identified genetic loci are insufficient to explain ethnic differences in diabetes risk. Nonetheless, interactions between Westernized diet and lifestyle and genetic background may accelerate the growth of diabetes in the context of rapid nutrition transition. Epidemiologic studies and randomized clinical trials show that type 2 diabetes is largely preventable through diet and lifestyle modifications. Translating these findings into practice, however, requires fundamental changes in public policies, the food and built environments, and health systems. To curb the escalating diabetes epidemic, primary prevention through promotion of a healthy diet and lifestyle should be a global public policy priority. (127).

In **2012-** Prabha Shrestha1 & Laxmi Ghimire did a review study titled "A Review about the Effect of Life style Modification on Diabetes and Quality of Life". The aim of this review was to examine diabetes and quality of life improvements through modifying life style. The data was collected by reviewing published articles from PubMed, Medline, Web of Science, and Google open access publications. The review identified prevention strategies which can reduce the risk and complications of diabetes. Life style modification in relation to obesity, eating habit, and physical exercise can play a major role in the prevention of diabetes. Nowadays, there has been progress in the development of behavioural strategies to modify these life style habits and it is not easy to accept for long term basis. If people maintain a balanced diet and

physical exercise this can have real and potential benefits for their prevention and control of complications from chronic diseases particularly for cardiovascular risk and diabetes. Healthy life style may best be achieved through public private partnerships involving government, partners organizations, health services providers, community and people living with diabetes. Effective strategies to reduce the incidence of diabetes globally and assist in managing the disease are urgently required.(128).

In-**2012**, Gregg EW, Chen H, Wagenknecht LE, et al; for the Look AHEAD Research Group. undertook a study titled,-"Association of an intensive lifestyle intervention with remission of type 2 diabetes (Look AHEAD)."

Look AHEAD (Action for Health in Diabetes) assessed the long-term effects (up to 11.5 years) of an intensive lifestyle intervention over 4 years on cardiovascular morbidity and mortality among 5,145 overweight/obese individuals with type 2 diabetes.

An analysis of Look AHEAD at 4 years showed that the percent reduction from initial weight was -4.7% in the intensive lifestyle intervention group and -1.1% in the diabetes support and education group ($P<0.001$).[2] Subjects in the intensive lifestyle intervention group had greater weight loss than those in the diabetes support and education group at all annual assessments at years 1-4.

This ancillary observational analysis of Look AHEAD examined the association of a long-term intensive lifestyle intervention with remission (partial or complete) of type 2 diabetes. A total of 4,530 Look AHEAD participants were included in the analysis (n=2,241 in lifestyle group n=2,262 in diabetes support and education group). Median time since diabetes diagnosis was 5 years; mean body mass index was 35.8 kg/m^{2}Participants assigned to intensive lifestyle intervention were

significantly more likely to experience partial or complete remission of type 2 diabetes than counterparts assigned to diabetes support and education.

In the first year, the prevalence of type 2 diabetes remission was 11.5% for the lifestyle group (95% CI, 10.1%-12.8%) compared with 2.0% in the diabetes support and education group (95% CI, 1.4%-2.6%). At Year 4, the rates were 7.3% (95% CI, 6.2%-8.4%) and 2.0 (95% CI, 1.5%-2.7%), respectively. (P<0.001 for each year.)

Among participants who experienced partial or complete type 2 diabetes remission, one-third in the intensive lifestyle group returned to a clinical diabetes status each year: 33.1% (95% CI, 27.4%-39.3%) in Year 2; 33.8% (95% CI, 27.9%-40.2%) in Year 3; and 31.6% (95% CI, 25.3%-38.6%) in Year 4. Approximately one-half of participants in the diabetes support and education group returned to a clinical diabetes status each year: 52.4% (95% CI, 42.2%-62.3%) in Year 2; 45.9% (95% CI, 35.6%-56.6%) in Year 3; and 43.8% (95% CI, 32.9%-55.4%) in Year 4. Participants in the intensive lifestyle group were more likely to experience continuous, sustained remission of type 2 diabetes: 9.2% (95% CI, 7.9%-10.4%) had at least a 2-year remission; 6.4% (95% CI, 5.7%-7.4%) had at least a 3-year remission; and 3.5% (95% CI, 2.7%-4.3%) had at least a 4-year remission. Rates for the diabetes support and education group: 1.7% (95% CI, 1.2%-2.3%; P<0.001) 2-year; 1.3% (95% CI, 0.8%-1.7%) 3-year; and 0.5% (95% CI, 0.2%-0.8%; P=0.02) for 4-year remission. Any remission of type 2 diabetes during the first year of the study was significantly associated with shorter diabetes duration, low body mass index, low baseline A1C, no insulin use, and greater 1-year weight loss. (129,130).

In **2013**, Evans, Jennifer L. in their study titled, "Achieving Better Control of Type 2 Diabetes in the Primary Care Setting: Focus on Lifestyle Modifications for

Weight Loss" This work was reported in *Evidence-Based Practice Project Reports.* Paper 33.

This project evaluated the use of a lifestyle modification program for adults, ages 30-64 years, with T2D and a body mass index BMI of greater than 25 kg/m2. Type 2 diabetes (T2D) afflicts millions of people worldwide, and the number of individuals diagnosed increases every day. There are many factors which have led to the significant prevalence of this disease and its primary co-morbidity, obesity. Research has identified many benefits to weight loss, including its positive effects on T2D .The program used motivational interviewing within the office setting and during follow up telephone calls for the duration of four months. The Transtheoretical Model and stages of change was used to guide the intervention. Participants(N = 16) were encouraged to decrease total fat intake to less than 30% of daily calories and to participate in 30 minutes of moderate to vigorous physical activity at least five days a week. Primary outcomes were percentage body weight lost and reported physical activity level. Stages of change were assessed and documented, as well. The data were analyzed through descriptive statistics and paired t-tests. Those participants, who met the physical activity goal, also met the weight loss goal. Overall, the majority of individuals both lost some weight and increased their weekly physical activity levels, even if they did not meet the outcome criteria of at least five percent body weight loss and a reported physical activity level of at least 30 minutes per day at least five days per week. This office-based intervention was simple to implement during routine provider visits and was successful for most of the patients. Through the use of motivational interviewing, providers were able to assist individuals to set small goals and overcome perceived barriers.(131).

In **2013**, Roberto Carlos Burini, Gabriel Augusto Torezan and Kátia Cristina Portero McLellan published a study titled " Behavioral Risk Factors and Effects of Lifestyle Modification on Adults with Diabetes: A Brazilian Community-based Study'.

The intent with this paper is to present researches and strategies (diet and physical activity interventions) that successfully improved plasma glucose control as a result of an effective lifestyle intervention program.

Lifestyle is directly related to the incidence of type 2 diabetes mellitus (DM-2), a risk dramatically elevated by obesity and inactivity. Several studies have verified that educational interventions can delay the onset of DM-2. Some of the interventions strategies utilized medication and diet, diet and/or physical exercise or the combination of diet and exercise, generally referred to a change in lifestyle. Despite the evidence that DM-2 can be preventive, there is still limited availability of effective prevention programs. DM-2 is considered an emerging public health problem as it is estimated that by the year of 2030 there will be about 366 million people with diabetes worldwide. DM2 remains a leading cause of cardiovascular disorders and many other complications. (132).

2014-Physical Activity and Body Mass Index and Their Associations With the Development of Type 2 Diabetes in Korean Men.This study was conducted by Duck-chul Lee, Ilhyeok Park, Tae-Won Jun, et al. The authors examined the independent and combined associations of physical activity and obesity with incident type 2 diabetes among 675,496 Korean men from the database of the National Health Insurance Corporation. During an average follow-up of 7.5 years (1996–2005), 52,995 men developed type 2 diabetes. Men with overweight, obese I, and obese II classifications had 1.47, 2.05, and 3.69 times higher risk of type 2 diabetes,

respectively, compared with normal weight men, and men with low, medium, and high activity had 5%, 10%, and 9% lower risk of type 2 diabetes, respectively, compared with inactive men after adjustment for confounders and physical activity or body mass index for each other. Overweight and obesity were detrimental within all activity categories, and meeting the activity recommendations (medium and high activity) was beneficial at all body mass index levels. Meeting the activity recommendations appeared to attenuate some negative effects of overweight or obesity, and the increased risk of type 2 diabetes due to inactivity was lower in normal weight men. Both preventing overweight or obesity and increasing physical activity are important to reduce the global epidemic of type 2 diabetes, regardless of body weight and activity levels. (133).

3. Diabetes and Blood pressure-

In **2005-** a study titled " effect of yoga based lifestyle intervention on state and trait anxiety" was published by Nidhi Gupta, Shveta Khera, R. p. Vempati, Ratna Sharma* and R. l. Bijlani.

The aim of the study was to find out the short-term impact of a comprehensive but brief lifestyle intervention, based on yoga, on anxiety levels in normal and diseased subjects. Considerable evidence exists for the place of mind body medicine in the treatment of anxiety disorders. Excessive anxiety is maladaptive. It is often considered to be the major component of unhealthy lifestyle that contributes significantly to the pathogenesis of not only psychiatric but also many other systemic disorders. Among the approaches to reduce the level of anxiety has been the search for healthy lifestyles. The study was the result of operational research carried out in the Integral Health Clinic (IHC) at the Department of Physiology of All India Institute

of Medical Sciences. The subjects had history of hypertension, coronary artery disease, diabetes mellitus, obesity, psychiatric disorders (depression, anxiety, 'stress'), gastrointestinal problems (non ulcer dyspepsia, duodenal ulcers, irritable bowel disease, Crohn's disease, chronic constipation) and thyroid disorders (hyperthyroidism and hypothyroidism). The intervention consisted of asanas, pranayama, relaxation techniques, group support, individualized advice, and lectures and films on philosophy of yoga, the place of yoga in daily life, meditation, stress management, nutrition, and knowledge about the illness. The outcome measures were anxiety scores, taken on the first and last day of the course. Anxiety scores, both state and trait anxiety were significantly reduced. Among the diseased subjects significant improvement was seen in the anxiety levels of patients of hypertension, coronary artery disease, obesity, cervical spondylitis and those with psychiatric disorders. The observations suggest that a short educational programme for lifestyle modification and stress management leads to remarkable reduction in the anxiety scores within a period of 10 days.(134).

In **2007**, Dharma Lindarto undertook a study titled "Effect of Lifestyle Modification and Metformin on Fetuin-A in Metabolic Syndrome".

The objective of the study was to evaluate the effects of lifestyle modification and metformin on fetuin-A in metabolic syndrome (MetS) as defined in 2006 by the International Diabetes Federation (IDF). Forty MetS subjects were randomly assigned to treatment with placebo (n=20) or metformin (n=20) in addition to lifestyle modification for 12 weeks.

All 40 participants completed the study. After 12 weeks, both groups had significant reductions in weight ($p<0.001$), body mass index (BMI) ($p<0.001$), waist circumference (WC) ($p<0.001$), systolic blood pressure (SBP) ($p<0.001$), and

diastolic blood pressure (DBP) ($p<0.001$). The placebo group also had significant improvement in fasting plasma glucose (FPG) ($p<0.001$) and C-reactive protein (CRP) (<0.05). Weight, BMI, WC, FPG, 2-hour postprandial glucose (2h-PPG), high density lipoprotein cholesterol (HDL-C), triglycerides (TG) and fetuin-A in the metformin group decreased significantly compared to the placebo group. Reduction of plasma fetuin-A was significantly associated with TG in the metformin group.

The author concluded that lifestyle modification and treatment with metformin for 12 weeks improved cardio-metabolic risk factors in MetS and reduced fetuin-A levels. Further investigations are required to confirm the effects of lifestyle modification and metformin after an extended follow-up period.(135).

In **2007**-Patrick Fleming and Marshall Godwin, in journal Canadian Family Physician reported a study titled "Lifestyle interventions in primary care-Systematic review of randomized controlled trials"

The objective of their study was to determine whether lifestyle counseling interventions delivered in primary care settings by primary care providers to their low-risk adult patients are effective in changing factors related to cardiovascular risk.

Their data sources were MEDLINE (PubMed), EMBASE, and CINAHL. These datas were searched from January 1985 to December 2007. The reference lists of all articles collected were checked to ensure that all suitable randomized controlled trials (RCTs) had been included.

They chose RCTs on lifestyle counseling in primary care for primary prevention of cardiovascular disease. The search was limited to English-language articles involving human subjects. Studies had to have been conducted within the context of primary care, and interventions had to have been carried out by primary care providers, such as family physicians or practice nurses. Studies had to have had a

control group who were managed with usual care. Outcomes of interest were cardiovascular risk scores, blood pressure, lipid levels, weight or body mass index, and morbidity and mortality.

Seven RCTs were included in the review. Only 4 studies showed any significant positive effect on the outcomes of interest, and only 2 of these showed consistent effects across several outcomes. The main effects were on blood pressure and lipid levels, but the size of these effects, while statistically significant, was small. There was no obvious benefit to one provider doing the intervention over another (eg, physician vs nurse), nor of the focus of the intervention (eg, on diet vs on exercise).

They concluded that lifestyle counseling interventions delivered by primary care providers in primary care settings to patients at low risk (primary prevention) appeared to be of marginal benefit. Resources and time in primary care might be better spent on patients at higher risk of cardiovascular disease, such as those with existing heart disease or diabetes. (136).

2009-Early onset type 2 diabetes mellitus: a harbinger for complications in later years clinical observation from a secondary care cohort. This study was conducted by S.H. Song and C.A. Hardisty.

The study aimed to determine the magnitude of diabetes com- plications and adequacy of risk factor management and to test the hypothesis that diabetes duration is an important contributing factor to these complications since little is known about the complication burden in later years among early onset type 2 dia- betes mellitus (T2DM).

This was a cross-sectional study of secondary care diabetes population. Data on glycaemic control, cardiovascular risk factors (overweight/obesity, hypertension, dyslipidaemia), cardiovascular disease (CVD) and microvascular complications

among those diagnosed before (early onset) and after (later onset) 40 years of age at different diabetes durations (<10, 10–20 and >20 years) were analysed. They found that out of a total of 2733 subjects identified, 527 had diabetes diagnosed below the age of 40 years. By the sixth decade of life, early onset cohort experienced high complication burden (CVD: 37.2%, retinopathy: 59.3% and neuropathy: 53.1%). Complication prevalence increased with diabetes duration but the increment rate was greater among early onset cohort. Compared with those diagnosed after 40, early onset cohort experienced similar burden of micro- vascular complications 13–20 years earlier. Diabetes duration was a significant predictor for microvascular and CVD complications. Prevalence of CVD risk factors was high (80–93%) regardless of the age of diagnosis and diabetes duration. Early onset subjects were more likely to have poorer glucose control (70–78%), untreated hypertension (26.3%) and a substantial number did not receive statin treatment for primary prevention (34.8%). They observed that early onset T2DM subjects are at substantial risk of developing diabetes complications in later years but at an earlier stage than later onset cohort and prolonged exposure to adverse diabetic milieu is an important contributing factor. They also found that management of risk factors for diabetes complications was inadequate among early onset subjects.(137).

2009-"Implications of ADVANCE in the management of blood pressure in diabetic patients". This study was conducted by B. Williams. Epidemiological studies in the 1970s established that high blood pressure (BP) is both common and a major risk factor for macrovascular and microvascular disease in people with type 2 diabetes. However, uncertainty remained about the benefits and safety of BP lowering in people with diabetes. Previous studies, such as the United Kingdom Prospective Diabetes Study (UKPDS) in the late 1990s, demonstrated that lowering BP is very

effective at reducing cardiovascular disease (CVD) and microvascular disease risk and, as a consequence, mortality. Questions remained, however, about whether there was a specific threshold below which BP lowering would be ineffective at reducing risk. The Action in Diabetes and Vascular disease: PreterAx and DiamicroN MR Controlled Evaluation (ADVANCE) study was designed with this key question in mind and set about lowering BP in people with diabetes, irrespective of their baseline BP, to determine whether this strategy would safely further reduce risk. The strategy employed was the addition of a combination of perindopril/indapamide, added to usual care, as part of a factorial study design that also examined the impact of "more versus less" glucose lowering. The BP-lowering arm of the ADVANCE study demonstrated that further BP lowering with perindopril/indapamide significantly reduced the risk of a combined end point of macrovascular and microvascular events and total mortality. This is a significant advance as it suggests that this treatment strategy will further reduce the risk for people with type 2 diabetes, irrespective of their prior treatment or baseline BP. This finding has important implications for people with type 2 diabetes and is a further step forward in improving treatment strategies for these patients beyond existing therapies to reduce their CVD and microvascular risk.(138).

In **2011**, a study was published in International Journal of Hypertension, titled, "Management of Hypertension and Diabetes in Obesity: Non-Pharmacological Measures" by Joseph M. Pappachan, Elias C. Chacko, Ganesan Arunagirinathan, and Rajagopalan Sriraman.

This paper aimed to outline the non-pharmacological measures for the management of hypertension and diabetes in obesity.

Obesity has become a global epidemic over the past few decades because of unhealthy dietary habits and reduced physical activity. Hypertension and diabetes are quite common among obese individuals and there is a linear relationship between the degree of obesity and these diseases. Lifestyle interventions like dietary modifications and regular exercise are still important and safe first-line measures for treatment. Recently, bariatric surgery has emerged as an important and very effective treatment option for obese individuals especially in those with comorbidities like hypertension and diabetes. Though there are few effective drugs for the management of obesity, their efficacy is only modest, and they should always be combined with lifestyle interventions for optimal benefit. (139).

In **2013**, Gregory A. Nichols, Sandra Joshua-Gotlib, and Shreekant Parasuraman, reported a study titled "Independent Contribution of A1C, Systolic Blood Pressure, and LDL Cholesterol Control to Risk of Cardiovascular Disease Hospitalizations in Type 2 Diabetes: An Observational Cohort Study".

The objective of the study was to estimate the independent association of control of glycosylated hemoglobin (A1C), systolic blood pressure (SBP), and low-density lipoprotein cholesterol (LDL-C) with risk of cardiovascular disease hospitalization.

The background of the study was that cardiovascular disease (CVD) prevention in diabetes requires broad-based treatment of dyslipidemia, hypertension, and hyperglycemia. The independent contribution of all combinations of risk factor control to CVD risk has not been evaluated. It was a non-concurrent longitudinal cohort study.

The study included 26,636 patients with type 2 diabetes who were members of an integrated group model HMO with multiple A1C, SBP, and LDL-C measurements.

Patients were followed for a mean (SD) of 5.6 (2.5) years until they died or disenrolled, or until 31 December 2010. The outcome was a first-observed CVD hospitalization. Using the mean of all A1C, SBP, and LDL-C measures during follow-up, they created dichotomous categories of A1C control (< 7 %), SBP control (< 130 mmHg), and LDL-C control (< 100 mg/dL) to estimate the incidence rate of CVD hospitalization associated with all combinations of risk factor control adjusting for demographic and clinical characteristics. They found that patients with no controlled risk factors (18.2/1,000 person-years, 95 % CI 16.5−20.2) or with only A1C in control (16.9, 15.0−19.0) had the highest rate of CVD hospitalization, whereas those with all three risk factors controlled (7.2, 6.2−8.4) or with SBP and LDL-C in control (6.1, 5.1−7.2) had the lowest rates. Those with only SBP or LDL-C in control, A1C and SBP controlled, or A1C and LDL-C controlled had statistically similar incidence between the highest and lowest rates.

The study concluded that maintaining SBP < 130 mmHg or LDL-C < 100 mg/dL was significantly associated with reduced CVD hospitalization risk, especially when both risk factors were well controlled. Maintaining A1C < 7 % was not independently associated with reduced CVD hospitalization risk.(140).

4. Diabetes & QOL.

In**1999**-Rubin RR, Peyrot M published a article titled “Quality of life and diabetes” in Diabetes Metab Res Rev. 1999. This paper reviews the published, English-language literature on self-perceived quality of life among adults with diabetes. Quality of life is an important health outcome in its own right, representing the ultimate goal of all health interventions. Quality of life is measured as physical and social functioning, and perceived physical and mental well-being. People with

diabetes have a worse quality of life than people with no chronic illness, but a better quality of life than people with most other serious chronic diseases. Their study showed that duration and type of diabetes are not consistently associated with quality of life. Intensive treatment does not impair quality of life, and having better glycemic control is associated with better quality of life. Complications of diabetes are the most important disease-specific determinant of quality of life. They found that numerous demographic and psychosocial factors influence quality of life and inferred that these factors should be controlled when comparing subgroups. Studies of clinical and educational interventions suggest that improving patients' health status and perceived ability to control their disease results in improved quality of life. Methodologically, it is important to use multidimensional assessments of quality of life, and to include both generic and disease-specific measures. They concluded that quality of life measures should be used to guide and evaluate treatment interventions. (141).

In **2000**, Diabetes Spectrum published a study titled, "Diabetes and Quality of Life" by Richard R. Rubin. This study reports on whether diabetes affect quality of life. Most studies report worse quality of life for people with diabetes compared to the general population, especially regarding physical functioning and well-being. When the comparison group is people with other chronic diseases, the picture is less clear, with relative quality of life varying by quality of life domain and the medical condition with which diabetes is being compared.

People with type 1 diabetes generally report better physical functioning and more energy than those with type 2 diabetes, though these differences are probably the result of factors that are associated with diabetes type, such as age or even treatment regimen..

He concluded that for those with type 2 diabetes, treatment intensification from diet alone to oral agents to insulin does seem to be associated with reduced quality of life. (142).

In **2000** a study titled "Quality-of-Life Assessment in Diabetes Research: Interpreting the Magnitude and Meaning of Treatment Effects" was published in journal of Diabetes Spectrum by Marcia A. Testa.

The background of this review is that when quality-of-life outcomes are used to evaluate treatment effectiveness in diabetes, the meaning and importance of the treatment effect relative to other clinical factors is often difficult to assess. In this context, this review addresses a major methodological on the interpretation of quality-of-life treatment effects in the study of diabetes. The interpretation question is discussed at two levels establishing meaningful intervals important to the individual patient and, second, estimating the benefit of a quality-of-life improvement or the risk of a quality-of-life worsening in populations. A brief checklist of critical questions particularly relevant to quality-of-life measurement and study design has been discussed.(143).

In **2012**, a study titled "The quality of life in patients with diabetes mellitus type 2" was published by Bosić-Zivanović D, Medić-Stojanoska M, Kovacev-Zavisić B. This article is from Serbia.

The background of this study is that the World Health Organization (WHO) contributed to increasing the understanding of the concept of quality of life. The aim of this study was to examine the differences in the quality of life, related to health, in patients with diabetes mellitus (DM) type 2 by age, gender and type of therapy. Their hypothesis was that people with diabetes have a lower quality of life than people without chronic illnesses.

They performed a cross-sectional study at the outpatient department of the Clinical Center in Novi Sad and the Health Center Ruma-General Practice. The group consisted of 90 patients with DM type 2, 41 men and 49 women. The age of respondents was from 40 to 80 years and they were classifed into four groups according to the ten-year age intervals. They applied WHO Quality of life questinnaire--BREF 100 composed of four domains: physical health, psychological health, social relationships and environment. The general questionnaire asks questions about socio-demographic data, duration of diabetes, the last value of blood glucose and glycosylated hemoglobin, training for self-control and its implementation, informing patients about their disease, therapy and its impact on daily activities and the presence of comorbidity. They used the following tests for statistical analysis: Student's t-test, F-test, ANOVA (one way).

Their study showed that the average duration of DM type 2 was 11.2 +/- 9.2 years. Most of the patients (76%) were trained to self-control and 91% received enough information about their disease. Oral hypoglycemic preparations were used by 49%, insulin by 21%, and oral drugs and insulin by 29% patients while 1% were on a special regime of a diet therapy. Daily activities were performed without difficulties by over 29%, with some difficulties by 41% and 30% of patients who could not perform daily activities. The patients with DM type 2 had significantly lower scores in all 4 domains of quality of life (physical health, psychological health, social relations, environment). The biggest influence was on physical domains (51.31). Education level had an impact on physical and psychological domains. Comorbidity was found in 83% of the respondents. The most common were: arterial hypertension (63%), chronic cardiovascular disease (46%), neuropathy (23%), impaired vision 24%, elevated blood lipids (39%) and amputation of toes or feet (2.2%). The average value

HbA1c in the group with comorbidity was 8.47% and in the group without comorbidity 6.46%. The subjects with comorbidity had low quality of life assessment in relation to the group without comorbidity: the domain of physical health (45.64 vs. 79.66), psychological health (50.3 vs. 76.86), social relations (52.97 vs. 75.46) and environment (52.7 vs. 75.06).

The authors concluded that diabetes mellitus type 2 has negative influence on the quality of life. It contributes to the presence of comorbidity. The occurrence of comorbidity was associated with higher glucosylated HbA1c values. There was no difference in the assessment of quality of life regarding gender, age, or the type of therapy used. The quality of life was assessed as low in patients with comorbidity. However, certain personality characteristics play a decisive role in self-evaluation. (144).

In **2007**, a study titled "Health related quality of life in patients with diabetes mellitus type 2" was published by Hervás A1, Zabaleta A, De Miguel G, Beldarráin O, Díez J. This article is originally in Spanish.

The study aims to evaluate the impact of diabetes mellitus type 2 on health related quality of life. This was a cross-sectional study, conducted in the basic health zone of the Foral Community of Navarre (12,200 inhabitants). Selection was done through simple random sampling (n=95) of the universe of patients diagnosed with diabetes mellitus type 2 of their basic health zone (n=655). Health Related Quality of Life was evaluated with generic questionnaires SF-36 and EQ-5D and comparison of the general population samples was carried out in Spain (SF-36) with a general population y>65 years of Navarre and Spanish diabetic population (EQ-5D).

Their study showed that the diabetic patients have a tendency to show results lower than the general population in the following health concepts of the SF-36:

"Physical Function" (76.6 +/- 27.2 SD), "Bodily Pain" (73.7 +/- 26.2 SD) , "General Health" (54.7 +/- 22.4 SD), "Social Function" (84.2 +/- 21.7 SD), "Role Emotional" (84.7 +/- 28.9 SD). Comparing the data with the general population >60 years, only two health concepts -"General Health" and "Role Emotional"- are equal to the reference values. With respect to the rates of respondents to some problem in the dimensions of the EQ-5D, the "Anxiety/Depression" dimension is outstanding with 43%. The value of the analogical visual scale in the diabetic patients was 64.6.

This study concluded that diabetes mellitus type 2 is related to a worse perception of quality of life related to health. The impact of certain diseases on the patients should not be measured only through the quantification of objective clinical parameters (such as morbidity or mortality).(145).

In **2003**, a study titled "Health-related quality of life deficits associated with varying degrees of disease severity in type 2 diabetes" was conducted by Sheri L Maddigan, Sumit R Majumdar, Ellen L Toth, David H Feeny, Jeffrey A Johnson and the DOVE Investigators. This study was reported from Canada.

The background of this study was that diabetes is a chronic medical condition accompanied by a considerable health-related quality of life (HRQL) burden. The purpose of this analysis was to use generic measures of HRQL to describe HRQL deficits associated with varying degrees of severity of type 2 diabetes.

The RAND-12 physical and mental health composites (PHC and MHC, respectively) and Health Utilities Index Mark 3 (HUI3) were self-completed by 372 subjects enrolled in a prospective, controlled study of an intervention to improve care for individuals with type 2 diabetes in rural communities. Analysis of covariance was used to assess differences in HRQL according to disease severity and control of blood glucose. Disease severity was defined in terms of treatment intensity, emergency

room visits and absenteeism from work specifically attributable to diabetes. To control for potential confounding, the analysis was adjusted for important sociodemographic and clinical characteristics.

They observed that PHC and MHC were significantly lower for individuals treated with insulin as compared to diet alone (PHC: 41.01 vs 45.11, MHC: 43.23 vs 47.00, $p < 0.05$). Individuals treated with insulin had lower scores on the vision, emotion and pain attributes of the HUI3 than individuals managed with oral medication or diet. The PHC, MHC, pain attribute and overall score on the HUI3 captured substantial decrements in HRQL associated with absenteeism from work due to diabetes, while the burden associated with emergency room utilization for diabetes was seen in the PHC and HUI3 pain attribute.

They concluded that generic measures of HRQL captured deficits associated with more severe disease in type 2 diabetes. (146).

In **2008**, Ruth Kalda, Anneli Rätsep and Margus Lember reported a study titled "Predictors of quality of life of patients with type 2 diabetes". This work was done at Department of Family Medicine, University of Tartu and Department of Internal Medicine, University of Tartu.

The background of this study is that patients with type 2 diabetes have a lower quality of life than the general population and also somewhat lower than patients with other chronic diseases. Thus one of the most important outcomes of treatment is optimizing the quality of life of the patient. This study examines the factors that most strongly influence the quality of life of patients with type 2 diabetes. 200 patients with type 2 diabetes were studied in Estonia in 2004–2005. A patient blood sample, taken during a visit to the family doctor, was collected. The family doctor also provided data on each patient's body mass index (BMI), blood pressure, and medications for

treatment of type 2 diabetes. Patients completed a SF-36 during a doctor visit, and also a special questionnaire which were provided to study their awareness about diabetes type 2. The study showed that mean age of the respondents was 64.7 (±11.1) years and the mean duration of the diabetes was 7.5 (±1.8) years. Logistic regression analysis showed that quality of life was most significantly affected by awareness of the complications and risk-factors of diabetes, and by the age, duration of the disease, and BMI of the patient. Patients who were less aware had a signifi cantly higher quality of life score (p 0.001 in all cases). The age and BMI of the patients as well as the duration of the diabetes all lowered the score of the quality of life. Their results showed that the main challenges for physicians in management of diabetes type 2 is to modify patient BMI and patient awareness.(147).

In **2012**, a study was published titled "A Review about the Effect of Life style Modification on Diabetes and Quality of Life" by Prabha Shrestha and Laxmi Ghimire.

The aim of this review was to examine diabetes and quality of life improvements through modifying life style. The data was collected by reviewing published articles from PubMed, Medline, Web of Science, and Google open access publications. The review identified prevention strategies which could reduce the risk and complications of diabetes. The review further revealed that life style modification in relation to obesity, eating habit, and physical exercise can play a major role in the prevention of diabetes. The authors reported that there has been progress in the development of behavioural strategies to modify these life style habits and it is not easy to accept these changes for a long term basis. But studies showed that if people maintain a balanced diet and physical exercise, this can have real and potential benefits for their prevention and control of complications from chronic

diseases particularly for cardiovascular risk and diabetes. The authors suggested that healthy life style may best be achieved through public private partnerships involving government, partners organizations, health services providers, community and people living with diabetes. They concluded that effective strategies to reduce the incidence of diabetes globally and assist in managing the disease are urgently required.(148).

In **2014**, Harish Kumar Srinivas, Mahesh Venkatesha, Raghavendra Prasad, reported a study titled" Quality of Life assessment among Type 2 Diabetic patients in rural tertiary centre".

This study was conducted with the objectives to assess the Quality of life (QoL) among diabetic patients with respect to anthropometry and blood investigations and assess the influence of risk factors on Quality of Life among Diabetic patients. Since, Quality of life assessment is considered as important measure of outcome in chronic disease management. With increase in prevalence of Diabetes in India it becomes important to assess the quality of life for better care and control.

This cross-sectional study was conducted for a period of 2 months among 180 type 2 diabetes mellitus patients attending rural tertiary care centre. A pretested and structured questionnaire was used to obtain the information on socio- demographic profile, diabetic history. Quality of life was assessed by WHOQOL-BREF. Statistical analysis was carried out by using EPI Info 7 software. Correlations, Students t test and logistic regression analysis were the statistical tests.

The outcome of the study showed that the mean age of males was 59.56 ± 9.64 and females was 60.90 ± 7.51. Mean scores of Quality of life with respect to physical, psychological, social and environmental domains were significantly higher among females compared to males ($p<0.01$). Quality of life domains and other continuous variables showed that there is significant positive correlation between age

and physical, psychological, social and environmental domains (r = 0.864, 0.396, 0.549, 0.420 respectively and p<0.001). Logistic regression showed that increase in age and HbA1c acts as independent factors to assess the Quality of life.

The study concluded that quality of life among diabetics needs improvement with proper treatment regimens ensuring good glycemic control.(149)

5. Diabetes & Neurobics.

1997- Yellow the color. YELLOW relates to the solar plexus chakra, situated below the ribs. The organs to which this chakra relates are the liver, spleen, stomach and small intestine. The endocrine gland is the pancreas. (150).

In **2001**, Diana W. Guthrie, and Maureen Gamble published an article titled "Energy Therapies and Diabetes Mellitus" in Diabetes Spectrum.

The background of their study is that people with diabetes require multiple interventions to reach their glycemic goals. Energy therapies have been a useful aid in improving health and well-being. Clinical interventions involve energy exchange in some form. Their article focuses on energy therapies that involve the presence of a therapist, whether local or long distance, to support and aid in the healing process. The literature on diabetes and healing therapies is sparse, but they found that, there is potential for energy therapy to assist individuals with diabetes in reaching goals for normoglycemia and high quality of life.

Their article deals with the finding that energy is all around us, within us, interacting internally and externally. The influence of disease on body energy fields and the influence of body energy fields on disease are areas just being explored in Western medicine. Western allopathic medicine has typically focused on illness, whereas energetic healing focuses on the connection of mind, body, and spirit. The

authors felt that, energy medicine may be useful as a complementary therapy and adjunct to standard allopathic medical approaches.

The influence of elevated or below-normal blood glucose on perceived or available energy is easy to surmise. Diabetes is a systemic condition that influences all body systems. A wide range of symptoms, from lowered cognitive function to irritability, depression, and lethargy are all indications of altered energy responses.

Energy medicine is any interpersonal, nonpharmacological intervention that brings about changes in heat, cold, congestion, circulation, or sensory processes. It may or may not involve the felt perceptions of the individual client. The presence and/or hands of the therapist initiate an alteration in heat, cold, or congestion and act in altering the client's experience of pain or other ailments that might deal with circulation.

Their work concludes that energy therapies aid in restoring balance, health, and normalized blood glucose levels in diabetes management. (151).

In **2004**, The centre for Human Energy Field Research, World Peace Centre, Pune, India. CHEFR-Integrated Health published a study titled "Energy Field Imaging with Polycontrast Interference Photography" by Dr Thornton WJA Streeter and John R Rogerson.

This detailed study relates chakras and their associated endocrine glands. Each chakra is related sub-anatomically to an endocrine gland through nerve plexus. Their work on navel chakras show that it works on the pancreas by regulating the metabolism and storage of glucose. Glucose level which provides constant energy for cells, is kept stable by proper modulation of this chakra.(152).

In **2007**, an article was published in info@holisticonline.com for diabetes treatment. This article was on Color Therapy. For diabetes treatment the paper recommends the following-

Radiate the following colors twice per day, one after the other allover the body:

Green color - for thirty minutes and yellow color- for fifteen minutes a day.(153).

In **2009**, an article titled "Cosmic Energetic Healing Brings Well-being" , describes the benefits of cosmic energetic healing.

Practitioners in Cosmic Energy Healing differ from other practices and traditions is that they do try not heal just one aspect of the sickness. The Cosmic Energetic Healing practitioner heals the whole person paying equal attention to the person's stress, anxiety, tension from this lifetime and other life times. The soul, spirit and inner being is taken into consideration as well as the physical illness. Laser Reiki is used to apply the laser point or zero point of Source energy in the application of higher frequency energy needed to restore wellness and good health. By improving a person's karmic problems or circumstances we've found that their health also improve as well.

The healing method of practitioners of Cosmic Energy is mostly based on the finding the energy blockage, transmuting the energy, or removing it, cleansing and restoring of the proper level of energy. The seven chakras are tested for the correct flow of energy.(154).

In **2014**, an article was published on "Color Therapy". This article states the following-

Treating a patient with color is known as Chromotherapy. A plenty of other natural methods are used alongside color therapy for treating diseases. By natural methods we mean:

Proper diet, Exercise, Adequate rest, and Yogic Asanas.

The reason for any particular disease can be traced effortlessly to the lack of a finicky color in the human system according to the belief of Chromotherapy. Applied colored light to the body is really beneficial in restoring imbalance. The history of practicing color therapy dates back to ancient centuries. This mode of treatment is used for more than 2500 years.

Pythagoras has revolutionary used color light curatively and 'color halls' were effectively used for curing diseases in ancient Egypt, India and China.

Niels Finsen of Denmark, the pioneer of modern color therapy, had studied thoroughly about the possibility of assisting the healing of wounds with visible lights after the famous discovery of solar ultra-violet energy way back in 1877. He had held back the formation of smallpox scars using red light. It was due to the apt initiative taken by the great scientist Niels Finsen of Denmark, the Light Institute for the photo treatment of tuberculosis, is lending its important hand in the field curing diseases through color therapy. The institute, built in 1896, is popularly known with the name "The Finsen Institute of Copenhagen".

- This paper states the benefits of yellow color for therapeutic purpose as-
- It is a symbolic color of joy and happiness
- The color of yellow energizes the activities of brain
- It stimulates both liver and spleen
- It is really beneficial for the patients who are suffering from diabetes.(155).

In **2014-** an article titled “Energy Medicine - a universal tradition” gives a quote by Albert Einstein which states that *“We may regard matter as being constituted by the regions of space in which the field is extremely intense... there is no place in this new kind of physics both for the field and matter, for the field is the only reality”* .

Energy is movement = vibration

All matter has a pattern of vibration and is permeated with energy. Matter is dense, slowing any vibration or energy, whereas air is much less dense. Energy medicine harnesses this inherent energy for healing. All life in the universe including human beings are animated by energy as well.

The concept of subtle energies exists in most cultures and medical systems, not only in homeopathy. The ancient Yogis, the Chinese and the Muslims, to name but a few, knew this fact of nature.

Kirlian photography takes pictures of energy fields with an electric current. It shows that the energy body extends beyond the physical body. For example you can feel when someone creeps into a room behind you. We all have energy bodies, and within these energy bodies the channels and systems exist to manage this energy. Most people's energy flows from right to left. "Where intention goes, energy flows" is a common saying. There are many forms of energy-medicine, they all draw on ancient knowledge.

In Traditional Chinese Medicine the inherent energy is called the qi. Energy therapies like Qi Gong and Tai Qi stimulate the energy of the patient to an optimum level, and thereby improve their health to such a degree that they are healed and do not get sick easily. In Hindu philosophy this vital energy is called prana. Yoga exercises enhance the flow of this life energy. In Islamic tradition it would be seen as

the desire of all life to blossom, to do the best according to their potential or inner nature. In Western thinking we are talking about the inherent life force.(156).

In **2014** a book was released titled "How to improve the energy of the Body" by Lily Rosenfeld.

This book describes the flow of energy within the human body, and suggests methods to improve health. The author states that many people are unaware that most of their health problems are due to the disruption of the energy systems of their body. The energy system is composed of channels through which energy flows, of energy centers and of subtle bodies, which make up the aura. Maximum health is possible to achieve by complete restoration of the electromagnetic field - the aura - that surrounds the body.

The aura is our genuine, authentic garment, responsible for the health of the physical body. It is important to treat the aura and the energy centers, and to sustain proper flow of energy in the meridians. This is an appropriate time to regard ourselves as a system of energy that performs in harmony at all levels - the physical, the emotional and the level of the mind.

The book explains ways to acquire vital energy, to sense it, to balance it or to transmit it to others in order to improve the quality of life. Illness is manifested in the aura a long time before appearing in the physical body. It is easier to deal with the potential of illness in the aura. Today, it is possible to see the aura, to treat the channels of energy and the energy centers to restore health. The write up concludes that the awareness of the invisible world of energies is a precondition for health, for peace and for realizing the full enjoyment of our life.(157).

An article was available in the net undated by Anna Cocilovo on

"Colored Light Therapy: Overview of its History, Theory, Recent Developments and Clinical Applications Combined with Acupuncture". The first part of the article is on" Physics of Colored Light Therapy" and second part is on "Color Theory".

Doctors Babbit, Pancoast, Pleasanton, Baldwin, Finsen and Dinshah have contributed ample empirical evidence of the value of colored light in medicine. The scientific explanation for this rests in quantum physics and color theory: the photoelectric effect first discovered by Heinrich Hertz (circa 1886), and the theory of light was elucidated by Albert Einstein. By the photo-electric effect, when light strikes any material substance, electrons are discharged, creating a current. In other words, light interacts with matter as the energy of the light is transferred to electrons.

In 1905 Einstein offered an explanation for this phenomenon in his Corpuscular Theory of Light, for which he was awarded his only Nobel Prize. He proposed that light is composed of corpuscular units, later called photons. A photon is the smallest unit of light and has a dual nature, being both particle and wave simultaneously. A photon travels at the speed of light and its energy is related to the frequency of its radiation. The energy of the photon is transmitted to the electron. The shorter the waves of light, the greater the energy of the photon, which results in stronger acceleration when that energy is transferred to the electron. The intensity of the light determines how many photons strike a given surface, and likewise, how many electrons are discharged. The higher the intensity, the greater the quantity of photons and the greater the number of electrons activated. The wave theory of light, held prior to this, was unable to account for the photoelectric effect.

The second part elucidates on color theory. Color is frequency within the visible spectrum of light, which composes a very small band of the total

electromagnetic spectrum, from violet at 400 nanometers (higher energy photon) through red at 780 nanometers (lower energy photon). Beyond violet in increasingly shorter wavelengths, are ultraviolet light, x-rays, and gamma radiation which contain tremendous amounts of energy. In the opposite direction, infrared and radio waves are longer wavelengths beyond the red end, with relatively very little energy.

Each color of the spectrum is composed of a band of frequencies. Therapeutic application of light to the body is accomplished by applying a single monochromatic wavelength within that band. According to G.C. Sander in 1926, when the body is healthy, it may be able to filter out whatever color frequency it needs from white light or sunlight. But if a person's health is compromised, the necessary color must be supplied. According to the photoelectric effect, the frequency of radiation determines the energy of the electrons emitted. This supports the rationale behind Dinshah's empirical system of color attributes, i.e., that individual frequencies have specific effects.(158).

B.K.Chandrashekar a post graduate from Punjab University, Chandigarh & a rajyogi, memory trainer, motivational speaker, neurobic expert, author of best seller - ' Science of mind ' & ' Invisible Doctor. 'His life is a living example of surviving from three major life threatening diseases of cancer, hepatitis – c and diabetics by mind power. He has pioneered the idea of concentrating yellow colour from the Supreme Soul and focussing the same on the pancreas to treat diabetes. He named this method as "Neurobics". (159)

6. Diabetes and Sanskar Re-modelling/ Behavioral Modification-

In **1999**, Feifer, Chris; Tansman, Mara published a article titled" Promoting psychology in diabetes primary care".

The article suggested guidelines for standardized integration of psychology into diabetes care. Since better diabetes management can be achieved by adding an explicit psychological component to diabetes treatment. They presented three cases that illustrate how integrated assessment and psychotherapy can improve glucose control through three mechanisms namely increasing patient acceptance of a disease state, enabling behavior change for self-care, and removing psychological barriers to disease control. The study concluded that the explicit treatment of psychological barriers to diabetes self-management would enhance standard medical practice, which normally relies on education to overcome treatment adherence problems.(160).

In **2000**, Wendy Satin Rapaport, Rebecca Taylor Cohen, and Matthew C. Riddle published an article in the journal called Diabetes Spectrum titled "Diabetes Through the Life Span: Psychological Ramifications for Patients and Professionals".

The background of the article is that like all chronic and progressive problems, including normal aging, diabetes has social, psychological, emotional, and spiritual aspects that demand attention. The authors felt that patients with type 2 diabetes and their health care providers must find their common ground to meet these challenges. Grief and shame at growing older and having medical problems afflict everyone, and denial of these feelings must be recognized and overcome. If not, patients will ignore or resist direction on lifestyle or medications. Psychological resistance to using insulin is a notable example. Providers' self-awareness and comfort with their similar feelings, empathy with patients' distress, ability to influence incremental change and place setbacks into perspective, and skill in supporting patients' positive efforts can strongly influence the process of treatment. Success with modern therapies still depends on individualization of treatment, patient empowerment, and the competency of the professional relationship. (161).

In **2000**, Lorraine C. Schafer published an article titled "Fostering Quality of Life in Individuals with Diabetes" in journal of Diabetes Spectrum.

In this article the author describes the life of an individual who has diabetes like a beautiful tapestry, one that is unique and intricately woven with bright and dark colors. The weaving of the colors symbolizes the balance between successes (bright colors) and challenges (dark colors), easy times and difficult times, predictable health care results and medical crisis, diabetes management and maintaining true personal authenticity (genuineness). Each time the individual with diabetes successfully negotiates a challenge with her diabetes and life, the tapestry of her life becomes more secure. Patterns develop that help the individual with diabetes negotiate life and diabetes management. The author concluded that as the patient develops confidence in herself/himself, the quality of life becomes good. (162).

In **2000**, in the journal of Clinical Diabetes was published an article titled "Empowerment and Self-Management of Diabetes" by Martha M. Funnell and Robert M. Anderson.

The background of their study formed the Chronic Care Model which has been tested as an effective approach for chronic illness care. This approach is based on actively involved patients working with informed, proactive health care teams. The authors worked with the empowerment philosophy which is in keeping with this approach to care. It involves establishing partnerships with individual patients and creating truly patient-centered practices. The study found that the benefits for patients include better communication with providers, greater satisfaction with care, improved metabolic and psychosocial outcomes, and emotional well-being. The benefits for providers included achievement of recommended standards of care, improved outcomes, and greater professional satisfaction.(163).

In **2002**, in the journal of Consult Clinical Psychology., was published an article titled "Diabetes and behavioral medicine: the second decade" by Gonder-Frederick LA, Cox DJ, Ritterband LM.

The article discusses the future of behavioral medicine in diabetes including topics such as the changing role of psychologists in diabetes care, the urgent need for more and better intervention research, the growing importance of incorporating a health system-public health perspective, and obstacles to the integration of psychobehavioral approaches into routine health care delivery. The paper stresses the fact that diabetes management depends almost entirely on behavioral self-regulation, and that Behavioral scientists have continued a collaboration with other health systems researchers to develop a holistic approach to this disease. The authors did a literature search and summarized the literature in 4 major areas namely self-management of diabetes, psychosocial adjustment and quality of life, neuropsychological impact, and psychobehavioral intervention development. Their article highlights the progress made in each of these areas over the past decade, as. They concluded that the emerging areas which are likely to become central in behavioral research, shall be diabetes prevention. (164).

In **2004**, an article titled "Behavioral and Clinical Factors Associated With Depression Among Individuals With Diabetes" was written by Wayne Katon, Michael Von Korff, Joan Russo, et al.

The objective of this study was to determine the behavioral and clinical characteristics of diabetes that are associated with depression after controlling for potentially confounding variables.

A population-based mail survey was sent to patients with diabetes from nine primary care clinics of a health maintenance organization. The Patient Health

Questionnaire was used to diagnose depression, and automated diagnostic, pharmacy, and laboratory data were used to measure diabetes treatment intensity, HbA1c levels, and diabetes complications.

They found that independent factors that were associated with a significantly higher likelihood of meeting criteria for major depression included younger age, female sex, less education, being unmarried, BMI ≥30 kg/m2, smoking, higher nondiabetic medical comorbidity, higher numbers of diabetes complications in men, treatment with insulin, and higher HbA1c levels in patients <65 years of age. Independent factors associated with a significantly higher likelihood of meeting criteria for minor depression included younger age, less education, non-Caucasian status, BMI ≥30 kg/m2, smoking, longer duration of diabetes, and a higher number of complications in older (≥65 years) patients.

Their study concluded that smoking and obesity were associated with a higher likelihood of meeting criteria for major and minor depression. Diabetes complications and elevated HbA1c were associated with major depression among demographic subgroups: complications among men and HbA1c among individuals <65 years of age. Older patients with a higher number of complications had an increased likelihood of minor depression. (165).

In **2009**, Jeanette M. Daly, Arthur J. Hartz, Yinghui Xu, Barcey T. Levy et al published an article titled "An Assessment of Attitudes, Behaviors, and Outcomes of Patients with Type 2 Diabetes".

The hypothesis of the study was that patient self-care behaviors, including taking medication, following a meal plan, exercising regularly, and testing blood glucose, influence diabetes control. The purpose of this research was to identify (1)

which barriers to diabetes management are associated with problem behaviors and (2) which patient behaviors and barriers are associated with diabetes control.

This was a cross-sectional study of linked medical record and self-reported information from patients with type 2 diabetes. A randomly selected sample of 800 clinic patients was mailed an investigator-developed survey. The study sample consisted of 253 (55%) individuals who had measured glycosylated hemoglobin (HbA1c) within 3 months of the survey date.

The study found that the barriers to each diabetes self-care behavior differed. Cost was the most common barrier to the 4 self-care behaviors. In a multivariable regression model, the belief that type 2 diabetes is a serious problem and depression were strongly associated with higher HbA1c levels. Lower HbA1c levels were significantly associated with being married and greater self-reported adherence-satisfaction with taking medication and testing blood glucose.

The study concluded that barriers that were significantly associated with HbA1c were specific to the behavior and varied across behaviors.(166).

In **2009**- Anja Frei, Anna Svarin, Claudia Steurer-Stey, and Milo A Puhan, published a article in the journal of Health Qual Life Outcomes, titled “Self-efficacy instruments for patients with chronic diseases suffer from methodological limitations - a systematic review”.

The aim of the study was to systematically identify all existing self-efficacy scales for five major chronic diseases and to assess their development and validation process. Since, Measurement of self-efficacy requires carefully developed and validated instruments. It is currently unclear whether available self-efficacy instruments for chronic diseases fulfil these requirements.

They conducted a systematic literature search in electronic databases (MEDLINE, PSYCHINFO, and EMBASE) to identify studies describing the development and/or validation process of self-efficacy instruments for the five chronic diseases diabetes, chronic obstructive pulmonary disease (COPD), asthma, arthritis, and heart failure. Two members of the review team independently selected articles meeting inclusion criteria. The self-efficacy instruments were evaluated in terms of their development (aim of instrument, a priori considerations, identification of items, selection of items, development of domains, answer options) and validation (test-retest reliability, internal consistency reliability, validity, responsiveness) process.

Of 584 potentially eligible papers they included 25 (13 for diabetes, 5 for asthma, 4 for arthritis, 3 for COPD, 0 for heart failure) which covered 26 different self-efficacy instrument versions. For 8 instruments (30.8%), the authors described the aim before the scales were developed whereas for the other instruments the aim was unclear. In one study (3.8%) a priori considerations were specified. In none of the studies a systematic literature search was carried out to identify items. The item selection process was often not clearly described (38.5%). Test-retest reliability was assessed for 9 instruments (34.6%), validity using a correlational approach for 18 (69.2%), and responsiveness to change for 3 (11.5%) instruments.

They found that the development and validation process of the majority of the self-efficacy instruments had major limitations. The aim of the instruments was often not specified and for most instruments, not all measurement properties that are important to support the specific aim of the instrument (for example responsiveness for evaluative instruments) were assessed. Researchers who develop and validate self-efficacy instruments should adhere more closely to important methodological

concepts for development and validation of patient-reported outcomes and report their methods more transparently. They proposed a systematic five step approach for the development and validation of self-efficacy instruments.(167).

In **2010**, CPlack K, Herpertz S, Petrak F, submitted a review in the journal of Curr Opin Psychiatry. titled, "Behavioral medicine interventions in diabetes".

The background of the review was that, poor glycemic control is prevalent in the majority of patients with diabetes and has a strong impact on medical as well as psychological outcomes. Psychological and behavioral variables are of particular interest, as the patients themselves are the most determining factor of treatment success. Consequently, a wide range of behavioral medicine interventions are aimed at improvement in diabetes self-management, coping strategies, blood glucose awareness, and stress reduction. This review provides an overview of randomized controlled trials (RCTs) which has been published from March 2008 to September 2009, that evaluated behavioral medicine interventions in patients with diabetes. The review summarizes the interventions' effects on metabolic control and other medical variables, as well as diabetes self-management and psychological outcomes.

They reviewed many studies that showed that, behavioral medicine interventions in the diabetes field encompass a number of different approaches with the goal of improving medical outcomes such as glycemic control as well as psychological outcomes. There is evidence for beneficial effects of recent behavioral medicine treatments in terms of improvement of metabolic control as indicated by decreased glycated hemoglobin (HbA1c). Furthermore, positive effects were observed regarding diabetes-related self-efficacy, self-management, proactive coping, and the reduction of psychological burdens and symptoms.

They concluded that behavioral medicine interventions are effective in diabetes treatment, especially in patients with a high level of diabetes-related distress, difficulty in coping, or insufficient blood glucose awareness.(168).

In **2013**, Shantanu Nundy, Jonathan J. Dick, Marla C. Solomon, and Monica E. Peek submitted a interview based study in the journal of Patient Educ Couns titled "Developing a Behavioral Model for Mobile Phone-Based Diabetes Interventions". This study explored the potential mechanisms by which a text message-based diabetes program affected self-management among African-Americans. Their study search revealed that behavioral models for mobile phone-based diabetes interventions are lacking. They conducted in-depth, individual interviews among 18 African-American patients with type 2 diabetes who completed a 4-week text message-based diabetes program. Each interview was audio- taped, transcribed verbatim, and imported into Atlas. ti software. Coding was done iteratively. Emergent themes were mapped onto existing behavioral constructs and then used to develop a novel behavioral model for mobile phone-based diabetes self-management programs. They found that the effects of the text message-based program went beyond automated reminders. The constant, daily communications reduced denial of diabetes and reinforced the importance of self-management (Rosenstock Health Belief Model). Responding positively to questions about self-management increased mastery experience (Bandura Self-Efficacy). Most surprisingly, participants perceived the automated program as a "friend" and "support group" that monitored and supported their self-management behaviors (Barrera Social Support).Their study concluded that a mobile phone-based diabetes program affected self-management through multiple behavioral constructs including health beliefs, self-efficacy, and social support. The study recommended that disease management programs that utilize mobile technologies should be

designed to leverage existing models of behavior change and address barriers to self-management associated with health disparities.(169).

In **2013**, David G. Marrero, Jamy Ard, Alan M. Delamater, Virginia Peragallo-Dittko, Elizabeth J. Mayer-Davis,Robin Nwankwo, and Edwin B. Fisher, published a consensus report titled "Twenty-First Century Behavioral Medicine: A Context for Empowering Clinicians and Patients With Diabetes".

This report emphasizes the fact that in the past decades, the sophistication of treatments for diabetes has increased dramatically, and evidence for effective interventions has proliferated. As a result, it is now possible to achieve excellent glucose control and reduce the risk of many of the complications associated with the disease. Despite these advances, however, many people with diabetes have less than optimal metabolic control and continue to suffer from preventable complications. The gap between optimal evidence-based medicine and actual practice can be great, dependent not only on the ability of the clinician to make changes in practice patterns but also on the central role of the patient in implementing optimal management plans in daily life. With recognition of the centrality of patients' actions to achieve optimal outcomes must come awareness that those actions reflect much more than simple "self-control." In addition to individual characteristics, the environment in which behaviors are enacted has great influence, from family eating patterns to the design of neighborhoods to workplace and national health policies. For patients and clinicians, these factors create the context or environment in which behaviors are enacted. This report cites diabetes as a prime example of this fundamental interaction of individual characteristics with the ecological or contextual factors. For example, Pima Indians living in the U.S. have the highest prevalence of type 2 diabetes of any population in the world, yet Pimas living traditional lifestyles in Mexico have relatively low levels

of diabetes. Ample evidence links genetics to diabetes within the Pima population, but exposure to an obesogenic environment is critical to expression of this very strong genetic propensity. The report concludes that the focus of diabetes management should be on the interplay between the individual and the context in which he or she behaves which is commonly cited in discussions of personal health choices and health and social policies. (170).

MATERIAL AND METHODS

This was a feasibility study to know if better diabetic control can be achieved using newer lifestyle modification programmes(LSMP) like Neurobics & Sanskar Re-modelling(SRM). The efficacy of the study was measured by observing the effects of these LSMPs on BMI, Blood Pressure, Blood sugar & WHOQOL domains. A pilot study was done 6 months prior to starting of this research work. This study was done on 20 samples . Institutional Ethical Committee permission was taken vide reference number DMIMS(DU)/IEC/2013-14/310 .

Research Design- The design of the study was interventional .

A total of 210 Diabetic patients were recruited for the study. Out of these ,90 patients did not fulfil the eligibility criteria for the study. The remaining 120 patients were enrolled for the research work. 58 patients ,out of these did not consent for the intervention. So, 62 patients were included in the study group of research study. The 58 patients cooperated for the investigations and formed the control group of the research work. This design is depicted in the flow chart of Figure-A.

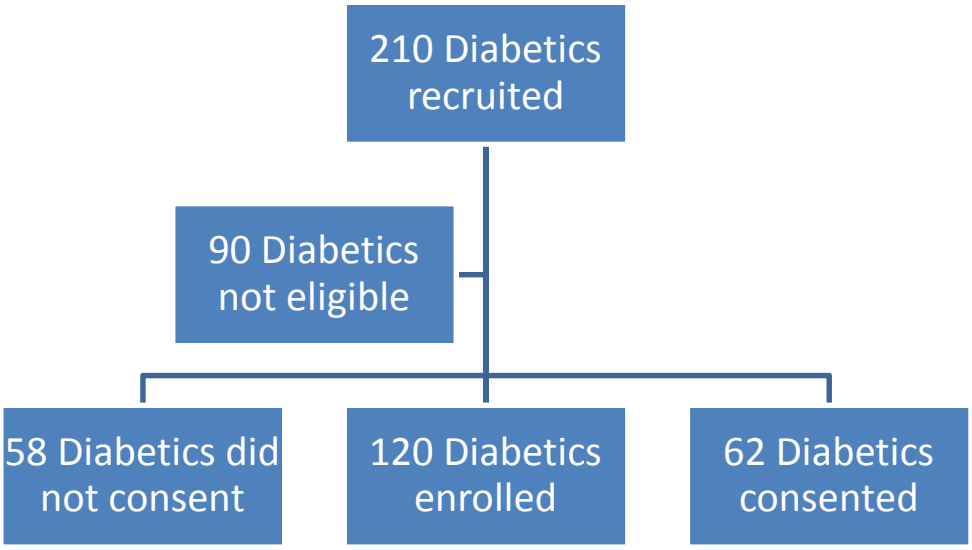


Figure A- Design of study showing recruitment of patients.

Intervention Programme-

The study group diabetic patients were educated on Neurobics & sanskar remodelling by Professional Trainers, using power point presentations. Along with this they were also apprised of their self management as regards to Diabetes care on the lines of AADE7TM- self Care behaviour framework- This included orientation to topics like-

1. **Healthy eating**-Making healthy food choices, understanding portion sizes and learning the best times to eat are central to managing diabetes. Diabetes education classes assisted diabetics in acquiring know how about the effect of food on blood glucose, sources of carbohydrates and fat, appropriate meal planning and resources to assist in making food choices. Skills taught include reading labels, planning and preparing meals. The study subjects were asked to follow the under mentioned food time table preferably-

Daily Food table

Time	Protein	Carbohydrate & Fibre	Fats	Vegetables/ Fruits
Breakfast	Mung sprouted	Suji preparation		
Lunch	Mixed Roti, Soyabeens, Rajma	Rice (brown preferably), Isabgul 2tsf in water	Ghee , buttermilk	Salads, mixed vegetables
Evening				Mixed seasonal fruits (quarter plate)
Dinner	Mixed roti	Isabgul 2tsf in water		mixed vegetables.

2. Being Active-

Brisk walking for 20-30 minutes daily at dawn or dusk for 5 days a week was advised.

Besides these certain asanas and pranayam specially for diabetes management was advocated like-

Ustrasana-

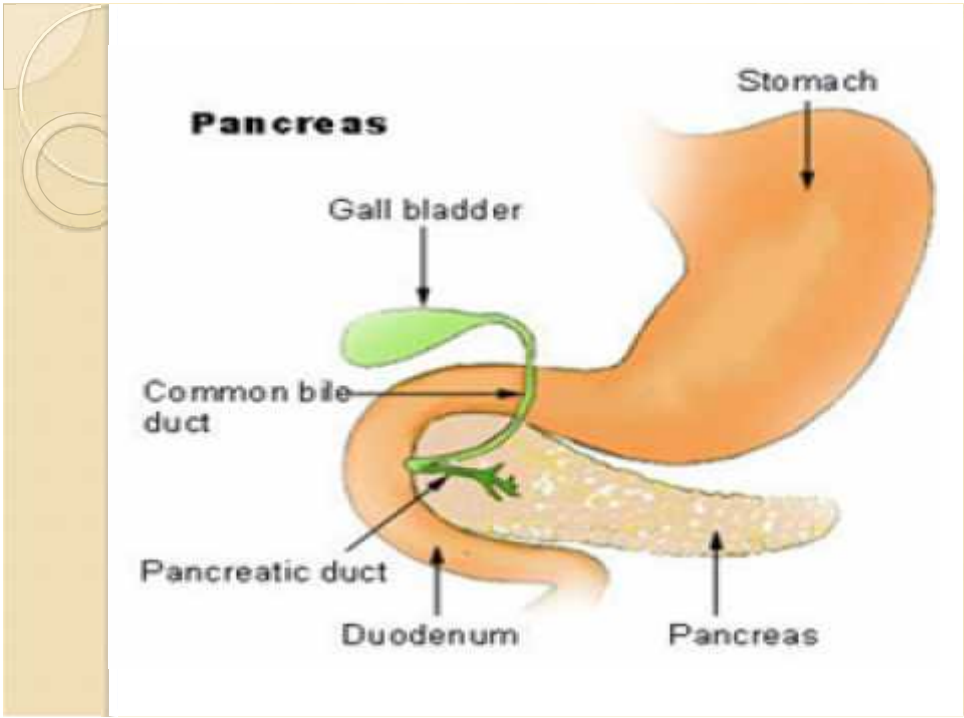
Bhujangasana

Ardha Chandrasana

SURYANAMASKAR

3. **Monitoring-**They were advised to have 3 monthly check up of Plasma glucose – fasting and Post meal, Blood Pressure and Weight.

4. **Taking medication**- Diabetics in study group were advised to take medicines as prescribed by their Physician **as well as** practice ***Neurobics*** (by visualizing yellow color light coming from the cosmos and perfusing their pancreas) and ***Sanskar re-modelling*** (by changing negative to positive thoughts with practice of Rajyoga Meditation). The control group was advised to take medicines only. Both the groups were oriented to the functional anatomy of the pancreas as seen in the diagram below through power point presentation.



5. Problem solving-

Diabetes educators took up issues like physical, emotional, cognitive, and financial obstacles and developing coping strategies. It was stressed that a person with diabetes must keep their problem-solving skills sharp because on any given day, a high or low blood glucose episode or a sick day will require them to make rapid, informed decisions about food, activity and medications. This skill has regularly to be used because even after living for many years with the disease, stability is never fully attained: the disease is progressive, chronic complications emerge, life situations change and the patient is aging.

6. Reducing Risks-

They were oriented to knowledge about standards of care, therapeutic goals, and preventive care services to decrease risk such as smoking cessation, and regular eye, foot and dental examinations . This knowledge was given to reduce diabetes

complications and maximize health and quality of life. As part of self care, they were given information about the 3 main diabetes complications namely neuropathy, nephropathy and retinopathy. Besides these, they were given an understanding on foot inspections, blood pressure monitoring, self-monitoring of blood glucose, and maintenance of personal care records.

7. Healthy copying-

Health status and quality of life are affected by psychological and social factors. Psychological distress directly affects health and indirectly influences a person's motivation to keep their diabetes in control. When motivation is dampened, the commitments required for effective self-care are difficult to maintain. When barriers seem insurmountable, good intentions alone cannot sustain the behavior. Coping becomes difficult and a person's ability to self-manage their diabetes deteriorates. (171).

To combat these type of situations the study group diabetics were referred to their nearby Brahmakumari Centres for daily or weekends support classes which ever is preferable to them. There, coping strategies are taught with practice of Rajyoga meditation.

The Diabetics in the control group were seperately oriented to the AADE7TM Self Care Behavior Framework. They were blinded to all information on Neurobics and Sanskar Re-modelling.

A group based , task oriented counselling model was developed on the lines of AADE7TM Self Care Behavior Framework. They included information provision, group discussion, self monitoring of behaviour, goal setting and planning. Program sessions were scheduled for 2hours. The study group participants were invited to the

Brahmakumari Centre ,Wardha to achieve complete ambience for the study. There , Diabetes education lecture was taken using power point presentation. They were oriented to topics like Diabetes, its cause, its prevalence rate in India, Indian Diabetes Risk Score(IDRS), Diabetes complications, Food chart and exercises for Diabetes, Neurobics/Energy Healing, Sanskar re-modelling/Behavioral Modifications and Rajyoga Meditation.

Neurobics in this study was performed as a simple exercise of visualization of cosmic colors and concentrating the cosmic color of yellow, visually on the pancreas. Yellow is a cheerful color when used in moderation. Lighter shades of yellow lend a light and breezy feeling. It is the colour of the solar plexus and it strengthens the nervous system. It has a good influence on thinking.(172,151,157).

First, the person is sitted in a comfortable chair, with feet firmly planted on the floor in front of him. He is advised to stay conscious, which helps in controlling the duration of the technique. This procedure is done for only 3 to 5 minutes in the beginning. Once he is comfortable with the technique he is instructed to follow the procedure for 8-10 minutes..

To start with, the person is asked to breathe deeply and evenly, feeling the cleansing power of oxygen permeating his body's cells as he breathes in, and the release of carbon dioxide waste as he breathes out.

After this brief relaxation, he visualizes the **soul** as a point of white light shining like a diamond in between the eyebrows.. Then, he focuses on the Supreme **Soul** (who is also a point of white light) and imagines all the color rays of rainbow energy flowing into his body. Next, focus is made on **the healing color of yellow** coming from the supreme soul, entering the body through the soul and perfusing the pancreas. The non believers in supreme soul were asked to focus their concentration

on the cosmos & imagine healing colour of yellow entering their body and perfusing the pancreas .They were asked to imagine that pancreas are generating more insulin by stimulation of beta cells, which is allowing improved glucose entry into cells, thus decreasing their plasma sugar levels.(159).

Figure- Neurobics

The next intervention given was sanskar remodelling for behavior change. The shortcoming of different LSMP Diabetic trials was the problem of adherence to the programme in the long run and efficacy check for the less motivated and general population. Unless people are motivated to change or to follow a certain guideline, there cannot be a desired outcome. Rajyoga meditation is a simple procedure which anyone can learn. People of any religion can practice it,as it is the study of ones own self. Rajyoga meditation basically builds on, ones energy levels by creating positive thoughts. These generated positive thoughts motivates an individual to adhere to a

program. Further these positive thoughts bring about a behaviour change. In this, the person is sitted upright and concentrates on a point of white light. There are 3 stages-

1. Initiation- in this stage , thoughts in the mind, come in randomly.
2. Concentration- He now, converts all negative thoughts with positive thoughts of peace, happiness, love. bliss. purity .knowledge & power .
3. Realization-This final stage involves feeling the emotions of these positive thoughts.

These practice of Rajyoga meditation is on the lines of Brahmakumaris.

The total study duration was for 1year. Out of this total study duration, the intervention period was 6months. The research work of intervention stared from April 2014 and was completed by September 2014. Facilitators received 2 days of training with theory and practical exercises. A project dietician supported facilitators and gave dietary counselling during one group session. Similarly, a yoga instructor

specialized in asanas and pranayama conducted 2hour of class for both the group of Diabetic patients.

Orientation class as per AADE7TM was held in the Brahmakumari centre Wardha for both the group of subject on 2 seperate days. Neurobics & Sanskar Re-medelling was also taught at the centre, immediately after the orientation class to the subject group. They were taught **neurobics** through video session by trained facilitators and to **sanskar remodelling(SRM)** through lecture by experienced Rajyoga trainers. They practised neurobics and SRM daily for 10 min in the morning and 10 min in evening. This group was reviewed in the centre every weekend for the first 3 months and after every fortnight for the last 3 months. Patients were called to Physiology department for all investigations. Pre-test and Post test datas were taken before the onset and after completion of the study. Patients were referred to their attending Physicians if they required medical care during the intervention.

Recruitment of Participants-

3months was the recruitment period. 210 patients were recruited for the study. 10 patients were recruited by word of mouth from Wardha city and the remaining were patients of Acharya Vinobha Bhave Rural Hospital, Wardha. Out of 210, 90 patients were not eligible for the study.

Inclusion Criteria:

1. Diagnosis of impaired glucose intolerance based on criteria adopted by the WHO in 1985, which was a fasting plasma glucose concentration of 140 mg/dl or higher or a plasma glucose concentration of 200 mg/dl or higher two hours after an oral glucose challenge.

2. 15-90 yrs of age.
3. No history of mental health problems or substance abuse likely to interfere with participation
4. Cancer affliction
5. Myocardial infarction in the past 6 months
6. Patients who consented for the study.

Exclusion Criteria:

1. History of Psychological problems likely to interfere with participation.
2. Chronic disease that would likely to limit the ability to continue with the study for 6 months
3. Thyroid or Liver disease
4. Physical disabilities deemed likely to interfere with participation in the study.
5. Patients who did not give consent to the study.

Thus, 120 patients were enrolled for the study. Out of these 58 patients did not give consent for the study .However they agreed for the baseline and conclusive investigative clinical tests. So, they formed the control group of the study. Hence, they were oriented to the basics of self care managemenrt in diabetes.

62 patients consented for the study and formed the study group. 10 patients recruited from Wardha, formed part of this group. This group was taught Neurobics and SRM.

Outcome Measures-

Data collection period was 3 months. All data were collected by the facilitators.

Baseline anthropometric measurement like height and weight were taken at recruitment. Body Mass Index or BMI was calculated using the formula- weight in kg divided by height in meter square as per FEHES 62.(173). Blood Pressure was measured manually using the standard Sphygmomanometer of Diamond, Regular model mercurial make. An average of consecutive 3 readings were taken as per FEHES 62.(173).

Blood Glucose was measured using a Glucometer namely BG03-Dr Morepen, Gluco one Blood Glucose monitoring system.

Quality of Life assessment was done using the WHOQOL –BREF, Field trial version, 1996 questionnaire. It has 30 questions which assesses 4 domains namely Physical, Mental, Social and Environmental. All the raw scores were converted to 0-100% scale score, using the WHOQOL score chart.

Therefore the key life style outcome measures were Blood Glucose, WHOQOL domain score, Blood Pressure and Body Mass Index.

Results were analyzed in the Physiology department of JNMC, Wardha. If any information was required patients were contacted.

Program Evaluation & Statistical Analysis-

Reliability test of Pilot study was calculated using test retest method. Statistical analysis was done using descriptive and inferential statistics using Wilcoxan Signed Rank test, z-test for difference between two mean and chi square test. The chi square statistics was used to compare each life style measures according

to differences in risk status and glucose tolerance at 6 months. Cox proportional Hazard Analysis was used to find out the impact of covariate on fixed predictor variable.

The software used in the analysis were SPSS 17.0 and Graph Pad 5.0 version and $p<0.05$ was considered as level of significance.

Concept of Neurobics and Sanskar Remodelling, as a variant of Rajyoga meditatiion-

In this study, Neurobics and SRM which are 2 different ways of practicing Rajyoga meditation are tested as Life style Modification Programmes(LSMP)) for managing Diabetes.

The unique and valued outcome of diabetes education is behavior change. Diabetes educators recognize the value of facilitating behavior change that can positively affect clinical indicators and lead to improved health status. Diabetes educators help patients with diabetes acquire the knowledge and skills necessary to manage their disease on a daily basis. However, knowledge alone will not lead to improved clinical outcomes and the resulting long-term outcome of improved health behavior change is also necessary for clinical indicators to improve. Measurable behavior change is the unique outcome of working of a diabetes educator.

American Association Diabetes Educators (AADE) aims at Diabetes self-management education. This begins with an assessment and development of an instructional plan, one that is heavily based on the patient's goals, interests, abilities, and needs. The diabetes educator helps the person with diabetes to identify, prioritize, and work toward individualized goals behavioral changes that lead to better self-management skills and self-care behaviors, better health and disease management,

improved quality of life, and independence in lifestyle choices. As the multi-layered plan is implemented, the diabetes educator is able not only to provide digestible amounts of information and instruction but to assess the patient's progress in learning, skill development, and behavior change. (174).

Measurable behavior change is the desired outcome of diabetes education. This can only be achieved by self awareness which is intrinsic to Rajyoga meditation(RM). Following principles are inherent to RM namely-

1. **Self –responsibility through self empowerment**- The word "healthy" is derived from two words, "heal" plus "thy" i.e to heal yourself. To heal oneself, one needs to be empowered by appropriate and proper information about heart, mind -body connection, psychological and conventional risk factors, stress management, diet , exercise, sleep. substance abuse and usual medical care.(175).
2. **Self –awareness** – The Hindi word for healthy is "swasth" which consists of "swa" meaning "inner self" ,and "sth" meaning "conscious". So the word "healthy" could also mean "inner self consciousness". Outer self –consciousness (of body, role or material things which are ever -changing and mortal) leads to instability and insecurity which in turn leads to anger, anxiety, depression type A behaviour, isolation and chronic life stresses. Conversely, inner self-consciousness (of spirit, which is enduring and immortal) leads to stability and security, which in turn leads to peace, love and happiness. So, by abstraction, a healthy lifestyle means an "inner self-conscious lifestyle. (175).
3. **Multi- dimensionality**- The current medical approach addresses only one dimension, the physical body, which might explain why despite medical advancements the epidemic of CAD (which is the usual consequence of Diabetes) has not been curbed. A human being is not one dimensional. Therefore, a new

model of health, "Soul- Mind-Body-Medicine"(three dimensional healthcare) is called for. As per this new model, health is a dynamic process of harmony in flow of spiritual energy (knowledge of truth, purity, peace, love happiness, bliss and power: of discretion, to judge, to withdraw, to pack up, to tolerate, to face. To accommodate, to cooperate), mental energy(Positive TEAM: thoughts, emotions. Attitudes and memories) and physical energy (healthy diet, exercise. Sleep and medication).(175).

4. **Biological clock/ circadian rhythm**- When activities are in rhythm with ones biological clock, they reduce energy expense and stress, and prove beneficial for the health of mind, intellect and body.(175).

About Rajyoga meditation (RM)- Its role in stress management-

Chronic stress is one of the cause of T2DM. Stress is defined as a stage of threatened homeostasis. Any disease is a stress for the body. Stress can be combated with inner strength.

Inner strength can be increased with RM. Rajyoga word has been derived from Raja meaning king and yoga meaning union between Soul (spiritual energy) and Supreme Soul (ocean of spiritual energy). Rajyoga meditation harmonizes spiritual, mental and physical energy, thereby increasing inner strength to lead a stress free healthy life. It enhances individuals power of determination to manage and practice positive thoughts, emotions, attitudes, memories and adhere to a healthy diet, exercise, sleep, medication and cessation of smoking.(175).

The process of RM basically involves the feeding of positive thoughts in the mind. These positive thoughts replace the different vagaries of the mind which have

become habits or sanskars into good habits or good sanskars. This process is now called as SRM. SRM then leads to behavioural modification.

RM involves the process of visualizing the positive thoughts. The subconscious mind understands the language of images only. The image of rainbow having seven colors is imagined to be emanating from the Supreme Soul or coming from the cosmos in RM. Each color symbolizes a quality namely-

1. Violet- Bliss
2. Indigo- Knowledge
3. Blue- Peace
4. Green- Love
5. Yellow- Happiness
6. Orange- Purity
7. Red- Power.

As, thoughts are seeds of all actions, these positive thoughts feed into subconscious mind, bringing about behavioural modification. This process of RM can be called as **Neurobics**.

With this two process namely Neurobics and SRM, all the participants in the study group were trained to inculcate these positive thoughts. They were also directed to adhere to the program.

Photograph 1: Introduction to subjects at Bramhakumaris (B.K) centre, Wardha.

Photograph 2: Lecture by facilitator

Photograph 3: Orientation to functional anatomy of pancreas

Photograph 4: Introduction to the topic of Diabetes

Photograph 5: Lecture on epidemiology of Diabetes

Photograph 6: Lecture hall in the B.K Centre

Photograph 7: Orientation to Daily Food table

Photograph 8: Lecture on Sanskar Remodelling / Behavioural Modification

Photograph 9: Neurobic practice session by Rajyoga Trainer

Photograph 10: Glucometer

Photograph 11: Blood sample taking from subject

Photograph 12: Blood sample being analyzed

OBSERVATIONS AND RESULTS

STUDY GROUP

Table 1: Distribution of patients according to demographic characteristics in study group

Demographic Characteristics	Mean	SD	Range
Age(yrs)	55.52	14.92	16-82
Gender	48/15		
Ht(meter)	1.66	0.10	1.50-1.80
Wt(Kg)	71.47	7.38	59-80

Table 2: Comparison of BMI in study group at pre and post test

	Mean	N	Std. Deviation	Std. Error Mean	Difference	z-value	p-value
Pre Test	26.33	63	3.26	0.41	1.14±0.75	11.95	0.000 S,p<0.05
Post Test	25.19	63	3.27	0.41			

Graph 1: Comparison of BMI in study group at pre and post test

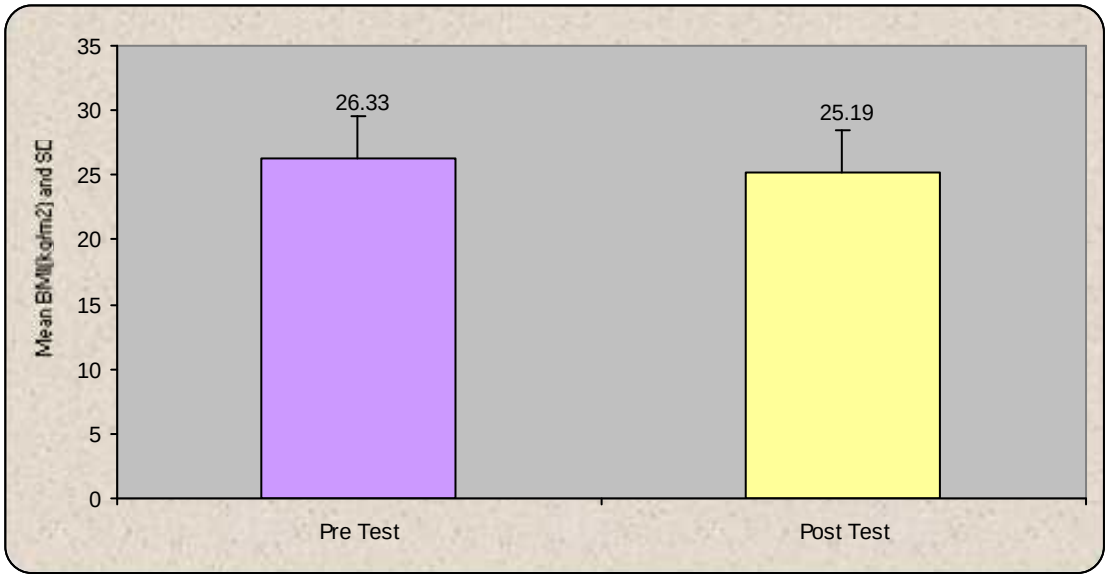


Table 3: Comparison of Waist circumference in study group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	70.63	63	15.14	1.90	0.12±0.49	2.05	0.045 S,p<0.05
Post Test	70.50	63	15.11	1.90			

Graph 2: Comparison of Waist circumference in study group at pre and post test

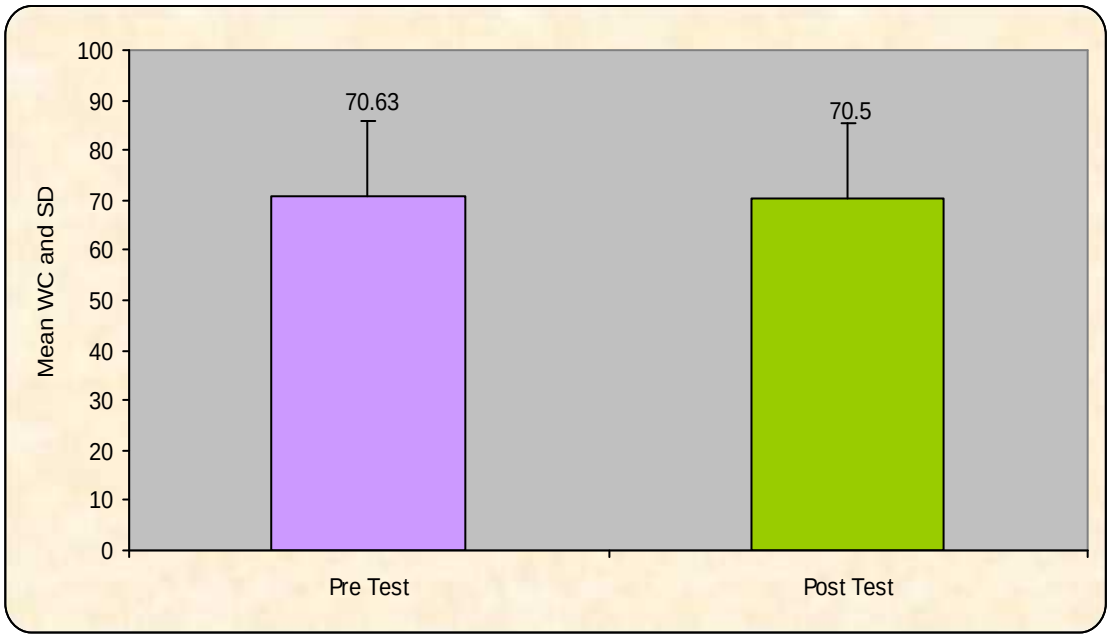


Table 4: Comparison of SBP (mmHg) in study group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	126.50	63	14.49	1.82	3.33±5.08	5.20	0.000 S,p<0.05
Post Test	123.17	63	10.44	1.31			

Graph 3: Comparison of SBP (mmHg) in study group at pre and post test

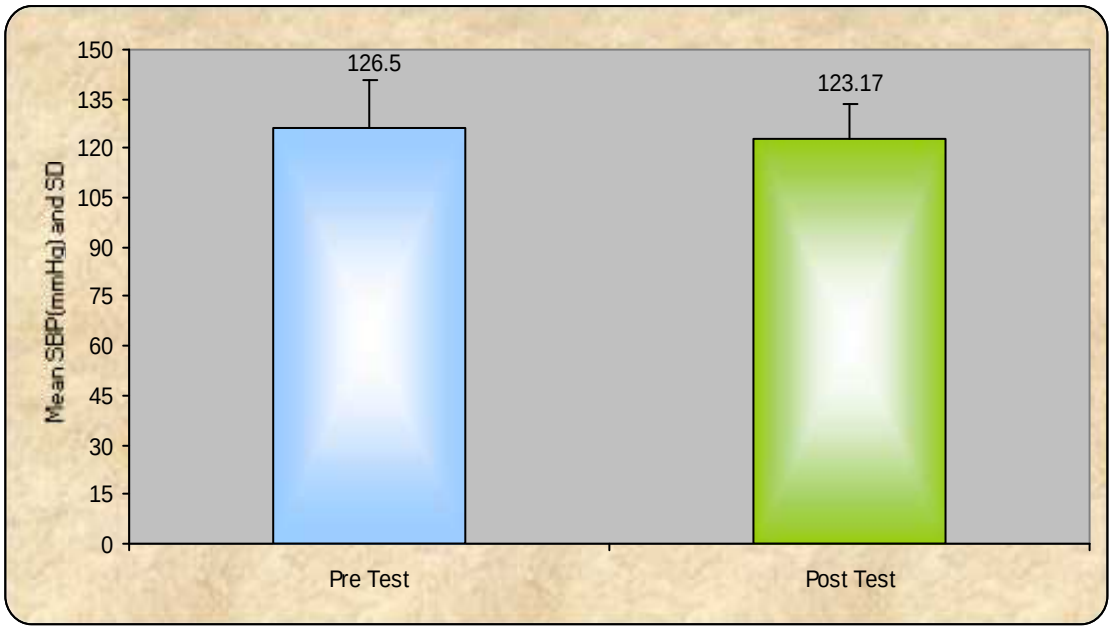


Table 5: Comparison of DBP(mmHg) in study group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	81.58	63	4.47	0.56	1.58±3.68	3.42	0.001 S,p<0.05
Post Test	80.00	63	1.79	0.22			

Graph 4: Comparison of DBP(mmHg) in study group at pre and post test

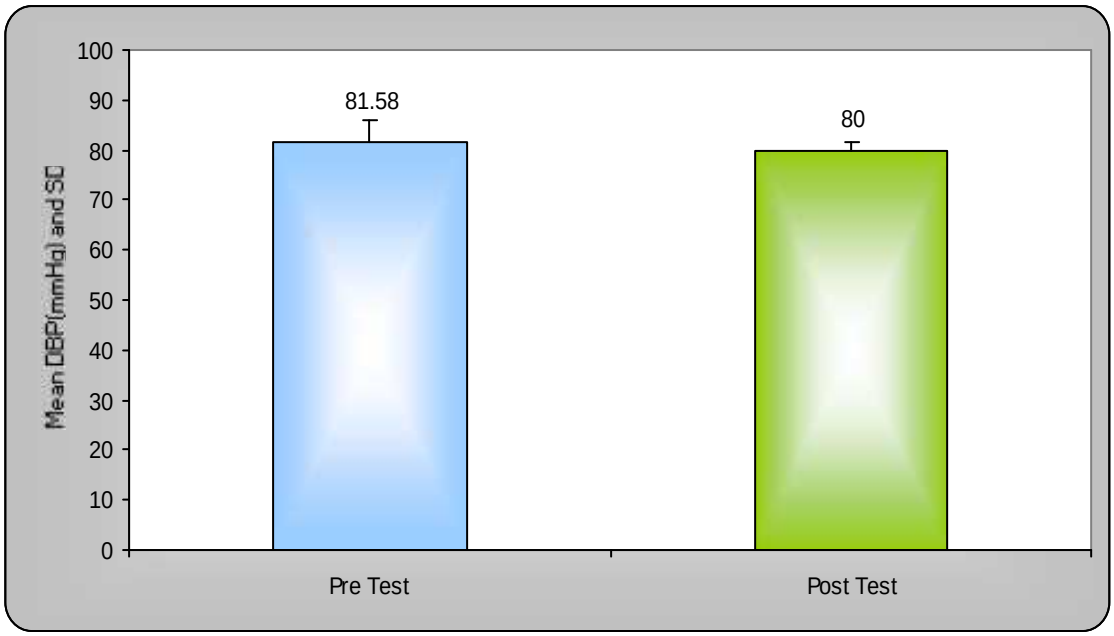


Table 6: Comparison of FBS in study group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	227.76	63	42.460	5.35	16.06± 14.57	8.74	0.000 S,p<0.05
Post Test	211.69	63	42.38	5.33			

Graph 5: Comparison of FBS in study group at pre and post test

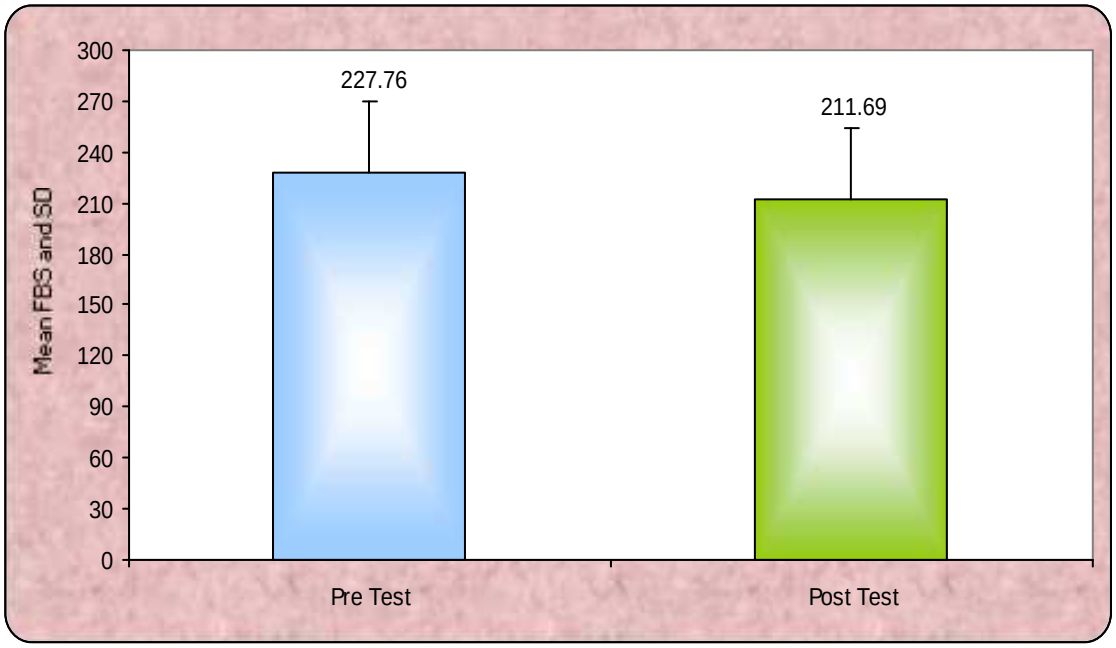


Table 7: Comparison of PP in study group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	372.73	63	65.51	8.25	21.84± 17.88	9.69	0.000 S,p<0.05
Post Test	350.88	63	67.18	8.46			

Graph 6: Comparison of PP in study group at pre and post test

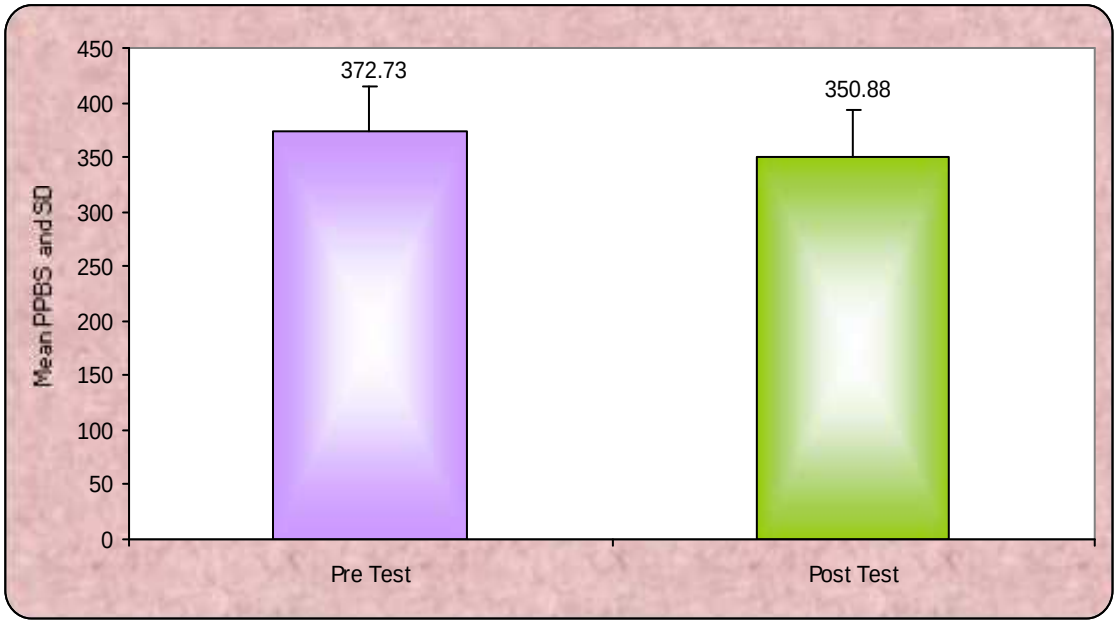
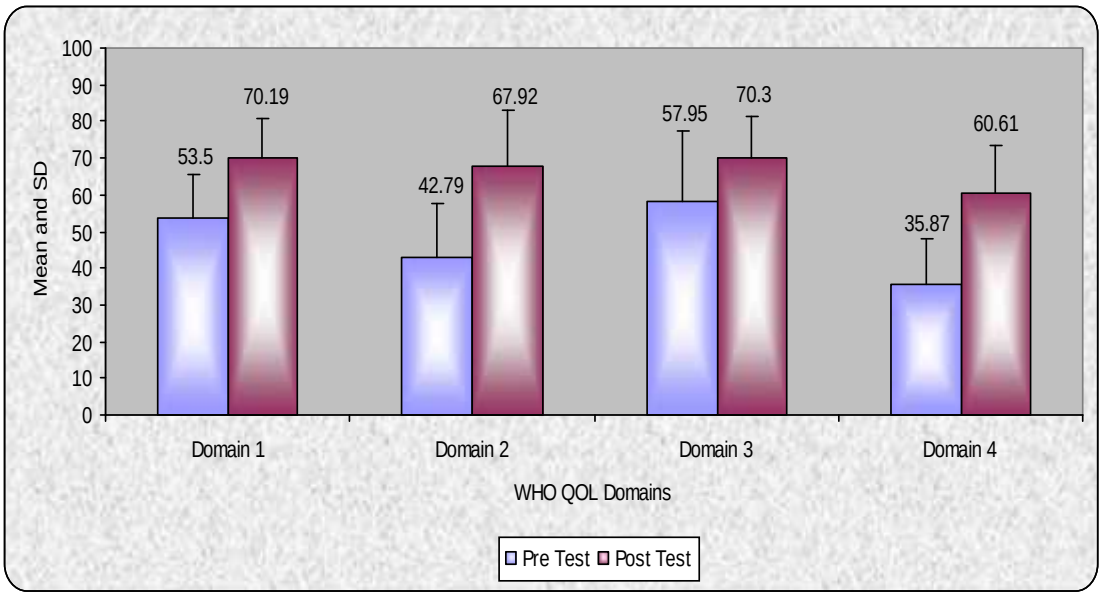


Table 8: Comparison of WHO-QOL domains in study group at pre and post test

WHO QOL Domains		Mean	N	Std. Deviation	Std. Error Mean	Difference	z-value	p-value
Domain 1	Pre Test	53.50	63	12.23	1.54	16.68±12.14	10.90	0.000 S,p<0.05
	Post Test	70.19	63	10.85	1.36			
Domain 2	Pre Test	42.79	63	14.82	1.86	25.12±16.67	11.96	0.000 S,p<0.05
	Post Test	67.92	63	15.05	1.89			
Domain 3	Pre Test	57.95	63	19.36	2.43	12.34±19.54	5.01	0.000 S,p<0.05
	Post Test	70.30	63	11.05	1.39			
Domain 4	Pre Test	35.87	63	12.12	1.52	24.76±14.82	13.24	0.000 S,p<0.05
	Post Test	60.61	63	12.86	1.62			

Graph 7: Comparison of WHO-QOL domains in study group at pre and post test



CONTROL GROUP

Table 9: Distribution of patients according to demographic characteristics in control group

Demographic Characteristics	**Mean**	**SD**	**Range**
Age(yrs)	57.68	13.39	17-81
Gender	46/11		
Ht(meter)	1.66	0.10	1.50-1.80
Wt(Kg)	71.36	6.48	59-80

Table 10: Comparison of BMI in control group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	26.29	57	2.97	0.39	0.01±0.13	1.00	0.32 NS,p>0.05
Post Test	26.28	57	2.96	0.39			

Graph 8: Comparison of BMI in control group at pre and post test

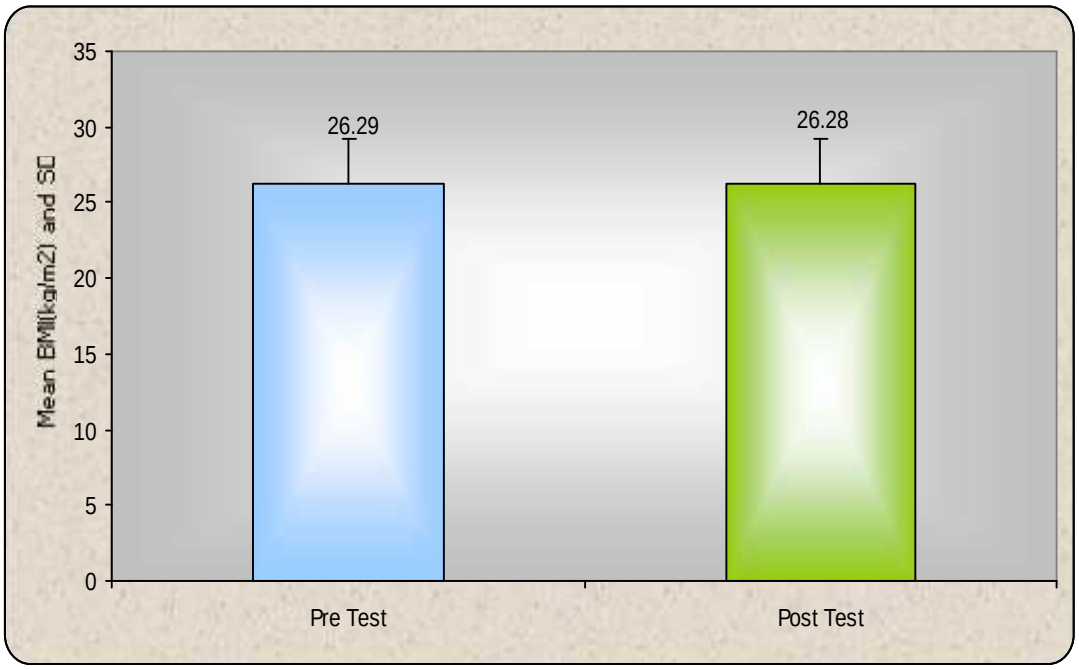


Table 11: Comparison of Waist circumference in control group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	67.19	57	13.26	1.75	0.28±1.17	1.080	0.07 NS,p>0.05
Post Test	66.91	57	13.15	1.74			

Graph 9: Comparison of Waist circumference in control group at pre and post test

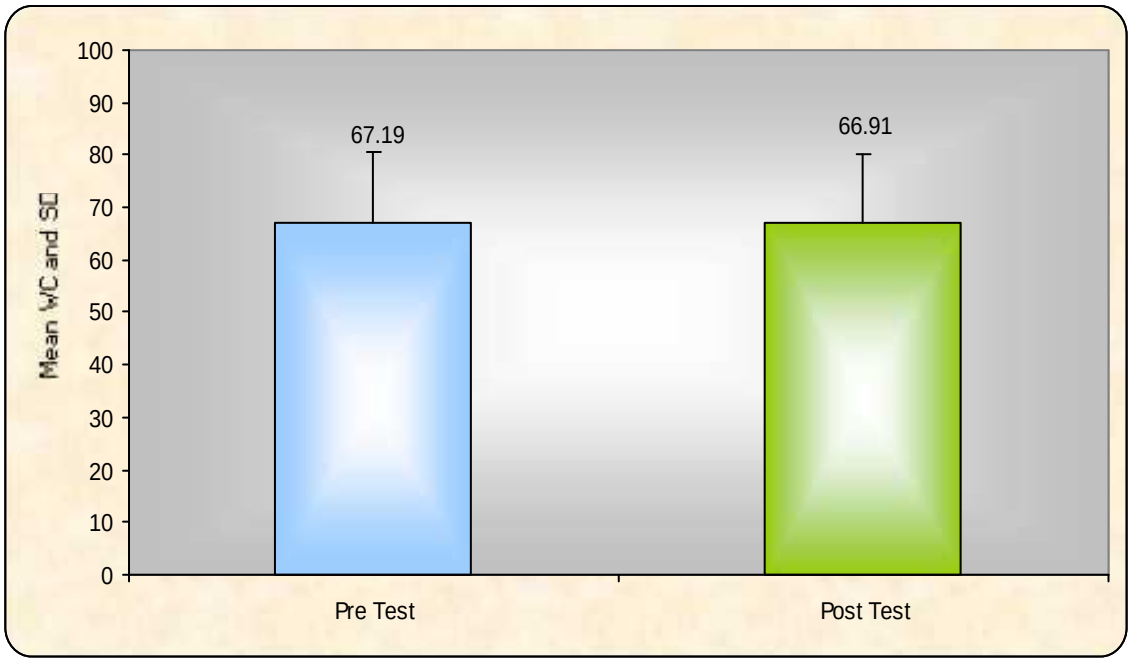


Table 12: Comparison of SBP(mmHg) in control group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	120.17	57	13.95	1.84	0.17±1.32	1.00	0.32 NS,p>0.05
Post Test	120.00	57	13.62	1.80			

Graph 10: Comparison of SBP(mmHg) in control group at pre and post test

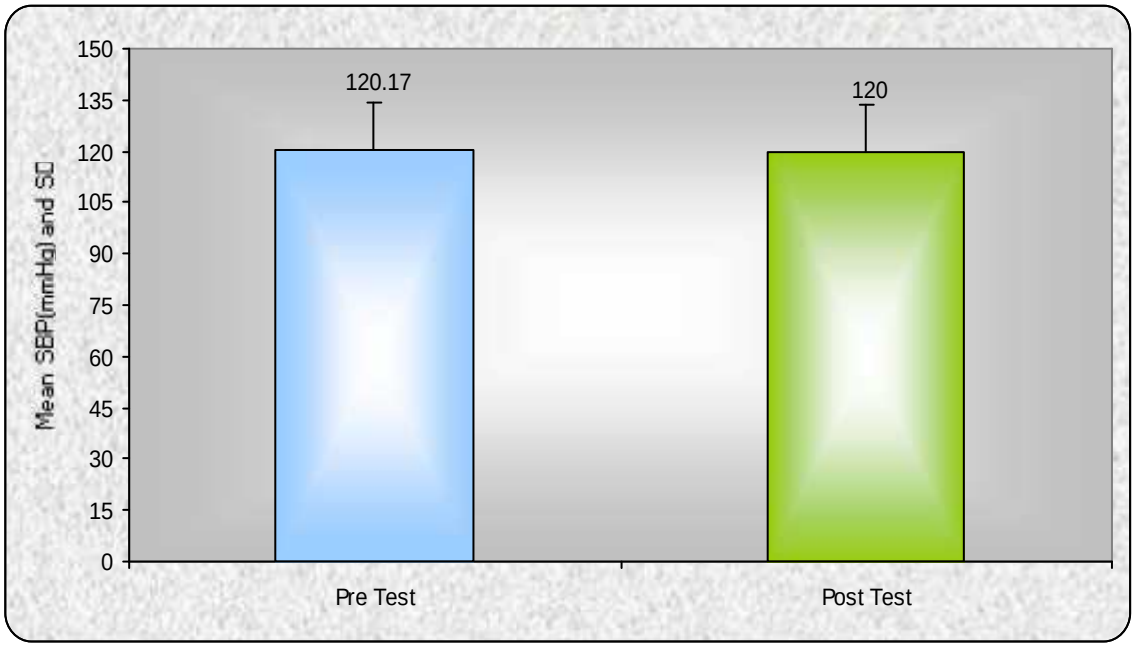


Table 13: Comparison of DBP(mmHg) in control group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	81.92	57	3.98	0.52	0.17±1.32	1.00	0.32 NS,p>0.05
Post Test	81.75	57	3.83	0.50			

Graph 11: Comparison of DBP(mmHg) in control group at pre and post test

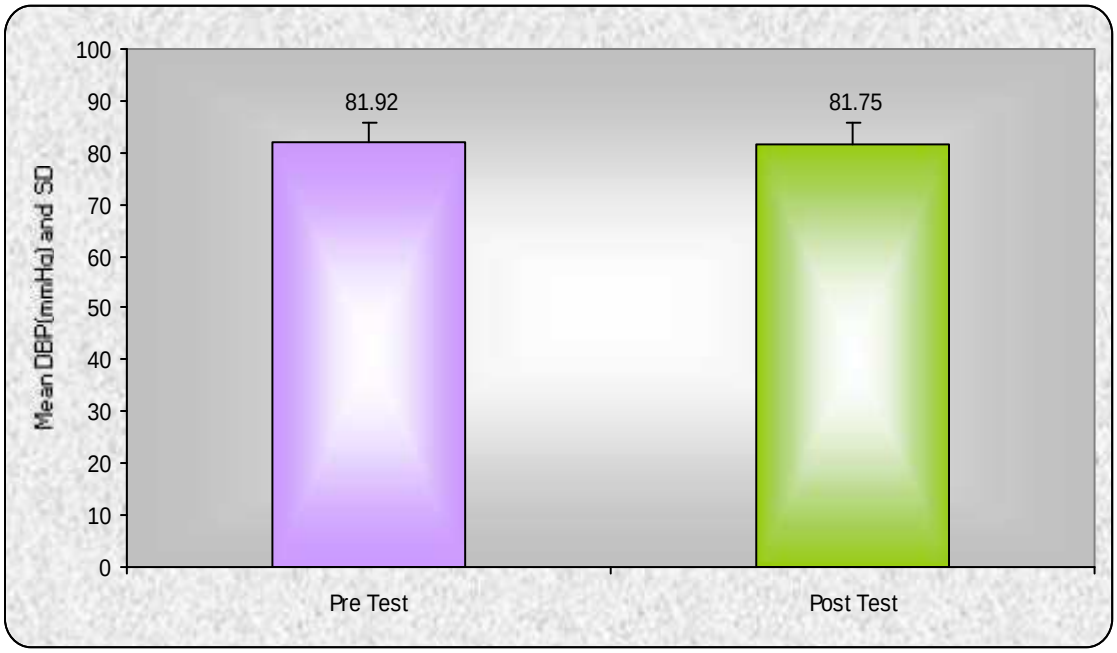


Table 14: Comparison of FBS in control group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	237.43	57	18.57	2.46	1.40±8.54	1.24	0.22 NS,p>0.05
Post Test	236.03	57	19.72	2.61			

Graph 12: Comparison of FBS in control group at pre and post test

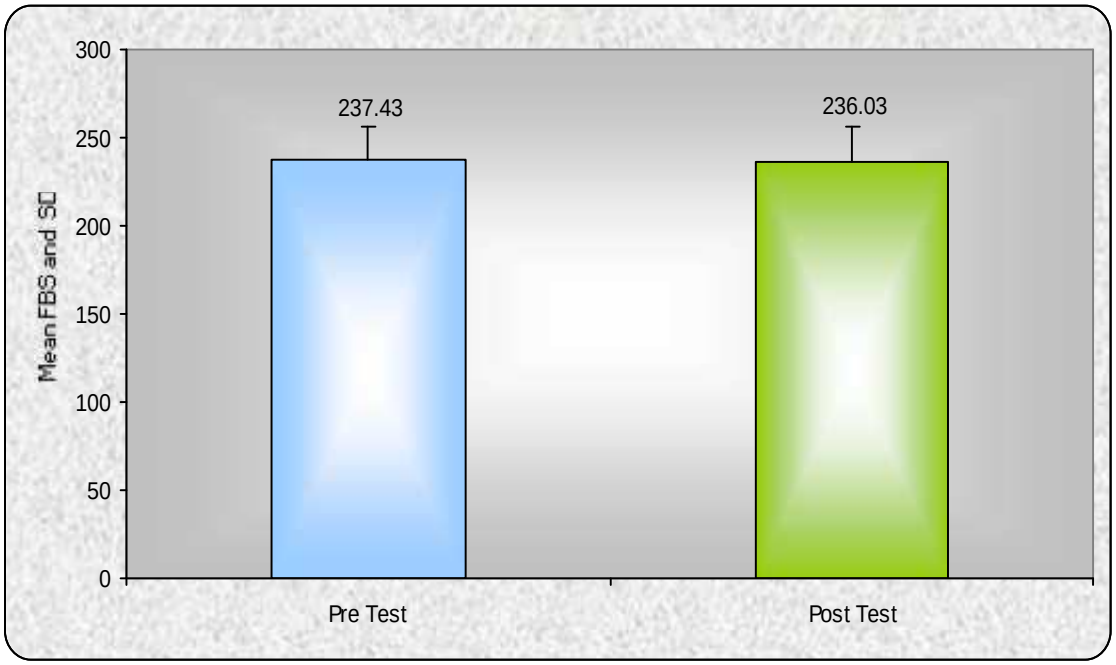


Table 15: Comparison of PP in control group at pre and post test

	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**Difference**	**z-value**	**p-value**
Pre Test	393.57	57	13.43	1.77	2.56± 9.50	2.03	0.057 NS,p>0.05
Post Test	391.01	57	16.29	2.15			

Graph 13: Comparison of PP in control group at pre and post test

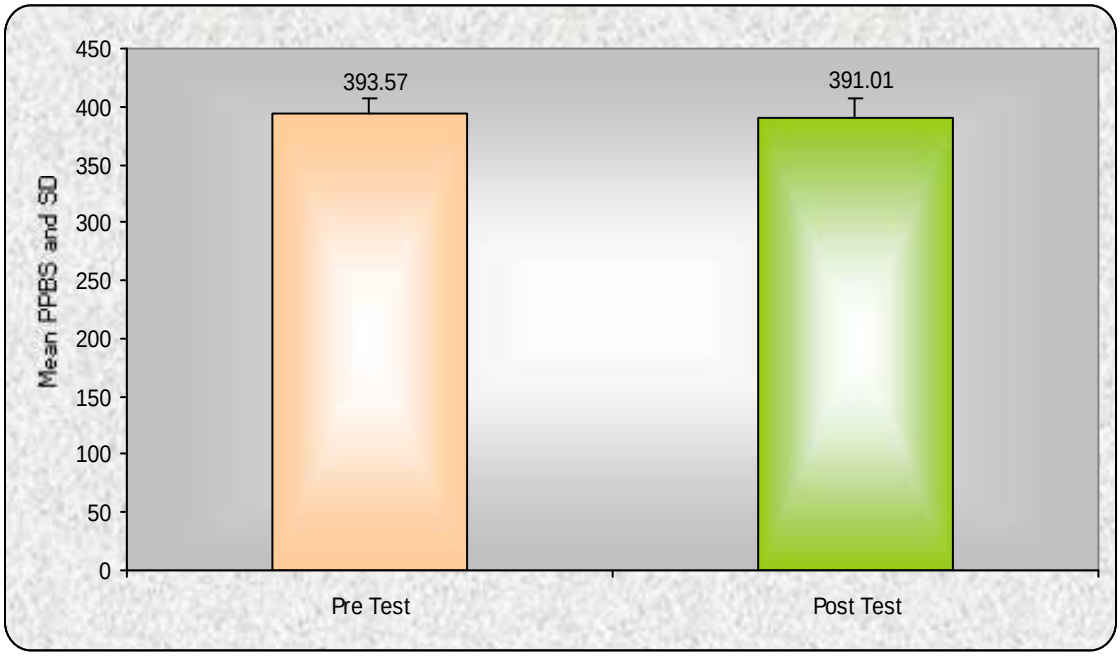
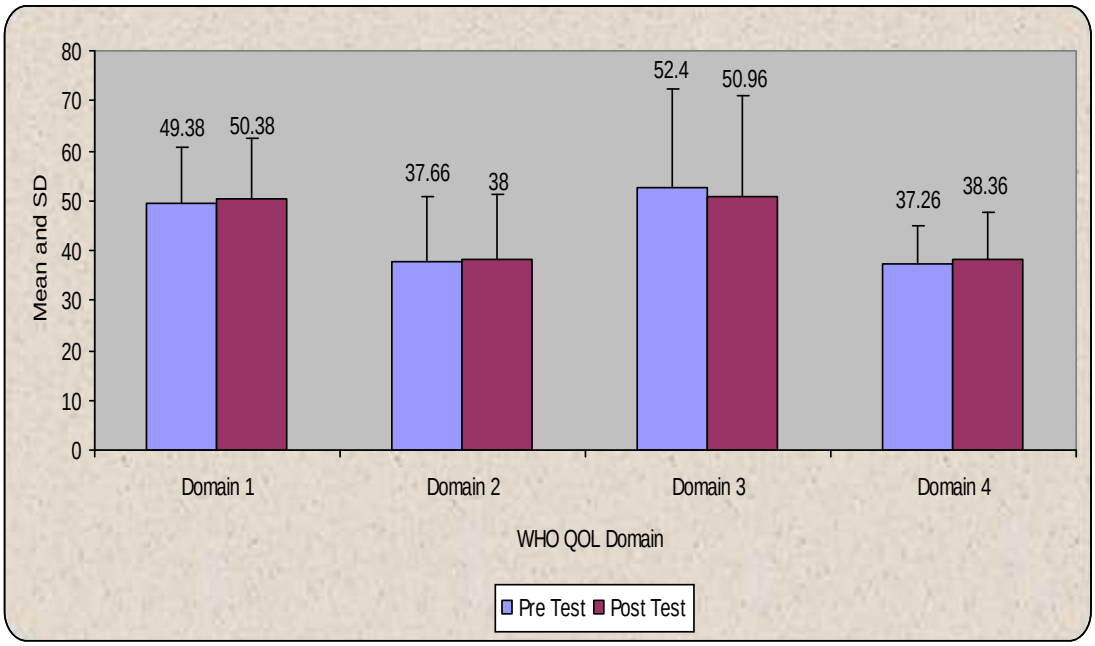


Table 16: Comparison of WHO-QOL domains in control group at pre and post test

WHO QOL Domains		Mean	N	Std. Deviation	Std. Error Mean	Difference	z-value	p-value
Domain 1	Pre Test	49.38	57	11.27	1.49	1.00±5.60	1.34	0.18 NS,p>0.05
	Post Test	50.38	57	11.94	1.58			
Domain 2	Pre Test	37.66	57	13.11	1.73	0.33±6.70	0.37	0.70 NS,p>0.05
	Post Test	38.00	57	13.02	1.72			
Domain 3	Pre Test	52.40	57	19.86	2.63	1.43±7.07	1.53	0.13 NS,p>0.05
	Post Test	50.96	57	19.86	2.63			
Domain 4	Pre Test	37.26	57	7.80	1.03	1.10±7.86	1.06	0.29 NS,p>0.05
	Post Test	38.36	57	9.08	1.20			

Graph 14: Comparison of WHO-QOL domains in control group at pre and post test



COMPARISON IN TWO GROUPS

Table 17: Distribution of patients according to medications in both the groups

Medications	Study Group	Control Group	χ2-value	p-value
Aactos	20(31.74%)	19(33.33%)	0.02	0.88,NS
Metformin	60(95.23%)	50(87.71%)	3.15	0.07,NS
Aten	2(3.17%)	6(10.52%)	4.91	0.02,S
Alog	0(0%)	1(1.75%)	2.02	0.15,NS

Graph 15: Distribution of patients according to medications in both the groups

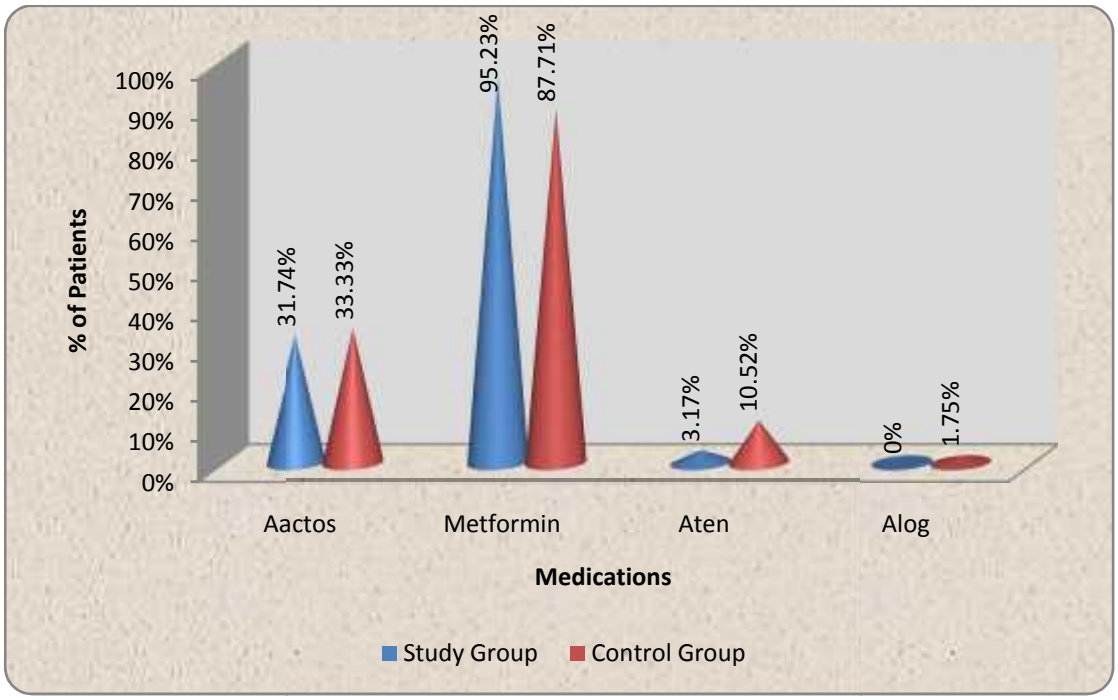
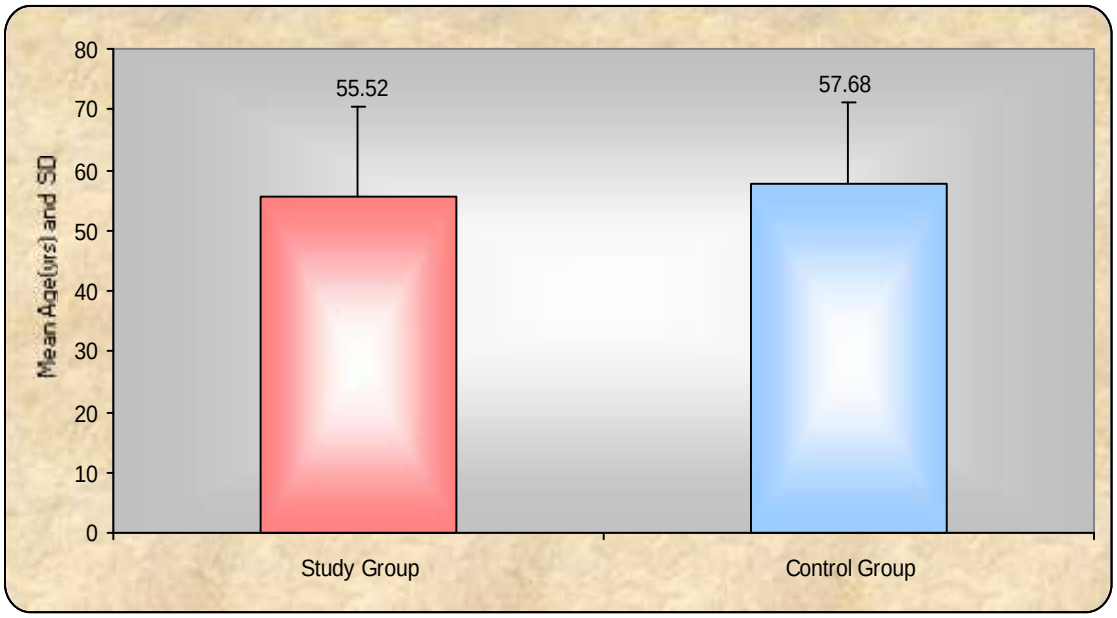


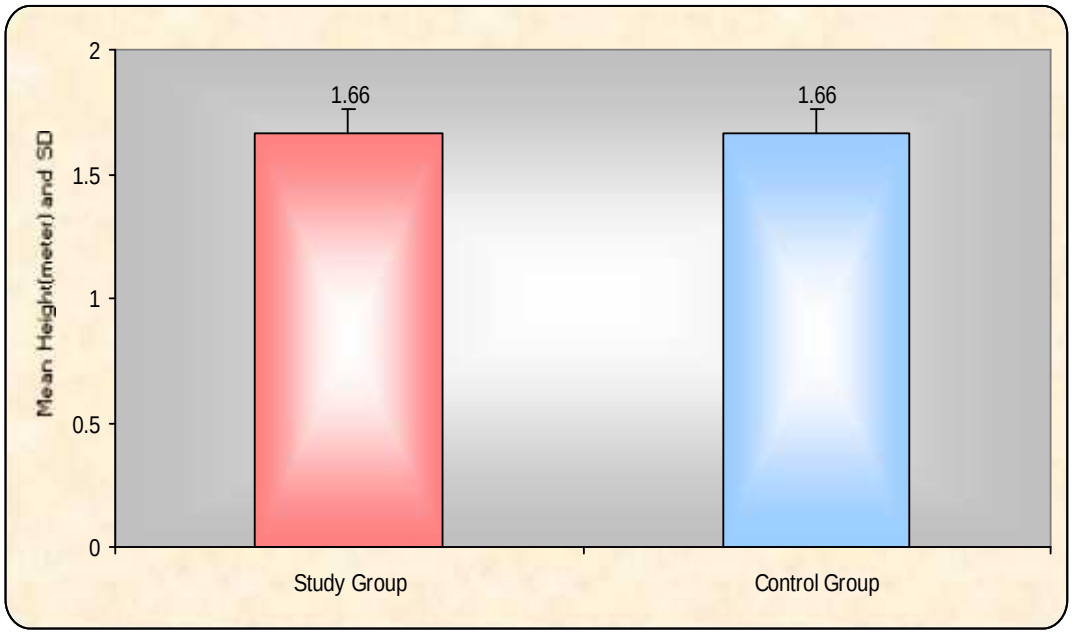
Table 18: Comparison of demographic characteristics in two groups

	Study Group	**Control Group**	**z-value**	**p-value**
Age(yrs)	55.52±14.92	57.68±13.39	0.83	0.40,NS,p>0.05
Ht(mtr)	1.66±0.10	1.66±0.10	0.00	1.00,NS,p>0.05
Wt(Kg)	71.47±7.38	71.36±6.48	0.08	0.93,NS,p>0.05

Graph 16: Comparison of age(yrs) in two groups



Graph 17: Comparison of height(meter) in two groups



Graph 18: Comparison of weight(kg) in two groups

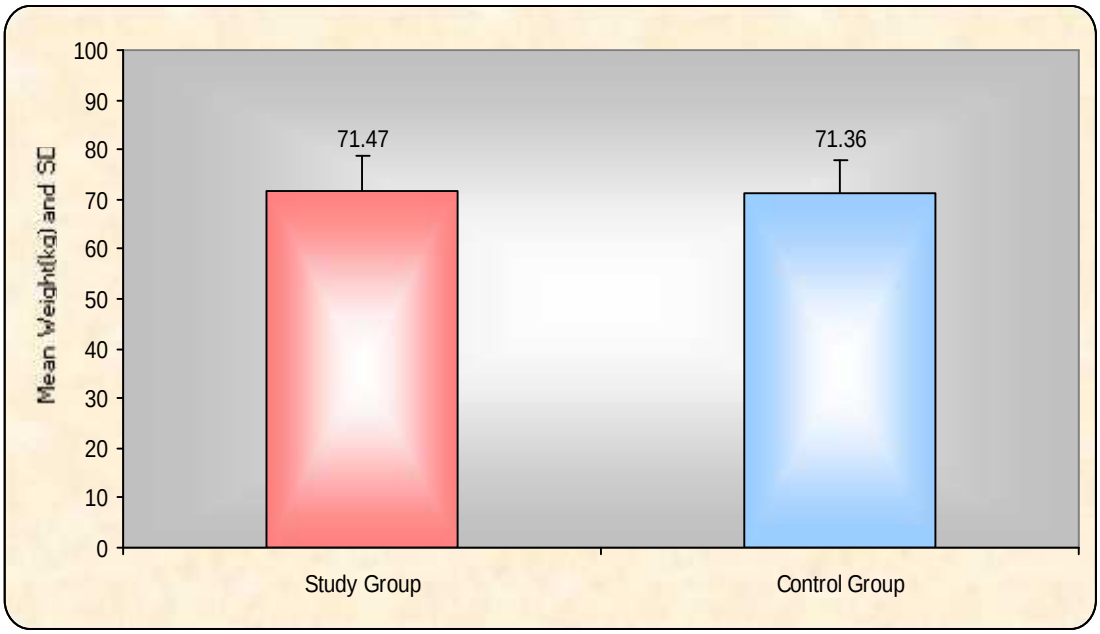


Table 19: Comparison of mean difference in BMI in two groups

Group	**Mean Difference**	**SD**	**z-value**	**p-value**
Study Group	1.14	0.75	11.03	0.000
Control Group	0.01	0.13		S,p<0.05

Graph 19: Comparison of mean difference in BMI in two groups

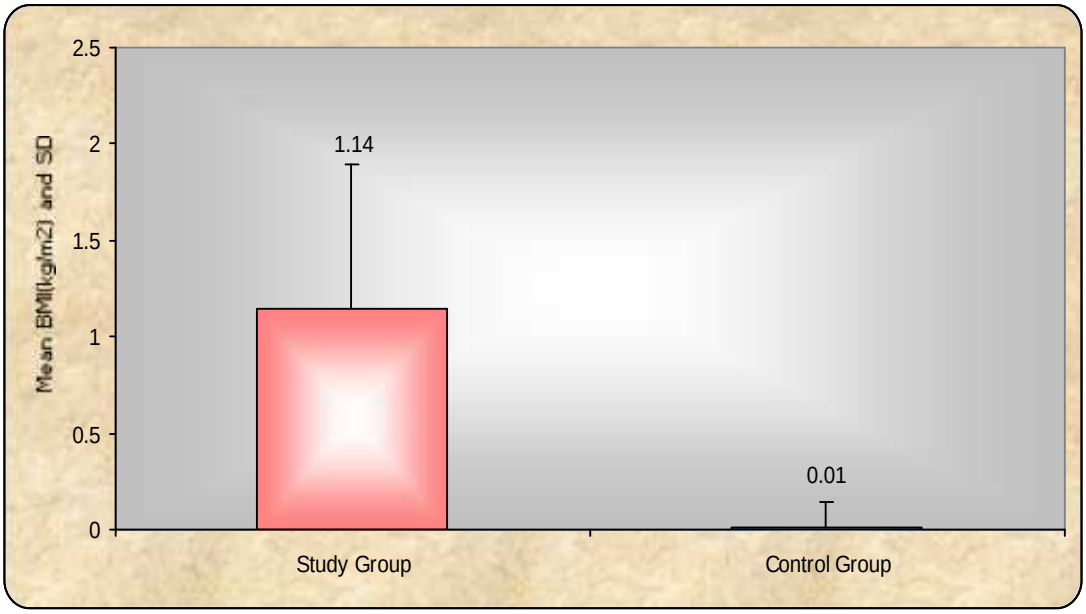


Table 20: Comparison of mean difference in Waist Circumference in two groups

Group	**Mean Difference**	**SD**	**z-value**	**p-value**
Study Group	0.12	0.49	0.95	0.34 NS,p>0.05
Control Group	0.28	1.17		

Graph 20: Comparison of mean difference in Waist Circumference in two groups

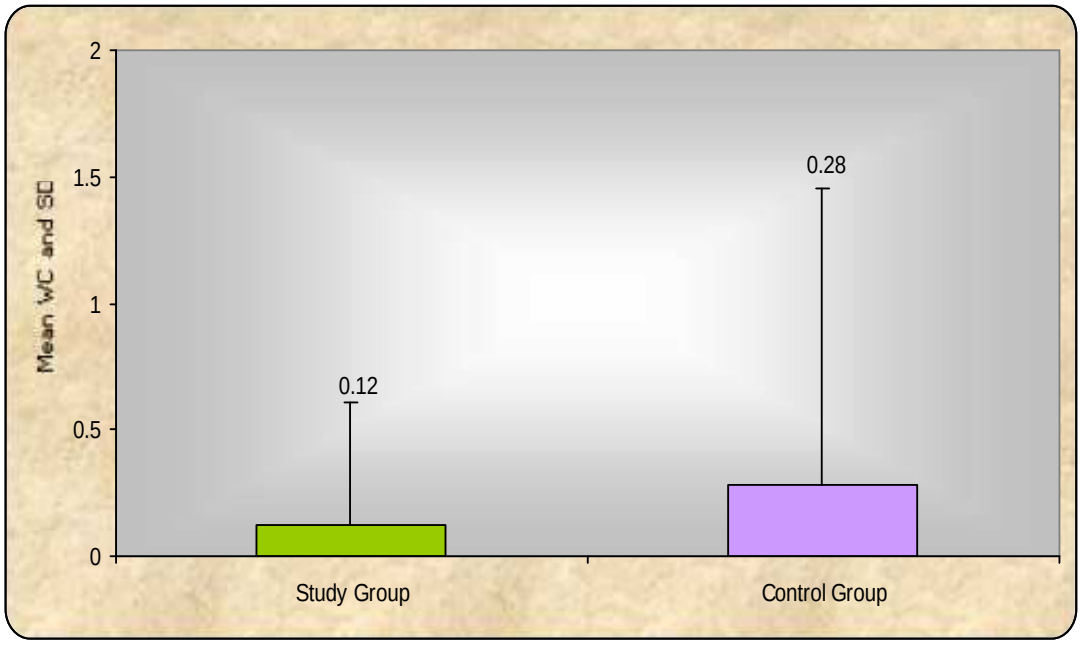


Table 21: Comparison of mean difference in SBP(mmHg))in two groups

Group	**Mean Difference**	**SD**	**z-value**	**p-value**
Study Group	3.33	5.08	4.55	0.000
Control Group	0.17	1.32		S,p<0.05

Graph 21: Comparison of mean difference in SBP(mmHg))in two groups

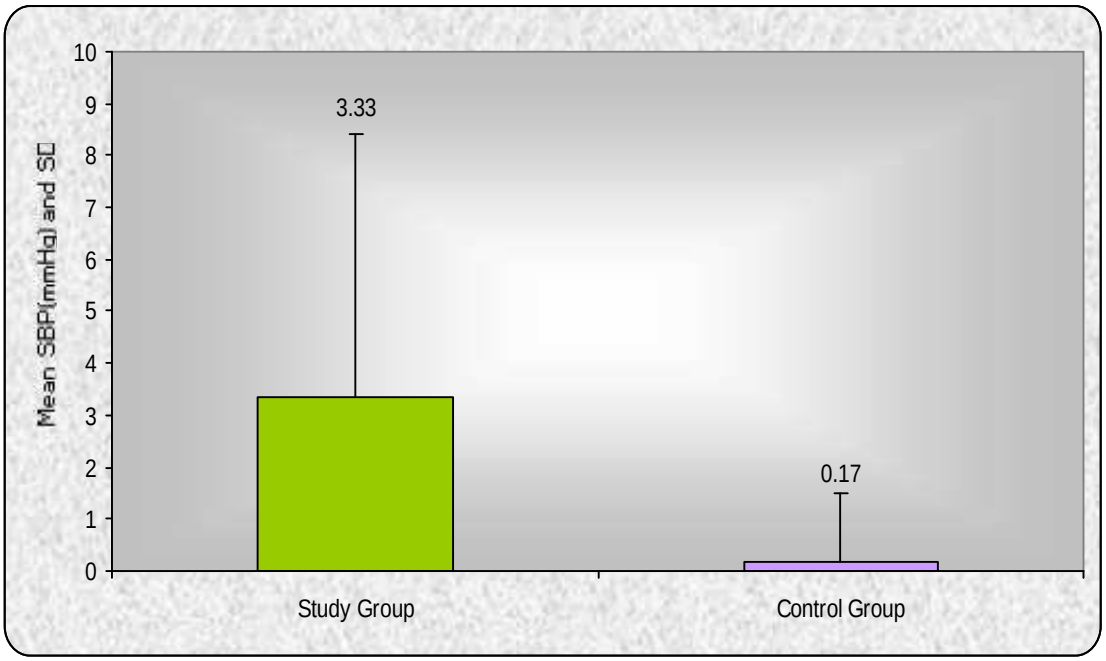


Table 22: Comparison of mean difference in DBP(mmHg))in two groups

Group	**Mean Difference**	**SD**	**z-value**	**p-value**
Study Group	1.58	3.68	2.73	0.007
Control Group	0.17	1.32		S,p<0.05

Graph 22: Comparison of mean difference in DBP(mmHg))in two groups

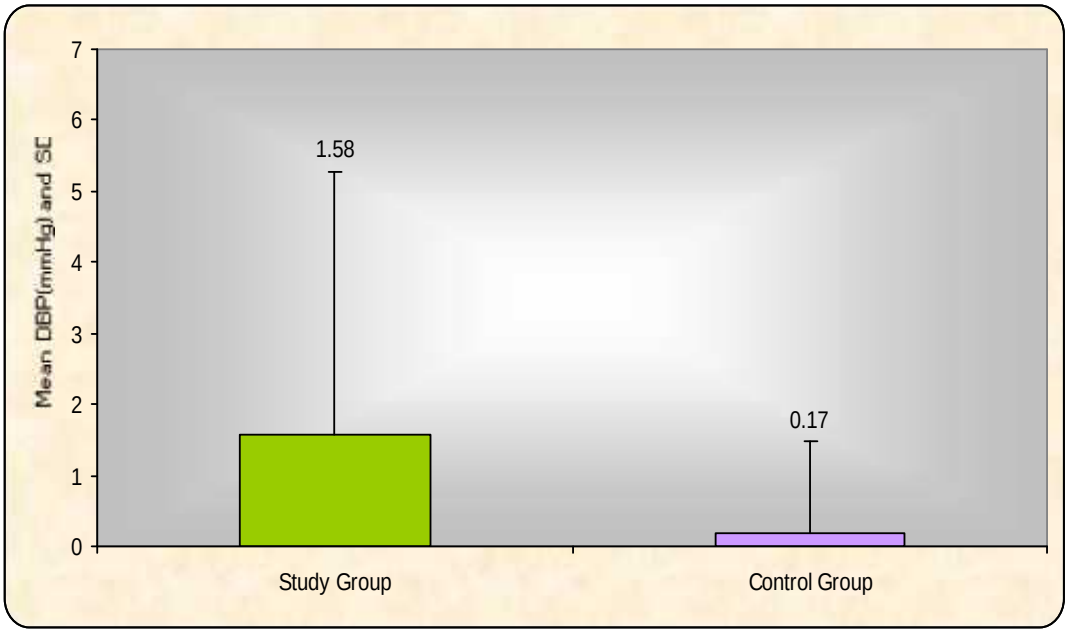


Table 23: Comparison of mean difference in FBS in two groups

Group	**Mean Difference**	**SD**	**z-value**	**p-value**
Study Group	16.06	14.57	6.63	0.000
Control Group	1.40	8.54		S,p<0.05

Graph 23: Comparison of mean difference in FBS in two groups

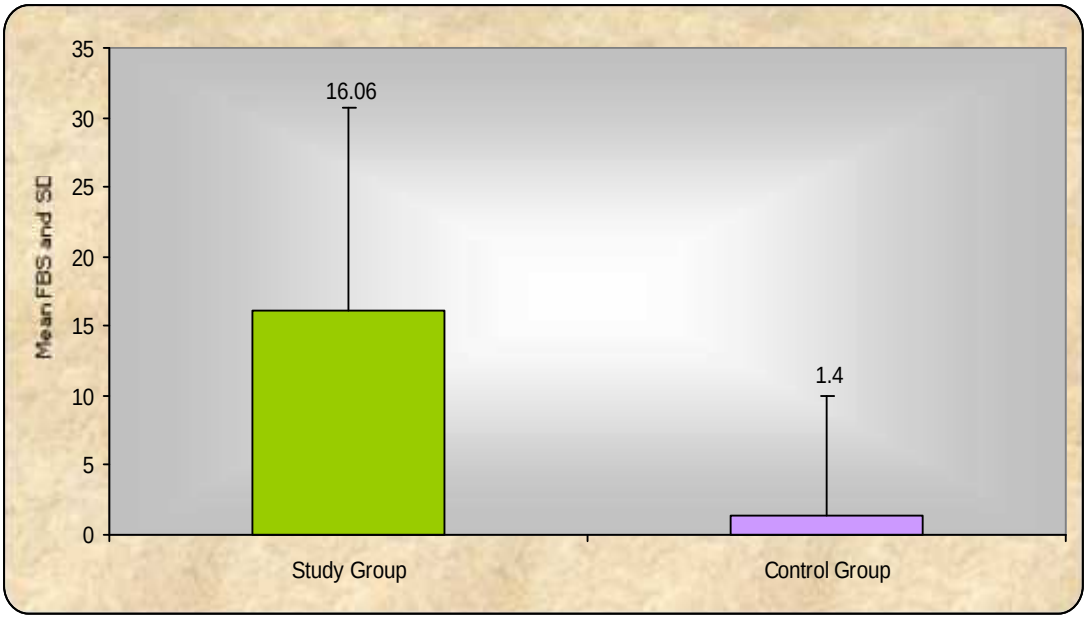


Table 24: Comparison of mean difference in PP Glucose in two groups

Group	**Mean Difference**	**SD**	**z-value**	**p-value**
Study Group	21.84	17.88	7.26	0.000 S,p<0.05
Control Group	2.56	9.50		

Graph 24: Comparison of mean difference in PP Glucose in two groups

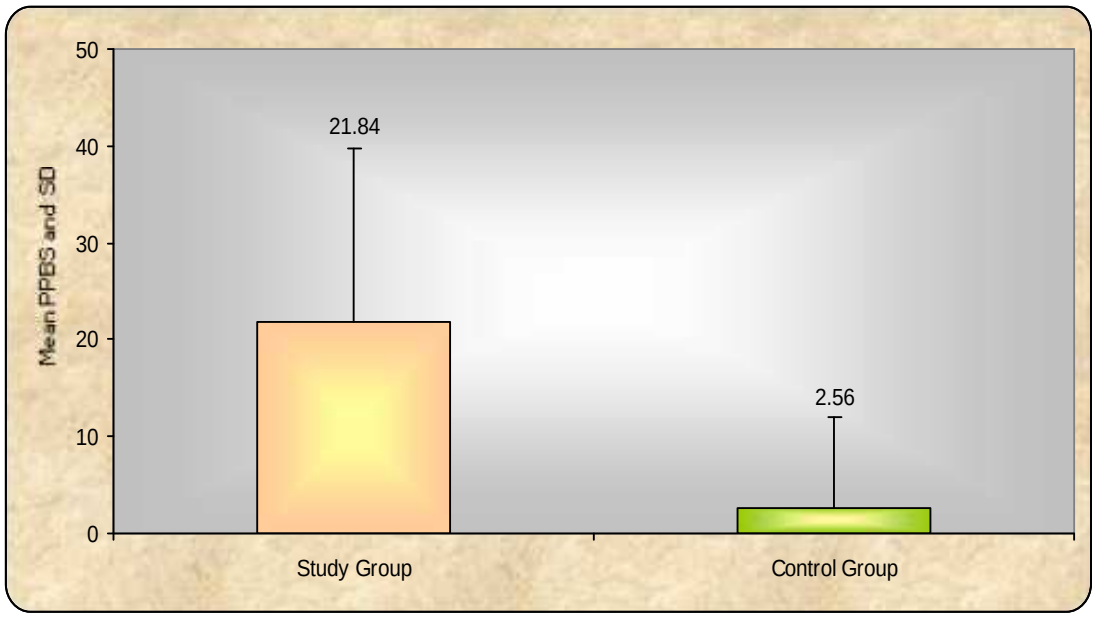


Table 25: Comparison of mean difference in WHO-QOL domain in two groups

WHO-QOL domains	**Group**	**Mean Difference**	**SD**	**z-value**	**p-value**
Domain 1	Study Group	16.68	12.14	9.22	0.000 S,p<0.05
	Control Group	1.00	5.60		
Domain 2	Study Group	25.12	16.67	10.87	0.000 S,p<0.05
	Control Group	0.33	6.70		
Domain 3	Study Group	12.34	19.54	5.23	0.000 S,p<0.05
	Control Group	1.43	7.07		
Domain 4	Study Group	24.74	14.82	11.05	0.000 S,p<0.05
	Control Group	1.10	7.89		

Graph 25: Comparison of mean difference in WHO-QOL domain in two groups

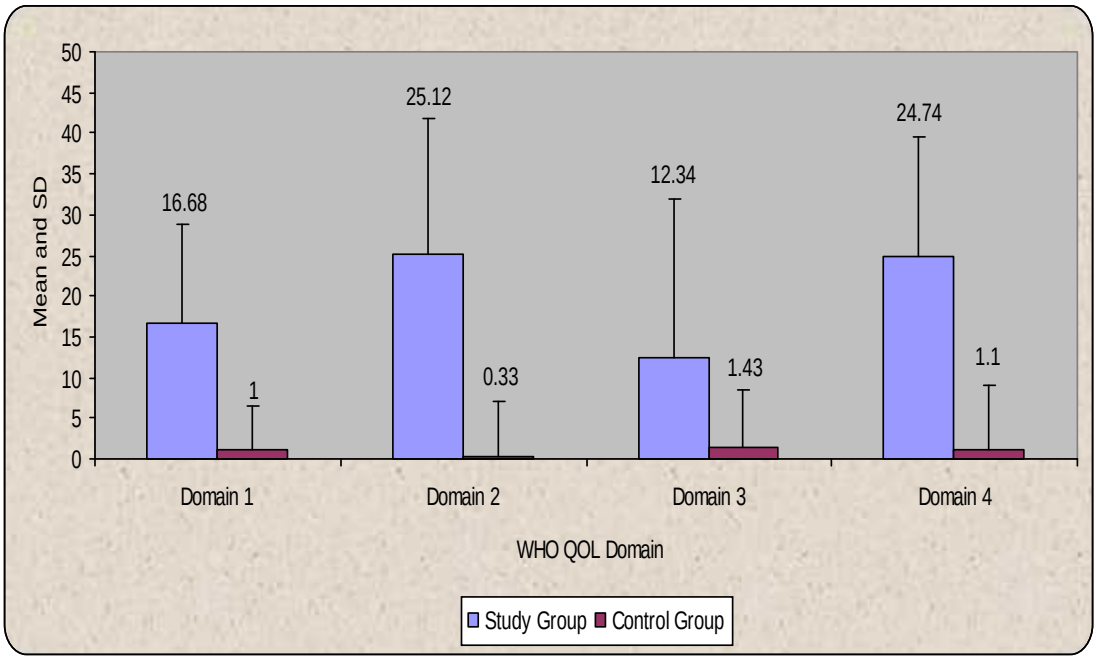


Table 26: Comparison of duration of disease in both the groups

Duration(yrs)	**Control Group**	**Study Group**	**χ^2-value**	**p-value**
0-3 yrs	29(50.88%)	44(69.84%)		
4-6 yrs	14(24.56%)	9(14.29%)		
7-9 yrs	6(10.53%)	5(7.94%)		0.019
10-12 yrs	8(14.04%)	4(6.35%)	11.76	S,p<0.05
13-15 yrs	0(0%)	1(1.59%)		
Total	57(100%)	63(100%)		
Mean±SD	3.89±3.62	2.75±3.56		

Graph 26: Comparison of duration of disease in both the groups

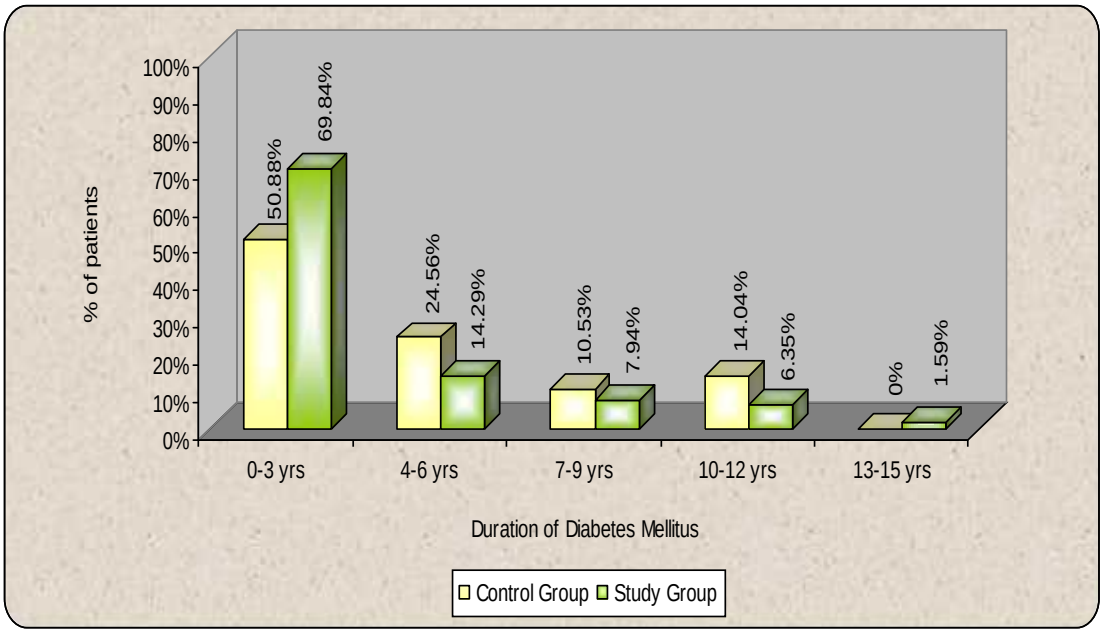


Table 27: Cox Proportional Hazard Analysis

	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	**Std. Error**	**Beta**		
FBS	-214.20	89.27		-	-
Age(yrs)	-0.44	0.29	0.157	1.503	0.139 NS,p>0.05
BMI	1.27	1.14	0.098	1.113	0.271 NS,p>0.05
Duration of DM	-2.72	1.22	0.228	2.231	0.030 S,p<0.05

	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	**Std. Error**	**Beta**		
PPBS	-429.30	128.60		-	-
Age(yrs)	-0.81	0.42	0.182	1.912	0.061 NS,p>0.05
BMI	0.99	1.64	0.048	0.604	0.548 NS,p>0.05
Duration of DM	-5.06	1.75	0.267	2.881	0.006 S,p<0.05

	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	**Std. Error**	**Beta**		
Domain 1	89.722	32.912		-	-
Age(yrs)	-0.395	0.103	-0.544	3.837	0.000 S,p<0.05
BMI	0.081	0.388	0.025	0.210	0.835 NS,p>0.05
Duration of DM	0.636	0.440	0.208	1.446	0.154 NS,p>0.05
FBS	-0.031	0.072	-0.121	0.430	0.669 NS,p>0.05
PPBS	0.015	0.050	0.093	0.301	0.765 NS,p>0.05

	Unstandardized Coefficients		**Standardized Coefficients**	**t**	**p-value**
	B	**Std. Error**	**Beta**		
Domain 2	82.509	47.517		-	-
Age(yrs)	-0.495	0.149	0.491	3.329	0.002 S,p<0.05
BMI	0.000	0.561	0.000	0.001	0.999 NS,p>0.05
Duration of DM	0.880	0.635	0.207	1.385	0.172 NS,p>0.05
FBS	-0.027	0.104	0.075	0.257	0.798 NS,p>0.05
PPBS	0.005	0.072	0.020	0.063	0.950 NS,p>0.05

	Unstandardized Coefficients		**Standardized Coefficients**	**t**	**p-value**
	B	**Std. Error**	**Beta**		
Domain 3	62.510	36.952		-	-
Age(yrs)	-0.213	0.116	-0.288	1.845	0.071 NS,p>0.05
BMI	0.419	0.436	0.124	0.961	0.341 NS,p>0.05
Duration of DM	0.359	0.494	0.115	0.728	0.470 NS,p>0.05
FBS	-0.005	0.081	-0.018	0.058	0.954 NS,p>0.05
PPBS	0.050	0.056	0.305	0.896	0.375 NS,p>0.05

	Unstandardized Coefficients		**Standardized Coefficients**	**t**	**p-value**
	B	**Std. Error**	**Beta**		
Domain 4	18.649	40.091		-	-
Age(yrs)	-0.505	0.125	0.586	4.025	0.000 S,p<0.05
BMI	-0.309	0.473	0.079	0.654	0.516 NS,p>0.05
Duration of DM	0.199	0.536	0.055	0.372	0.712 NS,p>0.05
FBS	0.007	0.088	0.023	0.078	0.938 NS,p>0.05
PPBS	-0.072	0.061	0.377	1.187	0.241 NS,p>0.05

Reliability Analysis:

	Statistics
Alpha	0.61
Reliability %	75.77
p-value	0.000, S,p<0.05

OBSERVATION

Pilot study was analyzed by using test - retest method of Reliability and Reliability is found to be significant (α ==0.61 and R = 75.77%).

Table 1 to Table 10 deals with findings of study group. Table 2 to 18 depicts findings of control group.

Comparison between 2 groups is shown from Table 19 to Table 28. Table 29 depicts the Cox proportional Hazard Analysis.

1. Age, height and weight-

The distribution of patients according to demographic characteristics in study group is seen in Table 1. The average age Height & Weight of the group was 55 years, 1.66 and 71.47 kg respectively. Table 9 shows the same in the control group were average age, height and weight were 57 years, 1.66 and 71.36 kg respectively Table 20 compares the above findings in both study and control group and shows both group were almost matche able. However the finding is statistically, non significant with $p > 0.05$.

Table 18 shows the compassion between 2 groups regarding Age, height and weight and the finding is not significant.

2. Body Mass Index (BMI)-

Table 2 shows the comparison of Body Mass Index (BMI) in study group. At pretest the value was 26.33 and at post test the value was 25.19. The z value of 11.95, corresponds to 0.00. This finding is statistically significant with $p < 0.05$. So as per Alternate hypothesis there is a significant difference in this two samples and the observed difference is not by chance. It is a true difference.

Table 10, shows comparison in control group. At pre test the mean BMI of the group was 26.29, at post test it was 26.28. The z -value was 1.00 which,

corresponds to p value of 0.32. This finding is not significant as $p > 0.05$. Table 19 shows the comparison between 2 groups. The mean difference in study group was 1.14 and control group was 0.01. This finding is statistically significant.

3. Waist circumference-

Table 3 shows the comparison of waist circumference in study group. The pretest value was 70.63 & and post test value was 70.50. The z-value was 2.05 which corresponds to p-value of 0.045, and this findings is statistically significant as $p < 0.05$. In the control group, the pretest finding was67.19 and post test value was 66.91, which is a non-significant findings with $p > 0.05$. This finding is seen from Table 11. Table 20 shows the comparison between 2 groups and the findings is statistically not significant with $p > 0.05$.

4. Systolic Blood Pressure-

The comparison of systolic Blood Pressure (SBP) in mms of Hg in study group is seen in Table 4. The mean pretest findings was 126.50 and the mean post test finding was 123.17. The z-value is 5.20 which corresponds to a significant finding as $p < 0.05$.

Table 12 shows the same comparison in control group. The mean pretest value was 120.17 and mean post test value was 120.00. The z value was 1.00 which corresponded to a p-value of 0.32 and this finding is non-significant as $p > 0.05$. Table 21 shows the comparison between 2 groups and the finding is significant with $p < 0.05$.

5. Diastolic Blood Pressure-

Table 5 shows the comparison of Diastolic Blood Pressure (DBP) in mm of Hg in the study group. The mean pretest and post test findings were 81.58 and 80.00 respectively. The comparison between the findings at pre and post test was

significant with $p < 0.05$. An insignificant comparison of DBP in control group is seen from Table 13, which shows a pretest value of 81.92 and post test value of 81.75 respectively.

Table 22 shows the comparison of mean difference of DBP between 2 groups. The z – value is 2.73 with a p – value of 0.007 and this finding is statistically significant ($p < 0.05$).

6. Fasting Blood sugar-

Table 6 shows the comparison of Fasting Blood Sugar (FBS) in study group. The pretest mean value is seen as 227.76 and the post test mean value as 211.69. The z value is 8.74 which correspond to a significant finding with $p < 0.05$.

Table 14 shows the comparison of FBS in the control group. The pretest mean value was 237.43 and the post test mean value was 236.03. The z-value was 1.24 which corresponded to a p-value of 0.22 and this comparison is statistically insignificant as $p > 0.05$. Table 23 shows the comparison between 2 groups and the finding is statistically significant ($p < 0.05$)

7. Postprandial Blood Sugar-

The post prandial blood sugar of study group is depicted in Table 7. It shows a pretest mean value of 372.73 and a post test mean value of 350.88. The z value was 9.69 which tallied to a test of significance with $p < 0.05$. Table 15 shows the same comparison in the control group. An insignificant finding ($p > 0.05$) is seen with a pretest mean value of 393.57 and a post test mean value of 391.01 respectively. Table 24 shows a significant finding between the 2 groups.

8. WHO-QOL Domains-

Table 8 shows the comparison of World Health Organization- Quality of Life (WHO-QOL) domains in study group. Domain 1 showed a pre-test mean value of 53.50 and post test mean value of 70.19. The z -value for this comparison was 10 which corresponded to a statistically significant p finding ($p < 0.05$).

In Domain 2 the pretest mean value was 42.79 and post test mean value was 67.92. The z-value was 11.96 and this comparative finding is statistically significant ($p < 0.05$)

Domain 3 showed a pretest mean value of 57.95 and post test mean value of 70.30. The z- value was 5.01 and this finding is statistically significant with $p < 0.05$.

In Domain 4, the pretest mean value was 35.87 and post term mean value was 60.61 with z- value at 13.24. This is a significant statistical finding ($p < 0.05$).

Table 16 shows the comparison of WHO – QOL domain in control group. Domain I shows a pre-test mean value of 49.38 and post test mean value of 50.38. with z value at 1.34. In Domain 2, the pretest and post test mean finding is 37.66 and 38.00 respectively. The z - value of this domain finding is 0.37 which corresponds to a p-value of 0.70. Domain 3 shows a pretest mean value of 52.40 and post test mean value of 50.96. The z value is 1.53 which tallies to a p value of 0.13. Domain 4 shows a pretest and post test mean value of 37.26 and 38.36 respectively. The z value is 1.06 which corresponds to a p value of 0.29. All findings of WHO – QOL domain in control group are statistically insignificant with $p > 0.05$.

Table 25 shows the comparison of mean difference in WHO –QOL domain in two groups. The comparative findings in the entire 4 domain is statistically significant with $p < 0.05$.

9. Medication-

Table 17 shows the distribution of patients according to medication in both the groups. The study shows a significant finding in relation to Aten tab when comparing both the groups. The x2 value was 4.91 which corresponded to a p – value of 0.02. The rest of the medication namely Actos, Metformin and Alog showed a insignificant finding when both groups were compared.

10. Duration of Medication-

When duration of medication intake was compared in between the groups, it was found that the maximum number of patients were in the range of 0 -3 years. This finding is seen from Table 26. The comparative findings seen in this table is statistically significant with $p < 0.05$.

11. Correlation of co-variate with Fixed predictor variable-

Table 27 shows the semi parametric Cox proportional Hazard analysis. This test allows analyzing the effect of several risk factors on fixed variable. The probability of the end point like any events of interest (recurrence of disease) is called the hazard. (or risk) This test assumes that the effects of different variable on survival are constant over time. The principle of this test is to link the survival time of an individual to covariates. This table shows which covariate has the most important impact on the fixed predictor variables. Out of several independent parameters which are correlated with FBS by using Cox proportional hazard analysis, only duration of diabetes mellitus is significantly correlated with FBS

and PPBS. Similarly, age in years is significantly correlated with Domains 1, 2, and 4.

DISCUSSION

Observational studies have provided firm evidence that multiple life style intervention decreases the risk of type 2 diabetes.

In this study the average age of subjects in the study group was 55 years and in the control group was 57 years. F. Eriksson & F. Lindgarde in their study selected diabetic Malmo male patients in the age group of 47-49 years. (101) Similarly Jaana Lindstrom, Anne Louheranta all had middle aged subject with impaired glucose tolerance (IGT) in their study (106). Ramachandran A, Snehalatha C et al too had subject with IGT in the mean age of 45.9 ± 5.7 years (111). Janna Lindstrom, Markku Peltonen et al in their study had middle age volunteers with IGT , which is in line with our study (112). Also, Mayur Patel, Yash Patel et al conducted a study on type 2 diabetic patients in the age group of 47.7 ± 10.9 years. (116). Like our study, Evans,Jennifer. L in their study evaluated T2 DM adults in the age group of 30-64 years. (131). Bosic- Zivanovic D, Medic-Stojanoska M et al of Serbia conducted a study involving T2DM patients in the age group of 40-80 years (144). An Indian study conducted by Harlsh Kumar Srinivas, Mahesh Ventakesha et al had T2DM males in the age group of 59.56 ± 9.64 and T2DM females in the age of group of 60.90 ± 7.51 as subject of their study. (149). Janna Lindstrom et al (2003) had middle aged subjects in their DPS study. (106).

The Body mass index (BMI) in the control group (Table 10) remained almost same at post test (26.28) whereas the post test finding in the study group showed a decline from 26.33 to 25.19. Our finding correlate to the studies of Knowler WC, Barrett -Connor E et al. W.K. Grylls, J.E. Mckenzie et al, Oksana. A. Matvienko et

al, Frank B. Hu, Prabha Shrestha and Laxmi Ghimire, Gregg. EW, Chen. H et al, Evans, Jennifer L, and Duck-Chul Leu , Ihyeok Park et al.

In the year 2002, Knowler WC, Barnett-Connor et al in their study had subjects with mean BMI of 34.0. After 2.8 Years of follow up, they found that life style intervention was more effective than metformin in reducing the incidence of diabetes in persons at high risk. (120) W.K.Grylls et al (2003) investigated the relations between life style factors (diet and exercise), glycated haemoglobin (HB A_1C) and BMI in older adults with diabetes. For females they found a 14% reduction in BMI while for males the reduction was only 5%. Also BMI decreased in age. They concluded that with increase in physical activity and by reducing energy from dietary sucrose there is promotion of weight control, specially in females. (121) Oksana A. Matvienko et al (2009) in their study had a sample of 29 T2DM patients who completed a 12 month behavior modification intervention to a achieve and maintain at least 7% weight loss and become more active. At 6 and 12 months of post test, 39% and 56% of patients had lost ≥5 % of their weight. The mean weight loss at 12 months was 6%. They concluded that weight related findings of this study were comparable with those of DPP (Diabetes Prevention Programme), and that implementation of DPP curriculum in a nonclinical setting can help some adults at risk for or in early stages of diabetes to improve anthropometric and certain metabolic outcomes. (114). Frank B. Hu (2011) found in their review study that Asian populations tend to develop diabetes at younger ages and at lower BMI levels than Caucasians. This study concluded that to curb the exalting diabetes epidemic, primary prevention through promotion of a healthy diet and lifestyle should be a global public policy priority. (127). Prabha Shrestha et al (2012) did a review study to examine diabetes and quality of life improvements through modifying life style and

found that life style modification in relation to obesity, eating habit and physical exercise can play a major role in the prevention of diabetes. (128). Gregg. E.W et al (2012) represent ed the Look AHEAD (Action for Health in Diabetes) research group. They assessed the long term effects (up to 11.5 years) of a intensive lifestyle intervention over 4 years on cardiovascular morbidity and mortality among 5,145 overweight /obese individuals with T2DM. An analysis at 4 years showed that the percent reduction was – 4.7 % in the life style intervention group and -1.1 % in the diabetes support and education group. This meant that subjects in the intensive life style intervention group had greater weight loss than those in the diabetes support and education group at all annual assessments at years 1-4.(129,130). Evans, Jennifer L (2013) in their project evaluated the use of a lifestyle modification program me for adults with T2DM having a BMI greater than 25 kg/m2. Primary outcomes were percentage body weight lost and reported physical activity level. They found that majority of individuals lost some weight and increased their weekly physical activity levels. (131). Duck-Chul Lee, Ilhyeok Park et al examined the association of T2DM in Korean men in their study. They found that overweight and obesity were detrimental within all activity categories like men with overweight, obese I, obese II classification. Their study had 1.47, 2.05 & 3.69 times higher risk of T2DM respectively as compared to normal weight men and men with low, medium & high activity had 5%, `10% and 9% lower risk of T2DM respectively, compared with inactive men after adjustment for confounders and physical activity or body mass index for each other. They concluded that meeting the activity recommendations (medium and high activity) was beneficial at all BMI levels. (133). Also H.E. Bays, RH Chapman et al (2007) reported that in the SHIELD study BMI was 27.8 kg/m^2 and in NHANES study it was 27.9 kg/m^2 and that increased BMI was associated with

increased prevalence of DM. (123). Ramchandra. A, Snehalatha C. et al (2006) had subjects with BMI of 25.8 +_ 3.5 kg/m^2 in their study of comparison between lifestyle modifications programme and metformin. They found no added benefit from combining them. (111) . Uzung Yoon, Lai Lai Kwok et al (2012) , in their electronic database search study took into consideration BMI as secondary outcome measures. Results of 7 trials which included 25 relevant publications were indentified. This systematic review illustrated that life style intervention can have beneficial effect on the incidence of diabetes. (117).

The waist circumference of subjects in the study group showed a significant decrease from a pretest value of 70.63 to a post test value of 70.50. In our study ,this finding is in line with many researchers like Jaana Lindstorm, Markku Peltonen et al, Oksana. A. Matvienko and James. D. Hoehrs, Mayur Patel, M. Patel et al, George. A. Bray, Kathleen A. Jablonski et al, and Dharma Lindarto.

Jaana Lindstorm et al (2008) in their study compared the intervention group (lifestyle intervention) with the control group as regards to waist circumference and found the intervention to be effective in preventing T2 DM. (112). Oksana. A Matvienko et al (2009) compared waist circumference in their subjects at 6^{th} & 12^{th} month of their study and concluded that weight related findings are comparable with those of DPP which means improved anthropometric outcomes in their study helped in diabetes prevention (114). Mayur Patel et al (2011) found significant difference between Gujrati male and female subjects with respect to waist circumference. Results of higher BMI (>-25kg/m^2) was significantly associated with hypertension among T 2 DM (116). George. A. Bray et al (2008) hypothesized that greater central adiposity is related to the risk of diabetes. So they measured waist circumference of their subjects and found that visceral adipose tissue (VAT) predicted diabetes (124).

Dharma Lindarto (2007) in their study, to compare lifestyle modification programme and Metformin had waist circumference as one of the parameters. He found that both the intervention for 12 weeks improved cardiovascular risk factors (135).

Our study showed a significant decrement in the SBP and DBP in the study group whereas a nonsignificant change was seen in the control group as regards to both the parameters. Many research studies fall in line with our findings namely of Oksana. A. Matvienko et al (2009) who found that SBP showed -8.4 mm Hg and DBP showed -7.0 mm Hg which indicated a significant improvement in participants with at least 5% weight loss at 12 months of study (114) . Mayur Patel et al (2011) had BP as one of their parameters of their study which aimed to described the profile of subjects with T2DM from Gujrat, India . They found that hypertension was prevalent among T2D subjects (116). Similarly, Uzung Yoon et al (2012) studied BP as a secondary outcome measure to find out efficacy of lifestyle intervention in reducing diabetes incidence. They reported that life style interventions can have a beneficial ffect on the incidence of diabetes (117). Nidhi Gupta et al (2005) in their study found significant improvement in anxiety levels of patients of hypertension with yoga based lifestyle intervention. (134). Dharma Lindarto (2007) found significant reduction in SBP & DBP in both the groups namely the study and placebo groups after 12 weeks of lifestyle modification programme and metformin therapy (135). Patric Fleming et al (2007) had BP as one of their outcomes of interest. They found that, there was significant positive effect on these outcomes but at a smaller level and concluded that lifestyle counseling intervention appeared to be of marginal benefit. (136). Joseph. M. Pappachan et al (2011) found that lifestyle interventions are safe first line non-pharmacological measures for treatment of hypertension preventions (139). Gregory A. Nicholas et al (2013) in their study estimated the independent association between

SBP with risk of cardiovascular disease (CVD) hospitalization, as diabetes mellitus is the forerunner of CVD. They found that patients with controlled SBP had lowest rate of CVD hospitalization (140). Ruth Kalda et al (2008) in their study had BP as one of the parameters and found that patients who were less aware of their disease i.e. T2D had higher quality of life score. (147).

The findings of our study show that there is a significant decrease in fasting blood sugar (FBS) from a pretest value of 227.76 to a post test value of 211.69 in the study group respectively. Similarly in the study group the post prandial blood sugar (PPBS) showed a fall from pretest value of 372.73 to a posttest value of 350.88. A significant finding was also noted on comparison between the pretest & post test values as regards to FBS & PPBS. There was a slight fall in the post test values of FBS & PPBS of the control group but this finding was statistically insignificant.

This improvement in sugar levels in the study group (Lifestyle intervention group) correlates with finding of many researches namely Ziao-Ren Pan et al (1997) who found that when proportional hazard analysis was adjusted for differences in baseline BMI and fasting glucose, the diet, exercise and diet-plus-exercise interventions were associated with 31% and 42% reductions in risk of developing diabetes, respectively (103). Jaana Lindstrom et al (2003) in their study named as "Finish Diabetes Prevention Study". (DPS) found that the intensive lifestyle intervention produced long term beneficial changes in biochemical parameters namely plasma glucose and reduced diabetes risk (106). Marco Mensink et al (2003) found in their study that lifestyle interventions improved glucose tolerance, even in less active population. This result was found after a 2 -hour combined diet and physical activity intervention programme, on glucose tolerance, in Dutch subjects.(107). Kazue Yamaoka et al (2005) in their met analysis of RCT'S on efficacy of Lifestyle

education to prevent T2DM, found that the lifestyle intervention reduced 2-4 plasma glucose by 0.84 mmol/L (95%CI 0.39-1.29) compared with the control group. They concluded that lifestyle education was effective for reducing both 2-n. plasma glucose and RR (relative risk) in high risk individuals and may be a useful tool in preventing diabetes. (108). Lindstrom. J. et al (2006) undertook a lifestyle intervention study for diabetes as a follow up of the DPS. After 4 years of intervention, they found that the incidence of T2DM was 4.3 & 7.4 per 100 person's years in the intervention and control group, indicating 43% reduction in relative risk. The participants were followed further for 3 years with no interventions and found that the beneficial lifestyle changes achieved by the participants in the intervention group were maintained after the discontinuation of the intervention, indicating 36% reduction in relative risk (110). Ramachandran. A.et al (2006) found that the progression of impaired glucose tolerance (IGT) to diabetes is high in native Asian Indians, who were younger, leaner and more insulin resistant than the multiethnic American, Finnish and Chinese populations. They found that both LSM (Life style – modification) and metformin (MET) significantly reduced the incidence of diabetes in Asian Indians and there is no added benefit from combining them (111). Jaana Lindstrom et al (2008) analyzed the interaction between the intervention assignment namely intensive lifestyle intervention and baseline risk factors on diabetes risk. Diabetes status was assessed out annually with repeated oral glucose tolerance testing and found that the intervention was most effective among the oldest individuals and that high risk groups were most likely to benefit from lifestyle intervention to prevent T2DM.(112). Li G, Zhang P et al (2008) did a 20 year follow up study to see the Long Term effect of lifestyle intervention to prevent Diabetes in China. This was called a China Da Qing Diabetes Prevention study. Compared with control diabetes

participants, those in the combined LSM groups had a 51% lower incidence of diabetes during the active intervention period and a 43% lower incidence over the 20 year period.They concluded that LSM intervention over 6 years can prevent or delay diabetes for up to 14 years after the active intervention, (113). Oksana. A.Matvienko et al (2009), conducted a study on 29 T2D patients. After 12 months of behavior modification intervention which aimed to achieve and maintain at least 7% weight loss, found that there was improvement in fasting glucose(-12%) in participants with at least 5% weight loss. They concluded that stages of diabetes, improve metabolic outcomes like plasma sugar (114). Gong Q. et al (2011) conducted a RCT of a 6 years lifestyle intervention in impaired glucose tolerance on diabetes related micro vascular complications. This was a follow up of "China Da Qing Diabetes prevention outcome study". They found that LSM intervention for 6 years in IGT was associated with a 47% reduction in retinopathy over a 20 year interval; which was primarily due to the reduced incidence of diabetes in the intervention group (115). Uzung Yoon et al (2012) reported the result of 7 trials on efficacy of lifestyle intervention in reducing diabetes incidence in patients with impaired glucose tolerance. They reported the ARR and RRR of different studies as follows-

(1) Indian Study ARR (Absolute Relative risk) = 16%, RRR =29 %(P=0.018),

(2) Japan: ARR = 6.3%, RRR = 65% ($p<0.001$)

(3) Sweden ARR = 4%, RRR = 25 %,(p= not significant),

(4) Da Qing ARR= 15%, RRR= 32% ($p<0.05$),

(5) SLIM: ARR = 20%, RRR = 53% (p= 0.025),

(6) DPP : ARR = 15% , RRR = 58% (significant) and

(7) DPS : ARR= 12 % , RRR = 52% (significant).Considering the heterogeneity in LSM interventions and follow up time, the systematic review concluded that LSM can have a beneficial effect on the incidence of diabetes. (117).

Dharma Lindarto (2007) in his study found a significant improvement in fasting plasma glucose (FPG) in both the study group and control group after 12 weeks of LSM intervention & placebo therapy. (135). Wayne Katon et al (2004) found that elevated HBA_1C were associated with depression after controlling for potentially confounding variables (165).

The present study showed an improvement in all the 4 domains namely physical, mental, social and environmental in the study group. These findings were statistically significant. The findings of control group were not statistically significant. This shows the importance of the interventions given. The comparative finding in all the 4 domains, in the 2 groups, was statistically significant. On literature search , our finding correlates with the work of Rubin RR et al (1999). Richard. R. Rubin (2000), Bosic – Zivanovic D et al (2012), Hervas. A et al (2007), Sheri. L. Maddigan et al (2003), Ruth Kalda et al (2008), Prabha Shrestha et al (2012), and Harish kumar Srinivas et al (2014).

Rubin RR et al in their review study found that duration and type of diabetes are not consistently associated with quality of life, and better glycemic control is associated with better quality of life (141). Richard R.Rubin in his study found that treatment intensification in T2D from diet alone to oral agents to insulin does seem to be associated with reduced quality of life. (142). Bosic-Zivanovic D et al found in their study that diabetic subjects with co morbidity had low quality of life assessment in relation to the group without co morbidity in the domain of physical health (45.64 vs 79.66),psychological health (50.3 vs 76.86), social relations (52.97 vs 75.46) and

environmental (52.7 vs 75.06). (144). Hervas A et al conducted a study which aimed to evaluate the impact of diabetes mellitus type 2 on health related quality of life. Their study showed that these patients have a tendency to show results lower than the general population in the health concepts like Physical function, Bodily pain, General Health, Social function and Role Emotional. This study concluded that T2DM is related to a worse perception of QOL related to health, and that impact of certain diseases on the patients should not be measured only through quantification of objective clinical parameters (such as morbidity and mortality). (145). Sheri. L. Maddigan et al found in their study that individuals treated with insulin had lower scores on the vision, emotion and pain attributes of QOL than individuals who managed with oral medications and diet. Analysis of covariance was used by them to assess difference in health related QOL according to disease severity and control of blood glucose. They concluded that generic measures of health related QOL captured deficits associated with more severity of the disease in T2DM. (146). Ruth Kalda et al examined the factors that most strongly influenced the quality of life. They found that patients who were less aware of the disease had a significantly higher quality of life score.(147).

Prabha Shrestha et al through their review study suggested that healthy life style may best be achieved through public private partnership and effective strategies were required to reduce the incidence of diabetes globally. (148). Similarly Harish Kumar Srinivas et al reported in their study that mean scores of QOL with respect to physical, psychological , social and environmental domains were significantly higher among females compared to males ($p<0.01$). Logistic regression showed that increase in age & Hb A_1 C acts a independent factors to assess the QOL, and that QOL among

diabetes needs, improvement with proper treatment regimens, ensuring good glycemic control.(149).

In our study most of the subjects, in both the groups were taking Metformin tablet. Similar finding was seen in a study by Ramachandran A. et al (2006). This study had 4 groups in which Group 2 was given only metformin (MET) tablet & Group 4 was given both LSM & MET. They found that LSM and MET significantly reduced the incidence of diabetes,(111). Also a study by George A. Bray et al (2008) found that none of the body fat measurements predicted diabetes in the metformin group. (124). Few studies have been found comparing LSM and Metformin .Most of the studies using LSM as an intervention has been used in prediabetics , with the aim of preventing diabetes or postponing the onset of diabetes.

When compared between 2 groups in our study it was found that significant number of subjects was taking Aten tablet, which indicated that hypertension, was commonly associated as comorbidity with diabetes.

Maximum number of subjects in both the groups had diabetes since 3 years. This finding is statistically significant. It is known that T2DM is often detected quite late due to lack of awareness. But,this is not so in the sample of subjects which we had for our research.

The Cox proportional hazard analysis in our study showed that only duration of diabetes mellitus correlated with FBS & PPBS, which indicated that the Covariate (duration of diabetes) had the most impact on the fixed predicator variables (FBS & PPBS).

This type of statistical test has been used in the study by Ziao-Ren Pan et al (1997). They used this test to determine if the incidence of NIDDM varied by

treatment assignment and found that LSM led to a significant decrease in the incidence of diabetes.

On similar lines, our study search showed ,that the work of George A. Bray (2008) also used this test for evaluating the association between visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT) , BMI and other measures of central adiposity, as predictors of development of diabetes. They found that VAT predicted diabetes in the LSM group.

Lastly, our study showed that out of several independent parameters which were correlated with different domains of QOL, using cox proportional hazard analysis, only age in years correlated significantly with Domain 1,2 and 4 respectively, which implies a better prognosis for patients. Studies by Ruth Kalda et al (2008) showed that quality of life was most significantly affected by awareness of the complications and risk factors of diabetes and by the age, duration of the disease and BMI of the patient. This was found using logistic regression analysis. They concluded that age & BMI of the patients as well as the duration of the diabetes, all lowered the score of QOL.(147).

Mehanism of favourable response of meditation-

Virtually all forms of meditation profess to alter everyday behavior.(176).

The most impressive evidence in favour of mind-body relationship , which meditation exploits for securing health- related benefits has come from **psychoneuroimmunology**.(177).

The favourable response which we got in terms of Blood Pressure and Blood Sugar can be explained in terms of **psychophysiological coherence.** In physiology coherence means entrainment, resonance and synchronization, all of which causes

harmony in different body systems resulting in increased synchronizationbetween the two branches of the autonomic system. A shift in autonomic, increased heart- brain balance towards increased parasympathetic activity, increased heart brain synchronization and increased vascular resonance is observed. Coherence patterns of physiological activity are obtained with positive thoughts. In terms of physiological functioning, coherence causes a number of health benefits by-1. **Resetting of baroreceptor sensitivity** which improves short term blood pressure regulation. 2. **Increased cardiac output** along with increased efficiency in fluid exchange, filtration and absorption between the capillaries and tissues. 3.**increased synchronization of cells t**hroughout the body. This results in increased efficiency and metabolic energy savings in all systems of the body.(178).

An elemental physiological phenomenon called the "**relaxation response"(**RR) has been shown to produce changes similar to meditation. It is an innate physiological response that is opposite of the stress response.(179). This RR can explain the beneficial effects on QOL, BMI, FBS and PPBS.

The RR has the potential to be elicited actively, i.e. consciously (in humans), not only automatically, but by the use of various techniques such as repetitive imagination or verbalization of a word, prayer, phrase, or even repetitive muscular activity, progressive muscular relaxation, meditation, yoga and other methods.(180). With regard to the central nervous system, the **RR activates areas in the brain** responsible for emotion and memory(e,g., anterior cingulate, hippocampal formation, amygdala) and may also serve the **control of the autonomic nervous system**.(181-183).

Bernie Siegel has stated *" science teaches us that we must see in order to believe, but we must also believe in order to see. We must be receptive to possibilities*

that science has not yet grasped , or we will miss them. It is absurd not to use treatments that work, just because we don't yet understand them." (184).

Thus, we understand that reasonable evidence exists for the use of Neurobics and Sanskar remodelling in the management of T2DM.

SUMMARY

Background of study-

Diabetes Mellitus is a metabolic disorder of multiple aetiologies characterized by chronic hyperglycemia with disturbance of carbohydrate, protein and fat metabolism resulting from defects of insulin secretion, insulin action or both. 2011 National Diabetes factsheet released on 26th Jan 2011 estimates about 246 million diabetics worldwide in the year 2010 with prevalence rates of 11.3% among the adults of 20-65 age group. WHO has also anticipated that number of people with diabetes will be more than double in 2030 as a consequence of population aging and urbanization.

Epidemiology of Diabetes-

Several studies on migrant Indians across the globe have shown that Asian Indians have an increased risk for developing type 2 diabetes and related metabolic abnormalities compared to other ethnic groups.

The onset of the disease in urban Indian adults is about a decade earlier than their western counterparts and the prevalence of type 2 diabetes mellitus constitutes about 85-95% of all the diabetes in developed countries accounting for an even higher percentage in developing countries. As per WHO report, diabetes mellitus stands 4th in order of non communicable diseases which has to be tackled in a warfooting worldwide. Non-communicable diseases(NCDs) stem from a combination of modifiable and non-modifiable risk factors.

Exacerbating matters has been a shift toward more sedentary lifestyles, which has accompanied economic growth, the shift from agricultural economies to service-

based economies, and urbanization in the developing world The pathway from modifiable risk factors to NCDs often operates through what are known as intermediate risk factors" – which include overweight/obesity, elevated blood glucose, high blood pressure and high cholesterol. Secondary prevention measures can tackle most of these risk factors, such as changes in diet or physical activity or the use of medicines to control blood pressure and cholesterol, oral agents or insulin to control blood sugar and pharmacological/surgical means to control obesity. Although intervening on intermediate risk factors may be more effective (and more cost-effective) than waiting until NCDs have fully developed, treating intermediate risk factors may, in turn, be less effective (and less cost-effective) than primary prevention measures or creating favorable social and policy environments to reduce vulnerability to developing disease.

The rise in the prevalence and significance of NCDs is the result of complex interaction between health, economic growth and development, and it is strongly associated with universal trends such as ageing of the global population, rapid unplanned urbanization and the globalization of unhealthy lifestyles. In addition to the tremendous demands that these diseases place on social welfare and health systems, they also cause decreased productivity in the workplace, prolonged disability and diminished resources within families. . If the challenges imposed on countries, communities and individuals by NCDs are to be met effectively this decade, they need to be addressed by a strong multistakeholder and cross-sectoral response, meaningful changes and adequate resources.

Underlying cause of Diabetes-

Emerging research clarifies underlying causes of this pandemic of insulin resistance including our refined, nutrient poor, high glycemic load diet, sedentary lifestyle and chronic stress. Novel etiologic factors including environmental toxins, food sensitivities, hormonal dysregulation, gut microbiology, latent infections, nutrient deficiencies and abnormal gene expression provide important diagnostic considerations and avenues for therapeutic intervention. A whole systems approach based on functional medicine provides a methodology for a comprehensive approach to this life-threatening and economically crippling modern disease.

Different Trials-

There were several clinical trials, but they were usually grossly underpowered, had flaws in design and conduct, and most used antidiabetes drugs as the intervention. Luckily, firm positive results from several randomized controlled trials using lifestyle intervention have become available during recent years. The bottom line is that these recent trials have unequivocally demonstrated that it is possible to reduce the rate of progression to type 2 diabetes in high-risk individuals with intermediate hyperglycemia. Other studies have evaluated the possibility that a multifaceted treatment approach including a focus on lifestyle factors (i.e., diet and physical activity) would be more beneficial than a primary treatment focus on glycemia. A number of large-scale RCTs (i.e., Da Qing DPS, MALMO Feasibility Study, Finnish DPS, United States DPP, Indian DPP, SLIM, and Japanese DPS trials) have been performed in persons who are at risk for T2DM (overweight/obese, IGT and/or IFG) in order to evaluate lifestyle modification of diet and physical activity. Findings indicated that the combined lifestyle intervention of dietary and physical activity

relative to the education control or usual/standard- care condition produced greater risk reduction for progressing to T2DM. The Finnish Diabetes Prevention Study(DPS) was one of the first controlled, randomized studies to show that type 2 diabetes is preventable with lifestyle intervention.

Diabetes self-management education (DSME), the process of teaching people to manage their diabetes, has been considered an important part of the clinical management of diabetes since the 1930s. The goals of DSME are to optimize metabolic control and quality of life and to prevent acute and chronic complications, while keeping costs acceptable.

The research evidence of IMAGE inspired national and local authorities and health care providers all over the world to start programs and activities to prevent type 2 diabetes and its complications. Based on the experiences from the clinical trials, as well as from the "real world" implementation programs, the IMAGE Study Group collated information in a systematic manner. The IMAGE deliverables include a European evidence-based guideline for the prevention of type 2 diabetes, a toolkit for the prevention of type 2 diabetes in Europe, and the quality indicators for the prevention of type 2 diabetes in Europe.

Rationale of taking up this study-

Recent findings from cardiovascular prevention trials among patients with longstanding diabetes cast doubt on the benefits of very intensive treatment of glycaemia but do highlight the benefits of treatment early in the course of the disease. Evidence suggests that weight loss and physical activity are the main drivers for diabetes prevention. However, a major challenge is how to implement these findings into "real world" healthcare systems. The resource intensive interventions used in

clinical efficacy trials need to be translated into pragmatic, more affordable, programmes, that can be delivered not only in routine clinical practice but also that retain their effectiveness. Despite advances in Diabetes management, many people with diabetes have less than optimal metabolic control and continue to suffer from preventable complications. The gap between optimal evidence-based medicine and actual practice can be great, dependent not only on the ability of the clinician to make changes in practice patterns but also on the central role of the patient in implementing optimal management plans in daily life. It is almost impossible to overestimate the impact of the DCCT on diabetes treatment and research. Seemingly overnight, large numbers of patients were expected to follow a demanding, intensive treatment regimen that previously had been recommended only for those who were most highly motivated and diligent in their diabetes self-management. Health care practitioners were also expected to know how to help patients achieve these lofty treatment goals. In addition to problems in implementing intensive treatment, questions arose concerning the effects of these regimens on quality of life (QOL) for patients. Intensive regimens also posed new dilemmas for health care practitioners and patients, not the least of which was the dramatic increase in risk for episodes of severe hypoglycemia when patients attempted to lower blood glucose (BG) levels. It quickly became clear that the greatest challenge to contemporary diabetes treatment was overcoming the many psychobehavioral and social–environmental barriers to optimal self-management.

Age old Indian Health concepts-

An ancient Indian saying is “Aahar,Baivhaar and Vichar is the key to healthy living. Relating to this age old dictum one has to practice **healthy eating** (their own

diet depending upon environment culture and biodiversity), **healthy behaviour** which can be achieved by Sanskar Remodelling and **Positive thinking** which can be practiced by a technique called as Neurobics.

Concept of Neurobics and Sanskar Re-modelling-

Neurobics are mental exercises, that can enhance the brain's performance. The term neurobics was coined by late neurobiologist Lawrence Katz and Manning Rubin. Neurobics can be considered as a part of Rajyoga meditation, as this meditation involves the process of creating positive thoughts.

Our medicine has typically focused on illness, whereas energetic healing focuses on the connection of mind, body, and spirit. Sanskar is a Sanskrit word meaning “Habits” or “usual Behavior”. Repeated actions causes a habit. Nowadays , it has become a habit to think negatively. This has become a usual behaviour or sanskar. This habit of negative thinking is changed to the habit of positive thinking by the practice of Rajyoga meditation. The already formed or modelled sanskar is re-modelled by this process and hence the process can be labelled as” Sanskar Re-modelling”(SRM). As one practices SRM, adoption of self –care behaviours become achieveable.

Different trials have shown the efficacy of balanced diet and adequate exercise in achieving glycemic goals. As the disease is multifactorial, these two interventions namely diet and exercise were not sufficient to tackle the problem satisfactorily.

Aim of study-

Hence we wanted to test two new interventions namely Neurobics and SRM. Our hypothesis is that these two interventions can be of additive support in the management of diabetes.

Technicalities-

A pilot study was done 6 months prior to starting of this research work. This study was done on 20 samples. The design of the study was interventional.

This was a feasibility study to know if better diabetic control can be achieved using newer lifestyle modification programmes(LSMP) like Neurobics & Sanskar Re-modelling(SRM). The efficacy of the study was measured by observing the effects of these LSMPs on BMI, Blood Pressure, Blood sugar & WHOQOL domains. A total of 210 Diabetic patients were recruited for the study. Out of these ,90 patients did not fulfil the eligibility criteria for the study.

The study group diabetic patients were educated on Neurobics & sanskar remodelling by Professional Trainers, using power point presentations. Along with this they were also apprised of their self management as regards to Diabetes care on the lines of AADE7TM- self Care behaviour framework- This included orientation to topics like-

1. Healthy eating,2. Being Active,3. monitoring 4. Taking medications,5. Problem solving,6. Reducing risks, 7. Healthy coping.

The Diabetics in the control group were seperately oriented to the AADE7TM Self Care Behavior Framework . They were blinded to all information on Neurobics and Sanskar Re-modelling.

Program sessions were scheduled for 2hours. The study group participants were invited to the Brahmakumari Centre, Wardha to achieve complete ambience for the study. The total study duration was for 1year. Out of this total study duration, the intervention period was 6months. Orientation class as per AADE7TM was held in the Brahmakumari centre Wardha for both the group of subject on 2 seperate days. Neurobics & Sanskar Re-medelling was also taught at the centre, immediately after

the orientation class to the subject group. They were taught **neurobics** through video session by trained facilitators and to **sanskar remodelling(SRM)** through lecture by experienced Rajyoga trainers. They practised neurobics and SRM daily for 10 min in the morning and 10 min in evening. This group was reviewed in the centre every weekend for the first 3 months and after every fortnight for the last 3 months. Patients were called to Physiology department for all investigations. Patients were referred to their attending Physicians if they required medical care during the intervention.

3months was the recruitment period. 210 patients were recruited for the study. Data collection period was 3 months. All data were collected by the facilitators.

Outcome parameters-

Baseline anthropometric measurement like height and weight were taken at recruitment. Body Mass Index or BMI was calculated using the formula- weight in kg divided by height in meter square as per FEHES 62. Blood Pressure was measured manually using the standard Sphygmomanometer of Diamond, Regular model mercurial make. An average of consecutive 3 readings were taken as per FEHES 62. Blood Glucose was measured using a Glucometer namely BG03-Dr Morepen, Gluco one Blood Glucose monitoring system.

Quality of Life assessment was done using the WHOQOL –BREF, Field trial version, 1996 questionnaire. It has 30 questions which assesses 4 domains namely Physical, Mental, Social and Environmental.. All the raw scores were converted to 0-100% scale score , using the WHOQOL score chart.

Therefore the key life style outcome measures were Blood Glucose, WHOQOL domain score, Blood Pressure and Body Mass Index.

Statistical application-

Reliability test of Pilot study was calculated using test retest method.

Statistical analysis was done using descriptive and inferential statistics using Wilcoxan Signed Rank test, z-test for difference between two mean and chi square test. The chi square statistics was used to compare each life style measures according to differences in risk status and glucose tolerance at 6 months. Cox proportional Hazard Analysis was used to find out the impact of covariate on fixed predictor variable.

Findings of our study-

Pilot study was analyzed by using test - retest method of Reliability and Reliability is found to be significant (α ==0.61 and R = 75.77%).

1. *Age, height and weight-*

   The average age Height & Weight of the study group was 55 years, 1.66 and 71.47 kg respectively. Table 9 shows the same in the control group where average age, height and weight were 57 years, 1.66 and 71.36 kg respectively.

   Table 18 shows the compassion between 2 groups regarding Age, height and weight and the finding is not significant.

2. *Body Mass Index (BMI)-*

   The mean difference in study group was 1.14 and control group was 0.01. This finding is statistically significant.

3. *Waist circumference-*

   Table 3 shows the comparison of waist circumference in study group. The pretest value was 70.63 & and post test value was 70.50. In the control group, the pretest finding was 67.19 and post test value was 66.91. This finding is seen from

Table 11. Table 20 shows the comparison between 2 groups and the findings are statistically not significant with $p > 0.05$.

4. *Systolic Blood Pressure-*

The comparison of systolic Blood Pressure (SBP) in mms of Hg in study group is seen in Table 4. The mean pretest findings was 126.50 and the mean post test finding was 123.17. Table 21 shows the comparison between 2 groups and the finding is significant with $p < 0.05$.

5. *Diastolic Blood Pressure-*

Table 5 shows the comparison of Diastolic Blood Pressure (DBP) in mm of Hg in the study group. The mean pretest and post test findings were 81.58 and 80.00 respectively. The comparison between the findings at pre and post test was significant with $p < 0.05$. Table 22 shows the comparison of mean difference of DBP between 2 groups. This finding is statistically significant ($p < 0.05$).

6. *Fasting Blood sugar-*

Table 6 shows the comparison of Fasting Blood Sugar (FBS) in study group. The pretest mean value is seen as 227.76 and the post test mean value as 211.69. This was a significant finding with $p < 0.05$.

Table 23 shows the comparison between 2 groups and the finding is statistically significant ($p < 0.05$)

7. *Postprandial Blood Sugar-*

The post prandial blood sugar of study group is depicted in Table 7. It shows a pretest mean value of 372.73 and a post test mean value of 350.88. This finding is significant. Table 24 shows a significant finding between the 2 groups.

8. WHO-QOL Domains-

Table 8 shows the comparison of World Health Organization- Quality of Life (WHO-QOL) domains in study group. Domain 1 showed a pre-test mean value of 53.50 and post test mean value of 70.19.

In Domain 2 the pretest mean value was 42.79 and post test mean value was 67.92.

Domain 3 showed a pretest mean value of 57.95 and post test mean value of 70.30. In Domain 4, the pretest mean value was 35.87 and post term mean value was 60.61. All these findings were statistically significant.

Table 16 shows the comparison of WHO – QOL domain in control group.

Domain I shows a pre-test mean value of 49.38 and post test mean value of 50.38. In Domain 2, the pretest and post test mean finding is 37.66 and 38.00 respectively. Domain 3 shows a pretest mean value of 52.40 and post test mean value of 50.96. Domain 4 shows a pretest and post test mean value of 37.26 and 38.36 respectively. All findings of WHO – QOL domain in control group are statistically insignificant with $p > 0.05$.Table 25 shows the comparison of mean difference in WHO –QOL domain in two groups. The comparative findings in all the 4 domain is statistically significant with $p < 0.05$.

9. Medication-

Table 17 shows the distribution of patients according to medication in both the groups. The study shows a significant finding in relation to Aten tab when comparing both the groups.

10. Duration of Medication-

When duration of medication intake was compared in between the groups, it was found that the maximum number of patients were in the range of 0 -3 years. This significant finding is seen from Table 26.

11. Correlation of co-variate with Fixed predictor variable-

Table 27 shows the semi parametric Cox proportional Hazard analysis. Out of several independent parameters which are correlated with FBS by using Cox proportional hazard analysis, only duration of diabetes mellitus is significantly correlated with FBS and PPBS. Similarly, age in years is significantly correlated with Domains 1, 2, and 4.

Relating with other global studies-

In this study the average age of subjects in the study group was 55 years and in the control group was 57 years.

The Body mass index (BMI) in the control group (Table 10) remained almost same at post test whereas the post test finding in the study group showed a decline from 26.33 to 25.19. Our finding correlate to the studies of Knowler WC, Barrett - Connor E et al. W.K. Grylls, J.E. Mckenzie et al, Oksana. A. Matvienko et al, Frank B. Hu, Prabha Shrestha and Laxmi Ghimire, Gregg. EW, Chen. H et al, Evans, Jennifer L, and Duck-Chul Leu , Ihyeok Park et al.

The waist circumference of subjects in the study group showed a significant decrease from a pretest value of 70.63 to a post test value of 70.50. In our study ,this finding is in line with many researchers like Jaana Lindstorm, Markku Peltonen et al, Oksana. A. Matvienko and James D. Hoehrs, Mayur Patel, M. Patel et al, George A. Bray, Kathleen A. Jablonski et al, and Dharma Lindarto.

Our study showed a significant decrement in the SBP and DBP in the study group whereas a nonsignificant change was seen in the control group as regards to both the parameters. Many research studies fall in line with our findings namely of Oksana. A. Matvienko et al. . Mayur Patel et al ,Nidhi Gupta etal, Patric Fleming et al , Joseph. M. Pappachan et al ,Gregory A. Nicholas et al and Ruth Kalda et al.

The findings of our study show that there is a significant decrease in fasting blood sugar (FBS) from a pretest value of 227.76 to a post test value of 211.69 in the study group respectively. Similarly in the study group the post prandial blood sugar (PPBS) showed a fall from pretest value of 372.73 to a posttest value of 350.88. A significant finding was also noted on comparison between the pretest & post test values as regards to FBS & PPBS. There was a slight fall in the post test values of FBS & PPBS of the control group but this finding was statistically insignificant. This improvement in sugar levels in the study group (Lifestyle intervention group) correlates with finding of many researches namely Ziao-Ren Pan et al, Jaana Lindstrom et al, Marco Mensink et al, Kazue Yamaoka et al, Lindstrom. J. et al, Ramachandran. A.et al, Jaana Lindstrom et al, Li G, Zhang P et al, Oksana. A. Matvienko et al and Uzung Yoon et al.

The present study showed an improvement in all the 4 domains namely physical, mental, social and environmental in the study group. These findings were statistically significant. The findings of control group were not statistically significant. This shows the importance of the interventions given. The comparative finding in all the 4 domains, in the 2 groups, was statistically significant. On literature search , our finding correlates with the work of Rubin RR et al (1999). Richard. R. Rubin (2000), Bosic – Zivanovic D et al (2012), Hervas. A et al (2007), Sheri. L.

Maddigan et al (2003), Ruth Kalda et al (2008), Prabha Shrestha et al (2012), and Harish kumar Srinivas et al (2014).

In our study most of the subjects, in both the groups were taking Metformin tablet. Similar finding was seen in a study by Ramachandran A. et al (2006).

When compared between 2 groups in our study it was found that significant number of subjects were taking Aten tablet, which indicated that hypertension, was commonly associated as comorbidity with diabetes.

Maximum number of subjects in both the groups had diabetes since 3 years. This finding is statistically significant. It is known that T2DM is often detected quite late due to lack of awareness. But, this is not so in the sample of subjects which we had for our research.

The Cox proportional hazard analysis in our study showed that only duration of diabetes mellitus correlated with FBS & PPBS, which indicated that the Covariate (duration of diabetes) had the most impact on the fixed predicator variables (FBS & PPBS).

Lastly, our study showed that out of several independent parameters which were correlated with different domains of QOL, using cox proportional hazard analysis, only age in years correlated significantly with Domain 1,2 and 4 respectively, which implies a better prognosis for patients.

Mehanism of meditation-

Virtually all forms of meditation profess to alter everyday behavior.

The most impressive evidence in favour of mind-body relationship, which meditation exploits for securing health- related benefits has come from **psychoneuroimmunology.**

The favourable response which we got in terms of Blood Pressure and Blood Sugar can be explained in terms of **psychophysiological coherence.** An elemental physiological phenomenon called the **"relaxation response"(RR)** has been shown to produce changes similar to meditation. It is an innate physiological response that is opposite of the stress response. This RR can explain the beneficial effects on QOL, BMI, FBS and PPBS.

Thus, this study provides reasonable evidence for the use of Neurobics and Sanskar remodelling as an effective adjunct therapy in the management of T2DM.

CONCLUSION

This interventional study was undertaken to find out whether newer life style modification techniques like Neurobics and Sanskar Remodeling can bring about better glycemic control. For this study a total of 210 diabetic patients were recruited out of which finally 62 patients were included in the study group and 58 patients were included in the control group. The different parameters checked were BMI, Blood Pressure, Blood Sugar & WHOQOL domains. Outcome of the study showed that.

1. Both the study and control group had comparable age, height and weight of subjects.
2. There was a statistically significant fall in BMI in between the pre & post test findings of study group. A statistical significance was seen on comparison between two groups.
3. There was a statistically significant decrease in waist circumference in between the pretest & post test finding of the study group.
4. Comparison of SBP at pretest and post test in the study group showed a fall and this finding is statistically significant. Also the comparison between 2 groups as regards to SBP was statistically significant.
5. Similar statistically significant finding was seen with DBP, in the study group.
6. The post test value of FBS& PPBS in the study group showed a fall when compared to pretest values of both. Comparative finding between study and control group showed a statistically significant finding.
7. WHO-QOL-Bref was used to analyze the 4 domains. This study showed that intervention used for the study group caused improvement in all the 4 domains. These findings were statistically significant.

8. In this study maximum number of patients were taking Metformin Tab. A significant finding was found with Aten tablet which indicated that hypertension, as a comorbidity existed, with diabetes.
9. Our maximum number of patients had diabetes for the last 3 years, which indicated good health awareness from their side.
10. Lastly it was found that duration of diabetes mellitus correlated with FBS & PPBS and age in years correlated with Domain 1,2,& 4 respectively.

With all these findings we finally conclude that Life style modification programme used in our study like Neurobics and Sanskar Remodelling can be used in the management of diabetes with routine medications.

LIMITATIONS OF THE STUDY

1. We used Glucometer for the study. Though Plasma estimation of glucose is much acceptable but there are comparable studies which shows almost equal efficacy of both. Besides this, we found the instrument more handy as we had to travel to different place in Wardha to collect blood samples.
2. Some patients, around 58 did not give consent for the study. Probably they were not motivated. This also indicated that newer feasible interventions can be introduced, when people have the will to do so.

RECOMMENDATIONS

1. Diabetes is a preventable disease when awareness about the disease exists. Hence Educational awareness should be commonly adopted at mass levels.
2. An evidence based guidelines to be developed for prevention of T2DM in context to Indian scenario.
3. Simple, non pharmacological, cost effective techniques like Neurobics and Sanskar Remodeling should invariably be taught to public at large so as to prevent this disease from assuming epidemic proportions.
4. A e- health training portal for training of prevention managers should be launched.
5. Diabetic patients to be counseled for adopting Neurobics & Sanskar Remodeling techniques as a supplement to their routine anti diabetic medications. This adoption might cut down on their dosage of drugs and cost of treatment in the long run.

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Annexure I

INSTITUTIONAL ETHICS COMMITTEE APPROVAL

Datta Meghe Institute Of Medical Sciences

(Deemed University)

(Established under Section 3 of The UGC Act 1956 vide Notification No F-9-48/2004 - U 3 Govt of India)

NAAC Accredited Grade 'A'

INSTITUTIONAL ETHICS COMMITTEE

Regd. Office : Airey Layout, Pratap Nagar, NAGPUR -440 022, Maharashtra (India) Ph-0712-3256528/3253754 Fax-07152-2245318-E-mail-info@dmims.org website-dmims.o

Comp Office : Sawangi (Meghe), Wardha - 442 004, Maharashtra (India), Ph-07152-287701,287702,287703, Fax-07152-287714, E-mail- Medical_jvda@sancharnet.i

Ref.No.: DMIMS(DU)/IEC/2013-14/310 Date: 15.10.2013

The Institutional Ethics Committee in its meeting held on **11-10-2013** has approved the following research work proposed to be carried out at Jawaharlal Nehru Medical College & A.V.B.R.Hospital, Sawangi (Meghe), Wardha.

This approval has been granted on the assumption that the proposed work will be carried out in accordance with the ethical guidelines prescribed by Central Ethics Committee on Human Research (C.E.C.H.R.)

The details of the proposed research work approved by the committee are as under:-

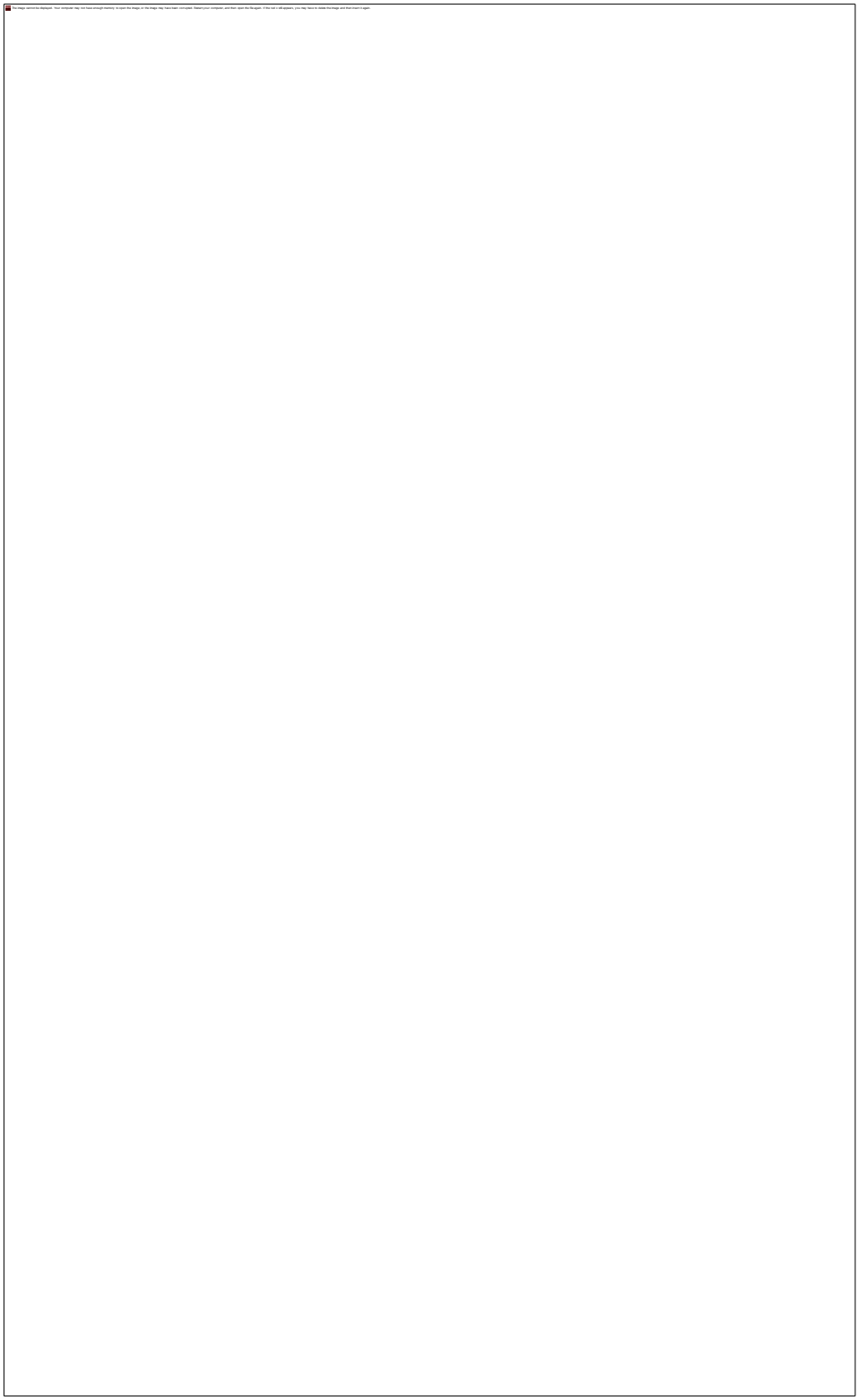
Sr. No.	Chief Investigator (Co-Investigator)	Department	Topic of the proposed research
1.	Dr. D.A. Biswas (Dr. Rucha Wagh)	Physiology	Role of Neurobics and Sanskar Remodelling in Diabetic Management.

(Dr.A.J.Anjankar)
Secretary
Institutional Ethics Committee
D.M.I.M.S. (D.U.)

Copy to :
1. Dr. D.A. Biswas, Dept. of Physiology
2. H.O.D. Physiology, J.N.M.C.

Annexure II

UNIVERSITY LETTER



Annexure III

PROFORMA

Name-_____Age_____Sex-_____

Address-_____

Phone-

Height- Weight- BMI- Waist circumference-

Dietary History-

Breakfast-

Lunch –

Dinner-

Brief History

About illness_____

_____

Clinical examination -

1 General –

2 CVS-

3 RS –

4 CNS-

Parameters-

Before intervention

1. Systolic Blood Pressure
2. Diastolic Blood Pressure
3. Fasting plasma glucose
4. Post meal plasma glucose
5. WHO -QOL findings
    a. Domain 1
    b. Domain 2
    c. Domain 3
    d. Domain 4

After intervention

Annexure IV

RESEARCH STUDY CONSENT FORM

Study Title- ***Role of Neurobics and Sanskar Remodelling in Diabetics.***

Researchers-Dr Dalia Biswas, Dr Rucha Wagh.

Background- You are being asked to take part in a research study carried out by Dr. Dalia Biswas for Phd research. This form explains the research study & your part in it, if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you dont understand. You can decide not to join the study. If you join the study , you can change your mind later or quit at any time. You will be explained carefully in the language you understand by the researcher.

This study has been approved for human subject participation by University Institutional Ethical Committee.

What is this Study about?

Diabetes Mellitus is a metabolic disorder of multiple aetiologies characterized by chronic hyperglycemia with disturbance of carbohydrate, protein and fat metabolism resulting from defects of insulin secretion, insulin action or both.(2) According to WHO, in India alone, diabetes is expected to increase from 40 million in 2006 to 79.4 million by 2030(3). The onset of the disease in urban Indian adults is about a decade earlier than their western counterparts and the prevalence of type 2 diabetes mellitus constitutes about 85-95% of all the diabetes in developed countries accounting for an even higher percentage in developing countries (4). Now it is beyond doubt that India actually has the highest number of diabetics in the world and government of India has launched the national programe for control of diabetes mellitus, cardiovascular disease and stroke in January 2008.

Neurobics is a simple exercise of visualization of cosmic colors and concentrating those colors visually on the organ involved. These neurobic is a variant of Rajyoga meditation. Therefore this study shall check the hypothesis whether neurobics, sanskar remodelling, vegeterian diet and moderate exercise has any effect in improvement of quality of life on regression of sugar levels in diabetics

What will I be asked to do if I am in this study?

- You will be tested for=

1) Fasting and post meal plasma glucose with glucometer
2) Psychological testing with WHO QOL

At pretest & at post test.

- You have to give details regarding Food chart.
- You have to Exercise daily for 30-35 min at sunrise and at sunset .
- You will practice Neurobics in the department of Physiology. Orientation class shall be taken for 7 days in dept of physiology, for 10 mins in the morning and 10 mins in evening.

Are there any benefits to me if I am in this study?

Yes. There are many benefits like-

- You get information about Life Style Modification Programmes to combat Diabetes.
- You get information about the different Diabetes tests.
- You get to know the result of these tests.
- With these information you may help others in future.

Are there any risks to me if I am in this study?

None. But certain discomfort may be there like-

- This finger stick test may be a little uncomfortable, but if it is very quick, & very little blood is drawn only a drop or two.
- As the blood pressure cuff or band tightens around the arm, this test may temporarily cause discomfort for a minute.

Qualified staff will conduct the tests. All necessary safety precautions will be taken when the tests are done. You may refuse if there is any discomfort.

Will my information be kept private?

No published results will identify you & your name will not be associated with the findings. All of your study records will be assigned the same identification number.

Are there any costs or payments for being in this study?

There will be no costs to you for taking part in this study.

Who can I talk to if I have questions?

To the Researcher.

What does my signature in this consent form mean?

1. You understand the information given to you in this form.
2. You have been able to ask the researcher questions & state any concerns.
3. The researcher has responded to your questions & concerns.
4. You believe yopu understand the research study & the potential benefits & risks that are involved.

Statement of Consent-

I give my voluntary consent to take part in this study.

Signature of participant **Date**

Name of participant

Annexure V

WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

_____

_____

[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores*	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:

* See Procedures Manual, pages 13-15

MASTER CHART
PRETEST STUDY GROUP

Sr No.	Name	Enrol no	Sex	Age-yrs	Ht-mts	wt-kgs	BMI	Waist circ	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain 4	Curr T/t	Diab since
1	Murlidhar	131070091	M	60	1.6	59	23	45	140	80	260	410	56	44	69	20	Metformin	8yrs
2	Kishore	131090052	M	40	1.8	70	22	80	110	80	210	388	69	63	75	26	Metformin no	
3	Mohan	131090128	M	45	1.7	70	24	78	120	80	250	390	38	25	31	18	Met	no
4	Laxmi	131160004	F	67	1.6	75	30	46	140	90	260	400	56	44	69	20	Actos, Met10	
5	Ramdev	131210085	M	60	1.6	69	27	48	140	80	250	400	56	44	69	20	Actos,	no
6	Madhukar	131260101	M	60	1.6	79	31	80	120	80	248	400	38	25	31	20	Met	7yrs
7	Vithal	131300027	M	65	1.8	80	25	88	120	80	200	390	56	44	69	20	Met	5yrs
8	Shrikiran	131300037	M	44	1.6	70	28	75	110	80	210	388	69	63	75	18	Met	no
9	Ramesh	131203017	M	36	1.6	75	30	80	130	80	260	400	38	25	31	26	Actos,Metno	
10	Bhaurao	1312050013M		73	1.8	75	23	80	130	80	250	400	69	63	75	20	Actos, Met10yrs	
11	Raju	1312100007M		35	1.6	75	30	82	110	80	240	410	38	25	31	26	Actos, Metno	
12	Mehboon	1312120198F		75	1.6	80	31	84	120	80	248	400	56	44	69	20	Actos,Met7yrs	
13	Ukanda	1312170186M		51	1.7	59	20	52	110	80	260	410	56	44	69	18	Actos, Met8yrs	
14	Husain	1401030007M		42	1.6	70	28	62	130	80	210	388	56	44	69	18	Met	no
15	Ramesh	140150118	M	45	1.7	67	24	45	120	80	250	390	56	44	69	31	Met	no
16	Narmada	140150118	F	70	1.6	75	30	68	130	80	260	400	38	25	31	38	Met	no
17	Ramdas	140180165	M	70	1.6	75	30	72	110	80	240	410	38	25	31	38	Actos,Metnos	
18	Shankar	140121076	M	70	1.6	69	28	52	150	80	250	400	38	25	31	38	Actos	no
19	Ulhas	140131033	M	47	1.7	59	21	40	110	80	260	410	56	44	69	31	Actos, Met3yrs	
20	Walmik	140204088	M	62	1.8	80	25	86	140	80	200	390	38	25	31	38	Met	5yrs
21	Khateswar	140213033	M	71	1.7	70	25	58	120	80	250	390	38	25	31	38	Met	9yrs
22	Kamal	1402140169F		65	1.8	80	25	88	140	80	240	370	38	25	31	38	Actos, Met2 yrsShars	
23	Sharad	140216013	F	76	1.6	80	31	78	150	90	260	400	38	25	31	38	Met	10yrs
24	Gulab	140220014	M	48	1.6	75	30	76	110	80	240	410	56	44	69	31	Met	no
25	Keshavrao	140220172M		64	1.7	70	25	45	150	90	250	400	38	25	31	38	Actos,Aten	10yrs
26	Sayyad	140304032	M	75	1.7	59	21	52	110	80	260	410	38	25	31	38	Actos,Met3yrs	
27	Ramkrsna	140304120	M	70	1.8	80	25	87	120	80	200	390	38	25	31	38	Met	5yrs

Sr No.	Name	Enrol no	Sex	Age-yrs	Ht-mts	wt-kgs	BMI	Waist circ	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain 4	Curr T/t	Diab since
28	Lakhanlal	140312120	M	76	1.6	70	28	84	120	80	210	388	38	25	31	38	Met	4yrs
29	Dharmnath	140313035	M	50	1.7	70	25	74	120	80	250	390	56	44	69	31	Met	2yrs
30	Deepak	140323008	M	40	1.8	80	25	92	110	80	240	370	69	63	75	56	Actos,Met	2yrs
31	Chindhu	140216013	M	50	1.6	80	32	90	150	90	260	400	56	44	69	31	Met	2yrs
32	Manoj	140327040	M	39	1.8	75	23	78	130	80	250	400	69	63	75	56	Met	no
33	Momad	140329027	M	65	1.6	75	30	82	140	80	240	410	38	25	31	38	Met	no
34	Meher	140404011	M	16	1.5	66	30	65	120	80	240	350	69	63	75	38	Met	3yrs
35	Sanjay	140407009	M	50	1.7	59	21	58	110	80	260	410	56	44	69	56	Actos,Met	3 yrs
36	Praful	140408077	M	28	1.8	80	25	92	120	80	200	390	69	63	75	31	Met	2yrs
37	Malti	140412015	F	67	1.7	70	25	72	120	80	250	390	38	25	31	56	Met	5yrs
38	Jagdish	140412137	M	40	1.8	80	25	89	110	80	240	370	69	63	75	38	Actos, Met	2yrs
39	Mahadeo	140415016	M	52	1.6	80	32	96	150	90	260	400	56	44	69	56	Met	2yrs
40	Durga	140423160	F	55	1.7	59	21	52	110	80	260	410	56	44	69	31	Actos,Met3yrs	
41	Chinduji	140408077	M	57	1.8	80	25	89	120	80	200	390	56	44	69	31	Met	2yrs
42	Tanbaji	140427004	M	65	1.7	70	25	75	120	80	250	390	38	25	31	31	Met	5yrs
43	Mahadeo	140429016	M	44	1.6	80	32	90	150	90	260	400	56	44	69	38	Met	2yrs
44	Manik	140430157	M	40	1.8	75	23	68	130	80	250	400	69	63	75	31	Met	no
45	Mohan	14053070	M	40	1.6	75	30	65	110	80	240	410	69	63	75	56	Met	no
46	Pankaj	140508173	M	20	1.5	66	30	56	120	80	240	350	69	63	75	56	Met	no
47	Deorao	140509015	F	82	1.7	59	21	66	150	80	260	410	38	25	31	38	Actos,Met	8yrs
48	Ramesh	140408077	F	55	1.8	80	25	94	120	80	200	390	56	44	69	31	Met	2yrs
49	Kusum	140425082	F	75	1.6	70	28	68	140	80	210	388	38	25	31	38	Met	4yrs
50	Ramdas	140427025	M	65	1.8	80	25	85	110	80	240	370	38	25	31	38	Actos,Met	3yrs
51	Manik	140430157	M	40	1.8	75	23	64	130	80	250	400	69	63	75	56	Met	no
52	Raju	140503070	M	48	1.6	75	30	68	110	80	240	410	56	44	69	31	Met	no
53	Mahant	140107071	M	60	1.5	66	30	66	120	80	240	350	56	44	69	31	Met	no
54	Momhad	1311900158	M	52	1.8	80	25	92	120	80	200	390	56	44	69	31	Met	2yrs
55	Dinesh	131104081	M	25	1.8	70	22	52	110	80	240	370	69	63	75	56	Actos,Met	no
56	Purosotam	a	M	57	1.6	62	25	56	120	80	118	212	69	63	75	56	Met	3yrs
57	Nilkanth	b	M	64	1.8	79	25	65	120	70	115	150	69	63	75	56	Met	1yr

Sr No.	Name	Enrol no	Sex	Age-yrs	Ht-mts	wt-kgs	BMI	Waist circ	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain 4	Curr T/t	Diab since
58	Sandhya	c	F	68	1.5	60	27	70	140	90	180	280	69	63	75	56	Met	5yrs
59	Manda	d	F	66	1.5	60	27	70	150	100	280	450	56	44	69	31	Met,Aten	15yrs
60	Aparna	e	F	72	1.6	70	28	65	150	90	118	160	69	63	75	56	Met	10yrs
61	Gauri	f	F	65	1.5	60	27	74	160	90	122	170	56	44	69	31	Met	11yrs
62	Niranjan	g	M	66	1.6	62	25	56	140	80	120	220	56	44	69	31	Met	6yrs
63	Sandya	h	F	58	1.5	60	27	45	130	80	100	200	56	44	69	31	Met	7yrs

MASTER CHART
POST TEST STUDY GROUP

Sr. No	Name	Enrol no	Sex	Age-yrs	Ht-mts	wt-kgs	BMI	Waist circ	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain 4	Curr T/t	Diab since
1	Murlidhar	131070091	M	60	1.6	59	23	45	130	80	240	380	56	44	69	31	Metformin	8yrs
2	Kishore	131090052	M	40	1.8	70	20	78	110	80	190	360	81	81	75	75	Metformin no	
3	Mohan	131090128	M	45	1.7	70	24	76	120	80	230	350	75	75	75	63	Met	no
4	Laxmi	131160004	F	67	1.6	70	28	46	130	80	240	380	69	69	75	63	Actos, Met10	
5	Ramdev	131210085	M	60	1.6	65	26	48	130	80	230	360	75	75	75	63	Actos,	no
6	Madhukar	131260101	M	60	1.6	70	31	80	120	80	248	400	75	75	75	63	Met	7yrs
7	Vithal	131300027	M	65	1.8	76	23	88	120	80	180	350	69	69	75	63	Met	5yrs
8	Shrikiran	131300037	M	44	1.6	65	26	75	110	80	200	360	75	75	75	63	Met	no
9	Ramesh	131203017	M	36	1.6	70	28	80	130	80	260	400	81	81	75	75	Actos,Metno	
10	Bhaurao	1312050013	M	73	1.8	72	23	80	130	80	250	400	69	63	75	31	Actos, Met10yrs	
11	Raju	1312100007	M	35	1.6	70	28	82	110	80	200	370	81	81	75	75	Actos, Metno	
12	Mehboon	1312120198	F	75	1.6	78	31	84	120	80	248	400	56	44	69	31	Actos,Met7yrs	
13	Ukanda	1312170186	M	51	1.7	56	20	52	110	80	240	380	75	75	75	63	Actos, Met8yrs	
14	Husain	1401030007	M	42	1.6	65	26	62	120	80	200	360	75	75	75	63	Met	no
15	Ramesh	140150118	M	45	1.7	65	23	45	120	80	220	350	75	75	75	63	Met	no
16	Narmada	140150118	F	70	1.6	72	29	68	130	80	240	360	69	69	75	63	Met	no
17	Ramdas	140180165	M	70	1.6	72	29	72	110	80	240	410	69	69	75	63	Actos,Metnos	
18	Shankar	140121076	M	70	1.6	65	26	52	140	80	250	400	38	25	31	63	Actos	no
19	Ulhas	140131033	M	47	1.7	55	20	40	110	80	220	390	75	75	75	63	Actos, Met3yrs	
20	Walmik	140204088	M	62	1.8	75	23	86	130	80	180	330	38	25	31	38	Met	5yrs
21	Khateswar	140213033	M	71	1.7	65	23	58	120	80	250	390	69	69	75	63	Met	9yrs
22	Kamal	1402140169	F	65	1.8	76	24	88	130	80	240	370	69	69	75	63	Actos, Met2 yrsShars	
23	Sharad	140216013	F	76	1.6	76	30	78	140	80	260	400	69	69	75	63	Met	10yrs
24	Gulab	140220014	M	48	1.6	70	28	76	110	80	210	360	75	75	63	63	Met	no
25	Keshavrao	140220172	M	64	1.7	64	23	45	140	80	210	370	69	69	75	63	Actos,Aten	10yrs
26	Sayyad	140304032	M	75	1.7	57	20	52	110	80	260	410	38	25	31	38	Actos,Met3yrs	

Sr. No	Name	Enrol no	Sex	Age-yrs	Ht-mts	wt-kgs	BMI	Waist circ	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain 4	Curr T/t	Diab since
27	Ramkrsna	140304120	M	70	1.8	75	23	87	120	80	200	390	69	69	75	63	Met	5yrs
28	Lakhanlalx	140213033	M	76	1.6	68	27	84	120	80	210	388	69	69	75	63	Met	4yrs
29	Dharmnath	140313035	M	50	1.7	65	23	74	120	80	210	360	75	75	75	63	Met	2yrs
30	Deepak	140323008	M	40	1.8	75	24	92	110	80	210	310	81	81	75	75	Actos,Met	2yrs
31	Chindhu	140216013	M	50	1.6	77	31	90	140	80	260	400	75	75	75	63	Met	2yrs
32	Manoj	140327040	M	39	1.8	70	22	78	130	80	210	380	81	81	75	75	Met	no
33	Momad	140329027	M	65	1.6	72	30	82	130	80	240	410	56	44	69	38	Met	no
34	Meher	140404011	M	16	1.5	64	29	65	120	80	220	330	69	63	75	56	Met	3yrs
35	Sanjay	140407009	M	50	1.7	55	20	58	110	80	260	410	75	75	75	63	Actos,Met	3 yrs
36	Praful	140408077	M	28	1.8	75	23	92	120	80	180	360	81	81	75	75	Met	2yrs
37	Malti	140412015	F	67	1.7	65	23	72	120	80	200	350	69	69	75	63	Met	5yrs
38	Jagdish	140412137	M	40	1.8	77	24	89	110	80	210	340	81	81	75	75	Actos, Met	2yrs
39	Mahadeo	140415016	M	52	1.6	76	30	96	140	80	260	400	75	75	75	63	Met	2yrs
40	Durga	140423160	F	55	1.7	55	20	52	110	80	260	410	75	75	75	63	Actos,Met3yrs	
41	Chinduji	140408077	M	57	1.8	78	24	89	120	80	180	350	75	75	75	63	Met	2yrs
42	Tanbaji	140427004	M	65	1.7	69	25	75	120	80	220	360	69	69	75	63	Met	5yrs
43	Mahadeo	140429016	M	44	1.6	79	32	90	140	80	240	380	75	75	75	63	Met	2yrs
44	Manik	140430157	M	40	1.8	73	23	68	130	80	200	360	81	81	75	75	Met	no
45	Mohan	14053070	M	40	1.6	70	30	65	110	80	210	380	69	63	75	56	Met	no
46	Pankaj	140508173	M	20	1.5	62	28	56	120	80	210	320	81	81	75	75	Met	no
47	Deorao	140509015	F	82	1.7	55	20	66	140	80	260	410	69	69	75	63	Actos,Met	8yrs
48	Ramesh	140408077	F	55	1.8	76	24	94	120	80	180	350	76	75	63	63	Met	2yrs
49	Kusum	140425082	F	75	1.6	66	26	68	130	80	210	388	69	69	75	63	Met	4yrs
50	Ramdas	140427025	M	65	1.8	76	24	85	110	80	210	320	38	25	31	38	Actos,Met	3yrs
51	Manik	140430157	M	40	1.8	72	23	64	130	80	240	360	69	69	75	75	Met	no
52	Raju	140503070	M	48	1.6	70	28	68	110	80	240	410	56	44	69	31	Met	no
53	Mahant	140107071	M	60	1.5	61	28	66	120	80	210	320	56	44	69	31	Met	no
54	Momhad	1311900158	M	52	1.8	77	24	92	120	80	180	360	56	44	69	31	Met	2yrs
55	Dinesh	131104081	M	25	1.8	65	20	52	110	80	210	330	81	81	75	75	Actos,Met	no

Sr. No	Name	Enrol no	Sex	Age-yrs	Ht-mts	wt-kgs	BMI	Waist circ	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain 4	Curr T/t	Diab since
56	Purosotam	a	M	57	1.6	59	24	56	120	80	115	200	75	75	63	63	Met	3yrs
57	Nilkanth	b	M	64	1.8	75	23	65	120	70	110	130	69	69	75	63	Met	1yr
58	Sandhya	c	F	68	1.5	58	26	68	140	80	160	260	81	81	75	75	Met	5yrs
59	Manda	d	F	66	1.5	60	27	68	140	90	260	410	75	75	63	63	Met,Aten	15yrs
60	Aparna	e	F	72	1.6	68	27	65	140	80	110	140	81	81	75	75	Met	10yrs
61	Gauri	f	F	65	1.5	60	27	74	140	80	116	170	75	75	63	63	Met	11yrs
62	Niranjan	g	M	66	1.6	60	24	56	130	80	110	190	75	75	63	63	Met	6yrs
63	Sandya	h	F	58	1.5	58	26	45	120	80	90	180	75	75	63	63	Met	7yrs

MASTER CHART
PRETEST CONTROL GROUP

Sr. No	Name	IPDno	Sex	Age	Ht-mts	Wt-kgs	BMI	Waist-cm	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain4	Medicatn	Diab since
1	Ganesh	140305003	M	36	1.6	69	27	44	110	80	250	400	69	63	75	56	Actos	no
2	Mohan	131203053	M	50	1.6	79	31	46	120	80	248	400	56	44	69	31	Met	7yrs
3	Gajanan	131107097	M	65	1.8	80	25	82	120	80	200	390	38	25	31	38	Met	4yrs
4	Ishwarath	131109150	M	47	1.6	65	26	46	110	80	240	370	56	44	69	31	Alog,Met	no
5	Shankar	131116004	M	51	1.8	75	23	72	130	80	250	400	56	44	69	31	Actos,Met	12yrs
6	Babanrao	131121072	M	70	1.8	75	23	74	130	90	250	400	38	25	31	38	Actos, Met	10yrs
7	Ismail	131128038	M	72	1.6	59	23	55	110	80	260	410	38	25	31	38	Met	8yrs
8	Sheikh	131130048	M	55	1.6	67	27	47	120	80	250	390	56	44	69	31	Met	no
9	Ramkrisna	131130050	M	75	1.8	80	25	86	110	80	240	370	38	25	31	38	Actos,Met	no
10	Namdev	131210188	M	65	1.6	69	28	48	110	80	250	400	38	25	31	38	Actos	no
11	Uttam	131219155	M	53	1.8	80	25	88	120	80	200	390	56	44	69	31	met	5yrs
12	Tanaji	140104029	M	48	1.8	80	25	88	110	80	240	370	56	44	69	31	Actos,Met	no
13	Rajaram	140118086	M	65	1.8	75	23	66	130	80	250	400	38	25	31	31	Actos,Met	6yrs
14	Gajanan	140128090	M	41	1.6	80	32	85	120	80	248	399	56	44	69	38	Actos,Met	7yrs
15	Sheikh	140211072	M	56	1.6	70	28	52	110	80	210	388	56	44	69	31	Met	4yrs
16	Gopal	140218023	M	68	1.8	75	23	65	130	80	250	400	38	25	31	31	Aactos,Met4yrs	
17	Sudhakar	140225029	M	60	1.6	80	32	80	120	80	248	399	56	44	69	38	Actos,Met	4yrs
18	Ramaji	140329149	M	75	1.7	70	25	56	150	90	250	400	38	25	31	38	Actos,aten15yrs	3yrs
19	Baban	140411077	M	65	1.6	70	28	68	110	80	210	388	38	25	31	38	Met	4yrs
20	Abdul	140417062	M	65	1.8	75	23	80	130	80	250	400	38	25	31	38	Met	no
21	Vitthal	140418094	M	46	1.6	75	29	64	110	80	240	410	56	44	69	31	Met	no
22	Chinduji	140418098	M	65	1.7	70	25	66	150	90	250	400	38	25	31	38	Actos,aten15yrs	
23	Ambadas	140422091	M	72	1.5	66	30	58	120	80	240	350	38	25	31	38	Met	7yrs
24	Gunwantr	140425082	M	70	1.6	70	28	76	110	80	210	388	38	25	31	38	Met	4yrs
25	Wamanrao	140427025	M	81	1.8	80	25	92	110	80	240	370	38	25	31	38	Actos,Met	10yrs
26	Ramdas	140506197	M	52	1.7	70	25	78	150	90	250	400	56	44	69	31	Actos,aten15yrs	10yrs

Sr. No	Name	IPDno	Sex	Age	Ht-mts	Wt-kgs	BMI	Waist-cm	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain4	Medicatn	Diab since
27	Jaywanta	140427004	F	65	1.7	70	25	55	120	80	250	390	38	25	31	38	Met	5yrs
28	Pandurang	140429016	M	75	1.6	80	32	89	150	90	260	400	38	25	31	38	Met,Aten	11yrs
29	Vasantrao	140503070	M	65	1.6	75	30	68	110	80	240	410	38	25	31	38	Met	no
30	Kanhailal	14052084	M	58	1.7	70	25	70	150	90	250	400	56	44	69	31	Actos,Aten10yrs	
31	Rupchand	140522097	M	59	1.5	66	30	78	120	80	240	350	56	44	69	31	Met	no
32	Waman	140522114	F	75	1.7	59	21	55	110	80	260	410	38	25	31	38	Actos,Met	8yrs
33	Varsha	140408077	F	17	1.8	80	25	84	120	80	200	390	69	63	75	56	Met	2yrs
34	Namdeo	140529050	M	40	1.6	70	28	56	110	80	210	388	69	63	75	56	Met	4yrs
35	Kusum	140427004	F	45	1.7	70	25	62	120	80	250	390	56	44	69	31	Met	5yrs
36	Ramdas	140427025	M	65	1.8	80	25	92	110	80	240	370	38	25	31	38	Actos,Met	3yrs
37	Bhimrao	140429016	M	50	1.6	80	32	90	150	90	260	400	56	44	69	31	Met	10yrs
38	Azgar	131224023	F	54	1.8	75	23	66	130	80	250	400	56	44	69	31	Met	no
39	Nanlibai	140510034	F	50	1.7	70	25	64	150	90	250	400	56	44	69	31	Actos,Aten10yrs	
40	Gautam	140522114	M	50	1.7	59	21	55	110	80	260	410	56	44	69	31	Met	5yrs
41	Rizwan	131221013	M	40	1.6	70	28	55	110	80	210	388	69	63	75	56	Met	1yr
42	Hira	140130063	M	65	1.7	70	25	54	120	80	250	390	38	25	31	38	Met	5yrs
43	Shalik	131106127	M	60	1.6	80	32	78	150	90	260	400	56	44	69	31	Met	6yrs
44	Girjabai	131224023	F	75	1.8	75	23	62	130	80	250	400	38	25	31	38	Met	1yr
45	Bhagvan	131110098	M	77	1.6	75	30	54	110	80	240	390	38	25	31	38	Met	1yr
46	Janardan	131110098	M	77	1.8	75	23	60	110	90	230	406	38	25	31	38	Met	7yrs
47	Kusum	131110254	F	47	1.5	60	27	56	110	80	240	390	56	44	69	31	Met	2yrs
48	Sahadev	1311150016	M	40	1.8	70	22	58	110	80	210	400	69	63	75	56	Met	1yr
49	Satyadev	131120011	M	60	1.5	60	27	70	110	80	240	390	56	44	69	31	Met	2yrs
50	Laxmi	131120230	F	42	1.6	65	26	55	110	80	210	400	56	44	69	31	Met	1yr
51	Babita	131129011	F	35	1.5	60	27	82	110	80	240	390	69	63	75	56	Met	1yr
52	Bhimrao	131201023	M	54	1.7	65	23	59	110	80	230	410	56	44	69	31	Met	2yrs
53	Feruman	131202003	M	70	1.6	70	28	66	110	80	240	390	38	25	31	38	Met	1yr
54	Kaushala	131202012	F	40	1.5	65	30	62	110	80	200	410	69	63	75	56	Met	3yrs
55	Ramesh	131202106	M	42	1.7	70	25	75	110	80	220	390	56	44	69	31	Met	3yrs

Sr. No	Name	IPDno	Sex	Age	Ht-mts	Wt-kgs	BMI	Waist-cm	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain4	Medicatn	Diab since
56	Ramdas	131207026	M	66	1.5	60	27	70	110	80	200	410	38	25	31	38	Met	1yr
57	Ramdas	131209021	M	62	1.7	70	25	68	110	90	220	390	38	25	31	38	Met	12yrs

MASTER CHART
POST TEST CONTROL GROUP

Sr. No	Name	IPDno	Sex	Age	Ht-mts	Wt-kgs	BMI	Waist-cm	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain4	Medicatn	Diab since
1	Ganesh	140305003	M	36	1.6	67	27	44	110	80	240	380	69	63	75	56	Actos	no
2	Mohan	131203053	M	50	1.6	79	31	46	120	80	248	400	56	44	69	31	Met	7yrs
3	Gajanan	131107097	M	65	1.8	80	25	82	120	80	220	400	38	25	31	38	Met	4yrs
4	Ishwarath	131109150	M	47	1.6	65	26	46	110	80	220	350	56	44	69	31	Alog,Met	no
5	Shankar	131116004	M	51	1.8	73	23	70	130	80	220	380	56	44	69	31	Actos,Met	12yrs
6	Babanrao	131121072	M	70	1.8	75	23	74	130	90	250	400	38	25	31	38	Actos, Met	10yrs
7	Ismail	131128038	M	72	1.6	59	23	55	110	80	260	410	38	25	31	38	Met	8yrs
8	Sheikh	131130048	M	55	1.6	67	27	47	120	80	250	390	56	44	69	31	Met	no
9	Ramkrisna	131130050	M	75	1.8	80	25	86	110	80	240	370	38	25	31	38	Actos,Met	no
10	Namdev	131210188	M	65	1.6	69	28	48	110	80	260	410	38	25	31	38	Actos	no
11	Uttam	131219155	M	53	1.8	80	25	88	120	80	200	390	56	44	69	31	met	5yrs
12	Tanaji	140104029	M	48	1.8	80	25	88	110	80	240	370	56	44	69	31	Actos,Met	no
13	Rajaram	140118086	M	65	1.8	75	23	66	130	80	250	400	38	25	31	31	Actos,Met	6yrs
14	Gajanan	140128090	M	41	1.6	80	32	85	120	80	248	399	56	44	69	38	Actos,Met	7yrs
15	Sheikh	140211072	M	56	1.6	68	27	52	110	80	200	350	56	44	69	31	Met	4yrs
16	Gopal	140218023	M	68	1.8	75	23	65	130	80	250	400	38	25	31	31	Aactos,Met4yrs	
17	Sudhakar	140225029	M	60	1.6	80	32	80	120	80	248	399	56	44	69	38	Actos,Met	4yrs
18	Ramaji	140329149	M	75	1.7	70	25	56	150	90	250	400	38	25	31	38	Actos,aten15yrs	3yrs
19	Baban	140411077	M	65	1.6	70	28	68	110	80	210	388	38	25	31	38	Met	4yrs
20	Abdul	140417062	M	65	1.8	75	23	80	130	80	260	410	38	25	31	38	Met	no
21	Vitthal	140418094	M	46	1.6	72	29	62	110	80	220	390	56	44	69	31	Met	no
22	Chinduji	140418098	M	65	1.7	70	25	66	150	90	250	400	38	25	31	38	Actos,aten15yrs	
23	Ambadas	140422091	M	72	1.5	66	30	58	120	80	240	350	38	25	31	38	Met	7yrs
24	Gunwantr	140425082	M	70	1.6	70	28	76	110	80	210	388	38	25	31	38	Met	4yrs
25	Wamanrao	140427025	M	81	1.8	80	25	92	110	80	250	380	38	25	31	38	Actos,Met	10yrs
26	Ramdas	140506197	M	52	1.7	70	25	78	150	90	250	400	56	44	69	31	Actos,aten15yrs	10yrs
27	Jaywanta	140427004	F	65	1.7	70	25	55	120	80	250	390	38	25	31	38	Met	5yrs
28	Pandurang	140429016	M	75	1.6	80	32	89	150	90	260	400	38	25	31	38	Met,Aten	11yrs

Sr. No	Name	IPDno	Sex	Age	Ht-mts	Wt-kgs	BMI	Waist-cm	SBP	DBP	Fast-glu	PP-glu	Domain1	Domain2	Domain3	Domain4	Medicatn	Diab since
29	Vasantrao	140503070	M	65	1.6	75	30	68	110	80	240	410	38	25	31	38	Met	no
30	Kanhailal	14052084	M	58	1.7	70	25	65	140	80	240	390	56	44	69	31	Actos,Aten10yrs	
31	Rupchand	140522097	M	59	1.5	66	30	78	120	80	240	350	56	44	69	31	Met	no
32	Waman	140522114	F	75	1.7	59	21	55	110	80	260	410	38	25	31	38	Actos,Met	8yrs
33	Varsha	140408077	F	17	1.8	80	25	84	120	80	200	390	69	63	75	56	Met	2yrs
34	Namdeo	140529050	M	40	1.6	70	28	56	110	80	200	360	69	63	75	56	Met	4yrs
35	Kusum	140427004	F	45	1.7	70	25	62	120	80	250	390	56	44	69	31	Met	5yrs
36	Ramdas	140427025	M	65	1.8	80	25	92	110	80	240	370	38	25	31	38	Actos,Met	3yrs
37	Bhimrao	140429016	M	50	1.6	80	32	90	150	90	260	400	56	44	69	31	Met	10yrs
38	Azgar	131224023	F	54	1.8	75	23	66	130	80	230	390	56	44	69	31	Met	no
39	Nanlibai	140510034	F	50	1.7	70	25	64	150	90	250	400	56	44	69	31	Actos,Aten10yrs	
40	Gautam	140522114	M	50	1.7	59	21	55	110	80	260	410	56	44	69	31	Met	5yrs
41	Rizwan	131221013	M	40	1.6	70	28	55	110	80	210	388	69	63	75	56	Met	1yr
42	Hira	140130063	M	65	1.7	70	25	54	120	80	250	390	38	25	31	38	Met	5yrs
43	Shalik	131106127	M	60	1.6	80	32	78	150	90	260	400	56	44	69	31	Met	6yrs
44	Girjabai	131224023	F	75	1.8	75	23	62	130	80	250	400	38	25	31	38	Met	1yr
45	Bhagvan	131110098	M	77	1.6	75	30	54	110	80	260	400	38	25	31	38	Met	1yr
46	Janardan	131110098	M	77	1.8	75	23	60	110	90	230	406	38	25	31	38	Met	7yrs
47	Kusum	131110254	F	47	1.5	60	27	56	110	80	240	390	56	44	69	31	Met	2yrs
48	Sahadev	1311150016	M	40	1.8	70	22	58	110	80	200	380	69	63	75	56	Met	1yr
49	Satyadev	131120011	M	60	1.5	60	27	70	110	80	240	390	56	44	69	31	Met	2yrs
50	Laxmi	131120230	F	42	1.6	65	26	55	110	80	210	400	56	44	69	31	Met	1yr
51	Babita	131129011	F	35	1.5	60	27	75	110	80	220	370	69	63	75	56	Met	1yr
52	Bhimrao	131201023	M	54	1.7	65	23	59	110	80	230	410	56	44	69	31	Met	2yrs
53	Feruman	131202003	M	70	1.6	70	28	66	110	80	240	390	38	25	31	38	Met	1yr
54	Kaushala	131202012	F	40	1.5	65	30	62	110	80	200	410	69	63	75	56	Met	3yrs
55	Ramesh	131202106	M	42	1.7	70	25	75	110	80	230	400	56	44	69	31	Met	3yrs
56	Ramdas	131207026	M	66	1.5	60	27	70	110	80	200	410	38	25	31	38	Met	1yr
57	Ramdas	131209021	M	62	1.7	70	25	68	110	90	220	390	38	25	31	38	Met	12yrs