"A STUDY OF LIFESTYLE INTERVENTIONS IN PATIENTS WITH TYPE2 DIABETES MELLITUS"

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ABSTRACT

Multiple studies provide evidence that diabetes nutrition therapy is effective for improving glycemic control and other metabolic outcomes. Because it reflects average glycemia over several months, hemoglobin A1c (HbA1c) is used to assess glycemic control. Overweight and obesity are common health problems in persons at risk for and with type 2 diabetes. Weight loss is also frequently recommended as the solution to improve glycemic control. This is a follow-up study to assess the impact of lifestyle intervention on clinical risk factors such as glycemic control (HbA1c) and weight in patients within Ahmedabad over a period of 3 months. In this research work we showed to evaluate the effects of lifestyle modifications, such as diet (Medical Nutritional Therapy), exercise (Physical Activity) and education on patients with type2 diabetes. During the study, 51 numbers of patients with T2DM were involved. Before screening, all enrolled participants were interviewed if they were wholly prepared to adhere for the interventions. The target population eligible to the lifestyle intervention trail was composed of men and women (non-pregnant), required group to be of age between 40 and 60 years, be resident within the Ahmedabad, have been diagnosed with type 2 diabetes not more than a year before study entry, and have persistent unsatisfactory glycemic control defined as HbA1c levels ≥ 11 %. This was a three-month intervention study based on statistical analysis.
for Medical Nutrition Therapy (MNT) and Physical Activity (PA) conducted with previously inactive 51 T2DM participants. Averaged across three months of follow-up study in the Ahmedabad, T2DM participants had great improvements in their Glycemic control (5.37 % decreases in HbA1c). Weight reduction was observed with greater improvements in this lifestyle intervention study (5.40 % decrease). Medical Nutritional Therapy (MNT) and Physical Activity (PA) are successful interventions in achieving declines in HbA1c and weight. Therefore, T2DM patients should be stimulated to participate in intervention programs. Lifestyle Interventions (LI) can produce and maintain significant weight losses and improvements in fitness in individuals with type 2 diabetes.

KEYWORDS: HbA1c, T2DM, Lifestyle Intervention, Nutritional Therapy, Physical Activity.

INTRODUCTION
Diabetes is a major silent killer worldwide. Diabetes is a disorder in which the body does not make or correctly use insulin. Our body needs insulin to help turn the food we eat into the energy and energy reserves that body needs to function properly. When insulin is out of balance, whole body is out of balance. It is a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects aforementioned. Diabetes is broken down into different types, with the most common forms being type 1 and type 2 diabetes. Some women also get diabetes when they become pregnant; this is called gestational diabetes. There are some other types of diabetes, which can be caused by genetic defects, diseases such as cystic fibrosis, organ transplantation, or AIDS treatment. In fact, there are more than ten different forms of diabetes. These include processes which destroy the beta cells of the pancreas with consequent insulin deficiency, and others that result in resistance to insulin action. Diabetes mellitus or type 2 diabetes, is one of the major non-communicable disease (NCD) and fastest growing public health problems in the world, is a condition difficult to treat and expensive to manage. The worldwide picture of diabetes is not much better either, with 387 million people with confirmed diabetes according to the latest census13. According to the 2014 estimate; the prevalence of diabetes in the world was 9%, among adults aged 18 years or older. It is projected that by the year 2035, those affected by diabetes will be around 592 million. The population with type 2 diabetes continues to increase worldwide. Among the total diabetes patients, 77% live in low- and middle-income countries and 40–49-year olds have the largest
number of people of any group. It is estimated that as many as 179 million people remain undiagnosed, for various reasons, but may be affected by diabetes.

Every seven seconds, diabetes causes the death of an individual worldwide, and in 2014 alone, 4.9 million deaths were attributed to diabetes with 80% of deaths related to diabetes reported from low- and middle-income countries. In 2014, the overall health expenditure, as a result of diabetes, was estimated as $612 billion, which is approximately 11% of the total spending on adults. Representing the South Asia region of the world, India is home to approximately 67 million (66,847.9 million) cases of diabetes, which is about 8.6% of the total adult population (20–79 years) and continues to grow at an alarming rate (IDF ATLAS, 2015).

It is predicted that the prevalence of diabetes in adults will rise from 6.4% in 2003 to 7.7% worldwide in 2025 (Zimmet et al, 2001). One of the concerns is that T2DM, once considered predominantly a disease affecting older people has grown exponentially in young adults under 40 years of age (Dabelea, 2014). It has also been estimated that the number of diabetes sufferers in the world will double from the current value of about 190 million to 325 million during the next 25 years. (Wild, S, 2004). A total of 95% population presents with T2DM whereas only 5% are reported to have type 1 diabetes mellitus (Boulé NG et al, 2001). It has been growing dramatically with urbanization. Diabetes is one of the largest global health emergencies of the 21st century. Each year more and more people live with this condition, which can result in life-changing complications. The rise in diabetes is happening beyond our borders. In 2010, the International Diabetes Federation estimated that 285 million people worldwide have diabetes and more than 430 million people will have diabetes by 2030. Diabetes and its complications are major causes of death in most countries. This figure compares with 98.4 million people in China and 24.4 million people in the USA. The Atlas has also projected that by 2035, the number of people with diabetes will increase by 55% around the world, with south-east Asia showing a 71% increase. The numbers of people projected to have diabetes in 2035 in China, India, and the USA are 142.7 million, 109 million and 29.7 million, respectively. This number might be even higher for India, because many diabetes cases in the country remain undiagnosed.

Type 2 diabetes is the fourth or fifth leading cause of death in most developed countries and there is growing evidence that it has reached epidemic proportions in many developing and
newly industrialized countries. The lowest rates of type 2 diabetes are found in rural communities where people retain traditional lifestyles (Amos et al, 2010).

Overweight and obesity are common health problems in persons at risk for and with type 2 diabetes. Weight loss is frequently recommended as the solution to improve Glycemic control (Evert et al, 2013). In persons with prediabetes, modest amounts of weight loss and regular physical activity are very effective in preventing or delaying the onset of type 2 diabetes. (Youssef G., 2012) Physical exercise has been considered as one of the cornerstones in the treatment of diabetes mellitus along with nutrition and medication since from the past 100 years ago [Sigal RJ et al, 2001]. Throughout the world, many researchers have focused on the effect of physical exercise in T2DM with regard to its action, impact on laboratory parameters and organ damage either in the form of in vivo studies or clinical studies.

The goals of diabetes nutrition therapy are nutrition interventions that promote healthy eating and assist in achieving glucose, lipid, and blood pressure goals (Richard D et al, 2015). Nutrition therapy interventions implemented by registered dietitians/nutritionists reduced HbA1c levels by an average of 1% to 2% (range -0.23% to -2.6%) depending on the type and duration of diabetes and the HbA1c level at implementation. For example, implementation of nutrition therapy in patients with newly diagnosed type 2 diabetes and an HbA1c of ~9% resulted in a decrease of ~2%, whereas persons newly diagnosed with HbA1c levels of ~6.6% experienced a decrease of 0.4%,6 both of which are significant and clinically meaningful (Marion et al, 2014). It’s a time of empowerment for people living with diabetes. Patients have never had so many tools and choices at their disposal. Every year, we see new technology for monitoring and treating diabetes. We also see more choices for people to manage diabetes on their own terms—whether it’s an application on a mobile phone that tracks readings or a better insulin pump for swimming laps in the pool. At the same time, scientists and health care providers are finding that tried-and-true methods in diabetes care—such as keeping blood glucose on target and maintaining a healthy weight—will help live a long life.

**STUDY FOR THE LIFESTYLE INTERVENTIONS**
In this research work we focused on clinical risk factor as Glycemic control (HbA1c) and weight in patients within Ahmedabad, Gujarat, India over a period of 3 months.
The aim of this study is to evaluate the impacts of Lifestyle Interventions, such as diet (nutritional therapy), exercise (physical activity) on patients with type 2 diabetes. Lifestyle Interventions included monitoring the two modifiable risk factors.

i) Physical Activity (PA)

ii) Medical Nutritional Therapy (MNT)

PARTICIPANTS

During the study, 95 patients with T2DM were involved. This was a three-month intervention study conducted with previously inactive 95 patients of type 2 diabetes mellitus. From the total of all patients with T2DM interviewed, 82 patients gave affirmative response to the study and showed interest. Before screening, all enrolled T2DM participants, who offered consent for the study, were spoken to if they were wholly prepared to adhere for the lifestyle interventions that included for Medical Nutrition Therapy (MNT) and Physical Activity (PA). Thus, the specific focus of this paper centered on the interventions.

The target population eligible to the lifestyle intervention trail was composed of men and women (non-pregnant), required group to be of age between 40 and 65 years, be resident within the Ahmedabad, have been diagnosed with type 2 diabetes not more than a year before study entry, and have persistent unsatisfactory glycemia control defined as HbA1c levels between 6% and 11%. As the study was aimed at lifestyle interventions, it was also crucial for participants to be overweight or obese. During participants’ clinic visits, weight was measured. Screening of participants was assisted by the doctors at the clinic too.

Exclusion criteria were pregnancy, cognitive limitations, medical reasons precluding dietary, presence of serious complications and major physical disability (incompatible with physical activity). All those who fulfilled the aforementioned criteria were screened to study with. Moreover, the patients those didn’t fall onto the inclusion criteria were excluded. Thus, there was no probability of considering randomized participants despite being diabetic and especially, T2DM. Only participants who attended 2-3 times at the clinic were eligible for the study. Study enrolment begun on 20th Jan, 2017 and was concluded by 21st April, 2017. Of the 95 patients who were potentially screened for the trial, 18 did not meet the criteria, and 6 participants showed unwillingness and were reluctant to compile the study and excluded participation. Thus, during the course of study, 71 participants responded to the recruitment effort and progressed for the intervention. After allocating for the intervention, 9 participants, did not complete the final 3-month assessment and were discontinued. Out of remaining 62
participants 7 participants discontinued the trial due to schedule conflict and 3 participants because of unknown reasons. 1 participant was excluded from data analysis because of non-compliance with the study protocol. Thus, of the 95 screened eligible patients, 51 completed the entire study including the 3-month assessment. The goal was to recruit approximately equal numbers of men and women and during the final assessment there were 23 females and 28 males. The follow-up process of patients was as shown in the Figure 1.

(Fig1. Follow up participants)

INTERVENTION
All of the patients with T2DM in the intervention study were those who were ready to undergo a three-month lifestyle modification programme composed of Medical Nutritional Therapy (MNT) and Physical Activities (PA). They were apprised with the knowledge which focused on adherence to nutritional therapy and exercise intervention. This crucial part was outstandingly executed by the doctors and dietician. Individual guidance was given during the study period. The goal was to experiment with methods for promoting individual changes in nutrition behavior (i.e., healthy diet and moderate regular physical activity).

Goals were tailored based on dietary recommendations and physical activity for people with type 2 diabetes. All patients were studied as outpatient. The recruitment started in January 2017. The intervention for participants started in April 2011, and the last case was completed
in April 2017. They were provided goals for lifestyle habits and were encouraged to employ self-monitoring. The participants’ readiness for weight loss bolstered up the study. Behavioural strategies, including self-monitoring, goal setting and problem solving were stressed. The study included SMART (smart, measurable, achievable, relevant and timed) goals for healthy diet intake, weight loss and physical activity. Strategies such as self-monitoring and goal setting were used to improve compliance with healthy lifestyle practices. Goal setting was implemented by providing the patients with guidance at the baseline visit. The telephone calls were conducted were often conducted to the participants for the information.

The participants were asked to engage in regular physical activity of moderate intensity for at least 150 minutes a week. Physical activity targets are based on the patients’ current levels of exercise. If one can’t find 30 minutes, he/she can break up the exercise into chunks—10 minutes here and there. Build up to 30 minutes gradually by the end of the study.

They were also asked to do more of aerobic exercise, yoga, pranayama. Participants need to puff to gain the benefits of exercise. Aim was moderate intensity. This means one should still be able to talk as performing exercise without becoming breathless. Changes in diet and increase in physical activity (walking, etc.) and exercise (running, cycling, etc.) are key components of the management of type 2 diabetes and guidelines recommend changes in these lifestyle characteristics for both prevention and management of the disease. (American Diabetes A., 2013)

The diet related goals were to eat healthy and not be rigid upon the body. The participants were asked to reduce carbohydrates and increase protein in their diet. Above all, they were told strictly to avoid trans-fats. Carbohydrate intake was also the dietary factor targeted for change because the monitoring of carbohydrate intake is considered a key strategy in achieving glycaemia control. Severely limit or eliminate sugar and grains in diet, especially fructose which is far more detrimental to health than any other type of sugar.

In brief, the study was designed to increase participants’ knowledge of healthy eating and physical activity, provide options and practical suggestions for safe weight loss and positive lifestyle changes, and familiarize participants with Medical Nutritional Therapy and Physical Activity.
ASSESSMENT

Eventually, a total of 51 participants gave effort for the study. The study was designed to be integrated into usual clinical practice; Therefore, all of the outcomes measures were regular tests or measurements performed during routine assessments and were abstracted from the patients’ records. During this study in Ahmedabad, the primary outcome measure included glycaemia control, HbA1c, while the secondary outcome measure was change in body weight. Results of laboratory tests performed during the first meeting were used as part of the baseline assessment of the participant's health status. Including the weight that was measured at the same time.

For study participants, all of the measures were assessed at baseline and 3 months. All of the enrolled participants attended a follow-up visit at 3-months, as a part of routine check-up for diabetes management. The individuals were recorded and analyzed for a period of 3 months. Computerized entry of data was collected from laboratory reports. The data includes patient details and is updated at each patient visit. The information and data were merged and analyzed. Eventually, all included participants’ data were collected and significant information was extracted.

Before the execution of this study, I prepared a data collection for the baseline measurements, which were collected through communication during interview. The data was also collected by clinic and home visits. The anthropometric, dietary and physical activity measures were assessed by the doctor and dietitian as part of the treatment for patients with T2DM. It helped me as I sat around them. Trained personnel, who worked at the clinic, recorded and performed all laboratory works. As part of the study protocol, participants were asked to provide their blood test results, particularly, HbA1c levels, which had been obtained at the clinic. Post the reports came from laboratory; the information was collected about the HbA1c levels. Thus, HbA1c was analyzed at baseline and at 3-months. The participants were weighed as they came down to clinic and took appointment to meet the doctor. To assess the quality and applicability of the data collected I often re-checked the information.

If I missed to get the information of any particular participant, the lab assistants supported me. The test results were used to assess participants’ changes in health status in response to the intervention. It should be noted that certain laboratory values were not available for some participants. For example, hemoglobin A1c and weight values were missing for some of the participants particularly because of the time constraints. The numbers of participants whose
laboratory tests were available for analysis are indicated in the flow chart. Assessments were completed by 51 and patients were whole heartedly thanked and acknowledged. Self-reported Physical Activity levels and Medical Nutrition Therapy by the participants were assessed.

ANALYSIS AND RESULTS

A recommendation Medical Nutritional Therapy (MNT) and Physical Activity (PA) was beneficial. The research was based on an estimate of the sample size for the study on data from the data I collected. Means reported at baseline are unadjusted averages. Over a period of 3-months, the primary outcome of the data revealed considerable reduction in weight and HbA1c levels. A vast majority of participants showed positive results that were in account with the objective of the study. During the concluding part of the data collection, descriptive statistics included number, percentage, mean, standard error, median, standard deviation, and minimum, maximum of the study factors were calculated.

Among the participants with T2DM, 5.37% reduction in HbA1c levels and 5.4% reduction in weight were observed. The difference in the baseline and 3-months rates of weight change in the participants with lifestyle intervention was significant. All of the patients in the intervention group that had undergone Medical Nutritional Therapy (MNT) and Physical Activity (PA) were then followed up at 3 months on all outcome measures. With a sample size of 51 participants, the patients with T2DM, leaving few, successfully could achieve reduction in weight and HbA1c levels. The difference in weight was of 1.0 kg to 8 kg and reduction in HbA1c levels were 0.2% to 1.2%. The limiting part of the study was that I could not have outcomes of HbA1C levels and weight for 19% of participants at 3-months as
Participants also reported that there was significant positive impact on body mass index (BMI), HbA1c, systolic blood pressure (SBP), diastolic blood pressure (DBP), high-density lipoprotein-c (HDL-c), and low-density lipoprotein-c (LDL-c).

One participant was excluded from data analysis because of incompliance, as explained earlier. Eventually, a total number of 51 participants, within Ahmedabad, Gujarat, India were assessed and their information was collected. The Lifestyle Intervention study gave considerable outcomes. Comparisons between the groups were made with a two-tailed unpaired t test is shown below.
CONCLUSION

Diabetes mellitus care is as much an art as science, and it is important to have a global view and open mind-set to learn best practices from various institutions around the world. The lifestyle intervention programme was effective in improving glycaemia control and weight control in patients with T2DM within the screened population of Ahmedabad. Medical Nutritional Therapy and Physical Activity are successful interventions in achieving declines in HbA1c and weight. Self-care of type-2 diabetes is an important part in diabetes management. The results of this study should be interpreted with caution because of the bias associated with the recruitment of volunteers, the lack of a control group, the relatively small sample size, the lack of ethnic diversity, and self-reported physical activity levels. I am hopefully looking forward, that this study can help some adults at risk for type 2 diabetes modify their lifestyle, lose weight, and improve certain metabolic outcomes.

In concluding, the analysis adds support to the idea that exercise is a cornerstone of diabetes therapy and findings of this study strongly support the ADA guidelines recommendation that in the treatment regimen of T2DM, optimal physical activity programs consist of regular physical activity combined with structured training must be added to supplement the effect of pharmacological intervention.

Larger randomized controlled studies are needed to validate these results and to identify key behavioral strategies that will improve compliance to lifestyle modifications in real life. Moreover, studies are warranted to establish the efficacy of exercise intervention in a more
differentiated approach for type 2 diabetes sub-populations within different stages of the disease and various levels of co-morbidity.

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