

Effectiveness of Specifically Modified Plant Based Dietary Intervention and Anti-Gravity Exercise in Type 2 Diabetics a Follow-up Study

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To cite this article:

Pramod Tripathi, Maithili Paranjape, Ritu Tripathi, Sukeshini Khandagale, Gandhali Bhagwat, Arjunlal Kakrani. Effectiveness of Specifically Modified Plant Based Dietary Intervention and Anti-gravity Exercise in Type 2 Diabetics a Follow-up Study. *International Journal of Diabetes and Endocrinology*. Vol. 3, No. 3, 2018, pp. 50-57. doi: 10.11648/j.ijde.20180303.13

Received: August 8, 2018; **Accepted:** October 12, 2018; **Published:** November 13, 2018

Abstract: To test the hypothesis that specifically modified plant based diet and anti-gravity exercises in Type 2 diabetics followed for a period of 10-14 weeks improves the glycemic control and reduces requirement of anti-diabetic medication. Around 386 confirmed diabetic participants enrolled in this study. Out of these 259 participants completed the study. This was a follow up study for a period of 10-14 weeks where the anthropometric measurements and biochemical parameters were measured at week 0 and at week 10-14 weeks. Medication was also monitored on a daily basis based on the blood glucose levels and change in medication was noted at the end of 10-14 weeks. After 10-14 weeks of consumption of modified plant based diet and anti-gravity exercises was accompanied by a significant reduction in anthropometric measurements like body weight ($p=0.0001^*$), BMI ($p=0.0001^*$), fat percentage ($p=0.0003^*$) and visceral fat percentage ($p=0.0002^*$). Lower anthropometric measurements was accompanied by a reduction in HbA1C ($p=0.000^*$), fasting ($p=0.038^*$) and postprandial ($p=0.000^*$) blood glucose levels. A reduction in the dosage and number of participants requiring oral hypoglycemic agents (OHA) and insulin was observed due to improved glycemic index. In the diabetic study population, intervention with modified plant based diet and anti-gravity exercises was associated with an improved glycemic control and reduced requirement of anti-diabetic medications. These findings may assist in development of a standard integrated protocol for treating diabetic patients thus reducing the pre-disposition to diabetic complications thus preventing or prolonging the onset of diabetes complications.

Keywords: Plant Based Diet, FFD (Freedom from Diabetes), Anti-Gravity Exercise and Type 2 diabetes, OHA (Oral Hypoglycemic Agents), Insulin, Intensive Program

1. Introduction

Prevalence of Type 2 diabetes has doubled in the past three decades, making it the most important public health challenge globally [1]. India has been experiencing a paradigm shift in its culture over the last few decades leading to a rise in the prevalence of obesity, diabetes and cardiovascular disease. Prevalence of diabetes is expected to rise from 40.9 million in 2007 to 69.9 million by 2025 [2]. Prolonged and uncontrolled diabetes is known to increase the

risk of micro and macro-vascular complications like myocardial infarctions, lower extremity amputations and end stage renal disease (ESRD)[3].

Diet, exercise and other lifestyle changes are the strategic parameters in the management of diabetes. Consumption of carbohydrates, fat and fiber are considered to be the key to dietary management. Previous study at Pritikin Institute, USA has shown that high carbohydrate plant based diets along with exercise in type 2 diabetics, reduced the oral hypoglycemic agents use, coupled with improved blood glucose, cholesterol and tri-acyl-glycerol levels [4, 5].

Studies have also shown that vegan diet is known to reduce the progression of the disease thus prolonging the onset of diabetic complications [6]. Consumption of animal products has also been associated with an increase in insulin resistance due to increase in visceral fat [7]. Studies have also shown that low fat, low glycemic index (GI) vegan diet is known to improve the glycemic control to a greater extent [8]. Raw foods containing high dietary fiber has been known to be

related to reduction of cholesterol [9] and reduction of postprandial glycemia [10].

This study hypothesizes a specifically modified plant based diet in combination with antigravity exercise prescribed for a period of 10-14 weeks would lead to an improved glycemic control and reduce the anti-diabetic medication in type 2 diabetes mellitus (T2DM).

2. Materials and Methods

2.1. Methodology Flowchart

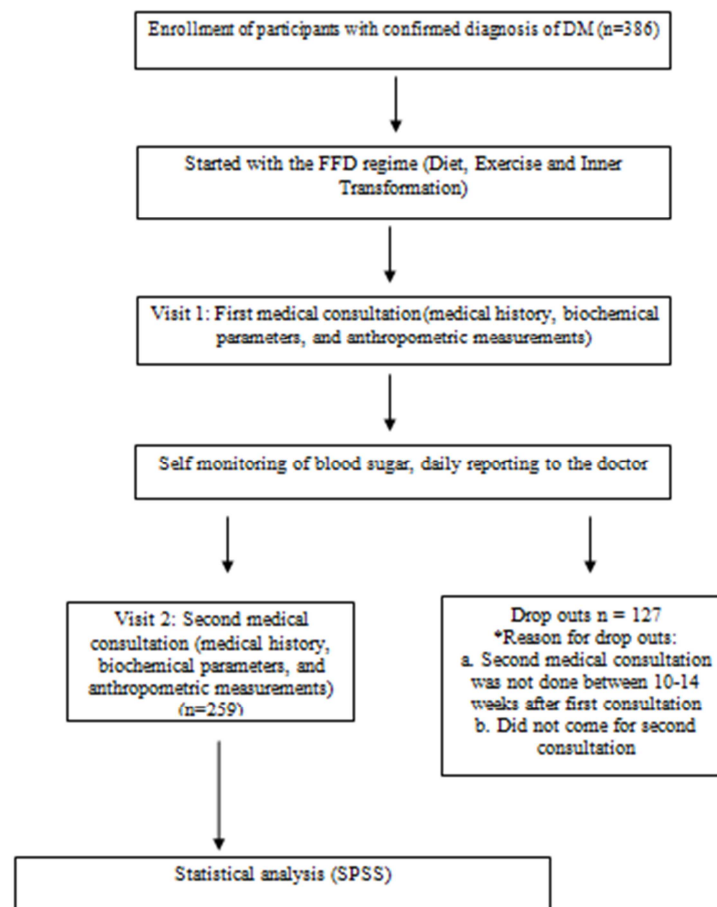


Figure 1. Methodology Flowchart.

Participants with Type 2 diabetes defined by a glycosylated hemoglobin of > 6.5 or a fasting blood glucose level of >126 or a postprandial level of >200 during 75gram oral glucose tolerance test or a random glucose level of $>200\text{mg/dl}$ or on any anti-diabetic medication were enrolled in the study from May 2015- December 2016. There were no exclusion criteria for enrollment. The study was carried out at Freedom from Diabetes Research Foundation (FFDRF), Pune and at Dr. D. Y. PatilVidyapeeth Deemed University, Pune. The study protocol was approved by Dr. D. Y. PatilVidyapeeth ethics committee. A written consent was obtained from all the participants enrolled. A total of

386participants enrolled in the study, out of which 259 participants completed the study. The enrollment took place under the FFD program called Intensive Program. The intensive program is a follow up program where in participants are enrolled in the program and their follow up with all the biochemical parameters is done initially and after a period of 10-14 weeks. During 10-14 weeks daily monitoring of glucose levels of all participants was done by the panel of FFD doctors over the mobile application. After enrollment and collection of preliminary data, the participants started following the dietary advice (Table 1) and started doing anti-gravity exercises. Two medical

consultations (one at the beginning of the program and second at 10-14 weeks) were included in the study and their time frames were on enrollment and after 10-14 weeks of first medical consultation. Participants who did not repeat their biochemical parameters between 10-14 weeks of their first visit were considered to be dropouts (Figure 1).

2.2. Demographic Data

On enrolment and consent of the participant, general information on demographic data consisting of age, gender, education, occupation, years of diabetes, and related medical data was collected.

2.3. Dietary Intervention

The participants were started on with a modified plant based diet which was high in fiber and anti-oxidants rich. The diet prescribed was modified such that the daily micro and macro-nutrient needs of the participants were met. The dietary modifications prescribed were as follows [11]. A nutrient dense drink called green smoothie made from locally available fresh green leafy vegetables, one low glycemic fruit and herbs was recommended on empty stomach. Participants were asked to avoid cereal grains in their breakfast. The recommended breakfast was a mix of 50% of raw foods in the form of sprouts/salads and 50% cooked food made from pulses/legume preparations. Lunch and dinner consisted of one cereal (grain) in a meal with an equal proportion of cereal, pulse, cooked vegetable and raw vegetable salad i.e. 25% of cereal, pulse, cooked vegetable and salad. The diet had sufficient quantity of soluble and insoluble fiber in the form of whole and sprouted pulse and legumes, raw vegetables in the form of salad. Intake of nuts and seeds around 15gm per day was also prescribed. Inclusion of 3-4 teaspoon (i.e. 15-20gm) of cooking oil per day was recommended. The diet provided approximately 55-60% carbohydrates, 15-20% proteins and 20-25% fat. All the participants were asked to strictly avoid milk and milk products, non-vegetarian foods and to limit intake of alcohol and smoking. Any other dietary changes required as per individual needs were made accordingly.

2.4. Exercise

Anti-gravity exercise was complimented with the dietary modifications. This included climbing the stairs up and down post 1 hour 45 minutes of lunch and dinner. The speed and the duration of this activity were tailored according to individual capacity. The participants were asked to increase time in accordance with increasing individual capacity going up to a maximum of 15 minutes per session. In addition to the anti-gravity exercise the participants were asked to do lymphatic, cardio and/or strength training exercises.

2.5. Anthropometric and Biochemical Parameters

Anthropometric measurements and biochemical parameters of the participants were measured at week 0,

which was considered to be the Visit 1 and at week 10-14, which was considered to be visit 2. The visit 1 and visit 2 were either in-person visit to the clinic or a telephonic consultation with the doctor at the clinic. When the participants reported at the clinic, anthropometric measurements were measured on Omron Karada Scan (model no HBF-375). Biochemical parameters were done by the participants as far as possible from an accredited lab, though participants from rural areas brought printed reports from local laboratories.

2.6. Daily Blood Glucose Levels

Monitoring of glucose levels on a daily basis was done by the assigned doctor over the mobile application. Each participant was asked to check their blood glucose levels using a glucometer on a daily basis and report their readings to their respective assigned doctors during the entire period of the study. Participants who were on insulin were asked to measure and report their blood glucose levels four times a day namely fasting and three postprandial readings, i.e. two hours after breakfast, lunch and dinner. Participants who were on OHA were asked to measure and report their fasting and any of the two postprandial readings during the day on a rotation basis. The medication dosage was titrated accordingly to avoid hypoglycemia and steady reduction or increase based on the levels.

2.7. Diabetic Status

The diabetic status of the participants was determined at the end of 10-14 weeks based on their glyco-sylated hemoglobin levels and their medication status. The categories made were as follows:

- a. Diabetes control was defined as excellent when fasting plasma glucose was <126 mg/dl and HbA1c $\leq 6.5\%$ when participant was off all diabetic medication
- b. Diabetes control was considered satisfactory when HbA1c was $\leq 7.0\%$, with or without diabetes medication usage.
- c. Improved glycemic status defined as lower fasting glucose and reduced HbA1c values, by at least 5% each, coupled with reduced or unchanged diabetes medication usage, or unchanged glycemia with decreased diabetes medication usage (decreased dosage and/or decreased number of medications and/or cessation of insulin).
- d. Unchanged glycemic status defined as no clear effect on glycemic status or diabetes medication requirements/dosage (changes in glycemia and medication usage that are in opposite directions (i.e., increases in one with decreases in other), as well as congruent but minimal changes in glycemia and medication usage like $<5\%$ changes).
- e. Worsened glycemic status defined as no clear effect on glycemic status or diabetes medication requirements/dosage (changes in glycemia and medication usage that are in opposite directions (i.e., increases in one with decreases of the other), as well as congruent but minimal changes in glycemia and medication usage like $<5\%$ changes).

2.8. Diabetic Medication Status

Medication status was monitored at visit 1 and at visit 2. At visit 1, the anti-diabetic medication that the participants were on was noted down. Medication status at visit 2 was the current medication as prescribed by the assigned freedom from diabetes doctor on the mobile application. The participants who were on anti-dyslipidemic medications during their first visit to the clinic were asked to discontinue with these medications for the next three months.

2.9. Statistical Analysis

Values are presented as mean \pm SD. Difference in parameters at visit 1 and visit 2 were determined using Paired

sample t test. The software used for analysis was SPSS for Windows version 20 and P value of <0.05 denoted statistical significance.

Table 1. Nutritional Information* of FFD Diet.

Nutrients	Amount
Carbohydrates	242gm
Energy	1600kcal
Protein	57gm
Fat	40gm
Total Dietary Fiber	65gm

(*calculated).

Table 2. Demographic characteristics of participants.

Parameter	Frequency	Valid percent
Gender (n=259)		
Male	128	49.4
Female	131	50.6
Education (n=259):		
10th	20	7.7
12th	9	3.5
Graduate	135	52.1
Post Graduate	95	36.7
Marital Status (n=259):		
Unmarried	3	1.2
Married	247	95.4
Widowed	9	3.5
Occupation (n=259):		
Business owner	36	13.9
Independent professional	22	8.5
Service	83	32
Housewife	67	25.9
Retired	47	18.1
Other	4	1.5
Dietary Pattern (n=220):		
Vegan	3	1.2
Vegetarian	116	52.7
Eggetarian	18	8.2
Non-vegetarian	83	37.7
Other Habits (n=244):		
Alcohol	26	9.9
Smoking	6	2.25
Tobacco	8	3.1
No habit	204	77.85

Table 3. Anthropometric measurements at Visit 1 and Visit 2.

Parameters	n	Visit 1		Visit 2		t value	p value
		0 weeks		10-14 weeks			
Anthropometric measurements:		Mean	SD	Mean	SD		
Weight (kg)	256	70.49	11.93	64.7	11.45	27.36	0.0001*
BMI	256	27.16	4.39	24.9	4.12	26.57	0.0001*
Waist circumference (cm)	187	91.52	11.45	85.91	11.26	11.27	0.0008*
Body fat (%)	117	32.26	7.63	29.59	7.84	9.625	0.0004*
Visceral fat (%)	117	11.85	5.84	9.6	5.23	11.27	0.0005*
Subcutaneous fat	117	25.42	8.83	23.06	8.58	9.77	0.0006*
Skeletal muscle mass	117	25.99	4.38	26.85	4.48	-6.64	0.0008*

Table 4. Biochemical Parameters at Visit 1 and Visit 2.

Biochemical Parameters:		Visit 1		Visit 2		t value	p value
		Mean	SD	Mean	SD		
HbA1C	254	7.82	1.43	6.72	0.84	13.77	0.0001*
Fasting BSL	237	134.9	45.04	128.52	34.21	2.085	0.038*
PP BSL	112	168	64.02	137.64	44.08	4.8	0.0001*
Iron	201	71.34	28.32	76.61	25.08	-2.946	0.04*
Hemoglobin (g/dl)	244	13.35	1.64	13.51	1.51	-2.66	0.008*
Blood urea nitrogen (BUN) (mg/dl)	215	10.76	5.81	11.01	4.5	-0.942	0.035*
Serum creatinine (mg/dl)	252	0.82	0.357	0.813	0.34	0.81	0.416
Uric acid (mg/dl)	236	5.09	1.514	5.39	2.75	-1.69	0.093
Calcium (mg/dl)	194	9.26	0.39	9.36	0.39	3.06	0.001*
Total cholesterol (mg/dl)	255	153.32	37.58	168.1	34.29	-6.00	0.0004*
HDL (mg/dl)	255	38.8	9.09	41.03	10.59	-3.83	0.0002*
Triglycerides (mg/dl)	253	128.79	55.08	125.98	63.92	0.81	0.417
LDL (mg/dl)	255	90.3	34.03	105.29	31.15	-6.19	0.0001*
VLDL (mg/dl)	248	25.96	12.59	25.08	12.94	1.059	0.290
Urinary micro albumin (μ g/dl)	144	23.25	44.99	10.68	15.52	3.629	0.0003*

Table 5. Comparison of dosage of anti-diabetic drugs at Visit 1 and Visit 2.

	n	Visit 1		Visit 2		t value	p value
		Mean	SD	Mean	SD		
Units of Insulin	80	44.46	34.6	10.66	22.4	8.76	0.0001*
Metformin	227	1143.39	646.96	515.43	654.32	10.59	0.0002*
Glimiperide	157	2.2	1.89	1.13	1.58	5.4	0.0002*
Gliclazide/Glizid	39	117.83	63.52	40	70.67	6.50	0.0005*
Pioglitazone	29	16.06	11.39	2.84	6.77	4.65	0.0000*
Sitagliptin	31	64.52	32.12	16.13	39.55	4.61	0.0001*
Voglibose	37	0.531	0.26	0.048	0.18	10.48	0.000*
Vildagliptin	42	65.47	37.43	19.1	34.72	5.09	0.0002*

3. Results

3.1. Characteristics of the Study Population at Baseline

The demographic characteristics of the participants are as shown in Table 2. It was seen that there were comparable number of males (n=128) and females (n=131) enrolled in the study. The education of the participants varied with around 88.8% of the participants being graduates and post graduates. Occupation varied as shown in Table 2. The dietary pattern showed that around 52% of the participants were vegetarian; while around 46% were egegetarians and non-vegetarians. A small percentage of participants reported of having other habits like alcohol, smoking or oral tobacco consumption. The average duration of diabetes was 122 weeks with a maximum duration of 420 weeks and a minimum duration of 1 week. Dietary compliance record of the participants showed that the participants followed the diet 80-100% as was prescribed to them.

3.2. Changes in Anthropometric Measurements and Clinical Biochemistry Parameters

Table 3 shows the changes in the anthropometric measurements at visit 1 and visit 2. The analysis present here has different 'n' being analyzed under each parameter based on the available data. A statistically significant decrease in all the anthropometric measurements was seen post 10-14 weeks of following the diet. Statistically significant decrease in body weight (p=0.0001), leading to a significant decrease in BMI

(p=0.0001*), waist circumference (p=0.0008*) was observed. Reduction in weight was due to a decrease in overall body fat (p=0.0004*) and also a decrease in subcutaneous fat (p=0.0006*), while there was an increase in muscle mass (p=0.0008*). The weight loss ranged from 0kg to 24.3kg with around 42.5% of the participants lost weight between 0kg-5kg, 48.2% of participants losing weight between 5.1-10kg and 9.7% of participants losing weight >10.1kg.

Decreases in anthropometric measurements were pointers towards better glycemic control. A statistically significant decrease in fasting (p=0.038*) and postprandial BSL (p=0.0001*) was observed at visit 2. Reduction in fasting and postprandial levels reduced the three months average blood glucose (HbA1C) (p=0.0001*). Thus the glycemic control of the participants improved on following the diet and exercise combination. The reduction in HbA1C ranged from 0.0-7.2 and the maximum reduction that was seen was from an HbA1C of 13 at visit 1 to 5.8 at visit 2. There was an increase in HbA1C observed in 34 participants though this increase in HbA1C was accompanied with a decrease in dosage of anti-diabetic medication (Table 4).

Levels of iron and hemoglobin showed significant increase while other biochemical parameters like renal parameters were within the normal levels before and after 10-14 weeks. It is also due to supplementation of Iron for the patients with iron deficiency. Level of calcium increased on following the diet (p=0.001*). Lipid profile of the participants showed a statistically significant rise in levels of total cholesterol, HDL and LDL. This fact has been discussed later. Triglyceride levels remained unchanged after 10-14 weeks. There was a significant

decrease in the urinary micro-albumin levels at visit 2.

3.3. Diabetes Status After 10-14 Weeks

As described in the methods section, the diabetes status of the participants was determined at Visit 2. It was seen that 26% of the participants had gone completely off medication and their HbA1C levels were <6.5, while the percentage of those who had HbA1C <7 was 28.2%. Thus these two categories which represented a good glycemic control contributed 54% of the participants. 26% of the participants showed improved glycemic status while 17.4% showed unchanged glycemic status. A small percentage of 0.4% showed worsened glycemic status.

3.4. Diabetic Medication at Visit 1 and Visit 2

The participants were divided into four categories based on their medication at visit 1 as participants only on OHA, participants only on insulin, participants on insulin & OHA and participants with no medication. Participants on only insulin and OHA or on both at visit 1 were analyzed individually and compared to those who have gone off medication at visit 2 are shown in Figure 2. Participants off OHA, insulin and both after visit 2 are shown in Figure 3.

Reduction in units of insulin was determined in those who were on insulin. Reduction in OHA was determined based on generic components of OHA as shown in Table 5. A statistically significant decrease in the units of insulin was seen. The range of insulin requirement during visit 1 was 6 units-240 units respectively, while during visit 2 the range was 6 units-110 units; thus a drastic reduction in the requirement was seen. The maximum reduction of insulin requirement that was seen was from 240 units of insulin at visit 1 to 56 units of insulin at visit 2.

It was observed that reduction in the dosage of individual components of OHA was 55% of metformin, 49% of glimiperide, 66% of gliclazide, 82% of pioglitazone, 75% of sitagliptin, 91% of voglibose, and 71% of vildagliptin.

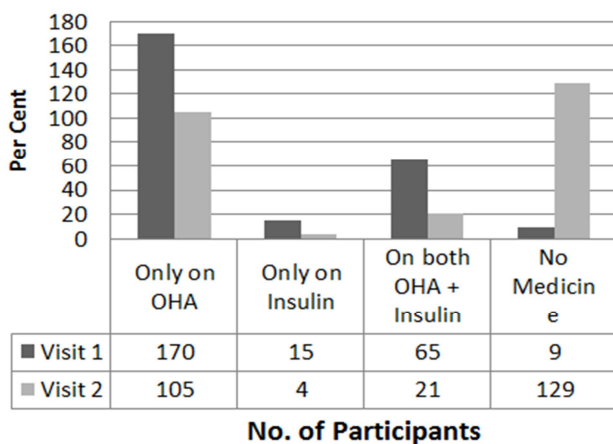


Figure 2. Comparison of number of participants only on OHA, Insulin and both Insulin & OHA with participants off OHA, Insulin and both Insulin & OHA at visit 1 and visit 2 respectively.

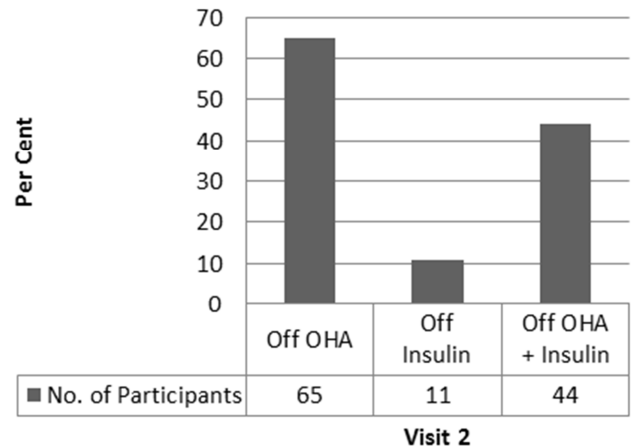


Figure 3. Percentage of population off OHA only and off Insulin only and off both OHA & Insulin at Visit 2.

4. Discussion

The objective of this study was to determine the effect of a specifically modified plant based diet and anti-gravity exercises followed for a period of 10-14 weeks on the glycemic control of type 2 diabetic participants and their effect on diabetic medication status.

Dietary changes are important for management of diabetes. Current dietary recommendations restrict the portion sizes and limit the amount of carbohydrates consumed though there is very little emphasis being laid on the type of carbohydrate consumed and their proportion. Blood glucose response on consumption of a diet high in GI has been linked to increased risk of type 2 diabetes, heart disease, obesity and metabolic syndrome [12].

Obesity in particular abdominal obesity is the key to development of diabetes and cardio-vascular disease [13]. Weight losses with lifestyle intervention [14], with reduction in total calorie intake are important to the management of diabetes for achieving a good glycemic control. Weight loss is also known to lead to a reduction of insulin resistance in diabetics, known to play a fundamental role in development of type 2 diabetes in participants with obesity [15]. A high visceral fat is also known to contribute to insulin resistance. Diet eliminating meat reduces visceral fat and thus the insulin resistance compared to the conventional diabetic diet [16]. This study showed similar results with a significant weight loss after 10-14 weeks of following the dietary recommendations and exercise. A drop in BMI from the overweight category (BMI 25-30) before intervention to the normal BMI category (BMI 18.1-24.9) after intervention was seen. Waist circumference also reduced along with a decrease in visceral fat, whole body fat and subcutaneous fat. A significant increase in the skeletal muscle mass was observed.

Vegetarian diet and vegan diet contains high amount of dietary fiber and is known to be associated with cholesterol reduction [9], reduced urinary losses of glucose [17], lowering of postprandial glycemia [10]. The diet containing mixed high fiber from different sources like cereals, vegetables,

fruits prescribed to type 2 diabetic patients showed a fall in postprandial glycemia and blood lipids though there was no change in HbA1C [18]. The fiber content of FFD diet was high as it consisted of plant based whole-foods like whole grains, legumes, fruits, vegetables, and nuts. Whole grains included whole-wheat, brown rice, millets, jowar and bajra. Studies have shown these foods to be protective against diabetes [19, 20]. Animal products which include foods like meat, egg, poultry and dairy products are known to be high in saturated fat and have been linked to insulin resistance, heart disease and certain forms of cancer [21]. Consumption of animal source food was avoided by the participants.

Vegan diet, when compared to omnivorous diet, is known to lower systolic blood pressure and has a lower glycemic index. Constitutionally, it contains higher amount of dietary carbohydrates, non-starch polysaccharides and polyunsaturated fats [22]. The results showed a significantly lower fasting and postprandial blood glucose levels which reduced requirement of anti-diabetic medication. The medication had to be monitored on a day to day basis and its dosage adjusted accordingly. This was of prime importance in order to avoid any episode of hypoglycemia. There was a reduction in the percentage of participants requiring insulin and oral hypoglycemic agents to maintain their blood glucose levels at normal; this was coupled with the finding that more than 50% of the participants had good glycemic control with an HbA1C of <7 at visit 2.

A reduction in the requirement of anti-diabetic medication was another reason for the weight loss in the participants. Many of conventional anti-diabetic medications are known to be associated with weight gain due to their glucose lowering mechanism [23, 24]. The results showed a significant increase in total cholesterol, low density lipoprotein and high density lipoprotein. This was due to the participants who were on anti-dyslipidemic medications were advised to discontinue for 3 months. If the lipid profile was within normal range i.e. <200mg/dl during the second visit then the drugs were not restarted and the diet was continued; else anti-dyslipidemics were restarted by the doctors. It was also observed that a significant rise in high density lipoprotein levels on following the diet. This was probably due to the anti-gravity exercise and consumption of soaked nuts and seeds like walnuts and flaxseeds. The levels of triglycerides and very low density lipoproteins remained similar and unchanged.

Regular physical activity is known to have many benefits like uptake of blood glucose by the muscles thus lowering the glucose levels, weight loss [25 – 27]. All above results were positive as all the participants followed the modified diet as well as the anti gravity exercises on a day to day basis.

5. Conclusion

The dual profile of therapeutically modified diet and anti-gravity exercises was found to be effective in the present study. In India, with locally available cereals, pulses, vegetables, herbs and fruits following the recommended diet is pocket friendly, as compared to insulin and oral hypoglycemic agents which, are financially taxing

inconvenient and also have tendency to cause hypoglycemia. Also the exercises recommended are easy to do without involving extra cost and time. They can be learnt and taught easily across populations and cultures. They create a stronger adherence and lifelong change for many because of the quick measurable results. These results give substantial evidence that obesity and predisposition to diabetes can be reduced if the recommended dietary changes with exercise are made early and support given to patients during implementation phase which automatically improves compliance. In already diagnosed diabetics these dietary modifications will lead to a better glycemic control thus prolonging or preventing the predisposition to diabetes complications. Further studies on the effect of this diet and exercise on medication status other than anti-diabetic medication needs to be explored.

Acknowledgements

The team would like to thank Dr. Anjali Radkar for her guidance in statistical analysis and Dr. Nasreen Shai for her inputs in manuscript writing.

Conflict of Interest

The authors declare that there is no conflict of interest.

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