

Effectiveness of a 7 Days Residential Integrated Lifestyle Modification Program on Type 2 Diabetes Mellitus: A Single Arm Observational Study

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Abstract: Diabetes Mellitus is leading cause of morbidity and mortality in India with its increased prevalence. This study assessed the impact of 7 days residential program named Transcendental Residential Program (TRP) of Freedom From Diabetes Research Foundation (FFDRF) on type 2 diabetes mellitus participants as a complementary therapy to pharmacotherapy. A retrospective observational study was conducted on 485 diabetes mellitus participants after obtaining the informed consent where they underwent integrated training under a team consisting of doctors, cooking experts, nutritionists, fitness trainer and stress management trainer. TRP was intended to bring in changes in habit patterns related to the four modifiable factors namely diet, physical activity, medicines and inner transformation (through stress release and developing positivity). After 7 days of the program there were statistically significant changes in the outcome variables like fasting blood glucose, postprandial blood glucose, weight and reduction in insulin and oral hypoglycemic medications. The results suggest the significance of a well planned lifestyle modification program of FFD and its impact on the clinical outcomes in type 2 diabetes mellitus. This study has a major limitation such as there was no control group. However, TRP when used as an adjunct to pharmacotherapy has shown to improve glycemic control and reduce the requirement for medication within a short period of time. Given the fact, despite many advances in pharmacotherapy, diabetes mellitus and its complications are still escalating. Therefore, a personalized integrated health program that helps participants to make a shift in their current lifestyle is the way subsequently to reverse this life threatening metabolic disorder.

Keywords: Diabetes Mellitus (DM), Lifestyle Intervention, Dietary Modification, Oral Hypoglycemic Agents (OHA), Transcendental Residential Program (TRP)

1. Introduction

Type 2 Diabetes Mellitus (DM) continues to be a major epidemic threat especially to the middle and low-income countries even if there is scientific advancement, sophisticated healthcare facilities, and improved literacy rate [1]. Recent epidemiological data states that nearly 387 million people globally are affected from DM with a

prevalence rate of 8.3% and the undiagnosed cases remains 46.3% [2]. Non-communicable Diseases (NCDs) are a major threat for global health responsible for 72% of deaths in 2016 [3]. DM is among the four major NCDs which need immediate global attention. International Diabetes Federation estimated that approximately 425 million people were diabetic in the year 2017 [3]. This number is expected to rise to 629 million by the year 2045 [3]. Out of which, more than 79% of subjects with DM currently live in low and middle

income countries, for example India [4]. India is considered as the “Diabetes Capital” of the world. India is home to 79 million of diabetics with a prevalence of 8.7% among the adult population. DM, in India, is mainly prevalent in urban dwellers with high income, high education and higher social class [4]. Due to this lifestyle changes causing decreased physical activity a change in diet to high fat, high energy intake are seen along with a rapid modernization era [3]. The actual extent and size of the burden which is characterized to DM is still unknown due to deficient data from the low and middle income countries [4]. Diabetes can cause death and disability directly, separating the dreaded complications [3]. Most notable complications are cardiovascular and renal diseases. The Global Burden of Disease (GBD) has included this information into their standardized burden estimation approach [3]. According to the GBD, the burden of DM involves those due to uncomplicated diabetes and the micro-vascular complications [3]. This raising burden of the disease is due to the shift in our approaches from a holistic to drug oriented therapeutics [4].

Literature also suggests that without promoting wholesomeness, the use of any drug is futile [5]. With proper testing, treatment and lifestyle changes, healthy eating as a strategy, promote walking; exercise, and other physical activities [6], there are beneficial effects on human health and prevention or treatment of diabetes. This study discusses about the impact of one-week (7 days) residential integrated lifestyle modification program on type 2 DM participants.

2. Materials and Methods

2.1. Study Site

The study was conducted at a residential integrated health care home at Pune, Maharashtra, India. The health care home is a facility which provides integrated health care under supervision of a team of doctors, nutritionists, fitness trainer and stress management trainer. The entire emphasis is laid on changing habit patterns related to the three modifiable factors namely diet, exercise and inner transformation (through stress release and developing positivity). Each patient received personalized counseling towards lifestyle changes targeting diet, exercise and stress management by respective teams.

2.2. Methodology

All enrolled participants were pre-diagnosed type 2 diabetics or were in pre-diabetic condition. Participants who had recent hospitalization due to diabetic complications or any other co-morbidity like heart problems/cancer were included in program on prior medical fitness from medical practitioner. In case found unfit they were excluded from attending the residential program. Participants with critical heart conditions (severe heart disease/several heart surgeries) were not allowed because this lifestyle modification can affect their health causing oedema due to fluid overload or can have congestive cardiac failure. High creatinine (>2

mg/dl) participants are not able to follow some parts of the FFDRF protocol due to their disorder as a result they were not allowed to enroll for this program in this study.

This was conducted as an observational study where 485 participants participated in the program. The participants were enrolled in batches between timelines. The daily dose adjustment was done by monitoring doctors at the residential program. The baseline characteristics are explained in the results section.

The study was approved by Royal Pune Independent Ethics Committee with DCGI Reg No: ECR/45/Indt/MH/2013/RR-16.

2.3. The FFD (*Freedom from Diabetes*) Protocol

The FFD protocol was implemented in the form of a residential program for 7 days called the Transcendental Residential Program. This program included dietary modification, exercise therapy, meditation techniques, stress release processes, patient education sessions and cookery sessions by respective teams. Blood glucose levels (Fasting and three postprandial BSLs - post breakfast, post lunch and after dinner) were measured on daily basis by using glucometer (Accu-Chek Active of Roche Diabetes Care India Pvt. Ltd. or Contour of Bayer or True result of Nipro or One Touch of Johnson & Johnson). The dietary modification included Green Smoothie empty stomach at 7 am and again at 4:30 pm. Breakfast was made from pulses or legumes with a proportion of 50% of raw and 50% of cooked food. Lunch and dinner had an equal proportion of cereal, pulse, cooked vegetable and salad. Alternate day juice feasting (to consume variety of low glycemic juices for the entire day without solid food) was followed. The different juices given were red juice - carrot, tomato, cinnamon powder; green juice - green apple, cucumber, mint, green sorrel, ginger, ridge gourd, lemon & spices; classic green juice -spinach, coriander, ash gourd, lemon, green capsicum, ginger and spices; white juice - bottle gourd, cucumber, lemon, ginger, garlic, spices. In small quantities following two liquids were also given: okra water - 2 pieces of okra per head soaked overnight in one glass water and bitter gourd shot - bitter gourd juice 30 ml (for every bitter gourd of length 5-6cm \equiv 100gm, one cucumber of the same length was used). Consumption of animal products, milk and milk products, refined foods were excluded from the diet.

Inner Transformation by meditation techniques included dynamic meditation [7], awareness (mindfulness) meditation [8], stress release technique (neuro-linguistic programming) [9], soul mind body meditation [9]. This was directed towards the release of stress at an emotional level; improve awareness and healing from within. Besides this, exercise therapy was also given, as it is regarded as one of the key elements in prevention and management of diabetes mellitus [10]. This was specifically done through anti-gravity resistance exercises like staircase climbing 2 hours after a meal, resistance band, walking, jogging along with yoga and mild form of high intensity interval training. Exercise sessions offered training for improving functional capacity

and strength of large muscle groups. Compliance ensured by the participants is around 90% for the exercise sessions.

2.4. Outcome Measures

The outcome measures were changes in the blood glucose level, blood pressure, anthropometric measures like weight and change in anti-diabetic medication. The data collected was analyzed was done using SPSS version 20 (Statistical Package for the Social Sciences).

3. Results

The study was conducted among 485 participants aged between 30 to 70 years, which included 269 males and 215 females. The baseline characteristics are tabulated in table 1

and table 2. All participants were recreationally active. All participants were under standard medical care along with FFDRF protocol.

All the participants showed significant reduction in the outcome variables post the FFDRF program. Wilcoxon-Signed rank test were used to compare within the group. Significant improvement was seen in fasting blood glucose level, postprandial glucose level and weight at the end of program. Statistically significant reduction was observed in the need for diabetes medication as well as in the insulin dosage. However, statistical significance shows an increase in the systolic blood pressure. This is due to the stress release sessions which induce emotional outbursts at the end of the program. The detailed results have been tabulated in table 3 and 4.

Table 1. Baseline characteristics of the participants on Insulin.

Parameters	Average	Std. Deviation
Age (years)	57.05	11.98
Height (cm)	163.57	9.11
BMI	26.325	4.06
HbA1C (%)	8.91	1.81
Diabetic Since (Years)	16.89	7.75

Table 2. Baseline characteristics of the participants on OHA.

Parameters	Average	Std. Deviation
Age (years)	54.38	11.31
Height (cm)	163.11	10.59
BMI	27.12	4.39
HbA1C (%)	8.10	1.08
Diabetic Since (Years)	9.55	6.36

Table 3. Inferences in participant's body parameters pre and post FFD program.

Parameters Measured	Pre inference (average)	Post inference (average)	P value
Fasting Blood Glucose (mg/dl)	154.39 (SD + 53.33)	107.18 (SD + 24.49)	0.0001*
Postprandial Blood Glucose (mg/dl)	200.54 (SD + 72.00)	136.56 (SD + 42.71)	0.0000*
Weight (kg)	72.48 (SD + 13.66)	71.64 (SD + 13.34)	0.0001*
Systolic Blood Pressure (mmHg)	138.30 (SD + 19.98)	141.05 (SD + 19.86)	0.006*
Diastolic Blood Pressure (mmHg)	80.27 (SD + 11.38)	80.07 (SD + 9.8)	0.885

(SD - Standard Deviation)

*p<0.05 is significant

Table 4. Inferences in changes in Oral Hypoglycemic Agents and Insulin.

Parameters Measured	Pre inference (average)	Post inference (average)	P value
Total Insulin Units	38.29 (SD + 26.28)	10.56 (SD + 13.72)	0.0001*
Metformin	1226.78 (SD + 574.9)	694.78 (SD +688.97)	0.0000*
Gliclazide	98.5 (SD + 63.51)	39.54 (SD +38.5)	0.0001*
Glimepiride	3.72 (SD + 2.05)	1.57 (SD +1.4)	0.0001*
Pioglitazone	10.63 (SD + 12.12)	3.95 (SD +3.44)	0.0001*
Sitagliptin	75.88 (SD + 33.7)	38.46 (SD +43.8)	0.0001*
Tenagliptin	20.28 (SD + 4.47)	13.75 (SD +11.42)	0.0001*
Voglibose	0.78 (SD +0.8)	0.03 (SD +0.2)	0.0003*
Vildagliptin	43.43 (SD + 41.40)	51.05 (SD +42.022)	0.0689

(S. D- Standard deviation)

*p<0.05 is significant

At the end of TRP, it was observed that, a maximum of 6 kg weight loss was seen, where all participants showed a minimum of 1 kg weight loss. 142 participants were on insulin before the TRP which was reduced to 72, with 70

participants had stopped external insulin, after TRP (Figure 1). A maximum reduction of insulin units observed were 106 units, where all patients had a total reduction of 9 insulin units. One participant showed a dramatic change in the

prescribed insulin units from 134 units to 0 units after TRP. 457 participants were on OHA before TRP which was significantly reduced to 302 participants on OHA with 155

participants free from medication of any kind after the TRP (Figure 2).

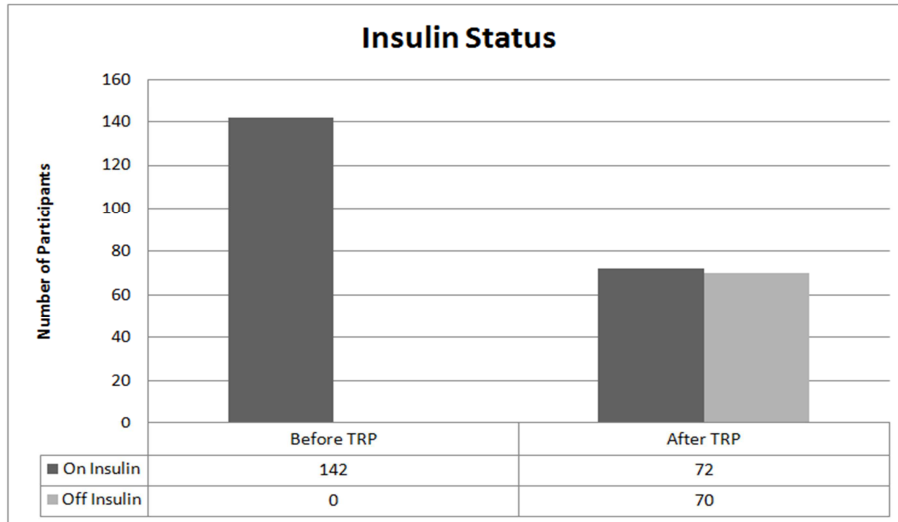


Figure 1. Insulin status before and after TRP.

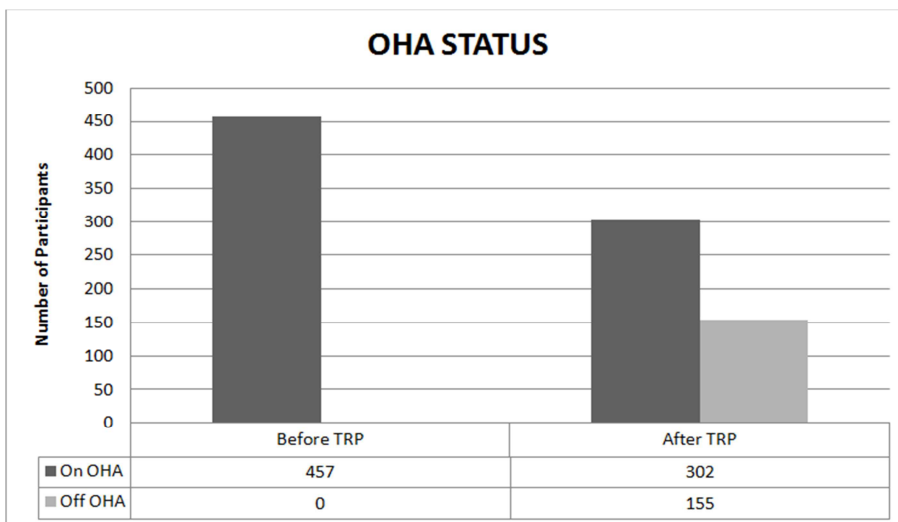


Figure 2. OHA status before and after TRP.

4. Discussion

The results suggest the significance of a well-planned lifestyle modification program as designed by FFD and its impact on the management of diabetes mellitus and its reversal. With statistically significant reduction in glucose levels and medications this was evident in our study participants. A scientific and innovative approach to food intake, exercise, stress release, meditation, group therapy and daily insulin/medicine dose adjustment by doctors giving individual attention can be termed as the responsible factors for this significant improvement. Earlier studies also reported the usefulness of person-centered models in the management of diabetes mellitus [12]. The results were in similar line with a previous study reported from India where Integrated Naturopathy and Yoga therapies had brought significant

effect on glycemic control and reduced the overall need for anti-diabetes medications [13]. An integrated residential health care model is warranted to bring about positive outcomes in management and reversal of diabetes mellitus. Juice feasting was intended for detoxification, alkalization, and rehydration, also to ensure adequate phyto-nutrient supply.

A study performed in the Diet of Hope Institute has shown similar results for participants with diabetes mellitus type 2 [14]. There were 67 participants in that study, which was performed for 6 weeks with lifestyle change and carbohydrate restrictions in their diet [14]. Out of these 67 participants, following the 6-week intervention period, two participants who were on insulin pumps had their doses reduced to half. 40 participants had 55.2 units of long acting insulin which reduced to 15.2 units of long acting insulin. 25 participants who were on long acting insulin or have stopped

were also had 52.2 units of short acting insulin which considerably reduced to 9.8 units of short acting insulin [14]. 24 participants who were on long acting insulin have been free from insulin at the end of six weeks of the program [14]. These results correlate with the present study, where one patient from the study has been on 137 units of insulin at the beginning of program. At the end of the 7-day TRP, the patient was free from insulin units and was only on OHA. Similarly, 24 participants out of 67 were off insulin at the end of 6 weeks [14], 70 were off insulin and 72 had their insulin units reduced drastically out of 142 participants, after the 7 days TRP (Figure 1).

Increased incidence and the prevalence of diabetes type 2 are mainly due to the adoption of a sedentary lifestyle with excessive food intake. According to this study, life style intervention alone is the natural way of preventing and potentially reversing the progress of type 2 diabetes [14]. Another study shows that dietary and exercise intervention improves the diabetes type 2 statuses reducing the risk associated with type 2 diabetes [15]. In this study the effect of insulin status of the current diet of participants is compared to the insulin resistant participants with the help of lifestyle change by the help of dietary and exercise regimen [15]. Increased physical activity and dietary modifications have improved the insulin sensitivity [15]. This study, thus, concludes that an aggressive lifestyle intervention which includes physical activity and diet modification is beneficial for diabetic participants [15].

A case report showed that patient was diabetic for 15 years and was diagnosed with grade III fatty liver. This patient reported to the FFDRF when his diabetic medication, Metformin, was 1500mg/day [16]. After following the FFDRF protocol for just 10 days, the patient was off medication. The patient lost 10kg in 12 weeks and 16.7kg in 6 months [16]. After the first 12 weeks, there was no evidence of fatty liver [16]. The patient reported a drastic reduction of fasting and postprandial blood glucose levels after stopping the medications [16]. The patient has cleared four Glucose Tolerance Tests (June 2016, October 2016, October 2017) of which the recent test was conducted on 4th September 2018 at the FFDRF [16]. This case report clearly states that lifestyle and dietary modifications has a positive response in the reversal of DM [16]. Another study showed that a specifically modified plant based diet and anti-gravity exercises improves the glycemic control and reduces the daily requirement of anti-diabetic medications in DM participants after following the FFDRF protocol for 10 to 14 weeks [17].

The baseline normalization was not sought for as we conducted this as a retrospective observational cohort. Moreover, participants who enroll in FFDRF program want to undergo lifestyle intervention on their self-will; it will be thus challenging and arguably unethical to implement a randomized controlled trial. However, the present study indicates the need of group-based interventions like FFDRF for achieving sustainable behavioral modifications through experiential learning and thereby improving participants'

ability to control, better manage or reverse diabetes for improving the clinical outcomes in the long run.

5. Conclusion

Upon following the FFDRF protocol for 7 days, the participants have showed a significant reduction in their weight and blood glucose levels. The need for insulin and OHA was also reduced dramatically. Almost 50% participants discontinued external insulin completely and 72.51% participants had their insulin dosage reduced. Almost 34% of participants discontinued OHA completely. Out of the 8 commonly prescribed OHAs, 7 medicine dosages were significantly reduced by 42.63%. The results clearly showed that, there was a reduction in the daily dose, even in those participants prescribed with insulin/ OHA which were not completely stopped.

This study validates that the FFDRF protocol when used as an adjunct to pharmacotherapy, not only helps in achieving glycemic control, but also significantly reduces the need for diabetes medications within a short period of time. Hence, this present study provides a practical model for health promotion through a week long Transcendental Residential Program (TRP).

Follow up studies of such groups are warranted to confirm the sustainability of the results obtained at the end of the program and the extent of diabetes reversal over long term.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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