INTRODUCTION

Epidemiological studies suggest that there is global increase in the incidence of diabetes, particularly in areas having significant economic improvement with industrialization. In 2002, the prevalence of type 2 diabetes mellitus (T2DM) in India was 2.4 percent in rural populations and 11.6 percent in urban populations [1]. Thirty-six percent of the anticipated global increase of 154 million people with diabetes is projected to occur in India and China alone [2]. Urbanization and rapid industrialization in developing countries is associated with a more sedentary lifestyle tending to increase the diabetes prevalence, so to some extent is a proxy for lifestyle changes. The challenge is to minimize the detriments of urbanization, as the process is unlikely to be reversed [3]. Specific lifestyle intervention programs have been shown to be efficacious in reducing diabetes incidence [4–6]. The American Diabetes Association (ADA) refers to this individualized management plan for the patient as diabetes self-management education (DSME). Medical nutrition therapy (MNT) is a term used by the ADA to describe the optimal coordination of caloric intake with other aspects of diabetes therapy (insulin, exercise, diet and request).
METHODS AND MATERIALS

This was a Randomised Control Trial (RCT), which was conducted at a well-equipped medical clinic at Agartala, Tripura as a part of Distant Fellowship in Diabetes (DFID) programme after ethical committee clearance under the guidance from Christian Medical College, Vellore.

Inclusion criteria

- Adult type 2 diabetes patients (18 to 64 years).
- Agreed to participate in the study.

Exclusion criteria

- Medical background, co-morbid condition requires special diet
- Patients cannot be available for regular follow up.

All the T2DM patients attending the clinic during 01.03.2017 to 31.11.2017 (fulfilling the inclusion criteria) were enrolled for the study. Considering HbA1c difference (effect size of the intervention) of 0.65%, standard deviation of 1.0, α level of 0.05 for a two-tailed test, power of 80%, sample size calculated was 45 (44.58). A loss of follow-up rate of 30% was considered (calculated figure of loss in follow up 13.37), we found that 59 (44.58 + 13.37) participants would be required for each group for statistical significance. For comparison, p value less than 0.05 was considered as significant.

A total of 200 T2 DM patients, attending the clinic during 01.03.2017 to 31.11.2017 were enrolled for the study after taking duly explained written consent. For all the patients, history was recorded; physical examination including waist hip ratio (WHR) and body mass index (BMI) was done. BMI was calculated as per Quetelet’s Index as weight in kilograms divided by height in meters squared. Basal metabolic rate (BMR) was calculated by applying the formula 24kcal/kg/day in Male and 22kcal/kg/day in Female. Total energy was calculated as BMR added with activity factor (i.e. Sedentary – 25-30% of BMR, Moderate active - 35-50% of BMR, Sedentary – 50-100% of BMR). Depending on all these factors, diet chart as per calorie requirement was provided to the patients [8, 9].

After considering the medical background and co-morbid condition of patients, if special nutritional measures were indicated beyond MNT in any patient, they were excluded. Likewise, if it was felt that follow up will not be possible due to work, distance, family, personal or any other issues; they were also not included in the study. Finally we selected 164 patients for the study. At the initiation of the study, adjustment of pharmacotherapy was done after having fresh estimations of glycated hemoglobin (HbA1c) and fasting plasma glucose (FPG) and post prandial plasma glucose (PPPG) values. In the continuation, no change in medication was made thereafter.

This study was a Randomised Control Trial (RCT). After selecting the subjects, they were divided into two groups with each group having 84 patients, using simple lottery. The patients, assigned to Group A, were given counseling regarding medical nutrition therapy on first visit and was named as Intervention Group. Patients of Group B were given counseling regarding the disease and personal care and were asked to follow the usual conventional diet as they were on before enrollment in the study, hence mentioned as Non-Intervention Group. All these patients were asked for review visits on biweekly basis for next three months. During follow up visits, dietary habits of patients were again scrutinized and necessary adjustments were advised for patients of intervention group. FPG, PPPG were repeated monthly. HbA1c was again estimated after completion of 3 months.

Seven(7) patients of intervention group had acute crisis during the study period (2 patients had sepsis following urinary tract infection, 2 patients had lower respiratory tract infections, 1 patient had Dengue Shock Syndrome, 1 patient acute pancreatitis, 1 patient had myocardial infarction) and four (4) patients of Non Intervention Group had acute crisis (1 patient had Infero-lateral wall myocardial infarction, 1 patient had Anterior wall myocardial infarction, 1 patient had septic shock following urinary tract infection, and 1 patient had acute pneumonia and needed ventilation) and they were excluded from the study analysis.

For final analysis of the study, we included only those patients who came for at least 2 visits during 3 months and a visit at the end of study period (total 3 follow up visit), therefore 6 patients of intervention group and 13 patients from Non – intervention group were excluded. Ultimately 138 patients were available for final analysis. We had 71 patients in Intervention group and 67 patients in Non-intervention group.

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As at least 59 participants were required in each group for the statistical significance of analysis of this study, even after exclusion, there was enough number of participants in both the group (71 in Intervention group; 67 in Non-intervention Group).

STATISTICAL ANALYSIS

Data were checked for normality (Shapiro – Wilk test) and Equality of Variance (Levene’s test). Inter-group comparison of parameters like Fasting and Post prandial Plasma Sugar, HbA1c, Weight, Body Mass Index and Waist hip ratio of both the group were compared by Welch’s t test, Mann- Whitney U test, Wilcoxon rank test as and when appropriate. Changes in two groups were again compared using unpaired t – test to see significance in difference. Statistical analysis was done using software SPSS version 20.

RESULTS

At the end of study period, a total of 138 patients were available for conclusive data collection. Out of these 138 patients, 71 patients were from Intervention group and 67 patients were from Non-intervention group. Therefore, 51.4% (N = 71) patients of final analysis were from Intervention Group and rests (48.6%, N = 67) were from Non-intervention group. Combining the both groups, 65 patients (47.1%) were male whereas 73 patients (52.9%) were female.

Table-1: Base line characteristics of study participants

<table>
<thead>
<tr>
<th>Base line characteristics</th>
<th>Intervention Group (N 71, 51.4%)</th>
<th>Non Intervention Group (N 67, 48.6%)</th>
<th>Test value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>54.8 ± 14.1£</td>
<td>53.3 ± 7.88£</td>
<td>0.786*</td>
<td>0.43</td>
</tr>
<tr>
<td>Weight</td>
<td>57(13)£</td>
<td>68 (11)£</td>
<td>1449**</td>
<td>0.00</td>
</tr>
<tr>
<td>BMI</td>
<td>24.4 (5.1)£</td>
<td>26.9(5.5)£</td>
<td>1670**</td>
<td>0.00</td>
</tr>
<tr>
<td>Waist Hip ratio</td>
<td>0.976(0.122)£</td>
<td>0.967(0.123)£</td>
<td>2071**</td>
<td>0.19</td>
</tr>
<tr>
<td>Fasting Blood sugar</td>
<td>144(49)£</td>
<td>144(50)£</td>
<td>2335**</td>
<td>0.85</td>
</tr>
<tr>
<td>Post prandial Sugar</td>
<td>211(99)£</td>
<td>220(103)£</td>
<td>2121**</td>
<td>0.27</td>
</tr>
<tr>
<td>HbA1c</td>
<td>7.10(0.95)£</td>
<td>7.40(0.6)£</td>
<td>1877**</td>
<td>0.06</td>
</tr>
</tbody>
</table>

*Welch’s t test, ** Mann- Whitney U test , £ Mean ± SD, £ Median (IQR)
At the initiation of study, the median of weight of Non Intervention group subjects was 68 kg with standard deviation (SD) of 11 kg. In the Intervention group, it was much lower with mean weight of 57 kg with SD of 13 kg (Table No 1). In the Intervention Group, the median BMI was 24.4 with standard deviation of 5.1, whereas median BMI of Non Intervention Group was found to be little higher as 26.9 with standard deviation of 5.5 (Table No 1). Significant difference was found between the study groups regarding parameters like weight and BMI at base line, hence in the final analysis these two parameters were not considered for inter group comparison. In Non Intervention Group patients, the change in median of body weight was 57 (SD 13) Kg to 56 (SD 12) Kg and it was significant (Table No 2). In the Non Intervention Group, change of BMI was from 26.9 (SD 5.5) to 26.8 (SD 5.3) and was found to be statistically significant. Similarly in the Intervention Group, there was statistically significant BMI change [from 24.4 (SD 5.1) to 23.9 (SD 4.5)]. (Table No 2). Changes of median

**Table-2: Changes of parameters within the groups**

<table>
<thead>
<tr>
<th></th>
<th>Initial value</th>
<th>End point value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight (Kg)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Intervention Group</td>
<td>68(11) €</td>
<td>66(11.5) €</td>
<td>0.02***</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>57(13) €</td>
<td>56(12) €</td>
<td>0.00***</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Intervention Group</td>
<td>26.9(5.5) €</td>
<td>26.8(5.3) €</td>
<td>0.04***</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>24.4(5.1) €</td>
<td>23.9(4.5) €</td>
<td>0.00***</td>
</tr>
<tr>
<td><strong>WHR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Intervention Group</td>
<td>0.967(0.123) €</td>
<td>0.966(0.103) €</td>
<td>0.00***</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>0.976(0.122) €</td>
<td>0.974(0.133) €</td>
<td>0.00***</td>
</tr>
<tr>
<td><strong>Fasting plasma sugar</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Intervention Group</td>
<td>144(50) €</td>
<td>128(35) €</td>
<td>0.00***</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>144(49) €</td>
<td>122(26) €</td>
<td>0.00***</td>
</tr>
<tr>
<td><strong>PP plasma sugar</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Intervention Group</td>
<td>220(103) €</td>
<td>188(33) €</td>
<td>0.00***</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>211(99) €</td>
<td>164(29) €</td>
<td>0.00***</td>
</tr>
<tr>
<td><strong>HbA1c</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Intervention Group</td>
<td>7.4(1.15) €</td>
<td>7.1(0.6) €</td>
<td>0.00***</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>7.10(0.95) €</td>
<td>6.60(0.40) €</td>
<td>0.00***</td>
</tr>
<tr>
<td><strong>BMI – Body Mass Index, WHR – Waist Hip Ratio, PP – Post prandial, HbA1c - Glycated Hemoglobin</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

At the end of the study, it was observed that there were changes in respect of weight, BMI, waist hip ratio, fasting blood sugar, post prandial blood sugar and HbA1c in both the group (Table No 2). Among the Non Intervention Group patients, median of the body weight changed from 68 (SD 11) to 66 (SD 11.5) with a significance level of 0.02. Among the Intervention Group patients, the change in median of body weight was 57(SD 13) K to 56 (SD 12) K and it was significant (Table No 2). In the Non Intervention Group, change of BMI was from 26.9 (SD 5.5) to 26.8 (SD 5.3) and was found to be statistically significant. Similarly in the Intervention Group, there was statistically significant BMI change [from 24.4 (SD 5.1) to 23.9 (SD 4.5)]. (Table No 2). Changes of median Waist Hip Ratio (WHR) in the Non Intervention Group, from 0.967(SD 0.123) to 0.966(SD 0.103) and in Intervention Group, from 0.98(SD 0.08) to 0.97(SD 0.07) was also statistically significant (Table No 2). There was significant change of fasting plasma sugar in Non Intervention Group as well as in Intervention Group (144(SD 50) to 128 (SD 35) and 144 (SD 49) to 122 (SD 26) respectively). Changes in regard to post prandial plasma sugar were also similarly significant in both the group (220 (SD 103) to 188 (SD 33) in Non intervention group and 211 (SD 99) to 164 (SD 29) in Intervention group ). (Table No 2). HbA1c changed from 7.4 (SD 1.15) to 7.1 (SD 0.6) in Non Intervention Group, with net change of 0.03. The change was significant (p 0.00). In Intervention Group, HbA1c

Table-3:  Inter-group comparison (Mann-Whitney U, Independent sample T test)

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group ( N 71) (Median changes)</th>
<th>Non Intervention Group ( N 67) (Median changes)</th>
<th>Intergroup relation ( p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHR</td>
<td>0.000 (IQR 0.0109)</td>
<td>0.000 (IQR 0.0153)</td>
<td>0.696</td>
</tr>
<tr>
<td>Fasting plasma Sugar</td>
<td>22.000 (IQR- 26.6588)</td>
<td>19.00000(IQR 20.5485)</td>
<td>0.015</td>
</tr>
<tr>
<td>PP plasma Sugar</td>
<td>32.000 (IQR 63.0776)</td>
<td>30.000 (IQR 35.0746)</td>
<td>0.321</td>
</tr>
<tr>
<td>HbA1c</td>
<td>0.500 (IQR 0.8206)</td>
<td>0.300 (IQR 0.3587)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Inter-group comparison of changes in median
parameters like Waist hip ratio, Fasting plasma Sugar, Post Prandial plasma Sugar, HbA1c of both the group
were compared by Mann-Whitney U, independent sample T test. No significant difference of
changes in these parameters between the two groups
could be observed regarding WHR and PP plasma Sugar (Table No 3). Whereas, when a change of Fasting
Sugar and HbA1c in both the group was compared,
significant difference between groups was observed
(Table No 3).

DISCUSSION

In this study we observed that there was
significant reduction of body weight in both the groups.
As there was significant change of weight, change of
BMI was obvious. We observed that both the variables
were of higher value for Non Intervention Group at
starting point of the study and for both cases of weight
and BMI, the difference between two groups was
significant. So inter group comparison of change in
these parameters were not considered. However in a
previous study significant weight loss as well as
reduction of BMI after dietary intervention for 90 days
was seen [10]. Again, in separate two systemic reviews
have there was short time benefit of dietary intervention
in regard of weight reduction [11, 12].

In the present study, waist hip ratio of both the
group was similar. Changes of median, in the Non
Intervention Group as well as in Intervention Group of
WHR were statistically significant. It was very
interesting that even within such a short duration,
significant change of waist hip ratio occurred. But in
inter-group comparison between the two groups,
difference in change of WHR was found statistically
not significant. Probably this change in WHR also may
be explained by the significant weight loss. In a
separate study, weight loss preferentially reduced
metabolically active visceral adipose tissue. Even
moderate weight loss (5–10%) has been associated with
disproportionate mobilization of visceral adipose tissue
with concomitant decrease in risk. [13] Earlier in a
study of overweight British white women, it was
demonstrated that weight loss was associated with
reduction in waist circumference(WC) and the largest
stable reductions in WC after 6 months produced
improvements in at least one of several risk factors(e.g.,
coresterol, low-density lipoprotein cholesterol,
and diastolic blood pressure) [14].

Importantly, we found significant reduction in
fasting as well as post prandial sugar in both the group
and again even with short term dietary intervention, the
inter-group difference was also found to be significant.
At baseline, HbA1c of the Non Intervention Group was
almost similar with that of the Intervention Group.
We did adjustment of medication before enrolling patients
for the study that likely contributed to improved
glycaemic status. Again, probably the reduction of FPG
and PPBG had impact on reduction of HbA1c. The
HbA1c change from 7.4 (SD 1.15) to 7.1 (SD 0.6) in Non Intervention Group, was significant (p 0.001).
In Intervention Group, HbA1c changed from 7.10 (SD
0.40) which was also significant (p 0.001). In
Intervention Group, HbA1c changed from 7.10 (SD
0.95) to 6.60 (SD 0.40) which was also significant (p
0.00). We observed greater reduction of HbA1c in
Intervention Group in comparison to Non intervention
group. Inter group correlation and comparison
confirmed significant difference in HbA1c reduction
(Table No 3) in Intervention Group in comparison to
group control. Hence, our study confirms the benefit of
dietary intervention for reducing HbA1c and further
improvement of glycemic control. Similarly, in a
previous study of 90 days of dietary intervention,
significant reduction of HbA1c was observed. [10]
other studies also observed significant reduction of
HbA1c (0.18 ± 0.16), [15] whereas finding of another
study regarding HbA1c of 7.1%±0.6 to 6.8%±0.5) (P =
.012), [16] compared to the control group by 0.30%,
was marginally higher than our finding. Finding of
0.4±0.14 % change of HbA1c after 72 week of
intervention in another study [17] was relatively lower than
our study finding. Though one study [18] could
not find any significant change of HbA1c with measure
of dietary regulation, two other studies, HbA1c
reduction of 0.02% [19] and HbA1c change of 1.5 %
[20]; found significant change in HbA1c.

Therefore, in conclusion, we may observe that
even short term strict adherence to medical nutrition
therapy can have significant impact on glycemic control
in type 2 diabetes patients. The present study was done
for short duration and also the study sample was small
like other previous studies. Normalcy of sample
distribution was not present among the groups in this study. So, probably a longer follow up study with large sample may be wished for better understanding of the role of medical nutrition therapy in type 2 diabetes.

REFERENCES