Effectiveness of Lifestyle Modification Counseling on Glycemic Control in Type 2 Diabetes Mellitus Patients

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Abstract

This study was carried out to assess the effectiveness of lifestyle modification counseling using lifestyle intervention holistic model and its adherence towards glycemic control in type 2 diabetes mellitus patients. This quasi-experimental prospective study was conducted among 224 type 2 diabetes mellitus patients in Delhi Diabetes Research Center, New Delhi. The study participants were allocated to lifestyle modification counseling group (intervention) and usual care (control) group based on receiving or not receiving lifestyle modification counseling using lifestyle intervention holistic model. Effect of counseling on glycemic control was assessed at baseline and follow up of both the groups at 3rd, 6th and 12th months after receiving lifestyle modification counseling. The collected data was analyzed for percentage, mean, median, standard deviation, chi-squared, t-test and Wilcoxon test. In this study, the lifestyle modification counseling proved to be effective and showed significant improvement in fasting blood sugar (175.5±32.3 to 144.7±17.6),postprandial blood sugar (275.5±61.3 to199.0±48.3), hemoglobin A1c by 9.3±1.5 to 8.4±1.3. Significant improvement was observed in diastolic blood pressure (82.6±7.0 to 79.4±6.1) and high-density lipoproteins cholesterol (47.3±10.5 to 58.8±5.6) from 3rd to12th months follow up with significant p value <0.001 in the intervention group. The study showed good adherence to balanced diet, physical activity, and tobacco and alcohol cessation but less adherence was observed towards meditation for stress management, regular checkups, and medicine adherence. Lifestyle modification counseling is an effective, noninvasive approach towards glycemic control in type 2 diabetes mellitus patients. Lifestyle intervention holistic model used in this counseling may be helpful for type 2 diabetes mellitus patients to improve adherence and self-care behavior towards the management of their diabetes.

Introduction

Type 2 diabetes mellitus is a complex and multifactorial metabolic disorder, occurring mainly due to insulin resistance in the peripheral tissue[1] and associated with various co-morbidities (obesity, hypertension, dyslipidemia and heart disease), which increase the rate of morbidity and premature deaths due to micro and macro vascular complications[2,3]. Diabetes mellitus is recognized as the epidemic disease of the 21st century affecting millions of people worldwide. The prevalence of diabetes has been increased dramatically from last twenty years and the disease is now a global public health problem. International Diabetes Federation, reports that 8.8% or 415 million are suffering from diabetes around the world and this number is expected to rise to 642 million by 2040[3]. According to IDF, India has a burden of 69.1 million cases of diabetes and this number is estimated to increase 123 million by 2040 and it is also estimated that India has the second highest cases of diabetes in the world after China[4,5]. Complications of T2DM can be costly due to its chronic nature and multi-organ involvement. These may include kidney failure, blindness, foot amputations and heart disease. The condition is also associated with an economic burden at patient and national level because of the frequent visits to the doctor and admissions to hospitals. There are several lifestyle factors such as sedentary lifestyle, changes in dietary habits, obesity, stress, physical inactivity, smoking, consumption of tobacco and alcohol which are associated with the development of type 2 diabetes mellitus (T2DM)[6-8].

Glycemic control is the main treatment goal in diabetes management, because it is associated with improved health outcomes and reduces the rate of severe complications and co-morbidities[9]. Along with the pharmacological treatment, management of diabetes requires patient commitment to comply with medical check-ups, blood glucose monitoring and regular medication therapy[10-17]. Adherence to the lifestyle interventions and self-care behaviors of the patients plays an important role in the management of T2DM and improves glycemic control, lipid profile, BMI and blood pressure, and reduces diabetes-related complications[18]. Non-adherence to medication and self-care may result in increased disease burden, worsen clinical outcomes, increased health care needs, frequent hospitalizations and increased health care costs[19].

Several studies indicated that a poor knowledge of diabetes and its management in T2DM patients is associated with a higher BMI, poor glycemic control, prolonged use of pharmacological treatment, and more complications and co-morbidities[20]. Hence repeated health education and lifestyle modifying interventions provided by physicians and other health educators are required[21]. The results of two randomized controlled trials showed a significant improvement in glycemic control and physiological parameters in T2DM patients following a six-month lifestyle intervention program[22-23].

Lifestyle intervention is an effective, non- invasive way to manage weight, glycemic control, blood pressure and to reduce the risk of fatal complications in T2DM patients[24-25].

There are only few studies in India, which have attempted to establish a comprehensive lifestyle intervention counseling program. We aimed to introduce such intervention and hypothesized that lifestyle counseling will be more effective than usual care and will improve glycemic control in T2DM patients.

Material and Methods
Study Design and Setting

This was a quasi-experimental prospective study conducted among 224 T2DM patients in Delhi Diabetes Research Center (DDRC), New Delhi, India. The study participants were allocated to lifestyle modification counseling (LMC) group or usual care (UC) group through consecutive sampling procedure. Delhi Diabetes Research Center is the health care organization, which provides treatment facilities to diabetes mellitus patients. This study was conducted in two phases in DDRC, New Delhi.

Eligibility Criteria

Participants were eligible if they were clinically and diagnostically confirmed to have T2DM for one year or longer, were of either sex, aged between 35 to 70 years with fasting blood sugarmore than 120 mg/dl, postprandial blood sugar more than 180 mg/dl, and HbA1c above 7 %. WHO and American Diabetes

Association (ADA) set a target of HbA1c 7 % to control diabetes, hence this figure considered in this account. Patients presenting with at least one co-morbidity (obesity, hypertension, coronary heart disease) with T2DM were included in this study.

Excluded were the patients who were not willing to participate or unable to give valid written consent, hospitalized at the time of recruitment, those with Type 1 and Gestational Diabetes, or patients with severe heart, liver or kidney failure as well as patients with severe complications of foot or unable to do physical activities. Additionally, patients who received multiple lifestyle intervention counseling within the last year and patients with a history of mental disorder, visual or, hearing problem were also excluded.

Sample size

Patients were recruited using consecutive sampling technique. The sample size (n=224) was considered to be statistical significant, 112 per group by taking 20 % lost to follow-up into the account. The following formula was used:

$$n = (z_{1-\alpha/2}\sqrt{(2p(1-p)} + z_{1-\beta}\sqrt{(p_s(1-p_s)} + p_t(1-p_t)))^2/(p^t-p^s)^2$$

Where $p = (p_t + p_s)/2$, pt is the proportion in LMC group and ps is the proportion in UC group.

Interventions

The intervention was conducted in two phases. The first six months were an active period where counseling was provided once a month. The second phase was the maintenance period where the participants were followed up for another six months. A comprehensive LMC program was consist of Lifestyle Intervention Holistic Model (LIHM) and used as a tool for counseling of participants to control T2DM. An experienced dietician, diabetes educator, physical trainer and diabetologist gave the lifestyle modification counseling sessions in DDRC, New Delhi. The counseling sessions were repeated at every month for 6 months and follow up and measurement of the study participants was done at baseline, 3rd, 6th and 12th month. All lifestyle intervention components were explained through counseling in the local language, supported by pictures, videos and face to face interviews and discussions with individual or group of individuals. Each session of lifestyle modification counseling took approximately 10-15 min. There were five key components of counseling session, which are described in Table 1.

Table 1: Five key components of Lifestyle Intervention Holistic Model (LIHM) used for Lifestyle Modification Counseling (LMC)

Intervention	Sessions Conducted by	Description of the Intervention	Rationale
Balanced diet	Dietician	Participants were motivated to follow diet chart strictly. They were also encouraged to reduce the intake of fatty, salty, and sugary food products and increase the intake of fibrous diet such as whole grain, green vegetables, and fruits.	Balanced diet help in glycemic control, weight & blood pressure management. Fibrous diet fruits reduce the blood sugar and cholesterol level.
Physical Activity	Physical trainer	Participants were motivated to adhere to the regular brisk walk for at least 30 minutes per day. Training of Mudrasana, Balasana, Vajrasana, Paschimottanasana, ArdhaMatsyendrasana, SuptaVajrasana, Dhanurasana, Shavasana) yogic exercise was given and advised to adhere the practice for 30 minutes per day.	Physical activity reduces the blood glucose level, cholesterol and triglycerides, blood pressure, and improves the response of the anti-diabetic drugs. It also helps in stress management and improvement in health-related

Tobacco & Alcohol Cessation	Health counselor	Motivational counseling was provided to the participants to quit Tobacco (smoking and chewing tobacco) and excess intake of alcohol.	quality of life. Cessation of tobacco and alcohol helps in management of diabetes and associated risk factors, coronary heart disease.
Stress Management	Diabetes educator and physical trainer	Psychological technique, counseling and breathing exercise advised for at least 15 minutes per day to control stress and advised to take proper sleep.	During meditation the level of stress hormone (adrenaline cortisol) reduced which further help in glycemic control.
Adherence to Routine Check-ups & Medication	Diabetologist	Participants were encouraged for routine medical check-ups (blood sugar fasting, PP, HbA1c, lipid profile) at appropriate time. They were also instructed to take their medicine regularly at the proper time without skipping.	Routine medical check-ups are necessary in order to obtain better diabetes management and make patients aware about complications. Medication adherence with lifestyle modification controls blood glucose more rapidly.

Control Group

Participants in the usual care group received standard care, which consisted of pharmacological and provision of pamphlets and booklets about various health topics.

Data Collection

The total data collection process was completed in one year and three months (three months for enrollment of the study participant and, one year for intervention and follow-up). Data on demographic, physiological and anthropometric measurements were collected from all participants at baseline data as well as at 3, 6 and 12 months from the beginning of the intervention. Adherence to the lifestyle intervention was assessed in the participants of the intervention group via the questionnaire at 3rd, 6th and 12th months.

Measurements

The primary outcome measures for this study was blood sugar fasting, blood sugar PP, and HbA1C. Fasting and PP blood glucose tests were analyzed using 'Contour Plus One' blood glucose monitoring system. HbA1c was assessed using an 'Alere Afinion AS100 analyzer'. Secondary outcome measures included weight, BMI, body fat, systolic and diastolic blood pressure, total cholesterol, triglyceride, LDL cholesterol, HDL cholesterol, and adherence to counseling. At baseline, the anthropometric measurements (weight, height, BMI, and body fat) were assessed in all study subjects. Height and weight of the participants were observed using a 'Stadiometer' and 'SECA' digital scale, and BMI was calculated using the formula of weight in kg divided by height in m^2 (kg/m^2). Body fat was measured with body fat caliper. Trained personnel assessed the blood pressure using 'Pagoda (mercury) B.P' instrument. Cholesterol was assessed by the CHOD-PAP method, triglyceride by GPO method, HDL-cholesterol by immune inhibition method and LDL was calculated using standard formula [LDL = Total Cholesterol - HDL - (Triglycerides/5)]. Adherence to lifestyle intervention (LIHM) among T2DM patients were assessed through lifestyle intervention adherence questionnaire. These questionnaires have 20 questions covering all key components of LIHM ; Balanced diet, Physical activity, Tobacco and Alcohol cessation, Stress management, Routine medical check-ups & Medication adherence. The response of the participants was based on a weekly time frame in seven-point Likert scale to answer the question expressed as "On how many of the last 7 days did you…?[26]. For these items, the higher scores reflect higher adherence rate except for items in questions:3, 4, 9,10,11,12.16,17 and 18, which

reflect unwholesome choices (such as foods high in sugar or fat etc.) and for these items, higher scores reproduce lower adherence.

Statistical Analysis

Statistical package for the social sciences (SPSS) software version 21 was used for all statistical analyses. In this study percentage and chi-squared test was used in the assessment of baseline demographic characteristics of the subjects. Mean,SD, sample paired & independent t- test was used for glycemic assessment, physiological and lipid profile assessment. LMC adherence in intervention group was assessed using median and Wilcoxon test.

Ethical Approval and Consent

Prior permission has been obtained from the concerned authorities of DDRC, New Delhi and Ethical approval was granted by SAAOL Heart Center (Ref.No.IEC/SHRF/Ph.D/P-01/29.04.2016) New Delhi. Informed consent has been obtained from all enrolled study participants.

Results
Recruitment and Response Rate of Participants

A total 312 T2DM patients were screened from DDRC of which 88 patients were excluded due to following reasons:12 patients having diabetes less than one year, 27 refused to give written consent, 33 refused to participate at follow ups, and 16 patients, having timing difficulties. A total of, 224 patients were enrolled. Ten patients from LMC group and twelve patients from the usual care group lost to follow up and were excluded from the analysis.

Baseline Characteristics of the Participants

The mean age was 51.4±9.3 in LMC group and 54.0±8.6 in the UC group. This study data has 118 (58.4%) males and 84 (41.6%) females. The majority of patients have co-morbidity of obesity (127), hypertension (150), and heart disease (68). In this study, 38.1% patients were having the family history of diabetes and more than half of (55.4%) patients were found non-vegetarian. Total number of smokers was 31, tobacco chewing history was 24 and excessive alcohol users were 51 in this study. The baseline characteristics of the study subjects are presented in Table. 2

Glycemic Control

There was a significant improvement in blood sugar fasting (175.5±32.3 to 144.7±17.6), blood sugar PP (275.5±61.3 to 199.0±48.3), HbA1c % (9.3±1.5 to 8.4±1.3) within the LMC group from baseline to 12 months follow up. If we compare both LMC and UC group, there was a significant change observed in blood sugar PP, and HbA1c with p<0.001. The details of results are given in Table. 3

Table 2: Baseline demographic characteristics of participants

Characteristics	Total n=202	Intervention n=102	Control n =100	p-value
Age (in years)	52.7±9.1	51.4±9.3	54.0±8.6	0.336
Gender				
Male (n)	118	48.3%	51.7%	
Female (n)	84	53.8%	46.4%	0.276
Locality				
Rural	42	76.2%	23.8%	
Urban	111	50.5	49.5%	
Semi-Urban	49	28.6%	71.4%	<0.001
Duration of Diabetes (in years)	7.9±6.2	7.93±6.4	7.93±5.9	0.797
Family History of Diabetes				
Yes	77	50.6%	49.4%	
No	125	50.4%	49.6%	0.973
Food Habits				
Vegetarian	89	50.6%	49.4%	

Non-vegetarian	112	50.0%	50.0%	
Vegan	1	100.0%	0.0%	0.609
Co-morbidities				
Obesity	127	66.67%	59%	
Hypertension	150	74.51%	74%	0.510
Heart Disease	68	37.25%	30%	
Risk Factors				
Smoking	31	9.8%	21%	
Tobacco chewing	24	10.78%	13%	0.155
Alcohol	51	20.59%	30%	

Table 3: Changes in glycemic control of participant's measurements from baseline to 3rd, 6th and 12th month follow-up with differences within and between groups over time

Variables		Treatment	Control	Difference between the group (p-value)
Blood sugar Fasting				
Baseline		175.5±32.3	154.2±28.5	0.000
3 Month		158.6±26.7	150.9±24.8	0.036
6 Month		142.0±26.3	142.8±29.7	0.851
12 Month		144.7±17.6	144.3±16.2	0.846
Difference	B-3M	<0.0001	0.228	
within group	B-6M	<0.0001	<0.0001	
(p-value)	B-12M	<0.0001	0.002	
Blood sugar PP				
Baseline		275.5±61.3	300.8±64.2	0.005
3 Month		239.6±58.2	280.3±54.9	0.000
6 Month		200.4±52.1	260.1±56.3	0.000
12 Month		199.0±48.3	269.6±53.3	0.000
Difference	B-3M	<0.0001	<0.0001	
within group	B-6M	<0.0001	<0.0001	
(p-value)	B-12M	<0.0001	<0.0001	
HbA1c %				
Baseline		9.3±1.5	9.9±1.9	0.025
3 Month		8.8±1.4	9.7±1.6	0.000
6 Month		8.4±1.3	9.7±1.6	0.000
12 Month		8.4±1.3	10.0±1.7	0.000
Difference	B-3M	<0.0001	0.085	
within group	B-6M	<0.0001	0.035	
(p-value)	B-12M	<0.0001	0.267	

Physiological Parameters

Significant changes was observed in body fat% and diastolic blood pressure from 3rd to 12th month follow-up between LMC and UC group with p<0.001. A significant change was observed in systolic B.P and pulse rate between LMC and UC group at 6th and 12th months.There was no significant change in weight and BMI throughout the follow-up. If we see within LMC, there was a significant improvement as being observed in Weight (74.4±14.5 to 72.6±12.3) Body fat %(30.7±5.5 to 29.2±3.8), Systolic B.P mmHg (134.9±16.0 to 124.7±9.5), Diastolic B.P (82.6±7.0 to 79.4±6.1), Pulse (76.6±3.7 to 74.9±2.5) from baseline to 12th months follow-up. The details of results are enclosed in Table 5.

Lipid Profile

There were significant changes being observed in HDL cholesterol between LMC and UC group from 3 to 12 month with p<0.001. There was a significant change, observed in LDL and total cholesterol at 6th and 12th. Significant reduction within the group was observed in total cholesterol (286.4±103.2 to 205.8±56.9), triglyceride (235.6±114.0 to 175.0±41.1), HDL cholesterol (47.3±10.5 to 58.8±5.6), and LDL cholesterol (192.1±91.2 to 111.9±54.8) from baseline to 12 months follow up. The details of results are given in Table 5.

LIHM Adherence Status

After lifestyle modification counseling the adherence was assessed through seven point liker scale which showed the significant improvement in diet chart(Q1), eat generous amount of fibrous diet(Q2), reduce to take sugar rich products(Q 3), reduce to eat junk foods(Q4), walk for 30 minutes (Q5), take stairs instead of using lift or elevator (Q7), walk by feet to market or office (Q8),consume tobacco (Q9), leave tobacco even you had strong feeling to consume it (Q10), drink alcohol (Q11), leave alcohol even you had strong feeling to drink it (Q12), get proper sleep(Q14), feel relax and happy (Q15), check your feet for any symptom of diabetes complication(Q20). The adherence was increased from 3rd month to 6th month follow-up but not sustained till 12th month except tobacco and alcohol cessation. In short, this study results demonstrates good adherence to diet, physical activity, and tobacco and alcohol cessation but lower the adherence to meditation for stress management, regular checkups and medicine adherence. Detail of LIHM adherence is given in Table. 4.

Table 4: LIHM adherence outcomes based on a weekly time frame in seven points Likert scale

S.No	Adherence to LIHM	After 3 months (Median)	After 6 months (Median)	After 12 months (Median)	3M-6M p-value	3M-12M p-value
1	Diet Chart	5	6	5	<0.0001	0.148
2	Eat fibrous diet	5	7	5	<0.0001	0.039
3	Eat sugar rich products	2	1	2	<0.0001	0.218
4	Eat junk food	2	1	2	<0.0001	0.153
5	Walk for at least 30 Minutes	5	6	5	<0.0001	0.641
6	Yogic Exercise	4	4	4	0.736	0.244
7	Take stairs instead of using lift or elevator	4	5	4	0.004	0.877
8	Walk by feet to your office or market	3	4	3	<0.0001	0.878
9	Consume tobacco (Smoking/ Chewing)	0	0	0	<0.0001	<0.0001
10	Leave tobacco even you had strong feeling to consume it	0	0	0	<0.0001	<0.0001
11	Drink Alcohol	0	0	0	<0.0001	<0.0001
12	Leave alcohol even you had strong feeling to drink it	0	0	0	<0.0001	<0.0001
13	Meditate to control stress	3	3	3	0.262	0.193
14	Get proper sleep	6	6	6	0.019	0.750
15	Feel relax and happy	5	6	5	<0.0001	0.617
16	Feel much stressed	4	4	4	0.714	0.596
17	Forget to take your regular medicines	1	1	1	0.901	0.499
18	Left your medicine when you feel better	1	1	1	0.641	0.869
19	Check your glucose level	2	1	1	0.849	0.878
20	Check your feet for any symptom of diabetes complication	5	6	5	<0.0001	0.882

Table 5: Changes in Physiological and Biochemical parameters of participant's measurements from baseline to 3rd, 6th and 12th month follow-up with differences in within and between groups over time

Variables		Treatment (n=102)	Control (n=100)	Difference between the group (p-value)
BMI				
Baseline		27.8±5.6	27.8± 5.6	0.891
3 Month		27.3±4.9	27.8±5.5	0.431
6 Month		27.0±4.8	27.7±5.4	0.327
12 Month		27.9±5.3	28.4±5.2	0.476
Difference	B-3M	<0.0001	0.300	
within group	B-6M	<0.0001	0.814	
(p-value)	B-12M	0.176	0.001	
Body fat				
Baseline		30.7±5.5	32.1±6.4	0.097
3 Month		29.9±5.1	31.9±5.9	0.015
6 Month		29.4±4.4	31.6±5.5	0.002
12 Month		29.2±3.8	31.4±5.0	0.000
Difference	B-3M	<0.0001	0.282	
within group	B-6M	<0.0001	0.033	
(p-value)	B-12M	<0.0001	0.016	
Systolic B.P				
Baseline		134.9±16.0	134.1±13.3	0.699
3 Month		129.5±13.1	131.1±11.9	0.367
6 Month		125.5±9.7	130.9±11.3	0.000
12 Month		124.7±9.5	131.1±12.3	0.000
Difference	B-3M	<0.0001	0.009	
within group	B-6M	<0.0001	0.003	
(p-value)	B-12M	<0.0001	0.012	
Diastolic B.P				
Baseline		82.6±7.0	84.6±6.5	0.043
3 Month		80.3±6.04	83.7±6.6	0.000
6 Month		78.9±4.8	83.5±6.1	0.000
12 Month		79.4±6.1	84.0±7.2	0.000
Difference	B-3M	0.001	0.281	
within group	B-6M	<0.0001	0.167	
(p-value)	B-12M	<0.0001	0.222	
Pulse				
Baseline		76.6±3.7	76.0±3.1	0.238
3 Month		75.1±2.6	75.6±2.9	0.190
6 Month		73.4±2.7	75.1±2.8	0.000
12 Month		74.9±2.5	76.3±3.1	0.001
Difference	B-3M	<0.0001	0.172	
within group	B-6M	<0.0001	0.008	
(p-value)	B-12M	<0.0001	0.581	
Total cholesterol				
Baseline		286.4±103.2	263.9±105.7	0.279
3 Month		247.1±80.1	255.9±100.8	0.621

3 Month		247.1±80.1	255.9±100.8	0.621
6 Month		213.2±83.9	271.2±99.9	0.002
12 Month		205.8±56.9	237.5±77.1	0.01
Difference	B-3M	<0.000	0.252	
within group	B-6M	<0.000	0.448	
(p-value)	B-12M	<0.000	0.010	
Triglyceride				
Baseline		235.6±114.0	194.5±63.2	0.031
3 Month		203.2±87.3	191.1±64.1	0.432
6 Month		172.9±62.7	185.3±70.7	0.352
12 Month		175.0±41.1	193.7±59.4	0.063
Difference	B-3M	<0.000	0.466	
within group	B-6M	<0.000	0.112	
(p-value)	B-12M	<0.000	0.913	
HDL cholesterol				
Baseline		47.3±10.5	48.5±9.9	0.572
3 Month		54.0±8.3	49.1±10.5	0.011
6 Month		59.1±6.9	50.4±10.7	0.000
12 Month		58.8±5.6	47.2±8.5	0.000
Difference	B-3M	<0.000	0.184	
within group	B-6M	<0.000	0.014	
(p-value)	B-12M	<0.000	0.164	
LDL cholesterol Baseline		192.1±91.2	170.0±97.1	0.241
3 Month		152.4±72.2	168.6±98.9	0.344
6 Month		119.5±80.7	183.7±96.5	0.001
12 Month		111.9±54.8	151.5±77.4	0.003
Difference	B-3M	<0.000	0.795	
within group	B-6M	<0.000	0.099	
(p-value)	B-12M	<0.000	0.033	

Discussion

The purpose of this study was to determine the effectiveness of life style modification counseling and its adherence of intervention holistic model on glycemic control and physiological parameters among type 2 diabetes mellitus patients at the 3rd, 6th, and 12th month follow-ups. The results of our study indicate significant reductions in body fat, systolic and diastolic blood pressure, pulse rate, blood sugar F and PP, HbA1C, and an increase in HDL-cholesterol was achieved during follow-ups as compared to the usual care group. Additionally, the adherence of intervention holistic model was increased. This study alsoshows significant improvement in adherence towards diet chart, fibrous diet, reduce intake of sugar rich products, junk foods, physical activity, stress management, checking glucose level and daily monitoringof feet for diabetes complications and it was enhanced from 3rd month to 6th month of follow-up but not sustained till 12 months. The study results conclude that life style modification counseling and its adherence can give significant and beneficial impact on diabetes control and management.

The studies done by Oldroyd *et al.,* and Norliza Ibrahim et al.,[27-28], assessed the impact of lifestyle interventions reported a decrease in the blood sugar PP in intervention group participants at 12 month follow up. In the present study, we found similar results, *i.e.* decrease in blood sugar PP (275.5±61.3 to199±48.2) in LMC group as compared to usual care group (300.8±64.2 to 269.5±53.2) participants that was statistically significant at 12-month follow up (p>0.05). Similar studies by Adachi et al and Spencer *et al.,*[22-23] demonstrated a significant decrease in HbA1c levels 0.7% and 0.8% respectively after lifestyle intervention. Our study showed a significant decrease in HbA1c levels (1.2%, p<0.01) after 12 months follow up. Studies were done by Greaves

et al., and Malkawi, *et al.,* found significant improvements in blood sugar levels, body weight and insulin resistance in the intervention group through diet and diet plus physical activity interventions with lesser use of anti-diabetic medicines compared to a control group[29-30]. Decrease in the body fat and improvement in glucose metabolism[31] is due to adherence of diet chart and increasing physical activity adherence in the LMC group that induced the decrease in total cholesterol, triglyceride, LDL and increase in HDL, as there were dose-response relationships between level of physical activity, HDL-cholesterol, and triglycerides[32].

In the present study, there was a significant reduction in body fat but no statistical significance was observed in body weight and BMI between groups but the mean weight loss in the LMC group (-2.12 kg) was similar to the mean weight loss demonstrated in the systematic review and meta-analysis by Dunkley *et al.,*[33] of -2.32 kg. Finnish diabetes prevention study and US Diabetes Prevention Program (DPP) validates that lifestyle intervention helped in weight reduction; maintain blood pressure,glycemic control and improved HDL cholesterol of T2DM patients[34-35]. A review of 11 studies on group-based education have shown significant improvement in HbA1c%, reduction in body weight and systolic blood pressure, and reduces the requirement for diabetes medication[36]. Studies done by Ghada Asaad *et al.,* Samah *et al.,* and Takuya *et al.,* have shown a significant improvement in glycemic control (fasting, PP and HbA1c) and diet adherence in the intervention group participant after lifestyle based intervention counseling similar to the present study[37-39].

In this study, there was significant increment in adherence at 6th month follow up, but that was not sustained till 12 month follow up,hence there is need of continuous counseling.The results of present study demonstrates significantly good adherence to diet, physical activity, and tobacco & alcohol cessation but showed significantly lower adherence to regular medication, stress management. Lin EH and Katon W *et al.,* in their study demonstrated that adherence to lifestyle practice minimize the burden of diabetes and improve clinical and physiological parameters which further reduce the hospitalization rate and economic burden[19]. The result of our study tries to establish significant improvement in sugar profile, systolic and diastolic blood pressure, pulse rate, lipid profile, HDL cholesterol and body fat. Greaves *et al.,* also found that Intervention is more effective with adherence, follow-up, behavior change self-monitoring and social support[29]. A study done by Tuomilehto J *et al.,* have been shown adherence to prescribed lifestyle modification similar to our study improve blood sugar levels and blood pressure and also reduce the risk of micro and macro-vascular complications of diabetes[40]. Similar studies done by Figueira *et al.,* and Shareef *et al.,* revealed the significant improvements in glycemic levels and medication adherence in the intervention group participants after educational counseling which support the results of our study[41-42]. Studies done by Fadare *et al.,* and Farzana Saleh *et al.,* observed a significant improvement in glycemic control, quality of life, reduction in medical treatment cost and short and long-term diabetes related complications of those patients who showed adherence to anti- diabetic medicines and self-management practice[43-44].

Limitations of the Study
Diabetes patients were selected from only one hospital of Delhi (DDRC) and hence the study findings may not be applicable to the entire diabetic population. There is no standard published tool to evaluate the adherence of the participants besides only self-developed questionnaires, adherence questionnaires were used. The participants responding to questions based on what they supposed to be the correct answer, and not necessarily what was true in their case. Furthermore, there was variability in some of the parameters related to glycemic control, as well as demographic profile at baseline. Also, the adherence of the control group was not measured and while it is assumed that there would have been no statistically significant change, it would have been beneficial to test them. These are most certainly areas that require further multi-centric randomized control study with larger population in different groups.

Conclusion
This study concludes that lifestyle modification counseling through lifestyle intervention holistic model (LIHM) and its adherence among T2DM patients was effective in improving both glycemic

control, physiological and lipid profile of LMC group as compared to usual care group of type 2 diabetes mellitus patients. Adherence behavior of the patients improved and enhanced diabetes management and control skills of LMC group patients. Further multi-centric randomized control trials are required to assess the effectiveness of this tool in larger population for long-term effectiveness.

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