

## Effects of a self-management educational program on metabolic control in type 2 diabetes

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**Background/aim:** India has 63 million diabetic people and the overall prevalence of diabetes in this country is 8.37%. Lifestyle modification by education is the most cost-effective strategy to have better metabolic control. The aim of this study was to investigate the effects of a self-management educational program on control of type 2 diabetes

**Materials and methods:** It was a randomized controlled interventional study conducted among 306 patients with type 2 diabetes mellitus attending the Diabetic Clinic at G.T.B. Hospital, Delhi, from March 2010 to May 2013. The intervention was in the form of group education based on a self-management program, which was earlier developed in the pilot study.

**Results:** The baseline characteristics were comparable in the two groups. After 6 months, there was a significant improvement in the HbA1c levels ( $P = 0.0001$ ), physical activity level ( $P = 0.001$ ), and BMI ( $P = 0.001$ ) in the study group as compared to the control group and this difference persisted even when analysis was done using generalized estimation equations.

**Conclusion:** The findings of this study proved that a self-management educational program is an essential component in the management of diabetes and provided concrete evidence that this is an effective instrument in the control of body weight, blood pressure, and glycated Hb levels in type 2 diabetes.

**Key words:** Diabetes, India, lifestyle, metabolic control, self-management

### 1. Introduction

Diabetes mellitus is a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action, or both (1). The estimated number of people with diabetes worldwide is expected to rise from 171 million in 2000 to 366 million in 2030 (2). Prevalence of diabetes in adults worldwide was estimated to be 4% in 1995 and to rise to 5.4% by 2025 (3). In addition, diabetes is associated with increased morbidity and premature death from cardiovascular disease, including stroke and myocardial infarction (4). The increasing rate of diabetes prevalence appears to be strongly related to lifestyle changes brought on by economic transition, industrialization, and globalization (5). In India, lack of awareness about diabetes and poor access to quality care, especially in villages, increases diabetes-related complications. Lifestyle intervention and modification by education is the most cost-effective strategy to

prevent type 2 diabetes (6). The main aim of education in diabetes is to create as much normality and stability in blood glucose levels as possible in order to avoid complications, while being constantly confronted with new situations and challenges (7–9). The considerable disparity in terms of availability and affordability of diabetes care and low awareness of the disease also add to poor glycemic control in patients (10–12). Young age at the onset of diabetes and a lack of good glycemic control are likely to increase the occurrence of vascular complications (13,14). The economic burden of treating diabetes and its complications is considerable. Recently, the Indian Government has initiated a national program for the management and prevention of diabetes and related metabolic disorders. Lifestyle modification would be an effective tool for the primary prevention of diabetes in Indians and is urgently needed in India to curb the rising burden of diabetes (15). This study was designed to evaluate the efficacy of a self-management educational program on metabolic control in type 2 diabetes.

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## 2. Materials and methods

This study was conducted in the form of an interventional study (RCT) to find out the effectiveness of a self-management educational program on metabolic control in type 2 diabetes. It was a randomized, parallel group trial study with equal randomization for the study and the control group. The project was conducted after a pilot study.

### 2.1. Study setting

The present interventional study was conducted in the Diabetes Clinic of the University College of Medical Sciences and Guru Teg Bahadur Hospital. The study was conducted from March 2010 to May 2013. Initially, a pilot study was done from December 2010 to June 2011 based on which a self-management educational package and tools were developed. Data collection was started in the second phase of the project for the main study, which was from August 2011 to September 2012. Data analysis and writing phase lasted from October 2012 to May 2013.

### 2.2. Population of the study

Subjects with symptoms of diabetes plus casual plasma glucose  $\geq 11.1$  mmol/L ( $\geq 200$  mg/dL) or fasting plasma glucose  $\geq 7.0$  mmol/L (126 mg/dL) or 2 h post 75 g glucose, plasma glucose  $\geq 200$  mg/dL were diagnosed with type 2 diabetes mellitus (T2DM). Patients with an HbA1c level of more than 8% were considered to have unsatisfactory glycemic control, while patients with an HbA1c value 8% or below were considered to have satisfactory glycemic control. Patients with type 2 diabetes registered for the first time in the Diabetic clinic, who were willing and able to participate in small group education sessions, and who gave informed consent were included. Patients who were pregnant, those diagnosed with gestational diabetes, those with a history of malignancy or severe enduring mental health problems, and those who were not primarily responsible for their own care were excluded from the study.

### 2.3. Study

The subjects were enrolled after an OGTT. All of the patients were diagnosed by an endocrinologist, based on revised WHO and IDF criteria. Consecutive newly registered subjects were randomly allocated to two groups (study group and control group) using computer generated random number tables. The control group were given unstructured education and received regular antidiabetic drug treatment as required. The aim of randomization was to remove the bias between the intervention and the control group. The study group was given a package of self-management education and also participated in this group education actively. We followed patients in both groups for a total of 6 months. Measurements for some metabolic parameters and other risk factors were made at

3 and 6 months. A separate follow-up questionnaire for collecting selected details of the patients was used at 3 months. The addresses, and landline and mobile numbers of the study subjects were noted in the questionnaire and diary notebook. As a routine practice in the Diabetes OPD, every patient was given an exact date after 3 and 6 months for follow-up. The control group included 154 subjects at the beginning while data were available for 123 patients at the 6-month follow-up. The overall attrition rate in the study was around 16%, with close to 12% in the study group and 20% in the control group. The loss to follow-up was compared between the study and control groups and no statistically significant difference was observed.

### 2.4. Intervention

The study group received the interventional package. The intervention was in the form of group education based on the self-management program, which was earlier developed and validated in the pilot study. The intervention team consisted of an endocrinologist, internist diabetologist, public health expert, investigator, dietician, and diabetes nurse educator. The comprehensive self-management educational program was administered using a PowerPoint presentation in small groups (4–12 participants). This group education program was designed based on the curriculum of standard self-management developed by the American Diabetes Association in 2002 and modified and tested in the study population in the pilot study. Based on this curriculum, there were 4 h of structured education in 2 weeks, i.e. a 2-h session per week. The self-management educational program consisted of an interventional package by group education, meal planning, planned physical activity, taking diabetic medication, improving quality of life, good metabolic control, and handling episodes of illness and of low and high blood glucose levels, and managing diabetes when traveling. After this, patients in the study group were given one self-management goal. The control group was continuing unstructured education and routine treatment.

### 2.5. Statistical analysis

The data collected through the questionnaires, clinical examination, and investigations were fed into MS Excel, from where they were transferred to SPSS version 20 for further analysis. There were some missing values as expected in an RCT lasting for 15 months. Appropriate tests of significance, such as chi-square, independent t-test, and McNemar's test were applied for univariate analysis. Generalized estimation equations (GEEs) were applied to find out the extent of change if any, between prevalence of risk parameters among the study and control groups over time with adjustment for various potential confounding factors. GEE analysis was done in all 306 subjects as the GEE takes missing data (for subjects lost to follow up at 3 and 6 months) as values missing completely at random.

**2.6. Ethical clearance**

Ethical approval was obtained from the Institutional Ethics Committee-Human Research of UCMS & GTB Hospital, Delhi. The individuals were enrolled in the study after their informed consent. The purpose of the study and liberty to drop out was explained in both Hindi and English, for easy comprehension.

**3. Results**

This study consists of a pilot study and the main study.

**3.1. Pilot study**

The pilot study was conducted from December 2010 to June 2011. In this phase we recruited 60 newly registered type 2 diabetic patients who came to the Diabetic clinic in OPD of GTB Hospital, being randomly assigned into two groups equally (Figure 1). After a 6-month follow-up we analyzed results for 48 patients (24 in each group). Sociodemographic data were as follows: mean age of participants was 45.42 (SD 7.3) ranging from 32 to 60 years. Twenty (41.7%) participants were male and 28

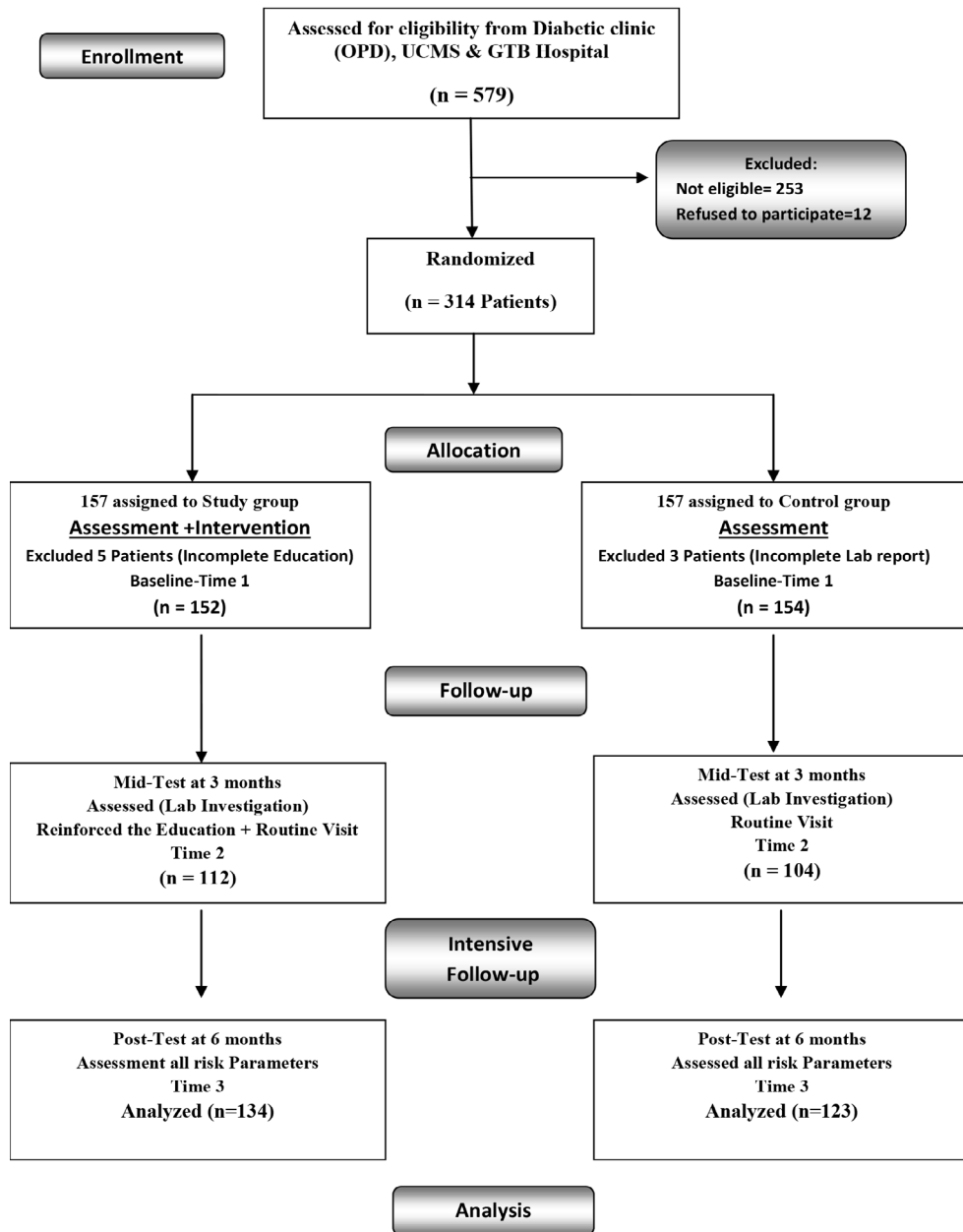
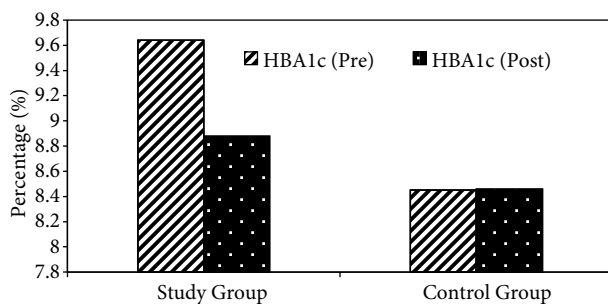


Figure 1. Flow diagram of RCT of SMEP in the present study.

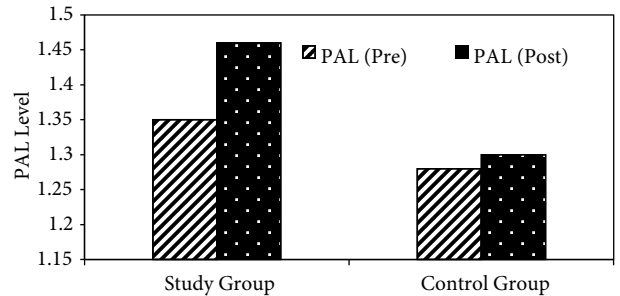
(58.3%) were female. The pilot study showed an attrition rate of 20% totally with 6 patients lost to follow-up in each group. These data were applied to our sample size calculation in the main study and our total sample size was increased to 314 from 280 (based on 10% earlier). The initial intervention included 4 classes each for 1 h totaling 4 h. Based on feedback obtained from the participants in the pilot study, the intervention was modified accordingly to 3 classes each for 1 and ½ h to improve the convenience for the patients and reduce the dropout rate. Sixty patients with type 2 diabetes mellitus were recruited in the pilot study (30 in each group). Data were collected based on a pretested questionnaire. After 6 months 48 patients (24 in each group) completed the study. Figures 2 and 3 depict the comparison of HbA1c and physical activity in the two groups before and after the pilot study.

### 3.2. Main study

Table 1 depicts the comparison of sociodemographic parameters of the subjects in the study and control groups. As shown in this table, the sociodemographic parameters in the study and control groups were not statistically significant ( $P > 0.05$ ) except for one. There was a statistically significant difference between subjects in the study and control groups for socioeconomic status ( $P < 0.043$ ). This table also shows a marginally statistical significance in the study and control groups for educational level ( $P < 0.051$ ). Table 2 demonstrates the comparison of risk parameters in quantitative scale between the two groups. As is clear from this table, the risk parameters in the two groups at baseline were not statistically significant. The proportion of the population with specific risk factors was measured in the two groups. The prevalence of high blood pressure as per JNC VII criteria among the study and control groups in our study was 55.9% and 51.3%, respectively. Hypercholesterolemia (total cholesterol  $> 200$ ) was 35.5% in the study group and 39% in the control group, hypertriglyceridemia (TG  $> 150$ ) was 44.1% and 44.2%, low HDL level (HDL  $< 40$ ) was 47% and 46%, and high LDL level (LDL  $> 100$ ) was 58% and 56.7% in the



**Figure 2.** Comparison mean of HbA1c in both groups (before and after pilot study).



**Figure 3.** Comparison PAL level in both groups (before and after pilot study).

study and control groups, respectively. The levels were comparable at baseline in both groups. Table 3 indicates the comparison of risk parameters in the study and control groups at baseline for categorical variables. There is no statistically significant difference in these risk parameters. Proportion of overweight patients (BMI  $> 23$ ) was 18.4% in the study group and 22.1% in the control group at baseline. The proportion of diabetics who were obese (BMI  $> 25$ ) was 56.6% in the study group and 49.4% in the control group. The dietary association in type 2 diabetes in this study was restricted to analysis of whether the participants consumed a predominantly vegetarian or nonvegetarian diet. The two groups showed comparable distribution of dietary habits ( $P = 0.907$ ). Table 4 describes the changes in mean HbA1c and physical activity level (PAL) in the study group as compared to the control group during the follow-up of 6 months. The mean reduction in the HbA1c was significantly higher in the study group as compared to the control group. Mean change in PAL also showed an increase in the study group over the control group and the differences were highly significant.

### 3.3. Generalized estimation equation

The GEE method with binary logistic was used taking each risk factor at two or three time points as dependent variable and time and other potential covariates as independent variables. Dependent variables were categorized as present or absent (binary). For time, the baseline was taken as the reference category. There was a statistically significant interaction between time and group with HbA1c. There was a significant reduction in percentage of patients with HbA1c  $< 7\%$  in both the study and control groups. However, the percentage reduction in odds ratio was higher in the study group compared to the control group (85.3% vs. 61.2%). PAL showed a significant interaction between group and time. The change with time was significant in the study group with a reduction in people with low PAL of 65.3%. However, this reduction was only 29.1% in the control group and this was not statistically significant (OR 0.247 vs. 0.709) (Figures 4 and 5).

**Table 1.** Comparison of sociodemographic profile of subjects in the study and control groups.

Sociodemographic variables		Study group Number (percent)	Control group Number (percent)	P-value
Age (years)	≤40	45 (29.6%)	31 (20.1%)	0.141
	41–50	60 (39.5%)	65 (42.2%)	
	51–60	47 (30.9%)	58 (37.7%)	
Sex	Male	64 (42.1%)	56 (36.4%)	0.304
	Female	88 (57.9%)	98 (63.6%)	
Urbanization	Urban	142 (89.6%)	138 (89.6%)	0.322
	Rural	10 (10.4%)	16 (10.4%)	
Religion	Hindu	100 (65.8%)	102 (66.2%)	0.935
	Others	52 (34.2%)	52 (33.8%)	
Marital Status	Single	12 (7.9%)	11 (7.1%)	0.803
	Married	140 (92.1%)	143 (92.9%)	
Education	Illiterate	53 (34.9%)	68 (44.2%)	0.051
	Primary-secondary & high school	64 (42.1%)	66 (42.9%)	
	Intermediate-graduate & postgraduate	35 (11.4%)	20 (13.0%)	
Family income (per month) rupees	<4000	43 (28.3%)	57 (37.0%)	0.258
	4000–15,000	85 (55.9%)	77 (50.0%)	
	>15,000	24 (15.8%)	20 (13.0%)	
Socio economic status	Upper	25 (16.4%)	12 (7.80%)	0.043
	Middle	36 (23.7%)	33 (23.7%)	
	Lower	91 (59.9%)	109 (70.8%)	

#### 4. Discussion

The main aim of this study was to evaluate the effect of a self-management educational program on metabolic control and risk parameters associated with type 2 diabetes. This study provided evidence that there would be better metabolic control and reduction in risk factors by secondary prevention via SMEP for diabetes and its complications. At baseline the two groups were similar with respect to the risk factors of diabetes included in the present study. The pattern of treatment at baseline was similar in the both groups via oral antidiabetic drugs (OADs) in 88.2% and 85.7%, insulin treatment in 10.5% and 11.7%, and insulin plus OADs in 1.9% and 1.3% in the study and control groups, respectively ( $P = 0.724$ ). Therefore, we measured glycated hemoglobin level (HbA1c) at 0 and 6 months, which is a better indicator of glycemic control over a period of time. The baseline HbA1c was comparable in the two groups, 9.78 vs. 9.69, and the results were comparable as well ( $P = 0.715$ ). While the change towards normality was significant in both groups, there was no significant difference in

the proportion of change in the two groups. Further, to account for the other factors and the longitudinal nature of this study, GEEs were used to test the significance of the difference. Though GEEs showed significant change with time of HbA1c levels in both groups ( $P < 0.000$  and  $0.001$ ), group time interaction was also significant ( $P = 0.011$ ). The percentage reduction in odds of participants having HbA1c levels  $< 7$  was higher in the study group compared to the control group (85.3% vs. 61.2%). In the PRECEDE study conducted by Salinero et al. (16) in Spain, to evaluate the effect of a health educational program by the PRECEDE model in type 2 diabetes, a 2-year intervention showed significant improvement in the intervention group. The findings in our study are similar to the results obtained from other studies. The DESMOND trial (17) showed significant change in HbA1c levels in both groups with higher change in the study group (1.49% vs. 1.69%), whereas the difference between the groups was not significant after adjusting for baseline and cluster effect ( $P = 0.52$  at 12 months). The Spanish trial (18,19), which assessed the outcome at 6 months, showed significant

**Table 2.** Comparison of risk parameters in the two groups at baseline (quantitative).

Risk parameters		Study group (n = 152)	Control group (n = 154)	P-value
		Mean ± SD	Mean ± SD	
Body mass index (BMI)		26.18 ± 4.5	25.44 ± 4.3	0.149
Waist Circumference	Male	91.38 ± (8.5)	88.79 ± (9.6)	0.122
	Female	90.02 ± (10.7)	90.41 ± (8.5)	0.786
Hip Circumference	Male	91.02 ± (6.4)	86.62 ± (6.6)	0.786
	Female	94.51 ± (9.3)	92.81 ± (6.9)	0.155
Systolic blood pressure		138.86 ± 19.1	137.05 ± 19.5	0.704
Diastolic blood pressure		84.55 ± 10.4	84.56 ± 11.5	0.479
Fasting blood sugar		187.68 ± 62.5	194.06 ± 74.9	0.420
2-h Postprandial		269.84 ± 90.5	271.82 ± 89.2	0.848
HbA1c		9.78 ± 2.06	9.69 ± 2.27	0.715
Cholesterol		186.32 ± 56.8	190.69 ± 55.5	0.715
Triglyceride		155.30 ± 93.4	168.12 ± 121.4	0.302
High density lipoprotein (HDL)		39.08 ± 10.2	40.16 ± 9.51	0.449
Low density lipoprotein (LDL)		111.26 ± 39.1	110.95 ± 47.5	0.960
VLDL		31.62 ± 20.1	31.88 ± 19.4	0.909
Physical activity level		1.47 ± 0.16	1.48 ± 0.20	0.716

**Table 3.** Comparison of risk parameters in the two groups at baseline (categorical).

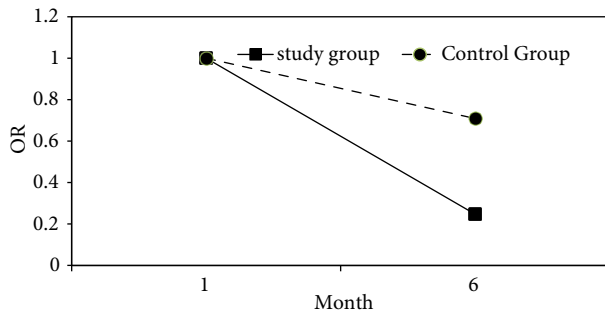
Risk parameters		Study group (n = 152)	Control group (n = 154)	Df	P-value
		Number (percent)	Number (percent)		
Smoking	Yes	11 (7.2%)	15 (9.7%)	1	0.540
	No	141 (92.8%)	139 (90.3%)		
Alcohol consumption	Yes	6 (3.9%)	3 (1.0%)	1	0.334
	No	146 (96.1%)	151 (98.1%)		
Tobacco chewing	Yes	11 (7.2%)	16 (10.4%)	1	0.421
	No	141 (92.8%)	138 (89.6%)		

**Table 4.** Mean changes in HbA1c and physical activity level (PAL) at baseline (T1) and after 6 months (T3) in the two groups.

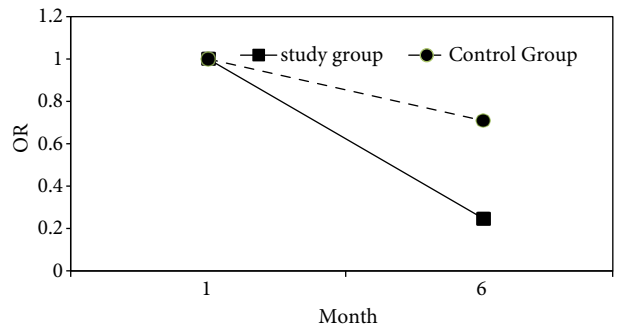
Variables	Study group Mean changes (SE)	Control group Mean changes (SE)	Net changes CI (95%)	P-value
HbA1c	1.60 (0.198)	0.68 (0.198)	0.925 (0.372–1.478)	0.001
PAL	0.113 (0.139)	0.0093 (0.146)	0.103 (0.642–0.143)	0.000

improvement in HbA1C levels in the study group with P value = 0.040 after controlling confounders and baseline differences using ANCOVA models. Steinsbekk et al.'s (20) review study analyzed 13 studies with 1827 participants

with HbA1C levels assessed at 6 months. In the pooled analysis, they found a mean difference of -0.44% and there was high statistical significance in favor of self-management interventions (P < 0.001). The heterogeneity



**Figure 4.** Risk reduction trend in HbA1c in the study and control groups.



**Figure 5.** Risk reduction trend in lack of physical activity in the study and control groups.

was 56% for these 12 studies because of 2 studies that had outlier values. They obtained a mean difference of  $-0.50\%$  after removing these two studies with high statistical significance ( $P \leq 0.001$ ) and heterogeneity of 33%. This change in HbA1C level can be considered a good indicator of glycemic control over a period of time, obtained at 6 months in our study, after 4 h of intervention, with statistical significance tested by robust models such as GEE, is a significant positive result, and helps in furthering the cause towards self-management education adaptation in an Indian setting. The Look Ahead trial (21,22) showed a significant improvement in HbA1C in the intensive lifestyle intervention group comparing to the diabetic support and education group. The mean changes were 0.36 and 0.09 in the two groups, respectively, with a difference of 0.27, which was highly significant ( $P < 0.0001$ ). Physical activity level measured at baseline and 6 months showed significant changes between the two groups. No significant change in the level of physical activity was obtained in the DESMOND trial (17) at 3 years ( $P = 0.58$ ). Steinsbekk et al. (20) conducted a systematic review that did not report change in physical activity or sedentary lifestyle from the pooled data; however, it mentioned one study (23) that showed a significant improvement in physical activity ( $P = 0.003$ ). The Spanish trial (18) reported on aerobic exercise and strength exercise, pre- and postintervention, although there was no significant difference between the intervention and control groups after 3 years. The results of GEE analysis showed only an increase in risk of having high LDL among the control group, whereas there

was no significant reduction in LDL in the intervention group. The difference was statistically significant ( $P = 0.001$ ). Other parameters of lipid profile did not have any significant difference between two groups after 6 months. The PRECEDE study (17) showed change only in HDL levels ( $P = 0.01$ ) and the other constituents of lipid profile had no statistically significant difference between the intervention and control groups. In the DESMOND trial (17,24), after 1 and 3 years, no statistically significant differences were observed in lipid profiles between the groups. The systematic review of randomized controlled trials by Norris et al. (25) reported a large number of studies that investigated the effects of self-management training on lipid levels.

## 5. Conclusions

The current study is the first comprehensive RCT in India, to the best of our knowledge, to examine the effect of an educational self-management package on metabolic control in type 2 diabetes. The results of this study provide evidence that SMEP is beneficial for diabetic patients and the healthcare system. SMEP can successfully reduce the risk factors associated with type 2 diabetes such as BMI, lipid profile, and physical inactivity; also SMEP is effective in improving glycemic control in type 2 diabetes mellitus. This study showed a significantly higher reduction in hemoglobin A1c levels in the study group compared to the control group, although both groups showed reduction from the baseline.

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