ORIGINAL RESEARCH

Effectiveness of a Video-Based Lifestyle Education Program Compared to Usual Care in Improving HbA1c and Other Metabolic Parameters in Individuals with Type 2 Diabetes: An Open-Label Parallel Arm Randomized Control Trial (RCT)

Uttio Gupta · Yashdeep Gupta ⬤ · Divya Jose · Kalaivani Mani ·

Viveka P. Jyotsna · Gautam Sharma · Nikhil Tandon

ABSTRACT

Introduction: This study was designed to investigate the effectiveness of a video-based lifestyle education program (VBLEP) in improving glycemic control in people with type 2 diabetes mellitus compared with usual care.

Methods: Patients on stable oral glucose-lowering agents for at least 3 months and HbA1c 7.5–10% were randomized in a 1:1 ratio. Primary outcome measure was the difference in change in mean HbA1c between groups.

Results: The participants ($n = 81$) had mean ($\pm$ SD) age of 50.1 ($\pm$ 9.4) years and HbA1c of $8.5 \pm 0.7\%$ (68.87 ± 7.56 mmol/mol). The

U. Gupta · Y. Gupta (✉) · V. P. Jyotsna · N. Tandon (✉)
Department of Endocrinology and Metabolism, All India Institute of Medical Sciences, New Delhi, India
e-mail: yash_deep_gupta@yahoo.co.in

N. Tandon
e-mail: nikhil_tandon@hotmail.com

D. Jose · G. Sharma
Department of Cardiology, All India Institute of Medical Sciences, New Delhi, India

K. Mani
Department of Biostatistics, All India Institute of Medical Sciences, New Delhi, India

follow-up data were available in 96% (78/81) of participants. Of 40 participants, 36 (90%) attended $\geq 75\%$ (≥ 3 out of 4) of the sessions in the VBLEP. In the intention-to-treat analysis, a significant reduction [0.6% 95% CI (0.1, 1.1), $p = 0.013$] in HbA1c was seen in the VBLEP group compared with usual care. A $\geq 1\%$ reduction in HbA1c was observed in 39.5% of participants in the VBLEP compared with 15% in the usual care arm. However, a $\geq 0.5\%$ reduction in HbA1c was observed in 65.8% of participants in the VBLEP compared with 37.5% in the usual care arm ($p = 0.012$). There was a significant change in weight and body mass index in the VBLEP group compared with usual care. The participants who were employed, had a family history of diabetes, had no diabetes-related complications, and were in the VBLEP group had higher odds of having a favorable HbA1c reduction ($\geq 0.5\%$, combined analysis both groups) from baseline.

Conclusion: The VBLEP demonstrated a significant and clinically relevant HbA1c reduction compared with usual care. A simple VBLEP, when delivered in an interactive manner, can aid in improving glycemic outcomes in the Indian population.

Trial Registration: CTRI/2017/05/008564.

Key Summary Points

Why carry out this study?

There have been no data on a video-based lifestyle education program (VBLEP) from India for management of diabetes.

This study was carried out to determine the effectiveness of a video-based lifestyle education program delivered to participants with uncontrolled diabetes.

What was learned from the study?

This study found that on intention-to-treat analysis, a significant reduction [0.6% 95% CI (0.1, 1.1), $p = 0.013$] in HbA1c was seen in the VBLEP group.

A $\geq$ 1% reduction in HbA1c was observed in 39.5% of participants in the VBLEP compared with 15% in the usual care arm. A $\geq$ 0.5% reduction in HbA1c was observed in 65.8% participants in the VBLEP compared with 37.5% in the usual care arm.

Presence of diabetes-related complications was less likely to be associated with achievement of a favorable outcome of $\geq$ 0.5% reduction in HbA1c.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) has become a major health burden globally. Medical nutrition therapy (MNT) and physical exercise are essential pillars for the management of diabetes [1]. However, adherence to these lifestyle measures has been sub-optimal in usual care for diabetes [2], resulting in poor glycemic control and a higher rate of diabetes-related morbidity and mortality [3]. To improve outcomes for patients with diabetes, structured lifestyle intervention programs have been designed and evaluated in multiple regions, and many of them were effective in improving glycemic and other metabolic parameters [4, 5].

India has nearly 73 million people affected by diabetes, and by 2045 the numbers are projected to increase to 134 million, which will make it the nation with the highest number globally [1]. Given the high burden of T2DM and its complications in India, effective programs are required that can improve outcomes over and above usual care advice on diet and exercise [2, 3]. However, most of the programs have focused on prevention, and little evidence, if any, exists on such programs for management of diabetes in India [4–8]. In an earlier program, called D-CLIP, participants received a culturally modified diabetes prevention program in a face-to-face intervention, and this resulted in a 32% relative risk reduction of T2DM [6]. A reality video-based lifestyle program based on D-CLIP was developed (12 modules of 15–20 min) and delivered through mobile devices [9]. This was recently tested in individuals at high risk of developing diabetes in India and was found to be effective [10]. In our study, we aimed to evaluate the same program (but compressed 12 modules into 4 videos), which were then delivered in person as an interactive sessions, in individuals with T2DM who had poor glycemic control. To the best of our knowledge, this is the first such VBLEP evaluated in individuals with T2DM from India.

METHODS

Settings and Study Design

This randomized controlled trial (RCT) was performed from June 2017 to October 2018 at the All India Institute of Medical Sciences (AIIMS), New Delhi, a tertiary care hospital in North India. The AIIMS ethics committee approved the study, and written informed consent was obtained from all participants. The study was done as per the ethics delineated in the Helsinki Declaration.

Patient Identification, Recruitment, Inclusion, and Exclusion Criteria

Individuals with T2DM, diagnosed at ≥ 30 years of age and willing to participate in the study as per protocol, were identified from the outpatient clinic of the Department of Endocrinology and Metabolism, AIIMS. Those with HbA1c 7.5–10% and on stable oral glucose-lowering agents for the last 3 months were eligible. Patients with stage 4 and 5 chronic kidney disease, chronic liver disease, cancer, terminal illness, severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy or macular edema, any cardiovascular event requiring hospitalization in the last 6 months or with active diabetic foot ulcer were excluded. In addition, patients on insulin or other parenteral diabetes therapies were excluded.

Procedure on Day of Testing and Measurements

Participants were advised to fast for at least 10 h for the first visit for the evaluation of the fasting plasma glucose, lipid profile, and HbA1c in the morning. Additional information such as the demographics and relevant medical and treatment history was collected. Weight, height, waist circumference, and blood pressure were recorded in fasting state using standard methods [11]. Serum total cholesterol, triglyceride, and high-density lipoprotein (HDL) cholesterol levels and glucose levels were measured directly using an automated biochemistry analyzer (Cobas Integra 400 plus; Roche Diagnostics, Mannheim, Germany). Low-density lipoprotein (LDL) cholesterol was calculated using the Friedewald equation, except in cases with serum triglyceride levels ≥ 400 mg/dl (4.5 mmol/l). Blood for HbA1c was measured by Toshiba G-8 (Tosoh Corp., Japan).

Intervention and Usual Care Details

Video-based lifestyle education program (VBLEP): The curriculum used in the D-CLIP diabetes prevention study was converted into a 12-week video-based reality television series [available as an app (free and commercial) from https://apps.apple.com/in/app/habits-diabetes-coach/id1016026169] [6, 9]. We further adapted and consolidated this content to create four sessions, delivered at weekly intervals, with permission from the developers of the reality television program (Janacare Solutions Private, Ltd, Bengaluru) (details provided in Table 1).

The participants in the usual care arm were prescribed dietary advice by a registered dietician and 30 min of walking at a speed of 5–6 km/h for at least 5 days a week.

We also evaluated yoga as an additional arm in this RCT to gain additional insights into this increasingly popular means of exercise in India. We used the same usual care group, against which each of the two lifestyle intervention arms was compared. This design benefited us as fewer participants (25% less) had to be recruited (using same usual group) with potential savings in cost and time. In this article we present and discuss the results of a video-based lifestyle education program compared with usual care.

Outcome Measures

The primary outcome measure was the difference in change in mean HbA1c between groups. Secondary outcome measurements were change in fasting plasma glucose (FPG), weight, body mass index (BMI), waist circumference, blood pressure, and lipid parameters.

Sample Size Calculation

With the following assumptions, mean HbA1c of 8.8, SD 0.6 [values from baseline parameters of individuals with HbA1c 7.5–10% enrolled at the Department of Endocrinology & Metabolism, AIIMS in the Delhi centre of INDEPENDENT (Integrating DEPrEssioN and Diabetes treatment) Study] [12], and a delta of 0.5 between the intervention and usual care arm, the estimated sample size was 36 in each arm. The assumed power and alpha were 90% and 2.5%, respectively. The alpha error adjusted for multiple testing as the study intended to compare two different lifestyle intervention

Table 1 Contents of the video-based lifestyle education program

Module 1: importance of self-monitoring	The importance of breakfast as a wholesome and balanced meal, along with sample meal plans
	How one can be in charge of their health beyond all daily challenges including overloaded work schedule, involved social life, healthy lifestyle changes
	Plan one's day by planning the right time for eating
	Eating healthy snacks along with sample ideas
	Being true to oneself and achieving success
	Sleeping well for a healthy lifestyle
	Staying on track during the weekend
	Rewarding oneself
Module 2: fat and calorie detective	Learn how fat and calories can affect your health
	Learn where to find them in your food
	Importance of portion sizes and measurement of food
	Being aware of fattening foods and hidden fats and switching to low-fat options to improve health and alleviate the risks of heart disease and diabetes
	Understanding that correlating the quantity of food eaten to its nutrient contribution (calories and fats) helps to remain within the fat and calorie budget for the day that is predetermined by one's initial weight
	Using one's skills to ration portions and choose food items judiciously by evaluating the consolidated caloric intake for the day
	Trying to find a balance through food and exercise
	Incorporating physical activity into your lifestyle
Module 3: having a balanced meal	Understanding the importance of taking a balanced meal and learning what it looks like
	Getting the relevance of the "My plate" concept
	Understanding what to eat from different food groups
	Learning the good side of everything especially fats
	Understand the balance between calories in and calories out by tipping the calorie balance and understanding the food serving sizes
Module 4: FITT for getting active	Techniques to make physical activity fun
	The FITT principle to balance your activity
	Exercises—leg raises and back extensions
	Reviewing what was learned and putting it to practice
	Understanding the serious threat of sedentary lifestyle

Table 1 continued

Module 5: learning about	Keeping food and activity cues by simplifying them
	Learning how our environment causes us to be unhealthy
	Becoming aware of temptations that might steer one off course
	Steps to problem solving
	Singling out areas in need of improvement and creating an action plan focusing on making these changes gradually
	Use tracking to one's advantage
Module 6: strategies for eating out	The healthy side of eating out
	Learning how to control what you eat when not at home
	Ordering healthy food
	Planning ahead when going out to eat with friends or family
Module 7: managing slip-ups	Managing and dealing with slip-ups
	Identify the reasons for a slip-up
	Identifying negative thoughts and learning how to manage them
	Stretching exercises and learning some seated stretching techniques
	Understanding common external triggers for mismanaging diet and exercise and dealing with them
Module 8: understanding social cues	Understanding social cues and how they affect us
	Making lifestyle changes using social cues to one's advantage
	Being aware of your social interactions and how they affect you
	Learning to positively affect outcomes of unhealthy social cues
Module 9: improving strength and flexibility	Improving strength and flexibility
	Strengthening one's exercise program and learning resistance training
	Standing up for your health
	Incorporating strength training into your activity routine
Module 10: volumetrics and eating mindfully	Understanding the importance and concept of volumetrics and eating mindfully
	High-volume, low-calorie foods—learning to eat more food that has fewer calories
	Eating mindfully by perceiving your physical and mental state
	Thinking before eating and being aware how one eats
	Paying attention to size, smell, texture, taste, and its other qualities
	Enjoying your meal to its fullest

Table 1 continued

Module 11: stress management and staying motivated	Maintaining the momentum
	Recognizing positive lifestyle changes made so far
	Stress management
	Combating stress with planned activity
Module 12: long-term heart health	Nurturing your heart into a healthy heart
	Understanding the importance of reducing risk of heart diseases by adopting positive lifestyle changes
	Understanding the importance of the new habits you have developed
	Using your skills to successfully keep the new habits you have created
	Keeping a schedule—tracking your new skill

programs vs. usual care (see details at trial registration site CTRI registration no.: CTRI/2017/05/008564).

Randomization, Allocation Concealment, and Blinding

Patients were randomized in a 1:1 ratio using block randomization with varying block size by computer-generated random numbers. Allocation concealment was done by using sequentially numbered opaque sealed envelopes. Since the intervention was apparent, the trial was open-labeled and non-blinded. However, end point outcome assessment was done by a person who was not aware of the patient group to remove bias.

Statistical Analysis

Stata 12.0 (College Station, TX, USA) was used for statistical analysis. Pearson chi-square test was used to compare qualitative baseline variables among the groups. Quantitative baseline variables were compared using student's t-test or wilcoxan rank sum test (as appropriate). Intention-to-treat and per protocol analysis was done for primary outcome. The difference in change in secondary outcomes in the two groups was assessed by per protocol analysis.

The effect of VBLEP on primary and secondary outcomes compared with the usual care group was analyzed using linear regression analysis. The adjustment for the baseline serum triglyceride level was done in adjusted analysis as it was different at baseline between the two arms. The predictors associated with favorable outcome (difference in HbA1c $\geq$ 0.5% from baseline) were determined using logistic regression analysis, and the results are expressed as odds ratio (95% CI). The results are reported as the difference in changes between the two groups (95% CI). Data are presented as number (%), mean $\pm$ SD, or median (q_{25}–q_{75}) as appropriate. $p < 0.025$ was considered statistically significant.

RESULTS

Baseline Characteristics

A total of 81 individuals were randomized, 41 participants in the usual care arm and 40 in the VBLEP arm. The participants ($n = 81$, women 48%) had mean ($\pm$ SD) age of 50.1 ($\pm$ 9.4) years, duration of diabetes 8.1 ($\pm$ 6.0) years, HbA1c 8.5 $\pm$ 0.7% (68.87 $\pm$ 7.56 mmol/mol), and BMI ($\pm$ SD) 27.7 $\pm$ 4.8 kg/m^2. Family history of diabetes in first-degree relatives was present in 66.7%; 42.0% and 39.5% were on blood

Table 2 Baseline characteristics of the participants

	Total $N = 81$	Usual care ($n = 41$)	VBLEP[#] ($n = 40$)	*P* value
Age (years)	50.1 ± 9.4	50.2 ± 8.6	50.1 ± 9.4	0.960
Male (%)	42 (51.9)	24 (58.5)	18 (45.0)	0.223
Education, graduate and beyond (%)*	29 (35.8)	18 (43.9)	11 (27.5)	0.124
Employed (%)	37 (45.7)	21 (51.2)	16 (40.0)	0.311
Family history of diabetes present (%)	54 (66.7)	26 (63.4)	28 (70.0)	0.530
Anti-hypertensive drug(s) (%)	34 (42.0)	15 (36.6)	19 (47.5)	0.320
Lipid-lowering medication (%)	32 (39.5)	18 (43.9)	14 (35.0)	0.413
Number of participants with oral glucose-lowering agents > 2 (%)	30 (37.0)	11 (26.8)	19 (47.5)	0.054
Participants with diabetes-related complication(s) (%)	28 (34.6)	12 (29.3)	16 (40.0)	0.310
HbA1c (%)	8.45 ± 0.69	8.39 ± 0.65	8.51 ± 0.74	0.449
HbA1c (mmol/mol)	68.87 ± 7.56	68.23 ± 7.08	69.51 ± 8.07	0.449
Weight (kg)	71.6 ± 13.0	70.4 ± 11.8	72.7 ± 14.1	0.441
Body mass index (kg/m^2)	27.7 ± 4.8	27.1 ± 4.1	28.4 ± 5.4	0.235
Waist circumference (cm)	99.5 ± 1.2	98.2 ± 8.7	100.8 ± 12.1	0.282
Systolic blood pressure (mmHg)	130.0 ± 18.7	130.5 ± 18.7	129.4 ± 19.0	0.800
Diastolic blood pressure (mmHg)	83.1 ± 9.5	83.0 ± 9.1	83.3 ± 9.9	0.879
Fasting plasma glucose (mmol/l)	8.6 ± 2.3	8.4 ± 1.5	8.8 ± 2.9	0.429
Total cholesterol (mmol/l)	4.3 ± 0.1	4.3 ± 1.0	4.4 ± 1.0	0.577
Triglycerides (mmol/l)	1.6 (1.3–2.1)	1.5 (1.2–2.0)	1.8 (1.5–2.4)	0.037
LDL cholesterol (mmol/l)	2.4 ± 0.8	2.4 ± 0.7	2.5 ± 0.9	0.891
HDL cholesterol (mmol/l)	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.2	0.983

Values expressed as No. (%), mean ± SD as appropriate. Triglycerides expressed as median (IQR)

LDL low-density lipoprotein, *HDL* high-density lipoprotein

[#] VBLEP: video-based lifestyle education program

*(≥ 15 years of school/college/university education)

pressure and lipid-lowering medications, respectively. Thirty individuals (37%) were taking > 2 oral glucose-lowering agents. The main difference between the two study groups was in serum triglyceride level ($p = 0.037$), which was adjusted during per protocol analysis (Table 2). Of the 81 participants, one from the usual care arm and two from the VBLEP were lost to follow-up (Fig. 1, consort diagram). Adherence was defined as 75% attendance to intervention (attending three out of four video sessions). Of the 40 participants, 36 (90%) were adherent to the intervention.
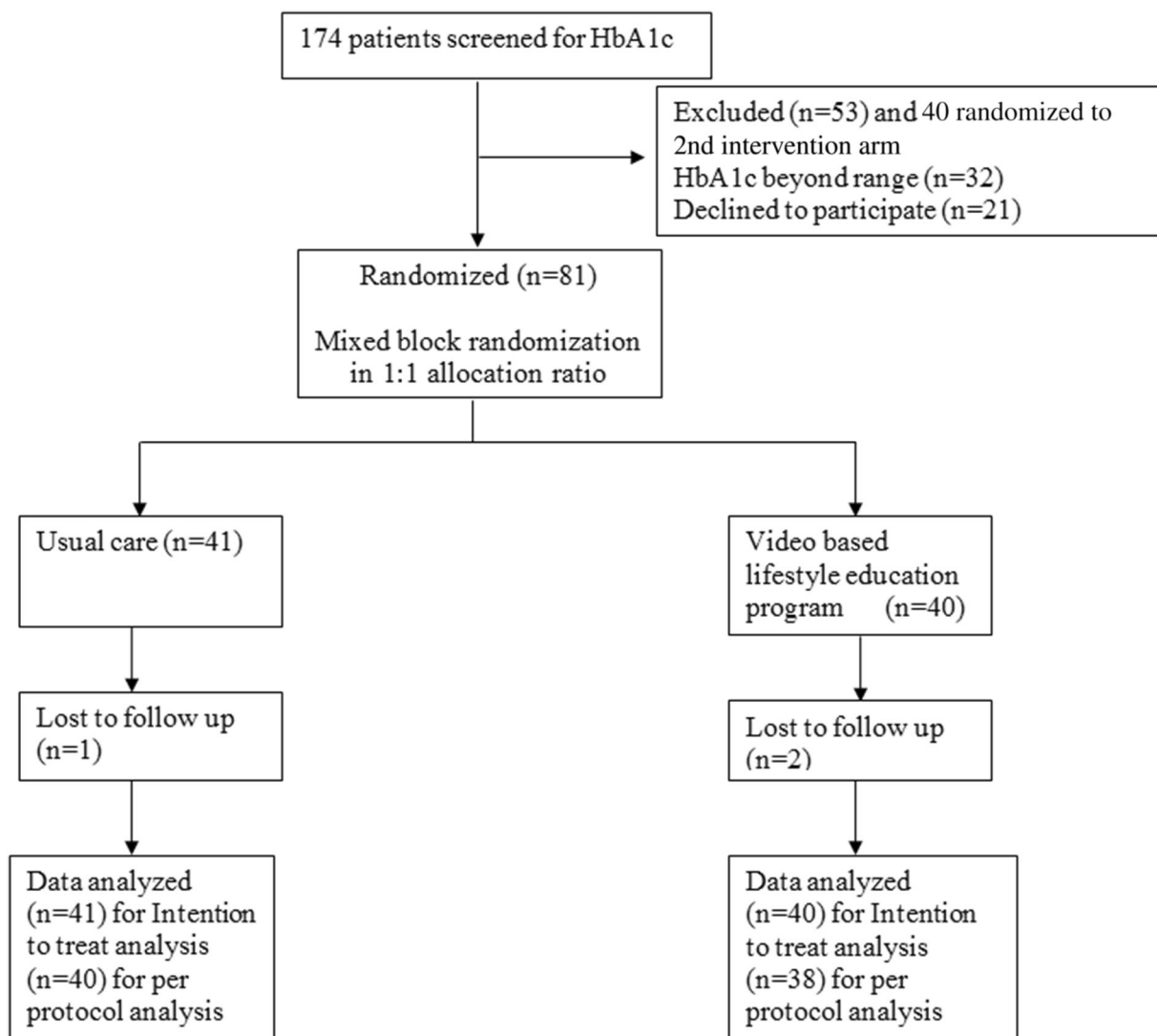
Fig. 1 Flow chart showing patient recruitment and follow-up

Effect on Primary Outcome Measure

On intention-to-treat analysis there was a significant difference [0.64% 95% CI (0.14, 1.14); 7.0 mmol/mol 95% CI (1.50, 12.50), $p = 0.013$] in HbA1c in favor of VBLEP compared with usual care, which remained significant in adjusted analysis (Table 3). The results remained significant even after adjustment for triglycerides, which was different at baseline in two groups. On further analysis on per protocol, the difference between the two arms increased further, and the results were statistically significant.

On further analysis, 6 (15%) participants from usual care and 15 (39.5%) from VBLEP had HbA1c reduction $\geq 1\%$, ($p = 0.012$). The reduction in HbA1c by $\geq 0.5\%$ was observed in 65.8% of participants in the VBLEP compared with 37.5% in the usual care arm.

Table 3 Effect of intervention on HbA1c outcome (primary outcome) in VBLEP vs. usual care

	Usual care (*n* = 41)	VBLEP (*n* = 40)	VBLEP vs. usual care difference in difference (95% CI)	*P* value
At baseline (%)	8.39 ± 0.65	8.51 ± 0.74		
(mmol/mol)	68.23 ± 7.08	69.51 ± 8.07		
After 4 months (%)	8.38 ± 1.37	7.86 ± 1.04		
(mmol/mol)	68.10 ± 14.96	62.38 ± 11.38		
Difference (%)	0.01 ± 1.29	0.65 ± 0.96	0.64 (0.14, 1.14)	0.013
			0.61 (0.10, 1.12)[a]	0.021
(mmol/mol)	0.13 ± 14.09	7.13 ± 10.45	7.00 (1.50, 12.50)	0.013
			6.63 (1.05, 12.23)[a]	0.021
PP analysis: (*n* = 78)	(*n* = 40)	(*n* = 38)		
At baseline (%)	8.40 ± 0.66	8.53 ± 0.75		
(mmol/mol)	68.26 ± 7.17	69.69 ± 8.18		
After 4 months (%)	8.38 ± 1.39	7.84 ± 1.06		
(mmol/mol)	68.12 ± 15.15	62.19 ± 11.60		
Difference (%)	0.01 ± 1.31	0.69 ± 0.97	0.67 (0.15, 1.19)	0.012
			0.64 (0.11, 1.17)[a]	0.019
(mmol/mol)	0.14 ± 14.27	7.51 ± 10.59	7.37 (1.68, 13.06)	0.012
			7.00 (1.19, 12.81)[a]	0.019

VBLEP video-based lifestyle education program

[a] Adjusted (for baseline triglyceride levels)

Effect on Secondary Outcome Parameters

There was a significant reduction in weight and BMI at 4 months in favor of VBLEP compared with usual care. There was also favorable reduction in fasting plasma glucose and waist circumference at 4 months in participants randomized to VBLEP (Table 4).

Predictors of Favorable Outcome (Difference in HbA1c ≥ 0.5% from Baseline)

Participants who were employed, had a family history of diabetes, had no diabetes-related complications, and were in the VBLEP group had higher odds of having favorable HbA1c reduction (≥ 0.5%, combined analysis of both groups). In addition, female subjects and those taking > 2 oral glucose-lowering agents, anti-hypertensive therapy, or lipid-lowering therapy had higher favorable outcomes (Table 5).

DISCUSSION

In this trial, we evaluated the effect of a VBLEP delivered over four sessions in participants with T2DM having poor glycemic control. We found a clinically relevant reduction in HbA1c (≥ 1% decrease) in many individuals (39.5%) and

Table 4 Effect of intervention on secondary outcomes at 4 months

	Usual care (*n* = 40)	VBLEP (*n* = 38)	VBLEP vs. usual care difference in change (95% CI)	*P* value
Weight (kg)	70.0 ± 11.7	72.2 ± 13.6	0.76 (0.10,1.41)	0.024
Body mass index (kg/m^2)	27.0 ± 4.0	28.4 ± 5.0	0.31 (0.04, 0.58)	0.024
Waist circumference (cm)	97.9 ± 8.4	99.1 ± 12.6	2.00 (0.14, 3.86)	0.036
Systolic blood pressure (mmHg)	125.2 ± 14.2	122.8 ± 14.4	− 0.11 (− 6.75, 6.53)	0.974
Diastolic blood pressure (mmHg)	80.6 ± 7.6	80.7 ± 7.4	− 0.96 (− 5.02, 3.09)	0.638
FPG (mmol/l)	8.5 ± 2.8	8.3 ± 2.2	0.56 (− 0.80, 1.92)	0.416
Total cholesterol (mmol/l)	4.2 ± 1.0	4.4 ± 1.0	− 0.07 (− 0.44, 0.30)	0.692
Triglycerides (mmol/l)	1.5 (1.1–2.0)	1.6 (1.3,2.3)		
LDL cholesterol (mmol/l)	2.4 ± 0.8	2.5 ± 0.9	− 0.04 (− 0.36, 0.29)	0.827
HDL cholesterol (mmol/l)	1.0 ± 0.3	1.0 ± 0.2	− 0.01 (− 0.09, 0.06)	0.747

Values adjusted for baseline triglyceride level

Table 5 Predictors of favorable outcome (HbA1C reduction ≥ 0.5%)

	Odds ratio (95% CI)	*P* value
Age	0.98 (0.93, 1.04)	0.485
Male gender	0.99 (0.41, 2.42)	0.991
Education: graduate and beyond[#]	0.92 (0.37, 2.33)	0.865
Employed	1.10 (0.45, 2.68)	0.834
Presence of family history of diabetes	1.72 (0.66, 4.45)	0.264
Oral glucose-lowering drugs > 2	1.15 (0.46, 2.91)	0.762
Allotment of group VBLEP	3.21 (1.27, 8.10)	0.014
Anti-hypertensive drugs (yes)	1.02 (0.40, 2.50)	0.972
Lipid-lowering medication (yes)	1.02 (0.41, 2.53)	0.962
Presence of diabetes related macro- or microvascular complications	0.74 (0.29, 1.87)	0.522

[#] (≥ 15 years of school/college/university education)

statistically significant mean reduction in HbA1c in the VBLEP (video-based lifestyle education program) compared with usual care. This suggests that a video-based structured real-life character-based education program, when delivered in person, may have greater benefits.

There was a significant reduction in weight and BMI observed in the VBLEP compared with the usual care group.

The study found a significant difference [0.6% 95% CI (0.1, 1.1); 7.0 mmol/mol 95% CI (1.5, 12.5), *p* = 0.013] in HbA1c in favor of the

VBLEP compared with usual care on intention-to-treat analysis, which remained significant in adjusted analysis. Furthermore, reduction in HbA1c by > 0.5% and 1% was seen in 65.8% and 39.5% of participants, respectively, in the VBLEP arm. The corresponding figures observed in the usual care arm were 37.5% and 15%, respectively.

Odgers-Jewell et al. recently reported findings on the effectiveness of group-based self-management education in T2DM [5]. The mean duration of diabetes (approximately 9 years) was similar to that in our study with greater HbA1c reduction (by 0.3%) in the intervention group. The benefits were greater in individuals on oral glucose-lowering agents and in those who had a baseline HbA1c > 7%. Delivery of the intervention by health care professionals from a single discipline in secondary/tertiary care hospitals was found to have the greatest benefits. These may be some of the reasons underlying the benefits reported in our study. Our study enrolled participants who were only on oral glucose-lowering agents for diabetes management and had baseline HbA1c ≥ 7.5% to ≤ 10%. The intervention was delivered in groups with 3–5 participants by a physician (Uttio Gupta) doing his fellowship in endocrinology at a tertiary care hospital. The session content was delivered in the form of real character-based videos covering education related to lifestyle modification for diabetes management. In between and after the videos, the endocrine fellow carried out reinforcements and discussions on important points/queries. In per protocol analysis for secondary outcomes, there was weight reduction in favor of the VBLEP compared with usual care. This effect was similar to that reported in the meta-analysis [8]. The effect on lipid and blood pressure parameters was not significant.

We also evaluated the factors associated with favorable outcome defined by HbA1c reduction of ≥ 0.5% from baseline at 4-month follow-up, irrespective of group allocation. The individuals who had lower education levels, were females, had a family history of diabetes, were on > 2 oral glucose-lowering agents, were taking anti-hypertensive treatment, and were on lipid-lowering therapy had higher odds of favorable outcome. The presence of diabetes-related complications was associated with a less favorable HbA1c outcome.

To the best of our knowledge according to the literature review, this is the first RCT from South Asia evaluating a real character-based television program for the management of diabetes. Using a video-based form of intervention delivered interactively adds to its strength. This study has provided preliminary insights into the magnitude of the effect that this form of intervention can have. A key limitation of our study was lack of long-term follow-up data since it was piloted for only 4 months. Long follow-up periods may have different implications for the outcomes and sustainability of benefits.

CONCLUSIONS

To conclude, a video-based lifestyle education program is an effective strategy to achieve better glycemic control in people with T2DM in addition to usual care. That nearly 40% of participants had > 1% improvement in HbA1c suggests that this simple technology-based education program made up of four videos can be easily incorporated in routine clinical practice.

ACKNOWLEDGEMENTS

Authorship. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Authorship Contributions. UG conducted the research and wrote the article. YG contributed to planning the research, interpreting the results, and drafting and revising the manuscript. NT contributed to the planning and design of the research, interpretation of results, and conception of the article. KM analyzed and interpreted the data. All authors were involved in the initial planning, execution of the study, critical review of the manuscript, and final approval of manuscript.

Prior Presentation. This study was presented as a poster at ESICON (Annual Conference of the Endocrine Society of India), 15–18 November 2018. The abstract was published in IJEM Supplement 1, November 2018 [http://www.ijem.in/temp/IndianJEndocrMetab22717-3287394_090753.pdf].

Disclosures. Uttio Gupta, Yashdeep Gupta, Divya Jose, Kalaivani Mani, Viveka P. Jyotsna, Gautam Sharma, and Nikhil Tandon have nothing to disclose.

Compliance with Ethics Guidelines. The AIIMS ethics committee approved the study, and written informed consent was obtained from all participants. The study was done as per the ethics delineated in the Helsinki Declaration.

Data Availability. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Open Access. This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 International License (http://creativecommons.org/licenses/by-nc/4.0/), which permits any noncommercial use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made.

REFERENCES

1. Cho NH, Shaw JE, Karuranga S, Huang Y, da Rocha Fernandes JD, Ohlrogge AW, Malanda B. IDF diabetes atlas: global estimates of diabetes prevalence for 2017 and projections for 2045. Diabetes Res ClinPract. 2018;138:271–81.

2. Hills AP, Misra A, Gill JMR, Byrne NM, Soares MJ, Ramachandran A, Palaniappan L, Street SJ, Jayawardena R, Khunti K, Arena R. Public health and health systems: implications for the prevention and management of type 2 diabetes in south Asia. Lancet Diabetes Endocrinol. 2018;6:992–1002.

3. Unnikrishnan R, Anjana RM, Mohan V. Diabetes mellitus and its complications in India. Nat Rev Endocrinol. 2016;12:357–70.

4. Huang XL, Pan JH, Chen D, Chen J, Chen F, Hu TT. Efficacy of lifestyle interventions in patients with type 2 diabetes: a systematic review and meta-analysis. Eur J Intern Med. 2016;27:37–47.

5. Odgers-Jewell K, Ball LE, Kelly JT, Isenring EA, Reidlinger DP, Thomas R. Effectiveness of group-based self-management education for individuals with type 2 diabetes: a systematic review with meta-analyses and meta-regression. Diabet Med. 2017;34:1027–39.

6. Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V, Indian Diabetes Prevention Programme (IDPP). The Indian Diabetes Prevention Programme shows that lifestyle modification and met form in prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). Diabetologia. 2006;49:289–97.

7. Ramachandran A, Snehalatha C, Ram J, Selvam S, Simon M, Nanditha A, Shetty AS, Godsland IF, Chaturvedi N, Majeed A, Oliver N, Toumazou C, Alberti KG, Johnston DG. Effectiveness of mobile phone messaging in prevention of type 2 diabetes by lifestyle modification in men in India: a prospective, parallel-group, randomised controlled trial. Lancet Diabetes Endocrinol. 2013;1:191–8.

8. Weber MB, Ranjani H, Staimez LR, Anjana RM, Ali MK, Narayan KMV, Mohan V. The stepwise approach to diabetes prevention: results from the D-CLIP randomized controlled trial. Diabetes Care. 2016;39:1760–7.

9. Muralidharan S, Mohan V, Anjana RM, Jena S, Tandon N, Allender S, Ranjani H. Mobile health technology (mDiab) for the prevention of type 2 diabetes: protocol for a randomized controlled trial. JMIR Res Protoc. 2017;6:e242.

10. Muralidharan S, Ranjani H, Mohan Anjana R, Jena S, Tandon N, Gupta Y, Ambekar S, Koppikar V, Jagannathan N, Allender S, Mohan V. Engagement and weight loss: results from the mobile health and diabetes trial. Diabetes Technol Ther. 2019;21: 507–13.

11. Goyal A, Gupta Y, Kalaivani M, Sankar MJ, Kachhawa G, Bhatla N, Gupta N, Tandon N. Concordance of glycaemic and cardiometabolic traits between Indian women with history of gestational diabetes mellitus and their spouses: an opportunity to target the household. Diabetologia. 2019;62:1357–65.

12. Kowalski AJ, Poongothai S, Chwastiak L, Hutcheson M, Tandon N, Khadgawat R, et al. The INtegratingDEPrEssioN and Diabetes treatmENT (INDE-PENDENT) study: design and methods to address mental healthcare gaps in India. Contemp Clin Trials. 2017;60:113–24.