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)

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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 (± SD) age of 50.1 (± 9.4) years and HbA1c of 8.5 ± 0.7% (68.87 ± 7.56 mmol/mol). The follow-up data were available in 96% (78/81) of participants. Of 40 participants, 36 (90%) attended ≥ 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 ≥ 1% reduction in HbA1c was observed in 39.5% of participants in the VBLEP compared with 15% in the usual care arm. However, a ≥ 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 (≥ 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 dietitian 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 |
| 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 |
| Singing 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 |
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 wilcoxon 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 ≥ 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 ± 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 (± SD) age of 50.1 (± 9.4) years, duration of diabetes 8.1 (± 6.0) years, HbA1c 8.5 ± 0.7% (68.87 ± 7.56 mmol/mol), and BMI (± SD) 27.7 ± 4.8 kg/m². Family history of diabetes in first-degree relatives was present in 66.7%; 42.0% and 39.5% were on blood programs vs. usual care (see details at trial registration site CTRI registration no.: CTRI/2017/05/008564).

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 |
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.

### 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/m²) | 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)
**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.

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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 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    | 0.12 (0.04, 0.20)                                        | 0.008  |
| (mmol/mol)       | 68.23 ± 7.08       | 69.51 ± 8.07   | 0.61 (0.10, 1.12)                                        | 0.21   |
| After 4 months (%)| 8.38 ± 1.37        | 7.86 ± 1.04    | 0.52 (0.11, 0.93)                                        | 0.010  |
| (mmol/mol)       | 68.10 ± 14.96      | 62.38 ± 11.38  | 0.63 (0.15, 1.11)                                        | 0.020  |
| Difference (%)   | 0.01 ± 1.29        | 0.65 ± 0.96    | 0.64 (0.14, 1.14)                                        | 0.013  |
| (mmol/mol)       | 0.13 ± 14.09       | 7.13 ± 10.45   | 7.00 (1.50, 12.50)                                       | 0.013  |

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
(mmol/mol) 0.14 ± 14.27 7.51 ± 10.59

VBLEP video-based lifestyle education program

a Adjusted (for baseline triglyceride levels)
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.

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/m²)        | 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)

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.

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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.

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