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Effectiveness of a group-based Diabetes Prevention Education Program (DiPEP) in a population with pre-diabetes: a cluster randomised controlled trial in Nepal

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ABSTRACT

Background Although several lifestyle intervention studies have been conducted in low/middle-income countries, there were no such studies in Nepal. Therefore, a group-based culturally tailored Diabetes Prevention Education Program (DiPEP) was conducted recently. The study aimed to evaluate the effect of DiPEP in glycated haemoglobin (HbA1c), weight, waist circumference, physical activity and diet among population with pre-diabetes.

Method A two-arm cluster randomised controlled trial was conducted in 12 clusters of two urban areas in Nepal. The DiPEP was a 6 month intervention (four 1-hour weekly educational sessions and 5 months of follow-up by community health workers/volunteers (CHW/Vs)). A postintervention assessment was done after 6 months. Linear mixed model was used to estimate the mean difference in primary outcome (HbA1c) and secondary outcomes (weight, waist circumference, physical activity and diet) between intervention and control arms, adjusted for baseline measure.

Results In intention-to-treat analysis with a total of 291 participants, the estimated mean difference in HbA1c was found to be 0.015 percentage point (95% CI −0.074 to 0.104) between the intervention arm and the control arm, while it was −0.077 (95% CI −0.152 to −0.002) among those who attended at least 3 out of 4 educational sessions. The estimated mean difference in weight (in participants who attended ≥1 educational session) was −1.6 kg (95% CI −3.1 to −0.1). A significantly lower grain consumption was found in intervention arm (−39 g/day, 95% CI −65 to −14) compared with the control arm at postintervention assessment.

Conclusion Although compliance was affected by COVID-19, individuals who participated in ≥3 educational sessions had significant reduction in HbA1c and those who attended ≥1 educational session had significant weight reduction. Grain intake was significantly reduced among the intervention arm than the control arm. Hence, group-based lifestyle intervention programmes involving CHW/vs is recommended for diabetes prevention.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Numerous studies have proven the effectiveness of group-based lifestyle interventions for diabetes prevention globally. Since there were no such studies at the community level in Nepal, we conducted a cluster randomised controlled trial by conducting Diabetes Prevention Education Program tailored to the Nepalese population.

WHAT THIS STUDY ADDS

⇒ Glycated haemoglobin and weight were significantly reduced among those who attended at least three and one educational sessions, respectively, compared with the control arm. Grain intake was also significantly reduced among the intervention arm compared with the control arm.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This lifestyle-based group educational intervention model for diabetes prevention can be expanded to similar settings in collaboration with local institutions in other regions of Nepal and other low/middle-income countries.

Trial registration number NCT04074148.

INTRODUCTION

Type 2 diabetes (T2D) is a chronic and potentially devastating medical condition with rapidly increasing prevalence globally.[1] The majority are living in low-income and middle-income countries (LMICs) with 90 million in South East Asian countries.[2] According to a recent meta-analysis, the prevalence of T2D in Nepal was estimated to be 10%.[3]

Pre-diabetes is a health condition where an individual has higher blood sugar level than normal but not high enough to be considered as diabetes.[4] The global prevalence of pre-diabetes is increasing steadily, including in Nepal.[2 3] A meta-analysis study in Nepal has reported the prevalence of pre-diabetes to be 19.4%.[3] Nearly, 5%–10% of individuals with pre-diabetes status converts to T2D in a year.[5] While diabetes has been associated with increased risk of cardiovascular diseases, chronic kidney disease, peripheral neuropathy, retinopathy and all-cause mortality,[6] an umbrella review of meta-analysis of prospective studies found that pre-diabetes has also been associated with 6%–101% increased risk of all-cause mortality, cardiovascular events, coronary heart disease, stroke, heart failure, atrial fibrillation, chronic kidney disease, total cancer, total liver cancer, hepatocellular carcinoma, breast cancer and all-cause dementia.[7] Pre-diabetes was also found to be associated with diabetic peripheral polyneuropathy and diabetic retinopathy.[5 8] Prevalence of vascular complications, macrovascular and microvascular complications were found to be 11.1%, 4.2% and 6.9%, respectively, among the individuals with pre-diabetes.[9] More than 90% of the individuals with pre-diabetes were found to have one or the other risk factor for macrovascular complications.[9]

Considering the increasing burden of diabetes on countries' economy, a cost-effective intervention may be a major public health strategy.[10] In this regard, group-based education sessions could be a promising strategy for diabetes prevention.[11] Evidence suggests that group-based intervention or those involving a collaboration of health professionals and lay health workers were more cost-effective than one-to-one interventions or the intervention solely administrated by health professionals.[10 12 13] Several studies have shown that the progression of pre-diabetes to T2D can be prevented or delayed by conducting interventions focusing on lifestyle factors and behaviour change among individuals with pre-diabetes.[14–17] A recent systematic review and meta-analysis focusing on LMICs showed that lifestyle interventions decreased the incidence risk ratio of T2D by 25%,[18] but no studies were found to be conducted in Nepal.[18] Hence, diabetes prevention intervention studies in Nepal are needed.

To the researchers' knowledge, no community-based diabetes prevention lifestyle intervention programmes have been implemented in the population with pre-diabetes in Nepal. Therefore, a 6-month group-based culturally tailored lifestyle intervention educational package called Diabetes Prevention Education Program (DiPEP) was developed and implemented at the community level in Nepal.[19] The objective of the present study was to evaluate the effect of the DiPEP in glycated haemoglobin (HbA1c) as the primary outcome; and weight, waist circumference, physical activity and diet as the secondary outcomes among people with pre-diabetes in a postintervention assessment.

METHODS

Trial design and study setting

It was a community-based open-label two-armed cluster randomised controlled trial (RCT) conducted in two urban settings, Patan and Dhulikhel of Nepal. Patan is the core area of Lalitpur Metropolitan City (LMC). The screening campaigns and baseline data collection were started from 25 October 2019. Due to the COVID-19, screening campaigns were completely stopped from mid-March 2020 onwards; data collection was done remotely using telephone calls during the times of lockdown (after mid March 2020). Physical intervention was started in the community from January 2020 and the whole intervention was paused from the start of the lockdown (mid-March 2020) until mid-August 2020. As a result, digital intervention was started from mid-August 2020 as an alternative of physical intervention. Although the postintervention assessment was planned 6 months after enrolment, it varied from 6 to 10 months due to the COVID-19 lockdown. Postintervention data collection was finalised by 30 September 2021.

Study participants and sample size

Individuals eligible for screening were (1) adults aged 18–64 years, (2) permanent residents of the study sites and (3) with no self-reported history of diabetes. The age was limited to 64 years based on WHO STEPS Surveillance Manual.[20] Permanent residency was verified by asking whether they had been living in the study sites for more than 6 months. The inclusion criteria for the RCT were as follows: (1) Indian Diabetes Risk Score (IDRS)≥60, (3) random blood sugar (RBS) 140–250 mg/dL and (3) HbA1c 5.7%–6.4%. Exclusion criteria were as follows: (1) type 1 diabetes (T1D) or T2D, (2) pregnancy, (3) critical illness and (4) HbA1c<5.7% or HbA1c≥6.5%.

Based on the previous study done in a Nepalese population with pre-diabetes at the worksite in Nepal,[21] a minimum difference of 0.12 percentage points in HbA1c between intervention and control arms was used to calculate the necessary sample size for the present study. The sample size was estimated to be 448, with 32 individuals in each cluster considering 14 originally planned clusters of 2 study sites. The significance level was set to 5%, power 80% and we assumed SD=0.36,(21) intracluster correlation coefficient=0.01,[22] and 30% lost to follow-up. The screening was to be continued until the target sample of 448 population with pre-diabetes was obtained. However, due to the COVID-19 lockdown, two clusters from Dhulikhel could not be reached for screening and two clusters of Patan were only partially reached. This led to a sample size of 308 individuals with pre-diabetes. Further, the exclusion of drop-outs at baseline data collection resulted in a postintervention sample size of 291.

Randomisation

Out of 29 administrative units (wards) in LMC, 10 urban wards representing core area of LMC (Patan) and four urban wards out of 12 wards of Dhulikhel Municipality

were selected for the study. Each ward having at least one health post or community health unit was operationalised as cluster for this study. They were randomised by the senior researcher (ArS) using computer-aided randomisation into the intervention arm and control arm. Randomisation was done before the conduction of screening campaigns. Each arm consisted of five clusters from Patan and one cluster from Dhulikhel. Participants of the corresponding clusters were enrolled and assigned to the respective arms by the researchers (PS, SD and SS) and other study nurses.

Data collection

Phase 1: screening and recruitment

The screening campaigns were organised in different sites (toles—a small unit of the ward) of each cluster. Written permissions were provided by both LMC and Dhulikhel Municipality to conduct the screening and data collection. Similarly, verbal permissions were provided by the ward chairmen of the allocated wards and representatives of the allocated screening sites to conduct screening campaigns. Information banners and verbal announcement about the screening campaigns in Nepali language were used before and during the screening campaigns to inform people about the campaigns.

The eligibility criteria was assessed among individuals who were interested for pre-diabetes screening. Once the eligibility criteria were met, individuals were informed about the aim of the screening, and verbal consent was obtained before registering sociodemographic data (age, gender, ethnicity and residency), clinical history (family history of diabetes), anthropometric measurements (waist circumference and hip circumference measurement), capillary blood tests for measurement of RBS and HbA1c. Since, the screening campaigns were conducted at the community level, only RBS and HbA1c tests were performed. These tests did not necessitate extended fasting (8 hours) like fasting blood sugar (FBS) or a 2-hour waiting period as with the 2 hour-PG test.[4] The RBS was measured using a glucometer (B. Brawn glucometer) following infection prevention measures.[20] HbA1c was measured from the capillary blood using point-of-care (POC) testing[4] which was practical for the community set-up screening campaigns as it does not require sample to be stored and transported to the laboratory.[23] DCA Vantage 2000 HbA1c analyser was used for the POC HbA1c test.[24] The details of these factors are discussed elsewhere.[19 25]

To economise the cost of HbA1c test, the screening of pre-diabetes was done in two steps. The first step included IDRS assessment comprised four components (age, family history of diabetes, waist circumference and physical activity) with a score ranged from 0 to 100[26] and RBS. The second step included HbA1c test, which was performed only among individuals with IDRS≥60 and RBS 140–250 mg/dL. Individuals with HbA1c in the range of 5.7%–6.4% were classified as having pre-diabetes[27] and were eligible for the RCT. They were informed about the study and written informed consent was obtained. If HbA1c was<5.7% or ≥6.5%, they were classified as individuals with normal glycaemia and high glycaemia, respectively,[27] and thus excluded from the RCT. Individuals with high glycaemia were advised to seek medical consultation.

Phase 2: baseline data collection

Face-to-face interviews were conducted to collect baseline data before the COVID-19 pandemic lockdown while data were collected via telephone calls during the lockdown phase. Baseline data included sociodemographic characteristics (marital status, education, occupation, living status, annual household per capita income), clinical history (history of pre-diabetes and history of hypertension), lifestyle characteristics (smoking history, history of alcohol intake, diet intake, physical activity and sleep history), anthropometric measurement (weight and height) and blood pressure measurement. Details have been published elsewhere.[19 25]

Phase 3: intervention phase

Intervention

The DiPEP curriculum was developed with inspiration from National Diabetes Education Programme[28] and Diabetes Prevention Programme[29] in the USA. The DiPEP was culturally tailored to Nepalese context considering availability of resources and preferences of Nepalese people and thus comprised of four 1-hour long weekly educational sessions in the first month followed by five consecutive months of follow-ups by the community healthcare workers/volunteers (CHCW/Vs). The educational sessions were limited to four based on the researcher's experience.[19] The four topics of educational sessions were (1) introduction of diabetes and pre-diabetes, (2) healthy diet and physical activity, (3) stress management and (4) management of social cues. In the context of healthy diet and physical activity, the intervention did not introduce new types of food. Instead, it focused on the portion sizes of available food. Further, the intervention included four simple home-based exercises for individuals who preferred indoor workouts. Furthermore, the intervention aimed to encourage participants to safeguard against T2D by maintaining their routine morning walk, as opposed to suggesting gym or jogging activities which might not have been practical for the local context. All sessions were conducted in Nepali language. The intervention package also included a diabetes prevention education brochure written in Nepali language, a diabetes prevention exercise calendar and a daily food logbook.

A group of 32 participants in a single intervention cluster were deemed to be too big for educational session. Thus, it was separated into 2 groups of 16 individuals each. However, in Dhulikhel, the group size was less than 16 and thus only one group was formed. All interventions were planned to be conducted physically. However, due to COVID-19, the intervention had to be modified from physical educational sessions to digital

educational sessions; from physical follow-ups to biweekly telephone calls; and from physical monthly meeting to digital monthly meeting.

Before the COVID-19 lockdown, the educational sessions were conducted physically every week in four groups. The sessions were followed by a weekly physical follow-up (maintenance class) conducted by the assigned trained CHCW/Vs and a monthly physical meeting with the study nurses. Two groups had the follow-up sessions before the lockdown phase while the other two groups could not start follow-up as planned. The physical follow-up included measurement of weight and blood pressure; assessment of the exercise calendar and daily food logbook; exercise session; and a question and answers (Q&A) session. An attendance register was maintained by the CHCW/Vs. Each group had one assigned DiPEP-trained CHCW/V and two peer leaders (one male and one female). The task of peer leaders was to encourage group members to attend the sessions. Interested family members of the participants were also invited in the group session. Details are provided elsewhere.[19]

After amendment of the research protocol and approval from the regional ethical committee considering the situation due to COVID-19, the intervention was conducted digitally by the researchers (PS and SD) every week for each of the remaining seven groups. The theory session was conducted by displaying a PowerPoint presentation and lecturing in the Nepali language whereas the practical session was conducted by displaying an exercise video. The exercise video consisted of the same four types of exercise of the DiPEP curriculum which were aligned with the local context. Q&A sessions were also included at the end of the session. Biweekly telephone calls were done by the assigned CHCW/Vs, and a monthly digital meeting was conducted by the researcher (PS) as the part of the follow-ups due to COVID-19.

Control

There were six clusters (five from Patan and one from Dhulikhel) in the control arm. Participants in the control arm were provided with the same diabetes prevention education brochure after baseline data collection with the aim of not depriving them of essential knowledge. Furthermore, everyone (including the intervention arm) was invited to a 1-hour educational session after the completion of the study in June 2022.

Phase 4: postintervention data collection

The postintervention data collection was planned to be done 6 months after start of the intervention educational sessions for individuals in the intervention arm and 6 months after recruitment for individuals in the control arm, but this varied from 6 to 10 months due to the COVID-19 lockdown. The postintervention data collection comprised the same variables as those registered at inclusion excluding IDRS, ethnicity, height and RBS. The data collection was done via telephone calls except for HbA1c, blood pressure, weight, waist circumference and hip circumference, which were measured in physical presence in the community following all required possible protective measures after upliftment of the lockdown (September 2020 and January–April 2021). Only a limited number of participants were invited per day at different interval of time following COVID-19 preventive measures.

Outcome measures

The primary outcome measure of the study was HbA1c. Secondary outcome measures were weight, waist circumference, physical activity and dietary intake. Both the primary and secondary outcomes were measured at the time of baseline data collection and at the postintervention assessment. Waist circumference was added as a secondary outcome in a protocol amendment after the trial was commenced. Other deviations from the protocol paper included analysis unit of diet in g/day instead of kcal/day and analysis of secondary outcomes weight, physical activity and dietary intake as continuous variables instead of categorical variables.[19]

Statistical analyses

STATA MP V.17 was used for data analysis. Categorical data were presented as numbers and proportions, mean (SD) was presented for continuous data with approximately normal distribution, and median and IQR for continuous data with skewed distribution. The intention-to-treat (ITT) principle was used for the main analyses. It minimises the effect of missing data and lost to follow-up occurred due to COVID-19. The analysis of the primary outcome was carried out using a linear mixed model[30] with HbA1c as the dependent variable, individual as a random factor nested within clusters, time point (baseline and postintervention assessment) as a fixed factor, and the interaction between intervention and time point as a covariate. Further, subgroup analyses were carried out to assess the impact of the number of educational sessions attended as the dose-response (one to four sessions). Subgroup analyses were also done based on mode of intervention (physical educational session/digital educational session/both) and types of follow-ups (no follow-ups/weekly physical follow-ups/biweekly physical follow-ups/monthly follow-ups). Similar analyses were performed for secondary outcomes. An unstructured covariance matrix was used. Robust SEs were estimated using a clustered sandwich estimator in all analyses. The results were presented as mean differences with a 95% CI. Two-tailed values of $p<0.05$ were regarded as statistically significant. Sensitivity analyses were performed in complete cases to assess the robustness of the main analyses. The Consolidated Standards of Reporting Trials 2010 checklist extended for cluster RCT was followed to report this study.[31]

RESULTS

Out of 6222 individuals enrolled in the screening campaigns, 308 individuals (5%) were detected with prediabetes (HbA1c 5.7%–6.4%). A total of 291 (94.5%)

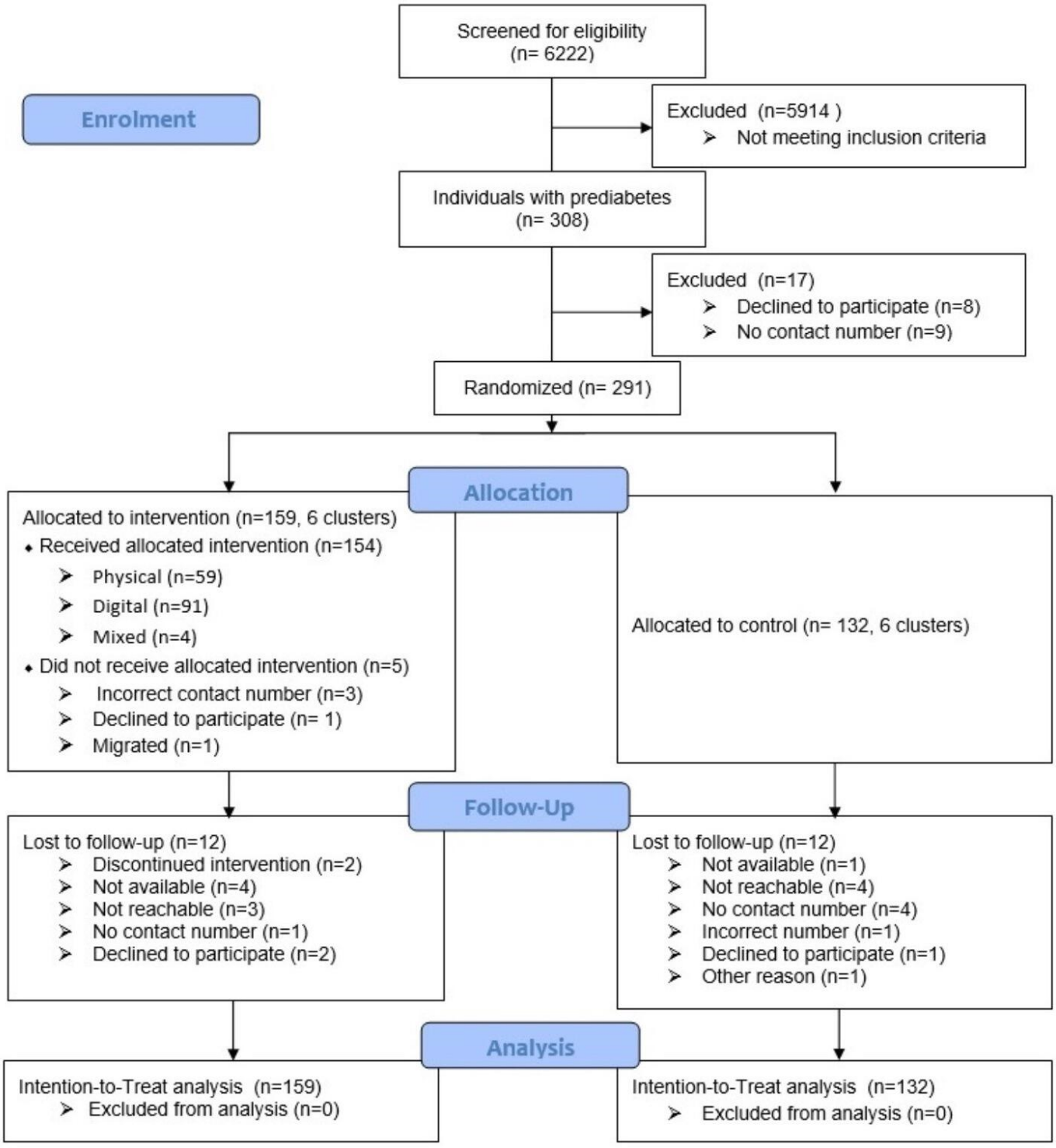

Figure 1 CONSORT diagram. Out of 6222 individuals screened, 308 were detected with pre-diabetes. Of 291 individuals who participated in the RCT, 159 were randomised to the intervention arm and 132 to the control arm. There were 12 individuals lost to follow-up in each arm. Intention-to-treat analysis included all the participants of the RCT. CONSORT, Consolidated Standards of Reporting Trials; RCT, randomised controlled trial.

agreed to participate and provided baseline data. Out of 291 individuals, 159 were recruited to the intervention arm and 132 to the control arm. Each cluster comprised 19–34 individuals in Patan and 6–10 individuals in Dhulikhel. All individuals of the RCT were included in the main analysis following the ITT principle (see figure 1). In the intervention arm, 9.0% reverted to normoglycaemia (HbA1c<5.7%), and 12.7% were detected with hyperglycaemia (HbA1c≥6.5), while in the control arm, 9.6% reverted to normoglycaemia and 13.9% were detected with hyperglycaemia in the postintervention assessment.

Table 1 Baseline characteristics of trial individuals (n=291)

Variables	Trial arms: Intervention (n=159) n (%)	Trial arms: Control (n=132) n (%)	Total (n=291) n (%)
Sociodemographic characteristics			
Age (years)*	50.7 (7.6)	50 (7.6)	50.3 (7.6)
Age (categorical) years			
18–44 years	32 (20.1)	32 (24.2)	64 (22.0)
45–64 years	127 (79.9)	100 (75.8)	227 (78.0)
Gender			
Male	51 (32.1)	51 (38.6)	102 (35.1)
Female	108 (67.9)	81 (61.4)	189 (64.9)
Anthropometric measurement			
Central obesity†	(n=159)	(n=132)	(n=291)
Yes (F>80 cm, M>90 cm)	156 (98.1)	127 (96.2)	283 (97.2)
No (F≤80 cm, M≤90 cm)	3 (1.9)	5 (3.8)	8 (2.8)
Clinical characteristics			
RBS	164.0 (22.6)	164.9 (22.6)	164.4 (22.6)
HbA1c*	5.97 (0.21)	5.96 (0.21)	5.97 (0.21)
Prediabetic stages			
HbA1c 5.7%–5.9%	83 (52.2)	73 (55.3)	156 (53.6)
HbA1c 6.0%–6.4%	76 (47.8)	59 (44.7)	135 (46.4)

*Mean (SD).
†As per WHO guideline for Central Obesity for Asian population based on waist circumference.
F, female; HbA1c, glycated haemoglobin; M, male; RBS, random blood sugar.

Table 1shows the baseline characteristics of 291 participants. The mean age was 50.3 years (SD, 7.6) and the majority of individuals were aged 45–64 years, were females and had central obesity. The mean HbA1c of the individuals was 5.97% (SD, 0.21). Baseline characteristics were well balanced between the two arms. Detailed sociodemographic and lifestyle characteristics are shown in online supplemental tables S1 and S2.

In table 2, the ITT analysis shows an estimated mean difference in HbA1c of 0.015 percentage points (95% CI −0.074 to 0.104) between the two arms in the total population included in the RCT (n=291). A statistically significant difference was observed in HbA1c among individuals who attended at least three DiPEP sessions −0.077 (95% CI −0.152 to −0.002). The estimated mean difference in weight at the postintervention assessment was −0.8 kg (−1.8 to 0.2) between the two arms. However, the results were statistically significant for those who attended at least one DiPEP session (−1.6 kg, 95% CI −3.1 to −0.1). No significant change in waist circumference between the two arms was found (0.1 cm, 95% CI −1.7 to 1.8).

The estimated mean difference in physical activity (measured by metabolic equivalents (METs)) between the two arms was 58 mins/week (95% CI −109 to 225) at the postintervention assessment. With regard to diet, there was a significantly larger reduction in total grain intake in the intervention arm than in the control arm (−39 g/day, 95% CI −65 to −14) (table 3).

Additional exploratory analyses by mode of intervention and types of follow-ups are presented in online supplemental tables S3 and S4. Individuals who attended physical intervention tended to decrease in HbA1c more than individuals who received digital interventions. There was a significant reduction in weight at the postintervention assessment among those who attended physical intervention (−2.1 kg, 95% CI −4.0 to −0.2). Complete case analyses produced largely the same results as the main analyses (not presented).

DISCUSSION

To the researchers' knowledge, this is the first RCT conducted in the community setting to evaluate the effectiveness of a lifestyle programme designed to prevent T2D in Nepal. No significant mean difference in HbA1c between the intervention and control arm was demonstrated in the ITT analysis. However, a statistically significant reduction in the HbA1c level was found among those who attended at least three out of four sessions of the DiPEP. The mean difference in weight was significantly

Table 2 Estimated effect of the intervention on HbA1c, weight and waist circumference

	Baseline		Postintervention assessment			
	n	Mean (SD)	n	Mean (SD)	Mean diff (95% CI)*	P value
HbA1c (primary outcome)						
Control (ITT)	132	5.96 (0.21)	115	6.11 (0.47)		
Intervention (ITT)	159	5.97 (0.21)	134	6.12 (0.40)	0.015 (–0.074 to 0.104)	0.74
Attendance						
≥1 session	73	5.95 (0.20)	69	6.04 (0.30)	–0.057 (–0.139 to 0.024)	0.17
≥2 sessions	56	5.96 (0.21)	54	6.07 (0.28)	–0.034 (–0.111 to 0.042)	0.38
≥3 sessions	36	5.98 (0.22)	35	6.03 (0.28)	–0.077 (–0.152 to –0.002)	0.04
All 4 sessions	22	5.95 (0.23)	22	6.02 (0.29)	–0.078 (–0.158 to 0.001)	0.05
Weight (kg) (secondary outcome)						
Control (ITT)	88	68.9 (11.5)	115	70.0 (11.0)		
Intervention (ITT)	101	69.8 (11.2)	134	68.8 (10.9)	–0.8 (–1.8 to 0.2)	0.12
Attendance						
≥1 session	49	69.2 (10.7)	69	68.2 (10.3)	–1.6 (–3.1 to –0.1)	0.04
≥2 sessions	38	69.5 (11.2)	54	68.5 (11.0)	–1.7 (–3.5 to 0.1)	0.07
≥3 sessions	26	68.8 (10.4)	35	66.9 (9.9)	–1.5 (–3.5 to 0.5)	0.13
All 4 sessions	17	69.4 (11.5)	22	67.6 (10.0)	–1.6 (–3.3 to 0.1)	0.07
Waist circumference (cm) (secondary outcome)						
Control (ITT)	132	97.3 (8.3)	115	93.5 (8.8)		
Intervention (ITT)	159	96.5 (8.2)	134	92.5 (9.6)	0.1 (–1.7 to 1.8)	0.90
Attendance						
≥1 session	73	95.9 (6.4)	69	92.4 (9.3)	0.1 (–1.7 to 1.8)	0.92
≥2 sessions	56	96.2 (6.6)	54	92.8 (9.9)	0.3 (–1.7 to 2.1)	0.84
≥3 sessions	36	95.0 (6.8)	35	91.8 (9.7)	0.1 (–1.9 to 2.1)	0.92
All 4 sessions	22	94.5 (7.3)	22	92.0 (11.3)	0.7 (–2.0 to 3.5)	0.60

*Mean difference between groups estimated by mixed linear model.
HbA1c, glycated haemoglobin; ITT, intention-to-treat analysis.

lower in the intervention arm at the postintervention assessment among those who attended at least one session. Further, a statistically significant difference in daily intake of grain between the two arms was observed.

In this study, 9.0% and 9.6% of individuals with pre-diabetes reverted to normoglycaemia in the intervention and the control arm, respectively, at the postintervention assessment. These proportions were lower than in previous studies.[32 33] Some individuals in the control arm also reverted to normoglycaemia as pre-diabetes detection can to some extent motivate lifestyle change even in the absence of an intervention programme.[34] Further, we had provided a diabetes prevention education brochure to the control arm participants after baseline data collection as practised in previous study.[35] The lack of a significant difference in HbA1c between the two arms in the present study was in line with the US-based study[36] but findings were in contrast with other studies.[33 37 38] HbA1c in the present study was significantly lower among those who attended at least three sessions, which confirms previous findings showing a positive relationship between attendance to sessions and reduction in HbA1c.[11 39]

Obesity is associated with insulin resistance[40] and is associated with the development of pre-diabetes[41] and T2D.[4] Lifestyle modifications have the potential to prevent both obesity and T2D.[42] In the present lifestyle intervention study, there was no significant change in the mean weight which was in congruence with studies from India[14] and Malaysia[37] but several other trials have demonstrated larger effects on weight.[33 36 38 43 44] The mean weight loss was larger among individuals who attended at least one DiPEP educational session (–1.6 kg). Not surprisingly,

Table 3 Estimated effect of the intervention on physical activity and diet

	Baseline		Postintervention assessment			
	n	Mean (SD)	N	Mean (SD)	Mean diff (95% CI)*	P value
Physical activity (METs) (secondary outcome)						
Control (ITT)	132	1643 (3065)	119	683 (563)		
Intervention (ITT)	158	1873 (3567)	139	750 (1190)	58 (–109 to 225)	0.50
Attendance						
≥1 session	73	2136 (4202)	68	812 (1560)	121 (–127 to 369)	0.34
≥2 sessions	56	2398 (4634)	53	894 (1749)	179 (–163 to 521)	0.30
≥3 sessions	36	1343 (2368)	34	685 (547)	20 (–201 to 241)	0.86
All 4 sessions	22	1608 (2872)	21	819 (647)	128 (–185 to 442)	0.42
Total grain (g/day)						
Control (ITT)	131	598 (199)	119	591 (148)		
Intervention (ITT)	157	537 (199)	137	530 (117)	–39 (–65 to –14)	<0.01
Attendance						
≥1 session	73	546 (170)	66	540 (128)	–33 (–66 to 0.04)	0.05
≥2 sessions	56	547 (166)	51	523 (119)	–52 (–84 to –20)	<0.01
≥3 sessions	36	566 (164)	34	534 (115)	–48 (–86 to –9)	0.02
All 4 sessions	22	541 (153)	21	523 (72)	–58 (–106 to –9)	0.02
Fruits and vegetables (g/day)						
Control (ITT)	130	216 (122)	119	275 (99)		
Intervention (ITT)	156	195 (104)	136	274 (116)	2 (–28 to 31)	0.90
Attendance						
≥1 sessions	72	215 (98)	66	277 (124)	2 (–32 to 35)	0.93
≥2 sessions	56	222 (93)	51	277 (125)	2 (–43 to 47)	0.94
≥3 sessions	36	251 (83)	34	297 (127)	19 (–27 to 65)	0.41
All 4 sessions	22	257 (85)	21	309 (124)	31 (–26 to 87)	0.29

*Mean difference between groups estimated by mixed linear model.
ITT, intention-to-treat analysis; METs, metabolic equivalent.

at least a single attendance in the educational session is needed to motivate individuals to reduce weight. It has also previously been shown that individuals who attend all sessions of an intervention experience larger weight loss than those who missed sessions.[45] Admittedly, the weight reduction in the present study was probably too small to be of clinical relevance.[46]

Waist circumference is one of the many indicators of obesity.[47] Waist circumference correlates closely with abdominal adipose tissue and abdominal obesity is an important risk factor for the adult-onset diabetes.[47] Waist circumference was one of the secondary outcomes of the present study, which did not show any significance in the mean difference in waist circumference, similar to the Indian study.[14] In contrast, a reduction in waist circumference was noticed in several other lifestyle intervention studies.[37 38 43]

Previous studies have reported mixed findings in terms of physical activity, either showing significant improvement in METs after intervention[37 38] or no significant difference in physical activity between the two arms.[44] We believe that the COVID-19 pandemic which restricted mobility for regular physical activity might have affected all three domains of Global Physical Activity Questionnaire (work, leisure, travel).[48] These partly explain the small difference in METs between the intervention and control arms in the present study. With regard to the dietary habits, several studies have shown significant improvement among individuals with pre-diabetes following lifestyle interventions.[38 43 44] The present study also showed a significant reduction in grain intake between the two arms. This indicated that individuals implemented the most readily applicable lessons from the DiPEP session in their dietary behaviour, such as to reduce the rice, which

is readily visible and perhaps it was easier to reduce this than to add fruits or vegetables to the diet. Furthermore, the provision of a daily food logbook might have motivated participants to improve their dietary intake.[45]

Strengths and limitations

Cluster randomisation minimises the spillover effect of the intervention to the control arm. The intervention was designed consideraing the local context of the study sites, which became an advantage for participants to implement the intervention in their daily life. The involvement of CHCW/Vs in the intervention was considered an important strategy to prevent T2D at the community level.

There are a number of limitations to this study. Due to the mandated lockdown during the COVID-19 pandemic, the estimated sample size was not met thus decreasing the statistical power to detect small, but possibly relevant effects. The research protocol had to be amended considering the COVID-19 situation. Since, the study was conducted in two urban settings, the results may not be generalised to other settings. Future large intervention studies with adequate statistical power are recommended to identify the nearly true effect of the intervention for diabetes prevention in Nepal. We have reported multiple p values, and the subgroup findings should be interpreted with caution since such analyses carry an increased risk of false positive conclusions.

Implication

Although partly inconclusive, the study may help fill some knowledge gaps in Nepal and other LMICs. The involvement of nurses and CHCW/Vs proved to be a good combination of workforce to bring actions at the community level. The results of the study may encourage policymakers to adopt this model within a community-based healthcare system throughout the country. However, more research should be conducted to measure the scalability of the intervention. A cost-effectiveness analysis of the DiPEP intervention is required to determine its economic impact. Future research should be conducted in a larger sample including different geographical, ethnic and cultural contexts. Future studies could also focus on family-based lifestyle intervention programmes.

CONCLUSION

Despite the COVID-19 pandemic, the study was able to demonstrate some positive effects of the intervention to prevent diabetes among individuals with pre-diabetes. A small proportion of the individuals of the RCT reverted to normoglycaemic status, but the intervention seemed to reduce HbA1c and weight provided that the individuals attended at least three and one educational sessions, respectively. Similarly, the intervention was also found to be promising in reducing total grain intake. Hence, group-based lifestyle interventions in the collaboration with grassroots level personnel such as community healthcare workers/volunteers can be recommended to prevent T2D at the community in low-resource settings.

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