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The impact of positive social reinforcement on time-to-attrition from the Diabetes Prevention Program in college students at high risk for Type II Diabetes (IMSPIRE-DPP): a study protocol for a phase 3, multicenter, cluster-randomized trial

A. Bhandari[1], A. Concha-Mejia[2], A. Vasquez[3], A. Peralta[4], A. Rivera[5], G. Vallejos[6], H. Lu[7], J. Cardoso-Mourao[8], L. Assad[9], L. Handal[10], L. Kirihara[11], M. DeCain[12], M. Deger[13], M. Jimenez[14], M. Schulz*[15], N. Mazariegos[16], N.V. Racu[17], N. Rincon[18], P. Parra[19], S. Arroub[20], S. Kalmadka[21], S. Olagun-Samuel[22], V. Balbuena[23]

#All authors have contributed equally to this work.
**Corresponding author: Miriam Schulz, PharmD. TranslaTUM, Center for Translational Cancer Research, Technical University of Munich, Ismaninger Str. 22, 81675 Munich, Germany. E-mail: miriam.schulz@tum.de*
Rest of author's affiliation at the end of the manuscript.

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Abstract:

Introduction: *The prevalence of type 2 diabetes mellitus (T2DM) in young adults has increased considerably in the past decade. Evidence shows that lifestyle modification programs such as the Diabetes Prevention Program (DPP) are effective in improving health behaviors and lowering the risk of diabetes. DPP follow-up studies have found that a lack of retention can reduce the effectiveness of such programs. Adding a positive social reinforcement platform is a novel strategy to provide educational resources to facilitate lifestyle changes. However, evidence regarding the effect of positive social reinforcement as a theory-based strategy to prolong retention within the DPP is limited. The current study protocol aims to evaluate the efficacy of the online Prevent Diabetes® Program, including a Positive Inter@ctiOn forum on time-to-attrition from the DPP among college students at high risk for T2DM.*

Methods: *This study protocol is a phase 3, multicenter, double-blinded, cluster-randomized, superiority, controlled trial conducted in West Virginia, Alabama, and Mississippi. Four hundred eigclthty college students will be centrally randomized in a cluster-wise 1:1 ratio to the online Prevent Diabetes® Program integrated with the Positive Inter@ctiOn forum or to the online Prevent Diabetes® Program alone for 12 months. The primary outcome is time-to-attrition from the DPP.*

Discussion: *Successful completion of the study will provide valuable information on whether implementing theory-based health behavior strategies can improve the retention of participants in the online DPP and contribute to enhancing DPP effectiveness.*

Keywords: *Diabetes Type 2; Positive Reinforcement; Lifestyle Behavior; College Students; Prevent Diabetes® Program; Diabetes Prevention Program*

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Abbreviations:
ADA: American Diabetes Association
AL: Alabama
BBI: Bang Blinding Index
CDC: Center for Disease Control and Prevention
CIs: 95% Confidence Intervals
CLT: Central Limit Theorem
DM: Diabetes Mellitus
DMC: Data Monitoring Committee
DPP: Diabetes Prevention Program
HR: Hazard Ratio
HIPAA: Health Insurance Portability and Accountability Act
ICC: Intracluster Correlation Coefficient
IWRS: Interactive Web Response System
MD: Missing Data
MS: Mississippi
NDPP: National Diabetes Prevention Program
PA: Physical Activity
PI: Principal Investigator
RCT: Randomized Clinical Trial
T1DM: Type 1 Diabetes Mellitus
T2DM: Type 2 Diabetes Mellitus
US: United States
WV: West Virginia

INTRODUCTION

Diabetes continues to be a public health burden worldwide, and its global prevalence is estimated to increase from 9.3% in 2019 to 10.2% by 2030 (Saeedi 2019). The disease is a significant cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation, leading to poor quality of life and high disability-adjusted life years (WHO, 2021). In the United States (US), the national prevalence of diabetes and prediabetes in adults aged ≥18 years was 10.5% and 1.8%, respectively (BRFSS 2020). At the state level, data showed that West Virginia (WV), Alabama (AL), and Mississippi (MS) have the highest prevalence of diabetes (15.7%, 14.8%, and 14.6%, respectively). It also showed a high prevalence of other conditions associated with an increased risk of prediabetes and type 2 diabetes mellitus (T2DM), such as obesity and limited physical activity (PA) (BRFSS 2020; ADA, 2020a). Since the prevalence of T2DM has increased in the young adult population, special attention has been given to them. College students represent a group of young adults in the US who are susceptible to unhealthy behaviors (Cockroft, 2019), leading to overweight (22.8%) and obesity (16%) (ACHA 2021).

Lifestyle modification programs such as the US National Diabetes Prevention Program (NDPP) have been proven effective in changing high-risk behaviors, reducing weight and HbA1c at 10-year and 15-year follow-ups (DPP Research Group 2002, 2004,2015). There is a strong correlation between longer retention of participants and the success of the programs in preventing or delaying the onset of T2DM in individuals with prediabetes or at high risk of T2DM (Cannon et al., 2020; Ramachandran, 2013). Furthermore, DPP follow-up studies have found that the lack of retention in the program reduces the impact of the intervention and have emphasized the need to identify strategies to improve the retention of participants —especially young adults— at the beginning and during the transition from core to maintenance sessions (Cannon et al., 2020).

Adding a positive social reinforcement platform is a novel strategy to provide educational resources to facilitate lifestyle change (Laforest et al., 2012; Skrine et al., 2019). Social reinforcement suggests that rewarded behavior (e.g., advice, praise, expression of empathy, concern, or direct aid [by others]) is likely to be repeated (Li and Lim 2015). As such, it is proposed as an essential driver of behavioral change and could play an important role in successfully improving outcomes of health-related programs like the DPP (Skrine et al., 2019). However, evidence regarding the effect of positive social reinforcement as a theory-based strategy to prolong retention within the DPP is limited. Therefore, we intend to support individuals in learning new competencies and changing unhealthy behaviors to prevent T2DM by implementing a structured "rewarding praises" system. Hence, this study protocol aims to evaluate the efficacy of the online Prevent Diabetes® Program integrated with the Positive Inter@ctiOn forum on time-to-attrition from the DPP among college students at high risk for T2DM.

MATERIALS AND METHODS

Trial Design

The study is a phase 3, multicenter, double-blinded, cluster-randomized, controlled superiority trial. The study will be conducted in WV, AL, and MS.

This protocol with the respective informed consent form will be submitted for review and approval by the respective local institutional review boards (IRBs). The ethics approval will be obtained before any research begins. In addition, the study protocol will be registered on ClinicalTrials.gov.

Randomization

After approval, eligible colleges will be randomly allocated as clusters in a 1:1 ratio to one of the two treatment arms: the online Prevent Diabetes® Program with the Positive Inter@ctiOn forum or the online Prevent Diabetes® Program alone. The randomization sequence will be computer-generated using STATA®/BE 17.0 (StataCorp LLC, TX, US). The study coordinator will assign the colleges to the treatment groups using an Interactive Web Response System (IWRS); the students who consent to participate in the study will be assigned to the treatment group in which the college was randomized.

Blinding

The study will be double-blinded. Participants, the outcome assessor team, and the data analysis team will be blinded (upon completion of the study). Blinding of study participants will be achieved by using cluster randomization and two different online Prevent Diabetes® Program platforms for each treatment group. Each participant will receive a Unique Identifier Number (UID) to ensure anonymity. An independent outcome assessor team will collect participants' data and send it to an independent data analysis team. The efficacy of blinding will be assessed at the termination of the study using the Bang Blinding Index (BBI).

Emergency unblinding

We anticipate minimal adverse events associated with the proposed behavioral intervention in our study. Treatment allocation of participants that withdraw from the study for emergency reasons will only be revealed to the treating physician; the participants will be withdrawn from the trial to avoid potential bias. In addition, participants will receive a card containing information about the clinical trial, the Principal Investigator (PI), and contact numbers to reach out to in case of medical emergencies.

Eligibility criteria

We will evaluate potential candidates according to the following criteria:

Inclusion criteria

Active full-time/part-time undergraduate or graduate student in an accredited US institution from WV, AL, and MS; aged 18-35 years; meets NDPP eligibility criteria (National Diabetes Prevention Program, 2021); actively participated in the first DPP session; owns and knows how to use electronic devices; has internet access, and gives voluntary informed consent.

Exclusion criteria

Prior diagnosis of T1DM or T2DM, glucose metabolism disorders, or any physical, cognitive, or psychological condition that significantly limits study participation; current participation in another lifestyle modification program or research study; former or upcoming bypass surgery; current use of weight loss medication or corticosteroids; pregnancy at the time of enrollment; and drop out of college.

Recruitment Strategy

The expected recruitment period is one year. After IRB approval, the research team will contact individual colleges and seek authorization to access the students' e-mail contacts and assess outcome measures on campus. Web-based advertising on colleges' social networks will be used to promote study enrollment. The study population will be recruited from 190 colleges throughout WV, AL, and MS. After participants' informed consent is obtained and documented by the site PI, preliminary screening for eligibility criteria will be conducted by reviewing candidates' health records and sending a study eligibility questionnaire via e-mail to all consented students (see **Figure 1**).

Adherence

Adherence-enhancing strategies will be implemented by specifically trained health coaches and include two webinars (a week prior and at six months) to address the use of the platforms, constant technical support, and reminders before the follow-up visits at 6 and 12 months via the DPP platforms. Adherence will be assessed by tracking the DPP mobile platform for participants' self-recorded information. At 4, 6, and 12 months within the study, participants will rate their compliance to the intervention and mention possible barriers to non-compliance through questionnaires delivered via the DPP platform.

Intervention

The Prevent Diabetes® Program is an online CDC-recognized DPP provided by Canary Coaches® (Canary Coaches®, 2021), commercially available since 2008. It consists of 16 self-guided weekly lessons and 8 self-guided monthly lessons aligned with the CDC's PreventT2 curriculum; 24/7 support; access to personal health coaches for 12 months; make-up

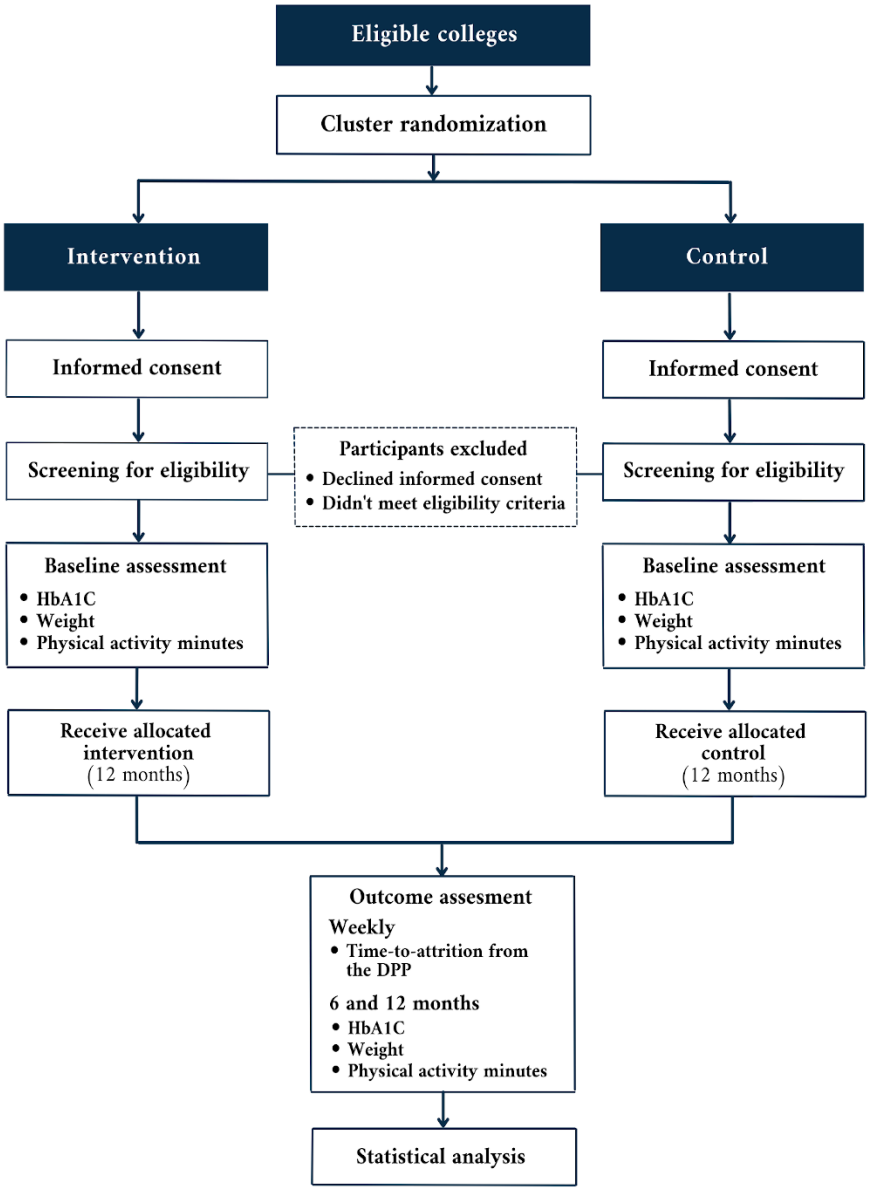

Figure 1. Trial flow diagram

sessions; and a group chat. It is available from participants' smartphones and tablets through the Canary DPP application (Android 5.0 or later; iOS 9.0 or later) or from computers or laptops via the Prevent Diabetes® web portal. In addition, Canary Coaches® will provide equipment to track weight (Fitbit® Aria Air Bluetooth Smart Scale) and enable synchronization with activity. tracking tools through the mobile application (e.g., Apple Health, FitBit, Google Fit) to monitor PA minutes. Nevertheless, a Fitbit® PA tracker will be provided to participants to wear during the daytime with required synchronization once a week.

After 6 to 8 weeks of registration submission, participants from each treatment group will be matched to a health coach from the program for individual sessions and have access to their respective platforms. Participation in the Prevent Diabetes® Program requires completing self-guided sessions of 25-45 minutes; PA for at least 30 minutes/week until reaching the goal of 150 minutes/week; daily tracking of meals and PA minutes.

The intervention group will additionally use the Positive Inter@ctiOn forum (**Appendix A**), based on the conceptual framework of the Reinforcement Theory (**Appendix B**). At the beginning of the trial, participants will receive a video tutorial with instructions to set up and use the forum via e-mail. For 12 months, a weekly forum topic related to the PreventT2 curriculum will

enable participants to post photos or comments anonymously (minimum of 1 post/day, or 5 posts/week). Post validation by the external coach will be required to avoid revealing participants' identities, inappropriate comments, or any content unrelated to the DPP and its main objectives. At the end of the week, every participant will have a Social Interaction Score — the sum of the number of participant posts' views and reactions and comments on other participants' posts— in which the individual with the highest score will enter the Weekly Challenge as the Challenger. The Challenger could choose a challenge from a premade list (**Appendix C**) and dare anyone from the group; the challenged participant has the autonomy to accept or reject the challenge. Whoever completes it will earn extra points for the subsequent week count and be rewarded with a Winner badge. The intervention will be delivered by health coaches not associated with Canary Coaches®, providing feedback to participants every 24 hours, unaware of participants' UID. Coaches should be board-certified behavior analysis therapists and receive an online DPP Lifestyle Coach training by a CDC-approved entity. The program coordinator from the DPP provider will provide a monthly review and evaluation of knowledge.

Prevent Diabetes® Program's privacy policy complies with the Health Insurance Portability and Accountability Act (HIPAA) requirements to protect participants' health and personal information gathered through the platform. In addition, mobile device management software (APPTEC360, Muttenz, Switzerland) will be implemented to protect all participants' personal information in case of loss or robbery of any electronic device.

Modification/Discontinuation

Possible adverse events related to the intervention could include severe musculoskeletal injury, post-PA cardiovascular events, and mental health issues. Participants will discontinue the intervention, and adverse events will be followed until resolution or stabilization. Participants who develop T2DM or another condition from the exclusion criteria during the trial will still have access to the DPP platform. However, they will be referred to a specialist for appropriate treatment.

Outcomes

The primary outcome is time-to-attrition from the DPP, and secondary outcomes are the percentage of weight change, HbA1C reduction, and mean PA minutes. Time-to-attrition from the DPP is defined as missing two consecutive core sessions and make-up sessions within the Core Session Phase (1-6 months) or missing two consecutive core maintenance sessions and make-up maintenance sessions within the Core Maintenance Phase (7-12 months) (Desai et al., 2020; Cannon et al., 2020). A session is completed when the participant has finalized the lesson's activities and recorded weekly body weight and PA minutes. Supposing that a participant cannot attend the core or maintenance sessions, in that case, the participant has the option to arrange an individual make-up session to be completed within the next two weeks after missing the respective core/maintenance session (CDC Diabetes Prevention Recognition Program 2021). The primary outcome will be recorded via weekly documentation of the active participation at the core/ maintenance sessions or the respective make-up sessions to determine the event "attrition" from the DPP per week.

Secondary outcomes will be measured at baseline, 6 and 12 months, irrespective of the event "attrition." 1) Percentage of weight change is determined with the equation [1- (final recorded weight in pounds ÷ initial recorded weight in pounds)] x 100 (CDC Diabetes Prevention Recognition Program, 2021). Bodyweight will be measured by a standard digital scale; participants will be encouraged to arrive at the approximate same time of day for weight measurement and wear similar clothes to avoid weight fluctuations related to clothes, water retention, food intake, and other valid reasons. 2) HbA1C reduction is the difference between initial HbA1C measurement and final HbA1C measurement at the respective time point (CDC Diabetes Prevention Recognition Program, 2021). HbA1C will be taken as a blood sample and measured in mmol/ml, per standard laboratory procedures, and reported as a percentage (%) unit according to the Diabetes Control and Complications Trial (DCCT). 3) Mean PA minutes is the sum of all recorded PA minutes (including 0s) divided by the number of all PA sessions (CDC Diabetes Prevention Recognition Program, 2021). This will be measured by a Fitbit® PA tracker that participants will wear during the daytime. PA minutes will be extracted from "minutes total of activity" intensity from the manufacturer's website using Fitabase (Small Steps Labs, San Diego, CA).

Data Monitoring

REDCap software will be used to record, assess, and monitor all data by an independent data monitoring committee (DMC). Members that will have access to the

database will be the principal investigator, forum manager, DMC, data analysis team, and study coordinator, who will also have access to the randomization and adherence database. The DMC will oversee the data for validation and discrepancy tracking. The database will be backed up every week, and after the study period of 12 months, it will be locked and be accessible only to an independent data analysis team. Cross-validation of methods between laboratories and measurement tools will be ensured before testing. Audits will be performed per protocol, and a centralized, risk-based monitoring committee will be assembled if required.

Interim analysis

We anticipate a low risk of adverse events that might require early study termination (Safarti et al., 2018); therefore, no interim analysis will be conducted.

Sample Size Calculation

Based on previous data (Cannon et al., 2020), an HR (0.7) of the event "attrition" happening at week 18 has been determined as the minimally clinically significant difference between both study groups. Assuming to be able to recruit six students each out of 80 colleges, we used a standardized intracluster correlation coefficient (ICC) of 0.05 (van Breukelen et al. 2012, 2018), a power of 90%, and an alpha of 0.05 to calculate a sample size of 240 students per arm and 480 in total. A sensitivity analysis was run to assess the influence of different numbers of clusters, ICC, and power values on sample size. An adjustment for dropouts in the sample size calculation for the primary outcome is not needed since a dropout in this study can be counted as an event. Calculations were done using STATA/BE 17.0.

Statistical Analysis

The Kaplan-Meier method will be used for the primary outcome to compare the time-to-attrition curves after 12 months descriptively. A two-sided clustered Log Rank test (Stedman et al., 2011) with an alpha of 0.05 will be utilized to evaluate a potential statistically significant difference between the curves, reported as a p-value. After assessing the validity of the proportional hazard assumption by the method of Schoenfeld residuals, Cox regression analysis will be performed to compare the hazard rates between groups. HR, 95% CI, and p-value will be stated.

The secondary outcomes of PA minutes, % weight change, and HbA1c reduction will be compared using an unpaired T-Test (2-sided alpha of 0.05; CLT). All analyses will be done on an individual level.

Missing Data

Missing Data (MD) will be assumed to be missing at random, and all statistical analyses will be conducted according to the intention-to-treat principle. This also applies to participants who develop severe adverse events, so they must withdraw from the trial as described in "Modification/Discontinuation." Therefore, they will be included in the primary analysis as censored events on an intention-to-treat principle. MD that occurs after a participant experiences the event "attrition" will exclusively affect secondary outcomes and will be addressed by multiple imputation methods. Sensitivity analyses based on the best-case scenario will be conducted to estimate the uncertainty of the missing data handling method. A per-protocol analysis will be added to assess the reliability of the results.

DISCUSSION

We propose a phase 3, multicenter, double-blinded, cluster-randomized, controlled superiority trial to evaluate the efficacy of the online Prevent Diabetes® Program with Positive Inter@ctiOn forum on time-to-attrition from the DPP among college students at high risk for T2DM.

Targeting college students from the three states of WV, AL, and MS with the highest prevalence of DM and DM-related complications facilitates the recruitment of our study participants. However, this may lead to reduced generalizability of the results due to differences in sociodemographic, economic, and educational levels. Since our study participants build up a specific group composition during their social reinforcement interaction activities, their posting and reciprocal motivating behavior might be influenced by that particular composition. Therefore, the impact of the social reinforcement component on future participants might differ between differently composed groups out of the target population. In addition, undetectable baseline characteristics such as shyness or anxiety might hinder a patient in the intervention group from actively using the social media platform, which might weaken the effect of the intervention. To prevent this, weekly reminders will be implemented to ensure that patients in the intervention group adhere to the intended protocol.

Using cluster randomization in our study design prevents unblinding study participants due to possible interaction during the study period. Since our primary

outcome is time-to-attrition, results on the efficacy of the intervention will not be biased due to unpredictable dropouts, one of the major challenges in behavioral intervention. For the first time, the addition of a theory-based positive social reinforcement component to a currently available online DPP will be investigated. Successful completion of the study will provide valuable information on whether implementing theory-based health behavior strategies can improve the retention of participants in the online DPP and contribute to enhancing DPP effectiveness. If the study fails to show a positive outcome, participants will still benefit from the attainment of new knowledge and skills necessary to prevent diabetes and related complications.

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Author affiliations

1 Department of Internal Medicine, St. John's Hospital, Springfield, United States
2 Clinica del Country, Fundacion Clinica Shaio, Bogotá, Colombia
3 Universidad de San Martín de Porres, Lima, Peru
4 Pontificia Universidad Católica Madre y Maestra, Santiago De Los Caballeros, Dominican Republic
5 Clinica Nogales, Bogotá, Colombia
6 Department of Obstetrics & Gynecology Clinica Alemana de Santiago, Chile
7 Nurix, United States
8 Instituto D'or de Pesquisa e Ensino, Rio de Janeiro, Brazil
9 University of Tübingen, Germany
10 Hospital Garrahan, Buenos Aires, Argentina
11 Núcleo de Pesquisa da Rede São Camilo, São Paulo, Brazil
12 Department of Ophthalmology. Georgetown University Medical Hospital, Washington, United States
13 ResMed Science Center, Munich, Germany
14 Pontificia Universidad Católica Madre y Maestra, Santiago De Los Caballeros, Dominican Republic
15 TranslaTUM, Center for Translational Cancer Research, Technical University of Munich, Munich, Germany
16 Hospital General San Juan de Dios, Guatemala, Guatemala.
17 Mea Scoliosis Foundation, Chisinau, Moldova
18 Instituto Neurologico de Colombia, Medellín, Colombia
19 Instituto Tecnologico de Santo Domingo, Santo Domingo, Dominican Republic
20 Hamad General Hospital, Qatar
21 Tokyo Medical and Dental University, Japan
22 International University of the Health Sciences, Basseterre, Saint Kitts and Nevis
23 Pontificia Universidad Católica Madre y Maestra, Santiago De Los Caballeros, Dominican Republic

Conflicts of interest

The authors have no personal or financial conflicts of interest related to this study protocol.

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