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Evaluation of a digital diabetes prevention program adapted for the Medicaid population: Study design and methods for a non-randomized, controlled trial

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ABSTRACT

Previous studies have shown that lifestyle modification can successfully prevent or delay development of type 2 diabetes. This trial aimed to test if an underserved, low-income population would engage in a digital diabetes prevention program and successfully achieve lifestyle changes to reduce their risk of type 2 diabetes.

Participants were recruited from three health care facilities serving low-income populations. The inclusion criteria were: a recent blood test indicating prediabetes, body mass index (BMI) > 24 kg/m^2, age 18–75 years, not pregnant, not insured, Medicaid insured or Medicaid-eligible, internet or smartphone access, and comfort reading and writing in English or Spanish. A total of 230 participants were enrolled and started the intervention. Participants' average age was 48 years, average BMI = 34.8, average initial HbA1c = 5.8, 81% were female, and 45% were Spanish speaking. Eighty percent had Medicaid insurance, 18% were uninsured, and 2% were insured by a medical safety net plan.

Participants completed a health assessment including measured anthropometrics, HbA1c test, and self-report questionnaires at baseline, 6 and 12 months. The 52-week digital diabetes prevention program included weekly educational curriculum, human health coaching, connected tracking tools, and peer support from a virtual group. Qualitative data on implementation was collected with semi-structured interviews with key informants to understand the barriers, keys to success, and best practices in the adoption of the program within the clinical setting.

This paper describes the study design and methodology of a digital diabetes prevention program and early lessons learned related to recruitment, enrollment, and data collection.

1. Introduction

The landmark Diabetes Prevention Program (DPP) trial demonstrated that lifestyle modification to promote healthful dietary intake, increased physical activity, and sustained weight loss is successful and more effective than prescription medication to prevent or delay the onset of Type 2 diabetes [1,2]. The success of the DPP lifestyle intervention in the original trial and the long-term salutary benefits found in the DPP Outcomes Study (DPP-OS) have firmly established the role of behavioral intervention as effective, safe, and sustainable for diabetes prevention [3]. With the preponderance of evidence supporting the DPP, policy efforts are successfully improving provider infrastructure and expanding health insurance coverage to make diabetes prevention more accessible to at-risk populations [4,5]. Translational efforts have disseminated the DPP through various modes of delivery, including in-person groups and online/digital formats. On average, these translational DPP efforts have achieved positive results in replicating the goals of the DPP, and have expanded the reach of lifestyle modification nationwide [6,7]. In particular, technology-enabled and digital versions of the DPP (utilizing remote coach access, internet platforms,

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telecommunications and smartphone apps) have achieved positive clinical efficacy, with several meta-analyses showing clinically meaningful weight-loss in the range of 3–4 kg [8], and digital programs performing comparable to or better than in-person programs in achieving meaningful weight loss and glycemic control [9,10].

While diabetes prevention efforts continue to proliferate, the incidence of Type 2 diabetes and obesity remain disproportionately higher among Americans from lower income brackets, particularly low-income Americans from underrepresented racial and ethnic groups [11,12]. As with all components of health care, concerted efforts are needed to ensure low-income individuals have equitable access to diabetes prevention programs. In fact, many DPP adaptations targeting low-income communities to better address socioeconomic challenges have been developed and tested, with modest but promising results [13–17]. Persistent limitations to many of the DPP adaptations is the dependency on face-to-face contact, location-based meetings, and time-restricted options for group sessions. Limited flexibility around work schedules, access to reliable transportation, or access to affordable childcare options are reported to pose challenges for potential participants to attend the required in-person DPP sessions [18,19]. People in rural areas face similar access obstacles when locations for DPP group sessions may be logistically prohibitive [20].

To address these logistical and scheduling barriers, remotely delivered DPP solutions using telecommunications and internet delivery present a viable option for hard-to-reach populations. While lower-income Americans continue to lag behind higher income groups in technology adoption and use of technology for health care [21], now over 60% of low-income Americans own a smartphone, and over half own a laptop and have broadband internet access at home [22]. Furthermore, a recent study found that 71% of surveyed low-income patients receiving care through medical safety net services (i.e., subsidized medical care for income limited, uninsured and underinsured individuals) were interested in using digital tools for health care communication [23]. Technology-enabled DPPs are now emerging to serve vulnerable populations with evidence of good engagement levels, improved knowledge, and increased behavioral intentions [24,25].

The purpose of this study is to evaluate a digitally-delivered version of the DPP that was specially adapted for lower-income populations. This evaluation collects both quantitative and qualitative data on the experience of patients utilizing the digital DPP to evaluate clinical outcomes and to better understand the clinic implementation of the program in facilities serving low-income populations. This paper outlines the methods used in conducting the trial and shows the results of preliminary baseline data analysis.

2. Methods

2.1. Study design

The trial is a non-randomized, controlled trial with historical, matched controls serving as the comparison group. A non-randomized design was chosen because sufficient resources were not available for a randomized clinical trial, and because there were no alternative programs available for the targeted population with prediabetes. Investigators were concerned that sites and participating clinicians would be less receptive to refer patients to the study if there was a control arm since some of their patients might not receive any services. An ethical and practical alternative with the resources available was to offer the program to all eligible patients that were identified, and utilize a historical comparison group.

A total of 230 participants were recruited over a 14-month period from three health care facilities serving Medicaid-insured, safety net insured, or uninsured individuals. The three facilities include a federally qualified health center located in Southern California, an outpatient clinic located within a large public teaching hospital in Southern California, and a clinic serving large numbers of Medicaid patients operating within a large, not-for-profit, integrated healthcare network in the state of Washington. All qualified participants enrolled in the trial were offered the digital DPP program. A comparison group was created using the same criteria used to determine study eligibility and was abstracted from de-identified records of patients who did not enroll in the trial. The study protocol was reviewed and approved by Western Institutional Review Board and the Health Sciences Institutional Review Board at University of Southern California.

2.2. Recruitment and eligibility criteria

Participants were initially identified through their electronic health record (EHR) or through referral from their primary care physician. Study coordinators made contact on behalf of the study through secure email, secure text messaging, or in-person meetings in the clinics. Coordinators had private conversations with all identified/referred participants to elicit their interest in participation and ensure that the following eligibility criteria were met: evidence of prediabetes defined by either a fasting blood glucose test of 100–125 mg/dL, glycosylated hemoglobin (HbA1c) test of 5.7–6.4%, or an oral glucose tolerance test result of 140–199 mg/dL performed within 6 months of the EHR review date; age 18–75 years at time of screening; insured through Medicaid, a federally subsidized Affordable Care Act marketplace plan, or uninsured; able to speak and read English or Spanish at a 5th grade level or higher; body mass index (BMI) greater than or equal to 24 kg/m^2; able to access and use the internet at least once a week; and able and willing to give informed consent to participate. Potential participants were excluded if they had any of the following: diagnosis of Type 1 or 2 Diabetes; taking insulin, metformin, or other hypoglycemic agent; pregnant or planning to become pregnant during the trial period; currently active/acute medical or psychiatric condition that would preclude program participation (i.e., under treatment for acute myocardial infarction, unstable hypertension); any physical limitation that would preclude unsupervised exercise (e.g., severe bone or joint pain); current or suspected drug or alcohol misuse; or instability in living situation that would preclude full participation.

2.3. Intervention

All enrolled participants received a language-and-literacy adapted version of the Omada Health Program. The Omada Health Program is a digital intensive lifestyle intervention that includes virtual group support, personalized health coaching, weekly lessons, and digital tracking tools. The program is a Diabetes Prevention Program (DPP) and is recognized by the Diabetes Prevention Recognition Program (DPRP) [4]. The program is 12 months long, with an initial intensive 16-week phase (considered the “Core” program by DPRP standards) followed by a 36-week maintenance phase. Participants are placed into small virtual groups with peers. They start the program at the same time, and are assigned to the same, live health coach. Each group has a private online social network where they can discuss goals, challenges, progress, and provide social support to one another at any time, similar to a private chat board or discussion board. Users asynchronously complete weekly health education lessons each week. The lessons are available on the digital platform and can be accessed through internet or smartphone. User communicate with their health coach and receive individualized counseling through private messaging on the platform; coaches also facilitate discussions on the group chat board. Users track meals using digital online tracking tools, track weight loss and physical activity using a wireless weight scale and pedometer, and monitor their engagement and weight loss progress. See Figs. 1 and 2 for visual examples of the program.

The linguistically adapted version includes all components of the standard digital DPP but has enhanced features for lower-literacy accessibility. In previous iterative development work, the following adaptations were made: 1) revision of the curriculum text and reading