Overcoming Barriers and Obstacles to Adopting Diabetes Devices

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1. PURPOSE OF THE STUDY

a. To address the need for increased support for initiating CGM, we developed a 4-session CGM-focused behavioral intervention called ONBOARD (Overcoming Barriers & Obstacles to Adopting Diabetes Devices). The current mixed methods study had two main goals: 1) to examine the feasibility and acceptability of a pilot of ONBOARD for adults with T1D; and 2) to examine preliminary evidence of the impact of ONBOARD on glycemic outcomes (i.e. time in glucose target range; diabetes distress). We hypothesized that ONBOARD would be feasible and acceptable for adults with T1D and lead to increases in time in range and decreases in diabetes distress.

2. STUDY PROCEDURES

a. Procedures

Once eligibility is confirmed, participants will be consented and enrolled. Once enrolled, a baseline assessment survey will be completed online via a secure site (REDCap) to obtain demographic and psychosocial data. Blood glucose meter and continuous glucose monitor will be downloaded. For participants not currently using CGM but would like to, we will work with the clinical team to get them started via standard clinical procedures. In addition, during our work with them (after the clinical start of CGM), we will use FDA-approved Dexcom guides as reminders of standard resources they have access to for CGM. Next, all participants will schedule four individual, 60-minute visits with study interventionist to complete ONBOARD sessions, each 3 weeks apart. If available, we will ask participants to provide a hemoglobin A1c result obtained in the 3 months prior to study enrollment or obtain this via their medical record. Visits will be conducted via a secure, HIPAA-compliant, videoconferencing software. Sessions will be recorded to ensure consistency and quality of the intervention across participants. Upon completion of 4 intervention sessions, participants will complete a follow-up 30-minute REDCap survey and will participate in a focus group to provide feedback on the intervention.

Blood glucose meter and continuous glucose monitor will be downloaded. If a hemoglobin A1c result was obtained during the course of the study, we will ask participants to provide this or obtain it via their medical record. Focus groups will be audio-recorded and use a semi-structured interview guide to ensure consistency across groups and will aim to elicit feedback about ONBOARD's clarity, health literacy level and comprehension. We will also elicit 1) session-specific feedback; 2) changes in device-specific knowledge and problem-solving skills after the intervention; 3) overall feedback on the intervention.

b. Procedure Risks

The study will be explained as part of the consent process. We will provide detailed information about the study, its purpose, and procedure. Participants will be given enough time to consider carefully their own participation and ask questions about the study prior to providing consent.

c. Use of Deception in the Study

NA

d. Use of Audio and Video Recordings

Intervention sessions and focus groups will be video and audio recorded by the software on Zoom, which is approved for high risk data. Transcripts will be anonymized prior to analysis. No personal identifying information will be included in any transcripts.

e. Alternative Procedures or Courses of Treatment

NA

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

NA

g. Study Endpoint(s)

Analyses are intended to iteratively refine ONBOARD intervention materials. Therefore, quantitative analyses will be descriptive and examine differences between baseline and post-intervention in terms of psychosocial variables, technology attitudes, and health outcomes. Qualitative analyses will use data from focus groups carried out post-intervention. Interviews will be digitally recorded, transcribed and anonymized, reviewed for completeness and accuracy, and then imported into the qualitative software package, NVIVO 10 (QSR International Pty Ltd., 2014). We will use content analysis to code transcripts, resolve discrepancies between coders, and capture key themes for areas of feedback on the intervention to refine each session.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Type 1 Diabetes (T1D) is a burdensome chronic disease; many adults with T1D do not meet treatment targets. The Centers for Disease Control and JDRF data estimate that there are around 2.5 million adults in the US with T1D (25, 26); 15,000 adults are newly diagnosed with T1D annually. T1D requires constant attention to glucose levels, food intake and physical activity, and insulin dosing decisions. Giving too much or too little insulin could result in hypo- or hyperglycemia, both of which carry risks of developing long-term complications. Hemoglobin A1c is the indicator that is closely associated with likelihood of developing future complications. National data show that the majority of adults do not meet ADA's recommended glycemic target of A1c<7.0% (86% of adults 18-25; 70% of adults over 25). Existing and emerging diabetes technologies can dramatically improve health and reduce burden, but adoption rates are low. Diabetes technology offers major advances in diabetes management that reduce self-management burden and improve health outcomes and quality of life for individuals with T1D. These devices include continuous glucose monitoring (CGM) systems and insulin pumps. CGM technology provides in- the-moment information about glucose levels, including direction and speed of change. CGM reduces management burden by reducing the need for frequent finger sticks. CGM has been shown to be cost-effective and to help adults improve both glycemic control and time spent in target glucose range without increasing risk of hypoglycemic episodes or diabetic ketoacidosis. The recent "Beyond A1c" Consensus Report highlighted the value of looking at time in range as another clinically meaningful outcome for T1D. Time in range (% of readings between 70-180 mg/dL per unit of time) captures continuous glucose variability over time through CGM data, whereas A1c provides a snapshot at single time points 3 months apart, and is more sensitive and specific than A1c testing. We know that currently, more than half (~62%) of individuals with T1D use insulin pumps in the US, while only 14% of adults with T1D currently use CGM. Further, a concerning proportion (27%) quit CGM within the first year due to the daily burden of using the device. Providing adults with T1D with the resources and tools to work through modifiable barriers could lead to continued CGM use and increased readiness for closed loop. Despite recommendations for structured education, there is no official standard of care for CGM initiation. Strong evidence from clinical trials support benefits of CGM for adults with T1D. The ADA also recommends that adults with T1D receive robust education, training, and support for CGM use. However, this recommendation comes from expert consensus and clinical experience, and there is a need to develop high- quality, evidence-based behavioral interventions to provide this recommended training and support. It is well understood that structured education enhances benefit from self-monitoring of blood glucose. Similarly, if adults with T1D receive comprehensive education and support when beginning to use CGM, they would have increased likelihood of using the devices and experiencing acute and long-term health and quality of life benefits. Given that CGM is becoming part of "usual care" for people with T1D and is a component of closed loop systems, the next key step is to test interventions that provide additional resources and support for CGM uptake versus CGM alone.Source: eProtocol Section 3a

b. Findings from Past Animal Experiments

NA

4. PARTICIPANT POPULATION

a. Planned Enrollment

We plan to enroll up to 40 participants.

b. Age, Gender, and Ethnic Background

c. We will actively recruit equal numbers of males and females between 18 and 50 years of age. Females are expected to comprise approximately 50% of the adult study sample. The study will not select with respect to the racial or ethnic background of the subjects as there are no race- or ethnic-specific hypotheses. The final study sample will be representative of the diverse ethnic population of patients in the Stanford Hospital & Clinics outpatient diabetes program and in the ethnically diverse Bay Area, with approximately 50% Caucasian participants, 25% Hispanic, 20% Asian, 2% African American, 3% Other. Vulnerable Populations

d. Rationale for Exclusion of Certain Populations

NA

e. Stanford Populations

NA

f. Healthy Volunteers

NA

g. Recruitment Details

Recruitment procedures will include direct contact and advertisements/flyers in clinics and postings with online Bay Area groups (e.g., JDRF, ADA, Carb DM), as well as referrals from treating physicians. Treating physicians may provide a study brochure which patients may use to contact study staff directly. Alternately, treating physicians may request permission for study staff to speak with the potential participant about the study during an appointment for usual care or to follow up with a phone call or email. We will also recruit from an independent list of non-Stanford clinic adults in the larger San Francisco Bay Area who have participated in closed loop trials at Stanford who have provided consent for contact about future trials (IRB-approved database).

h. Eligibility Criteria

i. Inclusion Criteria

1. Subject is age 18-50 years at time of screening

2. Subject is within first year of continuous glucose monitor use OR has not been using CGM regularly in the past 6 months

3. Subject has a clinical diagnosis of type 1 diabetes

4. Subject comprehends spoken and written English

Exclusion Criteria

1. Subject has a medical disorder that in the judgment of the investigator will interfere with completion of any aspect of the protocol.
2. Subject has a neurologic disorder that in the judgment of the investigator will affect completion of the protocol.

i. Screening Procedures

Screening procedures include a review of inclusion/exclusion criteria to assess eligibility. This information will be verbally elicited from potential participants.

j. Participation in Multiple Protocols

We will verbally elicit this information from participants. If participants are enrolled in another protocol, we will discuss the study with the PI to determine if it is safe for the subject to enroll in both protocols simultaneously.

k. Payments to Participants

Participants will receive up to an $100 Amazon gift card upon completion of the study ($25 for baseline assessment; $50 for all 4 intervention sessions; $25 for completing a focus group and survey at the end of the study).

l. Costs to Participants

NA

m. Planned Duration of the Study

The probable duration of the entire study is 2 years. We anticipate screening will require 5 minutes, activate participation in the study will require approximately 3 months, and analysis of participant data will require approximately 1 year. Surveys will require approximately 30 minutes each to complete and ONBOARD sessions and the focus group will require approximately 1 hour each.

5. RISKS

i. Psychological well-being

Data downloaded from the CGM and the home glucose meter will be collected for the study as measures of diabetes self-management behaviors. Some people may be uncomfortable with researchers' having such detailed information about their daily diabetes habits. Psychological and human factors testing may make study participants uncomfortable. Subjects are free to withdraw from the study at any time. We have psychologists and health care professionals who will be available to help study participants with their stress or anxieties.

ii. Economic well-being

Time away from school and/or work is a potential risk.

iii. Social well-being

Loss of confidentiality is a potential risk.

iv. Overall evaluation of risk

Low

b. Procedures to Minimize Risk

Subjects will continue to receive type 1 diabetes care from their usual provider. Subjects are free to withdraw from the study at any time. For security and confidentiality purposes, subjects will be assigned an alphanumeric identifier that will be used instead of their name.

c. Study Conclusion

Individual subjects will be removed from the study if circumstances develop during the study that, in the judgment of the investigator, make it inadvisable for the subject to continue with the study.

NA

d. Risks to Special Populations

NA

6. BENEFITS

It is expected that this protocol will yield knowledge about the impact of physical burden/hassle of wearing devices, managing data, social barriers, and trust in diabetes devices. Participants may learn something new about diabetes management, however, there is no guarantee of any benefit from participating in this research study.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.