ISPAD-JDRF Research Fellowship Award Six Month Progress Report

Title: Developing A Novel Intervention for Addressing Unhealthy Risk-Taking Behaviors Among Adolescents with T1D

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Project: Developing A Novel Intervention for Addressing Unhealthy Risk-Taking Behaviors among Adolescents with T1D

Problem Statement:

Despite recent technological advances in type 1 diabetes (T1D) treatment, adolescents with T1D are the only age group who have yet to experience improvements in glycemic levels.[1] Generally, the period of adolescence is a time of increasing independence and decreasing engagement in healthy behaviors, including T1D self-care tasks. Experts have developed behavioral interventions to address this known problem, with only small to moderate success in improving engagement in T1D self-care[2] and glycemic outcomes[3]. However, one factor that has received little attention, despite being common among adolescents, is risk-taking behavior.

Unhealthy risk-taking behaviors are behaviors that have the potential to be harmful or dangerous (e.g., substance use, risky driving, risky sexual behaviors). For adolescents with T1D, these behaviors are especially problematic because they can interfere with T1D care and/or carry additional health risks. For example, excessive alcohol use can lead to an inability to participate in T1D care tasks and cause alcohol-induced hypoglycemia. In general, risk-taking behaviors increase in adolescence, and adolescents with T1D are as, if not more, likely to engage in unhealthy risk-taking behaviors as their peers[4]. Furthermore, when adolescents with T1D engage in risk-taking behaviors (e.g., alcohol use), they generally do not take precautions to prevent T1D complications (e.g., monitoring blood glucose after drinking alcohol to prevent a significant hypoglycemic event, or ensuring someone with them knows they have diabetes)[5,6]. To define risk-taking behaviors that are specific to adolescents with T1D, we published a model for T1D-specific risk taking (see Figure 1)[7].

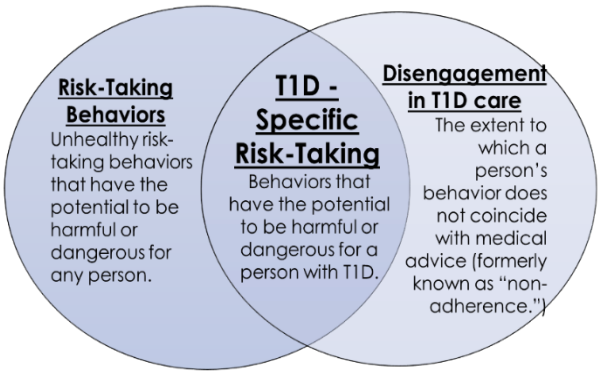


Figure 1. Adapted model for T1D-specific risk-

Fortunately, research on general adolescent risk-taking behavior has advanced and behavioral specialists have developed effective programs to reduce and/or prevent unhealthy adolescent risk-taking behaviors in the general population. The PI's research mentor developed such a program: Project TRAC (Talking about Risk and Adolescent Choices). Project TRAC reduces risk-taking behaviors by teaching adolescents the connection between emotions and behaviors, and by identifying and practicing emotion regulation techniques that adolescents can use in future, risky situations[8]. However, no intervention, including Project TRAC, targets T1D-specific risk-taking behaviors, and thus, misses the opportunity to address behaviors that for adolescents with T1D could be very dangerous and/or deadly (e.g., behaviors that could lead to acute T1D complications).

Goals:

To address this critical need for adolescents with T1D, the PI aims to adapt the Project TRAC manualized intervention to target T1D-specific risk taking among adolescents with T1D. To move this goal forward, she proposes to accomplish the following in the current study:

Aim 1: Engage adolescents with T1D via an online group to provide feedback on and suggestions for changes to the proposed content and structure of a new, T1D-focused risk-taking prevention intervention: "Talking about Risk and Adolescent Choices for youth with Diabetes" (TRAC-D).

Aim 2: Work with a group of stakeholder representatives to apply findings from the focus group to make adaptations to the original, empirically supported "Project TRAC" manual.

Upon completion of these aims, the expected outcomes are:

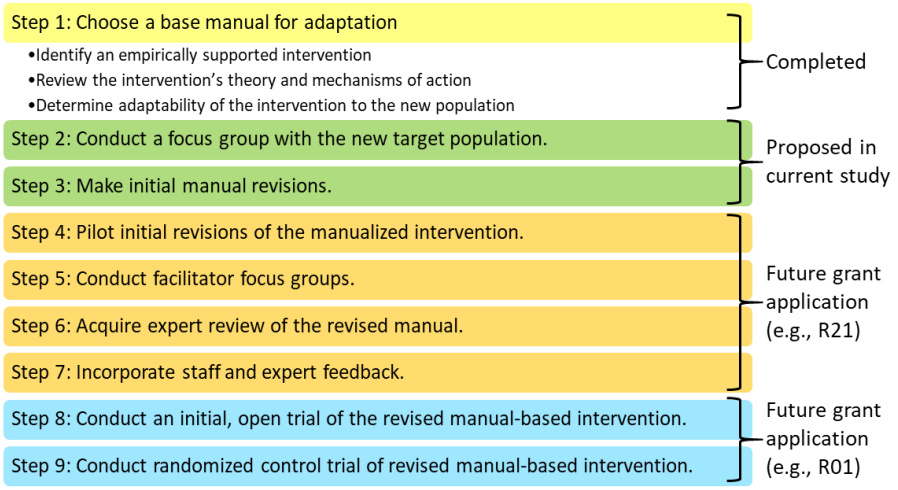
1. Novel qualitative data from adolescents with T1D about their ideas and preferences for a behavioral intervention that aims to reduce risk-taking behaviors among adolescents with T1D.
2. A new, manualized behavioral intervention that is ready for pilot testing as a part of a subsequent research grant. Developing this intervention is the next logical step in a program of research that is innovative in its focus on T1D-specific risk-taking behaviors and rigorous in its use of implementation science frameworks. Ultimately, the PI hopes that the new "TRAC-D" intervention will improve glycemic health, reduce the rate of acute T1D complications, and reduce unnecessary morbidity and mortality among adolescents with T1D.

Project Design:

Overview of Study Design. The current study will accomplish phase 1 of a larger program of research to adapt the TRAC manualized intervention for use in youth with T1D. Overall, this program of research incorporates steps of the Planned Adaptation Approach proposed by Goldstein et al.[11] (see Figure 2 for how this project fits into our larger research program).

The PI completed Step 1 of the Planned Adaptation Approach by selecting Dr. Houck's manualized TRAC intervention. Again, the PI selected TRAC because 1) it is empirically supported to reduce risk behaviors[8,12], 2) its theoretical and mechanisms of action are consistent with her theory of T1D specific risk taking[7], and 3) it has potential for adaptation to youth with T1D[8]. The current study will focus on completing Steps 2 and 3 (in green), which coincide with Aims 1 and 2, respectively.

Figure 2. Goldstein and colleagues' steps for adapting manualized



To execute the Planned Adaptation Approach, first, the PI will work with the TRAC intervention developer (Co-Mentor: Dr. Houck) to identify the intervention strategies that should be retained, so proposed changes will not interfere with or alter core mechanisms of the intervention. Second, she will identify population differences[13], and seek solutions to address these differences from adolescents with T1D. For example, she will keep the overall strategy for emotion regulation, and adapt the vignettes so that they are T1D-specific. Thus, a prompt posed to adolescents with T1D may include an explanation for what the original vignette is trying to accomplish and a question about whether the adolescents like our T1D-specific adaptations better. Finally, the PI will engage stakeholders (adolescents with T1D and diabetes healthcare providers) to make adaptations to the intervention content and anticipated clinical trial procedures,[13] (Aim 2) in preparation for a future pilot study.

Methodology for Aim 1: Engage adolescents with T1D via an online focus group to provide feedback on and suggestions for changes to the proposed content and structure of a new, T1D-focused risk-taking prevention intervention: TRAC-D.

Methodology for Aim 2: Work with a group of stakeholder representatives (diabetes healthcare providers and adolescents with T1D) to apply findings from the focus group to make adaptations to the original, empirically supported "Project TRAC" manual.

Progress to Date:

Established Research Team and Diabetes Healthcare Providers Stakeholder Group:

After the notice of award in December of 2021, Dr. Wasserman formed a group of healthcare providers, who in addition to the study mentors, would help in adapting the TRAC manualized intervention. The team of healthcare providers consists of Mentor: Susana Patton, PhD, ABPP, CDCES (expertise in diabetes behavioral intervention research); Co-Mentor: Christopher Houck, PhD (creator of the original TRAC intervention); Shilpa Gurnurkar, MD (a practicing pediatric endocrinologist who specializes in treating adolescents with T1D); and Kim Rossi, CDCES (a practicing certified diabetes care and education specialist and someone with lived experience of parenting an adolescent with T1D). We also secured the aid of a clinical research coordinator to assist with scheduling, documenting meetings, and recruiting adolescents with T1D for the online focus group and adolescent stakeholder group. This healthcare provider team has meet 3 times via virtual meetings to discuss plans for adapting the TRAC manual.

Identified Intervention Core Mechanisms and Targets for Adaptation:

As mentioned above, the health care provider stakeholder group has met 3 times via virtual meetings, and exchanged materials via an email chain. In these meetings, we have discussed overall plans and goals for this study, the theoretical basis for the TRAC intervention, and we have reviewed the first 2 sessions (out of 14 sessions) in the TRAC manual to decide what elements we intend to keep vs. change to address the unique needs of adolescents with T1D. From these virtual meetings, we have also started to compile a list of questions/ prompts that plan to ask in our online adolescent focus group.

Obtained IRB Ethics Approval for Engaging Adolescents with T1D:

In May 2022, we obtained approval from Nemours Children's Health Institutional Review Board for this study. Per the protocol, we proposed to recruit adolescents (age 12-16) with T1D to participate in the current study in one of two ways: 1- in the online focus group, or 2- as a part of our Youth Advisory Committee. For the online focus group, we will invite up to 40 adolescents with T1D selectively recruited to include participants of diverse demographic factors (age, gender, race/ethnicity) and risk-taking experience. For the YAC, we will invite up to 3 adolescents to participate in virtual meetings over the course of 3-4 months (up to 16 hours total).

Recruitment of Adolescents with T1D (age 12-16):

We are currently in the process of recruiting for this study. All communications with adolescents and their caregivers are done remotely (e.g., email, phone, patient portal). An EMR analyst identified current Nemours patients who met eligibility criteria, and a study team member electronically sent recruitment information to the adolescents' caregiver and followed up, as needed, with a phone call or text message. From the email, caregivers can click a link to access a HIPAA compliant Research Electronic Data Capture (REDCap) survey wherein they can review a study cover letter, verify their adolescent's eligibility, and provide contact and demographic information. The REDCap survey will also provide the adolescents and their caregivers information regarding the Youth Advisory Committee (YAC). Adolescents will have the opportunity to inform the research team if they would like to be considered for the online Yammer group, the YAC, or both on the initial REDCap survey. The study team then selectively contacts families to explain the study/enroll interested families in the YAC or Online Focus Group. To enroll, parents must consent, and adolescents will assent using online REDCap forms which will have the "Add signature" function for electronic authentication, and adolescents will complete the DSRI (adolescent measure of T1D-specific risk-taking behaviors). Adolescents will receive $5 for completing the DSRI.

We proposed to recruit about 75 adolescents with T1D to complete a questionnaire on diabetes-specific risk-taking behaviors, so that we could selectively invite about 40 adolescents to the online focus group and up to 3 adolescents to the youth advisory committee.

As previously mentioned, we are currently in the process of recruiting adolescents with T1D for the current study. We have completed several steps towards this goal:

1- Created the REDCap survey database to conduct eConsent for participants for this study. Parents are able to complete and sign parental permission forms, and adolescents are able to complete and sign assent forms via our REDCap database. Adoelscents are also able to complete the survey on the
2- Identified 330 adolescents (ages 12-16) in our electronic medical record, who are likely eligible for this study, and are engaged with our diabetes clinical team (i.e., have had an appointment in a diabetes clinic within the past year).
3- Sent recruitment email to 150 caregivers of youth with T1D. Still need to contact remaining 180 eligible families.
4- Of the 150 that have received a recruitment email:
    a. 10 have completed parent permission, adolescent assent, and the adolescent survey.
    b. 3 have completed parent permission, but adolescent portion is not yet completed
    c. 15 have expressed interest in the study, and are in active communication with the study team to find out more about the study before completing consent forms
5- Given that we would like to facilitate adequate representation across key demographic variables among study participants, we have started recruitment by primarily reaching out to families that are traditionally harder to recruit (e.g., non-white or Hispanic youth). Thus, the demographic information for the 10

enrolled participants, thus far, includes: 40% Black or African American, 50% Latina/Latino, and 10% White; 70% female, and age 12-16 (M=13.4).

Anticipated Completion/ Next Steps:

Given our current rate of recruitment, we anticipate that we will complete recruitment and start the Yammer online focus group and YAC advisory committee meetings by the end of July. The Yammer online group and YAC will run concurrently with our expert team meetings, to be held across August, September, and October. During these three months, we will discuss what needs to change from the intervention manual and obtain feedback about such changes from either the YAC or the Yammer group or both. In November and December, we will finalize changes to the intervention manual. Thus, we are on target to complete all study milestones and deliverables by the end of December.

Dissemination Plan: We plan to submit an abstract to the 2023 ISPAD conference to present our findings from this study, and manuscript(s) will be prepared in the Spring/ Summer of 2023. To further this line of research, we plan to submit a grant application to apply for future funding to pilot the newly developed TRAC-D intervention. We will submit the findings from this study in the preliminary studies section of the grant application. We are currently working on the grant application, with an anticipated submission in February of 2023.

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