

**JDRF Strategic Research Agreement (SRA)
Letter of Intent (LOI)**

1. Brief details of approach proposed, including hypothesis, scientific rationale and references to data.

Eating disorders (ED) in adolescents and young adults with type 1 diabetes (T1D) were found in 26% of participants, as well as significant associations between eating problems, insulin misuse, and microvascular complications[1]. In an 11-year longitudinal study of adult women with T1D (n=234), results showed insulin omission for weight control to be common (reported by 30% at baseline) with omission persisting over the follow-up period; this was associated with higher rates of diabetes-related medical complications and tripled risk of mortality[2]. A tripled risk of mortality is unacceptable, and we must understand more about the psychosocial aspects and treatment plans available to adolescents and young adults with T1D who have been diagnosed with an ED.

The focus of this proposal is to put diabetes at the center of the ED, not just an “addition” to current treatments for anorexia and bulimia. Although there is much guidance on how to treat in-patient and out-patient ED without diabetes, adding T1D and the possibility of insulin omission creates a complexity where a person with diabetes/ED needs to understand carbohydrate counting and label reading while avoiding obsession with calories. Specific knowledge is needed to treat an ED patient with T1D, including knowledge about the triggers for insulin omission (e.g., how does diabetes feed into their feelings of needing control), among other strategies to lose weight. This diabetes/ED knowledge is currently scattered among practitioners of ED, avoided (to a large extent) by health care providers, and not confidently addressed by diabetes educators. Before developing an intervention, we need a solid understanding of the psychosocial factors that are specific to treatment of diabetes and ED and feasible, flexible guidelines for further implementation. Therefore, the research question is, **“What are the protocols for treatment of ED with T1D specifically, and how could they be improved with input from clinicians, clients and families?”** This study will be conducted in two short-term goals over a period of four years, with an outcome of creating a resource of best practices for ED providers.

Aim 1: Obtain and discuss treatment guidelines/protocol for T1D/ED with healthcare and psychosocial treatment personnel in-patient eating disorder clinics (n=5) and outpatient clinics (n=15).

First, we will collect current guidelines/protocols in place at each of the 5 clinics listed on NEDA/Diabulimia HelpLine and 15 outpatient clinics to determine how they compare/contrast among clinics. Concurrently, we will interview clinic directors and psychosocial treatment personnel at each clinic (total n~50) to gain collective knowledge on the guidance and support that clients/caregivers receive in treating T1D/ED. Attention will be given to both psychosocial and clinical guidelines, and will include questions such as: (1) How do you treat a client with T1D/ED; (2) What happens if he/she needs to be hospitalized and, under what conditions; (3) How confident are you in your ability to treat T1D in addition to ED; (4) How do you manage diabetes devices during treatment; and (5) How long are clients with T1D/ED typically in treatment (in-patient and/or out-patient). We will audio-record responses from the health care personnel to these interview questions, which will be transcribed and systematically coded according to rigorous standards for qualitative research[3] to produce a written report of findings.

Aim 2: Interview adolescents/young adults with T1D who are in treatment at in-patient and out-patient ED clinics (n=25), those who previously have been in ED treatment <=5 years (n=25), and their dyad of caregivers/partners (n=50) to determine what elements of treatment have worked well, and what were barriers to treatment and success.

We will determine gaps and strengths in ED treatment from the perspective of the lived experience of people with T1D/ED and their loved ones. Questions might include: (1) How is ED in T1D different from other EDs and how should it be treated differently; (2) What kind of materials did you receive and did you read them/think they were helpful (what about stories from other people); (3) How could we better utilize your phone/text to help you; and (4) When do you most struggle in recovery and what helps you the most? Caregiver questions will be modified to reflect their perspectives. We believe that this number of individuals will be satisfactory to reach saturation (the qualitative criterion for adequate sample size),

based on the breadth of the research question. Research questions that are narrowly focused need fewer participants ($n \sim < 6$) to reach the point at which no further responses add to the data; and those that are broad, such as “tell me about your T1D/ED” need more participants ($n \sim > 40$). As the question becomes more complex and/or more data are needed to determine similarities/differences among participants, the more participants are needed. We plan to recruit a diverse sample ($n=50$) with T1D/ED, with attention to in-patient/out-patient contexts, SES, race and gender, so that results can be applied to a broad range of adolescents/young adults with T1D/ED (sampling plan in full application). Recruitment will occur at the institutions represented in this proposal: Joslin Diabetes Center (Boston, MA), Vanderbilt Medical Center (Nashville, TN) and Penn State College of Medicine (Hershey, PA). As with another study we conducted[4], participants will be also recruited from websites (NEDA, Diabulimia HelpLine) and blogs about T1D/ED. Responses will be coded systematically according to persons with T1D/ED and their caregivers (see table) and the resulting themes will be compared to the protocols that are currently in place to look for omissions/revisions. The data map will be integrated with the report from Aim 1.

Example of conceptualization of data map for person with T1D/ED

<i>Theme</i>	<i>Category</i>	<i>Code</i>	<i>Supporting Quote</i>
<i>Dig deeper to understand why they restrict insulin</i>	<i>Psychosocial aspects</i>	<i>Adults need to ask</i>	<i>"I wish people would just ask ... I don't know why I restrict, but it's always a thought running through my mind."</i>
			<i>"We [my mom and I] talk about it [insulin restriction], but she doesn't want to go deep. She doesn't ask enough questions."</i>
		<i>Need to be empathetic</i>	<i>"I haven't developed diabetes or ED overnight, so don't expect me to figure it all out right away. It's a really hard disease and it makes me sad."</i>

Although we have not conducted previous research in this particular area as a team, the team has extensive experience in psychosocial behaviors in diabetes through a qualitative research lens[3-19]; clinical experience with DEB/ED[20-27]; family support for diabetes and tailored feasibility studies[28-33]; and psychosocial risk factors in diabetes, primarily adolescents and young adults[34-45]. We also have key personnel with expertise in parent/families with ED (not just diabetes) and a CDE who works in an ED clinic. As I noted over the phone, the interest in this research is driven by the fact that I have T1D and am in recovery from an ED, which gives me additional insight into what living with both can be like.

2. Description of potential for translation into therapies, i.e., short and long-term development goals.

The short-term goals are listed in aims 1-2. Our assumption is that people with T1D/ED in the US are similar to those in other developed countries, although reimbursement and specific treatments are different. Although this study is conducted in the US, we have connections to King's College (London) and Steno Diabetes Center (Copenhagen) to expand. This research will set us up for continued collaboration to develop interventions that would be feasibly adopted, because we have engaged them in the conversation surrounding the recommendations for treatment for ED/T1D. The proposal is in response to the question, “How do we make sure that what we do is actually useful for health care professionals, people with T1D/ED and their caregivers/partners?” Therefore, three long-term goals are to: (a) conduct the same type of analyses in other countries; and (b) conduct interviews with CDEs to understand what they need to know in practice to help someone with T1D/ED and determine best practices; and (3) conduct an intervention where the new findings are integrated into in-patient and out-patient clinics for their effectiveness.

3. Does the proposed research include human subjects? Yes, but this research does not constitute a clinical trial. Proper institution review board approval will commence with an invitation for full proposal.