



Communication and coping intervention for mothers of adolescents with type 1 diabetes: Rationale and trial design

Sarah S. Jaser^{a,*}, Emily R. Hamburger^a, Sherry Pagoto^b, Rodayne Williams^a, Alison Meyn^a, Abigail C. Jones^a, Jill H. Simmons^a

^a Vanderbilt University Medical Center, USA

^b University of Connecticut, USA

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ABSTRACT

Mothers of adolescents with type 1 diabetes (T1D) experience high rates of depressive symptoms and diabetes distress, which are established risk factors for deteriorating glycemic control, problems with adherence, increased depressive symptoms, and poor quality of life in adolescents. Given that adolescents are a high-risk population for suboptimal glycemic control, novel interventions to improve outcomes in adolescents with T1D are needed. Building on effective interventions to treat depression in adults, and our own pilot work in this population, we developed a cognitive behavioral intervention, Communication & Coping, to target maternal depressive symptoms and parenting behaviors. The randomized controlled trial compares the telephone and Facebook-delivered Communication & Coping intervention, which promotes the use of adaptive coping strategies and positive parenting practices, to a diabetes education control condition on diabetes outcomes and psychosocial outcomes in adolescents with T1D. This paper describes the study rationale, trial design, and methodology.

1. Background and rationale

Mothers of adolescents with type 1 diabetes (T1D) experience elevated levels of depressive symptoms [1] which impair their ability to monitor and manage their child's diabetes [2,3]. T1D regimens are complex and demanding, and caregivers - especially mothers - experience stress related to the burden of treatment management. This stress is associated with increased risk for psychosocial problems in caregivers [4], with rates of clinically significant symptoms of depression evident in up to 61% of parents [5]. Further, maternal depressive symptoms are one of the strongest predictors of negative outcomes in adolescents, including deteriorating glycemic control, problems with adherence, poorer quality of life, and greater risk for depression [6–8]. Given that adolescents are a high-risk population for suboptimal glycemic control - with only 17% meeting treatment goals [9] - novel interventions to improve outcomes in adolescents with T1D are needed. Previous behavioral interventions for youth with diabetes have had only modest effects on glycemic control [10], many were time- and resource-intensive [11], and none have directly targeted maternal depressive symptoms. The proposed study is based on the premise that, by

reducing mothers' depressive symptoms and improving the quality of parental involvement, we will improve outcomes in adolescents with T1D.

Building on effective cognitive behavioral therapy (CBT) interventions for depression in adults [12] and positive parenting programs [13], our team has developed and pilot tested an intervention, Communication & Coping, for mothers of adolescents with T1D. In our pilot study of the intervention, delivered via individual telephone sessions, glycemic control improved in adolescents whose mothers participated in the program, and we found clinically meaningful effects on adolescent quality of life and depression. In addition, we found support for the effects of the intervention on the proposed mediators, maternal depressive symptoms and family conflict [14]. For the larger trial, we are including Facebook groups to provide social support and reinforce concepts from the telephone sessions. The current project is a randomized clinical trial, specifically targeting mothers who are experiencing mild to moderate depressive symptoms, to examine the efficacy of the Communication & Coping intervention as compared to a control condition (Diabetes Education).

Abbreviations: Cognitive Behavioral Therapy, CBT; type 1 diabetes, T1D

* Corresponding author at: Department of Pediatrics, Vanderbilt University Medical Center, 2525 West End Ave., Suite 1200, Nashville, TN 37232, USA.

E-mail address: sarah.jaser@vumc.org (S.S. Jaser).

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2. Study aims

The aims of the current study are to evaluate the effects of the Communication & Coping intervention on adolescents' diabetes outcomes and psychosocial outcomes over 12 months. We hypothesize that the adolescents of mothers who receive the intervention will demonstrate better glycemic control and better adherence to treatment than those in the control condition. In addition, we hypothesize that the adolescents of mothers who receive the intervention will report better quality of life and fewer depressive symptoms than those in the control condition. Further, we seek to evaluate whether these effects were driven by the targeted mediators (changes in maternal depressive symptoms and parental involvement). Finally, we plan to examine the differential impact of intervention effects across demographic factors (i.e., marital status, income, adolescent age, and sex).

3. Research design and methods

3.1. Conceptual framework

The proposed intervention is based on the Transactional Stress and Coping Model [15], which posits that the ways in which mothers cope with the stress of diabetes play an important role in both maternal and adolescent adjustment to the disease (see Fig. 1).

3.2. Study population

The target sample for this study is 154 mother-adolescent dyads. To be eligible, the mother (or female caregiver) must have an adolescent child aged 11–17, she must live with the adolescent at least 50% of the time, and the adolescent must be diagnosed with T1D for at least 12 months. In addition, the mother must be a regular Facebook user and report either mild to moderate symptoms of depression (Patient Health Questionnaire 9 score of 5–19), or moderate diabetes distress (Parent Diabetes Distress Scale score of 2 or higher). Both the mother and adolescent must be able to speak and read English. If the mother reports that she or her adolescent has a history of severe psychopathology (e.g., schizophrenia, bipolar disorder), they will not be eligible to participate in the study.

3.3. Recruitment

Participants will be enrolled at the Children's Diabetes Program at Vanderbilt. Interested mothers will provide verbal consent to complete a screening tool administered by trained study staff to determine eligibility. The screening tool will include the Parent-Teen Relationship sub-scale of the Parent Diabetes Distress Scale [PDDS, 16] to assess diabetes distress and the Patient Health Questionnaire [PHQ-9, 17] to assess maternal depressive symptoms. A mean score on the PDDS sub-scale of 2.0 or higher or a PHQ-9 score of 5–19 will indicate eligibility; however, a score of 20 or higher on the PHQ-9 indicates severe depression and will result in the participant being ineligible. In this case,

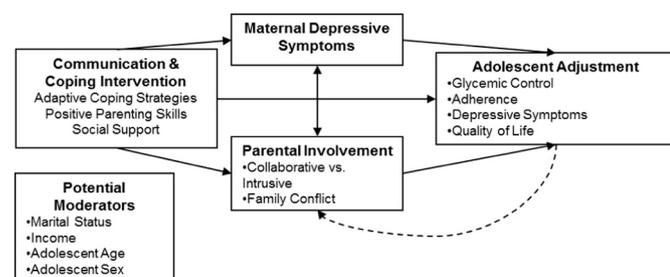


Fig. 1. Conceptual framework for the intervention, informed by the Transactional Stress and Coping Model, Thompson & Gustafson, 1996).

we will notify the participant of the exclusion and will refer them to the appropriate level of care. The screening tool will also include questions regarding severe psychopathology (e.g., schizophrenia, bipolar disorder) and individuals with a history of these disorders will be excluded. If not already in treatment, they will be referred for the appropriate level of care. Mothers must be regular Facebook users (have a Facebook account and log into Facebook at least 2–4 times/week).

Eligible mothers and adolescents will hear and see a description of the study and their participation in the study, as well as the risks and benefits, prior to giving written informed consent to participation. In line with the protocol approved by the University Institution Review Board, written consent/assent will be obtained before mothers and adolescents complete data collection in REDCap. They will also be asked to participate in a 15-min videotaped conversation about diabetes-related stress, which will be coded for parenting style (collaborative vs. intrusive involvement). For completing these tasks, both mother and adolescent will receive gift cards and retention items (e.g., mug, water bottle).

3.4. Randomization

After completing all baseline data, mothers will be given instructions to “friend” the study Facebook account. Once the mother has established a connection to the study Facebook account, the mother-adolescent dyad will be randomly assigned to the intervention or control condition, with equal numbers in each condition (see Fig. 2). Randomization will be stratified by the adolescents' treatment type (insulin pump vs. injections) and use of continuous glucose monitoring (CGM or no CGM) to remove the possibility of confounding by differences related to diabetes regimen. Randomization will be determined by a computerized program created by the study biostatistician.

3.5. Study activities

The active intervention period is 3 months. Upon randomization, mothers will be sent study binders with material corresponding to their intervention assignment (Communication & Coping or Diabetes Education materials). Mothers in both conditions will have 7 individual phone calls with a trained interventionist to discuss the information in the binders. Interventionists will be master's level staff with a psychology or social science degree who completed 40 h of training on medical management of T1D, behavioral goal-setting, didactic presentations, and mock intervention sessions with simulated parents (audio-recorded for quality control and feedback purposes). Calls will last approximately 10–30 min and will be scheduled at a time that is convenient for study participants (see Table 1). We will document the duration of each call.

In addition, mothers in both conditions will be assigned to a secret Facebook group corresponding with their condition. Each Facebook feed will deliver 1 post per day for 3 months. The posts will be on topics related to the group assignment, and participants will have the opportunity to post their own content and interact with other maternal caregivers in their group. A moderator (trained interventionist) will view and respond to all comments made by Facebook group members each day. Interventionists received training on how to implement counseling via Facebook, as well as on Facebook settings and Facebook-delivered interventions. Facebook data will be extracted using programming stored on a protected server and stored in a de-identified SPSS file. The use of secret Facebook groups ensures that only people in the groups will be able to see each other's comments and posts within the group. By having the participants “friend” our study Facebook account, we avoid potential issues related to adding the wrong person to the group.

To monitor the maternal caregiver's depressive symptoms, the PHQ-9 will be sent via automated text message to the maternal caregiver's mobile device every 2 weeks during the active phase of the

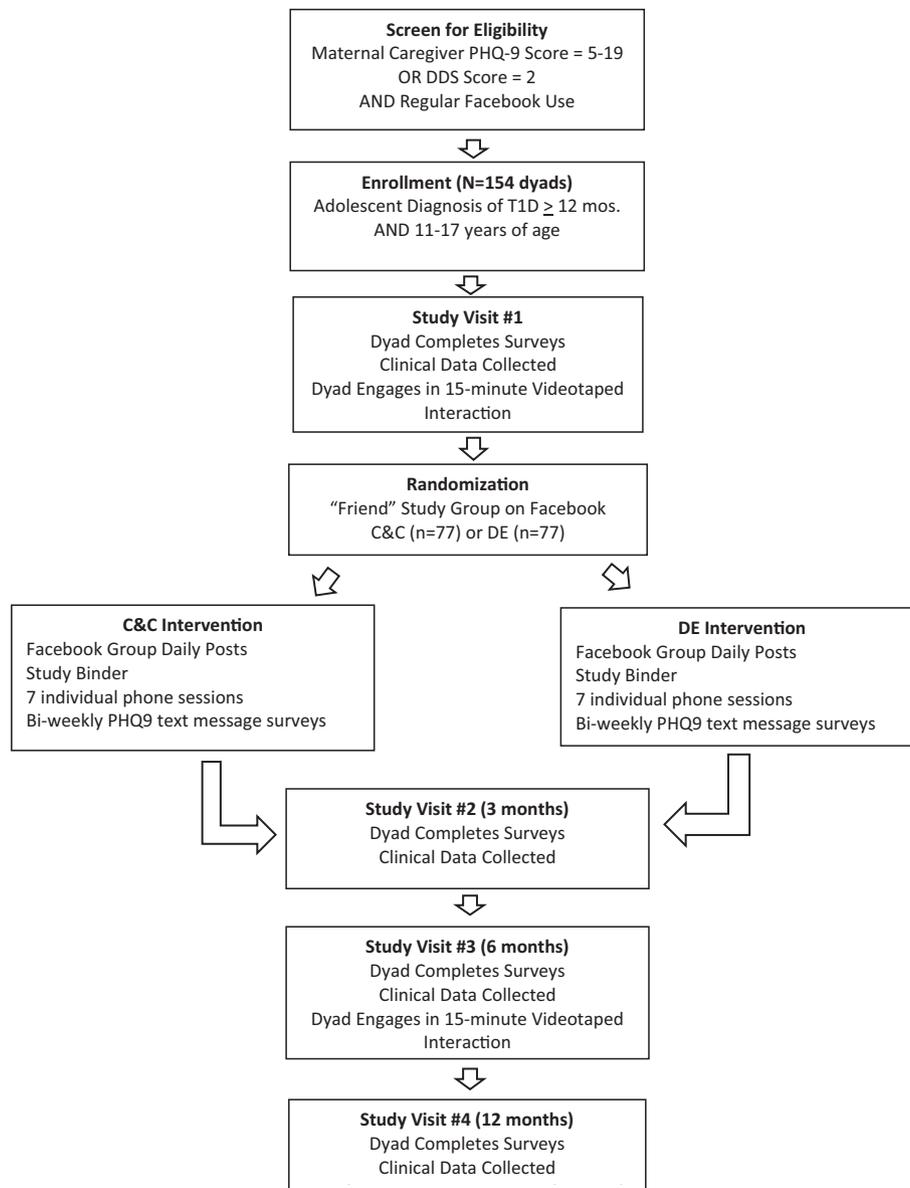


Fig. 2. Study activities.

T1D = Type 1 Diabetes. C&C = Communication and Coping intervention group. DE = Diabetes Education control group.

intervention. If a participant's responses constitute an elevated score (20 or greater), or they indicate any thoughts of self-harm or suicide, an email with resources, including crisis hotline numbers and mental health services, will immediately be sent to the participant. A trained staff member will also contact the participant via telephone within 48 h to assess for safety and make referrals as needed.

3.6. Facebook message pre-testing

A sample of Facebook posts were pre-tested among two groups of 5 mothers to obtain feedback about content, clarity, and acceptability. For 1 week, two posts per day were posted in each group, one in the morning and one in the late afternoon/early evening. The two groups received different content, including posts for both conditions (see Fig. 3), and all mothers were encouraged upon enrollment to “like” and

Table 1
Intervention session content.

Session number	Communication & coping topic	Diabetes education topic
Session 1	Stress and coping	Introduction to type 1 diabetes
Session 2	Importance of taking time for yourself	All about blood sugar
Session 3	Positive thinking and acceptance	Exercise, sports, and diabetes
Session 4	Praise and positive family time	Hypoglycemia
Session 5	Routines and consequences	Traveling with type 1 diabetes
Booster session 1	Review + working it out together	Review of sessions 1–2
Booster session 2	Review + thinking ahead	Review of sessions 3–5



Fig. 3. A. is an example of a post for the Communication & Coping Facebook group. B. is an example of a post for the Diabetes Education Facebook group.

engage with the posts to their preference. At the end of the week, the mothers were invited to complete an online survey, rating each post on several aspects, including clarity, degree of interest, and actionable advice. We also examined mothers' engagement with the posts, assessing the frequency of "likes" and reactions, general comments about the posts, as well as responses to the comments of other group members. These data were then used to refine and improve the content for the clinical trial.

3.7. Communication and coping intervention

Mothers assigned to the Communication & Coping group will have 7 phone sessions to discuss content related to coping with diabetes-related stress and positive parenting strategies, following the study manual mailed to participants after randomization (see Table 1). The content of this manual was assessed by Vanderbilt's Effective Health Communication Core, and each session was given a Suitability Assessment of Materials (SAM) score to objectively assess the materials for clear communication and health information design (content, literacy demand, graphics, layout and typography, learning stimulation, and cultural appropriateness). Scores of 70–100% are considered superior material suitable for low health literacy individuals [18]. On the SAM scale, our sessions were rated 78–86%, with a reading level of 6th–7th grade. In addition, the Patient Education Materials Assessment Tool (PEMAT) was used to assess the understandability and actionability of our intervention materials, offering specific suggestions to raise these scores further (e.g., add pictures, highlight goals for each session) [19]. On the PEMAT, the scores for individual sessions ranged from 79% to 92% (higher scores indicate that material is more understandable or actionable). All recommendations for changes were incorporated into the final versions of the manual.

In the Communication & Coping Facebook group, mothers will be encouraged to practice the skills they are learning in the individual phone sessions, troubleshoot barriers to using the new skills, and receive reinforcement from their peers. The group moderator will post daily messages to reinforce concepts and encourage mothers to elicit support from each other. For example, the moderator will post weekly messages encouraging mothers to engage in positive time with their children (Fun Friday posts, see Fig. 3). Similarly, posts will remind mothers to pay attention to how they are responding to stress.

3.8. Diabetes education control condition

Mothers assigned to the Diabetes Education group will have 7 phone

sessions to discuss content related to diabetes management, in line with the educational materials mailed to participants after randomization (see Table 1). These materials were based on information available on the American Diabetes Association website (www.diabetes.org) and the Juvenile Diabetes Research Foundation (www.jdrf.org) websites. In the Diabetes Education Facebook group, daily posts will include educational content (e.g., traveling with diabetes, treating hypoglycemia) to reinforce concepts covered in the phone sessions, and the moderator will respond to participants' comments.

3.9. Fidelity

To ensure fidelity, all sessions will be audiotaped, and 20% will be reviewed by a trained Research Assistant (RA) to determine interventionist adherence to the trial manual/intervention protocol. Fidelity checks will primarily consist of a cross-comparison of the content discussed during each telephone call to the manual's content for that session. Adherence coefficients will be calculated on an ongoing basis in order to determine the need for additional interventionist training or modification of session content.

3.10. Measures

The primary outcome, glycemic control, will be assessed with glycosylated hemoglobin (point-of-care HbA1c), measured at quarterly clinic visits as part of routine diabetes care. In addition, we will obtain data from adolescents' glucometers and/or continuous glucose monitors, to assess percent of values in range (70–180 mg/dL). These devices are uploaded as part of routine diabetes care. We will only plan to use data on time in range from adolescents using continuous glucose monitors (about 30–50% of the sample). Thus, this will be a secondary analysis. All other constructs will be assessed with validated measures (see Table 2). Follow-up data will be collected at regularly-scheduled diabetes clinic visits (baseline, 3 months, 6 months, and 12 months), so that questionnaire data corresponds with clinical data. All measures will be collected using REDCap, a secure web-based, HIPAA-compliant, data collection platform.

In addition, at baseline and 6 months, adolescent-mother dyads will participate in a 15-min videotaped conversation about diabetes-related stress, which will be coded for parenting behaviors (intrusive vs. collaborative involvement). Videos will be coded by trained research staff, blinded to intervention condition, using the Iowa Family Interaction Rating Scales [20]. To choose the topic for the video interaction, we will use the mother's highest-rated stressor on the Responses to Stress

Table 2
Study measures.

Measure	Construct	Items and scoring	Psychometric properties
Caregiver measures			
Patient Health Questionnaire (PHQ-9) [17]	Maternal depressive symptoms	9 items Score of 0–27	$\alpha = 0.89$
Responses to Stress Questionnaire (RSQ) [21]	Adaptive coping strategies	57 items Ratio scores calculated to indicate proportion of overall coping	Primary control coping $\alpha = 0.84$ Secondary control coping $\alpha = 0.84$ Disengagement coping $\alpha = 0.88$
Multidimensional Scale of Perceived Social Support (MSPSS) [59]	Social support	12 items Score of 1–7 (mean score)	$\alpha = 0.92$
Diabetes Family Conflict Scale (DFCS) [60]	Parental involvement	19 items Score of 19–57	Caregiver $\alpha = 0.81$
Self Care Inventory (SCI) [61]	Adolescent adherence	14 items Score of 0–5 (mean score)	Parent $\alpha = 0.72$
Parent Diabetes Distress Scale (DDS-P) [16]	Parent diabetes-related distress	20 items Score of 0–5 (mean score)	$\alpha = 0.94$
Revised Diabetes Knowledge Test [62]	Diabetes-related knowledge	14 item general test, 9 item insulin use subscale Total score 0–100% correct	General test $\alpha = 0.71$ Insulin use subscale $\alpha = 0.75$
Child Behavior Checklist (CBCL) [63]	Adolescent adjustment	113 items T scores calculated based on age and sex	Internalizing $\alpha = 0.90$ Externalizing $\alpha = 0.94$
Child measures			
Diabetes Family Conflict Scale (DFCS) [60]	Parental involvement	19 items Score of 19–57	Child $\alpha = 0.85$
Self Care Inventory (SCI) [61]	Adolescent adherence	14 items Score of 0–5 (mean score)	Child $\alpha = 0.80$
Pediatric Quality of Life 3.0 Type 1 Diabetes Module (PedsQL) [64]	Adolescent quality of life	28 items Scaled scores range from 0 to 100	Subscales range from $\alpha \geq 0.70$
Collaborative Parent Involvement Scale (CPI) [65]	Parental involvement	12 items Score of 12–60	Primary Caregiver $\alpha = 0.93$
Problem Areas in Diabetes (PAID) [66]	Adolescent adjustment	26 items Score of 23–156	$\alpha = 0.96$
Youth Self Report (YSR) [63]	Adolescent adjustment	119 items T scores calculated based on age and sex	Internalizing $\alpha = 0.90$ Externalizing $\alpha = 0.90$

Questionnaire [21], completed as part of the survey data collection, which lists diabetes-specific stressors. Mothers will rate the frequency of each stressor (e.g., remembering diabetes supplies) on a 4-point Likert scale ranging from 0 (never) to 3 (almost every day). Each dyad will be given a cue card with questions regarding the highest-rated stressor (e.g., What happened the last time we [had to remember diabetes supplies], what kind of emotions do we have when we [have to remember diabetes supplies]? How can we reduce this stress?) to guide their discussion during the videotaped interaction.

3.11. Data analysis

Baseline variables known to be associated with parenting including age, sex, income, and marital status will be compared by treatment group using the Kruskal-Wallis test (continuous variables) or Pearson's Chi-squared test (categorical variables). We will also examine if diabetes-related variables (e.g., duration of diabetes, baseline A1C) are associated with treatment group. A priori, we assume that our block randomization will lead to well-balanced groups so that we will not need to control for additional confounders. One of the advantages to a longitudinal repeated measures regression model is that it generalizes repeated measures ANOVA to allow for mis-timed or completely missing variables.

3.12. Effects of the intervention

We will estimate the effect of the intervention on each of the continuous outcomes by fitting linear mixed-effects models developed. In modeling, outcomes will be considered at their key timepoints (baseline, 3 months, 6 months, and 12 months) with treatment group and the interaction of treatment with time serving as the main explanatory variables. Such a model will allow us to test for any differences between treatment and control groups over time while accounting for baseline

values. While the randomized block design should minimize confounding, we will adjust for age, income, and marital status to improve precision. The results from the adjusted and unadjusted models will be compared with respect to their estimates of the treatment effects. Our interpretation will focus on describing clinically relevant treatment effects (e.g., A1C reductions of $\geq 0.5\%$, reduction from moderate to mild depressive symptoms) with corresponding confidence intervals, rather than just significance testing. We will include a random intercept to account for within-subject correlation. The error structure of the model is assumed to be compound symmetric, and the validity of this assumption will be examined by computing Akaike Information Criteria against other common structures. Subjects will be included in the analysis if they have an outcome measured at baseline and at least one outcome measured 6 or 12 months later. The 12-month timepoint is the main outcome timepoint, but by collecting data at 3 and 6 months as well, we will be able to assess hypothesized mediators.

Examining mediators will provide evidence for the mechanisms of change, offering direction for program implementation and future research. Investigating mediators of the intervention also allows us to test the theoretical basis and the effect of intervention on separate outcomes [22], such as glycemic control, and psychosocial outcomes. To assess direct and indirect effects of potential mediator variables, we will follow the steps outlined by MacKinnon and colleagues [23,24] to establish mediation. The bootstrap method will be used to obtain a 95% confidence interval for the total, direct, and indirect effects. We will test maternal depressive symptoms and parental involvement as mediators of treatment effects, maintaining consistent temporal ordering, by considering baseline randomized treatment, 3-month depressive symptoms and parental involvement variables as the mediators, and 6-month outcomes (treatment effects), as well as 12-month outcomes (sustained treatment effects) Our longitudinal data will also allow us to consider additional analyses that account for the bidirectional relationships between family functioning and depressive symptoms. In

addition, we plan to explore the relative strength of each mediator in explaining the effects on specific outcomes. Finally, if the hypothesized intervention effects on targeted mediators are not observed, we will further explore patterns of results.

To determine the feasibility of the intervention, we will examine recruitment and retention data. In addition, fidelity checks will be conducted by reviewing 20% of the telephone sessions, which will be coded for content by an independent rater. We propose a feasibility benchmark of $\geq 90\%$ fidelity. To evaluate acceptability of the intervention, we will examine participation (phone call attendance), adherence (completion of homework), and satisfaction ratings. We propose a feasibility benchmark of $\geq 80\%$ attendance.

3.13. Assessing biases caused by dropouts

Some subjects may not return for their follow-up visit and hence have missing values of their response variables. Frequently, such subjects (“dropouts”) are not a random sample of the entire cohort and an analysis of only the complete cases will bias the results. Indirect information about the nonrandom dropouts will be obtained by using binary logistic regression to predict dropout status based on all baseline predictor variables.

3.14. Moderators of intervention effects

While evaluating the main effects of interventions is critical to improving health outcomes, it is equally important to examine moderators of randomized clinical trials – even those that are unsuccessful – in order to determine *for whom* interventions may work [25]. Based on findings from the literature and our own earlier work, we will examine potential moderators, with a focus on marital status, income, and adolescent age and sex. Moderators will be tested by including an interaction term with treatment group in the regression models.

4. Discussion

In youth with T1D, the transfer of responsibility for management from parents to youth during adolescence frequently results in problems with adherence [26] and increased family conflict [27]. Despite advances in technology (e.g., insulin pumps, continuous glucose monitoring), many adolescents continue to have suboptimal glycemic control [28], with a minority of adolescents meeting recommended targets [9]. Poor glycemic control during adolescence increases risk for long-term microvascular and macrovascular complications, including retinopathy, neuropathy, and cardiovascular disease [29]. Adolescents with T1D are also at risk for poor psychosocial outcomes, including increased depressive symptoms and poor quality of life [30,31]. Thus, novel interventions are needed to improve glycemic control, adherence, and quality of life in adolescents with T1D. In line with the American Diabetes Association's new Psychosocial Standards of Care for people with diabetes and their family members [32], we propose to address the needs of mothers by testing the effects of an intervention aimed at promoting the use of adaptive coping strategies and positive parenting practices.

While fathers play an important role in diabetes management [33,34], mothers are typically the caregiver most directly involved in daily diabetes care activities [35], and they experience greater stress than fathers related to the “constant vigilance” of caring for a child with diabetes [5,36]. Mothers of teens with T1D commonly describe stress related to maintaining glycemic control, food management, blood glucose monitoring, and management away from home [16,37]. Parenting stress can interfere with disease management [38], and mothers' difficulty in coping with diabetes has been related to maternal psychological and well-being and parenting behaviors [39,40], and to adolescents' glycemic control, quality of life, and depressive symptoms [6,41]. Thus, by helping mothers cope more effectively with the stress of

diabetes, we have the potential to improve outcomes in both mothers and their adolescents with T1D. As part of the intervention, we encourage mothers to ask for help and share responsibilities with their partners, as an adaptive coping strategy. However, further studies are needed to evaluate how best to enhance paternal support.

The quality of parental involvement is also a strong predictor of adolescent adjustment [42], and positive parenting behaviors have been associated with better quality of life, fewer depressive symptoms [43,44], better adherence [43,45], and better glycemic control in adolescents with T1D [44,46,47]. In our observational studies of mother-adolescent dyads, we found that intrusive parenting behaviors, such as lecturing, predicted greater depressive symptoms in adolescents over time. In contrast, collaborative parenting behaviors, such as child-centered behavior and expressions of positive reinforcement, predicted better glycemic control 12 months later [48]. Thus, by giving mothers the skills to communicate more effectively and collaboratively with their adolescent children, the Communication & Coping intervention has the potential to enhance the quality of parental involvement, thereby improving outcomes in adolescents with T1D.

Increased social support also has the potential to reduce maternal depressive symptoms and improve parental involvement [4,49], but many mothers need help enlisting the support of others. For example, research suggests that fathers may not become involved in diabetes management until problems arise [50], and yet, paternal involvement is linked with fewer depressive symptoms in mothers [35]. Further, a recent review found that support from other mothers of children with T1D increases parents' satisfaction and engagement in behavioral interventions [51]. We included a social media component (Facebook group) in the current trial to provide social support and reinforce the skills they are learning in the individual sessions. Facebook is the ideal option for engaging with mothers of adolescents on social media, as the most recent Pew Research Report (2016) revealed that 86% of women ages 30–49 use Facebook (as compared with 33% for Instagram and 23% for Twitter) [52]. Including Facebook groups may support mothers in enlisting the help of other caregivers who understand and share their experiences. Previous studies of online patient communities revealed that participants reported improved knowledge about the condition [53], reduced anxiety [54], and improved ability to manage symptoms, take medication, implement lifestyle changes, and tolerate side effects [53]. Further, studies of health behavior interventions delivered via Facebook have demonstrated feasibility and acceptability in postpartum women [55] and young-onset melanoma patients [56]. To protect participants' privacy, only Key Study Personnel who have completed training in human subjects research will be involved in the Facebook group monitoring. However, there is the potential that mothers in the group could share information with others outside of the group. We will ask them to keep what is shared in the group private (similar to an in-person support group), but we also note this risk in our consent forms.

4.1. Limitations and risks

Possible risks for study participants include release of confidential data and worsening depression symptoms in mothers. Interventionists will refer all diabetes management questions to the child's health care team and provide clinic contact information. Further, a licensed clinical psychologist will provide ongoing weekly clinical research supervision throughout the trial. Any comments made during intervention calls or on the Facebook group that suggest the abuse of, neglect of, or inappropriate interactions with minors will be reported to the appropriate authority of the state in which the child resides. All research staff at all sites will complete annual training in Protection of Minors and Good Clinical Practice, and all research staff will be mandated reporters.

Despite evidence demonstrating the effectiveness of telephone-based CBT to reduce depressive symptoms [57], mothers who receive the intervention may not report reduced depressive symptoms. If this

happens, we plan to examine the data to determine for whom the intervention works. For example, it may be that a more limited range of scores on the screening tool (PHQ-9) predicts a better response to the intervention. Furthermore, we may find that the intervention does not have a significant effect on our hypothesized mediators. For example, it may be that changes in mothers' coping strategies have a direct effect on adolescent outcomes, due to adolescents' modeling more adaptive coping strategies.

5. Conclusions

The current study will evaluate the efficacy of a novel intervention for distressed mothers of adolescents with T1D. This intervention builds on effective CBT interventions for depression and positive parenting skills, and the intervention materials were developed to maximize engagement and health literacy. Further, by leveraging technology (phone calls and Facebook groups), the study design requires no in-person visits outside of regularly scheduled clinic visits, increasing the feasibility and potential for scalability. Finally, if proven efficacious, the current intervention has potential to extend to other pediatric populations (e.g., asthma, cystic fibrosis) by addressing parenting stress [58].

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