Communication and Coping Randomized Clinical Trial

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Description of Amendments

Date	Affected Section(s)	Summary of Revisions Made	Rationale
3-1-19	Study Procedures	Addition of the Satisfaction Survey at the 3-Month Study visit. Removal of the Dad's Active Support Scale (DADS)	Added to evaluate acceptability of the intervention. Removed to reduce the burden for participants. Measure was only valid for heterosexual couples. Additional questions added to Demographic questionnaire to capture secondary caregiver information.
4-16-19		Change to wording in recruitment script to obtain verbal consent for screening survey	Added the wording: "You are free to skip questions you do not wish to answer; however, this may affect your eligibility for the study." to let the participant know that skipping questions would affect eligibility.
6-17-19	Inclusion/ Exclusion Criteria	Addition of Parent Diabetes Distress Scale (Parent-DDS) as a measure of eligibility. Participant can either score 2 or higher on the Parent-DDS or have a score of 5-19 on the Patient Health Questionnaire 9 (PHQ-9) to be eligible.	In response to lower than expected enrollment, we expanded eligibility to include mothers who report clinically significant diabetes distress and who may benefit from intervention. We also expanded eligibility to include mothers who use Facebook 2-4 days a week rather than at least 5-6 days a week.
6-17-19	Enrollment/ Randomization	Mother will be friended on Facebook during enrollment rather than sent an email.	Ensures that mother gets into Facebook group on the day of enrollment.
8-19-19	Risks	Addition of the Youth Self Report procedure to protocol. If individuals mark item 18 or 91 on the YSR (items pertaining to suicide or self-harm), KSP will follow a protocol to ensure the safety and access to resource for the individual.	Formalized protocol to further assess and provide resources to teens that may be at risk for self- harm or suicide.
4-23-20	Study Procedures Consent	Expansion the satisfaction survey at the 3-month follow-up visit. Addition of the option for mothers assigned to the education group to receive the intervention materials after final data collection. Addition to the consent that investigators from	1) Addition of questions to the satisfaction survey to capture more information about the Facebook component of the program. 2) Several participants have expressed interest in learning coping strategies included in the intervention materials.

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		the University of Connecticut would have access to some participant data.	
5-26-20	Study Procedures	COVID-19 related changes to protocol, including remote enrollment and data collection and additional survey questions to assess the impact of COVID-19 on adolescents with type 1 diabetes and their mothers.	Given the COVID-19 pandemic and social distancing requirements, we have made changes to our protocol to allow for remote enrollment and data collection. We are also adding measures to assess the impact of COVID-19 on our study participants.
9-25-20	Study Procedures	The parent-child video interaction recordings for the baseline and 6-month time points will be done over ZOOM rather than in person because of the Covid-19 restrictions and social distancing. | This is a temporary change because of Covid-19, therefore we will report this to the IRB as a continuing review and retract this amendment.	Covid-19 restrictions and social distancing require us to do the video interactions over ZOOM so families who feel uncomfortable with in person data collection can still participate in all parts of the study.
10-5-20	Compensation	Study personnel will confirm each gift card serial number with the order invoice to ensure the gift card record reflects the accurate monetary value.	Protocol deviation occurred due to incorrect record keeping of Amazon gift card serial numbers. Gift cards worth $20 were incorrectly recorded by study personnel as worth $30. Therefore, $20 compensation was given to 4 dyads instead of the sufficient amount of $30. This was identified by comparing the gift card serial numbers with the numbers listed on the order invoice.
10-28-20	Study Procedures + Consent	Optional qualitative interviews for study participants to assess the impact of COVID-19 on diabetes management, stress and coping.	We received supplemental funding from NIDDK to study the impact of COVID-19 on diabetes management, stress and coping. Qualitative interviews will be conducted with current participants (adolescents with type 1 diabetes and their mothers) to address the following aims: 1. To understand how the experience of COVID-19 affects the routines and health behaviors of youth with T1D and their caregivers as various levels

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			of social distancing requirements are reduced. 2. To determine how the experience of COVID-19 affects mothers already experiencing diabetes distress and/or depressive symptoms and how mothers' experiences relate to their coping, social support and distress, with an emphasis on understanding what is similar to and different from their experiences with T1D prior to COVID-19.
11-3-20		The non-compliance submitted for this study on October 5th was submitted in error and should be removed.	
12-8-20	Consent	Discussed with the study team to prevent future occurrences.	The moderator posted to the Facebook study page, rather than to the private study groups. As such, mothers who were assigned to the intervention condition and control condition all received the post.
6-8-21	Recruitment	We have drafted language for distributing information about our study on Research Match and the Vanderbilt Research Notifications Distribution list to expand our recruitment efforts.	We are planning on recruiting through Research Match and the Vanderbilt Research Notifications Distribution list to reach more potential participants.
7-7-21	Recruitment	We are requesting approval to recruit using the Research Notification Distribution List and we are uploading language specifically for the Research Notification Distribution List with the contact information for our study.	We are requesting approval to recruit using the Research Notification Distribution List and we are uploading language specifically for the Research Notification Distribution List with the contact information for our study.
8-24-21	Consent	We will conduct training with the study team to clarify which protocols require a verbal consent and which protocols require a	Four participant dyads verbally consented to participate in the Covid Interview supplemental study but did not sign the consent and assent documents prior to completing the

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		written consent/assent.	supplemental interviews. We are now in the process of contacting these participants to sign the consent documents.
8-25-21	Study Procedures	We are adding questions to the parental COVID-19 supplemental measure.	In order to remain up-to date on how COVID-19 is impacting our current participants, we need to add additional questions to our COVID-19 survey measure. These additions are related to COVID-19 vaccination status and the use of telehealth clinic visits. Many COVID-19 restrictions currently in place (locally and domestically) are dependent on vaccination status. We will be asking participants if any adults (18+) and children (12-17) have been vaccinated in their household. Also, we are asking if their child has seen their diabetes provider via telehealth visit since this could impact their quality of care and one of our specific study aims (glycemic control). These will only be applied to the parent surveys.
3-9-22	Consent + Compensation	We want to offer $20 gift cards for completion of 6-month parent-child interaction videos to incentivize collection of this data point. These gift cards will be funded by the VUMC Division of Pediatric Psychology.	We were not able to collect parent-child interaction videos at baseline or the 6-month time point during the transition to a remote protocol, and we are not able to use 6-month videos that would not have a corresponding baseline video. Because of this, we have collected less 6-month videos than expected. Also, because of the switch to a remote protocol, we have several participants that will complete all other components of their 6 month follow up visit but will not schedule a time to collect the video with our team. We want to offer $20 gift cards for completion of 6-month videos to incentivize collection of this data point.
9-1-22	Study	Change in study coordinator from	

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	Coordinator	Troy Morrow to Fayo Abadula (currently KSP).	

1.0 Background

Mothers of adolescents with type 1 diabetes (T1D) experience high levels of depressive symptoms, which impair their ability to monitor and manage diabetes treatment effectively. The regimen recommended for type 1 diabetes is 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, with rates of clinically significant symptoms of depression evident in up to 61% of parents. 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. Given that adolescents are a high-risk population for suboptimal glycemic control - with only 17% meeting treatment goals - there is a critical need for novel interventions to improve outcomes in adolescents with T1D. Yet, previous behavioral interventions for youth with diabetes have had only modest effects on glycemic control, many were time- and resource-intensive, and none have directly targeted maternal depressive symptoms.

2.0 Rationale and Specific Aims

Based on the Transactional Stress and Coping Model, which views chronic illness as a stressor to which children and mothers attempt to adapt, the ways in which mothers cope with the stress of diabetes play an important role in both maternal and adolescent adjustment to the disease. 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 interventions to treat depression in adults, and our own pilot work in this population, the proposed study will use a rigorous approach to evaluate the efficacy of a cognitive-behavioral intervention for mothers of adolescents with type 1 diabetes to promote the use of adaptive coping strategies and positive parenting practices.

The specific aims of this project are:

1. Evaluate the efficacy of the Communication & Coping intervention as compared to an attention control condition on adolescents' diabetes outcomes (i.e., glycemic control, adherence) over 12 months. We will examine whether these effects were driven by the targeted mediators (maternal depressive symptoms, parental involvement).

    Hypothesis: The adolescents of mothers who receive the intervention will demonstrate better glycemic control and better adherence to treatment than those in the attention control condition.

2. Evaluate the efficacy of the Communication & Coping intervention as compared to an attention control condition on adolescents' psychosocial outcomes (i.e., adolescent depressive symptoms and quality of life) over 12 months.

    Hypothesis: The adolescents of mothers who receive the intervention will report better quality of life and fewer depressive symptoms than those in the attention control condition.

Exploratory Aim: Examine the differential impact of intervention effects across demographic factors (i.e., marital status, income, adolescent age, and sex).

3.0 Animal Studies and Previous Human Studies

Dr. Jaser and colleagues conducted a pilot study of the communication & coping intervention with 30 mothers of adolescents with type 1 diabetes, which supported the feasibility and initial efficacy of the intervention (http://psycnet.apa.org/record/2018-09864-003). Results from our pilot study indicated significant intervention effects on adolescents' quality of life and depressive symptoms. In addition, adolescents whose mothers received the intervention demonstrated promising improvements in glycemic control, and we found support for the effect of the intervention on mediating variables, with large effects on maternal depressive symptoms and family conflict.

4.0 Inclusion/Exclusion Criteria

List the criteria:

- mother or female caregiver to an adolescent (age 11-17)
- mother lives with adolescent at least 50% of the time
- adolescent child has been diagnosed with type 1 diabetes for at least 12 months
- mother uses Facebook regularly
- mother reports mild to moderate symptoms of depression (Patient Health Questionnaire 9 score of 5-19) OR mother reports diabetes distress (Parent/Teen Relationship Distress Subscale score of 2 or higher)
- mother and adolescent able to speak and read English
- mother and adolescent do not have a history of severe psychopathology (e.g., schizophrenia, bipolar disorder)

5.0 Enrollment/Randomization

Participants will be enrolled from the Children's Diabetes Program at Vanderbilt.

Due to the COVID-19 pandemic and social distancing requirements, a remote recruitment and enrollment protocol was established. KSP will review the diabetes clinic schedule, and participants who meet initial eligibility criteria (age, date of diagnosis) will be called the week of their clinic visit. The RA will introduce the study, and if mothers are interested, verbal consent for the screening questionnaire will be obtained. Mothers who consent will be emailed a link to the screening survey in REDCap. The RA will then email the mother to let her know if she is eligible or not. Eligible mothers will be asked to schedule a time for enrollment. At the preferred time, the mother and adolescent will be called, and the RA will provide each with a full description of the risks and benefits of the study. If they agree to participate, they will be emailed the link to sign the eConsent form in REDCap. The RA will stay on the phone while these are signed to answer any questions. Once consent/assent forms are signed, the parent and adolescent will be emailed links to complete the study surveys in REDCap. The mother will be asked to text the RA when these are completed or if they have any questions. The final enrollment will take place over the phone (demo text message and Facebook friending).

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 condition or attention control (equal numbers in each group). 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 insulin regimen. Randomization will be determined by a computerized program created by the biostatistician on the project (Chris Slaughter).

Participating mothers will be mailed a study binder and an A1C mail-in kit within 2-3 days of enrollment.

Adolescents' glycemic control will be assessed with HbA1c, which is obtained as part of regular clinical care. For adolescents who do not have an HbA1c value associated with a clinic visit (due to social distancing requirements), we will request that they use a mail-in kit. The kit includes clear instructions to provide a dried blood spot that is mailed to the lab (Coremedica). When the lab value is available, KSP will notify study participants.

6.0 Study Procedures

At baseline, 3 months, 6 months, and 12 months, mothers and adolescents will complete surveys consisting of measures are widely validated and have been used successfully by our research team in previous studies. Follow-up data will be collected at regularly-scheduled diabetes clinic visits, so that questionnaire data corresponds with clinical data. The measures take about 40 minutes to complete. Mothers will also complete a measure of depression (PHQ-9) via a link emailed to them by the study team biweekly during the active phase of the intervention (first 3 months). All measures will be collected using REDCap.

Demographics - completed by mother

Responses to Stress Questionnaire (RSQ) measures 3 coping factors: primary control coping, secondary control coping, and disengagement coping - completed by mother

Multidimensional Scale of Perceived Social Support (MSPSS) - completed by mother

Patient Health Questionnaire - 9 items (PHQ-9)-completed by mother

Generalized Anxiety Disorder Scale - 7 items (GAD-7) completed by mother

Diabetes Family Conflict Scale (DFCS) - completed by mother and adolescent

Self-Care Inventory (SCI) - completed by mother and adolescent

Pediatric Quality of Life Inventory (Peds-QL) diabetes-specific module - completed by adolescent

Child Behavior Checklist (CBCL) - completed by mother

Youth Self Report (YSR) - completed by adolescent

Problem Area in Diabetes - Teen (PAID-T) - completed by adolescent

Parent Diabetes Distress Scale (PDDS) - completed by mother

Collaborative Parent Involvement Scale - completed by adolescent

Revised Brief Diabetes Knowledge Test - completed by mother

COVID-19 Questions – completed by mother and adolescent

Satisfaction Survey – completed by mother at 3 month follow-up

At baseline and 6 months data collection, adolescent-mother dyads will participate in a 15-minute videotaped conversation about diabetes-related stress. To choose the topic for the video interaction, we will use the mother's highest-rated stressor on the Response to Stress Questionnaire (Connor-Smith, Compas, Wadsworth, Thomsen, & Saltzman, 2000), completed as part of the survey data collection, which lists diabetes-specific stressors. Mothers will rate the frequency of each stressor (e.g., worrying about "bad" numbers, 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 you 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. This protocol has been used successfully in other studies conducted by Dr. Jaser, and she has trained several cohorts of raters on the Iowa Family Interaction Rating Scales to be reliable coders.

The interaction will be recorded using study iPads. Video files will be transferred from the passcoded iPad to an encrypted study computer, and then uploaded to Enterprise Storage, the secure, shared drive. Video files will only be viewed by KSP.

Mothers in the study will have 7 individual phone calls with a trained member of our research staff to discuss the information in the binders. Calls will last approximately 10-30 minutes. Mothers assigned to the Communication & Coping group will discuss content related to coping with diabetes-related stress and positive parenting strategies, following the study manual mailed to participants after randomization. The content of this manual was reviewed by a coder trained in health literacy at Vanderbilt's Effective Health Communication Core. 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% to 100% are considered superior material suitable for low health literacy individuals (Doak, Doak, & Root, 1996). On the SAM scale, our sessions were rated 78% to 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, with specific suggestions to raise these scores further (e.g., add pictures, highlight goals for each session; Shoemaker, Wolf, & Brach, 2013). 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.

Mothers assigned to the Diabetes Education group will discuss content related to diabetes management, in line with the educational materials mailed to participants after randomization. These materials were based on information available on the American Diabetes Association website (www.diabetes.org). Mothers in the Diabetes Education group will be given the option to receive the manual containing the Communication and Coping content at the 12 month visit, after the mother has completed the study. The first 5 calls will occur weekly, and the last 2 "booster" calls will occur monthly. The calls will be scheduled at a time that is convenient for study participants. These calls will be audio recorded and 20% will be randomly assessed for fidelity by an objective rater. Audio files of the intervention sessions will be stored on the same secure, shared drive and will only be accessed by trained research staff to assess fidelity or for training purposes.

Study participants will be required to "friend" the study Facebook account before they are added to the secret groups to ensure that the correct person is added. All mothers in the study will receive 1 post per day for 3 months. The posts will be on topics related to the group assignment (communication and coping or diabetes education). A moderator will view and respond to all comments made by Facebook group members. Facebook data will be extracted using programming stored on a protected server and stored in a de-identified SPSS file.

7.0 Risks

Data collection requires participants (adolescents and mothers) to spend approximately 40 minutes at each collection (baseline, 3 months, 6 months and 12 months) completing surveys. At baseline and 6 months, they will spend an additional 15 minutes in a videotaped interaction.

Mothers will engage in 7 intervention phone calls that will last 30-45 minutes (the first 5 sessions will occur weekly, and the 2 booster sessions will occur monthly). In addition, we expect mothers to spend approximately 5 minutes per day reviewing Facebook posts. This is not anticipated to be an undue burden for the participants.

We will download data from the Facebook group including posts, comments, and reactions from the participants so that we can study these data to better understand how people participate in this component of the program. We will not download any data from participants' Facebook profiles or any posts to their feeds - only the posts, comments, and the posts/comments that participants react to in the study Facebook group.

The potential benefit of this study is the provision of new knowledge about innovative ways to improve diabetes management in adolescents with type 1 diabetes. In sum, the low risk of this study appears to be far outweighed by the larger, more compelling potential benefits.

Possible risks in the study include release of confidential data, worsening depression symptoms in mothers, indication of depression in adolescents, reports of harm to self or others, and reports of child abuse or neglect.

If mothers report severe symptoms of depression (PHQ-9 score of 20 or higher) or endorse the 9th item on the PHQ-9, indicating thoughts of self-harm, we will follow up with a depression protocol. A member of the research team will give the mother the resources handout, which includes crisis hotline numbers and mental health services. The PI (or the clinic social worker, if available) will follow up with the mother within 48 hours to discuss and will refer her to the ER or crisis hotline if needed.

If adolescents endorse items on the Youth Self Report (YSR) measure pertaining to suicide or self-harm, we will follow the following procedure for self-harm assessment. Item 18 asks individuals to rate from 0-2 (how often) "I deliberately try to hurt or kill myself." Similarly, item 91 reads "I think about killing myself." Scores of 1 indicate "sometime" and 2 indicate "usually." When the YSR is given during study enrollment, researchers will immediately check items 18 and 91. If a 1 or 2 is indicated on either of these items, the Pediatric Endocrinology social worker will be paged and will complete a risk assessment following clinic protocol. The PI will also be notified. If the clinic social worker is not available, research staff will administer the Columbia Suicide Severity Rating Scale (C-SSRS). If information gathered from the C-SSRS indicates low risk (non-specific ideation, no plan), individuals will be given information on local behavioral health resources and informed that the PI will check in with them within the next 48 hours. If the C-SSRS indicates high risk or risk is ambiguous the clinic social worker will be contacted again for further assessment and/or to transfer the patient for psychiatric evaluation. If the clinic social worker cannot be reached, the researcher will accompany the patient and their caregiver to the Children's Emergency Department for psychiatric evaluation.

We will download data from the Facebook group including posts, comments, and reactions from the participants so that we can study this data to better understand how people participate and how much response our posts garnered from the group. We will not download any data from participants' Facebook profiles or any posts to their feeds - only the posts, comments, and the posts/comments participants react to in the study Facebook group.

All children will receive clinical care throughout the course of the study. All diabetes treatment decisions will be made by the diabetes treatment team. All patients have access to the treatment team 24 hours/day and 7 days per week. Participants will be informed that they may discontinue the study at any time or skip any questions they do not feel comfortable answering. There are no potential legal or social risks to participants consenting to participate in this investigation. Parents will be told to follow the diabetes clinic providers' guidance on any questions related to diabetes management.

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 State of Tennessee Child Abuse Hotline (or 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 all research staff will be mandated reporters.

The PI will ensure that the trial is conducted according to the approved protocol and will be responsible for carrying out the data safety monitoring plan, which includes:
- Review of study components for data completeness and accuracy as well as protocol compliance
- Evaluate adverse events (AEs, described below) for severity, relationship to the research and actions to be taken
- Promptly report all severe AEs and unanticipated problems to the data and safety monitoring board, IRB, and NIH

KSP will complete human subjects training prior to any contact with participants and maintain annual training. KSP will also complete Good Clinical Practice training for social and behavioral research annually.

8.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Any adverse events occurring during the course of this trial will be collected, documented and reported by the PI (Dr. Sarah Jaser), to the Data and Safety Monitoring Board, along with reporting to the NIDDK and institutional review boards as required. Although not anticipated, if any event is identified that may have caused any type of harm to a participant, study accrual will be immediately halted until the study team and DSMB can review the event and determine if any study procedures need to be revised. Study accrual will only resume after review of study protocol has been completed and any recommended revisions made as suggested by the DSMB.

9.0 Study Withdrawal/Discontinuation

Study participants may contact the study team if they wish to withdraw.

10.0 Statistical Considerations

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.

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 time-points (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 ≥0.5%, >1 additional glucose check per day, 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.

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,[107] 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[108,109] 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.

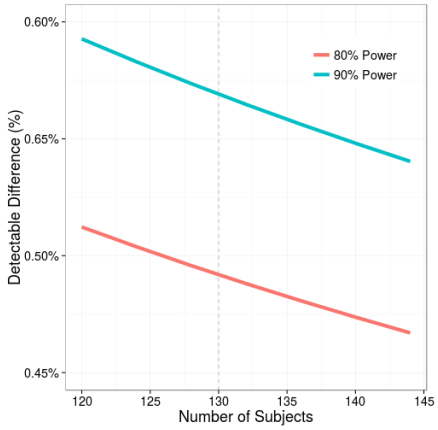
To determine the feasibility of the intervention, we will examine recruitment and retention data. In addition, fidelity checks will be conducted by reviewing 20% of the telephone sessions, which will be coded for content by an independent rater. We propose a feasibility benchmark of ≥90% fidelity. To 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 ≥ 80% attendance. We will also conduct exit interviews with mothers, which will be analyzed with a content analysis approach to identify themes across participants.

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 on the basis of all baseline predictor variables.

Exploratory Aim: Examine the differential impact of intervention effects across demographic factors (i.e., marital status, income, adolescent age, and sex).
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. 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.

Power and sample size:

We plan to enroll 154 subjects so that, after allowing for a 15% attrition rate, 130 subjects will be available for analysis. Preliminary data from our pilot study with 30 adolescents indicates that mean A1C is 9.0% with a standard deviation of 1.16% and a correlation between repeated measurements over time of 0.60. Under these assumptions, we will have 80% power to detect a 0.5% difference in A1C if 122 subjects are measured at all 4 time points or if 138 subjects are measured only twice (out of 4 possible time points). Since we expect to obtain ≥3 measurements on most of subjects, enrolling 130 subjects with 2 to 4 measurements each will provide sufficient power for Aim 1. For the SCI (a measure of adherence), using preliminary data in 30 subjects we estimated baseline scores of 23.6±4.2 with a correlation among repeated measures over time of 0.82. With 130 subjects measured at least twice, we will have 80% power to detect a 2.0 unit change due to treatment, which is an 8.5% difference from baseline.



Power calculations for mediation models were considered assuming 130 subjects will be available for analysis. In preliminary data, partial correlations of the mediators, PHQ9 and DFC, with A1C were 0.20 and 0.51, respectively. Correlations of the mediators with treatment were 0.52 and 0.54, respectively. Under these assumptions, we have 63% power to detect an indirect effect of treatment on A1C through PHQ9 and >99% power to detect an indirect effect of treatment on A1C through DFC. Calculations assume a 0.05 significance level.

Power for moderation will depend on the effect size of the moderation and if the moderator is measured on a continuous or categorical scale. For continuous moderators (adolescent age), we have 80% power to detect a 0.36% change in the treatment effect on A1C per 1-sd change in the moderator. For a binary moderator (frequency 50%), we have 80% power to detect a modification of the treatment effect on A1C of 0.55%. All calculations assume α=0.05.

Despite evidence demonstrating the effectiveness of telephone-based CBT to reduce depressive symptoms, there is a chance that mothers who receive the intervention will not report reduced depressive symptoms. If this happens, we would 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.

11.0 Privacy/Confidentiality Issues

Confidential participant data will be safeguarded by multiple password protection requirements, data encryption, and locked secure storage of paper documents.

Facebook interactions will be conducted in private (called "secret") Facebook groups. Secret groups allow permissions access to be managed and monitored by the study staff, only allowing approved study participants into the group. Any Facebook users not approved by study staff will not see the group content or that the group exists. All interactions in the group will be extracted using programming stored on a protected server and stored in an SPSS file.

Study participants will be required to "friend" the study Facebook account before they are added to the secret groups to ensure that the correct person is added. All mothers in the study will receive 1 post per day for 3 months. The posts will be on topics related to the group assignment (communication and coping or diabetes education). A moderator will view and respond to all comments made by Facebook group members.

Only Key Study Personnel (KSP) will have access to research information, and all KSP will complete training in Good Clinical Practice.

Participants will be identified with an ID number; names will not be included on any data outside of RedCAP. Only research staff who have completed IRB training and have been added as KSP have access to the study RedCAP. All identifying information will be destroyed at the earliest possible time following completion of the study. All data will be analyzed by groups, with no potential for individual patients to be identified. Any publications arising from the study will not contain personal information.
Digital files will be erased after completion of the study.

12.0 Follow-up and Record Retention

Duration of the study is anticipated to be 5 years. All data will be analyzed by groups, with no potential for individual patients to be identified. Any publications arising from the study will not contain personal information.
Research records will be maintained for at least three (3) years from the date the research is closed with the IRB. All Health Insurance Portability and Accountability Act (HIPAA) related documentation will be maintained for at least six (6) years from the date of the last use or disclosure of the Protected Health Information (PHI).