

Study Protocol

Title: Check It! 2.0: Positive Psychology Intervention for Adolescents with T1D

NCT Number: NCT02984709

Date: 10/12/2016

Research, Activities, Procedures, and Schedule of Events for Study Participants

Please check all that apply to your study and describe each below.

- Behavioral Observation
- Randomization
- Blinding
- Surveys, Interviews, Questionnaires
- Document and Artifact Collection
- Deception, Withholding or Postponing Medications/Treatments, or Imposing other Restrictions
- Audio/Video Recording
- Sham Procedure
- Specimen/Data Collection and/or Storage

DATA COLLECTION, STORAGE OF DATA/SPECIMENS, AND/OR ISSUES OF CONFIDENTIALITY - Describe the procedures that will be utilized to protect the privacy of the research participant. Include who will have access to the research information (for example, video/audio recordings, discovering information about the participant that could be harmful if released such as mental illness, genetic information, sexual preference, drug abuse, etc.) and where it will be stored.

All study documents (consent/assent forms, questionnaires) will be stored electronically in REDCap and will be secured with only study personnel having access to a unique username and password.

Describe how the confidentiality of participants' data will be assured. Include a description of any issues specific to the study that might increase the risk of breach of confidentiality. Describe how codes will be generated if codes are used to protect identities, and who will have access to such codes. If a certificate of confidentiality will be provided, include the name of the person holding the certificate. Describe the final disposition of research data when the study is concluded (e.g., will information be destroyed, will the PI maintain the information indefinitely, etc.).

Participants will be identified with an ID number; names will not be included on any data. Questionnaire data will be shredded after the completion of the study. All study documents will be kept for at least 6 years following the completion of the study. After the 6 year deadline, all data related to this study will be destroyed appropriately

RANDOMIZATION - Describe the randomization process (who will randomize, how will randomization be determined, etc.)

Participants will be randomly assigned to one of two conditions: Positive Psychology Intervention - Text-Messaging (n = 24 adolescent-caregiver dyads), Attention Control - Education (n=24 adolescent-caregiver dyads). A computer program will generate the randomization scheme in 12 blocks of 4. After

consent/assent is obtained, and the participants have completed baseline data, the RA will reveal to which condition he/she was assigned.

SURVEYS, INTERVIEWS, AND QUESTIONNAIRES - If surveys, interviews or questionnaires will be used as part of this study, indicate who will conduct the survey, interview or questionnaire and his/her qualifications. In addition, describe the setting and mode of administering the instrument (e.g., by telephone, one-on-one, group, etc.) and attach a copy of the instrument.

This study is a randomized, controlled trial composed of two conditions: Positive Psychology Intervention - TextMessaging (n = 24 adolescent-caregiver dyads) and Attention Control - Education (n=24 adolescent-caregiver dyads). At the beginning of the study, participants will be asked if they have a cell phone. If a participant does not have a cell phone (estimated at 10% of eligible adolescents), a basic cell phone and plan will be assigned to him/her for the active phase of the study (3 months). In order maximize the likelihood of participation, adolescents in all conditions will be asked the best days/times to contact them. Furthermore, the participants are asked to bring their glucose meters at each of the follow-up visit, to help track the effectiveness of the intervention, by obtaining number of blood glucose checks over the previous week. In addition, all adolescent participants will be required to complete a health behavior contract. This contract acknowledges that the participants agree and are committed to making a positive change in their lives by being proactive in their diabetes management. The contract states that the behavior that they are committing to do (i.e., BGM), when they will do it, and how often they will perform the target behavior.

For adolescents randomized to the Positive Psychology Intervention - Text Messaging group, the RA will instruct them to use the following empirically-validated exercises to induce positive affect :

1) Gratitude: Adolescents will be told that research shows that feeling happy helps people to handle challenges in their lives. We will ask them, "what are some small things that make you feel good, even for a few minutes (e.g., hearing your favorite song, finding the perfect pair of jeans. We will instruct them to do the following exercise: "As you go through your day, notice the small things that make you feel good and take a moment to enjoy them." Reminder messages will be sent through text messages.

2) Self-Affirmation (positive values): Adolescents will be asked to select from a list of positive values that are important to them (e.g. family, athletic ability, friendships). They will be instructed to think about the positive value when they are in a situation that makes it hard to check their blood sugar. Reminder messages will be sent through text messages.

3) Parental Affirmation: We will take the focus of parent-child communication away from diabetes management by asking caregivers to provide weekly positive affirmations to their adolescents, focused on non-diabetes strengths (e.g., "I heard you practicing your guitar - sounded great!" or "I had a great time when we _____.") Caregivers will receive weekly reminders via text message. Parents will be asked to respond back that they have successfully sent a positive affirmation to their child by texting the research team "yes".

4) Gifts: For those in the Text-Messaging Condition, an Amazon gift card (valued at \$5.00) will be sent via text (the redemption code will be sent via SMS to participants). Gifts will be sent every 2 weeks for 8 weeks (Weeks 2, 4, 6, 8). All adolescents will be given developmentally-appropriate diabetes education material at the time of enrollment (see attached for Educational Materials).

In addition, on weeks 2, 4, 6, 8, the Positive Affect Negative Affect Scale - Children (Brief Version) will be administered by SMS to all adolescents. This brief measure of affect consists of 10 questions, which will take less than 5 minutes to complete, and data will be stored in a secure online database.

For all participants that complete the study, an exit interview and evaluation will be administered at the final data collection (3 months) The series of questions will help the research investigators determine the feasibility and acceptability of the intervention and provide insight into areas of improvement (included as redcap survey attachment - teen).

A trained RA (Master's or Bachelor's level) will administer the survey to the participants on a study iPad at the diabetes clinic in a private space at each of the follow-up visits. The surveys are composed of 6 sections for the adolescents and 4 sections for caregivers.

Each section has specific directions and consists of multiple questions/choices pertaining to a particular measure. The measures are designed to evaluate the relationship between adherence and coping strategies in teens with type 1 diabetes.

The measures included on the adolescent's survey include:

Patient Health Questionnaire (PHQ-9): as a measure of current depressive symptoms. The PHQ consists of 9 items, and higher scores indicate higher current levels of depression, with a score of 11 or higher suggesting clinical levels of depression, with sensitivity of 89.5% and specificity of 77.5% for detecting major depression. If an adolescent endorses the item "Thoughts that you would be better off dead or of hurting yourself in some way?" the PI, a licensed clinical psychologist, will screen the adolescent to determine if emergency care is needed. Positive psychology interventions may have a larger effect in depressed individuals; therefore, it is important to measure depressive symptoms.

Positive and Negative Affect Scale for Children (PANAS-C): will be used to measure adolescents' affect. This measure consists of two 5-item scales to measure positive affect (i.e., joyful, cheerful, happy, lively, proud) and negative affect (i.e., miserable, mad, afraid, scared, sad). Respondents are asked to rate on a 5-point scale the extent to which they have experienced each particular emotion within the last week. This scale has demonstrated validity and reliability similar to that of the full scale PANAS-C and has been used in other studies in pediatric populations with mobile phone data collection

Responses to Stress Questionnaire (RSQ): will be used to measure coping style in response to diabetes-related stressors. The first 10 items of the measure list stressors tailored to reflect topics shown to be stressful for adolescents with T1D, followed by 57 items asking how the individual responds to these stressors. The RSQ has been shown to have good reliability and validity, including internal consistency (alphas form .73 to .85) and construct validity as reflected in results of confirmatory factor analyses. The

three coping factors on the RSQ will be used in the proposed study: primary control engagement coping (problem solving, emotional modulation, emotional expression), secondary control engagement coping (positive thinking, cognitive restructuring, acceptance, distraction), and disengagement coping (avoidance, denial, wishful thinking). To control for response bias and individual differences in base rates of item endorsement, proportion scores (i.e., type of coping over total coping) will be used for all analyses.

Self-Care Inventory (SCI-C): assesses key elements of the treatment regimen for T1D: diet, exercise, blood glucose monitoring, insulin administration, and attending medical appointments. The wording applies to various insulin regimens (i.e., pump and injections). It has been shown to have good reliability and validity. The Parent and Child versions will be used to measure adherence. The Overall Care scale and Blood Glucose Regulation subscales will be used in data analyses.

Pediatric Quality of Life (PedsQL): diabetes-specific measure will be used. Following recent recommendations, the 28 items will be summed to create a total diabetes-related quality of life score. Higher scores reflect better quality of life.

Revised Diabetes Family Conflict (DFC-C): will be used to evaluate conflict related to treatment management. Diabetes conflict is measured on 15 items regarding diabetes regimen activities, including BGM, and higher scores indicate more conflict. Good reliability has been established.

The measures included on the caregiver's survey include:

Demographic information: a questionnaire will be completed by the caregiver including information such as race/ethnicity, marital status, age and sex of child with T1D, caregiver's relationship to the child (i.e., biological parent, grandparent), adults living in the home, and screening information about the overall health status of the child. SES will be measured with separate items for parental income, occupation, and years of education.

Revised Diabetes Family Conflict Scale (DFC-P): will be used to evaluate conflict related to treatment management. Diabetes conflict is measured on 15 items regarding diabetes regimen activities, including BGM, and higher scores indicate more conflict. Good reliability has been established.

Self-Care Inventory (SCI-P): The Parent versions will be used to measure adherence (see above).

The Center for Epidemiologic Studies of Depression Scale (CES-D): will be used as a brief, self-report measure of depressive symptoms in caregivers. This measure is widely used with both clinical samples and community surveys, with excellent reliability (alphas ranging from .85-.90). Maternal depression has been linked with poorer glycemic control and lower quality of life in youth with T1D; therefore, it may be an important covariate to include in analyses.

In addition we will collect Glycosylated Hemoglobin (A1C) from the adolescent's medical chart and blood glucose monitoring data by downloading the adolescent meter. Glycemic Control: Glycosylated Hemoglobin (A1C), an objective criteria of metabolic control over the prior 8-12 weeks, is measured

quarterly in patients with T1D. Analyses will be performed using the Bayer Diagnostics DCA2000® machine.

Blood Glucose Monitoring Frequency will be obtained via home glucose meter download at the time of study enrollment (if possible) and again at 3 month clinic visit. This method has been used successfully as a measure of adherence in other studies. Incentives will be provided to increase the likelihood of adolescents bringing all of their glucose meters to their clinic visits (\$10 per follow-up visit). The survey will take approximately 30 minutes to complete.

DOCUMENT AND ARTIFACT COLLECTION - Describe any documents or other artifacts (e.g., student written assignments, EKG report, x-rays, etc.) that are to be collected and used as part of the research study.

Participant's A1C will be collected from their medical chart at enrollment and at the the 3 month follow-up visit. Additionally, we will be collecting numbers from the participants blood glucose meter at enrollment and at the the 3 month follow-up visit.

AUDIO/VIDEO RECORDING - Describe how the audio/video recordings will be stored, as well as how they will be disposed of when this research is complete. Describe how the participant's confidentiality will be maintained.

The participants will be administered an exit interview and evaluation that will be audio recorded. Laptops that have recording capabilities will be utilized to record the interviews. Interviews will be saved using the participant's ID number on a secure drive that only study personnel will have access to. Participant confidentiality will be maintained because no names will be used; only participant ID number will be used for identification.

Will the PI create a repository at VU/VUMC with any of the specimens and/or data for future use?

Yes

No

If all of your study is minimal risk, please indicate the categories that it fits 45 CFR 46.110 or 21 CFR 56.110:

N/A: Study is greater than minimal risk or Standard

(F)(1) Drugs or devices where no IND/IDE is required

(F)(2) Collection of blood by stick or venipuncture

(F)(3) Prospective collection of specimens by non invasive means

(F)(4) Collection of noninvasive data through routine clinical practice

(F)(5) Research on materials that have been collected for non research

(F)(6) Collection of data from voice, video, digital or image recordings

(F)(7) Research on individual or group characteristics (surveys)