Effectiveness of a Community-Based Intervention of Acceptance and Commitment Therapy for Type 2 Diabetes Management in a Rural and Underserved Community

NCT Number: N/A

Date: 07/28/2023

Study Design. The aims of this study are to evaluate 1) the feasibility, 2) acceptability, and 3) initial efficacy of a combined ACT+CGM+LE intervention compared to a CGM+LE intervention or LE alone on hemoglobin HbA1c among a sample of 60 individuals with T2D recruited from rural East Texas.

Table 2. Group Design

Group 1	Group 2	Group 3
ACT + CGM + LE	CGM + LE	LE (Control Group)

Study Procedure: *Recruitment, Screening, and Consent*: We will recruit participants using a range of mechanisms designed to cast a broad net. Our goal will be to regularly recruit from SHSU Physicians and later extent to these efforts to community partners – such as a church community in Riverside, TX, who have expressed interest in this type of intervention. At SHSU Physicians, all physicians will be made aware of the study and are willing to share study information with patients who meet our inclusionary criteria. Fliers will be placed in the waiting room and posted in the exam rooms. For our community partners, we will distribute fliers at community events. For instance, a pastor in Riverside, TX, is willing to post fliers and share information about the study with his congregation. In addition, we will include study announcements on our institutions' websites, social media outlets, and newsletters. The flier will also advertise that participation in this study would be a paid opportunity ($100 to $450, depending on eligibility). In all these recruitment activities, we will describe the study as delivering three non-pharmaceutical approaches to managing T2D, and that participants will receive one of these three approaches. We will invite those interested in contacting the project research coordinator (RC) by email or phone for additional information and/or to schedule a screening interview. The RC will follow up with interested individuals by phone, provide them with initial study information, and conduct an initial eligibility screening (i.e., confirm residency in a rural area by using their zip code, whether they are 18 years or older, fluent in English, and have T2D). The RC will assign eligible participants with a research ID and will then send eligible participants a Qualtrics link with the informed consent to sign electronically and complete self-report measures within 1-week of the scheduled intervention. Participants who do not complete the informed consent and self-report measures, but come to the intervention will be able to complete these on-site. One item in the demographic survey will ask about suicidal ideation. Before the participant starts the intervention, the RC will review this item with them and alert the licensed psychologist present who will assess the risk, identify the next steps for care, and determine the participant's suitability for the study. When participants arrive for the intervention, the research coordinator trained in using the HbA1c point-of-care device will obtain HbA1c from a blood sample drawn on the participant's finger. Baseline body composition and other anthropometrics will also be collected from each participant (15 minutes). Following collection of the blood droplet via the point-of-care device, participants will receive a $100 reimbursement (given prior to the intervention).

Randomization: The RC will have a shuffled stack of envelopes with a group assignment in each. As participants meet inclusion into the study, their information, including Study ID, will be placed in one of the shuffled envelopes. The envelope will be placed in another envelope and sealed. Once approximately 10 participants are randomized to each group, the RC will contact all participants who have been randomized to share the date and time of the intervention and ask them to complete the 30-minute baseline surveys comprised of self-report measures (located in measures section) that they will receive by email. If recruitment slows down, we will do the randomization once 5 participants express interest in the study. The RC will then send a unique Qualtrics link to each participant (to prevent participants from needing to enter identifying

information on the survey). The baseline self-report survey is described below in the Measures section.

Lifestyle Education (LE): Participants assigned to all groups will attend a 6 hour lifestyle educational meeting. The educational meeting will be managed by Dr. Kelly, and/or a trained medical/dietetic student under their direct supervision. Participants will be given information about how lifestyle choices, including daily dietary choices, affect blood sugar for people with T2D, and best practices related to checking blood sugar and carbohydrate counting if participants are on insulin therapy. These sessions will also include education on diabetes nutrition guidelines and improving self-management through better food and lifestyle choices. Participants will be given breaks between modules and one long lunch break.

Continuous Glucose Monitoring + Lifestyle Education (CGM+LE): Participants assigned to CGM+LE will attend the group LE workshop. CGM training will occur after the 5 hour lifestyle education delineated above (same content, but less informal discussion). This will include training on using blood glucose monitoring devices, setting up the App on the smartphone (including activating the hypoglycemic alarm) and how to apply the glucose sensors on the arm. If a sensor does fall off a participant, a member of the study team will provide a spare sensor to the participant. The glucose range for participants will be set at between 70 and 140 mg/dL, unless the study physician (Dr. Olaiya) determines otherwise. The CGM device will allow us to calculate the percentage of 'time in range' per day, peak glucose, nocturnal glucose and number of hypoglycemic events. The CGM training will be managed by Dr. Olaiya and/or Dr. Kelly, and a medical/dietetic students.

The Abbott FreeStyle® Libre® 3 (FDA approved) consists of a single use disposable electrochemical sensing unit which is placed on the upper arm and an App for smart phones where the participant can view their glucose data, including their current glucose reading, their 'trend arrow' so participants can see how glucose is changing, and their glucose history.
The FreeStyle system does not require user calibration. A sensor log will be maintained for accountability of all sensors received as well as used sensors (including the lot/serial number, expiration date, and the date). Sensors will be stored at manufacturers recommendations. The first sensor will be applied to the back of an upper arm (timing and serial number recorded) by the participant under supervision by Dr, Kelly or by the study physician (Dr. Olaiya). Participants can replace the sensor themselves every 2 weeks for 12 weeks (i.e., replaced 5 times) or have the study physician or trained medical student replace it. Participant data files (generated by the App) will be captured by the RC and provided to the investigators without any identifiable information (participant can share CGM data with the RC from within the App).
Participants will be given breaks between modules and one long lunch break.

Acceptance and Commitment Therapy + Continuous Glucose Monitoring + Lifestyle Education (ACT+CGM+LE): Participants assigned to ACT+CGM+LE will have both of the above modules in addition to three ACT modules based on Gregg et al.[8] and traditional ACT therapy[19]. Two facilitators will lead the ACT sessions: Dr. Marek or Dr. Ratcliff and one trained doctoral-level clinical psychology student under their direct supervision (i.e., one licensed provider paired with a student). We will run all sessions in a group format. Participants will be given breaks between modules and one long lunch break.

Follow-Up Assessments: Follow-up assessments will occur at approximately three-months and 12 months after the workshop. For each visit HbA1c will be collected by the study coordinator using the point of care device. Body composition and other anthropometrics as will also be collected from each participant. The RC will then send a unique Qualtrics link to each participant

(to prevent participants from needing to enter identifying information on the survey). As described above, the PI will be available to consult with the RC if a participant indicates suicidal ideation.

The LE and LE+CGM groups will all yield educational sessions that discuss diabetes lifestyle changes, such as diet, importance of blood glucose checking, exercise, etc. Those randomized to the ACT+CGM+LE group will be part of a multidisciplinary nutrition and psychological session that will last the full day (Table 1). The first 4 hours will be the same sessions LE and LE+CGM groups are exposed to; however, the last 3 hours will feature a specific ACT protocol for participants to learn and practice. These protocols would be delivered on the weekend when it would be feasible for participants to attend. LE session content is outlined in Table 1. LE sessions will be reinforced by print information the participants can use as reference material.

Participant Compensation: To compensate participants for their time and travel, we will develop a staggered reimbursement schedule to increase the likelihood of follow-up with longer-term outcome time points. We will reimburse participants $100, $150, and $200 for their baseline, 3-month, and 12-month follow-ups, respectively.

Blinding: This is a single-blind study in which the participants will not be aware of the purpose of the study, and the PI will be blinded to the self-reports and biomedical data unless any participant(s) report(s) suicidal ideation. Once all data are collected, the database will be shared with a statistical consultant to administer multilevel modeling from completers and an intent-to-treat approach using multiple imputation methods for missing data. Our statistical expert will also remain blind to the treatment groups as they analyze data and share study results with the team. Once data are analyzed, the RA will unblind the groups for us.

Participants: Inclusion Criteria are: 1) Diagnosed type 2 diabetes or yield a HbA1c ≥ 6.0 at screening; 2) at least 18 years of age or older; 3) able to speak English; 4) able to provide informed consent and participate in the study; 5) reliable access to a personal smartphone device. Exclusion Criteria: 1) reported suicidal ideation at the initial visit; 2) has evidence of acute psychosis that precludes informed consent; 3) appears to be cognitively impaired to the extent that precludes informed consent; 4) uses a heavy amount of alcohol or other substances; 4) is deemed by the multidisciplinary study team to be too medically complex for a more conservative treatment approach; 5) has a pacemaker or other implanted electrical medical device; 6) is pregnant or planning to be pregnant.

Measures

Primary Outcome Measures: This study will examine the group-by-time effect on Hemoglobin HbA1c (HbA1c). We expect to see a gradual reduction of HbA1c across our three time points and expect these reductions to be greater in the CGM+LE and ACT+CGM+LE groups compared to the LE group. To measure HbA1c, we will use a point of care device at each time point.

Secondary Outcome Measures: We have several secondary outcome measures, including 1) body composition and anthropometrics (including weight, height and waist circumference), 2) psychosocial factors including experiential avoidance, depression, and knowledge and adherence to T2D; 3) questionnaires on food insecurity, and health literacy.

Body weight will be measured with the participant in light clothing without shoes. Body height will be measured to the nearest 0.1 cm without shoes using a calibrated stadiometer at

screening only. Body weight and height will be used to calculate BMI (BMI = weight/height^2 (kg/m^2). Waist circumference will be measured at a level midway between the lower rib margin and iliac crest with the tape all around the body in a horizontal position, using a calibrated measuring tape.

Body composition will be estimated using the Seca mBCA 525 (already own this device). It is a mobile supine position medical body composition analyzer validated (against DXA and MRI) to the four compartment (4C) body composition model. Participants will lie down for 5 minutes to allow body water distribution to stabilize. Then eight electrodes will be attached to hands and feet and bioelectrical impedance, at nine different frequencies, will be measured. This is contraindicated for people with pacemakers or other medical electronic implants. Apart from total body fat mass and muscle mass measures, visceral fat and segmental muscle mass by extremity and torso region will be obtained. Changes in these parameters will be correlated to other study measures.

The FreeStyle® Libre® 3 (FDA approved) consists of a single use disposable electrochemical sensing unit which is inserted in the subcutaneous tissue of the upper arm and an App for smart phones where the participant can view their glucose data, including their current glucose reading, their 'trend arrow' so participants can see how glucose is changing and their glucose history. The FreeStyle system does not require user calibration. A sensor log will be maintained for accountability of all sensors received as well as used sensors (including the lot/serial number, expiration date, and the date). Sensors will be stored at manufacturers recommendations. The first sensor will be applied to the back of an upper arm (timing and serial number recorded) by the participant under supervision or by the study physician. Participants can replace the sensor themselves after 2 weeks or have the study physician or trained medical student replace it. Participant data files (generated by the App) will be captured by the RC and provided to the investigators without any identifiable information (participant can share CGM data with the RC from within the App).

We will assess experiential avoidance with the Acceptance and Action Questionnaire – 2 (AAQ-2)[24] - The AAQ-2 is a reliable and valid self-report measure of psychological flexibility and experiential avoidance. Next, we will assess depression via the NIH Patient Report Outcomes Measures Information System (PROMIS) scale for depression[25]. The NIH PROMIS measure for depression has eight items that reliably and validly assess the construct of depression. Last, we will administer the Diabetes Care Profile (DCP)[26], which will assess our participants' frequency and adherence to regular blood sugar monitoring and their understanding of T2D. We will collect all of these measures at four time points to assess change and maintenance over time.
Food insecurity will be assessed using the USDA Economic Research Services U.S. Adult Food Security Survey Module[27]. This validated survey tool has 10 items in a three-stage design with screeners. Screening keeps respondent burden to the minimum, which improves data reliability. This will allow us to explore if food insecurity impacts diabetes progression. This survey will be administered at baseline and at the 12-month follow-up.

Analyses: We will perform all analyses using an intention-to-treat and completers approach. We will analyze all randomized participants in the group to which they were randomized. We will first determine whether participants randomized to the two study arms differ on baseline characteristics, age, race, gender, disease severity, and medical or mental health comorbidities. We will use Chi-square tests for categorical variables and *t*-tests for continuous and ordinal variables.

We will examine the normality of the distributions of primary outcomes and will consider transformations such as the log or the inverse. To analyze our primary outcomes, we will test the homogeneity assumption before testing for differences between the treatment and usual care groups. If our analysis violates the assumption of equal variances, we will use statistical tests such as the approximate *t*-test, which uses individual sample variances instead of the pooled variance. In addition, we will obtain Satterthwaite's approximation of the degrees of freedom. For the regression models (see below), we will test whether the residual variances are equal, and if necessary, we will fit unequal variance models to obtain better estimates of the standard errors of the difference between groups. Finally, we will calculate effect sizes for all analyses to establish the magnitude of group differences.

To compare changes between the two groups over time, we will use a longitudinal, mixed-model analysis containing terms for the intercept, treatment, time period, and interaction between time and treatment. We will include any baseline characteristics that are significantly different in the model. The treatment effect will measure differences between the intervention and usual care group at baseline, and the time effect will measure whether there was an overall change over time in the outcome. The term of most interest will be the interaction between time and treatment, indicating whether there is a difference over time between the three groups. Using the random-coefficient model will allow us to fit a line for each participant using his/her available data, including participants with missing values, and maximize the power to detect differences.

We will use the primary outcome measure HbA1c as the dependent variable in the mixed model analysis. We will use the secondary measures as dependent variables in separate models to understand the treatment's impact on other aspects of diabetes functioning. As an exploratory analysis, we may consider classifying participants into categories, such as the presence or absence of depression, the presence or absence of hypertension, or the presence or absence of experiential avoidance. We would then modify the above approaches to run logistic-regression models in which the dependent variable is, whether or not the participant had these related issues.

In addition, we will conduct sensitivity analyses using tests for missing completely at random and tests for nonrandom missingness[29]. These will allow us to evaluate whether the reasons for loss to follow-up at the various time periods are related to the observed values of the outcome variables. Additionally, we will plot the data over time to visually assess changes in outcomes from baseline to one-year and to determine whether we need additional terms in the models to account for nonlinearity over time. We will also adjust for possible changes over time in measures such as medication usage by using time-dependent covariates measured at the follow-up assessments. In these models, the time-dependent covariate, treatment, and treatment-by-time interaction will be considered fixed; and the intercept and time will be considered random effects. Significant values for the interaction term will indicate that the outcome measure for the ACT+CGM+LE group differed from that of the LE and CGM+LE group.

Feasibility and Acceptability. We will use descriptive statistics to evaluate potential feasibility. Specifically, we will calculate the proportion of patients invited to participate who consented, the percentage of randomized patients that attended at least one session, and the percentage of randomized patients that completed three or more sessions. We will evaluate acceptability by examining the responses to the Client Satisfaction Questionnaire-8 (CSQ-8)[30]. We will first derive item-specific summary statistics for the eight items in the CSQ-8 questionnaire by arm. Next, we will use mean, SD, and quartiles to summarize the total score, which ranges between 8 and 32, and obtain the frequency and percent of participants with a score of 20 or greater. Finally, qualitative data from the open-ended items on the CSQ-8 will be analyzed using thematic analysis to identify themes of satisfaction and areas for future improvement.

Analytic Plan:

Power Analysis: Examining past studies using brief forms of ACT[8], we expect to see modest effect sizes when comparing CGM+LE and ACT+CGM+LE to LE and smaller effect sizes when comparing ACT+CGM+LE to CGM+LE. Our design will require a two-level, multilevel regression model to test whether the primary outcome differs between our groups over time. We thus seek to recruit 80 participants who are eligible for the study with the understanding that about 20% will not meet inclusionary criteria at the first visit and to account for attrition over time. Overall, we are expected to have a sample closer to 60 participants.

Analyses: We will perform all analyses using an intention-to-treat and completers approach. We will analyze all randomized participants in the group to which they were randomized. We will first determine whether participants randomized to the two study arms differ on baseline characteristics, age, race, gender, disease severity, and medical or mental health comorbidities. We will use Chi-square tests for categorical variables and *t*-tests for continuous and ordinal variables.

We will examine the normality of the distributions of primary outcomes and will consider transformations such as the log or the inverse. To analyze our primary outcomes, we will test the homogeneity assumption before testing for differences between the treatment and usual care groups. If our analysis violates the assumption of equal variances, we will use statistical tests such as the approximate *t*-test, which uses individual sample variances instead of the pooled variance. In addition, we will obtain Satterthwaite's approximation of the degrees of freedom. For the regression models (see below), we will test whether the residual variances are equal, and if necessary, we will fit unequal variance models to obtain better estimates of the standard errors of the difference between groups. Finally, we will calculate effect sizes for all analyses to establish the magnitude of group differences.

To compare changes between the two groups over time, we will use a longitudinal, mixed-model analysis containing terms for the intercept, treatment, time period, and interaction between time and treatment. We will include any baseline characteristics that are significantly different in the model. The treatment effect will measure differences between the intervention and usual care group at baseline, and the time effect will measure whether there was an overall change over time in the outcome. The term of most interest will be the interaction between time and treatment, indicating whether there is a difference over time between the three groups. Using the random-coefficient model will allow us to fit a line for each participant using his/her available data, including participants with missing values, and maximize the power to detect differences.

We will use the primary outcome measure HbA1c as the dependent variable in the mixed model analysis. We will use the secondary measures as dependent variables in separate models to understand the treatment's impact on other aspects of diabetes functioning. As an exploratory analysis, we may consider classifying participants into categories, such as the presence or absence of depression, the presence or absence of hypertension, or the presence or absence of experiential avoidance. We would then modify the above approaches to run logistic-regression models in which the dependent variable is, whether or not the participant had these related issues.

In addition, we will conduct sensitivity analyses using tests for missing completely at random and tests for nonrandom missingness[29]. These will allow us to evaluate whether the reasons for loss to follow-up at the various time periods are related to the observed values of the outcome variables. Additionally, we will plot the data over time to visually assess changes in outcomes from baseline to one-year and to determine whether we need additional terms in the models to account for nonlinearity over time. We will also adjust for possible changes over time in measures such as medication usage by using time-dependent covariates measured at the follow-up assessments. In these models, the time-dependent covariate, treatment, and treatment-by-time interaction will be considered fixed; and the intercept and time will be considered random effects. Significant values for the interaction term will indicate that the outcome measure for the ACT+CGM+LE group differed from that of the LE and CGM+LE group.

Sam Houston State University
Consent for Participation in Research

KEY INFORMATION FOR

A Randomized Control Trial to Test the Effectiveness of a Community-Based Intervention of Acceptance and Commitment Therapy for Type 2 Diabetes Management in a Rural and Underserved Community

You are being asked to be a participant in a research study about *whether various lifestyle interventions help improve type 2 diabetes.* You have been asked to participate in the research because *you have indicated that you have type 2 diabetes* and may be eligible to participate.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

Type 2 diabetes can be difficult to manage. Although we know your physician has likely given you some education about (and perhaps medication for) type 2 diabetes that can help you acquire the skills needed to control it, we are finding that this approach is not as effective as we had hoped. The purpose of this study is to see if some new ways to provide educate on how to control their type 2 diabetes may be more helpful.

If you decide you want to participate, we will ask you to fill out a 30-minute questionnaire (you can do this from home on your computer) and we will ask you to come in a total of three times over the years. The first visits will be about 7-8 hours long, with a several short breaks and one longer break for lunch. At this first visit, you will have a droplet of blood taken from your finger to test your blood sugar and attend a 6-hour workshop to learn more about diabetes and how to manage it. You may also receive a device called a continuous glucose monitor that you place on your arm that will track your blood sugar through an app. You will be with up to 10 other individuals with type 2 diabetes during this first visit.

The second visit will be scheduled about 3 months later and the last visit around one-year later. The 3 month visit and the 12 month visit are expected to last about 30 minutes. We will be collecting a droplet of blood from your finger to test your blood sugar. Before coming in for these two visits, we will ask you to fill out a 30-minute questionnaire (you can do this on your computer or over the phone).

By doing this study, we hope to learn *more about what components in type 2 diabetes education are most effective on long term blood glucose levels in persons with diabetes.* Your participation in this research will last about *one year as outlined in the paragraph above*.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may be interested in this study because it does not involve any form of medication or vaccine for type 2 diabetes and does not interfere with your current care. It is possible your blood sugar over the course of the year will lower as a result of this study. You will also have an opportunity

to learn about what type 2 diabetes is, why it occurs, and how to take care of it. You may also have an opportunity to pilot how a continuous glucose monitor works and see whether it is helpful in aiding in your understanding of how your type 2 diabetes works. You may also be part of some more novel approaches to understanding type 2 diabetes that may have a strong impact than general education. Last, you will be compensated throughout the duration of the study up to $450 in total.

For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to participate because of a fear of needles or blood. This study will require us to collect a droplet of blood from your finger to measure your blood sugar, or Hemoglobin A1c. We will be using a device similar to what you can find at a grocery or drug store and you may already be using a device like this. We have a board-certified physician on our study team should a medical need arise.

Some of the questionnaires ask about depression and may make you feel uncomfortable. Although it's unlikely that these questions would cause you to feel suicidal, both PIs (Dr. Marek and Dr. Ratcliff) are licensed clinical psychologists who will talk with you should feelings of suicide arise and discuss if other psychological treatment may be right for you. If at any time you would like to obtain treatment, the Sam Houston State University Psychological Services Center (1528 Avenue J, Huntsville, TX 77341) serves our community. You may reach them to schedule an appointment at 936-294-1210.

For a complete description of risks, refer to the Detailed Consent. *If you realize you do not want to participate, there is no harm in choosing not to participate. The care you are already getting from your doctor is still the standard of care.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The persons in charge of this study are *Dr. Ryan Marek (Department of Psychology and Philosophy) and Dr. Chelsea Ratcliff (Department of Psychology and Philosophy)* of the Sam Houston State University. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Office of Research and Sponsored Programs – Sharla Miles at 936-294-4875 or e-mail ORSP at sharla_miles@shsu.edu.

Sam Houston State University

Consent for Participation in Research

DETAILED CONSENT

A Randomized Control Trial to Test the Effectiveness of a Community-Based Intervention of Acceptance and Commitment Therapy for Type 2 Diabetes Management in a Rural and Underserved Community

Why am I being asked?

You are being asked to be a participant in a research study about *whether various lifestyle interventions help improve type 2 diabetes* conducted by *Dr. Ryan Marek (Department of Psychology and Philosophy) and Dr. Chelsea Ratcliff (Department of Psychology and Philosophy)* of the Sam Houston State University. You have been asked to participate in the research because *you have indicated that you have type 2 diabetes* and may be eligible to participate. We ask that you read this form and ask any questions you may have before agreeing to be in the research.

Your participation in this research is voluntary. Your decision whether to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Why is this research being done?

Type 2 diabetes can be difficult to manage. Although we know your physician has likely given you some education about (and perhaps medication for) type 2 diabetes that can help you acquire the skills needed to control it, we are finding that this approach is not as effective as we had hoped. The purpose of this study is to see if some new ways to educate persons on how to control their type 2 diabetes are helpful. If you decide you want to participate, we will be asking you to come in for a total of three times over the next year. These first visits will last approximately 7 hours. The second and third visits will be 3 months later and then 12-months later and will last approximately 30 minutes.

What is the purpose of this research?

The purpose of this research is:

To evaluate if a one-day workshop focused on diabetes education followed by 12-weeks of continuous glucose monitoring is feasible and acceptable.

What procedures are involved?

If you agree to be in this research, we would ask you to do the following things:

If you decide you want to participate, we will be asking you to come in for a total of three times over the next year. These first visits will last about 8 hours, and you will be with a small group of other individuals who have type 2 diabetes. The second and third visit will be scheduled about 3 months later and one-year later and will last about 30 minutes. Additionally, we will ask that you complete three 30-minute questionnaires from home using your computer or over the phone with the research coordinator before you come in for each of these three visits.

Visit 1 (Today),
The first visit may last up to 8 hours with a few short breaks and one longer break for lunch. We will be collecting a droplet of blood from your finger to test your blood sugar. You will then be asked to fill out some questionnaires. Afterwards, you will be with a few others who also have diabetes interested in participating in this study. You may also receive a newer blood glucose monitoring technology that you place on your arm that will track your blood sugar through a commercially available app on your phone. You will learn how to use this if you are in a group that is testing the technology. Please note that you may be randomized to a group that does not get the blood glucose monitoring.

,
Visit 2 and Visit 3:

These two visits (3 month follow-up visit and 12 month follow-up visit) are expected to last about 1 hour, at most. We will be collecting a droplet of blood from your finger to test your blood sugar. You will then be asked to fill out some questionnaires.

Approximately *up to 60* participants may be involved in this research at Sam Houston State University.

What are the potential risks and discomforts?

You may not want to participate because of a fear of needles or blood. This study will require us to collect a droplet of blood from your finger to measure your Hemoglobin A1c. We will be using a device similar to what you can find at a grocery or drug store and you may already be using a device like this. We indeed have a board-certified physician on our study team should a medical need arise.

Some of the questionnaires ask about depression and may make you feel uncomfortable. Although it's unlikely that these questions would cause you to feel suicidal, both PIs (Dr. Marek and Dr. Ratcliff) are licensed clinical psychologists who would be more than willing to speak with you should feelings of suicide arise and discuss if other psychological treatment may be right for you. If at any time you would like to obtain treatment, the Sam Houston State University Psychological Services Center (1528 Avenue J, Huntsville, TX 77341) serves our community. You may reach them to schedule an appointment at 936-294-1210.

If you are in the group that receives a continuous glucose monitor, the continuous glucose monitor patches must be replaced every two weeks. It is also possible that the adherence pad may

fall off, especially in more humid climates, and need to be placed back on. You will also learn how to ensure that your sensor is connected to the online account. The first one will be placed at your first visit and you will be trained on how to place the replacements on your arm from the comfort of your own home. It is important to note that some people find the experience of continuous glucose monitors unpleasant, uncomfortable, or painful to some degree. If you find that you cannot tolerate the continuous glucose monitor, please notify the study team.

One other unlikely risk is that your data are comprised by a hack or other form of technology data breech. We will have a database with your name, contact information, group membership assignment for the intervention, unique research ID, dates for which you participated in the study, and if you choose to withdraw from the study. The database will be not contain any other information that you provide and will be password protected on SHSU devices and services (e.g., OneDrive). This database will be destroyed at the conclusion of the study. A second database containing a research ID and all other data will be stored in a separate database with a different password in a different file location. This second database will be deidentified, meaning that it contains no possible identifier as to who you are with the exception of the research ID. This database may also be stored in a data repository in order to promote transparency and openness to the public. Your name and any other data that relate to your identity will not be stored in this database. In a data breech, a hacker would have a difficult time getting into both databases due to different passwords and it would not be immediately obvious that the two databases are somehow linked.

Are there benefits to taking part in the research?

You may be interested in this study because it does not involve any form of medication or vaccine for type 2 diabetes and does not interfere with your current care. It is possible your blood sugar over the course of the year will lower as a result of this study. You will also have an opportunity to learn about what type 2 diabetes is, why it occurs, and how to take care of it. You may also have an opportunity to pilot how a continuous glucose monitor works and see whether it is helpful in aiding in your understanding of how your type 2 diabetes works. You may also be part of some more novel approaches to understanding type 2 diabetes that may have a strong impact than general education. Last, you will be compensated throughout the duration of the study up to *$450* in total. Specifically, you will be paid *$100* for completing the first set of questionnaires and providing the blood drop sample at the start of the intervention, *$150* for the second visit, and *$200* for the third visit should you choose to participate.

What other options are there?

If you realize you do not want to participate, there is no harm in choosing not to participate. The care you are already getting from your doctor is still the standard of care.

What about privacy and confidentiality?

The only people who will know that you are a research participant are members of the research team. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the SHSU Protection of Human Subjects monitors the research or consent process); or
- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised.
Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

The deidentified research database will not contain your name, contact information, or any other information that may otherwise identify you. This database may also be stored in a data repository in order to promote transparency and openness to the public.

We will have a database with your name, contact information, group membership assignment for the intervention, unique research ID, dates for which you participated in the study, and if you choose to withdraw from the study. The database will be not contain any other information that you provide and will be password protected on SHSU devices and services (e.g., OneDrive). This database will be destroyed at the conclusion of the study. A second database containing a research ID and all other data will be stored in a separate database with a different password in a different file location. This second database will be deidentified, meaning that it contains no possible identifier as to who you are with the exception of the research ID. This database may also be stored in a data repository in order to promote transparency and openness to the public. In a data breech, a hacker would have a difficult time getting into both databases due to different passwords and it would not be immediately obvious that the two databases are somehow linke*d.*

This document is considered an informed consent. This will serve as your consent to be part of the study. This document will be signed by a member of the research team and yourself. You will also be given a copy to take home for your records. You can choose to withdraw from your study at any time.

What are the costs for participating in this research?

There are no costs associated with this study aside from your time, meals/snacks during your second visit (we ask that you bring snacks, a beverage, and/or transportation for lunch during the second visit), and means of transportation to the study site.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will not be reimbursed for any expenses for you participation in this research.

Can I withdraw or be removed from the study?

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

If you choose to withdraw, you may keep any compensation you have already received. You will not be eligible for further study compensation if you withdraw.

Who should I contact if I have questions?

The researchers conducting this study are *Dr. Ryan Marek, Dr. Chelsea Ratcliff, Dr. Kelly, Dr. Griffin, and Dr. Olaiya.* You may ask any questions you have now. If you have questions later, you may contact the researchers at: Phone: *(936)294-3614.*

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research participant, you may call the Office of Research and Sponsored Programs – Sharla Miles at 936-294-4875 or e-mail ORSP at sharla_miles@shsu.edu.

You may choose not to participate or to stop your participation in this research at any time. Your decision whether or not to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

If you are a student, this will not affect your class standing or grades at SHSU. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected.

If you are a staff person at SHSU, your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at SHSU.

You *will not* be offered or receive any special consideration if you participate in this research.

Agreement to Participate

I have read (*or someone has read to me)* the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research.

Consent: I have read and understand the above information, and I willingly consent to participate in this study. I understand that if I should have any questions about my rights as a research subject, I can contact *Dr. Ryan Marek* at *(936)294-3614* or by email at *rxm147@shsu.edu*. I have received a copy of this consent form.

Your name (printed):_____

Signature: _____Date: _____