Cognitive Training for Diabetes Self-Management
NCT04831775
March 30, 2022

Study Protocol and Statistical Analysis Plan

Research Design. A pilot RCT will be conducted with 66 adults with T2DM to evaluate the efficacy of the MAPSS-DM intervention to improve the primary outcome of overall cognitive function (e.g. verbal memory performance, use of cognitive strategies) and DM-SM. Drs. Cuevas and Stuifbergen completed a feasibility study of the intervention using a one group pre-test post-test design.[14] This proposed project expands that work by adding a 2-group RCT design with longer follow-up.
Mechanisms to Improve Rigor. The proposed study will reduce bias by 1:1 randomization of participants to the treatment or control group, blinding the data collector to group assignment, training the data collector to follow standardized protocols in collecting data, and randomly monitoring data collection to maintain reliability. Inclusion and exclusion criteria were designed to control for confounding variables. To ensure treatment fidelity, interventionists will be trained using the intervention manual and complete checklists after each class. Strategies for monitoring receipt of treatment (e.g. time spent online, weekly goals) will be used.

Intervention Description. The intervention is composed of 4 small-group webinar classes and home-based individual online cognitive skills practice. The four small-group 2-hr web-based classes are held over 8 weeks. Classes 1 & 2 will focus on common cognitive problems in T2DM and strategies to improve cognitive skills. Classes 3 & 4 focus on lifestyle changes to support cognitive functioning and DM-SM skills. Each online class will follow the same format: (1) introduction/revisiting content from the previous class and answering questions; (2) review of progress on the computer exercises; (3) practicing cognitive strategies in class; and (4) content on weekly topic. The facilitator will review participants' progress on the computer exercises, explore cognitive strategies and difficulties with performance, and prescribe exercises for the following weeks. Each participant will receive a workbook that reemphasizes class content. Intervention fidelity will be increased through use of the intervention manual (tested in PS#2) to ensure all content is covered. The interventionist will be trained by the PI, and will complete a self-assessment checklist after each class to verify content covered.

Computer Training Component. The computer-training component, developed by Posit Science, uses a model for cognitive training that adapts to the user through an integrated hierarchical structure.[48] The BrainHQ website houses the interactive program that runs on standard web browsers. Participants will only need a computer, smart phone, or tablet with Internet access to securely log onto the website. Each participant will be registered by the research staff using anonymous ID numbers that will allow unlimited access during the study. At the week 1 class, the interventionist will show participants how to log on and access the exercises via a screenshare option provided by the webinar program. The website stores each session a participant completes, and participants will be able to start subsequent sessions wherever they stopped the last time logged on. BrainHQ meets the Institute of Medicine's five requirements for a brain-training program: (1) transferability to other tested tasks; (2) transferability to real-world tasks; (3) evaluation with active control group with access to same product; (4) retention of trained skills; and (5) replication of findings.[51] The intervention group will be asked to practice 20 minutes, 7 days a week.

Comparison Group. Those randomized to the comparison group will receive a referral to the BrainHQ website. A specific amount of practice will not be prescribed, but participants' times and dates of practice will be downloaded from the website. Participants will receive a weekly phone call to maintain connection to the study, but no other intervention. Data collection will be on the same schedule as the intervention group.

Sample and Setting. People with T2DM will be recruited from Texas Diabetes & Endocrinology (TDE) that oversees the health care of over 3500 patients with T2DM per year (see letter of support). About 75% of TDE's patients are female, 36% Hispanic, and 3% African American. Dr. Cuevas has worked with TDE in prior studies. Information about the study will be provided to patients by the TDE health care team and notices will be posted in the clinic. Recruitment materials will instruct participants to call or email the PI for information.

Power analysis. Using data from our preliminary study, a power analysis was run to estimate sample size for the outcomes of decreased A1C, improved cognitive function (i.e. working memory, executive function) using G*Power. For a fully powered randomized trial, assuming a small-to-moderate effect size of d = .3, each group would need 64 subjects for the power to be 0.8 at a 0.05 significance level. However, the proposed study is the first comparison test of the MAPSS-DM. A goal of this pilot study is to determine feasibility and to estimate effect sizes. Hertzog has shown that 10–20 subjects per group are often adequate for evaluating feasibility in a pilot study, and 30 subjects are needed when estimating effect sizes.[49] Allowing for a 10% attrition rate (based on PS#2), 66 persons with T2DM (33 intervention and 33 control) will be recruited.

Recruitment & Enrollment. Inclusion criteria: age 45-70 years old, T2DM diagnosis for 2 years, access to phone and Internet, Score of ≥10 on the Perceived Deficits Questionnaire (PDQ), and an A1C of >7%.[50] Exclusion criteria: a diagnosis of dementia/head injury, score of >5 on the Mini-Cog, inability to speak English, and a T1DM diagnosis. For those who indicate interest in participating in the study, a screening assessment will be done either in person or by phone. A script of questions to verify that potential participants meet the inclusion/exclusion criteria will be followed. Participants will be asked the PDQ items that assess self-perceived cognitive difficulties, with questions such as "How often do you lose your train of thought when speaking?" using a 5-point scale ranging from 1 = never to 5 = almost always.[50] Potential participants must score at least 10 on the PDQ indicating some problems in at least 5 areas to participate. The Mini-Cog will screen potential participants for dementia.[51] A total score of ≤5 indicates lower likelihood of dementia. For those who meet the inclusion criteria and agree to participate, a meeting will be scheduled at a time and private location convenient to the participant. Eligible participants will meet with a GRA or PI, who will review the study's purpose and procedures, answer participants' questions, obtain signed consent forms, and collect baseline data.

Randomization. Seven cohorts of 10 subjects will be recruited during the study, and subjects in the cohort will be randomly assigned 1:1 to the intervention or control group using a computer-generated list of random numbers (following baseline testing). The intervention group will be further divided into class sizes of 10-5 participants. In prior cognitive rehabilitation studies, small intervention class sizes (n=10-12) enhanced self-efficacy through vicarious experience and modeling.[52] In diabetes education, online groups of 10-15 participants have been shown to be effective.[52-54]

Data Collection. Questionnaire data will be collected from all participants on an iPad and entered into REDCap at baseline (week 0), at completion of the intervention (week 10), and at 3 months post-intervention (week 22). A GRA who is blind to group assignment will administer the instruments and neruopsych tests in a private location to ensure completion, confidentiality, and privacy. Clinical variables will be gathered by medical record review: current medications, past A1C levels, and co-morbidities. The total data collection time will be about 60 min. Participants will receive a small incentive ($25) for completing the first two data collections and ($50) for the final assessment ($100 total). Data will be downloaded for analysis into IBM SPSS Statistics version 23.[55] All intervention participants will be invited to join a focus group after their final data collection to evaluate their perceptions of the acceptability of the MAPSS-DM intervention.

Table 1. Physiological Measures (pre- and post-intervention at week 2 and week 22)

A1C	Medical record	The national standard measure of glycemic control over a 3-month period.
BMI	Weight, height	kg/m^2
Self-Report Measures (pre- and post-intervention) Time to Administer ~30 minutes for this battery		
Demographics	Background information	Age, gender, years with DM, ethnicity/race, socioeconomic status, history of DM education, years of education
DM-SM	Summary of Diabetes Self-Care Activities[56]	18 items; Participants answer "how many days in the last week…" they performed DM self-management such as diet and physical activity. Inter-item correlations range from r = 0.20 to 0.76 for four SDCA subscales; 4-month test-retest reliability range from r = -0.05 to 0.78.
Self-efficacy	*Diabetes Empowerment Scale – Short Form*[57]	8 items; Brief assessment of diabetes related psychosocial self-efficacy. Responses are made on a 5-point scale (1 = strongly disagree to 4 = strongly agree) to items such as "I believe that I am able to turn my diabetes goals into a workable plan." Cronbach's alphas range from 0.81 to 0.96.
Depression	CES-D[58]	20 items; measures depressive symptoms. 4-point item response scale from rarely/none of the time to most/all of the time in 8 health dimensions: role limitations due to physical problems, social functioning, physical functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. Internal consistency ranged from 0.85 to 0.91 and test-retest reliability ranged from 0.45 to 0.70.
Perceived Cognitive Function	PROMIS v2.0 – Cognitive Function[59]	32 items; assess patient-perceived cognitive deficits including the areas of mental acuity, concentration, verbal and nonverbal memory, and verbal fluency. Reliability has been measured at 0.94 and test-retest correlation at 0.83. (Becker 2014)
Objective Cognitive Function Measures (pre- and post-intervention) ~ 35 minutes to administer		
Episodic memory	Picture Sequence Memory (NIH-Toolbox)[60]	Assessment of episodic memory. It involves recalling increasingly lengthy series of illustrated objects and activities presented in a particular order on the computer screen. Participants are asked to recall the sequence of pictures demonstrated over two learning trials. Participants are given credit for each adjacent pair of pictures (i.e., if pictures in locations 7 and 8 and placed in that order and adjacent to each other anywhere – such as slots 1 and 2 – one point is awarded) they correctly place, up to the maximum value for the sequence, which is one less than the sequence length (if there are 18 pictures in the sequence, the maximum score is 17, because that is the number of adjacent pairs of pictures that exist).

Executive Function and Attention	Flanker Inhibitory Control and Attention (NIH-Toolbox)[60]	Measures both a participant's attention and inhibitory control. The test requires the participant to focus on a given stimulus while inhibiting attention to flanking it. Scoring is based on a combination of accuracy and reaction time.
Working memory	List Sorting Working Memory (NIH-Toolbox)[60]	Assesses working memory. Requires the participant to sequence different visually- and orally-presented stimuli in two different conditions. In the 1-List condition, participants are required to order a series of objects (either food or animals) in size order from smallest to largest. In the 2-List condition, participants are presented both food and animals and are asked to report the food in size order, followed by the animals in size order.
Processing speed	Pattern Comparison Processing Speed (NIH-Toolbox)[60]	This measures speed of processing by asking participants to discern whether two side-by-side pictures are the same or not. Participants' raw score is the number of items correct in a 90-second period.
Attention, visual scanning, and motor speed	Symbol Digit Modalities Test[61]	Participants are given a series of symbols and digits and instructed to verbalize the digit associated with each symbol. The number of correct responses in 90 sec constitutes the score, and higher scores reflect better cognitive function.

Glucose Variability. Participants will wear CGMS devices for one week at specific intervals (week 0, week 5, week 11, and week 22). Abbott's FreeStyle Libre CGMS consists of a small, round sensor about the size of two stacked U.S. quarters—worn on the back of the upper arm for up to 14 days, which measures glucose every minute in interstitial fluid through a small (5mm long, 0.4mm wide) filament that is inserted just under the skin and held in place with a small adhesive pad.[62] A reader is scanned over the sensor to get a glucose result painlessly in less than one second. Each scan displays a real-time glucose result, a historical trend and the direction the glucose is heading. Participants will scan the sensors at least 2 times a day. CGMS data will be downloaded at each data collection visit. The stored amperometric data from the monitor will be transferred and converted to glucose concentrations after data collection is completed using an infrared link to a personal computer and are analyzed using the CGMS solution software which will be maintained by the research staff. The FreeStyle Libre system generates an Ambulatory Glucose Profile (AGP) that provides a visual snapshot of glucose levels, trends and patterns over time. The following five glucose composites will be calculated: (1) the overall mean, (2) the proportion of readings indicating hypoglycemia (%<70mg/dL), (3) the proportion of readings indicating hyperglycemia (% >160mg/dL), (4) the proportion of out of range readings (% either <70mg/dL or >160mg/dL) and (5) the SD of CGM glucose readings.[63] Compared with SMBG, 85.5% of FreeStyle Libre readings were clinically accurate and 99.0% were clinically acceptable on a Clarke error grid, using linear mixed modelling.

Statistical significance. The data will be evaluated for violations of statistical tests. If assumptions are violated, alternative tests will be used or the data will be transformed. Individual t-tests will be run on the baseline variables (e.g. A1C, cognitive function tests) to determine if significant differences exist between the intervention and control groups, and we will control for those baseline differences in subsequent analyses. Analysis will follow intent-to-treat principles. Correlations will examine the relationships between the major variables. The significance level will be .05 for each test.

Statistical Analyses. For Aim 1, we will use multilevel longitudinal models to estimate MAPSS-DM treatment effects on A1C, DM-SM and measurements of memory and executive function over time. Multilevel longitudinal models are generalizations of repeated-measures ANOVA that include every participant in the analysis, regardless of missing data, and will account for the clustering of measurements within participants. The model will also contain fixed effects for intervention (MAPSS-DM vs control) interacted with measurement occasion (baseline, 8 weeks, 3 months), as well as for cohort and baseline covariates. We will use the models to test for overall treatment effects ($p<0.05$), effects at each post-baseline time-point, and within-subject effects. Effect sizes will be expressed as Cohen's d. Additionally, We will use causal-mediation methods and exploit the longitudinal structure of the data collection to estimate the mediational role of cognitive function. We will regress each cognitive function measurement at 8 weeks (post-intervention) on the group assignment (MAPSS-DM or control), the same cognitive measurement at baseline, and demographic controls.[v&V2014] These regressions estimate the effect of the intervention on cognitive function at week 8. Next, we will regress the 3-month A1C and adherence measures at 3-months on the same variable at baseline, group assignment, cognitive measurements at week 8, and demographic controls. The average mediated effect of the intervention on A1C or adherence will be estimated by the sum of the coefficients on intervention from the first set of regressions multiplied by the coefficients on the corresponding cognitive measurements in the second regression, with Monte-Carlo confidence intervals and statistical tests.[64] For Aim 2, CGMS data will be downloaded at each data collection visit. Within subject change in the mean values of CGMS summary variables between pre-, during and post-intervention will be determined. The percentage of time spent in low

(<70mg/dL), normal (71mg/dL – 120mg/dL) and high (>160mg/dL) will be calculated. We will use analogous regression models to those in Aim 1 to estimate the effect of the intervention on glucose variability at post-baseline time-points, and mediational role of the of glucose variability in the intervention's effect on cognitive functions.

Potential sources of biological variation. To address the issue of potential differences in cognitive function, A1C, glucose variability, and DM-SM adherence between men and women, we will re-fit appropriate regression models from the analyses and include interaction terms between intervention group and sex.

UT Austin IRB Approved
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The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: Cognitive Training for Type 2 Diabetes
Principal Investigator: Heather Cuevas, PhD, RN, ACNS-BC, The University of Texas at Austin, School of Nursing

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Importan Information about this Research Study

Things you should know:

- The purpose of the study is to test an intervention to improve cognitive skills and examine glucose changes for people with type 2 diabetes.
- In order to participate, you must be 50 years or older, have type 2 diabetes, and have access to the Internet on a computer, tablet or smartphone.
- If you choose to participate, you will be asked to (1) answer questions about memory, ways of thinking, and diabetes self-management; (2) participate in online computer training for 20 minutes, 7 days a week and 4 online classes to help you improve your memory and learn more about diabetes self-management; and (3) wear a continuous glucose monitor. This will take 22 weeks.
- Risks or discomforts from this research include changing diabetes self-management (SM) habits, which may lead to temporary alterations on blood glucose although the goal of the intervention is to improve SM and ultimately improve blood glucose levels. Changing SM habits may result in fluctuating blood glucose levels leading to low blood sugar without a change in medication. You will be given information on monitoring for and managing low blood sugar prior to the start of the intervention. You will also be instructed to call your health care provider if you have any low blood sugar. There are minimal risks with wearing CGM sensors. Applying the sensor may cause bruising or bleeding and some patients may experience mild pain as the devise is fitted.
- The possible benefits of this study include that you may increase your knowledge.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

Wha is the study about and why are we doing it?

In the United States, 90-95% of the 30 million people with diabetes have type 2 diabetes (T2DM). Although the association between T2DM and cognitive dysfunction is not fully understood, we know T2DM increases the risk for cognitive problems and the rate of cognitive decline in those with T2DM is double that for those without it. Blood sugar levels that go up and down frequently may also lead to cognitive problems. For these reasons, we are conducting this study to test an educational program to learn if it can improve cognitive function and diabetes control.

Wha will happen if you take part in this study?

If you agree to take part in this study, a computer program will be used to select whether or not you will be in the group that participates in an online class to learn about skills to improve cognitive function and diabetes management or be in the group that uses online games only. The computer program is similar to flipping a coin to decide what study group you will be in. Participants in Group 1 will: (1) attend four, small group, 2-hour online classes that meet every other week for 8 weeks; (2) practice with cognitive skills with online computer games for 20 minutes, 7 days a week; and (3) wear a continuous glucose monitors (CGM) for one week, four times during the study -before the intervention, immediately after the intervention, 3 weeks after the intervention, and 3 months after the intervention. Participants in Group 2 will: (1) practice cognitive skills with online computer games (frequency and duration are up to you); and (2) wear the CGM for one week after Study Visit 1 and after 5, 11, and 22 weeks of practice with the computer games.

Study Visit 1: You will be sent a link to complete all the questionnaires and tests online. It should take you about 1 hour to complete all the questionnaires and tests. You will be asked about your diabetes history, past and current medical conditions, height and weight, and A1C. You will also complete questionnaires to assess how you manage diabetes, how confident you are in diabetes self-management, your mood, and how you feel about your cognitive function. You will also be asked to take 5 tests to assess your memory, your attention, how fast you can think, and motor speed.

You will also schedule a time to receive training on the use of a CGM and receive the appropriate supplies. The CGM measures glucose in the fluid under the skin. It consists of a sensor which is inserted into the skin, a transmitter attached to the sensor and a display device. Every 5 minutes the transmitter sends glucose readings to the display device. The display device stores the readings. You will wear the CGM at home for approximately 1 week to obtain baseline glucose assessment. You will not be able to see your glucose readings while wearing the CGM, but you will be provided with the results after you return the CGM to the study team. You will return approximately 14 to 21 days after screening so the study team can evaluate your usage of CGM.

All participants in the project will wear the CGM for one week, four times during the study.

Group 1: Participants in Group 1 will participate in four asynchronous, 2-hr online classes held over 8 weeks and taught by a Registered Nurse. Classes 1 & 2 will focus on common cognitive problems in T2DM and strategies to improve cognitive skills. Classes 3 & 4 focus on lifestyle changes to support cognitive functioning and DM-SM skills. Each online class will follow the same format: (1) introduction/revisiting content from the previous class; (2) review of progress on computer exercises; (3) practicing cognitive strategies in class; and (4) a weekly topic.

Participants in Group 1 will also practice with online computer games (BrainHQ) for 20 minutes, seven days a week. You will only need a computer, smart phone, or tablet with Internet access to log onto the secure website.

Group 2: The study team will contact you during weeks 5, 11, and 22 to initiate the CGM, review use of the computer games, and discuss any issues that you may have experienced.

Final Study visit: At week 22, both Group 1 and Group 2 will answer the same questions asked at the initial study visit about how you manage your diabetes, how confident you are in diabetes self-management, your mood, and how you feel about your cognitive function. You will also be

asked to take the same five tests you took at Study Visit 1 to assess your memory, attention, speed of thinking, and motor speed.

How long will you be in this study and how many people will be in the study?

Sixty-six people will participate in this study. The study will last for 2 years, but you will only be asked to participate for 22 weeks.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. They are minimal as there are no known physical risks to educational and computer assisted interventions except for potential loss of privacy or confidentiality.

Some participants may experience some stress by working through cognitive tasks that are unfamiliar. The main risk lies in changing diabetes self-management (SM) habits, which may lead to temporary alterations on blood glucose although the goal of the intervention is to improve SM and ultimately improve blood glucose levels. Changing SM habits may result in fluctuating blood glucose leading to low blood sugar without a change in medication. You will be given information on monitoring for and managing low blood sugar prior to the start of the intervention. You will also be instructed to call your health care provider if you have any low blood sugar.

There are minimal risks with wearing CGM sensors. Applying the sensor may cause bruising or bleeding and some patients may experience mild pain as the device is fitted. However, this pain is temporary and is similar to finger pricks for blood glucose monitoring. We will use the CGM equipment with other study participants. The sensors will not be shared. The transmitter wirelessly sends your blood sugar information from the sensor to the receiver. The transmitter, which snaps into the sensor, will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use. The FDA approved the CGM as a “single use device.” This means that they recommend that only one person use this device at a time as there is a rare risk that a bloodborne pathogen, such as Hepatitis B, may be spread if used with multiple patients.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

You might benefit from being in this study because there you may increase your knowledge about strategies to manage cognitive symptoms and improve cognitive functioning through the computer assisted training.

What will happen to the samples and/or data we collect from you?

As part of this study we will collect information from you about glucose control, diabetes self-management, and cognitive function. All of your answers and results will be kept on a secure, password protected sites (Qualtrics and UT Box). Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not

detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

BrainHQ data: All personal and customer data are kept confidential and stored securely by BrainHQ to ensure safety. The information that is created when you use BrainHQ; for example, the record of your internet protocol address or your usage, progress, and performance in the Apps (collectively, "Training Data"); is owned by Posit Science and its licensors. Individual personal information will never be shown to, sold, or used by anyone outside of BrainHQ or the research staff. We analyze data on an anonymous basis; it is aggregated with the data of many other participants. In the event that we share or publish the results of our studies, results will be aggregated with others or disguised to make it impossible to identify anything about individuals from the data.

How will we protect your information?

Your privacy and the confidentiality of your data will be protected. Answers to study surveys, cognitive test results, and glucose data will be collected in either a private exam room or location of your choice by a member of the research staff.

Your name will not be linked to any of the questionnaires, test results, or glucose data.

Information about you may be given to the following organizations:

- The study sponsor and/or representative of the National Institutes of Health
- Representatives of UT Austin and the UT Austin Institutional Review Board

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you.

A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

We plan to publish the results of this study. To protect your privacy, we will/will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

What if we learn something about your health that you did not know?

As part of this study, we may learn medically relevant information about you. If we learn something that you and your doctor did not know, we will contact you as well as your primary care physician.

How will we compensate you for being part of the study?

The University of Texas at Austin

You will receive a small incentive ($25) for completing the first two data collections and ($50) for the final assessment ($100 total). You will be responsible for any taxes assessed on the compensation.

You will receive an online Tango card for your participation in this study.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin. You are not waiving any of your legal rights by participating in this study.

What other choices do you have if you do not take part in this study?

There may be other ways of treating your condition if you do not wish to be in this research. Check with your health care provider to discuss other options.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, all data pertaining to your participation will be destroyed.

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Heather Cuevas, PhD, RN, ACNS-BC
Phone: 512-422-6059
Email: hcuevas@mail.nur.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

The University of Texas at Austin

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date