Continuous Glucose Monitoring with a Low Carbohydrate Diet to Reduce Weight in Patients with Pre-Diabetes

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Project Title: Continuous Glucose Monitoring with a Low Carbohydrate Diet to Reduce Weight in Patients with Pre-Diabetes

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List of Personnel:

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Busui, Rodica	Professor	Endocrine	CGM/Diabetes Expert
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Saslow, Laura	Professor	Nursing	Low-Carbohydrate Expert
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Abstract

Background

Type 2 Diabetes is preventable yet few people diagnosed with pre-diabetes attend diabetes prevention programs. New strategies are needed to support people with pre-diabetes who are working to reduce their risk of converting from pre-diabetes to type 2 diabetes. Lower cost continuous glucose monitoring (CGM) technology may facilitate supervised and clinic-based approach to diabetes prevention.

Objective

The objective of this single arm pilot and feasibility study is to show that CGM feedback combined with a low carbohydrate diet can reduce the percentage of time CGM readings are above the normal range in patients with pre-diabetes.

Methods

We will recruit 10-15 adult pre-diabetic patients from the Michigan Medicine, Family Medicine clinic at the Livonia Health Center. Participants will be identified by chart review and invited to participate by letter and screened for eligibility by phone call. Eligible participants will attend a baseline visit and 2 follow up visits at the clinic. They will wear two CGM sensors for a total of 20 days of glucose monitoring and they will receive instruction in low carbohydrate eating. Primary outcome will be participant satisfaction with secondary outcomes including feasibility, weight change, % of time glucose above 140, side effects of low carbohydrate eating and qualitative participant experience.

Impact/ Implications

Through this study we will demonstrate the feasibility using CGM with a low carbohydrate diet to reduce weight and risk of developing diabetes in patients with pre-diabetes.

1.0 Significance

Type 2 Diabetes is a preventable disease, but incidents of diabetes continue to increase worldwide. New strategies are needed to support people with pre-diabetes who are working to reduce their risk of converting from pre-diabetes to type 2 diabetes. Individualized treatment that incorporates feedback to the patient about their glycemic response to dietary choices may prove to be effective in helping patients change their diets. Newer low cost and user friendly continuous glucose monitoring (CGM) technology, costing approximately $25.00 for 10 days of continuous monitoring with real time feedback may facilitate diet and exercise behavior change. This approach which is initiated during a one-on-one clinical encounter rather than in a stand-alone behavioral group class incorporates close clinical but remote monitoring and lower carbohydrate strategies. Results from this study will provide pilot and feasibility data to support a large grant application to NIH.

Specific Aim #1: Determine if CGM feedback combined with a low carbohydrate diet can reduce the percentage of time CGM readings are above the normal range in patients with pre-diabetes.
Specific Aim #2: Test the feasibility and acceptability of having patient with pre-diabetes wear CGM sensors and record diet, exercise and side effects on a low carbohydrate diet.
Specific Aim #3: To determine if cravings and hunger correlate with glucose below the normal range as detected by CGM in patients with pre-diabetes.

2.0 Originality

The diabetes prevention program incorporates a traditional high-carbohydrate low-fat diet. Our previous pilot work has demonstrated that a lower carbohydrate diet plan can improve weight loss in patients with pre- diabetes. However, as with all behavior modification programs, adherence is a problem. By incorporating CGM feedback and monitoring into the lower carbohydrate program, patients will have the support they need to effectively change their behavior. While it is difficult to do the intensive training and support for dietary change in the context of a physician visit, the remote monitoring using CGM makes it more feasible to use an efficient team- based approach to individualized behavior change counseling in a clinical context.

Previous Work: Dr. Richardson was the Principle Investigator on the VA's National Diabetes Prevention Program Clinical Demonstration Project and she has published 10 peer reviewed original research papers related to diabetes prevention in the last 24 months. In addition, our low carbohydrate diabetes prevention research team recently completed a pilot and feasibility study of a low carbohydrate diabetes prevention intervention in which we enrolled 22 patients and which resulted in a mean weight loss of 9.4 pounds (SD 10.7), mean reduction in A1C: 1 (SD .2). Qualitative results support feasibility and acceptability of low carbohydrate diet for diabetes prevention

3.0 Methods

3.1 Study Design: Single arm pilot and feasibility study.

Outcomes;

Primary: Participant Satisfaction	Items on f/u survey and qualitative interview
Secondary:	
Feasibility	Successful recruitment, Successful sensor wears time 20/22 days, Data retrieved from sensor successfully
Weight Change	Weight at final visit – weight at 2nd visit
Knowledge of Low Carbohydrate Eating	Low Carb Knowledge Scale – final - baseline
Cravings and Hunger	Ratings on food logs
Intention to continue Low Carbohydrate eating	final survey question
Side effects of CGM wear, Low Carbohydrate eating	Side effect log
Utility of CGM feedback for changing diet	Qualitative Interview

3.2 Study Population and Recruitment:

As identified though MiChart and Data Direct searches, 10-15 adult Michigan Medicine patients who qualify based on inclusion and exclusion criteria will be contacted via US Mail regarding their participation in our study. This letter will explain the study and its requirements and will be accompanied by an opt-out postcard that can be returned if the patient no longer wishes to be contacted. Those who do not return the postcard will be contacted via telephone with further information about the study. Recruiting will also be accomplished through a posting on the UM Health Research website as well as printed materials such as fliers and brochures. Interested and eligible participants will be scheduled to attend a one-on-one in-person baseline visit with the study coordinator at Livonia Health Center.

3.3 Inclusion/Exclusion Criteria:

- 21+ years of age
- A1C 5.7 to 6.4
- No Diabetes medication including Metformin
- BMI >30
- Must speak, read, and write in English
- Must have a phone
- Must have a computer
- Interested in changing diet to improve health
- No current pregnancy
- No previous Bariatric surgery
- Must not classify as either Vegan or Vegetarian
- Must be a patient at the Livonia Health Center

3.4 Informed Consent: At the baseline assessment the Research Coordinator will thoroughly review the Informed Consent document with the participant. If valid informed consent is freely given the baseline data collection will begin.

3.5 Phase One, In-Person Appointment:

- Obtain a valid informed consent
- Baseline measurements including weight, height, and blood pressure

- Power point presentation outlining the study and the participant's role in Phase One.
- Teaching on continuous glucose monitor and how it will be used to monitor their blood glucose reactions to the food that they consume.
- Application of an Abbott Libre **Pro** sensor (no real time feedback) to the backside of the participant's non-dominant arm.
- The participant will be asked to:
    - leave the sensor in place for a period of 11 days
    - complete a food log during that time, documenting what they consume
    - Rate their postprandial hunger and fatigue 2 hours after eating
- Participants will be given a wrapped copy of the book, "Always Hungry" by Dr. David Ludwig and asked not to open the book until after they receive their health check phone call on Day 5.
- Participants will then be given the Study Coordinators contact information
- Appointments for the second and third meeting will be made.

3.6 Health Check Phone Call: Approximately 5 days after each new sensor is p

- A member of the study team will call the participant to ensure that the participant is experiencing no ill effects from wearing the sensor.
- The study team member will also answer any questions that the participant may have regarding the sensor or the study in general.
- The study team member will then ask the participant to open their copy of the book, "Always Hungry" by David Ludwig and encourage the participant to read chapters 1-5.

3.7 Phase Two, Intervention Appointment: Approximately 11 days after their first appointment:

- Participants will return to the Livonia Health Center for a second one-on-one meeting.
- Weight, and blood pressure will be repeated.
- Participants will then take a brief survey.
- The Abbott Libre Pro sensor will be removed.
- Data captured by the sensor will be uploaded and printed for the participant.
- All uploaded data will be reviewed with the participant and compared to their completed food Log.
- Participants will be shown a Power Point presentation that discusses their role in Phase Two.
- Abbott Libre **personal** sensor (with meter for real time feedback) will be applied to the back of the participants non-dominate arm.
- Participants will be taught about carbohydrates and the benefits of eating a low carbohydrate diet.
- Participants will be given a new food log and asked to:
    - document the food that they consume
    - rate their postprandial hunger and fatigue two hours after eating
    - document their blood sugar before and two hours after eating
- Participants will be given multiple resources to assist them in determining how many carbohydrates are in the foods they consume.
- Participants will be given the book entitled, "The Calorie King, Calories, Fat, and Carbohydrates," which lists the calorie, fat, and carbohydrate content of various foods.
- Possible side effects of low carbohydrate diet will be discussed with the participant and information on how to mitigate the effects of the diet will also be provided.

- Patients will be instructed to fill out a side effect log as well as their diet log during this phase.
- Participants will complete an information sheet, voluntarily suppling their address as well as any information about food allergies they may have.
- Participants will choose two recipes from a group of five options that they would like to make for themselves and/or their immediate family.

3.8 Grocery Delivery: Approximately two days following the participants second visit all of the ingredients for one of their chosen recipes will be delivered to the address provided. All of the ingredients for the second recipe that the participant has chosen will be delivered approximately five days later.

3.9 Follow-Up Visit: Approximately 11 days after the intervention visit:

- Participants will have the second sensor removed.
- Data obtained by the sensor will be uploaded and printed out for their review.
- Participant's data will be compared to their completed food log.
- Participants will also be provided with a letter to take to their Primary Care Physician (PCP) explaining the study and asking for a prescription for an Abbott Libre personal sensor so that the participant may continue tracking their blood glucose levels following the study.
- Participants will take the "Completion Survey"
- Participants will receive either a check or a voucher for $25.00 for completing the survey and all three of their in-person appointments.
- Participant wishes to continue wearing a CGM and has found that it has been an effective way to assist them in consuming a low carbohydrate diet, they will be given a letter addressed to their Primary Care Physician asking for a prescription to continue using the Abbott Libre personal CGM sensors and reader.

3.10 Semi-structured qualitative interview: After the participant has completed all three visits with the Research Coordinator and have worn both CGM sensors, they will receive a telephone call from the studies mixed methods interviewer who will conduct a semi-structured qualitative interview. Each participant will be asked a series of questions concentrating on their satisfaction with the CGM sensors and devices, how their diet has been effected by wearing the CGM sensors, and how they feel about having been diagnosed with pre-diabetes.

3.11 6-month Follow-up Telephone Interview: A member of the research team will call each participant six months after they have completed all three appointments to conduct a second semi-structured qualitative interview. Each participant will be asked a series of questions designed to ascertain whether or not the study has had continued impact on their diet and ability to prevent the transition to Type 2 Diabetes. The participant will be asked questions like whether or not they have continued their effort to avoid carbohydrates and whether or not they have worked with their Primary Care Physician to obtain their own personal continuous glucose monitor.

4.0 Feasibility

This is a pilot and feasibility study. Our team has extensive experience using older style CGMs in type 1 diabetic patients and we have conducted preliminary usability testing in 10 study staff using the new CGM sensors, however we have not conducted this type of intervention in patients with pre-diabetes recruited in a clinical

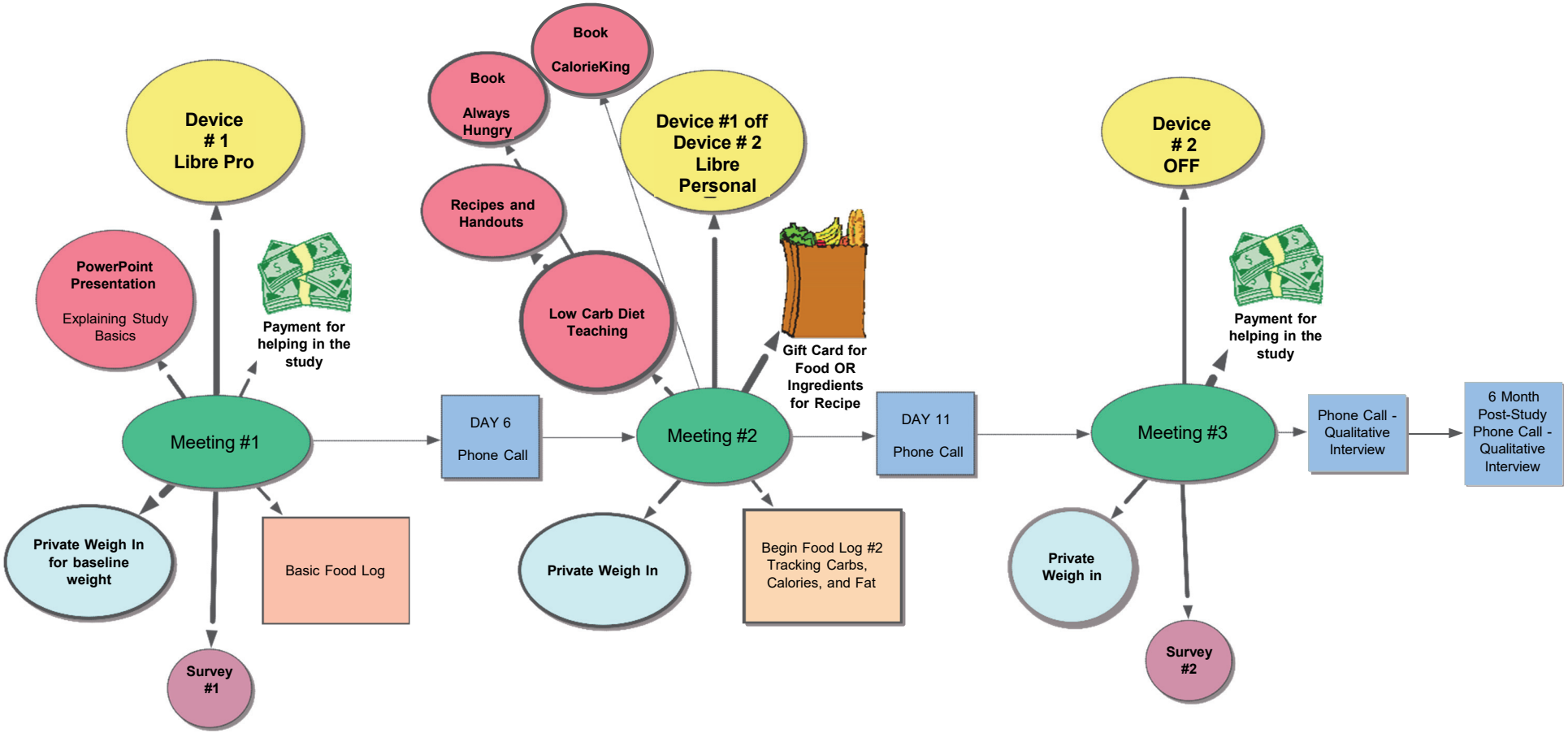
setting. Additionally, we have experience successfully teaching a cohort of patients with pre-diabetes to eat a lower carbohydrate diet for weight loss. We will incorporate some of the lessons learned from that pilot into this pilot and feasibility study as well. Recruitment for 10 to 15 individuals with pre-diabetes from the Livonia Health Center should not be difficult and the Livonia medical director has already agreed to support the trial. A full time research coordinator who is also an experienced medical assistant and who has experience using CGM will be conducting study procedures at Livonia

5.0 Qualifications

Name	Expertise
Richardson, Caroline	PI: A practicing Family Physician with a long track record of leading large federally funded Diabetes Prevention Program Implementation studies.
Buis, Laurie	Informatics/eHealth expert with experience conducting usability and feasibility studies using remote monitoring technology
Busui, Rodica	Endocrinologist and clinical trialist, CGM/Diabetes Expert
Czuhajewski, Christina	Informatics Design/Communication expertise
Dejonckheere, Melissa	Qualitative interviewer and coder
Mahmoudi, Elham	Health Economist to assist with estimating costs from the user perspective of eating a lower carbohydrate diet
Saslow, Laura	Low- Carbohydrate Expert
Sen, Ananda	Statistician
Stonebraker, Spring	Research Coordinator/Medical Assistant/CGM Expert

6.1 Timeline

	1	2	3	4	5	6	7-12?
Start – June 1	X						
Recruitment	X	X					
Data Collection	X	X	X	X		X	
Analysis				X	X	X	
Manuscript Preparation							X


Device # 1 Libre Pro
PowerPoint Presentation
Explaining Study Basics
Payment for helping in the study
Meeting #1
Private Weigh In for baseline weight
Basic Food Log
Survey #1
DAY 6
Phone Call
Book
CalorieKing
Book
Always Hungry
Recipes and Handouts
Low Carb Diet Teaching
Device #1 off
Device # 2
Libre Personal
Gift Card for Food OR Ingredients for Recipe
Meeting #2
Private Weigh In
Begin Food Log #2 Tracking Carbs, Calories, and Fat
DAY 11
Phone Call
Device # 2 OFF
Payment for helping in the study
Meeting #3
Private Weigh in
Survey #2
Phone Call - Qualitative Interview
6 Month Post-Study Phone Call - Qualitative Interview

3.2 Study Population and Recruitment

- Data Direct will be used to identify those patients at the Livonia Health Center that have pre-diabetes.
- Once those patients have been identified a MiChart search will be used to determine if other eligibility criteria are met and to obtain potential participants addresses.
- A letter explaining the study and the basic requirements for participation will be sent to the primary address of the potential participants.
- The letter will be sent along with a post card asking that the participant return the card if they do not wish to be contacted further.
- If we do not receive the post card back in the mail it will be assumed that the potential participant would like to participate in the study.
- A follow up phone call will be made to all of those identified and did not return the post card to explain the study in further detail and to make arrangements for their first appointment.
- In addition to the Data Direct search, a post about the study will be placed on the UM Health Research website asking for potential volunteers that meet the outlined criteria.

3.4 Informed Consent

- Each page of the informed consent document will be reviewed with the potential participant.

- After it is determined that the participant understands the Informed Consent document; the participant will sign and initial in appropriate places and freely give their consent to be part of the study.

3.5 Phase One, First In-Person Appointment

- Upon completion of this appointment the participant will receive either a check or a voucher for $25.00 in gratitude for taking the survey and for taking part in this study.

3.5.1 Measurements

- **Weight:**
  - Participants will be asked to remove their shoes, coats, and any other heavy outerwear.
  - Participants will be asked to set down any other belongings and empty their pockets of anything that may add additional weight to the scale.
  - Participants will then stand on the Livonia Health Center Clinic scale to be weighed.
  - Weight will be recorded on the Patient's measurement record labeled with their study ID only
- **Height:**
  - Participants will leave their shoes off and will stand with their back against the standard U of M clinic wall mounted height measurement board.

- Participant will push their heels back as far as they are able and will stand fully erect with shoulders back against the height board.
- The height indicator will be set to rest on the top of the participant's head
- The height will be documented on the Patient's measurement record labeled with their study ID only.

- **Blood Pressure:**
  - Participant will be asked to sit in a chair with their feet flat on the floor.
  - The appropriate sized arm cuff will then be applied to either the patient's upper right or upper left arm
  - The patient will leave their arm outstretched at an angle of approximately 90 degrees to their torso and resting on either the DynaMap Automatic Blood Pressure machine stand or something of similar height.
  - Patient's blood pressure will then be obtained via the automatic DynaMap blood pressure machine standard to all U of M clinics.
  - Blood Pressure will be documented on the patient's measurement record and labeled with their study ID only

- **HbA1c:**
  - The participant's most recent A1c level will be obtained from Michart and documented along with the date it was resulted on the patient's measurement record and labeled with their study ID only.

3.5.2 Baseline Survey

- Participants will be asked to complete a brief, survey of approximately 45 questions over a period of approximately 15 minutes.
- Survey will contain questions relating to: diabetes and diet experiences, hunger and cravings, post-prandial fatigue, carbohydrate knowledge, current attitudes about health, and numeracy.

3.5.3 PowerPoint Presentation

- Participant will be shown a series of slides describing the scope of the study as well as how the study will progress and what the participant's requirements are.
- The Participant will be given a printed copy of the slides to review
- The Study Coordinator will review each slide along with the participant, stopping to answer any questions that may arise.

3.5.4 Abbott Freestyle Libré Pro and Sensor

- Participant will wear an Abbott Libre Pro sensor on their arm for a total for 11 days
- The first day the sensor will be adjusting to the participants' unique physiology so that the most accurate blood glucose levels and estimated A1c will be reported.
- The participant will receive no real time feedback.

3.5.5 Continuous Glucose Monitor Application

- The application of the device will be explained in detail to the participant prior to application.
- The Participant will expose the upper portion on the backside of their non-dominate arm
- The medically trained Study Coordinator will use an alcohol wipe to clean a large circular area around where the CGM sensor is to be applied.
- After the alcohol dries the Study Coordinator will use a Skin-Tac wipe to create an adhesive surface in an area around where the CGM sensor is to be applied.
- The CGM sensor will be removed from the packaging and assembled according to packaging instructions and training.
- The Sensor application device will then be place gently against the application site and the plunger will be pushed in with slight force and will remain pushed in for 2 seconds.
- The sensor applicator will then be removed leaving the sensor in place.
- The applicator will then be discarded.

3.5.6 "Always Hungry?" by Dr. David Ludwig

- Participants will receive a wrapped copy of this New York Times #1 Bestselling book.
- Participants will be asked not to begin reading the book until Day 5 of Phase 1, after they receive their Health Check phone call.
- This book, broken in to 3 phases describes the science behind why our bodies gain weight, store fat, and how the food that we eat impacts our ability to change that.
- Contains multiple low-carbohydrate, high fat recipes and meal plans to assist in changing diet and increase knowledge about the foods that your body needs.

3.5.7 Phase One Food Log

- Participants will be asked to complete a daily food log
- Log asks participants to write down the food that they eat and what time they are it.
- Participants are asked to record their food intake in general terms rather than breaking it down in to chloric content, Protein content, or carbohydrate content
- Approximately 2 hours after eating participants will also document their level of hunger and post-prandial fatigue

3.5.8 Follow-Up Appointments

- Participants will be directed to the Reception Desk at the Livonia Health Center so that a member of the front desk staff can assist them in making their follow up appointments.
- These appointments will then be written down on a blank Calendar provided to each participant so that we can ensure that they are aware of when to arrive to remove their first

sensor, when to expect their Health Check phone call, and when visits two and three will take place.

3.6 Health Check Phone Call

- On Day 6 of the participant wearing the first sensor as well as on day 6 of participant wearing the second sensor
- Participants will receive a phone call from the study team's mixed methods qualitative Interviewer at a time prearranged when making other appointments
- Participant will be asked a brief series of questions designed to ensure that the participant is experiencing no ill effects from wearing the CGM sensor on their arm
- Interviewer will also ask questions regarding the participant's food log to ensure their understanding as well as to remind them to be documenting honestly
- Participants will be asked to unwrap their copy of Always Hungry? And begin reading chapters 1-5.

3.7 Phase Two, In person Appointment

3.7.1 Measurements

- Participants' Weight and Blood Pressure will be repeated as described In section 3.5 and documented in the participants measurement log.
- An estimated A1c will be obtained from the sensor data retrieved by scanning the sensor using the Abbott Libre Pro reader.

3.7.2 Letter to Primary Care Physician

- If the participants estimated A1C, as indicated on the report from their sensor, is higher than 6.4%, this would indicate that the participant may have progressed to Type 2 Diabetes.
- A letter addressed to the participant's Primary Care Physician will be given to the participant.
- This letter will describe to the physician that the participants estimated A1C fell in to the range of Type 2 Diabetes
- The letter will urge the Primary Care Physician to obtain a blood level A1C to assess the patient's true diabetes status rather than relying on the estimated A1C that we are providing the participant.

3.7.3 Sensor Scanning and Removal

- Using the Abbott Freestyle Libre Pro reader the study coordinator will scan the participants' sensor
- Sensor will then gently be removed from the participant's arm
- The area where the sensor was applied will be wiped down with an alcohol wipe to ensure that the area around the small puncture wound created by the microfilament remains free from any contaminants
- The Reader will be connected to the computer via USB and the sensor data will be uploaded by the Abbott Libre Pro software, Libre View.

3.7.4 Abbott Libre Reports

- A series of reports will be produced by the software based on the information obtained from the participant's sensor data.
- Reports will be labeled solely with the participant's study ID.
- Reports include: Daily Blood Glucose Pattern report, Glucose Pattern Insights report, A Daily Glucose Summary Report, and a Snapshot or 11-day summary report

3.7.5 PowerPoint Presentation

- Participants will be shown a series of slides containing information about the reports that they will receive based on their first sensor reading.
- Instruction about the information they will receive from their second sensor
- Participants will be given basic information about the relationship between carbohydrate intake and blood glucose levels.
- Participants will be taught about the Abbott Libre personal sensor and reader that they will be using during phase 2.
- Discussion and slides regarding the importance of low carbohydrate diet
- Teaching about the difference between simple and complex carbohydrates and which should be included in a healthy low carbohydrate diet and which should be avoided.
- As part of the teaching on low carbohydrate dieting we will discuss the health benefits and side effects that occur when transitioning to a lower carbohydrate diet.

3.7.6 Phase 2 Food Log

- Participants will be asked to complete a daily food log
- Log asks participants to write down the food that they eat and what time they are it.
- Participants are asked to record their food intake in general terms rather than breaking it down in to chloric content, Protein content, or carbohydrate content
- Approximately 2 hours after eating participants will also document their level of hunger and post-prandial fatigue
- Participants are asked to document the blood glucose reading that is displayed on their Abbott Libre personal reader when they wake up in the morning as well as their last reading before they go to bed.
- Participants will also log their blood glucose levels before every meal/snack and then again 2 hours later when they assess their hunger and post-prandial fatigue levels.

3.7.7 Abbott Freestyle Libré personal Sensor and Reader

- Following the PowerPoint presentation and low carbohydrate teaching, participants will have a new sensor applied to the underside of their upper arm on their non-dominate side.
- Sensor number 2 will be applied using the same technique that sensor number one was applied with. This method is outlined in section 3.5.5
- This new sensor will be calibrated to connect to the Abbott Freestyle Libré personal device which will allow participants to receive real time data as well as a glucose reading whenever they use their reader device to scan their sensor.
- Obtaining a reading from the sensor only requires that the reader pass in front of the sensor. This can be done through clothing and never requires a finger stick.
- Participants will be asked to scan their sensor at least once every 8 hours.

3.7.8 Side Effect Log

- Participants will be asked to document and side effects that they experience and when they occur on a side effect log.
- This log will be reviewed so that suggestions can be made about how they could further alter their diet to relieve these side effects.

3.7.9 The CalorieKing: Calorie, Fat, and Carbohydrate Counter (2017):

- All participants will receive a copy of the book, The CalorieKing: Calorie, Fat, and Carbohydrate Counter (2017).
- This book will assist the participants in deciding which foods to eat and which to avoid while eating in such a way as to reduce carbohydrate consumption.

3.7.10 Recipes

- Participants will be given 5 recipes that are copied directly from either, *"Always Hungry?"* By David Ludwig, or *Always Delicious* by Dawn Ludwig
- Participants will be asked to choose 2 of the recipes that they would like to make for themselves and/or their family.

3.8 Grocery Delivery

- After the participants have chosen two recipes that they would like to try from the five available options, Arrangements will be made to have all of the ingredients for these recipes delivered to the participant's home in two separate deliveries scheduled 5 days apart.
- The Research Coordinator will ask the participant to provide the address that they would like the groceries delivered to, the number of people in their family that the meal will be prepared for, and a list of any food allergies that they or their family members have.

3.9 One-on-one Follow-up Visit

- When Participants arrive for their second appointment they will again have their weight and blood pressure taken as outlined in section 3.5.1.
- The Second sensor will be removed and the reports produced by the sensor will be uploaded and printed out to be gone over with the participant
- The participant's food log will then be compared to the reports produced by the sensor so that some conclusions can be drawn regarding the participant's carbohydrate intake and the reaction of their blood glucose levels.
- The participant will complete one final survey that is designed to be taken within a 10-15 minute period.
- If the participant indicates that they would like to continue wearing the continuous glucose monitor a letter will be sent to their primary care physician requesting a prescription for the patient so that they may obtain one from their pharmacy.
- The participant will be given a check or voucher for their final payment of $25.00 for completing the study.

3.10 Semi-Structured Qualitative Interview

- After all three in-person visits have been completed
- The Mixed Methods Interviewer will call the participant to discuss the study
- Questions will revolve around the participant's satisfaction with the CGM sensors and the phase-two reader, how their diet was effected by the CGM sensor and information that it gave them, and how they feel about having been diagnosed with pre-diabetes.

3.11 6-Month Follow-up Telephone Interview

- Six months after the participant has completed all three study visits they will receive a telephone call from the studies Mixed Methods Qualitative Interviewer.
- The Interviewer will ask questions about the impact that the study has had on their diet, whether or not they have become diabetic and whether or not they made any effort to obtain their own continuous glucose monitor.