T2 Connect: Adaptation of a Digital Weight Loss Intervention Promoting Self-regulation for Use in Type 2 Diabetes

Unique Protocol Identification Number: UNCWR18-2805
National Clinical Trial (NCT) Identified Number: 03650088
Principal Investigator: Deborah Tate
IND/IDE Sponsor: n/a
Funded by: Michigan Center for Diabetes Translational Research
Version Number: 3.0
28 May 2020

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title: T2 Connect: Adaptation of a Digital Weight Loss Intervention Promoting Self-regulation for Use in Type 2 Diabetes

Study Description: The purpose of this study is to adapt a previously developed weight loss app implementation with a study population living with impaired glucose (pre-diabetes or type 2 Diabetes (T2DM)), integrating daily monitoring of blood glucose (BG) using continuous monitoring (CGM) into the intervention) and to conduct a pilot and feasibility study on the short-term impacts of the 12-week intervention in overweight adult patients with pre-diabetes or T2DM not being treated with medications to gather preliminary data in preparation for an R01 submission.

Objectives:

Primary Objective: The primary objectives of the study are to 1) review previously developed weight loss intervention features and adapt them to the needs and perspectives of those with impaired glucose or type 2 diabetes in a new modified intervention, 2) conduct a pilot and feasibility study on short-term impacts of the intervention in overweight adult patients with T2D not treated with medication (n=20) in preparation for an R01 submission.

Secondary Objectives: To explore the effect of the intervention on short-term blood glucose control, perceived self-control, and perceived quality of life.

Endpoints:

Primary Endpoint:

- Change in body weight (kg) from baseline to 12 weeks.

Secondary Endpoints:

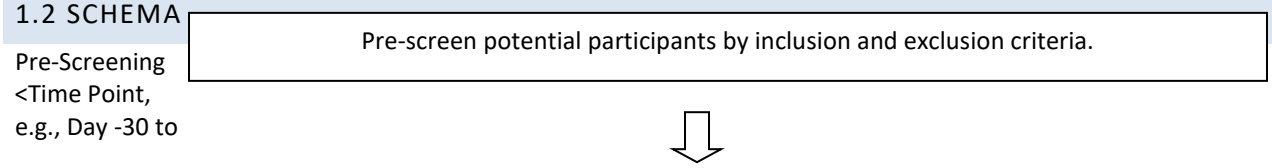
- Change in Body Mass Index from baseline to 12 weeks.
- Change in HbA1c from baseline to 12 weeks.
- Change in compliance behavior and efforts at diabetes self-control from baseline to 12 weeks as measured by the Diabetes Locus of Control Scale
- Change in Diabetes-related Quality of Life from baseline to 12 weeks as measured by the Diabetes Obstacles Questionnaire.

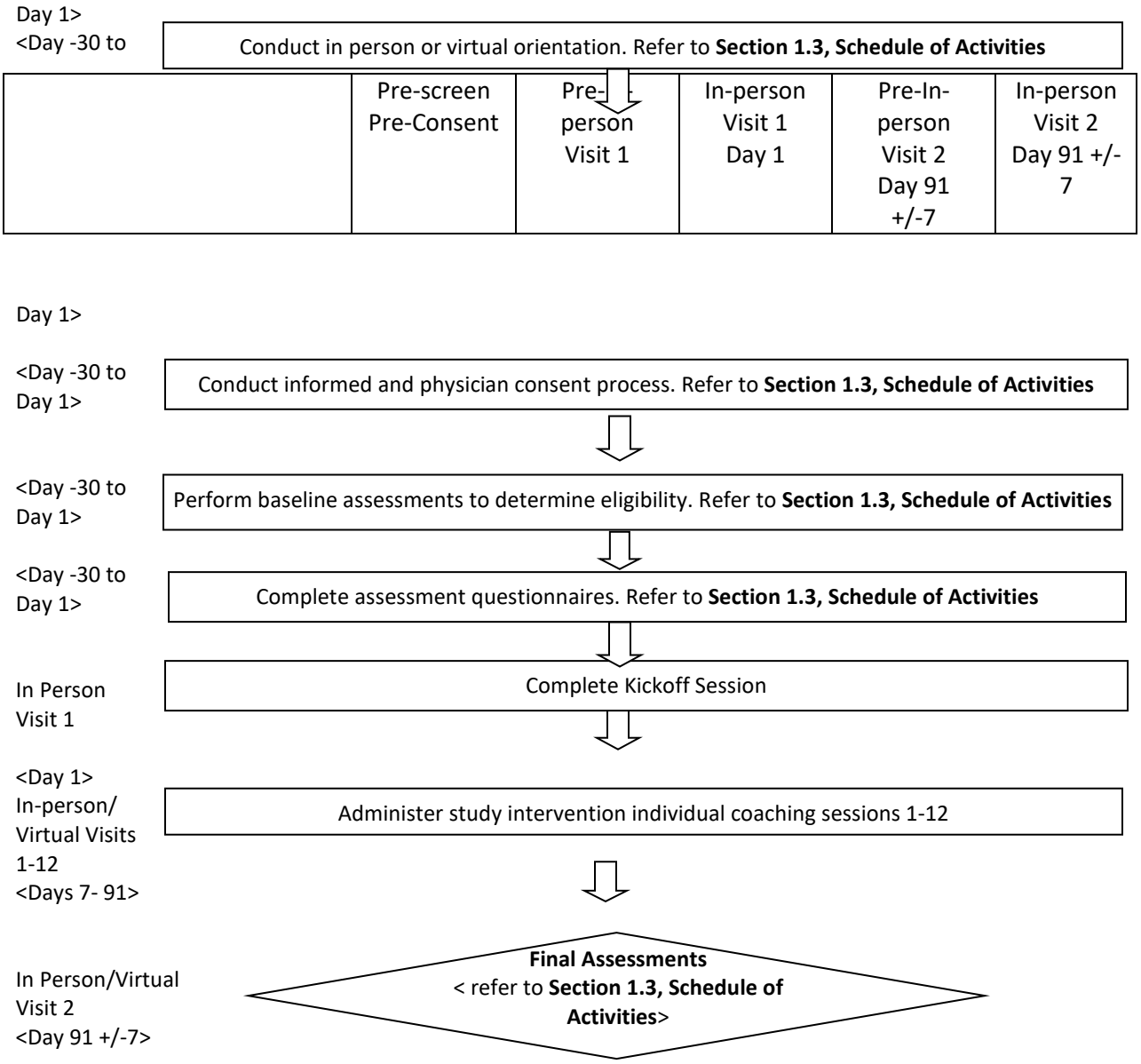
Study Population: Adults 18-65 years old with BMI 25-40 kg/m^2 who meet the criteria for pre-diabetes or type 2 diabetes and who do not take medication to manage their blood glucose.

Phase: Pilot

Description of Sites/Facilities Enrolling Participants:	Participants will be recruited and enrolled at the UNC Weight Research Center in Chapel Hill, NC.
Description of Study Intervention:	The intervention will be delivered through weekly in-person or virtual individual sessions; a mobile iphone app that integrates diet, weight, and physical activity; and continuous blood glucose data, to support self-regulatory behaviors. In the first weekly session, participants will be oriented to the intervention and provided with their self-monitoring tools. They will be encouraged to weigh and track physical activity with a wearable activity monitor, "Red" foods (using a simplified dietary self-monitoring approach that classifies foods in a "Traffic Light approach", weight using a wifi-enabled digital scale, and blood glucose daily (Abbot Freestyle Libre Continuous Glucose Monitor). They will be taught to use self-regulatory techniques for weight management and glycemic control. Similar to blood glucose self-regulation, participants are taught to compare the number on the scale each day to a standard or goal (weight loss goal) and, depending upon the comparison, make changes to their diet (i.e., Green foods or Red foods) and physical activity (i.e., moderate to vigorous physical activity (MVPA) or sedentary behavior (SB)) as needed. All participants will be given an initial weight loss goal of 5%.
Study Duration:	Approximately 12 months – participants will be accrued on a rolling basis.
Participant Duration:	Up to 4 months (screening and enrollment + 12-week intervention + follow-up assessment).

1.2 SCHEMA




Day 1>
<Day -30 to
Conduct in person or virtual orientation. Refer to **Section 1.3, Schedule of Activities**
Pre-screen Pre-Consent
Pre-In-person Visit 1
In-person Visit 1 Day 1
Pre-In-person Visit 2 Day 91 +/-7
In-person Visit 2 Day 91 +/-7
Day 1>
<Day -30 to Day 1>
Conduct informed and physician consent process. Refer to **Section 1.3, Schedule of Activities**
<Day -30 to Day 1>
Perform baseline assessments to determine eligibility. Refer to **Section 1.3, Schedule of Activities**
<Day -30 to Day 1>
Complete assessment questionnaires. Refer to **Section 1.3, Schedule of Activities**
In Person Visit 1
Complete Kickoff Session
<Day 1>
In-person/ Virtual Visits 1-12
<Days 7- 91>
Administer study intervention individual coaching sessions 1-12
In Person/Virtual Visit 2
<Day 91 +/-7>
Final Assessments
< refer to **Section 1.3, Schedule of Activities**>

Web Screening	X				
Phone Screening	X				
Orientation (In-person/Virtual)	X				
Informed Consent		X			
Physician Consent		X			
Demographics		X			
Contact Information		X			
iPhone Information		X			
Height			X		X
Weight			X		X
BMI			X		X
HBA1c			X		X
Diabetes-Specific Locus of Control		X		X	
Diabetes Obstacles Questionnaire		X		X	
Technology Acceptance Model-Continuous Glucose Monitoring		X		X	
Glucose Monitoring Satisfaction Survey		X		X	
Technology Acceptance Model-CGM-Follow-up				X	
Program Evaluation				X	
Medical Events					X

1.3 SCHEDULE OF ACTIVITIES (SOA)

2 INTRODUCTION

2.1 STUDY RATIONALE

Type 2 diabetes (T2D) represents a global public health crisis and is associated with increased rates of morbidity, mortality, and medical expenditures (1). Despite advances in prevention and treatment, rates do not appear to be subsiding (2,3). Of those living with T2D in the U.S., nearly 90% are overweight or obese (NIDDK). Modest reductions in weight (> 5%) have been shown to reduce symptoms, improve glycemic control, and reduce or eliminate pharmacotherapy regimens (4-6). Rates of conversion from prediabetes (impaired glucose) to diagnosed type 2 diabetes are of particular concern. It is estimated that 425 million adults worldwide are living with diabetes, representing a pronounced increase over the past few decades (7,8). In the United States, approximately 84 million adults (more than 1 out of 3) have prediabetes; however, 90% of people with prediabetes don't know they have it. Risk factors for prediabetes include overweight and lack of physical activity. While not everyone who is obese develops type 2 diabetes, obesity greatly increases the risk of developing type 2 diabetes.

In a 2017 Consensus Statement by the American Association of Clinical Endocrinologists and the American College of Endocrinology, the authors recommend weight loss of 5-10% for those with T2D whose BMI is > 25 kg/m^2 through comprehensive lifestyle intervention (9). Comprehensive lifestyle interventions are the gold standard in the behavioral treatment of obesity and diabetes (10). These evidence-based interventions include diet and physical activity prescriptions to reduce energy intake and increase expenditure; employ a variety of behavioral techniques to support these changes; and include in-person support from a multi-disciplinary team of interventionists. Changes in diet and activity as well as weight loss are essential for glycemic control in T2D. Lack of glycemic control leads to cardio- and micro-vascular complications that can significantly contribute to morbidity and mortality.

Glycemic control is generally measured using glycosylated hemoglobin (HbA1c), which evaluates longer-term (~over 3 months) management of blood glucose (BG) with a goal of <7% (11). More intensive daily monitoring of BG is associated with better glycemic control; however, few individuals with T2D not taking insulin follow a structured self-monitoring blood glucose (SMBG) regimen. Studies show that patients with T2D often lack the knowledge and skills to interpret BG information to make the necessary behavior changes to improve glycemic control (12,13). Use of SMBG has mixed results in the limited trials that have been conducted (14); however, there is evidence that it can be effective when patients monitor multiple times daily and are taught how to use the information (15). Therefore, optimizing SMBG with state-of-the-art knowledge of how it may be enhanced by and incorporated within effective behavior change may identify previously unrecognized benefits. In particular, incorporating SMBG in a lifestyle intervention may contextualize glucose levels more specifically, provide relevance to self-regulatory behaviors, increase feelings of self-control, and, thereby, improve ongoing self-management of T2D.

This pilot and feasibility study of an intervention called T2 Connect, will serve several aims toward applying for future NIH funding. The study will establish the feasibility of recruiting this population, integrating blood glucose self-monitoring data into the weight loss intervention and adaptation of the Traffic Light monitoring approach for weight loss in adults living with impaired glucose. These data and experiences, if promising, combined with data from prior studies, will position the team to apply for an R01 to demonstrate the initial efficacy of the intervention in a larger study population.

2.2 BACKGROUND

Comprehensive lifestyle interventions are intensive and typically result in average weight losses of 8-10% (11). Despite their overall efficacy, 30% or more of participants do not respond to treatment (i.e., lose 5% of initial body weight, which has been shown to confer clinically significant improvements in disease risk and outcomes) (16). There are many hypothesized reasons for non-response to treatment, including non-adherence to diet and exercise prescriptions and poor self-monitoring. Self-monitoring is a cornerstone in behavior change interventions (17) that, while effective, can be burdensome. Non-adherence may be due to psychological factors such as lack of feelings of control over disease management, low self-efficacy for change, or feelings of deprivation; cognitive factors such as intervention complexity and burden; and physical factors such as hunger or discomfort with physical activity. Effective interventions must promote sustainable changes in behavior which are reinforced by an individual's self-efficacy for engaging in the behaviors and positive reinforcement for attaining desired outcomes.

Self-regulation of behavior is an intervention approach to manage weight and to control blood glucose. Self-regulation involves having a goal, having access to information about whether the goal is being achieved, and if not, taking steps to restore equilibrium. Self-regulation has been widely applied to type 1 diabetes, where an individual must be knowledgeable about the level of blood glucose they are trying to achieve, monitor their glucose to see if there are discrepancies between their goal and their actual blood sugar, and then if there are discrepancies, they must adjust their diet, exercise, or insulin dose to reduce the discrepancy. Self-monitoring of blood glucose has been achieved by serial finger sticks throughout the day, although emerging technologies including continuous self-monitoring and flash self-monitoring are becoming more widespread and associated with tighter control (18).

Those who can adhere to self-monitoring are more likely to master self-regulation. In one study, patients with diabetes reported a fairly high willingness to self-monitor, which authors relate to the controllability of the disease (19). Being able to see the impact of one's behaviors on outcomes of interest (i.e., weight and glucose) may increase feelings of control and self-efficacy and provide the internal rewards that will sustain the behavior changes desired. We have successfully applied self-regulation in the context of weight loss and weight gain prevention interventions with the use of daily weighing to regularly assess outcome to inform diet and physical activity behaviors. Across the interventions, there was a high acceptability of daily weighing as a behavior change tool (20-23).

Diet self-monitoring is consistently associated with weight loss success across behavioral interventions (17), however, self-monitoring decreases over time. Diet self-monitoring traditionally consists of recording the types, amounts and nutritional content (typically calories and fat content) of all foods and beverages consumed daily for the duration of intervention. In a six-month weight loss study, self-monitoring adherence peaked at week 2 and dropped significantly after week 3. Other studies have shown adherence decline by 5 weeks (24-28). While mobile technologies introduced in the past 15 years have improved adherence, there remains a high percentage of program participants who are unable to monitor all foods eaten and meet a reduced calorie goal over an extended period of time, resulting in suboptimal weight outcomes.

Adherence to physical activity recommendations for weight management and diabetes control among individuals with T2D is also modest with the majority of patients generally sedentary (29,30). Interventions that use trackers (i.e., pedometers and accelerometers) to self-monitor physical activity have been effective in increasing physical activity in patients with T2D. However, comprehensive lifestyle interventions have similar rates of non-adherence to physical activity recommendations as dietary recommendations with only a subset of participants reaching recommended levels of MVPA (31). Emerging research suggests that reducing sedentary behavior in T2D also benefits glycemic control (32,33).

Self-monitoring blood glucose (SMBG) is an established treatment protocol in type 1 diabetes and in T2D treated with insulin. However, in those with T2D controlled through oral medications, SMBG is not common and, if implemented, is often not the structured regimen that is recommended for insulin-treated diabetes. A recent meta-analysis of SMBG with non-insulin treated T2D estimated modest reductions in HbA1c of 0.17% compared to no SMBG and a 0.27% reduction with structured compared to non-structured SMBG (15). Given the effectiveness of structured monitoring, the International Diabetes Federation recently supported structured monitoring for patients with non-insulin treated T2D as key component of care (34). Despite recommendations, clinical practice suggests that even if patients are monitoring BG, many do not use the information to modify their lifestyle or medications due to lack of knowledge or skills around self-management (13,35). Given the value of self-monitoring not only BG but also diet, physical activity and weight, an intervention that teaches the skills to self-regulate behaviors based on glucose and weight measurements could enhance improvements in glycemic control.

Diet, physical activity and weight loss directly affect blood sugar and vascular outcomes and the 2017 Consensus statement has specific recommendations for the diet and exercise prescription in T2D. It recommends weight management through a diet that is primarily plant-based, high in polyunsaturated and monounsaturated fatty acids, limited in saturated fatty acids and avoidance of trans fats, and limited sucrose-containing or high-glycemic index foods. Achievement of at least 150 minutes of moderate to vigorous physical activity (MVPA) (preferably > 175 minutes which has been significantly associated with weight loss in Look AHEAD (6) is also recommended.

Our research team has been conducting comprehensive behavioral lifestyle interventions for prevention of type 2 diabetes for over 15 years. Studies have used in-person, group and individual behavioral counseling with particular emphasis on uses of digital technology to support behavior change. We have published trials using daily weighing for weight loss (22) and for long term weight gain prevention (21). Both of these trials demonstrated significant benefit from the daily weighing interventions compared to controls.

We have also piloted a Red foods monitoring approach using mobile phones in mothers of preschool children. The Smart Moms study was a 6-month randomized controlled trial that tested the efficacy of a smartphone delivered intervention to reduce sugar-sweetened beverage and juice consumption among children ages 3-5 and maternal weight compared to a waitlist control group. The primary focus of the study was on limiting children's sugar-sweetened beverages, but mothers were also given dietary goals to help them lose weight, which included limiting caloric beverages to 8 fl. oz. per day and limiting "red foods" from the Traffic Light Diet to half of their baseline level of intake. To encourage adherence throughout the study, they engaged in a simplified form of self-monitoring that consisted of tracking their beverages, the number of times (not servings or calories) they consumed a "Red" food from the Traffic Light diet, and their weight daily in a small paper diary. They submitted their weekly totals via text message at the end of each week, which were used to create personalized feedback on their progress. Mothers also accessed lessons on a mobile-optimized website and received 3-4 text messages throughout the week. At 6 months, mothers in the Smart Moms group lost 2.4 kg at 6 months compared to a 0.9-kg gain in the control group ($p < .01$) (36). This Red foods monitoring approach was well received and will be adapted to the needs of type 2 diabetes in this study.

Another pilot successfully used daily weights from wireless scales along with objectively measured PA data using Fitbits. The WELL Body study evaluated the feasibility and efficacy of two 6-month interventions that used wireless scales, with or without activity trackers, and focused on daily self-weighing (DSW) to promote weight gain prevention among African American breast cancer survivors. African American women (n=35) were randomized to one of three groups: 1) DSW + activity tracking (INT+); 2) DSW (INT); or 3) delayed intervention control (CON). Intervention participants received a wireless scale and activity tracker (INT+ only) that transferred objective data to a mobile app and website, email lessons on weight control, and tailored feedback on objective weight (and activity data). The intervention encouraged use of DSW as the primary self-monitoring strategy to prevent weight gain. Participants in the INT+ group additionally were encouraged to track their physical activity daily. At 6 months, 62.5% of intervention participants were at/below baseline weight; those who weighed 6-7 days/week (n=10; 42%) lost more weight than those who weighed <6 days/week (-4.9±6.3% vs. -0.3±2.6%, p=0.02). Intervention groups maintained weighing frequency over the study period, with no decreases from week 1 to 24 (INT+, p=0.41; INT, p=0.14). Both intervention groups endorsed being very likely to continue DSW after the program and had favorable experiences with the scales, trackers and DSW (easy to do, easy to remember, helpful, positive) (20).

In this study, we will explore the feasibility of daily monitoring of BG and weight, self-monitoring of diet using the simplified Traffic Light system, self-monitoring of physical activity using a Fitbit

tracker, and appropriate displays of data in the app to facilitate comprehension and decision making to meet the needs of this patient population. It is hypothesized that the positive feedback achieved through the self-regulation loop results in improvements in feelings of control and goal attainment, which reinforce behaviors over time, resulting in sustainable behavior change and weight loss.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Emotional distress or Embarrassment (infrequent). We believe that potential psychological risks to participants are small. It is possible that some participants may find questions included in the questionnaires to be slightly emotionally distressing or embarrassing. Additionally, a participant may be embarrassed if friends, family, or acquaintances find out that the person is participating in or not successful in the program. However, these instances should be mild and rare to infrequent as they have the right to refuse to answer any questions. Participants will be encouraged to contact the Principal Investigator if they feel they have incurred any emotional distress as a result of study participation. As this is a voluntary study, a participant is free to exit the study at any point if they feel uncomfortable or do not want to continue.

Breach of confidentiality (infrequent). We expect a breach of confidentiality to be rare or infrequent. Most communication during the study period will take place via telephone, direct emails, or through the smartphone app either to deliver questions, conduct assessments, or remind participants to complete questionnaires. We do not anticipate any risks of harm as a result of these communications, however there is always a possibility that their scale data, tracker data, or activity in the app will be intercepted.

Steps to Ensure Confidentiality of Participants: All data records related to a participant's involvement in this research study will be stored in a locked file cabinet and/or in encrypted files on servers that adhere to the University policy on storage and transmission of sensitive data. Participant identity on these records will be indicated by an ID number, and the information linking these numbers with participant identity will be kept separate from the research records. In addition, all research databases will have password-controlled access, and this will be controlled by critical staff.

The Fitbit API will be used to access data from participants' scale, activity tracker, and Fitbit app. During the consent process, participants will consent for the data from their specific device IDs to be accessed by our study. They will need to enter their Fitbit username and password during the app setup process to allow Fitbit data to be sent to our study server. The study smartphone app uses a Standard OAuth 2.0 security model for logging in to Fitbit. The study uses temporary access tokens that are stored only on the user's device and is not stored on our servers. Therefore, Fitbit usernames and passwords will not be stored in any way with this study. Instead, the weight and tracker data will be connected to participants by their unique study ID that they will also enter during the app setup process. Data are transmitted on secure servers that adhere to the University of North Carolina at Chapel Hill policy on Sensitive Data. The risk of breach of confidentiality over the Fitbit websites will be partly subject to each individual's

comfort in sharing information in their individual profile. To further minimize the risk of breach of confidentiality, all participant activities on the Fitbit websites will be voluntary. Consent forms will also clearly communicate the risk of this type of disclosure to participants.

There are no major physical risks associated with participation in the study, which involves using a smart scale, activity tracker and glucose monitor, or the data collection visits.

1. Risks of physical activity: Infrequent risk. It is possible that participants may increase their physical activity in response to data and feedback viewed on the activity tracker. There may be some risk to increasing physical activity, including, but not limited to, injuries to the muscles, ligaments, tendons, and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, exacerbation of exercise-induced asthma symptoms, and very rare instances of heart attack, stroke, or even death. To help ensure safety, information on exercise safety will be provided to all participants.

Minimization of risks: To ensure medical readiness to begin physical activity, participants will complete a physical activity readiness questionnaire (PAR-Q). The PAR-Q assesses for the following medical conditions: heart problems, chest pains, faintness or dizzy spells, high blood pressure, bone, or joint problems such as arthritis that has been or could be aggravated by exercise, prescription medication use, and other medical reasons why exercise would not be advisable. Participants endorsing yes to any items on the PAR-Q (experience of heart problems, frequent chest pains, faintness or dizziness, bone or joint problems, on prescription medications for blood pressure or a heart condition) will be excluded from the study.

We also will monitor any major musculoskeletal problems that develop during the intervention (e.g., broken bones) using a medical events questionnaire at 3 months and determine whether these appear related to our study. Participants who develop musculoskeletal problems or other health problems that may affect safe participation will be instructed to stop exercising until the problem resolves and their physician approves resumption of physical activity.

Participation is fully voluntary, and we will ask participants to report any problems to the study researchers.

2. Risk of wearable devices: There is also the possibility of minor skin irritation associated with wearable devices.

Minimization of risk: We will recommend taking the device off occasionally, not wearing it too tightly, and keeping it clean and dry. If participants experience skin irritation, we will suggest that they contact a member of the study team to discuss the issue and determine whether they would like to continue participating in the study.

3. Risk of using a phone while driving: It is dangerous to pay attention to a cellular phone while driving, walking, or doing any activity that requires attention.

Minimization of risk: We will strongly recommend that participants exercise good judgment on this while participating in this study and will ask that they not open the application or view any notifications or messages while they are driving.

4. Risk of CGM: There is a small risk that the adhesive used to attach the sensor to the arm will cause skin irritation.

Minimization of risk: Through instructions on usage of the CGM will be provided to the participant at the beginning of the study. Proper placement and care will be emphasized and, if irritation does occur, participants will be instructed to discontinue use of the sensor and alert the study staff.

5. Risk of finger stick: Approximately 3 drops of blood will be removed by finger stick. This is a standard method used to obtain blood for routine hospital laboratory tests. The participant may experience pain when the lancet goes into their finger. Other than this momentary pain, the discomfort of finger stick should be minimal. However, in about 10% of the cases a small amount of bleeding under the skin will produce a bruise (hematoma). A small scar may persist for several weeks. The risk of local infection is less than 1 in 1,000.

Minimization of risk: Staff are trained in the sanitary collection of blood using gloves, prepping the area with an alcohol swab, having the participant apply pressure to the finger after the finger stick and application of a bandage if needed.

2.3.2 KNOWN POTENTIAL BENEFITS

This study may help researchers understand the acceptability of CGM in a pre-diabetes and T2D population and determine if incorporating daily monitoring of BG within the context of a behavioral weight loss intervention promotes self-regulation and adherence to lifestyle changes necessary for weight loss. Given the widespread prevalence of T2D and obesity, this study could inform larger trials that could lead to clinical recommendations.

The benefits of participation in a short-term program that includes weighing, increasing physical activity, and dietary changes may include weight loss and short-term improvements in activity and eating. Increased physical activity and healthier eating can also lead to other improvements in health, such as improved cardiovascular outcomes. Better glucose control (over time) could result in fewer vascular complications.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during weekly individual coaching sessions.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate adverse events form.

A Medical Events questionnaire will be administered at the 12-week follow up assessment. To capture any adverse events not reported during the individual coaching sessions.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Change in weight (kg).	Weight change at 12 weeks	The primary goal of the intervention is weight loss, thus change in weight is appropriate
Secondary		
1. Change in Body Mass Index (BMI) 2. Change in HbA1c from baseline to 12 weeks. 3. Change in compliance behavior and efforts at diabetes self-control from baseline to 12 weeks as measured by the Diabetes Locus of Control Scale 4. Change in Diabetes-related Quality of Life from baseline to 12 weeks as measured by the Diabetes Obstacles Questionnaire.	Change in measures at 12 weeks	1. BMI is commonly used to assess level of overweight. 2. Change in HBA1c is a valuable diagnostic clinical measure for glucose management over the past 3 months and is responsive to changes in diet, physical activity and weight. 3. Change in compliance behavior and efforts at diabetes self-control may moderate weight loss and HbA1c outcomes. 4. Change in obstacles to adhere to diabetes treatment recommendations may moderate weight loss and HbA1c outcomes.
Tertiary/Exploratory		
To examine the feasibility of using Continuous Glucose Monitoring in overweight individuals as an indicator of response to diet and physical activity behavior modification to promote weight loss. Acceptability and effectiveness of the Traffic Light diet Red food monitoring	1. Responses to Glucose Monitoring System Satisfaction Survey and Technology Acceptance Model-Continuous Glucose Monitoring at 12 weeks. 2. Adherence to Blood Glucose monitoring 1. Adherence to Traffic Light diet monitoring across the 12-week intervention	

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	Association between adherence to Red food goals and change in weight	

4 STUDY DESIGN

4.1 OVERALL DESIGN

This project will test a weight loss intervention delivered through a mobile app for use in non-medication treated type 2 diabetics and pre-diabetics. The app is designed to integrate self-monitoring data from wireless scales and physical activity trackers, allow self-monitoring of foods through a Traffic Light diet approach, serve as a portal for feedback on behaviors and outcomes, and provide a platform for behavioral lessons. We will use the app coupled with in-person support to inform future versions.

We propose a single arm pilot trial testing the feasibility of a behavioral weight loss intervention for adults with type 2 diabetes or prediabetes. Participants will be instructed to decrease intake of Red foods, weigh daily, monitor BG using a CGM system, and gradually increase minutes of physical activity. This 12-week intervention is aimed at promoting improvements in diet quality consistent with recommendations for T2D, a decrease in energy intake, an increase in energy expenditure, and modest weight loss with a goal of improving glycemic control. Participants will meet weekly with a lifestyle counselor (interventionist) to review data on all behaviors, weight, and BG. The session will include feedback on progress, discussion of core content, problem solving and goal setting.

Participants will be given activity trackers (Fitbit Inspire) and wireless digital scales (Withings) to use for the duration of the study. Dietary behaviors will be monitored using an app that our research team has developed to track foods using the Traffic Light system. Assessments will occur at baseline and 12-weeks. Weight will be collected in the clinic on calibrated digital scales (Tanita) during in-person counseling sessions. Adherence measures will include self-monitoring and activity tracking, attendance at individual sessions and achievement of weekly diet and activity goals.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This study is specifically designed to test the feasibility of conducting the intervention as well as to collect preliminary data to be used to develop and propose a larger randomized controlled trial. The proposed research is funded under a pilot/feasibility research program with limited funding. Therefore, a single group design with a limited number of participants is acceptable.

4.3 JUSTIFICATION FOR INTERVENTION

Weight loss is recommended for individuals with overweight or obesity and impaired glucose. Behavior change interventions are the first line of treatment and are effective at reducing weight and improving glycemic control. Weight loss of 5-10% is associated with clinical improvements.

Digital weight loss interventions that integrate behavior change techniques and supports including diet, physical activity, and weight self-monitoring have been shown to be effective for weight loss in adults.

Expert support is also a key component of behavioral weight loss interventions. In this study, we will use human counseling rather than automated feedback in order to best gather feedback and impressions on the feasibility of implementing this intervention given the exploratory nature of using the Traffic Light approach for diet monitoring and CGM for this non-insulin dependent population.

.4 END OF STUDY DEFINITION

The end of the study is defined as completion of the 12-week follow-up assessment shown in the Schedule of Activities (SoA), **Section 1.3**.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Currently age 20-65 years
- Diagnosed with type 2 diabetes or pre-diabetes
- Poor glycemic control (HbA1c $\geq$ 5.7%)
- BMI 25-40 kg/m^2
- Own an iPhone with a data and text messaging plan
- Have home Wi-Fi access
- Have the ability to read, write, and speak English
- Not meeting the American College of Sports Medicine recommendation of 150 minutes of Moderate to Vigorous Physical Activity each week
- Ability to attend weekly visits at the UNC Weight Research Program clinic
- Can obtain primary care provider consent that appropriation is appropriate

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

- Lost more than 10 pounds in the last 6 months
- History of weight loss surgery
- Currently participating in another physical activity or weight loss program or research study that may interfere with participation in this study
- Currently meeting exercise recommendations of 150 minutes per week of moderate-to-vigorous physical activity
- Currently pregnant, pregnant within the past 6 months, or planning to become pregnant within the next 4 months
- Planning to relocate in the next 4 months
- Cannot attend weekly visits at the UNC Weight Research Program clinic
- Pre-existing medical condition(s) that preclude adherence to an unsupervised exercise program, as determined by items endorsed on the PAR-Q (Physical Activity Readiness Questionnaire)
- Treatment of diabetes with insulin or oral medications
- Report taking prescription or over the counter medication with a known impact on metabolism or weight
- Current treatment for cancer
- History of clinically diagnosed eating disorder
- Diagnosis of schizophrenia or bipolar disorder
- Hospitalization for a psychiatric diagnosis within the last year
- Report a past diagnosis of or current symptoms of alcohol or substance dependence
- Unwilling or unable to wear the CGM device continuously for the duration of the study
- On dialysis
- Have an implanted medical device such as a pacemaker

All participants will be required to obtain consent from their primary care provider in order to participate.

5.3 LIFESTYLE CONSIDERATIONS

During this study, participants are asked to:

- Refrain from using over-the-counter medications, dietary supplements, and prescribed medications for the purposes of weight loss; however, they will not be withdrawn if use is reported. Medication usage will be assessed at the pre-enrollment screening and change in medications, as well as adverse medical events, will be assessed at the 12-week study visit and documented in the Medical Events questionnaire.

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or entered in the study. An example of a screen failure would be a participant who comes for the baseline assessment and does not meet the eligibility criteria (such as a BMI or HbA1c that is out of eligible range).

If the participant does not meet inclusion criteria, staff will inform the individual that they do not meet criteria for this particular study and ask if they would be interested in being contacted about future studies.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment

Participants meeting diagnostic criteria for Type 2 diabetes (not treated by medication) and prediabetes will be recruited from the community through informational listservs, as well as through the UNC Health Care system using lists generated by the Carolina Data Warehouse.

If needed, we will use the UNC Informational listserv and boosted Facebook posts to advertise as well. Interested participants will be directed to a web page with study information. If they wish to determine their eligibility, they will complete an online REDCap screening questionnaire. Participants initially eligible on the web screen will be contacted by phone to complete screening.

All recruitment advertisements will encourage potential participants to visit a website with study information (purpose, eligibility criteria, time commitment, and incentives). The recruitment website will also have a link to a preliminary online screening questionnaire, which directs participants to a secure REDCap survey. Initial screening of basic eligibility and demographics will be done online, including questions on age, race/ethnicity, height, weight, basic health history, type 2 diabetes diagnosis, access to technology and availability to participate. If the individual is initially eligible, study

staff will contact the individual by phone for complete screening. Individuals who are ineligible will be notified via email.

All individuals who respond to our advertising will be eligible for enrollment independent of gender and race/ethnicity. As women are generally over-represented in weight control studies, we do not anticipate having inadequate representation by women. Also, given the diversity of the patient population in the UNC system and similar (if not higher) rates of overweight among minorities, access to participation will not be limited for these groups.

Enrollment

Once an individual has been deemed potentially eligible to participate, they will be invited to the clinic for an orientation to the study where study staff will provide further information about the study and allow the potential participants to ask questions. This procedure, whereby potential participants have a chance to determine if the study is a good fit for them, has been effective in our past studies for high rates of retention. If the individual decides to participate, they will provide informed consent for participation. They will have their height, weight, and HbA1c measured and complete questionnaires. After completion of the baseline assessments, the in-person individual sessions will begin.

COVID-19 Modifications:

Orientation sessions were delivered via Zoom after March 15, 2020. If the individual decides to participate, study staff will send an email link to the Informed Consent Form for the study participant to review and electronically sign in REDCap. Once the consent is signed, the online study questionnaires will be deployed to the participant. Once questionnaires are complete, the participant will be scheduled to attend the baseline assessment visit at the clinic and to attend the kickoff session.

Incentives

Participants will receive $15 for completing the baseline assessment and $25 for completing the 12-week assessment. Participants who complete the 12-week assessment will be allowed to keep the Fitbit and scale.

The small incentives are meant to offset the time for completing the study questionnaires, transportation costs for coming to clinic for assessments, and to ensure that we get adequate follow-up data once the study has been completed by the participant. The Fitbit and scale are relatively affordable devices that are widely available to the general public.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

Intervention. The intervention is delivered through weekly in-person individual sessions and a mobile iphone app that integrates diet, weight, and physical activity data to support self-regulatory behaviors. Additionally, participants use a Continuous Glucose Monitoring system to track and manage blood glucose. In the first weekly session, participants are oriented to the intervention and provided with their self-monitoring tools. They are encouraged to weigh and track PA, Red foods and BG daily and taught to use self-regulatory techniques for weight management and glycemic control. Similar to blood glucose self-regulation, participants are taught to compare the number on the scale each day to a standard or goal (weight loss goal) and, depending upon the comparison, make changes to their diet (i.e., Green foods or Red foods) or physical activity (i.e., moderate to vigorous physical activity (MVPA) or sedentary behavior (SB)) as needed. All participants are given an initial weight loss goal of 5%.

Dietary Intervention
Participants are guided to follow a Traffic Light Diet approach where foods are categorized into Green, Yellow, and Red categories. Users are encouraged to increase Green foods, moderate Yellow foods, and limit Red foods. Foods in the Green category include fruits, vegetables and certain very lean proteins. They are low in calories, fat, and sugar, and rich in nutrients. The high volume, water content and fiber in fruits and vegetables and the protein from the lean meats and egg whites in this category help promote satiety while consuming fewer calories. The Yellow category includes moderately lean proteins, legumes, low fat dairy, whole grains, starchy vegetables, and low fat dressings. These foods are higher in calories than green food but are still a good source of nutrients. Red foods are high in calories, fat, and/or sugar and are not a good source of nutrients. The goal in the Traffic Light Diet is to increase Green foods and to limit Red foods. This emphasis on increasing healthful eating has been hypothesized to reduce feelings of deprivation and hunger (37,38). In the Traffic Light approach followed in this study, users are allowed unlimited Green foods and are not given a specific target for Yellow food servings.

Each participant is given a personalized Red foods limit, which is determined by baseline weight. The intent of the goal is to result in a caloric reduction of 500-1000 per day. Participants are asked to monitor all of their foods for the first two weeks in order to orient them to the Traffic Light Diet system and to give them and their counselor a good idea of their overall intake pattern. After the first two weeks, they have the option to only monitor Red foods. During individual counseling sessions, interventionists have the option to set a goal for Green and/or Yellow foods and have the participant monitor those in the app, and/or to reduce the participant's Red Food limit if weight loss is not

progressing as desired. Lesson content encourages building healthy meals around green foods and participants are provided with meal plans and recipes that models this meal pattern.

Baseline Weight	Red Food Limit
< 200 lbs	3
200 - < 250 lbs	4
250+ lbs	5

Physical Activity Intervention

The physical activity goal for the study is to progress the participant to at least 150 minutes of moderate to vigorous physical activity per week. An initial goal is based on baseline levels of PA as reported by the participant. Progression will occur each week based on individual progress of the participant.

Baseline Weekly MVPA	Active Minutes Goal
< 50	10 min/day
50-75	15 min/day
76-100	20 min/day
101-125	25 min/day
126-149	30 min/day
Maximum	**60 min/day**

PA GOAL PROGRESSION

When total active minutes for the week is equal to or above [AM Goal*5], then increase daily goal for the next week by 5 minutes

Otherwise, active minutes daily goal remains the same the next week

Example, if goal is 15 min/day, the 5-day equivalent would be 75. If participant gets 80 min, then daily goal increases by 5, to 20 min/day. But if participant only got 60 min, then their daily goal for the new week would stay at 15 min/day

Intervention app

During the first individual session, the interventionist will work with the participant to download the app onto the participant's smartphone, familiarize them with the app, and set personal goals for weight, diet and physical activity, and BG monitoring.

- Weight Goal and Monitoring: Participants will be provided a Withings Wi-Fi Smart Scale digital scale and instructed on setup and procedures for daily weighing.
- Dietary Goal and Monitoring: Interventionists instruct on the Red foods list and monitoring of Red foods in the app. They will be instructed on portion size estimation and self-monitoring best practices (timing proximal to consumption). During the first week, participants will be advised to monitor all of their foods and work towards meeting their daily Red food goal.
- Physical Activity Goal and Monitoring: Participants will be provided with a Fitbit Inspire and will set up the device and the app to allow for data transfer. They will receive a weekly physical

activity goal based on baseline physical activity reported on the online screener. Participants will also be advised on using the Fitbit to monitor sedentary time and to target sedentary behavior throughout the day.

- BG Goals and Monitoring: Participants will be provided with an Abbott Freestyle Libre device, which is a Continuous Glucose Monitoring (CGM) unit. Recent advances in technology have made CGM much less invasive and simplified, thereby allowing for a better picture of glucose control given the number of data points available without the burden that previous CGM units presented. The interventionist will work with the participant to set goals for monitoring and ensure comprehension of CGM procedures. Study participants will be instructed on placement of the CGM sensor on the back of the arm. The sensor is worn for 14 days continuously, and then replaced. The participant will scan the sensor using a handheld device or iPhone at different points throughout the day (upon waking, before meals, 1 ½ - 2 hours after meals, but no less than every 8 hours) and to "mark" eating and activity events in the scanning device or iPhone app. The data will be uploaded to the Freestyle Libre system. The study interventionist will have access to the data through a web-based portal and will review this information with the participant at weekly coaching sessions. Participants will be taught to interpret their blood glucose information and to use it to inform diet and physical activity behaviors.
- Feedback: The app provides graphical feedback comparing goals to behaviors and a weekly feedback message from the counselor that encourages adherence to the goals of daily weighing, monitoring and meeting Red foods and physical activity goals. For the purposes of this study, more rigorous intervention feedback will be delivered by the interventionist at weekly sessions.

Behavioral Lessons

A standard behavioral intervention based on the DPP (used by Dr. Tate effectively in both face to face and Internet formats) will be adapted for this protocol. Behavioral weight control approaches are founded on teaching skills and providing the support necessary to enable participants to adhere to the diet and physical activity prescription in their intervention. For the dietary intervention, materials will be adapted to reflect the Traffic Light Diet focus and modules for decreasing sedentary behavior will be added to those for increasing MVPA. Materials will be adapted with a focus on T2D. Additional materials and activities will be added specifically on self-regulation of weight and BG in relation to diet and physical activity behaviors. Lessons will be presented within the app. Brief review of the content will be done during individual sessions to assess comprehension and to explore personal applications.

Coaching Support

Individual counseling sessions will be semi-structured and led by Master's level or higher interventionists trained in behavioral weight control. Sessions will occur weekly (12 sessions) and typically last 30-45 minutes. For the first 4 weeks of the study, all sessions will be conducted at the UNC Weight Research Program clinic. Participants will be encouraged to attend in-person sessions for the duration of the study, however they will be given the option to complete the remaining 8 sessions through phone or video chat (Zoom) if desired. (Note: the remote mode of delivery became the primary delivery mode due to COVID-19 restrictions.)

6.1.2 DOSING AND ADMINISTRATION

Described in section above 6.1.1

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

To ensure intervention fidelity, study meetings will be held weekly. At these meetings, the research team will discuss issues relevant to study progress, including enrollment, participant safety (adverse events), participant retention, and protocol compliance. Summaries of the team meeting minutes will be available for inspection when requested by any of the regulatory bodies charged with the safety of human subjects and the integrity of data including, but not limited to, the oversight of the Office of Human Research Ethics (OHRE) Biomedical IRB, or the North Carolina TraCS Institute Data Safety Monitoring Board (DSMB).

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

This is a single arm study. Therefore, randomization is not applicable.

Due to the size of this pilot study and staffing limitations during the COVID-19 pandemic, study staff will not be blinded for the assessments. Assessment staff will be trained and strictly adhere to assessment protocol.

6.4 STUDY INTERVENTION COMPLIANCE

Interventionists will review food, weight, and activity progress through an administrative web portal prior to individual sessions. During the weekly session, the interventionist will review self-monitoring records with the participant, set weekly goals, review behavioral lesson content introduced in the app, facilitate problem solving of any barriers the participant is having, and adapt treatment recommendations based on the needs of the participant.

6.5 CONCOMITANT THERAPY

For this protocol, participants will be discouraged from using over-the-counter medications and dietary supplements, and prescribed medications for the purposes of weight loss; however, they will not be withdrawn if use is reported. Medication usage will be assessed at the pre-enrollment screening and change in medications, as well as adverse medical events, will be assessed at the 12-week study visit and documented in the Medical Events questionnaire.

6.5.1 RESCUE MEDICINE

N/A

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

Discontinuation of the study intervention without withdrawal from the study will only occur at the request of the participant if they are no longer willing or able to adhere to the study intervention for personal (not medical or safety) reasons. When a subject discontinues from the study intervention but not from the study, final assessment measures will be completed as indicated by the study protocol

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. Participants will be withdrawn from the study should they experience greater than minimal risk as described in section 2.3.

In addition, an investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Participants who become pregnant during the study, as weight loss is contraindicated.
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded on the Case Report Form (CRF). Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

The research team will provide continuous monitoring of participant safety and periodic reporting to the UNC IRB as required, including any Unanticipated Problems/Severe Adverse Events that may have occurred during the study. Data safety and monitoring activities continue until all participants have completed trials and until all participants have been followed to the point at which study-related adverse events would likely no longer be encountered.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to return for the 12-week follow up assessment visit and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to return to the clinic for a required study visit:

- The site will attempt to contact the participant, reschedule the missed visit within 4 weeks of the scheduled time frame, counsel the participant on the importance of maintaining the assigned visit schedule, and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 EFFICACY ASSESSMENTS

Note: Refer to the Schedule of Activities 1.3 for the timing and frequency of assessments.

Screening and Orientation

Screening, orientation, and enrollment procedures are described in section 5.5. At each point, study staff will confirm eligibility, as described. The participant has the choice to discontinue participation at any point. If participation is discontinued by staff or the participant, screening information will be held for the duration of the study and identifiers will be destroyed after the study is complete. Reasons for ineligibility will be retained for descriptive purposes.

Physical Measurements

Weight (kg) (primary outcome): Participants will be weighed wearing shorts and without shoes using a calibrated digital Tanita scale. Trained study staff will conduct these measurements following a standardized protocol. Two measures will be completed and the average of the two will be used. If the difference between the two measures exceeds 0.2 kg, a third measure will be taken.

Height (cm): Height will be measured at baseline using a wall-mounted stadiometer (Country Technology Inc, WI). Two measures of height will be taken and the average of the two will be used. If the two measures are not within 0.5 cm, a third measurement will be taken

BMI: Height and weight will be used to calculate BMI.

HbA1c will be measured with a fingerstick and analyzed on a point of care unit (Afinion Alere).

REDCap questionnaires:

Demographics. Participants will provide demographic information at baseline. They will provide age, gender, race/ethnicity, weight, and smoking history. (Baseline only)

Diabetes Specific Locus of Control.

We will administer an 18-item questionnaire consisting of three domains measuring diabetes-specific internal locus of control, powerful other locus of control, and chance locus of control (39).

Diabetes Obstacles Questionnaire. This is a diabetes-related quality of life questionnaire consisting of 30 items using a 5-point Likert-scale addressing social, psychological, cognitive, and behavioral obstacles (40).

Glucose Monitoring System Satisfaction Survey. This is a 15-item survey consisting of four scales including Emotional Burden, Behavioral Burden, Openness, and Trust. The survey is validated in Type 1 and Type 2 diabetes patient populations and assesses satisfaction with the device and its impact on quality of life. We have slightly modified four items to replace "diabetes" with "blood sugar" to better align with our population and research aims (41).

Personal Diabetes Questionnaire. This questionnaire will be used both as a secondary outcome to test the effect of the intervention as well as an assessment tool to inform the counselor at baseline in order to personalize the intervention. The following scales will be used: Weight Change Readiness Dietary Knowledge and Skills, Diet Decision Making, Eating Problems. Diet Barriers, Physical Activity, and Exercise Barriers. This is a validated measure of diabetes self-care behaviors, perceptions and barriers (42).

Technology Acceptance Model-Continuous Glucose Monitoring. This survey assesses usability and predictors of adherence to using the CGM device. Subscales include perceived reliability, information overload, technology-related self-efficacy, usefulness, ease of use, attitude, visibility of body change, and intention. We have added an item to assess helpfulness with weight management (in addition to blood sugar control) (43).

Program Satisfaction. Participants will be asked to complete a post-treatment program evaluation. Questions will ask about participants' perceptions and experiences with the intervention and may provide valuable information about how to modify the programs for future use in this population. Participants will be asked to report their overall satisfaction with the intervention they received. Additional satisfaction questions will assess specific treatment components including the topics of the weekly lessons and use of the app and activity tracker for self-monitoring. Post-intervention only.

Feasibility Measures. Adherence to digital scale use; activity tracking and physical activity patterns captured by the Fitbit; Blood Glucose monitoring and outcomes; Red food monitoring; and attendance at individual counseling sessions will be tracked.

Medical Events. Adverse medical events and changes to medications will be assessed at 12 weeks (staff administered).

8.2 SAFETY AND OTHER ASSESSMENTS

Safety management in this study is intended to achieve 4 objectives: 1) to minimize the occurrence of adverse effects; 2) to effectively manage adverse events as they relate to the study; 3) to identify when the intervention should be suspended because of concerns for participant safety; and 4) to determine when the intervention may be resumed after having been suspended.

Should any concerns arise during data collection, they will be addressed immediately by study personnel and the PI will be notified as soon as possible. Though unlikely, should any concerns arise after data

collection, subjects will be given the study coordinator's contact information to share their concerns and the PI will address concerns directly or through appropriate referrals. Any concerns that arise over the course of the study will be recorded and aggregated as part of the feasibility data and shared with the research team and the IRB as necessary.

We do not anticipate that any questions, anthropometric measurements, observations will cause discomfort or embarrassment, but participants may stop or refuse collection of data at any time. Participants will be informed of potential safety risks in the informed consent.

The research team will provide continuous monitoring of participant safety and periodic reporting to the UNC IRB as required, including any Unanticipated Problems/Severe Adverse Events that may have occurred during the study. Data safety and monitoring activities continue until all participants have completed trials and until all participants have been followed to the point at which study-related adverse events would likely no longer be encountered.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS (AE)

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, ***whether or not considered intervention-related***.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

A possible SAE is any event that may meet the following criteria (complete one SAE form for each event):

a. An event that was life threatening, or placed the participant at immediate risk of death

b. An event that caused persistent or significant disability or incapacity (lasted at least one month and changed the participant's life)

c. An event that required or prolonged a hospitalization

d. A pregnancy that resulted in a congenital anomaly or birth defect

e. Death

f. An event that caused other significant hazards or potentially serious harm to research subjects or others

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

A clinician with appropriate expertise in behavior and physiological adaptation will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study assessment visits and individual coaching sessions.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate adverse events form. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

Kristen Polzien will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the study team will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

The research team will report to the UNC IRB as required, including any Unanticipated Problems/Severe Adverse Events that may have occurred during the study. Data safety and monitoring activities continue until all participants have completed the trial and until all participants have been followed to the point at which study-related adverse events would likely no longer be encountered.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

NA

8.3.8 EVENTS OF SPECIAL INTEREST

NA

8.3.9 REPORTING OF PREGNANCY

Participants who become pregnant during the study will be withdrawn and the intervention will be withdrawn as weight loss is contraindicated. Pregnancies will be reported on the Medical Events form, should they occur.

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the DCC/study sponsor/funding agency within <insert timeline in accordance with policy> of the investigator becoming aware of the event
- Any other UP will be reported to the IRB and to the DCC/study sponsor/funding agency within <insert timeline in accordance with policy> of the investigator becoming aware of the problem

- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within <insert timeline in accordance with policy> of the IRB's receipt of the report of the problem from the investigator

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

NA

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s): n/a
- Secondary Efficacy Endpoint(s): n/a

9.2 SAMPLE SIZE DETERMINATION

Sample size was not determined using statistical methods. This was a pilot and feasibility study and the sample size was determined based on funding and logistics.

9.3 POPULATIONS FOR ANALYSES

The analysis population will be Intention-to-Treat (ITT) (i.e. all randomized participants)

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

App utilization will be explored using descriptive statistics examining sums of weighing days, tracker wear, days of BG monitoring, and days tracking Red foods. Preliminary analysis of change over time in weight and A1c will be conducted using paired t-tests. Estimates of change on physiologic and psychologic variables, along with others in the literature, will be used to estimate effect sizes for the R01.

9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

See 9.4.1

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

See 9.4.1

9.4.4 SAFETY ANALYSES

Safety endpoints will be analyzed as summary statistics during treatment and/or as change scores from baseline.

Each AE will be counted once only for a given participant), presented (e.g., expectedness, severity, frequency, and relationship of AEs to study intervention will be presented by System Organ Class (SOC) and preferred term groupings.

AE start date, stop date, severity, relationship, expectedness, outcome, and duration will be reported.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

See 9.4.1

9.4.6 PLANNED INTERIM ANALYSES

NA

9.4.7 SUB-GROUP ANALYSES

NA

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

NA

9.4.9 EXPLORATORY ANALYSES

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing details of the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention.

The following consent materials are submitted with this protocol:

- Participant informed consent
- Physician's consent
- Online screener
- Telephone screener

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

If the participant is deemed eligible and decides to participate, the participant will complete the consent form on-site or the study staff will send a link to the study participant to read and electronically sign the consent in REDCap.

All participants are required to obtain consent to participate from their Primary Care Provider.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study has no pre-specified criteria for discontinuation or closure.

10.1.3 CONFIDENTIALITY AND PRIVACY

Assessment data will be collected and managed by study staff. Online data collection will be done through RedCap, and paper forms will be entered by study staff into a RedCap form. Data will be stored without identifiers. After all study activities are completed, data will be de-identified. Longitudinal measurements will undergo consistency and outlier checks, be compared with raw data, and edited as required. Audit trails will be used to document any database changes.

To ensure confidentiality of participants, all survey data and scale/tracker/dietary records related to a participant's involvement in this research study will be stored in encrypted files on servers that adhere to the University policy on storage and transmission of sensitive data. Participant identity on these records will be indicated by an ID number, and the information linking these numbers with participant identity will be kept separate from the research records. In addition, all research databases will have password-controlled access, and this will be controlled by critical staff.

All data records related to a participant's involvement in this research study will be stored in a locked file cabinet and/or in encrypted files on servers that adhere to the University policy on storage and transmission of sensitive data. Participant identity on these records will be indicated by an ID number, and the information linking these numbers with participant identity will be kept separate from the research records. In addition, all research databases will have password-controlled access, and this will be controlled by critical staff.

The Fitbit API will be used to access data from participants' scale, activity tracker, and Fitbit app. During the consent process, participants will consent for the data from their specific device IDs to be accessed by our study. They will need to enter their Fitbit username and password during the app setup process to allow Fitbit data to be sent to our study server. The study smartphone app uses a Standard Auth 2.0 security model for logging in to Fitbit. The study uses temporary access tokens that are stored only on the user's device and is not stored on our servers. Therefore, Fitbit usernames and passwords will not be stored in any way with this study. Instead, the weight and tracker data will be connected to participants by their unique study ID that they will also enter during the app setup process. Data are transmitted on secure servers that adhere to University policy on Sensitive Data. The risk of breach of confidentiality over the Fitbit websites will be partly subject to each individual's comfort in sharing information in their individual profile. To further minimize the risk of breach of confidentiality, all participant activities on the Fitbit websites will be voluntary. Consent forms will also clearly communicate the risk of this type of disclosure to participants

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Questionnaire data as well as physical measurements including height, weight, and HbA1c data collected for this study will be analyzed and stored on password-protected encrypted file servers at the University of North Carolina at Chapel Hill. No specimens will be stored.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Medical Monitor**
Deborah Tate, Ph.D., Professor	NA
University of North Carolina, Chapel Hill	
1700 Martin Luther King Jr. Blvd. Suite 136, Chapel Hill, NC 27514	
919-966-5853	

dtate@unc.edu	

10.1.6 SAFETY OVERSIGHT

Safety oversight will be under the direction of the Office of Human Research Ethics (OHRE) Biomedical IRB and the Principal Investigator.

10.1.7 CLINICAL MONITORING

NA

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as all of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness.

Source documents and the electronic data --- Data will be initially captured on source documents (see **Section 10.1.9, Data Handling and Record Keeping**) and will ultimately be entered into the study database.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Assessment data will be collected and managed by study staff. Online data collection will be done through RedCap, and paper forms will be entered by study staff into a RedCap form. Data will be stored without identifiers. After all study activities are completed, data will be de-identified. Longitudinal measurements will undergo consistency and outlier checks, be compared with raw data, and edited as required. Audit trails will be used to document any database changes.

To ensure confidentiality of participants, all survey data and scale/tracker/dietary records related to a participant's involvement in this research study will be stored in encrypted files on servers that adhere to the University policy on storage and transmission of sensitive data. Participant identity on these records will be indicated by an ID number, and the information linking these numbers with participant identity will be kept separate from the research records. In addition, all research databases will have password-controlled access, and this will be controlled by critical staff.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained until data analysis is completed. At this point, any materials with identifiers will be destroyed.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP). The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

NA

10.1.12 CONFLICT OF INTEREST POLICY

Any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived

conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the University of North Carolina has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

During the 12-week study, participants will monitor their blood glucose using the Abbott Freestyle Libre Continuous Glucose Monitoring system. For the CGM, a representative of the device manufacturer (Abbott) will train research staff to instruct study participants on the use of the device. The device is commercially available and measures blood sugar without the need for finger sticks. It involves placement of a sensor on the upper arm and use of a scanning device to "read" the sensor. Use of the device is considered 'off-label' for individuals without diabetes.

The study interventionists in this study are trained in behavioral weight control, have served this role in weight control interventions in the lab for 5 – 15 years, and are Master's or PhD level in Health Behavior, Nutrition (and Registered Dietitian), or Exercise Physiology.

10.3 ABBREVIATIONS

API	Application Programming Interface
BMI	Body Mass Index
CDC	Centers for Disease Control
CGM	Continuous Glucose Monitor
DPP	Diabetes Prevention Program
HBA1c	Glycated Hemoglobin
IRB	Institutional Review Board
NC TraCS	North Carolina Translational and Clinical Sciences Institute
OHRE	Office of Human Research Ethics
PAR-Q	Physical Activity Readiness Questionnaire
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale
1	1/16/2019	Initial	NA
2	3/15/2020	In-person orientation, assessments,	COVID-19 restrictions

		counseling sessions suspended. Some final weights had to be done using remote weighing protocol (stepping on the Withings smart scale three times in a row, first thing in the morning).	
3	5/28/2020	Resume in-person assessments with the re-opening of the University effective June 1 for Human Subjects Research, following the guidelines of the Office of Research and the IRB. Transitioned to online consent to reduce the number of in-person visits necessary to conduct this study. We moved to conducting Orientation sessions via a Zoom call and send a link for the Informed Consent following the Orientation. The consent form will be deployed through REDCap and we will obtain an electronic signature. We will provide the study participant with a paper copy of the signed Informed Consent at the Baseline Assessment (which will take place in person).	COVID-19 restrictions

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12 APPENDIX

12.1 PARTICIPANT INFORMED CONSENT

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 7/8/2020
IRB Study # 18-2805
Title of Study: Adaptation of a digital weight loss intervention promoting self-regulation for use in type 2 diabetes
Principal Investigator Department: Health Behavior Operations
Principal Investigator Phone number: (919) 966-7546
Principal Investigator Email Address: dtate@unc.edu
Study Contact Telephone Number: (919) 966-5853
Study Contact Email: KEERICKS@email.unc.edu

CONCISE SUMMARY
This is a research study to test the effectiveness of a weight loss program that uses digital tools to help adults with type 2 diabetes or prediabetes lose a modest amount of weight and manage their blood sugar.

Participants will have their height, weight and HbA1c measured. They will complete questionnaires about their health and lifestyle at the beginning of the study and again at the end of the study (after 3 months). These procedures will take approximately 30 minutes. Participants will visit the clinic to get their digital tools (study app, a digital scale, an activity tracker and a Continuous Glucose Monitor, which is a small sensor worn on the back of the arm continuously and replaced every 14 days) and meet with a study coach who will teach them how to use the tools and to get started making changes to their physical activity and diet. This first visit will take 2 hours. Participants will use the tools for 12 weeks. Each week, participants will meet (remotely) with the study coach who will review their progress and set goals for the coming week. These visits will take 30-45 minutes.

Some participants will be invited to complete a 1-1 1/2 hour interview at the end of the study to give the research staff feedback about their experience.

There greatest risks of this study include the possibility of injury when increasing physical activity as part of the weight loss program, discomfort from the HbA1c fingerstick, and skin irritation from wearing the Continuous Glucose monitor on the arm.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to test a comprehensive lifestyle intervention that uses digital tools to support behavior change. This novel intervention uses a smartphone app that combines a simplified diet monitoring system, a connected scale, physical activity tracker and blood glucose monitoring along with coaching to promote weight loss and diabetes management.

You are being asked to be in the study because you meet the following criteria: 1) age 20 – 65; 2) diagnosed with type 2 diabetes or pre-diabetes and not taking medication used to treat diabetes; 3) have poor glycemic control (HbA1c $\geq$ 5.7%); 4) are overweight with a Body Mass Index (BMI) of 25-40 kg/m^2; 5) speak and write English; 6) not meeting the American College of Sports Medicine recommendation of 150 minutes of Moderate to Vigorous Physical Activity each week; 7) have an iPhone with a data and text messaging plan; 8) have home wi-fi access; 9) ability to attend weekly remote visits with staff from the UNC Weight Research Program; and 10) your primary care provider will provide written approval that participation in this study is appropriate for you.

Are there any reasons you should not be in this study?

You should not be in this study if you:

- Are currently participating in another physical activity or weight control program or research study that would interfere with this study;
- Have lost and kept off 10 or more pounds in the past 6 months or have ever had weight loss surgery;
- Take a prescription medication (e.g., insulin, metformin, other oral agents) to manage your diabetes;
- Regularly meet the American College of Sports Medicine recommendation of getting 150 minutes or more of moderate to vigorous physical activity each week;
- Take a medication that has a known effect on your metabolism or weight;

- Have a heart condition, chest pain during periods of activity or rest, loss of consciousness or any other reason you cannot participate in unsupervised exercise;
- Have an implanted medical device such as a pacemaker;
- Are currently being treated for cancer;
- Are on dialysis;
- Have substance abuse or mental health problems that would make it difficult to follow the recommendations of the program;
- Are moving out of the area within the next 4 months;
- Are unable to attend weekly sessions (either by phone or in-person at the clinic in Chapel Hill);
- Have been diagnosed with an eating disorder such as bulimia or anorexia;
- Are currently pregnant, have been pregnant within the past 6 months, or you are planning to become pregnant within the next 4 months;
- Are unwilling or unable to wear the Continuous Glucose Monitoring device for the duration of the study.

How many people will take part in this study?
There will be approximately 20 people in this research study.

How long will your part in this study last?
If you participate, your part in this study will last up to 4 months.

What will happen if you take part in the study?
If you choose to participate in this study, the following will take place:

Baseline Assessment and Kick-Off Session: After you consent to participate, you will complete a set of online questionnaires that will take you approximately 30 minutes. These questionnaires will include demographics and questions specific to your experience with diabetes. After completing the questionnaires, you will attend an in-person visit to have your height, weight, and HbA1c measured. For the HbA1c, you will have a finger stick and approximately 3 drops of blood drawn. Your sample will be analyzed on a point-of-care analyzer immediately after it is drawn. None of your blood will be stored. These measures will take approximately 15 minutes.

After completing the assessment measures, you will have a kick-off session with a study interventionist. You will receive a Study smartphone app, a Withings Wi-Fi-enabled bathroom scale, a Fitbit Alta activity tracker, and a Freestyle Libre CGM (Continuous Glucose Monitoring) system, all for your use during the study. The Freestyle Libre is a continuous glucose monitoring system that uses a sensor that is continually worn on the upper arm and a handheld reader, and does not require any finger sticks.

The Study smartphone app, Withings scale, and Fitbit activity tracker all require you to download an app onto your phone and set up a username and password for each. The Freestyle Libre also requires you to set up an account which can be accessed either through a smartphone app or from a computer. For each of these devices, you will give permission for the research study staff to have access to your data.

Study staff will help you set up the Fitbit, install the study's smartphone app on your iPhone, and will give you instructions on how to set up the scale at home. They will also instruct you on using your glucose monitoring system. In addition, staff will give you instructions on making changes to your diet and physical activity to help you lose weight and manage your blood sugar.

12-week Study Period: During the 12 weeks following your group session you will be asked to weigh yourself on the Wi-Fi scale in the morning, wear your Fitbit, track some of your foods in the study smartphone app, and wear your CGM sensor. For the purposes of the research study, it is important that you are the only person in your household who uses the scale and the Fitbit during the study. The data from your app, Fitbit, scale and Freestyle Libre will be transmitted to your study interventionist. It is anticipated that you will spend no more than 10-15 minutes per day tracking your foods and using the study app. You may receive text messages throughout the study for various reasons, which may include reminding you to sync your Fitbit, track your foods, or return to the study app if you haven't used it in a few days. You will receive no more than 3 text messages per week.

Once per week, you will meet with the study interventionist to review your data and progress, receive lesson materials that will help you to make healthy diet and activity changes in your daily life and set goals for the coming week. These meetings will take place remotely (video conference "zoom" or phone call). There will be a total of 12 sessions. Sessions will typically last 30 – 45 minutes.

Final Assessment: After the 12 weeks of the weight loss program, you will repeat the measures you completed at the beginning of the study. This will include a set of online questionnaires that will take approximately 30 minutes to complete and a final weight and HbA1c measurement. The measurements will take no more than 15 minutes. If you complete your final assessment, you will be able to keep your Fitbit and scale. You will be asked to return the CGM scanner. You may be invited to complete a 60-90 minute interview about your experience during the study. If you decide to participate in the interview, you will sign an additional consent form and will receive an additional incentive.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may also expect to benefit by participating in this study by receiving accurate and important information about weight loss and health. Your participation may help you lose weight, and could experience improvements in physical health associated with weight loss and making healthier choices. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

Risks of Increasing Physical Activity.

There may risks associated with increasing physical activity, including, but not limited to, injuries to the muscles or joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, exacerbation of exercise-induced asthma symptoms, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine. The study will provide you with information

and recommendations for safely starting an exercise program and increasing your physical activity and will make modifications to your program if you experience any of the above problems. The safest way to start becoming more physically active is to begin slowly and build up gradually. During this study, you will receive information on exercise safety. These are not intended to be a substitute for consultation with your personal physician and/or health care provider. You may want to talk with your doctor by phone or in person before you start becoming much more physically active. You should report any problems to the researchers.

Risks associated with Questionnaires

As part of the study, you will be asked about personal factors related to your weight related behaviors and health. You may feel uncomfortable while completing the surveys, because of the personal nature some of the questions. You can elect not to share this private information. You should contact researchers if you feel that you have experienced any emotional distress as a result of study participation.

Risk of Breach in Confidentiality

This would mean that a person or persons outside the study team will find out that you are participating in this study and/or access the information you share with the study. This is a very rare possibility. In-person assessments will take place in our study offices. The only study data stored on your phone will be foods you have tracked in your food log that have not yet been transferred to the study server (i.e. your food log is stored on your phone when you do not have an internet connection, but is transferred to the server as soon as you receive access to an internet connection and then deleted from your phone). Though the likelihood is very rare, it is possible that your data could be accessed by others should you lose your mobile device or lend the device to other people. In addition, there is a possibility that others may see your smartphone communications, including notifications or messages when the application is open, or see an open webpage while you are completing online questionnaires. If you would like, you may set up a passcode on your mobile phone to help prevent unauthorized access to your device, text messages, and research data. Additional information on how your study records will be kept private is written below.

Fitbit: You will also receive a Fitbit activity tracker. This device requires use of the companion Fitbit website and smartphone app. This is protected by a unique user login and password. Though you will need to enter your Fitbit username and password as part of the setup process for the study, we will not store your Fitbit username or password on our servers. In your Fitbit account settings, you will give permission for your Withings scale data to sync to your Fitbit account. All website information on your activity and weight data that are accessed by study staff will be kept confidential.

The risk of breach of confidentiality over the Fitbit website will be partly subject to your comfort with sharing information on your individual profile. Fitbit will have access to the data that you choose to track within the Fitbit app/website and the information you choose to include on your individual Fitbit profile, but they will not have access to any other information about you that is collected as part of the research study.

Freestyle LibreView. When you scan your Freestyle Libre sensor, your CGM data will be stored in the web-based LibreView software. Within your account settings, you will share this data with the research study staff. The study staff will not have access to your username or password. All website information on your blood glucose data that are accessed by study staff will be kept confidential.

The risk of breach of confidentiality over the LibreView website will be partly subject to your comfort with sharing information on your individual profile. LibreView will have access to the data that you choose to track within the app/website and the information you choose to include on your individual profile, but they will not have access to any other information about you that is collected as part of the research study.

Risk of Wearing Fitbit Activity Tracker
There is also the possibility of minor skin irritation associated with wearable devices. We recommend taking it off occasionally, not wearing it too tightly, and keeping it clean and dry. You should regularly clean your wearable device—especially after working out or sweating. Rinse the wearable device with water or wipe it with a small amount of rubbing alcohol. Do NOT use hand soap, body soap, dish soap, or household cleaners which could get trapped beneath the band and irritate skin. Always dry the wearable device well before putting it back on. If you start to experience skin irritation on your wrist, we suggest you remove the device and contact a member of the study team to discuss the issue and determine whether you would like to continue participating in the study.

Risk of CGM: There is a small risk that the adhesive used to attach the sensor to the arm will cause skin irritation. You will be provided with instructions on how to properly place the sensor. If excessive irritation does occur, you should remove the sensor and contact study staff.

Risk of finger stick: When you complete your baseline and follow-up assessment, you will have your HbA1c measured. Approximately 3 drops of blood will be removed by finger stick. This is a standard method used to obtain blood for routine hospital laboratory tests. You may experience a small amount of pain when the lancet goes in to your finger. Other than this momentary pain, the discomfort of finger stick should be minimal. However, in about 10% of the cases a small amount of bleeding under the skin will produce a bruise (hematoma). A small scar may persist for several weeks. The risk of local infection is less than 1 in 1,000. The site will be cleaned with an alcohol wipe prior to the finger stick to minimize this risk.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation. While you are continuously tracking your blood sugar, you may see previously unknown high or low blood sugar episodes. Both you and your coach will have access to this information on a daily basis. This information could benefit you so that you can work with the study coach and/or your primary care provider to better manage your blood sugar.

Will I receive any other clinical results?
Other clinically relevant results of this research will be communicated with you. You will receive a report of your weight and HbA1c (which measures longer-term blood sugar management) at the beginning of the study and at the end.

How will information about you be protected?
The study team will store any personal information you provide, your Wi-Fi scale and tracker data, and your location data in secure databases that comply with the University of North Carolina's policies on sensitive information storing and transmission. This means that there are very strong protections in place to keep your information from being accessed by individuals not authorized to access it. Any information that you share on paper forms will be stored with an ID that does not identify you personally and will be kept in locked file cabinets only accessible to study staff. Information you share through online questionnaires uses a secure server that complies with the University security policies. You will be asked to voluntarily allow the study team to access your Fitbit data through the Fitbit website by entering your Fitbit username and password. The study staff member who helps set up your devices will allow you to create and enter your Fitbit username and password on your own and will not need to see this information. Your usernames and passwords will not be stored by the study in any manner.

You will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Will you receive results from research involving your specimens?
You will receive the results of your HbA1c tests. The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the

risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty.

Will you receive anything for being in this study?
You will receive $15 after you complete the baseline assessment and $25 after you complete the 12-week follow-up assessment. You must complete the measures and questionnaires in order to receive the payment. If you complete the 12-week assessment, you will also be able to keep the Fitbit activity tracker and scale that you will use during the study. If you decide to withdraw from the study or do not complete all of the study assessments, we will ask you to return the Wi-Fi scale and Fitbit to the UNC Weight Research Program. You will receive CGM sensors and a scanner to read the CGM data. You will return the scanner to the study once the study procedures are complete. In the event that any device is lost or damaged, you will not be responsible for the cost, however, please alert study staff immediately so that the device can be replaced. As the devices used are costly to the researchers, care should be taken with them.

Who is sponsoring this study?
This research is funded by the University of Michigan Board of Regents. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participants will be shown a link that says "Next."
Thank you for reviewing the Informed Consent document. Please choose one of the following:

- I have read the information and voluntarily agree to participate in this research study. NOTE: A copy of this electronically signed informed consent will be provided to you at the baseline assessment visit, and signature of receipt will be collected at that time.
- I do not wish to participate in this research study.

SUBMIT

If the person picks yes, provide a message that says "You have indicated that you **will** participate in this research study. By signing below, you are granting consent to participate in this study." *(provide box and submit button). After submit, get text that says* "Congratulations on enrolling in this research study."

If the person picks no, say, "Thank you for your time. You have chosen **not** to participate in this research study. If you have any questions, please contact the UNC Weight Research Program."

12.2 PHYSICIAN CONSENT

PHYSICIAN CONSENT TO PARTICIPATE IN A DIET AND EXERCISE PROGRAM AT UNC-CHAPEL HILL

TO:		**RETURN TO:**
	Physician's Name	**Karen Hatley, MPH** **UNC Weight Research Program** **Lineberger Comprehensive Cancer Center** **1700 Martin Luther King Jr. Blvd., CB 7294**
	Address	**Chapel Hill, NC 27514**
	City State Zip	**Telephone: (919) 966-5853** **FAX: (919) 843-6663**
	( ) **Telephone Number**	***please give form to study participant to return to study staff or send directly**

Your patient _____ has asked to participate in a weight loss program for adults with type 2 diabetes or pre-diabetes who are not being treated with insulin or other medications at the University of North Carolina at Chapel Hill. This is a 3 month research study designed to help patients to change their eating and exercise habits and to examine the impact that this will have on short-term weight loss and glycemic control. This will involve the following:

A diet program that will reduce energy intake by focusing on tracking and reducing 'red' foods (higher calorie and/or fat foods) and increasing 'green' foods (plants and very lean protein).
A physical activity program that will be primarily home-based. The exercise will gradually be progressed from 50 minutes per week to 150 minutes per week with activities akin to brisk walking.
Continuous glucose monitoring (CGM), using a device that does not require calibration, used as a tool to interpret diet and activity changes and their impact on blood glucose and weight loss.
Behavioral modification techniques for changing eating and exercise behaviors plus weekly sessions with study staff to review self-monitoring records, set goals and review progress.
Digital tools including an iphone app, wifi connected digital scale, Fitbit activity tracker and Freestyle Libre CGM.

Please indicate below if this program seems appropriate for your patient or if you see any contraindications for his/her participation (*please check the appropriate box below)*.

☐ I know of no contraindications to this patient participating in any of the above components of the program.

☐ I feel that this program would not be appropriate for this patient for the following reason(s):

_____

_____

_____
Signature of Physician

Inclusion Criteria:

1. Currently age 20-65
2. BMI 25-50 kg/m^2
3. Normal or impaired glucose as determined by HbA1c fingerstick (<6.5%)
4. Own an iPhone with a data and text messaging plan
5. Have home Wi-Fi access
6. Have the ability to read, write, and speak English
7. Not meeting the American College of Sports Medicine recommendation of 150 minutes of Moderate to Vigorous Physical Activity each week
8. Ability to attend weekly visits at the UNC Weight Research Program clinic for one month and weekly in-person, phone, or video call for an additional two months
9. Can obtain primary care provider consent that participation is appropriate

Exclusion Criteria:

1. Lost more than 10 pounds in the last 6 months
2. History of weight loss surgery
3. Currently participating in another physical activity or weight loss program or research study that may interfere with participation in this study
4. Currently meeting exercise recommendations of 150 minutes per week of moderate-to-vigorous physical activity
5. Currently pregnant, pregnant within the past 6 months, or planning to become pregnant within the next 4 months
6. Planning to relocate in the next 4 months

7. Pre-existing medical condition(s) that preclude adherence to an unsupervised exercise program, as determined by items endorsed on the PAR-Q (Physical Activity Readiness Questionnaire)
8. Diagnosis of diabetes
9. Taking medications to treat prediabetes
10. Report taking prescription or over the counter medication with a known impact on metabolism or weight
11. Current treatment for cancer
12. History of clinically diagnosed eating disorder
13. Diagnosis of schizophrenia or bipolar disorder
14. Hospitalization for a psychiatric diagnosis within the last year
15. Report a past diagnosis of or current symptoms of alcohol or substance dependence
16. Unwilling or unable to wear the CGM device continuously for the duration of the study
17. On dialysis

No exclusion criteria shall be based on race, ethnicity, or gender.

12.3 ONLINE SCREENER

Welcome to the T2 Connect Research Study screening questionnaire. These questions will take you approximately 5-10 minutes to complete. Once you complete the screener and submit your responses, you will be contacted by a study staff member by phone or by email. If you continue with the screening questions, your responses to the questions will be kept for the duration of the study for descriptive purposes.

Do you give your permission to continue with the online questionnaire and to be contacted by study staff if you are determined to be eligible for this study?

☐ Yes ☐ No

- *If yes, continue screener*
- *If no, have message that says "*Thank you for your interest in our program. If you wish to be informed of future studies, click here." Link to www.uncweightresearch.org/participate_cap.asp

1. Do you read, write and speak English?
   ☐ Yes ☐ No (INELIGIBLE)

2. How did you hear about this program?
   ☐ Facebook post (sponsored)
   ☐ Facebook post by friend, family, co-worker, etc.
   ☐ Tweet by friend, family, co-worker, etc.
   ☐ Email from friend, family, co-worker, etc.
   ☐ Website
   ☐ Listserv: If so, which one: _____
   ☐ Word of mouth (friend, relative, co-worker, etc.)
   ☐ Another study participant. Name_____
   ☐ Flyer
   ☐ Other (please specify): _____

3. What is your gender? ☐ Male ☐ Female

WOMEN ONLY COMPLETE THE NEXT 3 QUESTIONS

4. Are you currently pregnant or breastfeeding? ☐ Yes (INELIGIBLE) ☐ No

5. Have you been pregnant in the last 6 months? ☐ Yes (INELIGIBLE) ☐ No

6. Do you plan on becoming pregnant in the next 4 months? ☐ Yes (INELIGIBLE) ☐ No

7. What is your age? _____

break

The information gathered on this page is collected for descriptive purposes and does not influence your eligibility to participate.

8. Are you of Hispanic or Latino or origin?
   ☐ Yes ☐ No

9. Which race to do consider yourself to be? (you may choose more than one category):
   ☐ Black or African-American
   ☐ Asian
   ☐ American Indian or Alaska Native
   ☐ Hispanic, Latino, or Cape Verdean
   ☐ Native Hawaiian or Other Pacific Islander
   ☐ White
   ☐ Other (Specify):_____

break

10. What is your current weight? _____ lbs.

11. What is your height? ____ ft _____ inches

    [BMI automatically calculated]
    *The formula to calculate BMI is (weight in pounds * 703)/(height in inches * height in inches)*

12. Have you lost weight in the past 6 months?
    ☐ No ☐ Yes If yes, how much have you kept off? _____ lbs. *(> 10 lbs = INELIGIBLE)*

13. Have you ever had weight loss surgery?
    ☐ No ☐ Yes *(INELIGIBLE)*

14. In a typical week, how many days do you do any physical activity or exercise of at least moderate intensity, such as brisk walking, bicycling at a regular pace, and swimming at a regular pace?
    ☐ None
    ☐ 1 day per week

☐ 2 days per week
☐ 3 days per week
☐ 4 days per week
☐ 5 days per week
☐ 6 days per week
☐ 7 days per week

15. On the days that you do any physical activity or exercise of at least moderate intensity, how long do you typically do these activities?

_____Minutes _____Hours

16. Have you ever had or are you currently receiving treatment for any of the following?

a. Pre-Diabetes or Diabetes ☐ Yes ☐ No (INELIGIBLE)

If yes, how is it controlled? _____
Diet and exercise
Prescription medication (INELIGIBLE)
Insulin (INELIGIBLE)
Other (describe)

b. Hospitalization in the past year for depression or other psychiatric disorder ☐ Yes (INELIGIBLE) ☐ No

c. Schizophrenia or bipolar disorder? ☐ Yes (INELIGIBLE) ☐ No

d. Alcohol or substance abuse? ☐ Yes (INELIGIBLE) ☐ No

e. Anorexia or bulimia? ☐ Yes (INELIGIBLE) ☐ No

f. Cancer ☐ Yes (Current treatment = INELIGIBLE) ☐ No

---

break

1. Has a doctor ever said that you have a heart condition AND that you should only do physical activity recommended by a doctor? ☐ No ☐ Yes (INELIGIBLE)

2. Do you feel pain in your chest when you do physical activity? ☐ No ☐ Yes (INELIGIBLE)

3. In the past month, have you had chest pain when you WERE NOT doing physical activity?
☐ No ☐ Yes (INELIGIBLE)

4. Do you ever lose your balance because of dizziness or do you ever lose consciousness?
   ☐ No ☐ Yes (INELIGIBLE)

5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
   ☐ No ☐ Yes

6. Is your doctor currently prescribing drugs for your blood pressure, cholesterol, or a heart condition?
   ☐ No ☐ Yes

7. Do you know of any other reason why you should NOT do physical activity?

☐ **NO** ☐ **YES**

8. Are you currently on dialysis?

☐ **NO** ☐ **YES** (INELIGIBLE)

9. Do you have an implanted medical device (for example, a pacemaker)?

☐ **NO** ☐ **YES** (INELIGIBLE)

If yes, please describe: _____

Break

25. Are you taking any prescription medications?

☐ **NO** ☐ Yes

26. Are you taking any non-prescription over the counter dietary supplements?

☐ **NO** ☐ Yes

Break

27. Do you have access to the Internet at home? ☐ Yes ☐ No (INELIGIBLE)

If yes, How do you access the Internet at home (Check all that apply)?

- ☐ Computer (desktop or laptop)
- ☐ Smartphone or cell phone
- ☐ Tablet

If yes, do you connect to the Internet using home Wi-Fi, or another method such as mobile wireless (smartphone hotspot, USB key, etc.)?

- ☐ Home Wi-Fi (wireless connection) (INELIGIBLE if not selected)
- ☐ Smartphone hotspot
- ☐ Other (please specify): _____

28. What kind of smartphone or cell phone do you have (Check all that apply)?

- ☐ Traditional cell phone (not a smartphone)
- ☐ iPhone (INELIGIBLE if not selected)
- ☐ Android
- ☐ Other smartphone
- ☐ I do not have a cell phone or smartphone

29. (If iPhone) Do you have a data plan to access the Internet and receive text messages on your iPhone?
    - ☐ Yes, unlimited
    - ☐ Yes, but in limited amounts
    - ☐ No, I only access the Internet on my smartphone when connected to Wi-Fi
    - ☐ Other (please specify): _____

30. Are you planning on moving out of the area within the next 4 months?
    ☐ Yes (INELIGIBLE) ☐ No

31. Would you be willing to come for weekly study visits at the UNC Weight Research Program in Chapel Hill?
    ☐ Yes ☐ No (INELIGIBLE)

32. Thank you for completing these questions. In order to complete your eligibility screening, a study staff member will need to contact you by phone. Please enter your contact information below.
    First Name:
    Last Name:
    Contact phone number:
    Email address:

33. What is the best time to reach you (select all that apply)?
    - ☐ Mornings
    - ☐ Afternoons
    - ☐ Evenings

34. If we call you to follow up about your eligibility, may we leave a message?
    - ☐ Yes
    - ☐ No

Please click "next" to complete the survey.
After Next, this message will appear: Thank you for completing the T2Connect research study screening questions. You will be contacted by a member of the study staff with information about your eligibility. Depending on the number of people interested in participating, it may take a few days for us to contact you. If you do not receive a call within 3-4 business days, please call our research center at 919-966-5852.

12.3 TELEPHONE SCREENER

1. When you filled out the online screening questions, you reported that your weight is _____ lbs. and your height is _____. Is this accurate to the best of your knowledge?

BMI = _____ ***MUST BE** 25 – 40;*

I*f BMI calc on edges of eligibility (25-27 or 38-40),* "If you are eligible after we finish these screening questions and you decide you would like to participate, we will confirm your height and weight at your first study visit at our center."

2. *If Yes to Cancer question 17.*

   In the online screener, you reported having been diagnosed with cancer in the past. Can you tell me when that was? Are you currently being treated for Cancer? (If current treatment, INELIGIBLE)

3. *If yes to Question 23 on web screen:* Do you know of <u>any other reason</u> why you should not do physical activity?

   In the online screener, you answered yes to the question "Do you know of <u>any other reason</u> why you should not do physical activity?" Can you explain? (INELIGIBLE if they can't do activity akin to walking and progress to 150 minutes of Moderate to Vigorous PA per week over time)

4. *If Yes to Question 25 on web screen: Are you taking any other prescription medications?*

You reported that you are taking prescription medications. Can you tell me the names of them? (Also ask what it is used to treat)
If Yes, specify: _____
(NOTE: look for meds with known effects on appetite or weight, oral steroids, diabetes meds--INELIGIBLE)

6. *If Yes to Question 26 on web screen: Are you taking any non-prescription over the counter dietary supplements?*

You reported that you are taking non-prescription over the counter dietary supplements. Can you tell me the names of them?

If yes, specify: _____

If other than vitamin/mineral supplement: Would you be willing to stop taking this supplement during the study period? ☐ **NO** (INELIGIBLE) ☐ Yes

7. Are you currently participating in any other weight loss of physical activity program?

8. Are you currently a member of any other research studies?

   ☐ **NO** ☐ Yes

If yes, describe _____
(If other study would interfere with following study protocol, INELIGIBLE)

Thanks for taking the time to answer my questions.

You submitted the following contact information on the website (*read their info. from the web report).* Has any of this changed? [*If so, note below].*

Name: _____

Street Address: _____

City: _____ State: _____ Zip Code: _____

Home Phone: _____Work Phone: _____ Cell Phone: _____

Email Address: _____

Staff note: ensure that participant is residing within a reasonable distance of the assessment site.

The information you've given me will be reviewed by the project coordinator to determine your eligibility for the study. If you are eligible, we will ask you to come in to our center for an orientation session so that you can hear more about the program, meet the staff, and ask questions before deciding whether or not to participate. If you decide to participate, you will sign an Informed Consent document and schedule your baseline assessment visit. This visit will take approximately one hour. You will be notified of the date and time of the orientation either by phone or by email.

[If you think they are definitely eligible, schedule them for an orientation visit. Tell them that the appointment will be confirmed by email.]

Do you have any last questions? Thank you for your time today.

OFFICE USE ONLY:

Eligible: ☐ Yes ☐ No
Reason_____

Scheduled orientation visit: ☐ Yes ☐ No

Date:____/____/____ and Time

Verify BMI: ☐ Yes ☐ No