Title: Healthy Eating and Active Living to Reverse Diabetes Pilot Study

Principal Investigator: Bailey, James E

CO-Is: Frankie Stentz, Satya Surbhi, Asos Mahmood, Tracy Bruen, Susan Butterworth, Umar Kabir, Rick Bloomer, Alexandria Boykins

Additional Research Personnel: Melissa Petersen, Susie Suttle, Colbie Andrews, Deborah Ogunsanmi

Abstract:

The HEAL Diabetes Program is a multicomponent intensive plant-forward healthy eating program designed to reverse diabetes. Several recent studies, most notably the Diabetes UK-funded Diabetes Remission Clinical Trial (DiRECT) in England and Scotland, have demonstrated that intensive programs for weight loss and weight loss maintenance can lead to long-term remission of diabetes for as many as half of patients with early Type 2 (adult-onset) diabetes. Furthermore, the U.S. Preventive Services Task Force has recommended that *all patients* with obesity and at highest risk for diabetes be referred to such intensive multicomponent behavioral weight loss interventions, but no such programs are available for people living in the low-income and underserved areas of Memphis. This effort will pilot an innovative, culturally tailored, and intensive healthy eating program designed to reverse diabetes based in the UTHSC Neighborhood Health Hub located in low-income neighborhoods to demonstrate that this approach will work in Memphis to improve and extend people's lives. The HEAL Diabetes Pilot Program will: a) engage and retain a minimum of 30 patients with Type 2 diabetes and obesity to participate in the program as well as 30 additional "control" patients who will receive routine care, and b) assess patient outcomes including weight loss and rates of diabetes remission using average blood sugar (hemoglobin A1c) over a six-month period.

BACKGROUND AND SIGNIFICANCE

A. Significance.

A1. Type 2 diabetes is epidemic among the medically underserved. The growing worldwide epidemic of Type 2 diabetes (T2D) and other obesity-associated chronic conditions (OCC) disproportionately affects minority and medically underserved subpopulations, impacting over 10 million people residing in medically underserved areas in the U.S.[1-3] Researchers have long known that weight gain and obesity are the main drivers of T2D,[1,4] but little progress has been made addressing obesity in primary and specialty care settings. Low income and African American patients are less likely to get recommended care for T2D and other OCC,[5] and as a result are much more likely to experience diabetes-related amputations, kidney failure, and premature death.[6,7] Yet despite low-income and minority populations facing special barriers to effective T2D self-care related to food insecurity and other social determinants of health (SDOH),[8,9] most T2D behavioral interventions are tailored for the majority, higher-income, patient populations. Thus, low-income and minority groups need specific culturally-tailored solutions that address any particular SDOH they face.[8,9] Life expectancy is markedly reduced in patients with T2D, largely through the impact of the multiple OCC that commonly accompany T2D, including cardiovascular disease, cancer, and chronic kidney disease.[10] Intensive medication therapy to lower blood sugar, cholesterol, and blood pressure in patients with T2D has led to modest improvements in real-world major clinical outcomes at best,[11] in part because of the challenges of adherence to multiple medications particularly among vulnerable and medically underserved populations.[7] Although weight management is considered essential therapy for people with T2D and other obesity-associated chronic conditions, lack of pragmatic approaches for implementing effective weight loss programs for this population has served as a critical barrier to achieving better outcomes for vulnerable patients with T2D.[12]

A2. Evidence on best diet composition supporting food as medicine hypothesis. Numerous studies have thus far clearly established the benefits of plant-forward diets (i.e. diets emphasizing plant-based foods).[13] Large observational studies have demonstrated substantial survival benefits for a plant-forward Mediterranean diet related to cardiovascular disease and multiple other chronic conditions.[14-16] A large randomized controlled trial (N=322) confirmed that both Mediterranean and low-carbohydrate diets have similar sustained impacts on weight and cardiometabolic health.[17,18] Studies of pre-diabetes and diabetes remission support a relatively high-protein diet (26-30% protein vs. 15%) for effective and sustained weight loss while maintaining lean body mass.[19-21] New evidence from an inpatient randomized controlled trial of ad libitum food intake shows that ultra-processed diets cause excess calorie intake and weight gain,[22] providing evidence that processed foods are primary vectors of obesity that must be eliminated from diets to achieve and sustain weight loss.[23]

A3. New powerful evidence demonstrating effectiveness of primary care-based multicomponent interventions for rapid weight loss, weight loss maintenance, and diabetes remission. The Diabetes Remission Clinical Trial (DiRECT), an open-label, cluster-randomized pragmatic trial in 49 primary care practices in low-income areas of Scotland and England, recently demonstrated that such interventions can achieve and sustain similar results to bariatric surgery.[21,24] DiRECT used health coaching by nutritionists in primary care practices, intensive preparation for change, total diet replacement (TDR), and physician-supervised medication discontinuation (PSMD), to achieve an average weight loss of 10.0 kg, diabetes remission in 46% of those in the treatment group at 1 year,[24,25] sustained remission in 36% at 2 years,[26] and substantial improvements in other biological health outcomes,[27,28] at low cost.[29] Best evidence from DiRECT and other studies suggests that these intervention components have the most potential to achieve similar outcomes in at-risk populations.

A4. Intensive multicomponent behavioral weight loss interventions most effective. The U.S. Preventive Services Task Force (USPSTF) concluded that adults with obesity benefit most from behavioral weight loss interventions that are intensive and multicomponent.[12,30,31] A systematic review of the Community Preventive Services Task Force found sufficient evidence to particularly recommend technology-supported multicomponent coaching or counseling interventions to help adults achieve and maintain weight loss.[32] Pragmatic trials of these multicomponent interventions in obesity-associated T2D are desperately needed. The USPSTF has called for well-designed pragmatic comparative effectiveness trials to test and disseminate multicomponent interventions in primary care settings and to provide evidence regarding most effective intervention components.[12,31] The USPSTF has identified subpopulations such as high-risk racial and ethnic groups as important targets for further outcomes research.[12] Communities that are predominantly African American, low-income, and in medically underserved areas of the South are among those in greatest need.[2,3,33,34] Over 40% of African American men and over 50% of African American women suffer from obesity.[34] Diabetes prevalence exceeds 18%.[35] Most patients with obesity-associated diabetes also experience additional OCC such as hypertension, hyperlipidemia, and arthritis that contribute to adverse outcomes.[36-39]

The USPSTF and other critical appraisals of the literature have identified the following component interventions as the most evidence-based and promising for achieving substantial weight loss and diabetes remission in medically underserved populations.

A4a. Motivational Interviewing-based Health Coaching (MI-based HC). Motivational interviewing (MI) has demonstrated efficacy and effectiveness across a range of behavior change outcomes.[40] Meta-analyses confirm that MI is more effective than traditional diabetes education and weight management programs in achieving weight loss.[41-48] Health coaching by non-clinical staff has been identified as among the lowest cost strategies for expanding primary care capacity to support diabetes self-care, with strong evidence of effectiveness from numerous clinical trials.[49,50] Moreover, recent systematic reviews have identified health coaching as among the most efficacious strategies for engaging patients in behavior change to help adults achieve and maintain weight loss,[12,31,32,51] and improve diabetes outcomes in disadvantaged populations.[51]

A4b. Tailored Motivational Text Messaging (TM). TM has been observed to be an effective, low cost approach for engaging patients in diabetes self-care.[52-56] Numerous studies employing TM have demonstrated improved glycemic control, healthy eating, and physical activity in patients with T2D.[52,54-56] Our prior research and those of others have also demonstrated that patients with diabetes are appreciative of TM from their doctor's office.[36,55-57] Further, systematic reviews have identified TM as among the most efficacious and low-cost strategies for engaging patients in behavior change[47,58,59] and have highlighted the importance of such technology-supported interventions to help adults achieve and maintain weight loss.[12,31,32]

A4c. Total Diet Replacement. Numerous studies have demonstrated the efficacy of TDR for supporting major changes in eating habits and weight loss for patients with obesity and T2D,[19,60-63] and TDR was a core intervention for the DiRECT study.[21,24,25,64] Although some of these studies used liquid meal replacements for initial weight loss, several others have used whole foods throughout.[19,60] Diet replacement with low glycemic whole food diets is associated with increased satiety and weight loss.[65,66] TDR requires complete substitution of the individual's habitual diet, giving a period of about 12 weeks to plan a new normal diet for life. Numerous recent studies have also demonstrated effectiveness for healthful food pharmacies, food banks, and food delivery in changing key obesity-related eating behaviors and addressing food access issues for low-income populations.[67-72]

A4d. Support Groups. Although conclusive evidence cannot be drawn regarding the relative effectiveness of group- vs. individual-based interventions, group counseling has served as a fundamental component of most successful multicomponent healthy eating, physical activity, and weight loss interventions.[12,73-75] Most notable among these are Look AHEAD (Action for Health in Diabetes),[76-80] the Activity Counseling Trial (ACT),[81,82] and

the Diabetes Prevention Program (DPP).[83-86] Consistent with the Social Cognitive Theory that undergirds the proposed study, evidence suggests that the most successful group counseling programs employ peer social support.[87-95] Recent systematic reviews have identified peer support groups as a promising strategy that can mitigate the effects of SDOH,[51,91,96] and improve T2D outcomes for African Americans[51,89] and the general population.[90]

A4e. Cooking Classes. Many successful multicomponent healthy eating and weight loss interventions such as the DPP[83-86] have employed cooking classes, and culinary medicine is emerging as a popular intervention among patients and providers.[97] Hands-on cooking classes can improve nutrient intake in people with obesity-associated T2D from diverse ethnic and socioeconomic backgrounds.[98] Further, cooking classes encourage home cooking and increase "food literacy" and self-efficacy or confidence in both basic technical culinary skills and competency to plan, choose, prepare, and consume nutritious food.[99-101] Consumption of meals at home has been associated with a decreased risk for T2D and less weight gain over time.[102]

A4f. Physician-Supervised Medication Discontinuation (PSMD). Numerous studies have highlighted the importance of PSMD for T2D and hypertension patients participating in intensive weight loss to avoid serious hypoglycemia and/or hypotension.[103,104] Most notably, PSMD was a core intervention for DiRECT.[21,24,25,64]

A5. Scientific Foundation. Our objective is to assess the effectiveness of a pragmatic intensive multicomponent weight loss intervention that leverages existing staff and resources in primary care settings with potential to achieve simultaneous improvements in multiple chronic conditions associated with obesity. The ***Healthy Eating and Active Living to treat Diabetes (HEAL Diabetes)*** pilot study seeks to reproduce the results of the DiRECT study using a similar multicomponent intervention culturally tailored for a U.S. medically underserved population. Data from surgical weight loss trials have shown that bariatric surgery can lead to simultaneous improvements in multiple metabolic parameters and chronic disease states, resulting in frequent diabetes remission and improved health outcomes.[105-112] Yet, until the recent DiRECT study,[21,24-26] little progress had been made in identifying practical behavioral weight loss approaches with similar outcomes. Now, multiple lines of recent evidence reviewed above are converging to demonstrate the component interventions most likely to succeed in achieving the substantial and sustained weight loss necessary to improve T2D outcomes. Based on small studies challenged to deliver culturally appropriate behavioral interventions, many researchers suggest that substantial weight loss and T2D remission are not obtainable or sustainable in low-income and minority populations.[113,114] The current study seeks to clearly demonstrate that this presumption is wrong.

A6. Summary. Although it is premature to conclude that the above intervention components are definitively the most efficacious, our review indicates they are among the most important for multicomponent interventions emphasizing whole foods. This demonstration project will use the above key evidence-based, community-engaged, and culturally-tailored components[115] in a "full-court press" clinic-based intervention based on the Chronic Care Model[116-118] to substantially impact major biological, metabolic, and patient-reported outcomes. The HEAL Diabetes study will test a primary and specialty care delivered multicomponent healthy eating and weight loss program designed to address and ameliorate the SDOH root causes of the T2D epidemic.[8,9]

B. Innovation.

The current study is innovative because it has potential to reframe the culture and paradigm of T2D treatment by demonstrating an effective, low-cost, and sustainable multicomponent behavioral intervention in real-world clinical settings. The literature has been biased through comparisons of high-cost surgical interventions with nutritional interventions too under-resourced to achieve similar efficacy. This research will allow us to identify and refine a behavioral treatment protocol that can reverse T2D in routine clinical practice. Further, the proposed study's focus on improvements in self-efficacy as a fundamental mechanism of action is innovative. Our approach draws on the strong evidence for effectiveness of motivational interviewing in multiple disease states[42,44,119-126] and all its component interventions are designed to enhance patient self-efficacy for healthy eating, physical activity, and weight loss.[127-134] The proposed study's selection and cultural tailoring of international best practices in T2D behavioral interventions for maximal impact based on extensive input from patients in a medically underserved U.S. population is also highly innovative.[115] Our study seeks to reproduce the results of the United Kingdom DiRECT study[24] by adapting its interventions in a culturally appropriate and sustainable way for a predominantly African American population in the U.S. As Gamburzew *et al*. note, developing multicomponent interventions that offer understandable nutritional guidance to medically underserved patients in real-world settings, requires specific targeting of ethnic minority populations.[135-140]

C. Approach

C1. Study Overview -Overall Goal, Aims, Design. The proposed pilot study replicates the inclusion criteria and outcome measures of the DiRECT study[21,24-26] and tests a multicomponent intervention similar to DiRECT's that is culturally tailored and informed by the preliminary results of our own Management of Diabetes in Everyday Life (MODEL) study.[142,143] The design is a randomized controlled pilot study in a sample of 72 patients with obesity-associated T2D. Eligible patients will be enrolled and randomized to one of the following two arms: 1) Multicomponent intervention (treatment) group (n=36), or 2) Usual Care (control) group (n=36) as detailed in **Table 1** below.

C1a. Study Overview. Research demonstrates that diabetes remission is achievable through weight loss, but pragmatic approaches that leverage existing staff and resources in the healthcare setting to deliver intensive behavioral lifestyle modification interventions are underdeveloped and underutilized. Our goal is to assess the effectiveness of an intensive multi-component plant-forward healthy eating intervention for patients with obesity-associated T2D. Our approach builds on the results of the Diabetes Remission Clinical Trial (DiRECT) study,[21,24-26] and the preliminary results of the Management of Diabetes in Everyday Life (MODEL) study,[142,143] to test a culturally tailored multicomponent intervention designed for a U.S. medically underserved population. This research design is an individually randomized controlled trial in 72 patients with obesity-associated T2D. The Healthy Eating and Active Living to Treat Diabetes (HEAL Diabetes) Study will assess a "full-court press," clinic-based intervention with these evidence-based components: 1) ***Intensive preparation for change*** to a plant-forward healthy eating program for weight loss, 2) ***Motivational interviewing-based health coaching (MI-based HC)*** support for healthy eating and physical activity, 3) ***Tailored motivational text messaging*** from the health coach, 4) ***Total diet replacement (TDR)*** with healthy food boxes for 3 months, 5) ***Health coach-led support groups***, 6) ***Cooking classes***, and 7) ***Physician-supervised medication discontinuation (PSMD)***. All components will be individually and culturally tailored to address social determinants of health serving as key barriers to healthy eating and physical activity. The U.S. Preventive Services Task Force concluded that adults with obesity benefit most from behavioral weight loss interventions that are intensive and multicomponent.[12,30,31] MI-based HC has been demonstrated to be among the most effective component interventions for weight loss.[41-48] Our team has extensive expertise implementing these interventions in the settings where low-income individuals with T2D and other obesity-associated chronic conditions receive routine care through the DiRECT,[21,24-26] our MODEL,[142,143] SafeMed,[157-161] and other[19,77-82,84,162-165] studies. DiRECT used health coaching in primary care practices, intensive preparation for change, TDR, and PSMD to achieve an average weight loss of 10.0 kg, diabetes remission in 46% at 1 year,[24,25] sustained remission in 36% at 2 years,[26] and improvements in key biological health outcomes[27,28] at low cost.[29,155] Best evidence suggests that these are among the components with the most potential to achieve similar outcomes in other at-risk populations. Preliminary results from the MODEL study indicate that primary care-integrated MI-based HC is well received, with highest self-reported levels of improvements in health behaviors, confidence, and health outcomes in the MI-based HC group, and overall retention of over 90% in 672 program participants. By directly supporting patients in achieving their health goals, MI-based HC is more effective at engaging patients in self-care than traditional diabetes education or weight loss classes.[41-48] Furthermore, health coaches integrated into practices are increasingly sustainable due to the growth of value-based payment initiatives.[141]

C1b. Specific Aims. In light of the recent evidence indicating that multicomponent behavioral interventions can achieve levels of weight loss and diabetes remission comparable to bariatric surgery, we seek to assess the effectiveness of the most evidence-based of these component interventions delivered in combination.

Aim 1: Provide preliminary demonstration of the feasibility, effectiveness, and operational and financial sustainability of a health coach-supported intensive weight loss and weight maintenance program designed for people in Memphis. Specifically, we will:

A. Assess our recruitment capability and resulting sample characteristics

B. Evaluate resources and ability to manage and implement the study and study interventions

C. Evaluate acceptability and suitability of intervention and study procedures (e.g. operational sustainability assessed through participant 3-, 6-, and 12-month program retention and attendance rates)

D. Preliminary evaluation of participant responses to intervention (see Aim 2 below)

E. Assess cost effectiveness of the multicomponent intervention (financial sustainability).

Aim 2: Quantify and compare the treatment and control groups on the following measures:

A. Primary **biological outcomes** of body weight, blood pressure (number of prescribed blood pressure medications), average blood sugar (hemoglobin A1c [A1c]), and diabetes remission (A1c ^{3} < 6.5%) after at least 2 months off all diabetes medications except for GLP-1 agonist and/or SGLT-2 inhibitor medications which patients will be allowed to continue or start if desired by patient and recommended by their physician.

B. Secondary **patient-reported outcomes** of self-efficacy and self-care activities related to general diet and exercise.

C1c. Goal. The HEAL Diabetes study addresses a critical need to identify effective, scalable, and sustainable behavioral weight-loss approaches to help medically underserved patients in the U.S. achieve substantial weight loss and diabetes remission. We will compare primary biological outcomes (body weight, number of prescribed blood pressure medications, A1c, and diabetes remission), secondary metabolic outcomes (fasting glucose, insulin, insulin resistance, lipid profile, and CRP levels), and secondary patient-reported outcomes (self-efficacy, self-care activities related to general diet and exercise, health-related quality of life, and average pain rating) at baseline and 12-months. Based on DiRECT and MODEL study experience and evidence from other key studies and systematic reviews, we hypothesize that the HEAL Diabetes intervention will result in weight loss ≥ 10 kg and diabetes remission in over 40%,[21,24-26] self-efficacy in plant-forward healthy eating will mediate its effects on primary biological outcomes, and it will be operationally and financially sustainable.[2,29,142,143,155]

Table 1: Program Interventions by Group*

Intervention Components	Multicomponent Intervention Group (Treatment)	Core Intervention Group (Control)
1) Intensive Preparation for Change and Education on plant forward healthy eating for weight loss	Guidebook, handouts	Guidebook, handouts
	Two (introductory and kickoff) health coach and nutritionist/registered dietician co-led sessions with intensive preparation for dietary change & weight loss	One traditional diabetes education session led by a pharmacist or nutritionist/registered dietician
2) Health Coaching - Motivational and educational support for healthy eating, physical activity, and weight loss	Individual HC sessions bi-monthly for first 3-4 months (Intensive Phase) and monthly for remaining 7-8 months (minimum of 14 sessions total)	–
	Health coach-led individual or group grocery store tours with individual patient reminders	–
3) Tailored motivational text messaging (TM)	Scheduled Registry-based TM and occasional individual TM from their health coach	–
4) Diet Replacement	Total diet replacement for months 2-4 using tailored healthy food boxes with recipes delivered weekly	Partial diet replacement for months 2-4 using grocery store produce vouchers
5) Support Groups	Monthly clinic-based, health coach-led or co-led sessions focused on MI-based group problem solving (added individual patient text and/or phone reminders)	–
6) Cooking Classes	Free monthly cooking classes with individual patient text and/or phone reminders	–
7) Physician-Supervised Medication Discontinuation	Baseline and follow-up physician visit (month 1 and month 2-4) with standardized instructions and protocol for partial medication discontinuation	Physician made aware of program participation and patients informed of need to discuss medications with physician

* See **Sustainability Plan** and **Facilities** for details on sustaining organizations and sustainability plans for each intervention.

C2. Justification, feasibility and preliminary data. The Center for Health System Improvement (CHSI) that Dr. Bailey directs has a longstanding close partnership with the participating health systems and our investigative team has deep experience with pragmatic clinical trials of lifestyle interventions in diabetes. Thus, our team has the capability to demonstrate the effectiveness of a promising multicomponent intervention strategy to achieve substantial weight loss and high rates of diabetes remission in underserved population.

C2a. Preliminary Data.

1. *Health coaching*. Health coaches are increasingly being integrated into clinical care and are increasingly sustainable due to the growth of value-based payment initiatives.[141] We have been refining a promising strategy to promote behavior change in patients with T2D, named Motivational Interviewing-based Health Coaching (MI-based HC) through our Patient-Centered Outcomes Research Institute (PCORI) funded Management of Diabetes in Everyday Life (MODEL) study.[142,143] Our qualitative results to date from nine focus groups of participants indicate that primary care integrated MI-based HC is particularly well received compared

to patients enrolled in TM and enhanced care arms, with health coaching arm participants reporting highest levels of overall program satisfaction and empowerment in taking charge of critical self-care activities.
2. *Tailored motivational text messaging (TM)*. Our previous survey (N=60) of 60 diabetes patients in medically underserved areas demonstrated high interest in receiving TM from the physician's office.[57] Our mixed-methods study (N=36) showed preferred TM characteristics.[143] We developed, refined, and are testing a registry-based TM system in MODEL.[142] Although MODEL program main outcomes data are not yet available, MODEL TM group participants report higher levels of satisfaction to date[144,145] and have a retention rate of over 90%.
3. *"Daniel Fast" diet*. Plant-based and plant-forward dietary plans offer multiple health benefits. The Daniel Fast is a biblically inspired dietary approach that is nutritionally equivalent to the Mediterranean diet and has received considerable recent attention. Bloomer *et al*. were the first to conduct a controlled experiment using the Daniel Fast[146] and have conducted both human and animal studies specific to this eating plan since 2009. The dietary approach is simple: individuals can consume *ad libitum* intake of plant-based foods with no processed foods, caffeine, or alcohol. A modified plant-forward version of the plan (i.e., allowing caffeine and one daily serving of meat and dairy) has been used with similar success.[147] Adherence to the Daniel Fast plan results in improvements in a variety of health related outcomes,[146-151] including reduced weight, reduced total and LDL cholesterol, blood pressure, insulin and HOMA-IR (Homeostatic Model Assessment for Insulin Resistance), C-Reactive Protein (CRP), and oxidative stress. Furthermore, Bloomer *et al*. have observed excellent compliance with this plan—nearly 80% over a six-month period in human subjects.[152] Animal studies have yielded similar findings.[153,154] Focus groups (detailed in **C2b4** below) demonstrate that most participants (82%) deem the biblically-based "Daniel Fast" diet is socially and culturally acceptable. Patients felt comfortable with their providers offering prayer (94%) and religious TM (82%) as part of a clinic-based healthy eating and weight loss intervention. Key informant interviews revealed that patients from Memphis' medically underserved areas are highly interested in this diet and many have used it.
4. *Focus groups*. Over the last six years, we have conducted over 24 focus groups and six surveys before and after the initiation of the MODEL study to assess the target population's preferences regarding clinic-based interventions to support diabetes self-care through healthy eating, physical activity, and weight loss.[36,57,142-145] These studies consistently demonstrate high interest in MI-based HC, TM, support groups, and plant-forward healthy eating for T2D. We recently conducted four focus groups of medically underserved patients with OCC to assess preferences regarding best ways for doctors' offices to support plant-forward healthy eating and weight loss, and components considered most effective, feasible, and culturally appropriate from the patient perspective (IRB# 19-06698-XP). Patients expressed high levels of interest in intensive plant-forward healthy eating and weight loss programs overseen by their doctors, particularly if it would help treat a chronic condition or reduce medication requirements. Concurrent surveys confirmed highest levels of patient interest in health coaching (100%), healthy food boxes with recipes (100%), TM from the doctor's office (82%), support groups (82%), and cooking classes (77%). Patients reported strong preferences for plant-forward diets that incorporated both lean meat and familiar traditional foods, rather than commercial liquid formula diets.
5. *DiRECT Study*. Dr. Lean and his team demonstrated that primary care-led weight management is both feasible and effective.[24,25] Using a 3-month low-calorie liquid diet, a 2–8 weeks structured food reintroduction, and monthly visits with a nurse or dietician for long-term weight loss maintenance, DiRECT achieved substantial weight loss and full remission of diabetes in nearly half of the participants. While the entire program has proved highly cost-effective and other healthcare costs fell,[29,155] providing a commercial liquid formula diet for 3 months is relatively expensive and is both culturally unacceptable and unsustainable due to expenses for long-term maintenance in low-income areas of the South. The challenges of eating a healthful diet for long-term maintenance are so high in these areas that we believe a whole food plant-forward diet is most likely to be successful if it is initiated from the outset of major dietary changes.
6. *Diet Composition, Diet Replacement and Prediabetes Remission*. Dr. Stentz, a member of our investigative team, has conducted a randomized clinical trial demonstrating remission of pre-diabetes to normal glucose tolerance in obese adults with high protein versus high carbohydrate diet.[19] She is currently completing a similar randomized clinical trial (IRB# 15-03832-FB) assessing the effects of a high protein diet on diabetes remission in T2D. She has extensive experience implementing TDR in clinical trials. She has also demonstrated a novel insulin resistance index to monitor changes in insulin sensitivity and glucose tolerance.[156] Further, the Mid-South Food Bank and Methodist Le Bonheur Healthcare (MLH, Memphis' largest health system) have shown that providing healthy food boxes to high-risk patients at hospital discharge reduced rehospitalizations by 34%

7. *Peer support groups*. Support group meetings were found to be very popular in our previous Centers for Medicare and Medicaid Services-funded SafeMed[157-161] and MODEL[142,143] studies in the target population for the current study. Our ongoing study of T2D remission and trajectories of glycemic change (IRB# 18-06224-XP) has shown that T2D patients in our target population achieve and maintain partial (A1c < 6.5 and ³ 5.7) and complete remission (A1c < 5.7) by 12.1% and 1.5%, respectively, at one year, and remission is highly associated with weight loss (p-value < .0001). Key informant interviews with "Healthy Living Heroes" in our target population who have achieved remission and Diabetes Wellness & Prevention Coalition (DWPC) Patient Advisory Council members indicate high levels of interest and willingness to serve as clinic volunteer peer mentors for support groups.
8. *Prevalence of obesity-associated chronic conditions*. Dr. Bailey has conducted a retrospective cohort analysis of adult patients with obesity-associated T2D seen in practice-based research networks participating in the Delta Clinical and Translational Science Consortium and the Southern Obesity and Diabetes Coalition (IRB# 18-06394-XP). This university-funded study demonstrated that of the 229,646 adult patients in the Mid-South's DWPC Registry and Practice-based Research Network (PBRN) from January 2016-December 2017, about 110,577 adults (48.2%) were obese (BMI≥30), and 34.2% of obese patients were diagnosed with ≥1 obesity-associated chronic condition (OCC). Of these patients, 10,707 (28.3%) had T2D. This study had a high representation of African Americans (55.8%) residing in low-income areas (69.4%).

C3. Conceptual Model. The theory of change underlying the current study is Social Cognitive Theory (SCT) developed by Albert Bandura and utilized in the DPP,[84,162] ACT,[81,82] and Look AHEAD weight loss interventions.[77-80] Bandura's theory postulates that behavior results from triadic influences between: 1) behavioral and cognitive processes influenced by the social/environmental context, 2) an individual's motivation and belief about the consequences of a behavior, and 3) an individual's self-efficacy concerning their ability to achieve a certain outcome.[166-168] Modeling healthy thoughts and behavioral goal-specific plans are key to the SCT approach. The proposed multicomponent interventions provide supportive role modeling for goal setting, reinforcement of physician advice, review of patient progress in self-care behaviors, timely review of feedback, and assisting patients in learning healthy behaviors and problem-solving skills. We chose this conceptual model because, in addition to guiding and informing the behavioral HC intervention at the individual level, it provides the necessary framework to test a multi-level intervention.

C4. Setting. The city of Memphis is majority African American (63.9%) and low income (average income $37,199 with 27.8% below the federal poverty level) ranking it as 2nd highest in poverty among the 36 U.S. cities with a population greater than 500,000).[169,170] The majority of people in Memphis live in HRSA-designated medically underserved and primary care health professional shortage areas (HPSA).[171] Memphis has a very high age-adjusted prevalence of adult obesity at 41.0% and diagnosed diabetes at 15.1% as of 2016.[172] Obesity and diagnosed diabetes rates are even higher among African Americans in Memphis.[34,35] Thus, this research targets the most vulnerable adult patients with obesity-associated T2D in the U.S.

C4a. Participant Recruitment Sites. Potential participants will be recruited with prominently displayed recruitment materials including flyers at the UTHSC Health Hub, the ShelbyCares on 3rd facility, and affiliated clinics. Health hub supervisors will be available to provide study information to potentially eligible patients. Final eligibility will be confirmed following intake completion and subsequent ability to contact patients by phone following intake (Run-in period). All data will be entered into the Research Electronic Data Capture (REDCap) application.

C4b. Study Population. Our inclusion and exclusion criteria closely mirror those of the DiRECT study, recruiting adult patients within 6 years of diagnosis of T2D and without serious complications (i.e. recent eGFR <30 mls/min/1.73 m^2) or requiring insulin.[21,24,64] All eligible individuals seen in participating locations will be offered participation.

Inclusion Criteria: Replicating the inclusion criteria of the DiRECT study,[21,24-26] this study includes all persons who meet the following criteria: 1) ≥18 years of age, 2) T2D of duration 0–6 years (diagnosis based on 2 recorded A1c tests, self-reported duration of diabetes confirmed by chart review), 3) A1c ≥ 6.5% at the screening visit, 4) Body Mass Index (BMI) ≥ 30 kg/m^2, 5) receiving care in a clinic the majority of whose adult patients reside in an HPSA, and 6) has a cell phone or smartphone with texting and voicemail capabilities.

Exclusion Criteria: 1) Current use of insulin or more than two hypoglycemic medications (either oral or injectable), 2) Recent routine A1c ≥ 12%, 3) Weight loss of >5 kg within the last 6 months, 4) Inability to understand consent procedures, 5) Inability to communicate using the English language, 6) Pregnancy or considering pregnancy, 7) Diagnosis of an unstable psychiatric condition, dementia, neurological disorder, or history of severe head trauma or brain tumor, 8) Diagnosis and/or hospitalization for severe depression in the last six months, 9) Evidence of cognitive impairment exhibited by difficulty either understanding, following

directions, or communicating clearly with program staff, 10) Exhibiting uncontrolled psychiatric symptoms and/or behaviors that may present a danger to program staff or to the study participants themselves, 11) Perceived unwillingness or inability to participate, 12) Plans to move from the area and change primary care physicians in the next year, and 13) People currently participating in another clinical research trial.
*Incidental Inclusion of Vulnerable Subjects (*Inclusion of Decisionally Impaired): This study will not incidentally include decisionally impaired persons, as an individual may have undiagnosed psychiatric, cognitive, or developmental disorders, or may have had previous substance abuse problems. If individuals meet the inclusion criteria, but are deemed unable to provide informed consent, they will not be accepted into the study. However, they will be informed of and offered all health hub services that are available outside of study.
Withdrawal Criteria If female participants become pregnant during the study, they will be removed from the study. Any participant who becomes seriously ill, injured, hospitalized, or incapacitated, will be suspended from participation until they return to normal health. If they do not return to normal health, they will be withdrawn. If I participant withdraws informed consent or no longer wants to participate, they will be withdrawn from the study.

C4c. Participant Identification and Recruitment.

Recruitment. Study participants will be recruited from UTHSC Health Hubs in Uptown and ShelbyCares on 3rd in South Memphis. The UTHSC Health Hub, located on 534 North Second Street, will serve as our primary recruitment and intervention site. Currently, the UTHSC Health Hub offers health coaches to provide a system of support in weight loss, blood pressure control, healthy eating strategies, physical activity, medication adherence, and thus providing access to a range of potential participants.
Recruitment Strategy.

- *Press Release*: A press release describing the study will be approved and distributed through the UTHSC Communications and Marketing department. The press release will be delivered via radio, local television, local newspapers, and local newsletters, as appropriate. The press release will occur at the beginning of recruitment.
- *Social Media Promotion:* Recruitment flyers will be posted on social media sites (i.e., Facebook, Twitter, Instagram)
- *Flyer:* Campaign Flyers will be displayed in various locations interested in participating. The flyers will include the study name, logo, brief description of the study, eligibility bullet points, and contact information including study phone number and website. Community locations are planned to include, but not limited to, the UTHSC Health Hub, churches, community centers, and local businesses. Flyers will be handed out at community events, such as health fairs and church gatherings in catchment areas. Additionally, flyers will be emailed as a PDF attachment interested parties and community organizations' listservs.
- *"Word-of-Mouth":* Members of the study team will distribute promotional items and make contact with community members and potential participants. Team members will be responsible for informing all interested persons about the study and as appropriate, provide marketing materials and/or study contact information. Study team members, particularly the RAs, HCs, and Research Coordinator are expected to maintain good relationships with those involved in recruitment.
- *Refer-a-Friend:* To encourage enrolled participants to inform other interested persons with diabetes about the study, the study team will encourage 'refer-a-friend.'
- *Study Website:* The health hub's website [https://uthsc.edu/healthhub/] will have a public page that is devoted to the HEAL Diabetes program and recruitment information. The webpage will include study name, logo, brief description of the study, eligibility inclusion criteria, and directions for interested individuals to contact the study staff.

Non-responders. Data including age, gender, body weight and height, and duration of diabetes will be recorded for all patients found to satisfy recruitment criteria upon screening who decline to participate. We will record reasons for non-participation. Characteristics of non-responders will be compared with those of participants to identify any recruitment bias, assess the representativeness of study participants, and help establish generalizability of the trial findings.

C4d. Randomization Strategy. Eligible participants will be randomized in a 1:1 ratio using a block design with blocks of size 8. We will select the block sequence at random and fill blocks of 8 before selecting a new block. This will guarantee approximately the same number of participants in each group throughout the trial. The SAS program will be used for implementing the randomization scheme. Randomization logs will be created by Dr. Mahmood and uploaded to the REDCap system. The study staff will use the REDCap system to randomize patients to either the Intensive Care (Treatment) group or Enhanced Care (Control) group. Study personnel who collect and manage data will be blinded to participants' treatment assignments.

C4e. Sample Size, Power, and Attrition. This trial aims to recruit a sample of 72 (36 in each group), which is a pragmatic decision based on the patient pool, budget, and two-year study period. We will recruit patients from the Health Hub and Tennessee Population Health Data Network (TN- POPnet). Given the study has broad eligibility criteria, we anticipate an estimated 20 adult patients with diabetes and obesity being eligible each month. This will provide a sufficient pool to enroll 8 patients/month and 72 patients over 9 months. We expect that after accounting for 15% attrition at 12-month follow-up, about 61 study participants will complete the study. The attrition rate is based on the evidence from our MODEL study and from Lean *et al*. This pilot study will help us to estimate the following: 1) Effect size for the study intervention, 2) Total number patients recruited, 3) Number of patients recruited each month, 4) Total time required to recruit patients, 5) Number of patients retained, and 6) Barriers and facilitators to recruitment and implementation of the interventions. The research will employ intensive *scientific rigor* in every stage of design and conduct to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results and the ability to reproduce the research findings.

C5. Multicomponent Motivational Interventions. All component interventions received by both the treatment and control groups will be delivered in phases as shown in **Table 2** below.

C5a. Intensive Preparation for Change and Core Educational Interventions. All patients will receive introductory education on plant-forward healthy eating for weight loss. Health coaches will lead two sessions (introductory and kickoff) for the treatment group; pharmacists or nutritionists will lead one traditional diabetes education session for the control group. All patients will receive evidence-based self-care tools included in the MODEL program toolkit[142,143] adapted from DPP,[84,162] ACT,[81,82] Look AHEAD,[77-80] and TARGIT,[163] and supplemental recipe and diet information adapted from DiRECT[21] and the Daniel Diet[174] program. Treatment group participants will also receive training in cognitive behavioral strategies employing these tools.

Treatment group sessions will begin with an icebreaker to foster authentic relationships and trust,[115] and will focus on goal setting, group problem solving, and preparation for intensive weight loss, and will include interactive education regarding the recommended intensive plant-forward diet including a small cooking demonstration. Treatment group participants will also participate in two individual health coaching sessions and TM in preparation for their "quit date" on which they initiate TDR with whole plant-based foods. All of these sessions will seek to engage both the patient and the person who does the shopping and cooking in the household to obtain buy-in from all family members regarding food replacement plans.

Table 2. Study Timeline, Intervention Phases and Components, and Study Procedures

Month(s)	Study Procedures	Treatment Group (Intervention Phases and Components)	Control Group (Intervention Phases and Components)
	Screening		
1	Baseline Visit (Randomization)	***Phase 1 -Intensive Preparation for Change:*** 1) Two (introductory and kickoff) health coach and nutritionist or dietician co-led support group sessions, 2) Health coaching, 3) Tailored motivational text messaging	***Phase 1 -Education:*** One traditional diabetes education session led by a pharmacist or nutritionist/registered dietician
2-4	Follow-up Visit 1 (Month 3)	***Phase 2 -Total Diet Replacement:*** 1) Total diet replacement for months 2-4 using tailored healthy food boxes with recipes, 2) Health coaching, 3) Tailored motivational text messaging, 4) Coach-led support groups, 5) Monthly cooking classes, 6) Physician-supervised medication discontinuation	***Phase 2 -Partial Diet Replacement:*** Partial diet replacement for 3 months using grocery store produce vouchers
4-6	Follow-up Visit 2 (Month 6)	***Phase 3 -Food Reintroduction:*** 1) Health coach-led individual or group grocery store tours with individual patient reminders, 2) Health coaching, 3) Tailored motivational text messaging, 4) Coach-led support groups, 5) Monthly cooking classes	***Phase 3 -Food Reintroduction:*** No additional activities
6-12	Follow-up Visit 3 (Month 12)	***Phase 4 -Weight Loss Maintenance:*** 1) Health coaching, 2) Tailored motivational text	***Phase 4 -Weight Loss Maintenance:*** No additional activities

		messaging, 3) Coach-led support groups, 4) Monthly cooking classes	

Phase 1 (preparation phase) educational sessions for both groups will focus on introduction to and preparation for initiating plant-forward healthy eating. But in the treatment group, participants will be supported in preparing to strictly follow a low-calorie plant-forward weight loss diet (approximately 800 to 1200 kcal/d). Recommended diet characteristics are detailed below (**C5d. Diet Replacement)**. Treatment group participants will be encouraged to track their adherence to prescribed low-glycemic diets with < 30% of calories from fat (< 10% from saturated fat) via easy-to-use logs. For the treatment group health coaches will help participants tailor their meals to their goals and preferences and TM will recommend similar meals. For both groups, emphasis will be placed on eating more fruits, vegetables, and other high-volume, low-energy-density foods. Continuous 30-minute moderate physical activity on over five days per week will be recommended.

C5b. Health Coaching. Participants in the treatment group will have their first individual session with their assigned health coach immediately after the baseline (randomization) visit. Health coaches will prioritize establishing rapport with the participant and identifying their motivations and initial goals using MI. HC program goals, plans for future individual sessions, and a written copy of their personal health goals will be given to them at the end of the session. Participation in the treatment arm will be monitored and supported by the assigned coach. The MI-based HC intervention will use MODEL toolkit content as described above.[77-82] HC will aim to meet with participants for individual HC sessions bi-monthly the first month (Preparation Phase–2 sessions following randomization) and throughout Phase 2 (TDR) for 3 months (6 sessions total).

Components of HC will be personalized to each patient based on: patient preferences for frequency of contact and setting (in-clinic, telephone, home visit, or community); stage of disease (regimen complexity, complications, etc.); and patient-identified health goals, needs, motivations, and barriers to change.

HC Training. Health coaches have been trained using the Health Sciences Institute all-inclusive Chronic Care Professional (CCP) and Registered Health Coach (RHC) Certification Program, a nationally recognized curriculum developed and vetted by credentialed, trained experts that encompasses evidence-based chronic care, wellness, disease management and MI-based HC.[175-180] This model is SCT-based and fits well within our conceptual framework. The training will be supported and supplemented by content-specific training related to the intervention protocol by behavioral health/HC expert trainer (Dr. Butterworth). In the event of staff changes, Dr. Butterworth will oversee the training of new coaches.

C5c. Tailored Motivational Text Messaging (TM). All treatment group participants will receive scheduled Registry-based TM, occasional individual TM, and assistance participating in the TM program from their health coach. TM will be tailored using patient's personal health goals and preferences using the MODEL study TM protocol[142] modified to allow occasional individual messages from their health coach; eliminate scheduled TM related to medication adherence; and incorporate additional scheduled TM related to benefits of and approaches to plant-forward healthy eating, potential for diabetes remission or cure, and optional religious health-related messages. The MODEL TM library includes over 5000 text message stems that have been extensively culturally tailored for low-income and African American individuals in our target population.[57,142,143] The dietary, physical activity, and weight loss messages are derived primarily from American Diabetes Association content.[181,182] The TM library uses Registry and study data (see **Facilities**) to personalize and tailor messages based on participant demographics, preferences (e.g. regarding frequency, preferred behavioral focus, and desire for religious health-related messages), potential barriers to self-care,[52] and responses to four instruments: the Revised Summary of Diabetes Self-Care Activities Questionnaire,[183-185] the Treatment Self-Regulation Questionnaire,[186] the Diabetes-39 quality of life instrument,[186-190] and the Perceived Competency Scale,[191] as has been previously described.[142] TM will be intensive during the first two Study phases. At any time, participants can change the frequency and behavioral focus of the messages by responding to monthly text-based questionnaires or by calling or texting their coach.

C5d. Total Diet Replacement. Our dietary intervention is based on the successful DiRECT model for TDR adapted to the cultural preferences of our patient population to focus on a whole food plant forward diet consistent with a modified "Daniel Fast" diet. The dietary intervention will be delivered in 3 phases (**Table 2**). In Phase 1 (preparation, 0-1 month) treatment group participants will prepare for TDR as described above. In Phase 2 (TDR, 2-4 months) treatment group participants will receive nutritionally and calorically complete food boxes tailored to participant food preferences sufficient to feed their whole family. Recipes and instructions for serving sizes to provide 800–1200 kcal/d low-glycemic whole food plant forward diet with relatively high protein (25-30%) and < 30% of calories from fat (< 10% from saturated fat) to replace usual foods, with ample fluids (2.25 L) will be included. The total diet replacement (TDR) phase is mostly plant-based, focusing on vegetables

and fruits, but will also include lean meat/protein, eggs, and non-fat or low-fat milk products. Intervention group participants will receive healthy food boxes for 3 months during this time. Grocery supplies will include some foods that can be eaten as snacks and some beverages (i.e. low-fat milk). The nutrition team will estimate energy requirements (within the low calorie diet range) and macronutrients including kilocalories and protein for each individual participant adjusted per equations such as the Institute of Medicines Estimated Energy Requirement (IOM EER) Equations for adults. Nutrition requirements will be adjusted for age, height, weight, level of exercise and presence of any co-morbid conditions. Macronutrients will be distributed accordingly per individual assessment so that despite daily total energy requirement needed to meet the Dietary Reference Intakes for individuals, the meal plans will fall in the lower carbohydrate diet range and higher percentage of total energy requirement from protein and healthy monounsaturated fats to ensure light ketosis. The nutrition team will use a spread sheet to help shoppers then determine total amounts of food needed per box per individual based on individual needs. Participants will be medically monitored by study personnel, including health coaches, nutrition specialists, and the medical director to ensure safe weight loss patterns and behaviors.

During Phase 2 healthy food boxes (i.e. grocery supplies with recipes) will be delivered to the home on a weekly basis for three months. Preference and special diets will be taken into consideration when putting healthy food boxes together. We will survey participants at baseline with questions about the whole families' food preferences, allergies, and special dietary concerns, like vegan, halal, kosher, etc. Nutritionist Dr. Tracy Bruen will train study personnel to use FARE, an app that will enable us to shop for individuals with identified food allergies as well as specific dietary preferences. Study personnel will be trained to use the app to verify that none of the food box contents include known allergies. Participants will be surveyed at baseline to collect a record of known food allergies/preferences a month before the diet replacement phase. Personnel will also be trained to find an appropriate replacement item without the known allergen. It is free and allows you to pick diet type and then scan an item in the grocery store to ensure it fits a participant's dietary needs. A food delivery service hired by the study who has undergone a background check through the university will deliver food boxes to the participant's home address scheduled at their convenience for 3 months (months 2 through 4). If participants are not at home or are unavailable, it is the assigned study personnel's responsibility to work with the participant to reschedule a delivery and accommodate the participant's schedule to ensure study participants have their weekly food provisions so that they are able to complete all study procedures. While the food boxes contain enough food to feed the whole family, family members should not be treated as study participants. They are not enrolled in the study and have not undergone consent or screening. Study personnel will not perform any study procedures on family. Food boxes are intended to help aid and support the study participant in completing study components.

Participants may elect to continue the TDR phase for up to 5 months if their commitments, or life events, prevent achievement of 15 kg weight loss at 3 months, or if they wish to achieve more weight loss. If BMI falls below 23 kg/m^2 during the TDR phase, participants will be moved forward to the weight loss maintenance phase. Near the end of TDR phase and in the first 3 months of the weight loss maintenance (WLM) phase, health coaches will encourage participation in individual or group grocery store tours and will assist patients with shopping and meal planning. In Phase 3 (WLM, 5-12 months) treatment group participants will be advised to follow a whole food plant forward diet and will be provided with an individually tailored energy prescription, to support weight stabilization and prevent weight regain. Patients will be advised to increase daily physical activity. If weight regain occurs, or if diabetes is found to have returned (A1c ≥ 6.5%) at any time during the 7-month WLM phase, health coaches will work with patients to develop personalized 'rescue plans' to reverse weight gain. Phase 3 (Food Reintroduction) and Phase 4 (Weight Loss Management) will again follow the same mostly plant-based (produce and lean protein, eggs, nuts, and seeds, and non-fat or low-fat milk products) guidelines.

C5e. Support Groups. Participants in the treatment group will be encouraged by their health coach and TM to participate in monthly health coach-led support groups focused on reporting progress and problems, and group problem solving using the framework proposed by Daaleman and Fisher for implementing peer support in diabetes self-management support groups.[87-95] Peer mentor "Healthy Living Heroes" who have achieved weight loss, diabetes remission, or improved control will frequently attend and share personal experience.

C5f. Cooking Classes. Treatment group participants will be encouraged by their coach and through TM reminders to attend free community cooking classes, occurring at least once a month at the central, north, and south Memphis locations (**Facilities**). Topics include whole food, plant-forward diet, macronutrients, meal planning and shopping, reading nutrition and ingredient labels, healthful meal choices for breakfast, lunch, dinner, and snacks, and healthy cooking skills. Classes will be led by either culinary medicine trained medical students, physicians, registered dietitians, and/or chefs; will be culturally tailored to meet the needs of the study population;[192,193] will encourage home cooking and increase "food literacy" and self-efficacy in basic

technical culinary skills and competency to plan, choose, prepare, and consume nutritious food;[99-101] and each class will conclude with nutrition discussion while sharing the food prepared during the class.

C5g. Physician-Supervised Medication Discontinuation. Oral hypoglycemic agents (OHA) will be stopped on commencement of TDR, and antihypertensive and diuretic drugs will be stopped or reduced by half (based on physician judgement) on commencement of TDR. OHA, antihypertensive, and diuretic drugs will be reintroduced (as per study protocols) if T2D or hypertension returns. Aspirin will be continued if prescribed because of a previous heart attack or stroke but will be discontinued if prescribed solely because of T2D. Beta-blockers prescribed for the management of angina will be continued. During the PSMD phase, participants will have their blood glucose monitored once a week at the health hub during the Total Diet Replacement and PSMD phase. Participants will also be encouraged to continue recommended monitoring by their primary care providers. For participants in the intensive care group, participants will only have some of their diabetes medications and/or antihypertensive medications discontinued or decreased according to the medication discontinuation protocol. The Medication Discontinuation Protocol gives discretion to the UTHSC Health Hub Medical Director, thus participants in this group will be allowed to continue medications if needed in the estimation of the Medical Director in consultation with their primary care physician. Although PSMD is one of the study procedures, if the Medical Director (in consultation with the primary care provider) decides that a participant needs to continue diabetes and/or antihypertensive medications, they will be allowed to continue them and will not be withdrawn from the study.

PSMD Guidelines. In general, antihypertensive, diuretic, and diabetes medications will be stopped by the Health Hub Medical Director on the day the total diet replacement and intensive weight loss phase begins. As a procedure, primary care providers' contact information is collected at baseline before other study procedures are implemented. Medical Director informs the patient's primary care doctor of any changes in regimen. This is a safety measure, because blood pressure is likely to fall on the very calorie-restricted diet. This protocol lays out the standard approach to be followed to allow clear description of the research findings. Individual clinical decisions may be necessary for a person's best interest. For all HEAL Diabetes intervention participants, in Week 4 of the Intensive Preparation for Change period participants, they are required to meet with the Health Hub medical director/covering physician for an online consultation to discuss their medication discontinuation plan. This session will allow them to make plans for medication reduction/discontinuation on day 1 of intensive weight loss diet following this protocol. The Health Hub Medical Director will seek to consult with the patient's primary care MD if possible, to discuss and get their approval on the plan. The Medical Director will also encourage the patient to arrange a primary care follow-up visit in 1-4 weeks to assess for hypo/hyperglycemia and low/high BP and provide patient with copy of their Medication Reduction/Discontinuation Instructions to share with primary care MD. When antihypertensive drugs are stopped, the Medical Director will emphasize the importance of avoiding sodium (salt).

Blood glucose will be monitored weekly at the UTHSC Health Hub months 2 through 4 (e.g., during the Total Diet Replacement phase) and periodically thereafter. Health Coaches and the UTHSC Health Hub medical director should encourage participants to continue any glucose monitoring recommended by their primary care physician or diabetes doctor and to contact their doctor and/or the UTHSC Health Hub Medical Director for blood glucose levels below 70 or above 300. Blood pressure will be monitored weekly at the UTHSC Health Hub for the 2nd – 4th months of the study (e.g., during the Total Diet Replacement phase) and periodically thereafter. Health Coaches and the UTHSC Health Hub medical director should encourage any self-monitoring recommended by their primary care physician. Advise participants to notify their healthcare provider and the Health Hub Medical Director for systolic blood pressure greater than 160 or diastolic BP greater than 100 with symptoms (acute vision changes, headache, chest pain, etc.) or systolic blood pressure greater than 180 or diastolic greater than 110 (regardless of symptoms). Advise participants to immediately call emergency medical services and seek emergent medical care for blood pressure readings 180/110 or higher AND symptoms of chest pain, shortness of breath, numbness, weakness, change in vision, difficulty speaking, or severe headache. In the three months of total diet replacement, participants should be seen at least once a week and should be offered blood glucose and blood pressure checks to assess for hyperglycemia, hypoglycemia, and/or hypertensive episodes. HEAL Diabetes Program Participant Medication Reduction/Discontinuation Instructions will be included in the intervention group's toolkits. Study personnel, including health coaches and the medical director will emphasize instructions for monitoring for adverse events related to blood pressure or blood glucose. Procedures for monitoring blood glucose and blood pressure will be included and further detailed in the Manual of Procedures (MOP).

Adverse events related to medication discontinuation are unlikely but may include hyperglycemia and hypertension. We will monitor those in the intervention group regularly for adverse events related to medication

discontinuation. Adverse event reports related to medication discontinuation may also come from self-reports from at home readings (blood pressure and blood glucose monitoring). Blood pressure and blood glucose screenings should be offered to participants at their weekly health hub visits, as well as through consultation with participants' primary care providers. Regular care providers and participants can call the medical director to report any abnormal or extreme readings that occur outside of health hub's regular monitoring. The health hub medical director and participant will work together to adjust medications based on individual needs and best interests. There is an existing medication reintroduction protocol. However, if a participant does not follow the diet plan which then causes irregular blood pressure or blood sugar, the participant will not be removed from the study. Health hub staff will monitor blood pressure and blood sugar weekly. If a participant needs to increase or reintroduce their medication, the medical director will do that using best judgment and available information.

C6. Cultural Tailoring. Because culture plays an integral role in forming individuals' health behaviors and many underserved populations have dietary preferences born from cultural influences and necessity,[192,193] all component interventions will be extensively culturally tailored. This tailoring will occur during the initial planning phase (see section **D** and **Milestones**) and on an ongoing basis to ensure that they are culturally congruent and appropriate based on the cultural values of the population served.[193,194] Interventions will be tailored to reflect the subjective culture (i.e., norms and attitudes), behavioral preferences, and expectations of the target population[193,194] using preliminary focus group data (see section **C2b4**), patient focus groups (three planned in Y1, and two each year in Y2-4), and DWPC Patient and Community Advisory Council focus groups (two total in Y1). We will also employ ongoing interview input from early drop-out, ongoing, and completed participants.

C7. Intervention Fidelity and Quality Control. We will focus on design, training, delivery, receipt, and enactment (see analysis section below). To ensure consistency of intervention content and delivery, we will use standardized treatment manuals and procedures. All staff will be thoroughly trained in interventions, and protocol knowledge will be tested among staff. Training will be standardized, tested, and repeated. Even among highly trained staff, slight deviations (intervention drift) from treatment protocol may occur over time. To protect against this, regular "booster" training sessions will be conducted with all members of the study team. The behavioral and HC investigator (Dr. Butterworth) will oversee the fidelity, quality control planning, and implementation of the HC and TM interventions respectively and will conduct intervention meetings bi-monthly and then monthly with staff to discuss difficult cases and help problem solve implementation and participant adherence issues. Fidelity of health coaching to best motivational interviewing practices[195] will be assessed regularly by a member of the Motivational Interviewing Network of Trainers (MINT) using a validated and standardized tool, based on the Motivational Interviewing Treatment Integrity coding system.[196] Health coaches will submit recorded patient sessions (with patient written permission) for coding and assessment bimonthly for their first 6 months of the employment, monthly for two years, and periodically as needed thereafter.

C8. Study Visits.

Screening Visit. Eligibility will be assessed. A1c will be obtained from through a blood draw (less than 1 teaspoon of blood) through a finger stick. Dr. Frankie Stentz will assay the patient's sample for HbA1c using the analyzer in the UT Endocrinology Lab to assess potential eligibility. In addition, patient's weight, height, BMI, and blood pressure will be measured using the scales the appropriates scales and validated protocols. Participants will also be required to provide a list of their current medications and name and contact information of the primary care provider in event that they are randomized into the intervention arm at the baseline visit. Participants will be informed of their rights to determine who has access to their personal health information (PHI) in compliance with HIPPA regulations. As part of informed consent patients will be extensively counseled regarding all components of the treatment and control interventions to confirm their interest and willingness to participate in all component interventions prior to enrollment. After informed consent, contact and demographic information will be obtained. If a study participant has difficulty reading the informed consent or other study data collection forms, project personnel will assist. At this visit, all baseline study measures will be obtained.

Baseline Visit. Following confirmation of eligibility at the screening visit, potential participants will be scheduled for a baseline visit at the health hub. Eligible participants will be randomly assigned to one of the two arms and informed of their group assignment. Participants will be randomized to the HEAL Diabetes arm or the usual care condition. We will randomize 20-24 participants for each recruitment wave, for a goal of approximately 12 per condition. Participants will be randomized 1:1 to the two study conditions in randomly permuted blocks of size 8 using SAS random allocation. The randomization list was generated through SAS at the start of the study before randomization. The list is managed by one of the PIs. Once a participant has been determined to be eligible, the PI will assign each participant to the next open assignment on the list. We will tell

them at the Baseline visit which group they were assigned. Additionally, participants will have their first introduction to the health coaches.

Follow-up visits 1–3. Outcomes will be assessed at the end of three months (Follow-up 1), 6 months (Follow-up 2) and at one-year (Follow-up 3). All survey measures described below will be conducted at the health hubs.

Additional In-Person Visits for intervention group:

- Individual health coaching over 6 months (14 sessions total) (1 hour)
- Group support sessions (6 sessions total) (1.5 hours)
- Cooking/Nutrition classes (6 sessions total) (2 hours)

C9. Participant Retention. Our procedures will include the following strategies to track and retain participants: 1) collecting names, addresses, and phone numbers of relatives and friends who will usually know the participant's whereabouts; 2) contacting participants with personalized letters and cards and remembering them at special times such as birthdays and holidays; 3) maintaining phone contact with participants throughout the study; 4) setting up a tracking database with names, addresses, phone numbers, email addresses, social media page information, and projected time windows; 5) taking a case management approach for handling difficult retention cases.

Participant withdrawal. If participants withdraw from the protocol or fail to return for follow-up visits, we will continue to collect utilization and clinical data unless they withdraw consent. Data analysis will use best available follow-up weights and A1c values (closest within a window of ±3 months from routine attendances) and end of study diabetes status for participants who discontinue the protocol. Drug intolerance, diet intolerance or poor compliance will be recorded; these patients will be included in intention-to-treat analyses.

Procedures for Involuntary or Voluntary Study Discontinuation

Phase 1-Intensive Preparation for Change. If participants are removed from the study or voluntarily stop participation, nothing will occur since they have only received educational instruction and no other study procedures. Data collected from their participation will be analyzed using the "intention to treat" principle.

Phase 2-Total Diet Replacement. If participants are removed from the study or choose not to continue, participants will be advised to follow up with their primary care provider and resume their diabetes and antihypertensive medication, as well as continue healthier diet and lifestyle changes. Participants will be informed that they can continue to receive Neighborhood Health Hub (NHH) services, including health coaching and group activities and education. Participants can also speak with the medical director and/or the PI if they have any questions about their ongoing care. In addition, participants may elect to have their glucose, blood pressure, and weight checked. Data collected from their participation will be analyzed using the "intention to treat" principle.

Phase 3-Food Reintroduction. If participants are removed from the study or choose not to continue, participants will be advised to follow up with their primary care provider and resume their diabetes and antihypertensive medication, as well as continue healthier diet and lifestyle changes. Participants will be informed that they can continue to receive Neighborhood Health Hub (NHH) services, including health coaching and group activities and education. Participants can also speak with the medical director and/or the PI if they have any questions about their ongoing care. If participants proceed with their 6-month assessment, data collected will be analyzed using the "intention to treat" principle.

Phase-4- Weight Loss Management. If participants are removed from the study or choose not to continue, participants will be advised to follow up with their primary care provider and resume their diabetes and antihypertensive medication, as well as continue healthier diet and lifestyle changes. Participants will be informed that they can continue to receive Neighborhood Health Hub (NHH) services, including health coaching and group activities and education. Participants can also speak with the medical director and/or the PI if they have any questions about their ongoing care. Data collected from their participation will be analyzed using the "intention to treat" principle. If participants proceed with their 12-month assessment, data collected will be analyzed using the "intention to treat" principle.

C10. Outcome Measures. Outcome Measures. As shown in **Table 3**, our primary *biological outcomes* assessing effectiveness (Aim 2) replicate the main outcome measures of the DiRECT study.[21,24-26] **Table 3** also details our secondary metabolic, patient-reported, and sustainability outcomes. To assess cost-effectiveness for Aim 1, we will calculate incremental cost of delivering the intervention to the study group compared to the control group by tracking all the program implementation costs, net of one-time costs associated with developing study materials or other costs that would not be expected to be incurred if the intervention were repeated or scaled up.

Table 3: Outcome Measures

Outcome Measures	Measurement	Schedule
Primary biological outcomes (Aim 2)		
Body weight (kg)	Body weight will be measured without shoes in regular clothes using calibrated scales (Befour Model: WH1061)	Baseline, 3-, 6-, and 12-month visits
		Weekly
Blood pressure (mm Hg)	Systolic and diastolic blood pressure using automated cuffs (Omron Model: HEM-907) using a validated protocol[197] and number of blood pressure medications by patient report supplemented by medical record review	Baseline, 3-, 6-, and 12-month visits
A1c (%)[198] and diabetes remission[21,24]	Metabolic assessments obtained using standard protocols with diabetes remission defined as A1c < 6.5% after at least 2 months off all antidiabetic medications except GLP-1 agonists and SGLT-2 agonist medications, from baseline, months 6 & 12	Baseline, 6-, and 12-month visits
Secondary metabolic and patient-reported outcomes (Aims 1 and 2)		
Self-efficacy	[129,130] Stanford Diabetes Self-Efficacy Scale	Baseline, 6-, and 12-month visits
Diabetes self-management	Two (out of six total) subscales of the revised Summary of Diabetes Self-Care Activities questionnaire for general diet and exercise	Baseline, 6-, and 12-month visits
Secondary sustainability outcomes (Aim 1)		
Program retention (operational sustainability)	Proportion of patients retained in study at each follow-up visit calculated by dividing the number who completed follow-up at each interval by the number expected.	3-, 6-, and 12-month visits
Cost effectiveness of the multicomponent intervention (financial sustainability)	Cost-effectiveness may be calculated using method employed by DiRECT[29,155] and recommended by Centers for Disease Control and Prevention.[199] Incremental total costs per patient related to primary outcomes of body weight (cost per additional kg weight loss), A1c (cost per additional unit A1c reduction), and diabetes remission (cost per additional diabetes remission) at one year calculated using an intention to treat analysis. Effectiveness measured as quality adjusted life years (QALYs) using EQ-5D.[200,201]	Following completion of data collection

Other Factors**.** Covariates will be measured at baseline. These will include demographic characteristics, marital status, education level, insurance, chronic conditions, and SDOH (using electronic health record data collected on all Health Hub clients), and health literacy.[206,207] At baseline, 6-, and 12-month visits, we will assess prescribed medications. Exposure to each component intervention will be assessed using health coach attendance logs.

C11. Analysis. We will evaluate the extent to which the program was implemented according to the protocol, examine if all components of the intervention were delivered in a standardized and reproducible format, and summarize the trial as a flow diagram following Consolidated Standards of Reporting Trials (CONSORT) guidelines.[214] Patient characteristics will be compared between study groups to assess integrity of the random assignment process. Data will be presented as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Results will be analyzed based on intention-to-treat.

For Aim 2, we will use baseline, 6-, and 12-month follow-up data to compare differences between treatment and control group means in continuous primary biological outcomes (body weight, blood pressure, and A1c) and secondary patient-reported outcomes (self-care activities related to general diet and exercise). We will use the MIXED procedure of SAS because this is a parallel groups trial with repeated measures assessed over time. In the context of repeated measures ANOVA, we will use t-tests within group to detect change from baseline to 12-months (Follow-up 3) and t-tests between groups to detect the effect of the treatment on the various outcome variables at 12-months. While the preceding hypothesis tests are *a priori* and not adjusted, other comparisons at the intermediary assessments will be adjusted using the Bonferroni method. To examine a difference in the proportion of patients who achieved diabetes remission at 12-month, we will use a chi-square test.

For Aim 1, we will assess intervention operational sustainability as detailed above and in **Table 3**. Based on MODEL study experience providing MI-based HC and TM interventions, we hypothesize that operational sustainability will be high with 12-month program retention rates of approximately 85-90%.

We will assess financial sustainability using cost-effectiveness analysis to estimate the incremental cost of providing the intervention compared with the control group as detailed in **Table 3** above. Our analysis will be

conducted from the payer perspective. Based on DiRECT study experience,[29,155] we hypothesize that the *HEAL Diabetes* intervention will be cost-effective when compared with control.[217]

C12. Study Limitations (Potential Problems and Alternative Approaches)

1. *Poor intervention fidelity*. Every effort will be made to ensure key intervention fidelity in all arms. For example, if a health coach resigns, their patient panel will be distributed among the other health coaches within or across health systems as has been done the MODEL study to avoid any interruptions in care.
2. *Low participant recruitment or retention*. It is possible that we will experience difficulties recruiting interested patients or that more than 20% of the participants will fail to complete the study, but we think this is unlikely given our MODEL study experience. In MODEL, we have recruited 672 similar T2D patients from the same clinics with 90% retention overall thus far. To prevent difficulties, we will closely monitor participants, discuss recruitment and retention at regular meetings, identify reasons for problems, and implement changes accordingly. If all retention strategies fail, we will increase number of participants to maintain adequate power.

D. Study Timeline and Future Directions

We expect that this study will provide preliminary evidence regarding the effectiveness of the HEAL Diabetes multicomponent intervention in improving weight and blood pressure and achieving diabetes remission. These results will provide pilot data for larger studies demonstrating the effectiveness of nutrition-based multi-component interventions as an alternative to pharmaceutical treatment alone for obese patients with early T2D. Our future research will focus on assessing: 1) long-term success in weight maintenance and diabetes remission, 2) comparative cost-effectiveness of bariatric surgery vs. a multicomponent behavioral intervention, 3) relative effectiveness of component interventions in supporting behavior change and sustained weight loss, 4) refinements of the multicomponent intervention model to strengthen most powerful intervention components, 5) impact of payment policy changes for multicomponent obesity interventions on Medicaid and other vulnerable populations, and 6) effectiveness of multicomponent interventions for additional high-risk populations including the broader population with obesity, those with prediabetes, and those with multiple chronic conditions associated with obesity.

E. Data Collection.

Collection Method. Data will be collected from a combination of EHR records accessed through REDCap or EPIC sourced from UTHSC Health Hub activities, blood samples, blood pressure readings, and weigh-ins, as well as from surveys and questionnaires conducted at baseline, 6-, and 12-months.

Viewing and Collecting. We will collect: a) Name, contact information, primary care contact information, medications, demographic data, comorbidity information, income, b) HbA1c levels, blood pressure readings, and weight data, c) scores on standardized tools (diabetes management and self-efficacy).

Deidentifying Data. Key personnel will deidentify data and participants will have unique participant ID numbers stored in REDCap. Access to the files will require permission from the program director, a UTHSC password, and IRB personnel approval. For each user, REDCap will require a REDCap profile, username, and password to enter the program. Study personnel will only have access to the database if the data manager has given them access. Any PHI fields will be stored in a separate form from other data collection forms. Data will be completely de-identified once the last assessment phase is complete. At this time the link between ID number and study data will be destroyed. Study data in the form of hard copies will be stored in a locked file cabinet managed by the program director and will be destroyed 3 years after completion of the study.

F. Data and Safety Monitoring Plan. Monitoring of the study is important for both assessment of safety of the intervention and interpretation of study results. We have a system for monitoring, scheduling, and tracking participants. Staff roles will clearly be delineated and there will be ongoing monitoring of the health education, nutrition support, and the health coaching provided. Participants will be followed for approximately one year. For any serious adverse event reported during the study, the nature, date of onset, duration, and resolution will be recorded. A co-investigator will monitor each participant for serious adverse events. If the serious adverse event is thought to be related to study participation by either the primary care provider and/or the physician investigators (Dr. Bailey), the investigator may request the participant to undergo a physical examination, psychiatric evaluation, and/or laboratory testing whenever appropriate local to the participant. All staff members are trained on the FDA and IRB criteria and policies for a Serious Adverse Event. Study staff will be trained in assessing and reporting serious adverse events for all study populations.

F1. Medical Monitoring.

F1a. Investigator and study team only. Monitoring of the study is important for both assessment of safety of the intervention and interpretation of study results. We have a system for monitoring, scheduling, and tracking participants. Staff roles will clearly be delineated and there will be ongoing monitoring of the health education

and the HC provided. Participants will be followed for approximately one year. For any serious adverse event reported during the study, the nature, and date of onset and resolution (duration), intensity will be recorded. A co-investigator will monitor each participant for serious adverse events. If the serious adverse event is thought to be related to study participation by either the primary care provider and the physician investigators (Dr. Bailey), the investigator may request the participant to undergo a physical examination, psychiatric evaluation, and/or laboratory testing whenever appropriate local to the participant. All staff members are trained on the FDA and IRB criteria and policies for a Serious Adverse Event. Study staff will be trained in assessing and reporting potential serious adverse events for all study populations.

F1b. Monitoring the Progress of Trials and the Safety of Participants. This study will be overseen by the Principal Investigator (PI) who is an MD, a Co-Investigator MD, a study statistician, program manager, and the research coordinator. The study will be monitored by the study team on an on-going basis for protocol compliance and adequate study progress. Every month after recruitment commences, the team will review the following information in detail: Subject accrual rate; Subject drop-out and the reasons for drop-out; Gender recruitment rate; Major and minor problems related to interventions; Subject compliance with the protocol; and Program Manager and/or Research Coordinator questions or concerns. Researchers are directly involved with this review so decisions about changes, modifications, or adaptations are decided and acted upon immediately.

It is anticipated that medical problems will occur during the study. The following is a summary of the plan of action based on the level of acuity of the problem. We do not expect major issues, emergencies, or urgent problems related to our intervention; however, in the case of these events, we will address these issues as outlined in the following paragraph. Emergent problems or those problems that are life threatening or require life-saving attention should be dealt with using the Emergency Medical System (EMS) by calling 911. For any events occurring at the intervention site (UTHSC Health Hub), health hub staff will provide basic life support as an interim measure when appropriate until EMS personnel arrive. The health hub staff will be responsible for notifying the participant's family or designated contacts and the participant's primary care physician. For events occurring outside of the health hub setting, participants will be instructed to call 911, and go to the nearest emergency room. Urgent medical problems or those problems that require the immediate attention but that do not require life-saving attention should be dealt with by taking measures to ensure the participants comfort and offering first aid as appropriate under the direction of the primary care physician at the respective site. Disposition plans should be made with the involvement of the participant, health hub staff, investigators, primary care physician and the participant's family or designated contacts should always be notified.

General medical problems or those problems that require attention should be dealt with by the primary care physician. The health hub staff should follow the primary care provider's directions regarding treatment, disposition, and follow-up. Documentation of the problem and actions taken should be placed in the participant's record. See Adverse Events for additional information.

F1c. Serious Intercurrent Illness Unrelated to the Study. If the participant has a major illness, is hospitalized, or has other physical issues that interfere with the assigned study intervention, participation in the study will be suspended until routine health is resumed by the participant. The study physician will determine whether or not it is medically safe to continue the study. If the participant has a major illness (i.e., broken bone, etc.) that does not interfere with the assigned study intervention, the study physician will determine whether it is safe for the participant to continue participation in the study.

F2. Data Safety and Monitoring. This study will be conducted in accordance with all applicable federal requirements for subject privacy and safety.

F2a. Informed Consent. Written consent will be obtained from each participant by study staff at the screening visit (SV) and reviewed with the participant prior to each of the subsequent visits for data collection purposes (i.e., surveys, blood draws). It will become part of the permanent study record. Each participant will be assured that study participation is voluntary and that they may withdraw at any time for any reason without jeopardizing their future care at this institution. At the time of obtaining written consent, the study staff/investigators will advise participants of the experimental nature of the study, the duration of the trial, alternate modes of treatment, and prevalent adverse events that might occur. Each participant will be questioned to ascertain whether they have understood the information. An opportunity for questions and discussion will be provided for each participant. The participant's signature on the consent form is required prior to the collection of any study measures and, if applicable, randomization. Each participant will receive a copy of the informed consent statement. The informed consent statement will be reviewed and approved by the Institutional Review Board (IRB) of the University of Tennessee prior to recruitment of participants.

F2b. Education on the Protection of Human Subjects. All key individuals responsible for the design and conduct of this research project have received education on the protection of human research participants. The curricula consisted of Internet computer-based training for researchers at the University of Tennessee. Study staff that will be hired for this project at a future date will also receive appropriate education on the protection of human research participants prior to interacting with the study participants.

F2c. Education on HIPAA. All key individuals responsible for the design and conduct of this research project have received education on protection and confidentiality of protected health information (PHI). We do not envision the risks to participants to be above that of a diabetic receiving health education from their primary physician or health educator. However, implementation of this intervention may increase a participant's risk for developing hypoglycemic episodes or hyperglycemic episodes. Although this study is associated with minimal risk, an independent, institutional data and safety monitoring will be appointed before enrollment of participants into the study.

F2d. An independent Data and Safety Monitoring Board (DSMB). DSMB will be formed prior to the enrollment of the participants. We plan to have this committee review the final protocol for the study and to periodically review study data for the occurrence of outcomes of interest. We will specifically ask the committee to address serious adverse events and the risk to benefit profile for all study participants. The DSMB will meet a minimum of once each year and be composed of five persons, who are not involved in the study in another capacity, with expertise in any one of the following fields: medicine, endocrinology, clinical trials, epidemiology, psychology, and biostatistics. Guidelines for recommendations for changes in the study protocol will be refined for use by the DSMB. The committee will review these guidelines and make recommendations for changing any component of the trial based on regular review of all pertinent study data.

- Dr. Surbhi, who is a co-investigator on this project, will have responsibility for analyzing interim data and preparing data and safety monitoring reports that the committee will review. These reports will include data on all adverse events and study outcomes for all study participants. Dr. Surbhi will be an ex-officio member of the committee and will not be blinded to participant group assignment. After the start of participant enrollment, we plan to conduct data and safety monitoring meetings in-person or via conference call twice a year. Data and safety monitoring reports will be sent to all committee members prior to the conference call.
- A Manual of Procedures will be developed for the study and the procedures will be strictly followed. All controlled trials personnel are trained in sessions that will cover all study procedures, including recruitment, informed consent, measurements, randomization, participant follow-up, and adverse events. Adherence to the procedures in the operations manual will be assured by periodic assessment and retraining. A co-investigator will monitor each participant for adverse events throughout the study using participant report and reports by primary care physician. All participants will be asked at each study visit about emergency visits, hospital visits, or other serious adverse events in the intervening period, and these reported events will be recorded in the study database. If significant differences in adverse events noted above are found, additional interviews of the participant experiencing these adverse events may be conducted at the discretion of the DSMB and any necessary remedial action taken will be recorded. At any point a participant may be withdrawn from the study for health-related reasons. Medical side effects of improvements in healthy eating, physical activity, and medication adherence will be explained as part of the informed consent process to each participant by trained study personnel and participants will be provided a copy of the informed consent statement that will include a written list of potential side effects prior to randomization. An attempt will be made to quantify the severity of each side effect by asking the participant to grade its importance or impact on quality of life.
- All participants will be encouraged to contact the study site if any episodes of severe hypoglycemia, hyperglycemia, or hospitalizations of any nature occur. In addition, physicians will be asked to notify the study site of any hospitalizations or severe episodes of hypoglycemia or hyperglycemia. Conversely, if the UTHSC Health Hub personnel uncover a morbid event in a study participant, the study staff will contact the participant's personal health care provider. The participants will have access to study personnel or to one of the physician investigators by telephone 24 hours each day through the on-call system in the event of medical problems related to the study. Our health systems have on-call systems that give the participants access to a physician investigator 24 hours a day. To further ensure participant safety, during the follow-up period we plan to assess wellbeing by physical assessment including blood pressure.

F3a. Adverse Events. We define serious adverse events as any adverse event or adverse reaction that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or congenital anomaly or birth defect. We define adverse events as any untoward medical occurrence in a participant or experimental investigation subject administered a study treatment and which does not necessarily have a causal relationship with this treatment. Because this is a pragmatic trial with minimal risks we will only be recording and reporting serious adverse events such as severe hypoglycemia, or less serious, hyperglycemia.

F3b. Classification of Events. In this study, the likelihood of serious adverse events associated with the planned interventions is very low, and mostly consists of a small possibility of serious hypoglycemic or hyperglycemic reactions associated with improvements in health habits as detailed below. All adverse events will be classified as to whether they are serious or not serious. An adverse event is considered serious if it is life threatening, prolonged or permanently disabling, requires or prolongs hospitalization for any cause other than routine delivery, is a congenital anomaly, or a major cardiovascular event. An event may also be considered serious if an investigator judges it to be a significant hazard or contraindication to continued study intervention or use of study medication. In addition, we will classify all adverse events regarding the relationship, severity, and expectedness as described below.

Relationship The following are expected adverse events that may occur during the trial:

*Related to Intervention**.*** Potential adverse events (AE) known to be associated with caloric restriction, weight loss, or improved medication adherence in patients with diabetes: hypoglycemia, hyperglycemia, malnutrition, bone loss, gall bladder disease. The DiRECT trial which employed a similar intervention found that severe hypoglycemia occurred between 0.2 to 0.57 times per 100 patient years in the treatment arm over the first 4 years of the study. [194] Potential AE's known to be associated with exercise in patients with diabetes: hypoglycemia, fracture or other injury, cardiac arrhythmia, cardiovascular event.

*Related to condition under study**.*** Potential AE's known to be associated with overweight or obesity include: diabetes, hypertension, dyslipidemia, cardiovascular disease (CVD), gall bladder disease, liver disease. All patients will be monitored at every data collection visit through the 12-month visit for the occurrence of these adverse events.

Severity During the trial participants will be queried to determine if a serious adverse event has occurred as described above and all adverse events will be identified through patient and provider report. All serious adverse events will be recorded. A serious adverse event is considered serious if it is life threatening, prolonged or permanently disabling, requires or prolongs hospitalization for any cause other than routine delivery, is a congenital anomaly, a major cardiovascular event, or cancer other than non-melanoma skin cancer. An event may also be considered serious if an investigator judges it to be a significant hazard or contraindication to continued study intervention or use of study medication.

Expectedness Adverse events will also be classified as to whether they are expected or unexpected. An unexpected adverse event is one for which the nature or severity is not consistent with information about the condition under study or intervention in the protocol, consent form, or program brochure. An expected event is one known to be associated with the intervention or condition under study. Thus, expectedness is related both to the intervention and to the condition under study. All serious or unexpected adverse events related to the intervention will be reported to the IRB and to the sponsor in a timely manner.

F3c. Data Collection Procedures for Adverse Events. As described above, a co-investigator will monitor each participant for serious adverse events throughout the study using participant and provider reports. All patients will be asked at each study visit about emergency visits, hospital visits, or other serious adverse events in the intervening period, and these reported events will be recorded in the study database and concordance with the registry assessed as described above. Participants will be asked at each study visit about any serious adverse events that may have occurred between study visits. All participants will be encouraged to contact the study site if untoward symptoms, illnesses, or hospitalizations of any nature occur. In addition, their relatives and their personal physicians will be asked to notify the study site of any hospitalizations or major illnesses. Conversely, if the health hub personnel uncover a morbid event in a study participant, the study staff will contact the participant's personal health care provider.

Reporting Procedures

- Data and safety monitoring reports will be sent to the IRB every 6 months during the adverse event reporting period.

Adverse Event Reporting Period

- Initiation of enrollment (May 1, 2023) through March 30, 2024.

Post-study Adverse Event

- Not expected

G. Ethical Considerations.

G1. Informed Consent. The consent process will take place at the beginning of the baseline appointment. We will allow time for discussion or questions about the study. Consent will be obtained by study personnel trained in the consent process. To be able to participate in the study, participants must be adults without impaired decision-making ability that are able to speak, read, and understand English. The consent process will include a discussion of the participant's understanding of what their participation in the study means, which will include, discussion of their rights, the protocol, all potential risks and benefits, and their options and contacts to express any concerns or complaints. A copy of the consent form has been provided with this application.

G2. Risks and Side Effects. Possible risks for being in this study include hypoglycemia, gallstones, temporary discomfort, or mental anguish adapting to the behavioral changes (i.e., new diet, increased movement and activity), and possibly breach of confidentiality and privacy by other participants during nutrition education classes. We will have procedures in place to minimize the potential for risks and side effects for participants.

- A possible side effect, Hypoglycemia, is a condition in which an individual's blood sugar (glucose) level is lower than the standard range. Participants will be carefully monitored and counseled on ways to decrease the risk of hypoglycemia. Staff and patients will be trained to recognize the signs and symptoms of hypoglycemia, in addition, a physician is available to provide supervised medication discontinuation for every participant.
- Gallstones are expected to be very rare (Less than 1% risk). However, this discomfort usually resolves or greatly diminishes within one week as long as participants stick with their healthy diet. This potential risk is not serious and is completely reversible. Participants will be carefully monitored and counseled on ways to decrease the risk of gallstones.
- Regarding discomfort and mental anguish, participants will be advised of the risks and benefits of participation and informed of their right to withdraw from the study at any time if they should choose to discontinue. Finally, participants will be advised on informed consent and their role in protecting the confidentiality and privacy of other participants and their own.
- Randomization: Although it is expected that both study treatments will be either beneficial or neutral (with no effect at all), it is possible that the treatment that a participant is assigned to, may later be shown to be less effective than other therapies.

G3. Benefits. Participants may or may not benefit from participating in the study. Benefits that may occur include weight loss and/or diabetes remission. Another tangible benefit for the experimental group is receipt of food subsidies during the study timeframe, while the control group will receive food vouchers. Societal benefits include providing evidence to support the use of multi-component behavioral change interventions to treat obesity and diabetes. Additionally, this research will contribute to a growing body of research on treating diabetes and other chronic illnesses using the 'food as medicine' hypothesis or medically-tailored meals as an alternative to traditional treatment.

G4. Alternatives to Participation. Should individuals choose not to participate, they have the option of standard care through options already available to them. Another alternative to participation is the health hub, where health coaches provide support in weight loss, blood pressure control, healthy eating strategies, physical activity, and medication adherence.

G5. Costs to Subjects. Costs to subjects include time investment and transportation expenses, but participants can be helped with free medical transportation. Economic burden to subjects includes the time needed for screening and study participation. Regarding the time commitment, we will do our best to work with subjects' schedules, so that any possibly resource-vulnerable individuals are not required to miss work or other important obligations in exchange for their participation. While there is no cost to participation in the study, if participants elect to receive motivational text messages, standard texting rates will apply.

G6. Compensation to Subjects. Although there are many potential benefits to participation, subjects will not receive monetary compensation outside of the food subsidies, food vouchers, and transportation expenses (as needed).

G7. Provisions for Vulnerable Subjects. The patient sample for this study is likely to include economically disadvantaged persons, as well as racial/ethnic minorities. Additionally, this study may unintentionally or unknowingly include participants who are considered decisionally-impaired due to psychiatric, cognitive or developmental disorders, substance abuse problems or individuals in chronic pain. The study team will take all necessary steps to assure that participants in this study are fully informed about and understand the study, as

well as their rights and protections. We will thoroughly explain the risks, benefits, costs, privacy, confidentiality, and ability to withdraw or refuse participation. Participants will undergo the consent process at baseline and will know that their participation in this study is voluntary and they have a right to refuse or withdraw participation at any point in the study. Individuals who are decisionally-impaired may still be capable of providing consent. If evidence is present that they are incapable of providing informed consent due to the incapacity to understand, an individual who is legally authorized to consent for them must sign and date the consent document in order for them to be included in the study.

G8. Subject Privacy and Data Confidentiality. REDCap will be used for data entry and management. Digital recorders will be used for recording audio from the group nutrition classes/support group sessions. The database and recordings will be maintained on UTHSC servers where security will be maintained through access controls. Once recordings are saved on the server they are deleted from the recorder. Recordings are used only for quality control and will not be transcribed. Access to the files will require permission from the program director, a UTHSC password, and IRB personnel approval. For each user, REDCap will require a REDCap profile, username and password to enter the program. Study personnel will only have access to the database if the data manager has given them access. UTHSC IRBs and their representatives, and study personnel will have access to the research data, as will the study sponsor if requested. All participants will be assigned an ID number, which will link them to their study data. PHI fields will be stored in a separate form from other data collection forms. Data will be completely de-identified once the last assessment phase is complete. At this time the link between ID number and study data will be destroyed. Study data in the form of hard copies will be stored in a locked file cabinet managed by the program director and will be destroyed 3 years after completion of the study.

H. Conflicts of Interest. There are no conflicts of interest for the PI or any member of the study team.

I. Plans for Dissemination of Findings. We will disseminate study findings through regional and national scientific meetings in the form of presentations and reports.

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K. Appendices