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Brief Title: Reducing Cardiometabolic Risk and Promoting Functional Health in Older Adults With Obesity and Prediabetes (Sustain-DPP)

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Consent to Participate in a Research Study: *Reducing Risk and Promoting Functional Health in Older Adults with Obesity and Pre-Diabetes*

Sustain-DPP Consent/Enrollment

Source of support. The National Institutes of Health/National Institute of Diabetes, Digestive, and Kidney Diseases (NIH-NIDDK) funds the study.

Study overview. Starting in 2018, Dr. Elizabeth M. Venditti and her research team from the University of Pittsburgh Medical Center (UPMC) and Pitt Public Health will partner with community centers in and around Allegheny County to offer the Diabetes Prevention Program (DPP)-Group Lifestyle Balance™ (GLB) research intervention to men and women, aged 60 years or older, with overweight/obesity and pre-diabetes.

We will examine how two long term weight management programs impact your risk factors for Type 2 diabetes and overall health in an 18-month long research study. That is why we call this study **Sustain-DPP.**

Once you are screened and enrolled, we will ask you to complete a 17-session program of group lifestyle sessions mostly by telephone, including videos, and may include some in person meetings during the first six months. The goal is to improve healthy eating, weight loss, and physical activity behaviors. Then, you will be randomly assigned (like the flip of a coin) to one of two forms of continued contact. Both follow-up programs include group phone calls, about one per month, for 12 more months.

We will also ask you to complete a total of four research assessment visits, each lasting about one hour in our office, and one hour of paperwork you will do at home and mail back to us, during the study.

Why are we doing this study? Obesity and pre-diabetes can harm the overall health and functional independence of aging adults but there are effective lifestyle interventions that can reduce or delay this burden. **Sustain-DPP** will examine how longer-term phone contacts impact your risk for Type 2 diabetes and your health. Lifestyle programs, such as the one being used here are being used in clinical practice and reimbursed by Medicare and other private insurers.

Research is needed to help us understand the best ways to deliver such programs. We plan to enroll 360 participants in **Sustain-DPP** over a three-year period.

Participation in the Sustain-DPP study is completely voluntary and the choice is yours. The following information will help you weigh the risks and benefits of enrolling and to decide whether the study is right for you.

Study intervention description (Months 1-5). In the first phase we ask you to complete 17 sessions (about one per week) guided by a trained and experienced lifestyle coach (an expert in behavior change for diet, weight loss and physical activity). The program is called Group Lifestyle Balance™ (GLB). It is based directly on previous research from the Diabetes Prevention Program (DPP). Here is what to expect.

- Groups will meet primarily by telephone conference call. Some of the first five meetings could be in person.
- About 6-12 people per group.
- The core program is seventeen 60-minute group sessions. The first session is to help you get comfortable with meeting by phone.
- You will also watch videos about healthy diet, weight loss and physical activity (online or DVD) and follow along in a workbook.
- The research program and any other materials are provided free of charge.
- You need access to a DVD player or a computer to watch the videos.
- You need access to a phone line (including assistive listening devices if needed) so that you can participate in group conference calls.

The goals of Sustain-DPP are to help you lose a modest amount of weight (5-7% of baseline bodyweight) and gradually increase your physical activity to 150 minutes/week. We will ask you to keep a record of your food intake and physical activity. We will ask you to monitor and record your weight weekly during the 24-month program.

A lifestyle coach will guide your efforts. We will encourage you to attend as many telehealth sessions as possible and participate in group discussions. A major focus of the intervention is problem solving for common barriers/challenges to healthy lifestyle change. Attendance and group discussion (by phone or in person) will help you achieve your goals.

Audio-recordings. A portion of the phone calls will be audiotaped to rate how well your lifestyle coach is following the protocol. Names will not be identified on these forms. Once data forms are completed the audiotapes will be destroyed.

Randomization and study intervention description (Months 6-18). By Month 6 you will be randomly assigned (like the flip of a coin) to one of two programs designed to help you sustain your healthy lifestyle changes.
Sustain DPP-30-minutes: Group phone calls (about one per month) include learning new session material with a new workbook and ongoing home assignments. Each call will last about 30 minutes. In addition, you will be offered some extra assistance from a physical activity expert (up to two contacts, either in-person or by phone) to help you build your activity program. We will encourage you to keep monitoring your diet, weight and physical activity.
Sustain DPP-15 minutes**:** Group phone calls (about one per month) that include motivational messages and social support for your lifestyle goals. Each call will last about 15 minutes.

Health care provider permission to participate. To inform your health care provider about the nature of this study and to confirm that you are safe to work on the nutrition, activity, and weight loss goals, we will ask you to get a signed referral form. We will give you a simple, one-page description of the program and a permission form to be returned directly to the study office by mail, or to a dedicated FAX number.

Overview of Enrollment Process. Once this consent form has been reviewed and discussed today, if you indicate you are willing and able to proceed, we will ask you to complete one assessment visit both to confirm your eligibility and collect baseline research data. If study screening confirms you are eligible, then you will undergo the full baseline (0) assessment. Similar assessment visits will be scheduled every 6 months for the next 18 months. Each visit will be described below. If you are not eligible then you will be free to leave.

Study Screening description (Month 0). Today you will begin with a 15-30-minute screening portion to complete the measures described below. They will help determine your eligibility for **Sustain-DPP**.

Weight and height: We will take these measures behind a curtain for your privacy and comfort. We ask you to remove your shoes. We will measure weight (using a digital scale) and height (using a stadiometer, like at the doctor's office) twice.

Body Mass index (BMI kg/m^2): BMI is a screening tool, calculated as weight in relation to height. BMI is often used to classify levels of overweight and obesity in relation to medical conditions. The cut point for overweight is 25 kg/m^2; for obesity, it is 30 kg/m^2. To be eligible for this study, you must have a BMI of at least 27 kg/m^2. We will calculate this measure first, because if your weight does not meet the cut-point, you will not continue with the fingerstick blood sample portion of the visit.

Blood sample: We will take a small amount of blood (less than 1 teaspoon) by a prick of the finger. We will test this sample immediately to measure your hemoglobin A1C and give you feedback. The A1C test provides information about a person's average levels of blood glucose, also called blood sugar, over the past 3 months. The A1C test result is reported as a percentage. The higher the percentage, the higher a person's blood glucose levels have been. A normal A1C level is below 5.7 percent. For this study, we will include persons with an A1C level ≥ 5.7 percent but ≤ 6.4 percent, which is considered "pre-diabetes". If your A1C level is outside this range (too low or too high) you will not be eligible to enroll and, after we answer any further questions you may have, you will be free to leave.

Study assessment description (Months 0-18). We will ask you to complete a total of four research assessments between Months 0 (baseline), 6, 12, and 18. If you have been screened as eligible by weight/BMI and the A1C fingerstick measure then you can complete the baseline assessment today. You will spend about two hours completing each of these assessments; one hour will be in person and one hour will be doing surveys at home. We will also ask you to use a hip-worn activity monitor for one week at home and track your daily steps. Well-trained, experienced and respectful research study staff conduct these visits. Physical assessment measures, survey and questionnaire details are summarized below.

In-Person:

Weight, height, waist: We will take these measures behind a curtain for your privacy and comfort. We ask you to remove your shoes. We will measure weight (using a digital scale) and height (using a stadiometer, like at the doctor's office) twice. We will measure your waist twice by placing a tape measure around your waist.

Body mass index (BMI kg/m^2): BMI is a screening tool, calculated as weight in relation to height. BMI is often used to classify levels of overweight and obesity in relation to medical conditions. The cut point for overweight is 25 kg/m^2; for obesity, it is 30 kg/m^2. To be eligible for this study you must have a BMI of at least 27 kg/m^2.

Blood pressure: We will ask you to sit quietly for five minutes, then take your blood pressure twice with a digital monitor. We will use an automatic inflatable cuff that matches your arm size.

Blood sample: We will ask you to not eat or drink anything except water for at least 12 hours prior to your morning visit. A trained phlebotomist will take a blood sample (no more than one tablespoon using standard needle-stick procedures) from your arm, to measure fasting lipids, glucose, insulin and HbA1c levels. Blood processing will be completed by the Advanced Diagnostic

Research Laboratories/University of Minnesota. We will offer you a healthy snack and beverage as soon as you complete this measure. In the event that venipuncture phlebotomy cannot be performed we will use the fingerstick blood sample to test your glucose and lipids.

Physical function tests: As you are able, we will (a) assess the strength of your dominant and non-dominant hand by asking you to squeeze a measuring device; (b) ask you to demonstrate different standing balance positions; (c) ask you to rise from a chair several times and (d) time you as you walk at your usual pace for 4.5 meters (15 feet), doing the test twice.

Mental status- functions such as attention and concentration, memory, verbal and spatial ability will be assessed by a trained and certified interviewer.

At Home:

Physical activity-objective measurement: We will ask you to wear an instrument called an accelerometer, for 7 days, around the time of each assessment visit. This device is like a pedometer that you wear on your waistband. The physical activity monitor is worn only during your waking hours.

Surveys and Questionnaires: We will ask you questions related to your physical, emotional, and psychosocial health and well-being, as summarized:

Diet- typical food/eating patterns; Physical activity- frequency and amount of time, per week, spent in activities at different levels of physical intensity; Depression scale- moods, feelings and emotions; Health related quality of life- how your physical and mental health status influences your perceived quality of life and well-being; Patient activation- how you feel about taking charge of your health care and medical conditions; Lifestyle change confidence- your belief in your ability to change behaviors related to diet, weight loss and physical activity; Medical history- whether you have ever been told by a health care provider that you have certain medical conditions; Medications- your current prescribed medication list; Use of medical services- how many days you have utilized outpatient, emergency room or inpatient hospital services.

Possible risks of research screening and assessment activities. There are some minor risks that may be associated with the study measures.

Blood draw: discomfort from the needle stick, pain, bruising, swelling or redness of the skin, lightheadedness, and on very rare occasion infection.

Body measurements: embarrassment associated with measurements of weight or waist.

Physical function tests: lightheadedness or imbalance with gait or chair stand tests, muscle strain or soreness with grip strength test, rare risk of injury or joint discomfort with any of the tests. After demonstration by staff, you can choose not to do some of the activities.

Surveys and questionnaires: minor discomfort in answering questions that are personal in nature. If you have a concern about any question, please speak to a staff member. You may refuse to answer questions.

Other. There is a rare risk that a breach of confidentiality could occur; however, every effort is made to prevent this from happening.

Possible risks of Sustain-DPP intervention activities.

Modest weight loss is associated with a few risks. It is common (likely) for participants to experience hunger, lightheadedness, and/or constipation when reducing calorie intake.

Rapid weight loss is sometimes associated with hair loss and gallstone formation. However, this program recommends a healthy balanced diet, rich in plant-based foods, and a regular pattern of meals and snacks (consistent with national dietary recommendations), and a weight loss rate of about 1-2 pounds per week, which may reduce this risk.

The risks associated with exercise occur occasionally (1-10% or 1-10 people in 100) and include fatigue, muscle soreness, and injury such as sprained ankles or pulled muscles. Risks are reduced by proper warm-up and cool-down periods.

There may be additional risk of heart problems for those who have a chronic disease or experience symptoms with exercise, although this risk is extremely small given the intensity of the recommended exercise, i.e., walking. The level of activity that we will recommend for you is thought to be more helpful than harmful, but there is a very small risk of heart attack or sudden death during exercise. Heart attack has been estimated to occur less than once out of 500,000 hours of exercise in people without known heart disease. The risk is greater in people with heart disease. It is important that you contact your health care provider before beginning your physical activity program or if you develop diabetes, heart disease or other related health problems during the study.

Possible benefits of research screening and assessment activities. You will likely receive no direct benefit from these measurements beyond getting notification of your results. We hope your participation leads us in refining a feasible, effective and sustainable way to disseminate treatments for overweight/obese, pre-diabetic preventions to high risk older adults.

Possible benefits of Sustain-DPP intervention activities. You may not receive any benefit from these intervention activities.

If successful in the lifestyle program, you may lose weight, become more active,

and/or reduce the level of one or more diabetes/heart disease risk factors.

Your participation in this research may benefit society by enhancing our understanding of the lifestyle intervention procedures and practices that are associated with reduced risk for diabetes and heart disease and improved health and well-being in older adults.

New information. You will be promptly notified if any new information arises during this research study that may change your mind about staying in the study.

Other health interventions in the community. Whether you participate or not will have no effect on your current or future medical care or other treatments offered in the community.

Payment for participation. Neither you nor your insurance company will be charged for any assessment or intervention activities in this study. For your time and effort, and to defray transportation costs, you will be reimbursed $25 when you complete each of the four assessment visits at Month 0 (baseline) 6, 12, and 18.

Injury because of taking part in this study. If you believe that research procedures have resulted in an injury to you, immediately contact Dr. Venditti, Principal Investigator. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. You and your health insurance provider will be billed for routine care services not connected with the study. You will be responsible for co-pays, co-insurances and deductibles not connected with the study.

Knowledge of my participation in the study and access to my medical information. All records related to your involvement in this study will be kept in a private, confidential locked file. Your identity is indicated by a case number and not by name. The information linking case numbers and your name is kept separate from these research records. In addition to the investigators listed below and research staff members, the only individuals who may have access to identifiable information about you are authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office who may monitor the appropriate conduct of this research study. Medical information/test results from this research study can be sent to your physician/health care provider only if you authorize it. It is University policy that research records are kept at least seven years after the final project report.

Withdrawal from the study. You can stop participating in this study at any time, even after signing this form. To do so, you should contact Dr. Elizabeth

Venditti or one of the individuals listed below. The information that you have provided prior to telling us you have withdrawn, will be retained. We will continue to use the research data that has already been collected.

Posting study description and study results. At study end, we will share results with you directly. Your research data may be shared with investigators conducting similar research. However, this information will be shared in a de-identified manner. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VOLUNTARY CONSENT: The above information has been explained to me. All my current questions have been answered. I understand the following.

I may always ask questions, voice concerns or complaints about any aspect of this research study, at any point during the study.

Questions, concerns or complaints will be addressed by Dr. Venditti or a member of her research team. I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions, obtain information, offer input, or discuss situations if the research team is unavailable.

❒ Yes, I give permission for test results in **Sustain-DPP** to be sent to my health care provider of record. Initial here _____.

❒ No, I do not give permission for test results in **Sustain-DPP** to be sent to my health care provider of record. Initial here _____.

❒ Yes, I am a member of the UPMC Health Plan. I agree to have my de-identified medical claims records examined and summarized. The purpose is to explore how intervention participation affects my medication use, emergency, inpatient and outpatient medical visits.
Initial here _____.

❒ No, I am a member of the UPMC Health Plan. I do not agree to have my de-identified medical claims records examined and summarized.
Initial here _____.

❒ Not applicable. I am not a member of the UPMC Health Plan.
Initial here _____.

❒ By signing this form, I agree to participate in the research study. A copy of this consent form has been given to me.

_____ _____
Participant's Signature Date

_____ _____
Participant's Printed Name Phone Number

CERTIFICATION OF INFORMED CONSENT: I certify that I have explained the nature and purpose of this research study to the above-named individual and I have explained the potential benefits and risks of study participation. I further certify that no research component of this protocol was begun until after this consent form was signed. Any question the individual has about the study has been answered, and a member of the research team will always be available to address future questions.

_____ _____
Signature of Person Obtaining Consent Role in Research Study

_____ _____
Printed Name of Person Obtaining Consent Date

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