Coverpage

Title: Advancement of Clinical Referral to Physical Activity for Cardiometabolic Disease Prevention

Brief Title: The Clinical Referral to Activity Study

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University of Pittsburgh

Graduate School of Public Health
Department of Epidemiology

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **Advancement of Clinical Referral to Physical Activity for Cardiometabolic Disease Prevention: Clinical Referral to Activity Study Baseline Consent**

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KEY INFORMATION

You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision. Your participation in this research study is completely voluntary.

Why is this research being done?

The purpose of this study is to develop, implement, and evaluate feasible intervention options for clinical care patients with cardiometabolic risk factors toward meeting the United States Centers for Disease Control recommended levels of physical activity for adults.

What procedures will be performed for research purposes?

If you choose to take part in this study you will be asked to complete the following:

- The intervention that you are randomly assigned to
- 3 study assessments

Your participation will last approximately 12 to 15 months.

What are the possible risks, side effects, and discomforts of this research study?

Risks and side effects related to the procedures include the potential risks of breach of confidentiality, discomfort, soreness, and bruising/bleeding. See the Risk section for a detailed description of the risks and procedures to mitigate these risk.

What are possible benefits from taking part in this study?

You will likely receive no direct benefit from taking part in this research study beyond receiving the results of your tests performed.

What treatments or procedures are available if I decide not to take part in this research study?

If you decide not to take part in this research study, you may continue your usual care with your physician. There are also other programs for improving physical activity available.

Who is being asked to take part in this research study?

You have been asked to take part in this research study because you have reported current physical activity levels that are below what the United States Centers for Disease Control recommends for adults, have at least one additional cardiometabolic risk factor (high blood pressure, high blood glucose, and/or overweight/obesity) and have expressed an interest in increasing your activity levels.

Males and females aged 40-70 years of age are being asked to take part in this study: it is anticipated that approximately a total of 54 individuals will take part in this study.

Where can I get more information on this study?

You can get more information on the study by contacting the investigators on the first page of this form. 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.

What procedures will be performed for research purposes?

If you choose to take part in this study you will be asked to complete the following:

- The intervention that you are randomly assigned to
- 3 study assessments

Interventions for Improving Physical Activity:

Participants will be randomly assigned to one of two intervention groups. Regardless of which intervention group you are assigned to you will receive intervention materials and support for lifestyle change developed from successful strategies for increasing physical activity. Both intervention programs will encourage you to meet physical activity goals. The recommended goals are to increase physical activity to 150 minutes per week (30 minutes, 5 days per week) through brisk walking or similar activity. You will be asked to keep a daily record of your step counts and time spent in planned exercise. You will be provided with tracking tools, including a commercial body-worn monitor to track your step counts and minutes of activity. The same tracking tools with be provided for both interventions. Information related to program participation, including tracking data, will be collected and may be used as part of this research study. Participants in both arms will need a computer where they can access study materials, as not all study materials can be accessed with a tablet or smart phone. Participants in both arms will receive support for behavior

change for 12 months. Both programs will be conducted online and you will be given all of the materials needed to complete the program you are assigned to. Specific procedures for planning, tracking, and reviewing your study progress will differ across the two study arms, but are expected to take the same amount of time per day to complete. If you choose to take part in this study, it is important that you make a commitment to spent an average of 10-15 minutes a day to plan, track, and review your activity progress while you are increasing your activity and about 5 minutes a day after that; regardless of the study arm you are assigned to.

Study Assessments

All study assessments will be conducted in a private office on the University of Pittsburgh Campus and at a Quest lab that is convenient to you. Questionnaires and Surveys will be completed through a secure online system. A tablet or laptop computer will be made available at in-person clinic visits for you to complete the questionnaires and surveys. Height, weight, waist circumference, and blood pressure will be taken in a private office. An accelerometer (see below) will be provided for you at each clinic visit. You will be provided with materials and return postage for returning the accelerometer to the study staff. An intravenous blood draw will be conducted by trained staff at a Quest lab. Arrangements can be made for you to use the Quest Lab closest to the University of Pittsburgh, the day of your in-person clinic visit or you can make arrangements to have your blood draw done at a Quest Lab that is convenient to you, within 10 days of your clinic visit. All participants will be asked to complete one assessment prior to taking part in either the intervention program and two assessments after taking part in either intervention program (at 6 and 12 months after program start). The total length of participation in the study is expected to be approximately 13 months.

ALL study participants will also be asked to complete the following at each assessment timepoint:

a. Medical and Lifestyle History (includes personal questions including questions about medical conditions you have, as well as questions about your lifestyle habits). This will take about 10 minutes

b. Weight and Height- Your weight and height will be measured twice and recorded. Body Mass index (BMI- a measure of your height in relation to your weight) will be calculated after the weight and height have been attained. This will take about 5 minutes.

c. Waist Measurement- a tape measure is placed around the waist and measurements are recorded twice. This will take about 5 minutes.

d. Blood Pressure- You will have blood pressure measured twice in your arm after resting for 5 minutes (using an automatic inflatable digital blood pressure monitor or manual aneroid sphygmomanometer with appropriate cuff size according to a standardized protocol). This will take about 10 minutes.

e. Movement evaluation- You will be asked to wear an instrument called an accelerometer that provides an evaluation of your movement for the 7 days following each clinic visit. The accelerometer is a relatively small activity monitor that will be worn on an elastic belt above the hip, similar to a pedometer. The accelerometer will give us information regarding the amount of time that you spend per day in different intensities of activity. If the data collection is not sufficient, you may be asked to wear the activity monitor for an additional week.

f. Surveys- You will be asked to complete several short surveys. These surveys will ask questions about your physical activity, how you feel about your health, and the costs and benefits of taking part in a healthy lifestyle program. These will take about 20 minutes to complete. You will also be asked to complete an additional brief survey related to study participation 6 and 12 months after you start the ActiveGOALS program

g. Blood sample-You will be asked not to eat or drink anything except water for at least 12 hours prior to this visit. A blood sample will be taken from your arm to measure fasting glucose, insulin, lipids (blood fats), and hemoglobin A1C (measure of the average blood glucose level control over 3 months time). The total amount of blood drawn is about 1 tablespoon.

What are the possible risks, side effects, and discomforts of this research study?

The possible risks of this research study include:

Height, Weight, and Waist Circumference: There is a minimal risk that measurement of height, weight, and waist circumference could result in psychological discomfort.

Blood Pressure: There is a minimal risk that blood pressure measurement could result in psychological discomfort for the participant. Tightness or rubbing from the measurement device

could also cause temporary discomfort.

Venipuncture Blood Sample: The risks of having your blood drawn by venipuncture include temporary discomfort from the needle stick, possible bruising or redness of the skin, lightheadedness, and on rare occasion, infection**.**

Questionnaires and Surveys: There is a minimal risk that revealing thoughts and perceptions regarding overall mental and physical functioning could result in psychological discomfort. There is also a minimal risk of breach of confidentiality.

Exercise: The risks associated with exercise occur occasionally (1-10% or 1-10 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 considering the intensity of the recommended exercise, i.e., walking. The level of exercise that we will recommend for you is thought to be more beneficial 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 physician before beginning any new physical activity program or if you develop diabetes, heart disease or other related health problems during the study. If you are pregnant or plan to become pregnant while you are participating in the study you will be asked to withdraw from the program.

Body-worn Monitors: Both monitors used for research assessments and those used by you for counting steps during intervention have a minimal risk of irritation or bruising (<1%). Monitors will not contain personal identification information or locational information.

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

To minimize risks to participants, all clinical measures will be taken by a trained laboratory technician. We will make a reasonable effort to protect your personal information. At all times, participant information will be handled in a confidential manner consistent with other research records, and individual names or results will not be specifically identified in any research publication.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

What are possible benefits from taking part in this study?

You will likely receive no direct benefit from taking part in this research study beyond receiving the results of your tests performed. If successful at improving your activity you may notice improvements in mood and/or physical wellbeing, there is a possibility that you could lose weight and/or reduce risk factors related to poor health outcome, particularly those related to heart disease and diabetes risk factors. Your participation in this study may benefit society by learning more about the value of clinical referral to lifestyle change.

What treatments or procedures are available if I decide not to take part in this research study?

If you decide not to take part in this research study, you may continue your usual care with your physician. There are also other programs for improving physical activity available.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet at the University of Pittsburgh. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release). We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (e.g., physician office) records during your enrollment in the study. The information that will be recorded will be limited to information concerning body mass index, blood pressure, and blood glucose and the diagnosis of the following conditions: diabetes, coronary artery disease, stroke, arrhythmia, congenital heart

defect, cardiomyopathy, abdominal aortic aneurism, and myocardial infarction. This information will be used for the purpose of verifying study eligibility and determining program success. Your research data may be shared with investigators conducting similar research; however, this information will be shared in a de-identified manner (without identifiers). This identifiable medical record information will be made available to members of the research team for an indefinite period of time. This authorization is valid for an indefinite period of time. Your data from this research study will be provided to your referring physician to inform them of your progress in the study but is not intended to be entered into the medical record.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the University of Pittsburgh and/or UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of internal hospital operations (i.e., quality assurance) and/or other administrative activities involved with the conduct of this study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court

subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Your referring physician and your physician's staff will have access to your study results.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

May I have access to my health-related information that results from my participation in this research study?

You will receive the results of the study including your pre and post-intervention Body Mass Index, waist circumference, and blood draw results. Your referring physician will also receive your study

results, including program participation and activity tracker results.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study. If any additional tests are required by your physician as a result of the tests that are completed you will be charged in the standard manner.

Will I be paid if I take part in this research study?

You will receive $30 for each assessment that you complete (assessments are described above). Participants starting immediately will be asked to complete a total of three assessments (one before starting the program and two after the program at 6 and 12 months after program start). You will not receive a compensation for an assessment until that assessment is completed. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 72% of the expected payment.

Who will pay if I am injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. 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. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will not affect your relationship with the University of Pittsburgh or with your health care provider.

You may be contacted again in the future for additional information relating to this study as necessary.

May I withdraw, at a future date, my consent for participation in this research study?

Yes. To do so, you must contact the investigators who are listed on the first page of this consent form. If you do so, you will no longer be permitted to participate in this study. If you withdraw from this study, we will continue to use the information we have collected.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, for example, you become pregnant during the program or for some reason you are unable to complete the majority of the sessions. If your health status changes, it is also possible that you referring physician could withdraw their permission for you to safely participant.

University of Pittsburgh

Graduate School of Public Health
Department of Epidemiology

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that 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 in the event that the research team is unavailable.

By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date