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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Feasibility and preliminary efficacy of a novel YouTube based physical activity intervention in overweight and obese adults at high risk for type 2 diabetes

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KEY INFORMATION

Feasibility and preliminary efficacy of a novel YouTube based physical activity intervention in overweight and obese adults at high risk for type 2 diabetes

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. Here is a summary so you can decide if you have any interest and want to read the full consent form.

Purpose of the research
The purpose of this study is to test if a video-based exercise program can be useful in helping people who are at high-risk of type 2 diabetes increase their physical activity.

Duration, number of study visits
If you enroll in the study, you will be asked to participate for 12 weeks. You will be required to participate in two assessments and one orientation session conducted via Zoom. Each session will take about 90 minutes.

Overview of study procedures
If you choose to participate in the study:

- We will guide you through measuring your blood pressure, blood sugar levels, blood cholesterol levels, weight, and waist circumference.
- We will ask you to use workout videos to increase your physical activity
- We will ask you to wear a physical activity tracker on your wrist and waist
- You will receive email and/or text reminders to use your selected workout videos
- You will receive a 15-30-minute call from the study team every two weeks
- You will be asked to share your experiences on our online forum
- At the end of the study, you will be asked to respond to the questionnaires that you did before enrolling in the study.

Other study specific information

- The study team will be able to see your daily physical activity patterns recorded by the tracker and the videos that you access on the PATH website.

Reasonable, foreseeable risks or discomforts

- You may feel tired or sore with starting a regular exercise. This is not unexpected and goes away as you get more fit. You should not exercise if you have acute pain and the feeling something is wrong.
- You may feel disappointed or upset if you are not successful in meeting your weekly physical activity goals

Reasonable, expected benefits

- If you manage to increase your physical activity, you may experience some of the benefits associated with physical activity, including reduced risk of diabetes and heart disease.

Why is this research study being done?
There is a need for programs that help people who are overweight increase their physical activity. Regular exercise can help reduce the risk of diabetes and heart disease. Recently, our study team developed a web-based "Physical Activity for The Heart" (PATH) program that uses YouTube workout videos to help people increase their physical activity. In this study, we plan to test if our PATH program is acceptable and helpful in promoting physical activity among individuals at high-risk of type 2 diabetes.

Questions about the study
If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

Who is being asked to take part in this research study?
We are asking 52 people who meet the following criteria to participate in this study:

- You have access to the internet
- Your age is between 40 and 70 years
- Your body mass index (BMI) is at least 25
- You exercise less than 90 minutes per week
- You are at high risk of developing type 2 diabetes
- You are available to participate in all study procedures

What are the procedures that will be performed for research purposes?
You have completed screening questionnaires that showed that you may be eligible for this study. If those questionnaires indicated that you would need to obtain clearance from your doctor, we will need your doctor's clearance to determine your eligibility. Your answers to those questionnaires, your doctor's clearance (if necessary), and the procedures that will be conducted at the Baseline Assessment will all determine if you are eligible.

All research activities are listed as follows:
Baseline Assessment: The Baseline Assessment will take place at a quiet place in your home. The study team will connect with you through a secure Zoom connection to guide you through the assessment which will take about 90 minutes. The study team will deliver or ship to you all the equipment that you need for the assessment. The baseline assessment will begin by a review of the data that you provided in the questionnaires, after which we will then measure your:

- Blood pressure
- Blood sugar levels
- Blood cholesterol levels
- Weight
- Waist circumference

You cannot join the study if you do not complete the baseline assessment, which includes measurements and questionnaires. If you remain eligible after these assessments, we will ask you to wear two physical activity trackers, one on your wrist and another on your waist for 7 days. After

that, you will be invited for a one-on-one session where your study group will be assigned. You cannot join the study if you do not complete the baseline assessment, which includes:

- a review of the questionnaires
- the measurements
- wearing the physical activity tracker for 7 days.

Once we are sure you have met all the study requirements, you will be invited for a 30-45-minute Zoom one-on-one session with the study team. If you remain eligible and are willing to participate in the study, we will use a computer program to randomize you into one of two groups. The groups are PATH treatment or Be active your way. Randomization means the computer chooses by chance, like a flip of a coin. We have no influence on the assignment to groups, nor can you choose, which group you are in. Those who enroll in the study will be asked to ship their dry blood spot kits using the prepaid envelopes, but to retain the assessment equipment until the end of the study. Individuals who do not enroll will be asked to return all the equipment and samples using the prepaid shipping box or by making a pickup arrangement with the study team.

If you are assigned to the Be active your way group, you will be provided with:

- An electronic copy of the Be Active Your Way booklet that is intended to help you integrate physical activity in your daily life.
- Twice a month newsletter focusing on general health topics.
- At the end of the 12 weeks, you will be given access to the PATH treatment (described below).

If you are assigned to the PATH treatment group, you will be given:

- access to the path website that includes workout videos that you will be using to help increase your physical activity.
- The study team will use your assessment data to determine the appropriate level for you to start the intervention (e.g., beginner PATH).
- You will access the workout videos in this level using a username and password that will be set up during this session.
- We will also discuss with you issues related to safety and how to report problems that may arise during the study. Every two weeks, you will receive a 15-30-minute phone call from the study team to review your physical activity routines and set your goal for increasing physical activity. The calls may be recorded for quality assurance.
- You will also receive automated motivational text/email reminders to do your scheduled workouts (e.g., *It is time for your workout! No matter how slow you go, you're already beating everyone sitting on the couch — S. Miller*).

Throughout the 12-week Study: You will be asked to self-monitor your daily physical activity. We will ask you to wear a physical activity tracker on your wrist for at least 10 hours per day when you are awake. The tracker will be connected to an app which will help us monitor your progress throughout the study. A staff member will help you set-up your tracker when you come in for baseline assessment.

12-week Assessment: Two weeks and one week before the end of the study, we will remind you (via text message, email, and phone call) to wear the physical activity trackers for 7 days before your end of study assessment. At the end of the study, the activity trackers will be retained by the study team for research purposes. At this Zoom visit, we will repeat all the tests we did at your baseline assessment:

- Blood pressure
- Blood sugar levels
- Blood cholesterol levels
- Weight
- Waist circumference

We also will ask you to complete the questionnaires that you did before enrolling in the study, and an end of study survey so that you can share your thoughts and feelings about the study. These will take about 40 minutes.

Adherence Checks: During the study, the study team will review your progress. In addition to random checks, at specified time periods: 4, 8 and 12 weeks, the study staff will review your self-monitoring and physical activity data. We may contact you if we detect that you are not wearing the tracker as instructed. You will not have to complete questionnaires or come in for assessment at 4 or 8 weeks.

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

Risk of measuring blood sugar and cholesterol levels

During the baseline assessment, we will ask you to prick your finger using a very fine small needle called a lancet. We will ask you to apply 5 drops of blood from your finger onto a test kit called the "HemaSpot™ SE kit." This will be shipped to you with other equipment. The procedure may cause minor brief pain (or rarely, bruise) at the point where the blood is taken. The state-of-the-art equipment supplied to you will make the procedure nearly painless. The sample with the dried blood spots will be sent to CoreMedica lab. It will only be used to test your blood sugar and cholesterol levels at baseline and 12 weeks. There will be no storage of any blood spots once they are analyzed.

Risk of increasing physical activity

Increasing physical activity may lead to muscle soreness. Some soreness is normal, but it should ease over time. You will be provided with a non-slip exercise mat to reduce the risk of slipping during home-based physical activity sessions. Other infrequent risks include feeling dizzy, chest pain or discomfort, and exercise-related cardiac events. During the one-one-one session, you will be advised how to safely engage in physical activity, and when to stop and call for medical help (911 and/or primary care provider) if there is a problem.

Risk of wearing physical activity tracker

Wearing a physical activity tracker on your wrist may cause some irritation on the wear location. The waist tracker is worn over cloth using a belt provided by the study and is not likely to cause irritation.

Risk of collection of private health information, internet, and text message use, and recording of phone calls

It is always possible that someone who is not involved in this study could access or view your private information that you provided us. We will not place your name on the research data but will instead use an ID code to identify you. It is unlikely that anyone other than limited study staff will be able to link your name to your private information.

Questionnaires completed on the online program will be protected using online data protection measures that are built into the program to prevent data from being released. Information containing your personal information (i.e. consent forms, contact information) will be stored in a separate location from the research data. The research data will be stored without anything that identifies you. Paper-based records are stored in locked filing cabinets in locked offices. Electronic data are stored in password protected databases on a secure server. Access to the research data is limited to members of the research team who have a need to access such information.

The phone call conversations will be recorded using a password protected recorder. These data will be deleted from the recorder as soon as they are uploaded on the secure Pitt server. Only the study team will have access to these data.

Although every reasonable effort has been taken, confidentiality during Internet communication, such as doing the surveys or getting text messages, cannot be guaranteed. It is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. To our knowledge, our previous studies using technology have not had this happen and the risk of breach of confidentiality is low.

What are the possible benefits from taking part in this study?

You may not receive direct benefit from taking part in this research study, but you may learn more about practical things that may help you become more physically active. If you manage to increase your physical activity, you may experience some of the benefits associated with physical activity including reduced risk of diabetes and heart disease.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as private as possible. All paper documents related to your involvement in this research study will be stored in a locked file cabinet. Your identity on the surveys will be indicated by a study ID rather than by your name. Research data that are stored electronically will be coded with your study ID number in password-protected databases.

You will not be identified by name in any publication of research results; all results are presented for the study groups, or in aggregate. Your research records will be destroyed when it is approved by the sponsor of this study or, as per University policy, at seven years following study completion, whichever should occur last.

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

No. This study will not involve the use or disclosure of your identifiable medical information

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

In addition to Dr. Kariuki and his staff, the following people will or may have access to identifiable information related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the sponsor of this research study, the Ruth Perkins Kuhn Grant committee, may review and/or obtain identifiable information related to your participation in this research study. This is for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. We may share de-identified data with other researchers or federal data repositories in the future.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

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 related to your participation in this research study indefinitely.

Is my participation in this study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or a health care insurance provider.

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

At any time, you may withdraw from this study. This includes withdrawing your permission to use your private information. If you withdraw your consent for the use of your identifiable information, you will also be withdrawn from being in this study. To withdraw your consent for participation in this study, please inform the PI on the first page at the phone, email or address listed. Any identifiable research information that we have collected before you withdrew will continue to be used and protected for confidentiality.

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

You will receive $30 for completing the baseline and end of study assessments. We will also reimburse you $40 if you use your data plan to access the workouts available on our PATH website. Although we hope that you will commit to do all the workout videos recommended for you each week, you must complete at least 70% of your weekly goal be eligible for this reimbursement. We will review your status every 4 weeks and provide more information about the terms of this reimbursement. You will have a choice to forego the $70 compensation if you would like to keep

the Fitbit tracker that you will use during the study. You will receive this reimbursement at the end of the study.

You will be paid on a reloadable debit card. All compensation is taxable income to the participant regardless of the amount. If you receive $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 26% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 74% of the expected payment.

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

There is no charge for participating in this study.

Will I have to pay for my injuries because of the Active You Study research procedures?

If you believe you have been injured because of the procedures that are performed for research purposes, immediately contact the Principal Investigator or one of the researchers listed on the first page. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided by UPMC hospitals. If you do not have access to a UPMC facility, you should seek emergency care from your local hospital and call the University of Pittsburgh Human Subject Protection Advocate (1-866-212-2668). It is possible that UPMC or our local hospital may bill your insurance provider for the costs of this emergency treatment, but none of these 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. Currently there is no plan for additional financial compensation. You do not, however, waive your legal rights by signing this form.

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VOLUNTARY CONSENT

All the above has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

_____

Participant's Printed Name

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, concerns, or complaints 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/Time