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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: Increasing Physical Activity in Rural Pennsylvanians: The PA Moves Trial – PCP Participant Protocol

PRINCIPAL INVESTIGATOR

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QUESTIONS ABOUT THE STUDY?

You can contact the study investigator listed above if you have any questions about the study, concerns, or complaints.

SOURCE OF SUPPORT:

The institution and investigators are receiving a grant from the National Institutes of Health National Cancer Institute to support this research.

RESEARCH CONSENT SUMMARY (KEY INFORMATION)

- The purpose of this voluntary research study is to determine the impact of an ECHO (Extension for Community Healthcare Outcomes) intervention on the likelihood that rural primary care providers (PCP) will refer their physically inactive patients to be more active.
- Participation in this study is voluntary
- Study procedures include:
 - Filling out surveys
 - Wearing a device called an accelerometer to measure your physical activity for a week
 - Participating in an ECHO intervention of 3 one-hour videoconferencing sessions
 - Speaking to patient participants about physical activity
- For this study, the main risks to know about are:

- Some of the survey questions may make you feel uncomfortable. You may skip those questions and still participate in this study.
- You may experience skin irritation with wearing the physical activity measuring device.
- There is always a risk of loss of confidentiality from participating in research. We take many steps to keep your information private.

INTRODUCTION

- This research is being done to address physical inactivity in rural communities.

People living in rural areas are diagnosed and die from cancer at higher rate than people living in cities. Physical activity has been shown to decrease the risk and occurrence of a variety of cancers, including bladder, breast, colon, endometrial, gastric, kidney, and prostate cancers. Being inactive can cause over 10% of breast and colon cancer cases. Compared to people living in cities, people living in rural areas tend to be less physically active. They're also more likely to be overweight/obese or have diabetes. Adults who are overweight, obese, or diabetic often have changes in the way their bodies deal with insulin, glucose metabolism, and inflammation. Physical activity is thought to reduce the risk of cancer by improving these issues over time.

PCPs and their staff can identify a patient's need for more physical activity, but may not have the time or resources to give advice or assistance. We have set up a telephone-based physical activity coaching program, called the MoveLine, to give inactive participants advice and assistance in becoming more physically active.

The purpose of this study is to determine if an ECHO intervention will impact the likelihood that PCPs will refer patients to the MoveLine for physical activity coaching. ECHO is a distance-learning model designed to provide continuing education for healthcare providers. This study has used this national infrastructure for education to create a course designed to improve healthcare provider's ability to counsel their patients about physical activity and refer them to a physical activity coaching service, the MoveLine, that we have developed.

- You are being asked to participate in this research study because you are a primary care provider or adjunct faculty from a Primary Health Network (PHN) clinic or a UPMC clinic serving rural populations.
- Approximately 32-48 PCPs will take part in this research study.
- If you choose to join this study, your participation will last for about 2 years.

RESEARCH ACTIVITIES

Randomization and Group Assignment

- This study will start with a practice cohort of 4 to 6 PCPs. All PCPs recruited during the practice cohort will receive the ECHO intervention.

- After that, the study is a randomized controlled trial with two groups: one group will receive the intervention now (active intervention) and the other group will be offered the intervention in the future (delayed intervention).
- Randomization will occur at the level of the clinic. The group assignment will be determined purely by chance, with an equal chance of ending up in either group, similar to flipping a coin (50%).

You will be asked to fill out surveys and wear a device called an accelerometer that measures your physical activity, and receive the ECHO intervention.

- Surveys will be done at the beginning of the study.
 - They will be provided to you, can be completed at home, and will take about 20 minutes
 - You are free to skip any questions that you would prefer not to answer
- An accelerometer will be worn at the beginning of the study.
 - It will be provided to you to wear for a week
 - When the week is over, you will return it in the postage-paid envelope we will give to you
- The ECHO intervention will be offered via real-time, interactive videoconferencing (Zoom sessions) held once weekly for 3 weeks (3 sessions total) at regularly scheduled times convenient to PCPs.
 - Sessions will last 60 minutes each and will include:
 - Didactic presentations from experts
 - Case studies from experts and PCP participants
 - Topics covered will include the following:
 - Introduction to PA Moves and How You Fit In
 - Ask, Advise, Connect: How to Talk to Your Patients About Physical Activity
 - Circling Back: What Happens if the Conversation Doesn't Work – Trying Again
 - After the ECHO series, you will complete
 - a brief evaluation questionnaire, which will take about 10 minutes
 - an ongoing check-in survey, given quarterly for one year, which will take about 5 minutes
 - You will receive 3 CME credits for completion of the ECHO sessions

STUDY RISKS

- Completing Surveys: There are no medical risks associated with completing surveys. However, you may become uncomfortable providing personal information. Any questions that make you uncomfortable can be skipped.
- Loss of Confidentiality: There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law

and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

- You may experience skin irritation with wearing the physical activity measuring device.

STUDY BENEFITS

There is no guarantee that you will benefit from this research. You may benefit from this research study by becoming more comfortable, knowledgeable, and skillful in talking to patients about physical activity.

CONFIDENTIALITY

- Protecting your confidentiality: Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Here are a few of the ways that we will protect the confidentiality of research participants and study data:
 - Research data will be coded.
 - All participants will receive a unique study code number.
 - The list that matches your name with your study code number will be kept in a locked file cabinet.
 - Paper research records will be kept in locked file cabinets behind locked doors.
 - Role-based security: only those approved to access your records will be allowed to do so
 - Electronic data will be password-protected
- The following people/groups will have access to your research record
 - The investigator, study staff, and other University of Pittsburgh professionals who may be evaluating this study
 - Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study
 - The sponsor, the National Institutes of Health National Cancer Institute will be provided de-identified information for safety and progress reports
- Future Research: We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity.
- Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. However, records may be kept indefinitely.

- 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 or documents that may identify you to anyone not connected with the research. This means they cannot provide them as evidence in legal proceedings unless you say it is okay. However, the Certificate of Confidentiality does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others.

PARTICIPANT ACCESS TO RESEARCH RESULTS

The materials from this research will not be included in your medical record. Individual or aggregate study results will not be directly provided to you.

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.

COMPENSATION FOR INJURY

If you believe you have been injured as a result 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 contact the study team. 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. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

WITHDRAWAL FROM STUDY PARTICIPATION

You can withdraw from this research study at any time. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team. Your decision to withdraw will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

It is possible that you may be removed from the research study by the researchers if, for example,

- You did not follow the instructions of the study team
- You did not complete the study activities
- There is a change in the status of your eligibility for the study

If you are withdrawn from the research, you will need to return the accelerometer we have loaned to you for the purposes of this research study, if you have one at the time of withdrawal.

CONSENT TO PARTICIPATE

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by the investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study. A copy of this consent form will be given to me.

Printed Name of Participant

Date

Signature of Participant

INVESTIGATOR CERTIFICATION

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 started until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date