DUKE UNIVERSITY HEALTH SYSTEM

NAME:

Consent To Participate In A Research Study
Movement-Oriented Behavioral Activation to Reduce Stationary Behavior DATE:
Protocol Number: Pro00108202

Concise Summary

The purpose of this research study is to determine the acceptability, feasibility, and effectiveness of behavioral activation to increase everyday movement and reduce the amount of time spent daily in positions of prolonged standing and sitting. This intervention is call Movement-Oriented Behavioral Activation (MOBA). Participants will undergo a 60-minute screening that includes health and lifestyle questionnaires, mobility testing and a six-minute walk. Participants will complete the same procedures after completing MOBA. Each participant will be randomly assigned to an intervention group or a wait-list group. Both groups will participate in the same MOBA group, but the intervention group participates first. If you are assigned to the wait-list group, you complete initial and follow-up assessments along with the intervention group, but do not participate in MOBA groups until after the intervention group is finished with their 12-week program. After this, the wait-list group will participate in the same 12-week MOBA group, and complete an additional follow-up assessment. MOBA groups meet once per week during the last hour of the workday, which will be paid time. During meetings, participants will set movement goals to reduce total time spent sitting and standing, and learn exercises and strategies to get more physical activity throughout the day and evening. Participants will be asked to record daily activities for review at weekly group meetings. At the end of the 12-week group, all participants, including those on the wait-list will be asked to complete the same questionnaires, mobility testing, and 6-minute walk as the beginning of the study. Some participants will be asked to participate in a focus group to share additional information about their experience in the study and the end of the study, and after 2 months. Total study duration for the intervention group is about 4 months. Total study duration for wait-list group will be about 8 months, which about half of that time spent in the waiting period.

The greatest risks of this study include the possibility of injury during physical activity and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to participate in a research study because you work in a job with a high level of prolonged standing and/or excessive sitting, which is described as stationary behavior. In this research study, we are examining the outcomes of a behavioral intervention on changes in stationary behavior. This study is sponsored by a grant from the National Institutes of Health (NIH). Portions of Dr. Potter's and the research team's salaries are paid by this grant.

Subject Initials_____

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Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully, and take your time making your decision. As study staff discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The details of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study staff if you are taking part in another research study.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the study staff will discuss with you. This discussion will go over all aspects of the research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign and date this form. You can choose not to participate, and you can choose to end your participation at any time during the study. Your decision to participate or withdraw will not have any current or future consequences on your employment with Duke University

WHY IS THIS STUDY BEING DONE?
The research we are doing is to evaluate behavioral strategies to increase physical movement throughout the day, including both work and home. The focus is to reduce long periods of time spent without movement, such as prolonged standing or sitting. Prolonged standing and/or sitting is described as stationary behavior. Stationary behavior is associated with decline in the body's strength, flexibility, and fitness, which can limit personal mobility. Stationary behavior is also a risk factor for medical conditions like heart disease and diabetes. The strategies taught in this study are called behavioral activation. Behavioral activation strategies help you identify personal reasons that you want to increase activity, help you select movement activities that are important to you, and teach you ways to schedule these activities into your day. Our version of behavioral activation is called Movement-Oriented Behavioral Activation, or MOBA. We are evaluating MOBA in a group setting to take advantage of the benefits of group support in changing behavior. The long-term goal of this research is to help people develop regular habits of movement to maintain their health and mobility as they get older.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Approximately 32 people are expected to enroll in this study. Because we are interested in workplace factors as part of reducing stationary behavior, we are focusing on individuals at

work. Because it is a group intervention study, we are focusing on a single workplace to make the study more convenient to participants.

WHAT IS INVOLVED IN THE STUDY?

Pre-study assessment:
The first visit for the study will be done near your workplace at Duke University. If you choose to take part in this study, you will first be asked to sign and date this consent form. We will ask you to complete questionnaires about your health, activity level, and other behaviors. We will ask you to complete a brief test of movement, and to complete a 6-minute walk test. We will also ask you to wear a small motion tracking device (an Actigraph) on your hip for a few days to record your regular activity level.

If you have difficulty completing a 6-minute walk or have high levels of symptoms consistent with depression, you may not be eligible to participate in the study at this time. If you are ineligible to participate at this time, we will provide you with information and resources about improving mood and physical mobility. This first visit will last approximately 1 hour.

Randomization procedures:
If you qualify for the study, you will be randomly assigned (like the flip of a coin) to participate in one of two ways: (1) you may be selected to start the intervention group and participate for 12 weeks, or (2) you will be selected to a wait-list group, which you means you will go about your regular activities for 12 weeks, at which time you will complete the post-study assessment (described below). Then you will participate in the MOBA group for 12 weeks, followed by another assessment at the end of the group sessions.

MOBA Sessions:
There will be 12 weekly sessions of MOBA, which will take place in a space close to where you work. There will be two group leaders with experience in MOBA and physical activity. As part of MOBA sessions, you will be asked to complete assignments, such as recording activity goals, and strategies for troubleshooting. Group leaders will explain these activities and help you complete assignments. You will also be asked to record activities and keep track of assignments during the week between sessions. Your therapy sessions will be audio or videotaped for use in evaluating the MOBA intervention. These group sessions will last about 1 hour, will occur at the end of the workday, and are counted as paid time.

Post-study assessment:
The post-visit assessment will be done near your workplace at Duke University. We will ask you to complete the same questionnaires and tests as in the pre-study assessment.

We will ask you to participate in an interview 2 months after the end of your MOBA group to discuss your experience with the intervention, including barriers to maintaining physical activity. This interview will be audio recorded for use in evaluating the intervention.

We would also like to interview individuals who decide not to participate in the study.

Your participation in MOBA during the workday, as discussed above, will count as paid time at work.

HOW LONG WILL I BE IN THE STUDY?
If you are selected for the intervention group (1st MOBA group), you can expect to be involved with the study approximately 16 weeks: (1) 12 active weeks of MOBA including pre- and post-study assessments, and (2) 2-month follow up interview. If you are selected for the wait-list control group (2nd MOBA group), you can expect to be involved with the study approximately 32 weeks: (1) 12 weeks non-active weeks but including pre- and post-study assessments, (2) 12 active weeks of MOBA including post-study assessment, and (3) 2-month follow up interview.

WHAT ARE THE COSTS?
There will be no cost to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
You will be compensated $120 for participating in the MOBA intervention, including pre- and post-assessment. You will be compensated $20 for participation in the 2-month follow up interview. Participants in the wait-list control group will receive an additional $70 compensation for the extra assessment visit, but will otherwise receive the same compensation. Participation that occurs during the workday will be compensated as paid work time.

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WHAT ARE THE RISKS OF THE STUDY?
You will be engaging in light physical activity during MOBA sessions, and these are expected to have minimal risk of injury. Pre-and post-assessment will also include light physical activity, which is also expected to have minimal risk of injury. Outside of work, you will be asked to engage in physical activities of your choice and intensity. These activities are expected to have minimal risk of injury. There will be questionnaires with items that ask about symptoms related to depression and anxiety; however, we have no reason to believe that any unpleasant thoughts or emotions will last long after the interview is over. You may refuse to answer any of the questions that make you feel uncomfortable.

There is also a potential risk of loss of confidentiality. Every effort will be made by the study staff to keep your information confidential; however, this cannot be guaranteed.

There may be risks, discomforts, or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct health benefit to you. We are predicting improvement mobility and fitness as a result of the MOBA intervention, but we cannot guarantee this will occur. We are predicting an increase in active and valued behaviors as a result of the MOBA intervention, but we cannot guarantee this will occur.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

All Duke paper data and research forms will be kept in a secure locked cabinet in Dr. Potter's office and will only be made accessible to members of the research team for this study. Your name and other personal identifying information will not be stored in the computer system databases that store your ratings, and thus individuals who might gain unauthorized access to your ratings will not know your identity. Audio or video recordings that could contain identifiable information will be destroyed no more than 6 years after the study is completed. Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the representatives from the Duke University Health System Institutional Review Board.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil,

criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project (NIH).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations

Your name and other personal identifying information will not be used in any scientific reports of this study by Duke, and will not be made available to representatives from the NIH, the primary funding source for the study.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the NIH. If you do not sign this consent form, it has no impact on your employment at Duke University.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your employment at Duke University. If you do decide to withdraw, we ask that you contact Guy Potter, PhD by email and let him know you are withdrawing from the study. His email is address is: guy.potter@duke.edu. If you use email please be aware that you may be at potential risk for a loss of confidentiality because email is not a secure means of communication.If you withdraw, we may ask you to provide information about reasons for withdrawing that will help us improve the study. If you prefer to write to Dr. Potter, please address correspondence to: Box 3903 Med Ctr, Durham, NC 27710. You may reach him by telephone at 919-668-1269.

WHAT ABOUT RESEARCH-RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Guy Potter at 919-812-7037.

CLINICALTRIALS.GOV

A description of this clinical trial will be available on https://clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or if you have problems, concerns, questions or suggestions about the research, contact Dr. Guy Potter at 919-812-7037.

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For questions about your rights as a research participant or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at 919-668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

I choose not to participate in the study, but I do agree to be contacted at later point to answer questions about my perceptions of the study, and the reasons I decided not to participate. I understand that I am under no obligation to participate at that time, and can decline to participate in the interview with no consequences to my relationship with Duke University.

_____
Signature of Subject Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time