Walk This Way: An RCT Comparing Self-paced Versus Moderate Intensity Physical Activity for Midlife Adults

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BROWN

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Walk This Way Research Study
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KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The goal of this study is to learn about people's thoughts and feelings about exercise, and their motivation to exercise.
- PROCEDURES: You will be asked to attend nine zoom appointments with a Brown University research staff member over the course of 12 months. During these sessions, you will be given information about the study, be asked to take your weight, and receive physical activity education. Before each of these sessions, you will be asked to complete on-line questionnaires about personal behaviors, thoughts, and emotions. You will also be asked to regularly use a smartphone application and wear an Actigraph activity monitor.
- TIME INVOLVED: The study will take 20 hours of your time over a period of 12 months, as well as the amount of time you choose to spend exercising.
- COMPENSATION: You will receive up to $591 total compensation for completing your assessment appointments, wearing and returning the Actigraph activity monitor as directed, completing the on-line questionnaires, and responding to the smartphone app on a daily basis. You will receive compensation in the form of Amazon.com electronic gift cards, after each assessment visit, and at the end of the study for responding to the smartphone app.
- RISKS: You could potentially experience minor injuries or muscle sprains due to participating in an exercise program
- BENEFITS: You will receive information about physical activity and strategies to overcome barriers to becoming more physically active. Participation in this program will help you to gain tools to motivate yourself to exercise, and may assist you in becoming more physically active.
- ALTERNATIVES TO PARTICIPATION: The alternative to participating in this study to become more physically active would be to work towards increasing your activity levels to 150 minutes/week through consultation with your doctor.

1. Researcher(s):

You are being asked to take part in a research study conducted by Dr. David Williams. Dr. Williams has a Ph.D. in Psychology and is a Professor of Behavioral and Social Sciences at the Brown University School of Public Health. Additional researchers involved in this study include Dr. Lauren Connell Bohlen at Brown University, and Drs. Jessica Unick, and Wen-Chih Wu at The Miriam Hospital, Lifespan. These researchers will be advising on study protocols related to exercise and helping to determine participant eligibility throughout the study.

We are enrolling approximately 500 adults who are Rhode Island residents and generally healthy but do not engage in regular exercise.

This document will explain the study to you and if you have any questions, you are welcome to ask a member of our research staff at any time. If you are interested in participating, you will be asked to consent to participate, which means that the study has been explained to you, that your questions have been answered, and that you agree to participate. You will be provided with a copy of this form for your own records. This process is called informed consent.

2. What is this study about?

You have been asked to participate in a Brown University Research study because you reported that you are not participating in regular exercise. This program is being sponsored by the National Institute on Aging (NIA). The purpose of this program is to understand more about people's thoughts and feelings about exercise, and what motivates people to exercise.

Another purpose of this study is to determine if our program is effective in helping people increase and maintain their physical activity. The program includes some components that have been used successfully in the past, plus additional components that are designed to increase your physical activity. For example, during this program you will be asked to exercise 5 times per week. Specifically, we will ask you to start a walking program. To help you do this you will receive a heart rate monitor and an electronic diary application to track your exercise on your smartphone.

3. What will I be asked to do?

The following section describes what your participation in this physical activity program will involve. The researcher, David M. Williams, Ph.D. or one of his colleagues will explain the program to you in more detail if you should want more information. You should feel free to ask questions.

If you decide to participate in this study, here is what will happen:

After today's session, you will be asked to complete two more remote sessions via Zoom before beginning the exercise program. The audio of these Zoom sessions will be recorded. Recording is required to ensure the researchers are able to capture your complete response. If you do not want to record your session, let us know *as this will affect your ability to participate in the study*. These three sessions (including today's session) are described in more detail below.

A. SESSION 1: You are currently at session one. At this session you will be oriented to the study and asked to electronically sign this consent form. During the screening process for this study, you told us about your health status, which was used to determine if there is any reason why it would be unsafe for you to participate. You are responsible for informing the study staff of any changes in your health or medications during the 12-month study.

If you decide to participate, you will be scheduled to attend session two. We will then also send you a link to complete a few online questionnaires about your thoughts and feelings about exercise, as well as some demographic information. Session one will take about 60 minutes to complete.

We do not require you to complete the full questionnaire at session 1, but it must be completed within three days of this appointment for you to remain eligible.

B. SESSION 2: During this session we will describe how to use the Actigraph activity monitor and the smartphone application that you will use for recording your exercise and your thoughts and feelings about exercise during the study. You will be asked to use the Actigraph activity monitor for a one-week period between sessions 2 and 3. You will also be asked to use the smartphone application between sessions 2 and 3. Specifically, you will be asked to respond to several questions each morning that will take about one minute to complete.

Before the end of session 2, we will ask you to complete an 'Actigraph monitor contract' which is a document that outlines some information about the device, instructions on how to wear it, expectations for your use of the device, and an agreement that you will return the device at the end of the 1-week wear period. We will also email you a copy of a letter addressed to your primary care physician (you will provide us with their name), for you to email, or bring to your doctor so that they are aware of your participation in this exercise program in case of any medical concerns. Session 2 will take about 60 minutes to complete.

After session 2 we will mail you a package containing study materials, including the Actigraph activity monitor, and pre-paid return packaging for you to mail the Actigraph activity monitor back to us after you have worn it for 7 days.

Before Session 3 we will mail you a package containing an electronic scale to measure your weight, and a heart-rate monitor which is to be worn on the arm when you exercise over the next 12 months. At the end of the 12-months, you can keep the scale and the heart-rate monitor.

C. SESSION 3: At session 3 we will view the information you entered in your smartphone app and discuss any problems you had using the smartphone application. You must be able to successfully use the smartphone app to participate. We will then ask you to take your weight on the scale that we will mail to you. We will also again assess your physical activity level to ensure that you are not currently engaging in regular physical activity. If you are found eligible for continuation in the study, you will have a 10-minute individual, exercise counseling session. During this session you will be given a 12-month walking program that involves walking five times per week for at least 10 minutes each day. We will also discuss with you some of the barriers to exercise and help you to set specific goals about when, where, and how to complete your walking sessions.

You will also be introduced to additional features on your smartphone application to help you exercise during the next 12 months of the study. We will explain how to use the heart rate monitor, and you will be asked to wear it each time you exercise so your heart rate can be recorded in your smartphone app. Session three will take about 60minutes to complete.

At the end of session three, you will begin the exercise program.

D. EXERCISE PROGRAM: You will be asked to walk 5 times a week for sessions of at least 10 minutes. During the 12-month program you will receive motivational messages through your smartphone app, as well as a way to monitor and track your exercise.

E. FOLLOW UP: In order to keep track of your progress, you will also be asked to attend 6 additional remote sessions via Zoom after you start the walking program. The audio of these sessions will be recorded. Recording is required to ensure the researchers are able to capture your complete response. If you do not want to record your session, let us know *as this will affect your ability to participate in the study.* These follow-up appointments will be at week 1 and months 1, 3, 6, 9 and 12.

At each of these appointments we will review the information in your smartphone application, and ask you whether there have been any changes to your medical history related to your ability to exercise. Additionally, at months 3, 6, 9 and 12 you will be asked to complete questionnaires, have your weight measured, and wear the Actigraph activity monitor for a one-week period.

If your medical status changes in a way that impacts your ability to exercise we will place you on a temporary medical hold. We may put you on a temporary medical hold if you have an illness or injury that makes you unable to exercise for more than one week, if you are afraid of making an injury or illness worse by exercising, if you experience any unusual pain or abnormal discomfort when you exercise, or if you are planning to see a doctor about an illness or injury that is interfering with your ability to exercise. If you are on a temporary medical hold we will ask that you still participate in the study, and use your smartphone application. You will not be asked to answer questions about your exercise when on a medical hold. You will still be able to earn the same amount of money in the study even if you are placed on a medical hold.

Once your doctor decides that you are able to exercise again you will need to contact the study staff to let us know. We will ask you to have your doctor sign a letter (we will provide a letter for you to give them) to confirm that it is safe for you to exercise. You can mail, or email us the signed letter: (Brown University, Box G-121S-8th floor 121 South Main St. Providence, RI 02912 or walkthisway@brown.edu).

Finally, we will call, text, and/or email you a few more times during the study to confirm your online assessment sessions.

Your participation in this study may last up to 20 total hours over 12 months, in addition to the time you choose to spend exercising.

4. Will I be paid?

You will be able to earn up to $591 for completing the study tasks.

Specifically, you will earn:

- $20 each for completing the baseline, 3-month, 6-month, 9-month, and 12-month assessment sessions, including return of the Actigraph activity monitor (total of $100). You will receive an Amazon.com electronic gift card after the completion of each of these tasks.

- Up to $491 for using the smartphone application every day during the 12-month study period. You will receive an Amazon.com electronic gift card for using the smart phone application at the end of the 12-month study

Additionally, you will be able to keep your heart rate monitor and scale if you attend the 12-month assessment session at the end of the study.

If you are placed on a temporary medical hold, or a hold of any kind during the study you will still be able to receive compensation for completing study-related tasks.

If you earn $600 or more from Brown University in a single calendar year (either in one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

5. What are the risks?

The materials you will receive while participating in this program contain information about injury prevention. However, the researchers cannot guarantee that no complications will happen to you. Increasing your physical activity level can have great benefits that usually exceed the risks. Nevertheless, there is always some risk associated with exercise.

When walking for exercise musculoskeletal injuries can occur. Previous injury or a current problem is a risk factor for future injuries. If you have or had an injury to your lower extremities including back, hips, knees or feet, please let the study staff know. If you do become injured during the study, you should call your doctor immediately and alert the study staff.

Although the Actigraph activity monitor is made of materials that are not known to be irritating to the skin (Polycarbonate and Polyvinyl Chloride), some irritation to individuals with sensitive skin may occur. If irritation of the skin occurs due to wearing the device, discontinue wearing the device and consult a doctor for treatment. Also, notify research staff that you have taken the device off since data collection will be affected.

6. What are the benefits?

You may not directly benefit from being in this research study. By participating in this study, you will receive information about physical activity and additional information about how you are thinking and feeling about becoming more physically active. Participation in this program may help you to motivate yourself to exercise which may assist you in becoming more physically active.

If you are able to begin and continue a program of regular physical activity you may also experience some health benefits. Medical science has established that regular physical activity reduces the risk of heart disease and stroke, helps control cholesterol levels, diabetes, obesity, and reduces high blood pressure for some people. Even modest levels of physical activity provide some benefit. Physical

activity helps in developing endurance, joint flexibility, and muscle strength--things that are especially important as people age.

7. How will my information be protected?

All of your records from this study will be treated as confidential and will be protected to the fullest extent of the law. Data will be deidentified and coded with an arbitrary ID number. Participant names will only be linked to ID numbers in a password-protected file on a secure Brown University server. Data with identifying information (i.e. consent forms, contact information) will be kept separate from coded deidentified data. Any collected data will be saved on a secure Brown University server, accessible only by Dr. Williams and authorized research staff. Any paper data will be stored in a locked file cabinet at Brown University.

Your privacy will be maintained over Zoom video conferencing. All meetings will be secured with waiting rooms and research staff will have control over meeting settings and restrictions to ensure your privacy. We will record the audio of Zoom sessions. We will only save the audio files from the recording, we will not keep any recordings of your video. We will maintain the audio files with a participant ID number rather than your name. All audio files will be saved to a secured computer server hosted by Brown University. We recommend that when scheduling your Zoom sessions, you select a time and date when you know you will be able to log-into the call from a location where you have adequate privacy. After completing the call, we recommend closing all internet browser windows, and closing the Zoom app if you are using it.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if there are any reports of child abuse, neglect, or harm to self or others.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. 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.

Finally, Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

8. Are there any alternatives to this study?

If you choose not to participate in this study, you are still free to participate in other physical activity programs in the community. You may also choose to perform physical activity on your own.

9. What if I want to stop?

You decide whether or not you want to be in the study. Participation is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. If you decide now to participate, you can change your mind later and quit the study. If the researcher or your doctor feels it is in your best interest, they may choose to take you out of the study temporarily or permanently at any time before you complete the study.

In addition, the sponsor (NIA) may choose to end the study at any time, for reasons unrelated to health care.

If you refuse to participate in or leave the study, your current or future relationship with Brown University will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about your taking part in this study, you may call ~~me, [research assistant]~~ our research team at 401-863-6514 or the Principal Investigator, David Williams at (401) 863-6248.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

Typing your name below, and clicking the 'Yes, I agree to participate' below confirms that you have read and understood the information in this document, are 50-64 years old and that you agree to volunteer as a research participant for this study.

You can save a copy of this form for your records by clicking here:

< provide URL to print PDF>"