



BROWN

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Physical Activity Promotion Based on Positive Psychology

Version 4, March 9, 2018

Research Study Volunteer Name

KEY INFORMATION:

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

- **PURPOSE:** The study is about increasing your physical activity through positive psychology.
- **PROCEDURES:** You will be asked to attend six one-hour group-based sessions at your local YMCA, and to complete questionnaires at two different time points. You will also receive text messages.
- **TIME INVOLVED:** The study will take 8 hours of your time over a period of 3 months, as well as the amount of time you choose to spend exercising.
- **COMPENSATION:** You will receive \$50 compensation for your time and a 3-month gym membership to the YMCA.
- **RISKS:** You could potentially experience minor injuries or muscle sprains due to participating in an exercise program, however the likelihood of this risk is low.
- **BENEFITS:** You will receive information about physical activity and strategies to overcome barriers to becoming more physically active. Participation in this program 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 an Associate Professor of Behavioral and Social Sciences at the Brown University School of Public Health. We are enrolling approximately 10 adults (age 18+) who are 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?

The purpose of this study is to test the effects of a new program designed to increase physical activity through a positive psychology intervention.

You have been asked to participate in a Brown University research study because you are interested in becoming more physically active, are over the age of 18, and can send and receive text messages.

The study will consist of volunteers, like yourself, who will all participate for 3 months.

You will be enrolled in the Positive Psychology and Physical Activity intervention designed to help you overcome barriers to physical activity, based on the principals of positive psychology. Positive psychology focuses on living, “the good life”, it is a scientific study of the factors that allow individuals to lead happy, well-lived and fulfilling lives. This program will involve six weekly one-hour group-based sessions at a local YMCA with a trained group leader. In addition to the in-person sessions, there will be text messages sent to you about physical activity that include positive psychology content

3. What will I be asked to do?

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

Before you leave today’s orientation session, I will ask you to complete some questionnaires about yourself, such as your age, and the amount of physical activity you have done in the past week. This will take about 20-30 minutes. We will then take your height, and weight, and observe you using exercise equipment.

After completing these questionnaires, you will be scheduled for 6 group-based sessions over the next 6 weeks. We will ask you to take a physical activity tracker with you to use over the next week before you begin the group sessions and again at the end of the 6 weeks.

You will then be asked to attend six weekly group-based meetings in which you will learn about overcoming barriers to physical activity using techniques from positive psychology. These meetings will be audio-recorded. You will receive a binder to take with you with information about all of these sessions.

To help you with the content from the sessions, you will also receive text messages with mini-exercises to complete related to the in-person group session you attended. You will receive text messages twice a day from us, once in the morning and once in the early evening. The text messages we send in the evening will be interactive, meaning we want you to reply to the text message. We will send you a reminder if you forget to respond to these texts.

After the sixth session is over, we will give you a physical activity tracker to wear for one week. One week after the 6-week program ends, you will be asked to come in to complete another packet of questionnaires and to return the physical activity tracker. We will ask you to repeat these procedures one more time at 3 months, but this time we will mail you the activity tracker. Please bring the activity tracker with you when you come in for your 3 month visit to answer more questionnaires.



If at any time you lose the activity tracker, or if it breaks, please contact a member of the study team immediately either via email [study_email@brown.edu], phone call, or text [401-xxx-xxxx].

Your participation in this study may last up to 8 hours in total over the 3 months, in addition to the amount of time you choose to spend exercising.

4. Will I be paid?

We will provide you with a 3-month membership to the YMCA upon arrival for your first group-session visit at the YMCA. You may earn a total of \$50 for completing the assessments at week 7 (\$25) and month 3 (\$25).

5. What are the risks?

We do not expect any discomfort or risks from participating in this research study. The materials you receive while participating in this program contain information about injury prevention. The researchers cannot guarantee that there will be no complications that will happen to you. Increasing your physical activity can have great benefits that usually exceed the risks.

Possible risks associated with physical activity include but are not limited to, injuries to the muscles, ligaments, tendons, and joints of the body. Other possible risks include sprains or strains, and possible broken bones from falls. Other risks associated with exercise include, but are not limited to, abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. The nature of the study will not increase the likelihood of injury or other risks beyond what would occur when you engage in physical activity on your own.

If you do become injured during the study, you should call your doctor immediately. You should also alert the study staff that you have been injured. You are responsible for the costs associated with an injury and we do not cover any costs you may incur due to injury.

6. What are the benefits?

By participating in this study you will receive information about physical activity and strategies to overcome barriers to becoming more physically active. Participation in this program may assist you in becoming more physically active. You may not directly benefit from being in this research study.

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 develop 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. A single, locked document will link participant names and ID numbers. 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 private, password protected computer accessible only by Dr. Williams and the research staff. Any paper data will be stored in a lockbox in the office of David Williams at Brown University.



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.ClinicalTrials.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.

8. Are there any alternatives to this study?

If you do not wish to participate in this study, but still wish to work on increasing your physical activity, there are many resources available through your local YMCA. Please contact a member of their staff to find out more.

9. What if I want to stop?

Taking part in research 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 refuse to participate in or leave the study, your current or future relationship with Brown University, or the YMCA will not be affected.

The researcher may choose to take you out of the study temporarily or permanently at any time before you complete the study.

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] at (401) 793-xxxx 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 would like more information about the rights of people who take part in research studies you may contact the Brown University Human Research Protection Program at (401) 863-3050 or IRB@brown.edu.

Do you have any questions?



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12. Consent to Participate

Do you give your permission to participate in this research study? Yes / No

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature

/

PRINTED NAME

Date