Title: Volunteering as an Intervention to Reduce Depression Among Adolescents: Investigating Neurobiological Mechanisms

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Wake Forest®
School of Medicine

Department of Family & Community Medicine

Consent Form Age 18+ to Participate in Research

# Volunteering and Depression in Teens

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## SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand whether volunteering in the community has a positive impact on teens who have been diagnosed with depression.

You are invited to be in this study because you are a teenager and are in treatment for depression. Your participation in this research will involve volunteering for 30 hours (2-3 hours per week for 10-15 weeks), completing 3 surveys (about 30 minutes each), 2 fMRI sessions (about 1.5 hours each) and one interview (about 15 minutes). I will also ask you to return my text messages every 2 weeks. The text messages are meant to check in to see how your volunteering is going, how many hours you have completed, and whether you need anything from me to facilitate your volunteering. I will contact you by email or phone call if you prefer. I can't guarantee that information shared in this way is secure and I will not be collecting any health information via text.

Participation in this study will involve volunteering, answering questions, and doing tasks in an fMRI machine. All research studies involve some risks. A risk to this study that you should be aware of is that some of the questions may be uncomfortable and the brain tasks may be hard. There is the possibility that you may benefit from participation in this study because you might enjoy the experience of volunteering and talking with me about the experience.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Parissa Ballard, PI. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a teenager who has been diagnosed with depression. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your health provider or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand whether volunteering in the community has a positive impact on teens who have been diagnosed with depression.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Ten people at one research site will take part in this study. In order to identify the 10 participants needed, we may need to screen as many as 50 because some people will not qualify to be included in the study.

## WHAT IS INVOLVED IN THE STUDY?

If you agree to participate, you will be asked to volunteer in the community each week (approximately 2-3 hours per week) over the course of 10-15 weeks, to complete surveys and an interview, and to participate in two fMRI sessions. First, you will work with study staff to come up with a meaningful volunteer experience and do any paperwork needed to get set up as a volunteer. You will be asked to complete a survey and an fMRI session. This means that you will be asked to get in an fMRI machine, which is like a tunnel with openings on both ends. You will be asked to lie still and complete a couple games while we take pictures of your brain. If you do not wish to participate in the fMRI portion of the study, you may still participate by volunteering and completing the surveys and interviews.

After the first survey and fMRI session, you will be asked to serve as a volunteer with an organization of your choice. Volunteer activities can include a range of activities such as volunteering at an animal or a homeless shelter. Dr. Ballard will provide a list of volunteer opportunities and help you identify one you might be interested in. You can schedule your volunteering when it works best for you but you should plan to complete 2-3 hours of volunteering each week. You will be asked to keep track of your volunteer hours. You will be asked to return text messages every couple weeks to answer a couple questions about how your volunteering is going. When you have completed 15 hours of volunteering, you will be asked to complete another survey. Once you have completed 30 hours of volunteering, you will be asked to complete a final survey, a short interview, and a second fMRI session. Again, you will be asked to lie still and complete a couple games while we take pictures of your brain. We will follow up 6 months later to ask a final set of questions about your volunteer experience and how you are doing. This is the end of the study, but you are welcome to continue volunteering.

As part of this research study, you will be audio-recorded during the interview. This is being done to make sure we gather important information from you. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audio recording before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audio recordings used in this research study:

_____ I would like the audio recording of me to be destroyed once their use in this study is finished.

____ The audio recording of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

## How Long Will I Be in the Study?

You will be in the study for about six months or until you complete 30 hours of volunteering and the surveys, interview, and fMRI sessions. We will also contact you 6 months after the end of the study to answer some final questions.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

## What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Some of these brain games are hard, and may make you upset or frustrated. The tests are hard for everyone, and the person giving you the test will let you take breaks when you need to take one. The fMRI study involves being in a confined space (fMRI machine) for about 45 minutes. Some of the questions that we ask can make some people uncomfortable. You will be able to skip any questions that you do not want to answer. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. If anything in the study worries you or makes you uncomfortable, let us know and you can stop.

As part of this study, you will be asked questions about your mood and behaviors. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

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MRI scanners have been in clinical use for about 20 years. During that time, no significant biologic side effects have been found with the use of standard clinical magnets. Unlike x-rays, CAT scans, and nuclear medicine studies, the MR machine does not use x-rays or other forms of radiation. The MR scanner uses a magnetic field and radio waves, and to the best of our knowledge, there are no risks to having an MR scan.

The MRI scans used in this study are done for research purposes, not to treat or diagnose medical illnesses However, some of the brain images could suggest that you have a medical condition. In the unlikely event that our results do suggest a possible medical condition, you and your physician (if you choose) will be told. Your doctor may tell you that you should have more tests. These tests will be recommended by your physician and are not part of this study. Although it may be in the best interest for your health to have these additional tests, you do not have to have them as part of this study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

If so:

Name of Primary Care Physician_____

Phone Number or Name of Practice_____

## Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, same sex partner (with no intention of changing sexual preferences for the duration of the study), or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study is that you may enjoy the experience of volunteering in the community.

Based on experience with volunteerism in other research studies, researchers believe it may be helpful for teens diagnosed with depression. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

## WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Your family and your mental health provider will know that you are in the study. If anyone else is given information about you, they will not know your name. Your parent may know that you took part in the study, but we won't tell them anything you said or did, either. When we tell other people or write articles about what we learned in the study, we won't include your name or that of anyone else who took part in the study. We will present aggregated information. We won't tell the volunteer organization that you participate in what the purpose of the study is or any information about you. However, if we write an article about this study and someone from the volunteer organization reads it, they may know that you were in the study of volunteering and depression in teens.

Everything you say and do will be private except in 3 situations. If we find out that someone has hurt you in the past, or is hurting you now, our staff will ask you questions about what has happened to you. Our staff may need to report this to the authorities. Second, if you tell us you want to hurt yourself or someone you know wants to hurt themselves, then our staff will ask you additional questions, and may need to talk with your parent (s) to help keep you (or others) safe. Third, if you tell us that you or someone you know has plans to hurt someone else or has already hurt someone else, then our staff will ask you additional questions and may need to talk with your parent (s) to help keep you and others safe.

## WILL YOU BE PAID FOR PARTICIPATING?

You will be paid a total of $125 if you complete the study. You will be paid $50 after the first survey and fMRI session are complete. You will be paid $75 after the volunteering, the second survey, and the fMRI session are complete.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Errett Fisher Foundation. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call [redacted].

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: questions about depressive symptoms and health-related behaviors.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

You can tell Dr. Ballard that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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 Web site at any time.

## What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Identifiers might be removed from your identifiable private information and after such removal, your information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

## Whom Do I Call if I Have Questions or Problems?

If you have questions at any time, you can ask us and you can talk to your parent about the study. We will give you a copy of this form to keep. If you want to ask us questions about the study, call or email the study investigator, [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

## Signatures

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

You have been selected to participate in a Magnetic Resonance (MR) scan for a research study. The MR machine does not use x-rays, but rather a magnetic field and radio waves to take pictures inside the body. At no time will the scanner be operated in a fashion that will pose any significant risk to you.

The MR room contains a very strong magnet. Before you are allowed to enter, we must know if you have any metal in your body. Several metal objects can interfere with the scan and can even be dangerous. So please answer the following questions carefully.

1 Do you have a cardiac pacemaker? Yes _____ No _____

2. Do you have a cerebral aneurysm clip (clip on blood vessel in brain)? Yes _____ No _____

3. Have you ever worked with, or been hit in the eye with a piece of metal? Yes _____ No _____

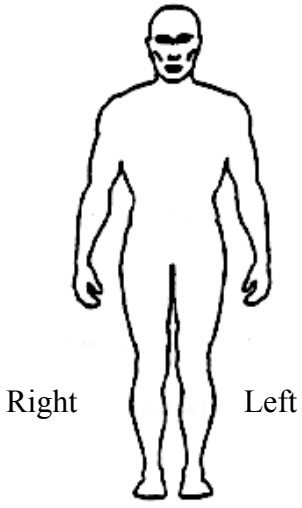
If so, is there any chance that a metal fragment may still be in your eye? Yes _____ No _____

5. Please list all major operations you have had with approximate dates:

6. Do you have any metal objects or devices implanted in your body? Yes _____ No _____
If yes, please list and show in diagram to the right:

7. Do you have any of the following items in/on your body?

| | | |
|---|---|---|
| Yes | No | Cardiac valve, wires, or defibrillator |
| Yes | No | Electrical stimulator for nerves or bone |
| Yes | No | Eye or ear implants |
| Yes | No | Bullets, BB's, or pellets |
| Yes | No | Metallic shrapnel or fragments |
| Yes | No | Infusion pump |
| Yes | No | Coil, filter, or wire in blood vessel |
| Yes | No | Orthopedic hardware (plates, screws, pins, rods, wires) |
| Yes | No | Surgical clips, staples, mesh or sutures |
| Yes | No | Eyelid tattoo |
| Yes | No | False teeth, partial plate, retainers, or magnetic braces |
| Yes | No | Hair pins, barrettes, wigs, rings, earrings, jewelry |
| Yes | No | Hearing aid |
| Yes | No | Drug delivery patch (smoking, estrogen, nitroglycerine) |




NOTE: Do not carry loose items, such as safety pins, money, pens, pencils, keys, coins, watches, pocket knives, or artificial limbs/prostheses into the scanning room. They may become damaged or cause injury.