Official Title: The Effects of Animal Assisted Therapy in Outpatient Psychiatry Clinics
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THE EFFECTS OF ANIMAL ASSISTED THERAPY IN OUTPATIENT PSYCHIATRY

Informed Consent Form to Participate in Research

Matt Kern, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to examine whether animal-assisted psychiatry outpatient visits reduce anxiety levels and improves long-term clinical outcomes of outpatient psychiatric patients. Your participation in this research will involve approximately monthly visits and last about 6 months.

Participation in this study will involve normal sessions with Dr. Kern as well as a therapy dog. All research studies involve some risks. If you have any dog allergy or previous animal related traumatic event, you may not benefit from participation in this study.

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 questions before deciding to join the study. The person in charge of this study is Dr. Matt Kern. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study by calling [redacted] and directing the information to the attention of Dr. Kern.

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 have been diagnosed with a psychiatric illness that could benefit from animal-assisted therapy. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor 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.

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Why Is This Study Being Done?

The purpose of this research study is to examine whether a session of animal-assisted therapy (AAT) reduces anxiety levels and improves long-term clinical outcomes of outpatient psychiatric patients as well as the impact on the doctor-patient relationship. Previous research in the in-patient psychiatric setting has shown encouraging results regarding the benefits of AAT. The goal of this study is to expand upon that previous data in the outpatient setting.

How Many People Will Take Part in the Study?

Up to 70 individuals from Dr. Kern's clinic

What Is Involved in the Study?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group.

If you take part in this study, you will be randomized to scheduled sessions with Dr. Kern either with or without AAT. Regardless of the study group you are in, two surveys will be administered which include the Patient Health Questionnare-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7). Your blood pressure will be measured before and after your visits.

How Long Will I Be in the Study?

You will be in the study for about 6 months until all the necessary data is collected. You can stop participating at any time.

What Are the Risks of the Study?

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. Being in this study involves some risk related to animal therapy. If you have any dog allergy or history of animal related trauma then you would not be eligible to participate in the study.

Exposure to an animal comes with the risk of being bitten, or obtaining an infection via scratch or exposure to parasites. Any incident should be reported to Dr. Kern, who will report this to the local IRB. Any event of scratching or biting (even incidental) should be reported to Dr. Kern. Any infections due to exposure to the animal should be reported to Dr. Kern.

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.

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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 may be improved anxiety and depression score levels given prior related research.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. Regular visits with Dr. Kern or another Atrium Health Wake Forest Baptist psychiatric provider will proceed as scheduled.

WHAT ARE THE COSTS?

All study costs will be paid for by the study. Costs for your regular medical care, including visit copays, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest Baptist Medical Center Department of Psychiatry. 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 ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes much of the same information that a normal psychiatric appointment would entail, including screening tools to assess your mood, anxiety levels, satisfaction with care, and vital signs like blood pressure.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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 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 interventions.

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. This is standard for most studies in which you might choose to participate.

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, which would not be used without your specific authorization. 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.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health

Information is shared with any of these groups it may no longer be protected by federal or state privacy rules. This is a standard procedure unrelated to your participation in the study.

Any Protected Health Information collected from you in this study that is maintained in the research records and will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. *Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.* You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Kern 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:

Matt Kern, MD

[redacted]

[redacted]

If you choose to revoke permission to use your Protected Health Information you will not be able to participate in the study. 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.

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. Declining 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 for any reason, such as if it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, or because the study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Kern, at [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

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____
Date:_____ Time:_____ am pm

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