Department of Veterans Affairs

Office of Research and Development (ORD)

Informed Consent Form Cover Page

Official Study Title:
Functional and Cognitive Rehabilitation of Hoarding Disorder

ClinicalTrials.gov Identifier:
NCT Number: NCT04697849

Document Date:
IRB Approval Date: 05/10/2022

Principal Investigator:
Dr. Catherine Ayers

Study Sponsor:
VA Office of Research and Development (ORD)

Study Status:
Recruitment Closed

Posting Requirement:
This informed consent form is being posted in compliance with VHA Directive 1200.05 and the revised Common Rule (45 CFR 46.116(h)).

Study Title: Functional and Cognitive Rehabilitation of Hoarding Disorder

Principal Investigator: Catherine Ayers, PhD

VA Facility: VA San Diego Healthcare System

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?
The purpose of this study is to find out more about effective treatments for hoarding disorder to better assist Veterans and other people who have difficulties throwing things away and with clutter.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?
Your participation will involve receiving 12 to 24 sessions of personalized treatment in your home, depending on the condition to which you are assigned. You will receive treatment once or twice a week over the course of 3 months. A clinician may come in person to your home or you may receive treatment through an online video teleconferencing program. Before you begin treatment, you will first complete a 2-hour assessment and treatment orientation session. You will complete this assessment again when you are halfway done with treatment , after you complete treatment , and 6 months after you have completed treatment. Your participation in the study will conclude after 9 months. The entire study will take about 5 years.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
A participant may choose to volunteer to participate in this study to receive help with their difficulties throwing things away and with clutter.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
A participant may NOT want to volunteer to participate in this study if they do not want to receive help for difficulties with throwing things away or with clutter. A complete description of risks is included in the Research Details Study Risks section. Participation is entirely voluntary. The alternative is to not participate. A complete description of alternate treatment/procedures is provided in the Research Details Alternatives section.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Dr. Catherine Ayers of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or if you would like to withdraw from the study, her contact information is: 858-552-8585 x2976

RESEARCH DETAILS

Study Title: Functional and Cognitive Rehabilitation of Hoarding Disorder

Principal Investigator: Catherine Ayers, PhD

VA Facility: VA San Diego Healthcare System

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Dr. Catherine Ayers, Ph.D. is asking for your consent to this research. You have been asked to participate because you have identified yourself as having difficulty throwing things away and have clutter in your home which has caused you distress. This is a non-medication study. It is being funded by the Department of Veterans Affairs. There will be approximately 130 participants. Participants include male and female Veterans who are 18 and older.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take 9 months. You will receive treatment twice a week over the course of 3 months for a total of 12 to 24 sessions, depending on the condition to which you are assigned. In addition, you will complete 4 assessments, 1 before treatment, 1 when you are halfway done with treatment, 1 after you complete treatment, and at 6 months after you have completed treatment. The entire study will take about 5 years.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you agree to be in the study, the following will happen to you:

a. Today you will be asked to answer questions related to any psychiatric symptoms, particularly anxiety related symptoms, you may have experienced. A research assistant will come to your home to perform this assessment, or it will be completed using a secure video teleconferencing program that you will access through your computer or tablet at home. You will complete questionnaires that ask about psychiatric symptoms and daily activities, and tests that examine your attention and other cognitive abilities. You may skip any question(s) or tasks that makes you feel uncomfortable. We will take pictures of your living room, kitchen, and bedroom in order to objectively establish the level of clutter in your home. To the extent that it is possible, we ask that you do not include identifying information (e.g., pictures of yourself or your family; pictures containing your address) in these pictures. This assessment appointment will last approximately two hours.

b. Following this assessment appointment, you will receive a treatment orientation session. During this appointment a study therapist will explain the treatment to you in detail you discuss the pros and cons of engaging in treatment at this time. you will have the opportunity to ask more detailed questions about the treatments offered.

c. You will be put into a study group by chance like a coin toss. You have a 50/50 chance of being placed in each group. You cannot choose your study group, but both groups will receive treatment. During the research, the research assistant who conducts your *assessment* appointments will not know which group you are in.

You will be randomized to one of two treatment groups:

1) Cognitive rehabilitation and exposure training (CREST) for hoarding which includes 24 sessions of individual, personalized training or

2) Case Management (CM) which includes 12 sessions of individual support for difficulties relating to your health and related life stressors.

d. After completing the treatment orientation session, you will schedule two weekly treatment sessions with your therapist. For these appointments your therapist will either come in-person to your home or conduct sessions remotely via a secure video teleconferencing program that you will access through your computer or tablet at home.

e. Similar to the evaluation appointment today, you will complete assessments when you are halfway done with treatment , after you complete treatment , and 6 months after you have completed treatment. You will complete 4 assessment appointments in total.

Personalized cognitive rehabilitation and exposure training will teach you how to manage day to day demands and learn to tolerate distress from discarding your possessions.

Case Management will help you to manage difficulties relating to your health and related life stressors. Your case manager will provide support and help to connect you with helpful services. Their recommendations will be personalized to you and your challenges.

All treatment and assessment appointments will be audio recorded. Assessment appointments will be recorded for data verification purposes. Treatment appointments will be recorded to monitor the study trainer's adherence to the treatment program.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

This investigation is considered experimental. This is the first study examining personalized cognitive rehabilitation and exposure training compared to case management.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

A. Common risks:

a. Feeling uncomfortable answering questions about your symptoms. You may refuse to answer any questions that make you feel uncomfortable.

b. Feeling uncomfortable challenging yourself to make decisions about your possessions.

B. Rare:

a. Loss of confidentially. Research records will be kept confidential to the extent provided by law. The results of this study may be published; however, you will not be identified in the published results.

There is always a chance that any procedure can harm you. In addition to the risks described above, you may experience a previously unknown risk or side effect. You will be informed if the researchers learn of any change in the amount of risk to you.

Questionnaires: Some people become uncomfortable at being asked questions about psychiatric symptoms. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

Photographs or audiotaping: The study team has explained that by signing this Informed Consent Document, you voluntarily authorize pictures or voice recording(s) to be made of you while you are participating in this study. Assessment appointments will be recorded for data verification purposes. Treatment appointments will be recorded to monitor the study trainer's adherence to the treatment program. Voice recording(s) will only be accessible by study staff and will be saved on a secure, encrypted research drive.

If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled.

Signature: _____ Date: _____

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study However, the information we get from this study might help others with hoarding disorder.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS RESEARCH STUDY?

Alternatives to treatment include care as usual with your primary care provider or seeking psychiatric care in the VA or other non-VA settings.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

While you are a participant in this study, you will be notified if any important new information is found that may affect your willingness to continue.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: Catherine Ayers, PhD at 858-552-8585 X 2976

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

If you decide that you no longer wish to participate in this study please call Dr. Catherine Ayers Principal Investigator of this study, at 858-552-8585 x 2976.

You should come in for a final visit if you decide to stop your participation in this study so that the investigators can ensure your health and well-being. The investigator may continue to review the data collected prior to your withdrawal from the study, but will not collect further information.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest. If you do not follow the study instructions, your participation in the study may be stopped.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Catherine Ayers Principal Investigator of this study, at 858-552-8585 x 2976.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

The assessments for which you receive compensation include the first assessment, an assessment following completion of the treatment, and an assessment 6 months after the completion of treatment. You will receive $20 per assessment with a bonus of $20 for completing all assessments, for a total of $80. You will not receive compensation for treatment sessions or the mid-treatment assessment. This payment will be made directly to your bank account using electronic funds transfer. You will be asked to provide your SSN for the purposes of this transfer. The VA San Diego Healthcare System provides oversight and resources for this study. Financial support for this study is provided by Department of Veterans Affairs.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or other related matters, you may contact Dr. Catherine Ayers Principal Investigator of this study, at 858-552-8585 x 2976.

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel, you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study related questions or concerns you can contact the research team at 858-552-8585 x1251.

Study Title: Functional and Cognitive Rehabilitation of Hoarding Disorder

Principal Investigator: Catherine Ayers, PhD

VA Facility: VA San Diego Healthcare System

FUTURE USE OF DATA AND RE-CONTACT

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in stored in the principal investigator's laboratory, VMRF room 216 in a locked cabinet, and destroyed in accordance with Records Control Schedule and under the direction of VASDHS Records Control Manager. Only approved study personnel will have access to this Information.

If you would like to be contacted via telephone by our program about future research, please check "yes" and initial below.

☐ **Yes, I may be contacted for future research opportunities as described**. _____ (initial)

☐ **No, I do not wish to be contacted for future research opportunities as described**. _____ (initial)

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. If you are not already a VA patient, a medical record including your name and Social Security number will be entered in the VA Computerized Patient Record System. You will also be asked to provide your SSN for payment purposes.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall. We will include information about your study participation in your medical record.

Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies without additional informed consent from you or your legally authorized representative.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, and federal compliance officers may look at or copy portions of records that identify you.

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 website at any time.

Study Title: Functional and Cognitive Rehabilitation of Hoarding Disorder

Principal Investigator: Catherine Ayers, PhD

VA Facility: VA San Diego Healthcare System

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Any presentations or publications from this information will not identify you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

_____ has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.

_____ _____
Participant's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date

A copy of this document will be provided to the research participant.

Study Title: Functional and Cognitive Rehabilitation of Hoarding Disorder

Principal Investigator: Catherine Ayers, PhD

VA Facility: VA San Diego Healthcare System

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, mental health treatment, etc.

The research team may also need to share your health information and the information it collects to other VA entities as part of the study progress. Other VA entities may include the Institutional Review Board, Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address:

Catherine R. Ayers, Ph.D., ABPP
VA San Diego Healthcare System
3350 La Jolla Village Drive (116B), San Diego, CA 92161

If you revoke this authorization, Dr. Catherine Ayers and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization. While this study is being conducted you will not have access to your research-related health records. Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study. Any deidentified study information that has been placed into a repository to be used for future research will not expire.

AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

A copy of this document will be provided to the research participant.

Study Title: Functional and Cognitive Rehabilitation of Hoarding Disorder

Principal Investigator: Catherine Ayers, PhD

VA Facility: VA San Diego Healthcare System

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.