**Official Title:**
Adapting the Unified Protocol to Facilitate Activity in Older Adults

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04/13/2023

Duke University Health System

**e-Consent to Participate in a Research Study**
**ADULT**
***Adapting the Unified Protocol to Facilitate Activity in Older Adults***

Concise Summary

The purpose of this research study is to explore the utility of a treatment for older adults who are having difficulty engaging in daily activities. The first study visit involves reading this consent form and completing questionnaires about symptoms of conditions, like anxiety and depression. After the first visit, you will be mailed a step tracker (pedometer) to track your daily step count that you will be able to keep once the study is complete. You will be randomized (like the flip of a coin) to attend 5 sessions of psychotherapy conducted by phone or videoconference (e.g., Zoom, WebEx) or complete a self-guided treatment on your own. After therapy ends, you will complete questionnaires about conditions like anxiety and depression as well as an interview about your experience to give feedback on the treatment.

The greatest risk of this study includes loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have indicated you experience symptoms of depression and/or anxiety and are having difficulty participating in your daily activities. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Andrada Neacsiu will conduct the study and it is funded by the National Institute of Aging. The sponsor of this study, the National Institute of Aging, will pay Duke University to perform this research, and these funds may reimburse part of Dr. Neacsiu and her staff's salary.

## WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Andrada Neacsiu will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

## WHY IS THIS STUDY BEING DONE?

Older adults commonly report symptoms of emotional distress (e.g., anxiety, depression) that negatively impact their physical and mental health and are associated with reduced engagement in daily activities.

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There is a need for brief treatments that can help older adults with these problems. The purpose of this study is to adapt a five session treatment to meet the needs of older adults.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 30 people will take part in this study.

**WHAT IS INVOLVED IN THE STUDY?**
If you agree to be in this study, you will be asked to electronically sign and date this e-consent form. If you do not sign this consent form, you will continue to receive care, but not as a part of this study. Choosing not to participate will not involve penalty or loss of benefits to which you are otherwise entitled (such as your usual care at Duke).

**Study Visit 1**
Participation in this study is voluntary. After signing e-consent, we will ask you to complete some self-report questionnaires. If you do not sign this consent form, you will continue to receive care, but not as a part of this study. During study visit 1, we will ask you to complete self-report questionnaires about emotions such as depression and anxiety. These questionnaires will be similar to the ones you complete when you visit your primary care doctor. This visit will be conducted remotely and you can complete the questionnaires online.

**Treatment Phase**
After signing consent and completing the questionnaires you will begin the treatment phase of the study. A member of the study team will mail to you a step tracker (pedometer) to keep track of the number of steps you take each day along with a measuring tape and black electric tape. They will provide you with an electronic form to keep track of the steps you take daily. You will begin to keep track of your steps 1 week prior to your first therapy session. You will also receive electronic instructions on how to prepare for the virtual physical function assessment using the measuring tape and black electric tape you received in the mail.

You will be randomized, like the flip of a coin, to receive five sessions of treatment that will either be delivered by a therapist or that you will complete on your own, at your own pace.

Both treatments are based on an existing treatment called the Unified Protocol (UP). The UP is an evidence-based treatment, meaning research suggests it can be helpful for people with problems like anxiety and depression. We believe it can also be helpful for older adults who want to increase their engagement in daily activities. This treatment teaches people coping skills to manage uncomfortable emotions such as depression and anxiety that may interfere in their lives. Coping skills include things like developing a better understanding of emotions, mindfulness, thinking about things differently, and changing one's behavior.

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In the first phase of this study, four participants received the UP and provided feedback about their experience. We have made changes to the UP to adapt it specifically to help older adults based on this feedback. Additionally, in the first phase of this study we gathered information to develop a self-guided version of the treatment, which participants can complete on their own. We will be delivering these two tailored treatments during this phase.

Prior to your first therapy session (either with an individual or self-guided), you will meet with a trained study team member over a video conference using Duke Zoom/WebEx who will administer the virtual physical function assessment. This will take approximately 15-20 minutes to complete and will be done before you start therapy and one week after you complete treatment.

If you receive therapist-delivered treatment, each talk therapy session is 50 – 60 minutes long. Ideally sessions will take place once a week. All sessions will take place remotely and can be completed at home via telehealth technologies. In each session, you will meet with your therapist and talk about how you are doing. You will be asked to share your daily number of steps you have taken over the past week. Then your therapist will teach you a coping skill and you will practice it together in session. Your therapist will ask you to practice each skill in between sessions in order to see if it is helpful in your day to day life. At your final fifth session, your therapist will remind you to continue tracking your number of steps over the next week and will schedule your 1 week follow-up post-treatment visit.

If you receive the self-guided treatment, you will complete sessions independently, approximately weekly, using an online platform. You will also report your daily number of steps you have taken over the past week via an online survey. After your final online platform session, you will receive a reminder to keep track of your steps over the next week and you will scheduled your 1 week follow-up post-treatment visit.

**Post-Treatment Assessment (One Week Follow-up)**
Once you finish treatment, approximately one week later, you will complete the same questionnaires that you completed at pre-treatment. Additionally, we will ask you to complete an interview with a member of study staff to tell them about your experience in treatment, and anything you would suggest changing to help make treatment more helpful. You will report your daily step count from the past week and complete the 15-20 virtual physical function assessment one final time.

**1 Month Follow-up**
Five weeks after completing your final treatment session, you will receive an email to complete the 1 month follow-up questionnaires, similar to the ones you completed at the beginning of the study. You will not need to meet with a member of the study team, and just be asked to complete these questionnaires remotely. If you have any questions, you may contact one of the study team members who can help guide you through this last study activity.

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## HOW LONG WILL I BE IN THIS STUDY?

We expect that you will be in this study for 12-17 weeks. During this time, we will ask you to complete up to 8 study visits if you receive therapist-delivered treatment or 3 visits if you receive self-guided treatment. These visits will take place remotely either by phone or videoconference (e.g., Zoom, WebEx). You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

## WHAT ARE THE RISKS OF THE STUDY?

There is the potential risk of loss of confidentiality. Every effort will be made by the study team to keep your information confidential, however this cannot be guaranteed. Your information (including the recording(s) of the interview and therapy sessions) will be kept in a database on password-protected computers at Duke and a remote secure database. These databases will be accessible only by research staff at Duke who work on this study. The information we collect will be used only for this study. Only study staff approved by the Duke University Healthy System (DUHS) Institutional Review Board (IRB) will have access to your information. None of your information will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law. You may stop your participation in this study at any time by notifying the study staff by phone 919-684-6714 or email andrada.neacsiu@duke.edu. If you are unable to find a private place to complete study visits, there is a risk of being overheard. You can tell the research staff at any time if you would like stop a visit due to privacy concerns.

<u>Risks of behavioral intervention procedures and assessment:</u>
It is possible that you may experience some unpleasant thoughts or emotions from the questionnaires, therapy sessions, and/or interview. However, we have no reason to believe that any unpleasant thoughts or emotions will last long after the interview is over. Some of the questions we will ask you as part of this study may make you feel temporarily uncomfortable, as they have to do with your emotional reactions and engagement in daily activities. You will be working with experienced clinicians in this study, and we will take steps to ensure that your levels of distress are manageable, not too distressing, and do not pose any danger to yourself.

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You may refuse to answer any of the questions and you may take a break at any time during the study. If at any time during the interview, tasks or therapy sessions, you experience strong thoughts of suicide or of wanting to hurt yourself, you should inform your study assessor or therapist. These trained study staff will work with you to better understand these thoughts, help manage the thoughts, and if you are at imminent risk of suicide after the conversation, you will be taken to the nearest hospital emergency room (for example: Duke ER).

As part of the study, you are being asked to complete a virtual physical function assessment 2 times in the study. You are reminded that if you do not feel comfortable, feel unsteady or like you are going to

fall, you can stop the virtual physical function assessment at any time. You may still participate in the study.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
You may benefit from taking part in this research study. The study procedures may help you better understand your symptoms, reduce the severity of these symptoms, and increase your engagement in daily activities. Benefits from these procedures cannot be guaranteed to any particular participant. As an indirect benefit you will also be providing information that will be helpful in expanding scientific knowledge about the brief treatments that are helpful for older adults experiencing emotional distress. Others may benefit in the future from information that is learned in this study.

**WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?**
Instead of being in this study, you have the following alternatives:

- You may seek psychotherapy through a clinic here at Duke
- You may seek psychotherapy through a clinic that is not a part of Duke

Please talk to your doctor about these and perhaps other options.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, address, telephone number, or any other direct personal identifier in study records disclosed outside of DUHS. For records disclosed outside of DUHS, you will be assigned a unique code number. Possible legal exceptions to confidentiality may occur if necessary to protect people from child abuse or neglect, or in cases of potential harm to oneself or others. In such cases, confidentiality would only be broken in order to protect people from significant harm or death. For records disclosed outside of DUHS, you will be assigned a unique code number and letter code. The key to this code will be kept in a secure database accessible only to Dr. Neacsiu and her research team. Your name and other personal identifying information will not be used in any scientific reports of this study, and will not be made available to representatives from any of the sponsors.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All data and research forms will be kept in a secure locked cabinet in Dr. Neacsiu's laboratory and will only be made accessible to members of the research team for this study. Your name and other personal identifying information will not be stored on the computer system that stores your ratings, and thus individuals who might gain unauthorized access to your ratings will not know your identity. Your video/audio recordings will also be stored using a unique code number, rather than your name. In order to keep in touch with you, we will collect phone numbers and an email address where you can be reached. This information will be encrypted and stored in a remote secure database.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the representatives from the DUHS Institutional Review Board. If your research record is reviewed by any of these groups, they may also need to review your entire medical record (if you receive your medical care at DUHS). The study results will be retained in your research record for at least six years after the study is complete. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from the study results at DUHS. Any research information in your medical record will be kept indefinitely. This information may be further disclosed by the sponsors of this study. If disclosed by the sponsor, the information is no longer covered by the

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federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed in any way.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

You will be audio and/or video recorded as part of this study so that the interviews and therapy sessions may later be rated for inter-rater reliability and adherence (to ensure that interviews and therapy are being conducted in a standardized manner). These recordings will be made using approved telehealth platforms (e.g., Zoom, WebEx, Jabber). If you are not willing to be recorded, you may indicate so below and will still be eligible to participate in the study. Recordings will be kept strictly confidential and will be directly recorded on the study staff's Duke computer using a web camera directly connected to the computer's hard drive. The recordings will then be immediately transferred from the computer's hard drive to the Duke protected hard drive that is maintained and secured by Duke IT in the Department of Psychiatry and Behavioral Sciences. The folder that will contain these recordings is protected and only accessible to members of the study team. The audio recordings may be reviewed by the key research and clinical staff members in Dr. Neacsiu's team. At the conclusion of the study you may review the recordings and delete any portions you may wish to delete. You have the right to request that we erase any parts of the recording, but you do not have a right to copy our recordings or any of our research material. These recordings will be destroyed at least six years after the study is completed.
Please indicate below whether or not you are willing to be audio and/or video recorded as part of this research study.

- ` I am willing to let the researchers audio and video record.
- I am willing to allow the researchers to ONLY audio record.
- I am NOT willing to allow the researchers to audio or video record.

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.

**WHAT ARE THE COSTS TO YOU?**
There will be no additional costs to you as a result of being in this study.

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If you are receiving medical treatment as part of your routine clinical care while taking part in this research study, your routine clinical care will be billed to you/your insurance company in the usual way.

**WHAT ABOUT COMPENSATION?**
Treatment in this study will be provided at no cost. Additionally, you will receive $40 for each study assessment you complete and $20 for the 1month follow-up questionnaires (up to $100 total). If you withdraw from the study early you will receive compensation for the parts of the study you completed.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Neacsiu at (919) 684-6714 during regular business hours. If outside regular business hours, please contact the Duke operator at 919-684-8111 and have Dr. Andrada Neacsiu paged.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Neacsiu in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC Box 3026 Durham, NC 27710. You will be asked to provide feedback about the treatment if you decide to withdraw early.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if he determines that it is no longer in your best interest to continue. Other reasons for the study doctor to withdraw you from the study include:

- You need treatment not allowed in the study.
- You miss 2 talk therapy sessions in a row and have not maintained contact with your study therapist or any member of the study team.
- Unanticipated circumstances arise that require the study to stop.
- Other administrative reasons arise that require the study to stop.

The sponsor or regulatory agencies may stop this study at anytime without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

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Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Neacsiu at (919) 684-6714 during regular business hours. If outside regular business hours, please contact the Duke operator at 919-684-8111 and have Dr. Andrada Neacsiu paged.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

If you experience thoughts of hurting yourself or someone else at any point during the study please let your therapist or another member of the study team know. If you are struggling with these kinds of thoughts and are unable to reach a member of the study team please consider using any of the following resources:

- National Suicide Prevention Lifeline: 1-800-273-8255
- Crisis Text Line: Text HOME to 741741 for free, 24/7 crisis counseling.
- Call 911 or go to your local emergency room.

**STATEMENT OF CONSENT**
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

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- "I have read the consent document and I wish to participate in the study."
- "I have read the consent document and I DO NOT wish to participate in the study."