

**CONSENT TEMPLATE**  
**Client Participants**  
**Lay-delivered Behavioral Activation in Senior Centers**

**Researcher**

[INSERT SITE PI NAME]	[INSERT SITE PI INFO]	[INSERT SITE PI DEPARTMENT]	[INSERT SITE PI PHONE NUMBER]
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**FOR ALL APPOINTMENT RELATED QUESTIONS (SCHEDULING, ETC) PLEASE CALL [INSERT SITE SPECIFIC CONTACT INFORMATION].**

**KEY INFORMATION ABOUT THIS STUDY**

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called “informed consent.” We will give you a copy of this form for your records.

You are being asked to take part in this study because you are 60 years or older and are experiencing symptoms of depression.

The purpose of this study is to compare 2 forms of interventions for senior center clients over 60 experiencing symptoms of depression. Some participants enrolled in the study will receive 9 weeks of a type of psychotherapy called “Behavioral Activation” as delivered by a Master’s level mental health clinician. Other participants will receive 9 weeks of a program called “Do More, Feel Better” as delivered by a trained non-professional volunteer. If you are eligible and agree to be in the study, you will be assigned randomly (like the flip of a coin) to the intervention delivered by either a Master’s level mental health clinician or a trained volunteer. “Behavioral Activation” is a psychotherapy aimed at re-engaging participants in activities they once found rewarding and enjoyed but have abandoned after they developed depression. “Do More, Feel Better” is a program also aimed at re-engaging participants in activities they once found rewarding and enjoyed but have abandoned after they developed depression.

You will participate in follow-up interview assessments via phone or video teleconferencing at weeks 3, 6, 9, 24 and 36 where we will ask you similar questions as the baseline assessment. These interviews will take approximately 1 hour. With your permission, we may also access data recorded by your senior center regarding the activities you participate in. Your total time commitment for the study, including “Behavioral Activation” or the “Do More, Feel Better” program sessions is approximately 14 hours over the course of 36 weeks. This study is funded by the National Institute for Mental Health.

**How many people will take part in this study?**

About 288 participants will take part in this part of the study.

**What will happen if I take part in this research study?**

If you agree, the following procedures will occur:

- First, you will participate in the baseline assessment which consists of two appointments to find out if you can participate in the main part of the study. During the baseline assessment we will ask you questions about your mood, health, quality of life, and cognition. Both baseline appointments will take 1 hour and 15 minutes. These will be completed by telephone or video teleconferencing (e.g., Skype, Zoom, Facetime) due to the COVID-19 pandemic. If COVID-19 restrictions lift, this assessment may be completed in person.
- If the baseline assessment interview shows that you can participate in the main part of the study and you choose to continue, the following will happen next:
  - You will begin 9 weeks of “Behavioral Activation” psychotherapy as delivered by a Master’s level mental health clinician, or 9 weeks of the “Do More, Feel Better” program as delivered by a trained non-professional volunteer. You will be assigned to “Behavioral Activation” or the “Do More, Feel Better” program randomly (like the flip of a coin). You will meet weekly with a Master’s level mental health clinician or trained volunteer for 30-45 minutes over the course of 9 weeks. These sessions will be completed by telephone or video teleconferencing (e.g. Skype, Zoom, Facetime) due to the COVID-19 pandemic. If COVID-19 restrictions lift, these sessions may be completed in person. If you agree, these sessions will be audio recorded for clinician and volunteer supervision. The audio recordings will be destroyed at the end of all relevant record retention requirements unless you consent to use of audio recording for future training purposes in which case we will retain the audio in our database on the secure server.

**Please agree or disagree with the following statements:** I give permission to audiotape assessments and sessions with study clinician or coach for training and supervision purposes. Study staff certified as trainers of “Behavioral Activation” or the “Do More, Feel Better” program will review some of the client sessions to ensure adherence and to provide feedback to the mental health clinician or volunteer.

☐ Agree ☐ Disagree

You give permission for the research team to use audio from a session with the study clinician or coach in future trainings as part of the research study. You may decline to give this permission and remain in the study.

☐ Agree ☐ Disagree

You give permission to the research team to audio record your meetings with the study clinician and assessors so they can be stored by the DMFB Study for future research purposes. You may decline to give this permission and remain in the study.

☐ Agree ☐ Disagree

- You will participate in follow-up interview assessments via phone or video teleconferencing at weeks 3, 6, 9, 24 and 36 where we will ask you similar questions as the baseline assessment. These interviews will take approximately 1 hour. With your permission, we may also access data recorded by your senior center regarding the activities you participate in. Your total time commitment for the study, including “Behavioral Activation” or the “Do More, Feel Better” program sessions are outlined below.

Week	Study Event	Time Commitment	Compensation
0	Baseline Assessment 1	1 hour and 15 minutes	\$15
0	Baseline Assessment 2	1 hour and 15 minutes	\$15
1	Behavioral Activation/Do More, Feel Better Session 1	30 – 45 minutes	
2	Behavioral Activation/Do More, Feel Better Session 2	30 – 45 minutes	
3	Behavioral Activation/Do More, Feel Better Session 3	30 – 45 Minutes	
	Week 3 Assessment	60 minutes	\$20
4	Behavioral Activation/Do More, Feel Better Session 4	30 – 45 minutes	
5	Behavioral Activation/Do More, Feel Better Session 5	30 – 45 minutes	
6	Behavioral Activation/Do More, Feel Better Session 6	30 – 45 minutes	
	Week 6 Assessment	60 minutes	\$20
7	Behavioral Activation/Do More, Feel Better Session 7	30 – 45 minutes	
8	Behavioral Activation/Do More, Feel Better Session 8	30 – 45 minutes	
9	Behavioral Activation/Do More, Feel Better Session 9	30 – 45 minutes	
	Week 9 Assessment	60 minutes	\$20
24	Week 24 Assessment	60 minutes	\$20
36	Week 36 Assessment	60 minutes	\$20
	<b>Total:</b>	Approx. 14 hours	\$130

### Study Location

All procedures will be completed via phone or video teleconferencing due to COVID-19 related restrictions. Should COVID-19 related restrictions lift, study appointments may be completed in-person.

**How long will I be in the study?**

Participation in the study will take approximately 14 hours over the course of 36 weeks.

**Can I stop being in the study?**

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, or if the study is stopped. If you do not wish to continue with the study, the researcher will provide you with referrals for alternative treatments and will follow up to address any issues you may experience that arise as a result of withdrawing from the study.

**What side effects or risks can I expect from being in the study?**

- The assessment interviews may result in fatigue; however you are free to take breaks during these interviews and spread them out over the course of two visits if you choose.
- Some of the questions asked during the interviews might make you feel uncomfortable; however you may choose to decline to answer any question at any time and still continue with the study.
- There is the possibility that we may discover findings that affect your health over the course of the study, such as untreated medical conditions, thoughts of self-harm, manic or psychotic symptoms, or drug or alcohol abuse. We will inform you of the nature of these findings and encourage you to follow through on referrals we provide to contact your primary care physician or local medical or psychiatric services.
- There is a slight risk of loss of confidentiality. A breach of confidentiality may result in psychological or social harm (embarrassment, guilt, stress). To ensure participant confidentiality, the information about you will be numbered and linked to your name only on a master list that is password protected and will be kept until the end of all relevant record retention requirements. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings. Study records are kept in a locked room in a locked cabinet or in a secure, password protected data system.

**Are there benefits to taking part in the study?**

You may experience a decrease in your depressive symptoms. In addition, the information that you provide may help health and social service professionals better understand how to treat older adults with depression.

**What other choices do I have if I do not take part in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do. In addition, you may seek therapy outside of this program.

**Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required

by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

**Please agree or disagree with the following statement:** In case of emergencies, I allow study staff to share and receive my relevant personal medical information (e.g., history of hospitalization or medical status in case of emergency) with the senior center I was referred by. This is completely voluntary. You may continue to participate in the study whether you agree with this information sharing or not.

\_\_\_\_ Agree    \_\_\_\_ Disagree

All identifying information collected as part of the study will be stored in a database on a secure server and will be password protected with limited access by the study team. Access will be limited to the research staff. No personally identifying information will be attached to study data or audio recordings. Study data and audio recordings will be labeled with a unique study identification number. The link between the personal identifiers and the related study data will be kept until the end of the study. At that time, the link to personal identifiers will be destroyed. Audio recordings will be in an electronic format and will be deleted at the end of all relevant record retention requirements unless you consent to use of audio recording for future training purposes in which case we will retain the audio in our database on the secure server.

The information and/or data that we obtain from you for this study might be used for future research. If we do so, that information and data may then be used for future research studies or given to another investigator without getting additional permissions from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, an independent review board will decide whether or not we need to get additional permissions from you.

We have a Certificate of Confidentiality from the federal National Institute of Mental Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;

- local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is November 30, 2025. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

### **National Institute of Mental Health Data Archive**

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying depression to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. We will collect information from you to create a unique ID code that cannot be linked to your identity. This information includes your legal name at birth, your date of birth, gender and city where you were born. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about depression more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults depression so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at <http://data-archive.nimh.gov>.

Please agree or disagree with the following statement: I wish to share my information using NDA.

- ☐ I wish to share my information using NDA .
- ☐ I do not want to share my information using NDA .

**What are the costs of taking part in the study?**

You will not be charged for any of the study treatments or procedures.

**Will I be paid for taking part in the study?**

You will receive \$15 for completing the Baseline 1 Assessment and \$15 for completing the Baseline 2 Assessment. You will receive \$20 for completing assessments at weeks 3, 6, 9, 24, and 36. This results in a total for \$130 if you complete all study assessment interviews. Study staff will discuss payment options, which may include check or gift codes, with you at the start of the study.

**What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

**Who can answer my questions about the study?**

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the study team at *[insert local study team contact info]*. 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.

If you think you have a medical problem or illness related to this research, contact *[insert site PI name]*, the study's principal investigator at *[insert site PI contact information]*. They will refer you for treatment.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the University of Washington Human Subjects Division at 206-543-0098.

**Future Contact**

Please agree or disagree with the following statement: I allow staff from the *[insert local site information]* to contact you in the future to ask if you may be interested in participating in future research studies.

☐ Agreed ☐ Declined

**Consent**

Please agree or disagree with the following statement: This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this form. If I have questions about my rights as a research subject, I can call the Human Subjects Division listed on this form.

☐ Agreed ☐ Declined