Pilot effectiveness trial of an ACT self-help workbook tailored specifically for prisons

4/20/2026

NCT06162624

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title: Pilot effectiveness trial of an ACT self-help workbook tailored specifically for prisons (3)

Lead Researcher: *Michael Koenigs, PhD (phone: (608) 263-1679),* 6001 Research Park Blvd., Madison, WI 53719

Institution: *University of Wisconsin-Madison, Department of Psychiatry*

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

A. Why are researchers doing this study?

Many people in prison have experienced depression and anxiety but do not have access to treatment. Researchers at the University of Wisconsin–Madison are conducting a study to learn more about a self-help mental health workbook tailored for the prison setting. We will be testing this workbook throughout several Wisconsin prisons.

We invite you to participate in this research study about a self-help workbook tailored for people who are in prison. Approximately 96 individuals will participate in this study. Your participation in this research study is voluntary. If you decide not to participate, your treatment at this institution will not be affected in any way.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Your participation in this research study is voluntary. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

B. What will I need to do in this study?

If you decide to participate in this research, you will be asked to complete an interview. During this interview, you will complete a reading activity and questionnaires about different mental health symptoms.

You will then be invited to participate by reading through a self-help workbook, completing one section each week for 8 weeks. Participants will be given one of two workbooks. Workbook selection for each participant will be done randomly, similar to the outcome of a coin flip.

If you are invited to participate in the study, you will be asked to fill out questionnaires about how you are feeling (e.g., your mood, depression symptoms), and your experience with the workbook. You will complete these questionnaires on four separate occasions: 1) before the treatment group starts, 2) during the treatment group, 3) one week after the treatment group ends, and 4) one month after treatment ends. Some sessions will take place in person and some sessions may take place over Zoom and Webex. The questionnaires will take around 60 minutes to complete each time and can be completed at your own pace with a tablet. A study team member can also read the questionnaires aloud and record your answers.

After completion of the workbook, a study team member will lead one or two conversations, for approximately 60 minutes each, where you may be invited and asked about what you liked or didn't like about the workbook. These conversations may be during a one-on-one interview or in a group setting, and may occur within 3 months of the final questionnaire visit (i.e., within 3 months of the 1-month post-treatment visit). After the eight weeks, we will also collect your workbook to scan and return it to you during one of our study sessions. None of this information will be added to your medical records or institutional files.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

C. What are some reasons I might – or might not – want to be in this study?

Possible benefits and reasons you may want to be in the study:	Possible risks and reasons you might not want to participate:
Comfortable having researchers ask questions about your mental health and past history. Willing to participate in a 8-week self-paced workbook about mental health and complete focus groups and/or one-on-one interview. You may experience an improvement in how you are feeling after completing a workbook. However, we cannot promise this will happen. Your participation in this research study may benefit other people in the future by helping us learn more about self-help mental health options for people in prison.	You may find the questionnaires to be boring or tiring. You may also feel uncomfortable with sharing information about your emotions and personality. It might be challenging to address your thoughts and emotions without the guidance of therapist. With any physical copy, there is a risk that you will lose the workbook, or that it will be taken or read by someone else. There is a risk that your study information could become known to someone who is not involved in the study. For instance, someone might find out that you have a history of depression. Breaking confidentiality in this way could happen if any of the data we collected were to be lost or stolen from the laboratory or if any data stored in the electronic database were damaged.

There will be no cost to you for the workbook and assessments that are part of this research study.

If you decide not to participate in this study or if you stop while the study is underway, it will not affect your status with the Department of Corrections.

D. Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

You do not have to be in this research study to get care for depression. If you decide not take part in the study, you have other choices. You may choose to seek treatment from Department of Corrections psychologist or social worker, or you may choose to take part in a different study, if one is available.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

E. How is research different from health care?

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question, like how safe or effective a mental health workbook is.

If you take part in this study, the main difference between your regular care and the care provided through this research study is that this study is focused on mental health symptoms. You may be able to get mental health treatment on an individual basis with Department of Corrections psychologists and mental health staff, but this type of self-help workbook in this study is using is not currently offered in Wisconsin prisons.

F. Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team Lead Researcher Michael Koenigs, PhD, at (608) 263-1679. You can mail Dr. Koenigs at 6001 Research Park Blvd., Madison, WI, 53719.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

G. If I take part in the study, what will I do?

If you decide to participate in this research, you will be asked to complete an interview. During this interview, you will complete a reading activity and questionnaires about different mental health symptoms.

After the initial interview, you may be invited to participate in **one** of two different 8-week self-help workbooks. One workbook focuses on expressive journaling, and the other

focuses on learning how to relate better to difficult thoughts and experiences. The workbook will take about 2 hours each week to complete, for an 8-week period.

If you are invited to participate in the study, you will be asked to fill out questionnaires about how you are feeling (e.g., your mood, depression symptoms), your experiences in the workbook, general demographic information, and things about your past experiences and history. You will complete these questionnaires on four separate occasions: 1) before the treatment (workbook) starts, 2) during the treatment, 3) one week after the treatment ends, and 4) one month after treatment ends. Some sessions will take place in person and some sessions may take place over Zoom or Webex. The questionnaires will take around 60 minutes to complete each time and can be completed at your own pace with a tablet, other electronic device, or paper form. A study team member can also read the questionnaires aloud and record your answers. After the workbook ends, you may be invited to up to two meetings lasting about 60 minutes each. These meetings may occur within 3 months of the final questionnaire visit (i.e., within 3 months of the 1-month post-treatment visit). The meetings may be group conversations led by a study team member, or one-on-one interviews with a study team member. If you cannot attend (scheduling, RHU, facility, availability) the group conversation, you may be invited for a one-on-one interview. The study team member will ask you what you liked or didn't like about the workbook. After the eight weeks, we will also collect your workbook to scan and return it to you during one of our study sessions.

As part of the study, we will collect audio recordings of the after-workbook focus group meetings or one-on-one interviews. Recordings will not be shared with anyone outside of the study team. Recordings will also be used to make sure we keep track of everything that participants liked or didn't like about the workbook. Recordings will be destroyed when the study is finished. A written copy of the recordings will be made for use in the research. We will delete directly identifiable information from the transcripts.

We will obtain data on conduct reports, cell entries by officers, reconviction, and re-incarceration via public records and/or request it from the DOC.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Results of tests, procedures, or questionnaires completed as part of the study
Things you tell the researchers about your physical and mental health

H. What happens if I say yes, but I change my mind later?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

You can leave the research at any time. If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. Participation in the study will have no effect on probation or parole.

You may completely withdraw from the study at any time. You also may choose to stop participation or skip any questions that you do not feel comfortable answering. If you withdraw, you will be paid for any tasks that you already completed, and your previous data will be included in the study. You also may be withdrawn by the study team if it is in your best interest.

If you decide to withdraw from the study, you may be asked to explain the extent of your withdrawal and the reason for your withdrawal. You can choose not to answer these questions. The purpose of asking about reasons for withdrawal is to better understand what barriers people experience related to completing the study treatment.

Your authorization for researchers to use your protected health information (PHI) will last up to 5 years following the end of this research study. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, an investigator may still consult public records.
- If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher: Michael Koenigs, PhD, 6001 Research Park Blvd., Madison, WI 53719

I. What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. This study is protected by a Certificate of Confidentiality from the National Institutes of Health. Obtaining a Certificate of Confidentiality means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study without your consent. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

However, we cannot promise complete confidentiality.

Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for carrying out or monitoring this study. For example, safety information, serious adverse events, or demographics may be shown to our study sponsors or committees such as Data Safety and Monitoring Board (DSMB). This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance to our protocol, such as the Human Research Protection Program.

We will contact the prison and/or DOC (and confidentiality will be broken) only under three conditions: (1) If you tell us that you plan to hurt yourself or someone else; (2) if you tell us that you plan to escape or start a prison riot; or, (3) if you report any sexual activity or sexual assault between resident or between residents and staff. Otherwise, we will not share your information with anyone, including other residents, prison staff, or other authorities.

We will ask you questions about depression, including thoughts and plans to harm yourself intentionally, throughout this study. If you report current plans to harm yourself, we will need to break confidentiality to let the psychologist at the prison know. If this occurs, we will talk to the psychologist right away. Mental health services at the prison will then follow up with you. If you report significant symptoms of depression, we will refer you to mental health services in the institution.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Data from this study will also be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about mental health and brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and brain science and how to help others who have problems with mental health and brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the study visit today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study

data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

Also, without revealing your identity, we might use information that we collect during this study for other research or share it with other researchers without additional consent from you. We may also publish and present the results of this research. For example, we may publish research data in journals or present data at conferences. However, we will keep your name and other identifying information confidential. This means that any data or results we may publish or present will not identify you directly.

We will store your personal information and the data we collect in this study securely. Any data you provide will be coded and stored in electronic and paper form in locked cabinets and secure computers in our research facilities. To protect your personal information, we use numbers instead of your name on all materials. Specifically, we will code your data with a five-digit number instead of using your name. Your name never appears in the same place as your responses. In order to keep correct records of participation, we must keep a key that allows us to link your identification code back to your identifying information (e.g., name), but this key is stored in a secure place at our office. Only study researchers will be able to connect your name and your unique five-digit number. To protect your privacy, we keep these number codes and your responses separate at secure locations at the University of Wisconsin-Madison.

Loss of confidentiality is a possible risk associated with allowing us to store your data. For example, if someone broke into the locked cabinets or hacked into the secure computers and stole this data, they would also have access to your data we have collected (e.g., depression symptoms). This could pose a risk legally, or to your reputation.

The research team will maintain the key/link between your data and your identifiable information (e.g., name, birthday) for 5 years. Following 5 years, the link between your data and your identifiable information will be destroyed. Stored data will not be shared with your health care providers or used in any treatment you receive outside of this study. Data that is de-identified will be stored for research purposes only and may be stored indefinitely.

The de-identified data collected in this study may be stored without an end date in a database that will allow us to compare your data with data from other formerly incarcerated individuals. The de-identified information we store about you will not include your name, only your 5-digit code.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record.

J. Will I receive the results of research tests?

Some of the questionnaires you will complete in this study may show that you are experiencing symptoms of emotional distress such as depression, suicidal thoughts, or anxiety. If the questionnaires show that you are experiencing **significantly worsening symptoms of emotional distress**, the study team will contact the psychologist at the prison. If necessary for your well-being, they will follow up with you to discuss and implement a safety and mental health plan.

K. Can I be removed from the research without my agreement?

It is possible that the researchers involved in this study will choose to stop the study and end your participation, even if you choose to participate today. You will be notified if such a situation happens. The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include:

- Your mental health declines significantly and the research team determines that the study is no longer in your best interest. If this occurs, the study therapist or another designated qualified professional will provide follow-up to help ensure your safety.
- The study is stopped by the sponsor or researchers.

L. What else do I need to know?

Will I receive anything for participating?

If you agree to take part in this research study, we will pay you $5 for completing each research study visit.

You will receive $5 for completing the consent/screening meeting. Following the consent/screening meeting, if you are determined to be eligible, you may be enrolled in the study.

If enrolled, you will receive $5 each time you complete a series of questionnaires at the following meetings: 1) at the beginning when you receive the workbook; 2) when you're halfway through the workbook (4 weeks after receiving the workbook); 3) after you've completed the workbook (8 weeks after receiving the workbook), and 4) one month after completing the workbook (12 weeks after receiving the workbook).

After you complete the workbook, you may also be invited to attend up to two interviews with a study team member in either a group or one-on-one setting. You will receive $5 for attending each interview. In total, you can receive up to $35 for participation in this study.

This money will be deposited into your account through the DOC.

How many people will be in this study?
We expect about 96 people will be in this research study.

Who is funding this study?
Funding for this research is provided by the National Institutes of Health

Agreement to participate in the research study

Please take as much time as you need to think over whether or not you wish to participate.

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	