Consent to Participate in Research

A Randomized Control Trial for Substance Use Problems

Introduction

You are being asked to participate in a research study conducted by Dr. Kent A. Kiehl who is the Principal Investigator and a scientist at the nonprofit Mind Research Network (MRN)[1]. This research is studying how well different treatments for alcohol abuse work. You are being asked to participate in this study because you are a female currently incarcerated within a correctional facility and may have experienced problems with alcohol use. This research study is funded by the National Institutes of Health.

This research study uses brain imaging (MRI) to examine brain function and structure. These scans provide information about how your brain works during simple tasks like reading and listening to sounds. The study also includes cognitive testing (measures of IQ, memory, language ability, problem solving, etc.) and clinical interviews.

This form describes the research study and explains the possible risks and benefits. If you have any questions, please ask one of the study investigators. Participation in research is voluntary. You don't have to agree and you can withdraw without penalty at any time. It is your alternative not to participate.

What will happen if I decide to participate?

- *Interview:* Study staff will meet with you in a private room and ask you questions about your life history, including past and current relationships with family and friends. The interview will include videotaping with audio recording. There will be multiple 1-2 hour interview sessions (total approx. 4 hours).
- *Testing:* You will complete paper-and-pencil and/or computer tests that measure attention, memory, problem solving, and your ability to use emotions in everyday life. These tasks take about 1-3 hours.
- *Self-report Packet:* You will be given a packet of personality questions to fill out. The packet takes about 1 hour to complete.
- *Treatment:* You may choose to participant in treatment or you may choose to participate in the research study but not the treatment. If you choose not to participate in treatment you will be invited to complete all study procedures, including MRI scans and follow up sessions, apart from treatment.

  If you choose to participate in treatment, you will receive 8 weeks of 2-hour weekly therapy sessions. You will also complete daily practice (approximately one hour) during the treatment. You will be given the practice sheets to complete on your own time.

  You will be randomly assigned (using a computer algorithm, 50/50 distribution) to one of two treatment groups:
  - (a) Mindfulness Meditation (MM) addresses craving and common relapse triggers with skills and techniques developed through mindfulness training.
  - (b) Relapse Prevention (RP) is intended to help addicts identify and cope with everyday situations that put individuals at risk for using addictive substances.

[1] Additional scientists working on the study are from the University of Wisconsin.

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Therapy sessions will be videotaped with the camera being aimed at the therapist, therefore only your voice will be recorded during these sessions. This taping is performed in order to make sure we fully understand your treatment needs, to ensure that your therapists are carrying out the treatment properly, and to help the research team learn more about the specific parts of the therapies that may affect their success. If you are transferred from the facility mid-treatment we will not be able to travel to another facility to continue the program. We may, however, contact you to continue other study procedures, including follow up sessions.

It is possible that at the time you volunteer for the study, the treatment groups will be full. In this case you will be placed on a waiting list. While on the wait list you will be invited to complete all study procedures apart from the treatment sessions.

- *Brain imaging (MRI):* You will lie back on a table and be placed into a long donut-shaped magnet. The MRI makes loud knocking noises. You will be given headphones to reduce the noise. In order to obtain good pictures, it is important that you do not move during the procedure. You will be able to talk with the technician during breaks or in case of emergency by pressing a call button. During the scans, you will perform tasks like listening to sounds and making decisions about words, phrases, pictures and video clips. The MRI sessions take about 1-1.5 hours each and you will have 3-6 scans during the study.
- The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. However, research MRI scans will be looked at by a medical doctor. The doctor's MRI report will be provided to the prison medical director. If an abnormality is found that requires urgent follow-up, we will contact the prison medical director to provide the results. Our study doctor or the research team is always available to answer any questions you may have about your MRI. If you are participating in multiple MRI scans, your MRI scans will be read every six months.
- *Follow up Interviews:* Every three months following the baseline phase of the study, you will be asked to come to our offices at The Mind Research Network or University of Wisconsin-Madison to complete follow up interviews and questionnaires. If you cannot provide your own transportation, we will arrange transportation for you via Uber Health (for travel up to 120 miles round trip). If travel to MRN/UW is not possible, alternate arrangements may be made (e.g., public location where privacy can be maintained). Reasonable travel costs will be paid for individuals residing outside Albuquerque or Madison (e.g., one hour or more away). This may include mileage (standard gsa.gov rates) and/or a flat rate ($20/hour of travel). If you are still incarcerated at the time of follow up, we will complete the follow-up sessions in the correctional facility. When entering correctional facilities is not possible due to COVID-19 restrictions, we have arrangements with the facility for you to complete follow-up assessments via non-recorded phone conversations in a private office.
- *Drug Testing:* You may not be able to participate in some study procedures (e.g., MRI scans) if you have had a recent positive drug screen or seem impaired in any way.
- *Other Information Collected*: We are studying long-term health and behavioral outcomes (e.g. future crimes, employment success). By signing this form, you are letting us look at your medical, institutional, and court/criminal records. We may also check your present or future education, employment, credit history, and driving records to check your status (i.e., do you have a job, good credit, etc?). We will check these records as often as every six months using public records, state databases, social media, or using a commercial background check company (i.e., SSC, Inc).

How long will I be in this study?

The first part (baseline) of the study will take about 14-30 hours (depending on if you are in a treatment or control group), broken into 1-2 hour sessions over approximately a 1 year period. If you are in the treatment group, you will also complete approximately one hour of daily practice during the eight weeks of treatment. We will then contact you every three months following the baseline phase of the study to administer follow-up assessments. The follow up sessions will take approximately one hour and will occur after your release from prison, or in prison if you are still incarcerated. Because we will follow up with you every three months, you will remain in the study indefinitely unless you request to stop. You can withdraw from the study, or any part of the study, at any time without penalty or loss of benefits to which are you otherwise entitled by writing the research staff with your request. You may send requests via regular US postal service or using the prison mail system. If you withdraw we will no longer contact you to collect information; however the data already collected will continue to be used for study purposes. The research staff can also end your participation in the study at any time if it's in your best interest, to protect study integrity or if the study is stopped.

What are the risks or side effects of being in this study?

The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection. You should report to the study staff any problems you experience while taking part in the study.

- MRI is considered to be safe and minimal risk. However, the scanner is a large magnet. This means that loose metal objects, like coins or keys, are not allowed in the MRI. If you have certain types of metal in your body, you cannot have an MRI scan. While in the MRI scanner you may experience a fear of small spaces or, in rare cases, muscle twitches. If you feel uncomfortable at any time, tell the staff. You can stop the MRI scan at any time. Although there are no known health risks to pregnant women or unborn children from MRI scanning, if you are pregnant, or think you might be pregnant, you will not be able to have an MRI scan. You can be rescheduled after you are sure you are not pregnant.
- Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on scans that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans by your medical provider. The costs for additional MRI scans are not covered by the study investigators or their institutions.
- There is a rare chance that tattoos – especially really dark or heavy tattoos - may get warm or tingle during the MRI scans. If you experience any heating/tingling from tattoos, tell us and we will stop the MRI scan. A cold compress may be applied to reduce any swelling on the tattoo.
- Participation in this study may produce anxiety/emotional stress. If you experience discomfort during the study, we will encourage you to visit the facility mental health center or contact your current physician or counselor if you are no longer incarcerated. We cannot break confidentiality to ensure that you seek help except in limited cases as outlined below.
- *Confidentiality:* Your research data (e.g., interviews, questionnaires) will not be shared with anyone outside the research team. It will not be shared with facility staff or the corrections department. Corrections staff only have access to your signed consent form, which contains no personal or research information. Your participation in this study will not have any impact on your status in the institution or play any role in legal proceedings such as probation/parole. Every effort will be made to protect the

information you give us. However, there is a small risk of loss of confidentiality that may result in stigmatization or other hardship. Procedures we will use to protect the information you give us are described below.

- Due to the nature of the prison environment, we cannot provide a private space for you to complete the daily practice sheets, which increases risk of loss of confidentiality. To help reduce this risk, we will provide a secure box in or near your unit. We encourage you to place the daily practice sheets in the box as soon as you have completed them. We use a coded number, not your name, to help maintain privacy on the practice data.

What are the benefits of being in this study?

You may receive benefits from participating in treatment. This may include possible reduction in alcohol use. Physical, psychological, occupational, familial and economic aspects of your life affected by alcohol use may also improve. There are also benefits to society that could result from increased knowledge about treatments for alcohol abuse that might be used to help other people with alcohol use problems.

In this study, the brain scans performed on you will be used solely for the purpose of gathering scientific information for this study. You will not be given a medical diagnosis or treatment for any brain condition, or other health problem by the investigators. Depending on the radiology report, your institution may follow up with you about the results. However, the radiologist may notice something in the images that could lead to early intervention if a problem was found.

Some people also find it helpful to talk to research staff about their background. However, there are no other direct benefits to you by participating in the study. We hope the knowledge gained will aid in the development of new treatments to help reduce alcohol abuse.

Will I be notified about future studies?

Dr. Kiehl or one of his associates may contact you again to participate in future studies. You are free to decline doing additional studies by letting research staff know when they get in touch with you or by sending a written request via prison mail or via US postal service that you do not wish to participate in future studies.

How will my information be kept confidential?

All of the data we collect about you will be coded with a unique research subject identifier (URSI). Hard copy (paper) research data collected from you, which is coded with your URSI, will be stored within a locked cabinet within the prison facility (only research staff have the key), and then brought back to MRN by research staff (usually each day) and placed in a locked file cabinet in our laboratory. Electronic data collected from you, which is coded with your URSI, is uploaded from our encrypted tablet computer to MRN's secure database. Data will be kept on password-protected computers, and stored securely in restricted and protected databases according to our information security policies.

Medical information created by this study will not become part of your medical record unless you request that research records be released to personal physicians. Only the MRI report will become part of your institutional medical record.

To further protect the confidentiality of your data, we have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This means the investigators cannot be forced (for example by court subpoena) to release research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

There are certain circumstances in which **we are required to break confidentiality**. If the investigators learn about abuse of a child or elderly person, facility escape or riot plans, or that you intend to harm yourself or someone else, we will report that information to authorities. The Certificate of Confidentiality does not prevent us from reporting this information.

The results of this study may be presented at meetings or in publications; however your identity (name, face, etc.) will not be disclosed.

Data Sharing:

If you previously completed any of the study procedures described above in a different research study with one of our collaborators, we may use that data rather than ask you to repeat the same procedure.

The de-identified data and results of this study will be shared with other researchers, presented at meetings, used for training purposes, and/or published. None of these results will include your name or any other identifying information. Information from your participation in this study may be reviewed by auditors from the Sponsor (NIH), MRN, federal and state regulatory agencies, and by the Institutional Review Board (IRB), which provides regulatory and ethical oversight of human research.

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.

Are there Financial Aspects to Participating?

Costs: There are no costs to you for being in this study.

Treatment if Injured: No commitment is made by the investigators or their institutions to provide free medical care or money for injuries to participants in this study.

Compensation: You will be paid $5.00 per hour for completing scans and assessments or interviews. In addition, you will be paid $1.25 per day for completing daily practice worksheets related to treatment. The research staff will tell you how much you may receive for your study participation. Payment will be given in the form of institutional credit. You will be paid once a month for hours completed in the previous month.

After you are released from incarceration, you will be paid a flat rate for completing follow-up assessments. If you are released prior to completion of clinical interviews or other study assessments, you will be paid an hourly rate for the completion of these assessments. The research staff will tell you how much you may receive for your study participation. Payment will be given in the form of cash, gift card, or money order after each study session.

Who can I call for questions?

You have the right to ask questions or to get more information about subject rights, or to make complaints or comments, to report research related injuries or to give input. Dr. Kiehl or his staff can be contacted at (505) 925-4516 or by mail at Mind Research Network, 1101 Yale Blvd NE, Albuquerque, NM, 87106.

If you would like to speak with someone other than the research team, have complaints or concerns regarding the study, have questions about your rights as a research subject, or would like to provide input, you may contact the IRB – Salus IRB at 800-472-3241 or by email at subject@salusirb.com or in writing at 2111 W. Braker Lane, Suite 100, Austin, Texas 78758. Reference study #18114.

Consent (ages 18 and older):

You are making a decision whether to participate in this study. Your signature below indicates that you read the information given (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research subject.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this form will be given to me.

_____	_____/_____	
Name of Adult Subject (print)	Signature of Adult Subject	Date *(MM/DD/YYYY)*

I have explained the research to the subject and answered all of her questions. I believe that she has received all of the information in this consent form and freely consents to participate.

_____	_____/_____	
Name of Research Team Member (print)	Signature of Research Team Member	Date *(MM/DD/YYYY)*