Cover Page
Participation Consent Form

Study Title: IntelliCare Study: Artificial Intelligence in a Mobile (AIM) Intervention for Depression

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Full Study Title: Artificial Intelligence in a Mobile Intervention for Depression and Anxiety (AIM)

Northwestern University
Department of Preventive Medicine

CONSENT FORM FOR RESEARCH

Title: Intellicare Study —
Field Trial

Principal Investigator: David C. Mohr, Ph.D.

Supported by [or Funded by]: National Institute of Mental Health.

Purpose/Introduction

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we (i.e., Northwestern University) would like to use information about you and your health.

What is the reason for doing this study?

This study is being conducted by David C. Mohr, Ph.D. from the Northwestern University Department of Preventive Medicine at the Feinberg School of Medicine, and aims to create a mobile phone intervention that utilizes "machine learning" to provide care for depression and anxiety. Machine learning, a branch of artificial intelligence, is a computer technology where a program learns from data collected continuously from patients, and then generates automated ways to help patients. The intervention, referred to as IntelliCare, can use the computer and data collected to tailor treatment content and send messages to motivate participants. The purpose of this study is to obtain preliminary information about the look and feel of IntelliCare, as well as information about its functions in the real world. This trial will also provide researchers with data which will help them develop the "machine learning" technology.

You are asked to take part in this study because you are 19 years of age or older, are interested in using and providing feedback about a mobile phone intervention for depression and anxiety, and are currently experiencing some of these symptoms yourself.

What you will do if you choose to be in this study?

Screening Assessment
The screening assessment consists of 2 parts: 1 telephone-based interview and 1 online questionnaire. These assessments will include questions about your recent mood and mental health history.

The phone interview will take up to 90 minutes to complete. The online survey will take about 30 minutes to complete and we ask that this questionnaire be completed on the same day as the phone interview, and no later than 24 hours after the phone interview has been completed.

Based upon information gathered during this screening assessment, a determination will be made as to whether you will be invited to continue in the study. All participants will be compensated $20 for completing this interview, regardless of final eligibility status.

Treatment:

If you are eligible for the study and choose to participate, a research study assistant will work with you to download the IntelliCare apps onto your personal Android smartphone. At that point, you will be asked to use the Intellicare mini apps which address specific treatment goals, and may include lessons about mood and behavior change or interactive tools to support behavior change.

The use of these apps will be supported by a member of our study staff. As a participant in this study, you have access to coach who will be available by phone, text message or email to work with you in how you use the IntelliCare apps. Your interactions with the coach are not expected to exceed 15 minutes each week.

Study staff may contact you by phone, text message or email as you use the phone application, to ensure it is working properly, ask for feedback about functions of the mobile phone application, and suggest possible changes.

Once installed onto your personal smartphone, the IntelliCare apps will begin collecting data about how and when you use the IntelliCare apps, and other applications on your smartphone. We will also collect information data on your location, movement, WiFi network, surrounding Bluetooth devices, mobile phone usage, and sounds in your environment. When this data is stored on our secure servers, it will not contain any identifying information about you. Collecting this information will help researchers better understand the phone- and app-use habits of IntelliCare users, which will help them build the "machine learning" technology.

The research team will continue to collect app use data after the end of the 8 week study as long as you choose to keep the apps installed on your smartphone.

Evaluations

After the initial screening assessment, we may ask you to complete up to two additional evaluations throughout the research study. These evaluations will likely come at the end of your 4th and 8th week of study involvement. These evaluations may consist of completing a telephone interview and questionnaires on the Internet via a secure link. These evaluations will be similar to the initial screening assessment and ask about your recent mood and experience with the IntelliCare apps, but the interview should not exceed 60 minutes.

Participants will be compensated $30 for completing the assessment at the end of week 4 and $40 for completing the evaluation at the end of week 8.

Audio Recording

All assessments and interviews are audiotaped. The purpose of these audiotapes is to ensure that the coaches and the people conducting the interviews are doing their jobs correctly. Only select members of the research team will have access to and will listen to these tapes. They will be destroyed at the end of the study. Audiotaping of your sessions is required in order to participate in this study.

What are some of the risks and discomforts that may happen to people who are in this study?

The risks from completing the questionnaires are minimal, but it is possible that you may experience emotional discomfort or increased anxiety as a result of answering questions about your mental health or reactions to the materials. You have the option of stopping at any time.

If you begin to feel emotional discomfort as a result of your participation in this study, you are encouraged to address this with the coach assigned to you so that you receive appropriate treatment.

What are some of the benefits that are likely to come from my being in this study?

The possible benefits to you from this study include helping to shape a new intervention for people experiencing depression or anxiety. Taking part in this study may help scientists to better understand how to treat depression and anxiety using new technologies. You may also see improvements in your mood and/or quality of life as a result of your participation in this study.

What other procedures or courses of treatment might be available to me?

You do not have to take part in this research study; participation is completely voluntary. Instead of being this study, you can opt out of participation. You will not have access to the coaching associated with these apps but you may still download IntelliCare Smartphone applications from the google playstore. If you choose not to participate in this study but decide to download the IntelliCare applications, you will be presented with a user acknowledgment that explains how the Center for Behavioral Intervention Technologies at Northwestern University collects and uses application and phone use data to improve the quality of the applications.

Are there any financial costs to being in this study*?*

There will be no costs to you for being in this study. However, participants will be asked to download the IntelliCare apps onto their personal smartphones and therefore any use of the apps will be associated with the use of personal data plans. Participants who have a limited monthly data package will be responsible for monitoring their data usage per their smartphone plans and will be responsible for paying any overages fees incurred as a result of exceeding their monthly data plans. The research study is not responsible for any overages and in no way endorses or expects participants to surpass their monthly data plan limits.

Will I receive payment for participation in this study?

You will not be compensated for using the IntelliCare application(s), but you will receive compensation for participating in the screening assessment ($20) and the evaluations at the end of weeks 4 ($30) and 8 ($40). Therefore, participants who complete all surveys and interviews within the 8 week period can earn up to $90 for their involvement.

Participation in the trial may include the use of texting, and as such, study staff will reimburse participants who do not already have an unlimited monthly texting plan for their upgrade to such. Reimbursement of up to $30 per month enrolled in the trial (up to two months) is possible.
Payments to participants will be made with either Amazon.com credits (click here for terms and conditions) or by check, depending on preference and availability at the time of your participation. The Amazon.com credits can be used for making online purchases through the Amazon.com website and there are no fees associated with this payment type. Hardcopy checks typically take about 3-4 weeks to process and subsequently, for participants paid by check, the $30 and $40 payments associated with evaluations at weeks 4 and 8 will be combined into one lump sum (if applicable) at the end of the study period.

What should I do if I am injured as a result of being in this study?

If you become more depressed or get an injury or illness as a result of answering the study questionnaires or using the application, you should seek medical treatment through your physician, a therapist in the community, or your treatment center of choice. Payment for this treatment will be your responsibility.

If you experience an emergency, such as thoughts about harming yourself or someone else, please call 911 or 1-800-SUICIDE immediately for assistance. Both these emergency numbers are available 24 hours every day.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Susan Kaiser is the research project coordinator. You can call her at (312) 503-1249, Monday-Friday, 9-5 CST. David Mohr, Ph.D. is the principle investigator on this study, and you can call him at (312) 503-1403, Monday-Friday 9-5 CST.

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time. You may withdraw from the study by calling or emailing the study coordinator, Susan Kaiser. Her phone number is (312) 503-1249, and her email address is susan.kaiser@northwestern.edu

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment to which you are otherwise entitled.

Your participation in this study may be discontinued by the investigator without your consent if we believe that your continued participation may be a danger to your health or well-being. If this occurs, we will provide you with appropriate referrals for your care. If we believe you are at imminent risk of harming yourself or someone else, we will contact emergency services to locate you and ensure the safety of you and others.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office for the Protection of Research Subjects. You can call them at 312-503-9338.

What about my confidentiality and privacy rights?

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information, including information that can identify you. For example, personal health information may include your name, address, or phone number.

Involvement in this research study may result in a loss of privacy, since persons other than us might view your study records. Unless required by law, only authorized individuals at Northwestern University, such as the Northwestern University Institutional Review Board and administrative staff in the Office of Research, can review your study records. They are required to keep your personal information confidential. This study is being funded by the National Institute of Health, which may also see your data in the case of an audit. However, information that could identify you, such as your name or address, will not be disclosed to individuals outside Northwestern University unless required by law.

Results of this study may be used for research, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected.

We may also be required by law to break confidentiality and disclose information if we believe that you are in imminent danger of harming yourself or someone else in order to prevent such harm from occurring. To protect vulnerable populations, we may also need to break confidentiality if you report knowledge of abuse or neglect of a child, elderly person, or disabled individual.

Your mobile phone will collect data on your location, movement, WiFi network, surrounding Bluetooth devices, mobile phone and app usage, and sounds in your environment. This information is also stored in a format that contains no identifying information about you, and the information is stored on secure servers for your protection. For example, recordings of the words spoken in your environment will not be stored; however, higher level information such as volume and pitch may be stored.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

We may share some of your information with people other than the researchers at Northwestern University who are conducting this study. Please note that any research information shared with people outside of the Northwestern University research team, will not contain your name, address, telephone or social security number or any other direct personal identifier. Personally unidentified study data including health information used, created, or collected in the research study and information that describes you but does not directly identify you (like your age, gender, race, state or zip code & smartphone sensor data) may be shared with the following people:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study).
- Other University research centers and contractors who are also working on the study.
- Study monitors and auditors, for example from funding agencies, who make sure that the study is conducted properly.
- Collaborating researchers from other universities or foundations outside of Northwestern University, who are collaborating to further research and agree to protect the data.

Please note that:

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to: David C. Mohr, Ph.D., Department of Preventive Medicine, Northwestern University, 750 N. Lakeshore Drive, 10th Floor, Chicago, IL. 60611.
- Unless you revoke your consent, it will not expire.

Optional Study Elements:

Contact about other research studies

Please initial one of the following to indicate your choice:

_____I agree that someone may contact me in the future to ask me questions about my health or to ask me to be in more research. Agreeing to be contacted increases the risk to my privacy. It will be my responsibility to tell the project if my contact information changes.

_____I do not agree that someone may contact me in the future to ask me questions about my health or to ask me to be in more research.

Permission to use anonymous comments and feedback

Please initial one of the following to indicate your choice:

I provide permission for the study team to use anonymous portions of my expressed opinions and impressions of the apps. These may be used in the design of future versions of digital interventions, promotional recruitment materials, the Center for Behavioral Intervention Technologies website, research papers, and presentations. My name or identifying information will never be associated with these opinions or impressions.

I DO NOT provide permission for the study team to use anonymous portions of my expressed opinions and impressions of the apps.

Consent:

I have read this consent form and the research study has been explained to me. I have been told whom to contact if I have more questions. I agree to participate in the research study described above; this is signified by checking the box below and typing my name in the space provided. I can request that a copy of this consent form be emailed to me for my records after I complete this authorization.

☐ I agree to participate in this research study

☐ I do not agree to participate in this research study