# MVP RCT: Mind and Voice Project Randomized Control Trial

# NCT04018807

# IRB Approval Date: October 3, 2019

# UNIVERSITY OF MICHIGAN AND HURLEY MEDICAL CENTER
# CONSENT TO BE PART OF A RESEARCH STUDY

## 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title:** MVP RCT: Mind and Voice Project – Part 2

**Company or agency sponsoring the study:** National Institutes of Health (NIH)

**Names, degrees, and affiliations of the researchers conducting the study:**

**Principal Investigator:** Quyen Ngo, PhD, Department of Emergency Medicine, University of Michigan.
**Study Coordinator**: Mandilyn Graham, MA, Department of Emergency Medicine, University of Michigan.

### 1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to learn new information about a certain condition and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. This may require you to change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying health behaviors and new ways to improve prevention programs for young adults seen in Emergency Departments. Health behaviors include relationships, physical and mental health, alcohol use, and conflicts with others. This research hopes to improve prevention and intervention programs for young adults seen in Emergency Departments. Your health-related information such as your survey responses will be collected for this research study.

This study involves a process called randomization. This means that the procedure you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feelings of discomfort, anxiety, or loss of privacy. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by helping us improve new treatment prevention programs for youth who seek treatment in the ED. More information will be provided later in this document.We expect the amount of time you will participate in this study will be over after you finish the 4-month follow-up.

You can decide not to be in this study. Alternatives to joining this study include asking your medical team in the ED for resources and seeking out community resources. If you should choose not to participate, your treatment in the ED will not be affected in any way.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

## 2. PURPOSE OF THIS STUDY

**2.1 Study purpose:**

We want to learn more about the health behaviors of young adults who come to the Emergency Department (ED) for medical care. Health behaviors include relationships, physical and mental health, alcohol use, and conflicts with others. The purpose of this study is to improve prevention and intervention programs for young adults seen in Emergency Departments. We want to learn how communicating with a therapist through the use of technology can help young adults reduce risk behaviors related to alcohol use and conflicts with others. We also want to compare this therapy to receiving community resources. We also want to learn about your opinions on the helpfulness of video therapy sessions and the type of material discussed.

## 3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

**3.1 Who can take part in this study?**

Patients between 18 and 25 years old who come to the Hurley Medical Center ED for medical care, have completed a brief screen, and based on screen answers, are eligible for this part of the study. You must have regular access to a smart device (such as smartphone or tablet) with live video capability (such as Skype, Google hangout, FaceTime), the ability to download an application, the ability to receive and send texts, and have your device with you today. You must also agree to have your sessions video and/or audio recorded.

**3.2 How many people are expected to take part in this study?**

About 200 people are expected to complete part 2 of this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

**4.1 What will happen to me in this study?**
You will be asked to participate in one of two different areas in the study. Whether you are put in one possibility or the other is completely random.

**Group 1: Remote Therapy**

**If you are placed in remote therapy**, you will be asked to participate in 8 video therapy sessions using your smart device, over the next 8 weeks.

First, you will be asked to spend 20 to 30 minutes today with a research team member setting up and practicing the 'video meeting room' on your smart device, as well as learning about the information that will be discussed during the video therapy sessions. You will also complete a brief survey and answer questions about recent drug and alcohol use and experiences with conflict in an interview that will take about 60 minutes.

Then, you will be asked to provide contact information to communicate with a research team member about scheduling your 8 video therapy sessions, and to answer questions by text messages.

Before each therapy session, your therapist will ask you nine questions by text messages that ask about how your week has been, and to confirm your appointment. You will also receive reminder texts following each appointment regarding information that was discussed during your session.

During each video therapy session that will take approximately 60 minutes each, you will be asked to meet privately with a research therapist using a live 'video meeting room' on your smart device. As part of these sessions, you will be asked to discuss your goals, and the challenges you face. The therapist will assist in helping you find strategies you feel will be the most helpful for dealing with any challenges. These 8 sessions will be audio

and/or video recorded. You must agree to have these sessions recorded in order to participate and you can give permission for that in section 12.

**Group 2: Community Resources**

**If you are placed in community resources**, you will be asked to complete a brief survey online and answer questions about recent drug and alcohol use and experiences with conflict in an interview that will take about 60 minutes.

You will receive an informational brochure about health behaviors including relationships, physical and mental health, alcohol use, and conflicts with others.

**Regardless of which part of the study you are asked to participate in**, you will participate in two follow-up interviews which will take place approximately 4 months and 6 months from the time you complete the initial assessment. These follow-ups will consist of a survey questionnaire and a brief interview.

**4.2 How much of my time will be needed to take part in this study?**

Today, if you are placed in remote therapy, you will spend up to 30 minutes with a research team member reviewing the video therapy information. You will also provide contact information and complete a 60 minute survey and interview about your experiences. After today, if you are placed in remote therapy, the 8 video therapy sessions will each take about 60 minutes, the phone/internet survey will take about 5 minutes, and lastly, the follow-up interviews will take about 90 minutes each.

**4.3 When will my participation in the study be over?**

Your participation in this study will be completed once the six-month follow-up interview is complete.

**4.4 What will happen with my information used in this study?**

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

The known or expected risks are loss of privacy and feelings of discomfort as a result of being asked personal questions. The therapy sessions will involve discussing sensitive topics such as your experience with conflicts and fighting that may make you anxious or uncomfortable. You will not be expected to discuss any topics that make you uncomfortable or that you do not wish to discuss and you can leave the therapy sessions at any time.

**The research staff are committed to ensuring the privacy and security of your data; however, if you are currently under court supervision or parole, please consider the fact that in the unlikely event of a data breach, information you may share with researchers regarding prohibited conduct could potentially affect your community supervision status.**

The researchers will try to minimize these risks by keeping your information confidential. We will not tell anyone your answers to interview questions. Your name will not appear in any reports. Consent forms and identifying information will be kept separate from the actual participant data. All identifying information will be kept locked at all times and computer files will be saved with passwords. For the video/audio recordings of the therapy sessions, we will ask you not to give your name or any information that would allow someone to determine your

identity in the recording. Recordings will be uploaded onto a secure computer server and stored in a password protected file. These recordings will be used only in a research setting by researchers involved in this project and the information will be kept confidential. Files will be destroyed following completion of the research project. We have obtained a Certificate of Confidentiality which also helps make sure that all your information remains confidential.

Privacy during the video therapy sessions will be achieved by the therapist being in a private interview room; no other person will observe the live video session and the therapist will allow you to survey the room where the therapist is located to ensure privacy and confidentiality.

As with any research study, there may be additional risks that are unknown or unexpected.

**5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

**5.3 If I take part in this study, can I also participate in other studies?**

*Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

**5.4 How could I benefit if I take part in this study? How could others benefit?**

You may not receive any personal benefits from being in this study. It is possible that discussion during the therapy sessions may be beneficial to you. As part of the written information you will be given, you will learn about resources including treatment prevention, mental health support, and treatment providers in the area. Results from this study may help us develop prevention and interventions that help young adults reduce risk behaviors related to alcohol use and conflicts with others.

**5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

## 6. OTHER OPTIONS

**6.1 If I decide not to take part in this study, what other options do I have?**

Participation in this study is voluntary. If you should choose not to participate, your treatment in the ED will not be affected in any way.

## 7. ENDING THE STUDY

**7.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

**7.2 Could there be any harm to me if I decide to leave the study before it is finished?**

It is not anticipated that any harm would be experienced if you decide to leave the study before it is finished. Your decision to withdraw your authorization (consent) for the research use and disclosure of your medical record information will have no effect on your current or future medical care at a Hurley Medical Center, an affiliated health care provider or your current or future relationship with a health care insurance provider.

**7.3 Could the researchers take me out of the study even if I want to continue to participate?**

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

## 8. FINANCIAL INFORMATION

**8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?**
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?**

You will be given $20 today for completing the initial survey and interview for your time and to help cover the cost of using data if you are put in remote therapy as you will set up your smart device for the video therapy sessions. Today you will go home with a gift card which will have amounts loaded onto it at different time periods depending on which part of the study are placed.

**If you are participating in remote therapy**, your gift card will be loaded with $10 for each of the 8 therapy sessions you complete to help cover the cost of data usage (up to $80).

**Regardless of which part of the study you are placed**, you will also receive $5 for notifying us of an address/telephone change. You will also receive $30 for completion of the 4-month follow-up interview.

The most you can receive for participating in the entire study is $140, depending on which group you are assigned.

**8.3 Who could profit or financially benefit from the study results?**
No person or organization has a financial interest in the outcome of the study.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

### 9.1 How will the researchers protect my information?

You may be worried about the privacy of your answers. We will not tell family or friends or hospital staff about what you said. Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. All paper forms will be stored in locked file cabinets. Computer data files will be saved with passwords. For the audio/video recordings, your name and other identifying information will not be included in the taping. These recordings will be used only in a research setting by researchers involved in this project and the information will be kept confidential. Audio files will be destroyed following completion of the research project. Text message data that you provide will be stored on a secure server with passwords.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: If we see (learn) something that would immediately endanger you, your child, or others, we may discuss it with you, if possible, or seek help. If the researchers learn about intent to do serious harm to yourself or others, however, they will take steps to protect the person(s) endangered even if it required telling the authorities without your permission - but we would only disclose information to the extent necessary to prevent harm to the person(s) believed to be endangered.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive such information, then the researchers may not use the

Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

We shall not allow anyone to see your record, answers, or test results, including clinical staff. You will not be identified in any reports on this study.

If you are put in the jail/prison during the follow-up period, we will keep study participation and previous test results confidential from parole officers and the department of corrections officials.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. 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.

**9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- All records relating to your condition, the treatment you have received, and your response to the treatment

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

**We encourage you not to record or save the video sessions on your device so that none of your information will be accidentally shared with anyone who picks up your phone. We also encourage you to use a password or passcode on your device. You are responsible for maintaining the privacy of the information discussed during the video therapy sessions conducted on your personal device.**

**9.3 What happens to information about me after the study is over or if I cancel my permission?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

You may withdraw, at any time, your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study. However, if you withdraw your authorization (consent) for the use and disclosure of your identifiable medical record information, you will also be withdrawn from further participation in this research study. Any identifiable medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your authorization may continue to be used and disclosed by the investigators for the purposes described above.

Hurley Medical Center is required by law to protect medical information about you. Information regarding HMC's privacy policy can be found at http://www.hurleymc.com/patient-privacy-policy/.

Study information that is kept within the University of Michigan Health System, is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

**9.4 When does my permission expire?**

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

## 10. CONTACT INFORMATION

**10.1 Who can I contact about this study?**

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

**Principal Investigator:** Quyen Ngo, PhD
**Mailing Address**: University of Michigan
Injury Prevention Center
2800 Plymouth Road

NCRC Building 10, Suite G080

Ann Arbor, MI 48109
734-764-2021

**Study Coordinator:** Mandilyn Graham, MA
**Mailing Address:** Hurley Medical Center
One Hurley Plaza, SON Room 313
Flint, MI 48503
Telephone: 810-262-4874
Email: mindandvoiceproject@med.umich.edu

**Hurley Medical Center:** F. Michael Jaggi, M.D.
Hurley Medical Center
One Hurley Plaza
Flint, MI 48503
Telephone: 810-262-9854

You may also express a concern about a study by contacting the Institutional Review Board listed below.

**University of Michigan Medical School**
**Institutional Review Board (IRBMED)**
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

**Hurley Medical Center**
**Institutional Review Board**
1 Hurley Plaza
Flint, MI 48503-5993
Telephone: 810-257-9974

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

## 11. RECORD OF INFORMATION PROVIDED

**11.1 What documents will be given to me?**

Your signature in the next section means that you have received copies of all of the following documents:

- You will receive a copy of the signed and dated informed consent. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*
- *You will receive a health pamphlet*

## 12. SIGNATURES

**Sig-A**

**Consent/Assent to Participate in the Research Study**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

**Sig-B**

**Consent/Assent to video/audio recording solely for purposes of this research**
This study involves video and/or audio recording. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

**Sig-G**

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name:
_____

Title:
_____

Signature: _____

Date of Signature (mm/dd/yy): _____