Written safety planning vs the Safety Net app: A prospective randomized pilot trial

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KEY INFORMATION FOR THIS STUDY (WRITTEN SAFETY PLANNING VS THE SAFETY NET APP: A PROSPECTIVE RANDOMIZED PILOT TRIAL)

This first page gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

We are asking you to choose whether or not to volunteer for a research study about whether people would be interested in working with a peer support specialist or other research staff member in order to create a safety plan. Peer support specialists are UAMS nonclinical staff members who are participating in Emergency Department (ED) clinical research and who have experienced mental health challenges, often as patients themselves. Peer support specialists and other research staff have received extensive training in safety planning, which is one way to help people manage thoughts of self-harm.

Please ask the research team if you have any questions about anything in this form. We have included detailed information after this page. If you have questions later, the contact information for the research investigator in charge of the study is on the next page.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The usual standard of care in the ED for patients who are having thoughts of harming themselves is for clinical personnel (i.e., psychiatric nurse or social worker) to assist them in completing a written safety plan. By doing this study, we hope to learn whether ED patients like you would be interested in obtaining more information about working with a peer support specialist or other research staff member in order to create either a written safety plan or an electronic safety plan. Your participation in this research will last about as long as it takes to fill out a safety plan and a survey (about 20-45 minutes).

WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer for this study to help us better understand the difference between a traditional written safety plan and an electronic safety plan. For a complete description of benefits, refer to the Full Consent.

WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study if you do not have the time to fill out the study survey, if you object to us looking in your medical record, if you object to working with a peer support specialist or other research staff member, or if you do not want other people to know (even anonymously) about your experiences with thoughts of self-harm. For a complete description of risks, refer to the Full Consent.

DO I HAVE TO TAKE PART IN THE STUDY?

No. It is okay to say no. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

If you are a student or an employee at UAMS, nothing about your academics or employment will change no matter what you decide.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

You can contact the person in charge of the study, Dr. Michael Wilson of UAMS, with any questions, suggestions, or concerns at .

If you have any questions, suggestions, or concerns about your rights as a volunteer in this study, or wish to speak to someone not directly involved in the research, you can call the UAMS Institutional Review Board at 501-686-5667 during business hours.

If you want to know more about the research, let the study team know so they can give you more information.

Also tell the study team if you have decided you don't want to be in the study. It is perfectly okay to say no.

University of Arkansas for Medical Sciences Informed Consent Form

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **You can still get your medical care from UAMS even if you are not in the study.**

Why am I being asked to be in this research study?

- When you arrived at the ED, you told the triage staff that you were having thoughts of harming yourself. The usual standard of care in the ED for patients who are having thoughts of harming themselves is for clinical personnel (i.e., psychiatric nurse or social worker) to assist them in completing a written safety plan. A safety plan is a brief intervention that is used for suicide prevention. We would now like to know how valuable an electronic safety plan is compared to a traditional written safety plan.
- We are asking people like you who are visiting the emergency department for thoughts of self-harm to participate. Up to 30 people over the age of 18 years old will be part of this study. All of these patients will come from UAMS.

What if I don't understand something?

- This form may have words you don't understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.
- You are free to ask questions at any time before, during, or after you are in the study.

What if I say yes, I want to be in this study?

We first will see if you qualify to be in the study. We will:

- Ask you some questions about yourself, including your age. These questions may be somewhat personal, and we will ask about your experiences with thoughts of self-harm and/or suicide.

If you are accepted into the study, we will do these things:

- We will ask you to answer some questions about yourself and your experiences with thoughts of self-harm and/or suicide. You may skip any question you do not want to answer. These questions are designed for you to answer them yourself. However, we can read the questions out loud and fill out the survey with you, if you like.
- A safety plan will be put together with the help of a nonclinical staff member (either a certified peer support specialist or research staff member). In order for us to determine if patients prefer to complete a traditional written safety plan or an electronic safety plan, you will be randomly assigned to one of two groups:
  - ✓ If you are in the first group, we will ask you to complete a traditional written safety plan with a nonclinical staff member.
  - ✓ If you are in the second group, we will ask you to complete an electronic safety plan with a nonclinical staff member.
- Please note that your chance of being in either group is random "like a flip of a coin toss," although we will not use a coin for this.
- This written safety plan or electronic safety plan will encourage you to a write or type the following items: personal signs of a crisis; helpful internal coping strategies; social contacts or settings which may distract from a crisis; family members or friends who can be contacted for help when in crisis; mental health professionals who can be contacted when in crisis; and ways to restrict access to lethal means. The safety plan will then be uploaded to your electronic medical records by UAMS clinical personnel.
- We will ask you to complete a study survey concerning your demographics, any history of previous suicidal behaviors, and satisfaction with the safety planning process.
- We will look in your medical chart to find out more information including your name, past medical history, psychiatric diagnoses, why you presented to the ED (in other words, your chief complaint), the number of your visits to the ED three months before and after today, treatment plan (length of stay in the ED, any diagnoses, and whether you were observed, admitted, discharged, or transferred) for today's visit, and your medical record number. This information is collected in order to compare the two groups in this study.

How long will this study take?

- We estimate that it will take at least 20-45 minutes or so to make a safety plan and answer the study survey.

Who will see the information about me that is collected?

- The local study team will know your name and have access to your information. We will do our best to make sure no one outside of the study knows you are part of the study.

- When we share the results of the study in medical journals, we will not include your name or any other information that allows people to identify you personally.
- There are people who make sure the study is run the right way. These people may see information from the study about you including information that identifies you. They are:
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires we tell the authorities if we learn
  - ✓ about possible child or adult abuse
  - ✓ that you might hurt yourself or someone else

Where and how long will my information be kept?

- We will code the information about you and your experiences with thoughts of self-harm and/or suicide and keep this in a separate file from your medical information.
- Only the researchers will have access to the code for your information.
- Clinical personnel will put the information on your safety plan in your medical record, this information will remain part of the medical record.
- We will store the information about you and your experiences with thoughts of self-harm and/or suicide for 7 years.

What if I say no, I do not want to be in this study?

- Nothing bad will happen. We will not collect research information about you.
- You can still complete a traditional written safety plan with clinical personnel which is the usual standard of care in the ED for patients who are having thoughts of self-harm.
- You can still get medical care at UAMS. The emergency department will still assist you with your mental health needs even if you choose not to participate in this study.

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

- You can stop being in the study at any time.
- Nothing bad will happen.
- You can still get medical care at UAMS.
- If you decide to stop being in the study, please tell the staff member that is collecting our data. You may also send the study doctor, Dr. Michael Wilson, an email at the UAMS Department of Emergency Medicine, . He will do everything

possible to remove your information. However, this may be impossible in some cases if the data has already been reported.

Can I be taken out of the study even if I want to continue?

Yes, the study doctor (or head researcher) can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.

If I stop being in the study, what will happen to any information collected from me in the study?

- We may be able to remove your information if it has not already been reported.

Will my information from the study be used for anything else, including future research?

- No. Your information will be used only in this study.
- Other investigators on this study team may see your data, but only after your name and all other identifying information is removed.

Will it cost me anything to be in the study?

- No. There is no cost to be in the study or to work with a peer support specialist or other research staff, but the emergency department visit will be charged to you or your insurance company in the usual way.

Will I be paid?

- Yes. You will receive a small payment ($25 gift card).

Will being in this study help me in any way?

- You may or may not benefit from being in this study.
- If you are in the study, you will be able to work with a peer support specialist or other research staff member.
- Being in the study may help us learn more about whether people find it valuable to complete an electronic safety plan compared to a traditional written safety plan.

What are the risks of being in this study?

The risks of being in this study include:

- Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.
- The questions could make you sad or upset.
- In addition, this study may involve other risks that are not currently known.

What if I get sick or hurt while I'm in this study*?*

- If you get hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care and/or follow-up care.
- If you are not here and get hurt or sick, and think it is because of the study, do these things:
  - ✓ tell your doctor or ER staff
    - the name of this study (say "the Safety Net app study" or "Written safety planning vs the Safety Net app: A prospective randomized pilot trial")
    - the name of the head researcher for this study (Dr. Wilson)
    - a copy of this form if you have it
- This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of payment is available.
- You will not give up any of your legal rights by signing this form.

What are the alternatives to being in this study?

You do not have to be in this study. If you do not want to be in this study, your options are:

- To not be in the study. In this case, we will not collect information about you.
- You can still get all regular medical care at UAMS.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about being in the study.
- The researcher will let you know by*:*
  - ✓ telling you in the emergency department

Where can I find more information about this clinical trial?

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At

most, the website will include a summary of the results. You can search this website any time.

- You can ask the research staff questions while you are in the emergency department or email Dr. Wilson at .

What if I have questions?

- Please call the head researcher of the study, Dr. Wilson at , if you:
  - ✓ have any questions about this study
  - ✓ have questions about your rights
  - ✓ feel you have been injured in any way by being in this study
- You can also call the (UAMS Institutional Review Board) at 501-686-5667 if you:
  - ✓ have questions about this study
  - ✓ have questions about your rights
  - ✓ can't reach the study team
  - ✓ need to speak to someone not directly involved with this study

What should I do if I want to be in the study?

- Sign this form. We will give you a copy of this form to keep.

By signing the document, I am saying:

- I understand that joining this study is voluntary.
- I agree to be in the study.
- Someone talked with me about the information in this document and answered all my questions.

I know that:

- I can stop any and all parts of the study at any time and nothing bad will happen to me.
- I can call the offices that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights, or if I wish to speak to someone not directly involved in the research.
- My decision will not change my medical care at UAMS.
- I do not give up any of my rights by signing this form.

I agree to be part of this study:

_____	_____
Your name (please print)	Your signature
_____	
Date	
_____	_____
Name of person obtaining consent (please print)	Signature of person obtaining consent
_____	
Date	