PHARM-S.A.V.E.S: Suicide Prevention Gatekeeper Training for Pharmacy Staff

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants: Community Pharmacy Staff

Consent Form Version Date: January 20, 2023
IRB Study #: 21-1062
Title of Study: Pharm-SAVES: Suicide Prevention Training for Pharmacy Staff
Principal Investigator: Dr. Delesha Carpenter
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CONCISE SUMMARY

The purpose of this research study is to evaluate the effectiveness of a new suicide prevention training (Pharm-SAVES) that was designed specifically for community pharmacy staff. Participants will complete three approximately 10-minute online training modules, or 30 minutes in total, for the first phase of the study. You will be asked to complete three surveys: one before training, one immediately following the training, and one at one month after the training. At one month post-training, you will be given the option to complete a 20-minute standardized patient exercise to further evaluate the effectiveness of the training. This is not required to complete the study. You will be provided with a separate consent form if you are interested in the standardized patient exercise. You may not directly benefit from being in this research study.
We do not anticipate major risks during the study; however, the greatest risks of this study include breach of confidentiality and emotional distress. Because your answers will be recorded via an online platform, there may be a chance that they cannot be kept confidential. In addition, the discussion of suicide and suicidal behaviors may make you feel uncomfortable.
If you are interested in learning more about the study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. You do not have to be in this study if you don't want to. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to scientifically obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your employer, or the University of North Carolina-Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to educate community pharmacy staff on how to identify patients who are at risk of suicide and refer them to appropriate resources (i.e. the Crisis Line). This study will do that by teaching community pharmacy staff to identify the signs of

suicide, to ask the patient if they are thinking about suicide, validate the patient's feelings, encourage the patient to seek treatment, and expedite referral by having the patient call the Crisis Line or calling the Crisis Line with the patient.

Are there any reasons you should not be in this study?

You should not be in this study if you: 1) are not at least 18 years of age, 2) are unable to read and speak in English, 3) are not employed as a pharmacist or pharmacy technician at a community pharmacy, and/or 4) are a floater or hold temporary employment status as a pharmacist or pharmacy technician at a community pharmacy.

How many people will take part in this study?

If you decide to be in this study, you will be one of 150 participants.

How long will your part in this study last?

Your part in this study will last approximately 75 minutes total, including a 30-minute training, over a one-month period.

What will happen if you take part in this study?

At the start of the study, you will be asked to complete an online survey. Then you will be asked to review an ~30-minute online module. Participants will be randomly assigned to either receive an interactive video case or not receive an interactive case as part of the module. At the end of the module, you will be asked to complete a 10-15-minute follow-up survey so you can receive CE credit for the training.

One month after you complete the training, the study coordinator will reach out to you to complete a final 10-15 minute survey. At that time, the study coordinator will also invite you to complete an optional 20-minute standardized patient assessment that will be recorded on Zoom. The standardized patient encounter is not required to complete the study.

What are the possible benefits from being in this study?

There may not be any direct benefit to you. However, this training will provide free suicide prevention education and we hope that information gained from this study will help to improve future suicide prevention gatekeeper training courses.

What are the possible risks or discomforts involved with being in this study?

You should not experience any discomfort by taking part in this study. However, the topic of suicide may make you feel uncomfortable. If you feel uncomfortable or wish to stop, you have the right to discontinue participation at any time. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new information during the study?

You will be given any new information gained during the study that might affect your willingness to continue your participation.

How will your privacy be protected?

You will be assigned an identification number when you agree to participate in the study. All data collected in this study will be recorded under the identification number, not your name. A list which links your name to the identification number will be kept in a password-protected file on a secure UNC server. Only Dr. Carpenter and the study staff members will have access to the list that links names to identification numbers. Participants will not be identified in any report or publication about this study. Nor will any deidentified data be used for any additional research without additional consent.

Although every effort will be made to keep research records private, there may be times when

federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected from this study up until the point of withdrawal will be retained, however no additional data will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will it cost you anything to be in this study?

There will be no costs for being in the study.

Who is sponsoring this study?

This research is funded by the American Foundation for Suicide Prevention (AFSP). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Will you receive anything for being in this study?

You will receive CE credit and a $20 Amazon eGift card for completing the post-training survey and an additional $30 Amazon eGift card for completing the 1-month follow-up survey.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

- ○ Yes. I wish to participate. (1)
- ○ No. I do not wish to participate. (2)