Designing a Mobile App to Support Academic Success for Student Veterans

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Title of Study: Designing a Mobile App to Support Academic Success for Student Veterans

Principal Investigator: Erin Reilly, Ph.D. VA Facility: VA Bedford Healthcare System

Sponsor of Study: Department of Veterans Affairs

We are asking you to choose whether or not to volunteer for a research study. This consent form will give you information about the study to help you decide whether you want to participate. Taking part in this study is completely voluntary.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is focused on developing a mobile health intervention to help student Veterans also managing mental health issues to improve their academic functioning. This mobile application is called *VetEd*, short for Veteran Education mobile app. It is being funded by the Rehabilitation R&D Small Projects in Rehabilitation Research (SPiRE). By doing this part of the study, we hope to learn what participants like about the VetEd mobile application and their reactions to the content.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

During the study, you will participate in one initial study visit to determine your eligibility for this study. This study visit could be done virtually or in person. This visit will involve an interview and several questionnaires. This visit will take about 2.5 hours of your time. If you are eligible for this study, you will be invited to participate in our testing of the *VetEd* mobile application. You will be asked to download the *VetEd* mobile application onto your personal mobile device and to use it over the course of four weeks. There will be two more study assessments. The next assessment period will take place halfway through your app use experience (2 weeks after your enrollment), and take about 45 minutes. The final assessment will take place after you finish using the app for 4 weeks, which will take about 2 hours. These study assessment sessions may be able to take place in person or virtually using VA-approved video-conferencing software like VA Cisco WebEx. In these sessions, you fill out several questionnaires and you will be interviewed about your thoughts about the *VetEd* mobile application. You will be given $80 the first study visit. You will then be paid $40 for the 2-week midpoint assessment, and $90 for the final 4-week assessment visit. You will be paid by a gift card. You may receive these gift cards at your next scheduled in-person or we can mail them to you.

We will ask you to provide the names of three people we can contact in case we have difficulty reaching you. This information will help us be able to reach you regarding this study in case we lost contact with you.

During the study, we will access information from your VA Health Records such as diagnoses, progress notes, and specific information concerning VA treatment to determine how your other treatments may be influencing your outcomes for this study.

We will ask to record your interview responses about the *VetEd* mobile app. You will not be able to participate in this study if you do not agree to be recorded.

2. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Using the mobile app focused on improving you educational functioning in this study may improve ability to use study strategies, cope with academic stressors, and knowledge of resources available to student Veterans.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is the possibility that answering some questions may be emotionally upsetting. You have the choice to not answer any question that makes you feel uncomfortable.

3. DO YOU HAVE TO TAKE PART IN THE STUDY?

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.

4. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Erin Reilly of the VA Bedford Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 781-687-4191.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to participate in a research study to test the usability and content of a mobile application to help student Veterans to meet their educational goals in higher education. This mobile application is called *VetEd*. You are invited to participate in teh usability testing phase of this mobile study, where we will show you parts of this program and ask you your thoughts about it. You are being invited to participate in this study because you are a Veteran who is currently enrolled in at least 2 college courses.

This research study will enroll Veterans enrolled in the VA Bedford Healthcare System and in the community. The Bedford VA Medical Center expects to enroll 15 research study subjects in this part of the study.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 24 months. Your individual participation in the project will take 4 weeks.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

Intake and Interview Procedures. If you decide to participate in this research study, you will have an in-person or virtual screening (by VA-approved video conferencing software) with a member of the research team and you will be asked to complete questionnaires. We will ask you about your academic experiences and current classes. You will also be asked questions about possible current and past psychological or emotional difficulties. This is done because such problems are sometimes associated with academic issues, and because such problems may affect your efforts to improve your educational functioning. These interviews and questionnaires will take about 2.5 hours of your time. We will also ask for the names, contact information, and a release of information for people that you know that would help us be able to get in touch with you. If you do not meet eligibility criteria during this screening, you will be excluded from participation. If you meet eligibility criteria, you will be asked to participate in the usability testing phase of the study.

Usability Testing Phase. You will be asked to download the *VetEd* mobile app onto your mobile device. We will ask you to engage in this app over the course of 4 weeks. You will be asked to engage with different content areas related to creating an online roadmap, strategies for leaning, coping with stressors, and learning more about VA resources. You can use this program at your own pace, but we ask that you complete two activities a week for a total of 8 activities over 4 weeks. Each activity should take about 15 minutes of your time.

Study assessment appointments. Study assessment appointments will be scheduled for 2-weeks and 4 weeks after you start to use the VetEd app. These appointments may be done in-person or virtually using VA-approved video conferencing software. At these appointments, we will ask you fill out a series of questionnaires about academic experiences, community reintegration, and psychological and emotional difficulties. We will also ask you interview questions about your experience with the mobile app and your satisfaction with it. We will audio or video record your responses to these interview questions. The total time for follow-up appointments will be 45 minutes for the 2-week assessment, and 2 hours for the final 4-week assessment. We will call you to remind you about your appointments.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

There may be unanticipated risks. If you are or become pregnant, the research may involve risks to the subject (or to the embryo or fetus) that are currently unforeseeable. If you have any unusual or uncomfortable feelings during the study, contact the research staff. You can reach a study staff by calling a member of the research team during normal business hours. You can also come into the Mental Health Clinic (Hours: Monday-Friday, 8:00 am-4:00 pm; Building 78, 2nd Floor; 781-687-4333). You may also come into the Bedford VAMC Urgent Care Center during their main hours (Monday-Friday, 8:00 am-4:00 pm; Building 78, 1st Floor; 781-687-2654) or after

hours. You may also call the doctor on call after hours (781-275-7500). If you become suicidal, hospitalization is possible.

Since we are concerned about your health and safety, there are some situations when we will contact your primary care physician or other clinical professional that is providing care for you, such as to inform him/her that:

- You need to be taken to Urgent Care for medical reasons
- You report suicidal thoughts or homicidal thoughts
- You are hospitalized
- You experience serious side effects that are a concern to you and/or the study team
- You experience an adverse event or reaction that occurs in the course of the study where the PCP or mental health provider has not already been informed.
- You may be potentially harmed by continued participation in the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others student Veterans.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY? (Include if applicable)

You are free to decline entrance into or withdraw your participation in this study at any time. If you decline to participate or withdraw from the study, and you desire treatment, you will be provided with information about mental health treatment in the VA and in the community. Mental health treatments at the VA include medications and counseling. Similar treatments are available through treatments in the community. A decision not to participate in this study or to withdraw from this study will not affect your ability to participate in other VA treatment, including VA educational services and mental health treatment.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this research may involve a loss of privacy. However, numerous safeguards will keep electronic and hard copy data secure. Your research records will be kept as confidential as possible. All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data.

We will ask to record your feedback interview after using the mobile application so that the study investigators can record the discussion and ensure the quality of the interview. These recordings will be only audio if groups are conducted in person, or video- and audio-recorded if occurring online through teleconferencing software. You can choose whether to participate in-

person or online. All recordings will be kept confidential and will be listened to only by study personnel. No video or audio recordings will be disclosed outside the VA. You will not be able to participate in this study if you do not agree to be audio or videotaped.

Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP) and the Government Accountability Office (GAO) may have access to the records.

Identifiers might be removed from the identifiable private information collected. After the removal, the information could be used for future research studies without additional consent from you.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You, or your insurance, will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. You may refuse to participate and your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may also discontinue participation at any time without penalty or loss of benefits to which you are entitled.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled by informing the PI (Dr. Erin Reilly) or other study staff via a phone call or in-person.

For data already collected prior to the participant's withdrawal, we will continue to review the data already collected for the study but cannot collect further information, except from public records.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call **Dr. Erin Reilly at 781-687-4191 during the day or have the doctor on call (781-687-2000) paged after hours.**

VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures. No money has been set aside for compensation in case of injury as a result of participating in this study however I have been told that I would still have the right to file any legal action.

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WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions about the research, you may contact Dr. Erin Reilly at 781-687-4191.

If you have any questions, concerns, or complaints about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board Coordinator, Denise Carr at 781-687-2839, and the information will be given to the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Reilly or study staff have explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.