Submission Type: Initial Date: 4-12-2023

IRB #: IRB-22-336
Title: Suicide Risk Assessment and Safety Planning Training Using an Online Patient Simulation: Assessing Acceptability and Preliminary Efficacy
Creation Date: 12-15-2022
Status: Review Complete
Principal Investigator: Christina Sellers

Section 1 Getting started

About Cayuse IRB
Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all numbered sections may appear. You do not have to finish the application in one sitting. All information can be saved.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark in the top-right corner of each section.

Prior to starting your IRB application, please be sure you have read the IRB Manual: Instructions to Investigators and completed CITI Training.

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the Cayuse IRB Procedures Manual.

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*required

I have read the information above and am ready to begin my submission

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✓ Yes

Getting Started

Throughout the submission, you will be required to provide the following, as applicable:

- Detailed Study Information
- Informed Consent Forms
- Study Recruitment Document(s)

Simmons University IRB

- You cannot begin data collection until a formal approval letter from the chair of the IRB has been received.
- Please submit the application as soon as possible.

Section 2 Investigator Information

*required

2.1 What is your status at Simmons University?

Student

✓ Faculty

Staff

*required

Principal Investigator

2.2 Name: Christina Sellers

After entering the appropriate PI, please click "view" under "trainings." This will show completed CITI trainings. If you do not see any trainings listed, and this person has completed the required CITI training, please attach the certificate here.

Sellers_CITI.pdf

Co-Investigator(s)

Your co-investigators will be required to certify this submission prior to review.

2.3

Name: Cali-Ryan Collin

After entering the appropriate Co-PI(s), please click "view" under "trainings." This will show completed CITI trainings. If you do not see any trainings listed, and this person has completed the required CITI training, please attach the certificate here.

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*required

Primary Contact

2.4 *Who should be contacted for questions or changes regarding this protocol? (Can be the same as Principal Investigator)*

Name: Christina Sellers

Faculty Advisor

2.5

If you are a student, please select your faculty advisor for this project. Your faculty advisor is required to guide you through the submission process and sign off on your protocol.

After entering the faculty advisor, please click "view" under "trainings." This will show completed CITI trainings. If you do not see any trainings listed, and this person has completed the required CITI training, please attach the certificate here.

Other Personnel

2.6 *Provide names of other personnel in this study who do not need access to this protocol (for example, student research assistants)*

Name: Eileen Dacey

Personnel at other institutions

2.7

Personnel at collaborating institutions cannot have access to our Cayuse database. You may download a copy of your protocol as a PDF and share it with them that way. Please add their names and their roles below.

Please attach the CITI training (or equivalent) certificate(s) of personnel from other institutions who are involved in your study.

If you cannot find the appropriate Simmons contacts, please contact the IRB via irbprotocols@simmons.edu

You may also share this form so that they may request a Cayuse account.

Section 3 Project Information

*required

3.1 Do you need assistance determining which type of application you should submit?

Projects include Human Subjects Research Project, Performance/Quality Improvement Project, or Classroom Project.

- Yes
- ✓ No

*required

3.2 Please select the type of project you are submitting.

- ✓ Human Subjects Research Project
- Classroom Project
- Performance Improvement Project

*required

3.3 Is this project being reviewed by another institution's review board?

- Yes
- ✓ No

*required

3.4 Is this project being submitted to a funding agency/organization?

Yes

✓ No

3.4.1 Is there any current funding for this project?

✓ Yes

3.4.1a Please choose the sponsor below and include the funding announcement (if available).

3.4.1b If agency is not listed, please provide the name here

Simmons University Faculty Fund for Research

3.4.1c Please upload the funding announcement here (if available).

No

*required

3.5 Start and End Dates of Project

Start Date

01-03-2022

End Date

01-01-2024

*required

Brief description of project

3.6

approximately 10 sentences or less

Suicide is the tenth leading cause of death in the United States, and the second leading cause of death among youth and adults aged 10-34 (Heron et al., 2021). As leading providers of mental health services who routinely work with clients with suicidal thoughts and behaviors (STBs), it is imperative that social workers be knowledgeable and confident and implement evidence-based practices for suicide risk assessment and safety planning. Online patient simulation (OPS) is an innovative pedagogical tool allowing students to build clinical skills while receiving both real-time and asynchronous feedback. Recent research has found OPS is a feasible and acceptable method to train new clinicians in suicide prevention skills and has suggested this may be a particularly well suited in educational settings (O'Brien et al., 2022). To our knowledge, no research has tested OPS as a way to train masters level social work students in suicide prevention. Therefore, we aim to pilot test an OPS for training masters level social work students in suicide prevention. **Specific Aim:** Use pre-post quantitative data to evaluate a pilot program training MSW students enrolled in SW464 with an OPS for suicide risk assessment and safety planning.

*required

Does your project involve any of the following populations?

3.7

Projects that involve any of the below "vulnerable" populations and involve greater than minimal risk may receive a full review.

- Children under 8 years of age
- Children 8-17 (under 18 years of age)
- Prisoners
- Economically disadvantaged
- Educationally disadvantaged
- Individuals with impaired decision-making ablity
- ✓ None of the above

*required

Does this project include secondary data analysis?

3.8 Secondary data analysis involves the re-use of data and specimens that were or will be collected for non research purposes or from research studies other than the proposed research study. The research materials generally will be publicly available materials, medical records or existing repositories of clinical specimens. Non contact between investigator and subject is allowed.

- Yes
- ✓ No

3.9 If you will be utilizing any outside agencies to conduct your research, please attach the appropriate permission letters or emails from the agencies indicating their willingness to cooperate with your research.

*required

Will you be recording identifiable, private information about individual subjects?

3.10 Private information is considered to be identifiable when it can be linked to specific individuals either directly or indirectly through a coding system. For example, collecting detailed demographic information or information on personal experiences qualifies the data collected as identifiable private information

- ✓ Yes

  By selecting this answer, you understand that you are obligated to protect and keep confidential any identifiable, private information gathered about individual

subjects through the conduct of your research; and you agree to keep such information confidential, unless you obtain the subject's express written permission to do otherwise.

*required

✓ I understand the above statement and agree to keep such information confidential, unless I have received the subject's express written permission to do otherwise.

No

*required

3.11 Will you be utilizing audiotapes or videotapes in your research?

Yes

✓ No

*required

3.12 When you have completed your contact with the research participant, will there be a debriefing session?

Yes

✓ No

Section 4 Project Description

Please fill out the questions below for human subjects research and performance improvement projects.

If a question is not applicable to your study or project, which may occur in cases of secondary data analysis or performance improvement projects, you may write "not applicable." Sufficient detail should be provided so that the IRB may determine the level of risk and the purpose of the proposed study or project.

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*required

General Description. Briefly describe the overall goals of the proposed research and the general procedures you plan to use in conducting your research project.

4.1

Suicide is the tenth leading cause of death in the United States, and the second leading cause of death among youth and adults aged 10-34 (Heron et al., 2021). As leading providers of mental health services who routinely work with clients with suicidal thoughts and behaviors (STBs), it is imperative that social workers be knowledgeable and confident and implement evidence-based practices for suicide risk assessment and safety planning. Online patient simulation (OPS) is an innovative pedagogical tool allowing students to build clinical skills while receiving both real-time and asynchronous feedback. Recent research has found OPS is a feasible and acceptable method to train new clinicians in suicide prevention skills and has suggested this may be a particularly well suited in educational settings (O'Brien et al., 2022). To our knowledge, no research has tested OPS as a way to train masters level social work students in suicide prevention. Therefore, we aim to pilot test an OPS for training masters level social work students in suicide prevention. **Specific Aim:** Use pre-post quantitative data to evaluate a pilot program training MSW students enrolled in SW464 with an OPS for suicide risk assessment and safety planning.

*required

Significance of the Study. Provide a brief theoretical and empirical rationale for why you believe this study is important. Include a concise review of literature including conceptual framework, and specific hypotheses to be tested and/or research questions

to be addressed.

Suicide is the tenth leading cause of death in the United States, and the second leading cause of death among youth and adults aged 10-34 (Heron et al., 2021). As leading providers of mental health services who routinely work with clients with suicidal thoughts and behaviors (STBs), it is imperative that social workers be knowledgeable and confident and implement evidence-based practices for suicide risk assessment and safety planning. Online patient simulation (OPS) is an innovative pedagogical tool allowing students to build clinical skills while receiving both real-time and asynchronous feedback. Recent research has found OPS is a feasible and acceptable method to train new clinicians in suicide prevention skills and has suggested this may be a particularly well suited in educational settings (O'Brien et al., 2022). To our knowledge, no research has tested OPS as a way to train masters level social work students in suicide prevention. Therefore, we aim to pilot test an OPS for training masters level social work students in suicide prevention. **Specific Aim:** Use pre-post quantitative data to evaluate a pilot program training MSW students enrolled in SW464 with an OPS for suicide risk assessment and safety planning.

The impact of suicide

As the tenth leading cause of death in the United States (Heron et al., 2021), there is an urgent need to equip social workers and other mental health providers to work effectively with youth and adults with STBs. The national cost of suicides and suicide attempts is estimated at $70 billion per year in lifetime medical and work-lost costs (Centers for Disease Control and Prevention, 2022). This toll is rising—between 1999 through 2018, the national suicide rate increased by 35% for the general population and by 54% for youth aged 10-19 (CDC, 2020). Highlighting the rising suicide risk for adolescents, the 2019 Youth Risk Behavior Survey found that during the previous 12 months, 18.8% of high school aged youth nationwide reported seriously considered attempting suicide, 15.7% of students had made a plan about how they would attempt suicide, 8.9% of students had attempted suicide ≥1 time, and 2.5% of students had made a suicide attempt requiring medical treatment (Ivey-Stephenson et al., 2020).

Need for more professional training

4.2

Research has shown that social work curricula devote little time to suicide prevention training, and social work students feel unprepared to work with clients who express suicidal ideation (Feldman & Freedenthal, 2006; Ruth et al., 2012). Feldman & Freedenthal (2006) surveyed 598 social workers from the 2002 membership roster of the National Association of Social Workers (NASW) and found that while 92.8% of respondents reported having worked with at least one suicidal client during their careers, only 21.2% reported receiving any formal training on suicide in their masters program. Ruth et al. (2012) surveyed deans, directors, and faculty members at accredited social work masters programs and found that while 90.7% reported that suicide education was part of the MSW curriculum, 57.4% of respondents estimated that students received four hours or fewer of suicide education and just 1.9% of programs had a specific course on suicide. Moreover, in a recent survey of 267 undergraduate and graduate social work practice instructors, Mirick (2022) found that in addition to supporting evidence-based practices, many practitioners endorsed non-evidence based practices including obtaining a no-suicide contract (50.9% of participants), immediate ER referral (29.2%), and immediate referral to inpatient care (11.2%).

Training in suicide prevention has positive impacts for social workers and their clients. Behavioral

health care providers who have received suicide prevention training report greater skills to address suicide risk, greater use of evidence based practices, and higher confidence than those without specialized training (LoParo et al., 2019; Wakai et al., 2020). Greater length of training has been found to be associated with greater confidence and comfort level with implementing suicide prevention skills, but even brief training can have a significant impact on skills, confidence, and comfort (LoParo et al., 2019; Wakai et al., 2020). Finally, social workers who attend continuing education on suicide score higher on their use of evidence based practices than those who do not, indicating the importance of continuing education on suicide prevention throughout social workers' careers (Mirick et al., 2022).

Simulation as a promising tool

Simulation, a form of experiential learning, is a pedagogical approach that is effective for teaching complex competencies and clinical skills (Kourgiantakis et al., 2020). Simulation provides students with equitable opportunities for practice and allows for assessment uniformity and reduction in assessment bias, while also decreasing the chance of the halo effect (Sampson et al., 2018). Simulated experiences that allow for critical thinking and reflective practice can help build a foundation of skills transferable from the simulated experience to real-life scenarios (Bogo et al., 2017). However, simulations are traditionally conducted in-person. It is essential to adapt simulation experiences to the ever-changing virtual environment, experimenting with various training delivery methods and platforms without sacrificing the quality of content (Schmutz et al., 2021). Online patient simulations (OPS) have emerged as a feasible and acceptable means of teaching clinical skill. OPS provides formative clinical practice opportunities that include opportunities for immediate feedback (Putney et al., 2021).

*required

Participant Population. Describe the characteristics of the participant population, highlighting any potential vulnerabilities in this research project. If your participant population includes vulnerable populations, please express rational for including these populations in your study.

4.3

The participant population is current Simmons University MSW students enrolled in a class during Spring 2023 semester.

This is not a vulnerable population with special protections according to the Belmont Report. However, participants may feel coerced to participate in this project given the PI is the instructor of the course. In order to protect against this risk, the PI will remain outside of the classroom during consenting and data collection procedures and remain blind to who consented to participate. There are no other population vulnerabilities known to this research team.

*required

4.3a *Participant Recruitment*. Describe plans and procedures for the recruitment of participants and the steps to obtain informed consent. Outline who will be recruited, by whom, from where, and how it will be accomplished. Include recruitment script and any recruitment materials in your attachments.

The study RA will attend the first class to introduce the study and obtain consent from interested students. Dr. Sellers will remain outside of the classroom at the time of consenting.

*required

Research Procedures and Sources of Research Material. Describe your research data collection procedures and identify the sources of research material obtained from individually identifiable living human participants in the form of specimens, records, or other data.

Study Design. The proposed research will be conducted by Dr. Sellers (PI) and Dr. Collin (Co-I). The goal of this research is to pilot test the effects of an OPS for suicide prevention skills and confidence

Ensuring students enrolled in the class are not withheld the OPS it will be offered to all students enrolled in Dr. Sellers campus-based section of the class, but for the purpose of this proposed study only consenting students data will be used.

The study RA will attend the first class to introduce the study and obtain consent from interested students. All consented students will complete the baseline assessment at this time. Dr. Sellers will remain out of the classroom during consenting and data collection. Week 2, all students will obtain access to the suicide risk assessment and safety planning OPS through SIMmersion. Students will have access throughout the entire semester to engage with the OSP. During the week 14 class, the student RA will collect the follow-up assessments while Dr. Sellers remains outside of the classroom.

4.4 Two measurement tools will be delivered at baseline and at 14 week follow-up to assess skills and confidence. In addition, we will measure student satisfaction (acceptability of the OSP) at the 14 week follow-up. Skills will be measured for both suicide risk assessment and safety planning. Student skill acquisition in suicide risk assessment will be assessed via scores on three domains: documentation and identifying next steps, covering assessment topics (ideation, intensity, behavior, and risk factors), and developing a collaborative relationship. Student skill acquisition with safety planning will be assessed via scores on three domains: covering safety planning topics (warning signs and triggers, distractions, people and resources, reducing risky behavior and making environment safe, identifying reasons for living, and confidence in plan), developing a collaborative relationship, and creating an effective safety plan. Students will also receive an overall simulation score for skill acquisition in both suicide risk assessment and safety planning. Confidence will be

measured using the Provider Confidence scale (Oordt, Jobes, Fonseca, & Schmidt, 2011), a 3-item assessment tool measuring provider confidence in working with suicidal patients. Questions include: 1) I am confident in my ability to successfully assess suicidal patients, 2) I am confident in my ability to successfully treat suicidal patients, and 3) I am hesitant to ask a patient if he or she is suicidal and are rated on a five-point Likert scale ranging from strongly disagree to strongly agree. Acceptability will be measured using the Training Evaluation Questionnaire (TEQ: O'Brien et al., 2019). The TEQ includes nine items rated on a 7-point Likert scale and includes questions such as: "How easy was the training to use?" (extremely easy to extremely difficult) and "How helpful was the training?" (extremely helpful to extremely unhelpful). Paired samples t-tests will be conducted to determine differences in the mean scores between timepoints for the sample to assess for pre to post changes. Descriptive statistics will be analyzed to assess for satisfaction.

*required

4.5 *Risks*. It is very unusual for human participants research to have zero risk to them. Describe any potential risks (For example, confidentiality and privacy matters; physical, psychological and social well-being; legal and financial risks, etc.) and assess their likelihood and seriousness.

There are two possible risks of participation including breach of confidentiality and participants feeling coerced to participate in this project. The measures collected are non-threatening. There are no other risks to participation.

*required

4.5a Technological and physical safeguards to protect data from inappropriate disclosure

Select all that apply

- ✓ Anonymizing data at point of collection (e.g. using Qualtrics to anonymize data)
- ✓ Locked room or space
- ✓ Behind a double lock (e.g. locked cabinet in a locked room)
- ✓ Restricted access to authorized research team members
- ✓ Password-protected computer or device
- Password-protected digital folder or online storage
- Encrypted file transfer

Secure Simmons University Google Drive (or secure drive from affiliated hospital or institution)

Destruction of source data immediately after processing

Destruction of audio or visual data after transcription or after data analysis has been completed

Modification of audio or visual data to eliminate identifiers

Other (describe below in 4.5c)

*required

4.5b What will you do with data or specimens at the conclusion of the study?

Select all that apply

I am not collecting any identifiers. I will retain data for the required retention period (at least 3 years after completion of the research. (45 CFR 46.115(b)) and then destroy it.

I will de-identify data or specimen logs and erase or destroy any related codes. I will retain data for the required retention period (at least 3 years after completion of the research. (45 CFR 46.115(b)) and then destroy it.

I will keep identifiable data for the required retention period (at least 3 years after completion of the research. (45 CFR 46.115(b)) and then destroy it.

I will destroy any leftover specimens.

✓ I will retain data and specimens for future use.

Other (describe below in 4.5c)

*required

Protection Against Risks. Elaborate on the procedures for protecting against or minimizing any potential risks in detail and assess their likely effectiveness. Where appropriate, describe provisions for secure storage of data.

4.5c Every precaution will be taken to protect participants' privacy and confidentiality. Administration and collection of data will be performed by the Research Assistant. Eligible subjects will be invited to participate and will receive informed consent, prior to administering the baseline measure. Consenting participants will be assigned a unique study ID which will be used for identification on all documents with the exception of a master list of participants; this list will be kept in a password protected electronic file on a secure, Simmons University computer, to which the Research Assistant and Co-I will have exclusive access. Dr. Sellers will

not have access to the master list. The data will be aggregated for purposes of analysis and reporting. Names of participants and other identifying information will never be linked to reports or presentations.

*required

Benefits. Discuss any direct, specific benefits *to participants*. (If none, please write "none")

4.6

The benefit of participation in this research is the opportunity to 1) contribute to the body of knowledge about the effective training of social work students with a focus on suicide-related content and 2) opportunity to engage in OPS to practice risk assessment and safety planning skills.

Informed Consent: Describe your consent process. (How and when you will distribute the informed consent document, when will it be collected, etc.)

4.7 ***If uploading consent form(s) please submit PDFs.***

The study RA will attend the first class to introduce the study and obtain consent from interested students. Dr. Sellers will remain outside of the classroom at the time of consenting.

Attach your consent form(s)

Please submit as PDF

ConsentForm.pdf

Recruitment Materials: Attach the materials (e.g. flyers, messages/emails, script(s)) that you will use to recruit participants.

4.8

4.9 *Study Tools*: Please attached any survey or interview questions, or other study tools relevant to your project.

Measures.docx

Section 5 Important Info

Thank you for completing your protocol. Please be sure to click "complete submission" on the bottom of the blue navigation panel to the left.

Your protocol will not be submitted for review until you, your faculty advisor, if applicable, and co-PIs, have "certified" the submission. You will do this under Submission Details. This step must be completed every time you make changes to your submission for review because it acts as your signature. Please refer to the user manual if you have questions about this step.

Once you submit your protocol for review, please allow 10 business days for review and feedback.

If you have any questions please contact irbprotocols@simmons.edu.

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*required

✓ I have read the above information and understand that my protocol is not submitted for review until I certify the submission on the submission details page. If applicable, I understand that my co-PIs and/or faculty advisor will also have to complete this step in order for my submission to be reviewed.

Section 6 IRB Office Use Only

This page may be used by the IRB Office to summarize and communicate with the reviewers, if applicable.