NCT04661566

Protocol ID: USUHS.2020-055

Optimizing a Multi-Modal Intervention to Reduce Health-Risking Sexual Behaviors: Component Selection Protocol with Statistical Analysis Plan

IRB-approved: 10/11/2022

EIRB Protocol Template (Version 1.24)

1.0 General Information

***Please enter the full title of your study:**

Optimizing a multi-modal intervention to reduce health-risking sexual behaviors: Component selection

***Please enter the Protocol Number you would like to use to reference the protocol:**

MWHR Phase II
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◉	**R and E** - Uniformed Services University of the Health Sciences (USUHS)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Landoll, Ryan R

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Quinlan, Jeffrey D, MD CAPT
Co-Investigator

B) Research Support Staff

Clark, Madison Fitzgerald
Research Coordinator

3.3 *Please add a Protocol Contact:

Clark, Madison Fitzgerald
Landoll, Ryan R

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * Has another IRB/HRPP reviewed this study or will another IRB/HRPP be reviewing this study? If Yes, answer the questions according to the IRB/HRPP Determination.

○ Yes ◉ No

IRB Name	Review Date	Determination
No records have been added		

4.2 * Is this a research study or a Compassionate Use/Emergency Use/HUD project?

◉ Yes ○ No

4.3 What type of research is this?

- ☐ Biomedical Research
- ☐ Clinical trial (FDA regulated)
- ☑ Behavioral Research
- ☐ Educational Research
- ☐ Psychosocial Research
- ☐ Oral History
- ☐ Other

4.4 Are you conducting this project in pursuit of a personal degree?

○ Yes ◉ No

4.6 * Is this human subjects research? (As defined by 32 CFR 219) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and

uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

(•) Yes ( ) No

4.7 * Do you believe this human subjects research is exempt from IRB review?

( ) Yes (•) No

5.0 Personnel Details

5.1 List any Research Team members without EIRB access that are not previously entered in the protocol:

Name: (Last, First, M.I.) Thornton, Kade Role on Protocol: Graduate Student Assistant	Phone Number:	Email Address: kade.thornton@usuhs.edu	Associated Institution: USUHS
Name: (Last, First, M.I.) De Hoyos, Victoria Role on Protocol: Graduate Student Assistant	Phone Number:	Email Address: victoria.de-hoyos@usuhs.edu	Associated Institution: USUHS
Name: (Last, First, M.I.) Austin, Katherine Role on Protocol: Recruitment Site Collaborator	Phone Number:	Email Address: katherine.c.austin2.mil@mail.mil	Associated Institution: Naval Hospital Camp Pendleton
Name: (Last, First, M.I.) Taylor, Stephanie Role on Protocol: Graduate Student Assistant	Phone Number:	Email Address: stephanie.taylor@usuhs.edu	Associated Institution: USUHS
Name: (Last, First, M.I.)		Email Address:	

Iqbal, Abeer Role on Protocol: Research Assistant	Phone Number:	abeer.iqbal.ctr@usuhs.edu	Associated Institution: USUHS
Name: (Last, First, M.I.) Norris, Colby Role on Protocol: Graduate Student Assistant	Phone Number:	Email Address: colby.norris@usuhs.edu	Associated Institution: USUHS
Name: (Last, First, M.I.) Gist, Galen Role on Protocol: Graduate Student Assistant	Phone Number:	Email Address: galen.gist@usuhs.edu	Associated Institution: USUHS
Name: (Last, First, M.I.) Iwuagwu, Richard Role on Protocol: Graduate Student Assistant	Phone Number:	Email Address: richard.iwuagwu@usuhs.edu	Associated Institution: USUHS

5.2 Will you have a Research Monitor for this study?

- ○ Yes
- ◉ No
- ○ N/A

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Other USU Intramural	: Research Development Testing and Evaluation (RDT&E) funds MWHR	1176318

Total amount of funding:

1176318

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

If Yes, complete and attach Conflict of Interest forms for all key personnel

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

◉ Yes ○ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
	The Miriam Hospital	Coordinating center	FWA00003538			: USUHS IRB #1
Navy	Naval Hospital Camp Pendleton	Recruitment				: USUHS IRB #1
	Joint Base Elmendorf-Richardson	Recruitment				: USUHS IRB #1
Navy	US Naval Hospital Okinawa	Recruitment				: USUHS IRB #1
Army	Fort Drum	Recruitment				: USUHS IRB #1

	Joint Base Lewis-McChord	Recruitment				: USUHS IRB #1
Air Force	Offutt Air Force Base	Recruitment				: USUHS IRB #1
Army	Fort Jackson	Recruitment				: USUHS IRB #1
Navy	Camp Lejeune	Recruitment				: USUHS IRB #1
Air Force	Keesler Air Force Base	Recruitment				: USUHS IRB #1
Navy	Naval Station Great Lakes	Recruitment				: USUHS IRB #1
Air Force	Travis Air Force Base	Recruitment				: USUHS IRB #1

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added					

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

(•) Yes ( ) No

8.4 Is this an OCONUS (Outside Continental United States) study?

( ) Yes (•) No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

( ) Yes ( ) No

9.0

Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Women's health; sexual and reproductive health; military

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

Sexual and reproductive health (SRH) issues such as unintended pregnancy, sexually transmitted infections (STIs), and STI-related cancers affect both servicemen and -women in the United States (US) military, and the rates of unintended pregnancy (Biggs, Douglas, O'Boyle, & Rieg, 2009; Heitmann et al., 2016) and STIs (Stahlman & Oetting, 2019) are, in fact, considerably high in the US military. In addition, SRH issues such as unintended pregnancy and STIs pose a threat to mission readiness (de Kanter et al., 2018; Erickson et al., 2017). Unintended pregnancy can disrupt military operations when service women must be removed from certain roles and/or be medically evacuated out of theater (K. Grindlay & Grossman, 2013; Krulewitch, 2016). In addition to the clear, direct effects of unintended pregnancy on the mission, unintended pregnancy among service members has been linked with negative physical and mental health outcomes for mothers and their babies and concerns from servicewomen about the advancement of their military career (Evans & Rosen, 1997; Krulewitch, 2016).

Despite access to contraceptives and other SRH services, rates of contraceptive use among servicewomen, particularly use of long-acting reversible contraceptives (LARCs), remain low (Erickson et al., 2017; Harrington, Shaw, & Shaw, 2017). Similarly, rates of STIs are also relatively high in active duty service members, and the rates of certain STIs like chlamydia, gonorrhea, and syphilis have increased among service members (Stahlman & Oetting, 2019). Strides have been made to identify barriers to sexual and reproductive healthcare (Manski, Grindlay, Burns, Holt, & Grossman, 2014), such as deployment (ACOG, 2012), improper contraceptive use (Stahlman, Witkop, Clark, & Taubman, 2017). However, a further need to explore and implement programs and processes to subvert these barriers remains (de Kanter et al., 2018; Erickson et al., 2017; Kate Grindlay et al., 2017; Seymour, Grindlay, Fix, & Grossman, 2018).

Health-risking sexual behaviors (HRSBs) like binge drinking and multiple sexual partners can lead to negative SRH outcomes like unintended pregnancy and STIs are well-documented in the military (Stahlman et al., 2014; Stahlman et al., 2015). For example, alcohol misuse during deployment has been associated with STIs and other HRSBs (O'Malley et al., 2017). HRSBs offer potential targets for improving the SRH of service members.

The Multiphase Optimization Strategy (MOST) is a framework for developing behavioral interventions efficiently, effectively, and economically (Collins, Kugler, & Gwadz, 2016). MOST involves three phases: Preparation (i.e., using or collecting data to inform development of intervention components), Optimization (i.e., conducting component selection experiments [CSEs] to experimentally evaluate the effectiveness of the intervention components), and Evaluation (i.e., conducting a randomized controlled trial [RCT] to experimentally evaluate the effectiveness of the overall intervention; (Collins et al., 2016). The critical element to MOST is the optimization phase. Using a factorial design in the optimization phase allows the effect of each intervention component to be evaluated and for observation of interaction effects (Collins, Chakraborty, Murphy, & Strecher, 2009) while maximizing statistical power using a smaller sample size compared to an RCT powered similarly to explore individual components of an intervention (Collins et al., 2009). The optimization phase then allows for time and resources to be saved by ensuring only optimized components are retained after the RCT in the final intervention package (Chakraborty, Collins, Strecher, & Murphy, 2009; Collins et al., 2009).

In civilian populations the MOST strategy has been implored successfully to develop electronic health (ehealth) interventions to reduce HRSBs that can lead to negative SRH outcomes such as STIs (Kari Christine Kugler et al., 2017; Kari C. Kugler et al., 2018; O'Malley et al., 2017). Generally, ehealth interventions are cost-effective and dynamic, and have the potential affect a

large audience (Elbert et al., 2014; Noar & Willoughby, 2012). In civilian populations ehealth—including mobile health (mhealth)—interventions repeatedly demonstrate success in positively affecting health behaviors and, specifically, HRSBs (Hogben, Ford, Becasen, & Brown, 2015; Lelutiu-Weinberger et al., 2018; Noar & Willoughby, 2012; Swendeman & Rotheram-Borus, 2010). Successful ehealth interventions are beginning to emerge in the military (Armstrong, Hoyt, Kinn, Ciulla, & Bush, 2017). Several electronic SRH interventions, most focusing solely on sexual assault, exist; however, it is unclear whether these programs have been successfully evaluated and if they are effective, and they would benefit from optimization (Orchowski, Berry-Cabán, Prisock, Borsari, & Kazemi, 2018).

The information-motivation-behavioral skills (IMB) model has been successfully used as theoretical framework in SRH interventions (Anderson et al., 2006; Chang, Choi, .Kim, & Song, 2014) as it can be used to explain HRSBs (C. M. Fisher, 2012; Mittal, Senn, & Carey, 2012). Theoretically-relevant, effective IMB-based interventions for SRH typically include: (1) the provision of information (e.g., STI transmission, STI and/or pregnancy prevention methods), (2) efforts to increase motivation to engage in non-risky sexual behaviors (e.g., normative and attitudinal support, values clarification), (3) behavioral skills training (e.g., sexual risk communication skills), and (4) accessible resources (e.g., acceptable medical services), delivered in acceptable formats (CDC, 2016; Fagerlin et al., 2013; J.D. Fisher, W.A. Fisher, Bryan, & Misovich, 2002; Long et al., 2016; Swendeman & Rotheram-Borus, 2010). In addition, interventions thrive when they are optimized for the environment and populations in which they are used (Barrera, Castro, Strycker, & Toobert, 2013).

An intervention for military personnel must consider the specific values, mission, and context of military populations and settings. Conducting an RCT using civilian-derived interventions for military personnel risks wasting valuable time and resources by evaluating an intervention that is not optimized to its setting. The MOST strategy is particularly well-suited to complex challenges like SRH in the military in that it allows for military culture and norms to be well-integrated into an intervention, as successful sexual assault prevention programs in the military have shown (Bennett, 2018).

This project aims to develop and optimize effective interventions within the US military to supplement standard SRH care at Military Treatment Facilities, reduce HRSBs in service members, and, overall, improve SRH within the military. Intervention components will be optimized such that they yield the greatest effects while conserving valuable healthcare service resources for service members and their families.

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions /hypotheses

This protocol covers data collection for Phase II of our funded research (the optimization phase). Phase II involves conducting component selection experiments (CSEs) to determine which intervention component(s) elicit the greatest improvements in outcomes of interest (i.e., improved knowledge, motivation, and behavior skills related to sexual and reproductive health [SRH] and reduced health-risking sexual behaviors [HRSBs]) in no more than 25 minutes of e-health content (i.e., the optimization criteria). The intervention components used in these experiments were determined by a previous research protocol (the preparation phase, Phase I). Deliverable will be determination by the research team if the optimized brief e-health intervention is suitable to advance to an randomized controlled trial (RCT) or if further preparation and optimization is necessary.

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

This study is the second phase in the multi-phase optimization strategy (MOST) framework (the optimization phase) to develop an optimized electronic health (ehealth) intervention to reduce health-risking sexual behaviors (HRSBs). This study involves a randomized (factorial) experiment to evaluate the individual effect of intervention components.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active duty service members, across all services.

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

The proposed research ultimately aims to reduce health-risking sexual behaviors (HRSBs) in military service women and men, which is expected to have a significant and positive effect on reducing sexually transmitted infections (STIs), STI-related cancer rates, and unintended pregnancy. This, in turn, is expected to improve service member physical and mental well-being and readiness to serve.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

Participants will be recruited via advertisement (e.g., physical posters and brochures, social media, condoms), word of mouth, or by approaching or being approached by a research team member (e.g., tabling around a base, giving a speech to a group). Participants may also be recruited via email or listserv (e.g., a base contact emails a flyer to their unit). Individuals who are interested in participating in the study will be directed to the anonymous, electronic Eligibility Screening Assessment (attached) in an online data collection software (e.g., REDCap, SurveyMonkey) via a URL, QR code, and/or bitly. Directly after completing the screening, eligible individuals will be prompted via an electronic link to the electronic informed consent (e-consent) form in a secure, online collection software (e.g., REDCap, SurveyMonkey) to provide informed consent to participate in the research study. Eligible individuals will then be engaged in an e-consent process and be asked to sign an e-consent form. Total involvement in the study is expected to take up to three hours of a participant's time over three-to-five sessions over approximately three months.

After signing the e-consent form, participants will be prompted to complete a contact information form to provide the research team with an email and telephone number. Participants will then be asked to complete a pre-intervention assessment, the study intervention, and a post-intervention assessment, respectively, which will all only be identified by a research identification number (RIN). Not until after completion of informed consent will participants be assigned a RIN and randomized to a treatment condition. A master document linking a participant's identity with her or his RIN will be accessible only by the PI and designees.

Participants will be randomized to one of the 32 treatment conditions, corresponding to all factorial combinations of randomized components. The randomization scheme will be generated based on a permutated block randomization procedure, with small random sized blocks. Randomization will be stratified by sex. The length of the intervention will vary based on which components (which treatment condition) the participant receives. The components include: (1) a basic sexual and reproductive health (SRH) education (not randomized), (2) video narratives, (3) skills building videos, (4) interactive scenarios, (5) a future life planning tool, and (6) epidemiological risk scenario.

The basic SRH education component is the only component that every participant will receive; all other components will have two levels (i.e., "on" or "off"). The exact educational content the participant receives in this component will be determined based on baseline SRH knowledge, which will be assessed in a pre-test (discussed below). In the basic SRH education component in

the app, participants will be presented with a series of screens with interactive content and occasional videos.

The narrative video component contains videos about situations related to SRH. This component is randomized and is either "on" or "off" (i.e., received or not received by a participant). Narrative videos will include stories of individuals engaging in positive and negative sexual health behaviors that leads to either positive and negative outcomes, respectively. Those who receive the narrative video component in the app will be expected to watch the assigned videos.

The skills building video component contains videos on how to perform or engage positive SRH behaviors, such as correctly using a condom and what to expect when having a Pap smear. This component is randomized and is either "on" or "off". Participants who receive this video component in the app will be expected to watch the assigned videos.

The interactive scenarios component guides participants through conversations surrounding SRH with select individuals (e.g., partner, healthcare provider, commander), providing suggestions on how conversations with these individuals may be had and why the conversations may be worth having. This component is randomized and is either "on" or "off". In the interactive scenarios component in the app, participants will select a type of individual from a list (pre-determined) to receive a list of topics to discuss with that individual. From there the participant will select the topic they wish to "discuss" and receive a click-through interactive scenario of how to discuss that topic with the selected individual. For example, an avatar (representative of the selected individual) approaches the foreground and says something (word bubble with text and audio). Then the screen changes to present the participant with three text options. The participant is prompted to select one of the options. The screen goes back to the avatar who responds (programmed algorithms) to that selected response. The participant is then prompted with another set of options on how to respond. Participants may have the option to turn on notifications related to this component (e.g., "Upcoming [conversation]? Want a reminder of what to say?").

The future life planning component involves a series of questions to help users plan future goals to put current decision making related to SRH into perspective and provide suggestions on how to stay healthy now to be able to achieve those goals later. This component is randomized and is either "on" or "off". In the future life planning component in the app, a participant will be presented with various goals (e.g., personal, career) to select and/or drag and drop. After goals have been selected, the participant will be given a summary page of feedback and suggestions that corresponds with their goals. Participants may have the option to turn on notifications related to this component.

The epidemiological risk scenario component involves tailored epidemiological risk information about relative risk of contracting a sexually transmitted infection (STI) and/or having an unintended pregnancy. Relative risk information will be determined by adjusting variables within the component (e.g., number of partners within the last month, percent of time using condoms). The epidemiological risk component is a randomized component and will be "on" or "off". In this component a participant will be able to set different factors (e.g., number of sexual partners, frequency of use of contraception/other preventative measures) and then "run" a simulation which shows a survival curve, or some other graphic, of his or her likely risk for contracting STI or experiencing unplanned pregnancy.

Participants will be emailed a link to complete the Participant Pre-Intervention Assessment (attached) in an online data collection software (e.g., REDCap, SurveyMonkey). The Pre-Intervention Assessment will be identified by RIN only. All questions must be answered. However, a participant may respond that she or he "Prefer Not to Answer" for any question. It is anticipated that this questionnaire will take a participant approximately 20-30 minutes to complete.

After completing of the Participant Pre-Intervention Assessment, a participant will be given an access code and PIN to use to access the app. She or he will then be instructed to download the application (app; intervention) to her or his smart phone (Andriod or iOS). A USU-based research team member will provide these codes and instructions to participants. Once the app is downloaded, a participant will open the app and immediately be prompted by the app to enter the given access code and PIN. After the access code and PIN are entered, the participant will be asked to complete the in-app SRH Knowledge Pre-Test Assessment (attached).

The SRH Knowledge Pre-Test Assessment will assess baseline SRH knowledge that will determine educational content received in the intervention. For example, if a participant answers the pre-test question(s) related to female reproductive anatomy correctly, then she or he will not have female reproductive anatomy content in the educational component of the intervention. All questions in the SRH Knowledge Pre-Test Assessment must be answered. After completion of the SRH Knowledge Pre-Test Assessment, the participant will complete the intervention in the app

that corresponds with the assigned treatment condition and that is tailored based on her or his completion of the SRH Knowledge Pre-Test Assessment. All interaction with the app will be identified only by the access code and PIN combination. It is anticipated that the app will take up to one hour to complete, depending on how many and what components a participant receives.

A USU-based research team member will then contact the participant via email to ask her or him to complete the Participant Post-Intervention Assessment (attached; identified by RIN only) in an online data collection software (e.g., REDCap, SurveyMonkey) around two weeks after the participant was asked to complete the app. All questions in the Participant Post-Intervention Assessment must be answered. However, a participant may respond that she or he "Prefer Not to Answer" for any question. It is anticipated that this questionnaire will take a participant approximately 20-30 minutes to complete. If the participant completes the Post-Intervention Assessment within the specified time frame then she or he will be eligible to receive an electronic $5 Amazon gift card (or code).

In addition to the quantitative surveys, participants may be invited to participate in a brief 15-to-30-minute, structured interview about their experiences using the app if they consent to do so on the informed consent document. Participants will be selected for interviews based on the criteria outlined in Section 13.1. If selected for an interview, participants will be contacted via email by a member of the USU team about scheduling the interview two-to-six weeks after being sent the code and instructions to access the app. Interviews will be conducted by a member of the USU team via telephone. Participants who complete the interview off duty will be eligible to receive an additional $5 Amazon gift card (or code). Non-completion of an interview, for any reason, will not affect a participant's primary participation in the research study.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

There are four assessments associated with this study: the Eligibility Screening Assessment, Participant Pre-Intervention Assessment, SRH Knowledge Pre-Test Assessment, and Participant Post-Intervention Assessment. The measures used in these assessments are in the attached "Measures" document. In addition to these assessments, data will also be collected on application (app; the intervention) usage and interaction. All Eligibility Screening Assessment data will be anonymous. All other data will be identified by a research identification number (RIN), not by participant name or any other identifying information. RIN will be assigned in the electronic data collection software (e.g., REDCap, SurveyMonkey) when a participant begins a Pre-Intervention Assessment. A master document linking a participant's identity with her or his RIN will be accessible only by the PI and designees at the Unifromed Services University of the Health Sciences (USU).

The Eligibility Screening Assessment is an anonymous screening assessment that will be administered to prospective participants electronically via an online data collection software (e. g., REDCap, SurveyMonkey). The Eligibility Screening Assessment will ask questions related to eligibility (e.g., age, military status) and, to ensure a purposive sample, demographics (e.g., gender, rank, military branch). All questions in the Eligibility Screening must be answered for an individual to be considered for eligibility in the research study.

The Participant Pre-Intervention Assessment will be administered to participants electronically via an online data collection software (e.g., REDCap, SurveyMonkey) following completion of informed consent. The Participant Pre-Intervention Assessment will collect demographic information and assess sexual and reproductive health (SRH) knowledge, attitudes, self-efficacy, sexual behavior, healthcare experiences, healthcare provider interactions, and general mental health. All questions in the Participant Pre-Intervention Assessment must be answered. However, a participant may mark that she or he "Prefer Not to Answer" for any question.

The SRH Knowledge Pre-Test Assessment will be administered to participants in the application at the onset of the intervention. The SRH Knowledge Pre-Test will assess baseline SRH knowledge that will be used to tailor select content in the app to the participant (see Study Procedures for more information and examples).

The Participant Post-Test Assessment will be administered to participants after completion of the intervention via an online data collection software (e.g., REDCap, SurveyMonkey). All questions in the Participant Post-Test Assessment must be answered. However, a participant may respond that she or he "Prefer Not to Answer" for any question. The Participant Post-Test Assessment assess sexual and reproductive health (SRH) knowledge, attitudes, self-efficacy, and acceptability of the intervention.

Data will also be collected on participants' interactions with the app. This data includes information such as information on how long participants spent on each component, how many times participants opened the app, and how many times participants accessed and completed components.

Participants who consent to opt-in to an additional structured, qualitative interview will be asked to complete an interview with a member of the USU team via telephone two-to-six weeks after receiving the intervention. The interview will ask participants about their experiences using the app, including-but-not-limited-to questions about graphics (aesthetics), barriers to use, and ease of use (see attached interview agenda). Interviews will be recorded, and recordings will be used to expand notes taken during the interview. Recordings will be deleted upon completion of interview notes.

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

○ Yes ◉ No

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

It is hypothesized that each intervention component will reduce at least some health-risking sexual behaviors (HRSBs) and increase health-promoting behaviors (e.g., condom use, obtaining effective contraception) and that each component will increase at least one antecedent to behavior--knowledge, motivations, or perceptions of behavioral skills. It is expected that each intervention component will have a small-to-medium effect on associated outcomes. Descriptive statistics will be calculated for all data including demographics and outcome variables (e.g., scale scores for attitudes, rates of condom use). Effect coding will be used to indicate the presence or absence of each intervention component. Per the multi-phase optimization strategy (MOST) framework, factorial analysis of variance will be used to calculate both main effects and the theoretically-relevant two-way interaction effects. Secondary analyses will be conducted to examine the information-motivation-behavioral skills (IMB) model whereby behavioral skills serves as a mediator between information and behavior change and between motivation and behavior change. Statistical software such as SAS and R will be utilized for analyses.

Interview data (typed notes) will be analyzed using framework matrix analysis.

11.2 Sample Size:

900 active duty service members

11.3 Total number of subjects requested (including records and specimens):

900

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

11.5 Please provide a justification for your sample size

Power analysis indicates that a sample of 720 will be sufficient to have 80% power to detect small main effects and interaction effects at a 5% significance level. Accounting for 20% attrition, up to 900 service members will be enrolled to reach target sample size.

Of this total sample, it is anticipated that 40 participants will be needed and selected to complete an interview. Qualitative data analysis does not lend itself to power analysis. Sample size was selected based on the experiences of our qualitative experts.

11.6 Data Analysis Plan: Complete description: Background, Objectives, Design, Step by Step how the project is going to be done, Data analysis plan:

Data analysis will be conducted consistent with the methods described in the "Statistical Considerations" section.

12.0 Participant Information

12.1 Subject Population:

Active duty service members

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [x] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [x] 65-74
- [x] 75+

17-75+ will be eligible as that is the age range for service members

12.3 Gender:

- [x] Male
- [x] Female
- [x] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons

- ☐ Educationally Disadvantaged Persons
- ☐ Physically Challenged (Physical challenges include visual and/or auditory impairment)
- ☐ Persons with Impaired Decisional Capacity
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, and Neonates
- ☐ Non-English Speakers
- ☐ International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	Participants are eligible if they are: 1) age 17 or older, 2) active duty military personnel, and 3) willing to be participate in all study activities if eligible and enrolled.

12.6 Exclusion Criteria:

Order Number	Criteria
1	Any participant (i.e., service member or provider) will be deemed ineligible to participate if they do not meet the eligibility criteria or are 1) unable to read, speak, or comprehend English, or 2) unable or unwilling to give informed consent.

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

Participants will be recruited across services via advertisement (e.g., physical posters, social media, condoms, nominal items like stress balls), word of mouth, or by approaching or being approached by a research team member, as well as via email or listserv. Individuals who express interest in taking part in the study will be asked to provide consent to be screened for eligibility (Eligibility Screening Questionnaire attached). After completing the screening, eligible individuals will be asked to provide informed consent, which will be collected by USU-based research team members.

The study sample will represent a convenience sample of individuals who voluntarily express interest in participating. Purposive sampling will also be employed to ensure adequate representation of female and male participants and each branch of the military. Participants will complete the intervention off-duty to minimize impact on military operational effectiveness.

Purposive sampling will also be employed when selecting interview participants from the group of participants who consented to complete an interview if selected. Participants will be selected to ensure appropriate representation of gender, sexual, and/or ethnic/racial identity and military rank and/or service and to ensure that there is a good mix of those who have and have not used the app. Demographics information from the Pre-Intervention (baseline) Assessment and analytics data on app use will be used to inform the selections. It will still be expected that participants complete this part of the study off duty as well.

13.2 Compensation for Participation:

Participants will be compensated for their participation via electronic Amazon gift cards (codes). Participants will be eligible to receive an electronic $5 Amazon gift card upon completion of the Participant Post-Intervention Assessment within the specified period of time if they indicate that they completed the survey off duty. Participants who complete the interview will be eligible to receive an additional $5 Amazon gift card upon completion of the interview off duty.

13.3 Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

Participant eligibility in the overall study will be determined by anonymous self-reported responses to screening questions including age and active duty military status. Participants will be invited to complete an interview based on their answers to demographic questions in the de-identified Pre-Intervention Assessment and whether or not they used the app (pulled from de-identified app analytics data). Medical records from the Military Health System (MHS) will not be utilized at any point during the study, and will not be used to identify subjects or confirm eligibility.

13.4 Consent Process: Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

After completing the Eligibility Screening Assessment, all eligible and interested individuals will be engaged in an electronic informed consent process via a secure, online collection software (e. g., REDCap, SurveyMonkey) prior to completing any other assessments, the study intervention, or qualitative interview. The informed consent document (ICD; attached) includes an explanation of the nature and purpose of the study, study procedures, risks and befits, confidentiality, and the voluntary nature of research studies. Prospective participants will be instructed on the consent form to call or email the Uniformed Services University of the Health Sciences (USU) research team with any questions. Once the signed ICD is returned to the study team, the participant will be permitted to be engaged with the intervention, assessments, and all other aspects of the study for which they consent (see Study Procedures). Participants will be informed to check an additional box after the signature line if they consent to be contacted about and participate in the qualitative interview. Participants will be offered a copy of their signed ICD.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

◉ N/A
○ Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

Prior to the destruction of the link between participant name and research identification number (RIN; maintained and accessible only by the PI or designee in a password protected file stored on a secure server), participants will be able to withdraw their participation in the study by contacting the PI (or designee). Those who request to withdraw will be allowed to do so and their data will be removed from analysis for both this study and any future research for which the participant originally consented. After a link between a participant's name and her or his RIN has

been destroyed, we will no longer have the ability to identify the participant's data and, thus, she or he will no longer be able to have their data removed from the data set.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

Potential risks include: 1) breach of confidentiality, 2) coercion, and 3) discomfort and/or offense due to intervention content (i.e., sexual and reproductive health [SRH]). Risks associated with *br each of confidentiality* are always a consideration, but , these risks are considered low in this instance as all data will be identified by a research identification number (RIN). Risk of *coercion* is possible as military personnel may feel compelled to participate in the research study if they are informed about the study by their medical provider or someone in their chain of command. Risks associated with *feelings of discomfort* prompted by the content of the intervention are possible as the intervention and associated assessments concern SRH. However, content was developed in consultation with experts to ensure the information presented is focused on medically relevant and operationally focused concerns.

14.2 Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

The potential risks (outlined above in "Risks of Harm") include: 1) breach of confidentiality, 2) coercion, and 3) discomfort and/or offense due to intervention content (i.e., sexual and reproductive health [SRH]).

Protecting Confidentiality. Every precaution will be taken to ensure data will be kept strictly confidential. During the informed consent process, potential participants will receive information about confidentiality, including who is able to view their data throughout the study. Data will anonymous or identified by a research identification number (RIN); thus, the only way to identify whether or not an individual participated will be via documentation of informed consent. All electronic informed consent documents (ICDs) will be kept on a secure network. Only the PI and designees will have access to ICDs.

Protection Against Coercion. Protocols and research staff trainings related to ethics, confidentiality, and other topics in human subject protection will ensure participants are informed of their rights as a research volunteer. Throughout the recruitment process potential participants and others involved in the recruitment process by word of mouth will be told that participation is voluntary. During the informed consent process potential participants will be informed of their rights as a research volunteer, including the right to not participate in the research study without repercussions, to refuse to answer any question, to withdraw from the study at any time. Although supervisors/commanders may share information to participate in this study with service members, they will not be involved in group recruitment or consent. The majority of the consent process will be conducted by civilian members of our lab team.

Protection Against Feelings of Discomfort. Participants may feel uncomfortable by the intervention content (i.e., SRH) and associated assessment questions. The intervention was planned to attempt to minimize making participants feel uncomfortable. However, it is possible that some may still fell some discomfort by the topic nonetheless. Participants will be instructed during the consent process to contact the study team via telephone or email with any concerns

or to report discomfort. Participants will also be permitted to skip any questions in the assessments they do not feel comfortable answering.

14.3 Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e. g., child or spouse abuse

As described in the section above ("Measures to Minimize Risks of Harm"), confidentiality protections include:

- Collecting data only identified by a research identification number (RIN)
- Using the informed consent process as an opportunity to inform potential participants about their rights as a research participant and to provide transparency in plans for data management.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

Potential benefits to the participant include an increased knowledge in sexual and reproductive health (SRH) information, self-efficacy related to reducing health-risking sexual behaviors (HRSBs), and decrease HRSBs. The intervention has the potential to significantly benefit the overall health and readiness of military personnel, as SRH issues such as sexually transmitted infections (STIs) and unplanned pregnancy degrade mission readiness.

14.5 Privacy for Subjects:

Describe the measures to protect subject’s privacy during recruitment, the consent process, and all research activities, etc.

In accordance with HIPAA policies at the Uniformed Services University of the Health Sciences (USU) and The Miriam Hospital (TMH), and despite data only being used for study purposes, participants' data will be treated in a manner similar to protected health information to afford it equivalent privacy protections. Recruitment will most be via word of mouth and advertisement online and on paper, so there are no privacy risks associated with this type of recruitment. Consent will be done electronically in a HIPAA-compliant software.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

Incidental findings are not anticipated as the app is not collecting personal health information.

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- (•) DSMP
- ( ) DSMB
- ( ) Both
- ( ) Not Applicable

A DSMP should describe the plan to monitor the data to verify that the data are collected and analyzed as specified in the protocol. Include who will conduct the monitoring, what will be monitored, and the frequency of monitoring. It should also include the plan to ensure the safety of subjects

The Principal Investigator (PI) or designee(s) will verify that all data has been collected and analyzed as specified. The project coordinator (or designee to be appointed by the PI) is responsible for reporting findings to the PI on a weekly basis. Deviations from the protocol will be reported to the PI within 24 hours of discovery by the research team so that a determination of notification to the Institutional Review Board (IRB) and any mitigation procedures can be implemented in a timely manner.

It is possible that participants may feel discomfort answering questions or consuming information related to sexual and reproductive health (SRH), despite the benefits that come from gaining knowledge about SRH. Participants will be encouraged to contact the research study or their healthcare providers if they experience distress. All research study members will be trained to refer participants to their healthcare providers.

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

No adverse events are anticipated. It may be possible that a participant may experience embarrassment, discomfort, or offense due to the subject matter of the intervention. If participants contact the research team reporting such feelings, the research team will be trained to refer them to appropriate services such as those for psychological and/or medical care if they have further concerns. Such feelings that cause greater than minimal interference with usual social and functional activities will be considered an adverse event. The PI will report any unanticipated adverse events to the Institutional Review Board (IRB) within 72 hours of discovery. When reporting the unanticipated adverse event to the IRB the PI will propose any amendments to the research protocol if applicable and as necessary.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

(•) Yes ( ) No

Please describe:

The study involves the use of an electronic health (ehealth) intervention, a smartphone (Android and iOS) application (app). A description of the components of this app can be found in Study Procedures. Attached is a rough schematic of what the app will look like.

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- [ ] Drugs
- [ ] Dietary Supplements
- [ ] Biologics
- [ ] Devices
- [x] N/A

18.5 Sponsor (organization/institution/company):

- [x] N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

( ) Registration is not required
( ) Registration pending
(•) Registration complete

"NCT" number:

NCT04661566

19.2 Defense Technical Information Center Registration (Optional):

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

20.0 References and Glossary

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20.2 Abbreviations and Acronyms:

App - Application
CSE - Component selection experiment
ehealth - electronic health
HSRB - Health-risking sexual behavior
LARC - Long-acting reversible contraceptive
ICD - Informed consent document
IMB - Information-motivation-behavioral skills
IRB - Institutional Review Board
mhealth - mobile health
MHS - Military Health System
MOST - Multi-phase optimization strategy
MTF - Military Treatment Facility
RCT - Randomized controlled trail
RIN - Research identification number
SA - Sexual assault
SRH - Sexual and reproductive health
STI - Sexually transmitted infection
US - United States