STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN

Study Title: Evaluating Cross-Cutting Sexual Assault and Alcohol Misuse Prevention Programming at the U.S. Air Force Academy

NCT Number: NCT06875284
Unique Protocol ID: 0218275.001.001.003

Document Date: March 28, 2025

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STUDY PROTOCOL

U.S. AIR FORCE ACADEMY IRB PROTOCOL:
RTI INTERNATIONAL PROJECT # 0219275.001.001.003

1. Preliminary Information
03/07/2024 (Amendment 9)

Who is engaged in this study? Check all boxes that apply. Note that if individuals from multiple institutions are performing the activities listed in the definition below, multiple institutions are engaged.

☒ USAFA

☐ OTHER DOD INSTITUTION(S)

☒ NON-DOD INSTITUTION(S) (This includes military members attending civilian universities)

AFMSA/SGE-C defines engagement as the following:
An institution is engaged in the research if its employees or agents obtain the following for the purposes of the research project:

- Data about the subjects of the research through intervention or interaction with them
- Identifiable private information about the subjects of the research
- The informed consent of human subjects for the research

If non-USAFA institutions will be engaged, have they or will they review this study?
If Yes to the above, enter the name of the IRB that has reviewed or will review the study here:
The current study is a collaboration between USAFA, RTI International, the University of Florida, and San Diego State University (SDSU).

The RTI and University of Florida IRBs have historically made separate determinations that the current protocol is exempt educational research. As of the date of this current amendment request, the University of Florida is no longer an engaged institution so will not review a protocol reflecting the changes proposed in this amendment request. Based on discussions with the RTI IRB, the RTI team will submit an exempt protocol request to RTI IRB reflecting the same changes indicated in this USAFA HRPP amendment request protocol. SDSU IRB has already determined that SDSU personnel study activities described in this USAFA HRPP amendment request protocol are not subject to IRB review.

The USAFA team will be the only research personnel directly engaged with participants. Regarding the activities specific to this amendment request, RTI and SDSU investigators will be involved in instructor training and consultation/support, overall study management, and data analysis. If, once the USAFA IRB makes a determination on review status, the investigators' status as non-engaged changes (following initial review) to require engagement with participants these individuals will be added to the protocol and appropriate institutional agreements will be put in place. In this potential scenario, the investigators will have no engagement with participants before the appropriate approvals are obtained and put into place.

If YES, STOP HERE and contact the IRB Administrator at 333-6593 or usafa.irb@usafa.edu.
If NO, CONTINUE with this submission form.

Title of Protocol: The USAFA Sexual Communication and Consent Study

Protocol # (provided by HRPP Administrator): FAC20210029E

Principal Investigator (PI) #1 Information *

Name & Rank: Dr. W. Ken Robinson
Organization & Position: USAFA, Violence Prevention Integrator
Email Address: warren.robinson@usafa.edu

FWA or DoD Assurance Number (if not USAFA personnel):

Principal Investigator (PI) #2 Information *

Name & Rank: Dr. Emily Schmied
Organization & Position: San Diego State University, School of Public Health, Assistant Professor
Email Address: eschmied@sdsu.edu
FWA or DoD Assurance Number (if not USAFA personnel): 00003782

Associate Investigator (AI) Information **

Name & Rank:
Organization & Position:
Telephone number:
Email Address:
FWA or DoD Assurance Number (if not USAFA personnel):

*** There is a limit of 2 PIs per study and a cadet cannot be a PI**
**** There is no limit on the number of AIs you may have**
***** Please add additional investigators or other types of research personnel at the end of this document before the signature blocks. Additional types of research personnel are defined in #3 of the instructions.**

2. Submission Type

Indicate the type of determination you are requesting (select one). **Exempt (see 32 CFR 219.104)**

Note: According to DoDI 3216.02, paragraph 3.5.a.(7), "Only designated federal DoD HRPP personnel are authorized to make determinations regarding whether or not an activity is HSR [human subjects research] or is exempt HSR." Accordingly, researchers must submit a determination request to the HRPP to obtain a determination prior to starting any activity that is or may be research with human subjects. HRPP personnel receive extensive training from the AF on how to interpret the definitions of study and human subjects provided in 32 CFR 219.102.

*It is the PI's responsibility to notify the HRPP if any changes or modifications are made in the study's design, procedures, etc. **BEFORE** executing those changes to ensure the changes do not change the study's determination.*

If your activity meets one or both of the following criteria, you should select that you are requesting a Not Human Subjects Research determination:

- *Your activity is not intended to contribute to generalizable knowledge (i.e., it is not research)*
- *Your activity does not involve intervention or interaction with living individuals, nor analysis of private individually identifiable data*

In the study description of your submission, clearly explain why your study meets one or both of the criteria above. If a given item is not applicable, simply respond N/A.

If neither of the above things are true about your activity, you are probably doing human subjects research. If you think that your study fits one or more of the exemption category descriptions in item D below, check that you are requesting an exempt determination. Otherwise, check that you are submitting your study for full IRB review.

A. Indicate the purpose(s) of your activity (*check all that apply*):

☒ Contribute to the body of knowledge in a given field ☒ Program improvement/support/assessment

B. Indicate whether your activity falls into any of the following categories (*check all that apply*):

☐ Scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected. Examples include oral history, journalism, biography, literary criticism, legal research, and historical scholarship.

☐ Public health surveillance activities that are necessary for a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

☐ Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative procedures.

☐ Authorized operational activities as determined by the Department of Defense in support of intelligence, homeland security, defense, or other national security missions.

C. Indicate the nature of the study procedures that you will use (*check all that apply*):

☒ Obtaining information or biospecimens through intervention or interaction with living individuals

☐ Use, study, or analysis of existing data or biospecimens

☐ Indicate here if the data are such that the identity of the individuals can readily be ascertained, either directly or through identifiers linked to the individuals. (*Note: Even if you have removed information such as name or social security number, the data may still be identifiable if there is sufficient demographic information in the data set.*)

☐ Indicate here if the data are medical data.

☐ If you checked the item above, has your study been reviewed by the 10 MDG's HIPAA compliance officer?

If not, you should discuss your study with the HIPAA officer and include documentation of that conversation with your documentation of resource approval from the 10 MDG. If you have responded "No" to this question and your study contains medical data, the HRPP will not review your study until you have accomplished this step.

D. If requesting an exemption determination, indicate the category under which you are requesting the determination (*Check all that you think might apply*).

☒ Category 1. Research, conducted in established or commonly accepted educational settings, that involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

☒ Category 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior (including video or audio recording). *Indicate which of the following criteria apply:*

☒ (i) The information obtained will be recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

☐ (ii) Any disclosure of the individuals' responses outside the research would not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation; or

☐ (iii) The information will be recorded in such a manner that the identity of the human subjects can readily be ascertained, either directly or through identifiers linked to the subjects. (*Note: A limited IRB review is required in this case. Normally, the USAFA HRPP conducts limited IRB reviews via expedited review.*)

☐ Category 3. Research involving benign behavioral interventions (interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant lasting impact on the subjects, and there is no reason to think the subjects will find the interventions offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording.

☐ Indicate here if subjects prospectively agree to the intervention and information collection.

☐ Indicate here if the study includes deceiving the subjects about the nature or purposes of the research.

☐ Indicate here if subjects authorize the deception by prospectively agreeing to participate in circumstances in which they are informed that they will be unaware of or misled regarding the nature or purposes of the research.

Indicate which of the following criteria apply:

☐ (A) The information obtained is recorded in such a manner that the identity of the subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

☐ (B) Any disclosure of the subjects' responses outside the research would not reasonably place them at risk of civil or criminal liability or be damaging to their financial standing, employability, educational advancement, or reputation; or

☐ (C) The information obtained is recorded in such a manner that the identity of the subjects can readily be ascertained, directly or through identifiers linked to the subjects. (*Note: A limited IRB review is required in this case. Normally, the USAFA HRPP conducts limited IRB reviews via expedited review.*)

☐ Category 4. Secondary research for which consent is not required: Secondary research using identifiable private information or identifiable biospecimens. *Indicate which of the following criteria apply*:

☐ (i) The identifiable private information or identifiable biospecimens are publicly available;

☐ (ii) The information is recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects;

☐ (iii) The research involves only information collection and analysis of identifiable health information covered by the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of "health care operations," "research," or "public health activities and purposes" as defined in 45 CFR 164.501 and 45 CFR 46.512(b), respectively;

☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities if

the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with the E-Government Act of 2002, if the identifiable private information collected, used, or generated will be maintained in systems of records subject to the Privacy Act of 1974, and (if applicable), the information used was collected subject to the Paperwork Reduction Act of 1995.

Note: Administrative data collected and maintained by USAFA are compliant with these regulations. If you are using data from CAMIS or Q2i, you must obtain a data use agreement from HQ USAFA/A9. If you do not include documentation of an agreement in your resource approval documents, the HRPP will not review your study until you obtain this document.

☐ Category 5. Research and demonstration projects that are conducted or supported by a Federal department or agency that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under these programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

☐ Category 6. Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level and for a use found to be safe by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.

☐ Category 7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use. (*Note: A limited IRB review is required for this category*. *Normally, the USAFA HRPP conducts limited IRB reviews via expedited review.*)

☐ Category 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use. (*Note: A limited IRB review is required for this category*. *Normally, the USAFA HRPP conducts limited IRB reviews via expedited review.*)

3. Human Subjects Research Experience

(Applies to "Exempt" and "Full IRB Review" submissions) Please describe the Principal Investigators' (PI) previous experience with human subjects research (e.g. Master's thesis research, Doctoral dissertation, grants, publications) in the space below. Discuss whether you have independently served as a PI or have previously served as an Associate Investigator (AI) under the supervision of a PI. Note that PIs are responsible for supervising AIs.

Dr. W. Ken Robinson is responsible for managing all aspects of a complex violence-related primary prevention program for USAFA. His work involves assessing and developing coordinated plans for reducing risk factors within the community and promoting protective factors supporting interpersonal and self-directed violence prevention and community resilience. Dr. Robinson earned his Doctorate of Ministry in Marriage and Family Therapy in 2013, and he has over 25 years' extensive experience working with command teams in program development to improve resilience, violence prevention and relational health of military members and their families. Prior to becoming the USAFA VPI in 2019, he served at Schriever AFB as the Wing Violence Prevention Integrator for 3 years and at Fort Carson for 6 years developing and implementing evidence-based programs to improve the overall military and family readiness of installation personnel.

As the USAFA site point of contact to the RTI Team and USAFA PI for the purposes of this regulatory protocol, Dr. W. Ken Robinson will be supported by Ms. Sonja Strickland, Program Director for the USAFA SAPR program. She has 9 years of experience as a SARC, 24 years' experience in victim advocacy, and annually coordinates ongoing SAPR programming and instructor training. She is the ideal support for the current study, as she will coordinate study logistics and be the on-site point of contact for trained instructors delivering the SCC program.

Dr. Robinson's and Ms. Strickland's efforts will be supported by the external research collaborators via weekly video conference. Please find the Resumes and CITI Certificates for Dr. Robinson and Ms. Strickland in **Attachments 1-4**.

4. Funding and Conflicts of Interest

(Applies to "Exempt" and "Full IRB Review" submissions)

A. Does your study have external funding? Yes

If yes, please describe the source and amount:

For 2021 BCT and 2022-2023 Academic Program Year (APY) Data Collection

Source: U. S. Army Medical Research Acquisition Activity
Award Type: Cooperative Agreement
Amount: redacted
Period of Performance: 15 August 2020 – 14 August 2023

For 2023-2024 APY Data Collection

Source: U.S. Army Medical Research and Development Command (USAMRDC)
Award Type: Contract
Amount: redacted
Period of Performance: September 2021 – September 2024

B. Do you have a financial interest in the outcome of this research? No

(*Example: You are testing the effect of an educational software on learning, and you may benefit financially from the sale of this software*.)

If yes, please describe:

Click or tap here to enter text.

C. Do you have a professional interest in the outcome of this research? No

(*Example: The outcome of this research may be linked to future job offers from a co-sponsor of the research*.)

If yes, please describe:

Click or tap here to enter text.

D. Do you have a personal interest in the outcome of this research? No

(*Example: The outcome of this research may benefit the financial, professional, or personal circumstances of a family member or close friend*.)

If yes, please describe:

STUDY DESCRIPTION

5. Background

Provide an introduction, background information, and a review of the relevant literature. Answer the question: Why are you doing this study?

Sexual Assault Prevention and Response (SAPR) is a top priority of the Department of Defense and the United States Air Force (USAF). The USAF SAPR office (HAF/A1Z) has partnered with RTI International and colleagues on the development and evaluation of a tailored web-based (delivered via government issued laptop) sexual assault prevention training that can be integrated into standard classroom training to align with the objectives of the Air Force Sexual Assault Prevention Strategy (USAF, 2015). The Sexual Communication and Consent (SCC) training is an evidence-based program to promote healthy relationships and bystander intervention, while also reducing risk factors for sexual assault victimization, revictimization, and perpetration (Kan et al., 2020; Scaglione et al., 2020). Upon initial anonymous screening of gender and individual risk factors, participants are electronically routed to one of five tailored web-based prevention programs that aim to:

- Prevent/reduce perpetration and promote healthy relationships and effective bystander intervention,
- Reduce revictimization among males,
- Reduce revictimization among females,
- Prevent initial sexual assault victimization among males, and
- Prevent initial sexual assault victimization among females

Adapted from sexual assault prevention programs that had previously demonstrated efficacy in college and high school samples (Foshee et al., 2004; Hanson & Gidycz, 1993; Marx et al., 2001; Salazar et al., 2014), SCC is innovative in its content and training approach. By integrating tailored web-based content into the universal classroom setting, we are able to support equal opportunity in training, while also following best practices in sexual assault prevention (i.e., providing unique content for men and women) and addressing critical risk factors not currently accounted for in military SAPR prevention training (e.g., the risk for male victimization/revictimization).

From 2015-2019, SCC was developed for and tailored to the USAF Basic Military Training (BMT) environment through an extensive and iterative formative research process. A large-scale feasibility study (n > 8700 trainees) conducted at BMT (Lackland AFB) from September 2019 - March 2020, revealed high levels of acceptability and engagement among trainees, appropriateness of the content and delivery in the BMT environment, implementation fidelity and feasibility (e.g., very few technological issues given the tablet delivery platform), and positive effects on trainee knowledge and attitudes related to sexual assault (see Scaglione et al., 2020).

From 2021 to present, SCC has been pilot tested at the U.S. Air Force Academy (USAFA) among basic cadets (referred to as basics/basic cadets until they complete Basic Cadet Training [BCT]). Specifically, in summer 2021, the program was pilot tested with nearly 160 basics (i.e., 1 BCT squadron). Based on 2021 pilot study findings and feedback obtained from basics, instructors, and website metadata, changes were made to the SCC program, ranging from minor (slight changes to the assessment instruments and timing of program components) to substantive (e.g., moving the tailored programming from a tablet to the web). This revised, web-based version of SCC was then evaluated in the entire 2022 BCT class, wherein half of the class was assigned to receive SCC and the other half of the class was assigned to receive standard SAPR Cadet Healthy Personal Skills (CHiPS) training, which is the USAFA BCT “Training-as-Usual” (TAU) program. SCC was delivered by USAFA HRPP-approved SAPR and affiliated staff/volunteers; CHiPS was delivered by contracted CHiPS instructors. Anonymous web-based surveys were administered at pre-test and post-test during BCT, 3-month follow-up, and 9-month follow-up. Analyses of 2022-2023 APY cohort data are ongoing, but initial findings suggest that SCC was acceptable, feasible, and effective on immediate (i.e., pre-test to post-test) outcomes. Low (<20%) DSAT response rates have also highlighted difficulties with follow-up assessment retention.

One interesting finding from the 2022 pilot study was that SCC yielded improvements on certain alcohol-related outcomes. This is of importance because (a) alcohol use is a risk factor for sexual assault, (b) alcohol

misuse is associated with other negative effects on health and well-being, and (c) the Department of Defense is interested in cross-cutting prevention efforts that protect against multiple adverse outcomes such as alcohol misuse and sexual assault. As SCC is a sexual assault prevention program and accordingly addresses alcohol use to the extent that alcohol is related to sexual assault risk or experiences, there is benefit in determining whether additional alcohol misuse prevention content is associated with even stronger desirable effects on alcohol use-related outcomes. One candidate alcohol misuse prevention program is eCHECKUP TO GO, a brief (30-minute), personalized, web-based alcohol misuse prevention program developed by San Diego State University (SDSU). Based on an eCHECKUP TO GO program user's anonymous alcohol-related demographic information (e.g., biological factors influencing BAC) and experiences (e.g., alcohol use behavior prior to arriving at USAFA), personalized feedback is presented to modify cognitive risk factors for alcohol use and correct inaccurate norms perceptions that may increase risk for alcohol (mis)use. eCHECKUP TO GO has demonstrated feasibility, acceptability, and efficacy in previous studies of first-year undergraduate students (Doumas & Anderson, 2009; Doumas, Kane, Navarro, & Roman, 2011; Henry, Lange & Wilson, 2004; Hustad, Barnett, Borsari, & Jackson, in 2010; Lane & Schmidt, 2007; Steiner, Woodall & Yeagley, 2005; Wilson, Henry & Lange, 2005). In a different USAFA study (FAC20220024H HS-2022-0009), eCHECKUP TO GO was successfully beta-tested in a small sample of 22 volunteer cadets; findings suggested eCHECKUP could be acceptable and feasible to implement at USAFA. Taken together, there is merit to conducting a follow-up pilot study to investigate whether incorporating eCHECKUP TO GO yields additional prevention programming benefits above and beyond SCC or CHiPS alone.

Summary of What Remains the Same Since the 2022-2023 APY Pilot: As was approved for the 2022-2023 pilot study, we will assign half of the incoming 2023 BCT class (i.e., 4 of 8 BCT squadrons) to receive either SCC or CHiPS (i.e., the TAU). Condition assignments will be made by the USAFA SAPR office, which oversees the administration of both programs. SCC and CHiPS will occur over 3 separate training sessions/days during designated SAPR BCT training time. SCC and study surveys will be facilitated by HRPP-approved SAPR staff/affiliated volunteers, and CHiPS will be facilitated by contracted CHiPS instructors (who will not facilitate any research study procedures and are therefore not engaging with basics in their role as study participants). We will gather feedback from basics/fourth-degree cadets, SCC training instructors, and the website back-end (e.g., metadata summarizing where cadets spent their time) to determine the SCC program's feasibility, acceptability, and ability to affect behavioral outcomes among USAFA basics/cadets. We will also examine the potential for immediate and sustained changes in basic/cadet knowledge, attitudes and skills related to sexual assault prevention. We will administer follow-up assessments during USAFA-permitted assessment times at approximately 3-months and 9-months post-BCT to examine SCC's effects on relevant distal (behavioral) outcomes.

Summary of Changes from the 2022-2023 APY Pilot: This amended protocol seeks to build on findings, integrate minor recommended modifications from the 2022-2023 pilot study, and evaluate the potential additive positive effects of eCHECKUP TO GO on study outcomes. Specifically, we propose to collect data from a second cohort of the incoming 2023 BCT class (i.e., basic cadets during 2023 BCT throughout their year as fourth-degree cadets during the 2023-2024 APY). This will allow us to merge data collected from the 2022-2023 and 2023-2024 cohorts to better detect statistically significant effects on low-base-rate sexual assault outcomes, especially among smaller, higher-risk subgroups (e.g., among cadets who experienced sexual assault victimization prior to arriving at USAFA BCT). Feedback collected during the 2022-2023 pilot study informed the application of minor adjustments to the SCC program to enhance the program content and ensure training stays within bounds of protected SAPR BCT training time. In the planned 2023-2024 follow-up pilot study, we will also weave eCHECKUP TO GO into the SAPR prevention training. To achieve this, 3 out of 4 BCT squadrons assigned to receive SCC will also complete eCHECKUP TO GO during protected SAPR SCC time, and 3 out of 4 BCT squadrons assigned to receive CHiPS will also complete eCHECKUP TO GO during protected SAPR CHiPS time. To facilitate accurate condition assignment in study analyses (which can be challenging due to the anonymous nature of data collection), we are also proposing to include a new item assessing BCT squadron name in the pre-test and post-test assessments. This new item has already been approved by CW and A9, and it cannot be used to identify individual participants.

This study will have an important impact on the refinement and implementation of sexual assault prevention programming at USAFA and will help SAPR meet its goals of supporting and ensuring cadet well-being and

readiness. The proposed research activities will enable us to appropriately tailor the SCC training to the target audience of USAFA cadets and will provide important insight into whether integrated sexual assault prevention and alcohol misuse prevention programming is superior to either approach alone. Further, if findings from the current study demonstrate the feasibility and acceptability of the SCC program in this population, the Academy may elect to continue implementing this program in the USAFA environment after the study concludes.

6. Objectives

List the objectives of the study or the hypotheses. It should be clear to the reviewers how the data you will collect will enable you to test the hypotheses or meet the study objectives.

These pilot studies will test the adapted SCC program in USAFA BCT across two cohorts with the goal of evaluating: (a) the feasibility of integrating eCHECKUP TO GO with SCC in the existing BCT framework (using the current SAPR training time); (b) acceptability of minor changes made to the SCC program content based on 2021 pilot study feedback; (c) cadet engagement with the web-based programs; and (d) cadet feedback on the tailored web-based and classroom content delivery. We will also employ a cluster-randomized repeated measures design (pre-test, post-test, 3-month follow-up, 9-month follow-up [see Attachments 7a-e, 8, and 9; Attachment 9 delineates which exact items within the outcomes measures will be asked at each time point]) to examine the programs' ability to achieve and maintain the intended educational and training outcomes, relative to the CHiPS TAU.

We hypothesize that there will be some variability in program acceptability among cadets in the five different SCC training programs (healthy relationships/bystander intervention promotion; male revictimization prevention; male primary victimization prevention; female revictimization prevention; female primary victimization prevention). Based on our prior work at BMT and the 2021 USAFA BCT pilot study, we expect data will support SCC implementation feasibility and acceptability as indicated by few technological issues and high implementation fidelity among instructors. We also expect to observe meaningful increases from pre-test to post-test in knowledge of sexual assault and consent (across all participants), self-efficacy to resist unwanted sexual advances (among those who receive the primary victimization and revictimization prevention trainings), and bystander intentions (among those who receive the healthy relationships and perpetration prevention training). Based on 2022-2023 pilot study findings and the supporting theoretical and empirical evidence, we also expect all basics to show meaningful improvements in alcohol-related outcomes from pre- to post-training, but even stronger improvements among basics who receive eCHECKUP TO GO compared to basics who do not also complete eCHECKUP TO GO. This study will build on our prior work at BMT and the USAFA BCT pilot studies by examining whether anticipated effects are sustained over a 3- and 9-month follow-up period, which will help inform ideal timing of implementation and/or the need for booster training sometime following BCT. Follow-up assessments at 3 and 9 months will also allow for the assessment of changes in low-base-rate or occasional behaviors that may require more time to be observed.

Objective 1: Assess the feasibility and acceptability of implementing SCC with four-degree USAFA basic cadets in BCT (referred to as basics/basic cadets until they complete BCT).

Objective 2: Assess SCC program efficacy on proximal (knowledge, attitudes, beliefs, self-efficacy) and distal (protective behavior use, first-year sexual assault prevalence) outcomes compared to the Cadet Healthy Interpersonal Skills (CHiPS) TAU program across cadets' first year at USAFA.

Objective 3: Compare the efficacy of SCC alone to the combination of SCC plus eCHECKUP TO GO for alcohol use outcomes.

Data from the 2022-2023 and 2023-2024 APY studies will be merged to maximize statistical power and our ability to assess and differentiate program effects as described in Objectives 1-3, above.

7. Study Methods and Procedures

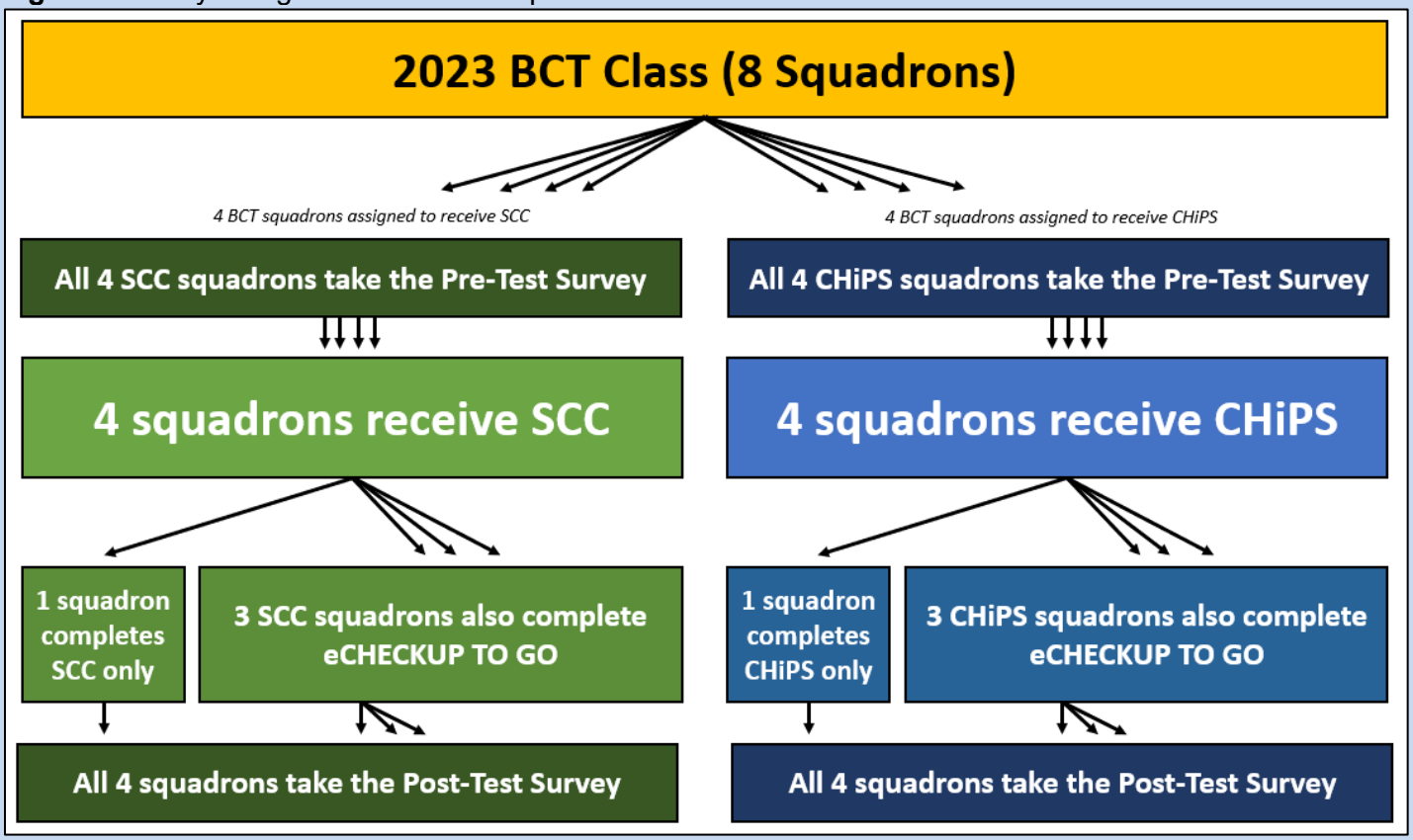
Describe the study methodology. Describe in detail all procedures the subjects will do in the order that they will do them, or what will be done to the subjects, (i.e., tasks and information to be gathered from or about the participants). Indicate whether subjects will be randomized for the study and describe the control and

experimental groups. Include descriptions of the facilities, equipment, and safety precautions, if applicable, the time for each task and total time for participation. Attach the data collection instruments or data items (e.g. interview script, survey tool, data collection form for existing data). Describe the analysis you will conduct to achieve your objectives. Your description of the research procedures should focus only on those procedures associated with participating in the research. If a participant will complete a given procedure regardless of whether or not s/he consents to participate in the research, then this procedure is not part of the research design.

Methods

This study will use a cluster-randomized repeated measures design. During 2022-2023, data collection and analysis compared SCC to CHiPS. The planned 2023-2024 follow-up pilot will involve four total conditions (i.e., SCC only, CHiPS only, SCC + eCHECKUP TO GO, and CHiPS + eCHECKUP TO GO). Assessments will be administered at pre-test, post-test, 3-month follow-up, and 9-month follow-up (Attachments 7b-e). Pre-test, post-test, and 3- and 9-month follow-up assessments contain identical questions for participants across all study conditions. Our team coordinated with and received approval from the Cadet Wing (CW) to integrate the SCC and eCHECKUP TO GO training and evaluation procedures into the existing SAPR training block currently designated for CHiPS during BCT (see Attachment 5 for CW approval documentation). Adapting the randomization approach successfully used during the 2022 BCT implementation for 2023 BCT implementation, the USAFA research team will randomly select, by BCT squadron, half of the incoming class to complete the SCC training, while the other half will complete the standard CHiPS training. Additionally, 3 out of 4 squadrons assigned to receive SCC and 3 out of 4 squadrons assigned to receive CHiPS will be assigned to also complete eCHECKUP TO GO during the SAPR training period. This study design (during the 2023 BCT period) is shown in **Figure A**, below.

Figure A. Study Design for 2023 BCT Implementation.



Although basics are required to complete assigned SAPR training, basics in both the SCC group and the CHiPS group will have an opportunity to indicate whether or not they would like to participate in the research study. (SAPR instructors will also let basics know they have the option to opt out of group SAPR training and receive alternative individual training content that meets SAPR training requirements.) By flight, basics will be

seated in their assigned SAPR training classroom; a trained instructor will introduce the purpose of the training and invite them to participate in the research study components (see recruitment script in Attachment 11). Basics who agree to participate will create a self-generated identification (ID) number on their assigned training government issued laptop (see confidentiality section below for additional details about how we will preserve participant confidentiality). Basics who do not want to participate in the research study will be instructed to enter all zeros ("0") or else "Prefer not to respond" answers to questions used to generate their self-generated participant ID number; this will allow them to continue with all aspects of the training without instructors or any other USAFA research personnel knowing their decision to decline participating in the evaluation. Their data will be excluded from the study prior to data analysis. Instructions for this consent procedure will be delivered orally via training instructors and in writing on basic cadets' government issued laptops prior to logging in to each training and/or data collection session (see recruitment script below). Basics will have the option to withdraw their consent to use their data at any time in the study. To avoid potential identification of non-participants, all basics will be informed that the surveys and trainings are tailored to them, so everyone will finish at different times and this is normal. We believe this protocol is a good candidate for consideration of exempt research status: BCT is an established educational setting within USAFA; SAPR training is a required component of BCT; the current study will test the feasibility of implementing an alternative training program and approach in the BCT environment, and evaluation assessments will be anonymous and analogous to typical end-of-course evaluations.

Facilities, Equipment, & Safety Procedures

Basics in all conditions will receive three SAPR training sessions during BCT. The first two sessions will each be approximately 2 hours long, and the third session will be 2-2.5 hours long. Training will occur face-to-face (with integrated, guided web-based training if receiving SCC or eCHECKUP TO GO training content) in a classroom setting. Classroom space will be provided by USAFA and coordinated/assigned by the SAPR office. Each basic will be instructed to bring a government-issued laptop on which they will complete training content and surveys. Basics will be provided with multi-directional privacy screens and individual headphones for use during program implementation to optimize participant privacy, and they will be instructed to lock their computers (e.g., CTRL+L) when they are not in use (i.e., during classroom activities, bathroom breaks).

Each BCT SCC training session and eCHECKUP TO GO training will be led by one or two trained instructors who are USAFA SAPR staff or affiliated volunteers. Many of the individuals who served as 2022 BCT implementation SCC instructors will again instruct during 2023 BCT implementation. Any additional staff/volunteers who become trained to lead SCC and/or eCHECKUP TO GO instruction will be added to this protocol via another amendment, and they will not be permitted to engage with study participants until review of their credentials/role (i.e., resumes, CITI certificates, and conflict of interest disclosures) have been approved by USAFA HRPP. Supporting documents for SCC instructors can be found in Attachments 12-14. In addition to their standard SAPR training, SCC/eCHECKUP TO GO instructors will complete a multi-day training on SCC and eCHECKUP TO GO content, delivery, and safety protocols. Training also includes hands-on practice facilitation of SCC content and equipment management and mock-completion of the eCHECKUP TO GO program (to become familiar with all elements of the web-based, self-guided alcohol misuse prevention content). Following training and throughout the study, research staff at external collaborating institutions will provide virtual (via phone or Zoom/Teams) technical assistance to SAPR staff and instructors to address any issues that come up during BCT implementation. As with all USAFA SAPR training, the SARC and/or a victim advocate will be on call during all instructional and data collection activities. Instructors will be thoroughly trained in recognizing and responding to distress, and they will follow standard SAPR procedures for making a referral or direct intervention and a warm hand off to the SARC or on-call victim advocate. Identical procedures have been in place and have worked without incident for the implementation of SCC at BMT (Lackland AFB) and in USAFA BCT during the 2021 and 2022 implementation.

Data Collection Procedures

This study will take place over two APYs to cover two enrolled cohorts, beginning with BCT 2022 and BCT 2023. Accordingly, data collection will span June 2022–April/May 2024.

BCT Assessments

All screener, feasibility, acceptability, and pre-test/post-test outcomes data will be collected on basics' government issued laptops in the BCT classroom environment.

The baseline survey includes the screener instrument and the pre-test outcome measures (Attachments 7a and 7b, respectively). The baseline survey will be administered to the entire incoming class during the SAPR/CWIC BCT briefing, which occurs prior to the designated SAPR training time during which SCC, eCHECKUP TO GO (for the 2023-2024 cohort), and CHiPS will be delivered. The screener will assess demographic characteristics, prior sexual assault experiences, and other forms of trauma that have been empirically linked to increased risk for sexual assault. Upon receiving a study ID, basics will complete a screening instrument, which will determine their classification within one of five prevention categories: female primary victimization or revictimization prevention; male primary victimization or revictimization prevention; or healthy relationships & bystander intervention promotion. For basics assigned to receive SCC, the screener survey will also route the basic into the corresponding tailored web-based SCC programming. Immediately following the screener, cadets will complete the pre-test assessment, which assesses knowledge, attitudes, and behavioral intentions specific to their assigned program (skip patterns will be utilized to tailor measures to each participant's program assignment based on the screening items and to minimize respondent burden).

At the end of each of the 3 designated training sessions, basics assigned to receive SCC will be asked to complete a brief (less than 5 minutes) acceptability survey. Basics assigned to receive CHiPS will complete a similar acceptability survey after Day 3 only. (See Attachment 8 for copies of both acceptability instruments). After completing the Day 3 acceptability survey, all basics will complete the post-test survey to examine any immediate program-related changes in knowledge, attitudes, and behavioral intentions (Attachment 7c). All acceptability and post-test survey instruments are integrated into the overall 6-6.5-hour training time. All assessments are derived from validated, gold-standard measures published in the sexual assault and alcohol misuse prevention empirical literature. As stated earlier, the Measurement x Timepoint Table (Attachment 9) summarizes which constructs will be assessed during each timepoint throughout the study.

Follow-up Assessments

The follow-up surveys will assess whether training effects on intended outcomes can be sustained over time. All fourth-degree cadets will be invited to complete an online survey during USAFA-approved assessment periods in the Fall and Spring semesters. At each time point, all four-degree cadets will receive an invitation to complete the follow-up survey, for instance as an email with an attached study recruitment flyer and link to the survey (see Attachment 11). Cadets will be asked to express their consent for the use of their data for research purposes (determined by the same self-generated ID procedures described above) after clicking on the survey link in the recruitment email. Unlike during BCT, cadets who enter the non-consent self-generated ID (i.e., all zeros ["0"] or "Prefer not to respond" answers to the items) will be directed to an end-of-survey thank you page (i.e., they will not see any outcome measures/questions). For the Spring 2024 survey, cadets will be invited to complete the survey using their own internet-connected device at a time and location of their choosing. A designated room on campus will be made available, should cadets prefer this quiet and private space to their dorm room or other area on campus. This room will be a general meeting area (e.g., conference room), not a classroom, reserved by Dr. Robinson through the schedulers that manage access to these buildings' access. A member of the IRB-approved study team with experience discussing sexual assault-related topics (e.g., USAFA SAPR staff) will be available to provide support if any cadets begin to experience distress.

Our study team appreciates the value and importance of cadet time. To minimize assessment burden, we will measure different constructs at each time point. The 3-month follow-up will assess sustained effects on knowledge, attitudes, etc. (see Attachment 7d). The 9-month follow-up will assess behavioral outcomes (see Attachment 7e).

Approval and Basis for Assessment Instruments/Items

All proposed measures have been reviewed and approved by the Survey Control Office (USAFA SCN 22-09 for the 2022-2023 cohort and SCN 23-06 for the 2023-2024 cohort; see Attachment 6 for documentation of

2023-2024 SCN approval). Furthermore, many measures proposed in the current study have undergone extensive legal review with HAF/A1Z and have received the appropriate approvals/waivers for administration in the field, as they have already been used in a large-scale feasibility study with high acceptability among ~8500 Airmen at USAF BMT, Lackland AFB (Scaglione et al., 2020). Although our prior work at BMT did not include 3- and 9-month follow-up assessments, members of the research team have routinely used these exact measures in online surveys with college-aged young adults without incident or reported participant distress (e.g., Hurtado et al., 2018; Reed et al., 2019; Scaglione et al., 2014; 2015; 2021). Furthermore, these measures were used in the 2021 and 2022-2023 APY pilot studies at USAFA without incident, and cadets reported high levels of acceptability and comfort with the measures. To minimize potential risk, SAPR staff will be on-call during all training activities and follow-up assessment windows, and all participants will receive a list of support resources during each training session and follow-up survey.

Additional Data Sources

In addition to assessing feasibility and acceptability from basics/cadets directly, we will also assess implementation fidelity via paper and pencil instructor feedback and observation forms (Attachment 10), and participant engagement/program completion through analysis of website metadata. External collaborating institutional staff who complete observation logs will not be engaged with/interact with participants, as they will only be sitting in on program sessions (in the back of the room, away from basics) to make notes about program fidelity and the USAFA classroom environment. Neither the feedback forms, observation logs, nor the metadata will include any identifiable information about participants.

Data Analysis Plan

Data from the 2022-2023 and 2023-2024 pilot studies will be combined whenever possible and appropriate to maximize statistical power and our ability to assess and differentiate program effects. Cohort-specific analyses may also be indicated in certain instances.

Data monitoring and analysis will be conducted by external collaborating institutions; all data will be anonymous and no personally identifiable information will be shared with external partners. Data download, sharing, and security procedures are described in detail in the “Confidentiality” section below.

Prior to testing for intervention effects, we will check for and address data entry errors, response inconsistencies, and outliers, following standardized data screening protocols. In order to characterize the sample and to aid in the interpretation of intervention effects, we will examine means, variances, and proportions for the main study outcomes for the entire sample and for relevant subgroups of participants (e.g., by gender, sexual orientation, and assigned tailored SCC program). A series of analyses will be conducted to examine the psychometric properties of multi-item measurement scales. Prior to running any inferential models, we will also examine the distributions of the dependent variables, as different specifications will be made for normally vs. non-normally distributed variables.

Univariate analyses will be conducted to examine the distribution of responses related to acceptability. Frequencies and percentages will be reported for categorical variables (e.g., the assessments of the amount of time spent on web versus classroom activities). To assess understanding of content and feasibility of dissemination of psychoeducational material to basics via classroom and tailored web-based programming, we will examine group- and individual-level changes in knowledge and attitudes from prior to training (pre-test) to after training (post-test assessment) and follow-up. Results will be reported as changes in frequencies and percentages for categorical variables and changes in means for continuous variables.

Where sample size allows, we will use conditional effects models to examine differences between pre-test and post-test assessments of acceptability ratings of the program conditions and preliminary program effects on proximal outcomes (e.g., sexual-assault-related knowledge, attitudes, beliefs; alcohol-related beliefs, protective strategies and intentions, and readiness to change alcohol use); we will use follow-up assessments to examine delayed effects on proximal outcomes and preliminary effects on distal outcomes (e.g., sexual assault victimization), again, where we are powered to do so. Assuming sufficient power and fulfillment of relevant statistical assumptions, latent growth models will be used to examine changes in proximal outcome measures across all three timepoints. Conditional effects and latent growth models are ideal for analyzing repeated

measures, as they account for nested data (multiple assessments within person), which violate the assumption of independence associated with traditional regression methods. Further, latent growth models allow for modeling of non-linear trends, which are common when evaluating program effects, as initial improvements often plateau or drop back down over time. To the extent that we are powered to do so (likely only for male healthy relationships and female primary victimization programs), mediation models will test program effects on hypothesized mechanisms of change. For example, we hypothesize, based on prior work, that men exposed to the healthy relationships and bystander intervention program will exhibit increased intentions to intervene, which will in turn increase actual bystander intervention behavior.

Results will be analyzed both at the aggregate level and by program intervention group. Specifically, we will closely monitor screener data to ensure the automated screening algorithm functions properly and that cadets are receiving the content that is most appropriate. We will also compare rates of prior victimization and perpetration recorded via comprehensive assessment versus a brief assessment to determine whether a brief assessment could be sufficient for group assignment while also minimizing cadet burden. We will examine trends in responses across groups (e.g., higher levels of enjoyment or engagement among cadets in one training group over another) and visually examine trends in knowledge and attitude change to ensure effects are in the intended direction. This will also allow us to monitor for unexpected trends, including potential negative impacts on cadets.

8. Sample Size and Power Analysis

(Applies to "Full IRB Review" submissions) Describe how many participants you will need in total and for each subgroup in the study. Explain why your sample sizes are sufficient to achieve your study objectives. If appropriate, provide the details of a statistical power analysis including the assumptions underlying the analysis that helped you to arrive at your chosen sample size. Note: For minimal risk studies, the IRB asks for the minimum number of subjects that you require. You may exceed this minimum without amending your study. For greater than minimal risk studies, the IRB approves a maximum number of subjects. You may not exceed this number without an amendment approved by the IRB.

N/A, Exempt status

9. Subject Recruitment Methods

(Applies to "Exempt" and "Full IRB Review" submissions, when appropriate) Describe how the prospective subjects will be identified for recruitment and the recruitment procedures. Particularly address the diminished autonomy of cadets (especially 4th class cadets) and how you will ensure that their participation is voluntary. Include the text of recruitment emails, announcement scripts to be used in classes or other settings and provide copies of flyers as attachments.

Basics will attend their assigned SAPR training during BCT. Trained SAPR instructors in civilian clothes will discuss the study with all basics face to face as part of the introduction to their required training. They will be asked to indicate their consent at the beginning of each assessment period by completing a series of questions to create a self-generated ID. At the end of each training day, cadets will be asked to provide feedback via their government issued laptops on the course materials and delivery from that day. Because participation is anonymous, all four-degree cadets will receive an email during the USAFA-designated assessment periods approximately 3 and 9 months after BCT inviting them to complete additional follow-up surveys. Throughout the USAFA-designated assessment period, the survey office will send reminder emails encouraging participation, which may also include a study-specific flyer and incentive information (for an example, see Attachment 11). Four-degree cadets may also be informed of the opportunity to voluntarily participate in follow-up assessments verbally by individuals outside of the chain of command (e.g., SAPR staff), such as at the end of a large-group briefing or other activity, or via the same flyers posted in permitted areas of campus (Attachment 11).

Fairness: All basics assigned to a particular BCT squadron will receive SAPR training (either SCC, SCC + eCHECKUP TO GO, CHiPS, or CHiPS + eCHECKUP TO GO) regardless of whether they wish to participate in the research study. Only data from basics/cadets who express their consent via creating a unique self-generated ID (i.e., basics/cadets who do not select all zeros ["0"] or "Prefer not to respond" in response to the

ID questions) will be included in the study. As such, this research protocol preserves fairness as the trainings will be the same for all 4th class cadets in the same BCT squadron. Neither specific inclusion nor exclusions of basics/four-degree cadets are planned, other than BCT squadron affiliation.

Diminished autonomy: By recruiting basics/four-degree cadets, we will be recruiting human subjects with diminished autonomy to participate. To account for this, persons with direct authority over potential subjects will not participate in recruitment and will not be present during recruitment processes. Furthermore, participants will never come in direct contact with the investigative research team; they will only interact with the instructional staff. SAPR instructors will wear civilian clothes during recruitment and recruitment will emphasize voluntary participation, direct benefits of participation, and measures taken to preserve participant anonymity. Participants will receive instruction that voluntary withdrawal from the investigation cannot be the basis for any retribution brought against the subject. Finally, participants will be given reasonable time to reflect on his or her participation and to ask questions of the training staff prior to deciding to participate in the study.

10. Potential Risks/Inconveniences:

(Applies to "Exempt" and "Full IRB Review" submissions) Describe any potential risks--physical, psychological, social, legal or other. Include total time required of subjects for participation and, if appropriate, how participation may affect availability for duty. Include an assessment or example of the severity and likelihood of the risk. Focus on research-related risks and inconveniences only.

The total time required for basics/cadets to participate in this study is about 90 minutes: 30 minutes for screening and pre-test administered via BCT CWIT, 20 minutes of surveys embedded in their 6-6.5 hours of BCT SAPR training, and 20 minutes each to complete the 3- and 9-month follow-up surveys administered during USAFA-approved assessment periods. Because all study activities occur during time specifically allocated for BCT SAPR training or assessments, basic/cadet availability for duty should not be affected.

Potential risks for study participants include slight psychological discomfort by talking and learning about psychological and relationship experiences that may not have been previously acknowledged or explored. For all participants, there is the potential risk of anxiety or discomfort concerning opinions, feedback, and beliefs. All possible measures will be taken to protect this information and confidentiality will be respected. While it is not anticipated that the proposed program will pose any threat to the physical or emotional well-being of participants, the research team will monitor subjects throughout the entire study via regular review of instructor feedback forms and participant feedback. Furthermore, due to potentially sensitive topics that will be assessed via surveys or discussed in the training, we have considered how potential distress for participants can be minimized and have developed a referral protocol for participants who experience emotional distress. In the unlikely event that a participant discloses abuse or intent to harm oneself or others, instructors will notify the PI and research team immediately, and we will notify the HRPP within 24 hours. Research staff and instructors will receive focused training on how to manage basics/cadets in crisis and will immediately refer any subject in suicidal crisis or in acute emotional distress to a local USAFA helping agency using a warm hand-off process to ensure safety. Based on data from over 8,700 trainees in BMT and successful pilot implementation at USAFA in 2021 and 2022 with positive cadet feedback, we can confidently state that these protocols are effective and there are no likely serious adverse effects of the proposed program.

There are also minimal risks associated with loss of confidentiality regarding participants' alcohol use data or identity as sexual assault survivors. Participants may be concerned about the effect that such a loss could have on their military careers or personal relationships. The likelihood of a loss of confidentiality is very low because participants will only be identified by an alpha-numeric unique ID, which cadets will generate at the beginning of the study, so it will never be linked to personally identifiable information. All participant data will be anonymous. While it is possible, given the small pilot sample size, that there will be unique gender/race/ethnicity combinations in the data, those data will never be linked with a course roster; only the SAPR Program Director/research coordinator (Ms. Sonja Strickland) will manage a roster to assure consistency in training across flights, and that roster will never be shared with course instructors.

11. Data Monitoring

(Applies to "Full IRB Review" submissions, when appropriate) If your study has risks that require monitoring of

the data (e.g. monitoring for potential side effects on participants) describe the data monitoring plan. Describe the conditions under which the study would be terminated early. Note that some non-medical studies may require data monitoring. For example, studies of sexual assault may require monitoring participants for adverse mental health reactions resulting from previous sexual assault experiences. If your study does not require data monitoring, put N/A in this section with a brief explanation of why data monitoring is not required.

N/A, Exempt status

12. Direct and Indirect Benefits

(Applies to "Full IRB Review" submissions) Describe as direct benefits where the participant will personally gain something from the study itself (e.g., a free body fat test). If there are no benefits, input the statement, "There are no direct benefits." Include any Indirect Benefits such as value to the scientific body of knowledge, information to improve a program, etc. Include only those benefits that are associated with participating in the research.

N/A, Exempt status

13. Risk/Benefit Analysis

(Applies to "Full IRB Review" submissions) Explain why you think the benefits of the research outweigh the risks from participating in the research.

N/A, Exempt status

14. Compensation

Describe what subjects will receive for taking part in the study. For example, if using the DF Subject Pool, state, "Subjects will receive extra-credit points in their [insert course number] course as it is stated in their course syllabus for participation in this study." Also include a statement regarding how this is affected if participation ends before completion of the experimental session. For example, if using the DF Subject Pool, state, "If participation in the experimental session is ended early, the subject will receive the amount of extra-credit equivalent to participation time."

Due to regulations at the United States Air Force Academy, participants will not be compensated for their time completing research activities during BCT (i.e., baseline, end-of-day acceptability, or post-test surveys). It is possible that the Spring 2024 follow-up survey will be eligible for time off via the Superintendent's Day authorization (through which cadets may be eligible for time-off for participating in any DSAT survey, not only our study's survey); this decision will be made at the USAFA leadership level and will affect all surveys administered during Spring 2024 DSAT, not only our study's 9-month follow-up survey.

15. Confidentiality and Data Management

A. What kind of data are you obtaining (*check all that apply*)?

☒ Quantitative ☐ Qualitative

B. Will you be obtaining data about individuals? *If you will only be obtaining aggregated data (e.g., graduation rate), select No.* Yes

C. *(If Yes to B)* Will you obtain a direct identifier such as name or social security number? No

D. *(If Yes to C)* Will you create a coded dataset in which you replace the direct identifier with unique alpha-numeric code specific to the study?

E. *(If Yes to D)* What will you do with the code sheet, the document linking the research-specific codes to direct individual identifiers?

F. (If Yes to B), Is it possible that some individuals could be identified indirectly through a combination of

demographic information? Unsure

Describe where the data or specimens will be stored, and how you will protect the data and/or specimens with respect to privacy and confidentiality. Provide a time table for destroying the data/specimens and identify how they will be destroyed, or provide a rationale for perpetual maintenance. Also specify who will access the identifiable data/specimens, and why they need access. If you intend to deposit your data in a data repository for use in replication studies as a part of the publication process, include this information and explain how you will make the data set non-identifiable prior to depositing it in a repository. If you are using data from Q2i or CAMIS, you must have an approved data use agreement that includes a plan for de-identification and/or destruction as a part of your submission. Note that you cannot close a study until you have either de-identified the data according to your data management plan or destroyed the data.

*Note: Anonymized data exclude direct identifiers such as names or social security numbers. De-identified data exclude **both** direct identifiers and indirect identifiers such as demographic information that could be used to identify an individual. Anonymized data are not necessarily de-identified; de-identification requires removing or otherwise masking demographic data so that it is impossible to identify an individual directly or indirectly.*

Data will be obtained directly from participating basics/cadets via self-report. In lieu of using participant names (or other identifying information), we will instead use a system-generated unique ID. As an additional safeguard, participants will be instructed to create a self-generated ID. Participants will create this ID by using a combination of variables, and the selfID is not shared with SCC instruction staff. Participants will be reminded multiple times that they can enter a predetermined value if they prefer to skip the question or if the question does not apply (e.g., “0” for single-digit responses or “00” for double-digit responses). A sample of questions include:

a. the subject’s gender (M or F),
b. the subject’s month of birth (e.g., 02 for February and 10 for October),
c. the number of siblings the subject has,
d. the first letter of state of birth (use first letter of birth country if not born in the U.S.),
e. whether born in an even numbered or odd numbered year (E or O),
f. the first two letters of the subject’s middle name, and
g. the first two letters of the high school the subject most recently attended.

A procedure for using similar questions to help link anonymous participant data has been described in the evaluation literature (Schnell et al., 2010) and was used in a previously implemented study of the CHiPS curriculum at USAFA. This ID procedure was used successfully in the 2021 (SCN 21-12) and 2022 (SCN 22-09) pilot study of SCC and effectively protected the confidentiality and anonymity of participants. This study will follow these successfully piloted procedures, and the ID and security questions will not be disclosed or linked to any personal identifying information maintained by the researchers or SCC/CHiPS instructional staff. This will ensure confidentiality and anonymity of participants while also providing a means of matching up responses from the same individuals over time.

Given neither the data management/analytic team nor the instructional staff will have participant rosters, it is highly unlikely any single participant could be identified by his/her data, directly or indirectly. Despite this low risk, we have implemented a number of additional physical, administrative, and technical controls to enhance data security and participant confidentiality.

Technological Privacy Safeguards:

This project will use a website hosted on RTI-controlled systems to collect data. The website is comprised of industry standard techniques; no proprietary services are being implemented or used. The system and its security controls (consistent with the National Institute of Standards and Technology (NIST) 800-53) were previously reviewed for a USAFA-issued PIA.

This website is serving distributed learning content utilizing technology developed under the Advanced

Distributed Learning Initiative (https://adlnet.gov/policy/dodi/); specifically, we are making use of the Experience API (xAPI). The xAPI sends data over HTTPS and stored data will be encrypted at rest. Cadets will access the website from their USAFA issued laptops with USAFA security controls built into those laptops. No project data is stored on the laptops, rather all project data is stored in the website system as they proceed to use the system.

Only trained research staff at partner institutions will have administrative access to the study data. Research staff will save de-identified data files to secure, password-protected share folders on institutional computers, which are also password-protected. None of the instructional staff will ever have access to the data provided by basics/cadets, further enhancing participant privacy and confidentiality.

At the end of the study, data files will be archived and stored in compliance with each institutions respective IRB data security protocols (e.g., in password protected files on limited-access computers) and retained for at least three years following study completion.

16. Informed Consent Process

(Applies to "Exempt" submissions under category 8 and "Full IRB Review" submissions) Describe the consent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing (whether there will be a waiting period), and steps taken to minimize the possibility of coercion or undue influence. Attach the Informed Consent Document (ICD) or request a waiver of documented informed consent.

If you are requesting a waiver of informed consent, or a waiver of some or all of the elements of informed consent, you must explain how your study satisfies the following waiver criteria from 32 CFR 219.116(f)(3):

i. The research involves no more than minimal risk to subjects (the risks from participating in the research are no greater than the risks from activities of daily life);

ii. The research could not practicably be carried out without the requested waiver or alteration;

iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

v. Whenever appropriate, the subjects or their legally authorized representative will be provided with additional pertinent information after participation.

Although SAPR training in BCT is mandatory, participation in this evaluation is voluntary. Instructors will make basics aware of the distinction between mandatory training and the voluntary evaluation using a recruitment script (see Attachment 11). Basics will also be provided with a printed copy of recruitment language, which they will be asked to review while instructors review key elements of the information and introduce the study. Upon logging in to their government issued laptops, basics will be asked to create their self-generated ID, which will serve as their consent for us to use their data in the evaluation of SCC and eCHECKUP TO GO. They will receive written and verbal instructions to enter all zeros ("0") or to select "prefer not to answer" to all of the ID generation items to indicate that they do not consent to their data being used in the evaluation. This procedure will be repeated at post-test (for CHiPS participants only) and follow-up surveys (for all participants) as a way to link their data anonymously over time. They are told they are welcome to withdraw their consent at any time by either entering all zeros ("0") or selecting "prefer not to answer" for their self-generated ID or by contacting the SAPR Program Director/research coordinator.

17. Relevant References from Literature

Provide full citations of references used above.

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18. Additional Information and Attachments

Include any information that did not fit above; reference the related page number and topic. List all attachments (e.g. ICD, training, CV, script).

Attachment 1. Robinson Resume

Attachment 2. Robinson CITI Certificate

Attachment 3. Strickland Resume

Attachment 4. Strickland CITI Certificate

Attachment 5. CW Approval of 2023-2024 SCC Follow-Up Pilot

Attachment 6. Survey Control Approval of 2023-2024 SCC Follow-Up Pilot

Attachment 7a. Screener survey

Attachment 7b. Pre-test survey

Attachment 7c. Post-test survey

Attachment 7d. 3Mo follow-up survey

Attachment 7e. 9Mo follow-up survey

Attachment 8. SCC and CHiPS acceptability survey

Attachment 9. Measurement x Timepoint Table

Attachment 10. Instructor Feedback Forms and Observer Logs

Attachment 11. Recruitment Materials (updated via Amendment 9)

Attachment 12. Instructor Resumes (names redacted)

Attachment 13. Instructor CITI Certificates (names redacted)

Attachment 14. Instructor COI Forms (names redacted)

Attachment 15. Research Coordinator CITI Certificate (Pokorny)

Attachment 16. Research Coordinator Resume (Pokorny)

Attachment 17. Research Coordinator COI Form (Pokorny)

Attachment 18. External Collaborator CITI Certificate, Resume, and COI Form (Schmied SDSU)

ASSURANCE STATEMENTS

The Determination Request Form should be reviewed and signed by all engaged research personnel, the Research Director or an individual with similar responsibility and authority, and the Department Head or equivalent of the PI's department. Scanned "wet" signatures or electronic signatures are acceptable, but please retain an editable copy of your document for possible amendments. Signatures beyond the PI are not required for "Not research involving human subjects" submissions.

ADDITIONAL RESEARCH PERSONNEL: (not included in Preliminary Information) Add additional personnel by copying and pasting the information in the box below.

Name & Rank: Sonja Strickland
Organization & Position: USAFA SAPR Deputy Program Manager
Telephone number: 719-333-6996
Email Address: Sonja.Strickland@usafa.edu
FWA or DoD Assurance Number (if not USAFA personnel):

Additional Personnel (see attachments for CITI Certificates, Resumes, and COI Forms):
Instructors
names redacted
Research Coordinator
Lisa Pokorny, USAFA SAPR, Licensed Clinical Social Worker

Principal and Associate Investigators' Assurance Statement (*must be signed by all research personnel whose activities engage their institution in human subjects research***): Add additional personnel by copying and pasting the information in the box below.**

I have read and understand 32 CFR 219, DoDI3216.02, AFI40-402, and USAFA policies concerning study involving human subjects and I agree:

1. **to promptly comply with all IRB laws, regulations, policies, decisions, conditions, and requirements;**
2. **to accept responsibility for the scientific and ethical conduct of this study;**
3. **to submit documentation of any publications or presentations that result from this study;**
4. **to appropriately amend or close a protocol prior to departing the Academy**

Principal Investigator
Dr. W. Ken Robinson
USAFA, Violence Prevention Integrator

US Air Force Academy

Endorsement by the Department Research Director or an individual with similar responsibility and authority (Note: No individual listed on this protocol may sign this section.)

This is to certify that I have reviewed this protocol and determined that it is scientifically valid, emphasizes good experimental design, and minimizes the use of and risks to human subjects.

N/A--waived

Endorsement by the Department Head or an individual with similar responsibility and authority (Note: No individual listed on this protocol may sign this section.)

I approve this research to be conducted by personnel within my department. I will ensure that the research personnel in my department comply with all IRB laws, regulations, policies, decisions, conditions, and requirements.

OTIS C. JONES, Colonel, USAF
Vice Superintendent
US Air Force Academy

(Signature waived for revision submission)

STATISTICAL ANALYSIS PLAN

Analysis Plan

Because of low follow-up survey participation rates among cadets who provided pretest survey data at the 3-month (13%) and 9-month (5%) assessments, only analyses of pre- to posttest data were conducted.[1] The outcomes examined and reported in this study were selected both because they were assessed at pre- and posttest and because they represent alcohol- and sexual assault–related factors that could reasonably change after participation in an integrated alcohol misuse and sexual assault prevention training (i.e., attitudes and knowledge). Study procedures and materials were reviewed by the USAFA Institutional Review Board and U.S. Army Medical Research and Development Command's Office of Human Research Oversight.

Descriptive statistics were computed for all variables to examine completeness and distribution. Group comparison tests (t-tests, chi-square tests, one-way analysis of variance) of participant characteristics at pretest were conducted to identify differences between conditions. To assess differences in change from pre- to posttest in outcomes by condition, we conducted mixed-effects multilevel models separately for each continuous outcome variable, with SCC + eCHECKUP TO GO set as the referent group. Independent variables included study condition (4-level: TAU, TAU + eCHECKUP TO GO, SCC, SCC+eCHECKUP TO GO), time, and time*condition. Covariates included cohort, race/ethnicity, and peer victimization. To examine moderation by sex, the models were replicated with the addition of interaction terms sex*time, condition*sex, and time*condition*sex. If the three-way interaction term was significant, models stratified by sex were computed. The same procedures were followed to determine whether condition effects were moderated by prior alcohol use. All analyses were computed in SAS version 9.4.

Measures: Sample Characteristics at Pretest

Sociodemographic information. All participants self-reported their age, sex, race/ethnicity, and sexual orientation.

Peer victimization. Past-12-month peer victimization was assessed with a three-item measure adapted from the Military Workplace Violence Study (Hourani et al., 2018). Participants self-reported how often one or more peers threatened their physical safety, put them through hazing activities, or harassed or bullied them (1: None of the time; 5: All of the time). Items were summed to create a continuous score.

Prior alcohol use. Participants self-reported their past-30-day alcohol use (as the number of drinks they typically had each day during a typical week during the month before arriving at USAFA) and were dichotomized based on whether they reported no alcohol use or any use.

Prior sexual assault victimization. Participants completed a 20-item measure derived from the Sexual Experiences Survey–Victimization (Testa et al., 2010) adapted based on cognitive testing with airmen (Goldstein & Scaglione et al., 2024). Items assessed whether participants had ever experienced unwanted sexual touching, intercourse, oral sex, anal sex, or other penetration. Participants were dichotomized based on whether they reported any or no prior sexual assault victimization.

[1] Analyses comparing 3- and 9-month survey responders and nonresponders identified systematic differences (in sex, prior alcohol use at pretest, and pretest readiness to change alcohol use behaviors) between the subsample of responders and total sample, indicating that presenting follow-up data could misrepresent the true program effects overall.

Prior sexual assault perpetration. Participants completed a 5-item measure adapted from the Sexual Experiences Survey–Perpetration (Johnson et al., 2017). Items presented combinations of behaviors that were and were not illegal according to the Uniform Code of Military Justice (e.g., "*Prior to arriving at USAFA, have you ever used a position of authority [such as being a coach, manager, or teacher] or taken advantage of someone in a compromising position [such as if you caught them breaking a rule] to have sex or do other types of sexual things with them when they indicated they didn't want to?")*. This assessment strategy facilitated effective screening of prior perpetration behaviors for the purposes of this study without leading participants to endorse specific illegal behaviors. Participants were dichotomized based on whether they endorsed any or none of the items.

Measures: Alcohol–Related Outcomes (Pre- and Posttest)

Normative perceptions of peer alcohol use were assessed with a modified version of the quantity/frequency/peak questionnaire often used in peer-normative feedback research (Baer et al., 1991; Dimeff, 1999; Doumas et al., 2020). Participants were asked how many days in the week the average cadet of their same age and gender drinks (0–7 days) and how many drinks that average cadet consumes per day (0–6 or more); for analysis, these values were multiplied to compute the number of estimated drinks consumed per week.

Readiness to change alcohol use behaviors was assessed with one item, "Please indicate your readiness to change your drinking behavior." Response options ranged from 0 "not at all ready" to 4 "very ready" (Reed et al., 2019).

Measures: Sexual Assault–Related Outcomes (Pre- and Posttest)

Knowledge of sexual assault was assessed using an 8-item scale adapted from previous research (Hanson & Gidycz, 1993, Kan et al., 2024). Participants were shown statements about sexual assault and indicated whether the statement was true or false; for example: "*Sexual assault always involves the use of physical force.*" Some statements were tailored to reflect participants' knowledge of sexual assault specific to the Air Force or USAFA. Respondents received a score indicating the percentage of correct responses.
Knowledge of effective consent was assessed with 7 true/false items that included statements pertaining to sexual consent such as, "*If you are in a steady relationship, you still have to get consent for sex*" (Salazar et al., 2014, 2023). A score indicating the percentage of correct responses was computed.

Self-efficacy to resist unwanted sexual advances was assessed among a subset of participants across conditions (only those assigned to the primary sexual assault victimization prevention or sexual assault revictimization prevention categories). Using a 6-item scale, participants rated their degree of confidence (1 = not at all confident; 7 = very confident) in their ability to use certain strategies in high-risk situations, i.e., "*How confident are you that you could successfully resist someone's pressuring if they were attempting to get you to consume alcohol, despite your wishes not to do so?"* (Hall, 1989; Kan et al., 2024; Marx et al., 2001). Individual items were summed to create a scale score ($\alpha_{Pretest}$ = 0.81).