

EMORY UNIVERSITY
Quantitative and Qualitative Study Protocols

Title	Preventing Sexual Violence in College Men: Adaptation and Impact Evaluation of <i>RealConsent</i> for Use in Vietnam
Short Title	RealConsent Vietnam
Principal Investigator	Kathryn M. Yount, PhD Asa Griggs Candler Chair of Global Health and Professor Hubert Department of Global Health
Sponsor(s)	Wellspring Advisors, LLC
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External Non-Emory Collaborators

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IRB	This protocol and Dr. Tran’s engagement in human subjects research activities will be reviewed and approved by the institutional review committee at Hanoi University of Public Health (HUPH).

Background and Significance

Introduction	<p>Problem. Sexual violence is any sexual act committed against a person without freely given consent. Men and women may experience sexual violence, but most victims are women. Women’s first experiences of sexual violence often occur in adolescence. In Asia and the Pacific, about 14% of sexually experienced adolescent girls report forced sexual debut. Thus, early prevention with men is critical; yet, young men often are difficult to reach and may resist programs that target sexual violence, not seeing themselves as potential perpetrators. Prevention with men that integrates a bystander framework, which treats men as “allies” of women, is one way to target attitudes and behaviors while decreasing resistance to participation. Project Goals. In this project, we will adapt an existing program for use with men attending one of two universities in Hanoi, Vietnam. We will test the impact of the adapted program on knowledge/attitudinal/emotional mediators, and in turn, on sexual violence perpetration and prosocial bystander behavior in this target group. The program is a novel, six-session, web-based serial drama and educational program designed to prevent sexual violence perpetration and to enhance prosocial bystander behavior in young men. The program has reduced the incidence of sexual violence among men attending an urban, public university in the Southeastern United States. Methods and Activities. We will use a mixed-methods design and the Center for Disease Control and Prevention’s Map of the Adaptation Process framework to adapt the program for college-going men in Vietnam, and then to test the impact of the adapted program in samples of men attending two universities in Hanoi. The qualitative research will have two steps. In step I, we will conduct semi-structured interviews with college men</p>
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	<p>(n=10) and women (n=10) to understand the social context of sexual violence in this setting, and focus group discussions (FGDs) with college men (n=12) and university stakeholders (n=12) to elicit feedback on the original program. From these data, we will create scripts in storyboard format of the adapted program. In step 2, we will conduct FGDs with college men (n=12) and university stakeholders (n=12) to elicit feedback on the storyboards and to refine the adapted Program to ensure acceptability. We will use grounded theory to analyze all transcripts inductively and deductively, identifying themes and patterns among themes and comparing the emergent theory with the underlying theory of change of the program. From the final storyboards, we will produce a web-based adaptation of the program in Vietnam. Finally, we will conduct a randomized controlled trial to test the impact of the adapted program (n=200), relative to a health-education control condition (n=200), on knowledge/attitudinal/emotional mediators, and in turn, on sexually violent behaviors, and prosocial bystander behavior in freshmen men attending two universities in Hanoi. Innovation and Long-term Impact. This project will be the first to adapt and to test the impact of a novel, theoretically grounded, web-based intervention to prevent sexual violence perpetration and to promote prosocial bystander behavior among young men for use in a middle-income country. If our project shows that the adapted program is effective cross-culturally, it will have exceptional potential for scale-up to prevent men's perpetration of sexual violence against women globally.</p>
<p>Background. Existing factors. Preliminary studies. Supporting literature.</p>	<p>Sexual Violence is Global and Disproportionately Burdens Women</p> <p><i>Sexual violence</i> is any sexual act committed against a person without freely given consent. Sexual violence ranges from unwanted sexual contact and non-contact sexual experiences to completed or attempted forced penetration.¹ Globally, about 7.2% of women 15 years or older report some form of non-partner sexual violence, and estimates for Southeast Asia are similar, at 5.2%.² Between 16.4% and 19.7% of women and girls globally have reported sexual abuse in childhood (before age 18),³ and 14.9% of sexually experienced adolescent women 15–19 years have reported forced sexual debut.⁴ In Asia and the Pacific, forced sexual debut in sexually experienced adolescent women is an estimated 13.8%.⁵ The physical, psychological, and economic aftermath of sexual assault often is severe for its victims,^{6,7} totaling \$127 billion yearly in medical costs, lost earnings, pain, suffering, and lost quality of life in the US alone.⁸ Men can experience rape and sexual assault, but women comprise 91% of victims.⁹</p> <p>Masculinity Norms Influence Men's Perpetration of Sexual Violence against Women in Vietnam</p> <p>Social cognitive theorists argue that behaviors are learned by observing others, and are reinforced by observing the associated rewards or consequences.^{10,11} In this way, boys who witness inter-parental violence or experience direct maltreatment may come to view violence in relationships as normal. In lower- and middle-income countries (LMICs),^{12,13} including sites in Vietnam^{14,15} and Bangladesh,¹⁶ witnessing male-on-mother violence or experiencing child maltreatment predicts men's later perpetration of partner violence.</p> <p>Hearn¹⁷ argues that "any learning (of violence or indeed anything else) is...gendered. Thus, boys may learn not only that violence is possible and is performed by older males, but also that it is done in the context of male domination more generally" (p. 27). In Vietnam, Rydstrom¹⁸ has characterized</p>

“violent inter-generational practices” between grandfathers, fathers, and grandsons or sons as “tangible manifestations of a masculine discourse...composed of a tradition of patrilineal ancestor worship [and] ideas about honor” (pp. 329-330). Confucianism stresses moral obligations in hierarchical relationships, such as father with child, older brother with younger brother, and husband with wife. Older persons are respected for their greater proximity to deceased ancestors, and the superior is expected to educate the inferior, who should return obedience, gratitude, and filial piety.^{19,20} Gendered privilege is embedded in this kinship system, as descent is traced through fathers.^{21,22} As such, senior men are viewed as superior to senior women,²³ and a senior man symbolically and customarily heads the household.^{18,24,25} Thus, the head of household has the right to raise, educate, and discipline junior male and female kin,^{21,22,26} for example, by instilling fear or using physical punishment.^{27,28} Such methods teach children “their subordinate role in the learning process” and the nature of social relations more generally.²⁹ For instance, a mother or grandmother would rarely beat a son, because doing so would challenge the male household head’s authority to assess when corporal discipline is “needed.”¹⁸

Violent intergenerational relations among male kin also reflect local ideas about “hot” superior masculinity and “cool” inferior femininity.¹⁸ When a father corporally punishes a son, the father elevates his own masculinity and demotes the boy to an inferior (feminine) position.¹⁸ Boys may even describe such violence as “justified” if they see themselves as at fault.¹⁸ In many male–male relational contexts in Vietnam, using violence to establish hierarchies among men and to reinforce violence is an accepted aspect of dominant masculinity.²⁸

In practice, new household arrangements are challenging these age-gender hierarchies.^{21,30-32} Since the 1990s, schooling attainments have reached gender parity³³ and women³⁴ increasingly migrate for work, spurring some husbands to assume unpaid family work.³⁵ These deviations from customary age-gender hierarchies may threaten the “entitlements” of senior men, spurring violence as a means to reinstate male dominance.²⁸ Thus, men’s dominance and use of violence not only is embedded in local patrilineal kinship systems, but also may increase in response to structural changes in gender relations.

The Legal Framework in Vietnam Favors Sexual Violence Prevention

In the context of social norms and kinship practices favoring male dominance, the State has pursued legal reforms to promote gender equality, penalties for gender-based violence, and violence prevention. The Law on Marriage and Family in 1986 gave men and women equal rights in marriage, and the Law on Gender Equality in 2006 sought to eliminate gender discrimination and to curb differential rights based on gender.³⁶⁻³⁸ The Penal Code of 1989 defined penalties for acts of sexual violence.^{39,40} Rape was defined legally as an act committed by someone who, through violence or its threat, or by using the victim’s helplessness or other means, forces the victim to have sexual intercourse against her will. Rape carries a punishment of imprisonment for two to seven years. Convicted offenders are barred from certain jobs or positions of responsibility for one to five years. Terms of up to 20 years or even life imprisonment could be imposed when victims suffer grievous bodily harm, perpetrators are known HIV carriers, or victims die or commit suicide because of the rape.⁴¹ A 2007 law codified definitions of physical, psychological, sexual, and economic violence as a step to prevent these forms of violence.^{42,43}

	<p>Preventing Sexual Violence Must Engage Men</p> <p>Despite legal reform, sexual and other forms of violence against women persist in Vietnam.^{37,43} In our research outside of Hanoi, men have discounted, excused, or denied many acts of violence.⁴⁴ As a result, men’s reported rates of sexual violence perpetration (0.2%) are lower than women’s reported rates of victimization (12.0%).¹⁵ Thus, prevention work with men is critical to create an environment where women’s bodily integrity and freedom from violence are possible.⁴⁵ Yet, young men often are difficult to reach^{46,47} and resist programs that target sexual violence, not seeing themselves as potential perpetrators.⁴⁸ Limited data also suggest that the behavior of bystanders, or witnesses of sexual violence, is gender-specific.⁴⁹ Although evidence from rigorous evaluations is limited,⁵⁰ prevention with men that integrates a bystander framework is a way to target attitudes and behaviors while decreasing resistance to participation⁵¹⁻⁵³ because men are treated as the “allies” of women.⁵⁴</p>
<p>Innovation. Generalizability. Intended purpose and audience for results.</p>	<p>The proposed project will disrupt several programmatic paradigms related to the prevention of sexual violence. First, interventions to prevent sexual violence by young men are rare in low- and middle-income countries.⁵⁵ This project will be the first to adapt and to test the impact of the program on sexual violence prevention and prosocial bystander behavior in college-going men in a middle-income country. Second, even in high-income countries, most programs entail in-person, small-group formats, which limit their reach and public-health impact.^{56,57} The program is a novel, theory-driven, evidence-based serial drama and educational program tailored to young men and delivered in six episodes via the web. Each of these novel features of the program warrant comment:</p> <ol style="list-style-type: none"> 1) Gender-specific programming. First, gender-specific content is shown to be more effective than gender-generic content in behavioral interventions to reduce drinking⁵⁸ and to prevent rape.⁵⁹ As such, programs to prevent sexual violence perpetration should be gender-specific.^{60,61} The program is the only gender-specific program commercially available for cross-cultural adaptation. 2) Evidence-based approach. Second, the program integrates well-known behavioral change techniques, which we will retain in the adapted program for Vietnam. These techniques include 1) providing information and instruction on obtaining effective consent for sex and intervening safely, 2) modeling communication and intervening behaviors; 3) showing positive outcomes for getting consent and intervening plus negative outcomes for perpetrating and not intervening; and 4) reinforcing with support and positive feedback.⁶² 3) Interactive, problem-based learning via educational entertainment. Third, the program uses several best practices, such as didactic presentation of material via video and infographics, problem-based learning with interactivity, and short videos or animations to model behavior. Problem-based learning activities with real-time feedback are core elements. These activities require the user to make a decision (e.g., “do something” or “stay out of it”) after viewing a brief filmed scenario. Based on his decision, the user is guided through a sequence of outcomes so each consequence of a poor choice is shown. This feature is based on theories of social learning by reinforced practice,⁶³ and the program enhances this formula by adding educational entertainment, starting and ending each module with a 3-minute episode of a professionally written,

	<p>produced, and edited serial drama based on formative research. In the US, most male participants rated the episodes as an effective or highly effective way to learn about consent and prosocial intervening behaviors.⁶⁴</p> <p>4) Web-based and mobile website platforms. Initially, behavioral change techniques were developed for delivery to small groups in person. Today, researchers are applying best practices for behavioral change techniques to web and mobile applications. Online behavioral-change programs tend to have larger effects when they include more behavioral change techniques,⁶⁵ deliver content that resonates with the user,⁶⁶ and integrate audio, graphics, and interactivity.⁶⁷ For example, a gender- or race-specific vignette may resonate (via vicarious learning) with a like user and, thus, have stronger effects on knowledge and motivation, because personal relevance enhances learning and increases motivation to complete the program. These techniques are part of the web-based platform of the program, and will be retained in the adaptation for Vietnam.</p> <p>The high video-production quality of the program, with rigorous scientific content based on principles of behavioral change tailored to young men, will appeal to educational leaders who seek to reduce sexual violence in their schools. The program has reduced the incidence of sexual violence perpetration in men attending an urban, public university in the Southeastern US.⁶⁸ Once developed, web-based programs like the program are less resource-intensive to adapt.⁶⁸⁻⁷⁰ If shown to be adaptable and effective in Vietnam, the program has exceptional promise as a cost-effective, scalable means to reduce the incidence of sexual violence against women globally.</p>
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Goals/Aims

The results from the qualitative research arm of this study conducted in AIM1 will inform quantitative research in AIM2 . Specifically:	
Qualitative Arm	
AIM1	We will conduct formative qualitative research to identify and to adapt non-core elements of the program to be acceptable to the local context and target population. The goals of the program are 1) to increase prosocial intervening behaviors, such as trying to stop a peer who is being coercive, which reduce the risk for sexual violence perpetration, and 2) to prevent sexually violent behaviors toward women.
Quantitative Arm	
AIM2	From the qualitative arm, we plan to adapt the program for use with college men in Vietnam and to test whether it: H1 improves their knowledge, attitudes, and emotional valence regarding sexual violence against women H2 increases their tendency to intervene to prevent such violence; and H3 reduces their propensity to perpetrate sexual violence against women.

Qualitative Study Design

Organizational structure of the team	Translation, Recruitment, Training, and Ethics/Research Committee Approval. Contributions to Data Collection, Analyses, Interpretation, Writing, and Dissemination Activities.
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	<p>CCIHP Site Principal Investigator: Tran Hung Minh, MD, MSc Research Assistants (Total = 2) for Pilot, SSIs, FGDs Interviewers: (4, ≥ Master’s level) Supervisor: (1, ≥ Master’s level)</p> <p>Emory University IRB Approval, Contributions to Data Collection, Analyses, Interpretation, Writing, and Dissemination Activities. Emory University Principal Investigator: Kathryn M. Yount, PhD Co-Investigator: Jessica Sales, PhD Consultant: Laura Salazar, PhD</p>
<p>Setting and location</p>	<p>Setting. The undergraduate system in Vietnam is a suitable context for adapting the program, given its similarities with the US context where the program originated. Undergraduate study is 4–6 years, with two foundational years and 2–4 years for specialization. Except for political education and national defense, universities design their own curricular and extra-curricular activities and maintain networks through the Ministry of Education and Training (MoET), professional associations, and Youth Union, all potential pathways to bring the program to scale in the future.</p> <p>Study site. The sites for this project are Hanoi Medical University (HMU) and Thang Long University (TLU), both in Hanoi. HMU is a 100-year-old state school with dental, medical, nursing, nutrition, public health, and paramedical/ ophthalmology technical programs. Its 1000 enrolled students are 40% men. TLU is a 24-year-old private university with 15 departments (e.g., math, business administration, social sciences). Its 7000 enrolled students are 45%-50% men. Both schools have provided letters of support for adaptation of the program with their students.</p>
<p>Study Population</p>	<p>In step 1 of the qualitative work, we will conduct semi-structured interviews (SSIs) with undergraduate men and women and meetings with university stakeholders. In step 2, we will conduct FGDs with college men..</p>
<p>Recruitment</p>	<p>Qualitative samples. Qualitative research participants will be men and women undergraduates and university stakeholders (administrators and faculty) at HMU and TLU. To recruit students, CCIHP personnel will contact department chairs to discuss the study with them. With their agreement, CCIHP will talk with faculty about the study and ask them to announce it in their classes using a flyer with a brief, standard project description. Students will contact the research team to take part. The team has used this strategy successfully to recruit undergraduates. CCIHP key personnel will hold separate meetings with university stakeholders to invite their participation. CCIHP will work with the chairs of departments to announce the study in their regular meetings and invite the staff to participate (who are interested in the topic of sexual violence/and or working in this field, want to learn about the program, have good understanding and information about male students’ relationships with female students or with other girls so that they can contribute effectively to give comments and adapt the program). Male focus group discussion participants will be recruited purposively to represent a range of ages, years of study, sexual experience, and other relevant demographic characteristics.</p>

Field Methods

MAP Step	Data Collection Method	Hanoi Medical University			Thang Long University			Total
		Men	Wome	Staff	Men	Wome	Staff	
Assess	Meetings with university staff	0	0	6 (5-6)	0	0	6 (5-6)	12
	Semi-structured interviews	5	5	0	5	5	0	20
Prepare A,P	Focus group discussions (size)	6 (5-10)	0	0	6 (5-10)	0	0	12
	Field diaries		4			4		8

Notes. A=assess step; P=prepare step

collection overview. In step 1 of the qualitative work, we will conduct semi-structured interviews (SSIs) with undergraduate men and meetings with university stakeholders. In step 2, we will conduct FGDs with college men.. Semi-structured lists of open-ended questions or viewing guides will guide each SSI and FGD, respectively, with options to probe unexpected responses. Interviewers will keep field diaries to record their observations and interactions during data collection. Table 1 shows the data collection plan for each MAP step. Participants will be reimbursed (\$5 per student \$15 per university stakeholder) for their time and will receive refreshments.

Semi-structured interviews. SSIs will allow us to explore the context of sexual relations and sexual violence among young people in Vietnam. Trained interviewers will elicit narratives about dating, sexual violence events, views about these events, and sexual violence generally. Narratives enable analyses of how a person's memories of the past and expectations of the future shape their understanding of personal experience.⁸³ Through narratives, we will explore how participants perceive acts of sexual and other forms of dating violence and understand "consent," "rape," local laws on sexual and other forms of dating violence, and forms of recourse for survivors. We will ask participants about their personal attitudes and about family and community norms. These data will clarify the context in which the program will be adapted.

Meetings with university staff. University staff (n=10-12) across the two participating universities will be granted access to program materials to view individually and provide written feedback. Research staff will meet directly with university staff to discuss their impressions of acceptability and relevance of program modules. Feedback from university staff will inform the direction of FGDs with university men.

Focus group discussions. Interactions among participants in FGDs can elicit diverse views on a topic, discussion and debate, explanations of issues, and "normative" data that would not emerge from SSIs.⁸⁴ We will conduct 12 FGDs with 5-10 university men each,, distributed evenly across universities. (Table 1). Groups will meet in an accessible location (e.g., school building) to view together 2 modules from the original program with subtitles in Vietnamese and provide feedback. As part of the FGD, they will be asked to complete viewing guides to assist in collecting their impressions of the program. These data will inform decisions about adaptations of the program. We will use their feedback to assess the acceptability and relevance of adaptations, ensure that the core elements of the program remain, and finalize changes to ensure acceptability and relevance.

Fieldwork and data management. Interviewers will be Vietnamese men and women (4:2) experienced in qualitative research on gender-based violence. Fieldwork at HMU and TLU will occur concurrently so learning from one site informs data collection at the other. CCIHP personnel will visit both sites regularly to supervise the work. Interviews will be in Vietnamese and will be transcribed and

	<p>translated into English at CCIHP. Collected data will include audio recordings, textual transcripts from the SSIs and FGDs and text from interviewer field diaries and viewing guides (Table 1).</p> <p>Quality control. We will listen to a random sample of 20% of the audio-files to confirm that transcripts are complete and accurate. One additional FGD each with young men and university staff will be conducted near the end of the analysis to share the findings and to ensure their credibility.⁸⁵</p>
<p>Informed Consent</p>	<p>Assurances, IRB approvals, and oversight: Our ethics protocol will follow WHO guidelines for research on violence against women.¹³¹ Ethical approval will be sought from CCIHP, Emory University, and Georgia State University. Team members have completed certification training in research ethics.</p> <p>Consent process. Informed consent will be sought when eligible participants are first asked to take part. Informed consent requires a clear understanding of the study’s purpose; voluntariness, nature, extent and duration of participation; extent of confidentiality; right to anonymity; and right to withdraw any time. Participants will be informed that, with permission, SSIs and FGDs will be audiotaped, and researchers will take notes. Because CCIHP does not feel written consent is suitable, we will audiotape verbal consent with a witness before starting interviews. Qualitative interviews will be conducted in private settings at the study sites, where the interviewer will provide more detail about the exact nature of the study, procedures, and any expected risks and benefits to eligible participants. Participants will be informed that audio-recordings will be kept in a locked cabinet or secure computer with limited access for a specified duration before being destroyed. All participants will be compensated appropriately for their time (without overcompensation) and qualitative research participants will be offered refreshments. Online consent will be obtained before participants will be allowed to view and participate in the online survey for the impact evaluation portion of this study.</p>
<p>Potential Risks / Discomforts. Protections.</p>	<p>College men and stakeholders taking part in step 1 FGDs may experience embarrassment or stress when giving opinions on the content of the program. College men and women taking part in SSIs and may feel stress or adverse psychological reactions to questions about personal experiences of sexual violence or may reveal related prior experiences, such as child maltreatment, dating violence, or witnessing parental violence. We do not foresee any risks for participating in round 2 FGDs, to elicit feedback on adapted scripts and segment materials, although some may experience some stress and embarrassment from reviewing these materials. College men may experience stress or adverse psychological reactions to survey questions about sexual violence perpetration or prior experiences of violence exposure.</p> <p>Protection against Potential Risks. Procedures to protect participants against risk include:</p> <ol style="list-style-type: none"> 1. CCIHP will identify and retrain field staff with prior experience conducting qualitative research on gender-based violence. Local staff will be prepared to handle potential risks. 2. Every effort will be made to enhance disclosure and to ensure the accuracy of collected data.¹³¹ for example, we will avoid questions with abstract or value - laden terms (e.g., “abuse”) and use questions that guide SSI participants through specific instances of sexual violence. Also, we will match female participants with mature, female interviewers who are similar in age and experienced at discussing

	<p>sensitive issues. Similarly, male interviewers will interview male study participants, or will be interviewed in private via the online survey platform.</p> <p>3. Before starting a SSI or quantitative online survey, participants will be told their responses are confidential and they can, at any time, stop the interview and request assistance using the contact information provided on the consent forms.</p> <p>4. Before starting a FGD, participants will be told the guidelines for participation, such as “please do not discuss what was said during the group with others outside this group,” “be respectful of each other’s comments and do not talk over each other,” “if you do not want to answer a question, you do not have to,” and “if you need to leave, please let us know by raising your hand and we can help you leave the group.”</p> <p>5. We will state that participants have the right to withdraw any time during their SSI, FGD, survey, or viewing of the program.</p> <p>6. SSIs and FGDs will be audiotaped. The digital file will be transcribed verbatim; participants will be identified numerically. Transcribed files will be stored on a password-protected computer in a locked office at CCIHP, accessible only to study staff. After data analysis, digital files will be destroyed to protect confidentiality.</p> <p>7. Counseling services will be offered to participants experiencing adverse psychological reactions associated with participating in SSIs, FGDs, or review of the program materials. Services will be provided by the Center for Studies and Applied Sciences in Gender – Family – Women and Adolescent (CSAGA) a non-governmental, non-profit organization that promotes the rights of women and children vulnerable to violence and discrimination. CSAGA operates 6 counseling hotlines and a counseling hotline by the Ministry of Labour and Social affairs (for children). CCIHP also operates a website and free online counseling for youth on gender, sexuality, and sexual violence. A resource list with numbers and websites for counseling services will be provided for all participants.</p> <p>8. Procedures to minimize loss of confidentiality include encryption to maintain the confidentiality of participants’ identity and their data. Collected data will be identified only by identification numbers with no personal identifiers. Personal identifiers will be redacted from transcripts, and pseudonyms will replace names. Confidential data will be kept in a locked office file cabinet with restricted access. Names will be stored in a separate locked cabinet and will not be linked to study data.</p> <p>9. We will work with our respective IRBs to obtain a Certificate of Confidentiality.</p>
Benefits	<p>Study participants will receive no direct benefit from their involvement in this research. The insights gained from this study, however, should improve college men’s engagement in prevention of sexual violence against women. Considering the extensive protections to be undertaken to minimize potential risks to participants in this research, and the substantial anticipated benefits for future research and policy development, no problems are anticipated that outweigh the advantages of the proposed research.</p>
Compensation	<p>Participants will be reimbursed (\$5 per student \$15 per university stakeholder) for their time and will receive refreshments.</p>
Data Management and monitoring	<p>The qualitative data will consist of verbatim, textual responses to open-ended questions administered in face-to-face interviews and group discussions with men and women. University staff and FGD participants will also provide written data in viewing guides to be completed while viewing program content either individually or</p>

	<p>as part of a FGD. Information linking the names of specific individuals will be kept in a locked filing cabinet and a security-protected computer. Given the sensitivity of the topic under study, it is especially important that the instruments to be used in these interviews are well designed, and that the interviewers are well trained in the conduct of research on sexual violence. To these ends, we will employ interviewers who have worked with us previously on studies related to gender and violence. These interviewers also will receive refresher training on the issue of sexual violence, ways of asking questions about sensitive topics, the management of difficult situations that may arise from the discussion of these issues, the importance of and methods for ensuring confidentiality, and the safety and protection of participants in the study. Every effort will be made to enhance disclosure and to ensure the accuracy of the data that are collected. We will avoid general questions that use abstract or judgmental terms (e.g., “abuse”), and use questions that guide the study participants through a range of specific acts, settings, and circumstances of violence. We will be mindful of study participants’ interpretations of the questions and terminology, and the effects of question ordering on responses. Our experience suggests that interviewers who are similar in age and matched on gender to the participants and who are skilled at discussing sensitive issues can enhance trust.</p>
<p>Plans for analysis</p>	<p>Qualitative data analysis entails a “search for patterns in data and for ideas that help explain why those patterns are [present].”⁸⁶ We will use a grounded-theory approach, or techniques to identify categories and concepts that emerge from text and to link them into substantive and formal theories.⁸⁶ This approach combines deductive and inductive techniques to discern general themes while allowing new understandings and sub-themes to emerge. We also will use narrative analysis, which preserves the particularities of a narrative while framing individual narratives within larger socio-cultural patterns.⁸⁷ The use of multiple sources of data, or triangulation, enhances the validity of data obtained from a single source.⁸⁴ Thus, notes from field diaries and verbatim transcripts of the FGDs and SSIs will be coded similarly and analyzed through constant comparative analysis.⁸⁸ Two study team members will code all notes and transcripts separately using the MaxQDA qualitative software program; one in English, and one in Vietnamese. Emory and CCIHP key personnel will supervise the coding to verify that findings are grounded in the data. The team will discuss cases when the RAs disagree, and themes on which two or more team members agree will be included in the final analysis. These steps adhere to qualitative data analytic strategies in the social and behavioral sciences.</p>
<p>Confidentiality</p>	<p>All key personnel have completed the Human Participant Protections Education for Research Teams online course, sponsored by NIH or the Social/Behavioral Research course through CITI.</p> <p>As previously detailed in the protections of risk section, above, we are careful to ensure confidentiality. Several strategies will be used <u>to ensure the confidentiality of participants</u> in the research.</p> <ol style="list-style-type: none"> (1) Interviewers will receive strict instructions about the importance of maintaining confidentiality. (2) Interviewers will not conduct research within their own communities of residence. (3) The names of study participants will not be written on questionnaires or interview guides. Instead, unique numeric codes will be used to distinguish the questionnaires and textual transcripts of study participants. (4) If identifiers are needed to link a questionnaire with a household location or a particular study participant, these identifiers will be kept separate from the questionnaires in a locked cabinet or separate, secure computer with access

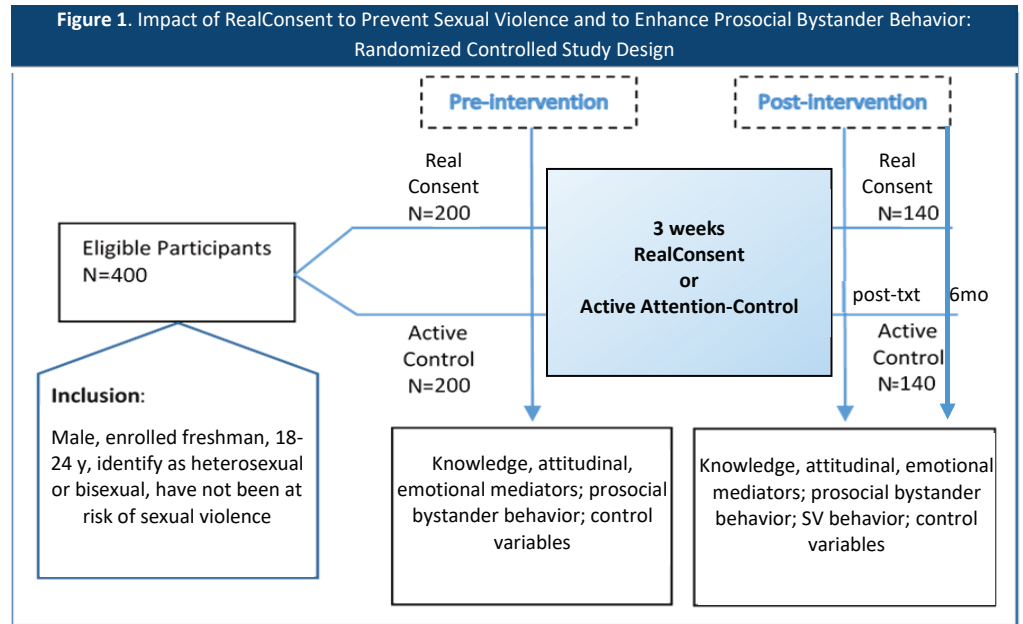
	<p>restricted to only the immediate research team.</p> <p>(5) Digital recordings that are made during the qualitative interviews will be kept on a password protected computer with limited access only for the transcribers and researchers on the project. Recordings will be destroyed upon completion of the study (we will keep them available during the data analysis in case questions arise that require a review of the recording.)</p> <p>(6) The research team will take particular care during the presentation of the findings to ensure that no one community or study participant can be identified in the transcripts. To ensure the anonymity of communities and study participants involved in the research, all identifying names of study participants and locations that are recorded in the transcripts will be changed to pseudonyms.</p> <p>(7) Identifiable data will be stored securely in REDCap or an equivalent HIPPA compliant data system. User defined access will be provided to members of the study team. Only de-identified data will be downloaded to password protected computers for further analysis.</p>
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Quantitative Study Design

Organizational structure of the team	<p>Translation, Recruitment, Training, and Ethics/Research Committee Approval. Contributions to Data Collection, Analyses, Interpretation, Writing, and Dissemination Activities.</p> <p>CCIHP Site Principal Investigator: Tran Hung Minh, MD, MSc Research Assistants (Total = 1)</p> <p>Emory University IRB Approval, Contributions to Data Collection, Analyses, Interpretation, Writing, and Dissemination Activities.</p> <p>Emory University Principal Investigator: Kathryn M. Yount, PhD Co-Investigator: Jessica Sales, PhD Consultant: Laura Salazar, PhD</p>
Setting and location	<p>Setting. The undergraduate system in Vietnam is a suitable context for adapting the program, given its similarities with the US context where the program originated. Undergraduate study is 4–6 years, with two foundational years and 2–4 years for specialization. Except for political education and national defense, universities design their own curricular and extra-curricular activities and maintain networks through the Ministry of Education and Training (MoET), professional associations, and Youth Union, all potential pathways to bring the program to scale in the future.</p> <p>Study site. The sites for this project are Hanoi Medical University (HMU) and Thang Long University (TLU), both in Hanoi. HMU is a 100-year-old state school with dental, medical, nursing, nutrition, public health, and paramedical/ ophthalmology technical programs. Its 1000 enrolled students are 40% men. TLU is a 24-year-old private university with 15 departments (e.g., math, business administration, social sciences). Its 7000 enrolled students are 45%-50% men. Both schools have provided letters of support for adaptation of the program with their students.</p>
Quantitative Study Population	<p>Men 18–24 years and identifying as heterosexual or bisexual and enrolled at HMU and TLU as freshmen on 9/1/2019 are eligible.</p>

Recruitment

Study design. Based on learning from the qualitative work, we will conduct a RCT with eligible college men to test the impact of the program on promoting prosocial bystander behavior and preventing sexual violence perpetration, through improvements in the seven knowledge, attitudinal, and emotional mediators over a seven month study period, with a baseline survey and two follow-up surveys 0 and 6 months post-intervention. Figure 1 depicts the basic RCT design.



Survey sample and power. Men 18–24 years and identifying as heterosexual or bisexual and enrolled at HMU and TLU as freshmen on 9/1/2019 are eligible. According to recent enrollment figures, about 890 men matriculate yearly at HMU and TLU. Given a cooperation rate of 67% in similarly focused research among male Atlanta-based undergraduates,⁶⁸ this pool is sufficient to recruit a sample of 400 freshman men for participation in this study.

We computed the required sample sizes to detect our hypothesized effects with a power of .80. We used a Monte Carlo approach⁹¹ to calculate the required sample sizes 1) assuming an attrition rate of 30%; based on 2) Cohen’s medium-to-large-effect-categorization⁹² with regards to the proportion of the variance accounted for, R², by the model (.13 and .26) using corresponding values for a and b;⁹³⁻⁹⁵ and 2) a desired power level of .80. The computer program, Mplus,⁹⁶ was used to complete the computations.

To recruit students, CCIHP personnel will contact department chairs at each university to discuss the study with them. With their agreement, CCIHP will talk with faculty about the study and ask them to announce it in their classes using a flyer with a brief, standard project description. The department chair will obtain email and phone numbers of students. The team has used this strategy successfully to recruit undergraduates. The study staff will utilize student phone numbers to contact students to make sure they check their emails.

Field Methods

Data collection overview. After consent, participants will be assigned randomly, with an equal allocation to Real-Consent or a health-education

control program, using block randomization with random block sizes. Participants and analysts will be blinded to assignments.

Outcomes will be assessed at baseline, posttest (just after finishing the last module), and six months (Table 2). We will consider confounders and modifiers, like social desirability, emotional adjustment, sensation seeking, sexual behavior, aggressive peers, peer and social network diversity, peer social support, witnessing family violence, family cohesion, and social support (Table 2). Questions will model others in the field.⁶⁸

Table 2. Primary (Behavioral) and Secondary (Knowledge/Attitudinal/Emotional) Outcomes at Baseline, Posttest, and Six-Month Follow-Up				
Construct	Scale	Sample item	#	Resp
Primary Outcomes				
Bystander self-efficacy	ROLB self-efficacy to intervene in SV ¹⁰¹	When I hear a sexist comment I indicate displeasure	8	1-7
Bystander intervention	ROLB self-behavior subscale ¹⁰¹	walk into my room & roommates are watching porn	5	1-7
Intimate Partner Violence	Revised Conflict Tactics Scale (CTS2) SV ¹⁰²	Used force to make partner have sex	7	1-6
Sexual Violence	Sexual Experiences Survey Rev. (SES-R), SV ¹⁰³	put my penis, fingers, objects into so's butt w/o...consent	8	0-3
Secondary Outcomes (Knowledge, Attitudinal, Emotional Mediators)				
Knowledge of law	Knowledge of legal defs of assault/rape scale ¹⁰⁴	Sex intercourse w/so <16 [is legal if] he/she gives consent	9	T/F
Knowledge of consent	Knowledge of informed consent to have sex ⁶⁸	If a woman dsn't physically resist sex, she has given consent	14	T/F
Norms degrading wn	ROLB other-behavior subscale ¹⁰¹	Rmate suggests...give alcohol to your date to 'loosen her up'	5	1-7
Gender attitudes	Hostility Toward Women Scale ^{105,106}	...many times women flirt w/men just to tease/hurt them	10	T/F
Gender attitudes	Hyper-Gender Ideology Scale short form (HGIS) ¹⁰⁷	If men pay for a date, they deserve smthg in return	19	1-5
Rape attitudes	College Data Rape Attitude & Behavior Survey ¹⁰⁸	...sex jokes and innuendos are only fun & harmless	20	1-5
Rape attitudes	Illinois Rape Myth Acceptance (IRMA) ⁴⁸	Rape happens when a man's sex drive gets out of ctrl	17	1-5
Dating violence attitudes	Attitudes Toward Male Dating Violence Scale ¹⁰⁹	A guy should not insult his girlfriend	39	1-5
Empathy for rape victims	Rape Empathy Scale (RES) ⁵⁴	In general,...rape is not...provoked by the rape victim	19	1-5
Control Variables				
Alcohol use	National College Health Assessment Survey ¹¹⁰	# drinks consumed when last partied	1	#
Sexual behavior	Safe Sex Behavior Questionnaire (SSBQ) ¹¹¹	engage in sex intercourse on the first date	7	1-4
Sexual communication	Communication self-efficacy ¹¹² (to discuss sex)	can discuss...using condoms w/any sex partner	4	1-10
total items and time required			192	42 m

Note. SV = sexual violence; α indicates the reliability of the scale in other samples.

Informed Consent

Assurances, IRB approvals, and oversight: Our ethics protocol will follow WHO guidelines for research on violence against women.¹³¹ Ethical approval will be sought from CCIHP, Emory University, and Georgia State University. Team members have completed certification training in research ethics.

Consent process. Informed consent will be sought when eligible participants are first asked to take part. Informed consent requires a clear understanding of the study's purpose; voluntariness, nature, extent and duration of participation; extent of confidentiality; right to anonymity; and right to withdraw any time. Online consent will be obtained before participants will be allowed to view and participate in the online survey for the impact evaluation portion of this study.

Potential Risks/Discomforts

College men may experience stress or adverse psychological reactions to survey questions about sexual violence perpetration or prior experiences of violence exposure.

Protection against Potential Risks. Procedures to protect participants against risk include:

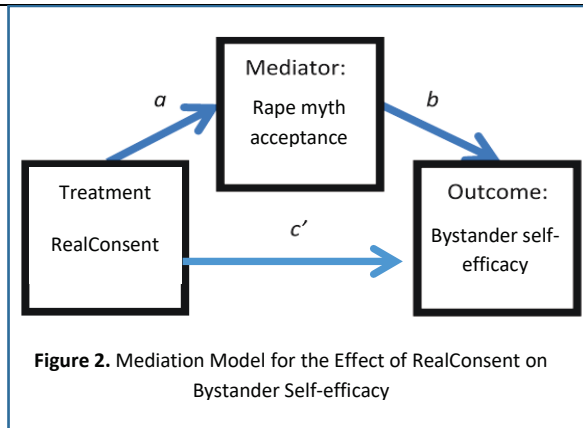
1. CCIHP will identify and retrain field staff with prior experience conducting qualitative research on gender-based violence. Local staff will be prepared to handle potential risks.

2. Every effort will be made to enhance disclosure and to ensure the accuracy of collected data.¹³¹ For example, we will avoid questions with abstract or value-laden terms (e.g., "abuse") and use questions that guide SSI participants through specific instances of sexual violence. Also, we will match female participants with mature, female interviewers who are similar in age and

	<p>experienced at discussing sensitive issues. Similarly, male interviewers will interview male study participants, or will be interviewed in private via the online survey platform.</p> <p>3. Before starting a SSI or quantitative online survey, participants will be told their responses are confidential and they can, at any time, stop the interview and request assistance using the contact information provided on the consent forms.</p> <p>4. Before starting a FGD, participants will be told the guidelines for participation, such as “please do not discuss what was said during the group with others outside this group,” “be respectful of each other’s comments and do not talk over each other,” “if you do not want to answer a question, you do not have to,” and “if you need to leave, please let us know by raising your hand and we can help you leave the group.”</p> <p>5. We will state that participants have the right to withdraw any time during their SSI, FGD, survey, or viewing of the program.</p> <p>6. SSIs and FGDs will be audiotaped. The digital file will be transcribed verbatim; participants will be identified numerically. Transcribed files will be stored on a password-protected computer in a locked office at CCIHP, accessible only to study staff. After data analysis, digital files will be destroyed to protect confidentiality.</p> <p>7. Counseling services will be offered to participants experiencing adverse psychological reactions associated with participating in SSIs, FGDs, or review of the program materials. Services will be provided by the Center for Studies and Applied Sciences in Gender – Family – Women and Adolescent (CSAGA) a non-governmental, non-profit organization that promotes the rights of women and children vulnerable to violence and discrimination. CSAGA operates 6 counseling hotlines and a counseling hotline by the Ministry of Labour and Social affairs (for children). CCIHP also operates a website and free online counseling for youth on gender, sexuality, and sexual violence. A resource list with numbers and websites for counseling services will be provided for all participants.</p> <p>8. Procedures to minimize loss of confidentiality include encryption to maintain the confidentiality of participants’ identity and their data. Collected data will be identified only by identification numbers with no personal identifiers. Personal identifiers will be redacted from transcripts, and pseudonyms will replace names. Confidential data will be kept in a locked office file cabinet with restricted access. Names will be stored in a separate locked cabinet and will not be linked to study data.</p> <p>9. We will work with our respective IRBs to obtain a Certificate of Confidentiality.</p>
Benefits	<p>Study participants will receive no direct benefit from their involvement in this research. The insights gained from this study, however, should improve college men’s engagement in prevention of sexual violence against women. Considering the extensive protections to be undertaken to minimize potential risks to participants in this research, and the substantial anticipated benefits for future research and policy development, no problems are anticipated that outweigh the advantages of the proposed research.</p>
Compensation	<p>Each participant will receive graduated payments for completing the baseline, immediate posttest, and six-month follow-up assessments (\$6, \$8, \$10; total \$24). Using only participants’ emails, we will create PayPal accounts (www.PayPal.com) and automatically deposit payments for participants. In</p>

	<p>other internet-based studies,¹¹³ this payment method has reduced costs and expedited payment versus issuing checks. Several options are available: 1) using only participants' emails, we will create PayPal accounts (www.PayPal.com) and automatically deposit payments for participants; 2) phone card for participants: phone card number will be emailed to participants according to their email submission after completion of each questionnaire; and 3) payment for participants through hosting website of the adapted program through an e-financial solution. In Vietnam, several e-finance platforms are available, but it would depend on the host that we may use.</p>
<p>Data Management and monitoring</p>	<p>Data systems will be designed to handle the concurrent collection, processing, secure storage, and analysis of project data. New data will be aggregated progressively via a web-based data-entry application (REDCap). Each participant will be assigned a unique number identifying him across waves. The web application will transmit data entered by each participant through an encrypted network connection to a centralized database running on a secure network and infrastructure, ensuring secure electronic data movement. A CCIHP programmer will create, and a CCIHP data manager will run, applications for more refined range/ consistency checks in the centralized database. Systematic data collection errors can be identified, resolved, and documented using a workflow module of the REDCap application. Some statistical software can access data in the central database and store derived variables there. For analyses done with external statistical software, de-identified data will be extracted and held on HIPAA compliant secure networks and computing workstations.</p>

Plans for analysis

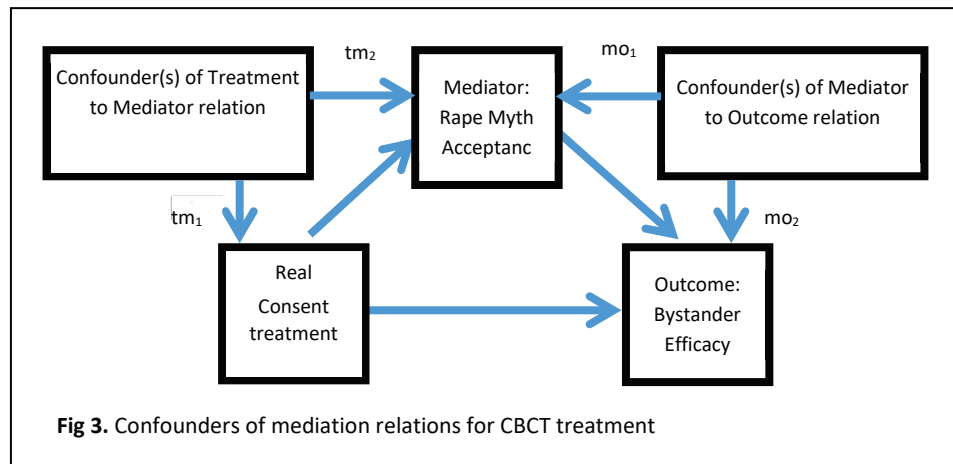


Descriptive analyses. We will perform univariate analysis of all demographic, screening, mediating, outcome, and control variables for the program and the health-education control groups, individually and combined, to explore distributions, outliers, and missingness. The associations between individual pairs of variables will be examined. Baseline differences on these variables between the program and health-education control condition will be tested. The psychometric properties of the various instruments will be assessed and confirmed.

Intent-to-treat analysis. To assess our aims based on the randomization scheme,¹¹⁴ we will perform mediation analyses via path analysis.^{115,116} Namely, we will assess first whether, relative to men randomized to the health-education control group, men randomized to the program will have improved mediating outcomes (H1). With reference to Figure 2, each of these relationships is represented by path a, or the direct effect of treatment on the mediator. Testing the significance of each path allows us to assess the impact of the program on each mediator. The standardized effect coefficients will serve as effect size measures of the treatment to mediator relations.

We then will assess the impact of the program on our main outcomes (H2, H3). With reference to Figure 2, each of these relationships is captured by the product of the two paths, ab , or the indirect or mediating impact of the program on our primary outcomes, transmitted through the individual mediators. Testing the significance of each product allows us to assess the significance of each path. To test these mediated effects, we will use confidence intervals derived from the bias-corrected percentile-based bootstrap approach, a resampling technique, as the valid use of regular standard errors relies on the unrealistic normality assumption, given that the products of two normally distributed regression coefficients is not normally distributed in general.^{117,118} A consequence is that the power of the test is reduced.¹¹⁷ The bootstrap approach is suitable here, as it allows researchers to assess the test statistics associated with these mediated effects without knowledge of their true distributions.⁸⁹ The standardized indirect effect coefficients with confidence intervals will serve as effect size measures of the various mediation effects.

We will test the robustness of the results obtained by investigating potential confounders of paths a and b, which may result in biased estimates. Figure 3 shows how confounders may affect the estimates of relationships between 1) treatment and mediator with tm_1 and tm_2 , and 2) mediator and outcome with mo_1 and mo_2 , which may be biased as a result of omitted or confounding variables.^{117,119} As there will be randomization of the program treatment but not of the mediator variables, most confounders on the treatment-to-mediator relation should be eliminated. Still, we will, perform a balance check on randomization using the control variables listed in Table 5. If imbalance on certain variables is detected, those variables may be controlled for when estimating path a, the program treatment-to-mediator relation. We also will assess the sensitivity of the results to the potential confounders on the mediator-to-outcome relation, path b, using a propensity score approach.^{120,121} The propensity score, or the probability that an individual receives a specified level of the mediator, given a set of observed covariates chosen from Table 5, will be estimated and used as a covariate in the mediation model to estimate path b. The results will be compared to those without any adjustment to detect if possible biases exist due to omitted observed confounders, and if they do, what the directions and magnitude are.



We will perform the intent-to-treat analyses using the software program, Mplus.⁹⁶

Supplemental analyses in the program group. We will conduct several analyses in the program group to assist with the interpretation of findings from the intent-to-treat analyses. First, to gauge possible dose-response relationships between engagement with the program, such as total contact time over the six-session program, and individual post-treatment mediator and outcome variables, we will examine their partial correlations for participants assigned to the program group, adjusting for their corresponding baseline values.¹²² Second, we will assess differential program impact by examining differences in pretest-posttest change scores in mediator and outcome variables across socio-demographic characteristics, such as age, and risk groups, such as alcohol use.

Analytic issues and strategies. 1) We note and will address relevant analytical issues in this application. Reports of sexual violence. While men may systematically underreport SV perpetration, our own research suggests that men's reported rate of IPV perpetration (37%) can be similar to women's

	<p>reported rate of IPV exposure (43%) with appropriate quality controls.^{15,123} Our decision to use an online computer-assisted-self-interview platform should enhance disclosure by maximizing the possibility for privacy during the interview. Differential non-participation/attrition. We will explore the differential non-participation/attrition of men to assess for risk of response bias. With the baseline screening, socio-demographic, and other control data, we will model the response probability and use the estimated response probability to compute weights to correct for unit nonresponse using the covariates in Table 5. Estimates on the various outcomes before and after reweighting, and under different assumptions with respect to missing data, will be compared. Item non-response. For covariates with a non-response rate of $\geq 5\%$, we will test for differences between responders and non-responders. We will compare non-responders and responders and may use multiple imputation, assuming the data are missing at random, to fill in the missing values.¹²⁴⁻¹²⁶ Noncompliance. As some participants in the program group may not receive the program, we will estimate complier-average causal effect (CACE) of the program by estimating two latent classes of compliers and non-compliers using engagement of the program as well as covariates and control variables.^{127,128} The CACE results will afford comparisons with and robustness assessment of those of the intent-to-treat analyses, and allow an examination of potential predictive factors of engagement with the program and its intervention implications.¹²⁹ Outliers. We will assess the sensitivity of the results to outliers. We will exclude univariate outliers if their z scores exceed ± 3. Multivariate outliers will be diagnosed using Mahalanobis distance and excluded if $p < .0001$. Results from the complete and reduced data sets will be compared. Convergence issues and improper solutions. We will assess the causes of convergence issues and improper solutions when running the path analyses, such as model misspecification, non-identification, and collinearity—and we will remediate by specifying suitable start values and model re-specifications.¹³⁰ Generalizability. To simplify logistics and enhance feasibility of the RCT, our study sites are two universities. This strategy does not permit generalization to college men in Vietnam, but the two sites enhance the overall diversity of the sample. We will describe our sample clearly to help others understand the young men to whom study findings may be relevant and generalizable.</p>
<p>Confidentiality</p>	<p>All key personnel have completed the Human Participant Protections Education for Research Teams online course, sponsored by NIH or the Social/Behavioral Research course through CITI.</p> <p>As previously detailed in the protections of risk section, above, we are careful to ensure confidentiality. Several strategies will be used <u>to ensure the confidentiality of participants</u> in the research.</p> <ol style="list-style-type: none"> (1) Interviewers will receive strict instructions about the importance of maintaining confidentiality. (2) Interviewers will not conduct research within their own communities of residence. (3) The names of study participants will not be written on questionnaires or interview guides. Instead, unique numeric codes will be used to distinguish the questionnaires and textual transcripts of study participants. (4) If identifiers are needed to link a questionnaire with a household location or a particular study participant, these identifiers will be kept separate from the

	<p>questionnaires in a locked cabinet or separate, secure computer with access restricted to only the immediate research team.</p> <p>(5) Digital recordings that are made during the qualitative interviews will be kept on a password protected computer with limited access only for the transcribers and researchers on the project. Recordings will be destroyed upon completion of the study (we will keep them available during the data analysis in case questions arise that require a review of the recording.)</p> <p>(6) The research team will take particular care during the presentation of the findings to ensure that no one community or study participant can be identified in the transcripts. To ensure the anonymity of communities and study participants involved in the research, all identifying names of study participants and locations that are recorded in the transcripts will be changed to pseudonyms.</p> <p>(7) Identifiable data will be stored securely in REDCap or an equivalent HIPPA compliant data system. User defined access will be provided to members of the study team. Only de-identified data will be downloaded to password protected computers for further analysis.</p>
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