Clinical Study Protocol

MKit: A Pilot Study Testing A Life Skills Application to Address Interpersonal Relationships in College

Sponsor:	Michigan Institute for Clinical and Health Research 1600 Huron Parkway Building 400 Ann Arbor, MI 48109 Michigan State Police Campus Sexual Assault Grant msp-csagrant@michigan.gov
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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with the International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 312, and/or CFR Part 812)

National Institutes of Health (NIH)- funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

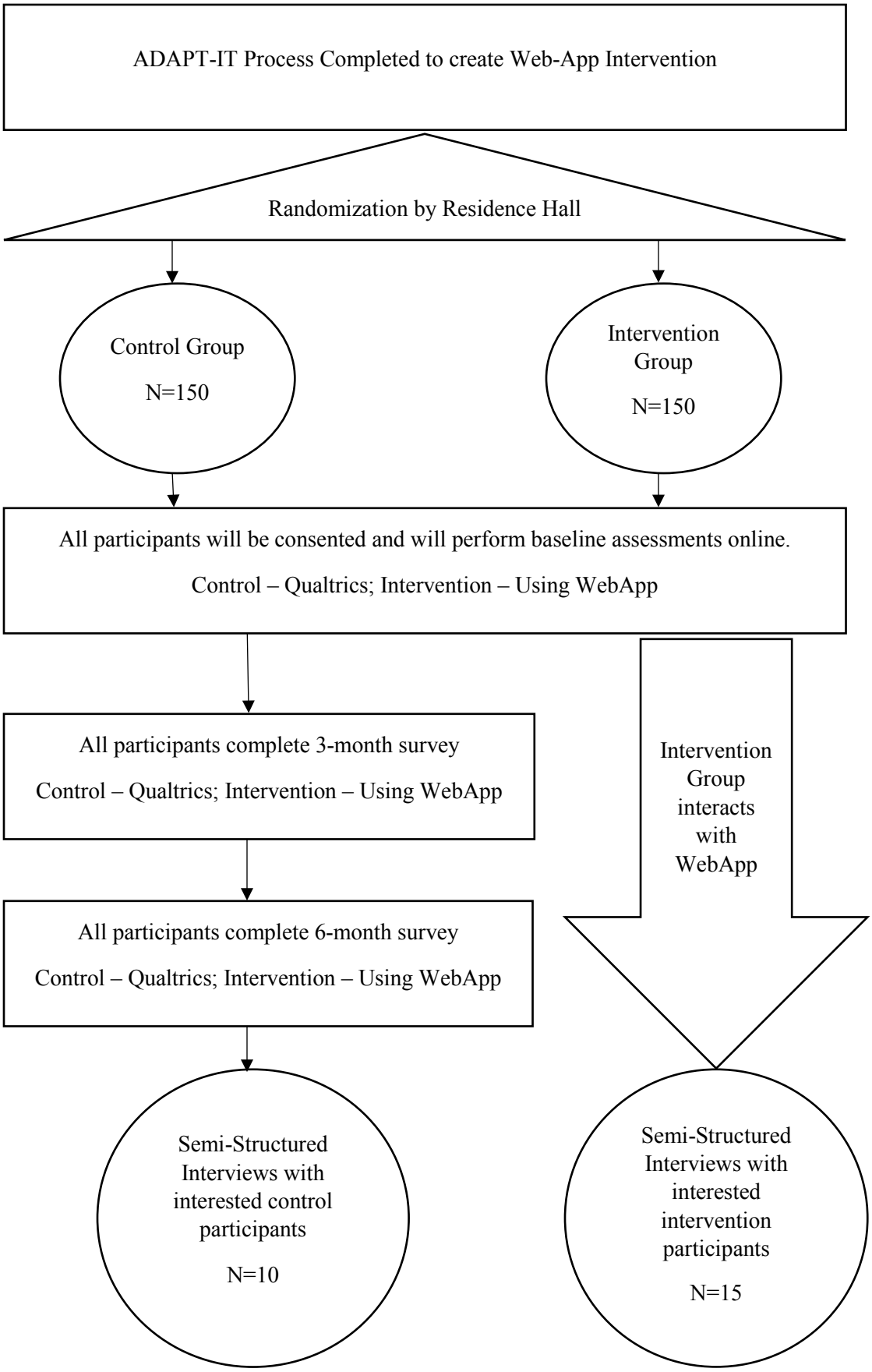
The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent; using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Participant Duration:	For pilot study – 9 months
Title:	MKit: A Pilot Study Testing a Life Skills Application to Address Interpersonal Relationships in College
Study Description:	This study utilizes implementation science principles to culturally adapt a pre-existing web-based application (WebApp) for use with college students. We will use the ADAPT-ITT process to adapt the WebApp to a diverse (race, ethnicity, gender/sexual identity) college population with a focus on life skills and holistic self-care as reinforcement to currently available primary prevention programming available to freshman students. Our hypothesis is that the adapted WebApp will be safe, acceptable, and students will be willing to use it as a reinforcement to current university primary prevention programming.
Objectives:	• Primary: To evaluate the safety, usability, acceptability, and willingness of using the adapted WebApp among a randomized sample of 300 first year university students. • Secondary: To complete preliminary evaluations on efficacy measures such as sexual victimization/perpetration, rape myth acceptance, and power in sexual relationships to allow for power calculations for a future R-level submission.
Endpoints:	• Primary: Safety (qualitative interviews), Usability (System Usability Scale, Brooke, 1986), Acceptability (investigator generated), and willingness to use (qualitative interviews). • Secondary: Sexual victimization/perpetration (Sexual Experiences Survey, Koss et al., 2007), Illinois Rape Myth Acceptance – Modified (McMahon & Farmer, 2011), Sexual Relationship Power Scale (Pulerwitz, Gortmaker, & DeJong, 2007)
Study Population:	300 first year university students (150 Control Group, 150 Intervention Group)
Phase:	Pilot
Description of Sites/Facilities Enrolling Participants:	University of Michigan Residence Halls (South and West Quad)
Description of Study Intervention:	Web-based app that uses a life skills approach to address healthy relationships and sexual violence.
Study Duration:	2 years 9 months

1.2 SCHEMA


ADAPT-IT Process Completed to create Web-App Intervention
Randomization by Residence Hall
Control Group
N=150
Intervention Group
N=150
All participants will be consented and will perform baseline assessments online.
Control – Qualtrics; Intervention – Using WebApp
All participants complete 3-month survey
Control – Qualtrics; Intervention – Using WebApp
All participants complete 6-month survey
Control – Qualtrics; Intervention – Using WebApp
Intervention Group interacts with WebApp
Semi-Structured Interviews with interested control participants
N=10
Semi-Structured Interviews with interested intervention participants
N=15

1.3 SCHEDULE OF ACTIVITIES (SOA)

Procedures	**Preparation before recruitment**	**Baseline**	**3-month follow-up**	**6-month follow-up**	**Post-study semi-structured interviews**
Randomization by residence hall	X				
Demographics		X	X	X	
Healthy Relationship Knowledge Questions		X	X	X	
Illinois Rape Myth Acceptance Scale – Modified		X	X	X	
Sexual Experiences Survey		X	X	X	
Sexual Relationship Power Scale		X	X	X	
System Usability Scale			X	X	
System Acceptability			X	X	
User Data			X	X	
Reaction to content					X
Perceived safety					X
Desirability					X
Willingness for future use					X

2 INTRODUCTION

2.1 STUDY RATIONALE

There have been minimal attempts at providing reinforcement for students around the primary prevention of sexual violence and nobody has approached this topic with the consideration of holistic well-being in mind. Many of the currently available primary prevention programs include a one-time interaction and do not provide reinforcement throughout the student's college career (Banyard, Moynihan, & Plante, 2007; Foshee et al., 2004; Moynihan et al., 2015; Taylor, Mumford, & Stein, 2015; Taylor, Mumford, Stein, & Woods, 2015). Principles of learning suggest that attitude change and skill training are more effective with reinforcement (Skinner, 1958). There is a need for holistic interventions that provide students with the means to address all of the physical, emotional, and social changes they may be experiencing during their transition to young adulthood. Past research has emphasized that life skills and social competency are promising approaches that address individuals within their ecological context (Krug, Mercy, Dahlberg, & Zwi, 2002).

2.2 BACKGROUND

With a national annual incidence rate of 5%, rape is the most frequent violent crime that occurs on college campuses (Finn, 1995; Fisher, Cullen, & Turner, 2000). Nearly 80-90% of college students know the perpetrator, which increases the likelihood that the rape will be completed, rather than attempted (Fisher et al., 2000; Karjane, Fisher, & Cullen, 2005). Furthermore, many college survivors do not perceive or acknowledge their experiences as a rape, often because of lack of evidence, the absence of a weapon, or because alcohol and/or drugs were involved (Fisher, Daigle, Cullen, & Turner, 2003; Karjane et al., 2005). These characteristics of sexual assault in college therefore contribute to the underestimation, under reporting, under prosecution, and low rates of seeking post-assault services among college survivors (Bondurant, 2001; Karjane et al., 2005).

Despite the high prevalence of rape in the United States, an event with long-term negative effects on a survivor's health, few survivors receive comprehensive post-assault care. In the period immediately following a rape, about half of all survivors will have evidence of physical trauma, up to 30% contract a sexually transmitted infection (STI), and 5% of female survivors become pregnant (Resnick et al., 2000). Specific to college survivors, about 20% report physical injuries (Fisher et al., 2000), many fear social consequences so they alienate themselves from campus activities or drop out of school, and it appears that college women who experience post-traumatic stress disorder (PTSD) from an assault may use substances and/or sexual behavior to reduce distress (Messman-Moore, Ward, & Brown, 2009). Post-assault, survivors can access comprehensive health services through referral by rape crisis centers or via the emergency department from specially trained sexual assault nurse examiner (SANE) programs. Comprehensive care includes 1) treatment of physical injuries or other sequelae of the assault, 2) pregnancy prevention including options if emergency contraception is not effective, 3) STI screening and treatment, 4) psychological care for PTSD, 5) forensic and victim services, and 6) legal care including safety from the perpetrator and the ability to report the assault and press

charges if the survivor desires (Tjaden & Thoennes, 2006). However, only one in five women raped as an adult reported their rape to the police and of these reported rapes prosecution rates were only 37% (Tjaden & Thoennes, 2006). Thus, the prevalence of rape is under reported, under prosecuted, and many women do not seek care after experiencing rape due to multiple barriers to care (Munro, 2014).

Even with the high prevalence and severe physical health, mental health, and social outcomes associated with sexual violence, there are limited data available on effective primary prevention programs (Centers for Disease Control, 2016). A recent systematic review of primary prevention programs for sexual violence identified only three primary prevention strategies that have demonstrated significant effects on sexual violence including *Safe Dates*, *Shifting Boundaries*, and the 1994 Violence Against Women Act (VAWA) Funding (DeGue et al., 2014). However, there are promising trends that favor multisectoral programs that engage stakeholders to challenge the acceptability of violence and the underlying social risk factors. There is strong consensus among researchers that more rigorous evaluation of promising programs is needed in order to continue to address sexual violence (Ellsberg et al., 2015).

Furthermore, recent national legislation has also highlighted the need for primary prevention of sexual violence. The *Dear Colleague Letter* issued by the Obama Administration in 2011 recommended that institutions of higher education implement preventive education programs focused on sexual violence for incoming students. The 2014 VAWA prescribed more specific recommendations that new students and employees must be offered primary prevention and awareness programs focused on domestic violence, sexual assault, stalking, and rape. The 2014 VAWA acknowledged specific content that should be included in these programs but did not stipulate how these programs were to be administered to incoming students. Thus, each institute of higher education implements primary prevention programming individually, often using a combination of web-based, in-person, and performance based methods.

Many college campuses rely on online learning modules to meet the requirements of the 2014 VAWA; however, there is a lack of evidence on the effectiveness of these programs and the potential that mobile or web-based applications hold for the prevention of sexual violence. Technology has become a ubiquitous modality for communication and accessing knowledge across the United States. In 2011 the White House called for initiatives that leveraged technology to prevent dating and sexual violence (Rosenthal, 2013). This resulted in the creation of a mobile application called *Circle of 6* (http://www.circleof6app.com/), which makes it easy to contact a person in your circle to let them know where you are and what you need. More recently, a randomized controlled trial at a university in the Southeastern United States found a web-based bystander intervention approach, *RealConsent,* significantly reduced sexual violence perpetration and increased knowledge around consent, intervening, and rape myths and decreased negative attitudes around hostility toward women (Salazar, Vivolo-Kantor, Hardin, & Berkowitz, 2014). However, neither of these technology-based approaches targets the social and cultural constructions of sexual violence that promote gender inequality and discrimination nor do they offer holistic approaches to primary and secondary prevention (Dartnall & Jewkes, 2013).

A holistic approach recognizes college students as individuals transitioning into young adulthood. The transition into young adulthood is associated with myriad of preventable health problems including higher rates of mortality and more involvement in health risk behaviors (Ozer et al., 2012). Additionally, college students are often learning to manage school, work, new relationships, stress, conflict, and their own health for the first time as independent young

adults. A holistic approach aims to identify the student's goals and needs by increasing their ability to make decisions based on their personal values while also addressing communication skills in interpersonal relationships as an upstream approach to reduce sexual violence in the campus community. Positive and respectful communication within interpersonal relationships may help prevent some types of unwanted sexual activity. Furthermore, when students make decisions consistent with their values, they may be less likely to engage in behaviors or encounter situations where sexual assault perpetration or victimization could occur.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

There is no more than minimal risk to the study subjects. There is a rare risk that a participant may experience emotional discomfort related to survey or semi-structured interview questions. All participants will receive resources to help alleviate any potential discomfort and will have the opportunity to skip any questions they choose. The rare possibility of breach of confidentiality exists. All data will be stored on a secure, HIPAA-compliant server and drive with monitored and controlled access to reduce this risk.

2.3.2 KNOWN POTENTIAL BENEFITS

The study participants will have the direct benefit of receiving information through a holistic, life-skills approach to addressing interpersonal relationships and sexual violence. This content may help them to navigate their own relationships.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The minimal risks associated with this study are reasonable given the potential impact of the project. The results of this study will provide the basis to scale-up this innovative intervention to reach a high-risk and vulnerable group, as college females are among those at the highest risk for sexual violence. This study therefore provides the opportunity to develop a low-cost/high-impact reinforcement intervention that could improve interpersonal relationships and reduce sexual violence within college campuses. As such, the available information suggests that the present clinical study has an acceptable risk-benefit ratio.

3 OBJECTIVES AND ENDPOINTS

Objectives	Endpoints	Justification for Endpoints
Primary		
To evaluate the safety, usability, acceptability, and willingness of using the adapted WebApp among a randomized sample of 300 first year university students.	Safety will be assessed through qualitative interviews Usability will be measured through the System Usability Scale (Brooke, 1986)	The endpoints are common outcomes of interest for studies of technological interventions. These outcomes will be measured throughout the study, to observe changes overtime with continued exposure to

	Acceptability will be measured through an investigator generated scale Willingness to use will be assessed through qualitative interviews	the intervention. These endpoints are important outcomes, as interventions must be safe, acceptable, and usable to ensure broad scale uptake.
Secondary		
To complete preliminary evaluations on efficacy measures such as sexual victimization/perpetration, rape myth acceptance, and power in sexual relationships to allow for power calculations for a future R-level submission.	Sexual victimization/perpetration will be measured using the Sexual Experiences Survey (Koss et al., 2007) Rape myth acceptance will be measured using the Illinois Rape Myth Acceptance – Modified (McMahon & Farmer, 2011) Relationship power differentials will be measured using the Sexual Relationship Power Scale (Pulerwitz, Gortmaker, & DeJong, 2007)	The endpoints are important, as the WebApp under study is a primary sexual violence prevention intervention. As such, experiences of sexual violence victimization and perpetration, as well as rape myth acceptance and relationship power (both upstream factors contributing to sexual violence perpetration) are outcomes of interest. Though this pilot study is not powered to detect changes in these secondary outcomes, obtaining data for power calculations for a larger study is a key component of this study.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This project builds on the current momentum to address the primary prevention of sexual violence within United States institutions of higher education as well as the proliferation of web-based applications. We will test a culturally and contextually adapted evidence-based application, MKit, with incoming university students (age range expected to be 18-25 years old) using the ADAPT-ITT (Assessment, Decision, Adaptation, Production, Topical experts, Integration, Training, Testing) framework (Wingwood & DiClemente, 2008). The web-based application was created through collaboration with students, stakeholders, and topical experts and developed by the Center for Health Communications Research (CHCR) through a modification of the pre-existing iCON platform. This process will allow us to translate clinical research on the life skills approach to impact the health and well-being of university students.

A before-and-after quasi-experimental, mixed-method pilot design will be used to gather acceptability and safety data as well efficacy trends. Two residence halls (West Quad and South

Quad) at the University of Michigan will be randomized to receive either: (1) the control arm (n=150) which will receive usual care only (all incoming students receive three programs about healthy relationships and sexual violence including Haven, Relationship Remix, and Change it Up) or (2) the usual care (n=150) described above and the web-based intervention (MKit). We will use cluster-randomization by residence hall (to minimize contamination associated with individual-level randomization of students living in the same residence hall). Following the informed consent process, students in both conditions will complete a baseline survey of 85 questions. Baseline measures will include: 1) demographic data, 2) 20 items from the Sexual Experiences Survey (SES) will measure past experiences with sexual violence (Koss et al., 2007), 3) investigator developed questions on knowledge about sexual violence, 4) 22 items from the modified Illinois Rape Myth Acceptance Scale to measure attitudes endorsing rape myths (McMahon & Farmer, 2011), and 4) 6 items from the Sexual and Relationship Power Scale (SRPS) will measure the multidimensional nature of power in relationships (Pulerwitz & Barker, 2000). All of these are measures have been validated and used extensively in the United States to measure knowledge and attitudes related to gender based violence. Following the survey, students in the Intervention group will be given the opportunity to interact with the application at their own pace, choosing which content to view in the order they prefer.

The Control group will only receive the usual care delivered to all incoming University of Michigan students, which includes Haven (an online course about sexual violence), Relationship Remix (an interactive program about healthy relationships and sexual violence delivered by peers), and Change it Up (a theater based performance on bystander intervention). The Intervention group will receive the usual care described above as well as access to the adapted web-based application. They will be encouraged to interact with the web-based application throughout the study. Data will be collected on the content viewed by the participants, as well as the amount of time they spend within each content area, and the order in which they view the content.

At 3 and 6 months, we will repeat all baseline measures in both groups. Participants in the Intervention group will also be asked to complete the 10-item System Usability Scale (Brooke, 1996) and an investigator creates 5-item acceptability scale.

Post-intervention semi-structured interviews will be conducted with 25 participants including 15 participants from the intervention group and 10 participants from the control group to assess perceived safety, reaction to content, desirability, willingness to continue using the content, and willingness to recommend the content to others. Prior to commencing the interviews, we will ask each participant to complete a paper demographic survey.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This is a before-and-after quasi-experimental, mixed-method pilot design with three survey collection points and a post-study semi-structured interview component. This study will be performed with healthy college students to determine the safety, acceptability, and usability of the WebApp.

The endpoints are common outcomes of interest for studies of technological interventions. These outcomes will be measured throughout the study, to observe changes over time with continued exposure to the intervention. These endpoints are important outcomes, as interventions must be safe, acceptable, and usable to ensure broad scale uptake. As the WebApp under study is a

primary sexual violence prevention intervention, experiences of sexual violence victimization and perpetration, as well as rape myth acceptance and relationship power (both upstream factors contributing to sexual violence perpetration) are outcomes of interest. Though this pilot study is not powered to detect changes in these secondary outcomes, obtaining data for power calculations for a larger study is a key component of this study.

This study compares usual care for the prevention of sexual violence with care as usual plus the intervention. Both groups will receive interventions currently in place, ensuring that standard care is not withheld from any participant. As the intervention under study is intended to supplement and reinforce current primary prevention programming, the study design will measure the acceptability and preliminary efficacy of broad scale-up of the intervention to the broader college campus.

4.3 JUSTIFICATION FOR DOSE

Intervention group participants will have six months to interact with the WebApp content, as this time period should present sufficient time for meaningful short-term change in the outcomes of interest. Further, the study will run for the duration of the school year, allowing study staff to follow students from the beginning of the school year to the end of the school year as they interact with the WebApp content.

4.4 END OF STUDY DEFINITION

A participant is said to have completed the study if he or she has completed all three surveys, including the baseline, 3-month, and 6-month surveys, shown in the SOA.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

For the pilot study, individuals who meet the following criteria will be considered eligible to participate in the study:

1. Currently enrolled as a student at the participating university
2. Participated in Relationship Remix in Fall 2017 as a first-year or transfer student
3. Willing to participate in the study
4. Able to speak and read English

For the semi-structured interviews, individuals who meet the following criteria will be considered eligible to participate in the study:

1. Currently enrolled as a student at the participating university
2. Participated in Relationship Remix in Fall 2017 as a first-year or transfer student
3. Participated in the pilot study
4. Willing to participate in the study
5. Able to speak and read English

5.2 EXCLUSION CRITERIA

Not Applicable

5.3 LIFESTYLE CONSIDERATIONS

Not Applicable

5.4 SCREEN FAILURES

As all participants will be recruited directly from Relationships Remix, a program for currently enrolled University of Michigan students, all participants are exceedingly likely to be eligible for the study given the inclusion criteria.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Students from the target sample, first-year University of Michigan college students, will be recruited for the study. Two residence halls (West Quad and South Quad) at the University of Michigan will be randomized to receive either: (1) the control arm (n=150) which will receive usual care only (all incoming students receive three programs about healthy relationships and sexual violence including Haven, Relationship Remix, and Change it Up) or (2) the usual care (n=150) described above and the web-based intervention (MKit). We will use cluster-randomization by residence hall (to minimize contamination associated with individual-level randomization of students living in the same residence hall). At the end of the Relationship Remix program, a brief announcement will be made about the opportunity to participate in a research study about healthy relationships and palm cards will be distributed (see recruitment materials). We will recruit specifically from Relationship Remix to ensure that all experimental and control subjects receive the same primary prevention programming currently in place on campus. Interested students will receive a palm card with a link to either the MKit web-based application (Intervention) with an access code to sign-up for the website, or a link to the baseline consent and Qualtrics survey (Control) without access to the web-based application. At the end of the study, students from each condition will be invited to participate in an in-person semi-structured interview. Students will receive the invitation to participate in the semi-structured interview on the final page of their 6-month follow-up survey. Students who opt to share their email address with the study team at that time will be contacted to set-up an in-person interview based on user status for the intervention (consistent user of MKit, frequent user of MKit, minimal user of MKit) and a diverse group based on gender, race/ethnicity, and age for the control group. Semi-structured interviews will be conducted with participants from both the Control group (n=10) and the Intervention group (n=15).

The Intervention group will receive the usual care described above as well as access to the adapted web-based application. They will be encouraged to interact with the web-based application throughout the study. Built-in reminders to the web-based application, an email alert, and a text-message alert (if the participant chooses to share their phone number) remind participants about their goals and encourage retention and continued engagement.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

This study will test a web-based application focused on healthy relationships and sexual assault. The web-based application will provide information and resources using a life-skills approach. Participants will also have the opportunity to set personal goals, find resources, and evaluate their interpersonal relationships and self-care. This web-based application will have the ability to be utilized on any smartphone, tablet, laptop, or desktop computer.

6.1.2 DOSING AND ADMINISTRATION

Intervention group participants will have six months to interact with the WebApp content, as this time period should present sufficient time for meaningful short-term change in the outcomes of interest. Further, the study will run for the duration of the school year, allowing study staff to follow students from the beginning of the school year to the end of the school year as they interact with the WebApp content. Study participants can choose to interact with the WebApp and take study surveys whenever is comfortable and safe for them to do so.

6.2 PREPARATION/HANDLING/STORAGE/ACCOUNTABILITY

6.2.1 ACQUISITION AND ACCOUNTABILITY

The web-based application was created through collaboration with students, stakeholders, and topical experts and developed by the Center for Health Communications Research (CHCR) through a modification of the pre-existing iCON platform. CHCR will maintain the WebApp servers throughout the entirety of the study.

6.2.2 FORMULATION, APPEARANCE, PACKAGING, AND LABELING

Not Applicable

6.2.3 PRODUCT STORAGE AND STABILITY

Not Applicable

6.2.4 PREPARATION

The web-based application was created through collaboration with students, stakeholders, and topical experts and developed by the Center for Health Communications Research (CHCR) through a modification of the pre-existing iCON platform.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Study subjects will be randomized into one of two groups: 1) Intervention (WebApp and current prevention programming on campus) or 2) Control (current prevention programming on campus only), with 150 students in each group. We will use cluster-randomization by residence hall (to minimize contamination associated with individual-level randomization of students living in the same residence hall).

This study will not involve blinding.

6.4 STUDY INTERVENTION COMPLIANCE

Not Applicable

6.5 CONCOMITANT THERAPY

Not Applicable

6.5.1 RESCUE MEDICINE

Not Applicable

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

All participation is voluntary. There is no penalty to anyone who decides not to participate or who wishes to end participation during the study. All participants may choose not to answer a question at any point in the study.

If a participant discontinues use of the intervention during the research study, their data will be retained for attrition analyses.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWL FROM THE STUDY

All participation is voluntary. There is no penalty to anyone who decides not to participate or who wishes to end participation during the study. All participants may choose not to answer a question at any point in the study. All participants may choose to withdraw from the study at any time.

If a participant withdraws from the research study, their data will be retained for attrition analyses.

7.3 LOST TO FOLLOW-UP

If a participant withdraws from the research study or is lost to follow-up, their data will be retained for attrition analyses.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 EFFICACY ASSESSMENTS

The efficacy of this study is not a primary outcome as this is a pilot study focused on safety, acceptability, usability, and willingness to use. However, a number of measures will be used to gather preliminary data for future scale-up at all three time points (baseline, 3-months, and 6-months). Study participants' experiences with sexual violence (victimization and perpetration) will be assessed with 20 items from the Sexual Experiences Survey (SES) (Koss et al., 2007). Endorsement of rape myths will be measured with 22 items from the modified Illinois Rape Myth Acceptance Scale (McMahon & Farmer, 2011). The multidimensional nature of power in relationships will be measured by 6 items from the Sexual and Relationship Power Scale (SRPS) (Pulerwitz & Barker, 2000). All of these are measures have been validated and used extensively in the United States to measure knowledge and attitudes related to gender based violence. Additionally, knowledge about healthy relationships will be assessed with an investigator created 8-item scale.

8.2 SAFETY AND OTHER ASSESSMENTS

The safety of the WebApp will be assessed through post-intervention semi-structured interviews, conducted with 25 participants including 15 participants from the intervention group and 10 participants from the control group.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the study staff. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

The Principle Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of

resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The Clinical Research Coordinator will record all reportable events with start dates occurring any time after informed consent is obtained until the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

The Primary Investigator will immediately report to the sponsor any adverse event, whether or not considered study intervention related, including breach of confidentiality or lack of safety whether there is a reasonable possibility that the study intervention caused the event. All adverse events (AEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. Other supporting documentation of the event may be requested by the study sponsor and should be provided as soon as possible.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

The Primary Investigator will immediately report to the sponsor any serious adverse event including lack of safety whether there is a reasonable possibility that the study intervention caused the event. All serious adverse events (SAEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. Other supporting documentation of the event may be requested by the study sponsor and should be provided as soon as possible.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

Not Applicable

8.3.8 EVENTS OF SPECIAL INTEREST

Not Applicable

8.3.9 REPORTING OF PREGNANCY

Not Applicable

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEM REPORTING

The Primary Investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the study sponsor within 7 days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and to the study sponsor within 14 days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 7 days of the IRB's receipt of the report of the problem from the investigator.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

Not Applicable

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Primary Endpoint: The WebApp is safe, usable, acceptable, and participants will be willing to use the WebApp.

Secondary Endpoint: The explore preliminary differences between the intervention and control groups in regards to experiences of sexual violence victimization and perpetration, rape myth acceptance, and sexual relationship power.

9.2 SAMPLE SIZE DETERMINATION

Formal sample size calculations were not performed because this is a pilot feasibility study. The number of subjects was chosen based on feasibility and is considered sufficient to meet the study objectives.

9.3 POPULATIONS FOR ANALYSES

All data collected through the pilot study process will be utilized for the analyses related to feasibility, usability, and acceptability. The data collected from the semi-structured interview subjects will be utilized to analyze the safety of the application and the willingness of participants to use the application.

9.4 STATISTICAL ANLYSES

9.4.1 GENERAL APPROACH

The survey data will be analyzed using the Statistical Package for the Social Sciences (SPSS); all p-values will be set at <.05. Descriptive statistics will be assessed first. The baseline, 3-month post, and 6-month post-intervention tests will be examined for measures of central tendency, measures of dispersion, and frequency distribution on outcomes. Analysis of variance (ANOVA) will be utilized to determine if the scores on the baseline and follow-up tests differ significantly among the two arms. Usability and acceptability scores will be assessed among those in the intervention group.

We are not powered to assess outcome measures (sexual violence experiences/behaviors, rape myth acceptance, or sexual relationship power); however, we will look at the direction of effects for our outcome measures to allow for power calculations for a future R-Level submission. The results of this project will establish the safety and usability of this adapted web-based application for future scale-up.

For the semi-structured interviews, all audiotapes will be transcribed verbatim. Data analyses will be conducted using an iterative process and the constant comparative method of analysis (Glaser, 1992). Member checking will contribute to credibility through validation of the research findings by participants. A codebook will be developed after repeated high-level reading of the transcripts by the study team. Data will be coded and grouped into categories to facilitate abstraction and concept analysis.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT

The safety of the WebApp and the willingness of participants to use the WebApp will be assessed through post-intervention semi-structured interviews, conducted with 25 participants including 15 participants from the intervention group and 10 participants from the control group. The usability for the WebApp will be assessed at two time points (3-months and 6-months) using the 10-item System Usability Scale (Brooke, 1996). The acceptability of the WebApp will be assessed at two time points (3-months and 6-months) using an investigator created 5-item acceptability scale. Usability and acceptability scores will be assessed among those in the intervention group.

For the semi-structured interviews, all audiotapes will be transcribed verbatim. Data analyses will be conducted using an iterative process and the constant comparative method of analysis (Glaser, 1992). Member checking will contribute to credibility through validation of the research findings by participants. A codebook will be developed after repeated high-level reading of the transcripts by the study team. Data will be coded and grouped into categories to facilitate abstraction and concept analysis. An audit trail will be established to allow others to follow the decisions made by the research team (Sandelowski & Barroso, 2003). The results of the semi-structured interviews will be used to: 1) update the content of the WebApp, as needed; 2) assess the safety of the WebApp; 3) assess the usability and willingness to use the WebApp; and 4) assess the acceptability of the WebApp.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT

Preliminary analyses of the survey data (sexual violence victimization and perpetration, rape myth acceptance, and sexual relationship power) will be analyzed using the Statistical Package for the Social Sciences (SPSS); all p-values will be set at <.05. Descriptive statistics will be assessed first. The baseline, 3-month post, and 6-month post-intervention tests will be examined for measures of central tendency, measures of dispersion, and frequency distribution on outcomes. Analysis of variance (ANOVA) will be utilized to determine if the scores on the baseline and follow-up tests differ significantly among the two arms. Usability and acceptability scores will be assessed among those in the intervention group.

We are not powered to assess outcome measures (sexual violence experiences/behaviors, rape myth acceptance, relationship power); however, we will look at the direction of effects for our outcome measures to allow for power calculations for future scale-up.

9.4.4 SAFETY ANALYSES

The safety of the WebApp will be assessed through post-intervention semi-structured interviews, conducted with 25 participants including 15 participants from the intervention group and 10 participants from the control group.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Study groups will be compared on baseline characteristics, including age, race/ethnicity, gender, student group involvement, sexual orientation, and relationship status.

9.4.6 PLANNED INTERIM ANALYSES

Not Applicable

9.4.7 SUB-GROUP ANALYSES

Primary and secondary endpoints will be analyzed based on gender, race/ethnicity, student group involvement, sexual orientation, and relationship status.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will be listed by measure and time point.

9.4.9 EXPLORATORY ANALYSES

We are not powered to assess outcome measures (sexual violence experiences/behaviors, rape myth acceptance, sexual relationship power); however, exploratory analyses will be performed to assess the direction of effects for our outcome measures to allow for power calculations for future scale-up.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and electronic documentation of informed consent is required prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol:

- Pilot Control Group Consent Form
- Pilot Intervention Group Consent Form
- Semi-Structured Interview Consent Form

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. For the pilot study, participants will read through the consent online prior to completion of the baseline survey and make the determination to participate in the study individually. The participant will sign the informed consent document prior to any study activities. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, and that the study is not connected to their schooling.

For the semi-structured interview, the investigator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participant will sign the informed consent document prior to any study activities. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, and that the study is not connected to their schooling. A copy of the informed consent document will be offered to the participants if they would like it. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, funding agencies, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor and/or IRB.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsors and their interventions. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible. Study participants can choose to interact with the WebApp and take study surveys whenever is comfortable and safe for them to do so.

The information we collect will only be seen by the research team. We will not link the email address or any identifiable information of any participant to any of the survey or application use data collected. All data will be reported in aggregate. Research data will be stored on a secure,

HIPAA-compliant server and drive with monitored and controlled access for study staff and investigators. The web-based survey will be hosted on secure servers.

The WebApp is hosted on virtualized servers provided by the University of Michigan Information Technology Services group. The virtualized servers are housed at two redundant data centers. These data centers provide protection from lengthy outages, 24/7 staffing, restricted physical access and disaster recovery. Virtual servers are backed up automatically onto encrypted tape for recovery and security. The data centers also reduce the use of physical resources such as electricity and air conditioning.

All servers and the back end databases are password protected. The server runs the RedHat Linux 7 Enterprise operating system. Security patches and updates are downloaded and installed automatically. Each server is also protected by firewalls to restrict network access to the server. The study web application software communicates directly with the database on the same server so unencrypted participant data is not transmitted on the Internet.

For the semi-structured interviews, we will not use names on any written documents or on digital audio recordings. All participants will be assigned unique, coded, confidential identifiers (code numbers), which will be used to label all notes, memos, and transcripts. The key linking the participant's identity to their unique coded identifier will be kept in a confidential manner in a database on a secure server, with access only by the Primary Investigator and the research staff. We will protect all physical documents by securing them in a locked file drawer in the PI's locked office.

For both the quantitative and qualitative data, we will discuss data in aggregate with no reference to identification of any individual in particular. The participants will decide if they want to share their email address with the study team to participate in the semi-structured interview portion of the study. Interviews will be held in a private room on campus.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

All retained data will be stored for five years and will be de-identified. We will protect all physical documents by securing them in a locked file drawer of the PI's locked office. Research data will be stored on a secure, HIPAA-compliant server and drive with monitored and controlled access for study staff and investigators. We will discuss data in aggregate with no reference to identification of any individual in particular.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Clinical Research Coordinator**
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10.1.6 SAFETY OVERSIGHT

This study does not qualify for oversight by a Data and Safety Monitoring Board (DSMB).

10.1.7 CLINICAL MONITORING

Clinical monitoring is conducted to ensure that the rights and well-being of trial participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and with applicable regulatory requirement(s).

- The Center for Health Communications Research will ensure the WebApp and study surveys remain in good working condition throughout the duration of the study.
- Independent audits of the survey data will be conducted by study staff to ensure monitoring practices are performed consistently.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The investigators will perform internal quality management of study conduct, data, documentation, and completion.

Any study problems with the WebApp, including any problems with the study WebApp and surveys, communicated through the study email address (umhealthyrelationships@umich.edu) by study participants, will be addressed by the study team in a timely fashion.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, and timeliness of the data reported.

The WebApp is hosted by the Center for Health Communications Research (CHCR) at the University of Michigan. They will make de-identified data available for study personnel on a dashboard. They will also make emails available in batches only (not connected with data) to allow study personnel to send incentives.

Semi-structured interview recordings are the responsibility of the study staff and will be saved to a secure, password-protected computer in a timely manner. Digital audio files will be transcribed and deleted within 6 months of recording.

10.1.9.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an International Conference on Harminosation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if

applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

10.1.10 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site investigator to use continuous vigilance to identify and report deviations. All deviations must be addressed in study source documents and sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

10.1.11 PUBLICATION AND DATA

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

Not Applicable

10.3 ABBREVIATIONS

ADAPT-ITT	Assessment, Decision, Administration, Production, Topical Experts, Integration, Training, Testing
AE	Adverse Events
ANOVA	Analysis of Variance
CFR	Code of Federal Regulations
CHCR	Center for Health Communications Research
CRF	Case Report Form
DSMB	Data and Safety Monitoring Board
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
MOP	Manual of Procedures
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
PTSD	Post-Traumatic Stress Disorder
SAE	Serious Adverse Events
SANE	Sexual Assault Nurse Examiner
SES	Sexual Experiences Scale
SOA	Schedule of Activities
SPSS	Statistical Package for the Social Sciences
SRPS	Sexual and Relationship Power Scale
STI	Sexually Transmitted Infection
UP	Unanticipated Problems
US	United States
VAWA	1994 Violence Against Women Act
WebApp	Web-Based Application

10.4 PROTOCOL AMENDMENT HISTORY

Not Applicable

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