Study Protocol and Statistical Analysis Plan

Brief Title: Study of Long-term Efficacy and Mechanisms Underlying the Impact of a Web-based Sexual and Relationship Health Promotion Program with Young Adult Community College Students

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The purpose of this study is to conduct a three-arm randomized control trial with older adolescents (i.e., ages 18-19) attending community college**.** Community college campuses were randomized to either the: (1) intervention group (i.e., *MASH-YA*); (2) active control group (i.e., sexual health programming from *MASH-YA* without MLE content); or, (3) wait-list control group. Students from each campus completed online questionnaires at pretest, posttest, 6m, and 12m follow-ups. Using this research design, there were several specific aims of this project. First, while research has shown that media literacy education (MLE) is an effective approach to sexual health education, little is known about the independent effects of using MLE in sexual health programming over and above sexual health programming that does not include MLE. Therefore, **Aim 1** is to evaluate the incremental effects of MLE on primary and secondary health outcomes. Second, research is needed to better understand the mechanisms underlying MLE's impact on sexual health outcomes and explore how these effects may differ from the mechanisms underlying the effects of sexual health programming that does not include MLE. Understanding the mediators of behavioral effects would advance theory and inform the development of other theory-based MLE prevention programs. Therefore, **Aim 2** is to compare the mechanisms underlying *MASH-YA*'s effects on health outcomes to the mechanisms underlying the effects of the active control program. Third, while a previous study established *MASH-YA*'s immediate positive effects on older adolescents' media processing and sexual health outcomes, research is needed to explore if the program's effects are enhanced, diminished, or sustained over time. Therefore, **Aim 3** is to evaluate the long-term efficacy of *MASH-YA* on proximal (i.e., media literacy skills; sexual health cognitions, beliefs, intentions, and willingness) and distal outcomes (i.e., sexual behaviors; dating violence; sexual assault) compared to active control and wait-list control groups. Replication of the findings from a short-term evaluation of *MASH-YA* in conjunction with evidence of long-term behavioral effects would establish a strong evidence base for the effectiveness of the *MASH-YA* program for use with community college students and would help identify how to optimize the long-term impact of the program on health behaviors (e.g., include boosters).

The procedure for conducting the research study is as follows:

1. Approximately thirty community college campus sites will be randomized to one of the three conditions and approximately 67 students will be recruited to participate from each of the campuses.
2. Interested students will complete a brief eligibility screener on the study website. They will be notified onscreen immediately if they are *potentially* eligible to participate. To pass this first screener, students must meet the aforementioned inclusion criteria. Other screener questions are included to gather demographic data that will be used to ensure diversity of the sample and used to distract students from the key eligibility questions.
3. Students who do not pass the first screener will receive a message telling them they are not eligible, thanking them for their interest, and providing the study team email address in case of questions. No personally identifying information will be collected from ineligible students at this stage.
4. Students that pass the first screener will be directed to a second screener. The purpose of this screener is to determine if the student is enrolled at a community college campus that is one of the campuses the study is recruiting from. This screener asks students to input

their community college/campus, college email address, and a contact phone number. If the student does not have a college email address, they may select to be contacted by a study team member to verify their college enrollment.

5. After completion of the second screener, potential participants will be directed to the online consent form. Students will see one of three messages at the top of the consent form, depending on whether or not the system was able to automatically verify that their college campus is a study recruitment site. In the interest of providing a smooth experience to the participant if their college campus becomes a recruitment site later, the system allows all individuals who complete the second screener to complete the consent form. Potential participants are encouraged to contact research staff members with any questions.
6. Students who wish to be considered for participation in the study will complete the online consent form, which includes a place to indicate consent to participate; enter their contact information, contact preferences, and secondary contact information; and verify their age (i.e., choose to upload a temporary photo of their ID or request to be contacted by a study team member). Participants will be asked to verify their age either through uploading on the consent form an image of some form of ID that includes a birthdate or showing the ID to a study team member in person (when available) or through web conferencing. After a study team member verifies the age from an uploaded image, the image will be deleted. Participants do not necessarily have to show proof of ID to be enrolled in the study, but the research team will attempt to verify all participants' age at some point during their time in the study.
7. Study staff will initially scan incoming consent forms for students enrolled at designated campuses. Any students who indicate that they attend a campus that is not part of the study will be marked as ineligible. (As new campuses are added to the study, study staff will review "ineligible" individuals and may categorize them as "eligible" if recruitment begins at their campus.)
8. Potentially eligible students who provide a college email address on the consent form will receive an email with a link to verify their email address. If a student had indicated on the screener that they do not have access to a college email address or do not click the link to verify their college email address, a study team member will contact the student to obtain proof of student status. Acceptable methods may include emailing a picture of their college ID or showing it on a video call, or providing some other proof that they are enrolled at the stated college. Students cannot be enrolled in the study until student status is verified.
9. On the consent form, participants will be asked for their preferred email address to receive study communications and incentives (Amazon gift cards) over the study period of one year. Before receiving communications at this address, they will need to verify that they can receive emails at this address by clicking a link that is emailed to them.
10. Students will also be asked on the consent form to provide their study communication preference for receiving survey links and reminders (email or email/text) on the consent form. Upon submitting the consent form, anyone who opts-in to receive texts will receive an SMS message with a verification link to determine that they can receive texts at their number.
11. Researchers may need to contact participants if they have information left blank on the consent form.

12. To ensure a diverse sample with respect to race, ethnicity, and gender, not all eligible students that complete consent forms will be enrolled in the study. If space is available in the study and the eligible participant is a student at one of the designated community college campuses, a member of the project staff will enroll the participant into the study arm to which their campus was randomized.
13. Upon enrollment, participants will receive a link to complete the online pretest questionnaire via text or email, depending on the communication preference they indicated on the consent form. Participants will be asked to complete the questionnaire within seven days and will receive reminders if not completed. If participants do not complete the pretest questionnaire in seven days, a researcher will follow-up through email, phone, or text. After another seven days have passed, if the student has not completed the pretest, they will be dropped from the study. A new participant will be enrolled in their place, when possible.
14. Upon completion of the pretest questionnaire, participants will receive a different link depending on condition. Participants on campuses assigned to the intervention group will receive a link to review *Media Aware*. Participants on campuses in the active control group will receive a link to review the active control program. Both of these groups will be told they will have two weeks to review their program and complete the Student Feedback Questionnaire (SFQ) when they have finished reviewing their assigned program. However, participants in the intervention and active control groups will have access to their assigned programs for another two weeks, until the posttest. After completing the pretest, participants on campuses assigned to the wait-list control group will receive a message stating that the next step will be another questionnaire in four weeks.
15. Links for future questionnaires will be sent based on the completion date of the pretest questionnaire: posttest (after four weeks); 6m follow-up; 12m follow-up.
16. A few weeks before the 6-month questionnaire and 12-month questionnaires are sent, a check-in message will be sent to the participants preferred and college email address to confirm that the address is still valid. Researchers will follow-up with participants who do not respond to the email.
17. Once the wait-list control participants complete the 12m follow-up questionnaire, they will receive a link to access *Media Aware* and be asked to review the program and complete the Student Feedback Questionnaire (SFQ). Wait-list control participants will be told they will have two weeks to review their program and complete the Student Feedback Questionnaire (SFQ) when they have finished reviewing their assigned program. However, they will have access to *Media Aware* for another two weeks.
18. Students participating in the study will receive a $20 Amazon e-gift card for completing the pretest questionnaire, a $30 Amazon e-gift card for completing the review of the program and Student Feedback questionnaire (SFQ), a $30 Amazon e-gift card for completing the posttest questionnaire, a $40 Amazon e-gift card for completing the 6-month follow-up questionnaire, and a $50 Amazon e-gift card for completing the 12-month follow-up questionnaire. Students who complete all study components will receive $170 in Amazon e-gift cards over the course of the year-long study.

Statistical Analysis Plan

Preliminary Data Analyses. Preliminary analyses may involve data entry and management activities. Qualitative data will be coded by trained study team members, and reliability will be calculated. Psychometric analyses will be conducted to study the reliability, validity, and distributions of key variables. Missing data may be handled in each outcome analysis (i.e., posttest, 6m follow-up; 12m follow-up) with an appropriate imputation method, and estimates and standard errors will be pooled and adjusted for imputations, if warranted (Schafer, 1997).

Clinical Trials Outcome analyses**.** A series of multilevel regression analyses will be conducted to test for the effectiveness of the intervention versus the wait-list control group as well as the intervention versus the active control group on students' primary and secondary health outcomes and media-related outcomes at the post-intervention, 6m, and 12m follow-up. These analyses should reveal if *Media Aware* improves primary and secondary health outcomes and if those effects last, degrade, or emerge over six and twelve months.

For additional information see:

Scull, T. M., Dodson, C. V., Evans-Paulson, R., Reeder, L. C., Geller, J., Stump, K. N., & Kupersmidt, J. B. (2022). Evaluating the mechanisms and long-term effects of a web-based comprehensive sexual health and media literacy education program for young adults attending community college: study protocol for a three-arm randomized controlled trial. *Trials*, *23*(1), 521.