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Brief Title: Interventions to Improve Reproductive Health Among Adolescents

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STUDY PROTOCOL

To address the need for a facilitator training that was cost-effective, easily accessible, and delivers the MPC content with the same effectiveness as the currently available in-person training, we developed and tested a prototype of an online simulator-based training for facilitators of MPC using a mixed method approach of survey assessments and teacher observations. Using a randomized controlled trial for the pilot test of the prototype, we randomly assigned a convenience sample of 53 adults to receive either online simulation training or in-person training for one activity within the MPC program. Using non-inferiority analysis (Schumi & Wittes, 2011), a statistical technique that specifically tests for similarity between groups, we hypothesized that participants who received the online simulation training would perform no worse than the in-person group on knowledge, self-efficacy, fidelity and quality of instruction via self-report survey and teacher observations. We also examined the self-reported acceptability, usability/applicability, likability and overall impressions among the online simulation group.

Making Proud Choices Prototype

To assess feasibility of using a simulated training environment to train educators to address the challenges of a skills-based sexual health curriculum such as MPC, the prototype focused on the content from one activity, the "Condom Line-Up", which is one component of the "Developing Condom Use and Negotiation Skills" module. According to the developer, this activity is highly interactive, relying on the facilitator's skill in processing student comments in a sensitive and constructive manner, as well as sensitive in nature (i.e., focusing on the use of condoms for adolescents). These qualities made the activity a good choice for this "proof of concept" phase. The in-person version of the training lasted approximately 25 minutes. The online version was comparable in length and included three elements: a) Didactic training: facing the learner, a master trainer avatar provides the rationale, learning objectives and goals for the activity; b) demonstration which entailed a virtual facilitator teaching the topic and virtual youth having typical reactions and responses, in a side-view of a classroom; and c) simulation teach-back: the view switches to the point of view of the learner, with the learner playing the role of the facilitator. For instance, a scene starts in which the virtual facilitator begins to teach to the virtual youth. Throughout the module, the scene pauses (at approximately 20 spots), and the learner is given at least 4 options on what action to take next. Although a best option exists, all options have some elements of better and worse responses. After the learner chooses an option, written text appears providing feedback about the option chosen. Learners are encouraged to go back and see how the class reacts if they had chosen other options as a way to maximize learning. Compared to many traditional online trainings that are unable to simulate the true give-and-take of a classroom environment, this innovative technology allows for the closest approximation to the feedback received from in-person training. Further, this approach can better reinforce information than in-person training in which there is no opportunity to witness the myriad of youth reactions.

Participants

In 2017, participants (those who represent potential MPC facilitators) were recruited to be a part of the pilot test using a combination of flyers posted at local universities and online advertisements (e.g., Craigslist, Facebook). Two-hundred forty-seven individuals expressed interest in the study, 93 of whom were excluded because they were younger than 21 years of age or had prior experience with MPC or providing other STI or pregnancy prevention education. Out of the 154 eligible individuals, the research team reached 123, and using a random number generator, randomly assigned 62 individuals who agreed to participate to either the online simulation (31 participants) or in-person (31 participants) training. Ultimately, 53 attended the day of pilot test (31 online simulation and 22 in-person). All participants

received one hundred dollars for participation in the pilot study. All participants provided written informed consent. All study procedures were reviewed and approved by RAND Corporation's Institutional Review Board (IRB).

Training and Fidelity Observations

All trainings occurred at the same facility, run by staff with extensive experience training MPC facilitators from a variety of backgrounds. Both the simulation-based and in-person groups were trained on the same Condom Line-Up activity. Participants in the simulation-based training group completed the training individually at their own pace as they would in real-world practice (average time = 31 minutes). The self-paced approach allowed participants to take as much time as they preferred to review and practice the lessons, as well as an opportunity to complete tasks multiple times if desired. Participants in the in-person training group received trainings led by a trainer with extensive experience training MPC facilitators. In-person trainings were offered to groups of 4-8 participants each; these were 20-minute sessions with an additional 5-minutes for Q&A following the training. The in-person approach allowed participants the opportunity to hear other participants' questions and the trainer's responses, providing the opportunity to think about questions that they may otherwise not have considered. All participants completed pre- and post-training surveys. Following the post-survey, each participant completed a demonstration teaching where they conducted the Condom Line-Up activity from start to finish to a group of staff trained to emulate teens and provide scripted responses during the session. Each participant was videotaped for the demonstration teaching.

Measures

Pre- and post-training surveys assessed knowledge, self-efficacy, facilitator skills, and beliefs and impressions related to the use of the online prototype. Observation measures focused on fidelity to curriculum for the Condom Line-Up activity and quality of the instruction.

Demographics

Participants provided demographic information on race/ethnicity, age, gender, education, and experience working with youth and teaching HIV/STI programs.

Facilitator Knowledge

Knowledge of the curriculum (objective and rationale of the Condom Line-Up) and knowledge of the steps of proper condom use was assessed using three items informed by the MPC curriculum (e.g., To the best of your ability, please select the rationale for engaging students in an activity that shows them the proper steps for using condoms safely.). Responses were coded as correct or incorrect. We examined each knowledge item individually in the analyses.

Facilitator Self-efficacy

Self-efficacy of teaching sexual health education was assessed using three questions (e.g., How confident are you that you can teach teens how to correctly use condoms?) rated from 1 (not at all) to 7 (extremely). We created a self-efficacy scale score by averaging the scores of the three items for each participant (α = .93 for pre-test and α = .94 for post-test).

Facilitator Skills

Participants responded to four open ended questions assessing facilitator skills related to handling sensitive questions, creating a safe and inclusive environment, engaging students, and handling whispering during a presentation on proper condom use. For example, participants responded to the following scenario: [You are preparing to teach a class of high school students about safe condom use strategies. A student raises their hand and says "Why do we all have to do this? Some people here believe in waiting till marriage to have sex." Another student then shouts out "Virgin!" and the class laughs. What do you do?] The purpose of these open-ended questions was to present participants with typical scenarios, ask for an open-ended answer (as opposed to choosing from a list of possible responses), and then rate their answer. Two independent coders (blinded to condition), who were trained by a senior researcher on the team, rated the videotaped responses as 2 for "done correctly," 1 for "done partially correct" and 0 for "not done correctly." The intraclass correlation coefficient (Cicchetti, 1994) was .76 for the pre-survey

responses and .79 for post-survey responses.

Beliefs and Impressions of the Prototype

Participants from the online simulation group also responded to questions assessing their perceived acceptability, applicability, liking, and overall impressions of the training. In addition to assessing the impact of the simulated training environment on learning the material, it is important to determine what potential teachers think about the simulation as this would likely influence its adoption into schools (Khlaif, 2018). To assess acceptability, participants rated 19 items on a scale of 1 (strongly disagree) to 7 (strongly agree) from the Post-Study System Usability Questionnaire (PSSUQ) (Lewis, 1995), a well-known, valid and reliable (α =.91 or higher) measure that assesses perceptions of the technical aspects of computer-based systems and programs (e.g., system usefulness, information quality, and interface quality). To assess usability and applicability to teaching youth about sexual health and safety, participants completed the Moore and Benbasat (1991) measure of factors that predict adoption of a new technology, specifically, relative advantage (e.g., "Using the online training would make my job easier."), compatibility (e.g., "The online training fits into my work"), ease of use, and result demonstrability (e.g., "I could talk to others about the consequences of using the online training"). Wording was adapted to be relevant to the online simulation training. Items were rated on a scale ranging from 1 (strongly disagree) to 7 (strongly agree) (α = .96). Participants rated likability with one item: [On a scale of 1 to 7, with 1 being disliked it very much and 7 being liked it very much, how much did you like the appearance of the Condom Line-Up e-training overall—the colors, the pictures, the buttons, etc.?]

Finally, participants' overall impressions of the training were assessed using a 4-item measure, rated on a 7-point Likert-scale (very difficult to use to very easy to use, very boring to very interesting, very amateurish to very professional, and very basic to very informative). Items were averaged to create an overall impression score (Cronbach alpha = .90)

Fidelity and Quality of Instruction

Each of the nine components from the Condom Line-Up were rated independently by two coders from the videotapes as 2 for "done correctly," 1 for "done partially correct" and 0 for "not done correctly." Coders received training on coding rules from a senior researcher on the team and one of the MPC training developers. Coders practiced the coding scheme on a subset of subjects in a group format where coders rated alongside a senior researcher on the team. Coder disagreement (>1-point difference) was discussed with the measure developer to reach a consensus. After training, two coders rated sub-activities of all the remaining 45 subjects. Inter-rater reliability using intra-class correlations (ICC) (Cicchetti, 1994) ranged from .78 to .98, all within the good-excellent range. Final scores were calculated as the average of the two coders' ratings.

STATISTICAL ANALYSIS PLAN (SAP)

First, we performed $\chi 2$ tests and *t* tests to assess whether the two groups differed on demographic and background variables, and pre-test scores on knowledge, self-efficacy and facilitator skills. Second, we examined the non-inferiority of online simulation to in-person by comparing two groups in post-training knowledge, pre-post change in self-efficacy and facilitator skills, and post-training scores of fidelity and quality of instruction. Non-inferiority analyses assess whether a new treatment or approach (e.g., online simulation) is acceptably efficacious as an existing approach (i.e., in-person training) (Althunian et al., 2017). Or, in other words, the new approach or treatment is not less effective than the existing approach by more than a small pre-specified amount. This amount is known as the non-inferiority margin.

To test non-inferiority of the online simulation training, we constructed a two-sided 95% confidence interval (CI) for the difference between online simulation and in-person (computed as in-person minus online simulation) for: (a) change in percent correct for knowledge of the curriculum (objective and rationale of the Condom Line-Up) and knowledge of the steps of proper condom use, both computed as post-test minus pre-test, using the method described in Farrington and Manning (1990), (b)

change in self-efficacy and facilitator skills (computed as post-test minus pre-test) using *t*-test statistic, and (c) scores of fidelity and quality of instruction based on the role-play activity after the trainings using the *t*-test statistic (Table 5). Non-inferiority of online simulation to in-person (meaning the online simulation group was no worse than the in-person group) could be claimed if the upper bound of the CI of the difference was less than the margin of non-inferiority. Based on standard practice (e.g., Schoneveld et al., 2018) and consensus among the developers of the MPC training on an acceptable difference between in-person and online simulation scores, the non-inferiority margin was set at 5% for percent correct of knowledge items, 0.5 *SD* of the in-person change in self-efficacy and facilitator skills, and 0.5 *SD* of the in-person scores of fidelity and quality of instruction. All tests were performed in SAS 9.4. (SAS Institute, 2013)

INFORMED CONSENT FORM (ICF): E-TRAINING AND SURVEY

What is the purpose of the study?
Thank you for your consideration to participate in our research study. dfusion, a small woman-run business in the San Francisco Bay Area, and the RAND Corporation, a non-profit research organization based in Santa Monica, CA are developing a prototype of an online, avatar-based virtual training for facilitators of the program Making Proud Choices (MPC), an evidence-based, safe-sex approach to teen pregnancy and HIV/STD prevention. Your participation in this study will help inform the development of this training for facilitators of Making Proud Choices.

What will I be asked to do?
As part of the study, you will complete the online training as well as two surveys (one before and one after the training) and a performance observation. The training will focus on one module of the larger MPC program. The surveys and the training will be completed at your own pace on a computer. The surveys will ask about your experience using the training, as well as your knowledge and attitudes related to sexual health education. For the performance observation, you will be asked to role play one of the skills learned in the training session in front of two of our staff while being videotaped. The videotape allows us to review your role playing after the session is complete. The study session including the training, surveys and performance observation will take approximately 2.5 hours.

What are my rights during the study?
Participation in the study is voluntary. You may skip any question on the surveys and the role playing and may leave the study at any time without consequence.

Will I receive anything for completing the survey?
As a thank you for your time, you will receive a $100 gift card, which will be distributed at the end of the 2.5-hour study session.

How will my privacy be protected?
Although we have your contact information from the study recruitment period, your contact information will not be connected to your survey responses or training sessions. All data collected as part of your study participation will be kept confidential. The risk of identification from your data is no greater than usual daily activity. Files containing your personal contact information will be password protected and only accessible by project staff to protect your confidentiality.

What if I have questions about the study?
You have the right to ask, and have answered, any questions about the study. If you have questions at any time you should contact Regina Firpo-Triplett, MPH, at dfusion at regina.firpo@dfusioninc.com or Matt Chinman, Ph.D. at the RAND Corporation at chinman@rand.org.

What if I have questions about my rights as a study participant?
All research with human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a survey participant you may contact, anonymously, if you wish, James Tebow, Ph.D., at the RAND Human Subjects Protection Committee: 310-393-0411 x4173 or tebow@rand.org.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Research Participant (Print)

_____ _____
Signature of Research Subject **Date**

INFORMED CONSENT FORM (ICF): IN-PERSON TRAINING AND SURVEY

What is the purpose of the study?
Thank you for your consideration to participate in our research study. dfusion, a small woman-run business in the San Francisco Bay Area, and the RAND Corporation, a non-profit research organization based in Santa Monica, CA are developing a prototype of an online, avatar-based virtual training for facilitators of the program Making Proud Choices (MPC), an evidence-based, safe-sex approach to teen pregnancy and HIV/STD prevention. Your participation in this study will help inform the development of this training for facilitators of Making Proud Choices.

What will I be asked to do?
As part of the study, you will complete the an in-person training as well as two surveys (one before and one after the training) and a performance observation. The training will focus on one module of the larger MPC program. The surveys will be completed at your own pace on a computer and the trainings will be done in a group setting. The surveys will ask about your knowledge and attitudes related to sexual health education. For the performance observation, you will be asked to role play one of the skills learned in the training session in front of two of our staff while being videotaped. The videotape allows us to review your role playing after the session is complete. The study session including the training, surveys and performance observation will take approximately 2.5 hours.

What are my rights during the study?
Participation in the study is voluntary. You may skip any question on the surveys and the role playing and may leave the study at any time without consequence.

Will I receive anything for completing the survey?
As a thank you for your time, you will receive a $100 gift card, which will be distributed at the end of the 2.5-hour study session.

How will my privacy be protected?
Although we have your contact information from the study recruitment period, your contact information will not be connected to your survey responses or training sessions. All data collected as part of your study participation will be kept confidential. The risk of identification from your data is no greater than usual daily activity. Files containing your personal contact information will be password protected and only accessible by project staff to protect your confidentiality.

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_____
Name of Research Participant (Print)

_____ _____
Signature of Research Subject **Date**

INFORMED CONSENT FORM (ICF): E-TRAINING FOCUS GROUPS

What is the purpose of the study?
Thank you for your consideration to participate in our focus group. dfusion, a small woman-run business in the San Francisco Bay Area, and the RAND Corporation, a non-profit research organization based in Santa Monica, CA are conducting this focus group to learn more about your experience using the online avatar-based facilitator training for Making Proud Choices.

What will I be asked to do?
We will be asking the group questions about your experience using the online facilitator training, including questions about how easy or difficult it was to use the training, what features you liked and didn't like, and your opinion of the training overall. The focus group session is expected to last approximately 90 minutes.

What are my rights during the survey?
Your participation is your choice, and you can stop or leave at any time without any negative consequence. We will ask the group a lot of questions, but you do not have to answer them if you do not want to.

Will I receive anything for completing the survey?
As a thank you for your time, you will receive a $50 gift card for participating in the focus group, which will be distributed at the end of the 90-minute session.

How will my privacy be protected?
Many of the questions ask about your personal experience with the training, but because this is a group discussion, please don't say anything you wouldn't want others to know and talk about. While our study team will keep what you say confidential—we are not collecting your names and will not share information about you with anyone—we cannot promise you that others in the group will do the same.

What if I have questions about the study?
You have the right to ask, and have answered, any questions about the study. If you have questions at any time you should contact Regina Firpo-Triplett, MPH., at dfusion at regina.firpo@dfusioninc.com or Matt Chinman, Ph.D., at the RAND Corporation at chinman@rand.org.

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