Dr. Eric Study Protocol and

Statistical Analysis Plan

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Study Purpose and Rationale

Adolescents frequent the emergency department (ED), making up more than 19 million visits each year. Adolescent ED patients admit to infrequent condom use, with rates as low as 40% at last intercourse. Adolescent sexually transmitted infection (STI) detection rates in the ED are as high as 26%, depending on symptomatology. For many of these adolescents, the ED is their only source of medical care, and their communication with outpatient medical providers around sexual health topics is poor, especially regarding effective contraceptives. The ED visit is a potential missed opportunity to educate and motivate these males to participate in healthy sexual practices.

ED-based digital interventions are a way to educate, motivate, and facilitate behavior change. In the ED, wait times can be long, resources are limited, and medical providers are busy. Digital interventions targeting ED patients, such as those that screen and briefly intervene have reduced risky behaviors, such as alcohol misuse, violence, and aggression. Technological interventions in the ED show promise to improve depression symptoms, increase STI testing, and increase contraceptive initiation. Yet, it remains unknown if an adolescent male sexual health intervention is potentially efficacious in the ED setting.

The objective of this study to conduct a pilot randomize controlled trial (RCT) of an ED-based sexual health intervention, entitled Dr. Eric (Emergency Room Interventions to Improve Care) We hypothesized that Dr. Eric will be feasible in the ED setting, be acceptable to male ED patients, demonstrate fidelity, be adopted by users, and show potential efficacy to increase condom use.

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Study Design, Procedures, and Data Analysis

Strategy and Sample:

We will conduct a pilot randomized controlled trial of up to 130 sexually active adolescent males aged 14-21 years who have been sexually active with females in the past 3 months. Exclusion: (1) do not own a mobile phone, (2) are too ill per the attending, (3) are cognitively impaired, (4) do not speak English, (5) want their partner to become pregnant in the next year, (6) are known COVID positive, (6) want their sexual partner to become pregnant in the next year, or (7) were previously enrolled in any of our qualitative interviews evaluating the Dr. Eric app. We will purposively sample males ages 14- 17 and 18-21. All patients, regardless of chief complaint, are eligible for screening.

Study Procedures

Recruitment and Safety:

We will recruit participants at our single center from the Pediatric Emergency Department and Adult Emergency Department. A member of the research team will identify potentially eligible patients using the electronic medical record (EMR). Our EMR reveals the age of each patient. The research team member will ask the medical provider caring the patient if we can approach the patient.

The study team will approach the potential participant as per standard practice of first checking that the treating physician has deemed the patient clinically stable and potentially appropriate for the research study. The research coordinator will introduce the study in accordance with the emergency medicine exemption policy and present the letter from the study PI and Medical Directors of the Emergency Departments. A member of the research team will then privately confirm eligibility and explain the study in full to the eligible patient in a private location by reviewing the informational form and answering all questions. If the patient is willing to discuss the study with a member of the study team, the research coordinator will proceed with consenting the subject. If the patient or/and family would like to talk to their treating physician more about the study, that will occur.

Research coordinators will screen ED patients during consecutive hours, Monday-Friday, 8am to 10pm, with some limited time for enrollment during weekend hours. Participants will be enrolled with informed consent. For participants aged 14-17, we will obtain 2-person verification of agreement to participate such as the research coordinator and ED attending. Participants will receive a $10 gift card for enrollment.

Participants will be assigned to intervention versus usual care arm with 1:1 allocation ratio by using a computer-generated block randomization. We will conceal allocation by using sequentially numbered envelopes which were opened after consent. Neither the research team member nor the patient will be blinded to arm assignment; outcome assessors will be blinded. Participants will receive a $10 gift card.

Standard care (SC) arm:

Participants randomized to the SC arm will receive standard medical care as determined by the ED provider, which is typically referral to a primary care or adolescent provider. Mobile telephone numbers will be collected for follow up purposes.

Dr. Eric Intervention arm:

After consenting, participants will interact with an ED-based iPad and the Dr. Eric app for a recorded period of time. The goal of Dr. Eric is to educate and motivate adolescent males to both use condoms and communicate with their sexual partners about effective contraceptive methods. The Dr. Eric app consisted of two parts—an ED-based app consisting of tailored educational sexual health modules followed by 10 weeks of once-a-week interactive text messages.

All participants will complete a brief survey of to assess his acceptability of the app. The participant enters his phone number and then receives a welcome text. After ED discharge, we will send texts directly to the participant's phone via short message service (SMS). Texts are sent every 7 days for a total of 12 text message cascades.

As an incentive and thank you for completing follow up, those in both the Dr. Eric Intervention arm and SC arm will have the option to receive a one-time shipment of condoms in discrete packaging sent to their home address. This is voluntary and opt-in. The participants will indicate their decision within the Dr. Eric app and/or verbally, privately to the research coordinator.

Participants will complete a baseline questionnaire to assess demographics, access to care, as well as sexual behaviors, beliefs, and attitudes. Follow up data will be collected from both arms any of the following ways: (1) online survey texted at 6 weeks and 3 months after enrollment; (2) if not response in one week, then we email the link to the survey; and (3) phone follow up and/or text weekly until completion.

Data Storage:

Consent: Participants will review the consent on the iPad. No signature will be required.
Baseline questionnaire and follow up questionnaires: We will use a password-protected system.
Enrollment and follow up logs: We will store all data in the Microsoft Teams.

Outcomes:

We will evaluate established health service implementation measurements. *Feasibility* is the extent to which the innovation can be used in this setting. *Acceptability* is the extent to which the innovation was agreeable to a stakeholder. *Adoption* is the user's intention or decision to use the intervention. *Fidelity* is the extent to which an intervention is used as intended.

Our primary efficacy outcome is condom use. This self-reported outcome will be calculated within each group by dividing the total number of episodes of vaginal intercourse by the total number of times a male condom was used during vaginal intercourse over the past 4 weeks via self-report. This outcome has been used in prior RCTs and is associated with decreased pregnancy risk and STIs. Additional secondary outcomes were also collected.

Statistical Analysis Plan

All data will be analyzed using IBM SPSS®. We will summarize implementation outcomes using standard descriptive statistics. To determine our primary efficacy outcome, condom use at 6 and 13 weeks, we will analyze a per protocol population which included all randomized patients who complete follow up and were sexually active in the past 4 weeks. We will report percentages of condom use (number of sexual encounters using a condom / number of sexual encounters over the past 4 weeks via self-report) within each arm. We will also build a multiple logistic regression model of proportion of condom use (number of sexual encounters using a condom / number of sexual encounters over the past 4 weeks via self-report) adjusting for age (as a continuous variable) and baseline consistent condom use (as a binary variable) with arm as the main predictor. We also will use this model to measure additional binary secondary outcomes at 6 and 13 weeks including consistent condom use and condom use at last intercourse. We will perform a sensitivity analysis of our primary outcomes by removing outliers who may have skewed the model. We will also perform descriptive statistics on additional secondary outcomes and assess differences between those who were lost to follow-up and those who were not.