Mhealth for Pre-exposure Prophylaxis Adherence by Young Adult Men Phase 2

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Mhealth for Pre-exposure Prophylaxis Adherence by Young Adult MSM, Phase II

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1.0 Background

In 2017, people age 13-29 represented 23% of the U.S. population, yet accounted for 41% of new HIV diagnoses (Avert, 2019; Ocfemia et al., 2018). Within this group, HIV rates were highest among young men who have sex with men (YMSM), especially minority YMSM (Avert, 2019; Ocfemia et al., 2018). Indeed, among African American YMSM, new HIV infections increased 48% from 2006-2009 (CDC, 2011). Latino YMSM are also at higher HIV risk compared to their non-Latino white peers, accounting for 25% of new HIV infections among young people (CDC, 2019a). Not surprisingly, the greatest increase in sex without condoms between 2005 and 2014 was among YMSM (Paz-Bailey et al., 2016). Clearly, there is a public health imperative to prevent new HIV infections among YMSM. And, because minority YMSM are at especially high risk, there is a health equity imperative to do so as well.

Pre-exposure prophylaxis, or PrEP, is a breakthrough medication for preventing HIV. PrEP treatment involves a daily pill (known by the trade name Truvada). Consistent, daily adherence to PrEP reduces HIV risk by 92-99% (CDC, 2019b). PrEP treatment guidelines also include the use of condoms and HIV testing every 3 months (CDC 2017). NIH has designated preventing HIV/AIDS, including through PrEP, as a high-priority topic for research support using AIDS-designated funds. The CDC (2017; 2019b) estimates at least 1 in 4 MSM are PrEP candidates. Due to the alarming rise in HIV among YMSM, the CDC also strongly recommends that healthcare providers reach out to this group, in particular, for PrEP treatment (CDC, 2012; 2019a).

Moreover, the CDC (2017) recommends that all PrEP patients receive adherence support as strong adherence is key to PrEP effectiveness. Adhering to PrEP may be especially hard for YMSM because, developmentally speaking, young adults are less able to appreciate the benefits of consistent prevention and/or are less good at planning ahead than adults who are older (Simpson, 2008; Steinberg 2008). Mhealth is an ideal way to reach young people due to the ubiquity of mobile phone ownership and use among adolescents and young adults (Taylor & Silver, 2019). Many studies of the impact of text messaging on medication adherence have been conducted, and results show that, across chronic conditions, text messages can have a positive impact (Thakkar et al., 2016). Partly because of this, there are now a plethora of multi-feature mobile apps to support medication adherence, yet very few of these apps have been clinically evaluated (Ahmed et al., 2018; Santo et al., 2016; 2017). Thus, the need for a PrEP mhealth adherence app for culturally-diverse YMSM remains urgent, which is why we are eager to move forward with Phase 2 of DOT.

2.0 Rationale and Specific Aims

The specific aim of conducting formative focus groups (or interviews) and an RCT is to develop and evaluate a mobile health application, DOT, to promote adherence to PrEP medication among young adult MSM ages 18-35.

3.0 Inclusion/Exclusion Criteria

Inclusion Criteria: Subjects who meet the following inclusion criteria will be considered for participation in formative focus groups:

a) Self-identify as male
b) Age 18-35
c) Have sex with men
d) Currently taking PrEP
e) Own a smartphone
f) Would like to participate in a focus group to provide feedback on a mobile app to support PrEP adherence

Inclusion Criteria: Subjects who meet the following inclusion criteria will be considered for participation in the RCT:

a) Self-identify as male
b) Age 18-35
c) Have sex with men
d) Currently taking PrEP
e) Own a smartphone and would like support for taking PrEP

Exclusion criteria: Those who meet any of the following criteria will be excluded from participation in formative focus groups:

a) Males who do not meet the above criteria
b) Currently use I.V. drugs

Exclusion criteria: Those who meet any of the following criteria will be excluded from participation in the RCT:

a) Males who do not meet the above criteria
b) Currently use I.V. drugs

4.0 Recruitment, Enrollment and Consent Procedures

Formative focus groups or interviews: As per our program officer permission, formative research will be conducted via zoom, via zoom focus group or, in the event that we cannot schedule enough

people at the same time, via zoom individual interviews. Potential focus group participants will be recruited through Tufts, PALSS, Craigslist and UserInterviews. As done in our prior online studies (including the phase 1 of this study), potential participants will read the informed consent online. The consent will emphasize that participation is voluntary and will not in any way affect employment or access to any services received from any provider, agency, or clinic. If a participant has questions he would like answered before signing, he will be informed to contact the study investigator. Participants will be emailed a signed copy of the consent document.

RCT: Potential RCT participants will be recruited from Userinterviews, Craigslist, and from Tufts and PALSS. Participants drawn from the latter two sites will be identified through referrals from Dr. Kogelman and Ms. Hampton-Julious and through signs posted in the respective locations. Interested individuals will be emailed a study link with study criteria. As in the Phase 1 evaluation of this study,, eligible RCT participants will complete informed consent online using Qualtrics software. The consent will describe procedures and potential risks. It will emphasize that participation is voluntary and will not in any way affect employment or access to any services received from any provider or agency or clinic, and that participants can discontinue involvement at any time. Participants will receive by email a signed copy of the consent document.

5.0 Study Procedures

The proposed study will include 2 zoom focus groups of 6-8 individuals each (or zoom interviews with the same number or individuals), which will solicit feedback on text messages and the usability of the prototype app and be approximately 2 hours long, and a randomized control trial (RCT) to evaluate the effectiveness of the DOT intervention on PrEP adherence among young adult MSM on PrEP. For the RCT, those who meet study criteria will complete online baselines in Qualtrics, then be randomized by Qualtrics to either the intervention group (DOT mobile app) or the control group (2page document offering PrEP adherence education).

Study procedures:

Formative Focus Groups/Interviews: After signing an online informed consent form, individuals will meet together for a 2 hour conversation (either in a focus group or interview), during which they will provide feedback on new text messages and the usability of the prototype app. Focus groups will be audiotaped. Participants will receive a $75 Amazon gift card at the end of the focus group.

RCT (both arms): Those who consent to the RCT will automatically receive a link to collect demographic data, e.g. age, ethnicity, education, income, and length of time on PrEP, and the baseline assessments. Qualtrics will then randomize participants to the intervention or control arm. Intervention and control participants will be offered a $20 Amazon gift card for completing baselines. At study completion (12 weeks), all participants will receive a text and email informing them that it is time to re-take baseline assessments. After completion, they will receive a $155 Amazon gift card.

RCT Intervention Group: Intervention participants will receive a link to download the DOT mobile app from our website. During the 12-week study period, intervention participants will receive 3 types of messages: pill reminders, educational, and motivational (including new ones targeting stress). The

DOT app will also include a link to the DOT online community (with online community rules that each participant must agree to before become a part of the community) and a “GET HELP NOW” link to the federal crisis intervention program. We have attached the online community rules for IRB review.

RCT Control Group: Control participants will be emailed a 2-page written PrEP patient education based on PrEP patient information on the CDC website, emphasizing the importance of daily adherence, use of condoms, and 3-month HIV testing while on PrEP.

6.0 Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others

We do not consider the time demand on participants to be a serious risk because the informed consent procedures make it very clear that they can terminate their participation at any time. To address the potential risk of participant discomfort or embarrassment due to participation in the RCT or focus group study, we will emphasize in our informed consent that participation is completely voluntary. We will also state that, despite protections, there remains a risk of privacy loss for all study participants, and individuals uncomfortable with this risk should not participate in the study. Any adverse events will be reported to the IRB, and any suspension of the project by the IRB will be communicated to NIH.

Focus groups risk: We consider the risks to focus group participants to be minimal. There is a minor risk that other members of the focus group will know that a given participant is taking PrEP to prevent HIV. We will be clear in consenting that such a risk exists.

RCT risk: We consider the risks to RCT participants to be minimal. Participants will complete questions at baseline and 12 weeks focusing on PrEP adherence, PrEP knowledge, PrEP selfefficacy, PrEP treatment guidelines, and stress burden. We see the content of these questions as posing minimal risk to participants overall. No participants experienced distress in Phase I when asked similar questions.

There is additional risk to RCT intervention participants that someone will see their text messages and realize that the participant is taking PrEP. Provisions against this risk will be outlined in the informed consent, and include measures such as: 1) disguising the app as DOT, which does not reveal the app’s purpose; 2) separate app login for accessing educational and motivational texts; 3) disguising such texts as “daily fitness news” or “notifications”; and 4) the option to select surrogate language for pill reminders. In the RCT informed consent, we will also advise participants randomly assigned to the intervention group who have concerns about privacy that they should only log in to the app when they are alone, and delete any texts they would not wish others to view. We will relate to participants that while there is inherent risk to moving data, state-of-the-art and HIPAA-compliant security protections are in place for any data in transit. Specifics about the length of data storage according to Massachusetts state law, as well as security protections for data storage, are detailed in the RCT informed consent as per the NIH project officer’s request.

We will point out that RCT participants assigned to the control group face the risk that someone may view the PrEP education materials emailed to them as part of the study. If this concerns them, they should destroy the materials after reading them or move them to a secure place. We provide recommendations to participants about securing these documents in the informed consent as per the NIH project officer's request.

Despite all the security safeguards and precautions, we will point in the RCT informed consent that there is still a risk of privacy loss and that participants should not participate if they are concerned about the risk.

7.0 Study Withdrawal/Discontinuation

We will emphasize in our informed consent that participation is completely voluntary and that participants can excuse themselves from the study at any time with no negative repercussions.

8.0 Statistical Considerations

The sample size of 110 for the RCT is based on our Phase 1 pretest results and an a priori power analysis for a multiple regression with 4 predictors of PrEP adherence, which was conducted to determine a sample size with a power of at least 90% with a two-sided alpha level of .05. The desired minimum sample size was 92 participants (Rosner, 2010). In the event of 20% attrition, we added 20% additional participants to the sample, and set 110 as the total sample size. Therefore, even if the study encounters diminished recruitment or greater post-recruitment attrition, it should still be possible to detect moderate effects.

9.0 Privacy/Confidentiality Issues

The research study will be monitored by the research team and the Pearl IRB. All study staff (PI, project manager, research assistant, consultants) will have completed human subjects training. Although the RCT study will be implemented online, the team will nevertheless review RCT data collected via Qualtrics for accuracy and safety. All data collected will have patient identifiers removed. No reports or papers based on the project will use any individual level data or include participant names or identifying information.

All study procedures (formative and RCT) will be reviewed by Pearl IRB. Only aggregate level deidentified data will be transferred between sites and/or aggregated on-site, with any data stored on secure servers and transmitted via secure protocols, encrypted email, password-protected media, and other appropriate protections.

10.0 Follow-up and Record Retention

Informed consent documents and a master list linking the participants' names to their number will be kept in a password-protected computer, separate from other study documents. Only the PI and study staff have access to these data. All participant data gathered via the HIPAA-compliant Qualtrics platform will be removed from Qualtrics at study conclusion and stored in a secure, encrypted drive on an EHG computer. These measures are outlined in the RCT informed consent.