Research Protocol

Using eHealth to reach Black/African American and Hispanic/Latino men who have sex with men regarding treatment as prevention and pre-exposure prophylaxis: Protocol for a small randomized controlled trial

Jacob J. van den Berg, PhD1,2, Taylor Silverman, AB1, M. Isabel Fernández, PhD3, Kirk D. Henny, PhD4, Zaneta J. Gaul, MSPH4, Madeline Y. Sutton, MD4, Don Operario, PhD1,2

1Center for Alcohol and Addiction Studies, Brown University School of Public Health, Providence, Rhode Island, USA
2Department of Behavioral and Social Sciences, Brown University School of Public Health, Providence, Rhode Island, USA
3Division of Health Professions, College of Osteopathic Medicine, Nova Southeastern University, Fort Lauderdale, Florida, USA
4Centers for Disease Control and Prevention, Atlanta, Georgia, USA

Correspondence: Jacob J. van den Berg, PhD
Center for Alcohol and Addiction Studies
Brown University School of Public Health
121 South Main Street
Providence, RI, 02912 USA
Tel: 401-863-7566
Fax: 401-863-6647
Email: jacob_vandenberg@brown.edu

Trial Registration: ClinicalTrials.gov (NCT03404531)
Abstract

Background: Black/African American and Hispanic/Latino men who have sex with men (MSM) in the United States continue to be disproportionately affected by Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS). Uptake of and knowledge about bio-behavioral HIV prevention approaches, such as Treatment as Prevention (TasP) and Pre-Exposure Prophylaxis (PrEP), are especially low in these populations. eHealth campaigns and social media messaging about TasP and PrEP may help to fill this gap in knowledge and lead to increased uptake of such strategies; however, no evidence currently exists examining the effects of these targeted forms of communication on TasP and PrEP uptake in these populations.

Objective: The objective of this paper is to describe the protocol for a three-part study aiming to develop and evaluate an eHealth intervention with information about TasP/PrEP for Black/African American and Hispanic/Latino MSM.

Methods: Phases 1 and 2 will involve focus groups and cognitive interviews with members of the target populations, which will be used to create a culturally-tailored, interactive website and applicable social media messaging for these men. Phase 3 will be a small, randomized, controlled trial of the eHealth intervention, in which participants will receive guided social media messages plus the newly developed website (active arm) or the website alone (control arm), with assessments at baseline and six months.

Results: Participant recruitment began in August 2017 and will end August 2020.

Discussion: Public health interventions are greatly needed to increase knowledge about and uptake of bio-behavioral HIV prevention strategies such as TasP and PrEP among Black/African American and Hispanic/Latino MSM. eHealth communication campaigns offer a strategy for engaging these populations in health communication about bio-behavioral HIV prevention.
Keywords: pre-exposure prophlaxis; treatment as prevention; men who have sex with men; eHealth; Black; African American; Hispanic; Latino; HIV; social media
Introduction

There were an estimated 973,846 people living with HIV in the United States (US), as of 2015; the Centers for Disease Control and Prevention (CDC) further estimate that roughly 38,500 new infections occur annually [1]. Men who have sex with men (MSM) accounted for about 70% of those new infections in 2015, despite comprising just 2% of the country’s population [2]. Moreover, roughly 70% of the new diagnoses that year were comprised of Black/African American or Hispanic/Latino MSM [2].

Black/African American and Hispanic/Latino MSM continue to be disproportionately affected by HIV/AIDS in the US. These racial and ethnic disparities in HIV/AIDS rates are also apparent in the Providence, Rhode Island (RI) Metropolitan Area, where new HIV/AIDS diagnoses among MSM increased between 2007 and 2011 even as total new diagnoses declined [3]. Moreover, 30% of newly diagnosed individuals in RI from 2009-2013 also presented with AIDS, with MSM status being the leading risk factor, suggesting that a significant number of RI MSM are only reaching care late in the course of their disease [3].

Effective bio-behavioral interventions for HIV prevention in such high-risk populations include Treatment as Prevention (TasP) and Pre-Exposure Prophylaxis (PrEP). TasP refers to the use of antiretroviral treatment (ART) to decrease the risk of HIV transmission between serodiscordant partners by reducing the viral load in the infected individual’s fluids to very low levels. TasP has been shown to have the potential to reduce HIV transmission to the partner without HIV by more than 96% [4]. PrEP is the daily ingestion of an oral single-tablet combination ART by HIV-uninfected individuals. PrEP has been shown to have a greater than 99% chance of preventing HIV acquisition in adherent individuals, as confirmed by multiple studies [5, 6-9]. However, knowledge about and uptake of PrEP and TasP remain low among
Black/African-American and Hispanic/Latino MSM [10, 11]. Though results vary across studies, PrEP uptake is estimated at just 9.8% for Black/African American MSM and 6.6% for Hispanic/Latino MSM [12]. Barriers to PrEP uptake identified by previous research include lack of cultural competency in public health initiatives, stigma related to homosexuality and HIV serostatus, lack of targeted internet outreach, and low health literacy in the target populations [13].

One highly promising strategy to increase awareness, knowledge, behavioral intentions, and potential uptake of public health interventions that is underutilized in this context is eHealth, which refers to the use of a range of electronic technologies (e.g. online social networking sites and applications, YouTube, and interactive websites) to provide health information [14-17].

eHealth has recently moved to the forefront of health communication because of its cost-effectiveness, high levels of accessibility and acceptability in many populations, and effectiveness in previous public health campaigns [18-22, 16]. Eighty-four percent of all American adults use the internet [23] and MSM of all racial and ethnic groups have been found to have high rates of participation on online social media sites [24]. Recent research found that MSM frequently prefer information about HIV prevention (e.g., PrEP) to be disseminated in electronic forms such as email and websites [21]. However, a recent review of the published literature did not find any evaluations of health interventions using social media to increase TasP or PrEP uptake in these high-risk populations, demonstrating its novelty.

Further, cultural tailoring, or the use of targeted messages for certain populations on the basis of known subgroup differences, has also been found to increase efficacy compared to generic health messaging [25-26]. For example, Kreuter and colleagues utilized messages to prompt African American women to increase mammography and healthy food consumption by
104tailoring those behavioral changes toward values such as religiosity, collectivism, and racial pride [26]. Yet few existing websites or online sources of HIV prevention information are tailored to Black/African American and Hispanic/Latino MSM. In addition, data on eHealth, and particularly social media’s utility for minority populations, remain limited.

Objective

The objective of this paper is to describe the protocol of a three-part study aiming to develop and evaluate an eHealth intervention with information about TasP/PrEP for Black/African American and Hispanic/Latino MSM. One part of this project will involve the creation of a culturally-tailored, interactive website for Black/African American and Hispanic/Latino MSM in the Providence Metropolitan Area, based heavily on feedback from members of the population. In addition to creating the population-specific website containing culturally-sensitive information about TasP and PrEP, we aim to develop population-specific social media messaging to promote the website and prompt participants to access it. These messages will be grounded in the Information-Motivation-Behavioral Skills (IMB) and Social Cognitive Theory (SCT) frameworks, widely-accepted evidence-based approaches for promoting behavioral changes related to HIV-risk reduction [27-32]. We hypothesize that using theory-based and culturally-relevant social media messages will increase knowledge of TasP and PrEP among Black/African American and Hispanic/Latino MSM, positively affect their attitudes and behavioral intentions towards the interventions, and ultimately increase uptake. The overall objective of this study is to improve HIV prevention strategies among high-risk minority MSM through novel utilization of eHealth.
Methods

Study Design

This will be a three-part study that includes focus groups and cognitive interviews to develop an eHealth intervention for Black/African American and Hispanic/Latino MSM, and a small, randomized, controlled trial (RCT) to evaluate that intervention. In Phase 1, we will use four to six focus groups of five to eight participants each to learn about TasP, PrEP, and social media usage in the target population, as well as feedback on an existing interactive website (http://www.men2menri.org/). The website was previously developed by members of our team targeting white MSM in RI. Phase 2 will use cognitive interviews with eight participants and an open pilot with 16 participants to develop and assess the acceptability of IMB/SCT-grounded social media message content designed to motivate and encourage access to our newly developed and culturally-tailored interactive website. In Phase 3, we will conduct a small RCT (n=100 participants, with 50 in each arm) comparing the combination of sending IMB/SCT-guided messages plus the newly developed and culturally-tailored interactive website (active arm) to the website alone (control arm). Study materials (e.g., recruitment flyers, interview guides, questionnaires, website, and social media messages) and findings (e.g., qualitative and quantitative data) will also be assessed by a Community Advisory Board made of six to 12 members from the local community who reflect the target populations. The study is approved by the Brown University Institutional Review Board (#1612001661) and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention’s project determination process.

Participant recruitment

Participants will be Black/African-American and Hispanic/Latino MSM who are 18 years and older living or working in the Providence Metropolitan Area (all of Rhode Island and Bristol
Participants must also fit the CDC definition of “high-risk,” i.e. have engaged in condomless anal intercourse within the past six months; be biologically male and identify as male; and be able to give written informed consent in English or Spanish. For Phase 3, participants must also report not being on PrEP if HIV-negative or in HIV care or on treatment if HIV-positive at the time of enrollment in the study. Participants for all phases of the study will be recruited by study staff using a variety of methods including advertisements online and on public transportation; posted signs and flyers in local community and commercial venues; and in-person outreach at places where the target population congregates, such as community-based organizations, clinics, bars, and clubs. Individuals interested in participating will be screened for eligibility over the phone using the aforementioned criteria. Participants will provide written informed consent prior to participating in the focus group, cognitive interview, or baseline assessment.

Procedures and interventions

For all phases, participants will complete a demographics form at the time of their enrollment. For Phase 1, we will attempt to stratify the groups by race/ethnicity (Black/African-American vs. Hispanic/Latino) and HIV serostatus (HIV-positive vs. HIV-negative). Focus groups will be facilitated by two trained staff members in English or Spanish using a semi-structured discussion guide, and will last roughly two hours. In both parts of Phase 2, we will attempt to have a balance of participants from each of the four categories from Phase 1 (Black/African-American HIV-negative, Hispanic/Latino HIV-negative, Black/African-American HIV-positive, and Hispanic/Latino HIV-positive). The cognitive interviews will be two to three hour sessions in English or Spanish using a semi-structured interview guide with open-ended questions, also administered by a trained member of the research team. All Phase I focus groups and Phase II
interviews will be digitally recorded and professionally transcribed. For the open pilot portion of Phase 2, participants will attend individual information sessions at the study location to be given a broad description of the intervention and view the website. They will then participate in the newly developed intervention (website plus messages) for one week. Participants will lastly return to the study location to complete a brief (one hour) qualitative individual interview about the website and messages.

Phase 3 participants will be randomly assigned to either have access to the website with culturally tailored social media messages (intervention condition) or the website alone (control condition). Participants will be stratified as in Phases 1 and 2. Block random assignment in batches of 10, by HIV status and race/ethnicity, will be used to keep the sizes of the intervention or comparison groups similar. Participants will physically come to the study site at enrollment for study description, consent procedures, website demonstration, randomization, demographic and HIV treatment and prevention history information collection, and baseline assessment; and then will come again six months later for the follow-up assessment. Participants will be assigned a research identification number which will be used for all data collected to ensure confidentiality. Participants will be compensated in cash $40 for the focus group, $50 for the cognitive interview, $35 for the open pilot, and $80 for the small RCT ($40 for the baseline assessment and $40 for the 6-month follow-up) plus a potential $10 for transportation/child care costs incurred to attend study sessions. Eligible individuals will be allowed to participate in only one phase of the study.

Measures

Phases 1 and 2 measures will involve using qualitative interview guides, informed by the extant literature and developed by the team, to identify important themes in the data. For Phase 3,
participants will complete the study assessment at enrollment (baseline) and at a six-month follow-up, which will be digitally-administered using iPads. The assessment will include questions about HIV testing history, date(s) of previous testing, and source of previous testing; confirmation of those tests, viral load, CD4 count, linkage and retention in care, HIV medication, adherence and viral load if HIV-positive, and consideration of PrEP including barriers and facilitators, if HIV-negative. It will also include measures to assess participants’ knowledge, attitudes, and behavioral intentions toward TasP and PrEP use. Other measures will include event-level characteristics of sexual-risk episodes over the past three months, using the Timeline Follow-Back (TLFB) interview, with information on sexual activities, relationship with partner(s), partner gender, use of alcohol or drugs prior to or during, and use of condoms for each episode. Phase 3 will also involve fidelity monitoring of participants’ use of the intervention, including information about when they check or receive messages, if they reply to messages and/or input information via messages, and if they log calls to study staff.

Study Outcomes

The primary outcome of the study will be levels of and increases in TasP or PrEP uptake in the intervention group compared with the control group, as determined by using assessment data from Phase 3. Secondary outcomes include increases in levels of TasP and PrEP-specific knowledge, favorable attitudes, and behavioral intentions regarding TasP and PrEP among participants in the intervention group. Lastly, we will explore decreases in sexual-risk behaviors in the intervention group relative to the control.

Study Timeline

Development of this project began in May 2016. Participant recruitment for Phase 1 began in August 2017, and is scheduled to be completed in August 2018. Phase 2 recruitment will begin in
August 2018, and is scheduled to be completed in August 2019. Phase 3 recruitment will begin in
August 2019, and is scheduled to be completed in August 2020.

Planned Analyses

For the qualitative analyses in Phases 1 and 2, research staff will independently read and code
professional transcriptions of the focus groups and interviews, and will convene regularly to
discuss emerging themes and systematically establish categories. Finalized thematic codes will
provide an exhaustive categorization tool of concepts and themes described by participants.
Multiple coders will analyze subsets of data, inter-rater reliability will be assessed, and any
discrepancies will be resolved with discussion.

In Phase 3, we will first assess the randomization process by comparing baseline
demographic variables of participants in each arm; any variable for which randomization did not
result in equal proportions in each arm will be incorporated into the multivariate models as a
potential confounding variable. Next, we will conduct primary inferential analyses to test our
primary hypothesis (IMB/SCT messages sent over social media will increase TasP and PrEP
uptake among the men in the intervention arm versus control arm) followed by our secondary
hypotheses. Since the primary and tertiary outcome measures are binary, we will first compare
proportions by randomization arm separately for each measurement period using standard
bivariate analytic techniques (e.g. Spearman rank-order correlations, odds ratios, Fisher's exact
test). We will use Ordinary Least Squares (OLS) regression on our secondary measures of
knowledge, attitudes, and behavioral intentions, which are assessed using continuous scales. We
will contrast outcomes in the intervention versus comparison groups over time via generalized linear mixed models (GLMM). Given the binary nature of our TasP/PrEP uptake and sexual-risk measures, we will specify a logit link function for our GLMM models.

We will follow an intent-to-treat (ITT) design and data from all enrolled participants will be included in the analysis, regardless of level of intervention use. Comparisons of characteristics of participants who are lost-to-follow-up to those who are evaluated will be conducted to assess for systematic patterns that could influence results. Following ITT principles, all participants randomized will be included in the data analyses.

Discussion

The goal of this project is to add to the science about HIV prevention interventions and eHealth among Black/African American and Hispanic/Latino MSM in the U.S. More effective interventions are necessary to reduce the burden of HIV for racial and sexual minority men. If the intervention is effective, social media messaging and culturally-tailored online information could be a low-cost, high-impact way to increase uptake of HIV prevention methods in these high-risk populations. This study will also generate much-needed data on social media’s utility for eHealth interventions among Black/African American and Hispanic/Latino MSM. While eHealth has substantial potential, it remains hard to assess its ability to motivate behavioral change given the lack of data available, particularly for racial/ethnic minority MSM.

Study limitations

There are study limitations that are important to highlight. First, given that this study will focus on Black/African American and Hispanic/Latino MSM living in the Providence Metropolitan Area, our findings may not generalize to Black/African American and Hispanic/Latino MSM living in other areas of the U.S. Second, our results will be based upon data that is self-reported
by participants, which is subject to recall and social desirability biases. Third, the website and social media messages that we will develop, based upon feedback from the focus groups and cognitive interviews, will be limited by the constant evolution of technology and its outpacing of research.

Study strengths

Despite these limitations, this study has a number of strengths including its utilization of a combined approach to TasP/PrEP uptake that leverages advances in social media as a platform for motivating behavioral change to potentially overcome some of the noted barriers to utilization of HIV treatment and prevention services. Another strength of this study comes from the use of social media messages grounded in IMB/SCT to provide targeted groups with timely information and motivational cues accessing the website about TasP and PrEP. Another advantage is the website will be culturally-tailored and specifically designed by and for Black/African American and Hispanic/Latino MSM. Lastly, findings from this research have the potential to influence policy guidelines and recommendations for TasP/PrEP uptake for high-risk groups.

Conclusions

Development and evaluation of this newly developed, culturally-tailored website will allow for improved implementation and delivery of TasP/PrEP and help prevent HIV acquisition and transmission among high-risk Black/African American and Hispanic/Latino MSM in the U.S. The results of this study will be used for a larger-scale trial to test the effectiveness of the combined messages, plus the newly developed culturally-tailored interactive website, on behaviors leading to HIV treatment and prevention for these two populations. In addition, future
research will be conducted to examine the long-term effects of the website on TasP/PrEP adherence among its users.
Acknowledgments: The authors are grateful to the Minority HIV/AIDS Research Initiative Program of the Centers for Disease Control and Prevention for their support of this research (U01PS005117; PI: van den Berg). The authors would like to thank members of the Adolescent Medicine Trials Network for HIV/AIDS Interventions Scholars Program for their original feedback on this research. Support was also provided in part by the National Institute on Alcohol Abuse and Alcoholism (U24AA022000; PI: Operario).

Conflicts of interest: None declared.
References


Abbreviations:
1. AIDS = Acquired Immune Deficiency Syndrome
2. ART = Antiretroviral Treatment
3. CDC = Centers for Disease Control and Prevention
4. GLMM = Generalized Linear Mixed Models
5. HIV = HIV Immunodeficiency Virus
6. IMB = Information-Motivation-Behavioral Skills
7. ITT = Intent-to-Treat
8. MSM = Men who have sex with Men
9. OLS = Ordinary Least Squares
10. PrEP = Pre-Exposure Prophylaxis
11. RCT = Randomized Controlled Trial
12. RI = Rhode Island
13. SCT = Social Cognitive Theory
14. TasP = Treatment as Prevention
15. US = United States