Investigating the Effectiveness of an Entertainment Education Short Film for Internalized HIV Stigma Reduction, Intimate Partner Status Disclosure Intentions, and Antiretroviral Medical Adherence Intentions: A Randomized Controlled Trial Among Black Women Living with HIV in the Southern U.S.

ClinicalTrials.Gov Identifier: NCT03898063

April 1, 2020

IRB#: 20170967

1) Protocol Title

An experimental investigation of the effects of an entertainment education short film on internalized HIV-related stigma, sexual partner status disclosure and antiretroviral therapy (ART) medical adherence among Black HIV-positive women in the Southern U.S.

2) Objectives*

This investigation seeks to understand if and how, the *90 Days* film can be used as an intervention to address HIV-related stigmas, intimate partner status disclosure and HIV ART medical adherence among Black HIV positive women. HIV-related internalized stigma is unique to this population as it relates to the negative internalized attitudes possessed by an HIV positive individual (Kalichman et al., 2009). Therefore, conducting this research with HIV positive participants is paramount in understanding the impact of entertainment education on internalized stigma and status disclosure.

3) Background*

The Joint United Nations Programme on HIV/AIDS (UNAIDS; 2015) has proposed the 90-90-90 treatment target with hopes of ending the AIDS epidemic. "By 2020, 90% of all people living with HIV will know their HIV status. By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART). By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression" (UNAIDS, 2015). Within the Southern U.S., among all women, Black women account for 67% of new diagnoses (CDC, 2019). Nationally, Blacks are less likely to adhere to ART regimens and reach viral suppression. Such combination poses a local public health crisis to reaching the national goals for HIV prevention. The CDC (2017a) recommends HIV status disclosure among sexual partners as a primary preventive measure to reduce the HIV burden by increasing the likelihood of using prophylactic measures. Furthermore, HIV status disclosure has been empirically linked to increased ART adherence (Stirratt et al., 2006) another advocated HIV prevention method. Problematically, psychological inhibitions such as internalized HIV stigma, negative beliefs and devaluing of one's self due to positive HIV status, often inhibit status disclosure and medical adherence (Chaudoir & Fisher, 2010; Herek, 1999; Turan et al., 2017). In the case of HIV-positive Black women, race and gender-related stigmas make status disclosure markedly more difficult (Henkel, & Kalichman, 2008).

Considering the central role of status disclosure and medical adherence in managing the HIV epidemic, identifying effective strategies that address such inhibiting mechanisms is critical. The present proposal contributes to this literature by conducting an experimental evaluation of a short entertainment education (EE) film about HIV status disclosure and management among Black HIV positive women living in Miami. EE refers to prosocial, persuasive messaging embedded into entertainment media (Moyer-Gusé, 2008). Entertaining media can influence persuasive outcomes through a variety of cognitive and emotional mechanisms. However, one particular strength of EE is it can provide social scripts for complex social interactions like HIV status disclosure. Moyer-Gusé, Chung and

Jain (2011) found participants who viewed a television program addressing HIV testing and sexual health dialogue reported higher levels of self-efficacy for engaging in these difficult conversations. Moreover, in comparison to a condition in which sexual discussion modeling was not demonstrated, participants who viewed the full episode were more likely to discuss HIV storylines with others (Moyer-Gusé, et al., 2011). In this regard, EE may provide a less threatening method for initiating sexual health discourse (Moyer-Gusé, et al., 2011). For understandable reasons, people are hesitant to disclose their HIV status. Moyer-Gusé's (2008) entertainment overcoming resistance model (EORM) provides a rationale for how EE can overcome this resistance.

4) Inclusion and Exclusion Criteria*

Participants for the manipulation check will be Black women between the ages of 18-45, clinically diagnosed with HIV/AIDS. For the main study, participants will be Black women ages 18-50, clinically diagnosed with HIV/AIDS. Women who are pregnant or think they may be pregnant will not be excluded from the study; as there is minimal risk associated with this research. No data will be collected regarding one's pregnancy or baby. In addition, the study will require participants to speak and comprehend English. Respondents will also need to have a working email address so that they can receive their compensation. Additionally, for those currently enrolled, they will need an email address to receive a study reminder for their follow up survey. Participants from the previous iteration of the 90 DAYS focus group will only be able to participate in the manipulation check. For the main study, participants from the previous 90 DAYS focus group iteration will be excluded.

5) Procedures Involved*

We propose a randomized clinical trial (RCT) with a pre and post questionnaire assessing two conditions: (1) standard-of-care brochure (control condition) and (2) the EE film (treatment condition). For those currently enrolled in the study (N = 3) outcomes will be assessed with two post questionnaires, the first to assess intentions immediately after exposure to the study conditions and the second to assess lasting effects of the intervention on behavior one month later. The second questionnaire will primarily evaluate participants' disclosure attitudes and beliefs, intimate partner disclosure intentions, medical adherence intentions, disclosure behavior, adherence behavior and reported internalized stigma. However, for newly enrolled participants only one post questionnaire will be assigned. Therefore, after completing the pre-test, intervention, and immediate post-test, they will not complete a follow up questionnaire. Thus, instead of participating in two waves of data collection, newly enrolled participants will only participate in one wave of data collection.

Prior to beginning the study, researchers will conduct a manipulation check for the PSA to ensure it is yielding the intended effects. The pre-test of the PSA will be conducted with 15-30 research participants. For the manipulation check, participants will provide verbal consent in place of signed consent. Therefore, completing the pre and post-test questionnaires will serve as their agreement to study participation. Participants will either be randomly assigned to view the PSA or to the control condition in which no stimulus will be used. Study conditions will

be randomly assigned based upon the dates of data collection. Participants viewing the PSA will complete a brief pre-stimulus questionnaire. Once completed, respondents will view a brief (30-60 seconds) PSA addressing key points displayed in the *90 DAYS* narrative. At the conclusion of viewing the PSA, participants will complete a brief post-test questionnaire. If assigned to the control condition, participants will only complete the brief post-test questionnaire. All participants in the manipulation check will be compensated $25 for their participation in the manipulation check.

Traditionally, Black women within the U.S. are a hard to reach population for research involvement (Jones, Lacroix, & Porcher, 2017). Literature suggests that Black women often experience an amalgam of barriers to research engagement such as: lack of transportation, need for a babysitter, and extensive caregiving responsibilities for loved ones (Webster et al., 2018). Considering this, the National Institutes of Health is strongly encouraging researchers to identify strategies that increase study participation among this demographic (Jones, Lacroix, & Porcher, 2017). For this reason, the current study will align with peer reviewed research and conduct the experimental sessions for the main study via the online Qualtrics platform (Jones, Lacroix, & Porcher, 2017). All responses to questionnaires will be anonymous.

Due to the sensitive and hard to reach nature of this study population, multiple recruitment strategies will be implemented. Firstly, a two-step recruitment process will be employed. Based upon the inclusion and exclusion criteria, clinic staff throughout the Jackson Health System as well as other HIV service providers across the state of Florida, will inform patients of the study via print and virtual flyers, sent via email. Dependent upon the study schedule, research team members maybe stationed at recruitment sites to speak with interested patients who desire further information. If research staff are not onsite, interested participants can contact the identified study team member listed on the recruitment flyer should they have further questions. All virtual flyers will be sent by clinic staff via a restricted email server to patients who have agreed to be contacted via email by their health provider. For patients who receive a printed or virtual copy of the study flyer, if they are interested in participating, they will visit the Qualtrics link provided on the flyer. Once they are on the study site, participants will read the consent form which thoroughly outlines the study's purpose, inclusion criteria, risks, benefits, compensation, voluntariness, and researchers' contact information. Should participants decide the study is a good fit for them, they will be able asked to consent by clicking the "next" button. Upon clicking the "next" button participants will be asked screening questions based upon the study's inclusion criteria (See updated measures guide). Once screened, if participants meet the eligibility requirements they will be guided through the study. Should participants not meet the eligibility criteria, they will be redirected to the end of the study and thanked for their time. Participants will be fully aware via the consent form that they can withdraw from the study at any time.

The second recruitment method will consist of paid targeted Facebook advertising. This recruitment strategy has yielded successful results in similar populations as the

current study (Jones, Lacroix, & Porcher, 2017; Mitchell & Petroll, 2012). Using data provided by the Centers for Disease Control and Prevention (CDC) and geographic information systems mapping, researchers will run Facebook advertisements in specific states, across the Southern U.S., that are identified to have moderate to increased prevalence of HIV among Blacks. In addition to using specific states, as carried out by other researchers, study investigators will set specific criteria to distinguish which Facebook users will be exposed to the ad (Jones, Lacroix, & Porcher, 2017). The inclusion criteria for the Facebook advertisements will include: Black women between the ages of 18-50 living within the Southern U.S. Similarly to those who receive the print or virtual flyer, participants recruited via Facebook will be able to click on the link in the advertisement to be redirected to the study's consent form. If they deem the study is a good fit for them, they will proceed by clicking the "next" button. Once they select "next", participants will complete the pre-test questionnaire, view one of the assigned stimuli, and complete the initial post questionnaire. Once all anonymous responses have been submitted, a randomized code will be provided to participants. Participants will be instructed to enter this randomized code along with their email address to receive compensation. Three weeks after completing the pre- and post-test questionnaire, participants will receive a reminder, via the provided email, to complete the follow up questionnaire. Similarly, to part one of the main study, once all anonymous responses are submitted, participants will receive a randomized code. They will be asked to enter the randomized code and their email address to receive their final compensation. Lastly, researchers will also request HIV servicing agencies to post the study flyer on their Facebook pages.

The third recruitment strategy consists of using a Qualtrics panel. According to Qualtrics, "*A market research panel, also known as an online sample, is a group of people recruited to respond to a survey. They are typically chosen from a pre-arranged pool of respondents who've agreed to be contacted by a market research service in order to respond to surveys."* Employing the study inclusion/exclusion criteria, Qualtrics panel, recruits willing participants for study participation. Participants recruited via the Qualtrics panel will be compensated directly via Qualtrics. They will receive a $50 gift card for their participation.

Across all forms of recruitment, study conditions will be randomly assigned via the Qualtrics system. Once a participant provides consent and is screened for study inclusion, participants will complete the pre-test questionnaire. After completing the pre-test questionnaire, respondents will be assigned to one of two study conditions. They will either be asked to view one of the following: a brochure on safe disclosure or the 90 DAYS film. Upon completing one of the interventions, participants will be asked to immediately complete the post-test questionnaire. For participants recruited outside of the Qualtrics Panel, once all anonymous responses are submitted, they will be directed to a separate link to enter their randomized generated code and email address. The purpose of the randomized code is to verify that the participant completed the study. The purpose of the email address for those currently enrolled is two-fold. Firstly, it will allow researchers to compensate participants with a virtual $30 Amazon gift card. Secondly, it will allow researchers to provide a follow up email, within 3-4 weeks, containing the link to the second

post-test survey. Participants will be compensated with a $20 virtual Amazon gift card. Altogether, currently enrolled respondents in the main study (N = 3), will receive a total of $50 for their participation in the study. After each data collection, participants will be reminded of their right to withdraw their responses from the study without penalty.

For newly enrolled participants, whether recruited via Qualtrics, social-media, health agencies, or word-of-mouth, only one wave of data collection will occur. Once participants complete the pre-test, intervention, and immediate post-test, they will not be re-contacted 3-4 weeks later for a follow up post-test. Newly enrolled participants who complete one wave of data collection will also be compensated with a total of $50 in e-gift cards; just as their counterparts who were enrolled in two waves of data collection.

For participants randomly assigned to the pamphlet only condition, an opportunity to view the short film will be available upon submitting their anonymous responses to the post test survey.

6) Data and Specimen Banking*

N/A

7) Data Management

To maintain participants' privacy, identifying information will be safely maintained in a secured password protected file that only study team members will have access to. The study will be administered using Qualtrics survey software. All quantitative data will be analyzed using SPSS 24 and Mplus.

8) Risks to Subjects

There are no physical risks anticipated with participation in this study. It is possible that participants may experience some stress in completing the questionnaire, and/or some inconvenience in the time taken to participate in the two waves of this study. A breach of confidentiality is also a potential risk, but measures will be taken to minimize that risk (please see confidentiality section below). Due to anticipating minimal risks, this study will not assess adverse effects.

9) Potential Benefits to Subjects

No direct benefit can be promised to you from being in this study.

10) Compensation

Participants in the PSA pre-test will be compensated $25. Light refreshments or lunch will be served during PSA pre-test sessions. Currently enrolled participants in the main study will be compensated with virtual Amazon gift cards oppose to cash. Participants will receive $30 for the first part of the main study and $20 for the follow up questionnaire of

the main study. Due to only participating in one wave of data collection, newly enrolled participants will receive one payment. However, just as those currently enrolled, newly enrolled participants will also be compensated with $50 via gift card. Altogether, all participants in the main study (current and new) will be compensated $50 in virtual gift cards. Participants recruited via Qualtrics will be compensated directly through Qualtrics. They will be compensated the amount agreed upon by their provider, which will be a minimum of $50 in Tango gift cards. Participants recruited via all other strategies will be compensated via email with a total of $50 in Amazon e-gift cards.

11) Vulnerable Populations

Minors, prisoners and those unable to consent will be excluded from the study. Pregnant women will not be excluded from the study. This study is presumed to have minimal risk. No data will be collected regarding one's pregnancy or baby.

12) Setting

Participant referrals and onsite recruitment will take place at the UM HIV Clinics at Jackson Memorial Hospital as well as other HIV service providing agencies across the Southern U.S., such as the AIDS Healthcare Foundation (AHF), Care Resource, Big Bend Cares, Neighborhood Medical Center, and Bond Community Health Center. Lastly, virtual recruitment will be conducted via Facebook and Qualtrics panel.

The PSA manipulation check will be conducted in the University of Miami's Clinical Translational Science Institute room or on the 7th Floor of the Soffer Clinical Research Center (CRB; rooms 710N or 710Q) located at 1120 NW 14th Street, Miami, Fl, 33136 and the Batchelor Childrens Research Institute, 1580 NW 10th Avenue, Miami, FL, 33136, 2nd floor conference room.

Paper data for the PSA manipulation check will be stored at in the principle investigator's office at 5100 Brunson Drive, room 3013, Coral Gables, FL, 33146. All electronic data and audio/video recordings will be stored on the password protected computers of research team members responsible for data analysis.

The main study will be conducted virtually, via Qualtrics software.

13) Resources Available

All researchers have completed CITI certification. The principal investigator, Dr. Nick Carcioppolo, is an expert in health communication and entertainment persuasion. He has published in a number of scholarly journals including *Communication Research, American Journal of Health Behavior,* and *Journal of Health Communication.* Dr. JoNell Potter is an expert in HIV/AIDS and women's health and much of her research focuses on status disclosure among intimate partners. In addition, Dr. Potter is also the Chief of Women's HIV Service at the University of Miami. Some of Dr. Potter's scholarly research has been published in the *Journal of Health Communication, Health Communication*, and *Journal of the Association of Nurses in AIDS Care.* Lastly, Jazmyne Simmons has worked as a

certified HIV/AIDS tester and counselor. To this end, her expertise will be employed in conducting the focus groups and onsite participant recruitment.

14) Prior Approvals

N/A

15) Recruitment Methods

Multiple strategies will be employed for participant recruitment. For the PSA pre-test phase, participants will be recruited by self-referral, word of mouth, or referred by a staff member or provider from the University of Miami, Jackson Memorial Hospital, including the HIV clinics, as well as other HIV service providers. More specifically, the research team will partner with Care Resource and AIDS Healthcare Foundation for participant referrals. Each of these agencies service our target population. As part of a memorandum of understanding, Care Resource will be compensated for their assistance with patient referrals for the study. Their referral process will include contacting qualified participants to inform them of the study, as well as referring interested patients within clinic to the study. AIDS Healthcare Foundation will inform patients within clinic of the study and refer them to the research team if they desire to participate. Dependent upon the study schedule, research team members maybe stationed at recruitment sites to immediately enroll participants. To maintain confidentiality throughout the recruitment process, the two-step approach will be employed. Firstly, potential participants may view the recruitment flyer or be referred by UM or JMH staff, or other HIV service providers, who will inform patients of the study, including the purpose of the study and participation criteria. Second, patients who express interest in participating will be referred to a research team member who will provide further information. Due to the sensitive nature of this study, should a patient decline to participate, they will not be referred to the research team.
Should a participant agree to partake in the study, they will be provided consent forms from a study team member as well as the pre-questionnaire. If research staff are not onsite, interested participants will contact the identified study team member listed on the recruitment flyer. Researchers will partner with the Behavioral Registry Study at the University of Miami. This partnership will provide contact information for willing potential research participants that meet the inclusion criteria.

Additionally, as a form of recruitment for the main study, HIV servicing agencies across the Southern U.S. will be asked to share the virtual flyer on their Facebook pages. Lastly, using data from the CDC and GIS mapping, researchers will employ targeted Facebook recruitment using Facebook ads. Ads will be run in Southern U.S. states that are identified to have a moderate to high prevalence of HIV. Further, ads will be displayed among Facebook users in the selected states, who meet the study criteria.

Lastly, a Qualtrics panel will be used for recruitment. According to Qualtrics, “A market research panel, also known as an online sample, is a group of people recruited to respond to a survey. They are typically chosen from a pre-arranged pool of respondents who’ve agreed to be contacted by a market research service in order to respond to surveys.” Employing the

study inclusion/exclusion criteria, Qualtrics panel, recruits willing participants for study participation. Participants recruited via the Qualtrics panel will be compensated directly via Qualtrics. They will compensated the amount agreed upon by their provider. However, compensation will be at least $50 in gift cards for their participation.

Eligibility is restricted to black women ages 18-50, living in the Southern U.S., that have been clinically diagnosed with HIV/AIDS, who can read and comprehend English.

Note that participation is voluntary, and all participants will have the right to choose whether to participate or not.

16) Local Number of Subjects

The first iteration of the study enrolled 50 participants. For the current iteration of the study up to 30 phase one participants will be enrolled for the PSA pre-test. Up to 400 study participants will be enrolled for the main study. Altogether, this study will enroll up to 500 participants.

17) Confidentiality

The pre-test survey for the PSA will not ask any personally-identifying information. The pre- and post-film surveys and follow up-questionnaire will not ask any personally-identifying information. However, we will collect contact details (email address) of participants in order to schedule the second wave of the investigation and compensate participants. Contact details will be stored separately from the survey responses and will be deleted after data collection is complete. No personally identifiable information will be included in any written reports of the results.

18) Provisions to Protect the Privacy Interests of Subjects

Only authorized members of the study team will have access to the data. Lastly, an assigned research team member will contact participants to provide a reminder of the follow up survey. Participants will be individually contacted and compensated via email.

19) Consent Process

The consent process for the PSA pre-test will be as follows. Firstly, clinic providers and staff will inform patients of the study, including the purpose of the study and participation criteria. Second, patients who express interest in participating will be provided contact information for a research team member who will be able to provide further information on the study. Due to the sensitive nature of this study, should a patient decline to participate, they will not be referred to the research team. The study team member will provide the interested participant with the consent forms to read and ask any questions to their full satisfaction and understanding. After the consent forms are signed and copies given to the participant, the study team member will administer the pre-questionnaire.

Due to the main study being conducted via the Qualtrics survey software, participants will be provided a thorough consent form. Should the participant agree to participate, their consent will be determined based upon their decision to select "next" and complete the study. Moreover, all participants for the PSA manipulation check and main study will be informed of their right to remove themselves from the study or withdraw their responses at any time without penalty. Respondents will also have the contact information of the study team in case they have questions.

20) Process to Document Consent in Writing

For both the PSA manipulation check and the main study, participants will document their consent by completing the study questionnaires. Therefore, while informed consent will transpire, signed consent will not. This will reduce the amount of personal identifiable information reported.

References

AIDSVu. (n.d.) Miami (Miami-Dade County) Highlights. Retrieved from: https://aidsvu.org/state/florida/miami/

Centers for Disease Control and Prevention. (2017). *Living with HIV*. Retrieved from: https://www.cdc.gov/hiv/basics/livingwithhiv/index.html

Centers for Disease Control and Prevention. (2019). *HIV in the Southern United States.* Retrieved from: https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf

Chaudoir, S. R., & Fisher, J. D. (2010). The disclosure processes model: Understanding disclosure decision-making and post-disclosure outcomes among people living with concealable stigmatized identity. *Psychological Bulletin*, *136*(2), 236-256. doi: 10.1037/a0018193

Herek, G. (1999). AIDS and stigma. *The American Behavioral Scientist*, *42*(7), 1106-1116

Henkel, K. E., Brown, K., & Kalichman, S. C. (2008). AIDS-related stigma in individuals with other stigmatized identities in the USA: A review of layered stigmas. *Social and Personality Psychology Compass*, *2*(4), 1586-1599. doi: 10.1111/j.1751-9004.2008.00116x

Jones, R., Lacroix, L. J., & Porcher, E. (2017). Facebook advertising to recruit young, urban women into an HIV prevention clinical trial. *AIDS Behavior*, *21*, 3141-3153

Kalichman, S. C., Simbayi, L. C., Cloete, A., Mthembu, P. P., Mkhonta, R. N., & Ginindza, T. (2009). Measuring AIDS stigmas in people living with HIV/AIDS: the internalized AIDS-related stigma scale. *AIDS CARE*, *21*(1), 87-93. doi: 10.1080/09540120802032627

Mitchell, J. W., & Petroll, A. E. (2012). Patterns of HIV and sexually transmitted infection testing among men who have sex with men couples in the United States. *Sexually Transmitted Diseases*, *39*(11), 871-876

Moyer-Gusé, E. (2008). Toward a theory of entertainment persuasion: Explaining the persuasive effects of entertainment-education messages. *Communication Theory*, *18*, 407-425. doi: 10.1111/j.1468- 2885.2008.00328.x

Moyer-Gusé, E., Chung, A. H., & Jain, P. (2011). Identification with characters and discussion of taboo topics after exposure to an entertainment narrative about sexual health. *Journal of Communication*, *61*, 387-406. doi: 10.1111/j.1460-2466.2011.01551.x

IRB#: 20170967

Stirratt, M. J., Remien, R. H., Smith, A., Copeland, O. Q., Dolezal, C., & Krieger, D. (2006). The role of HIV serostatus disclosure in antiretroviral medication adherence. *AIDS and Behavior*, *10*(5), 483-493. doi: 10.1007/s10461-006-9106-6

Turan, B., Budhwani, H., Fazeli, P. L., Browning, W. R., Raper, J. L., Mugavero, M. J., & Turan, J. M. (2017). How does stigma affect people living with HIV? The mediating roles of internalized and anticipated HIV stigma in the effects of perceived community stigma on health and psychosocial outcomes. *AIDS Behavior*, *21*, 283-291. doi: 10.1007/s10461-016-1451-5

Webster, K. Carter, A., Proulx-Boucher, K., Dubuc, D., Nicholson, V., Kerrigan, B., Claudine, G.,…(2018). Strategies for recruiting women living with human immunodeficiency virus in community-based research: Lessons from Canada. *Progress in Community Health Health Partnerships, 12*(1), 21-34

United Nations Programme on HIV/AIDS. (2015) Understanding fast-track: Accelerating action to end the AIDS epidemic by 2030. Retrieved from: http://www.unaids.org/sites /default/files/ media_asset/ 201506 _JC2743_Understanding_FastTrack_en.pdf