Game Changers: Pilot Intervention to Empower HIV Clients as Prevention Advocates in Uganda

November 13, 2018

PROTOCOL SUMMARY

1. Background and Rationale

Stagnant, high HIV prevalence in Uganda calls for innovative approaches to prevention. Uganda, as elsewhere in sub-Saharan Africa, has a generalized HIV epidemic with new infections caused by heterosexual sex (~80%) or mother-to-child transmission (~20%), and <1% due to homosexual sex, blood transfusions or other causes. HIV prevalence has stagnated at ~7% since 2005, with a continued annual incidence of about 130,000.

Empowering people living with HIV (PLWH) to be change agents for HIV prevention draws on the full armament of existing prevention paradigms. Prevention for Positives and Treatment as Prevention have targeted the risk and treatment behaviors of PLWH, but current paradigms do not take advantage of the potential for PLWH to be change agents for HIV prevention within their social networks. Receipt of HIV care often comes with renewed health and a sense of community and support from HIV-positive peers, and our research suggests that most HIV-positive clients actively encourage friends and family to seek HIV testing and care, and reduce risk behavior. Drawing on theoretical frameworks for network-based social influence, and established relevant interventions, this study will pilot test Game Changers - an intervention that aims to empower and mobilize PLWH to be agents for HIV prevention and behavioral change in their social networks.

2. Objectives

The primary objective of this study is to assess feasibility, acceptability, and preliminary intervention effects of the Game Changers Intervention on: a) protective behavior of PLWH (condom use, number of partners, engagement in HIV care, ART adherence); and b) diffusion of prevention messages across the network, as assessed by the content and extent of communication with network members about protective behaviors (condom use, number of partners, HIV testing, engagement in HIV care, circumcision), HIV disclosure, and HIV stigma.

3. Study Design

We will screen approximately 500 PLWH at the Infectious Disease Institute (IDI) clinic to arrive at a sample of 96 participants who will be randomized to intervention or wait-list control (each evenly stratified by gender). There will be 4 gender-specific intervention groups and one control. The intervention consists of 6 workshops, which will occur approximately every other week. Participants will be asked to complete a workshop evaluation form after each workshop. Participants will be interviewed at baseline, 3-4 months after baseline, and again 6-7 months after baseline. The wait-list control will receive the intervention upon completion of the final follow-up assessment has been completed by all intervention groups.

Participants will be asked to recruit 1-3 of their social network members to participate in three interviews. We expect to screen approximately 180 social network members to arrive at 90 participants.

4. Methods

Screening/Recruitment

There will be one screening/recruitment procedure for all PLWH participant-related procedures. The coordinator (who will be part of the clinic staff) will obtain the list of eligible clients scheduled for clinic visits during the recruitment period and will approach these individuals in the waiting room while they wait to see their provider to inform them of the study and assess their interest in participating. Alternatively, the coordinator will be at the clinic during days/times when potential participants are expected to be there. When clients are screened individually by the coordinator, they will be informed of the eligibility criteria and the legal risks of participation if they engage in same-sex sexual behavior or commercial sex work. Clients who express interest will be initially screened for age (to ensure they are 18 years of age or older), sex (to ensure adherence to the strata described above), length of time in care, and having disclosed serostatus to at least one person. Clients will then be given an information sheet and consent form that explains the project in detail. They will be given the option to provide signed consent to participate at the clinic that day, or to take the materials home and consider, with instructions to return the signed consent form to the coordinator if they are interested. This allows gay clients to withdraw their interest without disclosing their sexuality. Clients will be assured that all information collected is confidential, and no identifying information will be collected and stored unless the person is eligible and enrolls in the study.

Procedures

Participants will be randomized to be in the Game Changers program or in the wait-list control condition. The **Game Changers** program will consist of 6 workshops conducted by trained IDI personnel. Stigma reduction and self-acceptance, comfort and competence with HIV disclosure, and healthy, positive living, form the foundation for effective prevention advocacy, and are the focus of the initial workshops. With the foundation set by the first few workshops, the last few workshops provide participants with skills, confidence and support for engaging in prevention advocacy with members of their network, and with education about tailoring messages.

The 6 workshops will be implemented over about three months. Each workshop will last about 2 hours and will be facilitated by 1-2 trained counselors with experience conducting group trainings and working with people living with HIV. The workshops will be administered in a group format to facilitate an interactive social process, social reinforcement, modeling, role-

plays and other interactive components of skills building; groups are most effective in developing self-identity as members of a community in which members rely on each other for support. A workshop evaluation survey will be conducted at the conclusion of each workshop.

PLWH interview and social network assessments will be conducted by trained IDI personnel. The interview and social network assessment both will be administered in a single session in either English or Luganda as preferred by the participant. The first interview will last approximately 2.5 hours, and the second two interviews will last approximately 2 hours.

The interviews will collect information about participant demographics; engagement with HIV care, prevention advocacy; knowledge/beliefs about and adherence to HIV medication; HIV-related self-efficacy; HIV status disclosure; discrimination and stigma; social support; physical and mental health status; alcohol use; and relationship status and sexual behavior. During the social network assessment portion, participants will be asked to list 20 adults (18+ years) with whom they have had contact within the preceding year (e.g., friends, family, other community members). We will collect first name and last initial for each social network member to avoid the potential for confusing individuals who might have the same first and last initial, and to assist with linking network member data across assessments (to assess network change over time). For each social network member listed we will collect information about demographics; perceived serostatus; description of the relationship between the PLWH participant and the individual; PLWH participant's engagement in prevention advocacy with the individual; social support provided by the individual; and the individual's expression of HIV-related stigma. We will also ask for a description of how often individuals listed in the social network assessment interact with each other.

Interview data and social network assessment data will be collected using an offline version of EgoWeb. Hard and soft copies of raw data, including participant identifiable information will be kept at IDI, and only computer files with de-identified data will be kept at RAND. The IDI study coordinator will keep a linking file that matches study IDs with participant names. The linking file will be stored separately from research data. Interview and network assessment data will be exported to transmittable files (e.g., Excel), and then the study coordinator will remove identifying information and insert study IDs into this file prior to transmittal to RAND. The file will be transmitted to RAND via SFTP, after which it will be moved to a secure RAND server and accessible to authorized personnel only.

Social network member interviews will be conducted by trained IDI personnel. The interview will be administered in either English or Luganda as preferred by the participant. The first interview will last approximately 2 hours, and the second two interviews will last approximately

1-2 hours. These interviews will assess participants HIV protective behaviors (e.g., condom use) and receipt of prevention advocacy from the intervention participant.

Interview data will be will be collected using an offline version of EgoWeb. Hard and soft copies of raw data, including participant identifiable information will be kept at IDI, and only computer files with de-identified data will be kept at RAND. The IDI study coordinator will keep a linking file that matches study IDs with participant names. The linking file will be stored separately from research data. Interview data will be exported to transmittable files (e.g., Excel), and then the study coordinator will remove identifying information and insert study IDs into this file prior to transmittal to RAND. The file will be transmitted to RAND via SFTP, and will be accessible to authorized personnel only.

Focus groups will occur at the conclusion of the intervention, and topics will include participants' overall attitudes about the program, the facilitators, and different program activities, as well as how the program might be improved. We will conduct 5 groups, one for each intervention group, and 1 for the wait-list control group (after wait-list control participants receive the intervention).

The groups will be facilitated using a structured guide of topical areas and questions. Open-ended questions will be asked before probing questions to avoid biasing responses. The initial open-ended format allows for exploring new leads and related topics and generates rich personal narratives. Standard probes (verification; compare and contrast) will be used. Facilitator training will be conducted by Bogart and Matovu, and will cover the discussion guide, sensitivity issues, and confidentiality. Each focus group will last ~60 minutes.

Note that participants may be called or texted as a reminder about the focus group session, if they provide their contact information to the interviewer.

Focus groups will be audio-recorded and transcribed. Before beginning the session, the facilitator will assign numbers to participants and ask that they use these numbers to identify themselves and others in the group when speaking. As a result, audio recordings of the focus groups will have no identifying information, will be stored on a password-protected, encrypted file, and then destroyed once a transcript has been completed (within one week of administration). Transcripts will be transmitted to RAND via SFTP, after which they will be moved to a secure RAND server and accessible to authorized personnel only. Any hardcopy notes or other files resulting from the focus groups will be retained by IDI.

Medical chart data obtained by RAND will include date of HIV diagnosis, last two CD4 counts and HIV viral loads, and prescribed HIV medication, and will be provided by the IDI clinic where PLWH participants receive care and will be recruited for this study (IDI is the main clinical

referral center for HIV at Mulago Hospital, and manages these medical charts). Hard and soft copies of raw data, including participant identifiable information will be kept at IDI, and only computer files with de-identified data will be kept at RAND. The IDI study coordinator will keep a linking file that matches study IDs with participant names. The linking file will be stored separately from research data. The study coordinator will remove identifying information and insert study IDs into this file prior to transmittal to RAND. The file will be transmitted to RAND via SFTP, after which it will be moved to a secure RAND server and accessible to authorized personnel only. Medical chart data will be merged with other datasets using the study ID.

Workshop evaluation surveys will be administered to participants by IDI personnel at the end of each workshop to elicit data on usefulness of the workshop, comfort with specific exercises, and ideas for improvement. No identifying information will be collected in this survey.

Survey data will be entered into a spreadsheet and transmitted to RAND via SFTP. If onsite data entry is not possible, scanned copies of the surveys will be transmitted to RAND via SFTP. Any hardcopy files resulting from the survey will be retained by IDI.

5. Statistical Analysis

We will primarily use an intent-to-treat approach, with secondary analyses involving study completers. In addition to comparing the arms at each time interval, we will apply generalized mixed models (linear for continuous or ordinal outcomes; logistic for binary outcomes) to our repeated-measures data to examine how intervention effects change over time, using an indicator for study arm, an ordinal indicator of time, and time by arm interaction to indicate whether change differs between the arms.

Aim 1: To assess feasibility and acceptance of the intervention, we will examine recruitment (# who sign up as interested in participating each recruitment day) and retention, workshop attendance (# who attend all workshops), and participant feedback elicited in the process measures (ratings of benefit; recommendation to peers). We will also compare the characteristics of the participants with that of the larger clinic population using routine data collected by IDI in order to assess the degree of selection bias caused by our recruitment strategy.

Aim 2: To assess preliminary intervention effects on the outcomes (protective behavior of the HIV-positive clients: condom use, number of partners, engagement in HIV care, ART adherence), and diffusion of prevention messages across the network (content and extent of communication with network members about protective behaviors, including condom use, number of partners, HIV testing, engagement in HIV care, circumcision; HIV disclosure; and HIV stigma), we will primarily use an intent-to-treat approach, with secondary analyses involving

study completers. In addition to comparing the arms at each time interval, we will apply generalized mixed models (linear for continuous or ordinal outcomes; logistic for binary outcomes) to our repeated-measures data to examine how intervention effects change over time, using an indicator for study arm, an ordinal indicator of time, and time by arm interaction to indicate whether change differs between the arms. A random-effects approach allows us to incorporate the heterogeneity among participants. We will use imputation for item nonresponse and account for non-random dropouts using logistic regressions that assign weights to retained participants that are inversely proportionate to the predicted probability of the participant being retained; if dropout is random, analyses will incorporate design effects when calculating standard errors and significance tests. With the intervention administered in groups, these analyses need to account for clustering of the data; however, the number of groups receiving the intervention is too small to reliably estimate the ICC to adjust standard errors; hence, we will use standard regression methods and explore the sensitivity of significance levels and conclusions to a range of plausible ICC values (.005 to .05) for the outcomes. We will also control for and examine interaction effects with intervention process variables (e.g., number of workshops completed), participant characteristics (e.g., ART status, gender, age), and alter characteristics (e.g., position in the network, HIV status, knowledge of ego's HIV status). This will enable us to address Aim 3, to explore the context of prevention advocacy, including differentiating types of alters who received more, versus less, prevention advocacy, as well as characteristics of participants who engaged in more prevention advocacy throughout the network, to a larger number of alters.