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Controlled Trial of Game Changers: A Group Intervention to Train HIV Clients to be Change Agents for HIV Prevention in Uganda

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TABLE OF CONTENTS

A. ABSTRACT (SPECIFIC AIMS)

In Uganda, HIV prevalence is estimated to be 6.2% among those aged 15-64, and is higher (6.9%) in Kampala, the proposed study setting.[1-3] In addition, 74% of people living with HIV (PLWH) know their status, 89% of those who know their status are on antiretroviral treatment (ART; 72% of all PLWH), and 78% are virally suppressed (56% of all PLWH). Only 56% of men and 42% of women used a condom at last sex with a casual partner, and <10,000 people are estimated to be on pre-exposure prophylaxis (PrEP).[4] Despite some progress in the fight against the epidemic, political and cultural barriers, including limited government funding and HIV stigma,[5] impede HIV prevention and have led to projections of rapid increases in HIV incidence.[3]

PLWH can be powerful change agents for HIV prevention within communities. Our research suggests that as PLWH receive ART and restore their health, they are motivated to protect their social network members and engage in prevention advocacy (i.e., encourage friends and family to seek HIV testing and care and reduce HIV risk); however, the quality of this advocacy is hampered by challenges related to message content, style and timing of delivery, and the selection of appropriate recipients for advocacy. With effective advocacy training, mobilizing PLWH to be change agents within their networks has the potential to be a “game changer” for HIV prevention, particularly in high-prevalence settings where virtually every family is touched by HIV. In the proposed research, we will conduct a randomized controlled trial (RCT) of *Game Changers*, an 8-session peer-led group intervention that aims to empower and mobilize PLWH to be agents for HIV prevention in their social networks. By decreasing stigma among PLWH and their social network members, as well as training PLWH on key strategies to engage social network members in discussions around HIV, *Game Changers* provides PLWH with the tools to do prevention advocacy and is facilitated by peers who are from participants’ communities and living with HIV. *Game Changers* was developed through an NIMH-funded R34 in partnership with the Infectious Diseases Institute (IDI), a public-private partnership in Kampala that provides care to PLWH, that trains healthcare workers on HIV care and treatment, and conducts research to address the HIV epidemic. As part of the intervention development process, the team conducted focus groups with PLWH and social network members, and engaged with community stakeholders, including a community advisory board. Our pilot RCT with 98 PLWH and 57 social network members revealed promising preliminary intervention effects on reduced internalized stigma and increased HIV-serostatus disclosure to social network members among PLWH, as well as increased condom use and HIV testing among social network members.

The **Specific Aims** are:

1. To conduct a fully powered RCT of *Game* Changers to test intervention effects on the primary outcomes of increased HIV testing, reduced condomless sex, and decreased enacted HIV stigma among social network members of participating PLWH.
2. To test intervention effects on the secondary outcomes of reduced internalized HIV stigma, increased HIV serostatus disclosure, and increased viral load suppression among participating PLWH, and PrEP uptake among their social network members.
3. To examine whether increased HIV prevention advocacy by PLWH mediates intervention effects on their social network members’ increased HIV testing and condom use, and whether increased HIV disclosure by PLWH mediates intervention effects on social network members’ reduced HIV stigma.
4. To conduct a cost-effectiveness analysis of the intervention.

We will recruit 210 PLWH, randomizing 105 to the intervention and 105 to a no-intervention control condition. Each PLWH will be asked to recruit social network members (up to 4, with expected average of 3.5 network members per participant) to complete assessments (736 total network members, 368/arm), and test intervention effects on social networks. All participants will complete surveys at baseline, and 6-, 12-, and 18-months post-baseline. The cost-effectiveness analysis will inform policymakers about whether *Game Changers* is a feasible intervention in which to invest.

Our approach is particularly timely in the era of biomedical interventions, which require widespread penetration of effective HIV prevention and care messaging into communities. Positioning PLWH as central to the solution for controlling (vs. causing) the HIV epidemic has the potential to reduce HIV stigma and improve prevention outcomes at the individual, household, and network levels. Consistent with theories of social diffusion, cognitive consistency, and social influence, studies show peer advocacy interventions reduce HIV risk in advocates themselves.[6-10] However, with the exception of our pilot work, we are unaware of studies of the effects of prevention advocacy by PLWH with family, friends and community members. If successful, the intervention will be a significant innovation for the field, as it targets advocacy to all types of social network members rather than specific peer or risk groups, and uses social network information to strategically target advocacy.

SIGNIFICANCE

HIV Prevalence Remains High in Uganda

About 1.2 million people are living with HIV in Uganda. HIV prevalence is estimated to be 6.2% among those aged 15-64,[1] and is higher—6.9%—in Kampala, the proposed study setting.[2, 3] In addition, 74% of people living with HIV (PLWH) know their status, 89% of those who know their status are on antiretroviral treatment (ART; 72% of all PLWH), and 78% are virally suppressed (56% of all PLWH).[11] A recent study of 20 Ugandan health facilities found that only 53% of newly diagnosed individuals are linked to care within 1 month.[12] Only 56% of men and 42% of women used a condom at last sex with a casual partner,[13] and <10,000 people are estimated to be on pre-exposure prophylaxis (PrEP) through demonstration and research studies.[4] These findings highlight the continued significant gaps in the HIV care continuum in Uganda.

Innovative, Low-Cost Strategies are Needed for HIV Prevention

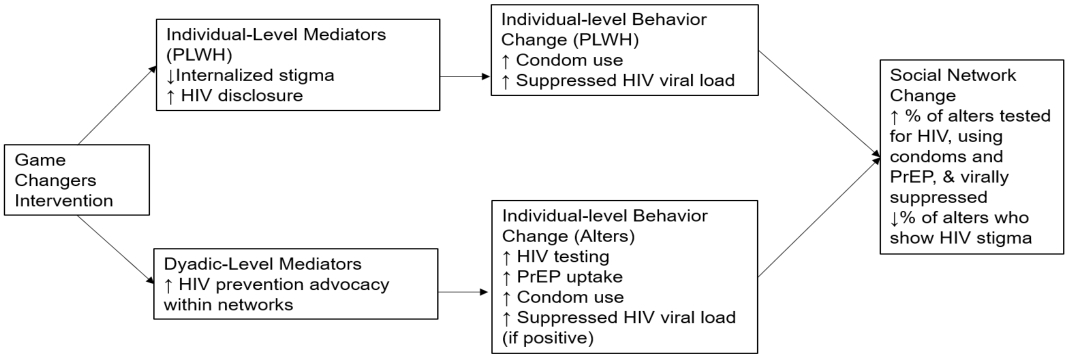
In Uganda, political and cultural barriers, including limited government HIV funding and HIV stigma,[5] have impeded HIV prevention and led to projections of rapid increases in HIV incidence.[3] Innovative, easy-to-implement solutions are needed that do not depend on public resources, can reach a large number of people efficiently, and reduce stigma while promoting prevention. In the proposed research, we will conduct a randomized controlled trial (RCT) of just such an intervention, *Game Changers*, in which peers (PLWH) rather than professionally educated providers are the catalysts for change within social networks and communities. Research suggests that peer-based HIV prevention programs can be effective at increasing condom use and can be more cost effective than employing professionally educated providers; however, few rigorous effectiveness and cost effectiveness analyses exist of such interventions in developing countries.[14-20] Thus, we propose to conduct an effectiveness and cost-effectiveness analysis that will provide essential information for guiding community-based programming decisions in resource-limited settings.

Empowering PLWH to be Change Agents Draws on the Full Armament of Prevention Paradigms

Mobilizing PLWH as change agents for prevention *integrates and extends components of major prevention paradigms*: (1) advocating for protective behaviors (e.g., condom use, HIV testing, PrEP) among network members (promoting primary prevention);[21] (2) increasing protective behaviors in PLWH advocates and their HIV-positive peers through advocacy (Prevention for Positives);[22-24] and (3) advocating for linkage to HIV care and ART adherence among people who test positive (Treatment as Prevention).[25, 26]

Receipt of HIV care often comes with renewed health, and our research suggests that essentially all PLWH have actively encouraged friends and family to seek HIV testing and care, and reduce HIV risk.[27, 28] Harnessing this natural tendency for advocacy holds tremendous promise for HIV prevention in high prevalence settings such as Uganda, where every family is touched by someone living with HIV; mobilizing the >1 million Ugandans who are receiving HIV care to be change agents *can enable widespread penetration of HIV prevention messaging*. Our research indicates Ugandan PLWH have dense, interconnected networks,[29] and have disclosed to many people in their network,[30] suggesting that transfer of HIV prevention messages and knowledge can be efficient. In sum, *PLWH could become an essential part of the solution to HIV, rather than being stigmatized as the source of the problem*. PLWH have access to at-risk individuals within their networks, and *are in the position to be influential and credible in conveying prevention messages to family and friends* given their close relations, and their ability to exemplify the benefits of HIV testing and care on health.[31]

Figure 1. Conceptual Model of *Game Changers* Intervention



Prior HIV Prevention Interventions and Theories of Behavior Change provide a Solid Scientific Premise

Game Changers, which is based on recommended approaches to network-based and prevention interventions,[32, 33] acts through individual- and dyadic-level mediators to change behaviors of both PLWH and their social network members (i.e., alters) (see Fig. 1). We start with the assumption that effective advocacy requires coping with internalized HIV stigma and self-acceptance. Reduced internalized stigma is linked to increased HIV disclosure,[34] which is essential to encouraging others to engage in HIV protective behaviors. *Game Changers* provides coping strategies to navigate stigma and discrimination (effective in our prior research[35]) through experience-sharing and role plays, and using compassion-focused therapy principles.[36-39] *Game Changers* helps PLWH to reduce shame and increase self-compassion and empathy for others to reduce internalized stigma. As stigma decreases, PLWH are more comfortable disclosing their serostatus, which is part of managing stigma, gaining self-acceptance and community reintegration[40]—and thus key to effective prevention advocacy. Disclosure enables a person to share their experiences of living with HIV, which raises the credibility of their advocacy, as they have experienced the consequences of risk behavior and the benefits of ART. Some may assume or speculate that a person who advocates for HIV protective behaviors is HIV-positive, so selection of targets for advocacy calls for considering whether the target knows the advocate's serostatus or whether the advocate is comfortable disclosing their status to the target. The consequence theory of disclosure[41] posits that disclosure decisions involve weighing both risks and benefits. Among the benefits of disclosure is increased social support, associated with better individual health and more prosocial behaviors.[42-51] Although research in sub-Saharan Africa reveals that most responses to disclosure are supportive,[52-54] the risk of negative responses such as rejection and abuse are real, particularly for women given the gender power differential present in African cultures.[41] *Game Changers* draws on existing HIV disclosure interventions[55] using role playing and sharing of experiences to help participants develop disclosure decision-making skills and awareness of when and whom to disclose to and discuss HIV with.

Regarding dyadic-level mediators, *Game Changers* leads to increased quantity and better quality of prevention advocacy among PLWH. *Game Changers* uses adapted HIV prevention advocacy strategies from interventions such as Mpowerment,[56] and Popular Opinion Leader (POL)[57] interventions, as well as an effective intervention developed by Bogart (MPI) in South Africa.[57-59] Strategies include looking for "teaching moments," (i.e., opportunities when alters seem more open to a message of behavior change such as after a radio ad for an HIV testing event), role playing how to initiate conversations about HIV, and learning effective communication skills (e.g., reflective listening; using empathy rather than confrontation).

Game Changers is innovative in its efforts to optimize information dissemination and behavior change throughout change agents' social network by encouraging PLWH to target advocacy to strategically chosen network members (most at risk; most popular/connected members; members that bridge different groups). Prior social network interventions provided less guidance about strategic alters to target for advocacy. In intervention sessions, PLWH map their own social network, identifying groups of alters, well-connected alters, and alters to whom they have disclosed as a visual tool for selecting alters for advocacy. The network map enables PLWH to understand how alters are connected (or not connected), and how advocating to alters in strategic positions could help to reduce stigma and increase protective behaviors in the network as a whole.[60, 61] By engaging in advocacy with members who are popular or who bridge distinct network components, PLWH may be able to advocate more efficiently, as they encourage alters to share the information with others.

Our model specifies that PLWH's advocacy can result in behavior change for both PLWH and their alters. To be effective advocates, PLWH must model the behaviors they encourage others to adopt, by prioritizing healthy, positive living (e.g., condom use, ART adherence). *Game Changers* draws on evidence-based interventions designed to help PLWH live healthy lives[62, 63] and uses role plays to build skills and self-efficacy, problem-solving techniques, and goal setting to help participants attend to their health.[64] Moreover, cognitive consistency[65] theory suggests that encouraging others to adopt a behavior increases the odds that the advocate will adopt the behavior—resulting in increased condom use and viral suppression. By engaging in prevention advocacy discussions, alters' HIV prevention behaviors are hypothesized to improve (HIV testing, and PrEP and condom use; care engagement and adherence if positive). *Game Changers* draws on social diffusion theory[32, 66-68] and principles of social influence[69] to posit that behavior change can be initiated by a few, and diffused to others, through social norm change, by harnessing the power of people in the network whom alters see as supportive and credible,[10, 57, 70-72] and by delivering an intervention to alters across networks.[73] *Game Chan*gers targets the HIV protective behaviors of both PLWH advocates and alters, as well as processes (disclosure, advocacy) needed to support behavior change at the individual and network levels.

INNOVATION

***Game Changers* empowers PLWH to act as change agents within their overall social network—not only with other PLWH or those in the same HIV risk group**. Other peer prevention interventions[7, 8, 14, 31, 57, 58, 74] target specific sub-populations or high-prevalence communities and advocate to other members of the same group.[7, 8, 14, 31, 57, 58, 74] Similarly, PLWH have been trained to advocate for HIV protective behaviors with other PLWH—*but no existing program empowers and trains PLWH to engage in advocacy with both HIV-negative and -positive members, peers and non-peers, in their social network, to disseminate prevention* *advocacy widely*. *Game Changers* takes the unique perspective that all PLWH can be trained to be agents of change, regardless of their position in the community. With essentially every family and network affected by a PLWH in high prevalence settings like Uganda, *Game Changers* has the potential to dramatically impact the epidemic through its emphasis on targeting advocacy across the whole network. *Game Changers is one of the few network-based interventions that uses information about one's social network to teach participants how to strategically select network members for advocacy.* During the intervention, participants easily create their own network diagram on paper and are told how to identify alters who bridge network clusters or who are most connected, to more efficiently reach individuals throughout the network and obtain greater network change.

***Game Changers* catalyzes behavior change throughout the HIV prevention and care continuum among individual PLWH and their alters**. Most HIV prevention and adherence interventions focus on change of one behavior at the individual level (e.g., adherence counseling in one-on-one sessions). By including both PLWH and their alters, and integrating and extending each major HIV prevention paradigm currently in play (as described above), *Game Changers* can improve outcomes from HIV prevention to care. Prior social network interventions for HIV prevention have produced mixed results, with some studies showing beneficial effects for both those engaging in advocacy[9] and network recipients of the advocacy,[6, 7, 10] and a recent systematic review revealed significant effects on sexual health behaviors,[75] but some interventions have resulted in no or weak effects.[70, 75] Further, few social network interventions have been scaled up in the real world, though low resource settings may be the most cost effective context for such interventions, as networks could help maximize efficient spread of information and behavior change.[73] Our pilot work (see Preliminary Studies) suggests *Game Changers* leads to behavior change among both PLWH and their alters. Thus, *Game Changers* is unique, efficient, and potentially cost-effective in its multi-level, multi-behavior focus, requiring only the cost of training and paying peer facilitators to spread HIV prevention messages to the community.

***Game Changers* addresses HIV stigma at multiple levels**. Few stigma reduction interventions have been effective, and few studies have measured their structural effects, such as on social networks. One effective intervention mobilized healthcare providers to reduce HIV stigma among other healthcare providers, but did not examine effects on their social networks (e.g., family, friends).[76] By increasing open discussions about HIV across social networks within communities, *Game Changers* may contribute to stigma reduction.

APPROACH

Preliminary Studies

The multidisciplinary team combines expertise in behavioral HIV intervention research in the US and sub-Saharan Africa, social network analysis, and HIV testing. **Glenn J. Wagner, PhD** (lead MPI, Senior Behavioral Scientist, RAND), is a clinical psychologist who conducted much of the formative work on which the proposed intervention is based; he currently is conducting two RCTs in Uganda, one on safer conception counseling among HIV-affected couples, and one on evidence-based depression care among HIV-positive pregnant women. He will lead the intervention component of the study. **Laura M. Bogart, PhD** (MPI; Senior Behavioral Scientist, RAND), a social psychologist and stigma expert, is PI of the R34 on which the proposed study is based. She has evaluated HIV prevention interventions in sub-Saharan Africa, including interventions to improve HIV testing and PrEP use among Ugandan fisherfolk, to increase HIV self-testing intervention in Botswana, and to improve parent-adolescent communication about sex and HIV in South Africa.[59, 77, 78] She will lead the evaluation and analysis components of the study. **Harold (Hank) D. Green, Jr., PhD**, (Co-I; Adjunct Researcher, RAND; Associate Professor, Indiana University School of Public Health Department of Applied Health Science), is an expert in applied social network analysis (e.g., development and evaluation of network-based interventions) and HIV. **Erik D. Storholm, PhD**, (Co-I; Behavioral Scientist, RAND adjunct), is a licensed clinical psychologist with expertise in compassion-focused and cognitive behavioral therapy who develops and evaluates interventions for HIV prevention and PrEP use. **Sebastian Linnemayr, PhD** (Co-I., Senior Economist, RAND), will conduct the intervention cost-effectiveness analysis; he is conducting an ART adherence RCT in Uganda and collaborated with Bogart and Wagner on a cost analysis of their HIV testing intervention for Ugandan fisherfolk. The Uganda team will be led by **Joseph KB Matovu, PhD, MHS** [Co-I; Senior Research Associate, Makerere University School of Public Health/MakSPH], an expert in HIV testing who collaborated on the pilot R34. He will be the intervention lead in Uganda. **Violet Gwokyalya, PhD** (Co-I; Project Director; MakSPH) has extensive experience conducting HIV behavioral research and worked with Wagner in coordinating two prior NIH-funded longitudinal intervention trials with PLWH in Uganda. **Stephen Okoboi**, **PhD, MPH** (Co-I., Deputy Head of Research, IDI), has conducted research on HIV prevention, stigma, and ART use with Wagner and Linnemayr; he will be the evaluation lead in Uganda.

***Game Changers* Pilot**. We developed and conducted a pilot study of *Game Changers* at IDI, the proposed study setting. We engaged community members on IDI's community advisory board (CAB) and the National Forum of People Living with HIV/AIDS Networks in Uganda (NAFOPHANU), to obtain input throughout the study, and in the development of this proposal (see letters of support).

Initial Formative Research (R24 HD056651, R21 MH087249). Wagner and Green conducted studies documenting prevention advocacy among PLWH in Uganda. All PLWH reported encouraging at least one alter (friends, family, partners, etc.) to engage in protective behaviors.[27, 28, 79, 80] However, much advocacy involved only general cautionary messages about HIV, rather than advocating specific protective behaviors, highlighting the potential for training to improve advocacy quality. Prevention advocacy was associated with lower internalized stigma, more disclosure, and more condom use, ART adherence, and HIV care engagement, consistent with our conceptual framework (Fig. 1). The study also found that participant reports of alter characteristics had a 70-90% accuracy rate comparing respondent assessments against alter reports, in terms of PLWHs' perceptions of alters' HIV status (89%), HIV care engagement (86%), and ART use (71%).[81, 82]

Focus Groups on Intervention Acceptability (*R34MH111460*). We used the above formative research results as the basis for developing *Game Changers*. In an R34 led by Bogart, the team conducted 6 focus groups of PLWH (n=31) and 2 focus groups of social network members to whom they disclosed (family, friends; n=16). Participants (24 women, 23 men) were recruited at IDI's HIV clinic. We found high anticipated acceptability for *Game Changers*: both PLWH and social network members were enthusiastic about the program. Participants liked that the program would help them build skills; they were motivated to have conversations about HIV but did not know how to initiate them. They also felt that the program could help to reduce HIV stigma in their communities. As one PLWH said, *"…when we approach [them], it is really difficult to talk to them because you are scared… this program will help us get the techniques on how to approach the people*"; a social network member said, *""…if you are trained you can learn how to start [conversations on HIV] and then you build from that, but starting is always hard*." Another social network member said: *"… people have a way they perceive HIV positive people, they stigmatize, neglect them… it is hard so I would like if I get a chance to talk to the HIV positive and negative people and show them that positive people are also humans*."

We used the focus group results to develop the intervention. We integrated examples of conversation starters and stigmatizing and supportive reactions to HIV conversations that came up in the focus groups in the intervention manual, as role plays and examples of situations that participants might encounter in their social network. Participants described ideal characteristics of intervention facilitators, including being HIV-positive; having experience as a counselor with a strong ability to communicate clearly and create a supportive environment; and having HIV-related medical knowledge. There were differing opinions regarding the need for groups to be single or mixed sex; therefore, in the pilot (described below) we conducted two same-gender and two mixed-gender groups, and found the mixed gender groups to be highly acceptable; participants spoke of wanting to learn advocacy skills to use in their entire network, not only skills that were relevant for one gender.

Game Changers Pilot RCT.[83] 98 PLWH and 57 alters participated in the pilot RCT across four intervention-control cohorts (with a wait-list control group).[83] The pilot intervention was the same as the intervention outlined below for the proposed study. Participants were interviewed at baseline and ~5-months and ~8-months post-baseline. Results showed high feasibility, acceptability, and preliminary effects, consistent with our conceptual model. In terms of feasibility, of the 98 participants recruited (51 intervention, 47 control), 97 (99%) and 93 (95%) completed assessments at months 5 and 8, demonstrating very high retention. Retention was also high in intervention sessions, with 60% of the intervention group attending all sessions and each session attended by an average of 76% of participants. Reasons for missed sessions included being out of town, conflicting work/school schedules, sick or caring for someone sick, moved, and transportation issues.

To test the feasibility of recruiting alters, we asked each of the 98 PLWH to refer up to 3 alters; 214 alters were referred by 89 (91%) PLWH (average of 2.3 alters (out of max. of 3) referred by each, suggesting little difficulty in identifying alters to recruit). However, since alter recruitment was added post-hoc to the study design (and with no designated funding in the budget), we decided to try to contact only 135 alters. Of the 135 alters, 17 (13%) were already enrolled (15 as PLWH, 2 as alters) and thus were ineligible, and 1 was withdrawn. Of the remaining 117, 34 (29%) could not be reached (did not answer the phone or had a nonworking number); and 26 (22%) declined because they were busy, lived far, or were sick. Thus, 57 alters (49%) were enrolled; 35 from intervention participants and 21 from control participants. The characteristics of the recruited alters (61% female, 32% family, 68% friends, 14% sex partners; 43% HIV+) were similar to that of all alters listed in the index participant networks (53% female, 37% family, 63% friends, 4% sex partners; 28% HIV+), which increases confidence that the recruited alters represent the larger network. We did not repeatedly try to contact alters, nor incentivize enrollment with alternative forms of assessment (e.g., phone, home visit, etc.). In the proposed study, we will have resources to hire staff to focus on alter interviews, and to make multiple call attempts, interview alters by phone, reimburse alters for transport, and travel to interview alters outside of Kampala; plus, unlike in the pilot, in the proposed study when an alter is unable to be reached, we will ask the index participant to refer additional alters for us to contact. With these changes, we expect a much higher rate of alter recruitment in the proposed study; nonetheless, our recruitment and power analysis procedures accounted for a potential 50% enrollment rate of referred alters.

Post-session feedback forms and post-intervention focus groups with intervention participants and facilitators indicated high acceptability. On individual session feedback forms, on a scale of 1 (*did not like at all)*, to 5 (*liked very much)*, average ratings were 4.7 (SD = 0.5), across all sessions. In the focus groups, participants reported very positive attitudes toward the intervention, highlighting the skills they learned for HIV serostatus disclosure, as well as the content on stigma. Participants reported that they increased their disclosure and prevention advocacy, especially on condom use and HIV testing. For example, a participant said, "*This training has given me the confidence to face someone and disclose to them that am HIV positive and advise them to go for testing and if found positive I encourage them to start on medication immediately. Personally, I used to fear… now I can take all my drugs openly without any fear.*" Participants also said the intervention helped them to live positively and improve their own ART adherence, while also learning how to support other PLWH to do the same. Uniformly, the three facilitators enjoyed the intervention and said they saw participants improve: "*Those who came back and reported that they had disclosed to a, b, c, they had talked to somebody about HIV relating their own stories. So, to me that was a very good experience that the participants had taken so passionately to share and take on this prevention advocacy aspect.*" Participants also requested additional skills building for supporting social network members who recently tested positive: "*Everyone gets scared when they are hit with the news that they are positive. So, when I talked and convinced my friend and he checked his status, he found out that he was positive, so how do I counsel him?*" Facilitators suggested strengthening the content around testing in terms of preparing alters for the test and supporting them afterward. They also suggested referring alters to get tested at the IDI clinic, where the intervention is conducted, so that that alter testing and linkage to care could be tracked through medical records.

The intervention showed preliminary effects consistent with hypotheses. Among alters at month 5, condomless sex with main partners in the past month decreased by 7.7% (46.2% to 38.5%) in the intervention group vs. an increase of 10.5% (57.9% to 68.4%) in the control group; this was a large effect (Cohen's *d* = .76), despite marginal statistical significance in this underpowered small pilot [OR (95% CI)= 0.3 (.1-1.2), p=.08]. Among the 20 alters who were HIV-negative prior to the 5-month follow-up and who were not tested for HIV between baseline and the 5-month follow-up, 5 of 15 intervention alters (33.3%) vs. 1 of 5 control alters (20.0%) reported being tested for HIV post-intervention (in between 5- and 8-month follow-ups), which represents a small-to-medium effect size (Cohen's *d* = .30). In terms of mediators, alters of intervention participants were significantly more likely to report engaging in prevention advocacy discussions (mainly on HIV testing, condom use, and ART) in their social networks (p=.04). Note that, because we only interviewed a small number of alters for feasibility rather than to detect effects, we did not interview all alters with whom the PLWH did prevention advocacy, and PLWH did not do prevention advocacy with all alters interviewed. Thus, we would expect effects to be stronger in the proposed study, in which we will recruit a larger number of alters.

Results for PLWH also showed effects consistent with hypotheses. Compared to controls at baseline vs. follow-up, intervention participants were more likely to report engaging in prevention advocacy [b (SE) = 0.4 (0.2), p = .017], especially related to HIV testing, condom use, and number of partners (all ps < .05). Intervention participants were less likely to feel internalized [b (SE) = -0.3 (0.1), p = .012] and anticipated HIV stigma [b (SE) = -0.5 (0.2), p = .011], and to have concerns about disclosure [b (SE) = -0.3 (0.1), p = .028], and were ten times more likely to have disclosed to a main partner [OR (95% CI) = 10.0 (1.5-67.7), p = .022], compared to control participants. Moreover, intervention participants were more likely to report that all of their alters had been tested (p<.10), and that they disclosed to a greater proportion of alters (p=.05). The intervention also had effects on social network structure: intervention participants' networks became denser over time, with more and stronger connections among alters [b (SE) = 0.1 (0.3), p = .004].

Summary of Preliminary Studies. The team is well-positioned to conduct this RCT, with a great deal of expertise in the proposed study content and methods, and the demonstrated feasibility, acceptability, and preliminary efficacy of *Game Changers*. Based on our pilot, we changed intervention content and methods for the proposed RCT, some of which we already tested for feasibility with the pilot wait-list control group. As requested by pilot participants in the post-intervention focus groups, we added content, practice, and instruction on social network mapping and more opportunity for prevention advocacy practice (e.g., role plays on HIV stigma and pre-and post-HIV testing support). We also added content related to PrEP (e.g., information about PrEP, and role plays and strategies about how to do prevention advocacy around PrEP), given increased availability in Uganda, especially for key and priority populations (e.g., sero-discordant couples). However, since PrEP access is still limited and not available for all, we will examine it as a secondary outcome only. As noted above, we will modify alter methods, to employ more staff to track alters, ask staff to travel to alters who live away from Kampala, and provide a higher incentive (e.g., for transportation costs); we will also conduct interviews with alters by phone. These revised procedures should decrease the number of alters who decline (or who are not referred) because they live far away or are too busy to come to the site (~20% of the alters referred in the pilot). Nonetheless, we will plan for a 50% alter enrollment rate and ask PLWH to refer up to 7 alters (up from 3 in the pilot), with a target of enrolling an average of 3.5 (and no more than 4/participant).

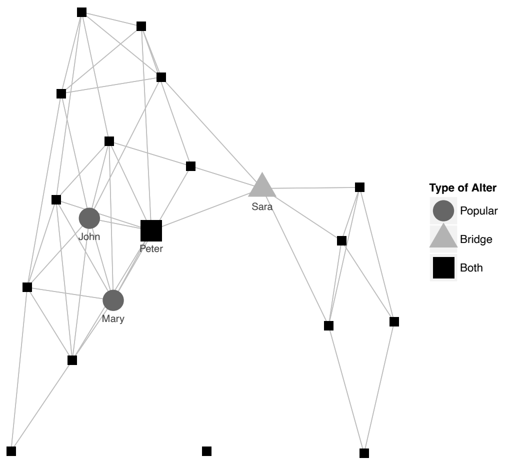
Study Methods

Setting. The study will be conducted at IDI, which provides outpatient HIV care to ~8,000 active patients and conducts HIV-related clinical trials. Luganda is the native language, but people with a secondary education often speak English, and all clinic staff are fluent in English.

Community Engagement, We will partner with two community stakeholder groups, as in the pilot (see letters of support): IDI's community advisory board (CAB) and the National Forum of People Living with HIV/AIDS Networks in Uganda (NAFOPHANU), to obtain input at critical study points 1-2 times/year on the assessment, intervention content (e.g., updates/ resources for HIV prevention), interpretation of results, and next steps for intervention dissemination, if it is shown to be cost-effective. IDI's CAB and NAFOPHANU have ~20 members each from diverse community groups (e.g., clergy, activists, youth leaders, expert patients). Notably, for the pilot, NAFOPHANU disseminated the facilitator job ad, and the facilitators were NAFOPHANU members. Members of both groups will receive transport costs and refreshments for each meeting.

Intervention Content and Structure. The intervention component of the study, including developing and finalizing the intervention manual, and oversight of facilitator training and supervision, will be led by Wagner (MPI). The Facilitator Manual, available in English and Luganda, was iteratively revised in the pilot based on feedback from the CAB and NAFOPHANU, and focus groups with participants and facilitators (see Preliminary Studies). The intervention consists of 8 sessions (first 4 are weekly, and last 4 are every two weeks) over three months. Internalized stigma reduction and self-acceptance, comfort and competence with HIV disclosure, compassion for oneself and others, and healthy, positive living, form the foundation for effective prevention advocacy, and thus are the focus of the first 3 sessions (see Fig 1 and Table 1). ***Session 1*** uses compassion-focused therapy principles[36-39] and cognitive behavior therapy strategies developed in Bogart's prior intervention research[35] to <u>break down internalized stigma</u> and build peer support and solidarity, setting the stage for the remaining sessions by introducing the overall vision for empowering PLWH to become change agents for HIV prevention. With participants feeling more confident and supported, ***Session 2*** emphasizes the need for self-compassion and empathy when making disclosure decisions, and focuses on <u>building HIV disclosure decision-making skills</u>, knowing whom to disclose to and when, and how to initiate and navigate disclosure conversations. ***Session 3*** focuses on building skills and motivation for <u>healthy, positive living</u> so that advocates' own behavior (e.g., condom use, adherence) is consistent with the behavior they encourage in others; participants also receive basic HIV information and learn how to address common HIV myths. Session 3 also introduces the concept of social networks, and how knowledge about one's own social network can help to make disclosure and advocacy decisions. ***Session 4*** begins the advocacy training. Participants use a novel method (developed in our pilot) to <u>map their social network</u> <u>to determine "strategic alters"</u> (see Fig. 2).[84] Participants are given a "bulls-eye" handout and 20 post-its (Fig. 3). They list the nicknames or initials of up to 20 alters (10 to whom they are close and 10 to whom they are less close, using differently colored post-its), and then put check-marks on the post-its of alters to whom they have disclosed, and stars on the post-its of alters with whom they have discussed HIV. Next, participants place the post-its on the bulls-eye, with post-its closer to the center representing alters who are closer to the participant and

Figure 2: Personal network highlighting strategically positioned alters



post-its clustered together (and encircled) to represent sub-groups of alters who are close to each other (e.g., immediate family members). The bulls-eye diagrams are used as a tool for advocacy training. Using the diagram, participants identify and select strategic alters (Fig. 2), including *popular* (with many connections to other alters) and *bridging* (who connect two distinct groups of alters) alters, who can facilitate efficient transfer of norms and information in the network; and *functionally strategic alters* (e.g., community opinion leaders such as religious leaders),[85] as well as alters perceived to be at high risk for HIV. Strategically positioned and high-risk alters are highlighted in discussions about disclosure decision-making and comfort disclosing to alters, to position them for possible advocacy. In prior research,[86] including in Uganda,[80] we showed participants their diagrams to facilitate a discussion of their networks, and had little difficulty with people being able to understand these concepts.[86] In the pilot, participants were able to map their networks and select alters for prevention advocacy.

The remainder of Session 4, and ***Sessions 5 through 7***, provide participants with skills, confidence and support for engaging in prevention advocacy, with education about tailoring messages differently by age, gender and relationship to the index participant; participants engage in role plays around HIV testing, condom use, PrEP, stigma, engagement in care, and ART adherence (using communication skills from Bogart's prior intervention research in sub-Saharan Africa[59]), with a diverse array of targets for advocacy (e.g., women, men, sex partners, youth and family members). Participants are encouraged to bring their own role-play examples to the group, which further increases the diversity of role plays, as well as the relevance and application to their personal lives. ***Session 8*** provides a review of prevention advocacy skills, with additional practice and role plays, and aims to inspire a commitment to ongoing prevention advocacy.

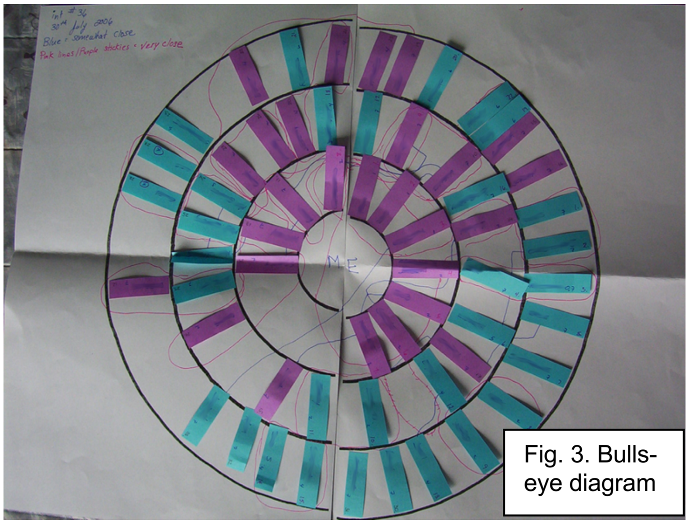


Fig. 3. Bulls-eye diagram

Each session includes refreshments and is facilitated by two trained HIV-positive peer facilitators (not clinic staff or providers) with experience leading groups and HIV education. The group format facilitates an interactive process, with social reinforcement, modeling, and role plays. All sessions use sharing of experiences to build support and solidarity; group problem solving and role plays to build skills and self-efficacy; personal goal-setting for positive living, disclosure, and advocacy; and take-home activities to reinforce practice of new skills and generate personal experiences for discussion in the sessions. Role plays enable new skills to be practiced and observed, and for facilitators to assess whether skills have been mastered or whether more practice is needed. Low educational levels are common, so the take-home activities do not require writing; rather, participants are asked to engage in an activity (e.g., disclosure, prevention advocacy) and report back. Having two weeks prior to the final two sessions allows for more time to acquire experiences with disclosure and advocacy that can then be shared in the subsequent session.

The intervention manual emphasizes that PLWH should not feel pressured to disclose or advocate with any specific alter, and that they should weigh potential risks and benefits when deciding whether to disclose or advocate with an alter. The intervention also includes training for dealing with situations when alters reveal illegal or sensitive information (e.g., same-sex sexual behavior, sex work). Training emphasizes that the goal of advocacy is to encourage protective behaviors, not to elicit or act on incriminating information. If a target discloses such behavior, participants will be trained to encourage him/her to reflect on how their behavior may be related to HIV risk and discuss ways to reduce risk. Importantly, the anti-gay and mandatory HIV testing and notification laws in Uganda *do not* compel citizens (or healthcare providers or researchers) to report others.

Table 1. *Game Changers* Session Content

Topic	**Content**	**Take-Home Activity**
1: Introduction and Stigma Reduction	• Introduce goals; set rules for confidentiality • Introduce and define self-stigma, prevention advocacy, and disclosure decision-making • Use discussion of stigma experiences and strategies for coping with stigma to model adaptive coping and	Practicing Self-Compassion: Focus on a difficult experience; acknowledge and accept one's own suffering;

	promote self-compassion	offer oneself self-compassion
2: Empathy, Self-Compassion, and HIV Disclosure	• Define empathy and self-compassion, with the aid of role plays • Discuss healthy disclosure decision making; use sharing of experiences to highlight potential risks and benefits of disclosure • Convey importance of establishing a basis of empathy and self-compassion, and comfort with disclosure and discussing HIV, prior to conducting prevention advocacy	Set Personal Goals for Disclosure: Assess pros and cons of disclosure to at least one social network member, and practice initiating disclosure conversations
3: Positive Living, HIV Facts and Myths, and Introduction to Social Networks	• Share experiences with disclosure and coping with stigma since last session; provide reinforcement and problem solving of challenges • Present accurate HIV information and address common HIV myths • Discuss how credible advocacy for HIV prevention requires being able to model behaviors in one's own life (positive living) • Set personal goals related to positive living (e.g., adherence) • Introduce the concept of social networks as key to doing advocacy	Listing Social Network Members: In preparation for the next session, participants are asked to think about whom they consider the 20 most important people to them
4.Prevention Advocacy I	• Share experiences with disclosure and advocacy since last session; provide reinforcement and problem solve challenges • Show participants how to map their own social network and identify alters to whom they have disclosed and discussed prevention, and to whom they would like to do so • Define the concept of strategically positioned alters and discuss where strategically positioned alters are in participants' network maps • Use network maps and strategically positioned alters to highlight how participants can play a key role in their community through advocacy • Discuss how advocacy protects others, and how PLWH are credible prevention messengers; validate fears and anxiety re: advocacy • Introduce strategies for effective advocacy (teaching moments, open-ended questions, rephrasing); use role plays to build skills	Set Personal Goals for Prevention Advocacy; Practice Prevention Advocacy: Use network map to select alters to target for disclosure and advocacy, including strategically positioned alters
5-7: Prevention Advocacy II-IV	• Share experiences with disclosure and advocacy since last session; provide reinforcement and problem solve challenges • Discuss how to support alters after they have been tested for HIV • Use role playing to practice and model effective advocacy	Same as Session 4
6: Wrap Up & Review	• Share experiences with disclosure and advocacy since last session; provide reinforcement and problem solve challenges • Use role plays to practice and model challenging scenarios • Share experiences with program; Affirm commitment toward goals	N/A

Note: All sessions (except session 1) begin with a review, and all sessions end with an uplifting song/blessing to build solidarity.

Scalability and sustainability are a concern for interventions in low resource settings, especially when they take place in the context of overcrowded clinics with overburdened staff. The social network analysis and enrollment and tracking of network alters are part of the research evaluation only, not the intervention, and would not be present in its roll out. Further, clinic providers are not involved in intervention implementation, as the intervention is facilitated by trained peers, which is common in resource limited settings. For example, HIV+ peer mothers in antenatal care clinics throughout Uganda are trained to implement an 18-session, monthly 2-hour Family Support Group program rolled out by the Ministry of Health to promote PMTCT.

Facilitator Training, Supervision, and Fidelity Monitoring. Four bilingual (Luganda, English) HIV+ peer facilitators (2 men, 2 women) will be trained by Wagner, Storholm, Gwokyalya, and Matovu to implement the intervention. Lay peers were selected to facilitate the sessions, rather than clinic staff or providers, because of the success of other peer-led group interventions,[87, 88] including a multi-session group program (the Family Support Group) in Uganda led by HIV+ peers in antenatal clinics.[89] This approach promotes the scalability of the intervention if shown to be effective, as it does not add further burden to already overwhelmed providers or disrupt the provision of HIV care service delivery. All HIV clinics in Uganda typically have a minimum of 3-4 volunteer HIV+ "expert clients" who are trained to assist providers and staff. Expert clients generally have a range of expertise and skills including experience conducting group education talks and providing psychosocial counseling, so it is feasible to identify those with the necessary skill set to effectively facilitate a program such as *Game Changers*. The training will be conducted with the full study team to facilitate mock implementation of exercises. The training will cover manual review (objectives for each session, step-by-step scripts, and key points) and group facilitation skills (building rapport, active listening, managing dominating and shy participants, and dealing with group conflict). Gwokyalya and Matovu will observe the initial administration of each session by each set of facilitators to provide feedback and further training as needed. To monitor fidelity, sessions will be audio-recorded and Gwokyalya and a research assistant will listen to recordings and complete a fidelity rating form weekly. Facilitators also will complete ratings after each session on whether objectives were met, exercises completed, level of participant engagement, difficulties encountered, and areas to improve. Gwokyalya will write up a summary of each session, including number of participants, reasons for any participant missing the sessions, and key points. After reviewing the ratings and summary notes, Gwokyalya and Matovu will meet with the facilitators in weekly supervision sessions (Wagner will join in biweekly via Zoom), to discuss areas for improvement and any issues that arose. Gwokyalya and the RA's ratings on whether key elements were covered will be tested for achieving adequate inter-rater consistency ($\kappa \geq .80$).[90]

Randomized Controlled Trial of *Game Changers*

Overview. The proposed design is an individually randomized group-treatment trial using a clustered design.[96] We will recruit 210 PLWH and randomize 105 to the intervention and 105 to a no-intervention control arm. Each PLWH will be asked to recruit social network members (alters to whom they have disclosed) (736 total, 368/arm). All participants will complete assessments at baseline, and 6, 12 and 18 months post-baseline to assess improved HIV prevention behaviors within the network, mediators of improved behaviors, and HIV outcomes. Participants will be divided into 7 cohorts of 30 (within each cohort, 15 intervention and 15 control). Intervention implementation for the 7 cohorts will be staggered, such that two will be conducted at a time (i.e., 60 PLWH and 210 alters for two cohorts at a time), except the last wave in which there will be one cohort of 30. Wagner will oversee the implementation of the intervention program, while Bogart will oversee the assessment, data collection and analysis components of the trial.

Randomization. A blocked 1:1 randomization design with stratification by gender (with randomly alternating blocks of 2, 4, and 6 to prevent anticipation of condition) will ensure balance across arms. All groups will be mixed sex (with approximately equal numbers of men and women/group), and a male and a female facilitator will conduct each group. The statistician will use a random number generator to devise a randomization log and a set of sealed numbered randomization envelopes (to prevent condition foreknowledge). After completing the baseline survey, the interviewer will open the corresponding envelope and record the condition. Although individual randomization entails contamination risk, this type of group intervention—where recipients attend several sessions that use structured content and group interaction to target multiple aspects including internalized stigma, comfort and skills with disclosure, and how and who to engage in advocacy with-- is less conducive to contamination. Statistical models suggest ≥30% of the control arm must receive the equivalent of a full-strength intervention to result in meaningful contamination,[97] so with a multi-component, multi-session intervention like Game Changers it is highly unlikely that casual communication between intervention and control participants could result in meaningful contamination. We will assess and control for whether control participants communicated with intervention peers about intervention content.

Eligibility Criteria for PLWH include (1) ≥18 years-old, (2) in care for > 1 year (because they are more likely to be medically stable, adjusted to their HIV diagnosis, and ready to engage in advocacy), and (3) disclosed their HIV status to at least one person. All PLWH also will be patients at IDI's clinic, where they will be recruited. Clients will be excluded if they participated in the intervention as part of the prior R34 pilot study. **Eligibility Criteria for Alters** include (1) ≥18 years-old; (2) referred by a PLWH enrolled in the study; (3) know the PLWH's serostatus; and (4) willing/able to do the first study visit in person. (After initial screening/baseline visit, other alter study visits can be done by phone, or interviewers can travel to meet alters.) As described below, PLWH will be asked to recruit up to 4 alters for participation in assessments.

Recruitment. As in the pilot, to recruit PLWH: (1) clinic staff and expert patients (who work with clinic staff to track patients) will refer eligible patients to interviewers, who will be in the waiting area of the clinic on weekdays (M-F) every day during the recruitment period for each cohort; and (2) interviewers (who will be IDI staff) will approach all patients in the waiting area on the same designated days, to inform them of the study. Interviewers will cross-check the names of referred patients with IDI clinic records to verify that they are patients at IDI who have been in care for > 1 year and disclosed to at least one person. In the pilot, only one person was screened ineligible due to the disclosure criterion. Because we will enroll two intervention-control cohorts at a time, we need to recruit 60 participants at a time (30 per cohort) or per wave of recruitment; each wave of recruitment will take place over 3 months (30 PLWH and 105 alters enrolled and surveyed per month, 1.5 PLWH and 5-6 alters per day), followed by a 3-month period when the intervention and attention control program are implemented with the two cohorts, and no further recruitment until the next wave of recruitment in the next quarter (see Timeline).

Due to Uganda's law against homosexuality and high societal homophobia, we will take measures to protect those who engage in same-sex sexual behavior or identify as a sexual minority. When patients are screened individually, they will be informed of the eligibility criteria and told there are legal risks to those who self-identify as having had sex with or current sexual attraction for someone of the same sex, and if they choose to participate, they may put themselves at risk of inadvertently disclosing their sexual orientation if they advocate about HIV. They will be told that they are welcome to take the consent form home for consideration, after which they can contact the coordinator for formal screening, if still interested. This allows sexual minority individuals to withdraw their interest without disclosing their sexual orientation. Alternately, if individuals would like to enroll at that time, we will enroll them on the day we approach them. We have found these enrollment procedures to be feasible in our pilot (and no one disclosed same-sex sexual behavior). Self-exclusion due to same-sex sexual behavior will not impede the impact of the intervention on Uganda's HIV epidemic, as male-to-male sexual transmission represents <1% of new HIV cases[98, 99] (although this is likely an underestimate).

To recruit alters, during the baseline social network assessment (see below), we will elicit the names of 20 alters in the PLWH's social network, and ask PLWH to identify alters who know their serostatus. In our prior studies, 87% were able to list 20 alters, and 96% were able to list at least 16 alters. At the end of the interview, PLWH will be asked to select, from the list of alters who know their serostatus, up to 7 alters whom they would be willing to refer to the study; this should be feasible, as the pilot revealed that an average of 13 of the 20 alters knew the participant's HIV status. If they refer more than 4 alters, we will randomly select 4 to target for recruitment (to limit selection bias), although we aim to recruit an average of 3.5 alters per index participant, given that we do not expect to be able to recruit 4 alters from all participants. The decision to recruit 4 is based on a need to balance interviewing enough alters to be sufficiently representative of the person's network, while also being feasible to collect the data from the large sample of overall alters in a longitudinal design. We will request that the PLWH call each selected alter at the end of the interview, and to describe the study opportunity in the presence of the interviewer, who can then immediately schedule a study visit. If any of the 4 refuse to participate or cannot be reached, we will randomly select additional alters on the list of those referred from the index participant until 4 have agreed and enrolled; if only 4 were referred, we will ask the PLWH to refer additional alters, if possible. To enhance alter enrollment, we will allow for phone-based interviews and for staff to travel to meet alters outside of Kampala after the first study visit, and provide a sufficient incentive to cover transport costs; nonetheless, our request for index participants to refer up to 7 alters allows for a 50% alter enrollment rate, in order to achieve our goal of enrolling 3.5 alters per index participant. Given the large number of alters (105/cohort; 210 for two cohorts at the same time), alters will be interviewed over a 2-month period (~25-30 alters per week) at baseline and follow-up. We used similar procedures successfully in our pilot.

Assessment: Overview. Under the leadership of Bogart (MPI), the assessment was developed to include individual-level survey questions for PLWH and alters, and a social network assessment for PLWH only. The 60-75 min. assessment for PLWH and 20-minute assessment for alters will be administered at baseline and months 6, 12, and 18. The 6-month interim period is consistent with the Ugandan Ministry of Health recommendation for repeated HIV testing every 6 months (one of our primary outcomes), and the 18-month follow-up period will allow us to better assess durability of effects. Participants will receive 30,000 Ush (~$8) per assessment, and 30,000 Ush (~$8) transportation reimbursement for each intervention session. We will collect tracking information (phone numbers, mapped addresses, contacts for family/friends with whom they have frequent contact). Clinic staff, including "Linkage Facilitators" (i.e., expert patients identified by IDI clinic staff who track patients) will help to track patients that we have difficulty reaching (if participants consent). In our other 12-month longitudinal studies of PLWH in Uganda, we have achieved ≥90% retention, and retention in our R34 pilot was >95% for both PLWH and alters at the final month-8 follow-up. Assessments will be administered on laptops using Egoweb,[101] social network and survey data collection and analysis software developed at RAND. The assessments include the following sections, which we have refined across multiple studies in the US and Uganda (and translated into Luganda; alphas below provided from Ugandan studies).

Individual-Level Outcomes. Sexual Behavior (condomless intercourse) in the past 6 months will be assessed with standard items on number of partners; number of times engaged in intercourse (vaginal or anal) and of those, number of times a condom was used; and perceived HIV serostatus of partner(s).

Alters' HIV Testing (among alters of negative or unknown serostatus) will be assessed. At every time-point, alters will report whether they have been tested for HIV and if so, the date of their most recent test and result,[100] and whether they intend to get tested in the next 6 months (1, not at all, to 5, very much) or start HIV care and ART (if warranted). Self-reported HIV testing and status has been found to be reliable.[101-104]

PrEP Use among alters. PrEP is currently only available to key populations, so only a subset of uninfected alters will be able to access it. If alters report taking PrEP, we will ask where they obtain PrEP, the date PrEP was initiated and self-reported adherence using an adapted Visual Analog Scale for ART Adherence.[105] If the alter receives PrEP at IDI, we will obtain medial release to confirm PrEP use with medical records.

HIV Outcomes. For PLWH participants and HIV-positive alters, we will obtain medical release to abstract HIV viral load and HIV diagnosis date from medical records. Because all PLWH will be patients at IDI, we will be able to obtain medical chart data easily. Self-reported ART adherence[106] as well as engagement in HIV care (number of HIV care visits attended during each follow-up period) will also be assessed.

Potential Mediators. For both PLWH and alters, Prevention Advocacy will be assessed with a scale developed for our pilot, measuring the extent to which participants discussed different HIV-related topics (e.g., HIV testing, PrEP, condom use, ART use) with people they know in the past 6 months (1=not at all to 5=very much; α=.87 PLWH, α=.90 alters); PLWH and alters also will be asked about discussions with each other. Among PLWH, we will assess Internalized HIV Stigma (Internalized AIDS-Related Stigma Scale, α=.69)[107] and HIV Disclosure (if they have disclosed to some, none, or all family and friends in separate questions[108]).

Potential Covariates/Moderators: Both PLWH and alters will be asked Socio-Demographic Characteristics (age, sex, education, work status, income, relationship status). PLWH will additionally be asked Medical Characteristics (HIV diagnosis date), Health-related Quality of Life [physical health (α=.81) and mental health (α=.89) items from PROMIS],[109] Competing Needs for Care (e.g., taking care of someone else),[110] social support (from the MOS Social Support Survey, α=.78),[111] and depression (PHQ-9, a validated screener).[112]

Social Network (PLWH only). We will use a longitudinal personal, egocentric network approach to assess the network of ties surrounding PLWH participants, the range of alters whom participants interact with, and participants' understanding of connections among alters.[113-116] This assessment is only for purposes of evaluation and not related to the simpler, paper and pencil bullseye elicitation process that is part of the intervention content (and thus not a factor in scaling up implementation). *Alter Elicitation*: Participants will list first names and last initials of 20 individuals with whom they have been in communication in the past 6 months (e.g., in person, phone, text), starting with those most important to them. Research has demonstrated that 20 alters reliably captures variability for most network characteristics.[117] *Network Structure*: Respondents will indicate whether they think each unique pair of alters knows each other and how often they interact. Each affirmative response corresponds to a link in a network diagram between two alters. Based on this information, one can determine how interconnected the network is.[32, 33] Using Egoweb,[118] we will derive *density*, the proportion of ties that exist relative to the total number of possible ties; *Alter Degree Centrality*, the number of relationships a network member has (importance/ connectedness); and *Components*, groups of three or more individuals completely separated from others (connected only to the PLWH), which, when combined with the size of the *largest component* (of groups of three or more individuals), provides information on network fragmentation.[119] After assessing network structure, the interviewer will use Egoweb's network visualization capabilities to create a network diagram that will be used to ask open-ended questions about clusters of individuals or well-connected individuals, to understand relationships around prevention advocacy. We will ask participants to identify alters with whom they have talked the most and least about HIV, and describe the last HIV conversation they had with an alter. We used similar questions to interpret results in our prior work.[78]

Network Composition: Using PLWH's reports, we will assess alters' demographics; relationship (e.g., family, friend, partner) and closeness to ego (PLWH); interaction frequency; and usual mode of interaction (e.g., in-person, text). For each alter, we will ask the PLWH if they have disclosed his/her serostatus to the alter, and if the PLWH knows the alter's serostatus and testing status. If the participant thinks the alter is HIV-positive, we will ask whether the participant thinks the alter is in care and on ART. *To assess prevention advocacy*, we will ask participants if they have encouraged each alter regarding HIV protective behaviors (e.g., HIV testing, PrEP, condom use, ART use if positive). By assessing alter characteristics, we can measure the context of prevention advocacy, i.e., characteristics and network position of individuals who are prevention advocacy recipients. To assess enacted stigma among alters, participants will be asked whether they have heard each alter express stigmatizing beliefs (ever and since last assessment), as we have done previously,[120] whether they have avoided the alter because they believe he/she would mistreat them (anticipated stigma) and whether the alter has rejected them (enacted stigma). We will derive network composition indicators (% of different types of alters; e.g., men/women, disclosed to, tested).

At each follow-up, we will use Egoweb's longitudinal features developed in our prior research to update network information. Participants will be asked the network elicitation questions, and then shown a list of alters from the prior assessment, allowing them to match alters named at follow-up against those previously included. The few personal social network studies that have measured networks longitudinally suggests that networks can change substantially in a short time.[121, 122] These methods allow us to examine whether the intervention is associated with network change, e.g., greater density, as in the pilot.

Process Evaluation. To inform future dissemination, following implementation science methods,[123-125] we will assess *feasibility* in terms of: recruitment rate (# recruited/month, of # expected); refusal rates, and intervention retention. *Acceptability*, the extent to which people delivering or receiving an intervention consider it to be appropriate,[126] will be assessed via facilitator and participant post-session evaluation forms (how much facilitators and participants liked the session on Likert scales, and why). Wagner and Matovu will use standard qualitative analysis methods[127-132] to code open-ended responses, independently reading all responses to develop an initial list categorizing positive and negative feedback, from which they will develop a codebook. Using *Dedoose*, they will independently code a randomly selected 20% of responses to assess consistency ($\kappa \geq .80$).[133, 134] Results will be discussed with community stakeholders to guide refinement for dissemination.

Statistical Analysis

Aims 1-3. Primary analyses will use a standard intent-to-treat approach, applying generalized mixed models (linear for continuous outcomes; logistic for binary outcomes) to the repeated-measures data to examine how intervention effects change over time, using an indicator for study arm, timepoint (baseline vs. follow-up), and timepoint by arm interaction to indicate whether change differs between arms. Our statistical methods will be consistent with advances in the analysis of personal network research,[66, 135-137] accounting for any correlation among participants in the same intervention group sessions, and among alters referred by the same PLWH (ego), by adjusting standard errors for statistical inference tests with a sandwich estimator as implemented in SAS v 9.4.[96, 138-141] 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. In follow-up analyses, we will explore interactions between each potential moderator and arm, including sex (of ego and/or alter, and concordance between the two) to examine if these variables moderate the intervention effects. If interactions with categorical moderators are significant, we will conduct post-hoc simple main effects t-tests with Bonferroni corrections. For continuous moderators,[142] we will graph significant interactions at low and high levels of each score (±1 SD). We will conduct post-hoc simple main effects t-tests with Bonferroni correction by comparing differences between discrete points on the regression lines. If *Game Changers* shows significant effects on hypothesized mediators (Aim 3), to test mediation we will compare: (a) Aim 1 models, adding baseline measures of mediator(s); and (b) the same models as in (a), adding post-intervention measures of mediator(s).[143] We will examine whether including post-intervention mediator(s) in (b) decreases the coefficient for intervention effects on outcomes relative to the corresponding coefficient from (a). We will use a bootstrapping approach to test whether mediators account for effects.[144, 145]

Statistical Power. We calculated power for alter reports of condomless sex at month 18. Based on the pilot, we assume 65% of control alters will report condomless sex at month 18. Starting with 736 alters, and assuming ~15% attrition by month 18 (which is conservative, based on 98% alter retention over 8 months in the pilot, and <10% attrition over 12 months in our other studies in Uganda), we will have 625 alters; accounting for within-ego clustering gives us an effective sample size of 612 for ICC=.01 or 568 for ICC=.05. For ICC=.01, we will have .80 power to detect a group difference of 10.3% (i.e., an intervention rate of 54.7%), and for ICC=.05, we will have power to detect a 10.7% group difference. These differences represent small effect sizes (Cohen's d =.23-.24). For PLWH index participants, using pilot data, we estimate the ICCs of our secondary outcomes to be small-to-moderate (0-.16), and assume 15% attribution and 7 intervention groups (either Game Changers or attention control), with an average cluster size of 12.9 (90 intervention participants/7 groups).[96, 140, 141] After accounting for within-group correlations, we will have 80% power to detect medium to large differences (.41-.58 SD, based on the outcome) between the study arms at follow-up.

Aim 4. We will compare *Game Changers* vs. the attention control group in the marginal cost of decreasing alters' condomless intercourse.[146] Using standard methodologies,[146] we define cost-effectiveness ratio (CER) by the difference in per-capita cost of the intervention versus control group divided by the difference in their average effectiveness: $\mathrm{CER} = \frac{\mu_{c2}-\mu_{c1}}{\delta_{e2}-\delta_{e1}}$ **:** μ_{c2} is the per-capita cost of *Game Changers*, μ_{c1} is the per-capita cost of the attention control group, δ_{e2} is the percentage of alters reporting any condomless intercourse, and δ_{e1} is the percentage for intervention alters. We will estimate confidence intervals with bootstrap methods.[147] The analysis will be performed from the provider perspective, as we cannot accurately incorporate patient-incurred costs (e.g., given variation in opportunity cost), but we will track the number and length of time spent by patients in intervention and attention control sessions, and assess transportation time and costs. We will use a micro-costing approach recommended by the US Panel on Cost-Effectiveness in Health and Medicine, tracking all costs associated with implementing *Game Changers* and the attention control as estimated from data collected from IDI Finance (e.g., facilitator compensation) and the team.[148] We will collect data using Drummond's checklist of critical elements and follow best practices to maximize comparability of results with other studies.[149] The cost per resource will be calculated by multiplying the quantity used by unit cost; total cost will be derived by adding individual costs.[150] Fixed (capital) costs (e.g., overhead) will be allocated as the hours per week the premises are occupied for the intervention or attention control group. Capital costs will be annualized using a discount rate of 3% with an assumed lifespan of 30 (buildings) and 10 (furniture) years.[150] The analysis will take into account all intervention or attention control group session costs, but exclude costs incurred by participants (e.g., for time) and associated with research. The facilitators will record time spent on the sessions on simple-to-use forms, identifying each activity (e.g., training, preparation, in-session) and session-related materials (e.g., consumable materials). We will differentiate between intervention development (e.g., training) and ongoing costs. Ongoing costs will be tracked to determine any cost efficiencies over time. Within those, we will differentiate between fixed intervention costs and marginal costs of adding a patient, to provide information for generalizability.

PROTECTION OF HUMAN SUBJECTS

1. Characteristics of Participants

We will recruit 210 people living with HIV (PLWH) and randomize 105 to the intervention and 105 to the no-intervention control arm. Each PLWH will be asked to recruit up to 4 social network members (alters) to whom they have disclosed (736 total (allowing for average of 3.5 recruited per index participant), 368/arm). Eligibility Criteria for PLWH include (1) ≥18 years-old; (2) in care for > 1 year (because they are more likely to be medically stable, adjusted to their HIV diagnosis, and have disclosed to several people, and thus more likely to be ready to engage in advocacy); and (3) disclosed their HIV status to at least one person. Eligibility Criteria for Alters include (1) ≥18 years-old; (2) referred by a PLWH enrolled in the study; (3) know the PLWH's serostatus; and (4) willing/able to do the first study visit in person. (Other alter study visits can be done by phone, or interviewers can travel to meet alters.) PLWH will be asked to refer at least 7 alters for participation in assessments, in order to ensure enrolling up to 4 alters.

2. Sources of Materials

The data sources in need of safeguarding include self-report survey and social network data (collected at baseline, and 6-, 12-, and 18-months post-baseline); chart abstracted medical data; audio-recordings of intervention sessions; and facilitator, supervisor and participant ratings of intervention sessions. Data for the cost analysis (e.g., study staff documentation of time and resources for intervention activities) will be collected but are not considered to be human subjects data.

3. Potential Risks to Participants

Psychological distress**:** Distress may result from issues raised during intervention sessions, such as sharing stories about HIV stigma.

Breach of confidentiality**:** Violation of participant confidentiality is possible, but we believe the safeguards that we have integrated into the study methodology, as described below, will effectively limit this risk.

Harm from HIV disclosure or advocacy**:** There is a risk that participation in the intervention sessions could result in the participant disclosing their HIV serostatus to a social network member who has a negative reaction, including discrimination, violence, hostility, social rejection, and abandonment. Engagement in advocacy discussions could also result in social network members reporting illegal behaviors to the participant (e.g., same-sex sexual behavior; sex work; not notifying sex partners of HIV infection; use of illicit drugs).

4. Adequacy of Protection Against Risks

Protection Against Risk

Informed Consent. During the consent process, potential participants will receive a detailed description of the study, including the nature of the participant's involvement in the study, the possible risks and benefits of participation, and the participant's ability to withdraw from the study at any time without consequence. The participant will have the opportunity to ask questions about the study, after which informed consent will be obtained. Each participant will be given a copy of the consent form to keep.

Due to Uganda's law against homosexuality and high societal homophobia, we will take further steps during the informed consent process to protect PLWH who engage in same-sex sexual behavior or who identify as a sexual minority. When clients are screened individually by the coordinator, they will be informed of the eligibility criteria and told that there are legal risks to clients who self-identify as having had sex with or current sexual attraction for someone of the same sex, and if they choose to participate, they may place themselves at risk of inadvertently disclosing their sexual orientation if they advocate to people in their social network about HIV. Specifically, as we did in our pilot study, we will tell participants, "If you choose to participate, it is important to consider the legal risks of participation for people who have had sex with or current sexual attraction for someone of the same sex and for commercial sex workers. You should not say anything in the intervention sessions that you want to keep private from others, and you should not talk about illegal activities in the intervention sessions or when you advocate to people in your social network about HIV." The PLWH then will be told that he/she is welcome to take the consent form home for consideration, after which he/she can contact the coordinator for formal screening, if still interested. This allows sexual minority clients to withdraw their interest without disclosing their sexuality. Alternately, if patients would like to enroll at that time, we will enroll them on the day we approach them. In addition, to decrease risk and ensure confidentiality, we will not record participants' sexual orientation or same-sex sexual behavior, even if a participant volunteers such information. Such information would put participants at legal and social risk. Thus, even if data were subpoenaed or seized by government officials, participants who engage in same-sex sexual behavior would not be identifiable. We have found these enrollment procedures to be feasible in our R34 pilot, and no potential participant or enrolled participant in our pilot disclosed same-sex sexual behavior.

Psychological Distress*.* Participants will be referred to a counselor at the clinic if warranted and/or desired by the participant. Participants also have the right to refuse to answer specific questions and can end their participation in the study or intervention at any time.

Confidentiality. To protect confidentiality, all research data will be kept in locked file cabinets and/or secure password protected computers, and will be available only to members of the study team. Data will be identifiable only by study ID numbers. Personal information including participants' name, address, and phone number will be stored separately from all research data. All data collected will be kept confidential and not shared with the client's physician or other clinic staff, or any of their social network members whom they may recruit to participate. Participants will be informed of these conditions during the informed consent process.

We also will ensure that response options will useful for our analytic purposes but general enough to ensure that any cross classifications will not lead to any cell in such a table having fewer than four individuals, following procedures established by the Add Health study. In the event that certain variables still result in such a possibility, we will eliminate that variable from any data set that will be made publicly available.

To protect alters' confidentiality in the social network data, we will strive to maintain the highest ethics associated with social network analysis, following foundational guidelines associated with social networks research and identification of secondary participants. With respect to possibly risky behaviors or sensitive characteristics (e.g., HIV serostatus), we will ask respondents to provide us with their own idea of how probable a particular behavior or characteristic is, not to report directly on the network member's behavior or characteristics.

During the beginning of the first intervention session, the importance of and commitment to maintaining the confidentiality of all that is shared in the group will be emphasized. These procedures are critical to establishing a safe environment for participants to feel comfortable being open and candid. Audio recordings of the sessions will have no identifying information, will be stored on a password-protected, encrypted file, and then destroyed at the end of the study. All study staff will receive training on confidentiality.

As described above, no identifying information will be collected from clients who are deemed ineligible during screening; therefore, if any client indicates they are a sexual minority during screening, there will be no records that would enable their identification.

Harm from HIV disclosure or advocacy. Among the goals of the intervention sessions are to improve participants' ability to make effective decisions regarding disclosure of their HIV status and engaging in HIV prevention discussions with members of their social network. These workshops will be designed to help participants recognize the full range of responses that they may encounter when disclosing their status or discussing HIV, including the potential for recipients of such information to act with hostility, violence, discrimination, or other negatives responses. Hence, the workshops focus on decision-making regarding these behaviors, and improving judgment for when such behaviors will be beneficial versus harmful, rather than encouraging all participants to disclose or advocate prevention regardless of risk for harm. Further, participants are encourages to engage in advocacy with network members who know the participant's HIV status. Participants are only eligible if they have disclosed to at least one network member; this is a criterion suggested by our IRB, in order to protect participants from others suspecting their sero-status if they engaged in advocacy without disclosure. These procedures cannot prevent all negative responses, but should minimize such risks.

If while engaging in advocacy with a network member, the network member discloses illegal behavior such as failure to notify their sex partner of their HIV infection, sex work, illicit drug use, or same-sex sexual behavior, the participant will receive training during the intervention to encourage the person to reflect on how their behavior may be related to HIV risk to themselves or others and discuss measures that could be taken to reduce this risk. The training will emphasize that the purpose of the advocacy is to protect one's family and friends and encourage protective behaviors, not to elicit or act on incriminating information.

5. Potential Benefits to Study Participants

The intervention may help clients to manage stigma and the psychological process of adjusting to HIV, to stay healthy, to make better disclosure decisions, and to engage in effective HIV prevention advocacy, with the goal of decreasing HIV rates in their social networks and communities.

Participants (both PLWH and their alters) will receive 30,000 Ugandan Shillings (Ush; ~$8) per assessment, and PLWH will receive 30,000 Ush (~$8) transportation reimbursement as well as refreshments during each intervention session. These incentive amounts were based on participant feedback during the pilot regarding the need for incentives to cover transportation costs. The incentive amounts are allowable per Makerere University IRB guidance, which we sought when planning this protocol.

6. Importance of the Knowledge to Be Gained

This study will provide information about the impact of activating PLWH as change agents for increasing HIV protective behaviors among themselves and their social networks. By including both PLWH and their alters, *Game Changers* has the potential to reduce HIV stigma and improve outcomes from HIV prevention to care in individuals, households and social networks.

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