LinkPositively: A Technology-Delivered Peer Navigation and Social Networking Intervention to Improve HIV Care

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UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN

Instructions for completing the Research Plan are available on the HRPP website.
The headings on this set of instructions correspond to the headings of the Research Plan.
General Instructions: Enter a response for all topic headings.
Enter "Not Applicable" rather than leaving an item blank if the item does not apply to this project.

Version date: 9/30/2013

1. PROJECT TITLE

IRB Project #: 191398

LinkPositively: A Technology-Delivered Peer Navigation and Social Networking Intervention to Improve HIV Care Across the Continuum for Black Women Affected by Interpersonal Violence

2. PRINCIPAL INVESTIGATOR

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3. FACILITIES

Primary study activities will take place at the following locations:

San Diego County: UC San Diego AntiViral Research Center, located at 220 Dickinson St., Suite A, San Diego, California 92103

Los Angeles County: Charles R. Drew University of Medicine and Science, Clinical and Translational Science Institute, 1731 East 120th St., Los Angeles, California 90059

Alameda County: WORLD, located at 389 30th St., Oakland, California 94609 (Recruitment ONLY, no participant enrollment or human subjects interaction)

Oklahoma City County: Guiding Right, Inc., offices at multiple locations including 1420 NE 23rd Oklahoma City, Oklahoma 73111, 2809 NW 31st Oklahoma City, Oklahoma 73112, and 2809 NW 31st Oklahoma City, Oklahoma 73112

Tulsa County: Guiding Right, Inc., 4619 S. Harvard Tulsa, Oklahoma 74135

The study is a collaborative project between UC San Diego (UCSD), and San Diego State University. UCSD is the primary institution. San Diego State University, Charles Drew University, and Guiding Right, Inc. will rely upon the University of California San Diego IRB approval for UCSD IRB Project #191398, in accordance with the SDSU/UCSD Agreement and Process for Joint IRB Review of Faculty Protocols and the Basic Health and Human Services Policy for Protection of Human Research Subjects, 45 CFR 46.114, which states, "Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort."

Charles Drew University and Guiding Right, Inc. will participate in human subjects enrollment and data collection, and has agreed to use the UCSD Consent Form under the Reliance Agreement.

4. ESTIMATED DURATION OF THE STUDY

3 Years (12/01/2019 – 11/30/2022)

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

We will develop and pilot test a culturally tailored, trauma-informed smartphone app, called *LinkPositively*, for Black WLHA affected by interpersonal violence. Core components of LinkPositively include: a) Virtual Peer Navigation that includes phone and text check-ins and 4 weekly one-on-one video sessions to build skills to cope with barriers and navigate care; b) Social Networking platform to receive peer support; c) Educational and Self-care database with healthy living and self-care tips; d) GPS-enabled Resource Locator for HIV care and ancillary support service agencies; and e) ART self-monitoring and reminder system. Guided by the Theory of Triadic Influences and Syndemic Theory, the study will be conducted in 2 phases with corresponding aims. In Phase 1 (Aim 1), 4 focus groups with Black WLHA with experiences of interpersonal violence, one focus group with peer navigators, and 4-6 key informant interviews with providers will be conducted to determine which app features, content, and functions are most likely to support downloading, initiating use, and sustaining engagement over time. Aim 1 will culminate in usability testing by Black WLHA affected by interpersonal violence (n=8), to finalize intervention components and procedures. In Phase 2 (Aim 2), we will pilot test LinkPositively to assess feasibility and acceptability and determine preliminary effects of the intervention on HIV care outcomes (i.e., retention in care, ART adherence, viral suppression) and mechanism of change variables (i.e., social support, self-efficacy). Through a randomized control trial (RCT), participants will be randomly assigned to either the intervention arm (n=40) or control arm (Ryan White standard of care, n=40), with follow-up at 3- and 6- months. This study will benefit the advancement of HIV prevention science by harnessing technology to promote engagement in HIV care, while improving social support through peers and social networking–all under the auspices of being trauma-informed for Black WLHA with experiences of interpersonal violence.

6. SPECIFIC AIMS

Aim 1: Develop the LinkPositively mobile intervention through focus groups (FGs) with Black WLHA affected by interpersonal violence, peer navigators, and service providers, and refine iterations through input from the San Diego CFAR Disparities Core CAB.

Four FGs, with 6-8 HIV-positive Black WLHA reporting a lifetime history of interpersonal violence by an intimate partner (n=2 FGs) and non-intimate partner (n=2 FGs); one FG with 4-6 Peer Navigators employed at HIV clinics/service agencies; and 4-6 key informant interviews with service providers will be conducted in San Diego, CA. Group differences will be explored to optimize LinkPositively across different types of reported perpetrators. The outcomes will be feedback on proposed intervention components and suggestions for new features, as well as recommendations for how to address challenges to engagement with LinkPositively. Aim 1 will culminate in usability testing by Black WLHA affected by IPV (n=8), to finalize intervention components and procedures.

Aim 2: Conduct a pilot randomized controlled trial to assess the feasibility, acceptability and preliminary
impact of the LinkPositively intervention for Black WLHA affected by interpersonal violence, in preparation for a large-scale R01.

Eighty Black WLHA ever experiencing interpersonal violence will be randomly assigned (1:1) to receive LinkPositively or standard of care Ryan White services, with self-reported, biological, and clinical outcomes collected at baseline, 3- and 6-month follow-up visits. Intervention use data will be collected throughout the intervention period to examine feasibility, acceptability, and the associations between components used and study outcomes. Primary outcomes are retention in HIV care, ART adherence, and viral suppression, whereas socio-structural mechanism of change variables are social support and

activation of social support networks, self-efficacy, and utilization of ancillary support services. To minimize recall bias and/or social desirability bias, that may occur with the use of audio computer-assisted self-interviews, we will use objective data to measure the main outcomes. Retention in HIV care and viral suppression will be based on medical record data and ART adherence will be measured using hair samples assayed for tenofovir and emtricitabine. The proposed study will benefit the advancement of HIV prevention science by harnessing mobile technology to promote retention in HIV care and ART adherence among US Black WLHA affected by interpersonal violence and co-occurring adverse mental health and substance abuse – an underserved, marginalized population. If the LinkPositively intervention is efficacious through an eventual R01 mechanism, it will change the paradigm for addressing the unique HIV treatment needs for Black women dually affected by HIV and interpersonal violence.

7. BACKGROUND AND SIGNIFICANCE

Background and Significance

Black women are disproportionately affected by HIV and interpersonal violence. Black women living with HIV/AIDS (WLHA) in the US are less likely to be engaged in HIV care and adherent to antiretroviral therapy (ART) compared to other racial/ethnic groups (1-3). Black WLHA account for 61% of diagnoses among women of all races and ethnicities (4), only 56% are retained in care (1), and 49% virally suppressed (1). Black WLHA are particularly affected in San Diego County, CA, with HIV prevalence rates 8 times higher than that observed for White WLHA (5) and are underserved and understudied. Blacks on ART in San Diego are less likely to be virally suppressed than Latinos or Whites (6). Concurrently, Black women are disproportionately affected by interpersonal violence, defined as ever experiencing physical (e.g., hit, slapped, choked), sexual (e.g., forced vaginal/anal sex), and/or psychological (e.g., yelled at, belittled, controlling behaviors) abuse by a male intimate partner (e.g., spouse, boyfriend, dating partner) or non-intimate partner (e.g., relative, friend, stranger). Interpersonal violence is comprised of commonly reported forms of violence (i.e., intimate partner violence (IPV), rape, contact sexual violence, childhood abuse). Whereas the national prevalence of lifetime IPV is 45% (7), Black women report 35% higher IPV than White women (8). Moreover, although national data estimates the lifetime prevalence of rape among Black women at 21% (7), community-based samples estimate prevalence rates of rape as high as 38-54% (9-12).

Interpersonal violence and co-occurrence of adverse mental health and substance abuse contribute to poor HIV care continuum outcomes. WLHA experience high rates of lifetime physical, sexual, or psychological abuse (67%) (13), lifetime IPV (55%) (14-15), and past year IPV (27%) (16), a rate double the US national average. A history of abuse or trauma among WLHA is also associated with ART non-adherence, lower CD4 counts, reduced viral suppression, and increased mortality (14, 17-20). A recent study found that among HIV-positive women, those who reported recent trauma had over 3 times the odds of antiretroviral failure compared to their counterparts (17, 21). WLHA also experience co-occurring syndemic conditions with 15-24% reporting heavy or hazardous drinking of alcohol (22-23), 11-15% reporting active drug use (24-25), and 30% suffering from post-traumatic stress disorder (PTSD) (15). Black women are more likely to experience these conditions (26) than their White or Latina counterparts. In the few studies that account for co-occurring syndemic conditions using a summative score, higher syndemic scores (i.e., IPV, substance abuse, binge drinking, adverse mental health, and sexual risk-taking) were associated with poor ART adherence among HIV-positive men and women (27), and HIV-positive youth (28), and reduced viral suppression among HIV-positive women of color (29).

Socio-structural barriers contribute to poor HIV care outcomes, whereas social support mitigates the effect. In addition to interpersonal violence and co-morbid adverse mental health and substance abuse, Black WLHA also face socio-structural barriers affecting retention in care and ART adherence, such as HIV-related stigma and medical mistrust (30). HIV stigma is the most noted barrier to consistent access to and utilization of HIV care services for Black women (30-31). Experiences of racism, conspiracy beliefs, and the quality of relationships impact engagement in HIV medical care (32). Race-based medical mistrust predicts

lower ART adherence among Black WLHA (33). However, social support through formal and informal networks may be important to address these complex issues, and has improved engagement in HIV care among Black WLHA (34-37). Specifically, women with abuse histories are more likely to seek formal help at service agencies, after seeking support and encouragement from informal social networks (38). Studies collectively suggest that socio-structural factors, including lack of social support and HIV-related stigma, need to be considered by providers and underscore the importance of relationships and communication between patients, providers, and the support networks of Black WLHA (30).

Mobile technology interventions to address HIV prevention are limited among women. Given high rates of Internet access and smartphone infiltration across genders and races/ethnicities, mobile health (mHealth) technology interventions have emerged as one approach to support lifelong engagement in HIV care (32,39). Mobile technology such as mobile phones and other wireless computing devices offers advantages for women with a history of interpersonal violence such as confidentiality, more efficient and safer care, and empowerment (40-44). A majority of women (88%) in the US use the internet, with no differences in internet use by race/ethnicity (89% of Whites; 87% of Blacks) (45). In the US, cellphone ownership is highest among Black adults (98% vs 94% of White adults), and approximately three-quarters of adults across all races/ethnicities own a smartphone. Smartphone use is highly prevalent among Black individuals overall (72%) (46) and those with low socioeconomic status (85%-90% for Black women) (46-47). Moreover, 52% of Black women use a smartphone to access health information at least weekly. However, based on a 2013 review solely focused on smartphone applications (apps) for HIV/sexually transmitted disease care and prevention, most smartphone apps failed to create engaging and attractive apps (48), provided limited psychological and emotional support resources, and miss important opportunities for intervention (e.g., did not include messages about HIV prevention or medication adherence (48)). Unfortunately, these limitations to realizing the potential impact of mHealth interventions persist.

Peer Navigation has been highlighted as a successful model of care in improving outcomes along the HIV care continuum (49). Peer Navigators are HIV-positive, medication-adherent role models living with a similar shared experience and community membership as their target populations. Peer navigators provide social support and positive modeling of engagement-supportive behaviors to their clients, helping to build clients' self-efficacy in patient-provider communication and increase clients' trust and confidence in the health care system; offsetting the negative impact of socio-structural barriers (i.e., fear of gender-/racial-bias driving medical mistrust, stigma, and discrimination (50)) on HIV care. Peer Navigators also build clients' self-efficacy for future engagement in the HIV care system. Peer Navigation for improving retention in care among WLHA has been found to be feasible, acceptable, and efficacious in the US and low- and middle-income countries (51-55). Peer navigation has improved ART adherence and viral suppression (55-57), although some studies have found no effect (58), perhaps due to small samples or the lack of informal social support. Peer navigation with other forms of informal peer support, would likely provide greater opportunities to reduce social isolation, build community, and share strategies for addressing syndemic and other (e.g., risky sexual behavior) factors for Black WLHA. A recent analysis of messages posted on a closed Facebook group for a young adult HIV program showed that members provided high levels of emotional and social network support.

Preliminary Data

mHealth Interventions. Dr. Keith Horvath (mPI) is currently PI on four mHealth intervention studies addressing the HIV prevention and care continuum. Thrive with Me (TWM; R01DA039950) is a responsive (i.e., adjusts to fit most devices) website that uses: informal peer support (similar to Facebook); tailored ART adherence and HIV-related information; self-monitoring of ART adherence, mood and drug use; and gamification components to improve ART adherence among HIV-positive adult MSM. Based on encouraging results of a pilot trial (59), an efficacy trial of TWM is underway in which 400 adults (age ≥18 years) HIV-positive MSM in New York City with sub-optimal ART adherence will be randomized to receive TWM for 5 months or an information-only control, and followed for 17 months. An interim analysis of community wall posts found that HIV-positive MSM spontaneously initiated discussions with each other on sensitive topics, such as ART adherence and sexual risk reduction strategies, and provided informational and emotional support to one

other (60). As part of the UNC/Emory Center for Innovative Technology (iTech), within the new Adolescent Trials Network (ATN), TWM is being adapted for and subsequently tested among 350 HIV+ youth (15-17 years) and young adults (18-24 year; U19 HD089881). Also, as part of ATN's iTech, the team is leading a technology-based stepped care intervention for transgender and gender non-binary youth to reduce sexual risk behavior and increase PrEP uptake through tailored SMS messages, a culturally-tailored mobile app, and individualized e-coaching (U24 HD5109014). Finally, Dr. Horvath recently completed a native app (available on iOS and Android) intervention to increase regular HIV testing.

Peer Navigation. The BRIDGES Project (PI: Dr. Stockman; Consultant: Dr. Cloitre; California HIV/AIDS Research Program; HD15-SD-059) is a Peer Navigation RCT intervention among Black and Latina women in San Diego, CA that provides trauma-informed Peer Navigation to improve linkage to and retention in HIV care and ancillary support services. Upon completion of the pilot test, women reported improvements in coping self-efficacy, self-efficacy to activate social support networks, and had increased retention in HIV care over a 3-month period (61). Ms. Dillard Smith (Consultant) leads an HIV service organization (WORLD) in Oakland, CA, that has implemented peer navigation services into their programs. The Peer Advocate program at WORLD hires Peer Navigators, including Black WLHA – with life experiences similar to the women they serve (e.g., histories of physical, sexual, and psychological abuse; adverse mental health; substance abuse) – who provide emotional and practical support to WLHA, and help them navigate the medical and social services systems. Ms. Dillard Smith and WORLD led a peer navigation intervention (Kaiser-funded study) to improve engagement in HIV care and ART initiation among out-of-care HIV-positive women of color. Of the 84 women enrolled (62), 48% experienced lifetime physical abuse, 42% experienced lifetime sexual assault, 29% used substances in the past month, and 29% had attempted suicide. At 6-month follow-up, women in the intervention group had less missed HIV care visits and more access to ancillary services than women in the control group (Ryan White case management services). In both groups, there were increases in the proportion of women initiating ART. These findings demonstrate the utility of a peer-based navigation program in improving retention in HIV care and ART uptake.

8. PROGRESS REPORT

N/A.

9. RESEARCH DESIGN AND METHODS

Study Overview: This study will be conducted in 2 phases, corresponding to the study aims:

Phase 1 (Aim 1): Developing LinkPositively with input from Black WLHA with a lifetime history of interpersonal violence, peer navigators, and providers, and the San Diego Center for AIDS Research (CFAR) Disparities Core Community Advisory Board (CAB). Phase 1 will culminate in usability testing, Beta Testing, by Black WLHA affected by interpersonal violence (n=8), to finalize intervention components and procedures.

Phase 2 (Aim 2): Piloting an RCT to evaluate feasibility, acceptability, and the preliminary effect of LinkPositively among Black WLHA with a lifetime history of interpersonal violence. This multi-component, culturally tailored, and trauma-informed mHealth intervention will primarily aim to increase retention in HIV care, ART adherence, and viral suppression for Black WLHA affected by interpersonal violence. The four components of LinkPositively will achieve these aims directly by improving self-efficacy for coping, social support networks, and utilization of ancillary support services (i.e., domestic violence, mental health, substance abuse), and indirectly by reducing HIV stigma and medical mistrust.

Study Setting: The study will take place in three California counties (San Diego, Los Angeles, and Alameda) and two Oklahoma counties (Oklahoma and Tulsa). In San Diego County, between 1981 and 2011, the proportion of AIDS cases among White persons dropped (70% to 42%) while the proportion of cases among people of color increased considerably (19% to 58%).While African American persons represent 5% of the county's population, they make up 13% of individuals diagnosed with HIV. Moreover, the AIDS rate is almost 8 higher among African American women, compared to White women. Similar HIV prevalence rates are

observed for African American women in other counties in California (Los Angeles and Alameda) and Oklahoma (Oklahoma City and Tulsa), with African American women disproportionately affected.

Study Population:

AIM 1

In Phase 1 (Aim 1), eligible participants for the focus groups and interviews will be: (1) Black WLHA (including transgender women) with a history of interpersonal violence (n=6-8 per FG; total of 4 FGs); (2) Black WLHA (including transgender women) with a history of interpersonal violence who act in a professional capacity as a Peer Navigator (n=4-6; one FG); and (3) Key Informants (n=4-6) will be leadership at local clinics and community-based organizations known to provide services to women in the areas of HIV/AIDS care and domestic violence services, such as UCSD Owen Clinic and Mental Health America. Phase 1 will culminate in usability testing, Beta Testing, by Black WLHA affected by interpersonal violence (n=8; 4 with histories of interpersonal violence perpetrated by a current or former intimate partner and 4 with histories of interpersonal violence perpetrated by a non-intimate partner [e.g., family member, friend, stranger]), to finalize intervention components and procedures.

AIM 2

In Phase 2 (Aim 2), eligible participants for the RCT will self-report: (a) female gender (including transgender women), (b) Black or African American racial/ethnic background, (c) aged 18 years or older, (d) HIV-positive status, (e) ever experienced physical, sexual, and/or psychological abuse by a current or former partner or non-partner (e.g., relative, friend, stranger), (f) owner of a smartphone with internet browsing capabilities, and (g) English speaking. Purposive sampling will be used to ensure that groups are balanced with respect to type of perpetrator (current or former intimate partners [e.g., spouse, boyfriend, dating, casual] and non- intimate partners [e.g., family member, friend, stranger]) and retention in HIV medical care status (linked to care but have fallen out of care [i.e., no ART prescription filled, no viral load labs, or no HIV care visits with an ART-prescribing provider in the past year] versus linked to and retained in care [i.e., ART prescription filled, viral load labs, or HIV care visits with an ART prescribing provider in the past year]).

Study Screening and Enrollment:

AIM 1

In Phase 1 (Aim 1), three separate recruitment strategies will be imposed based on the distinct types of focus groups, key informant interviews, and beta testing.

- Black WLHA with a history of interpersonal violence (n=6-8 per FG; total of 4 FGs and n=8 Beta Testing) will be recruited from organizations in San Diego, CA that provide HIV testing and/or treatment to WLHA, all of which are represented through membership in the San Diego CFAR Disparities Core CAB. We will also recruit Black WLHA through presentations at organizations providing HIV-related services such as Mental Health America San Diego and the Center for Community Solutions Rape Crisis Center. Finally, we will distribute flyers and advertisements through street outreach efforts, community events, and newspapers such as the Voice and Viewpoint, an African American local newspaper. We have successfully utilized these recruitment efforts in previous studies. Interested women be screened over the phone. They will provide verbal consent to be screened, then asked questions regarding eligibility, demographics, and computer literacy.
- Peer Navigators (n=4-6; one FG) will be identified by Dr. Stockman's contact with leadership at local clinics and CBOs known to employ peer navigation approaches and represented on the CAB (e.g., UCSD Mother, Child and Adolescent HIV Program and San Ysidro Health Center). Invitations will be extended to each organization with a flyer to be provided to PNs.
- Key Informants (n=4-6) will be identified by Dr. Stockman's in-person or phone contact with leadership at local clinics and community-based organizations known to provide services to women in the areas of

HIV/AIDS care and domestic violence services such as UCSD Owen Clinic and Mental Health America. Print and electronic promotional materials will include a brief description of the study and the study phone number to call for more information about the study.

For all focus groups, interviews, and beta testing, participants will be asked to provide Dr. Stockman and Dr. Tsuyuki with contact information. Focus group and interviews will be scheduled for dates and time convenient for the participants. All participants will review informed consent documentation and provide informed consent prior to commencement of the focus groups or interviews.

AIM 2

In Phase 2 (Aim 2), we will conduct the pilot RCT with 80 women from the study population. Potential participants will be recruited through community contacts across San Diego County, Los Angeles County, Alameda County, Oklahoma City County, and Tulsa County. Members of the research team have established relationships with the following key organizations that provide HIV testing and/or treatment to WLHA and these organizations are represented through membership in the San Diego CFAR Disparities Core CAB: UCSD Owen Clinic, UCSD Mother, Child and Adolescent HIV Program, Family Health Centers of San Diego, San Ysidro Health Center. We will also extend recruitment to Black WLHA through presentations at organizations providing HIV-related services such as Mental Health America San Diego, Neighborhood House Association, and the Center for Community Solutions Rape Crisis Center. In Los Angeles County, we will recruit from the following community-based organizations: UCLA Family AIDS Network, AIDS Project Los Angeles, Maternal Child Adolescent Clinic, OASIS Clinic, East LA Women's Center, Alta Med, and JWCH Institute. In Alameda County, we will recruit from WORLD, an HIV service organization for women of color. In Oklahoma City and Tulsa Counties, we will recruit from Guiding Right, Inc., a Black-focused community-based organization. In all counties, we will distribute flyers and advertisements through street outreach efforts, community events, and newspapers such as the Voice and Viewpoint, an African American locally based newspaper. Finally, we will employ Facebook Advertising to recruit women through social media, including on the platforms Facebook and Instagram, and using the Facebook Audience Network to run advertisements on other websites the target population is likely to utilize. We have successfully utilized these recruitment efforts in previous studies. Further, we will employ Build Clinical, an organization that assists academic researchers in study enrollment through technology and novel data-driven approaches.

Depending on the recruitment source, the following initial contact method may be employed: (1) Women may see the study advertisements in the community. Women interested in participating in the study will contact the study staff using the study phone number and email address listed in order to receive study information. At the time of the initial contact, women will be provided information regarding LinkPositively. Women will then express whether or not they are interested in the study. (2) Women may be recruited via service agencies or enrolled participants. By reviewing the study advertisement, interested women may request that their contact information be provided to the study team in order to initiate the first contact. At the time of the initial contact, women will be provided information regarding LinkPositively. Women will then express whether or not they are interested in the study. (3) Women may see the study advertisement on social media. By following the link on a social media advertisement, women can review the study website and complete the screener online (see below) and provide contact information for the Project Coordinator to directly contact them. At the time of the initial contact, women will be provided information regarding LinkPositively. Women will then express whether or not they are interested in the study.

Depending on the preference of the potential participant, the following screening method may be employed: (1) If a potential participant would like to be screened by phone for eligibility, the study staff will seek verbal consent to screen the participant. If consent is obtained, then a 10-minute screener will be conducted to assess eligibility. Screening questions will include age, biological sex, preferred gender identity, pregnancy status, HIV status, and sexual and reproductive history. (2) If a potential participant would like to be screened digitally for eligibility, the potential participant can follow a link on the advertisement, the study website, or via a link sent to them directly by the study staff. This link will take them to an eligibility screener via REDCap survey

or to a secure survey via Build Clinical. The survey link will first notify potential participants that by continuing to the study screener, they are providing consent to be screened digitally. If consent is obtained, then a 10-minute screener will be conducted to assess eligibility. Screening questions will include age, biological sex, gender identity, self-reported HIV status, and measures pertaining to lifetime trauma, mental health, post-traumatic stress, past year physical and/or sexual violence, and substance and alcohol use. Due to the highly sensitive nature of this study, ability of potential participants to screen digitally will reduce participant burden in the screening process and increase participant options in the screening process, as is aligned with a trauma-informed approach to working with WLHA.

After eligibility is determined, eligible participants who screened through REDCap will be asked to provide the study staff with their contact information (phone number, email address), along with the names and corresponding contact information (e.g. phone number) of up to 3 individuals who may be contacted if the research team is unable to contact the participants for study initial visits and/or follow-up visits. The research team will only contact these alternative contacts if we cannot reach the participants through 10 attempts (total) on different days and times using the contact details that the participants provided the research team. Eligible participants who are recruited through Build Clinical will provide contact information through the secure participant management platform, which is kept secure using server authentication and data encryptions that are the same as those used in healthcare institutions. Data is transmitted via HTTPS, and Build Clinicals uses a Transport Layer Security (TLS) 1.2 with a 2048-but server key lengths and industry-leading modern browsers. No subject data other than eligibility screening data is stored by Build Clinical. All servers are based in the US, and data will be deleted upon request from the UCSD research upon closing of the study. The screening survey used through Build Clinical is identical to that used in REDCap.

Participants deemed eligible for the study will then be linked to the Project Coordinator to schedule a baseline study visit at the UCSD Antiviral Research Center in San Diego County, the Charles R. Drew University Clinical and Translational Science Institute in Los Angeles County, WORLD in Alameda County, and at Guiding Right, Inc. offices in Oklahoma City and Tulsa Counties. At the baseline visit, participants will review and sign informed consent documentation to be enrolled in the study.

Study Visit Procedures

AIM 1

In Phase 1 (Aim 1), interested WHLA, Peer Navigators, and Key Informants will participate in one focus group or in-depth interview, lasting approximately 90-120 minutes. All FGs will be held at the UCSD research field office location in Hillcrest (The Webster Building), a centrally located neighborhood in San Diego. Key Informant Interviews will occur at a location convenient for the key informant, such as their office. Each session will last approximately 2 hours and will be conducted in English. Participants will be asked to review and sign the informed consent form, which will explain the study procedures, confidentiality, risks and benefits of participation, and payment incentives. Participants will be given the opportunity to ask questions about interview procedures, and “group rules” will be reviewed prior to beginning the session (in the case of the FGs). To ensure confidentiality, participants will be asked to use a pseudonym in lieu of their name. Participants will also be asked to sign a confidentiality clause and encouraged to use and refer to each other by pseudonym only. FG and key informant interview questions will be developed by the research team and reviewed by the CAB. Questions specific to smartphones and apps will include: (1) experiences with smartphones and apps; (2) important features in an app; (3) influences of decisions to download, use, and maintain apps; features desired in regularly used apps; (4) suggestions for content and features of an app to help engage women in HIV medical care and ancillary support services; (5) prompts provided based on proposed app components: video function, social networking, educational tips, and GPS-based locator service.
Topics and questions specific to HIV care, interpersonal violence, and associated mental illness and/or substance abuse will include: (1) aspects of HIV care most challenging to navigate as Black WLHA; (2) how barriers have been overcome, such as interpersonal violence, leading to improved engagement in HIV care or

other support services; (3) intersectional stigma due to being Black, a woman, HIV-positive, and affected by interpersonal violence, and distrust of the health care system; (4) type of appointments that clients would need support in; and (5) types of support needed after appointments (e.g., managing medication side effects). Next, participants will be informed that the research team is building a smartphone app to improve retention in HIV medical care and ART adherence, while linking to other ancillary support services (e.g., domestic violence, mental health, substance abuse). Participants will be asked to reflect on the following topics: (1) features and functions that would attract them to the app; (2) visual look of the app; (3) importance of photos or characters of people on app look like them or their friends; (4) thoughts on proposed name, LinkPositively and suggested changes; (5) feedback on notifications (usually called push notifications) that may pop up on the home screen or near the app; and (6) suggestions to address privacy and safety concerns. The FG or key informant interview will end by asking participants to comment on anything else to consider during the app development process, thanking them for their time, and compensating them $50 cash.

In Phase 1 (Aim 1), we will conduct beta testing to obtain feedback from a small group of women on intervention components, and to identify any navigation problems. Beta testing will be informed by the Health and Human Services Agency guidelines for best practices to assess user reaction to content, design, and functionality of the LinkPositively app. Screening and written informed consent will be conducted in-person. The consent will describe the purpose of usability testing and a description of the LinkPositively app to be tested. Women will be asked to download and navigate the LinkPositively app and reflect upon their experiences over a 2-week period. Specifically, we will ask women to provide feedback on their experiences with: 1) completion of a profile to be effectively linked to a matched virtual PN; 2) ease of initial text or videoconference with virtual PN; 3) use and functionality of the social networking platform with other users; 4) use of the resource center to identify one HIV service provider or organization, outside of the clinic or organization they frequent, and 2 ancillary support service agencies (i.e., domestic violence, mental health, substance abuse), and 5) educational tip functionality in terms of receiving tips and submitting questions.

At the end of two weeks, Dr. Stockman or Dr. Tsuyuki will conduct a semi-structured qualitative exit interview soliciting participant and Virtual PN feedback and suggestions specific to each intervention feature, noting suggestions for improvement. Participants will be asked to assess the LinkPositively app's features usability, design, content, and functionality. Participants will also complete the 10-item system usability scale (SUS), a validated, industry standard scale used to evaluate a variety of products and services, including websites, mobile phones, and computer software. Virtual PNs will also participate in a FG where we will obtain feedback on navigating the Coach-User interface (e.g., video and phone feature to speak with women, texting appointment reminders and private messages to women), difficulties with session content, satisfaction with the process (e.g., linkage to external support services, support networks, match between PN and client), and suggestions for improvements. Upon completion of a qualitative exit interview, participants will receive $50 for their participation and to cover the cost of data used during beta testing. A usability report will include compiled data from participants and PNs, list of common problems, and recommended design-improvements that will be used in the final iterative stages of app development.

After beta testing is completed, we will share findings with the CAB and improve the LinkPositively app design, content, and functionality based on findings from the usability testing process. Drs. Horvath and Stockman will meet with RCG to discuss refinements centered on the identified usability study findings.

AIM 2

In Phase 2 (Aim 2), Participants enrolled in the study will attend three data collection study visits: Baseline (Month 0), Follow-Up 1 (Month 3), and Follow-Up 2 (Month 6).

Baseline Study Visit. Women who meet eligibility criteria and are interested in participating in the study will undergo the written informed consent process at their baseline visit. After consenting, participants will provide contact information (e.g., name, cell phone number, email address, and/or social media username) to be

contacted for follow-up assessments. Informed consent, completion enrollment paperwork, and assessments will occur in field offices in San Diego County (UC San Diego AntiViral Research Center, located at 220 Dickinson St., Suite A, San Diego, California 92103), Los Angeles County (Charles R. Drew University of Medicine and Science, Clinical and Translational Science Institute, 1731 East 120th St., Los Angeles, California 90059), Alameda County (WORLD, located at 389 30th St., Oakland, California 94609), Oklahoma City (Guiding Right Offices, 1420 NE 23rd Oklahoma City, Oklahoma 73111, 2809 NW 31st Oklahoma City, Oklahoma 73112, and 2809 NW 31st Oklahoma City, Oklahoma 73112) and Tulsa County (Guiding Right, Inc.,4619 S. Harvard Tulsa, Oklahoma 74135). Following the baseline visit, participants will be randomized using a randomization sequence at a 1:1 ratio into the intervention or control arm on a rolling basis.

All Study Visits. At all study visits (Baseline, Follow-Up 1, Follow-Up 2), participants will undergo an interviewer-administered quantitative survey and biological sample collection (hair). An increasing payment schedule will be used to enhance motivation to complete surveys. Specifically, women will receive $25 for completing the baseline visit, $30 for completing the 3-month follow-up visit, and $40 for completing the 6-month follow-up visit, with a $10 bonus for completing all 3 visits. Due to the ongoing COVID-19 pandemic, follow-up study visits may occur virtually, over the secure video conference platform Zoom. For all in-person study activities, participants and staff will be required to wear face masks and physically distance when feasible. If participants do not have access to a face mask, one will be provided to them upon entry to the private research office space. Additionally, all participants will be screened for symptoms of COVID-19 by the Research Associate one day in advance of all in-person study visits, and again upon arrival at the private research office space.

Quantitative Survey. The quantitative survey will include the following sections: (1) Demographic questions (e.g. age, biological sex at birth, gender identity, race/ethnicity, education, sexual orientation, marital status, employment, number of children, housing status, medical insurance status, food insecurity); (2) Socioeconomic status; (3) Mental health and behavioral health history (e.g. depression, anxiety, alcohol and substance use diagnosis and/or abstinence, lifetime history of trauma); (4) HIV care and treatment history (e.g. obtaining medical care, usual source of medical care, treatments, medications, insurance status, barriers to HIV treatment, self-reported adherence, adherence self-efficacy); (5) Support and Coping (e.g. social support, coping self-efficacy, ancillary support utilization); (6) Health care interactions (e.g. HIV stigma, medical mistrust) (7) Syndemic factors (e.g. interpersonal violence). [See Quantitative Survey].

Biological Sample Collection. After completion of the interviewer-administered survey at baseline, 3- and 6-month follow-up, the Project Coordinator or Research Associate (trained in hair sample collection by Dr. Gandhi) will retrieve a hair sample from participants. All participants will be compensated $25 per visit, upon completion of hair sample collection. The hair sample collection kit is comprised of scissors, piece of tin foil, two patient labels, plastic (e.g., Ziploc) bag, alcohol swabs, and desiccant pellet. The following steps will be followed for hair sample collection: (1) Clean the blades of a pair of scissors with an alcohol pad; (2) Lift up the top layer of hair from the occipital region of the scalp at the back of the participant's head. Isolate a small thatch of hair (~100 fibers of hair) from underneath this top layer; (3) Cut the small hair sample as close to the scalp as possible. For short or cropped hair, the Project Coordinator can let hair fall directly into the piece of tin foil. For braided hair, cut hair thatch from in-between braids or dread locks; (4) Keep fingers on the part of the hair that was furthest away from the scalp and put the hair sample down on an unfolded piece of tin foil; (5) Put a thin label over the end of the hair sample that was furthest away from the scalp; (6) Refold the foil over to completely enclose the hair and place a study ID label on the folded piece of foil; (7) Place the folded piece of foil inside the plastic bag and seal the bag. Hair samples will then be securely mailed to the UCSF Hair Analytical Laboratory, led by Dr. Gandhi, where liquid chromatography/tandem mass spectrometry will be used to assess antiretroviral concentrations in hair samples over the past 3 months (3cm of hair). Given the ongoing COVID-19 epidemic, all participants will also be trained in hair self-collection at their first (baseline) visit, and given labeled kits for self-collection of hair samples at home should the participant's follow-up visit occur virtually. If the follow-up visits occur virtually, study staff will arrange a date and time to pick up the hair samples at a location convenient and safe for the participant, shortly after the virtual study visit.

Medical Record Chart Abstraction

During the passive follow-up period (7-12 months post-baseline), the research team will utilize the signed Release of Information (ROI) forms and HIPAA Authorization Forms of all study participants (participant consent collected at Baseline Study Visit), in order to request medical chart data for all participants from local HIV care providers to obtain data on clinic visits, HIV viral load, and CD4 values. Data will be entered into the REDCap Electronic Data Capturing System. These medical chart data extractions will be conducted periodically, given the staggered enrollment period.

To safeguard confidentiality, for the quantitative data collection, each participant will receive a unique patient identification number (PID) and names will never be used in conjunction with PID numbers. This unique PID number will appear on the survey, tracking forms (e.g., scrip payment receipt, cell phone tracking form), locator and screening forms. Participant confidentiality will be maintained through use of the unique PID and secure networks where data are stored. All laboratory data will be electronically transferred to the UCSD Data Management Center via password protected electronic files. At the UCSD Data Management Center, all computer files will be identifiable only by the PID number.

Intervention Trial:

Treatment Conditions. Following the Baseline Visit, participants will be randomized at a 1:1 ratio to an intervention arm or control arm. The Biostatistician team will generate the randomization sequence to ensure that randomization occurs independent of the core research team. Participants will be informed of their study group assignment immediately after completion of their baseline survey.

Control Arm. Women assigned to the control arm will be connected with and will receive self-directed (non-Peer Navigation supported) treatment as usual at agencies and institutions in San Diego, Los Angeles, Alameda, Oklahoma City, or Tulsa County following the Ryan White HIV/AIDS Program standard of care (i.e., referrals to physical, dental, and mental health services; medical case management; and ancillary services [e.g., alcohol/substance use recovery, family support]). Women who are not already receiving services and do not have other means of receiving services or are not under medical case management elsewhere will be referred to care. Alternatively, women may request case management services via Ryan White HIV/AIDS Program at a preferred location.

Using the Ryan White standards of care, goals will be set to create an individual care plan related to medical care, housing, financial, and other resources as needed. Referrals will be made to appropriate services (e.g., primary care, housing, benefits counseling, transportation, food, legal services, support services) based on intake interview. Women who require a higher level of care (e.g., significant mental health concern, at risk or falling out of care) and do not have other means of receiving services or are not under medical case management elsewhere may request case management services via Ryan White HIV/AIDS Program in San Diego, Los Angeles, Alameda, Oklahoma City, or Tulsa County.

Participants requiring medical case management will have a case file that provides appropriate participant follow-up and tracking information. Case Managers will have in-person contact with all participants at least every 90 days to assess further need for services. Either the participant or the Case Manager may initiate a given contact. The case manager will have in-person or phone contact with participants at least every 30 days to discuss changes and progress towards meeting goals of the individual care plan and an in-person meeting with each participant at least once every 90 days. Participants will be re-assessed at least once every 120 days. It is important to note that the medical case management approach is self-guided versus intense peer navigation assistance, meaning that participants will learn the responsibility to move toward autonomy with their HIV care.

Intervention Arm. Women assigned to the LinkPositively intervention arm will have access to all four components of the LinkPositively app, as described below. At the baseline visit, women will be introduced to the LinkPositively application. Study staff will train participants on how to download the app onto their

smartphone, explain the five components, utilizing each component, with emphasis on contacting their assigned PN. Within the first week of participants being assigned, virtual PNs will schedule and complete a one-on-one, video intake session with the participant. During this one-on-one intake session, the PN will conduct a thorough participant needs assessment to connect her to HIV medical care via local health clinics and identify other areas of need, services of need, and assisted referrals. These areas include but are not limited to domestic violence services, mental health care, substance abuse treatment, and housing and legal support. PNs will provide trauma-informed, intensive emotional and informational support, including guidance on accessing information (e.g., agency name, address, website, contact information) about referred services.

The LinkPositively App will deploy the following interactive components:

1. Social Networking. We will develop a platform for Black WLHA with a lifetime history of interpersonal violence to connect with each other via a social networking feed (similar to Facebook). Users will create a user Social Networking Profile by choosing an alias name, avatar (virtual character to represent themselves), and include any information they wish to share about themselves. The user profiles will be monitored and protected from personal-identifying information, in order to maintain the participant's confidentiality. Within the feed, users will have the opportunity to share information, stories, and successes, as well as ask questions and advice from the other women via posts. The platform will be interactive, as users will be able to react to (via icons including thumbs up, heart, smile emoji's) and comment on user's posts. The platform content (including posts and information shared) will be monitored daily by study staff to ensure confidentiality is maintained and appropriate behavior, language, and actions are upheld. The feed will not be accessible to the PNs, in order to allow all participants to engage with each other without the bias of PNs and to limit contamination in the evaluation on the preliminary effects of the separate components of LinkPositively.

2. Education and Self-Care Tips. We will create 200-250 brief educational, self-care, and healthy living tips, as well as tips for best strategies for overcoming the effects of interpersonal violence (e.g., adverse mental health, substance abuse). Tips will rotate daily; such that 2-3 daily tips will appear in the users feed. Also, users will be able to search the database of tips using keywords. Women will be able to submit questions to study staff regarding additional education on the HIV care continuum or interpersonal violence, which will be answered by expert investigators and posted anonymously on the social networking feed for all participants to see. Additionally, to motivate participants to engage with LinkPositively, women will earn points based on use and engagement. Distinct levels with corresponding points will then unlock new features in the app. Such features will include videos that promote self-care (e.g., guided mindfulness meditation, yoga as therapy, exercise, etc.), as well as education and empowerment (e.g., testimonials from survivors of interpersonal violence), which will be embedded into the app at designated levels. These features will be unlocked for users as they meet each level. Women will be able to see their current level status and how many points they need to unlock additional self-care and educational videos and testimonials in the profile area to encourage use and engagement.

3. Resource Locator. A resource database will be developed by the study team to assist women to identify HIV, domestic violence, and other ancillary support service agencies nearby. Women will be able to search the database for specific services (e.g., HIV care; Financial, Mental Health; Substance Abuse) in a specified radius (e.g., 5 miles, 20 miles, 50 miles), which will generate a list of organizations and their characteristics, such as address, phone number, type of organization (i.e., HIV, interpersonal violence [e.g., domestic violence shelters], mental health, substance use), website URL, days/hours of operation, service eligibility requirements (if any), fee information, clinical and support services offered (e.g. HIV testing, HIV treatment, STD testing, domestic violence shelters, rape crisis centers, mental health counseling/therapy, support groups, substance use programs). By clicking on the address, the smartphone's GPS mapping app will be enabled to show user's location relative to the agency locations. Users will have the option to apply filters to the resource list by the aforementioned

characteristics, in order to display specific agencies based on desired needs or characteristics. There will also be the opportunity for users to comment and rate the agency, similar to Yelp functionality.

4. ART Self-monitoring and Reminders. Within the notification center of the app, users will receive automated medication reminders and appointment reminders, and will be prompted to respond in real time to whether or not they took their medications that day and whether or not they attended their scheduled appointments.

5. Virtual Peer Navigation. Study participants will be matched with a trained, trauma-informed virtual PN—based on shared lived experiences —who deliver this component of the intervention using a HIPPA-compliant videoconferencing software, Zoom Conference. Participants can link to their Zoom PN meeting by clicking on a link within the LinkPositively app to connect with their matched PN. First, the assigned PNs will conduct an intake/needs assessment and create goals, case plan with their assigned clients, discuss ways to maximize the effectiveness of the LinkPositively app, and link clients to HIV medical care and ancillary support services, as well as other local resources. Next, a total of 5 structured PN sessions will occur over a five-week period. Two sessions will focus on emotional intelligence: (a) increasing emotional awareness, understanding trauma and other co-occurring syndemic conditions (e.g., mental health disorders, substance abuse) including emotional responses to them, and (b) cultivating emotional regulation and distress tolerance, specific to PTSD following interpersonal violence. The third session will focus on activating social support networks, specifically, identifying and changing relationship patterns (i.e., understanding negative relationship patterns based on interpersonal violence experiences and other syndemic conditions and identification of alternative and more adaptive interpersonal schemas). The fourth session will address how interpersonal violence (e.g., power and control dynamics, disclosure of violence) can impact existing socio-structural barriers (e.g., HIV stigma, medical mistrust) and developing strategies to obtain care and support while accounting for these issues. The fifth and final session will focus on aspects of medical mistrust and discrimination in the context of HIV care and discuss skills to improve patient-provider communication. Each session will last 1 hour and occur at a convenient time for the participant. Women will be able to text/call their PN during and after the 5-week period if they have questions or seek to debrief after sessions or appointments. In the backend of the website app, PNs will enter case notes on PN sessions and check-ins, set notifications and appointment reminders, and send their assigned participants direct messages that will show up only on that participant's profile. PNs will also be able to view women's responses in the real time data on medication and appointment outcomes, to inform their upcoming session and/or check-in. In addition to video conference/phone sessions and check-ins, participants will receive automated daily medication reminder text messages, scheduled appointment alerts, and access daily postings in the education and self-care tips component of the app.

After completion of each intervention activity, participants enrolled in the intervention group will receive an email with a link to complete a brief evaluation of the intervention. Completion of this evaluation is voluntary.

Retention of Participants

AIM 1

Given that participation is only for one-time point, no retention is required for this portion of the study.

AIM 2

We expect to reach our sample size utilizing partnerships established through the UCSD Center for AIDS Research (CFAR) Disparities Core Community Advisory Board (CAB), of which Dr. Stockman is Director, and through standard outreach methods. Following other projects led by Dr. Stockman and other members of the investigative team, we expect a retention rate of at least 85% in the first follow-up visit and another 80% in the second follow-up visit. Nevertheless, we will strive to engage and maintain our sample. To do this, we will

implement tactics to improve retention. Specifically, we will: (1) Utilize an increasing payment schedule to enhance motivation to complete study visits. Specifically, women will be offered $30 and $40 for completing 3- and 6-month study visits, with a $10 bonus for completing all 3 study visits (2) collect contact information for three people (e.g., friends, family members) who would likely have knowledge of participants' whereabouts; (3) provide study cell phone number for ease of study staff calling or texting participants and participants calling or texting study staff with any questions or concerns; (4) maintain frequent contact with participants to check in about their service needs which include any linkages the study team can provide to resources in the community; and (5) as appropriate, sending text messages on participants' personal cell phone or assigned study cell phone with birthday and holiday greetings, and congratulations messages for graduations and other important events. We also will make it easy for participants to stay in touch with our team by providing a toll-free phone number, email and web addresses (in addition to the study cell phone). Given our target sample size and short follow-up period, we are confident that the aforementioned approaches will maximize retention in our study.

Data Management

Quantitative data will be managed by Dr. Jain. The study staff will be responsible for questionnaire development and coding of the survey. Through the UCSD Central and Translational Research Institute (CTRI), the research team will utilize REDCap (Research Electronic Data Capture) application for quantitative data. REDCap is a secure, password protected, HIPAA compliant web-based application for building and managing online surveys and databases. Laptop and/or tablets will be used for survey data collection using the REDCap application. Each survey file will be digitally stamped with the user, date and time of use, machine information. All computer files in the field will be automatically backed up. The project coordinator will be trained to extract and compile survey files; encrypted, password protected files will be sent weekly to Dr. Jain. Each study participant will have a unique identifier. No personal information will be recorded in the surveys. A UCSD data manager will merge all REDCap datasets together, reconcile them into a standard version, and export a final REDCap dataset into SAS or SPSS data sets, instantly ready to use by any statistical software. To ensure quality of the data collection, the data manager will make bi-weekly tracking and missing data reports. Hard copies of field notes will be maintained by the Project Coordinator in a locked filing cabinet, available to study personnel if data concerns arise. Study investigators will refer to these field notes as necessary in the coding and analysis stages. All data will be backed up daily and stored using password protection. Dr. Jain will merge data, reconcile them into a standard version, and export into a SAS dataset. Biomarker data from UCSF's HAL laboratory (hair samples), will be sent weekly to the UCSD research team via password protected electronic files.

10. HUMAN SUBJECTS

Human Subjects

Anticipated WLHA demographics to be enrolled in LinkPositively.

AIM 1

In Phase 1 (Aim 1), we will conduct focus groups (FGs) and in-depth interviews. Eligible participants will be Black WLHA (including transgender women) with a History of Interpersonal Violence (n=6-8 per FG; total of 4 FGs); Black WLHA (including transgender women) with a History of Interpersonal Violence who act in a professional capacity as a Peer Navigator (n=4-6; one FG). Key Informants (n=4-6) will be leadership at local clinics and community-based organizations known to provide services to women in the areas of HIV/AIDS care and domestic violence services such as UCSD Owen Clinic and Mental Health America. Phase 1 will culminate in usability testing, Beta Testing, by Black WLHA affected by interpersonal violence (n=8; 4 with histories of interpersonal violence perpetrated by a current or former intimate partner and 4 with histories of interpersonal violence perpetrated by a non-intimate partner [e.g., family member, friend, stranger]), to finalize intervention components and procedures.

AIM 2

In Phase 2 (Aim 2), we will conduct a randomized control trial study design with follow-up. Eligible participants will self-report: (a) female gender (including transgender women), (b) Black or African American racial/ethnic background, (c) ages 18+ years, (d) HIV-positive status, (e) ever experienced physical, sexual, and/or psychological abuse by a current or former partner or non-partner (e.g., relative, friend, stranger), (f) owner of a smartphone with internet browsing capabilities, and (g) English speaking. Purposive sampling will be used to ensure that groups are balanced with respect to type of perpetrator (current or former intimate partners [e.g., spouse, boyfriend, dating, casual] and non- intimate partners [e.g., family member, friend, stranger]) and retention in HIV medical care status (linked to care but have fallen out of care [i.e., no ART prescription filled, no viral load labs, or no HIV care visits with an ART-prescribing provider in the past year] versus linked to and retained in care [i.e., ART prescription filled, viral load labs, or HIV care visits with an ART prescribing provider in the past year]).The total possible sample size for the study will be 80 women living with HIV/AIDS (WLHA). Of 80 enrolled women, 40 will be randomized to the intervention arm and 40 will be randomized to the control arm.

Eligibility

The following eligibility criteria will apply to all WLHA enrolled into the study, including WHLA FGs, Peer Navigator FGs, Beta Testing, and the Randomized Control Trial:

Inclusion criteria:

- Aged 18 years or older
- Self-identification as a cis-gender or transgender woman
- Self-identification as Black or African American
- Living with HIV/AIDS
- Ability to speak and understand English
- Ever-experienced physical, sexual, and/or psychological abuse by a current or former partner or non-partner
- Owner of a smartphone with internet browsing capabilities

Exclusion criteria:

- Unwillingness to participate in the study
- Cognitive impairment that would limit participation with study procedures

The interviewer will assess cognitive impairment. If during the consent process, a participant appears to be suffering from paranoia, auditory hallucinations, has sporadic outbursts, or is not capable of comprehending the interview or materials, she will be excluded from the study. Although we may enroll transgender women due to ethical service-delivery considerations, we recognize that trans-tailored PN-based programs may be more ideal for this population. Additionally, although our sample is heterogeneous in terms of where they fall on the HIV care continuum, they share similar experiences with interpersonal violence, which are the communality and focus of LinkPositively- to ultimately improve outcomes along the care continuum.

11. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

Recruitment of Participants

Eligible WLHA will be identified through the following methods:

Social Media. Social media outlets, including posting information about the study on an open Facebook group (e.g., local support groups for WLHA) and online ads that appear on Facebook and Instagram. Our study team has previously been successful in recruiting hard-to-reach populations through this method. When running advertisements on social media, the comment option on advertisements will be turned off, so as to avoid inadvertently “outing” women with HIV. Additionally, Build Clinic will provide support for distribution of

advertisements via social media, using IRB-approved advertisements. Both will link interested women to a secure survey with the exact same screening content.

San Diego Center for AIDS Research (CFAR) Disparities Core. Outreach methods employed by the San Diego Center for AIDS Research (CFAR) Disparities Core will include distribution of flyers to community-based agencies that have been identified as potential recruitment locations of HIV-related research and have been included in a community partner database (n=20) housed within the San Diego CFAR Disparities Core. We will also utilize the recruitment and retention subcommittee of the Disparities Core Community Advisory Board (CAB) to promote and advertise the study and our need for Latina and Black women. The Disparities Core CAB is composed of Black and Latino health community leaders in San Diego. Specifically, the recruitment and retention subcommittee holds targeted outreach events at local community events and health fairs to speak to underserved groups, particularly, Blacks, Latinos, and American Indian/Native Americans about ongoing research and the need for their participation to address disparities in HIV research.

Newspaper Advertisements. Advertisements will be run in local newspapers. Dr. Stockman has previously had significant success with the recruitment of women of color utilizing the San Diego Reader.

Traditional Advertisements. Flyer advertisements (ads) will include banner ads and flyers that will be posted at bus stops, libraries, transitional housing facilities, social service agencies, and businesses located in central San Diego, Los Angeles, Alameda, Oklahoma City, and Tulsa communities that have at least 10% or more Black and Latino residents.

12. INFORMED CONSENT

Verbal consent to screen potential participants for eligibility will be sought from all potential participants, and receipt of verbal consent to screen will be documented by study staff. Screening will occur using a telephone screening script.

For eligible participants who choose to enroll, we anticipate that written informed consent will be obtained from all enrolled participants at the time of their in-person baseline study visit. the informed consent process will follow all relevant regulatory guidelines and will generally include both verbal and written components obtained by authorized and trained study personnel at UCSD. Documents and other communications will be developed to inform each potential research participant as clearly as possible about the potential risks, benefits and alternative approaches available for each research study. In all currently foreseeable circumstances, documentation of informed consent will be in the form of a signed and witnessed written document in a language and at a level that is appropriate to the patient population recruited. The informed consent procedure is designed to maximize the potential participant's comprehension of study procedures and to ensure that participation is voluntary. Prior to study implementation, we will seek approval from the UCSD Institutional Review Board (IRB) Committee on Human Research. The informed consent process, along with data collection will only occur in San Diego, Los Angeles, Alameda, Oklahoma City, and Tulsa counties.

In scenarios of high risk of infection (COVID-19), we are additionally requesting a Waiver of Documented Consent/Assent to obtain oral consent/assent, should we be unable to proceed with in-person data collection and consenting processes. The UCSD Human Resources Protection Program (HRPP) Institutional Review Board has classified this research as involving no more than minimal risk. Additionally, no procedures within the study require written consent outside of the research project. This will allow for the research team to enroll participants and focus groups and interviews via phone or video conference, significantly reducing the potential for exposure to infectious disease. Consent will be obtained by trained and authorized research staff. Consent will be documented by study staff obtaining informed verbal consent using an oral consent form.

13. ALTERNATIVES TO STUDY PARTICIPATION

Participants will have the option to not participate in the study. Participants who are not interested in participating in the study are welcome to take a referral list of local resources in the San Diego, Los Angeles, Alameda Oklahoma City, or Tulsa County community (e.g., legal, support groups, childcare, etc.).

14. POTENTIAL RISKS

Potential Risks

The risks associated with participation in the study are primarily psychological, given the nature of factors associated with Black WLHA with a history of interpersonal violence. These risks are discussed below:

Psychological Risks: In the treatment group (intervention arm), participants may experience psychological distress while talking about issues (e.g., adverse mental health, intimate partner violence, HIV disclosure) raised during one-on-one sessions with virtual peer navigators and phone/text check-ins. Distress may also occur when participants are not interacting with the virtual peer navigator. In the standard of care group (control arm), participants may also experience distress. Participants will be asked questions about mental health and intimate partner violence. As a result, participants may be uncomfortable or experience stress or emotional pain in responding to these questions. Participating in the intervention could also lead to self-awareness about the limitations of one's knowledge of HIV care and treatment, as well as barriers (e.g., substance use, adverse mental health, discrimination, etc.). Participants may also disclose their HIV status for the first time to peers who are enrolled and interacting on the social networking platform, which may cause psychological distress.

Physical Risks: We will collect hair samples at 3- and 6-month follow-up assessments, which could cause some physical discomfort. However, the amount of hair collected is equivalent to the daily amount of hair strands that are lost and the hair sample collection procedure itself is considered noninvasive. All research staff members will be trained by Dr. Gandhi (Consultant) in hair sample collection procedures. Confidentiality: There is potential for violation of participant confidentiality if others find out about participants' HIV status or study participation. In addition, women who may be in an abusive relationship, may be concerned that their partner will find out about their participation in the intervention. For eligible participants, as a result of participating in this study, it is possible that these participants may be identified by others, including law enforcement, such as those who may be a victim or perpetrator of violence.

There is also some risk that the study personnel will receive reports of physical abuse and violence perpetrated against participants. These incidences will be handled per mandatory reporting protocols.

Per IRB policy—violence that is related to the conduct of the protocol will be reported to the IRB as an adverse event. Violence unrelated to the protocol that is communicated during the information gathering associated with the protocol will be reported to the authorities under state law, but would not be reportable as a research-related adverse event. In the event of violence related to the study protocol, an incident report will be filed with the UCSD IRB. Also, if during the course of participating in any phase of the research study, the participant reveals current abuse/neglect or planned danger to self or others, the study personnel will report this to Dr. Stockman, who will make the appropriate referral as required by law.

Loss of Confidentiality: For eligible participants, as a result of participating in this study, it is possible that these participants may be identified by others, including law enforcement or healthcare personnel, as being a woman living with HIV/AIDS. We will conduct interviews in private locations (i.e., UCSD clinic offices). There is also a slight risk that confidentiality may be breached in the management of data, although multiple safeguards will be implemented to avoid this risk. Participants will be made aware of this risk during the consent procedure (see Data and Safety Monitoring Plan, below).

COVID-19: Given the ongoing COVID-19 epidemic, there is a risk associated with in-person study activities, during which participants could come in contact with staff or other individuals in the Webster Building who may have COVID. To mitigate this risk, all staff will undergo weekly COVID-19 testing, as per UCSD guidelines, complete a daily symptoms attestation, and utilize all appropriate personal protective equipment (facemask, faceshield, gloves, etc.). Additionally, all participants will be asked to wear at least a facemask (if the participant does not have access to a facemask, one will be provided to them), and any other protective

equipment they would like. Further, surfaces will be disinfected between all participant visits, physical distancing will be maintained whenever feasible, and no more than one participant and one staff member will occupy the study space at a given time.

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

Protections Against Risks:

Procedures for minimizing potential risk to research participants will be directed and adapted to the participants, local agencies, and interventions required for each participant. Anticipated risks include increased stress or emotional pain from study participation. Research participants will be closely monitored by experienced clinical and research staff with the goal of minimizing, recognizing and mitigating these risks to the best of our abilities throughout the conduct of the project.

There is the possibility of physical risk to other during the course of the study. Previous UCSD IRB-approved research has established procedures to manage participant reports of violence affecting WLHA. The IRB policy at UCSD is that violence that is related to the conduct of the protocol must be reported to the IRB as an adverse event, whereas violence unrelated to the protocol that is incidentally communicated during the information-gathering procedures associated with the protocol may be reportable to civil authorities under applicable laws (e.g., harm to adult or minor dependents), but would not be reportable as a research-related adverse event. In the event of violence related to our study, an incident report would need to be filed with the UCSD IRB. To date, our team has not had a single report of violence related to our other projects that have been conducted with WLHA. If, during the course of an interview, assessment, or intervention session, a participant reveals current abuse or planned danger to others, the staff member will make the appropriate referral as required by law, and immediately inform the PI, Drs. Stockman within 12 hours. Typically, the participant would be referred to mental health counseling. Dr. Stockman would file a report with the UCSD IRB within 24 hours.

Additional risks might include the loss of privacy of individuals and confidentiality of data. Procedures to minimize these risks include maintaining storage of hard copies of personally identifiable private information in limited access secure locations; assigning alphanumeric codes without personally identifiable information to all recorded or transmitted data; maintaining strict electronic data security protocols for the management of all study related electronic data. Although there is inherent risk associated with the systematic collection of any personal data, the data management protocols that have been developed within our university have been extremely effective over the past three decades. We will remain vigilant about data security and will modify our procedures in response to any perceived or real risks to breaches in the security of our data. Additionally, all audio recordings for data collection purposes will be destroyed one year after completion of the study.

We will adhere to all applicable regulatory guidelines and local laws and regulations for patient confidentiality and safety monitoring and protection. We are aware of (and have substantial experience in) the DHHS regulations and OHRP guidance (45 CFR 46) required for research involving human subjects. All research staff have been trained and certified in human subjects' protection, and certifications are updated every two years by the UCSD Office of HRPP and every three years through on-line CITI training, as required by the NIH/NIAID.

Our research and clinical staff will monitor all participants for adverse events. The first level of safety involves direct observation of and interaction with research participants by trained research personnel throughout the conduct of the study. In addition to interactions at protocol-specified visits, study participants are provided with multiple avenues of communication with research investigators and staff. These include unscheduled visits at the discretion of the study participant, telephone and internet-facilitated communication. The second level of safety involves protocol-specified visits and laboratory studies that are tied to objective severity grading scales for assessment of adverse events. All adverse events are monitored by trained research staff and reviewed with study investigators. Adverse events of protocol-specified severity grade are reported to the institutional

IRB of record, to the data management center, if applicable to the NIH and the Food and Drug Administration in accordance with institutional, regulatory and funding guidelines. Aggregated adverse events for each protocol are reviewed at specified intervals in scheduled meetings at the research unit and are reported to the IRB of record as appropriate based on regulatory guidance described above.

All investigators have completed the Human Subjects Training and Certification Program. We will ensure that all hired staff complete the same program as well, and will be provided in-depth training on all study procedures, emphasizing our roles to minimize risk to participants and study data, across all study activities. Dr. Stockman (PI), an epidemiologist, has over 15 years of experience training staff to conduct confidential and sensitive interviews with vulnerable populations, including drug users and abused women. She will oversee all aspects of the study and ensure effective dissemination of findings. Additionally, she will provide guidance on the design, implementation, data analysis, and dissemination of findings, as well as provide expertise on evaluation techniques and study implementation. In addition, the Research staff will receive extensive training in mixed methods research (e.g., informed consent, data collection, qualitative interviewing techniques, etc.) and approach questions with sensitivity and in a supportive manner. All staff are trained to connect participants to local resources (e.g., legal, support groups, childcare, etc.) that are available at reduced or no cost.

The UCSD team are established in training staff to conduct study activities (data collection and intervention sessions) in a confidential and sensitive manner that is responsive to the variability associated with interpersonal violence experiences among WLHA. Dr. Stockman will work closely with staff to support and monitor the study's activities. All project staff will be trained to approach questions with sensitivity, in a supportive manner and to provide appropriate referrals when needed. All staff conducting interviews will be trained not to press participants to answer questions that seem to be distressing to them, and sessions will be terminated if the participant becomes too distressed, too fatigued, and/or too frustrated by the effort. If participants feel they are in need of psychological/mental health services, interviewers will refer the participant to counseling services or make arrangements to connect them with another local service agency, so that they may speak with someone about their concerns. Also, if during the course of the interview, the participant reveals planned danger to self or others, or child or elder abuse, the research team will report to San Diego, Los Angeles, Alameda, Oklahoma City, or Tulsa County law enforcement officials (police department and/or Child Protective Services) in accordance with State mandated reporter timelines and procedures.

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

Data will be managed by the research team and at CFAR Biostatistics and Modeling Core, which has substantial experience with managing and analyzing data from Dr. Stockman's research projects. The following provisions will be taken depending on the data source.

Participant Data

Participant privacy will be protected during screening, study enrollment, and study sessions by conducting all procedures in a private office or meeting space at the following locations:

San Diego County: UC San Diego AntiViral Research Center, located at 220 Dickinson St., Suite A, San Diego, California 92103

Los Angeles County: Charles R. Drew University of Medicine and Science, Clinical and Translational Science Institute, 1731 East 120th St., Los Angeles, California 90059

Alameda County: WORLD, located at 389 30th St., Oakland, California 94609

Oklahoma City County: Guiding Right, Inc., offices at multiple locations including 1420 NE 23rd Oklahoma City, Oklahoma 73111, 2809 NW 31st Oklahoma City, Oklahoma 73112, and 2809 NW 31st Oklahoma City, Oklahoma 73112

Tulsa County: Guiding Right, Inc., 4619 S. Harvard Tulsa, Oklahoma 74135

All data collected from enrolled participants, including both hard copy and electronic data, will be identified only by the participant's study ID and will be protected against access by anyone except authorized staff connected to the study. Hard copy data will be stored in locked cabinets in secure offices at the Webster Building, Suite 302. Hard copy data forms and Peer Navigators notes collected will be shredded 12 months after the completion of the study. Audio recordings will be stored on an encrypted, cloud-based, secure drive. Audio records will be transcribed verbatim and de-identified, and transcriptions will be stored in the same manner as all electronic data. Audio recordings will be destroyed one year after the completion of data collection.

Electronic data, specifically participant personal information will be kept in Ripple™, a secure web application designed for the storing and management of personal identifying information of research participants. Ripple was initially developed at the University of Michigan to provide a user-friendly, web-based secure interface where research teams can centralize the storage and management of research participants' personal information, including name, participant ID, demographics, and study workflow (e.g., appointments). Participant information managed with Ripple is private and secure. This information is kept in fully encrypted format inside dedicated databases that are segregated from other Ripple accounts and thus only authorized study staff will have access to the study data. Likewise, Ripple infrastructure complies with the privacy and security guidelines of the Health Insurance Portability and Accountability Act (HIPAA), including 2048-bit data encryption in transit and at rest, automatic logoff, audit trail, daily backups in triplicate dedicated servers, firewall, custom access permission for lab members, zxcvbn password strength estimation, and enterprise administrative safeguards to prevent unauthorized staff from accessing participant information. Furthermore, Ripple is used only for storing personally identifiable information of participants and is not used to capture other research data (e.g., questionnaires, health records, etc.). This ensures that the personally identifiable information and research data are segregated. No data electronic data shall be stored on any desktop computers, laptop computers, and/or agency computers in order to maintain confidentiality of participant data and project data integrity.

All identified study records will be destroyed three years following completion of the study.

Quantitative Survey Data

The quantitative survey questionnaire development, management, and data entry will be conducted in Research Electronic Data Capture (REDCap), which is a secure web application for building and managing online surveys and databases. REDCap is provided and managed by UC San Diego Altman Clinical and Translational Research Institute (ACTRI). REDCap is available to all UC San Diego faculty and staff, and to users outside the organization who have sponsorship from UC San Diego faculty. Tablets and laptops will be used for de-identified data and quantitative survey data collection using REDCap. Each study participant will have a unique study identifier. No personal information will be recorded in the survey questionnaires. The Statistician and the Project Coordinator will be trained to extract and compile quantitative data. The Statistician will merge all data warehouses together, reconcile them into a standard version, and export a final data warehouse into a SAS dataset. No data electronic data shall be stored on any desktop computers, laptop computers, and/or agency computers in order to maintain confidentiality of participant data and project data integrity.

17. POTENTIAL BENEFITS

There may be no benefit to you from participating in this research. Some participants may experience improved health as a result of linking to HIV treatment and ancillary support services. The potential benefit to others is substantial, in terms of reduced HIV-related morbidity/mortality and HIV infections averted via HIV Treatment as Prevention (TasP) methods that could become measurably more effective as a result of this research. Although our study is not designed to reduce alcohol or drug use, WLHA who request it will be referred to substance abuse treatment services. All participants will be provided with facilitated referrals for additional services (e.g., childcare, social services). Study participants may benefit from this study by gaining a sense of community and empowerment. Additionally, participants may acquire skills to learn to cope with

interpersonal violence and navigate HIV care and ancillary support service agencies, self-confidence to navigate social support networks from other peers utilizing LinkPositively, knowledge from the EducatedPositively database (that contains healthy living and self-care tips), and social support from other peers utilizing LinkPositively. The study investigators will regularly review the unique risk-benefit ratio for each participant, with both global and local considerations in mind.

18. RISK/BENEFIT RATIO

The PI judges the potential benefits to society (through linking Black WLHA also affected by interpersonal violence to HIV treatment needed for decreases in overall HIV incidence, and supporting the deployment of coping mechanisms to better attend to the effects of interpersonal violence experiences) to outweigh the risks to participants, which have been shown to be effectively manageable through our prior research.

19. EXPENSE TO PARTICIPANT

There will be no charge to participants for any of the procedures conducted for the study or at the study office. Participants may incur treatment costs if they choose to link to medical care for their HIV diagnosis. Those costs will vary depending upon where the participant seeks care and her insurance coverage. For most participants, HIV medical care will be available at little-to-no charge through programs offered by MediCaid, MediCal, and local Ryan White-funded services. Neither the participant nor anyone else will be billed for participation in this research study.

20. COMPENSATION FOR PARTICIPATION

Participants will receive compensation, once completing each of the following:

Phase 1 (Aim 1):

- Focus Groups ($50) [24-32 participants]
- Key Informant Interviews ($50) [4-6 participants]
- Beta Testing ($50) [8 participants]

Compensation for Phase 1 participants will be $50 total.

Phase 2 (Aim 2):

- Baseline Study Visit ($25) [All participants]
- Follow-Up 1 Study Visit (3 months post-Baseline) ($30) [All participants]
- Follow-Up 2 Study Visit (6 months post-Baseline) ($40) [All participants]
- Completion of all Study Visits ($10) [All participants]
- Hair Sample Collection at Baseline, Follow-up 1, and Follow-up 2 ($25 at each visit) [All participants]

Compensation for Phase 2 participants will be up to $180.

Additionally, we will provide assistance to participants in accessing transportation to study visits in the form of a) a public transportation day pass that can be used on local buses and light rail trains throughout San Diego, Los Angeles, Alameda, Oklahoma City, or Tulsa County or b) a scheduled ride between a location of the participant's choosing to the study visit location, using rideshare service Lyft Concierge, provided via the existing University of California San Diego contract with Lyft Concierge. Should a participant choose to be provided with a ride by Lyft Concierge, the reason for the participant's visit to the study visit location will not be disclosed.

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

Investigators and Consultants

Jamila K. Stockman, PhD, MPH (Multiple Principal Investigator). Dr. Stockman is an infectious disease epidemiologist, Associate Professor, and Vice Chief in the Division of Infectious Diseases and Global Public Health in the Department of Medicine at the University of California, San Diego. She is also Director of the San Diego Center for AIDS Research Disparities Core. For the past 15 years, she has conducted quantitative, qualitative, mixed methods, and intervention research on gender-based violence, mental health, substance use, and HIV/STIs in Black women in the United States (US), Caribbean, and US-Mexico border region. Dr. Stockman's ethnic minority background has been advantageous to working with Black/African-American women in urban cities (e.g., Baltimore, Washington, DC) and Black/African-Caribbean women (e.g. US Virgin Islands) through the cultural competence and trust often required in conducting research with such populations. Specifically, Dr. Stockman served as co-investigator on the Abuse Status and Health Effects among African-Caribbean and African-American Women Study (ACAAWS; #P20MD002286), an NIMHD-funded study in collaboration between Johns Hopkins University and the University of the Virgin Islands. For the ACAAWS, Dr. Stockman created and executed the study design, data collection, analysis, and publication of data on the ACAAWS study, which examined health risk behaviors among Black/African-American women and Black/African-Caribbean women. Currently, Dr. Stockman serves as principal investigator for The ESSENCE Project (#R01HD077891), in collaboration between UC San Diego and Johns Hopkins University to evaluate the impact of environmental and physiological factors on the association between sexual violence and HIV among Black women in Baltimore, MD. Dr. Stockman has also participated in a number of health disparities-focused mentoring programs and completed a NIDA-funded Mentored Scientist Career Development Award (#K01DA031593), which provided training in the areas of qualitative, mixed methods, and intervention research. Taken together, this training and previous research experience has prepared her for this R01 grant proposal. As m-PI of the LinkPositively study, Dr. Stockman will be responsible for managing the research budget and timeline, supervising the research team, liaising with the study mPI (Dr. Horvath), co-investigator (Dr. Tsuyuki) and expert consultants (Dr. Cloitre and Dr. Gandhi), leading team meetings, overseeing the field-based research activities and troubleshoot problems occurring on-site, ensuring adequate protection of human subjects, overseeing quantitative and biological data collection, overseeing data analysis of quantitative data based on survey data, interpreting scientific findings, and disseminating scientific findings at local, national and international meetings, as well as in peer-reviewed journals.

Keith J. Horvath, PhD (Multiple Principal Investigator). Dr. Horvath is an Associate Professor in the Department of Clinical Psychology at San Diego State University. Dr. Horvath has served as PI and Co-Investigator on multiple NIH-, CDC-, and foundation-funded grants and has over a decade of experience in mHealth intervention research, HIV primary and secondary interventions, and technology use assessment. Dr. Horvath currently leads the Thrive with Me (PI: Horvath) and YouTHrive (PI: Horvath & Amico) studies, both of which are mobile responsive Web Apps that include peer support, HIV and ART informational content, and adherence self-monitoring. He recently was awarded funding from NICHD for TechStep (PI: Horvath & Reback), which is a technology-based stepped care intervention to reduce HIV risk behavior and increase PrEP uptake among transgender and other gender nonconforming youth. He is currently co-PI of a NIMH-funded pilot study, called PrEP iT!, to develop and test a mobile app to improve PrEP adherence and engagement in PrEP care among young adult MSM taking PrEP (PI: Horvath & Baker). He recently completed a NIDA-funded pilot study of a mobile app to improve ART adherence among stimulant-using MSM. Preliminary results showed strong feasibility, acceptability and significant improvement on self-reported ART adherence and reductions in stimulant use. For these studies, Dr. Horvath has worked closely with the technology development team, and therefore is highly experienced in overseeing the development of mHealth interventions from conception to the final version used in the RCT. He is experienced in administering projects (e.g., staffing, research protections, budget), collaborating with other researchers on multidisciplinary teams, and authoring peer-reviewed publications. As mPI of the LinkPositively study, he will attend weekly in-person or virtual (using Zoom) meetings with Dr. Stockman to discuss study progress and address any problems as they arise. Dr. Horvath will lead the development of the LinkPositively mobile web app, including the integration of feedback from women into the UX design of the app, the development of the back-end data capture databases, guiding internal testing of the app, creating the usability testing plan and writing the usability report, creating the onboarding protocol (i.e., the protocol for how users will be trained on the app) for the RCT, and overseeing the monitoring of the app during the RCT. Dr. Horvath will collaboratively work with

Dr. Stockman to ensure that the mobile app is community tailored and responsive, in the conduct and analysis of focus groups data, in the development of study instruments, and in analyzing and reporting of data from the RCT.

Kiyomi Tsuyuki, PhD, MPH (Co-Investigator). Dr. Tsuyuki is an Assistant Professor in the Division of Infectious Diseases and Global Public Health in the Department of Medicine at the University of California, San Diego. Dr. Tsuyuki's research aims to elucidate how social stress and violence victimization cause HPA axis dysregulation and disparities in HIV and substance use among racial and ethnic minorities. She was awarded an NIAAA Mentored Scientist Career Development Award (#K01AA025009) aimed to integrate HPA axis biomarkers with behavioral science research; this research aims to elucidate mechanisms by which social stress "gets under the skin" to cause HPA axis dysregulation and enhance susceptibility to substance misuse, violence, and HIV among Latinos. Dr. Tsuyuki also has extensive research experience examining the association between violence against women and HIV. Specifically, Dr. Tsuyuki is currently Co-I of ESSENCE Project (#R01HD077891; PI: Stockman) which is a clinical sample of Black women in Baltimore, MD. Also, she was Co-I of a study examining violence and HIV among women in Brazil (World Bank/Sexual Violence Research Initiative (PI: Stockman). Dr. Tsuyuki is an emerging investigator with expertise in community-based participatory research (CBPR) and over 10 years of health programmatic experience working with women in the U.S. and Latin America. She has expertise in socio-structural and syndemic barriers to HIV care engagement and outcomes among racial and ethnic minorities in the U.S., including Black women. Dr. Tsuyuki is involved in several social network interventions to improve HIV outcomes among marginalized populations delivered via mobile phone apps. Dr. Tsuyuki is also an active member of the Community Advisory Board for UCSD's Center of AIDS Research Disparities Core. In this role, she serves as an academic liaison for community-based organizations that conduct HIV disparities research. Relevant to the proposed project, Dr. Tsuyuki will provide expertise in community-based research, violence, and women living with HIV. Dr. Tsuyuki will be responsible for overseeing participant recruitment, assisting in data collection and statistical analyses, and the active dissemination of scientific findings via presentations at research conferences and manuscript publications.

Sonia Jain, PhD (Co-Investigator). Dr. Jain is a Professor in the Division of Biostatistics & Bioinformatics in the Department of Family Medicine and Public Health at UCSD. She earned a Ph.D. in Statistics at the University of Toronto in Toronto, Canada and has been at UCSD since 2002. Dr. Jain's specialty is clinical trials, the Bayesian statistical analysis of medical data and developing new methodology to analyze complex data. She is currently serving as the lead Biostatistician on several NIH-funded studies in HIV, substance abuse, Kawasaki Disease, and was Director of the Biostatistics Core of the DOD-funded INTRuST Consortium in PTSD/TBI. She is currently Director of Biostatistics in the Biostatistics and Modeling (BAM) Core for the Center for AIDS Research (CFAR) at UCSD and is involved in several HIV research collaborations, including serving as the Director of the Biostatistics Core of the CCTG (California Collaborative Treatment Group) clinical trial network and the "Preventing Injecting by Modifying Existing Responses" (PRIMER) study. Dr. Jain's serves as a key collaborator in these investigations and works closely in conjunction with the PIs and study team on issues related to design, conduct, monitoring, and analysis of the study. Dr. Jain currently collaborates with Dr. Stockman on a California HIV/AIDS Research Program funded Enhanced Peer Navigation Intervention for Women Living with HIV/AIDS and the ESSENCE Project (#R01HD077891). Her statistical lab has biostatistical expertise in the following areas: nonparametric Bayesian statistics, Bayesian biostatistical methods, design and analysis of clinical trials and observational studies, statistical genetics and genomics, neuroimaging, longitudinal analysis (including mixed effects modeling and generalized estimating equations), missing data imputation, time-to-event analysis, analysis of high-dimensional data, computational statistics (e.g. Markov chain Monte Carlo techniques), smoothing statistics, etc. Dr. Jain's lab has extensive collaborative experience in areas such as pulmonary disease, HIV/AIDS, substance abuse, infectious diseases,
Alzheimer's Disease, Stroke, PTSD, TBI, cancer, and radiology. Dr. Jain's unique experience makes her uniquely suited to oversee the statistical and analytical needs of LinkPositively. Relevant to the proposed project, Dr. Jain will coordinate the CFAR BAM Core to coordinate randomization, data monitoring and analysis for this study. Additionally, the BAM Core under the guidance of Dr. Jain will lead statistical design

and statistical considerations, and will oversee the randomization process, data cleaning and analyses. Lastly, the BAM Core will contribute to the interpretation and dissemination of study findings for the proposed intervention.

Marylene Cloitre, PhD (Consultant). Dr. Cloitre is Clinical Professor of Psychiatry and Behavioral Sciences in the School of Medicine at Stanford University and Associate Director of Research in the Division of Dissemination and Training at the National Center for Post-Traumatic Stress Disorder (PTSD) located at the Palo Alto VA Health Care Service. For the past 20 years, her research and clinical work has focused on PTSD and the long-term effects of trauma on social and emotional functioning. She has received funding from federal agencies continuously for the past fifteen years on the assessment and treatment of adolescents and adults who have experienced childhood abuse and traumatic loss. Additionally, Dr. Cloitre is the creator of the Skills Training in Affect and Interpersonal Regulation STAIR Program, which is an evidence-based cognitive behavioral therapy for individuals suffering from chronic and complicated forms of PTSD, as well as for individuals with PTSD and co-occurring disorders (i.e., syndemic factors such as substance use and adverse mental health). Dr. Cloitre has an ongoing collaboration with Dr. Stockman with the goal of incorporating skills training in affect and interpersonal regulation to help women living with HIV. For the proposed project, Dr. Cloitre will provide guidance in the development phase of the project as it relates to the intervention component
focusing on helping participants develop skills to cope with trauma and syndemic-related affective distress and training of Virtual Peer Navigators in this area. This intervention component will be adapted from Dr. Cloitre's ongoing work in this area. Dr. Cloitre will also provide guidance on the implementation and evaluation phases of the intervention. Dr. Cloitre will lend her expertise in the area of interpretation of study findings (working with Drs. Stockman and Horvath) and contribute to the preparation of manuscripts.

Monica Gandhi, MD, MPH (Consultant). Dr. Gandhi is a Professor of Medicine and Associate Division Chief (Clinical Operations/ Education) of the Division of HIV, Infectious Diseases, and Global Medicine at University of California, San Francisco (UCSF). She also serves as the Medical Director of the HIV Clinic ("Ward 86") at San Francisco General Hospital. Dr. Gandhi is a leading HIV physician, researcher and Director of the Hair Analytical Laboratory (HAL) at UCSF where she has pioneered the use of small hair samples to monitor patient antiretroviral (ARV) adherence and exposure. Given the limitations of self-report to monitor adherence, our methods to analyze antiretroviral concentrations in small hair samples provide an objective biomarker of adherence and exposure to treatment in HIV infected individuals. Dr. Gandhi has found that hair levels of ARVs are the strongest independent predictor of treatment outcomes in the context of HIV and have also shown a dose-dependent relationship between numbers of doses of ARVs consumed per week and concentrations in hair, enabling us to estimate the average level of adherence to ARVs based on hair levels. Moreover, Dr. Gandhi has examined the acceptability and feasibility of hair collection in a number of health settings and found hair collection and analysis to be highly feasible. Finally, she and her team have found hair levels of ARVs to increase pre-and-post adherence interventions in multiple settings. For the proposed project, Dr. Gandhi will provide guidance on the appropriate collection methods for the hair samples and training of research team staff. UCSF's HAL, led by Dr. Gandhi, will conduct the assays of antiretroviral concentrations in hair samples using sensitive methods employing liquid chromatography/tandem mass spectrometry. Lastly, Dr.
Gandhi will help in the interpretation of the ARV drug concentration data in the analytic phase of the study.

Carla Dillard Smith, MPA (Consultant). Ms. Smith is the Interim Executive Director of Women Organized to Respond to Life-threatening Disease (WORLD), a community-based HIV service organization in Oakland, CA. Since 1992, an on the ground researcher and public policy guru, Ms. Smith intimately understands the challenges facing communities to fully address the epidemic and WORLD's mission. In her role as Interim Executive Director of WORLD, Ms. Smith supports the organization's commitment to mobilize and sustain a comprehensive and inclusive HIV/AIDS support services and advocacy for women in Oakland and the East Bay. Prior to joining WORLD, Ms. Smith served as Deputy Director at CAL-PEP, where she oversaw strategic partnerships resulting in significant HIV resources in local East Bay communities, helped to launch and implement 15 community-based HIV/AIDS prevention and education projects leading to national best practice

models, and doubled as the agency's Research Director, serving as principal investigator on several behavioral research projects, including longitudinal studies, and co-authoring 10 articles recognized as evidence based practice. For the proposed project, Ms. Smith will provide her expertise in the trauma-informed and peer navigation components of the intervention. Additionally, she will provide guidance in the development and implementation of the LinkPositively smartphone web app, be available for routine meetings through the duration of the project, as well as participate in the interpretation and dissemination of scientific findings related to the pilot intervention.

Additional Research Team

Katherine M. Anderson (Clinical Research Coordinator). Ms. Anderson will serve as the liaison between the research team and the technology partners, such as communicating feedback about technical problems and functionality of the LinkPositively web app during development. She will also assist with focus group and RCT protocol development, and IRB submission. Ms. Anderson will provide feedback on the overall study implementation, lead and/or co-lead abstracts and manuscripts submitted for scientific meetings and publication, respectively.

Danielle M. Campbell (Doctoral Student). Ms. Campbell is a doctoral student in the UCSD/SDSU Joint Doctoral Program (JDP) in Public Health and Site Investigator at Charles R. Drew University of Medicine and Science and Guiding Right, Inc.. She will assist with development of the educational tips component of the smartphone app, standard operating procedures manual, and baseline and follow-up surveys. Ms. Campbell will also assist with reporting activities (e.g., progress reports to NIH and IRB continuing review), active monitoring of the intervention during the RCT, conducting periodic data checks during the RCT, data cleaning and de-identification, data analysis, and assisting with manuscript preparation and dissemination.

Alexandra Fernandez DeSoto (Research Associate). Ms. Fernandez Desoto is a Bilingual Research Associate in the Division of Infectious Diseases and Global Public Health, Department of Medicine at the University of California, San Diego. She received her Bachelor's degree in Public Health at the University of California, San Diego in 2018 and is currently enrolled in an MPH degree program at San Diego State University. Ms. Fernandez DeSoto will be responsible for administering field work activities including participant enrollment, data collection, and tracking study participants. Ms. Fernandez DeSoto will also assist with abstract and manuscript preparation and dissemination.

Wanda London (TBN), Virtual Peer Navigator. Ms. London will have a case load of 20 women each at any given time. Ms. London has a wealth of experience working with women living with HIV and navigating services for women living with HIV/AIDS in community-based organizations and HIV clinics. She has been trained by Dr. Cloitre (Consultant) in trauma-informed care. These women will function as Virtual Peer Navigators for the project via the mobile application for Black WLHA with lifetime experiences of interpersonal violence, with the goal of improving retention in care and adherence to antiretroviral medication. She will conduct initial intake assessments with participants enrolled into the intervention arm of the pilot trial. She will then provide support to participants through four weekly one-on-one video support sessions designed to build coping skills. Each session will last 1 hour. Peer Navigators will be available to participants through text messages or calls during and after the 5-week period if they have questions or would like to debrief. She will complete CITI training prior to working on the study.

To Be Named (TBN), Virtual Peer Navigator. The Peer Navigator will have a case load of 20 women each at any given time. The TBN Virtual Peer Navigator hired for this project will have previous experience serving as a Peer Navigator for women living with HIV/AIDS in community-based organizations or HIV clinics and will be trained by Dr. Cloitre (Consultant) in trauma-informed care. These women will function as Virtual Peer Navigators for the project via the mobile application for Black WLHA with lifetime experiences of interpersonal violence, with the goal of improving retention in care and adherence to antiretroviral medication. Specifically, she will conduct an initial intake assessment with participants enrolled into the intervention arm of the pilot trial. She will then provide support to participants through four weekly one-on-one video support sessions designed

to build coping skills. Each session will last 1 hour. Peer Navigators will be available to participants through text messages or calls during and after the 5-week period if they have questions or would like to debrief. The Virtual Peer Navigator will complete CITI training prior to working on the study.

22. BIBLIOGRAPHY

1. Dailey AF, Johnson AS, Wu B. HIV care outcomes among blacks with diagnosed HIV—United States, 2014. MMWR Morbidity and Mortality Weekly Report. 2017;66(4):97.
2. Centers for Disease Control and Prevention, Prevention. HIV among African Americans fact sheet. Atlanta: Author Retrieved from http://www cdc.gov/nchhstp/newsroom/docs/CDC-HIV-AA-508 pdf. 2014. Accessed February 20, 2019.
3. CDC. HIV Continuum of Care, U.S., 2014, Overall and by Age, Race/Ethnicity, Transmission Route and Sex. CDC. Published 2014. Updated July 27, 2017. Accessed February 15, 2019.
4. Center for Disease Control and Prevention. HIV Surveillance Report. CDC. Published 2016. Updated February 14, 2018. Accessed February 5, 2018.
5. County of San Diego. HIV/AIDS Surveillance Program Epidemiology Report, 2016. San Diego County Health and Human Services Agency, Public Health Services, Epidemiology & Immunization Services Branch, San Diego, CA.
6. Moore, David. Personal Communication. University of California, San Diego, HIV Neurobehavioral Research Program. March 1, 2019.
7. Breiding MJ, Smith SG, Basile KC, Walters ML, Chen J, Merrick MT. Prevalence and characteristics of sexual violence, stalking, and intimate partner violence victimization--national intimate partner and sexual violence survey, United States, 2011. MMWR Surveill Summ. 2014;63(8):1-18.
8. Hien D, Ruglass L. Interpersonal partner violence and women in the United States: an overview of prevalence rates, psychiatric correlates and consequences and barriers to help seeking. Int J Law Psychiatry. 2009;32(1):48-55.
9. Basile KC, Smith SG, Fowler DN, Walters ML, Hamburger ME. Sexual Violence Victimization and Associations with Health in a Community Sample of African American Women. J Aggress Maltreat Trauma. 2016;25(3):231-253.
10. Campbell JC, Lucea MB, Stockman JK, Draughon JE. Forced sex and HIV risk in violent relationships. Am J Reprod Immunol. 2013;69 Suppl 1:41-44.
11. Stockman JK, Hayashi H, Campbell JC. Intimate Partner Violence and its Health Impact on Ethnic Minority Women [corrected]. J Womens Health (Larchmt). 2015;24(1):62-79.
12. Draughon JE, Lucea MB, Campbell JC, et al. Impact of Intimate Partner Forced Sex on HIV Risk Factors in Physically Abused African American and African Caribbean Women. J Immigr Minor Health. 2014.
13. Cohen MH, Cook JA, Grey D, et al. Medically eligible women who do not use HAART: the importance of abuse, drug use, and race. Am J Public Health. 2004;94(7):1147-1151.
14. Dale S, Cohen M, Weber K, Cruise R, Kelso G, Brody L. Abuse and resilience in relation to HAART medication adherence and HIV viral load among women with HIV in the United States. AIDS Patient Care and STDs. 2014;28(3):136-143.
15. Machtinger EL, Wilson TC, Haberer JE, Weiss DS. Psychological trauma and PTSD in HIV-positive women: a meta-analysis. AIDS Behav. 2012;16(8):2091-2100.
16. Illangasekare S, Tello M, Hutton H, et al. Clinical and mental health correlates and risk factors for intimate partner violence among HIV-positive women in an inner-city HIV clinic. Women's Health Issues : official publication of the Jacobs Institute of Women's Health. 2012;22(6):e563-569.
17. Machtinger EL, Haberer JE, Wilson TC, Weiss DS. Recent trauma is associated with antiretroviral failure and HIV transmission risk behavior among HIV-positive women and female-identified transgenders. AIDS Behav. 2012;16(8):2160-2170.

18. Schafer KR, Brant J, Gupta S, et al. Intimate partner violence: a predictor of worse HIV outcomes and engagement in care. AIDS Patient Care and STDs. 2012;26(6):356-365.
19. Meade CS, Hansen NB, Kochman A, Sikkema KJ. Utilization of medical treatments and adherence to antiretroviral therapy among HIV-positive adults with histories of childhood sexual abuse. AIDS Patient Care and STDs. 2009;23(4):259-266.
20. Hatcher AM, Smout EM, Turan JM, Christofides N, Stockl H. Intimate partner violence and engagement in HIV care and treatment among women: a systematic review and meta-analysis. AIDS (London, England). 2015;29(16):2183-2194.
21. Anderson JC, Campbell JC, Glass NE, Decker MR, Perrin N, Farley J. Impact of intimate partner violence on clinic attendance, viral suppression and CD4 cell count of women living with HIV in an urban clinic setting. AIDS Care. 2018;30(4):399-408.
22. Cook RL, Zhu F, Belnap BH, et al. Longitudinal trends in hazardous alcohol consumption among women with human immunodeficiency virus infection, 1995-2006. American journal of epidemiology. 2009;169(8):1025-1032.
23. Cook RL, Zhu F, Belnap BH, et al. Alcohol consumption trajectory patterns in adult women with HIV infection. AIDS Behav. 2013;17(5):1705-1712.
24. Cook JA, Burke-Miller JK, Steigman PJ, et al. Prevalence, Comorbidity, and Correlates of Psychiatric and Substance Use Disorders and Associations with HIV Risk Behaviors in a Multisite Cohort of Women Living with HIV. AIDS and Behavior. 2018:1-14.
25. Cook JA, Grey DD, Burke-Miller JK, et al. Illicit drug use, depression and their association with highly active antiretroviral therapy in HIV-positive women. Drug and Alcohol Dependence. 2007;89(1):74-81.
26. Beckett M, Collins R, Burnam M, et al. Mental health and substance abuse issues among people with HIV: Lessons from HCSUS. Retrieved March 2019;1:2009.
27. Blashill AJ, Bedoya CA, Mayer KH, et al. Psychosocial Syndemics are Additively Associated with Worse ART Adherence in HIV-Infected Individuals. AIDS Behav. 2015;19(6):981-986.
28. Kuhns LM, Hotton AL, Garofalo R, et al. An Index of Multiple Psychosocial, Syndemic Conditions Is Associated with Antiretroviral Medication Adherence Among HIV-Positive Youth. AIDS Patient Care and STDs. 2016;30(4):185-192.
29. Sullivan KA, Messer LC, Quinlivan EB. Substance abuse, violence, and HIV/AIDS (SAVA) syndemic effects on viral suppression among HIV positive women of color. AIDS Patient Care and STDs. 2015;29 Suppl 1:S42-48.
30. Geter A, Sutton MY, Hubbard McCree D. Social and structural determinants of HIV treatment and care among black women living with HIV infection: a systematic review: 2005-2016. AIDS Care. 2018;30(4):409-416.
31. Sangaramoorthy T, Jamison AM, Dyer TV. HIV Stigma, Retention in Care, and Adherence Among Older Black Women Living With HIV. The Journal of the Association of Nurses in AIDS Care : JANAC. 2017;28(4):518-531.
32. Gaston GB, Alleyne-Green B. The impact of African Americans' beliefs about HIV medical care on treatment adherence: a systematic review and recommendations for interventions. AIDS Behav. 2013;17(1):31-40.
33. Pellowski JA, Price DM, Allen AM, Eaton LA, Kalichman SC. The differences between medical trust and mistrust and their respective influences on medication beliefs and ART adherence among AfricanAmericans living with HIV. Psychology & Health. 2017;32(9):1127-1139.
34. Kalichman SC, Ramachandran B, Catz S. Adherence to combination antiretroviral therapies in HIV patients of low health literacy. Journal of General Internal Medicine. 1999;14(5):267-273.

35. Gardner LI, Marks G, Metsch LR, et al. Psychological and behavioral correlates of entering care for HIV infection: the Antiretroviral Treatment Access Study (ARTAS). AIDS Patient Care and STDs. 2007;21(6):418-425.
36. Knowlton A, Hua W, Latkin C. Social support networks and medical service use among HIV-positive injection drug users: implications to intervention. AIDS Care. 2005;17(4):479-492.
37. Hall BJ, Sou KL, Beanland R, et al. Barriers and Facilitators to Interventions Improving Retention in HIV Care: A Qualitative Evidence Meta-Synthesis. AIDS Behav. 2017;21(6):1755-1767.
38. Bent-Goodley TB. Health disparities and violence against women: why and how cultural and societal influences matter. Trauma Violence Abuse. 2007;8(2):90-104.
39. Jongbloed K, Parmar S, van der Kop M, Spittal PM, Lester RT. Recent Evidence for Emerging Digital Technologies to Support Global HIV Engagement in Care. Curr HIV/AIDS Rep. 2015;12(4):451-461.
40. Bacchus LJ, Bullock L, Sharps P, et al. Infusing Technology Into Perinatal Home Visitation in the United States for Women Experiencing Intimate Partner Violence: Exploring the Interpretive Flexibility of an mHealth Intervention. J Med Internet Res. 2016;18(11):e302.
41. Klevens J, Sadowski L, Kee R, Trick W, Garcia D. Comparison of screening and referral strategies for exposure to partner violence. Womens Health Issues. 2012;22(1):e45-52.
42. Glass N, Eden KB, Bloom T, Perrin N. Computerized aid improves safety decision process for survivors of intimate partner violence. J Interpers Violence. 2010;25(11):1947-1964.
43. Tarzia L, Murray E, Humphreys C, et al. I-DECIDE: An Online Intervention Drawing on the Psychosocial Readiness Model for Women Experiencing Domestic Violence. Womens Health Issues. 2016;26(2):208-216.
44. Koziol-McLain J, Vandal AC, Nada-Raja S, et al. A web-based intervention for abused women: the New Zealand isafe randomised controlled trial protocol. BMC Public Health. 2015;15:56.
45. Pew Center. Internet/broadband fact sheet. Internet, Science & Tech. 2017.
46. Perrin A. Smartphones help blacks, Hispanics bridge some - but not all - digital gaps with whites. August 31, 2017. Website: https://www.pewresearch.org/fact-tank/2017/08/31. Accessed March 20, 2019.
47. Jabour SM, Page A, Hall SF, Rodriguez L, Shields WC, Alvanzo AA. Information and Communication Technologies Interest, Access, and Use: Cross-Sectional Survey of a Community Sample of Urban, Predominantly Black Women. J Med Internet Res. 2018;20(8):e248.
48. Muessig KE, Pike EC, Legrand S, Hightow-Weidman LB. Mobile phone applications for the care and prevention of HIV and other sexually transmitted diseases: a review. Journal of Medical Internet Research. 2013;15(1):e1.
49. National HIV/AIDS Strategy for the United States –Updated to 2020. https://obamawhitehouse.archives.gov/sites/default/files/docs/national_hiv_aids_strategy_update_2020.pdf: White House;2015. Accessed February 15, 2019.
50. Best Practices for Integrating Peer Navigators into HIV Models of Care. https://www.aidsunited.org/data/files/Site_18/PeerNav_v8.pdf: AIDS United;2015.
51. Shacham E, López JD, Brown TM, Tippit K, Ritz A. Enhancing adherence to care in the HIV care continuum: the Barrier Elimination and Care Navigation (BEACON) project evaluation. AIDS and Behavior. 2018;22(1):258-264.
52. Cabral HJ, Davis-Plourde K, Sarango M, Fox J, Palmisano J, Rajabiun S. Peer Support and the HIV Continuum of Care: Results from a Multi-Site Randomized Clinical Trial in Three Urban Clinics in the United States. AIDS Behav. 2018.
53. Steward WT, Sumitani J, Moran ME, et al. Engaging HIV-positive clients in care: acceptability and mechanisms of action of a peer navigation program in South Africa. AIDS Care. 2018;30(3):330-337.

54. Okeke NL, Ostermann J, Thielman NM. Enhancing linkage and retention in HIV care: a review of interventions for highly resourced and resource-poor settings. Curr HIV/AIDS Rep. 2014;11(4):376-392.
55. Higa DH, Marks G, Crepaz N, Liau A, Lyles CM. Interventions to improve retention in HIV primary care: a systematic review of U.S. studies. Curr HIV/AIDS Rep. 2012;9(4):313-325.
56. Cunningham WE, Weiss RE, Nakazono T, et al. Effectiveness of a Peer Navigation Intervention to Sustain Viral Suppression Among HIV-Positive Men and Transgender Women Released From Jail: The LINK LA Randomized Clinical Trial. JAMA Intern Med. 2018;178(4):542-553.
57. Cabral HJ, Davis-Plourde K, Sarango M, Fox J, Palmisano J, Rajabiun S. Peer Support and the HIV Continuum of Care: Results from a Multi-Site Randomized Clinical Trial in Three Urban Clinics in the United States. AIDS Behav. 2018;22(8):2627-2639.
58. Genberg BL, Shangani S, Sabatino K, et al. Improving Engagement in the HIV Care Cascade: A Systematic Review of Interventions Involving People Living with HIV/AIDS as Peers. AIDS Behav. 2016;20(10):2452-2463.
59. Horvath KJ, Oakes JM, Rosser BS, et al. Feasibility, acceptability and preliminary efficacy of an online peer-to-peer social support ART adherence intervention. AIDS and Behavior. 2013;17(6):2031-2044.
60. Amico K, Shato, T, Ecklund, A, Horvath, KJ. A qualitative analysis of anonymous posts and comments from the Thrive with Me (TWM) ART Adherence Intervention for HIV-positive Men who have Sex with Men (MSM) 12th International Conference HIV Treatment and Prevention Adherence; 2017; Miami, FL.
61. Stockman JK, Falvey E, Saito J. Preliminary findings from pilot phase of EmPower Women. 2018.
62. Carey-Grant C, Dillard Smith C, and WORLD. HIV Test and Treat Initiative: 2nd CHANCE (Creating a Healthy and Nurturing Community Environment). Kaiser Research Foundation;2016.

23. FUNDING SUPPORT FOR THIS STUDY

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24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

We plan to collect hair samples from participants at all study visits. The following steps will be followed for hair sample collection: (1) Clean the blades of a pair of scissors with an alcohol pad; (2) Lift up the top layer of hair from the occipital region of the scalp. Isolate a small thatch of hair (~100 fibers of hair) from underneath this top layer; (3) Cut the small hair sample as close to the scalp as possible. For short or cropped hair, the Project Coordinator can let hair fall directly into the piece of tin foil. For braided hair, cut hair thatch from in-between braids or dread locks; (4) Keep fingers on the part of the hair that was furthest away from the scalp and put the hair sample down on an unfolded piece of tin foil; (5) Put a thin label over the end of the hair sample that was furthest away from the scalp; (6) Refold the foil over to completely enclose the hair and place a study ID label on the folded piece of foil; (7) Place the folded piece of foil inside the plastic bag and seal the bag.

The hair samples will then be securely mailed to the UCSF Hair Analytical Laboratory, led by Dr. Gandhi, where liquid chromatography/tandem mass spectrometry will be used to assess antiretroviral concentrations in hair samples over the past 3 months (3cm of hair).

Given the above plan, a biological materials transfer agreement (MTA) will be secured prior to any biological sample transfer between UC San Diego and UC San Francisco.

25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

This study does not involve investigational drug(s).

26. IMPACT ON STAFF

This study does not involve nursing, laboratory, pathology, or pharmacy staff from UCSD.

The Principal Investigator, Co-Investigator, and staff are employees of the UC San Diego Department of Medicine. The co-Principal Investigator and staff are employees at the San Diego State University. The remaining Co-Investigator and Consultants are faculty at UC San Francisco, Stanford University, and leadership at WORLD (non-profit agency) in Oakland, CA.

27. CONFLICT OF INTEREST

The Principal Investigator, Co-investigators, Consultant, Project Coordinator, and staff do not have any conflicts of interest to report.

28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

This study is not cancer-related.

29. OTHER APPROVALS/REGULATED MATERIALS

The study does not require additional UCSD approvals or authorizations.

30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

This study does not require Surrogate Consent or Decisional Capacity Assessment.

Statistical Analysis Plan

The statistical plan includes measuring feasibility of delivering the intervention, the acceptability of the LinkPositively intervention, and the impact of the intervention.

Feasibility The first step in assessing feasibility of delivering the intervention was by creating a Consort flow diagram tracking screening, eligibility, decision to participate, participation at baseline, and participation at 3-month and 6-month follow-ups. The second step in assessing feasibility was to compute the percentage of participants at baseline who were retained at 3-month follow-up and 6-month follow-up, and comparing proportion trends between the intervention and control groups. We used the following retention cut-off percentages to assess feasibility: a) 90+% = strong feasibility; b) 80-89% = acceptable feasibility; c) 70-79% = modest feasibility with a need for improvement; d) <70% = unacceptable.

Acceptability We assessed acceptability of the intervention by asking participants in the LinkPositively group about: 1) the quality rating of the program/app, 2) whether or not they received the type of program/app they were anticipating, 3) to what extent the program/app met their needs, 4) whether or not they would recommend the program/app, 5) level of satisfaction with the help received; 6) whether or not the program helped them deal more effectively with their problems, 7) level of satisfaction with the program received, and 8) whether or not they would seek help from the program/app again.

These measures of acceptability were assessed at both 3-month and 6-month follow-ups. At each timepoint, we computed mean scores and standard deviations, as well as median scores and interquartile ranges, for all continuous variables. We calculated frequency and percentages for all categorical variables.

Intervention Impact To estimate the preliminary effect of the intervention on primary outcomes we examined differences by group (intervention vs control) in responses to HIV care outcomes over time, ART adherence over time, and mental health outcomes over time. Responses were collected at baseline, 3-month follow-up, and 6-month follow-up. Due to the small n's, we calculated median scores and interquartile ranges for all continuous variables, and frequency/percentages for categorical variables. These statistics were stratified by group, and trends were compared, but significance could not be calculated due to low power.