

Onboarding Positives and PrEP Users to Engage Negatives (OPPEN): Peer-driven Education to Link YMSM of Color to PrEP

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BACKGROUND

Pre-exposure prophylaxis (PrEP) uptake has been slow among young men who have sex with men (YMSM), particularly those of color who experience high rates of HIV infection in the United States. Limited PrEP knowledge, unfamiliarity with how to access PrEP, medical mistrust, and stigma are barriers to PrEP care engagement among YMSM, including those of color. Peer-driven social network interventions that train individuals as peer educators to disseminate information about HIV prevention and treatment in their social networks have been implemented to address similar barriers and improve HIV outcomes within marginalized populations. YMSM of color engaged in HIV/PrEP care often employ resilience processes to overcome barriers to HIV prevention and care. As such, training YMSM of color engaged in HIV/PrEP care as peer PrEP educators may position them as credible sources of information who can influence behavior change (i.e., PrEP care engagement) among YMSM peers of color in their social networks via their ability to disseminate culturally competent PrEP messages in the context of their personal experiences using these resilience processes to navigate barriers to care.

METHODS

This study will pilot Onboarding Positives and PrEP users to Engage Negatives (OPPEN), a peer-driven PrEP education social network intervention, and use a randomized controlled trial study design to evaluate its acceptability, feasibility, and preliminary effect on PrEP care engagement among YMSM of color in San Diego, California. YMSM of color engaged in HIV/PrEP care (i.e., indexes; N=70 with up to two-thirds engaged in PrEP care) will be enrolled and randomized (1:1) to OPPEN (N=35) or a time- and attention-matched control condition (N=35) using a randomizer programmed in REDCap. Once enough indexes are randomized to each condition to complete a small group (4-8 indexes), the trained health educator will deliver OPPEN or control sessions to the groups over five weeks. Sessions will consist of three two-hour small-group and two one-on-one one-hour booster sessions. At the end of the third session, all indexes will be given coupons to recruit YMSM peers of color in their social networks to the study (i.e., peer-recruits). Based on prior work, we assume that ~2 peers will be recruited per index and expect ~140 peer-recruits to undergo HIV testing. HIV-negative peer-recruits will learn about PrEP and be asked if they are interested in starting PrEP. Those interested in starting PrEP will then undergo the PrEP care engagement process, which includes scheduling a PrEP visit within two weeks and helping with enrollment in California's PrEP assistance and Medicaid expansion programs, if eligible and needed. Indexes and peer-recruits will complete surveys at baseline and three-month study visits. Peer-recruits will also complete brief phone check-ins one-month post-baseline. Data collected via surveys (baseline and three-month study visits) and medical records will be used to evaluate the preliminary effect of OPPEN on PrEP interest, linkage, and uptake among peer-recruits (AIM 2) and theory-based mechanisms targeted by OPPEN among indexes and peer-recruits (AIM 3). OPPEN acceptability and feasibility will be evaluated using a mixed-methods approach (AIM 4). All participants will provide written informed consent. All study procedures were approved by the institutional review board at the University of California, San Diego (UCSD).

OPPEN Intervention

Drawing on existing peer-driven social network interventions, the diffusion of innovations (DOI) and information-motivation-behavioral skills (IMB) models, and Harper et al.'s resilience framework (RF), indexes randomized to the OPPEN intervention will receive peer PrEP educator training sessions over five weeks (three two-hour small-group sessions and two one-on-one one-hour booster sessions) from a trained health educator using an intervention manual. To build indexes' capacity to conduct targeted outreach and PrEP education with YMSM peers of color in their social networks, training content and activities will include HIV/PrEP information, peer outreach and education strategies, peer-specific outreach and education planning, skills to disclose HIV/PrEP use and share experiences with HIV/PrEP care, role-playing, and support during peer outreach. Training sessions will also support indexes' dissemination of IMB-based educational PrEP messages in the context of their HIV/PrEP care experiences to (1) increase accurate PrEP information, (2) enhance personal and social motivation to

use PrEP, and (3) build self-efficacy and strengthen behavioral skills to navigate PrEP care. During Session 1, indexes will receive a binder of materials on content covered during each session to support their retention of the content covered, implementation of the knowledge and skills learned, and dissemination of accurate PrEP information and resources during peer outreach. Sessions 1-3 will occur prior to indexes' peer outreach. At the end of Session 3, indexes will receive coupons to recruit YMSM peers of color in their social networks with whom they discuss PrEP to the study. Booster sessions will occur in the first two weeks of peer outreach to support indexes' success as peer PrEP educators. To enable indexes to support one another between OPPEN sessions and during peer outreach, each small group of OPPEN indexes will be invited to join a private Facebook Group at the end of Session 1.

Control Condition

Indexes randomized to the time- and attention-matched control condition will receive a diet and nutrition focused intervention over five weeks (three two-hour small-group sessions and two one-on-one one-hour booster sessions) from a health educator trained to deliver manualized diet and nutrition content. During Session 1, indexes will receive a binder of materials on content covered during each session to support their retention of the content covered and adoption of diet and nutrition behavior change. Sessions will mirror a similar balance of didactic learning, problem solving, and skills building used in OPPEN, but will only focus on changing one's personal diet and nutrition behaviors. No information on PrEP nor training in DOI-informed peer outreach and education skills or IMB-based educational PrEP messages will be provided to indexes. At the end of Session 3, indexes will be given coupons to recruit YMSM peers of color in their social networks to the study. Indexes will be asked to inform their peers that they may be eligible to participate in a study. Indexes will not be asked to recruit peers via discussions about PrEP. Booster sessions will support indexes' success in adopting healthy diet and nutrition behaviors. To enable indexes to support one another's diet and nutrition behavior change, each small group of control indexes will be invited to join a private Facebook Group at the end of Session 1.

Recruitment

Indexes: YMSM of color engaged in HIV/PrEP care will be recruited from UCSD's HIV/PrEP clinics, ongoing UCSD studies with MSM, and other clinical settings and community-based organizations that serve YMSM in San Diego. Service providers at each recruitment site will inform potentially eligible patients/participants/clients of the study and collect contact information (via a consent to contact form) from those who are interested in learning more about the study, which study staff will use to follow-up with them within two business days. Additionally, recruitment flyers will be posted at recruitment sites and other physical and social media venues frequented by YMSM in San Diego and shared within the personal and professional networks of LGBTQ community leaders in San Diego.

Peer-Recruits: Similar to respondent-driven sampling, a chain referral sampling technique often used to engage marginalized populations, all indexes will be asked to recruit YMSM peers of color in their social networks to the study. Indexes will recruit peers using coupons provided to them by the health educator at the end of their third OPPEN or control session. Coupons will include study contact information (i.e., phone number, email address, physical address) and a coupon ID that will be used to link the peer-recruit to the index who recruited them. To facilitate timely recruitment, indexes will be asked to distribute coupons within two weeks and will be compensated for each peer they recruit who presents at the study site with a coupon (i.e., peer-recruit).

Data Collection Procedures

Data sources include surveys, social network inventories (SNIs), qualitative interviews, and medical records. In addition, qualitative interviews and OPPEN and control sessions will be audio recorded. Interview recordings will be transcribed for analysis and session recordings will be reviewed to monitor the health educator's fidelity to the OPPEN intervention and control condition content and manuals. Surveys will be programmed in REDCap and administered to indexes and peer-recruits at baseline and

three-month study visits via computer-assisted self-interviewing (CASI) to collect information on primary outcomes, secondary outcomes, and other individual characteristics. SNIs will be programmed in Network Canvas and interviewer-administered at baseline and three-month study visits to collect data on the following about YMSM peers in participants' social networks: socio-demographics, sexual orientation, relationship type, closeness, and duration, frequency of interaction, trust, support, perceived/known HIV and PrEP status, HIV/PrEP status disclosure, and conversations about sexual health behaviors, including PrEP. Qualitative exit interviews will be conducted at the end of three-month study visits with a random sample of OPPEN indexes and OPPEN peer-recruits using a semi-structured interview guide that will further assess acceptability and feasibility. Data related to peer-recruits' PrEP care visits (visit dates, laboratory results, PrEP prescription/injection) will be abstracted from their medical records. Peer-recruits will sign a HIPAA Authorization form and Release of Information (ROI) form at baseline giving the study permission to abstract PrEP-related data from their medical records.

Primary Outcome Measures

PrEP interest (AIM 2; peer-recruits only): Baseline CASIs will ask participants to use 5-point Likert scale responses (very uninterested to very interested) to indicate their interest in taking oral PrEP (*How interested are you in taking oral PrEP to prevent HIV?*) and injectable PrEP (*How interested are you in taking injectable PrEP to prevent HIV?*). PrEP interest will be defined as responses of "interested" or "very interested" for either oral or injectable PrEP.

PrEP linkage (AIM 2; peer-recruits only): Medical record evidence of a PrEP care visit date within three months of baseline. Three-month follow-up CASIs will also assess PrEP visit attendance since baseline.

PrEP uptake (AIM 2; peer-recruits only): Medical record evidence of an oral PrEP prescription or PrEP injection within three months of baseline. Three-month follow-up CASIs will also assess oral and injectable PrEP initiation since baseline.

Secondary Outcome Measures

Conversations about PrEP – DOI mechanism targeted by OPPEN (AIM 3; indexes only): Three-month follow-up SNIs will ask participants whether they talked about PrEP with YMSM peers in their social networks in the last three months. Participants will be classified as having had conversations about PrEP if they reported talking about PrEP with >1 YMSM peer in their social network. Secondary analyses will consider the proportion of YMSM peers in their social networks with whom they had PrEP conversations and changes in that proportion from baseline to follow-up.

PrEP information – IMB skills mechanism targeted by OPPEN (AIM 3; peer-recruits only): Baseline CASIs will ask participants to indicate whether 13 items included in a PrEP knowledge scale are true, false, or don't know. Item responses will be scored as correct (1) or incorrect/don't know (0) and summed to create a score such that higher scores indicate greater PrEP knowledge (range: 0-13).

PrEP motivation – IMB skills mechanism targeted by OPPEN (AIM3; peer-recruits only): Baseline CASIs will ask participants to use 5-point Likert scale responses (strongly disagree to strongly agree) to indicate how much they agree or disagree with items measuring PrEP attitudes (5 items), PrEP stigma (5 items), subjective PrEP norms (6 items), and descriptive PrEP norms (6 items). Item responses will be summed to create a score such that higher scores indicate greater motivation to use PrEP (range: 22-110).

PrEP behavioral skills – IMB skills mechanism targeted by OPPEN (AIM 3; peer-recruits only): Baseline CASIs will ask participants to use 4-point Likert scale responses (very hard to do to very easy to do) to respond to 8 items designed to measure their self-efficacy to initiate and stay on PrEP. Responses will be summed to create a score such that higher scores indicate greater PrEP self-efficacy (range: 8-32).

Session Acceptability (AIM 4; indexes only): Three-month follow-up CASIs will ask participants to use 5-point Likert scale responses (strongly disagree to strongly agree) to indicate how much they agree or disagree with 21 acceptability items related to the OPPEN/control sessions they participated in (e.g., overall rating of sessions, satisfaction with information provided and session activities, perceptions of the health educator, experiences of distress during sessions, and willingness to recommend sessions to a friend). Mean scores of participants' responses to the 21 items will be computed such that higher scores indicate greater acceptability (range: 1-5).

Session Feasibility (AIM 4; indexes only): Three-month follow-up CASIs will ask participants to use 5-point Likert scale responses (strongly disagree to strongly agree) to indicate how much they agree or disagree with 5 feasibility items related to the OPPEN/control sessions they participated in (e.g., it was easy for me to attend the sessions, it was easy for me to talk to peers in my social network after participating in the sessions). Mean scores of participants' response to the 5 items will be computed such that higher scores indicate greater feasibility (range: 1-5).

Acceptability of Interaction with Referring Index (AIM 4; peer-recruits only): Baseline CASIs will ask participants to use 5-point Likert scale responses (strongly disagree to strongly agree) to indicate how much they agree or disagree with 9 acceptability items related to their interaction with their peer (i.e., referring index) when they referred them to the study (e.g., satisfaction with, perceived helpfulness/burden of peer interactions, experiences of distress during peer interactions). Mean scores of participants' responses to the 9 items will be computed such that higher scores indicate greater acceptability (range: 1-5).

Feasibility of Interaction with Referring Index (AIM 4; peer-recruits only): Baseline CASIs will ask participants to use 5-point Likert scale responses (strongly disagree to strongly agree) to indicate how much they agree or disagree with 2 feasibility items related to their interaction with their peer (i.e., referring index) when they referred them to the study (e.g., it was easy for me to determine if PrEP was right for me after interacting with my peer). Mean scores of participants' responses to the 2 items will be computed such that higher scores indicate greater feasibility (range: 1-5).

Quantitative Data Analysis

We will compare individual- and network-level covariates of indexes by condition assignment (OPPEN vs. control) and peer-recruits by the condition assignment of their recruiting index using two-sided tests ($\alpha=0.05$). Multivariable models will include potential confounders that differ between comparison groups and are known/suspected to be related to the outcomes. Models will also consider product terms (one at a time) between the exposure of interest and these covariates to examine whether they modify OPPEN's effect. To explore differences in outcomes based on the type of care in which indexes are engaged (HIV or PrEP), we will also consider product terms that include index type (engaged in HIV care or PrEP care). Final models will exclude non-significant product terms. Analyses restricted to peer-recruits will use generalized linear mixed models (GLMMs) (categorical outcomes) and linear mixed models (continuous outcomes) to model outcomes as a function of the exposure of interest as a fixed effect with random index effects to account for correlated outcomes among peers recruited by the same index. AIM 2: We will use unadjusted and multivariable logistic GLMMs to examine OPPEN's effect on PrEP interest, linkage, and uptake among peer-recruits. AIM 3: We will use unadjusted and multivariable logistic regression to examine OPPEN's effect on reporting PrEP conversations with peers at follow-up (DOI) among indexes. We will use unadjusted and multivariable linear mixed models to examine OPPEN's effect on PrEP information, motivation, and behavioral skills scores (IMB) among peer-recruits. Findings will be used to identify content that may need refinement to bolster OPPEN's impact prior to a future efficacy trial. AIM 4: We will use unadjusted and multivariable linear regression (indexes) and linear mixed effects models (peer-recruits) to examine differences in acceptability and feasibility scores by study arm. Power: Consistent with the R34 mechanism, AIMS 2-4 are not powered to detect significant differences in outcomes by study arm.

Qualitative Data Analysis

Transcripts will be reviewed and coded by ≥ 2 team members. Consensus on iterative coding, procedures, and modifications to coding will occur through weekly team meetings. An audit trail of data collected and team meetings - time, place, and persons providing and collecting or analyzing information - will be kept throughout the study. Thematic analysis: (1) Transcripts will be uploaded into MaxQDA. (2) Team members will read through transcripts to create an initial code list based on *a priori* topics (i.e., deductive) and emerging themes (i.e., inductive). Codes will be iteratively applied and compared across participants to (a) explore and refine emergent themes and (b) contextualize relationships between participants' experiences delivering/receiving PrEP messages and PrEP interest, linkage, and uptake. (3) Through these comparisons, we will further condense participant experiences into broad themes. (4) Emergent themes will reflect observations made across participants not captured in *a priori* coding. (5) Themes will be illustrated with participants' verbatim quotes.

Triangulation and Refinement

Using a mixed-methods approach (AIM 4), we will triangulate quantitative and qualitative data on acceptability and feasibility. Specifically, qualitative data will be iteratively explored to help contextualize quantitative findings and generate unanticipated hypotheses we can explore with the quantitative data. Through this process, we will aim to identify areas of convergence and divergence as they relate to implementing OPPEN with YMSM of color. This will provide more nuanced insights into our findings and allow for the integration of the research team's interdisciplinary interpretations to further refine OPPEN prior to a future efficacy trial.