Official Title of Study: Evaluating a Structural and Behavioral HIV Risk Reduction Program for Black Men

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APPENDIX 1 – MEN Count Study Protocol

Background

The Making Employment Needs (MEN) Count intervention was originally developed and pilot tested using a community-based participatory research approach via funding from the National Institute of Mental Health Grant R21MH085614 grant in Boston, MA.[1] The MEN Count study aimed to determine the efficacy of the MEN Count intervention in terms of its impact on incident STI and heterosexual risk for HIV (i.e., unprotected sex with multiple female sex partners in the past 90 days) among Black heterosexual men (n=454). The two armed quasi-experimental evaluation study enrolled participants in either the MEN Count counseling intervention or an attention comparison group focused on stress reduction. Participants were assessed via survey and HIV/STI testing at baseline and 6- and 12-month follow-ups to test the hypotheses that MEN Count participants, relative to attention comparison participants, would: (a) report a reduction in sexual risk, as measured by unprotected sex episodes and transactional sex in the past 90 days at each follow-up; and (b) have lower incident STI across the follow-up period. This study also aimed to examine the MEN Count intervention's impact on social determinants of health outcomes including employment and homelessness, as well as the intervention's impact on expected mediators (i.e. masculinity ideologies, social-structural factors, and social-cognitive factors) of behavior change, and to explore whether these factors mediated the relationship between the intervention and study outcomes.

Methods/Design

Setting

This study primarily took place in a local STI clinic in Washington D.C.

Curriculum Development

After pilot testing, prompts were embedded into the curriculum to identify checkpoints when MEN Count case managers (CMs) should provide referrals for HIV/STI testing. Prompts were also added to help CMs inquire about the participant's employment situation, potential violence in relationships, HIV/STI testing history and managing HIV risk.

MEN Count Peer Counselors

MEN Count CMs received professional development and training opportunities related to: stress management, anger management, DC resource referrals, mental health status assessment, substance abuse or addiction detection, sensitivity training about gender and sexual identity and LGBT diversity, healthy masculinity, and case note writing.

Pilot Testing

To ensure high quality implementation in the clinic setting prior to the RCT, the MEN Count intervention and evaluation measures were piloted with 10 eligible Black men recruited from a community-based organization and stakeholder referrals in order to provide qualitative and quantitative feedback on the

[1] Raj A, Dasgupta A, Goldson I, Lafontant D, Freeman E, Silverman JG. Pilot evaluation of the Making Employment Needs [MEN] count intervention: addressing behavioral and structural HIV risks in heterosexual black men. *AIDS Care.* 2014;26(2):152-159.

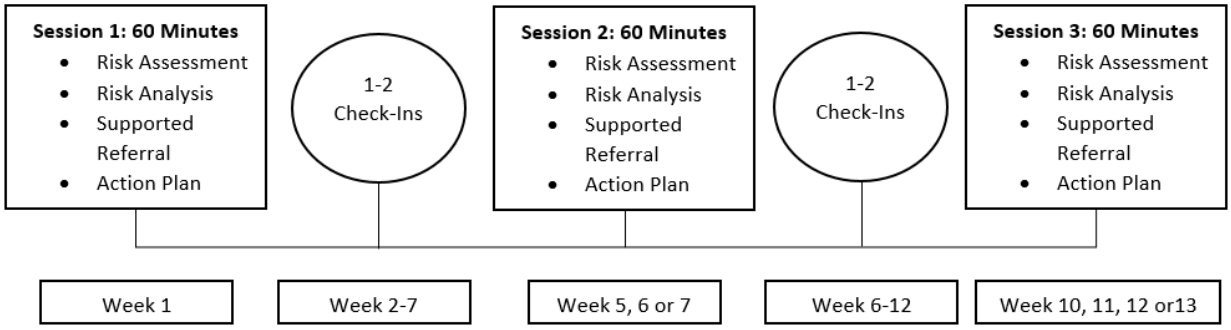
intervention and protocol procedures. Pilot participants completed the baseline survey, MEN Count intervention sessions given over the course of two months, follow-up survey and a brief interview about their response to the program. Feedback from the pilot was used to tailor the intervention to the clinic setting. Participants received $35 cash at baseline and $25 for their feedback interview.

Intervention

For the MEN Count study, participants received $30 cash at baseline and an additional $40 at six-month follow up and $50 at 12-month follow up. Clinic and study staff provided standard of care HIV/STI counseling and testing, including support for follow-up and linkage to care or treatment if a participant received a positive HIV/STI test result. To document intervention participants' understanding of how the intervention affected their HIV/STI risk and protective behaviors, in-depth interviews were conducted with a subsample of participants (10%) at follow-up, and with all study CMs to assess their perspectives on program implementation and impact. Participants received a $50 cash incentive for their participation in the 60-90 minute interview.

Each session included: 1) Personalized employment, housing stability and sexual risk assessments; 2) Guided examination of why identified risks (e.g., multiple sex partners, non-condom use) occur, considering theory-supported risk factors including traditional masculinity ideologies, substance use, mental health, and low HIV/STI knowledge and risk perceptions; 3) Identification of social or health service (e.g., substance abuse treatment and mental health services) referrals or known job opportunities to reduce concurrent sexual partnerships affected by these concerns; 4) Support for maintenance in stable job or housing situations when frustrations about these occur; and 5) Problem solving via an action plan of concrete steps the client could take to reduce non-condom sex practices and to stabilize their housing and employment; and recognition/positive reinforcement of enactment of action plans (Sessions 2&3).

Figure 1: Structure and Timing of MEN Count Intervention Delivery over 60-90 Days



"Washington D.C., 2014-2017"

Attention-Comparison Condition. The stress education and reduction program offered to control condition participants followed the same 60-90 day 3-session structure of the MEN Count intervention. This program focused on how to reduce stress and tension via diet, exercise, and effective

communication. Excluded from focus were issues of HIV/STIs, substance use, and masculinity ideologies. The program did retain linkage to job placement and housing resource provision, however.

Eligibility

At recruitment, staff screened potential study participants to assess eligibility. Eligible participants self-identified as Black or African American men, aged 18 years or older and English fluent; reported sex with two or more women in the past 12 months AND unprotected vaginal sex in the past 12 months; reported homelessness in the past 6 months (at least one night in shelter or on the streets) OR current unemployment (currently having no legal employment for money); were willing to participate in the MEN Count program, complete surveys, and be tested for STIs; and could provide contact information for themselves and two other individuals through whom we could reach them. Exclusion criteria were outlined on the basis of their potential impact on study participation or intervention testing effects. Participants were excluded from the study if they: planned to leave Washington D.C., Maryland, or Virginia in the next 6 months, were cognitively impaired (based on Folstein Mini-Mental Exam at recruitment or baseline testing), and/or had self-reported health status that prohibited them from participating in the program.

Methods for Data Collection.

Quantitative. Study staff used mobile tablet surveys to collect detailed data on participants' demographics, risk behaviors, HIV/STI risk profile, and HIV/STI knowledge, attitudes and risk perceptions. Trained research staff conducted surveys in a private room at the study site. Study participants could opt to enter their survey responses directly into the tablet survey system in real-time on their own, or study staff could enter responses. Study staff uploaded completed surveys securely and directly to a secure server system. For STI testing, researchers collaborated with a D.C. area STI clinic and established a confidentiality agreement to share participant HIV/STI test results for only those participants that enrolled in the study and consented to have their HIV/STI results shared for the purposes of this study. The STI clinic shared participant HIV/STI test results with the program manager securely on a monthly basis. In order to link baseline survey and follow-up data, surveyors uploaded research ID-assigned (i.e., de-identified) test result data to the database.

Qualitative. Qualitative interviews lasted between 45 and 60 minutes were conducted by the D.C.-based project director, a Black woman, and a Black male graduate research assistant either in-person or by phone. The semi-structured interview guide included questions designed to elicit feedback about participants' experiences with the program, including what they liked and did not like about the program, the perceived effectiveness of the program in terms of facilitating housing and employment, and ways to improve the program.

Data Management. All data collected for this study were assigned a unique identifier at each time point to facilitate linkage of longitudinal data over time. The web-based tracking system to which data were uploaded included only data with research ID numbers as identifiers.

Data Safety and Monitoring. A data safety and monitoring board was created to assure adherence to safety protocols intended to protect participants and monitor data protection efforts.

IRB

The MEN Count protocol and study materials were approved by the Institutional Review Boards at The George Washington University, The University of California San Diego, and the District of Columbia Department of Health.

Power Calculation

Power calculations were conducted based on am intended sample size of 504 and assumed two-sided tests with a 0.05 type I error rate. Power calculations were focused on reduction of STI incidence as it was the more conservative analysis. A 25% attrition rate, assumed to be high and to be expected for this population, resulted in an assumed n=378 participants at follow-up. Power calculations were based on a two-sided Poisson regression of a dependent variable of counts (i.e. number of incident STI cases) on a binary independent variable (treatment group) with proportion of 0.50 (i.e. 189 participants) in each group adjusting for age, marital status, employment and homelessness (assuming the estimated R-squared of the independent variable regressed on these four covariates is 0.04). The estimates used for these power calculations were based on a recent HIV intervention study with young Black heterosexual men recruited from STI clinics. The STI clinic study found that comparison group participants were almost 3 times as likely to be STI-infected at follow-up relative to intervention participants. MEN Count pilot data were too small to see intervention impact on STI but did document a baseline STI rate of 13% in this target population. Using these data, the proposed sample size of n=378 would have at least 80% power to detect a rate ratio (Group 1/Group 2) of at least 0.28 (intervention incidence rate=2%), 0.31(intervention incidence rate=2.5%), 0.34 (intervention incidence rate=3%) or 0.36 (intervention incidence rate=3.6%), respectively, assuming the 1-year cumulative STI incidence rate in the Comparison Group is 7%, 8%, 9%, or 10%.

Though difference-in-difference multivariate regression models were used to assess outcomes (see below), analyses were also performed as outlined by power calculation assumptions (e.g. utilizing Poisson models and specified covariates) and also found null results for the incident STI outcome.

Analytic Plan

Outcome analyses were designed to focus on four outcomes of interest (defined in greater detail below): incident non-viral STI, sexual risk, homelessness, and unemployment. The primary comparison of outcomes by treatment group was assessed using mixed-effects multivariate regression models (logistic and multinomial, dependent on outcome) with random effects on individual to account for repeated measurements over time. The treatment effect was evaluated via a time-by-treatment arm interaction term. A categorical time effect was used. This treatment effect can be interpreted as the individual-level effect of the intervention, and this analytic strategy addresses problems of attrition, missing data, variable timing of subject visits and other possible unintended violations of design common to longitudinal studies. Demographic covariates were included in all outcome models if they were significantly associated with treatment group at baseline in bivariate chi-squared tests at $p<0.20$. For each outcome, additional potential covariates were included if they were associated with the given outcome in bivariate chi-squared tests at $p<0.05$. Dose effects of the MEN Count intervention were evaluated using a similar analytic strategy, examining a time-by-dose interaction instead of time-by-study arm.

Outcome Definitions

Pursuant to previous HIV prevention research with Black heterosexual men that used ordinal index of sexual risk categorization, sexual risk was categorized as very low, low, medium, and high.[2] Very low sexual risk was defined as having one partner and consistent condom use. Low sexual risk was defined as having multiple partners and consistent condom use OR one partner and no/inconsistent condom use. Medium sexual risk was defined as having multiple partners, no/inconsistent condom use and not participating in transactional sex. High risk was defined as having multiple partners, no/inconsistent condom use, and participating in transactional sex. Participants reporting sex with men in the prior 90 days (n=20) or who reported that they themselves or (one of) their partner(s) was HIV-positive (n=31) were excluded from the sexual risk outcome analysis given the known differential HIV risk profile for these subpopulations and small numbers of participants in each.

Where data for the direct item on number of female sex partners was missing (n=1) or inconsistent with other partner-related responses (n=36 reported both main and non-main partners in this time frame, but only 1 partner on the direct item), responses to questions about having had sex with a main and other partner(s) were used. Consistency of condom use was determined based on the ratio of the number of condom protected vaginal or anal sex acts to the total number of vaginal or anal sex acts in the past 90 days. Consistent condom use was categorized as yes (number of acts with condom equal to total number of acts) or no (number of sex acts with condom use less than total number of acts). Transactional sex was defined as answering yes to any of the following items: having had sex for money, having given money in exchange for sex, having had sex for a place to stay, having had sex for drugs, or having given drugs in exchange for sex in the past 90 days.

Homelessness was characterized as at least one night of homelessness in the past 90 days. Participants were categorized as having experienced homelessness if they answered 'homeless on the streets' or 'homeless in a shelter' in response to the question 'what best describes your living situation in the past 90 days?' or if they had a non-zero response to either of two questions asking how many of the previous 90 days the participant was homeless on the streets or homeless in a shelter.

Employment was assessed via a single item asking the participant's current employment status. Participants could indicate that they were not employed, were not legally employed but had a job with income, or were legally employed full-time or part-time. Participants reporting that they were unemployed or illegally employed were categorized as unemployed.

Process Evaluation

Quality assurance and process evaluation efforts aimed to ensure a high quality program via collection of data through eligibility screeners, surveys, and brief qualitative interviews regarding program feedback. Process evaluation determined fidelity to the intervention as well as confirmed and reviewed intervention sessions delivery. A licensed clinical social worker (LCSW) on the research team provided clinical supervision to the peer case managers delivering the MEN Count intervention and control

[2] Bowleg, L., Burkholder, G. J., Massie, J. S., Wahome, R., Teti, M., Malebranche, D. J., & Tschann, J. M. (2013). Racial discrimination, social support, and sexual HIV risk among Black heterosexual men. *AIDS and Behavior, 17*, 407-418. doi:10.1007/s10461-012-0179-0

condition. Group phone meetings were held monthly (more frequently, if needed) with the case managers, along with the case manager's project manager. Initially, sessions took place every two weeks when case managers were new. As the study progressed and client sessions ended, clinical supervision session frequency diminished. Clinical supervision check-ins involved discussion of the following topics. First, any crisis "SHADE" (Suicide, Homicide, Abuse, Drugs, Eating/Health issues) situations shared with case managers since the last clinical supervision check-in were prioritized. Discussion was then held on intervention delivery (as scripted, in 1-hr period) as well as any challenges with regard to covering the session material. During this time, the LCSW shared insights gleaned from listening to the case managers' recorded sessions with clients. The LCSW provided feedback and recommendations about how to strengthen case manager sessions, ways to include intervention material, and suggested case management resources and treatment plans. Finally, the LCSW and program manager discussed any questions or challenges from case managers regarding recruitment or follow up and assisted with developing solutions (such as modifications to follow-up surveys, transportation vouchers for participants to attend sessions, and more frequent check-ins between sessions).