RUNNING HEAD: Intervention for newly HIV diagnosed MSM

The Development and Feasibility of a Brief Risk Reduction Intervention for Newly HIV Diagnosed Men who have Sex with Men

Kathleen J. Sikkema, PhD[1,2], Nathan B. Hansen, PhD[3], Arlene Kochman, MSW[2], Jonathan Santos, MSW[4], Melissa Watt, PhD[2], Patrick A. Wilson, PhD[5], Allyson DeLorenzo, MSW, MPH[2], Jay Laudato, MSW[4] and Gal Mayer, MD[4]

[1]Duke University, Department of Psychology and Neuroscience

[2] Duke University, Duke Global Health Institute

[3] Yale University, School of Medicine, Department of Psychiatry

[4] Callen-Lorde Community Health Center

[5] Columbia University, Mailman School of Public Health, Department of Sociomedical Sciences

Address all correspondence to: Kathleen J. Sikkema, Ph.D.
Duke University
Department of Psychology and Neuroscience
417 Chapel Drive
Box 90086
Durham, NC 27708-0086
kathleen.sikkema@duke.edu

ABSTRACT

Men who have sex with men (MSM) represent more than half of all new HIV infections in the U.S. Utilizing a collaborative, community based approach, a brief risk reduction intervention was developed and pilot tested among newly HIV diagnosed MSM receiving HIV care in a primary care setting. Sixty five men, within three months of diagnosis, were randomly assigned to the experimental condition or control condition and assessed at baseline, 3- and 6- month follow up. Effect sizes were calculated to explore differences between conditions and over time. Results demonstrated the potential effectiveness of the intervention in reducing risk behavior, improving mental health, and increasing use of ancillary services. Process evaluation data demonstrated the acceptability of the intervention to patients, clinic staff and administration. The results provide evidence that a brief intervention can be successfully integrated into HIV care services for newly diagnosed MSM and should be evaluated for efficacy.

Keywords: HIV/AIDS, HIV prevention, men who have sex with men (MSM), community psychology, intervention

INTRODUCTION

Men who have sex with men (MSM) represent the largest group of people living with HIV/AIDS in the United States, making up 57% of all new HIV diagnoses (Hall et al., 2008). Recent studies have documented increases in HIV risk behavior and newly diagnosed HIV infections as well as other sexually transmitted infections among MSM (Chen et al., 2002; Ekstrand, Stall, Paul, Osmond, & Coates, 1999; Rietmeijer, Patnaik, Judson, & Douglas, 2003; Sanchez et al., 2006). Based on HIV reporting data available from 33 states between 2001 and 2006, the number of reported HIV cases among MSM increased by 8.6%, while decreases in diagnoses were observed in all other transmission categories. The increase was particularly strong among minority MSM (African Americans, Hispanic and Asian/Pacific Islanders) and young MSM (aged 13-24 years) (CDC, 2008). The reemergence of the HIV epidemic among MSM is likely due in part to a shift in perception, from viewing HIV as a terminal illness to viewing HIV as a chronic, manageable condition (Jaffe, Valdiserri, & De Cock, 2007) and a resulting sense of complacency related to HIV prevention behaviors (Valdiserri, 2004). Intervening early with newly diagnosed MSM in order to introduce and sustain sexual risk reduction behaviors is of great public health significance (Weinhardt, 2005).

Prevention with persons living with HIV/AIDS (PLWHA), commonly referred to as secondary or positive prevention, has become a central component of a multi-pronged approach to fighting the HIV epidemic (CDC, 2003a). Approximately 70% of PLWHA in the U.S. are sexually active after learning of their infection (Crepaz et al., 2009), and while the majority respond to their HIV diagnosis by adopting lower risk sexual behaviors (Crepaz et al., 2009; Weinhardt et al., 2004), a substantial proportion continue to engage in high risk sexual behaviors (Bing et al., 2001; Crepaz et al., 2009; Marks, Crepaz, Senterfitt, & Janssen, 2005; Mills et al., 2006). With regard to MSM, studies indicate that over 50% of recently diagnosed MSM report sexual risk behavior within 3 – 12 months of diagnosis (Colfax et al., 2002; Gorbach, Drumright, Daar, & Little, 2006).

Evidence suggests that positive prevention efforts should target people soon after HIV diagnosis. The newly diagnosed may include those with recent infection, which confer an increased HIV-transmission potential (Koopman et al., 1997; Wawer et al., 2005) due partially to high viral load (Novitsky et al., 2010; Quinn et al., 2000) and have been linked to nearly 50% of primary infections in some predominantly MSM populations (Brenner et al., 2007). From a behavioral perspective, the first year after receiving a diagnosis appears to be a critical period for risk reduction, particularly for men (Weinhardt, 2005). An HIV positive diagnosis can serve as a "wake up call", presenting a window of opportunity to assess and change one's behavior (Valle & Levy, 2008). Health behavior theory suggests that the heightened emotions of a diagnosis and the reevaluation of one's identity can help to make an individual more ready to introduce risk reduction behaviors (Prochaska, Redding, Harlow, Rossi, & Velicer, 1994). Failure to take advantage of this "teachable moment" (Fabiano, 1993; McBride, Emmons, & Lipkus, 2003) may be a missed opportunity to reduce HIV transmission risk at a critical period.

HIV counseling and testing, the typical prevention intervention delivered to people with new diagnoses, has resulted in only modest behavior change (De Rosa & Marks, 1998; Weinhardt, Carey, Johnson, & Bickham, 1999), and reports suggest that behavioral changes are often not maintained, particularly among MSM (CDC, 2001; Crepaz & Marks, 2002; Stall et al., 2003). As HIV testing within health care settings becomes more routine (Branson et al., 2006), the resultant increase in diagnoses must be coupled with strategies to minimize ongoing transmission (Pillay & Fisher, 2007), including effective counseling for individuals who test positive (Weinhardt, 2005). The HIV medical care setting has been increasingly recommended as an important venue for delivering prevention messages and carrying out secondary prevention interventions among HIV-infected patients (CDC, 2003b; Grimley, Bachmann, Jenckes, & Erbelding, 2007; Institute of Medicine, 2001; Marks et al., 2002; Myers et al., 2010; Rose et al., 2010; Safren et al., 2010). However, barriers to positive prevention efforts include the limited availability of effective interventions and a lack of integration between prevention and

care (Metsch, Gooden, & Purcell, 2005; Morin et al., 2004), which appears to be especially true for MSM (Marks et al., 2002).

Given the disproportionate burden of HIV among MSM, the benefits of early intervention for positive prevention, and the paucity of research in this area, there is urgent need for the development and evaluation of HIV positive prevention interventions that can be delivered to newly diagnosed MSM in the HIV primary care setting. The primary objective of this study was, in partnership with a large non-profit community health center, to develop, pilot test, and assess the potential effectiveness of a theoretically-based brief risk reduction intervention to reduce HIV transmission risk among newly diagnosed MSM. We explored whether the intervention reduced sexual risk behavior, substance use, traumatic stress related to being diagnosed with HIV, and increased uptake of services offered at the community health center.

METHODS

Setting and participants

The study was conducted in collaboration with a Federally Qualified Health Center (FHQC) in New York City, specializing in care for the lesbian, gay, bisexual, and transgender (LGBT) community. The development and feasibility evaluation of this intervention utilized a community-based participatory research design, with community members and researchers as joint contributors in all phases of the project, including development of the original research questions, conduct of formative research, intervention development, participant recruitment and pilot intervention trial implementation.

Newly diagnosed MSM enrolled in the feasibility study between November 2006 and September 2007. Study inclusion criteria included: (1) diagnosis of HIV positive serostatus within the past 3 months, identified through testing at or referral to the FQHC's HIV Primary Care Clinic and receipt of HIV care at the community health center; (2) male-to-male sexual behavior or self-identification as gay or bisexual male; (3) unprotected anal intercourse (UAI) in the 6 months prior to diagnosis; (4) age 18 or older; (5) English speaking; and (6) provision of

written informed consent for study participation. Specific exclusion criteria included impaired mental status detected at screening by the Mini Mental Status Exam. All study procedures were approved by Institutional Review Boards at all collaborating organizations.

Procedures

Iterative Process to Develop the Brief Risk Reduction (BRR) Intervention. The intervention idea originated from providers at the FQHC and was formulated in collaboration with the research partners. FQHC providers were interested in a brief risk reduction intervention for newly diagnosed MSM that provided a supportive context for "positive sexuality" following an HIV diagnosis. Noting an increase in newly diagnosed MSM at the community health center, and having encountered structural barriers to lengthy prevention interventions and physician delivered interventions, the community partners were interested in an innovative approach to positive prevention that could be effectively delivered by HIV counselors. The primary responsibility of these HIV counselors was to deliver a state-defined and required pre-and post-test counseling for HIV antibody testing, including education and prevention.

A focus group with the HIV counselors (four men, two African American and two Latino, all MSM; and two women, one Caucasian and one Latina) from the FQHC was conducted. The counselors noted that the greatest concerns of newly diagnosed MSM were disclosure, health care needs and substance use. HIV counselors were concerned that the current post test counseling protocol, delivered in a single session immediately following diagnosis, was not sufficient to address sexual risk, substance abuse or the emotional needs of the men who tested HIV positive. They also noted that men who had received on-site post-test counseling often re-contacted them following their first physician appointment, wanting to talk further about their diagnosis. Thus, counselors suggested providing sessions following completion of the patient's initial physician appointment in order to discuss treatment options and tailor risk reduction strategies within their medical care plan (e.g., viral load, STI treatment, adherence counseling). Additionally, counselors felt a single session was insufficient to develop an

individually-tailored risk reduction plan that was appropriately responsive to the context of newly diagnosed men. Finally, counselors felt a booster session would be useful to troubleshoot any problems men were having with their risk reduction plan or in adapting to HIV care.

The results of the formative phase led to the development of a brief three-session intervention. The first session emphasized information relevant to the sexual health of men with a new HIV diagnosis (both medical and transmission risk information were provided in the context of positive sexuality), the second session focused on disclosure decision making, and the third session was structured to be a booster session that would address risk reduction as it relates to health or treatment related concerns. A follow up focus group with the same FQHC HIV counselors was then conducted to refine the proposed intervention approach and manual.

The intervention framework and draft manual were then reviewed by members of an ongoing FQHC support group of newly HIV diagnosed MSM. Group members' feedback was positive, and agreed that it would be most helpful to have sessions with an HIV counselor after their initial physician appointment, in order to integrate information about their lab results and treatment plan into the risk reduction counseling. Further, members said that by that time period, typically within four weeks of diagnosis, some of the shock of receiving the HIV diagnosis had subsided, the diagnosis seemed more "real" to them, and they were more ready to do something about it. Following this feedback, it was decided to initiate delivery of the intervention following the first physician visit.

Based on feedback from this iterative process, we developed a detailed intervention training manual and counselor workbook, and collaboratively named the project *Positive Choices* (*PC*). FQHC HIV counselors received intervention training and were given guidance to distinguish the intervention from their post-test counseling and tailor the content of it to the needs of newly diagnosed MSM. Counselors completed three 90 minute training sessions, after which they demonstrated adequate familiarity with the session content and intervention protocol. Throughout the intervention process, counselor feedback was solicited and incorporated when

possible within the intervention framework, meeting regularly with the project director to monitor intervention fidelity.

Pilot intervention trial design. Potential participants were informed of the study by HIV test counselors following receipt of diagnosis or during their first post-diagnosis visit with a clinic nurse and/or case manager. Men who were interested in participating were referred to the study coordinator and screened for study eligibility. If eligible, the baseline assessment was administered, and participants were then randomly assigned to the intervention or control condition. After completion of the three-session intervention, and three months after the baseline, a post-assessment was administered. A follow-up assessment was administered three months later, at month six of study participation. Intervention condition participants also completed a four-item evaluation of the helpfulness and appropriateness of the intervention. Following the completion of intervention delivery with all participants, a brief survey was conducted with senior administrators, clinic staff, and intervention counselors to assess the feasibility of integrating the intervention into the HIV primary care setting.

Measures

Outcome measures were administered using a computer assisted survey instrument (CASI) at baseline, 3- and 6- month follow up. At baseline, the 3-month retrospective period captured all behavior post diagnosis, with some possible overlap pre- HIV diagnosis for a small number of participants. The average time period from date of diagnosis to the baseline assessment was 2.5 months.

Sexual risk behavior. At each assessment point, participants reported the number of sexual partners and frequency of unprotected anal intercourse (UAI) with both primary and non-primary partners, by HIV serostatus, in the past three months. Due to small sample size and focus on intervention feasibility, counts of UAI were summed across all sexual partners.

Alcohol and substance use was assessed by asking participants to report on the quantity and frequency of alcohol and substances over the previous three months (Halkitis & Parsons,

2002). Substances included alcohol, crack/cocaine, methamphetamine, marijuana, amyl nitrate (poppers), club drugs, and heroin.

Traumatic stress specific to the HIV diagnosis was measured using the Impact of Events Scale-Revised (IES-R) (Weiss, 1996). This 22-item scale assesses the experience of posttraumatic stress for any specific life event and its context. The IES-R measures three categories of traumatic reactions: intrusive experience, such as ideas, feelings or bad dreams in relation to a traumatic event (e.g. "I thought about it when I didn't mean to," "I had waves of strong feelings about it;" α=0.79, current sample), avoidance of certain ideas, feelings, and situations (e.g. "I stayed away from reminders of it," "I tried not to think about it;" α=0.88, current sample), and hyperarousal, such as feeling keyed up or on edge (e.g., "I felt irritable and angry," "I was jumpy and easily startled;" α=0.88, current sample). All questions were asked in relation to the respondent's recent HIV diagnosis, and how often they experienced the symptoms over the previous seven days.

Participants reported having been diagnosed with or experiencing physical symptoms associated with *sexually transmitted infections (STIs). Service utilization* was assessed with questions about the frequency of using various services offered at the FQHC (e.g. case management, support groups, mental health and substance abuse services) over the past three months. CD4 counts and viral load at time of diagnosis were extracted by medical record review.

Intervention

Participants in the control condition received the FQHC's comprehensive standard of care (C-SoC), which included regular meetings with nurses, cases managers, and physicians, referrals for mental health and substance abuse providers, and optional participation in a newly diagnosed support group. Health promotion behaviors, related primarily to medication adherence, were addressed during clinic visits with all patients, but a standard prevention intervention was not offered in routine medical care.

Participants in the experimental condition received the C-SoC, plus the brief risk reduction intervention entitled *Positive Choices* (*PC*). The *PC* intervention consisted of three 60 minute individual sessions; typically the first two sessions were delivered within two weeks after the initial physician visit and the third session one month later. All sessions were delivered by FQHC HIV counselors or social workers and included components centered on principles from the Information, Motivation and Behavior Skills (IMB) model, including relevant information, motivation enhancement, and development of behavioral skills (J. D. Fisher & Fisher, 1992).

Sessions one and two focused on developing a personalized risk reduction plan through: 1) delivering information relevant to sexual health in newly diagnosed MSM, such as increased transmission risk with high viral load (e.g., acute infection, STI symptoms), increased risk in relation to substance abuse, the importance of HIV disclosure, and strategies to maintain healthy sexual relationships while living with HIV; 2) increasing motivation for transmission risk reduction by instilling a sense of personal vulnerability to the consequences of risk behaviors and a sense of personal responsibility for protecting the health of others; and 3) developing behavioral skills for health protection such as disclosure decision-making and communication skills, and self management skills around substance abuse. Session three was a booster session to review the personalized risk reduction plan over the previous month and address integration of risk reduction into the overall treatment plan, address barriers to implementation, and practice communication skills that can aid the participant in the HIV primary care setting.

Each counselor completed a quality assurance (QA) worksheet detailing the extent to which content, skills, and exercises to be covered within each intervention sessions were addressed. Adherence to the PC intervention protocol was high, with 91% of the protocol covered specific to each session, and all of the intervention components covered over the course of the three sessions. Intervention exposure was also high with participants attending an average of 2.7 sessions; 86% attended all three intervention sessions.

Data analysis

Since this was an intervention development and feasibility study, it was not powered for statistical comparisons between conditions. Therefore, we present three categories of data to support the feasibility, potential effectiveness, and acceptability of the PC intervention. First, we present descriptive data that supports the need for brief risk reduction interventions for newly HIV diagnosed men. Second, to examine the potential effectiveness, we computed the effect sizes (Cohen's *d*) (Cohen, 1988; Cohen, 1992) for each study outcome variable in each of the study conditions and then compared the difference in the effect sizes between the two intervention conditions. The effect size was computed by dividing the difference between the mean at time 1 (baseline) and the mean at time 2 (3-month follow up) by the pooled standard deviations; and doing the same for time 1 (baseline) and time 3 (6-month follow up). Third, we present process data from the implementation of this study that support the feasibility and acceptability of the PC intervention from both patient and provider perspectives.

RESULTS

Description of sample

Sixty five participants were enrolled in the pilot trial and randomly assigned to the intervention (n=35) or control (n=30); 53 men completed the 3-month follow-up (82% retention) and 50 completed the 6-month follow up (77% retention). Additionally, 31 of the intervention participants (89%) completed the intervention process evaluation. Participants' mean age was 32.4 years (s.d.=7.8). The sample included 51% who identified as white (a quarter of them recent Eastern European immigrants), 20% African American, 12% Hispanic or Latino ethnicity, 11% mixed race, 5% Asian and 1% Pacific Islander. The mean education was 14.7 years.

One-half of participants were likely recently infected, based on a negative HIV test result within the past 12 months. Viral load (mean=117,945 copies per mL; SD=194,130; range 400 to >750,000: 28%>=100,000; 44%>=50,000; and 76%>=10,000) and CD4 counts (mean=515; SD=243; range 18-1112 with 42% > 500) at time of diagnosis also suggested that many participants were in the earlier stage of infection, including high viral loads indicative of the

potential for increased risk of transmission. Among those with a negative HIV test within the past six months, 37% had viral loads greater than 100,000 copies per mL.

Screening data

Over the 10-month referral period, 204 men who tested HIV positive (120 from the FQHC and 84 from external sources referred to FQHC for HIV primary care) were informed of the study. Ninety men expressed interest in study participation and 84 were screened for study eligibility; 69 men were eligible and 65 men (77% of those screened) enrolled in the study. Among the 65 eligible participants, substance use was normative, with 99% reporting substance use in the six months before the HIV diagnosis, and 90% in the three months prior. Almost 90% reported use of substances co-occurring with sexual behavior in the six months prior to diagnosis. In the three month period prior to receiving an HIV diagnosis, study participants reported high levels of HIV risk behavior. All were sexually active in this three month period, with an average of 13.6 partners (s.d.=47.8; median=3.0; range 1 - 300) and 21.3 anal intercourse occasions (s.d.=64.6; range 0 - 400). Almost all (90%) reported unprotected anal intercourse (UAI) in the three months prior to diagnosis (inclusion criteria was UAI in 6 months prior to HIV diagnosis), with an average of 13.1 occasions of UAI (s.d.=43.3).

Baseline data

Behavioral and psychosocial baseline data, collected on average 2.5 months post HIV diagnosis, are provided in Table 1. Following the HIV diagnosis, nearly three-fourths of the men were sexually active and over 55% reported UAI. Of the 27 men who reported primary partners, 60% said their primary partners were HIV-negative, and 56% of those reported that they engaged in UAI with these primary partners (14% of the full sample). Of the 39 men who reported non-primary partners, 73% reported UAI with at least one of those partners. Co-occurring sexual activity and substance use was common, with frequent alcohol use, and over one-third reporting any use of substances other than alcohol (methamphetamine, cocaine, marijuana and club drugs).

Preliminary outcomes for 3- and 6- month follow-up

Follow-up data for participants who completed all three assessments (n = 50) are presented by condition over time (Table 2). Effect sizes (Cohen's *d*) for each condition, and the differences between the condition effect sizes, demonstrate the potential effectiveness of the intervention in comparison to the control in terms of risk behavior and mental health indicators.

As shown in Table 2, substantial differences between effect sizes were observed in risk behaviors (number of partners, frequency of UAI, and alcohol use) between the two conditions at three-month follow-up. Participants in the control condition reported an increased frequency of UAI and alcohol use, while participants in the *PC* intervention condition reduced their number of sexual partners and use of alcohol, even while increasing overall rates of sexual activity. *PC* intervention participants reported a slight decrease in frequency of UAI, but no apparent change in substance use. While the percent of *PC* intervention participants reporting current STI symptoms increased only slightly, control participants almost doubled in report of STI symptoms. Finally, *PC* intervention participants reported greater reductions in traumatic stress (IES-R), and a large increase in services utilized within the FHQC.

The *PC* intervention effects were similar at six-month follow-up. As shown in Table 2, *PC* intervention participants continued to report greater reductions in sexual risk behavior, including frequency of UAI, and less frequent alcohol use compared to control participants, while control participants reported increases in sexual risk behavior. *PC* intervention participants also demonstrated reductions in substance use and traumatic stress, and increased service utilization.

Process evaluation

PC participants provided a very favorable assessment of the intervention. All participants agreed or strongly agreed with all items: 75% strongly agreed and 25% agreed that their experience with the program was positive and they felt supported as a newly diagnosed person; 60% strongly agreed and 40% agreed that each session was appropriate to his needs; and 80%

strongly agreed and 20% agreed that they would recommend this program to a newly HIV+ person. Open-ended comments were overwhelmingly positive, suggesting that the counselors were “very supportive” and “helpful.” For example one participant wrote: “I enjoyed participating in this study…it brought me to think about where I am in dealing with my situation and the impact it has on others.”

Staff and administrators gave further support to the intervention. Three-quarters of the staff and administrators responded that they felt all the following statements were “very true” (4 on a 4-point scale): 1) *PC* enhances the current services offered at the clinic; 2) *PC* program fits well into the structure of the clinic; and 3) I would like to see *PC* program continue at the clinic. Of the five administrators, four said statements regarding the sustainability of the intervention were “very true” and one said all statements were “true”. Items included (paraphrased): If our research shows that *PC* is beneficial, we will: 1) plan to integrate into our current services; 2) work with available resources to allocate existing funds to implement the program; and 3) be willing to seek out additional funds to implement the program (if necessary). The HIV counselors also strongly endorsed the intervention content with all rating the following items “very true”: 1) the *PC* workbook is a good tool to discuss risk reduction; and 2) *PC* is easily adaptable into my work as a counselor.

DISCUSSION

This study examined the feasibility of an HIV primary care-based risk reduction intervention for newly HIV diagnosed MSM. The findings support our conceptual framework that an intervention to reduce sexual risk behaviors post-diagnosis may help avert new HIV infections by maximizing a window of opportunity that arises soon after receiving an HIV positive diagnosis. During the period after an HIV diagnosis, people re-assess their identity and behaviors, and may be more willing to integrate changes in sexual behavior (Prochaska et al., 1994), while adjusting to new aspects of their sexuality as an HIV positive person. Consistent with the literature, many individuals in our study reduced risk behavior immediately post

diagnosis (Bing et al., 2001; Nicole Crepaz et al., 2009; Marks et al., 2005; Mills et al., 2006). However, continued transmission risk behavior was evident among a subset of this high risk sample. This is of particular public health significance as a large proportion of our sample was likely recently infected with HIV and a significant portion had a high viral load. Effect sizes across outcome variables demonstrated the potential effectiveness of the intervention, and our findings demonstrate the feasibility and acceptability of collaboratively conducting an efficacy trial of this nature in a community-based health center.

Participants in the *PC* intervention, in comparison to control participants who received only comprehensive standard of care services, reported greater reductions in sexual risk behavior and alcohol use, fewer STI symptoms, less traumatic stress, and an increase in clinic service utilization. These impacts were mostly maintained at the six month follow up, suggesting the potential for a longer term benefit of early intervention. Reductions in substance use, improvements in mental health, and increased uptake of ancillary services (such as case management, mental health services, and substance use treatment referrals) could be independent or related outcomes following the *PC* intervention. These secondary outcomes support the need to focus on the mental health and substance abuse issues of newly diagnosed men, which may in part explain their high risk sexual behavior. Previous research has demonstrated that addressing psychological coping in HIV-positive people resulted in reductions in sexual transmission risk behavior (Sikkema et al., 2008) and substance use (Meade et al., 2010). Although the *PC* intervention did not have a comprehensive focus on mental health, the intervention did reduce symptoms of traumatic stress, which may in part be responsible for the impact of the intervention on sexual behavior. Future studies should be designed to examine mediators of effective positive prevention interventions, in order to increase our understanding of the causal mechanisms through which these interventions work (Sikkema et al., 2010). Health behavior theory informs many of our interventions, and theoretical constructs such as motivation and behavioral skills from the Information-Motivation-Behavioral Skills (IMB) model

(Fisher & Fisher, 1992), self efficacy from the Social Cognitive Theory (Bandura, 1986), and attitudes and intentions from the Theory of Reasoned Action (Fishbein, Ajzen, Albarracin, & Hornik, 2007), need to be examined as mechanisms of behavior change. In addition, as positive prevention interventions increasingly respond to the call to be multi-dimensional in their approach (Fisher, Smith, & Lenz, 2010), we should employ sophisticated evaluation designs that allow us to parcel out the impact of different intervention components.

The study has several limitations. First, as a feasibility study, the sample size is small and findings are preliminary. Second, due to the limited sample size, unprotected anal intercourse (UAI) was summed across relationship status and partner serostatus. Future studies with larger sample sizes should examine sexual risk behavior by partner serostatus (HIV positive, HIV negative or unknown serostatus). Third, while the retrospective period for sexual behavior was three months, not all participants completed the baseline assessment three months post diagnosis. Thus, it is possible that sub-portions of the behavioral risk at baseline occurred before the participant had confirmed knowledge of his HIV diagnosis. Related to this issue, we defined a new diagnosis as occurring within the prior three months, and initiated intervention at approximately three months after receiving an HIV diagnosis for methodological reasons (sufficient period of time to assess behavioral risk) and to provide an initial adjustment period. It is possible that the intervention would be more appropriate sooner after diagnosis for some, including before any transmission risk behavior occurs, and beyond three months for others who may be experiencing other stressful events related either to the HIV diagnosis or life chaos that necessitates stabilization. Future research should address this question, as well as the impact of this type of intervention on adherence to medical care and antiretroviral treatment, given the potential for suppression of viral load as a prevention strategy. Fourth, the effect sizes for reducing sexual risk were relatively small. However, the effect size differences between conditions were moderate for some variables (.47 and .44 for UAI at 3 and 6 month follow-up), and, to date, positive prevention interventions have shown limited effects with MSM. For

example, a meta-analysis of 15 HIV positive prevention randomized trials reported a small (d = 0.16), but significant positive effect of the interventions with MSM in reducing unprotected sexual transmission risk behavior (Johnson, Carey, Chaudoir, & Reid, 2006). The more successful interventions, which included both motivational and skill-building components, had somewhat larger effects (d = 0.32). HIV positive MSM appear to benefit less from such existing interventions (Johnson et al., 2006). It is also important to note that although *PC* intervention participants reported greater reductions in risk behavior, since there were differences between conditions at baseline, actual frequency of risk behaviors were not necessarily different at follow up. Lastly, since the study was conducted in a large community-based health center serving a diverse patient population in a major city, the results may not generalize to other HIV primary care settings. Further tailoring to community norms and social context may be needed in future research.

Importantly, the conduct of this feasibility trial demonstrated the value of a collaborative, community-based approach to behavioral health intervention research (Bogart & Uyeda, 2009). The successful collaboration between research and community partners was evident throughout all phases of the project. This included the development and refinement of the research question and intervention content, enrollment of racially and ethnically diverse high risk MSM, fidelity to the intervention as delivered by FQHC HIV counselors, and positive feedback from both participants and FQHC staff and administration regarding the acceptability of the intervention and the potential for translation of the research into practice. The preliminary data suggest that an efficacy trial is warranted and the collaborative research process that included university and community partners demonstrated the feasibility of conducting a larger trial of this nature. The field would benefit from a full scale randomized controlled trial to draw more determinative conclusions about the ability of the *Positive Choices* intervention to reduce HIV transmission risk behavior among newly diagnosed MSM.

ACKNOWLEDGEMENTS

This research was supported by a supplement to P30-MH66294, the Duke CFAR (P30-AI064518), R01-MH078731, and the Gilead Foundation. We gratefully acknowledge Sharon Neufeld and Baishakhi Taylor for data management and analysis, our longstanding collaboration with the Callen-Lorde Community Health Center, and the individuals who offered their participation in this study.

References

Bandura, A. (1986). *Social foundations of thought and action : a social cognitive theory*. Englewood Cliffs, N.J.: Prentice-Hall.

Bing, E. G., Burnam, M. A., Longshore, D., Fleishman, J. A., Sherbourne, C. D., London, A. S., et al. (2001). Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States. *Arch Gen Psychiatry, 58*(8), 721-728.

Bogart, L. M., & Uyeda, K. (2009). Community-based participatory research: partnering with communities for effective and sustainable behavioral health interventions. *Health Psychol, 28*(4), 391-393.

Branson, B. M., Handsfield, H. H., Lampe, M. A., Janssen, R. S., Taylor, A. W., Lyss, S. B., et al. (2006). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep, 55*(RR-14), 1-17; quiz CE11-14.

Brenner, B. G., Roger, M., Routy, J. P., Moisi, D., Ntemgwa, M., Matte, C., et al. (2007). High rates of forward transmission events after acute/early HIV-1 infection. *J Infect Dis, 195*(7), 951-959.

CDC. (2001). Primary and secondary syphilis--United States, 1999. *MMWR Morb Mortal Wkly Rep, 50*(7), 113-117.

CDC. (2003a). Advancing HIV prevention: new strategies for a changing epidemic--United States, 2003. *MMWR Morb Mortal Wkly Rep, 52*(15), 329-332.

CDC. (2003b). Incorporating HIV prevention into the medical care of persons living with HIV. Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. *MMWR Recomm Rep, 52*(RR-12), 1-24.

CDC. (2008). Trends in HIV/AIDS diagnoses among men who have sex with men--33 States, 2001-2006. *MMWR Morb Mortal Wkly Rep, 57*(25), 681-686.

Chen, S. Y., Gibson, S., Katz, M. H., Klausner, J. D., Dilley, J. W., Schwarcz, S. K., et al. (2002). Continuing increases in sexual risk behavior and sexually transmitted diseases among men who have sex with men: San Francisco, Calif, 1999-2001, USA. *Am J Public Health, 92*(9), 1387-1388.

Cohen, J. (1988). *Statistical Power Analysis for the Behavioral Sciences* (2nd ed.). Hillsdale: Lawrence Erlbaum Associates, Inc.

Cohen, J. (1992). A power primer. *Psychological Bulletin, 112*(1), 155-159.

Colfax, G. N., Buchbinder, S. P., Cornelisse, P. G. A., Vittinghoff, E., Mayer, K., & Celum, C. (2002). Sexual risk behaviors and implications for secondary HIV transmission during and after HIV seroconversion. *AIDS, 16*(11), 1529-1535.

Crepaz, N., & Marks, G. (2002). Towards an understanding of sexual risk behavior in people living with HIV: a review of social, psychological, and medical findings. *AIDS, 16*(2), 135-149.

Crepaz, N., Marks, G., Liau, A., Mullins, M. M., Aupont, L. W., Marshall, K. J., et al. (2009). Prevalence of unprotected anal intercourse among HIV-diagnosed MSM in the United States: a meta-analysis. *AIDS, 23*(13), 1617-1629.

De Rosa, C. J., & Marks, G. (1998). Preventive counseling of HIV-positive men and self-disclosure of serostatus to sex partners: new opportunities for prevention. *Health Psychol, 17*(3), 224-231.

Ekstrand, M. L., Stall, R. D., Paul, J. P., Osmond, D. H., & Coates, T. J. (1999). Gay men report high rates of unprotected anal sex with partners of unknown or discordant HIV status. *AIDS, 13*(12), 1525-1533.

Fabiano, P. (1993). Peer-based HIV risk assessment: a step-by-step guide through the teachable moment. *J Am Coll Health, 41*(6), 297-299.

Fishbein, M., Ajzen, I., Albarracin, D., & Hornik, R. C. (2007). *Prediction and change of health behavior : applying the reasoned action approach*. Mahwah, N.J.: L. Erlbaum Associates.

Fisher, J. D., & Fisher, W. A. (1992). Changing AIDS-risk behavior. *Psychol Bull, 111*(3), 455-474.

Fisher, J. D., Smith, L. R., & Lenz, E. M. (2010). Secondary Prevention of HIV in the United States: Past, Current, and Future Perspectives. *JAIDS Journal of Acquired Immune Deficiency Syndromes, 55*, S106-S115 110.1097/QAI.1090b1013e3181fbca1092f.

Gorbach, P. M., Drumright, L. N., Daar, E. S., & Little, S. J. (2006). Transmission behaviors of recently HIV-infected men who have sex with men. *J Acquir Immune Defic Syndr, 42*(1), 80-85.

Grimley, D. M., Bachmann, L. H., Jenckes, M. W., & Erbelding, E. J. (2007). Provider-delivered, theory-based, individualized prevention interventions for HIV positive adults receiving HIV comprehensive care. *AIDS Behav, 11*(5 Suppl), S39-47.

Halkitis, P., & Parsons, J. T. (2002). Recreational drug use and HIV-risk sexual behavior among men frequenting gay social venues. *Journal of Gay and Lesbian Social Services, 14*(4), 19-38.

Hall, H. I., Song, R., Rhodes, P., Prejean, J., An, Q., Lee, L. M., et al. (2008). Estimation of HIV incidence in the United States. *JAMA, 300*(5), 520-529.

Institute of Medicine. (2001). *No time to lose: Getting more from HIV prevention*. Washington, DC: National Academy Press.

Jaffe, H. W., Valdiserri, R. O., & De Cock, K. M. (2007). The reemerging HIV/AIDS epidemic in men who have sex with men. *JAMA, 298*(20), 2412-2414.

Johnson, B. T., Carey, M. P., Chaudoir, S. R., & Reid, A. E. (2006). Sexual risk reduction for persons living with HIV: research synthesis of randomized controlled trials, 1993 to 2004. *J Acquir Immune Defic Syndr, 41*(5), 642-650.

Koopman, J. S., Jacquez, J. A., Welch, G. W., Simon, C. P., Foxman, B., Pollock, S. M., et al. (1997). The role of early HIV infection in the spread of HIV through populations. *J Acquir Immune Defic Syndr Hum Retrovirol, 14*(3), 249-258.

Marks, G., Crepaz, N., Senterfitt, J. W., & Janssen, R. S. (2005). Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs. *J Acquir Immune Defic Syndr, 39*(4), 446-453.

Marks, G., Richardson, J. L., Crepaz, N., Stoyanoff, S., Milam, J., Kemper, C., et al. (2002). Are HIV care providers talking with patients about safer sex and disclosure?: A multi-clinic assessment. *AIDS, 16*(14), 1953-1957.

McBride, C. M., Emmons, K. M., & Lipkus, I. M. (2003). Understanding the potential of teachable moments: the case of smoking cessation. *Health Educ Res, 18*(2), 156-170.

Meade, C. S., Drabkin, A. S., Hansen, N. B., Wilson, P. A., Kochman, A., & Sikkema, K. J. (2010). Reductions in alcohol and cocaine use following a group coping intervention for HIV-positive adults with childhood sexual abuse histories. *Addiction, 105*(11), 1942-1951.

Metsch, L. R., Gooden, L., & Purcell, D. W. (2005). Interventions in community settings. In S. C. Kalichman (Ed.), *Positive prevention: Reducing HIV transmission among people living with HIV/AIDS*. New York: Kluwer Academic.

Mills, E. J., Nachega, J. B., Buchan, I., Orbinski, J., Attaran, A., Singh, S., et al. (2006). Adherence to antiretroviral therapy in sub-Saharan Africa and North America: a meta-analysis. *JAMA, 296*(6), 679-690.

Morin, S. F., Koester, K. A., Steward, W. T., Maiorana, A., McLaughlin, M., Myers, J. J., et al. (2004). Missed opportunities: prevention with HIV-infected patients in clinical care settings. *J Acquir Immune Defic Syndr, 36*(4), 960-966.

Myers, J. J., Shade, S. B., Rose, C. D., Koester, K., Maiorana, A., Malitz, F. E., et al. (2010). Interventions Delivered in Clinical Settings are Effective in Reducing Risk of HIV Transmission Among People Living with HIV: Results from the Health Resources and Services Administration (HRSA)'s Special Projects of National Significance Initiative. *AIDS Behav, 14*(3), 483-492.

Novitsky, V., Wang, R., Bussmann, H., Lockman, S., Baum, M., Shapiro, R., et al. (2010). HIV-1 Subtype C-Infected Individuals Maintaining High Viral Load as Potential Targets for the â€œTest-and-Treatâ€ Approach to Reduce HIV Transmission. *PLoS ONE, 5*(4), e10148.

Pillay, D., & Fisher, M. (2007). Primary HIV Infection, phylogenetics, and antiretroviral prevention. *J Infect Dis, 195*(7), 924-926.

Prochaska, J. O., Redding, C. A., Harlow, L. L., Rossi, J. S., & Velicer, W. F. (1994). The transtheoretical model of change and HIV prevention: a review. *Health Educ Q, 21*(4), 471-486.

Quinn, T. C., Wawer, M. J., Sewankambo, N., Serwadda, D., Li, C., Wabwire-Mangen, F., et al. (2000). Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *N Engl J Med, 342*(13), 921-929.

Rietmeijer, C. A., Patnaik, J. L., Judson, F. N., & Douglas, J. M., Jr. (2003). Increases in gonorrhea and sexual risk behaviors among men who have sex with men: a 12-year trend analysis at the Denver Metro Health Clinic. *Sex Transm Dis, 30*(7), 562-567.

Rose, C. D., Courtenay-Quirk, C., Knight, K., Shade, S. B., Vittinghoff, E., Gomez, C., et al. (2010). HIV Intervention for Providers Study: A Randomized Controlled Trial of a Clinician-Delivered HIV Risk-Reduction Intervention for HIV-Positive People. *JAIDS Journal of Acquired Immune Deficiency Syndromes, Publish Ahead of Print*, 10.1097/QAI.1090b1013e3181ee1094c1062.

Safren, S., O'Cleirigh, C., Skeer, M., Driskell, J., Goshe, B., Covahey, C., et al. (2010). Demonstration and Evaluation of a Peer-Delivered, Individually-Tailored, HIV Prevention Intervention for HIV-Infected MSM in their Primary Care Setting. *AIDS and Behavior*, 1-10.

Sanchez, T., Finlayson, T., Drake, A., Behel, S., Cribbin, M., Dinenno, E., et al. (2006). Human immunodeficiency virus (HIV) risk, prevention, and testing behaviors--United States, National HIV Behavioral Surveillance System: men who have sex with men, November 2003-April 2005. *MMWR Surveill Summ, 55*(6), 1-16.

Sikkema, K. J., Watt, M. H., Drabkin, A. S., Meade, C. S., Hansen, N. B., & Pence, B. W. (2010). Mental Health Treatment to Reduce HIV Transmission Risk Behavior: A Positive Prevention Model. *AIDS Behav, 14*(2), 252-262.

Sikkema, K. J., Wilson, P. A., Hansen, N. B., Kochman, A., Neufeld, S., Ghebremichael, M. S., et al. (2008). Effects of a coping intervention on transmission risk behavior among people living with HIV/AIDS and a history of childhood sexual abuse. *J Acquir Immune Defic Syndr, 47*(4), 506-513.

Stall, R., Mills, T. C., Williamson, J., Hart, T., Greenwood, G., Paul, J., et al. (2003). Association of co-occurring psychosocial health problems and increased vulnerability to HIV/AIDS among urban men who have sex with men. *Am J Public Health, 93*(6), 939-942.

Valdiserri, R. O. (2004). Mapping the roots of HIV/AIDS complacency: implications for program and policy development. *AIDS Educ Prev, 16*(5), 426-439.

Valle, M., & Levy, J. (2008). Finding meaning: African American injection drug users' interpretations of testing HIV-positive. *AIDS Care, 20*(1), 130-138.

Wawer, M. J., Gray, R. H., Sewankambo, N. K., Serwadda, D., Li, X., Laeyendecker, O., et al. (2005). Rates of HIV-1 transmission per coital act, by stage of HIV-1 infection, in Rakai, Uganda. *J Infect Dis, 191*(9), 1403-1409.

Weinhardt, L. (2005). HIV diagnosis and risk behavior. In S. C. Kalichman (Ed.), *Positive prevention: Reducing HIV transmission among people living with HIV/AIDS*. New York: Kluwer Academic.

Weinhardt, L. S., Carey, M. P., Johnson, B. T., & Bickham, N. L. (1999). Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985-1997. *Am J Public Health, 89*(9), 1397-1405.

Weinhardt, L. S., Kelly, J. A., Brondino, M. J., Rotheram-Borus, M. J., Kirshenbaum, S. B., Chesney, M. A., et al. (2004). HIV transmission risk behavior among men and women living with HIV in 4 cities in the United States. *J Acquir Immune Defic Syndr, 36*(5), 1057-1066.

Weiss, D., & Marmar, C. (1996). The Impact of Events Scale-Revised. In J. W. T. M. Keane (Ed.), *Assessing psychological trauma and PTSD* (pp. 299-411). New York: Guilford.

Table 1. Baseline Characteristics of Newly HIV Diagnosed MSM (n = 65)

	%	Mean (s.d.)
Sexually active*	73.8%	-
Number of partners*	-	4.7 (9.6)
Reported UAI*	55.4%	-
Number of UAI acts*	-	6.5 (15.02)
Reported STI symptoms	20%	-
Days alcohol used*	-	15.3 (20.8)
Used other drugs*	67.6%	-
IES-R Intrusion	-	14.8 (6.5)
IES-R Avoidance	-	14.9 (7.9)
IES-R Hyperarousal	-	9.6 (6.3)

*Reported over previous 3 months

Table 2. Baseline to 3- and 6-Month Follow-up Intervention Changes between Study Conditions

	Intervention (N=29)			Control (N=21)			Effect Sizes 3-Month Follow Up			Effect Sizes 6-Month Follow Up		
	Pre: % or Mean (s.d.)	3-Mo: % or Mean (s.d.)	6-Mo: % or Mean (s.d.)	Pre:% or Mean (s.d.)	3-Mo: % or Mean (s.d.)	6-Mo: % or Mean (s.d)	Intervention	Control	Difference	Intervention	Control	Difference
Primary Outcome Variables												
Sexually Active	69.0%	86.2%	86.2%	76.2%	75.0%	85.7%						
# Partners[1]	3.4(3.9)	2.3(2.3)	3.1(4.8)	2.7(4.9)	2.6(2.2)	3.2(3.8)	0.35	0.03	0.33	0.07	-0.11	0.18
UAI[1]	3.6(5.4)	3.3(5.7)	2.8(4.6)	1.0 (1.6)	2.1(3.7)	1.7(3.4)	0.05	-0.42	0.47	0.16	-0.28	0.44
Secondary Outcome Variables												
STI Symptoms	27.6%	31.0%	24.1%	14.3%	25.0%	28.6%						
Substance Use*	62.1%	62.1%	51.7%	57.1%	45.0%	57.1%						
Alcohol use (# days)	20.5(23.5)	14.9(13.9)	16.9(18.5)	19.0(17.9)	23.1(8.4)	18.2(19.8)	0.30	-0.31	0.61	0.17	0.04	0.13
IES-R Intrusive	16.5(8.1)	10.0(6.4)	9.2(6.3)	13.7(6.9)	10.2(7.0)	9.2(6.2)	0.90	0.51	0.39	1.02	0.69	0.33
IES-R Avoidance	15.1(7.3)	10.4(6.8)	9.6(6.6)	14.1(7.4)	10.3(6.3)	10.4(6.6)	0.67	0.56	0.11	0.79	0.53	0.26
IES-R Hyperarousal	10.0(6.1)	5.2(5.0)	5.2(4.6)	8.0(6.0)	5.5(4.8)	4.8(4.3)	0.90	0.62	0.40	0.90	0.62	0.28
Services Used **	0.9(1.1)	1.9 (0.9)	1.4(1.0)	1.2(0.9)	1.4(0.9)	1.2(0.8)	1.00	0.22	0.78	0.48	0.00	0.48

[1] 3 outliers in each condition (total 6) were excluded from the sexual behavior calculation.

*Any use and includes cocaine, marijuana, meth, club drugs.

** Mean score of participants using any of the following services: post-test counseling, mental health counseling, psychiatric services, sexual health clinic, and primary care.