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Title

Small Randomized Controlled Trial of the New Passport to Wellness HIV Prevention Intervention for Black Men Who Have Sex With Men (BMSM).

Permalink

<https://escholarship.org/uc/item/1373904v>

Journal

AIDS Education and Prevention, 32(4)

ISSN

0899-9546

Authors

Harawa, Nina T
Schrode, Katrina M
McWells, Charles
et al.

Publication Date

2020-08-01

DOI

10.1521/aeap.2020.32.4.311

Peer reviewed



DIVISION OF GENERAL INTERNAL MEDICINE
& HEALTH SERVICES RESEARCH
UCLA DEPARTMENT OF MEDICINE
DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA
911 BROXTON AVENUE
LOS ANGELES, CALIFORNIA 90024

May 26, 2020

Dr. Francisco Sy
Editor
AIDS Education and Prevention

Re: Manuscript #2003

Dear Dr. Sy,

Thank you for accepting with major changes our manuscript entitled, “Small Randomized Controlled Trial of the New Passport to Wellness HIV Prevention Intervention for Black Men Who Have Sex with Men (BMSM).”

We have thoroughly addressed the reviewers comments and suggestions. They have significantly improved the manuscript. Below, we provide each reviewer comment and our responses. Then you will find our final version of the paper, the references, tables, supplemental tables, and figure. In addition to responding to the reviewer feedback, we made minor stylistic changes and grammatical edits, replaced many of the references to testing with screening, and added our funders to the acknowledgements. I am also attaching the copyright form.

Please contact me if there is any additional information that I can provide:
nharawa@mednet.ucla.edu or 310-794-8078.

Sincerely,

Nina T. Harawa, MPH, PhD
Professor

Department of Medicine
David Geffen School of Medicine at UCLA

Department of Psychiatry and Human Behavior

Charles R. Drew University of Medicine and Science

AIDS Education and Prevention-An Interdisciplinary Journal

Manuscript Number: 20003

Manuscript Title: Small Randomized Controlled Trial of the New Passport to Wellness HIV Prevention Intervention for Black Men Who Have Sex with Men (BMSM)

Manuscript Date Sent: 3/31/2020

Review Date Due: 4/30/2020

Editorial Review Form

	Excellent	Good	Fair	Poor
METHODOLOGY AND SCIENTIFIC SOUNDNESS				
Appropriateness of Study Design			X	
Adequacy of Data Analysis		X		
Extent to Which Findings Support Conclusions		X		
WRITING QUALITY				
Conciseness		X		
Overall Length in Relation to the Study Findings and Importance		X		
Clarity		X		
SIGNIFICANCE OF THIS CONTRIBUTION				
Scientific Importance	X			
Originality and Innovation	X			
Contribution to Advancement in the Field of HIV Prevention Education	X			

RECOMMENDATION:

ACCEPT: No Revision Minor Revision

REVISE & RESUBMIT (Major Revision)

REJECT

COMMENT: Please provide your brief general comment to the editor here. The detailed comments to the authors should be provided on the next page (s).

This is an interesting intervention. Given the under-recruitment and under powered design, I would encourage the authors to think of their trial as a pilot RCT. I've also encouraged several other elements that need to be added/refined in their manuscript. Happy to review a revision if you offer them a R&R.

Reviewer's Name: Reviewer 1

Date **4/14/2020**

(Indicate your name on this page only. Please do not indicate your name in the remarks to the author)

Manuscript Number: **20003**

REMARKS TO THE AUTHOR(S)

Please make general remarks, followed by specific comments on the design, methods of data analysis, presentation of data, results, and discussion. Do not indicate your name on this page.

This is an interesting and exciting intervention focused on Black MSM. Several questions/concerns require the authors' attention to strengthen the manuscript even further:

1. SDH. The authors make reference throughout of how their intervention will address the social determinants of health, yet this concept is not defined or operationalized systematically throughout the manuscript. Please clarify throughout. Moreover, greater specificity on how the intervention improved SDH indicators should be included in the Results.

We acknowledge that this should have been more clearly discussed. We have added a definition and have worked to make clarifications throughout the manuscript. In the Results, we have also included a more detailed description of changes in unmet needs, as well as observed changes in income, homelessness, and employment status.

2. Theoretical framework. It is important to clarify how the intervention was informed, if at all, by intervention theories. Could the authors include a subsection regarding their theoretical model? Also, are there mechanisms of change that could be used to suggest that the intervention modified the proposed constructs driving the change? This will strengthen the rigor of their intervention work.

We have added an extensive discussion of the theoretical frameworks that informed the intervention. One of the proposed mediators of change was unmet needs, which reflect social determinates we have added a more detailed description of findings related to unmet needs as well as to homelessness, employment, and income. Other proposed mediators of the PtW intervention are extensive and would require a separate manuscript and, ideally, a larger sample to fully explore.

3. Under enrollment. The authors should include early in the Results section a subheader focused on explaining why the study was under enrolled (if it was originally proposed to enroll N=180). Given the under-recruitment and under powered design, I would encourage the authors to think of their trial as a pilot RCT rather than a definitive RCT.

We agree that the study ended up being more of a pilot than a definitive RCT. However, we intended for it to be a fully powered RCT. We have added some of the reasons for underenrollment to our discussion of the study limitations.

4. Unprotected anal sex. Please clarify what is meant by “unprotected”.

We have changed this language to condomless sex.

5. Services. Beyond the count of unmet services, could the authors include a count per life domain (e.g., housing, employment, etc).

We have added a Supplemental Table 4 which shows this information by group and within changes over time.

6. Effect Sizes. Please include measures of effect size for all intervention analyses (both within and between group analyses).

We have added to Table 2, within-group differences in the outcomes between baseline and follow-up and standard errors. Table 3: Odds ratios from the results of generalized linear mixed models and logistic regressions comparing changes in key outcomes over time between intervention groups, already provides the between-group effect sizes.

7. Retention. Supplemental table 1 should be included as a regular table in the manuscript.

Given the order in which these data are presented and the number of tables, we have maintained this table in the supplemental materials and added two additional tables, based to this section based on your other suggestions..

8. Sample. The authors should discuss how age might affect participants’ need to navigate social resources and social support. Given that the mean age is around 45 years of age, do the authors believe that the intervention would be different or more impactful if it had focused on younger populations who may need greater support in learning how to navigate different health and social services? This should be discussed in greater depth in the Discussion.

We have added the following to our Discussion: “The participants’ older age may also have contribute to a reduced intervention effect. Younger participants may have more to learn from the Peer Mentors and have had fewer occasions to have been disqualified from specific types of benefits and services.”

9. Intervention conditions. In the Discussion, the authors should note that their “comparison” arm is still an intervention in itself; thus, future evaluation of the PtW might have a larger effect size when compared to “usual care”.

That both study arms are interventions is noted in the first line of the Discussion and discussed further in the second paragraph of this section. Because of both funding limitations and the well-documented high HIV risk experienced by Black MSM, we did not include a usual care comparison arm. We agree that a usual care comparison might have shown a large effect size and included this point in the discussion.

AIDS Education and Prevention-An Interdisciplinary Journal

Manuscript Number: 20003

Manuscript Title: Small Randomized Controlled Trial of the New Passport to Wellness HIV Prevention Intervention for Black Men Who Have Sex with Men (BMSM)

Manuscript Date Sent: 03/13/2020 **Review Date Due:** 04/13/2020

Editorial Review Form

	Excellent	Good	Fair	Poor
METHODOLOGY AND SCIENTIFIC SOUNDNESS				
Appropriateness of Study Design			X	
Adequacy of Data Analysis		X		
Extent to Which Findings Support Conclusions			X	
WRITING QUALITY				
Conciseness		X		
Overall Length in Relation to the Study Findings and Importance		X		
Clarity			X	
SIGNIFICANCE OF THIS CONTRIBUTION				
Scientific Importance		X		
Originality and Innovation		X		
Contribution to Advancement in the Field of HIV Prevention Education			X	

RECOMMENDATION:

 ACCEPT: No Revision Minor Revision

X REVISE & RESUBMIT (Major Revision)

 REJECT

COMMENT: Please provide your brief general comment to the editor here. The detailed comments to the authors should be provided on the next page (s).

This paper covers an important area for HIV prevention work for which there is a great need currently. Unfortunately, the conclusions that can be made from the work presented are limited by the design used. The writing is generally clear but is often not concise and occasionally unclear. My main recommendation is to include information about the theoretical basis and the rationale for the intervention approach and the design. Additionally, I suggest they reframe the conclusion not to be about efficacy but rather to focus on how the current results demonstrate the need for a more rigorous evaluation that would focus on efficacy as well as feasibility to implement (cost due to intensity and human resources needed to conduct the full intervention). I do not think evidence is shown for this being an effective intervention.

Reviewer's Name: Reviewer 2

Date 04/01/2020__

(Indicate your name on this page only. Please do not indicate your name in the remarks to the author)

Manuscript Number: 20003

REMARKS TO THE AUTHOR(S)

Please make general remarks, followed by specific comments on the design, methods of data analysis, presentation of data, results, and discussion. Do not indicate your name on this page.

This paper covers an important area for HIV prevention work for which there is a great need currently. Unfortunately, the conclusions that can be made from the work presented are limited by the design used. Additionally, the authors do not present enough theory-based justification for the approach.

The authors state in the discussion that the intervention was effective. Due to the design of the study reported, this claim cannot be made. The strongest statement possible is that the intervention appeared to be associated with the change in outcomes. There are too many additional factors that cannot be controlled for to make a claim about effectiveness. Improvement observed may have been due simply to attention. A wait-list control or some other type of non-intervention comparison, even a standard of care condition, would have provided a much stronger basis for making statements about effects due to PtW.

We have made our statements more circumspect and addressed the Reviewers point about a standard-of-care condition:

“Increases in engagement with HIV prevention and HIV/STI testing among Black MSM were observed in both the peer-supported and the non-peer-supported versions of the Passport to Wellness intervention. Particularly large gains were observed in awareness of pre- and post-exposure prophylaxis, use of PrEP, and testing for HIV and STIs. persistent use of PrEP lagged well behind, however, with just 15 (25%) starting PrEP and 8 (53%)

of those who started PrEP remaining on the drug. Although local campaigns to increase awareness of PrEP and PEP were running during the intervention, awareness in the population studied remained low, suggesting that these local efforts were not responsible for the increases in awareness that we observed.

Multivariate analyses did not show statistically significant group differences in uptake of HIV/STI services over time. It is important to note that both arms of Passport to Wellness constituted an intervention whose participants increased their engagement in HIV prevention and HIV/STI screening. The inclusion of “standard-of-care” control arm, may have shown a larger effect size. The lack of a significant difference between the arms suggests that the peer support component did not provide added benefit. However, the study was underpowered as compared with the proposed sample size of 180, so a larger study is needed to address this question.”

I strongly recommend that the authors reframe their discussion to focus on these results supporting a more rigorous evaluation of the intervention. It is noted that they make such a statement in final conclusion of the paper, but that statement is at odds with the interpretation that it is effective. I also strongly recommend that they more clearly state how this approach is likely to address an impactful gap in HIV prevention for this population.

Our reframing about more clearly calls for a better powered evaluation of efficacy. Our elaboration of the theoretical foundations of the intervention address the potential impact of the Passport to Wellness intervention for addressing this gap.

Please include a limitation concerning the large amount of resources needed to deliver the intervention. The number of interactions and one-on-one intense intervention work may be a feasibility burden for other organizations to start up and sustain delivery of the intervention with fidelity.

We have added the following line to the last sentence of the paper, “Given the intervention’s intensity, a clear assessment of what components are most efficacious would allow for the identification of the most streamlined approach for widespread implementation.”

Please also clearly state the theoretical support for the approach taken in this intervention. The following sentence, for example, “PtW includes some approaches that have been used in other interventions but not in the same manner or to promote the same outcomes” falls short of an explanation of what drove the decision making about what to include in the intervention. It is not stated if the choices to include these previously used approaches is guided by a theory or by experience or something else. Please clearly state what the intervention design is based on.

We have reformatted the Methods to provide a section on the intervention that discusses its theoretical foundations, as well as detailing the four components of the full intervention. The sentence quoted here was not intended as a rationale for the

intervention, but a description of what makes it different from other published interventions.

Please include a rationale for developing two versions of the intervention. Please also specify behavior change theory or other relevant theories that support adding the peer-supported component. Also note that all comparisons essentially examine the effect of the peer-supported version. The paper currently does not state how theory supports this question or why it would be practically important in the field. This should be explicitly stated.

The section on the Intervention discussed above addresses the theoretical relevance of the peer components. The last line of the Introduction states: “We conducted an initial assessment of the effectiveness of both a peer-supported and a non-peer supported version of PtW on HIV/STI testing and PrEP knowledge/uptake, by doing a head-to-head comparison using an RCT design.” To the preceding paragraph, we have added the following line, “Given the biomedicalization of HIV prevention, we were particularly interested in whether lay health approaches, such as patient navigation that that have been used successfully to promote engagement in care among people with disease conditions, could be used to promote prevention and early disease detection.”

Please elaborate on the theoretical basis for including motivational interviewing as part of the training for the mentors and how it relates to the intended mechanism of change in the intervention. For example, if the rationale for the approach was just a novel way to ensure that participants were screened for services and had help navigating those services, this should be stated. It seems like there is more to the thinking, but it is not clearly stated. For another example, it is unclear how mentors ‘holistically’ address the health needs of participants as it is not described. The description (p.10) states that at the conclusion of the development of the passport, the participant gets a list of services and activities. Are these all part of a network of available services that the mentors will help the participants to navigate? Please clarify.

We added the following to the Peer Mentor training section of the Intervention description: “ ‘Motivational interviewing is a style of patient-centered counselling developed to facilitate change in health-related behaviors. The core principle of the approach is negotiation rather than conflict.’ [Treasure, J. (2004). Motivational interviewing. *Advances in Psychiatric Treatment*, 10(5), 331-337. doi:10.1192/apt.10.5.331]. Motivational Interviewing is a behavior change approach respected as an effective process for helping people move through the stages of change, regardless of where they start. It can be used by both professional and lay practitioners and is consistent with the client-centered focus of PtW.”

Regarding the holistic nature of the intervention, we added “Development of the Passport was intended to holistically address the participant’s physical, social/emotional, and spiritual health needs to help remove these barriers. Hence, referrals could include educational or legal resources as well as spiritual resources. A list of local LGBT-accepting faith communities of various denominations was developed for the latter, and a committee of faith leaders also advised the study.”

The Wellness Passport and Peer Mentor sections of the intervention now discuss in greater detail the referrals provided and the role of the Peer in facilitating access to them.

Additional comments:

Please clarify if any of the Peer Mentors had any prior relationships with participants. If so, please describe the procedures for how this was handled.

We added the following to the Peer Mentor section describing the training: “During PM training, we emphasized the importance of avoiding personal relationships that had the potential of creating a conflict of interest and asked that PMs disclose if previous such relationships existed with any assigned participants. Late in the project, the partner of one PM enrolled in the program. After careful review and discussion with both the PM and his partner, the research team proceeded with several safeguards: the participant would have another PM, the PM who was the partner would not have access to any of the participant’s information, and scheduled appointments were carefully orchestrated to ensure neither were at the office at the same time.”

Given the described variation in frequency of weekly meetings, please describe the rationale for this flexibility and if these data were collected an included in any analyses (although it appears that some of these data were collected (p.12)). There could be many reasons for this variation in intensity and interaction (including both number of interactions and mode (i.e., voice, text, face-to-face)). This variation could conceivably moderate intervention effects and seems like a reasonable research question. It may also have implications for resources needed to implement the intervention by others.

The PtW intervention is an individualized one. Although there was guidance on ideal numbers of peer/participant interactions, they adjusted to the needs and desires of the participant. This flexibility was appropriate to the client-centered intervention approach and the differing participant needs and stages of change. Data on frequency of sessions was collected but not included in this analysis.

Similar to mentor interactions, the group activities seem to be an important part of the intervention. Please describe the rationale for not rigorously measuring these interactions with regard to frequency and clarify why data are presented later in the manuscript. This could also be a key moderator of the intervention effect. The authors even state this to be a key component. This should be noted in the limitations of the paper. Additionally, if it is a key component, please clearly state the theoretical basis for stating so.

We have included the theoretical basis for these activities in the expanded section on the intervention and noted in the Limitations the incomplete data collection on this aspect of the intervention. We agree that frequency of participation in both the peer and group aspects of the intervention could have modified the intervention effect. However,

because of the small sample size and the lack of observed differences between the peer- and non-peer supported versions of the intervention, we did not explore potential differences by dose.

The authors refer to a 4-month pilot that informed modifications to the intervention and to the study design. Please provide a citation to either an internal report or a publication if available. If not, please add a sentence or two summarizing the modifications to both the intervention and the study design.

We added the following to the Recruitment section of the Methods: “After completing a 4-month pilot of the full intervention with 24 participants, we made modifications to the intervention and study design. These included providing tools to clarify the incentive structure for participants and for streamlined incentive tracking; developing a clear policy for handling lost gift cards, and adding stickers to the cards to remind participants that cards were reloadable and should not be relinquished after purchasing items; and providing additional training on retention strategies. The required documentation by Peer Mentors also required extensive retraining, reinforcement, and easier-to-use tools. In addition to implementing these modifications, Peer Mentors received additional compensation each month if they provided complete documentation of their activities.”

There are many unanswered questions about the change in inclusion criteria. What were demographic differences existed between participants recruited with original and with revised criteria? How many were recruited with original and with revised criteria? Was it balanced between the two intervention arms? What sensitivity analyses were conducted? Were there any differences in outcomes between these two groups? These are very significant factors as they relate to changes in the outcomes presented.

Sample size concerns do not allow for a detailed sensitivity analysis. We have, however, added two tables to the appendix that provide a basic one. The first shows the sociodemographics of those enrolled under each criteria; no statistically significant differences were observed. The second shows changes over time within groups defined by the entry criteria. With one exception, the same outcomes reached statistical significance. Note: tests were not performed for changes in outcomes related to the entry criteria. We have added a description of these findings to the Results.

Consider that if sexually active men who had not been tested in the prior year, saw an increase in HIV and STI testing, that can be attributable to any number of things. The study design does not allow a conclusion that such an increase is due to the intervention. There is no methodological way to eliminate the possibility that these increases were actually just a result of HIV testing becoming ‘more common’ in the local population during the study.

In addressing the concerns stated earlier about the comparison arm and our use of language indicating effectiveness, we have addressed these concerns.

Please include how long on average it took to complete the assessment.

Information added.

Please provide the amount of compensation for participation and completing an assessment.

Information added.

Please describe how the situation was handled when a participant was determined to be ineligible based on the baseline survey after they had been randomized. Please also state how many participants for which this was the case.

A total of 25 randomized enrollees were determined ineligible. Approximately half of these were determined ineligible at baseline, compensated and told that they could not continue. The remainder were determined ineligible later, either after a review of their baseline assessment or after indicating to a study team member that they had given incorrect information and were not eligible.

Please include citation to support the statement in the discussion that PrEP awareness remains low in this population today.

We modified this statement and clarified that we were referring to changes observed in study enrollees over time. The revised statement reads: “Although local campaigns to increase awareness of PrEP and PEP were running during the intervention, an examination of baseline awareness and receipt of PrEP/PEP education comparing those enrolled in the first and second years of the study suggest that these local efforts were not responsible for the increases in awareness that we observed.”

Minor or specific editing comments:

On page 2, fix typo: ‘determinates’

Page 5, ‘Special Project[s] of National Significance’

Page 7, ‘During the study’s [first] 12 months,’

Page 8. ‘The Data Manager carried [out] this process’

All corrections made.

Page 11. Please clarify if logistic regression was conducted for outcomes with binary values. As currently stated, (‘For outcome variables with baseline frequencies of 0 or 100%’) it is a little confusing if all that is meant is that these were dichotomous 0 and 1 outcomes.

We revised this sentence to the following: “Some outcome variables had baseline frequencies of 0 or 100% (for example, 0% of the non-peer participants had used PEP at baseline). For these variables, we performed logistic regression to compare between the groups only at the 6-month follow-up.”

I did not have a copy of Figure 1 so could not review it.

Provided with minor corrections.

**Small Randomized Controlled Trial of the New Passport to Wellness HIV Prevention
Intervention for Black Men Who Have Sex with Men (BMSM)**

Nina T. Harawa, MPH, PhD

Katrina M. Schrode, PhD

Charles McWells, BA

Robert E. Weiss, PhD

Charles L. Hilliard, PhD

Ricky N. Bluthenthal, PhD

Corresponding Author: Nina T. Harawa *Ph: 310 794-8078*

E: NHarawa@mednet.ucla.edu

(NTH) Department of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA

(CM) Los Angeles Centers for Alcohol and Drug Abuse, Los Angeles, CA

(NTH, KS and CLH) Department of Psychiatry, College of Medicine, Charles R. Drew
University of Medicine and Science, Los Angeles, CA

(REW) Department of Biostatistics, UCLA Fielding School of Public Health, Los Angeles, CA

(RNB) Department of Preventive Medicine, Keck School of Medicine, University of Southern
California, Los Angeles, CA

Small Randomized Controlled Trial of the New Passport to Wellness HIV Prevention

Intervention for Black Men Who Have Sex with Men (BMSM)

Acknowledgments

We thank our study manager, Jason McCuller; support staff, Pam Coleman, Chauncey Faulks, and Qiana Montazeri; our community collaborators; AJ King who assisted with grant writing; and most importantly, our study participants and Peer Mentors for making this study possible.

This study was supported by grants from the California HIV/AIDS Research Program (CHRP) TL13-LACA-576 (PI, McWells) and TU4-LA-594, OS17-LA-003 (PI, Harawa). Dr. Harawa and Dr. Schrode's time was also supported by NIH/NIDA grant R01DA039934 (PI, Harawa). Dr. Harawa received additional support from the UCLA Clinical and Translational Science Institute (CTSI) NIH/NCATS grant UL1-TR001881 (PI, Dubinett). Drs. Weiss and Harawa were also supported on the Center for HIV Identification, Prevention, and Treatment (CHIPTS) NIH/NIMH grant P30MH058107 (PI, Shoptaw).

Abstract

We developed and tested Passport to Wellness (PtW), a client-centered intervention to improve engagement in HIV/STI prevention and services to improve social determinants of health among BMSM using incentives and peer support. We assessed PtW's impact on HIV/STI screening and pre/post -exposure prophylaxis (PrEP/PEP) knowledge/uptake using a randomized trial that compared the full intervention to one lacking peer support. We examined overall changes and used generalized linear mixed models to compare changes within groups surveyed at baseline and six months. We enrolled 80 eligible BMSM, among 399 screened. Among retained participants (34 peer-supported; 27 comparison), *overall* increases were observed in HIV (30% to 87%; $p < 0.001$) and STI (28% to 80%; $p < 0.001$) testing within the prior 6 months, PrEP and PEP awareness, and PrEP use. Statistically significant *between group* differences were not observed. Tailored prevention planning, incentives, and addressing social determinants may help move Black MSM along the HIV prevention continuum.

Keywords: HIV prevention; HIV testing; pre-exposure prophylaxis; Black/African American MSM; post-exposure prophylaxis.

Introduction

Men who have sex with men (MSM) continue to be impacted disproportionately by HIV in the United States (U.S.). In 2017, MSM accounted for more than half of all new diagnoses in the U.S. and 6 dependent areas (Centers for Disease Control and Prevention (CDC), 2018, 2019a). Black MSM experience extremely high rates of HIV (CDC, 2018; CDC, 2019b). In 2017, BMSM accounted for the largest estimated number and percentage of new HIV diagnoses among MSM (CDC, 2019a). They also experience poorer HIV outcomes. Hall, Byers, Ling, & Espinoza (2007) found that BMSM were less likely than White MSM to be alive three years after AIDS diagnosis, attributing this to late diagnosis of HIV and lack of access to adequate treatment. According to one particularly troubling estimate, approximately 60% of Black MSM will become HIV infected by the age of 40 (Matthews, Herrick, & Coulter, 2016). In 2016, CDC estimated their lifetime risk to be 50% (CDC, 2016).

Notably, sexual risk and substance use behaviors do not explain the differences in HIV incidence rates between Black and other race MSM. A systemic review and meta-analysis of studies comparing behavioral risk factors and social determinants found that BMSM are more likely than MSM of other races to encounter social and economic challenges such as lower income, unemployment and incarceration, and stigma and discrimination related to HIV and same-gender sexuality (Millett, Flores, Peterson, & Bakerman, 2007; Millett, Peterson, & Flores, 2012; Maulsby, Millett, & Lindsey 2014). These negative social determinants of health result from social structural disadvantages and may contribute to delays in HIV/STI diagnosis and treatment, increased participation in exchange sex, and decreased disclosure of HIV status (Millett, Peterson, & Flores 2012). These in turn contribute to increased STI prevalence and

undiagnosed HIV seropositivity, lower access to quality HIV care services, and reduced HAART utilization and adherence among people living with HIV (Millett, Peterson, & Flores 2012; Maulsby, Millett, & Lindsey 2014). Undiagnosed and un/undertreated HIV disease increase community viral load and transmission risk among people living with HIV. In 2017, just 57.4% of Black PLWH in the US was estimated to be virally suppressed (Harris et al., 2019).

Uptake of biomedical prevention -- pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) -- is also suboptimal among BMSM. Both national and local estimates show low rates of uptake and large disparities. In 2018, of the Black people CDC estimated to have indications for PrEP, just an estimated 5.9% were prescribed PrEP, compared with 10.9% for Hispanics/Latinos, and 42.1% for non-Hispanic Whites (Harris et al., 2019). Of the 82 HIV-negative or unknown serostatus Black MSM who were interviewed in the 2017 cycle of National HIV Behavioral Surveillance in Los Angeles, just 22% had used PrEP in the past 12 months and just 5% had ever used PEP (Sey & Ma, 2018). At the time of this survey, PrEP had been locally available for more than 4 years among Black MSM (BMSM), and PEP had been available for over 10 years, both at no cost for most people.

We developed the Passport to Wellness (PtW) intervention to address this challenge of delayed HIV diagnosis and high rates of HIV and STIs, in the context of social determinants that undermine healthcare seeking and preventive behaviors among Black MSM. We selected a combination of approaches to best meet the social, cultural and health literacy needs of at-risk BMSM in Los Angeles who are HIV negative or unaware of their HIV status – holistic and client-centered wellness plans, small incentives, peer navigation, and peer support. PtW includes some approaches that have been used in other interventions but not together or to promote the

same outcomes. The HTPN 061 study of BMSM utilized client-centered peer health navigation but with professional staff and did not study uptake of biomedical prevention services (Koblin, Mayer, & Eshleman, 2013). A Special Projects of National Significance (SPNS) project used peer navigators and social incentives (e.g., free group outings) with a substance-using HIV-positive population to increase care engagement; however, it did not attempt to increase screening and prevention among those who were unaware of their HIV status (HRSA Pilot Final Report 2006, unpublished). McCoy, Shiu, & Martz (2013) tested social network incentives to promote testing by BMSM, but did not engage peers as mentors or navigators. To our knowledge, none of these interventions was holistic in that participants were also supported and incentivized to address wellness goals not specific to HIV or substance use. Given the biomedicalization of HIV prevention, we were particularly interested in whether lay health approaches, such as patient navigation that have been used successfully to promote engagement in care among diverse patient populations with a range of conditions, could be used to promote prevention and early disease detection in Black MSM.

We developed and tested the Passport to Wellness (PtW) intervention to improve engagement with the HIV prevention continuum among Black MSM (BMSM). PtW uses client-centered wellness plans (called Passports) designed to improve social determinants of health and incentives designed to encourage utilization of prevention, testing, and other services to address participants' wellness goals (Dangerfield, Harawa, McWells, Hilliard, & Bluthenthal, 2018). We conducted an initial assessment of both a peer-supported and a non-peer supported version of PtW on HIV/STI testing and PrEP knowledge/uptake, by doing a head-to-head comparison using a randomized controlled trial (RCT) design.

Methods

The study was approved by the Charles R. Drew University, University of California Los Angeles, and University of Southern California Institutional Review Boards, and all participants provided written informed consent. It was registered on Clinicaltrials.gov, Identifier: NCT02932384.

Recruitment

After completing a 4-month pilot of the full intervention with 24 participants, we made modifications to the intervention and study design. These included providing tools to clarify the incentive structure for participants and for streamlined incentive tracking; developing a clear policy for handling lost gift cards, adding stickers to the cards to remind participants that cards were reloadable and should not be relinquished after purchasing items; and providing additional training on retention strategies. The required documentation by Peer Mentors also required extensive retraining, reinforcement, and easier-to-use tools. In addition to implementing these modifications, we provided the Peer Mentors additional compensation each month if they provided complete documentation of their activities.

We then initiated recruitment for the RCT in October 2015 and enrolled participants throughout Los Angeles County through April 2017. The Peer Mentors and eventually two dedicated recruiters conducted direct outreach at public venues, community-based organizations, parks, and events. We also recruited through provider referrals and fliers placed at public venues. In addition, we conducted limited recruitment online via Craigslist.com, Instagram, and a study website. Outreach materials provided brief study information, including a phone number to call

for more information and eligibility screening. Interested participants could also be screened during field recruitment. The study was originally powered to enroll 180 eligible participants and retain 135-153 (75-85%) of these.

Interested MSM were eligible to enroll if they identified as a Black/African-American man, were at least 18 years of age, and resided in Los Angeles County. Participants had to be HIV-negative or unaware of their status and to report condomless anal sex with a man or a transgender woman in the last 6 months. During the study's first 12 months, participants also had to report not having been tested for HIV in the prior year (or to have been recruited from an HIV testing site where their last test was more than 12 months prior). However, due to strong local efforts, HIV screening had become more common among the target population, and many potential participants were deemed ineligible due to recent HIV screening. In addition, efforts to encourage PrEP use among at-risk individuals were ramping up. For these reasons, in September 2016, the recent HIV screening exclusion criterion was removed and replaced with one excluding participants who had used PrEP in the prior 6 months.

Enrollment and randomization

Individuals who screened eligible were invited for an in-person interview at the study office (co-located at either the Downtown or Hollywood offices of the Los Angeles Centers for Alcohol and Drug Abuse or L.A. CADA). Following informed consent, participants were administered an audio computer-assisted self-interview (ACASI) baseline assessment and assigned to a study arm. Participants were randomized 1:1 to the peer mentor intervention or non-peer mentor PtW intervention arm (Figure 1: Passport to Wellness trial CONSORT chart). As new participants were enrolled, they were sequentially assigned to the next pre-determined allocation. Allocations

were generated in batches of size 6-30 as enrollment progressed. The Data Manager carried out this process using a procedure for random balanced block allocation in SAS v9.2 and placing the allocations in sealed envelopes to be opened at completion of each interview. Due to this allocation process, both intervention groups had the same proportion of participants recruited under the two sets of enrollment criteria (56% under the first criteria and 44% under the revised criteria).

Assessments

In-person ACASI assessments were administered at baseline and 6 months after enrollment. Assessments took from 30 minutes to 3 hours to complete, with a mean of 76 minutes (SD = 29). Research staff administered most of the survey by reading the questions to participants and marking their responses on the computer. Participants used the computer to answer particularly sensitive questions themselves, with the option of hearing the questions read through headphones. Participants in both study arms were provided compensation in the form of \$25 gift cards upon completion of each survey.

The survey assessed a variety of background characteristics, service needs, and attitudes, perceptions, and knowledge related to HIV, PrEP, PEP, trust in healthcare, and sexuality. The primary outcomes assessed were: 1) HIV status, 2) HIV screening, 3) STI screening, 4) awareness and use of PrEP, 5) awareness and use of PEP, and 6) access to care (having health insurance and a regular provider). Due to the protocol modifications, beginning in September 2016, a new question about PrEP use in the previous 6 months was included in the screener. The survey also repeated eligibility questions. If a participant's responses to the baseline survey

indicated ineligibility, he was informed that he was not eligible and compensated for his time but discontinued from further participation. In some cases, this review of the baseline survey occurred after participants had completed randomization.

Participants were also asked to complete shorter assessments (5-20 minutes) in person or by phone at 1 and 4 months after enrollment. These interim assessments focused on service needs and the participant's experience with the Peer Mentor (if part of the intervention group). Because the primary outcomes were not measured during these assessments, these data do not contribute to the current analysis.

Passport to Wellness Intervention

The Passport to Wellness intervention has four components: 1) all participants received a customized wellness plan (or Passport) that included referrals to health and support services and incentives for accessing those services; 2) all participants were awarded incentives for providing documentation of completed Passport activities; 3) participants assigned to the Peer Mentor (PM) intervention arm were also paired with a trained Peer who provided support, encouragement, and navigation; and 4) individuals assigned to this arm were also given the opportunity to attend social/education group outings.

Theoretical Background

PtW was based on principles of patient navigation and contingency management, as well as social impact, social comparison, and social cognitive theories. It stemmed from the work of the Co-PI, a Black MSM who is living openly with HIV and who has provided services to people living with HIV and/or substance use disorders (SUDs) in Los Angeles for over 20 years. The

specifics of the intervention were informed by our formative research (Dangerfield, Harawa, McWells, Hilliard, & Bluthenthal, 2018). A discussion of each of the components is described below.

Wellness Passports

At completion of the baseline survey, a report was generated based on participants' responses to questions about sociodemographics and potential HIV risk factors. Examples include indicators of SUDs, low HIV knowledge, unstable housing, multiple sex partners, and internalized HIV stigma and bi/homonegativity. The report also included unmet needs, reflecting negative social determinants of health that participants identified from a list of 12 possible types of services including employment assistance, food and grocery assistance, and SUD treatment. Using this report as a starting point, the Passport Developer worked with the participant to develop his Passport, a personalized wellness and services plan. The Passport Developer was the aforementioned Co-PI and supervisor of the Peer Mentor/Recruiter team.

Although the study goals involved HIV and STI prevention and early detection, participants often had other needs or concerns that presented barriers to accessing or prioritizing these activities. Development of the Passport was intended to holistically address the participant's physical, social/emotional, and spiritual health needs to help remove these barriers. Hence, referrals could include employment or legal resources as well as spiritual resources. A list of local LGBT-accepting faith communities of various denominations was developed for the latter, and a committee of faith leaders advised the study. Other potential referrals were informed by participants in our formative research and members of our community advisory board who were asked to identify trusted local providers to at-risk Black MSM (Dangerfield, Harawa,

McWells, Hilliard, & Bluthenthal, 2018). Together, the participant and Passport Developer identified key services and activities to include on the Passport based on the participant's priorities. At the end of the discussion, the participant received a printed, paper copy of their Passport that included the participant's personal wellness goals and details for accessing related referrals.

Incentives

A simple version of contingency management was used to provide additional motivation for participants to follow through with their wellness plan. They received incentives for accessing services and activities listed on their Passport. To receive the compensation, the participant had to provide documentation of their visit in the form of a provider signature on the Passport or a time-stamped photo from the visit. If a Peer Mentor accompanied a participant from the intervention arm, the Peer Mentor could also sign the Passport to verify the visit.

At the beginning of the intervention, each participant received a reloadable gift card to a major retail store. Completion of Passport items earned the participant points that were redeemable 1:1 for dollars. The total earned could be redeemed and loaded onto the gift card at the end of each month. Alternatively, participants could choose to save their points each month, which would earn them an additional 10 points.

The amount of compensation available varied by activity type. Limits were imposed to the number of times a participant could receive compensation for the same activity, avoid unnecessary screening, and encourage participants to complete the other steps of their wellness plan. Participants in each study arm could earn a maximum of 200 points through Passport activities, including 5 points for each non-medical activity (cap: 100) and 10 points for each

medically related activity (cap: 30). Those in the intervention arm received 5 points for each meeting with their Peer Mentor (cap: 50). Participants in the comparison arm could earn 10 points for providing updated contact information at 1 month, and an additional 10 points for updating at 4 months. If a participant lost his card, unredeemed or newly earned points were redeemable via un-reloadable gift cards, but any remaining balance on the lost card was not replaced.

Peer Mentors

Participants assigned to the intervention arm were paired with a Peer Mentor who provided navigation to Passport services, encouragement, and support. Multiple theoretical perspectives supported our choice of Peers rather than professionals. One such perspective is dynamic social impact theory, which holds that communication (such as health education) from a communicator that is similar to the individual and credible is more likely to achieve change in the recipient (Nowak, Szamrej, & Latané, 1990). An additional perspective comes from social comparison theory (Festinger, 1954) which postulates that people make use of information received from others to self-evaluate (Festinger, 1954), for self-enhancement (Schachter & Singer, 1962) and self-improvement (Wood, 1989). When the peer is viewed by others as having overcome similar challenges (e.g., successful in their recovery from SUDs or community re-entry), they may be better positioned to help the recipient effectively make use of the health intervention/information/resource being provided.

Peer Mentors were recruited through outreach to local community-based organizations, Internet job postings, and the networks of the investigators. The hiring process included completion of a non-traditional position application that highlighted their related personal

experiences and motivation. They were initially screened over the phone and then were interviewed in-person by the community Co-PI and the Clinical Supervisor prior to selection. Peers received a monthly stipend through the community partner, L.A. CADA.

The Peer Mentors changed over the study course, as some dropped out and new Peers were recruited. Over the study course, 14 BMSM were trained as Peer Mentors; 11 of these were assigned participants. Four were between 18 and 29 years, 3 were between 30 and 49 years, and 7 were 50 or over.

All Peer Mentors underwent extensive training in human subjects' research, motivational interviewing, basic counselling skills, boundaries, cultural competency, HIV (including PrEP and PEP), and other STIs. "Motivational interviewing is a style of patient-centered counselling developed to facilitate change in health-related behaviors. The core principle of the approach is negotiation rather than conflict" (Treasure, 2004). Motivational Interviewing is a behavior change approach respected as an effective process for helping people move through the stages of change, regardless of where they start. It can be used by both professional and lay practitioners and is consistent with the client-centered focus of PtW. The importance of avoiding personal relationships that had the potential of creating a conflict of interest was emphasized, and PMs were asked to disclose if previous such relationships existed with any participants. Late in the study, the partner of one PM enrolled. After careful review and discussion with both the PM and his partner, the research team proceeded with several safeguards: the participant would have another PM, the PM who was the partner would not have access to any of the participant's information, and scheduled appointments were timed to ensure both were not at the office at the same time.

Participants selected their preferred Peer Mentor after viewing short biographical videos. If the preferred or assigned Peer Mentor was no longer able to take on additional participants, the participant was paired with the next preferred Peer Mentor. Peer Mentors provided support and guidance to the participant in accessing the services listed in his Passport. They helped address any barriers the participant had in accessing services and often accompanied him to appointments.

The intention was for Peer Mentors to meet with their participants weekly for the first 6-8 weeks; however, meeting frequency varied greatly depending on the preferences and availability of participants. After the initial 6-8 week period, Peer Mentors stayed in touch with participants on at least a weekly basis by phone or text, and with intended monthly in-person meetings for the duration of the intervention. During the final 2 months, the Peer Mentors worked with their participants to plan for the transition out of the intervention. This process involved identifying intrinsic motivators for the participant to continue engaging in health-promoting prevention services and behaviors.

Social/Educational Group Activities

Another key component of the full intervention arm was group social/educational activities designed to create fun, engaging, and sober activities in which participants could socialize with other Black MSM, in addition to the Peer Mentor team. Many activities involved African American history, experience, or culture. Most groups began with a shared meal and an informative discussion on a topic relevant to wellness, such as self-esteem, interpersonal violence, or biomedical prevention. In total, 13 in-house movies were offered (all with post-viewing Peer-led discussions), in addition to 15 different outings. This initiative created

additional opportunities for PtW participants to complete Passport activities related to their need for social connection, health information, or stress release. Due to the informal nature of the activities, documentation of attendance was somewhat inconsistent, resulting in probable underestimation of attendance.

The rationale for including group activities was the research team's experience in observing the increase in pride in one's black history observed in other programs that had included this element. In addition, in our formative research focus groups with BMSM who were living with HIV, psychosocial determinants of unhealthy behavior discussed included a fatalistic outlook on life, seeing one's self as a social outcast, reluctance to attend programs that are perceived as gay, and experiencing negative peer pressure. A theoretical rationale for including a group element can be found in social cognitive theory (SCT) (Bandura, 1986). SCT posits that self-efficacy, a mediator of behavior change (DiClemente, Faithhurst, & Piotrowski, 1995), develops through mastery experiences, vicarious or observational learning, and social persuasion, all of which can be fostered in peer-led group activities.

Data Analysis

All analyses were conducted using SAS v9.2 and limited to participants who were confirmed to be eligible from baseline survey responses and who completed the 6-month follow-up assessment. Descriptive statistics and chi-square and McNemar tests were used to examine sociodemographic differences between members of each intervention group at baseline and changes over time within arms. To determine the effect of the intervention on prevention outcomes, we used generalized linear mixed models (GLMM) with a logit link function. The independent variables included in the mixed models were group assignment, time point (baseline

or 6-month follow-up), and the interaction of the two to examine differences in change between groups, controlling for baseline. Some outcome variables had baseline frequencies of 0 or 100% (for example, 0% of the non-peer group participants had used PEP at baseline). For these variables, we performed logistic regression to compare between the groups only at the 6-month follow-up. In both GLMMs and logistic regression, we also included baseline demographic variables related to prior incarceration and monthly income to correct for baseline differences between the intervention arms with $p < 0.10$. We addressed 0 cells resulting from frequencies of 100% at 6-month follow-up using penalization with data augmentation (Greenland, Mansournia, & Altman 2016). We report odds ratios and 95% confidence intervals for each outcome.

Results

We screened 399 potential participants. Of whom, 174 were determined preliminarily eligible, and 105 were interviewed and randomized. Twenty-five participants were determined to be ineligible following randomization and excluded. Approximately half of these were determined ineligible at baseline, compensated and told that they could not continue. The remainder were determined ineligible later, either after a review of their baseline assessment or after indicating to a study team member that they had given incorrect information and were not eligible. A total of 61 (76.3%) of the 80 eligible randomized participants completed the 6-month follow-up interview, including 27 who were part of the non-peer supported comparison arm and 34 who were part of the peer-supported intervention arm. Statistically significant sociodemographic differences were not observed between those who were and were not retained (See Supplemental Table 1) or between those enrolled before versus after the change in enrollment criteria (Supplemental Table 2).

The baseline socio-demographics for those completing the follow-up interview are shown in Table 1. The mean age was 44.3 ± 11.2 years. Most (72%) had at least completed high school, but only 39% were currently employed or students. Seventy-four percent had a monthly income less than \$1000 and 31% considered themselves homeless. Most self-identified as homosexual, gay, or same gender loving (64%). Participants reported a mean of 1.9 (SD = 1.9) un-met needs, although some reported as many as 7. Seventy percent of participants had experienced incarceration, and a small number (8%) had engaged in sex work in the past six months. Few differences were observed between the intervention groups (Table 1), but participants in the intervention arm were more likely to report a history of incarceration and lower income.

The vast majority of those in the Peer Mentor arm participated by meeting with their Peer Mentors (91%) and attending movie nights/field trips (62%). Participants had a median of 6 (interquartile range (IQR) = 2-7) meetings, and 82% met with their Mentors at least twice. The median number of participants attending each of the social events was 4.5 (IQR = 3-6). An open-ended question, asking participants in both arms about their experience with the project yielded consistently positive feedback about the interventions.

Counts and percentages for the key outcome variables are reported in Table 2. There were statistically significant improvements in awareness of PrEP and PEP and in recent HIV and STI screening in the prior 6 months in both groups. Use of PrEP in the prior 6 months increased from 0% to 22% for participants in the Peer Mentor intervention arm and from 0% to 9% for participants in the non-Peer Mentor arm. We saw somewhat comparable baseline levels of awareness (53% vs. 70% for PrEP and 41% vs. 33% for PEP) and statistically significant increases in both PrEP awareness and STI screening among participants regardless of when they enrolled (Supplemental Table 3).

A preliminary analysis of changes in reported service needs and socioeconomic status was conducted to examine the potential impact of the intervention on social determinates of health. While statistically significant changes in the mean numbers of overall unmet needs were not observed, comparison group participants reported statistically significant declines in unmet needs for housing and transportation and intervention group participants reported statistically significant declines in unmet needs for healthcare benefits (Supplemental Table 4). Consistent with these observations, homelessness among control group participants declined from 33% to 19% ($p = 0.0455$). Large declines were also observed among full intervention group participants (29% to 15%, $p = 0.0588$), although they narrowly missed the criterion for statistical significance. Statistically significant changes in income and employment status were not observed (data not shown).

The results of GLMMs assessing changes in outcome variables from baseline to 6-month follow-up between groups are presented in Table 3. While 10 of 15 odds ratios favored the Peer Mentor intervention group at 6-month follow-up, confidence intervals were wide and none of the ratios for between-group changes in outcomes was statistically significant. The study was underpowered to find significant differences. The reported frequencies for most outcomes increased substantially over time in both intervention arms. For example, 32% of the Peer Mentor group had recently tested for STIs at baseline compared to 88% at follow-up, but the non-Peer comparison group also increased – from 23% to 70% – resulting in an OR=3.47 (95% CI 0.63-19.50).

Discussion

Increases in engagement with HIV prevention and HIV/STI screening among Black MSM were observed in both the peer-supported and the non-peer-supported versions of PtW. Particularly large gains were observed in awareness of pre- and post-exposure prophylaxis, use of PrEP, and screening for HIV and STIs. Persistent use of PrEP lagged well behind; however, with just 15 (25%) starting PrEP and 8 (53%) of those who started PrEP remaining on the drug. Although local campaigns to increase awareness of PrEP and PEP were running during the intervention, an examination of baseline awareness and receipt of PrEP/PEP education comparing those enrolled in the first and second years of the study suggest that these local efforts were not responsible for the increases in awareness that we observed.

Multivariate analyses did not show statistically significant group differences in uptake of HIV/STI services over time. It is important to note that both arms of the PtW trial constituted an intervention whose participants increased their engagement in HIV prevention and HIV/STI screening. The inclusion of “standard-of-care” control arm may have shown a larger effect size. The lack of a significant difference between the arms suggests that the peer support component did not provide added benefit. However, the study was underpowered as compared with the proposed sample size of 180, so a larger study is needed to address this question.

Other findings are worthy of note. Despite their high levels of poverty, participants reported fairly high levels of healthcare access, with 38 (62%) having both healthcare insurance and a regular medical provider at baseline. Both the Affordable Care Act and its predecessors in Los Angeles, such as the Low Income Health Program, likely account for this (Chen, Vargas-Bustamante, Mortensen, & Ortega, 2016; Sommers, Chua, Kenney, Long, & McMorrow, 2016).

In addition, the population older age distribution (64% ages 45 or older) may have increased the likelihood that participants had providers to address chronic health conditions that grow more common with age. The participants' older age may also have weakened the intervention's potential impact. Younger participants may have more to learn from the Peer Mentors and have had fewer occasions to experience barriers or disqualifications from specific benefits and services.

Study limitations include under recruitment, generalizability, mid-course protocol changes, and incomplete documentation of participation in the group activities. Our population of eligible enrollees was less than half what we planned resulting in part from the ending of an L.A. CADA HIV testing site that was a planned source of recruits. Other challenges in recruiting the population of interest, particularly younger participants, included some resistance to participation in a randomized trial and lack of follow through from initial contact through enrollment. For example, younger men expressed a desire to join and participate with their friends that could not be guaranteed given the design. The study was carried out in a single large urban center and men of low SES were over represented, potentially limiting generalizability to rural and suburban areas and to higher SES BMSM. Finally, the study aims and eligibility criteria shifted about a year into enrollment, with a greater emphasis on promoting uptake of PrEP and the inclusion of men who had recently tested for HIV. Despite these limitations, the study was successful in reaching a high-need, high-priority population, and large gains in uptake of screening and prevention services were observed.

Conclusions

The PtW intervention may have promise for increasing engagement in the HIV prevention care continuum among Black MSM – something that is sorely needed. However, larger studies are needed to demonstrate efficacy and test the impact of specific intervention components. Given the intervention’s intensity, a clear assessment of what components are most efficacious would allow for the identification of the most streamlined approach for implementation.

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Table 1. Selected baseline sociodemographic characteristics of Passport to Wellness Intervention trial participants followed at both time points (n=61)

	Non-Peer Mentor Intervention (n=27)	Full Peer Mentor Intervention % (n=34)	difference % ± SE
Age (mean ± SD)	46.9 ± 8.1	42.2 ± 13.0	4.6 ± 2.9
Education Level			
≤ High school	22 (6)	32 (11)	10 ± 11.3
High school diploma	33 (9)	26 (9)	7 ± 11.8
Some college	44 (12)	41 (14)	3 ± 12.7
Homeless	33 (9)	29 (10)	4 ± 11.9
Ever incarcerated	58 (15)	79 (27)	21 ± 11.8
Sex work in last 6 months	4 (1)	12 (4)	8 ± 6.7
Monthly income			
< \$1000	60 (16)	85 (29)	25 ± 11.2
\$1000-\$1999	18 (5)	6 (2)	12 ± 8.4
≥ \$2000	22 (6)	9 (3)	27 ± 9.4
Employment/Student status			
Full or part time	44 (12)	35 (12)	9 ± 12.6
Unemployed	22 (6)	26 (9)	4 ± 11.0
Unable to work/Disabled	33 (9)	38 (13)	5 ± 12.3
Number of unmet needs			
0	31 (9)	31 (12)	0 ± 11.9
1-3	50 (13)	41 (13)	9 ± 12.8
4+	19 (5)	28 (9)	9 ± 10.8

Note: No differences in % met the p<0.05 criterion for statistical significance.

Table 2. Changes in key outcomes between baseline and 6-month for the comparison and full-intervention Passport to Wellness groups.

	Non-Peer Mentor Intervention			Full Peer-Mentor Intervention		
		(n=27)			(n=34)	
	Baseline	6-month	difference %	Baseline	6-month	difference %
	% (n)	% (n)	± SE	% (n)	% (n)	± SE
Has a regular medical provider	59 (16)	62 (16)	0.0 ± 10.9	68 (23)	71 (24)	+2.9 ± 6.6
Has health insurance	85 (23)	93 (25)	+7.4 ± 5.0	91 (31)	94 (32)	2+.9 ± 5.1
<i>Has ever heard of PrEP</i>	56 (15)	89 (24)*	+33.3 ± 9.1	65 (22)	100 (34)*	+35.3 ± 8.2
Has used PrEP in the last 6 months^{ab}	0 (0)	9 (2)		0 (0)	22 (7)	
Is currently using PrEP^b	0 (0)	11 (3)		0 (0)	15 (5)	
<i>Has taken part in an informational session about PrEP</i>	22 (6)	70 (19)*	+48.1 ± 9.6	24 (8)	91 (31)*	+67.6 ± 8.0
<i>Has ever heard of PEP</i>	37 (10)	70 (19)*	+33.3 ± 9.1	38 (13)	88 (30)*	+50.0 ± 8.6
Has ever used PEP	0 (0)	4 (1)	+3.7 ± 3.6	3 (1)	3 (1)	0.0 ± 0.0
Is currently using PEP	0 (0)	4 (1)	+3.7 ± 3.6	0 (0)	0 (0)	0.0 ± 0.0
<i>Has taken part in an informational session about PEP</i>	15 (4)	48 (13)*	+33.3 ± 9.1	9 (3)	59 (20)*	+50.0 ± 8.6
Has ever been tested for HIV	85 (23)	93 (25)	+7.4 ± 9.0	88 (30)	97 (33)	8.8 ± 6.4
Has tested for HIV in the last 6 months^b	30 (8)	81 (22)	+51.9	29 (10)	91 (31)	61.8
<i>Has tested for STIs in the last 6 months</i>	23 (6)	70 (19)*	+50.0 ± 11.2	32 (11)	88 (30)*	+55.9 ± 8.5
Diagnosed with HIV at most recent test^b	0 (0)	4 (1)		0 (0)	6 (2)	

^aWas only asked after change in eligibility criteria, so reflects responses from only a subset of participants.

^bStatistical tests not run, because baseline value was determined by the eligibility criteria. Italics indicate those outcomes that were part of the primary study aims.

*asterisk indicates $p < 0.05$ for 6-month compared to baseline

Table 3. Results of generalized linear mixed models (GLMM) and logistic regressions comparing changes in key outcomes between the Peer-Supported and non-Peer Supported Passport to Wellness Intervention groups.

Multivariate GLMM or Logistic		
	OR [95% CI]	p-value
Healthcare access		
Has a regular medical provider	1.23 [0.24-6.30]	0.801
Has health insurance	0.47 [0.03-7.54]	0.588
PrEP engagement		
Has ever heard of PrEP	3.00 [0.24 - 38.29]	0.391
Has ever used PrEP	0.66 [0.07-6.00]	0.709
Has used PrEP in the last 6 months ^a	3.03 [0.60-16.40]	0.197
Is currently using PrEP ^a	1.48 [0.31-7.00]	0.625
Has taken part in an informational session about PrEP	3.26 [0.44-24.08]	0.242
PEP engagement		
Has ever heard of PEP	2.68 [0.41-17.30]	0.295
Has ever used PEP ^a	0.80 [0.04-14.89]	0.875
Is currently using PEP ^a	0.39 [0.03-4.85]	0.462
Has taken part in an informational session about PEP	2.10 [0.33-13.30]	0.426
HIV/STI screening		
Has ever been tested for HIV	1.45 [0.09-24.06]	0.792
Has tested for HIV in the last 6 months	1.53 [0.21-11.03]	0.668
Has tested for STIs in the last 6 months	3.47 [0.62-19.50]	0.155
Tested positive for HIV^a	1.58 [0.13-19.44]	0.721

Notes: All models controlled for income and incarceration history.

PrEP: Pre-exposure prophylaxis

PEP: Post-exposure prophylaxis

HIV: Human immunodeficiency virus

STI: Sexually-transmitted infection

^aStatistical results based on logistic regression of data from 6-month follow-up survey

Supplemental Table

Table S1. Selected baseline sociodemographic characteristics of trial participants that completed or did not complete (n=80)

	Completed % (n=61)	Did not complete % (n=19)	difference % ± SE
Age (mean ± SD)	44.3 ± 11.2	41.6 ± 9.5	2.7 ± 2.9
Education Level			
≤ High school	28 (17)	26 (5)	2 ± 11.6
High school diploma	30 (18)	26 (5)	4 ± 11.6
Some college	43 (26)	47 (9)	4 ± 13.1
Homeless	31 (19)	37 (7)	5.7 ± 12.6
Ever incarcerated	70 (42)	79 (15)	9 ± 11.1
Sex work in last 6 months	8 (5)	11 (2)	2.3 ± 7.9
Monthly income			
< \$1000	74 (45)	74 (14)	0 ± 11.5
\$1000-\$1999	12 (7)	16 (3)	4 ± 9.4
≥ \$2000	15 (9)	11 (2)	4 ± 8.5
Employment/Student status			
Full or part time	39 (24)	32 (6)	22 ± 12.7
Unemployed	25 (15)	47 (9)	15 ± 11.2
Unable to work/Disabled	36 (22)	21 (4)	
Number of unmet needs			
0	31 (21)	32 (6)	13 ± 13
1-3	45 (26)	58 (11)	13 ± 9
4+	24 (14)	11 (2)	2.7 ± 2.9

Note: No differences in % met the p<0.05 criterion for statistical significance.

Table S2. Selected baseline sociodemographic characteristics of trial participants enrolled under different criteria (n=61)

	No PrEP restriction % (n=34)	No HIV testing restriction % (n=27)	difference % ± SE
Age (mean ± SD)	44.3 ± 11.2	41.6 ± 9.5	2.7 ± 2.9
Education Level			
≤ High school	28 (17)	26 (5)	2 ± 11.6
High school diploma	30 (18)	26 (5)	4 ± 11.6
Some college	43 (26)	47 (9)	4 ± 13.1
Homeless	31 (19)	37 (7)	5.7 ± 12.6
Ever incarcerated	70 (42)	79 (15)	9 ± 11.1
Sex work in last 6 months	8 (5)	11 (2)	2.3 ± 7.9
Monthly income			
< \$1000	74 (45)	74 (14)	0 ± 11.5
\$1000-\$1999	12 (7)	16 (3)	4 ± 9.4
≥ \$2000	15 (9)	11 (2)	4 ± 8.5
Employment/Student status			
Full or part time	39 (24)	32 (6)	7 ± 12.4
Unemployed	25 (15)	47 (9)	22 ± 12.7
Unable to work/Disabled	36 (22)	21 (4)	15 ± 11.2
Number of unmet needs			
0	31 (18)	32 (6)	1 ± 12.2
1-3	45 (26)	58 (11)	13 ± 13
4+	24 (14)	11 (2)	13 ± 9
	44.3 ± 11.2	41.6 ± 9.5	2.7 ± 2.9

Note: No differences in % met the p<0.05 criterion for statistical significance.

Table S3. Changes in key outcomes between groups enrolled under different criteria

	no PrEP restriction			no HIV testing restriction		
		(n=34)			(n=27)	
	Baseline	6-month	difference %	Baseline	6-month	difference %
	% (n)	% (n)	± SE	% (n)	% (n)	± SE
Has a regular medical provider	65 (22)	73 (24)	+6.1 ± 8.5	63 (17)	59 (16)	+3.7 ± 8.3
Has health insurance	97 (33)	97 (33)	0.0 ± 4.2	78 (21)	89 (24)	+11.1 ± 6.0
<i>Has ever heard of PrEP</i>	53 (18)	94 (32)*	+41.2 ± 8.4	70 (19)	96 (26)*	+25.9 ± 8.4
Has used PrEP in the last 6 months^{a,b}	0 (0)	14 (4)		0 (0)	19 (5)	
Is currently using PrEP^b	0 (0)	12 (4)		0 (0)	15 (4)	
<i>Has taken part in an informational session about PrEP</i>	24 (8)	82 (28)*	+58.8 ± 8.4	22 (6)	81 (22)*	+59.3 ± 9.5
<i>Has ever heard of PEP</i>	41 (14)	82 (28)*	+41.2 ± 8.4	33 (9)	78 (21)	+44.4 ± 9.6
Has ever used PEP	0 (0)	3 (1)	+2.9 ± 2.9	4 (1)	4 (1)	+3.7 ± 3.6
Is currently using PEP	0 (0)	3 (1)	+2.9 ± 2.9	0 (0)	0 (0)	0.0 ± 0.0
<i>Has taken part in an informational session about PEP</i>	12 (4)	65 (22)*	+52.9 ± 8.6	11 (3)	41 (11)*	+29.6 ± 8.8
Has ever been tested for HIV	79 (27)	94 (32)	+14.7 ± 8.5	96 (26)	96 (26)	0.0 ± 5.2
Has tested for HIV in the last 6 months^b	18 (6)	94 (32)		44 (12)	78 (21)	
<i>Has tested for STIs in the last 6 months</i>	21 (7)	82 (28)*	+63.6 ± 8.4	37 (10)	78 (21)*	+40.7 ± 10.8
Diagnosed with HIV at most recent test^b	0 (0)	10 (3)		0 (0)	0 (0)	

^aWas only asked after change in eligibility criteria, so reflects responses from only a subset of participants.

^bStatistical tests not run, because baseline value was determined by the eligibility criteria.

Italics indicate those outcomes that were part of the primary study aims.

*asterisk indicates $p < 0.05$ for 6-month compared to baseline

Table S4. Changes in frequency of unmet needs between groups enrolled under different criteria

	Without peer (n=27)			With peer (n=34)		
	Baseline % (n)	6-month follow-up %(n)	difference % ± SE	Baseline % (n)	6-month follow-up %(n)	difference % ± SE
<i>Housing</i>	37 (10)	15 (4)*	-22.2 ± 9.6 -25.9 ±	32 (11)	32 (11)	0.0 ± 5.9
<i>Transportation</i>	44 (12)	19 (5)*	11.2	29 (10)	24 (8)	-5.9 ± 9.2
Financial assistance	15 (4)	11 (3)	-3.7 ± 8.3	29 (10)	15 (5)	-14.7 ± 7.4
Employment services	15 (4)	11 (3)	-3.7 ± 8.3	15 (5)	21 (7)	+5.9 ± 7.1
Food services	11 (3)	11 (3)	0.0 ± 9.1	18 (6)	12 (4)	-5.9 ± 8.3
<i>Health care benefits</i>	4 (1)	4 (1)	0.0 ± 5.2	24 (8)	3 (1)*	-20.6 ± 8.1
Child care	0 (0)	0 (0)	0.0 ± 0.0	3 (1)	0 (0)	-2.9 ± 2.9
Legal assistance	11 (3)	11 (3)	0.0 ± 9.1	15 (5)	12 (4)	-2.9 ± 8.8
Needle exchange	0 (0)	0 (0)	0.0 ± 0.0	0 (0)	0 (0)	0.0 ± 0.0
Mental health	22 (6)	11 (3)	-11.1 ± 9.6	29 (10)	12 (4)	-17.6 ± 9.7
Drug or alcohol treatment	4 (1)	4 (1)	0.0 ± 5.2	3 (1)	3 (1)	0.0 ± 4.2
Smoking cessation	7 (2)	11 (3)	+3.7 ± 6.4	6 (2)	12 (4)	+5.9 ± 5.8
Total # unmet (mean ± s.d.)	1.7 ± 1.7	1.1 ± 1.3	0.6 ± 0.4	2.0 ± 1.4	1.4 ± 1.6	0.6 ± 0.3

*asterisk indicates $p < 0.05$

Figure 1

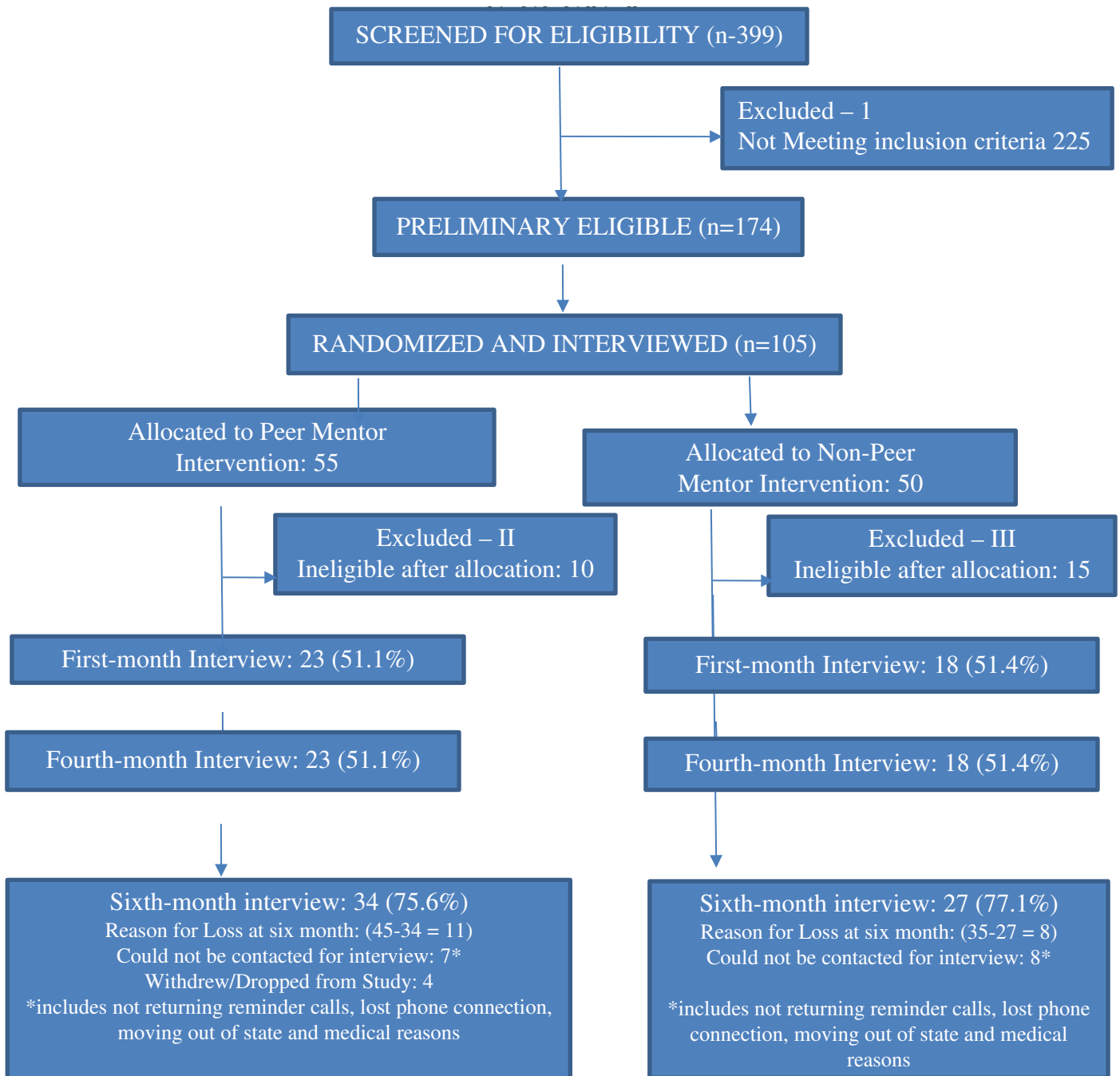


Figure Caption

Fig1. Participant CONSORT chart for the Passport to Wellness intervention trial