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A randomized controlled trial of a culturally congruent intervention to increase condom use and HIV testing among heterosexually active immigrant Latino men

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Abstract

This randomized controlled trial tested the efficacy of an HIV prevention intervention to increase condom use and HIV testing among Spanish-speaking, heterosexually active immigrant Latino men. A community-based participatory research partnership developed the intervention and selected the study design. Following baseline data collection, 142 immigrant Latino men were randomized to the HIV prevention intervention or the cancer education intervention. Three-month follow-up data were collected from 139 participants, for a 98% retention rate. Mean age of participants was 31.6 years and 60% reported being from Mexico. Adjusting for baseline behaviors, relative to their peers in the cancer education comparison, participants in the HIV prevention intervention were more likely to report consistent condom use and receiving an HIV test. Community-based interventions for immigrant Latino men that are built on state of the art

prevention science and developed in partnership with community members can greatly enhance preventive behaviors and may reduce HIV infection.

INTRODUCTION

Although Texas, California, New York, and Florida have experienced a large influx of Latino immigrants, recent trends in immigration patterns have resulted in changing demographics in the southeastern United States (US). Currently, North Carolina (NC) has one of the fastest growing Latino populations in the United States.(1) Immigrants to the Southeast are more likely from rural communities in southern Mexico and Central America, as opposed to those who traditionally immigrated to the US and were from northern regions of Mexico. Besides farmwork, including agriculture and poultry processing, many immigrants in the southeastern US work in furniture manufacturing, construction, and service industries.(2–8)

Latinos in the US continue to be disproportionately impacted by the HIV/AIDS epidemic. Latinos have the second highest rate of AIDS diagnoses of all racial and ethnic groups. Latinos accounted for nearly 20% of the total number of new AIDS cases reported each year – over three times greater than that for non-Latino whites.(9) Rates of reportable sexually transmitted diseases (STDs) also are higher among Latinos than among non-Latino whites. Gonorrhea, chlamydia, and syphilis rates are two to four times higher among Latinos than among non-Latino whites.(10) Many southeastern states, including NC, consistently lead the nation in reported cases of AIDS, gonorrhea, chlamydia, and syphilis.(6, 9, 10)

A complex combination of factors contribute immigrant Latinos' HIV vulnerability, including language (not speaking English), a lack of understanding of HIV transmission and prevention strategies and of available healthcare services,(3, 11–15) attitudes and beliefs that may not support safer sex,(3, 4, 16–20) and discomfort with talking about sex among partners and with healthcare providers.(3, 14, 21–23)

Gender role socialization prescribes that men must avoid “feminine behaviors,” be perceived as powerful, be and appear dominant, and prove their manhood by taking risks. This often is called “machismo”.(24, 25) Having multiple partners or sex with sex workers may imply masculinity. Engaging in risk may affirm some immigrant Latino men's masculinity while using condoms may be perceived as being weak.(3, 4) Furthermore, poverty, harsh labor conditions, and racial discrimination may challenge Latino self-image and traditional values.(5, 21, 25) Immigrants must cope with conflicting cultural and social norms and expectations while attempting to adjust to life in a new country.(4, 11, 26–29) Norms and expectations, including those related to sexual behavior and gender roles (whether “positive” or “negative”, “healthy” or “unhealthy”) may be challenged,(13, 30, 31) and for some, the subsequent stress and depression may result in higher rates of risk behavior and, as a consequence, increased rates of HIV and STDs.(18, 20, 32, 33)

Loneliness associated with social isolation resulting from immigration also may contribute to risk behaviors, including increased alcohol consumption and episodic binge drinking that may lead to sexual risk. Many men leave their families and support networks and come to the US. Missing their families and communities coupled with finding themselves in challenging living situations may further lead to risk behavior.(4, 17, 34–38)

Moreover, undocumented Latinos report fearing discovery and deportation and thus avoid formal systems of health care, which reduce the likelihood of exposure to preventive education and access to healthcare services.(3, 4, 32, 39, 40) They also may distrust the healthcare system and providers.(3, 41) Limited clinic hours, lack of bilingual and bicultural

resources and insufficient public transportation also may adversely affect access to HIV prevention resources (e.g., condoms, counseling, testing, care, and treatment).(3, 17, 21, 32, 42)

Furthermore, immigrant Latinos coming to the southeastern US are arriving in communities that lack bilingual service provision and other infrastructures to meet their needs. These communities also have a history of anti-immigration sentiment.(3, 11, 43, 44)

Although further research is needed to more fully understand the factors influencing HIV risk among immigrant Latinos, the current state of knowledge offers potential leverage points for intervention designed to reduce sexual HIV risk behaviors. These include (a) increasing knowledge of HIV/AIDS, effective prevention strategies, and how to access healthcare services in local communities; (b) recognizing, exploring, and addressing issues of sexual silence, gender role socialization and masculinity, and immigration; (c) building skills in communication, safer sex negotiation, and condom use; (d) building supportive networks within immigrant Latino communities; and (e) working with systems of health care to reduce barriers to access, build trust, and meet the healthcare needs of immigrant Latinos.

Despite the impact HIV and STDs are having on Latino populations, few resources exist to contribute to reducing and eliminating disparities in adverse sexual health outcomes experienced by this vulnerable population. Although interventions exist that provide insight into HIV prevention interventions for Latino men (e.g., VOICES/VOCES[45] and *Modelo de Intervención Psicomédica* [MIP; 46]), there are no community-based behavioral interventions with evidence of efficacy in reducing sexual risk of Spanish-speaking heterosexually active immigrant Latino men in the US. Most immigrant Latinos in the southeastern US are at sexual risk for HIV; injecting-drug use is not a prevalent mode of transmission.(6, 47) Thus, our community-based participatory research (CBPR) partnership in NC responded to the need and desire for HIV prevention interventions among immigrant Latino men living in rural NC. The objective of this study was to test whether participants randomized to a small-group HIV prevention intervention increased condom use and HIV testing when compared to their peers randomized to a cancer education comparison intervention.

METHODS

Community-based Participatory Research (CBPR)

CBPR has emerged as a viable approach to research to equitably involve community members, organizational representatives, and academic researchers in all phases of the research endeavor.(48, 49) Among CBPR's benefits, the involvement of representatives from each group ensures more informed understanding of health-related phenomena from various perspectives and the development of interventions that are more likely to be effective.

Our CBPR partnership, which has been previously described,(50–52) developed an intervention known as HoMBReS-2: Hombres Manteniendo Bienestar y Relaciones Saludables-2 (Men-2: Men Maintaining Wellbeing and Healthy Relationships-2). Based on the successes of the original *HoMBReS* intervention that used a lay health advisor (LHA) approach to HIV prevention, harnessing an existing soccer league in rural NC as a community resource,(3, 53–55) *HoMBReS-2* was designed as a small-group intervention with four modules designed to increase condom use and HIV testing among heterosexually active immigrant Latino men.

Study Design

During the process of implementing and evaluating the original *HoMBReS* intervention, members of the CBPR partnership increased their understanding of the power of scientific evidence to guide policy, specifically HIV prevention funding priorities. The dearth of interventions designed to meet the priorities and needs of immigrant Latinos in the Southeast motivated the CBPR partnership to develop *HoMBReS-2* and test it using a randomized controlled trial (RCT) design. Thus, a two-arm RCT was conducted with baseline data collection and a single follow-up assessment three months after the intervention was delivered.

Human subject oversight was provided by the Institutional Review Board of Wake Forest University Health Sciences.

Participants and Recruitment

Inclusion criteria for study participants were: self-identifying as Latino or Hispanic; being native Spanish speaking; being ≥ 18 years of age; self-identifying as male; and providing informed consent. Exclusion criterion was having participated in HIV prevention interventions (e.g., the original *HoMBReS* intervention[53]) previously. Study team members distributed recruitment materials and approached and screened Latino men for eligibility in *tiendas* (small Latino community-focused grocers), laundromats, businesses that employ large numbers of Latinos (such as poultry plants, construction sites, and hotels), sports leagues, English as a Second Language (ESL) classes, housing communities and apartment complexes, and Latino restaurants throughout rural central NC.

After potential participants were identified and screened, study team members scheduled a meeting to complete informed consent procedures and baseline assessments. Participants entered the study in waves that averaged 20 participants per wave rather than the entire cohort to avoid delays between recruitment, randomization, and intervention delivery. Each participant was randomized by his selecting an envelope that contained an appointment card including the date(s), time(s), and location of their intervention (either HIV prevention intervention or cancer education intervention); 15 HIV prevention intervention cards and 15 cancer education cards were included in each wave because recruitment occurred in the community and sometimes with groups of men.

A sample size of 120 was determined *a priori* based on condom use power calculations established using previously reported condom use among immigrant Latino in NC.(56) However, because of community interest in participating in both the HIV prevention intervention and the cancer education comparison, a sixth wave was implemented for a total of 142 study participants. Of the 145 men screened, all met inclusion criteria and 142 elected to enroll in the study, yielding a 98% participation rate. See Figure 1 for participant allocation and retention.

Data Collection

Data were collected privately in the offices of CBPR partners and in the homes of participants by native Spanish-speaking male study team members. All data were collected using the interviewer-administered assessment. Audio Computer Assisted Self-Interview (ACASI) was not used given formative data(3, 57, 58) and feedback from partnership members that suggested that participants were more likely to engage with a well-trained interviewer who could establish rapport and trust. This approach was thought to be culturally congruent given that some Latinos value *personalismo*, which is a cultural feature that tends to stress the importance of warm and friendly interactions and interpersonal engagement.(59) Furthermore, utilizing an interviewer-administered assessment overcame

both poor literacy and vision (resulting from lack of access to vision services). Participants were paid \$35.00 for the baseline and \$55.00 for the three-month follow-up assessments.

Measures

The assessment was comprised of 262 items based on self-report and required about 45–60 minutes to complete, depending on the skip patterns of each participant. Most items had predefined response options with binary, categorical, or Likert-scale response options to facilitate administration. Socio-demographic characteristics were assessed, including age, country of origin, educational attainment, employment status (employed year round, employed in seasonal work but not year round, and unemployed), income, and sexual identity. These items have been successfully used with immigrant Latinos in rural NC.(53, 60)

Acculturation was measured using the Short Acculturation Scale for Hispanics, a 12-item scale with three subscales: respondent language use ($\alpha=0.76$); respondent media use ($\alpha=0.85$); and respondent ethnic social relations ($\alpha=0.68$).(61)

Knowledge of HIV transmission and prevention was assessed through the summation of correct responses to 18 true-false items(56) and knowledge of STD transmission and prevention was assessed through the summation of correct responses to 10 true-false items. (56) Other psychosocial mediators were assessed included mastery(62; $\alpha=0.56$), male role attitude(63; $\alpha=0.67$), condom use self-efficacy(64; $\alpha=0.97$), and condom use expectancies(65; $\alpha=0.95$).

Perceived AIDS-related stigma was measured using an established measure that has been found reliable in English, Xhosa, and Afrikaans.(66) The scale also had satisfactory internal reliability ($\alpha=0.89$) in this sample. Items were reverse coded as necessary so that higher scores indicated higher knowledge, mastery, male role attitude, condom use self efficacy and expectancies, acculturation, and AIDS-related stigma.

Behaviors related to HIV and STDs also were measured, including gender of sexual partners, type of sexual activity (vaginal and anal), and condom use. The first dependent variable for this evaluation was consistent condom use during vaginal or anal sex during the past three months. Participants were asked to report their frequency of condom use during the past three months with all partners on an ordinal scale of “always”, “most of the time”, “about half the time”, “once in awhile”, and “never” for vaginal and anal sex. Consistent condom use was coded as “always”. The second dependent variable was HIV testing during the past 12 months. These items have been successfully used with immigrant Latinos in rural NC.(53, 60, 67)

Items that did not already exist in Spanish were translated into Spanish using a committee approach to translation that focuses on meaning and provides a process for iterative revision throughout the development process.(68, 69) A group of individuals with complementary skills, including translators (including native Spanish speakers from Mexico and Central America), a translation reviewer, content specialists, and a questionnaire design expert was convened. The translation was completed by multiple translators independently. The committee met to discuss versions of the translation; a reconciled version was created and reviewed and approved by the CBPR partnership.

Prior to administration, the assessment was pre-tested and revised to enhance comprehension, personal relevance, credibility, and acceptability.

Intervention Methods

The intervention was a small-group intervention designed to be interactive and activity-based. It included rapport and trusting building activities; didactic teaching; DVD segments that served as role modeling and triggers for discussion; role plays; group discussion; and skills building, practice, and feedback. It was based on social cognitive theory(70) and empowerment education,(71) blended locally collected data on risk among heterosexually active Latino men,(3, 4, 12, 53–55, 72) and addressed the priorities established by the CBPR partnership, including (1) increasing awareness of the magnitude of HIV and STD infections among Latinos in the US and NC; (2) providing information on types of infections, modes of transmission, sign and symptoms, and local counseling, testing, care, and treatment options; (3) increasing condom use; (4) bolstering the positive and reframe the negative aspects of what it means to be a man, a Latino man, and an immigrant Latino man; and (5) increasing the use of health care within an environment that lacks bilingual and bicultural services and within communities in which anti-immigration sentiment often is high.(3) The intervention is designed to build a foundation of knowledge about HIV, given that these immigrant Latinos have had very limited exposure to HIV information and have high levels of misconceptions.(3, 4, 12, 14, 53, 54, 73) The intervention also addresses the challenges immigrants face in the Southeast, a part of the country that lacks an established history of Latino immigration and the infrastructure to meet their needs. The abbreviated intervention modules and learning objectives are outlined in Table 1.

The intervention was peer led; three Latino men from rural NC were recruited and trained to serve as peer educators known as *compañeros de salud*. They were natural leaders within the community.(74) They were committed to developing their skills and positively impacting the health and wellbeing of immigrant Latino men like them within their communities; two had been former lay health advisors who had worked with soccer teams to promote condom use and HIV testing.(53, 57) All were native Spanish speakers; only one of the three spoke English, although limited. They were trained to implement the intervention by the study team.

The *compañeros de salud* were trained in four sessions. The training included the epidemiology of HIV and health disparities, HIV transmission, risk behavior, cultural and social influences on sexual health, access to healthcare services, predictors of behavior change, and group facilitation. The training was didactic and interactive and included role-playing exercises to provide opportunities to practice skills and receive feedback and suggestions to enhance their facilitation and communication skills.

One session also reviewed the study design and basic research concepts, including fidelity, bias, and evaluation, and human subjects protection. The *compañeros de salud* were evaluated pre- and post-training, and the results of these evaluations were used to tailor the training to their needs. The project coordinator and an observer were present during all intervention sessions to ensure fidelity.

A fourth *compañero de salud* was similarly selected and trained to implement the cancer education comparison intervention that was developed for this study by the CBPR partnership. To reduce potential contamination, he was not trained in the components of the HIV prevention intervention. The cancer education comparison intervention was delivered in one 2-hour session and focused on prevention of cancers particularly relevant to men: prostate, lung, and colorectal cancers.

The HIV prevention and cancer education comparison interventions were implemented on Saturday and Sunday mornings within the community.

Data Analysis

Analyses were performed using an intent-to-treat protocol with participants analyzed in their assigned study arms from randomization irrespective of the number of sessions attended. (75) Six participants attended the incorrect arm, and again according to the intent-to-treat protocol, analyses were conducted based on the arm to which they were originally randomized. At baseline, descriptive statistics summarized demographic characteristics, psychosocial mediators, and risk behaviors between intervention and comparison arms. Differences between arms at baseline were assessed using Student's t-tests or Wilcoxon rank sum tests for continuous variables and Chi-square or Fisher's exact tests for categorical variables. Intervention differences were assessed using logistic regression on follow-up outcome measures after adjusting for baseline characteristics. Additional covariates were considered in multivariable modeling for increased precision of intervention effects. Included covariates in the multivariable model were chosen *a priori* based on theoretical considerations and literature review regarding factors that might affect condom use and HIV testing. Interaction effects were checked first after centering continuous variables and none were significant at the 0.10 level.(76)

For sensitivity analyses regarding missing data, multiple imputation was used to impute missing data and compare these results to those in the complete-case analysis.(77, 78) We performed multiple imputation using chained equations (MICE).(79, 80) Twenty imputed datasets were created and then pooled to account for the within and between imputation variation. All analyses were performed using SAS v9.2 (SAS Institute, Cary, NC) and Stata v11.1 (StataCorp, Inc, College Station, TX). A two-sided P-value < 0.05 was considered to be statistically significant.

RESULTS

Baseline

Of the 142 participants, 72 were randomized to the HIV prevention intervention and 70 to the cancer education intervention. All participants reported being from outside the US; all were Spanish speaking with limited English-language use. Mean age and consistent condom use differed between the intervention and comparison arms at baseline. No other differences between the arms were observed at baseline (see Table 2).

Quality Assurance and Attrition

Trained observers attended all study sessions to assess fidelity; 100% of the intervention activities were implemented with fidelity. Participant attendance was high; 80% (n=58) of participants randomized to the HIV prevention intervention sessions attended all of the HIV prevention intervention sessions, and 91% of participants randomized to the cancer education intervention attended the one-session cancer education comparison intervention (n=64). A total of three participants were lost to three-month follow-up, two in the HIV prevention arm and one in the cancer prevention arm.

Intervention Effects

Intervention effects are presented in Table 3. At follow-up, participants in the HIV prevention intervention had significantly higher consistent condom use and HIV testing relative to participants in the cancer education arm. Specifically, adjusting only for baseline condom use, intervention participants had higher condom use during the past three months than those in the comparison arm (adjusted odds ratio [AOR]=3.52; 95% confidence interval [CI]=1.29–9.63; $P=.014$). Adjusting for baseline condom use and covariates, intervention participants had higher condom use during the past three months than those in the comparison arm (AOR=11.2; 95% CI=1.2–101.8; $P=.032$). Using multiple imputation to

examine sensitivity of results to missing data, intervention participants had higher condom use during the past three months than those in the comparison arm when adjusting only for baseline condom use (AOR=2.61; 95% CI=1.07–6.34; $P=.035$), and when adjusting for baseline condom use and covariates (AOR=3.87; 95% CI=1.31–11.5; $P=.015$).

Adjusting only for baseline HIV testing, intervention participants had higher HIV testing during the past twelve months than those in the comparison arm (AOR=5.18; 95% CI=2.26–11.9; $P<.001$). Adjusting for baseline testing and covariates, intervention participants had higher HIV testing during the past twelve months than those in the comparison arm (AOR=18.3; 95% CI=3.59–92.9; $P<.001$). Again, examining sensitivity using multiple imputation, intervention participants had higher HIV testing during the past twelve months than those in the comparison arm when adjusting only for baseline HIV testing (AOR=6.2; 95% CI=2.83–13.6; $P<.001$), and when adjusting for baseline HIV testing and covariates (AOR=9.51; 95% CI=3.52–25.6; $P<.001$).

DISCUSSION

This is the first RCT of a community-based small-group intervention designed to reduce sexual risk behaviors among heterosexually active immigrant Latino men to demonstrate efficacy. Analysis of self-reported data indicated that compared to their cancer education comparison peers, participants in the HIV prevention interventions were significantly more likely to report consistent condom use during the past three months and HIV testing during the past 12 months.

The *HoMBReS-2* intervention was designed to be culturally congruent and gender specific. It was based on locally collected formative data; previous experiences with developing, implementing, and evaluating HIV prevention interventions; sound health behavior theories; and the real, lived experiences of immigrant Latinos living in rural NC. Although the intervention used language that could imply either female or male sexual partners, it was designed specifically for immigrant Latino men who had sex with female partners. However, it is noteworthy that although all participants reported sex with females in the previous three months, three self-identified as “gay/homosexual.” In discussions with the interventionists and review of observer’s notes, discussions of same-sex behavior by participants were not common; they were not completely absent either. Because the intervention was designed to address notions related to masculinity, there was some discussion of same-sex behavior.

Although a dismantling study would help identify the possible reasons the *HoMBReS-2* intervention was efficacious, this intervention built on what is currently known about efficacious and effective HIV prevention interventions including (1) incorporating locally collected ethnographic data and tailoring to the defined audience (i.e., heterosexually active immigrant Latino men) to meet locally identified needs, (2) being gender specific (e.g., targeting men not both men and women), (3) having solid theoretical foundations (i.e., social cognitive theory and empowerment education), (5) discussing barriers to, and facilitators of, condom use and HIV testing, (6) exploring gender norms and expectations, (7) increasing awareness, knowledge, and positive attitudes and beliefs about risk reduction, (8) increasing risk reduction norms and social support for protection, (9) providing positive reinforcement for healthy behavior change, (10) skills building through role plays and practice, and (11) guidance on how to utilize available services.(8, 81–86)

It has been suggested that four or more sessions may be key to HIV prevention interventions reducing risk; however, although this intervention included four modules and multiple sessions, it did not include four separate sessions. The success of this intervention may be

attributable to a combination of factors, including the careful inclusion of what is known about HIV prevention interventions (81–88) as well as several other factors.

First, Latino men, who represent a new trend in immigration to the US, have identified HIV and STDs as health priorities. They want to learn about sexual health given the higher rates of disease when compared to other health concerns.⁽³⁾ Cancer has been identified as a concern as well by immigrant Latino men in rural NC given the frequency cancer is mentioned within popular media. Second, the intervention was developed by a CBPR partnership that included community members (e.g., immigrant Latino men), organizational representatives, and academic researchers – all of whom worked together through an iterative and systematic intervention development process that helped to ensure that the intervention blended sound science with the lived experiences of immigrant Latino men. The development of the intervention and the study design were not imposed by academic researchers; rather, the intervention, its content and activities, and the study design were based on iterative negotiation among CBPR partners. Third, this CBPR partnership had successful experiences developing and implementing other HIV prevention interventions for Latinos and was able to build on lessons learned from these experiences to develop *HoMBReS-2*.^(53, 55, 57) For example, DVD segments were developed to add to the teaching modalities that the intervention harnessed. Fourth, *HoMBReS-2* focused heavily on building condom use skills and included multiple activities to allow for skill development, practice, and correction. For example, condom use errors during initial condom skills activities were high; because this intervention did not focus on other risks (e.g., injecting-drug use), intervention content focused on activities to develop these skills. Fifth, an important component to the intervention included acknowledging the challenges that Latino men face in using condoms and being HIV tested. For example, a DVD segment followed a Spanish-speaking Latino man as he went through the actual testing process at a local health department. It showed the difficulties of getting an interpreter, the embarrassment of having a female interpreter and nurse, and types of questions that one is asked and the rationale behind the data that the health department or other testing sites collect.

Sixth, the *HoMBReS-2* intervention was implemented by well-trained peer leaders from the community itself. Natural helper-led interventions, including those led by peers, are an important approach in health promotion and disease prevention.^(15, 74) Peers can teach skills, model health-promoting behaviors, and serve as credible role models because they are from the community and they speak the same “language”. They understand the “real world”, practical challenges of change, and the risks individuals take when changing. Peers also can help change norms and expectations that influence behavior. They can offer social support for performance of desired behaviors and for avoidance of health-compromising behaviors. Little has been published about using a peer-led approach for HIV prevention among Latino men; another study using a peer approach was found to reduce risk indices using a one-sample pretest-posttest design.⁽⁸⁹⁾ This study offers evidence that immigrant Latino men can be effective serving as peer educators.

The Use of CBPR

This study was successful in recruiting a sample of 142 immigrant Latino men (participation rate = 98%) and retaining 98% of them at three-month follow-up within communities in which publicity over partnerships between local law enforcement and US Immigration and Customs Enforcement and recent allegations that public health department records had been used in deportation proceedings have contributed to fears and general distrust among many immigrant Latinos. Within this socio-political environment, this population is even more difficult to access and suspicious of research.^(3, 44) However, the trust that this CBPR partnership had in the local community, the prioritization of sexual health among Latino men, insights of the community partners, and the recruitment skills of the study team

enabled this study to overcome these challenges. In fact, a sixth recruitment wave was implemented due to the local Latino community's interest in both the HIV prevention and cancer education interventions.

Limitations

This study was conducted in NC among immigrant Latino men. Generalization of the findings to other Latino populations or contexts may not be appropriate. Although the demographics of Latinos immigrating to NC tend to represent those coming to the southeastern US more broadly, these assumptions have not been well tested particularly given the heterogeneity within Latino communities. Furthermore, the intervention was designed to reduce sexual risk given that injecting-drug use is not a prevalent mode of transmission among immigrant Latino men in NC.(6, 47) It was not designed to reduce risk through injecting-drug use. This study also relied on self-reported sexual behavior. However, self-reported behavior has been found to be reliable if collected carefully.(90, 91) Further research with a larger sample size could use biological outcomes to evaluate the intervention. This study also had a short follow-up period; longer studies must be initiated to explore maintenance and decay of behavior change over time.

The comparison intervention was not equivalent in the length, and future tests of this intervention should implement a comparison intervention that is more comparable in length. Furthermore, although the comparison *compañero de salud* was not trained in the HIV prevention intervention in order to reduce potential contamination, possible interventionist effects were not controlled using this approach. Similarly, data were not blinded, and despite randomization two significant baseline differences were observed (i.e., age and consistent condom use). These differences may reflect the small sample size and were controlled for statistically in evaluating intervention differences.

Finally, because they could not attend the intervention to which they were assigned and did not call the study telephone number to reschedule, six participants decided to go with someone they knew who had a session at a different day and/or time. Thus, they attended a different study arm from which they had been randomized. When these participants presented themselves to attend a session for the incorrect arm, study staff decided that it was better to maintain smooth community relations than turn them away, particularly given the need to maintain trust within this community. Participants did not prefer one study arm over the other; rather, they were relying on informal social networks to help them problem-solve when they had complications to study participation, just as they rely on informal networks to solve other problems they face, such as getting a car without documentation or finding a job. (3, 54)

Conclusions

Glaring gaps exist in the current intervention arsenal available to reduce the risk of HIV among some vulnerable populations, including Latino populations.(20, 82) There is a dearth of culturally congruent interventions to prevent HIV. The *HoMBReS-2* intervention is promising; it was found efficacious in increasing consistent condom use and HIV testing among a community-based sample of immigrant Latino men.

More rigorous study designs (e.g., a comparison intervention that is equivalent in length) and longer follow-up periods are necessary to explore the affects of the HIV prevention intervention and the maintenance of condom use and HIV testing behaviors. Moreover, determining whether this type of intervention can impact HIV-related behaviors of other Latino communities deserves exploration. For example, could this intervention serve as a foundation for other targeted or enhanced interventions to reduce risk among within other

communities of heterosexually active Latino men, Latino farmworkers, Latino MSM, and/or Latina women.

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Resumen

Este estudio controlado y aleatorizado evaluó la eficacia de una intervención de prevención del VIH para incrementar el uso del condón y de pruebas del VIH entre inmigrantes latinos heterosexuales activos hispanohablantes. Una colaboración de investigación participativa basada en la comunidad desarrolló la intervención y seleccionó el diseño del estudio. De acuerdo a una recopilación inicial de datos, 142 hombres latinos inmigrantes fueron asignados de forma aleatoria a la intervención de prevención del VIH o a la intervención de educación sobre cáncer. Se realizó una recopilación de datos a los tres meses a 139 participantes, con un índice de retención de 98%. La edad promedio de los participantes fue de 31.6 años y 60% reportó ser originario de México. Tomando en consideración los comportamientos en la evaluación inicial, en relación con sus pares en la comparación con educación sobre cáncer, los participantes en la intervención de prevención del VIH reportaron más probabilidad de uso consistente del condón y pruebas de VIH. Intervenciones basadas en la comunidad para inmigrantes latinos hombres realizadas utilizando ciencia de última generación y desarrollada en colaboración con miembros de la comunidad pueden cuantiosamente incrementar comportamientos preventivos y reducir infección por el VIH.

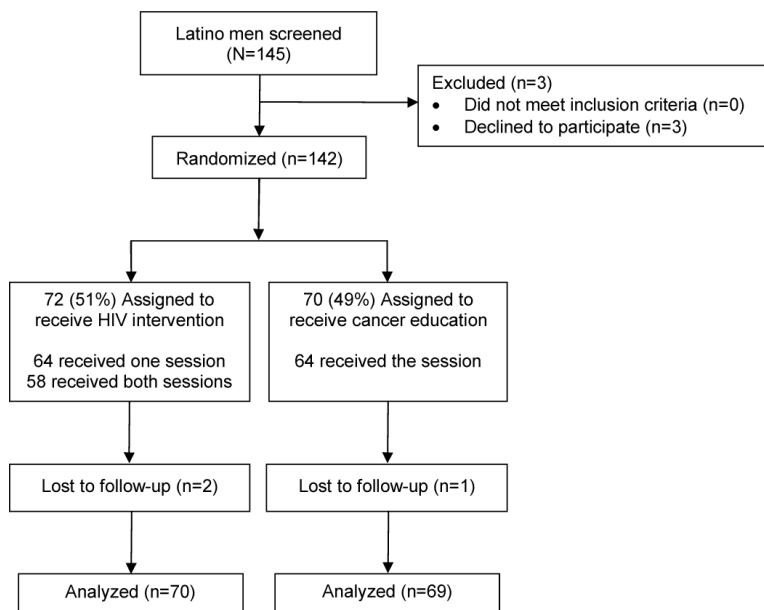


Figure 1.
Participant allocation and retention

Table 1The *HoMBReS-2* small-group intervention curriculum outlined

Module	Abbreviated Learning Objectives - Upon completion of the training session, participants will be able to:
(1) Intervention overview and introduction to sexual health	<p>Explain the purpose of the intervention</p> <p>Describe the magnitude of HIV and STDs within the Latino community</p> <p>Recognize the importance of learning how to prevent HIV and STDs</p> <p>Identify common STDs, including HIV, and their symptoms and treatment</p>
(2) Protecting ourselves	<p>Identify and distinguish myths from realities about HIV and STD transmission, prevention, symptoms, and treatment</p> <p>Explain how to protect oneself and the community from HIV and STD transmission, includes the correct selection, use, and disposal of condoms</p> <p>Negotiate condom use with a sex partner</p>
(3) Cultural norms that affect our health	<p>Describe how the environment affects an individual and community health, includes reciprocal determinism</p> <p>Reframe negative and reinforce positive socio-cultural norms and expectations that influence decisions, specifically masculinity, what it means to be a Latino man, and the effects of immigration</p>
(4) Review	<p>Delineate common modes of HIV and STD transmission and prevention</p> <p>Learn what life is like for a heterosexual Latino man living with HIV</p>

Table 2

Comparability of the HIV prevention intervention and the cancer education comparison arms at baseline

Characteristic	HIV prevention intervention ^a (n=72)	Cancer education intervention ^a (n=70)	P
Sociodemographics			
Age in years	29.7 (±9.9), range: 18–53	33.9 (±11.3), range 18–66	0.02
County of origin			0.1
El Salvador	10 (13.9)	9 (12.9)	
Guatemala	12 (16.7)	7 (10.0)	
Honduras	3 (4.2)	4 (5.7)	
Mexico	41 (56.9)	43 (61.4)	
Nicaragua	0	2 (2.9)	
Other	6 (8.3)	5 (7.1)	
< High school education or GED equivalent	44 (61.1)	38 (54.3)	0.6
Employed year round	45 (62.5)	44 (62.8)	0.4
Sexual identity			0.3
Bisexual	0	1 (1.4)	
Homosexual/Gay	2 (2.8)	1 (1.4)	
Heterosexual	69 (95.8)	67 (95.8)	
Don't know	1 (1.4)	1 (1.4)	
< \$20,000 / year estimated income	36 (66.7)	30 (62.5)	0.7
Acculturation			
Language use ($\alpha=0.76$)	1.52 (±0.59), range 1–3.4	1.45 (±0.47), range 1–3	0.5
Media use ($\alpha=0.85$)	2.11 (±0.109), range 1–5	2.14 (±0.97), range 1–5	0.9
Ethnic social relations ($\alpha=0.68$)	1.62 (±0.51), range 1–3	1.6 (±0.65), range 1–4	0.9
Mediators			
Knowledge of HIV transmission and prevention	5.78 (±2.88); range 0–11	6 (±2.59); range 0–11	0.6
Knowledge of STD transmission and prevention	3.64 (±2.28), range 0–8	3.75 (±2.22), range 0–7	0.8
Mastery ($\alpha=0.56$)	2.76 (±0.35), range 2.14–3.86	2.85 (±0.45), range 2–3.86	0.2
Male role attitude ($\alpha=0.67$)	2.78 (±0.3), range 2.13–3.5	2.68 (±0.45), range 1.13–3.63	0.1
Condom use self-efficacy ($\alpha=0.97$)	2.97 (±0.48), range 1.2–4	2.99 (±0.48), range 1.95–3.89	0.8
Condom use expectancies ($\alpha=0.95$)	66.78 (±13.46), range 37–111	66.6 (±13.42), range 29–97	0.9
AIDS-related stigma ($\alpha=0.89$)	2.37 (±0.43), range 1–3.19	2.4 (±0.46), range 1–3.2	0.7
Behaviors			

Characteristic	HIV prevention intervention ^a (n=72)	Cancer education intervention ^a (n=70)	P
Condom use during vaginal or anal sex with all partners, past 3 months	25 (34.7)	15 (21.4)	0.03
HIV testing, past 12 months	20 (27.8)	24 (34.3)	0.3

^aN (%) or mean (SD), as appropriate

Table 3

Logistic regression modeling of consistent condom use and HIV testing

Model	Unadjusted baseline		Unadjusted follow-up		AOR (95% CI)	P
	I*	C*	I*	C*		
Consistent condom use with all partners, past 3 months	34.7%	21.4%	62.8%	30.0%		
Baseline adjustment ¹ (n=91)					3.52 (1.29, 9.63)	.014
Baseline and covariates adjustment ² (n=53)					11.2 (1.2, 101.8)	.032
Multiple imputation with baseline adjustment ³ (n=139)					2.61 (1.07, 6.34)	.035
Multiple imputation with baseline and covariates adjustment ⁴ (n=139)					3.87 (1.31, 11.5)	.015
HIV testing, past 12 months	27.8%	34.3%	71.0%	31.6%		
Baseline adjustment ¹ (n=113)					5.18 (2.26, 11.9)	<0.001
Baseline and covariates adjustment ² (n=64)					18.3 (3.59, 92.9)	<0.001
Multiple imputation with baseline adjustment ³ (n=139)					6.2 (2.83, 13.6)	<0.001
Multiple imputation with baseline and covariates adjustment ⁴ (n=139)					9.51 (3.52, 25.6)	<0.001

* I=HIV prevention intervention group; C=Cancer education comparison group

¹ Adjusted for baseline measure

² Adjusted for age, acculturation, AIDS-related stigma, mastery, knowledge of HIV and STD transmission and prevention, male role attitude, condom use self-efficacy, and condom use expectancy at baseline

³ Modeling performed after multiple imputation with 20 imputed datasets, adjusted for baseline measure

⁴ Modeling performed after multiple imputation with 20 imputed datasets, adjusted for age, acculturation, AIDS-related stigma, mastery, knowledge of HIV and STD transmission and prevention, male role attitude, condom use self-efficacy, and condom use expectancy at baseline