ABSTRACT

Objective: This pilot study tested the efficacy of a brief, novel, theory-driven, self-guided, home-based intervention designed to promote condom use among young men who have sex with men (YMSM).

Participants: Thirty YMSM were recruited from a large public U.S. Midwestern university during spring of 2012.

Methods: The intervention was tested using a repeated measures design with the primary follow-up assessment occurring 6 weeks after enrollment.

Results: Forty-five percent of men reported a reduced frequency of unprotected insertive penile-anal intercourse in the past 30 days compared with baseline ($p = .01$). Consistency of condom use improved ($p = .013$) as did motivation to use condoms correctly, condom use self-efficacy, and condom attitudes. All participants indicated that they were glad they participated, would recommend the program, and that overall, they had liked the program.

Conclusions: This pilot study supports an expanded trial of this intervention with MSM at high-risk of acquiring HIV/STIs.

A Novel, Self-guided, Home-based Intervention to Improve Condom Use Among Young Men who have Sex with Men

The Centers for Disease Control and Prevention estimated that 57% of new human immunodeficiency virus (HIV) infections in the United States occurred among men who have sex with men (MSM).[1] HIV prevalence is highest among MSM under age 30 and the proportion of those who are unaware of their HIV infection is higher among younger MSM than their older counterparts.[1] Approximately half of the new HIV infections in the United States are among young men who have sex with men (YMSM) ages 13 to 24 years.[2] Because college-aged MSM are a unique sub-group of YMSM who are at high risk for acquiring HIV or other sexually transmitted infections (STIs), an effective HIV and STI prevention intervention that targets college-aged MSM could have public health importance. The need for theory-driven, brief, risk-reduction interventions affecting the sexual health of college students has been noted.[3-5]

Most condom-use programs focusing on youth and young adults have had mixed results and often require intensive resources; these factors have limited translation of efficacy trials into practice.[4] Many clinics do not have adequate staff to implement interventions, and a need exists for brief, evidence-based, condom-use promotion programs. Hence, we created a novel, brief, theory-driven, self-guided, home-based program designed to promote consistent and correct condom use that requires minimal introduction by clinic or program staff. *The Kinsey Institute® Homework Intervention Strategy (KIHIS)* features condom use "homework assignments" while promoting consistent and correct condom use among young men by focusing on condom-use skill, enjoyment, and self-efficacy. The *KIHIS* places the impetus for change on the client, focusing on solitary behavioral practice of condom-use skills without the pressure and experiences that are often inherent in partnered sexual interactions. In contrast to practicing

condom application on a penile model, this intervention more closely parallels the real life situation in which condoms are applied during a sexual interaction. The principles underlying this approach were taken from the behavioral therapy approaches most commonly used to treat problems in sexual functioning.[6-8,9,10] These approaches involve clients engaging behavioral assignments (called "directed practice") which are done at home and are designed to reduce "demand" by focusing on the giving and receiving of pleasure rather than experiencing orgasm.

The PLISSIT model used in behavioral sex therapy comprises the following components: permission, limited information, specific suggestions, and intensive therapy.[6] Sexual function problems are often addressed within the first three levels.[6] These were incorporated into the *KIHIS* in the following ways: (1) permission was provided via the discussion of the "normalcy" of condom use, hence reducing embarrassment; (2) limited information was given on correct condom use, making condom use more pleasurable, and the range of available condoms; (3) specific suggestions for "homework" activities were given in which participants practiced using a variety of condoms and lubricants. Similar to the sex therapy approach, the *KIHIS* intervention behavioral exercises were designed to increase an individual's focus on pleasurable sensations in a "non-demand" situation without the presence of a partner. Taking ample time and becoming more familiar with the touch and feel, smell, and sight of condoms is stressed.

Some major barriers to condom use relate to sexual arousal, sensation decrease, erection difficulties, and condom fit-and-feel problems.[12,13] Prior interventions designed to increase correct and consistent condom use have insufficiently addressed these sexual aspects of condom use. In the *KIHIS* program, the sexual arousal aspects of condom use are emphasized. A recent pilot study of *KIHIS* reported significant positive effects on condom use experiences, confidence in the ability to use condoms, self-efficacy for condom use, and condom comfort as well as

reduction in breakage and erection problems among young heterosexual men despite a small sample of only 30 men.[7] The aim of the current study was to evaluate the efficacy and acceptability of the *KIHIS* intervention among YMSM. We hypothesized that an increase in condom use and more positive attitudes toward condoms would be found post-intervention compared with baseline.

METHODS

Study Design

This study was a repeated-measures study design with two follow-up assessments. After the two-week intervention period, participants received a link through their e-mail to complete an immediate post-test questionnaire (T2). Four weeks later, another e-mail link was sent for participants to complete the delayed follow-up questionnaire (T3). Following completion, participants were given an additional consent form and asked to participate in an evaluative interview asking about their experience with and perceptions of the program.

Study Sample

A sample was recruited from a Midwestern university and its immediate surrounding areas. Recruitment involved flyers posted on the university campus, at a local gay-friendly bar in town, and student housing. Recruitment emails were sent to potential participants during spring 2013 via the GLBT student support services, sexuality panel volunteer listservs, and classes on sexuality and gender. Referral from enrolled participants was also used. Eligibility criteria included: being male; having used a male condom for penile-anal intercourse (PAI) with a male partner at least once in the past 30 days; age 18 to 29; ability to read, write and comprehend English; having used condoms inconsistently (less than always) in the past month; and having

regular access to the Internet. The study was approved by the university's institutional review board.

Intervention and Procedure

Men interested in the study were given a link to the screening survey. Those eligible to participate in the study viewed an online consent form that explained the purpose of the study and what participants were expected to do. After consenting, participants were assigned a number according to the order of enrollment and given a link to complete the pre-test or baseline questionnaire (T1). Initial meetings with the research assistant were scheduled by email. At that time, participants were instructed on the *KIHIS* intervention and study protocol, given a condom "ditty bag," and shown how to correctly apply a condom on a penile model.

The ditty bag included eight different types of condoms (3 of each brand) and four different brands of water-based and silicon lubricants (5 of each kind). Participants were asked to practice on their own with at least six different types of condoms during the next two weeks. These homework assignments entailed applying the condoms, focusing on their sexual arousal and sensations related to the aspects of the condoms they liked or disliked, proceeding to orgasm if they desired, and taking off the condom correctly. Participants were also encouraged to use lubricants if they felt that this increased sensations. In addition, participants were given an online link and asked to complete a condom rating form for each of the condoms they tested within 24 hours of each condom-use event. The purpose of the ratings were to encourage men to focus on the various sensations while using each of the condoms.

At T1, demographic and background information, sexual history, and attitudes toward condoms were assessed (see Table 1). Only the attitude measures were re-assessed at T2 whereas attitudes, motivation to use condoms correctly, and behavioral measures (e.g., frequency of

insertive anal intercourse and condom use) were re-administered at T3. Both T1 and T3 assessments used a 30-day recall period at T1 and T3.

Men were paid $15 for completing the T1 assessment and attending the initial session, $5 if they completed at least six condom ratings within the two-week period, $5 for completion of T2, and $25 for completing the T3 assessment. They were paid an addition $5 for the intervention evaluation interview, totaling $55 for completion of the entire study.

Measures

Behavioral Measures: The frequency of insertive penile-anal intercourse (IPAI) and condom use during the past 30 days were assessed at T1 and T3 to determine both frequency of unprotected IPAI and consistency of condom use for IPAI. Consistency of condom use was calculated as the percentage of time that a participant used a condom for IPAI (number of times a condom was used divided by the number of times he used a condom, then multiplied by 100).

Condom Motivation: Condom motivation was assessed by a single item "I am highly motivated to use condoms correctly." Response options were 1 (strongly agree) to 5 (strongly disagree).

Condom Use Self-Efficacy: Condom use self-efficacy was assessed using the seven-item measure, Condom Use Self-Efficacy[14] which asked how easy or difficult it would be to: (1) find condoms that fit properly; (2) put a condom on correctly; (3) keep a condom from drying out during sex; (4) keep a condom from breaking during sex; (5) keep an erection while using a condom; (6) keep a condom on while withdrawing; and (7) use a condom from start to finish. Response options were 1 (very difficult) to 5 (very easy).

Condom Attitudes: Five items adapted from the Multidimensional Condom Attitude Scale[13] were used: (1) condoms can make sex more stimulating; (2) condoms ruin the sex act; (3)

condoms are uncomfortable for both partners; (4) condoms are lots of fun; (5) the use of condoms is an interruption of foreplay. Response options were 1 (strongly disagree) to 5 (strongly agree).

Condom Use Experience: The Condom Use Experience subscale from the Condom Barriers Scale,[10] assessed the following seven items: (1) condoms rub and cause irritation; (2) condoms do not feel good; (3) condoms interrupt the mood; (4) condoms feel unnatural; (5) condoms don't fit right; (6) condoms prohibit closeness to partner; and (7) condoms change the climax or orgasm. Response options were 1 (strongly agree) to 5 (strongly disagree).

Negative Condom Attitudes: Additional negative condom attitudes were assessed with the following items: (1) condoms do not fit me well; (2) condoms are uncomfortable; (3) condoms help me last longer; (4) condoms decrease my sensation too much; and (5) condoms make it difficult for me to stay hard (maintain an erection). Response options were 1 (strongly agree) to 5 (strongly disagree).

Interview on Evaluation of Program: The interview asked men to rate the program and its effect on his attitudes and behaviors. For list of items, see Table 3. Two open-ended questions were also asked: (1) please tell us what you liked about this program; and (2) please tell us what we can do to improve the program.

Data Analysis

We hypothesized that: (1) unprotected IPAI would decrease; (2) consistency of condom use would increase; and (3) attitudes toward condom would improve following the *KIHIS* intervention. Therefore, one-tailed tests of significance were used. As T2 involved a repeat assessment of only subset of attitude measures and the changes in these were maintained at six weeks, we present only the comparison of T3 data with the baseline (T1). Descriptive statistics

were used for sample description and dependent variables for T1 and T3. The Wilcoxon Signed Rank Test was used to examine the change in frequency of unprotected IPAI events. Cronbach alphas were calculated for each scale score. When item elimination was indicated, items were dropped from the scale (see Results). Paired t-tests were used to compare continuous data (overall scale scores and post-hoc analyses of items).

RESULTS

Sample Description

Thirty-six eligible participants were enrolled at baseline (T1); six were excluded for not completing the immediate posttest (T2) or the six-week follow-up assessment (T3), leaving a final sample of 30 men who completed all assessments. Table 1 contains demographic information on the sample. Half (50%) of the sample were white, 16.7% were black, 16.7% Asian, 6.7% multi-racial, and 10% other. Thirteen percent of participants reported an ethnicity of Hispanic or Latino. The ages of participants ranged from 18-29 years with a mean of 21.5 (SD = 2.6) years. Eighty-seven percent (86.7%) identified as gay and 13.3% as bisexual.

(Table 1 about here)

Behavioral Data

A sizable proportion of men reported less frequent unprotected IPAI at follow-up compared with baseline. The frequency of unprotected IPAI in the past 30 days decreased for 44.8% (13/29) of men, stayed the same for 44.8% (13/29), and increased for 10.3% (3/29) (Related Samples Wilcoxon Signed Rank Test, $p = .011$). Men with reduced unprotected IPAI reported having practiced with significantly more condoms (mean = 5.85, SD = 2.11) than the no change or increased unprotected IPAI groups (mean = 3.94, SD = 2.02) ($t = -2.48$, df 27, $p =$

.010). Consistency of condom use also improved (see Table 2). At T3 men used condoms a mean of 73.4% of the time they had IPAI compared with 59.6% at T1 (t = 2.395, df 24, p = .013).

(Table 2 about here)

Attitude and Motivation Measures

As can be seen in Table 2, motivation for correct condom use also significantly increased from T1 to T3 (t = 2.608, df 28, p = .007). Overall Self-Efficacy Scale scores (Cronbach alpha at T1 = .55) significantly improved (t = 5.20, df 29, p < .001) with post-hoc comparison revealing significant improvement in all items except "find a condom that fits properly." Scores also significantly improved on the Condom Attitudes Score from the MCAS (Cronbach alpha .81; t = 1.20, df 29, p = .028), with post-hoc item analysis indicating significant higher agreement that "condoms can make sex more stimulating" (t = 2.16, df 29, p = .020) a trend for higher endorsement of the "condom are lots of fun" item (t = 1.56, df 29, p = .065) and significantly greater disagreement that "condoms interrupt foreplay" (t = 2.35, df 29, p = 013) at T3 compared to T1.

Two items were removed from the Condom Use Experience Scale and one from the Negative Condom Attitudes Scale because they did not correlate well with the other items yielding final Cronbach alphas of .81, and .79, respectively. There was significantly greater disagreement with the statement "condom decrease my sensation too much" at T3 compared to T1 (t = 3.12, df 29, p = .002). There were non-significant trends found for positive changes these two scales.

Interview Evaluation of KIHIS Program

Table 3 presents data from the ratings on the evaluation of the program. Twenty-two men opted to participate in the additional interview. The majority of participants indicated the

program helped them find condoms they liked, increased their confidence, made them more accepting of condoms, and increased their likelihood of using condoms. All agreed that they were glad they had participated in the program, would recommend it to others, and that they liked it overall. More than 90% agreed that directions on condom use were helpful, the ditty bag was cool, and trying on different condoms helped them decide what they liked best. Eighty-three percent (82.6%) agreed that that practicing with condoms alone was a good idea.

(Table 3 Here)

In response to the open ended item about what they liked about the program, responses included:

> *"I have always used condoms, but never had so many at my disposal. This helped me in terms of which ones I liked versus the ones I did not think so highly of. It helped me become more comfortable and confident with condom usage."*
>
> *"The educational value of using condoms. Never been taught from a programmatic perceptive. Made me feel more comfortable with condoms, and took away from the awkwardness."*
>
> *"I never thought about using condoms on my own before, but it's a good way of finding out which ones are right for you."*
>
> *"It was a good way to reinforce how to correctly wear a condom, or an appropriate way to put on a condom."*

In response to the open-ended question of how to improve the program, feedback focused on the importance of a user-friendly, web-based system for submitting condom ratings and a greater focus on lubricants.

COMMENT

This pilot study suggests that a brief, novel, theory-driven, self-guided, home-based intervention may be effective in increasing condom use, improving attitudes toward condoms, and condom use self-efficacy among YMSM. Improvements in the frequency of condom use for insertive penile-anal sex were observed for nearly one-half of the sample. This change in behavior was supported by favorable increases in the hypothesized psychosocial mediators; i.e., motivation to use condoms, condom attitudes, and condom use self-efficacy. Men who practiced more often with condoms were more likely have decrease frequency of unprotected IPAI. All the men indicated that overall they liked the program, were glad they participated, and that they would recommend the program to others. More than nine out of ten YMSM agreed that *KIHIS* helped them find the condoms they like to use and that they felt more confident using condoms. Despite the low sample size, the observed effect size was large and statistically significant. The current findings are consistent with the results of an earlier pilot study that tested this intervention with men who have sex with women.[7]

This novel intervention promoted condom use using a theory-based approach to behavior change. Further, this study included a program evaluation component that suggests very good acceptability of the program. The instructions to practice condom application and evaluate the fit and feel of condoms by masturbating with a condom on appear to be acceptable activities for men. Some participants expressed enthusiasm because this study gave them an opportunity to try various condoms that otherwise they would never have used. More than 90% indicated that directions on how to use condoms correctly were helpful.

This type of low-intensity, brief intervention is precisely what the United States Prevention Services Task Force has recommended be developed and disseminated.[15] Moreover,

the self-guided, home-based nature of this program means that it can be used in low-resource settings that have minimal staff hours to dedicate to prevention education.

Limitations and Conclusion

Study limitations include the lack of a control group and the use of a small convenience sample. Additionally, this pilot study was based on self-report and had no biological outcome measure. Notwithstanding these limitations, this pilot study supports the need for a larger trial, perhaps with MSM at high-risk of acquiring HIV or other STIs. Future research should test the *KIHIS* among minority populations of MSM and determine whether insertive partners who complete the program also translate what they learn to receptive partners and if they "coach" the insertive partner in condom use when they become the receptive partner. Further research should also explore innovative methods of intervention delivery, including online methods accessible via mobile phones and the effects of minimal-contact modes of delivery such as mailing condoms and lubricants and instructional DVDs to men. Given the dearth of efficacious interventions available for MSM,[16-18] the findings from this pilot study provide a starting point for a new approach to fostering protective behaviors for YMSM.

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