Longitudinal Effects of SafeTalk, a Motivational Interviewing-Based Program to Improve Safer Sex Practices Among People Living with HIV/AIDS

Carol E. Golin,
Division of General Medicine and Clinical Epidemiology, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Department of Health Behavior and Health Education, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

University of North Carolina Center for AIDS Research, Chapel Hill, NC, USA

UNC Sheps Center for Health Services Research, 725 MLK Jr. Blvd., Campus Box 7590, Chapel Hill, NC 27599-7590, USA

Jo Anne Earp,
Department of Health Behavior and Health Education, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Catherine A. Grodensky,
Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Shilpa N. Patel,
Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Chirayath Suchindran,
Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Megha Parikh,
Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Seth Kalichman,
Department of Psychology, University of Connecticut, Storrs, CT, USA

Kristine Patterson,
Division of Infectious Diseases, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Heidi Swygard,
Division of Infectious Diseases, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Correspondence to: Carol E. Golin, Carol_Golin@unc.edu.

E. Byrd Quinlivan,
University of North Carolina Center for AIDS Research, Chapel Hill, NC, USA

Division of Infectious Diseases, School of Medicine, University of North Carolina at Chapel Hill,
Chapel Hill, NC, USA

Kemi Amola,
Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill,
Chapel Hill, NC, USA

Zulfiya Chariyeva, and
Department of Health Behavior and Health Education, Gillings School of Global Public Health,
University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Jennifer Groves
Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill,
Chapel Hill, NC, USA

Carol E. Golin: Carol_Golin@unc.edu

Abstract

Programs to help people living with HIV/AIDS practice safer sex are needed to prevent
transmission of HIV and other sexually transmitted infections. We sought to assess the impact of
SafeTalk, a multicomponent motivational interviewing-based safer sex program, on HIV-infected
patients' risky sexual behavior. We enrolled sexually active adult HIV-infected patients from one
of three clinical sites in North Carolina and randomized them to receive the 4-session SafeTalk
intervention versus a hearthealthy attention-control. There was no significant difference in the
proportion of people having unprotected sex between the two arms at enrollment. SafeTalk
significantly reduced the number of unprotected sex acts with at-risk partners from baseline, while
in controls the number of unprotected sex acts increased. Motivational interviewing can provide
an effective, flexible prevention intervention for a heterogeneous group of people living with HIV.

Keywords

Introduction

Since the advent of highly active antiretroviral therapy, people infected with HIV are living
longer, healthier lives that include sexual relationships [1-5]. Most people discontinue risky
sexual behavior when diagnosed with HIV. While the degree of safer sex practiced for each
individual may vary over time [1, 6], on average, about 30% continue to engage in risky
behavior after diagnosis [1, 7-10]. Of concern, high rates of sexually transmitted infections
have been noted among some samples of people living with HIV [11-16].

Prior research has identified several factors that are associated with practicing risky sexual
practices among people living with HIV. These include health beliefs that HIV treatment
reduces transmission [17, 18], lower self-efficacy to practice safer sex [19, 20], better health
status [20, 21], substance use [19, 22], stressful life events [20, 23], perceived stigma [24],
and having sex in a committed relationship [17, 25]. Additionally, engaging in unsafe sexual
practices has been associated with having low behavioral control over condom use and a
lack of communication with sex partners [19]. These factors can be considered when
developing programs to reduce risky practices [1, 8-10].

Not only has headway been made in understanding the factors associated with HIV risk, but recent meta-analyses have also shown that HIV prevention programs targeting people living with HIV can be effective [26]. Moreover, programs found to be most effective were based on theories of behavior change; targeted HIV transmission risk behaviors; included skills-building; delivered by counselors or medical providers; were intensive; lasted longer than 3 months; and were conducted where clients received medical care [27, 28].

Clearly, programs must consider multiple risk factors and multiple components of intervention efficacy. Motivational interviewing (MI), an effective theory-based, client-centered counseling approach, is individualized in nature and a particularly promising strategy for addressing the complex, multidimensional drivers of safer sex practices among people living with HIV [29]. Using a conceptual model based on a comprehensive literature review, formative research, and social cognitive theory [30] to guide our intervention development, we developed SafeTalk—an MI-based, multi-component program to enhance safer sex practices among people living with HIV. Previously, we demonstrated that the SafeTalk intervention was feasible; patients found it important, acceptable, and potentially useful [31]. In the present study, we report its effect on patients' sexual HIV transmission risk behavior.

Methods

Overall Study Design

The intervention was evaluated in a two-armed, block-randomized, controlled trial of: (1) an intervention group whose members received SafeTalk, a four-session MI-based safer sex program, or (2) a control group whose members received A New Leaf, a four-session heart-healthy attention-matched control program [32]. The intervention assignment was concealed from those collecting data. Our goal was to deliver the sessions monthly whenever possible for both treatment groups during the first 4 months of study participation; however, we allowed flexible windows to accommodate patients with extenuating scheduling needs. Most counseling sessions were conducted in person, although in December 2007 we introduced the option of undergoing counseling by telephone to participants who reported difficulty travelling severe enough to hinder their ability to complete the intervention. Of the 110 to whom it was offered at study consent, 64 participants elected to have some sessions by phone (6 participants had all 4 sessions by phone, 7 people had 3 phone sessions total, 19 had a total of 2 phone sessions, and 32 had only one session by phone). A baseline and three follow-up evaluations were conducted at 4-month intervals.

All study procedures were approved by the University of North Carolina at Chapel Hill's Office of Human Research Ethics that is responsible for ethical and oversight of research that involves human subjects.

Sample

Study Sites—The study was conducted at three HIV clinics in North Carolina. Recruitment began in July, 2006 at a university-affiliated infectious diseases (ID) clinic; in September, 2006 at an urban county health department HIV clinic; and in March, 2008 at a community health center HIV clinic in a smaller city.

Participant Enrollment and Follow-up—Eligible participants were: (1) at least 18 years old; (2) HIV-infected; (3) receiving HIV treatment at one of our three study sites; (4) English-speaking; (5) cognitively able to complete consent and counseling; and (6) self-reported having oral, anal, or vaginal sex in the last 12 months. Potential participants were excluded if it was their first visit to the clinic, they or their provider deemed them too sick,

they knew that they would be leaving the clinic before the duration of study participation, or they had participated in another safer sex MI program within 6 months. At the community health center, we recruited only men to prevent co-enrollment with another safer sex study.

To recruit, the university-affiliated ID clinic utilized a research screener who provided the study staff with a list of scheduled patients who had been prescreened for eligibility and previously provided informed consent to be approached for any potential research projects. Over 90% of all clinic patients had pre-consented to be approached for research. At the other two sites, medical providers and clinic staff prescreened patients when they came to clinic visits. The prescreened eligible and interested patients were referred to study staff for further screening. We also posted fliers and screening forms at all three clinics and an affiliated AIDS service agency.

At all three sites, all patients who expressed potential interest were taken to a private room to complete eligibility screening, provide Informed consent and give extensive contact information. Patients who declined participation that day but expressed interest in participating in the future were approached at their next clinic visit.

Subjects received a gift card to a popular local grocery store worth $25.00 for each survey and $15 for each counseling session in addition to vouchers for parking, bus, and meals when needed.

Intervention Program: SafeTalk—Details of the SafeTalk intervention and its development have been described elsewhere [31]. Briefly, we refined a standardized, 13-step MI safer sex program that we had previously tested for feasibility in a demonstration project at one of our study sites [33]. The enhanced safer sex program SafeTalk incorporated several elements identified as important for effective "prevention with positives" programs and involved the following: four consecutive monthly, one-on-one MI sessions, with a series of five CD-booklet pairs that helped prepare patients for each MI session and provided tailored safer sex information; and four booster letters, each linked to the content of the preceding MI session. We included four sessions because we believed this was the minimum number that would allow a first session to primarily establish rapport, a second to identify and set initial goals and strategies, and the third and fourth to follow-up on, and then boost, the original goals, respectively. Four monthly sessions allowed the duration of the program to give adequate time for behavior change to take place and be able to be assessed in the designated time frame of our study measures (3 months).

Attention-Matched Control Program: New Leaf—We adapted an intervention entitled "A New Leaf… Choices for Healthy Living" [32, 34, 35], a structured nutrition and physical activity counseling program to prevent cardiovascular disease among low-income adults with limited literacy residing in the southeastern United States as the attention-matched control. We adapted the program to include information relevant for HIV-positive individuals and to mirror the SafeTalk format and materials.

Program Delivery and Quality Control—To ensure intervention quality, each SafeTalk MI counselor: (a) had a Masters level degree in Social Work, Counseling, or Health Behavior and Health Education; (b) underwent a 2.5 day training in HIV counseling and testing; (c) completed a manualized 5 day SafeTalk training in motivational interviewing conducted by a MINT trainer (CEG) that integrated advanced MI skills with HIV "prevention with positives" counseling that included intensive practice using the 13-step protocol, and a review of intervention fidelity.

Participants were asked to complete the four monthly SafeTalk or New Leaf counseling sessions within the first 4 months following study enrollment. Each session was intended to last 40–60 min, although 5% of them lasted less than 15 min and another 5% lasted longer than 60 min. Sessions were audio-recorded when participants granted consent (151 intervention participants agreed to be recorded and had at least one session recorded; a total of 275 sessions were recorded). Counselors also completed a detailed data recording sheet immediately following each session to document: (1) session content (e.g. topics selected for discussion, goals set, strategies identified) to be used for the individualized booster letters and; (2) degree of fidelity maintained for each of the 13 steps. To enhance intervention quality, each counselor reviewed her sessions weekly with a licensed, trained clinical counselor, and the entire team of counselors met monthly together with the clinical supervisor and the principal investigator to discuss counseling sessions. These reviews focused on improving MI technique, managing difficult cases, and resolving ethical dilemmas.

Data Collection Procedures—Participants completed an audio computer-assisted self interview (ACASI) (Nova Research Co) at baseline, and then at 4, 8 and 12 months after enrollment. Using headphones, respondents selected and entered responses into the computer unless they requested help from study staff. This approach allowed increased privacy to reduce the social desirability bias of responses to sensitive questions [36, 37]. Each survey lasted 30–60 min and assessed participants' risky sexual behavior, demographic and clinical characteristics, psychosocial factors, attitudes, beliefs, and sexual relationships. We assessed CD4 counts from medical records.

Measures

Outcomes—Risky Sexual Behaviors—The interview gathered detailed information about sexual behaviors over a 3-month recall period. Separate but equivalent versions were used for men and women, allowing the language and questions to be consistent with respondents' genders and the reported gender(s) of their sex partners. Participants were asked, by partner gender and for HIV-positive, HIV-negative, and HIV serostatus-unknown partner types, respectively, how many of each partner type they had and how many times they had had insertive or receptive vaginal or anal intercourse with this type of partner in the last 3 months, as well as how many times they had used a condom. Based on this information, for each participant we calculated how many times he or she had had unprotected vaginal or anal sex with ANY partner (UAVI = Unprotected Anal/Vaginal Intercourse) as well as with any AT-RISK (HIV-negative or unknown serostatus) partner (TRB = Transmission Risk Behavior).

Primary outcome: As the a priori primary test of efficacy of the intervention, we used TRB in the 3 months before the 8-month survey. We selected TRB as our primary outcome because it represented the behavioral outcome most likely to contribute to a reduction in HIV incidence. We selected 8 months because it was the first time point following the end of the intervention and thus allowed us to observe an effect of the entire intervention and yet to assess later, at 12 months, whether this effect attenuated.

Secondary outcomes: We also assessed: (1) the number of UAVI acts reported at 8 months post baseline and (2) the number of UAVI and TRB acts at 4 and 12 months post baseline.

Other Measures—To describe our sample, we measured several other independent variables. These are presented in Table 1.

Demographic Factors—We assessed participants' age, race/ethnicity, gender, education level, income, employment status, health insurance coverage and current relationship status. We determined participants' sex preference subgroup (men who have sex with men (MSM), men who have sex with women (MSW), or women who have sex with men (WSM)) from their gender and the gender of their reported sexual partners at baseline. Those who did not report any sex partners at baseline were categorized based on their gender and self-identified sexual orientation. Men who reported either male and female sex partners or bisexual orientation were categorized as MSM.

Clinical Characteristics

We assessed reported undetectable viral load in the last 6 months, time since HIV diagnosis, current antiretroviral use, and chart-abstracted CD4 count.

Psychosocial Factors

We asked participants if they had "ever been in prison or jail?" or "ever been molested, sexually attacked, raped, sexually abused or forced to have sex?" We assessed emotional well-being using 7 items from the SF-36 Health Survey [38]. The Cronbach's alpha for the scale was 0.860.

Behavioral Factors

We asked how frequently participants binge drank (5 drinks in a single day for men, 4 drinks for women), which we dichotomized as any or no binge drinking. Participants were also asked whether or not they had used each of 12 substances in the past 3 months. Because few participants reported substance use other than crack/cocaine during the past 3 months, we categorized each participant as having used or not used crack/cocaine.

We asked participants the number of men and women with whom they had had oral, vaginal, or anal sex in the past 3 months. We assessed whether or not participants were in a "primary relationship" defined as "someone you have lived with or seen a lot, and to whom you have felt a special emotional commitment."

Analyses

We performed a two-sample test of equal proportions to determine whether the dropout rate of respondents differed by treatment arm. We conducted descriptive analyses to examine the characteristics of the whole sample and of each treatment group. Because some subjects failed to complete information at all four time points (baseline, 4, 8, and 12 months) we had missing data during the follow-up months (90 participants missing at 4-month follow-up, 120 at 8 months, and 183 at 12 months); therefore, we used multiple imputation procedures to handle the missing data [39]. The SAS procedures PROC MI and MIANALYZE were used for this purpose (SAS Institute, Cary, NC). With these imputed data we also conducted descriptive analysis of UAVI and TRB for each intervention group at each time point. Four respondents reported a large outlying value for the number of unprotected sex acts (for example, 417 UAVI acts over a 3-month period). In a sensitivity analysis we set these large values as missing and reanalyzed the data with the multiple imputation procedures.

To conduct our primary test of efficacy, we compared the SafeTalk and New Leaf groups regarding the number of TRB acts they had at 8 months, controlling for baseline TRB count. Because the outcome variables are count variables, Poisson regression model was used to test the difference in the rate of occurrence of sexual acts in the two intervention groups. A significant regression coefficient (β) for SafeTalk indicates the difference in the rate of occurrence of TRB in the two treatment arms. The quantity "exp (β)" represents the ratio of

occurrence of the mean number of sexual activities (TRB) between the two groups. One can also interpret $100*(\exp(\beta))$ as the percentage change in expected number of sexual acts between the two intervention arms. Because intervention delivery site was used as a stratification variable in treatment randomization, it was included in the model as a control variable. We conducted the same analysis for our secondary outcome variable, UAVI at 8 months.

To determine the treatment effects on the two outcomes, UAVI and TRB acts, over time, we used the longitudinal information available for these variables. To take into account the correlation among these longitudinal measures, we used the Generalized Estimating Equation (GEE) procedure to test the difference between the treatment groups in the value at each time point and trend over time using the SAS procedure PROC GENMOD (SAS Institute, Cary, NC). The Poisson regression model contained time (as three dummy variables with baseline as reference), treatment, and treatment and time interaction. Significant treatment and time interactions would indicate that the treatment effect varied by time.

Results

Study Participants and Participation

During the recruitment period, 1,278 patients were eligible to be screened for the study based on eligibility criteria (at least 18 years old, English-speaking, HIV-infected, and receiving HIV treatment at one of our three study sites). Of these, 376 declined further screening and 67 were missed. Of the 835 approached and screened further, 179 were not eligible based on sexual behavior, intending to leave the clinic, or cognitive inability to provide consent, and 164 declined participation in the study. Of the 164 declining, 97 (59%) did not have time for the study, 15 (9%) were not interested, 20 (12%) had travel or transportation difficulties prohibiting study participation, 2 (1%) were too sick, and 30 (18%) declined for other reasons. Of 492 participants who enrolled in the study, two were unable to complete a baseline survey at enrollment and withdrew from the study at a later date, leaving a baseline study sample of 490 participants. Of these: 296 were from the university-affiliated infectious diseases (ID) clinic; 165 from the urban county health department HIV clinic; and 31 from the community health center HIV clinic. After completing the baseline survey, 248 were randomized to the intervention arm and 242 were randomized to the control arm (Fig. 1).

Sample characteristics (Table 1) were similar in both groups, with a mean age of 43 years, a majority being African American, about one-third being women, about one-fourth having less than a high school education, about 60% making less than $10,000 annually, and nearly two-thirds being unemployed. About 80% were on antiretroviral therapy and half had an undetectable viral load. Approximately 60% had a main partner, with a mean number of partners of 1.3 (SafeTalk) and 1.4 (New Leaf).

Retention and Study Sample

Of the 490 enrolled at baseline, 410 (84%) were retained at 4-month follow-up, 370 (76%) at 8 months, and 307 (63%) at 12 months. The proportion of participants selecting some phone counseling was evenly distributed by intervention arm. Between the 64 individuals who elected to receive some counseling by phone and all other participants, we found no statistically significant differences in race/ethnicity, education, income, housing stability, insurance, or relationship status between those who did and did not receive phone counseling. Defining dropout as those participants who did not complete the 8-month survey, the dropout rate was 23% for those randomized to New Leaf and 26% for those

randomized to SafeTalk, with no statistically significant difference in these proportions ($P =$ 0.37). Three quarters of those who dropped out at 8 months simply were lost to follow-up. Among those who we reached who did not complete an 8-month survey, reasons for this include the following: death (2%); illness (2%), withdrawal (2%); lack of time (2%); incarceration (8%); transportation difficulties (4%); migration (1%); work conflicts (2%); feeling the study was no longer relevant (2%); discontinuing clinical care at the study site (3%); personal challenges (1%); and no reason given (1%). The analysis sample (using imputed values) included observations at all time points for all 490 individuals.

SafeTalk Intervention Effects on Outcomes

Unadjusted Values for TRB and UAVI by Treatment Group. Table 2 shows the observed mean number of UAVI and TRB acts by treatment group at baseline and each follow up. Of note, there was no statistically significant difference in unprotected sex between the two arms at enrollment.

Primary Test of Efficacy (TRB) and of Test for Change in UAVI (Table 3). Controlling for baseline TRB and site, SafeTalk reduced the average number of TRB acts at 8-month follow-up by 87% compared with controls ($P < 0.0001$). Controlling for baseline UAVI and site, SafeTalk reduced the number of UAVI acts at 8-month follow-up by 73% compared with controls ($P < 0.0001$).

Longitudinal Analyses (Table 3 and Fig. 2a, b)

The regression coefficients in Table 3 indicate that the relative risks of occurrence of TRB (rate of occurrence of TRB in the SafeTalk group in relation to New Leaf) are 1.81, 0.25, 0.14, and 0.28, respectively at baseline, 4, 8, and 12 months. The P-values indicate that these differences were not significant at baseline ($P = .43$) and at 4 months ($P = .10$). However, SafeTalk significantly reduced TRB act rates at 8 and 12 months. The predicted means in Fig. 2a show that at 8 months, the average occurrence of TRB in the SafeTalk group is 0.27 (reduced from a level of 2.00 at baseline), whereas in the New Leaf group, the average TRB acts at 8 months was 1.9 (an increase from 1.10 at baseline).

The number of UAVI acts decreased in the SafeTalk arm from the baseline to follow-up surveys at all time points while increasing in the New Leaf control arm at all but the 12-month time point; however, the difference in UAVI between the two groups was not statistically significant.

Discussion

This study demonstrates that a multi-component, one-on-one MI-based program for a heterogeneous group of people living with HIV can effectively reduce the amount of risky sexual behavior with at-risk partners at 8 months follow-up compared with an attention-matched control condition, our primary test of efficacy. Moreover, this reduction was maintained at 12 months follow-up. The effect size of these changes is consistent with other studies of successful behavioral interventions [27]. Further, the number of unprotected acts with *any* partner also improved in the SafeTalk arm while it worsened among controls, although the difference between groups only achieved statistical significance in the 8-month Poisson regression model but not in the longitudinal GEE analysis.

The effect of the intervention on the number of risky sex acts is consistent with the harm reduction approach of the SafeTalk MI counseling style. This approach emphasizes setting achievable goals. Reducing the average number of unprotected sex acts with at-risk partners from 2.0 to 0.5 has the potential to reduce transmission of HIV to these partners.

It is also interesting that the intervention's impact on a reduction in the number of unprotected sex acts with at-risk partners was significant over time at 8 and 12 months, but not for changes that occurred in unsafe sex with any partner. At-risk partners in this study were defined as partners of HIV-negative or unknown serostatus, implying that sexual behavior with HIV-positive partners accounts for the difference in significance between these two outcomes. This finding is consistent with the focus of the Safe Talk intervention, which was on reducing HIV transmission. It is also possible that patients are willing to modify their (and their partners') behavior to avoid exposing uninfected partners, but that avoiding exposing partners who are already infected with HIV to additional HIV strains is not as strong a motivation for behavior change.

The efficacy of the SafeTalk intervention for unprotected vaginal or anal intercourse with at-risk partners may have resulted from several factors. First, we based the program on MI principles and on social cognitive theory with an emphasis on enhancing self-efficacy and skills-building, factors known to improve healthy behaviors [31]. Skills-building in the SafeTalk intervention included not only condom use skills, but also communication skills such as condom negotiation and serostatus disclosure, which are critical for a "prevention with positives" program. Second, the intervention was delivered by professional counselors who were trained in MI and met regularly with a clinical supervisor to review their techniques and taped sessions to ensure quality control and fidelity. Third, a counseling protocol that focused on inviting participants to identify their specific needs related to safer sex (such as addressing environmental factors) allowed counselors to address issues most salient to participants in a heterogeneous sample that included MSM, MSW, and women from both rural and urban areas in the southeastern United States. Fourth, the use of booklet/ CD pairs and booster letters to support the MI sessions likely served to enhance the effects of counseling. In particular, the use of realistic characters and actual patient vignettes that were vetted in formative work and refined based on input from other individuals living with HIV [31] likely facilitated participants' comfort with the program. Offering the program through clinics where participants already had established trusting relationships with clinic personnel may have facilitated program acceptance and rapport-building with the counselors. These findings are consistent with those of meta-analyses identifying a number of intervention features characteristic of successful prevention with positives interventions [27]. Finally, our longitudinal study design allowed us to demonstrate the extent to which changes were maintained over time.

Our results may not be applicable to HIV positive individuals with different risk profiles, such as injection drug users or persons from urban settings living in the Northeast or on the West coast of the United States, because these populations were not represented in our study. Although the measurement of sexual behavior using ACASI represents a methodological improvement over interviewer-administered data which can be biased by socially desirable responses and recall errors [36, 37], some reporting error may be differential in nature, biasing results away from the null. For example, participants receiving safer sex counseling may be more likely to understate their risky sexual behaviors. In another study, however, we did find a correlation between our ACASI-reported behaviors and sexually transmitted infection (STI) outcomes (Quinlivan EB, Golin CE, Patel S, et al. Trichomonas vaginalis infections among HIV-infected individuals receiving medical care in North Carolina. *In preparation*). However, reporting bias in the other direction is equally possible; that is, those receiving the MI counseling might be more likely to report risky behavior than those not receiving it because its nonjudgmental nature may make patients feel more comfortable admitting to risky behaviors. If this type of reporting bias were present, our current findings would underestimate the effect size.

Conclusions

In conclusion, MI delivered to HIV positive patients monthly in clinic over a 4-month period and enhanced by audiovisual materials can provide an effective prevention intervention for a heterogeneous group of people living with HIV. The individualized nature of MI and the tailored nature of the SafeTalk materials allowed the counselors to target the program to each client's unique needs and behaviors. In response to the growing number of people living with HIV, a compelling need exists to support effective prevention programs such as SafeTalk that can be easily disseminated and incorporated into the clinical setting. In this study, SafeTalk relied on training Masters level counselors. However, widely disseminating it to more resource-limited settings may require retesting its implementation, training and using less highly educated counselors to carry it out. We believe that the use of relatively low tech audio and visual materials can facilitate and further standardize this process.

Acknowledgments

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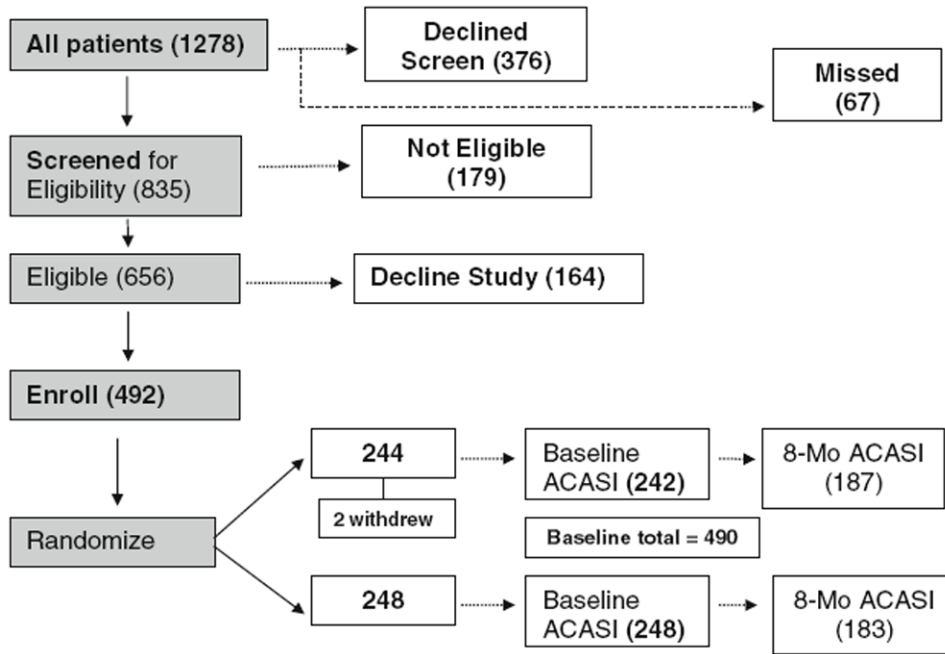
Fig. 1.
Eligibility and enrollment for a 2-arm randomized, controlled trial of SafeTalk
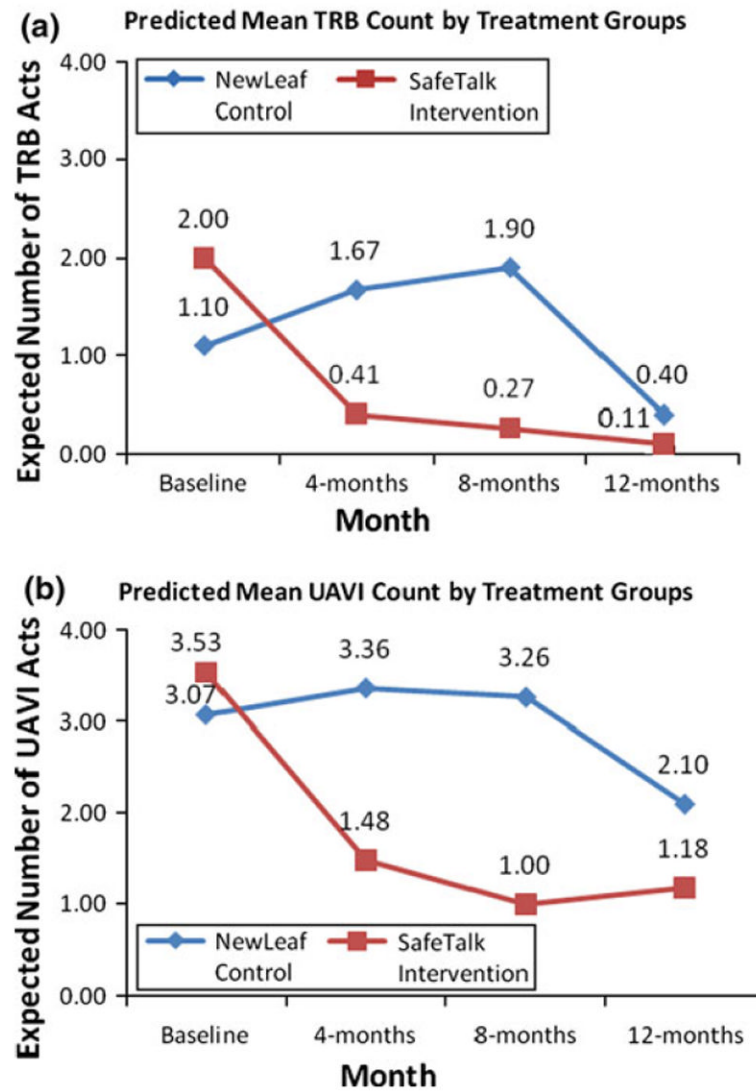
Fig. 2.
a Predicted mean counts of Transmission Risk Behavior (TRB). **b** Predicted mean counts of Unprotected Anal/Vaginal Intercourse (UAVI)

Table 1

Baseline descriptive characteristics of sample by treatment group

	New leaf control N (%)	SafeTalk intervention N (%)	Total sample N (%)
Sample size	242 (49.39)	248 (50.61)	490 (100)
Demographics			
Age N (Mean, Std)	241 (42.7, 8.4)	246 (42.6, 9.7)	487 (42.6, 9.0)
Race/ethnicity			
Black/African-American	165 (68.46)	182 (73.68)	347 (71.11)
White, non-Hispanic	54 (22.41)	46 (18.62)	100 (20.49)
Other	22 (9.13)	19 (7.69)	41 (8.40)
Sex preference subgroup			
MSM	97 (40.59)	88 (36.07)	185 (38.30)
MSW	63 (26.36)	67 (27.46)	130 (26.92)
WSM	75 (31.38)	86 (35.25)	161 (33.33)
WSW	4 (1.67)	3 (1.23)	7 (1.45)
Education			
Less than high school	63 (26.14)	57 (23.08)	120 (24.59)
High school graduate or GED	77 (31.95)	85 (34.41)	162 (33.20)
At least some college or technical school training	101 (41.91)	105 (42.51)	206 (42.21)
Income			
$10,000 or less	128 (55.90)	139 (59.15)	267 (57.54)
$10,001 to $40,000	82 (35.81)	78 (33.19)	160 (34.48)
More than $40,000	19 (8.30)	18 (7.66)	37 (7.97)
Employment			
Working part- or full-time	82 (33.88)	83 (33.47)	165 (33.67)
Not working	160 (66.12)	165 (66.53)	325 (66.33)
Had health insurance	157 (68.26)	170 (69.11)	327 (68.70)
Relationship status			
Single, not living with a partner	119 (49.38)	118 (47.97)	237 (48.67)
Single, living with a partner	58 (24.07)	41 (16.67)	99 (20.33)
Married	26 (10.79)	37 (15.04)	63 (12.94)
Separated/divorced/widowed	38 (15.77)	50 (20.33)	88 (18.07)
Sexual identity			
Straight/heterosexual	128 (53.33)	145 (59.18)	273 (57.47)
Gay/homosexual	83 (34.58)	70 (28.57)	153 (32.21)
Bisexual	19 (7.92)	19 (7.76)	38 (8.00)
Other/not sure	10 (4.16)	11 (4.49)	21 (4.42)
Clinical characteristics			
Had undetectable viral load in last 6 months	128 (52.89)	121 (48.99)	249 (50.92)
Duration of diagnosis			
Less than one year	16 (6.69)	21 (8.57)	37 (7.64)
1–9 years	112 (46.86)	120 (48.98)	232 (47.93)

	New leaf control *N* (%)	SafeTalk intervention *N* (%)	Total sample *N* (%)
10 years or more	111 (46.45)	104 (42.45)	215 (44.42)
Currently on HAART	192 (79.34)	197 (79.44)	389 (79.39)
CD4 count <200	45 (20.64)	35 (15.63)	80 (18.1)
Psychosocial characteristics			
Sexual abuse	105 (43.57)	103 (41.53)	208 (42.54)
Incarceration	130 (53.72)	145 (58.47)	275 (56.12)
Emotional well-being N (Mean, Std)	241 (2.6, 0.9)	245 (2.5, 0.8)	486 (2.6, 0.9)
Behavioral characteristics			
Binge drinking in past 3 months	100 (40.98)	92 (39.15)	192 (40.08)
Crack/cocaine use in past 3 months	50 (21.01)	39 (17.03)	89 (19.06)
Number of sex partners N (Mean, Std)	236 (1.4, 2.0)	243 (1.3, 1.4)	479 (1.4, 1.8)
Had main sex partner	131 (55.74)	139 (57.44)	270 (56.60)

Table 2

Baseline and follow-up unadjusted outcomes by treatment group

	Baseline	**4-month**	**8-month**	**12-month**
UAVI count				
SafeTalk Mean (SD)	3.86 (27.35)	1.68 (6.22)	1.10 (3.21)	1.30 (7.10)
New Leaf Mean (SD)	3.32 (13.75)	3.66 (29.60)	3.54 (32.64)	2.31 (16.12)
TRB count				
SafeTalk Mean (SD)	2.66 (26.91)	0.57 (3.72)	0.37 (1.33)	0.17 (0.81)
New Leaf Mean (SD)	1.44 (9.03)	2.19 (28.97)	2.58 (32.23)	0.53 (4.04)

UAVI unprotected anal/vaginal intercourse with any partner, *TRB* transmission risk behavior, UAVI with At–Risk Partner

Table 3

Adjusted parameter estimates for Transmission Risk Behavior (TRB) and Unprotected Anal/Vaginal Intercourse (UAVI) at eight months and using longitudinal Generalized Estimating Equation (GEE)

	TRB parameter estimate	Std error	P-value	UAVI parameter estimate	Std error	P-value
Test of efficacy						
8-month outcome	−2.05	0.39	<0.0001	−1.28	0.27	<0.0001
GEE results						
SafeTalk effect	0.60	0.76	0.43	0.14	0.52	0.79
Visit2	0.42	0.95	0.66	0.09	0.58	0.87
Visit3	0.55	0.92	0.55	0.06	0.63	0.92
Visit4	−1.01	0.59	0.09	−0.38	0.41	0.37
Arm * visit 2	−1.99	1.22	0.10	−0.96	0.77	0.21
Arm * visit 3	−2.54	1.14	0.03	−1.32	0.79	0.10
Arm * visit 4	−1.86	0.92	0.04	−0.71	0.70	0.32