

6 Online tailored intervention

Davidovich, U., de Wit, J.B.F., & Stroebe, W. Using the Internet to reduce risk of HIV-Infection in steady relationships: A randomized controlled trial of a tailored intervention for gay men. In submission.

6 Online tailored intervention

Using the Internet to reduce risk of HIV-Infection in steady relationships. A randomized controlled trial of a tailored intervention for gay men.

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Abstract

Objectives

Relationships are a high-risk setting for HIV-infection. This paper describes the development and efficacy-testing of an online theory-based tailored intervention which prepared single gay men to practice safe sex with future steady partners—labeling it the ‘cognitive vaccine approach’

Methods

The target was the promotion of negotiated safety (NS): steady partners testing for HIV and reaching agreements to either be monogamous or to only have safe sex outside the relationship in order to have safe unprotected anal intercourse with each other. The intervention content was based on the information, motivation, behavioral-skills model and the intervention was tailored according to knowledge, motivation, and skill-related deficiencies of each participant. Condom use was promoted as the default alternative for NS. Using an online randomized controlled trial we examined the effects of a tailored versus non-tailored version of the intervention. The cognitive effect (i.e. response efficacy, intentions, and perceived behavioral control (PBC) was measured directly after the intervention and, after 6-months, the behavioral effect (i.e. NS and condom use) via e-mail follow-up.

Results

Online recruitment produced 1013 single gay or bisexual men. The median age was 33 (SD=11.1). Analyses revealed that both tailored and non-tailored interventions increased response efficacy ($p \leq .001$), but only the tailored intervention increased intentions to practice negotiated safety and to use condoms with future partners ($p \leq .05$). No effect was found for PBC. Follow-up on behavior indicated that the men in the tailored intervention were

more likely to practice NS with their new partner (OR=10.50, 95%CI 1.19-92.72). Intentions to practice NS at time 1 mediated the intervention effect on behavior.

Conclusions

The tailored intervention significantly increased NS behaviors at a six months follow-up and rendered the cognitive vaccine approach effective. The motivational component of the intervention seems to have been the most effective one in inducing behavioral change.

Introduction

Steady relationships are an underestimated setting of HIV transmission between gay men. High rates of risky unprotected anal intercourse (UAI) between steady partners have been documented [1, 2], and high rates of HIV-transmission have been attributed to steady partners [3]. These findings point to the urgent need to promote safe sex between steady partners, a need which long eluded HIV-prevention efforts that often focused on promoting safe casual sex.

To protect themselves from HIV-infection during anal intercourse, steady partners can choose between two strategies: condom use or negotiated safety. In the latter strategy, steady partners have UAI with each other but are both tested negative for HIV and keep their relationship monogamous, or have only safe sex outside the relationship [1, 4, 5].

In this paper we will present the development and efficacy of a cognitive-behavioral intervention to promote safer sex between gay steady partners. This intervention does not promote the use of condoms but rather the practice of negotiated safety since the strategy of condoms has consistently failed to generalize into the setting of steady relationships [6-8]. The target group for the intervention was single gay men. Targeting single men to promote safe sex between steady partners might seem paradoxical, but this approach was based on empirical findings. In a previous study [9], we found that in over 50% of the cases, men who had risky UAI with their steady partner had engaged in that behavior within the first three months of the relationship. Such a rapid onset of sexual risk leaves only a small window-of-opportunity for prevention before men have already put themselves

6 Online tailored intervention

at risk. Our aim was therefore to prepare single gay men to have safe sex with future steady partners by what might be called a ‘cognitive vaccine’ approach.

The content of our intervention was empirically based on previous research into the determinants of sexual risk behavior in steady relationships [1, 3, 7-16]. Its theoretical framework is the Information, Motivation, Behavioral skills (IMB) model [17-19] used successfully in the past to promote HIV-prevention behaviors in various target groups, including gay men [20].

The IMB model postulates that the promotion of HIV-preventive behaviors requires the increase of knowledge, motivation, and skills concerning such behaviors. To increase knowledge of negotiated safety procedures and improve skills to engage in negotiated safety, we did not use additional theoretical guidelines; however, we used components of other theoretical frameworks to operationalize the motivation component of the IMB model. Based on the theory of planned behavior [21], we corrected faulty beliefs regarding sexual risks in relationships. Correct beliefs regarding HIV risk-taking in relationships should contribute to creating more positive attitudes and, eventually, stronger intentions towards protective behaviors. Based on the health-belief model principles [22, 23], we aimed to increase the sense of vulnerability to HIV infection by steady partners and to increase perceived benefits for HIV-testing. Both should result in the increase of motivation to engage in negotiated safety.

The combination of the IMB-model principles and the HIV-prevention needs of our target group as reflected from empirical studies we conducted and consulted, produced the prevention modules which constituted our intervention. However, the resulting large number of these modules raised concern that the prevention message might become too long and detailed, lowering its potential impact. One solution was to offer the intervention modules selectively, according to the actual needs of the targeted individuals.

Interventions that are matched to individual needs are called “tailored interventions”. The concept of “tailoring” is broad [24], as one can match the intervention to many individual characteristics. These include cognitive

aptitude [25, 26], motivation to engage in certain behaviors [28, 29], socio/cultural demographics [30, 31], and behavioral risk profiles [32, 33]. Tailoring can enhance the individual relevance of the intervention by removing components which are not needed by an individual—making the final message more concise in comparison to its non-tailored version. Tailoring also provides an excellent way to prioritize information in complex interventions. Intervention developers often need to omit a few helpful intervention components just in order to keep their messages brief. Making difficult choices as to which components to remove can be avoided when prevention messages are tailored, since relevant but less crucial components can simply be offered ‘on demand’. Several literature reviews that examined the efficacy of various tailored interventions in diverse medical settings have presented a positive picture of the behavioral effect these interventions have, compared to non-tailored or standard-of-care interventions [34-36].

To facilitate the application of the tailoring principles in our negotiated safety intervention, we chose the internet as the communication medium. The popularity of the internet among gay men in the Netherlands, with usage estimates that range between 80%-90% [unpublished data Amsterdam cohort studies among homosexual men, 2002], has opened new horizons for HIV-prevention activities [37, 38]. One of the biggest advantages of the internet is that it allows easy interaction with the users on an individual level. Men can be provided with “smart” interventions that first detect their individual needs and, subsequently, offer the tailored support online. This type of contact mimics the interactive qualities of an individual counseling session but, with the help of internet, the traditional one-on-one counseling session is changed into ‘one-on-mass’ sessions.

All though the realm of tailored online interventions is new, evidence of its efficacy is reported in interventions aimed at reducing depression [39] and promoting healthy eating [40]. A meta-analysis of randomized controlled trials of online interventions versus non-online interventions shows a stronger effect on behavior for the online interventions, though those examined were not necessarily tailored [41]. Evaluation of tailored HIV-prevention interventions online is still scarce to non-existent. Bull et al [42] conducted a randomized controlled trial to evaluate the effect of an online

6 Online tailored intervention

tailored HIV-prevention intervention. However, low retention rates in their trial prevented them from making any statements on the effect of the intervention.

The goal of the present study was to examine whether an online intervention which is based on the IMB-model principles and tailored according to individual needs will help single gay men to practice negotiated safety with future steady partners. To examine its efficacy, we conducted a randomized controlled trial with two intervention conditions and one control condition. The first intervention condition was not tailored, offering participants the full array of intervention modules. The second intervention condition offered a tailored version, by which participants received the modules that matched their individual needs. The control condition offered no intervention. A cognitive-assessment questionnaire to examine the intervention effect on the social-cognitive determinants of sexual behavior was administered directly after the intervention. The behavioral effect was measured six months later.

Our main hypothesis was that the tailored intervention would be the most effective in bringing about cognitive and behavioral change. We also hypothesized that although our intervention did not explicitly promote use of condoms, the promotion of negotiated safety might indirectly stimulate the use of condoms. For example, participants who were persuaded of the need to have safe sex with steady partners but did not wish to get tested for HIV or make sexual agreements with their partner, might choose the condom strategy.

Methods

Recruitment

To participate in the study a person had to be male, HIV-negative or of unknown serostatus, single, and open to a steady relationship with a man in the future. We included only men of negative or unknown HIV serostatus because our prevention message promoted negotiated safety: UAI between steady partners of a concordant negative HIV-status.

Participants were recruited online via banners (i.e., internet advertisements), editorials, and links placed in 18 websites popular among gay men in

the Netherlands. To obtain a diverse sample of gay men, we used websites that varied in theme or in services offered. Each of the sites focused on one of the following: sex chat, social interaction (i.e., non-sexual chat sites), gay-related information (e.g., entertainment and events), sexual health information, and gay organizations. The banners, editorials, and links called for participation in a study about sex in steady relationships and were designed to attract men who have sex with men.

Recruitment continued for two months. Power analysis indicated that based on an .05 significance level, power of 0.8, and a reduction of 20% in the prevalence of risk behavior, we required a minimum of 107 men for each condition of the trial, or a minimum total sample of 321 men. Based on previous experience with online recruitment, we expected to obtain the needed number of participants within the 2-month recruitment period.

Procedures

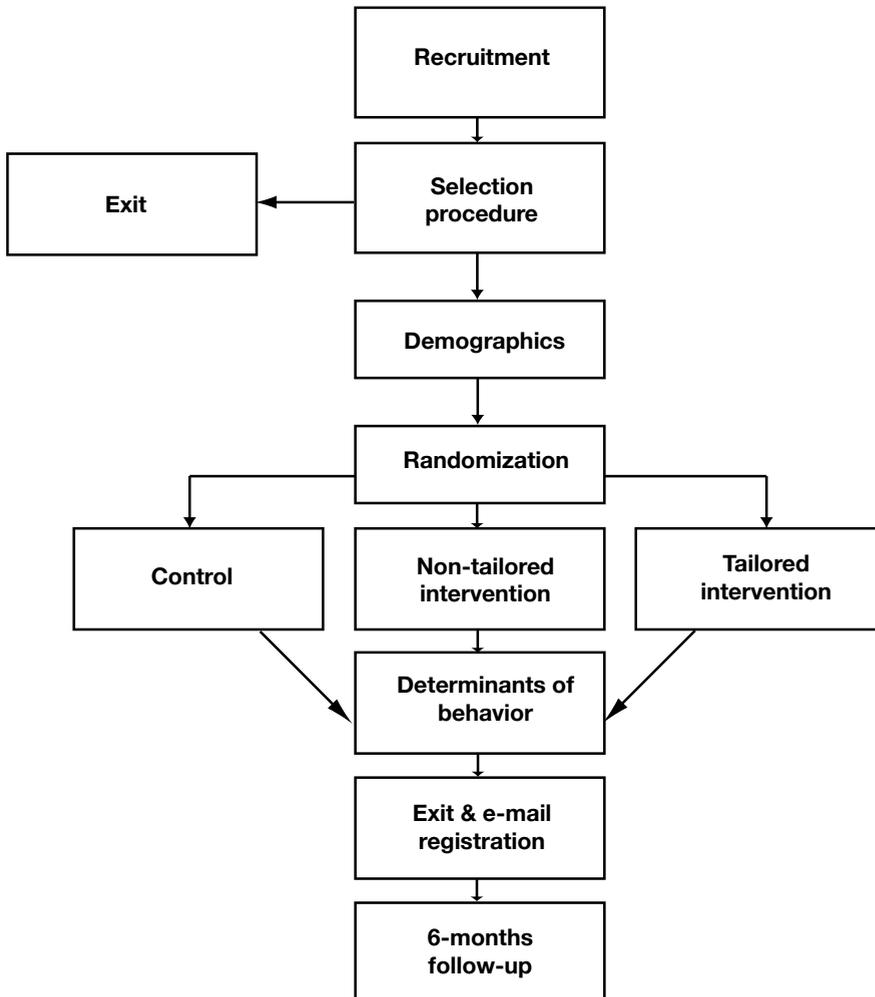
After recruitment and eligibility checks, an online informed consent form was presented. Subsequently, demographics and detailed information on HIV-testing behavior were obtained. Participants were then assigned at random to one of the three conditions: the tailored intervention, the non-tailored intervention, and the control. Once the interventions were completed, the cognitive assessment questionnaire was presented. Since controls did not receive any intervention, they were given the cognitive assessment directly after randomization. All participants were then asked to take part in the follow-up, and for that purpose to leave us their e-mail address. At this stage they received a second online informed consent form regarding the procedures of the longitudinal part of the trial. Participants were informed that 40 prizes were to be raffled amongst those who fully completed the follow-up. Each prize had a maximum value of 50 euros. After sending us their e-mail address, participants were thanked for their participation so far.

Six months later, an e-mail was sent to all who had agreed to take part in the follow-up. The e-mail contained an exclusive online link to a personal online questionnaire that asked participants about their present relationship status. Those with a new steady partner were asked about the practice of negotiated safety and condom use with that partner. Directly after the questionnaire, those who were initially assigned to the control condition received

6 Online tailored intervention

the online tailored intervention. Those who failed to respond within two weeks to the first call for follow-up received one reminder by e-mail. For a schematic overview of the study, see Figure 1. The study and its procedures were examined by the medical ethics committee of the Amsterdam Academic Medical Center and were granted exemption of approval.

Figure 1 Schematic overview of the flow of the randomized control trial



The intervention

The intervention was comprised of information-providing, motivation-enhancing, and skill-building modules. The information modules focused on explaining the proper procedures of practicing negotiated safety and testing for HIV, with special attention to considering the window phase and complying with negotiated safety agreements. The window phase relates to the time (a maximum of three months) from contact with the HIV virus until standard HIV-tests can detect the infection. The motivation modules emphasized the risk of HIV-transmission via the steady partner, providing facts on the latter as a source of HIV-transmission. The motivation modules also stressed the severity of HIV infection in the light of the suggested reduction in perceptions of threat from HIV-infection because of antiretroviral therapy [43-47]. This was done providing information on the burden and complications of antiretroviral therapy. To further increase motivation, we attempted to correct faulty beliefs regarding HIV transmission, HIV testing, and the making of sexual agreements. An example of a problematic belief: “Having once had UAI with my steady partner makes it pointless to use condoms or practice negotiated safety with him – the harm has already been done”. Much attention was given to address fear of HIV testing and the feelings of trust and intimacy that are associated with sexual risk-taking with steady partners [7, 10, 13].

To improve skills needed to practice negotiated safety, intervention modules were provided that facilitated communication between partners on issues such as mutual HIV testing and reaching of sexual agreements by, for example, suggesting strategies for conversation openers with the partner, scenarios of discussions, and decision-making tips. Our intervention did not explicitly focus on promoting the use of condoms but did provide basic information on condoms. We continuously suggested condoms as a default option for safe sex if negotiated safety was not a feasible option for the couple.

Tailoring of the intervention

In line with the recommendations of Barak and Fisher [48], the presence of informational, motivational, and skill barriers to safe sex were assessed prior

6 Online tailored intervention

to the intervention, through a “tailoring questionnaire”. This consisted of a series of dichotomous items, one item per barrier, with each item corresponding to a specific module in the intervention. Once the tailoring questionnaire was completed, the computer immediately compiled the relevant modules to compose the tailored intervention message. The complete list of the tailoring items is presented in Table 1. Not all the intervention modules were tailored. Some modules, such those addressing risk perceptions, were considered generally relevant and were provided to all the participants receiving the intervention.

Table 1 Tailoring items and scores for the tailored intervention condition presented in order of their ‘inadequacy-score’, that is, from the most salient problematic theme or belief to the least salient one. (n=340)

The tailoring item	agree/yes
You know clearly what consequences an HIV test can have for your health insurance	32%
You know clearly where you can get tested for HIV (also anonymously) and what that test costs	59%
You find it difficult to talk to a steady partner about sex outside the relationship	38%
You are afraid to learn the results of an HIV test, and that stops you from getting tested	32%
If you already had few incidents of anal sex without a condom with your steady partner, there is little point to have safe sex with him in future	26%
You find it difficult to talk to a steady partner about taking an HIV test	24%
You feel an HIV test is really necessary in order to have safe sex without a condom with a steady partner	82%
You see no advantages in knowing your HIV status	15%

Cognitive determinants of behavior

The cognitive assessment directly after the intervention was to establish how successful we were in improving knowledge, motivation, and skills related to negotiated safety among participants in the trial. We used response efficacy as the indicator for the impact of the information component that intended to teach participants how negotiated safety can protect against HIV-infection. Response efficacy reflects the knowledge of, and the belief in, these benefits. Response efficacy is not normally an indicator of knowledge but of motivation [49], however, the protective value of negotiated safety was an essential theme in the information/knowledge module of the

intervention, and with response efficacy we measured the correct processing of this information.

Intentions to practice negotiated safety and to use condoms with future steady partners served as the indicators for the cognitive impact of the motivational components of our intervention [21, 50]. The intentions to use condoms were included because of our hypothesis that promoting negotiated safety could indirectly motivate some men to use condoms.

Perceived behavioral control for engaging in negotiated safety was used as the indicator of the impact of the skills-enhancing components of the intervention. While perceived behavioral control does not measure the actual capability to perform the skills, it does indicate the perceived ease with which a skill can be practiced, and thus could indicate that a person does not perceive any barriers to perform the desired skills and therefore will be more likely to perform them [21,50]. The cognitive determinants of negotiated safety and condom use were measured as follows:

Response efficacy was measured by two items. The Pearson's correlation between the items was $r=.50$ ($p<.001$). The two items are: 1) "Anal intercourse without a condom with a steady partner is safe if we are both tested negative for HIV and agree to be monogamous - [1] totally agree - [5] totally disagree"; 2) "Anal intercourse without a condom with a steady partner is safe if we are both tested negative for HIV and agree to have only safe sex outside the relationships - [1] totally agree - [5] totally disagree."

Intention to practice negotiated safety was composed of the intentions to test for HIV, to reach agreements about sex outside the relationship, and to warn the partner in case sexual risk outside the relationship has occurred. Each intention was measured with two items. The intention to practice negotiated safety was established by computing one score based on the mean scores of all the sub-items (Cronbach's Alpha = .81). One item example: "If in the future I will have a new steady partner, I will make sure we both get tested for HIV" - [1] very unlikely - [5] very likely.

Intentions to use condoms were measured by two items . The Pearson's

6 Online tailored intervention

correlation between the items was $r=.76$ ($p<.001$). One item example: “If in the future you will have anal sex with a steady partner, will you use a condom with him?” - [1] Certainly not - [5] certainly will.

Perceived behavioral control regarding HIV testing, making of sexual agreements, and warning each other in case sexual risk outside the relationship had occurred was measured in each case by two items. The Pearson’s correlations between each pair of items were between .82 and .89 (all $p<.001$). One item example: “To reach an agreements with a future steady partner to always have safe sex outside the relationships is - [1] very difficult for me- [5] very easy for me.”

Behavioral Measures

After a six-months, the behavioral impact of the intervention was assessed by measuring the practice of negotiated safety with newly acquired steady partners. In addition, we measured condom use as a secondary behavioral outcome for the intervention. The sexual risk behavior variable we created was therefore multinomial and included the following three categories: practiced negotiated safety, always used condoms, or had risky UAI. In order to establish the outcome variable of sexual risk behavior, the following components were measured:

HIV status: Participant were asked to indicate whether they were HIV-negative, positive, or of unknown status. Participants who reported being HIV-negative were asked how they established their status. An HIV-negative status was considered valid if participants reported a negative HIV-test result. Participants were also asked to report instances of UAI with casual partners after their last HIV test or in the three months before their last HIV test. The latter question sought to examine whether men considered the window phase. If participants had never been tested for HIV, they still were considered HIV-negative if they indicated they had no previous sexual experience or no sexual-risk incidents, ever. Sexual risk incidents were defined as having had unprotected insertive or receptive anal intercourse, experiencing condom breakage, or having had receptive oral contact with ejaculation with any partner in the past.

Condom use: Participants were asked whether they had had anal intercourse with their steady partner, and if they did, whether they always used condoms. The variable was dichotomized to include the categories ‘did and did not always use condoms with the steady partner’.

Negotiated Safety: Participants reporting any unprotected receptive or insertive anal intercourse were asked whether they practiced negotiated safety, defined as follows: both partners had to know they were HIV-negative according to our HIV-status criteria, both partners agreed to be either monogamous or have no UAI outside the primary relationship, and partners agreed to warn each other in case UAI took place outside the relationship. The negotiated safety outcome variable was dichotomized to include the categories ‘did or did not practice negotiated safety with the steady partner’.

Risky UAI: Sexual risk was established if partners did not use condoms during anal intercourse and at the same time did not properly practice negotiated safety.

Table 2 Drop-outs in the trial represented in retention rates per phase of the trial and per trial condition, including estimations of mean elapsed participation time per phase.

Trial phase	Control	Non-tailored condition	Tailored condition
Randomization	333 (100%)	340 (100%)	340 (100%)
Intervention	327 (98%) 0 min.	284 (84%) 30 min.	292 (86%) 10-30 min
Cognitive assessment	300 (90%) 8 min.	260 (76%) 8 min.	273 (80%) 8 min.
E-mail registration	244 (73%) 2 min	203 (60%) 2 min.	221 (65%) 2 min.
Six months Follow- Up	140 (42%) 12 min	107 (31%) 12 min.	128 (38%) 12 min.

Drop-out analyses

Drop-out during each phase of the trial was registered by the computer program. An overview of the drop-out per phase and per trial condition, including elapsed time estimates per phase, is presented in Table 2. The largest drop-out rate among all three conditions was noted during the e-mail registration phase and during the initiation of follow-up. Further investigation revealed that an average of 37% per condition were lost to follow-up

6 Online tailored intervention

due to e-mail addresses that were no longer valid six months after enrollment . These were usually the e-mail addresses of free e-mail providers, which are easy to acquire yet also easy to abandon. We conducted regression analyses to examine differences in attrition between the control and intervention conditions as to age, ethnicity, education level, and sexual orientation. No statistically significant differences in attrition among the conditions were detected for any of these demographic variables.

Additional analysis examined whether different drop-out patterns across the conditions were associated with different levels of motivation to practice negotiated safety. Our concern was that men who dropped out during the trial were less motivated to practice negotiated safety than men who remained, and that such dropping out was more evident in the intervention than the control conditions. Such a difference in drop-out patterns could indicate the occurrence of motivational confounding and influence the results of the trial. To investigate whether motivational confounding did take place, we conducted a logistic regression analysis with dropping out as a dichotomous outcome variable, hence, whether a participant did or did not complete the trial. As predictor variables, we entered the intention to practice negotiated safety and a multinomial variable which clustered participants according to the three trial conditions. The model examined the interaction effect between the intention to practice negotiated safety and the trial-condition on drop out. We assumed that if no significant interaction was detected, no motivational confounding had occurred. The analysis revealed no significant interaction effect (OR=.92, 95%CI .75-1.14).

Results

The participants

In total, 1035 men were found eligible to participate in the study and completed the first informed consent form. Our computer program was able to identify whether a person tried to use the same computer to enter the study more than once. We closely examined such cases and deleted those in which we suspected double or more entries (e.g. by finding the same or similar demographics or e-mail addresses). Further, we deleted entries that were clearly entered illogically or with mischievous intent. A total of 22 cases

were deleted because of the above reasons. Our final sample for time 1 consisted of 1013 single men. Their mean age was 33 years (SD=11.1); 21% (213/1013) were of non-Dutch ethnic background, and 53% (537/1013) were highly educated (university level or equivalent). According to a 5-point sexual-orientation scale, 63% (636/1013) were exclusively attracted to men, 18% (183/1013) were primarily attracted to men, 17% (177/1013) were equally attracted to men and women, and 2% (17/1013) were primarily attracted to women. Of the 1013 participants at time 1, 66% (668/1013) provided us with their e-mail address for the purpose of follow-up, and of those, 56% (375/668) participated in the follow-up 6 months later. Of the men who participated in the follow-up, 35% (130/668) had a new steady partner by then. Our follow-up analysis was based on these 130 men.

HIV-status & testing behavior

Of all participants, 58% (584/1013) reported never being tested before for HIV, and 58% (586/1013) indicated they did not know their HIV status. Of all the participants, 42% (427/1013) reported knowing for sure that they were HIV-negative. Asked how they knew their HIV status, 53% (227/427) reported having the results of an HIV-test, while 47% (200/427) said they were never tested but were certain they had never engaged in any risky sexual behavior in the past. Of those who were certain they were HIV-negative based on a negative HIV test result, 15% (33/227) reported UAI with one or more casual partners during the three months before their last HIV test, and 17% (39/227) reported UAI with casual partners after taking their HIV test. Although both lapses compromised the validity of their HIV-negative test result, this was not reflected in their perception of their HIV status.

Tailoring

The scores of the tailoring items are presented in Table 1. The items are presented in order of their 'inadequacy-score', that is, from the most salient problematic theme or belief to the least salient one. The most frequently used tailored modules, which represent the most salient problematic themes, were those dealing with lack of knowledge regarding practical issues concerning HIV testing, difficulties in discussing sexuality outside the

6 Online tailored intervention

relationship, and dealing with fear of the result of an HIV test.

Effects on determinants of negotiated safety & condom use

Directly after the intervention was administered, we examined its impact on knowledge, motivation and perceived behavioral control regarding the practice of negotiated with steady partners and motivation to use condoms. A series of one-way analyses of variance was conducted with a three-level factor contrasting the control condition with the tailored and the non-tailored intervention conditions. Results are presented in Table 3. The time 1 analyses revealed that both men in the non-tailored intervention and the tailored intervention conditions scored better than controls on response efficacy. However, it was only the tailored condition that produced significantly higher intentions to practice negotiated safety or to use condoms with future steady partners. No effect was found for perceived behavioral control.

Table 3 Univariate analysis of variance of the cognitive effect at time 1, contrasting the control condition with the non-tailored and the tailored conditions.

Determinant	Main effect	Mean score Control (ref.)	Non-tailored	Tailored
Response efficacy	17.34***	3.01 (1.27)	3.45 (1.18)***	3.55 (1.21)***
Intention: negotiated safety	2.05	4.09 (.79)	4.16 (.80)	4.22 (.81)*
Intention: condom	2.29	3.90 (1.09)	4.01 (1.08)	4.09 (1.07)*
PBC [§] : mutual HIV-test	.35	3.48 (1.19)	3.56 (1.18)	3.50 (1.16)
PBC: agreement monogamy	.60	3.76 (1.15)	3.77 (1.11)	3.85 (1.18)
PBC: agreement safe sex outside the relationship	.53	3.64 (1.31)	3.69 (1.29)	3.75 (1.26)
PBC: agreement warning partner	1.25	3.44 (1.23)	3.59 (1.20)	3.56 (1.19)

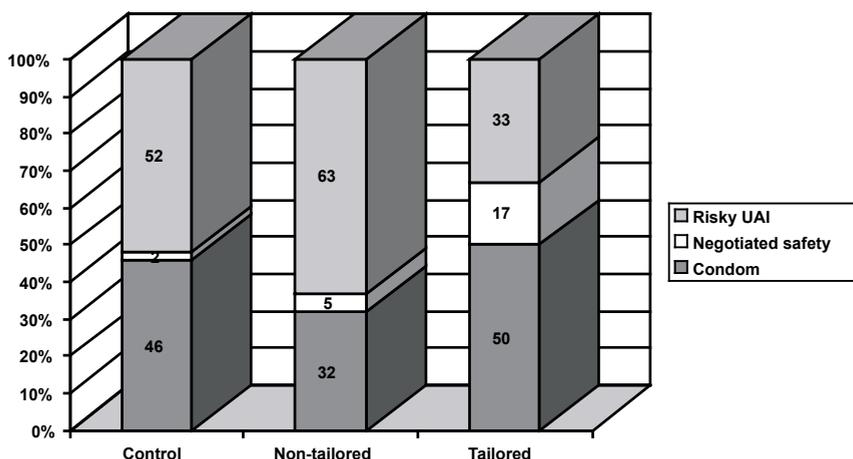
* = $p \leq .05$, ** = $p \leq .01$, *** = $p \leq .001$,

[§] = Perceived behavioral control (PBC)

Effect on sexual behavior

The behavioral effect of the intervention was measured at follow-up after six months. The percentages of those who practiced negotiated safety, used condoms, or had risky UAI with a new steady partner, per condition of the trial, are presented in Figure 2. The figure shows that the practice of negotiated safety and the use of condoms was the highest among men in the tailored condition. To examine these differences statistically, we conducted a multinomial regression analysis using one outcome variable which combined three behavioral categories: negotiated safety, condom use, and risky UAI (the last serving as the reference category). The model was significant ($\chi^2=9.12, p<.05$), and the results of contrast analyses are presented in Table 4. The contrast analyses revealed that, in comparison to men in the control condition, the men in the tailored condition were significantly more likely to practice negotiated safety with their new steady partner six months after being exposed to the intervention. No other contrasts were statistically significant, including that of condom use. The elevated rates of risk behavior we observed in the non-tailored condition were likewise not statistically significant when compared to the control condition.

Figure 2 The practice of risky unprotected anal intercourse (UAI), negotiated safety, and the use of condoms per the three trial conditions at 6-months follow-up.



6 Online tailored intervention

Table 4 Multinomial regression analysis of the effect of the intervention conditions at follow-up, with the control condition as the reference category, on the practice of negotiated safety, condom use, and risky unprotected anal intercourse, with the last serving as the outcome reference category.

	Trial condition	OR	95% CI
Negotiated Safety vs. risky UAI	Tailored	10.50	1.19 - 92.72
	Non-tailored	1.62	.14 - 19.07
Condom vs. risky UAI	Tailored	1.66	.68 - 4.02
	Non-tailored	.55	.22 - 1.37

Mediation analysis

We wished to examine which of the components of the intervention — the informational, motivational, or skills enhancing — were effective in bringing about behavioral change at follow-up. We therefore examined whether knowledge and perceptions of the efficacy of negotiated safety (i.e. response efficacy), intentions, and perceived behavioral control at time 1 could mediate the tailored intervention effect on behavior at follow-up. To establish mediation, we followed the procedures suggested by Baron and Kenny [51]. The first step was to establish the effect of the tailored intervention on response efficacy, intentions and perceived behavioral control at Time 1. This effect is reported in Table 3 and considering the tailored intervention had no effect on perceived behavioral control at time 1 the latter could not have been a mediator and was therefore excluded from the rest of the analysis.

The second step was to correlate, using a logistic regression model, response efficacy, and the intention to practice negotiated safety at time 1 with behavior at time 2. Results showed that the correlation of intention was significant (OR=2.4, 95%CI 1.04-4.37): the higher the intention to practice negotiated safety at Time 1, the higher the likelihood that men practiced negotiated safety with their new steady partner at follow-up. The correlation between response efficacy and behavior was not significant (OR=.83, 95%CI .51-1.35) and the former was excluded from the rest of the analysis. The last step in establishing mediation was to examine whether the effect we found for the tailored intervention on the practice of negotiated safety will drop below the significance level when the intention variable was added to the model. The intention to practice negotiated safety would then be

expected to retain its significant effect on behavior. This analysis confirmed the mediation hypothesis: the effect of the tailored condition on negotiated safety became non-significant (OR=1.65, 95%CI .13-20.19), while the effect of intention on the practice of negotiated safety was significant (OR=4.84, 95%CI 1.06-22.3).

Discussion

This study examined the efficacy of an online tailored and non-tailored interventions in reducing risk of HIV transmission between steady partners. Results show that the tailored intervention had the desired effect on knowledge and motivation to practice negotiated safety with steady partners: it produced better response efficacy towards negotiated safety and higher intention to practice negotiated safety with future steady partners than did the control condition. Most importantly, the follow-up on sexual behavior provided evidence for a behavioral impact of the tailored intervention. Men in the tailored condition were significantly more likely than men in the control condition to practice negotiated safety with new steady partners six months after the intervention was administered. No such effect was found for the non-tailored condition. Our findings show that the tailored intervention was successful in preparing single men to have safe sex with future steady partners, showing our ‘cognitive vaccine’ approach to be effective.

In further support of the efficacy of our online tailored intervention, the mediation analysis we conducted demonstrated that intention to practice negotiated safety mediated the effect of the tailored intervention on behavior. The mediation effect suggests that the motivational components of the intervention were the most effective component in bringing about the desired behavioral change among the men in the study. This could also suggest that, among the group of men we studied, the levels of knowledge and skill to engage in negotiated safety were sufficient and what men required was the motivation to engage in negotiated safety. However, our measurements of the impact on knowledge and of skills were limited as these determinants of the IMB model were only indirectly measured during the assessment of the cognitive effect of the intervention (i.e. knowledge through response efficacy, and skills through perceived behavioral control).

The superiority of the tailored intervention to its non-tailored coun

6 Online tailored intervention

terpart in bringing about cognitive and behavioral change, as hypothesized, suggests that the tailored component was essential to its success. Offering a tailored prevention message that the only advantage it has over its non-tailored equivalent is that it filters out personally irrelevant intervention modules seems to be sufficient to increase the impact of the intervention. This type of tailoring also ensures that the prevention message is as concise as possible, which probably further assists the cognitive processing of the prevention message. This type of tailoring is simple to execute and requires minimal interactive and ‘diagnostic’ efforts. A simple questionnaire suffices to tailor an intervention this way and is therefore easy to operationalize online.

Interestingly, although the tailored intervention influenced intentions to use condoms with future steady partners, these intentions did not result in actual condom use six months later. We know that the condom strategy is less popular for sex with steady partners than with casual partners [1] and the findings here seem to further support this assumption. It could be that when gay men are single, they are likely to think and judge the use of condoms according to their current sexual experiences, which is likely to be with casual partners, and therefore assume they could, or want, to do the same with future steady partners. However, once they have that partner, the condom strategy is either not applied or bypassed for negotiated safety. Gay men might therefore have encountered in the relationships elements which reduced their initial motivation to use condoms or had inaccurate (i.e. overconfident) estimations of their capabilities to use condoms with future steady partner.

A factor in the success of the intervention is perhaps the very fact that it promoted negotiated safety. Historically, negotiated safety was never imposed on gay men “from above”, by any health or prevention authorities. It is a strategy that grew and developed from within the gay community. The term ‘negotiated safety’ was coined in 1993 by Kippax et al. [4] based on observations of an already existing behavioral phenomenon. Negotiated safety is a common-sense strategy that reconciles the need to have UAI in a steady relationship with the need to maintain personal health and the health of loved ones. Although the practice of negotiated safety is challenged by

several social-cognitive and behavioral barriers [9, 10] it symbolizes freedom; freedom from dealing with condoms and potential freedom from worrying about an HIV infection. This context might have made negotiated safety an easier behavior to promote. Nowadays, there is occasional skepticism that HIV-prevention efforts can still generate behavioral change. The findings of this study suggest that the combination of an empirically and theoretically founded intervention that promotes a behavior that is congruent with the true needs of its target group, can produce the desired behavioral change.

A potential limitation of our study is the drop out during the trial. However, attrition analyses provided no indication that the cognitive and behavioral effects we found were the result of a selective drop-out pattern. The drop-out rate in this trial is probably more due to the character of online experiments and less to the content of the intervention. During the intervention and the cognitive assessment phase of the trial, participants could remain completely anonymous. This was allowed in order to maximize the initial participation in the trial and, indeed, the drop out rate was relatively small during these phases. However, for the longitudinal part of the study, participants had to provide their e-mail address. Once required to give up anonymity and commit to the longitudinal part, many probably chose to click off, and this choice was most likely unrelated to the condition they were assigned to. Similarly, the large loss to follow-up due to e-mail addresses that were no longer valid was, again, not a matter that is likely to differ across the conditions of the trial.

While evaluating internet interventions online might prove challenging, its advantages are numerous. First, interactive communication online is available 24 hours a day and, indeed, our user-logs showed participation during the whole day as well as during the small hours of the night. Second, our participants came from almost every region in the Netherlands, with good representation of low educated men and ethnic minorities. Achieving such geographic and demographic variability in an offline setting would have involved much more logistic effort and a higher price tag.

But above all, an online tailored intervention can fulfill some of the functions of a one-on-one counseling session. A well designed online

6 Online tailored intervention

intervention can put into use its interactive programming to conduct a basic anamnesis of the cognitive and behavioral deficiencies that relate to the behavior of individuals. The program can immediately offer solutions to individuals in the form of intervention modules matched to their needs. While we do not suggest that computer-based counseling can or should replace the personal contact of an HIV-prevention counselor, we have demonstrated how the former can successfully take place online and bring about the desired behavioral effect. Online tailored interventions can attend to thousands of people, yet, offer an individualized response. In this way we are a step closer to realizing the HIV-prevention dream: to offer personalized HIV counseling to a mass scale of people, anytime, anywhere.

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Acknowledgements

The authors' gratitude goes to the AIDS-Fonds, the Netherlands, which funded this study through Grant 4013 and to all the participants in the longitudinal online study. Special gratitude goes to Gerben-Rienk Visser for the excellent programming of the site and databases and his patience (!); Sellvation Marketing in Utrecht for the design; and to the sponsors of the online study: restaurant the Hemelse Modder, De Condomerie, Gaydar, De GayKrant, C.O.C Amsterdam and Expreszo Magazine. English revision by Lucy D. Phillips.