Computer-Assisted Intervention for Safer Sex in HIV-Positive Men Having Sex With Men: Findings of a European Randomized Multi-Center Trial

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Objective: Men who have sex with men (MSM) are the key population most affected by HIV in Europe. We performed the first European multicenter, simple-randomized parallel-group study to test the effectiveness of a theory-guided computer-assisted intervention to improve safer sex among HIV-positive men who have sex with men.

Methods: Between February, 2011 and February, 2013, 112 participants were enrolled in 8 different European HIV-care settings. Intervention participants received 3 individual counseling sessions facilitated by trained service providers using computer-assisted tools. The control-group received sexual health advice delivered as part of regular HIV care. Outcome behavior (self-reported condom use at last intercourse; combined HIV transmission risk score), its influencing factors, and mediating variables were assessed at baseline, and at 3 and 6 months follow-up. Mixed effects models were used to compare primary outcomes (condom use at last intercourse, HIV transmission risk score), and mediation analysis to explore intervention effects.

Results: Condom use at last intercourse increased more among intervention than control participants at 3 months follow-up (odds ratio of 3.83; $P = 0.03$), but not significantly at 6 months follow-up. Intervention participants reported a lower transmission risk at 3 months follow-up than controls (odds ratio compared with baseline of 11.53 and 1.28, respectively; $P = 0.008$), but this effect became nonsignificant at 6 months. Intervention effects were mediated by the proximal variables, self-efficacy to negotiate condom use and condom attitudes.

Conclusions: This intervention showed short-term effectiveness. The intervention should be replicated in other settings, eventually investigating if booster-counseling sessions would yield a longer lasting effect.

Key Words: HIV, safer sex, theory-based intervention, condom use, men having sex with men, behavioral counseling

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INTRODUCTION

HIV infection is a major public health concern in Europe. In 2013, 30 countries in the European Union/European Economic Area (including European Union Member States, Norway, Iceland, and Liechtenstein) reported 29,157 new HIV cases. Of those, 42% were reported among men having sex with men (MSM), accounting for the majority of new HIV cases with unprotected sex between men as the predominant HIV transmission mode.[1] Among MSM living with HIV, growing numbers of other sexually transmitted infections (STI) such as gonorrhea and syphilis have also been observed, attributed to condom less sex.[2–4] Several European studies reported such evidence. For instance,

a European multicenter study found that 42% of 705 sexually active, HIV-positive MSM in 14 European countries reported at least 1 occasion of unprotected vaginal or anal intercourse with a casual partner in the previous 6 months.[5,6] The European MSM internet survey, an online survey with more than 180,000 MSM from 38 European countries participating, reported that almost twice as many HIV-positive MSM had unprotected sexual encounters with casual partners, compared with HIV-negative, and untested MSM.[7]

Unprotected sexual intercourse has been linked with biological, psychological, social, and contextual determinants often interacting with each other.[8,9] Among psychological determinants, mental health (eg, depressive symptoms and substance abuse),[10] negative attitudes towards condom use,[11] and low self-efficacy to adopt protective behavior[12] were shown to correlate with unprotected sex. Self-efficacy or the perceived ability to exert personal control over behavior change[13] is a central construct in empirically validated behavior change theories such as social cognitive theory (SCT)[14] and the Information-Motivation-Behavioral skills model (IMB),[15] and was found to highly correlate with individuals' health behaviors including sexual activity for MSM.[16] Treatment optimism, ie, a decreased concern about HIV transmission because of the availability of effective combination antiretroviral treatment (cART), treatment fatigue eventually leading to declined adherence over time, and improved quality of life of HIV-infected MSM may also contribute to increased sexual risk behavior.[17] More recently, the widespread use of the internet for partner selection may have facilitated online initiation of condom less sex.[18,19] Studies systematically testing the effectiveness of behavioral interventions to increase safer sex among MSM[18,20,21] reported larger intervention effects for people living with HIV (PLHIV) compared with uninfected MSM.[22] In general, reviews consistently identified that intervention effects are bigger when interventions are theory-based, include participants' skill building, and delivered by trained professionals.[21] It has been recognized that for behavioral interventions to be effective, delivery channels must be appealing to the target group's needs and preferred lifestyles. Increasing evidence also shows that the use of internet-based tools and mobile technology can effectively contribute to the achievement of health objectives.[22–27] However, few interventions targeting MSM[28,29] or PLHIV[30–32] have used randomized controlled designs as the gold standard for their evaluation. None of them were conducted in a European context.[18]

To fill this void, we developed and evaluated a theory-guided computer-assisted safer sex intervention for PLHIV. The intervention was based on complementary behavioral theories, ie, SCT,[14] the IMB model,[15] and dual process approaches in health risk decision making[33] (see methods section for more details). It targeted 2 key populations most affected by HIV in Europe, HIV-positive MSM and HIV-positive women, and men from ethnic minorities. To the best of our knowledge, this is the first behavioral intervention addressing safer sex for PLHIV in Europe which has been evaluated using a randomized controlled design.

This paper presents only the effectiveness results obtained in the target group of HIV-positive MSM, looking at whether the intervention can support them effectively in improving condom use. Because of target-group specific behavioral patterns and their underlying determinants, the results for heterosexual PLHIV are analyzed and reported separately. The trial results are further explored using mediation analysis,[34,35] an approach that identifies which specific aspects of the intervention lead to its outcome. In line with the intervention's underlying theories, we hypothesized that the intervention effect is not only achieved directly but also indirectly through improving specific psychological constructs that facilitate behavior change (ie, self-efficacy, attitudes),[13,36,37] and mood which likely influences protection motivation.[10] More specifically, the following hypotheses were tested:

- Study participants receiving the intervention report have decreased condom less sex compared with individuals receiving regular treatment at 3 and 6 months after completion of the intervention.
- The intervention effect can be explained by potential mediators. The intervention effectively increases self-efficacy to negotiate condoms and favorably changes condom-use attitudes, which in turn increase condom use. Also the role of depressed mood as a mediator is explored,[10] ie, if the intervention can improve the participant's mood, it may also increase condom use.

METHODS

This multicenter, simple-randomized controlled parallel-group study was conducted in 8 European countries (ie, HIV care centers serving MSM patient populations in Belgium, Italy, France, Germany, The Netherlands, Poland, Spain, and England). Investigators belonged to the Eurosupport 6 network (ie, a multidisciplinary consortium of HIV clinics, community-based and research organizations).

Development and Delivery of the Brief Computer-Assisted Counseling Intervention

The intervention mapping protocol[38] facilitated intervention development, implementation, and evaluation across the sites through a series of systematic steps including a needs assessment (focus group research with PLHIV and service providers),[39] resulting in identification of main determinants influencing sexual risk behavior. Target-group specific change objectives were formulated and practical intervention strategies were selected based on empirical evidence.[38] The systematic approach to intervention development, the detailed content, and the main results of the process evaluation were reported elsewhere.[40] Several complementary theories informed the intervention development. Guided by the IMB model, an empirically validated HIV behavior change theory,[5,15,41–43] the intervention addressed motivations and behavioral skills including self-efficacy. We further built on SCT to address relevant influencing factors from the participant's personal and social environment such as attitudes and social norms, and to induce behavior change through role-modelling and guided practice.[13,14] In addition, theories emerging from cognitive neuroscience provided insight into

how behaviors are emotionally driven. "System 1–System 2 Thinking"[43,44] differentiates between intuitive decision-making in affect-laden situations (ie, automated brain processing or fast thinking), and a rational, analytical decision-making (slow thinking). Dual process theories have been surprisingly absent from research on sexual risk.[45] Yet, they can contribute to explaining the gap between safer sex knowledge and practice. This particular theory base led to developing computer-assisted tools depicting personal stories about safer sex acted by role models using sexualized images rather than traditional methods of cognitive "education." We hypothesized that this approach addresses emotions and affects facilitated insight into the effects of sexual arousal on sexual decision making, which subsequently would improve motivation for using condoms.[46]

The intervention, labelled as "CISS" (computer-assisted intervention for safer sex) consisted of 3 semistructured counseling sessions delivered by service providers, who worked with the participants through a series of video materials and interactive slide shows available on a DVD (for the time of the study period). Counseling sessions took about 50 minutes, with an interval of 3 weeks between sessions. Session 1, "Who am I?" focused on exploring participants' emotional response to individual problems with safer sex, using the filmed role models. Participants could choose the personally most relevant clips addressing barriers to safer sex from a menu with 5 relevant topics congruent with the determinants identified in the needs assessment: relationship issues, emotions and mood, sexuality and pleasure, drugs/alcohol and sex, HIV, health and sex (including sexual problems and infectiousness). Session 2, "Working Through" focused on developing personal solutions for the identified problems that would fit participants' context and lifestyles using video clips and interactive slide shows featuring self-assessment tools (eg, a thermometer to measure the "risk temperature") and educational slides. Counselors guided the participants in working though these materials. Session 3, "Making your plan" identified the necessary steps to achieve the behavioral goal through the counseling interaction and resulted in a personalized risk reduction plan. The counseling style adopted a motivational interviewing (MI) approach, with problem solving and cognitive behavioral goal setting strategies to identify personally tailored solutions with safer sexual behaviors.[47]

Three different versions of the DVD were available, each with tailored recognizable role models, and relevant topics: one designed for MSM, one for heterosexual migrant women, and one for heterosexual migrant men. The combination of personally relevant computer-assisted materials and MI counseling achieved a high degree of individual tailoring through matching participants' needs in a cross-cultural perspective, while using the same theory base to ensure coherence across settings. All staff delivering the intervention received a 2 day training facilitated by the intervention developers.

Study Setting and Participants

Seven HIV treatment centers and 1 community-based organization from 8 European countries providing HIV care for MSM delivered the intervention. Participants were recruited between February, 2011 and February, 2013. All consecutive patients were invited to participate in the screening procedure if they met the following criteria: aged 18 or above, diagnosed HIV-positive for at least 6 months, able to understand the study goal and procedures involved, fluency in 1 of the study languages (Dutch, English, German, French, Italian, Polish, Portuguese, Slovak, Spanish), and providing written informed consent. MSM self-identified as men having (regular or occasional) sexual contacts with other men. According to the sample size calculation, we needed a sample of 182 participants to detect a difference in intervention effect of 20% in the control group and 40% in the intervention group with a power of 80%.

Procedures

Participants were enrolled through a two-step procedure. An online screening instrument assessed eligibility (see Table 1). Participants who reported any condomless sex, and at least "some importance" to be safe when having sex, were automatically directed to the baseline questionnaire, a computer-administered self-interview. Figure 1 describes the flow of participants through the study.

Upon completing the baseline questionnaire, participants were randomly assigned to the intervention (CISS) or control condition using a computerized randomization procedure concealed from study investigators. Participants in the control group received sexual health counseling as part of the regular care offered at their clinic. Each participant received an information leaflet providing information on local sexual health services. Controls were also offered to receive the intervention after completion of the study. Participants allocated to the intervention group received 3 CISS counseling sessions as described above.

Study participants completed computer-administered self-interview questionnaires at three consecutive timepoints (see Fig. 1): at T2 (after completion of the intervention) only process evaluation data were collected (results are presented elsewhere),[40] and at T3 and T4 (three and six months after completion of the intervention respectively) a questionnaire assessed variables to compare with the baseline instrument. Participants did not receive any incentives for their study participation. The coordinating center's ethics committee (Institute of Tropical Medicine, University of Antwerp, Belgium) provided ethical approval.

Measures

The baseline and the 3 and 6 months follow-up questionnaires assessed the outcome variable condom use and relevant socio-demographic and health-related variables. In addition, psychosocial variables were assessed such as HIV disclosure, substance use, mental health, and the psychological constructs attitudes and self-efficacy related to condom use as relevant mediators. Table 1 presents these variables and their measurements.

The primary outcome variable was condom less sex at the 3 months follow-up assessment measured in 2 ways:

TABLE 1. Measures Used

Domain	Variable Assessed	Question	Answer
Screening questions		"Over the last 3 mo have you always used a condom with all partners on all occasions of anal or vaginal sex?"	Yes/No
		"How important is it for you to be safe when you are having sex?"	Five-point Likert scale from "irrelevant" to "extremely important"
Socio-demographic variables	Relationship status	"Do you currently have a steady sexual relationship?"	No, single/Yes, male partner/Yes, female partner
	Highest educational level	"What is your highest education completed?"	Lower secondary/Higher secondary/ Apprenticeship/Higher education
	Employment status	"Are you currently employed?"	Yes/No
Health-related variables	Physical condition	"How would you describe your HIV-related health?"	No physical complaints/Physical complaints
	HIV-treatment	"Are you currently on antiretroviral treatment?"	Yes/No
	Viral load	"What was your most recent viral load?"	Undetectable/Detectable/I don't know
HIV-disclosure	HIV-disclosure to main partner	"Does your partner know you are HIV-positive?"	Yes/No
	HIV-disclosure to casual partners	"Do casual sexual partners know you are HIV-positive?"	(almost) No one/Some of them/(almost) All of them
Substance use		"How often have you been under influence of alcohol when you have had sex?"	(almost) Never/Sometimes/(almost) Always
		"How often have you been high on drugs when you have had sex?"	(almost) Never/Sometimes/(almost) Always
Mental health	Depression	DASS 21 depression scale[48]	
	Anxiety	DASS 21 anxiety scale[48]	
	Stress	DASS 21 stress scale[48]	
Psychological constructs	Attitudes towards condom use	Sexual risks scale-attitudes toward condom use,[49] 13 items rated on a 5-point Likert scale	"Strongly agree"/"Strongly disagree"
	Condom use self-efficacy	Self-efficacy for negotiating condom use, 5 items rated on a 1–10 scale[50]	"Cannot do at all"/"Certain that I can do"
Intention to use condoms		"Are you intending to start using condoms consistently within the next 30 days?"	Yes/No

DASS, Depression Anxiety and Stress Scale.

"condom use at last sexual intercourse," and a refined HIV transmission risk score. The rationale for introducing such a score rests on 2 considerations. Firstly, HIV-infected persons are 96% less likely to transmit HIV to uninfected sexual partners, if viremia is suppressed under effective antiretroviral treatment.[51,52] Secondly, the occurrence of STI other than HIV facilitates HIV infection through local ulcers of the receptive partner, thereby increasing the risk of HIV transmission.[53] Given the increasing incidence of STI among MSM,[2–4] we combined several variables into a score reflecting a nuanced individual HIV transmission risk profile: numbers of unprotected sexual contacts (with main and casual sexual partners with HIV-negative or unknown status), participants' viral load, and self-reported STI diagnosis in the previous 3 months (see Table 2 for details). This score was developed to account for available evidence on reduced infectivity of PLHIV treated effectively with cART,[52,53] their awareness of viral load and its implication on transmission risk,[54–56] and increasing STI incidences among MSM.[2–4]

Scores from participants who reported no condom less encounters were automatically set to "0" because there was no transmission risk, regardless of their current viral load and STI diagnoses. For further analysis, we dichotomized this outcome variable into "high transmission risk" vs."low transmission risk" (score >1 vs. score≤ 1).

All study instruments were developed in English and translated into 8 study languages using appropriate quality checks.[57]

Statistical Analysis Plan

Stata version 12.1 was used for statistical analysis. Descriptive statistics for socio-demographic, health-related, mental health variables, and HIV disclosure, as well as for the additionally computed outcome variables ("transmission risk score," "lower transmission risk") were calculated using baseline data and subsequently compared between the intervention and control groups.

To compare the CISS intervention and control group, we modelled the evolution over time for the outcome variables by linear or logistic mixed effects model including a random intercept. Tests for a difference in time evolution between intervention groups were applied at 5% significance level. We then used mediation analysis[34,35] to explore the intervention effect at the 3 months follow-up assessment. Mediation analysis is a model seeking to identify the

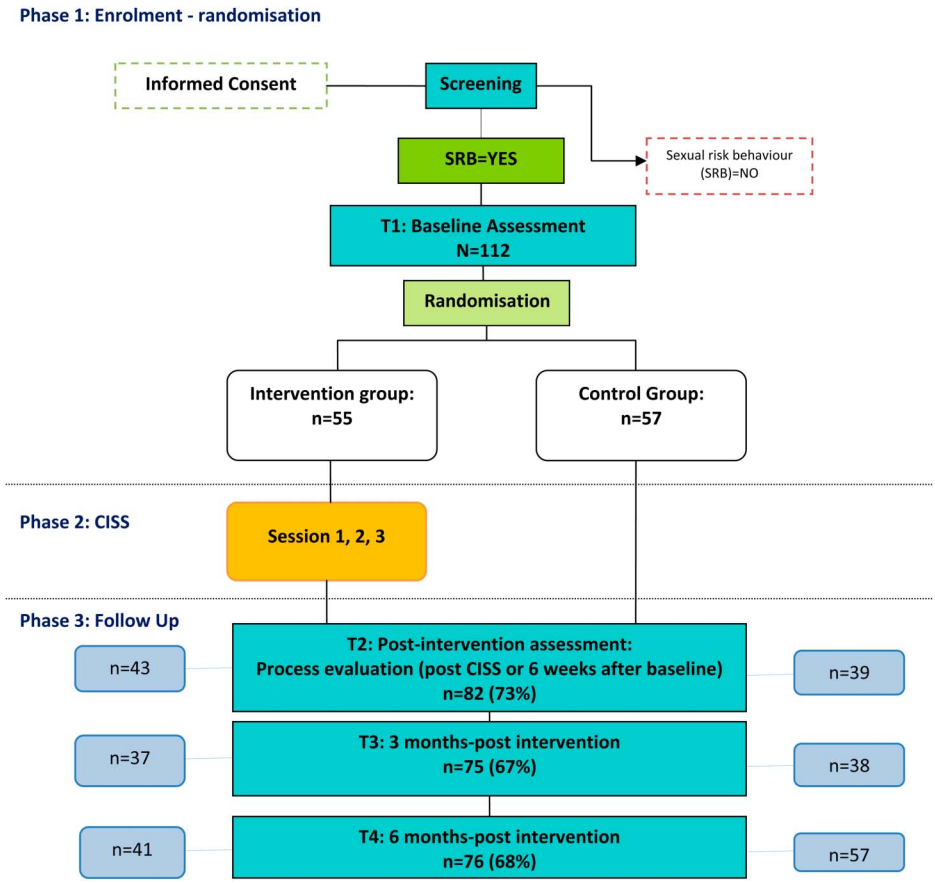

FIGURE 1. Flowchart.

mechanism that underlies an observed relationship transmitting the effect of an independent variable on dependent variables (ie, the outcome behavior). In line with the above mentioned theories, we explored the operationalized constructs self-efficacy to negotiate condom use and attitudes towards condoms as potential mediators, because they have

TABLE 2. HIV Transmission Risk Score at Baseline

Score Indicator	Number/category	Value Assigned	Intervention Group (CISS), n (%)	Control Group, n (%)
No. occasions of unprotected sexual encounters with main partner, with HIV-negative, or unknown status	0	0	46 (85.2)	47 (83.9)
	1–6	1	4 (7.4)	4 (7.1)
	7–12	2	3 (5.6)	0
	>12	3	1 (1.9)	5 (8.9)
No. occasions of unprotected sexual encounters with casual partners, with HIV-negative, or unknown status	0	0	29 (54.7)	28 (50.0)
	1–6	1	16 (30.2)	18 (32.1)
	7–12	2	4 (7.6)	3 (5.4)
	>12	3	4 (7.6)	7 (12.5)
Viral load	VL undetectable	0	38 (69.1)	38 (66.7)
	VL unknown	1	2 (3.6)	2 (3.5)
	VL detectable	3	15 (27.3)	17 (29.8)
STI diagnosis reported (past 3 mo)	No	0	36 (65.5)	32 (56.1)
	Unknown	0.5	2 (3.6)	3 (5.3)
	Yes	1	17 (30.9)	22 (38.6)
Total score: median (Q1; Q3)	Range: 0–10	0–10	1 (0; 3.5)	1 (0; 3.0)

VL, viral load.

been shown to be highly correlated with condom use, and to be modifiable through behavior change interventions.[37] Likewise, based on previous research[10] and our needs assessment,[39] assuming that people who had depressed mood were not motivated to use condoms, we explored depressed mood as a potential mediator. For the outcome variable condom use at last intercourse, 3 generalized linear regression models were used to test the effect of theoretically grounded mediator variables (ie, condom use self-efficacy measured by the *Self-efficacy for Negotiating Condom-use Scale*; attitudes towards condom use measured by the *Sexual Risk Scale Scale*; depression measured by the Depression Anxiety and Stress Scale 21; for measures see Table 1). This allowed for splitting the total intervention effect into one pathway where the intervention is associated with the outcome by changes in the different mediators (ie, indirect effects) and another pathway with directly observed changes.

RESULTS

Descriptive Analysis

As displayed in Figure 1, we enrolled a total of 112 MSM across 8 study sites, which was lower than the calculated sample size. Fifty-five men (49%) were assigned to the CISS group, and 57 men (51%) to the control group. Eighty-two men (73%) filled in the postintervention process evaluation questionnaire. At the 3 and 6 months follow-up, 75 (67%) and 76 men (68%), respectively, were retained in the study. Thirty-six men (32%) were lost to follow-up at the 6 months follow-up assessment; they were comparable with those retained with respect to the variables "intervention group," "having a partner," "health status," "viral load," "stress," "anxiety," "depression," and "transmission risk score" at baseline, suggesting a nondifferential drop-out.

At baseline, participants in the intervention- and control group were compared for socio-demographic, health-related and psychological variables, HIV disclosure, and the different outcome variables including the indicators that were used for computing the HIV transmission risk score (see Table 2). Rates of condom less sex at last intercourse with all partner types were 65% and 70%, respectively, for CISS and control group participants (see Table 3). Median age of the participants in the CISS group at baseline was 40 years (interquartile range 32–47), and in the control group 42 years (interquartile range 33–45).

TABLE 3. Baseline Differences for Selected Variables Between Participants in Intervention Group and Control Group (n = 112)

Variable Assessed	Intervention Group (CISS), n (%)	Control Group, n (%)
Relationship status		
Single	29 (52.7)	32 (56.1)
With a male partner	26 (47.3)	23 (40.4)
With a female partner	0 (0.0)	2 (3.5)
Education		
Lower secondary (9 years education)	2 (3.6)	7 (12.3)
Higher secondary (12 years education)	17 (30.9)	11 (19.3)
Apprenticeship	11 (20.0)	13 (22.8)
Higher education (university/college)	25 (45.5)	26 (45.6)
Employment status		
Unemployed	18 (32.7)	21 (36.8)
Employed	37 (67.3)	36 (63.2)
Under influence of alcohol when having sex		
(Almost) always	3 (5.5)	6 (10.5)
Sometimes	19 (34.6)	22 (38.6)
(Almost) never	33 (60.0)	29 (50.9)
Under influence of drugs when having sex		
(Almost) always	7 (12.7)	3 (5.3)
Sometimes	8 (14.6)	14 (24.6)
(Almost) never	40 (72.7)	40 (70.2)
No physical HIV-related complaints	32 (58.2)	39 (68.4)
On antiretroviral treatment	46 (83.6)	49 (86.0)
HIV-disclosure to main partner	24 (88.9)	20 (90.9)
HIV-disclosure to casual partners		
(Almost) all of them	13 (26.0)	13 (25.0)
Some of them	5 (10.0)	16 (30.8)
(Almost) none of them	32 (64.0)	23 (44.2)
Considering consistent condom use	31 (56.4)	27 (47.4)
Planning consistent condom use	25 (45.5)	30 (52.6)
Condom use at last intercourse	19 (34.5)	17 (29.8)
Transmission risk score (median + IQR)	1 (0–3.5)	1 (0–3)
Lowered transmission risk	34 (65.4)	32 (58.2)

IQR, interquartile range.

Intervention Effect

Table 4 provides an overview of the odds ratio (OR) at the different follow-up assessments compared with baseline of reported condom use at last intercourse, and of low transmission risk. For the transmission risk score, mean change from baseline is shown.

Participants from both groups had improved at 3 months follow-up compared to baseline, but CISS-participants were more likely than controls to report condom use at last intercourse [ie, yielding an OR of 3.83 between CISS and control participants; 95% confidence interval (CI): 1.15 to 12.76]. This difference was statistically significant (P = 0.03). Six months after the intervention, the OR of protected sex was 2.15; 95% CI: 0.69 to 6.78), which was not significant (P = 0.19).

The proportions of men using a condom at last intercourse were 35% (n = 19; 95% CI: 23% to 48%) at baseline in the CISS group and 30% (n = 17; 95% CI: 20% to 43%) in the control group (data not shown in table). This increased to 68% (n = 25; 95% CI: 51% to 80%) and 45% (n = 17; 95% CI: 30% to 60%) respectively at the 3 months follow-up assessment. At the 6 months follow-up assessment,

TABLE 4. Risk Difference Between Intervention and Control Group at 3 and 6 mo Follow-up Assessments for 3 Outcome Measures

	Intervention Group (CISS)		Control Group		
	Estimate	95% CI	Estimate	95% CI	*P*
3 mo follow-up					
Condom use at last intercourse (OR)	6.77	2.48 to 18.52	1.77	0.72 to 4.32	0.03*
Transmission risk score (mean difference)	−1.19	−1.80 to −0.57	−0.68	−1.27 to −0.09	0.20
Lowered HIV transmission risk (OR)	11.53	2.58 to 51.52	1.28	0.50 to 3.28	0.008*
6 mo follow-up					
Condom use at last intercourse (mean difference)	5.46	2.16 to 13.79	2.53	0.98 to 6.52	0.19
Transmission risk score (mean difference)	−0.67	−1.25 to −0.09	−0.51	−1.14 to 0.12	0.70
Lowered HIV transmission risk (OR)	1.64	0.64 to 4.22	1.25	0.47 to 3.36	0.67

*sign. $P < 0.05$.

it dropped to 66% (n = 27; 95% CI: 51% to 78%) for CISS participants, whereas among controls the rate was 49% (n = 17; 95% CI: 33% to 64%).

We also compared the 2 groups with respect to the outcome measure HIV transmission risk score. We observed no significant intervention effect on the score 3 months post intervention (difference in mean change from baseline of −0.51; 95% CI: 1.29 to 0.28; $P = 0.20$). Likewise, the difference observed at the 6 months follow-up assessment was not significant (difference in mean change from baseline of −0.16; 95% CI: 0.94 to 0.63; $P = 0.70$) (see Figure S2, Supplemental Digital Content, http://links.lww.com/QAI/A765).

Using "lower transmission risk" as outcome variable yielded a significant difference between the 2 groups, 3 months after the intervention. The OR of success at 3 months compared with baseline was 1.28 in the control group and 11.53 in the CISS group (ratio of ORs 9.01, CI: 1.78 to 45.71; $P = 0.008$). This effect became nonsignificant at the 6 months follow-up-assessment (ratio of ORs 1.31, CI: 0.38 to 4.54; $P = 0.67$).

Exploration of the Intervention Effect Using Mediation Analysis

We explored the significant intervention effect for condom use at last intercourse at 3 months post intervention. Mediation analysis was used to divide the total intervention effect into a direct intervention effect (ie, not mediated by improvements on the proximal variables), and indirect effects through changes in the mediator. Comparing CISS with control group participants, the average increase in self-efficacy was 6.36, in attitudes 3.12, and in depression 2.34.

Improved self-efficacy accounted for 43% of the total effect ($P = 0.02$), whereas favorable changes in attitudes towards condom use accounted for 22% ($P = 0.16$). Improvements on negative mood states did not mediate the intervention effect; only 2% of the overall effect was explained by changes in depressive mood states ($P = 0.71$) (see Figure S3, Supplemental Digital Content, http://links.lww.com/QAI/A765).

DISCUSSION

This brief computer-assisted safer sex intervention for HIV-positive MSM showed short-term effectiveness at 3 months post intervention in increasing condom use at last intercourse and in increasing the proportion of men with lower HIV transmission risk. This was mainly explained by an improvement in participants' self-efficacy to negotiate condom use, on which the intervention had a positive effect. Our results add to a growing body of evidence on effective computer-assisted interventions delivered by health care providers to support risk reduction in HIV-positive patients.[29] In the treatment as prevention-era for PLHIV, safer sex encompasses more than just condom use, as HIV-positive MSM employ a variety of harm reduction strategies.[58] Although the tailored CISS approach can be used for working on different aspects of safer sex, we measured condom use as the primary outcome of this study. The difference in risk detected between the 2 groups was roughly as expected, ie, 23% for condom use at last intercourse (at the 3 months follow-up). However, condom use also improved over time for the controls. The fact that all participants were motivated to work on safer sex, independent of which group they were allocated to, may have influenced the outcome behavior. Many studies have shown that sustaining safer sexual behavior over time is challenging.[59] In our study, the difference in condom use rates (at last intercourse) dropped from 23% difference achieved at the 3 months follow-up to 17% difference at the 6 months follow-up assessment, which is an almost comparable effect in the range of the 20% difference expected. The CISS concluded with an individualized risk reduction plan in session 3. There was no follow-up opportunity for participants to assess its usefulness in real life with their counselors. A reinforcing booster session to evaluate and adapt the personalized risk reduction plan if needed, could potentially contribute to sustaining behavior change. Although the added value of adding such a booster session has been documented elsewhere,[60] future research should determine if it could also improve the CISS effectiveness.

A review of computer-based interventions found similar efficacy levels as interventions delivered by service providers,[61] with rather small effect sizes for condom use. All but 2 interventions included in this review had follow-up periods of 6 months or less. Because no meta-analytic reviews for computer-assisted interventions delivered in HIV-care exist, we compare our findings with single studies

using similar approaches. Our results compare favorably with recent studies combining counselor-facilitated interventions with computer messaging, which were successful in reducing both the rate of condom less sexual encounters and the number of sexual partners.[28,29]

The mediation analysis showed that the proximal variables, self-efficacy and—to a lesser extent—attitudes partially mediated the intervention effect, as has been shown in other domains of health behavior[62]; for instance, interpersonal communication in mass media campaigns for smoking cessation.[63,64] This confirms the importance of self-efficacy and attitudes as mediators of condom use, as found in other research.[14,16,65] Because they can successfully be modified through tailored counseling strategies, they can be seen as potent intervention components. The CISS provided opportunities for increasing self-efficacy through role-modeling and adequate counselor feedback, and setting up step-wise behavioral goals. Because the CISS was not designed to reduce depressive symptoms in HIV-positive people, the small intervention effect explained through an observed change in depressive mood seems reasonable.

Study Limitations

Study participation was voluntary and motivation was an inclusion criterion. Self-reported outcome data may potentially be biased, eg, because of under-reporting sexual risk behavior or false assumptions about partner's HIV status. Randomization was not blinded, which lies in the nature of the intervention. The overall number of HIV-positive MSM screened was not registered, therefore, we can neither compare participants with nonparticipants nor assess the reasons for declining participation. More importantly, we could not recruit the desired number of participants, resulting in reduced power. Barriers to recruitment related to both the individual level (eg, motivation, fear to discuss problems with condom use in HIV-care settings) and structural issues (eg, legal barriers in countries where HIV transmission can be legally prosecuted, HIV-stigma). As observed elsewhere, even individual-focused interventions face challenges in addressing multilevel factors.[66] Loss-to-follow-up can be a source of bias, especially if participants who return differ from those who drop out, but this was not the case in our study. Our retention rates (67% at the 3 months and 68% at the 6 months follow-up) are within an acceptable range for prospective studies.[67] Nevertheless, difficulties to recruit and, to a lesser degree, to retain patients in the study make generalization of the study results difficult. The transmission risk score represents an approach to measure outcome reflecting the complexity of risk reduction strategies in line with current harm reduction practices.[68] It could represent an important addition to using a simple measure of epidemiological risk (ie, any act of condom less sex),[69] but the score needs validation in future research.

Clinical Implications

Model predictions have shown that in the long run, the positive impact of effective cART may be outweighed by an increase in risk behavior of at least 30% for MSM.[70] Therefore, in the era of biomedical prevention strategies, behavior change to increase safer sex among MSM is an important tool in combination prevention. Despite the study limitations, we conclude that our intervention was effective in the short-term in changing some of the factors influencing safer sexual behaviors (ie, attitudes and self-efficacy) and thereby improving condom use. The CISS could thus be a valuable tool for future combination prevention, particularly when integrated in regular HIV-care to further reduce thresholds.

The strength of this study lies in its pan-European approach, demonstrating the intervention's effectiveness under "real-life" conditions. Because this multicenter trial included MSM from different European contexts and HIV-care settings, we expect that the CISS could generally benefit heterogeneous MSM populations in Europe despite sociocultural differences because of its high degree of tailoring,[71] which has been described as a success factor for effective interventions.[72] Tailoring results in prevention messages, with a higher chance to be perceived as personally relevant leading to behavior change.[73] The CISS achieves tailoring through the combination of visually appealing target-group specific computer-assisted tools, which give an important role to the counselor for guiding participants through the materials, and for creating an accepting, nonjudgemental, and empathic atmosphere. The CISS has been designed to be delivered by professionals in 3 sessions, however, with a minimum amount of specific training to ensure fidelity to the intervention and work with limited resources. As shown in other research, MI-counseling interventions using the right dosage of 3 to 4 sessions can indeed strengthen clients' safer sex self-efficacy.[74] The DVD has been translated into an open-source online program to support positive prevention strategies in HIV-care and prevention settings.

In conclusion, our computer-assisted intervention for safer sex showed short-term effectiveness. However, the intervention should be replicated in other settings, eventually investigating if booster-counseling sessions would yield a longer lasting effect.

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