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Development of a theory-guided pan-European computer-assisted safer sex intervention

Christiana Nöstlinger1,*, Ruth Borms2, Joanna Dec-Pietrowska3, Sonia Dias4, Daniela Rojas5, Tom Platteau6, Wim Vanden Berghe1, and Gerjo Kok7, The Eurosupport 6 Study Group

1Department of Public Health, ITM’s HIV/AIDS Center, Institute of Tropical Medicine, Nationalestraat 155, Antwerp B-2000, Belgium, 2Sensoa, Antwerp, Belgium, 3Counselling and Sexology Unit, University of Zielona Góra, Zielona Góra, Poland, 4Institute of Tropical Medicine and Hygiene, Lisbon, Portugal, 5MIRE (Mission Innovation, Recherche, Évaluation), AIDES, Paris, France, 6Department of Clinical Sciences, ITM’s HIV/AIDS Center, ITM, Antwerp, Belgium, and 7Faculty of Psychology, University of Maastricht, Maastricht, The Netherlands

*Corresponding author. E-mail: cnoestlinger@itg.be

Summary

HIV is a growing public health problem in Europe, with men-having-sex-with-men and migrants from endemic regions as the most affected key populations. More evidence on effective behavioral interventions to reduce sexual risk is needed. This article describes the systematic development of a theory-guided computer-assisted safer sex intervention, aiming at supporting people living with HIV in sexual risk reduction. We applied the Intervention Mapping (IM) protocol to develop this counseling intervention in the framework of a European multicenter study. We conducted a needs assessment guided by the information–motivation–behavioral (IMB) skills model, formulated change objectives and selected theory-based methods and practical strategies, i.e. interactive computer-assisted modules as supporting tools for provider-delivered counseling. Theoretical foundations were the IMB skills model, social cognitive theory and the transtheoretical model, complemented by dual process models of affective decision making to account for the specifics of sexual behavior. The counseling approach for delivering three individual sessions was tailored to participants’ needs and contexts, adopting elements of motivational interviewing and cognitive-behavioral therapy. We implemented and evaluated the intervention using a randomized controlled trial combined with a process evaluation. IM provided a useful framework for developing a coherent intervention for heterogeneous target groups, which was feasible and effective across the culturally diverse settings. This article responds to the need for transparent descriptions of the development and content of evidence-based behavior change interventions as potential pillars of effective combination prevention strategies.

Key words: health promotion programs, HIV/aids, Europe, intervention, action plan
INTRODUCTION

Positive prevention has been increasingly recognized as an effective building block for overall HIV prevention (Fisher et al., 2010). It has the twofold goal of protecting the health of people living with HIV (PLHIV) and preventing HIV transmission to their sexual partners. Positive prevention has been framed in a human rights perspective, with tight links to sexual and reproductive health (SRH) and rights (GNP+/UNAIDS, 2011). This implies that PLHIV, as anybody else, should be able to experience satisfying, responsible and safe sex lives. Many sexual health issues of PLHIV are similar to those of non-infected peers (WHO, 2007), but some are potentially more challenging, i.e., the impact of viral load on HIV transmission, coinfection with other sexually transmitted infections (STIs), issues of HIV disclosure to sexual partners, sexual dysfunctions and HIV-related stigma (Boonstra, 2006). HIV care services are often the main entry point for care provided to PLHIV, constituting a setting where patients can be counseled, reinforcing behavior change towards safer sex lives (Gerbert et al., 2006). Various reviews have identified criteria for behavioral interventions to be effective, and have recognized a sound theoretical base as a critical success factor (Crepaz et al., 2006; Kirby et al., 2006; Lorimer et al., 2013). For interventions to be effective, they must use delivery channels that are appealing to the target group’s needs and preferred life styles. Recent evidence supports the use of ICT (information communication technology), with efficacy levels similar to personal interventions (Noar et al., 2009). Using such innovative tools can be relevant for settings with limited resources and high work load.

In Europe (EEA or European Economic Area countries), the two key populations most affected by HIV are men-having-sex-with-men (MSM) and migrants from countries with generalized HIV epidemics (40 and 37%, respectively, of new HIV cases in 2012) (ECDC, 2013a). However, little has been invested in developing evidence-based sexual health interventions for these key populations in the European context (ECDC, 2013b).

To fill this gap, the overall aim of this study was to contribute to the evidence-base of effective sexual health interventions for PLHIV, by developing, implementing and evaluating a theory-guided intervention package for MSM and migrants living with HIV. The package consisted of a brief provider-delivered counseling intervention using computer-assisted tools, accompanied by a training and resource package (TRP). The purpose of this article is to describe transparently how we developed the intervention guided by the Intervention Mapping (IM) protocol (Bartholomew et al., 2011), a systematic method supporting the development of theory- and evidence-based health promotion interventions. The objective of this paper is to document transparently how theory and evidence were used to systematically develop the intervention in culturally diverse settings (i.e. 10 European countries: Belgium, France, Germany, Italy, the Netherlands, Poland, Portugal, Slovak Republic, Spain, and UK) and to describe the intervention’s content.

METHODS

The evidence-base for IM is sound and widely documented within, [e.g. (Van Kesteren et al., 2006; Mikolajczak et al., 2008)] and beyond the HIV field [e.g. (van der Veen et al., 2012; Voogt et al., 2013)]. The six iterative IM-steps and their respective tasks are: (i) needs assessment: defining prioritized positive prevention needs of PLHIV, and selecting the relevant, desired outcome behaviors; (ii) change objectives: detailing what the intervention intends to change, selecting personal and external determinants believed to influence the outcome behavior, considering the characteristics of the target groups; (iii) theoretical methods and practical strategies: selecting validated behavior change theories and translating them into intervention strategies to achieve the program objectives; (iv) program planning and development: the actual design of the intervention including piloting the materials; (v) program adoption: developing an implementation system for the participating settings; (vi) evaluation: assessing the intervention’s effectiveness, in our case combining a randomized controlled trial with process evaluation. Because intervention adoption and evaluation took place during the same study, we combined steps 5 and 6.

RESULTS

Step 1: needs assessment

We adopted a sequential mixed method approach in our formative needs assessment combining exploratory and confirmatory research questions. First, we conducted an in-depth study on positive prevention needs among PLHIV and their service providers between 2008 and 2009. Using a grounded theory approach, we collected data through 37 focus groups discussions and 20 in-depth interviews. In total, 114 service providers and 110 PLHIV (39% women and 61% men) from 12 EU countries participated in the qualitative research. Specific methods and detailed results were published elsewhere (Nöstlinger et al., 2008). Results yielded two main areas of unmet needs: PLHIV’s continuous struggle with sexual risk reduction and fertility-related decisions (child desire and contraceptive needs). Study participants expressed concerns about
potentially transmitting HIV and although perceiving the lifelong need adhering to safer sex, using condoms remained challenging.

Similar and different issues emerged for the two key populations: both groups shared negative attitudes towards condom use, however, with culturally different meanings. While both groups felt condoms were counteracting feelings of intimacy and pleasurable sexuality, migrants perceived condoms as indicating unfaithfulness. Migrant women lacked skills asserting condom use. Both groups lacked communication skills about their HIV status (MSM predominantly with casual partners, migrants with regular and casual partners). For both groups, mental health issues, e.g. depressive feelings, reduced self-esteem and the perceived importance to protect one’s own health impacted on protection behavior. Affect was a critical element in sexual situations for both MSM and migrant men, who reported sometimes having felt the urge to engage in condomless sex to experience sexual pleasure, in spite of intentions to behave differently.

Many of the themes emerging from this inductive research were similar to constructs in the information–motivation–behavioral (IMB) skills model (Fisher and Fisher, 1993). Subsequently, we validated an adapted IMB model, based on the results of the qualitative research, for positive prevention through a European multi-site cross-sectional study using self-administered, anonymous surveys in a clinical sample of 1549 PLHIV (consisting of 898 MSM and n = 651 heterosexuals: 56% women and 44% men) in 14 countries (including four Central/Eastern European countries). We added variables such as partners’ HIV status, mental health and social norms to the IMB model (Nöstlinger et al., 2010; Nöstlinger et al., 2011). Overall, 68% of the respondents reported consistent condom use during the last 6 months, while for MSM this was 56% (regular and casual partners). Higher self-efficacy, and supporting subjective norms increased condom use, while having sex with an HIV positive partner (‘sero-sorting’) decreased it. We also assessed service providers’ experiences with sexual health advice and their professional support needs through an online survey sent to 184 European HIV service providers (HIV clinics and community-based organizations). Among 61 respondents (46 from Western-, and 15 from Central/Eastern Europe), none used evidence-based tools for sexual health counseling. Many felt inadequately equipped for sexuality counseling, and recognized capacity building needs (Borms et al., 2008). Our findings were in line with research on sexual risk behavior among PLHIV in Europe, highlighting risk and vulnerability factors in both key populations (Bouhnik et al., 2007; Prost et al., 2008). Based on these findings, we defined the desired health promoting behavioral outcomes and synthesized the most important determinants for sexual risk reduction.

Table 1: Overview of POs per target group: MSM and migrants

<table>
<thead>
<tr>
<th>Performance objectives for MSM</th>
<th>Performance objectives for migrants/ethnic minorities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To disclose HIV to steady and casual sexual partners</td>
<td>1. To disclose HIV to steady and casual sex partners</td>
</tr>
<tr>
<td>2. To make accurate sexual risk assessments</td>
<td>2. To make accurate sexual risk assessments</td>
</tr>
<tr>
<td>3. To reduce the number of (concurrent) sexual partners</td>
<td>3. To reduce the number of (concurrent) sexual partners</td>
</tr>
<tr>
<td>4. To adopt sexual practices that are less risky (e.g. ‘harm reduction’ strategies)</td>
<td>4. To adopt sexual practices that are less risky (e.g. ‘harm reduction’ strategies)</td>
</tr>
<tr>
<td>5. To plan ahead for the adoption of safer sex behavior</td>
<td>5. To plan ahead for the adoption of safer sex behavior</td>
</tr>
<tr>
<td>6. To plan ahead for the adoption of condom use behavior</td>
<td>6. To plan ahead for the adoption of condom use behavior</td>
</tr>
<tr>
<td>7. To negotiate safer sex with steady and casual sex partners</td>
<td>7. To negotiate safer sex with steady and casual sex partners</td>
</tr>
<tr>
<td>8. To negotiate condom use with steady and casual sex partners</td>
<td>8. To negotiate condom use with steady and casual sex partners</td>
</tr>
<tr>
<td>9. To use condoms correctly and consistently with steady and casual sex partners</td>
<td>9. To use condoms correctly and consistently with steady and casual sex partners</td>
</tr>
<tr>
<td>10. To make informed decision on contraceptive use</td>
<td>10. To make informed decision on contraceptive use</td>
</tr>
<tr>
<td>11. To make informed decision on fertility-related issues (e.g. safe conception, prevention of mother-to-child transmission)</td>
<td>11. To make informed decision on fertility-related issues (e.g. safe conception, prevention of mother-to-child transmission)</td>
</tr>
</tbody>
</table>
motivation and its underlying attitudes/beliefs; self-efficacy, and the relevant behavioral skills to perform the behavior; external determinants related to social support from partner and peers, and reinforcement through service providers. We created a matrix of change objectives, by crossing POs with determinants. We then added specific performance and change objectives for fertility-related behaviors for heterosexual migrants living with HIV (see Supplementary material, Appendix). Self-efficacy, for instance, hypothesized to affect all POs, was translated into several distinct change objectives, such as: feeling confident to be able to disclose one’s HIV status to a new sexual partner or feeling confident to be able to plan ahead for using condoms with a casual sexual partner.

**Step 3: choosing theoretical intervention methods and practical strategies**

In this step, we linked the change objectives via theory- and evidence-based methods to practical strategies. To account for the heterogeneity of the target groups, we used a tailored approach: a client-centered counseling strategy based on an individual risk assessment and adapted to personal characteristics and barriers to achieve the envisaged outcome (Rimer and Kreuter, 2006). Practical strategies were based on motivational interviewing (MI) techniques (Miller and Rollnick, 2002). MI involves a client-centered, directive method to promote intrinsic motivation, uncovering and resolving ambivalence towards behavioral goals. The counseling interaction aimed at addressing personal risk factors, discrepant personal information and individual barriers to change. We trained counselors to use relevant MI elements, such as expressing empathy (i.e. non-judgmental and reflective listening, acceptance that problems with safer sex and condom use are normal), developing discrepancy (i.e. highlighting differences between personal values and current behavior), rolling with resistance (i.e. facilitating new perspectives), supporting self-efficacy and making concrete plans for change. Change techniques based on the transtheoretical model (Prochaska and Velicer, 1997) were used when compatible with MI techniques. The social cognitive theory served as additional evidence base for the selection of practical strategies (Bandura, 1986) including counseling techniques based on cognitive-behavioral therapy, i.e. giving tailored, normative feedback on the participant’s personal account. These theoretical approaches all work with concrete goal setting and rationale planning enabling clients to plan for condom use in risky situations.

While most behavioral HIV-risk reduction models concern ‘reasoned behavior’, sexual decisions are often taken in emotional ‘hot’ situations (e.g. sexual arousal, need of intimacy and fear of rejection) (Slavin et al., 2004). In such situations, attention shifts to immediate goals related to the motivational state rather than to distal general goals, as indicated by behavioral and neuro-cognitive research (Slovic et al., 2005). This suggests that behavior results from a dynamic interplay between an impulsive associative system, which is largely automated, and an executive control system, which regulates reflective-rational processes (Bechara et al., 1999). Dual process models have located these cognitive sub-systems in different brain areas and related them to different modes of thinking (Kahneman, 2003). This evidence has been applied to economic decision making (Kahneman, 2011), to addiction (Wiers and Stacy, 2006), but not yet widely to HIV-risk behavior (Grenard et al., 2013). Yet, it may provide a valuable explanation for the gap between intuitive decision taking in sexual situations (‘fast thinking’) and rational decision making (‘slow thinking’). This evidence provided the rationale for selecting computer-assisted visual aids as intervention tools avoiding purely educative messages and aiming at evoking feelings, which enable participants to engage emotionally with their fast thinking mode. We hypothesized that this would allow for better insight in dissonant behavior, on which the counseling can reflect (Table 2).

**Step 4: program planning and development**

Busy clinical schedules in HIV care settings required a short intervention. Brief face-to-face counseling interventions can effectively reduce sexual risk behavior, ranging from single (Eaton et al., 2012) to multiple session interventions (Johnson et al., 2009). In line with evidence on the efficacy of ICT interventions (Portnoy et al., 2008; Noar et al., 2009) our brief counseling intervention, labeled as ‘CISS’ (computer-assisted intervention for safer sex), used computer-assisted tools available on a DVD. Materials were issued in three tailored, target-group-specific versions: for MSM, heterosexual migrant women and men.

The CISS was delivered in three sessions of 50 min each, with 2 weeks intervals in-between. The first session was an exploratory session, in which participant and counselor explored the values and meanings of safer sex and individual barriers. This session, entitled ‘Who am I?’ offered a choice of video clips depicting personal accounts of specific problems with safer sex, emotions and coping styles. Topics included relationships; emotions and mood; pleasurable sex; drugs and alcohol use; HIV, health and sex; risk and brain training; community-related issues. Materials differed per target group and were gender specific. The counselor’s task during the first session was to explore in an unbiased way how participants related
to safer sex and their personal barriers towards it, based on which a personally meaningful video was introduced. The counselor followed up by identifying and discussing the participants’ emotional response and motivations. The realistic video clips and the emotion-focused counseling style were meant to induce heuristic thinking, consistent with the dual process theories. Optional homework consisted of exploring other videos, preparing participants for the second session.

The second session ‘working through’ offered more rational, verbally dependent modes of addressing barriers to safer sex. Counselors and clients had a choice of video clips and interactive slide shows, narrowing down potential behavioral solutions. The counselor’s task was supporting participants in identifying personal facilitators towards adopting condom use and safer sex, relating to their specific relationship contexts. This led to defining short- and medium-term behavioral objectives.

<table>
<thead>
<tr>
<th>Determinant</th>
<th>Method: theory/construct</th>
<th>Strategies and tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td>Transtheoretical model (TTM): Consciousness raising (in counseling context)</td>
<td>Information delivery (through interactive learning material; working through section)</td>
</tr>
<tr>
<td></td>
<td>Active learning (dual process theory)</td>
<td>Video material (‘Who am I?’ section; ‘Working through’ section; Resources section)</td>
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<tr>
<td></td>
<td></td>
<td>Personal information (counselor)</td>
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<tr>
<td></td>
<td></td>
<td>Homework assignments</td>
</tr>
<tr>
<td>Affect and</td>
<td>Modelling (SCT)</td>
<td>Empathic counseling dialogue</td>
</tr>
<tr>
<td>emotions</td>
<td>Self-monitoring and self-reevaluation (TTM)</td>
<td>Based on MI and CBT techniques</td>
</tr>
<tr>
<td></td>
<td>Affective change (SCT)</td>
<td>Video material (‘Who am I?’ section; ‘Working Through’ section)</td>
</tr>
<tr>
<td>Beliefs/</td>
<td>Consciousness raising (TTM)</td>
<td>Counseling dialogue: reflective listening</td>
</tr>
<tr>
<td>motivation</td>
<td>Self-reevaluation of personal norms (TTM)</td>
<td>Reinforcing personal change through face-to-face counseling</td>
</tr>
<tr>
<td></td>
<td>Modelling (SCT)</td>
<td>(emotive and cognitive)</td>
</tr>
<tr>
<td></td>
<td>Anticipated regret (TTM)</td>
<td>Role models demonstrate behavioral solutions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Working through solutions and stimulating imagination about undesired outcomes of unprotected sexual behavior</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Homework assignments</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>Modelling (SCT): Beliefs in own self-efficacy; dealing with partner/peer pressure</td>
<td>Modeling (through videos, dialogue and empathic open questioning)</td>
</tr>
<tr>
<td></td>
<td>Guided practice (SCT)</td>
<td>Working on intrinsic motivation (MI)</td>
</tr>
<tr>
<td></td>
<td>Dramatic relief (TTM)</td>
<td>Uncovering ambivalence</td>
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<tr>
<td></td>
<td></td>
<td>Rolling with resistance</td>
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<tr>
<td></td>
<td></td>
<td>Developing discrepancy</td>
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<tr>
<td></td>
<td>Decisional balance (TTM)</td>
<td>Cognitive-behavioral therapy (CBT): clarifying valued life directions</td>
</tr>
<tr>
<td></td>
<td>Persuasion (dual process theory)</td>
<td>(long-term planning); personal meanings of sex, safer sex, and condoms</td>
</tr>
<tr>
<td>Behavioral</td>
<td>Goal setting (goal setting theory)</td>
<td>Setting up a personalized behavioral plan to reach goal</td>
</tr>
<tr>
<td>skills</td>
<td></td>
<td>Tailored normative feedback through the counselor</td>
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<tr>
<td></td>
<td></td>
<td>Homework assignments</td>
</tr>
<tr>
<td>Subjective</td>
<td>Modelling (SCT)</td>
<td>Empathic counseling dialogue</td>
</tr>
<tr>
<td>norms</td>
<td>Building skills for resisting social pressure (SCT)</td>
<td>Based on CBT techniques</td>
</tr>
<tr>
<td>Social support</td>
<td>Mobilizing social networks and social support (Coping Social Support Theory)</td>
<td>Encouraging participants to seek social support and engage in dialogue with partners/peers (counseling)</td>
</tr>
<tr>
<td></td>
<td>Helping relationships (TTM)</td>
<td>Based on CBT techniques (trusting, accepting and utilizing the support of caring others for attempts to behavior change)</td>
</tr>
<tr>
<td></td>
<td>Linking individuals to support organizations or peer support</td>
<td></td>
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</tbody>
</table>
In the third session ‘making a plan’, counselor and participant worked on a concrete, tailored solution towards the defined objectives on condom use and safer sex. Specific small goals, which can be confidently achieved, have been identified as important for behavior change (Malouff et al., 2007). Counselors-assisted participants in breaking-down a complex goal, such as ‘using condoms correctly and consistently’ into specific small, but realistic and feasible steps. Visual goal-planning software (Goal-enforcer) allowed for creating a hierarchy of specific steps necessary to achieve the final goal, and organizing these steps. Alternatively, an MI-based worksheet could be used, identifying the same steps, and barriers and facilitators (Table 3).

All the materials, particularly the scripts for the stories/role-plays were developed based on clinical experiences provided by key resource patients. Collaborators in community-based organizations and project partners provided feedback to the narratives. All materials were pre-tested in five countries with access to sufficient patients allowing for adequate piloting (Belgium, France, Germany, the Netherlands and the UK; including both experiences with clinics and community-based organizations). Feedback obtained (i.e. technical issues, translation issues and improvement of the interactive materials for session 2) informed the CISS pilot version used for the evaluation study. Video materials were subtitled in nine European languages. Written materials were translated using professional translation services.

**Steps 5 and 6: intervention implementation and evaluation**

*Adoption and implementation plan:* Integrating new sexual health interventions into regular care may potentially encounter barriers on the organizational level (Berer, 2004). In order to ensure smooth implementation, we installed service provision groups (SPGs) in the various settings consisting of key service providers (doctors, nurses, resource patients and peers) in line with the ‘linkage groups’ described in IM. These groups supported the implementation and execution of the evaluation study, promoted the project within their own settings, gave advice on implementation procedures, and provided feedback on interim evaluation results.

Eurosupport 6 partners from nine countries (i.e. HIV clinics and community-based HIV service organizations from Belgium, France, Germany, Italy, the Netherlands, Poland, Portugal, Spain and UK) implemented the intervention between February 2011 and August 2013 among the three target groups. Service providers who delivered the intervention came from different professional backgrounds (mostly counselors, but also psychologists, sexologists and physicians). They received a two-day training on using the CISS materials and on enhancing their counseling skills provided by the intervention developers. This included intercultural counseling skills.

During the enrolment phase, we encountered problems in recruiting study participants. In terms of recruiting study participants, we could only achieve 53% of the required sample size (i.e. $n = 192$ instead of 364 patients). In some clinical settings, patients were reluctant to report sexual risk behavior during screening (which assessed unprotected sexual intercourse during the last 3 months, and the importance of behavior change). This was most obvious in Slovakia, where criminalization of HIV transmission acted as a structural barrier. In this country, upon being enrolled in HIV care, PLHIV had to sign a compliance statement, through which they agreed to consistent condom use and were informed that they could be penalized when having condomless sex. Patients thus may have found it difficult to come forward and freely discuss problems with condom use with their counselors, even if they were not their regular service providers. Unfortunately, there were no alternative recruitment channels available in Slovakia, hence we had to discontinue the study. But even without such discriminatory policies in place, social desirability may have led patients across all settings to underreport problems with safer sex. The SPGs provided several ideas how to improve recruitment, which subsequently were implemented: inviting patients with a recent STI diagnosis, expanding the study settings through local networks (i.e. with additional clinics and civil society organizations), promotion of the CISS through various local and regional channels (patient organizations’ websites and community-based events).

**Evaluation plan**

We combined a randomized controlled trial to assess the interventions’ effectiveness with a process evaluation, to assess feasibility, acceptability, and service providers’ fidelity to the intervention. Although the CISS included content in relation to reproductive health (e.g. fertility-related and contraceptive issues), the quantitative evaluation’s primary outcome was consistent condom use for both MSM and heterosexual participants. For the process evaluation, both CISS participants and providers filled in an online survey after completion of the intervention. The latter also assessed their likelihood to work with the CISS materials in the future. A qualitative analysis of the patient documentation forms delivered additional process data (e.g. topics addressed, specific problems encountered and referrals).

We received ethical approval from the Ethics Committee (EC) of the Institute of Tropical Medicine/University of
Upon screening and obtaining informed consent, we randomly assigned 192 participants to either intervention or control condition. Participants in the intervention condition received the three CISS counseling sessions, control participants received treatment as usual but were offered the intervention after study completion. Self-reported online questionnaires assessed sexual risk and underlying determinants at baseline, 3 and 6 months follow-up moments in both groups. IM steps 1 and 2 provided the basis for

<table>
<thead>
<tr>
<th>Session 1: ‘Who am I?’</th>
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<tbody>
<tr>
<td>1. Assess client’s personal meaning and concerns in relation to sexual activity, safer sex and condom use</td>
<td>Introduce intervention/counseling session&lt;br&gt;Set agenda with client&lt;br&gt;Explore personal meanings, client’s concerns/barriers&lt;br&gt;Reflect and summarize</td>
</tr>
<tr>
<td>2. Determine barriers: Select one or two video clips under the ‘Who am I?’ section, tailored to clients’ needs</td>
<td>Discuss portrayed situation/behavior and own behavior&lt;br&gt;Explore feelings in relevant situations, normalize problems with safer sex/condom use&lt;br&gt;Explore other relevant barriers to safer sex/condom use&lt;br&gt;Discuss pro and cons of current behavior&lt;br&gt;Discuss contradictions in belief, motivation and behavior&lt;br&gt;Provide factual information, if needed&lt;br&gt;Explore and encourage self-efficacy</td>
</tr>
<tr>
<td>3. Summary</td>
<td>Reflect and summarize&lt;br&gt;Optional: give home-assignment using the CISS (DVD)&lt;br&gt;Make next appointment</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Session 2: ‘Working through’</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assess and reinforce progress</td>
<td>Introduce counseling session&lt;br&gt;Relate back to first session&lt;br&gt;Discuss assignment (if given)</td>
</tr>
<tr>
<td>2. Determine solutions: Select one or two of the video clips or slide shows under the ‘Working through’ section, tailored to clients’ needs</td>
<td>Discuss portrayed situation/behavior and/or information given in relation to own situation&lt;br&gt;Explore relevant facilitators of safer sex/condom use&lt;br&gt;Explore overall behavioral goal, valued life directions (long-term planning)&lt;br&gt;Discuss pro and cons of current behavior versus behavior change&lt;br&gt;Explore feelings and normalize problems with safer sex/condom use&lt;br&gt;Provide factual information, if needed&lt;br&gt;Explore and encourage self-efficacy</td>
</tr>
<tr>
<td>3. Summary</td>
<td>Reflect and summarize&lt;br&gt;Optional: give assignment using the CISS&lt;br&gt;Make next appointment</td>
</tr>
</tbody>
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<tr>
<th>Session 3: ‘Making a plan’</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assess progress and reinforce progress made</td>
<td>Introduce counseling session&lt;br&gt;Relate back to second session&lt;br&gt;Discuss assignment (if given)</td>
</tr>
<tr>
<td>2. Develop personalized behavioral plan</td>
<td>Set sub-steps for achieving the behavioral goals&lt;br&gt;Compile and document sub-steps and behavioral goals into one personalized (document to be handed to the client: print-out of goal-enforcer or MI working sheet)&lt;br&gt;Discuss barriers and facilitators for maintenance&lt;br&gt;Explore and encourage self-confidence</td>
</tr>
<tr>
<td>3. Summary and conclusion</td>
<td>Reflect and summarize&lt;br&gt;Give opportunity for client to evaluate the sessions</td>
</tr>
</tbody>
</table>

### Table 3: Overview of the CISS counseling sessions

**Session 1: ‘Who am I?’**

1. Assess client’s personal meaning and concerns in relation to sexual activity, safer sex and condom use
   - Introduce intervention/counseling session
   - Set agenda with client
   - Explore personal meanings, client’s concerns/barriers
   - Reflect and summarize
2. Determine barriers: Select one or two video clips under the ‘Who am I?’ section, tailored to clients’ needs
   - Discuss portrayed situation/behavior and own behavior
   - Explore feelings in relevant situations, normalize problems with safer sex/condom use
   - Explore other relevant barriers to safer sex/condom use
   - Discuss pro and cons of current behavior
   - Discuss contradictions in belief, motivation and behavior
   - Provide factual information, if needed
   - Explore and encourage self-efficacy
3. Summary
   - Reflect and summarize
   - Optional: give home-assignment using the CISS (DVD)
   - Make next appointment

**Session 2: ‘Working through’**

1. Assess and reinforce progress
   - Introduce counseling session
   - Relate back to first session
   - Discuss assignment (if given)
2. Determine solutions: Select one or two of the video clips or slide shows under the ‘Working through’ section, tailored to clients’ needs
   - Discuss portrayed situation/behavior and/or information given in relation to own situation
   - Explore relevant facilitators of safer sex/condom use
   - Explore overall behavioral goal, valued life directions (long-term planning)
   - Discuss pro and cons of current behavior versus behavior change
   - Explore feelings and normalize problems with safer sex/condom use
   - Provide factual information, if needed
   - Explore and encourage self-efficacy
3. Summary
   - Reflect and summarize
   - Optional: give assignment using the CISS
   - Make next appointment

**Session 3: ‘Making a plan’**

1. Assess progress and reinforce progress made
   - Introduce counseling session
   - Relate back to second session
   - Discuss assignment (if given)
2. Develop personalized behavioral plan
   - Set sub-steps for achieving the behavioral goals
   - Compile and document sub-steps and behavioral goals into one personalized (document to be handed to the client: print-out of goal-enforcer or MI working sheet)
   - Discuss barriers and facilitators for maintenance
   - Explore and encourage self-confidence
3. Summary and conclusion
   - Reflect and summarize
   - Give opportunity for client to evaluate the sessions
identifying the primary and secondary endpoints (i.e. ‘condom use at last intercourse’ and a combined HIV transmission risk score reflecting personal risk reduction strategies rather than epidemiological risk alone). While the evaluation study’s detailed results will be reported elsewhere, we can conclude that the intervention was effective at the 3 and 6 months follow-up, achieving a difference in self-reported risk reduction between intervention- and control group in the expected range (~20%). The process evaluation showed that it was feasible to adopt the CISS in the various settings. Participants (n = 78) and service providers (n = 82) were satisfied with the intervention. On the participants’ side, 80% found the CISS useful in reducing HIV transmission risk. A similar proportion felt confident to be able to have safe sex in the future; and about two-third reported that they found the personalized risk reduction plan in particular helpful to achieve their personal safer sex goals.

On the service providers’ side, 84% said they would use the CISS with a similar patient in the future. Generally, the following items were perceived as the intervention’s strong points: the structured approach helped to define and normalize safer sex problems by framing them as the client’s ‘personal project’ that can be realized; the videos were evaluated as quite helpful especially in empowering women. Weak points referred to the lack of time in implementing such an intervention in regular care or counseling; some technical problems with the performance of the DVD; and that not all factors contributing to unsafe sex were covered by the videos, for instance street drug use was not considered.

For the TRP development, service providers and project partners provided additional feedback on the intervention’s content and feasibility upon completion of the evaluation study. The TRP supports service providers in using the CISS and more broadly, in safer sex and positive prevention counseling in the different settings. The TRP consists of the CISS intervention manual, an implementation manual, a (self-)training manual for SRH and sexual counseling and a reference guide (handbook on positive prevention). The TRP stresses the importance of intercultural dimensions through addressing intercultural counseling skills in the training manual, discussion of migrant-specific context-related issues in the implementation manual and specific chapters on the target groups in the reference guide.

**DISCUSSION**

IM enabled us to develop a coherent-positive prevention intervention for European HIV care settings, which proved effective in HIV outpatient clinics, providing HIV treatment and psychosocial support. We have demonstrated that IM is a feasible, helpful and systematic tool for developing an evidence-based and theoretically guided behavior change intervention for complex and emotionally driven health behaviors, such as safer sex.

We believe that through the use of IM the development process and ultimately the intervention may have benefited in several ways: The strong emphasis on the needs assessment during the first step allowed for tailoring the intervention to the needs of heterogeneous target groups. Formulating not only an overall behavioral objective but developing target-group-specific change objectives in step 2 allowed for developing a coherent intervention while still meeting the sexual health needs of clients from different (sub)-cultural backgrounds. The requirement of selecting evidence-based theories and practical strategies in step 3, forced us to scrutinize the available evidence and think creatively about overcoming the knowledge-practice gap in behavioral interventions (Sligo and Jameson, 2000). This step led us to applying an innovative approach to supporting sexual behavior change. In the actual process of program planning (step 4), we investigated and utilized the evidence on ICT-based interventions guided by recently published reviews and meta-analyses (Webb et al., 2010), of which so far only few have worked with IM (van der Veen et al., 2012). While the CISS does not fully qualify as a computer-based intervention, defined as an intervention solely relying on computer-tools, it adopts computer-assisted tools that pro-actively support the counseling process. Our study thus adds to the growing evidence on using IM for developing effective computer-assisted interventions. In step 5, we encountered specific implementation challenges. Developing linkage systems through SPG in the respective settings was meant to create ownership among service providers and civil society organizations, but apparently was not sufficient to overcome existing structural barriers hindering recruitment. For the challenges encountered during the implementation process, the major one being low uptake of the intervention, IM—applied in the context of a strict project schedules—provided useful guidance. Barriers arose on different levels: next to the structural barriers related to stigma as described above, we encountered provider-related barriers (e.g. motivation to refer clients to the study, lacking staff resources to implement ‘competing’ interventions at the same time, a changing prevention agenda, particularly among community-based organizations and in some cases counselors’ fear of being ‘evaluated’ when using the tools in the framework of a study). Individual barriers referred to some clients’ low motivation to change behavior.

While selecting HIV care settings for intervention delivery corresponded to service providers’ needs for evidence-based tools to address SRH (as assessed and described under step 1), we were limited in addressing
external determinants. IM was helpful in developing solutions through constant feedback and facilitated locally adapted strategies for improved recruitment. It should be noted that the study had started before the release of the Swiss Statement (Vernazza et al., 2008), a consensus statement presenting evidence that HIV-positive individuals on effective antiretroviral therapy and without STIs were sexually non-infectious. This statement had quite some repercussions on the prevention discourse during the project’s lifetime leading to a growing recognition of sexual harm reduction strategies mainly among MSM communities. This may have affected the perception of this type of intervention promoting condom use, as less relevant. Low uptake of behavioral interventions was found also in other studies looking at both the patient and the provider level (Desai et al., 2013). Finally, IM has provided a useful framework for conducting a theory-guided rigorous evaluation, which we undertook in step 6. We recognize, however, that the current RCT design—while offering the best internal validity—and a somewhat limited process evaluation, did not directly result into further adaption and improvement of the CISS materials as such. The results of the process evaluation were mainly used to adapt the TRP, as described above.

Through its interactive character, IM requires a certain degree of flexibility, which can be challenging: In our study, the difficulties PLHIV had in accessing the intervention pointed to the need to tackle structural determinants. Clearly, interventions in a clinical setting do not occur in a vacuum. In theory, IM provides a sound framework to integrating additional levels of the ecological model. This would have required further interventions such as adding stigma reduction components, making it truly a combination prevention intervention (Hankins and de Zalduondo, 2010). Unfortunately, we were not able to expand on the external determinants, as this would have exceeded our resources in terms of time and costs issues.

Conclusions and implications for future implementation

In spite of these limitations, we conclude that our study contributed to the evidence-base of (short-term) effective behavioral sexual health interventions, the first study of its kind in a pan-European setting. As such the intervention may serve as one pillar of effective combination prevention strategies as recommended by UNAIDS (UNAIDS, 2010). To support CISS implementation under real life conditions, service providers will have access to the TRP guiding them in safer sex counseling and in working with the CISS in different organizational settings, for instance, first- and second-line care facilities, such as general practitioners and specialists catering for HIV positive patients. Strict screening procedures (required in a randomized controlled trial) will not apply anymore. It remains to be seen whether this will improve the uptake. Also of potential interest would be to evaluate the CISS using reproductive health-related outcomes among heterosexual participants, which could broaden its future target group. The SPG structures will also be important in sustaining the future use of the CISS. A specific website is currently under development for dissemination. The CISS and the TRP will be available free of charge to service providers interested to use it non-commercially. With this account on intervention content and development, we hope to contribute to a mind-shift of service providers and counselors working in positive prevention, shifting from mere sexual risk reduction to supporting overall sexual health and wellness of PLHIV.

SUPPLEMENTARY MATERIAL

Supplementary material is available at Health Promotion International online.

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